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Governance of Health Research Involving Humans in Developing Countries: The Nigerian Example

Cheluchi Onyemelukwe

GOVERNANCE OF HEALTH RESEARCH INVOLVING HUMANS IN DEVELOPING COUNTRIES: THE NIGERIAN EXAMPLE

by

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To the One Who Makes Dreams Come
My God and Saviour

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Abstract

An intense debate has occurred regarding research involving humans in developing countries in recent years. Research in this area has focused mainly on examining the ways in which the economic inequalities in healthcare between developing countries and developed countries have affected the types of research conducted in developing countries by external sponsors. Research has also focused on how these inequalities, and the difficulties in applying the international ethical guidelines, give rise to ethical concerns and controversies. Recent literature has therefore examined several ethical concerns in health research in developing countries. What is missing in the literature on research oversight in developing countries, however, is a broader analysis from a governance and legal perspective which critically examines the structure and adequacy of any existing governance systems and the potential effect of these systems on the protection of human participants in these countries. The major argument that this thesis makes and attempts to explore, therefore, is that there is need to take a more comprehensive and systemic view of the regulation of research involving humans in developing countries. This is particularly necessary given steps taken recently by several developing countries to establish governance mechanisms for health research involving humans. To undertake this analysis, the thesis adopts a hybrid framework of governance, drawing from the understandings and strengths of "traditional" and "new" governance. This framework acknowledges the important role of government but also takes into account other components which may not always be dependent on government and law. Further, in line with this framework, the thesis argues for the need to recognise, in scholarship and operation, the interrelationships between the different components of research governance – ethical, institutional, and legal. For more specific analysis, the thesis focuses on Nigeria, a populous, influential, developing country in Africa, which has taken steps in recent years to regulate health research involving humans. It examines the historical and political context of these governance efforts, and analyses the adequacy of current governance arrangements. Based on the analyses, it makes several recommendations to improve the emerging governance arrangements for health research involving humans in Nigeria.

List of Abbreviations

AHEC	Australian Health Ethics Committee
AIDS	Acquired Immune Deficiency Virus
AJIL	American Journal of International Law
AJLM	American Journal of Law and Medicine
Am. J. Pub. Health	American Journal of Public Health
ANRS	France's Agence Nationale de Recherches sur le Sida
AZT	Azidothymidine
BMJ	British Medical Journal
CAM	Complementary and Alternative Medicine
CCLT	Canadian Cases on the Law of Torts
CDC	Center for Disease Control
CIDA	Canadian International Development Agency
Chi. J. Int.' L.	Chicago Journal of International Law
CIHR	Canadian Institutes of Health Research
CIOMS	Council for International Organisation of Medical Sciences
CMAJ	Canadian Medical Association Journal
Colum. J. Eur. L	Columbia Journal of European Law
Conn. J. Intl. L.	Connecticut Journal of International Law

DfID	United Kingdom Department for International Development
DRA	Drug Regulatory Authority
EDCTP	European-Developing Countries Clinical Trials Programme
EGE	European Group on Ethics in Science and New Technologies
ENLR	Eastern Nigeria Law Reports
FDA	Food and Drug Administration
FLWA	Fletcher Forum of World Affairs
Fordham Urb. L.J.	Fordham Urban Law Journal
Geo. Wash. Int'l L. Rev.	George Washington International Law Review
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GNP	Gross National Product
HAART	Highly Active Antiretroviral Therapy
HapMap	Human Genome and the International Haplotype Mapping Project
Health L. J.	Health Law Journal
HIV	Human Immune-Deficiency Virus
HRECs	Health Research Ethics Committees
Hum. Rts. Q	Human Rights Quarterly
ICCPCR	International Covenant on Civil and Political Rights
ICG	International Crisis Group

ICH-GCP	International Conference on Harmonisation's *Harmonised Tripartite Guidelines for Good Clinical Practice*
ICMR	Indian Council of Medical Research
IDRC	International Development Research Centre
IMF	International Monetary Fund
Ind. Int'l & Comp. L. Rev.	Indiana International and Comparative Law Review
JAMA	Journal of the American Medical Association
JAMWA	Journal of the American Medical Women's Association
JICA	Japan International Cooperation Agency
J.L. Med. & Ethics	Journal of Law, Medicine and Ethics
J. Gender, Race and Just.	Journal of Gender, Race and Justice
McGill L.J	McGill Law Journal
MDCN	Medical and Dental Council of Nigeria
MDG	Millennium Development Goals
MMV	Medicines for Malaria Venture
MRC	The United Kingdom Medical Research Council
NAFDAC	National Administration for Food and Drug Administration and Control
NBAC	National Bioethics Advisory Commission
N. Eng. J. Med.	New England Journal of Medicine
NIH	National Institute of Health
NGOs	Non-Governmental Organisations

NHMRC Council	National Health and Medical Research
NHREC Committee	National Health Research Ethics
NHS	National Health Service
NMA	Nigerian Medical Association
NWLR	Nigeria Weekly Law Reports
OHRP	Office for Human Research Protections
Que Sup Ct	Quebec Supreme Court
SCSN	Supreme Council of Sharia Nigeria
STDs	Sexually Transmitted Diseases
TAC	Treatment Action Campaign
TCPS	Tri-Council Policy Statement
TDR	Tropical Diseases Research
UCH	University College Hospital, Ibadan
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNESCO	United Nations Educational, Social and Cultural Organiisation
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
U. Pa. L. Rev	University of Pennsylvania Law Review
USAID	United States Agency for International Development
WHO	World Health Organisation

WNLR	Western Nigeria Law Reports
WTO	World Trade Organisation
Vand. J. Transnat'l L.	Vanderbilt Journal of Transnational Law
Yale J. Health Pol'y L. & Ethics	Yale Journal of Health Policy, Law, and Ethics

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Chapter One

Introduction

1.1 Introduction

Over the past decade, an intense debate has occurred regarding research involving humans in developing countries. Although there is concern about the limited proportion of health research conducted in developing countries, the most controversial part of these debates has focused on the ethics of research in developing countries in the face of existing economic disparities between developed and developing countries, important questions of global justice and equity and the arguably greater vulnerability of research participants in developing countries.

What naturally follows, then, is concern about how adequately research participants in such countries are protected and the existence and sufficiency of any governance mechanisms for that purpose. Past events in several countries, including developed countries, underscore the need for regulation and oversight of health research involving humans. These include the atrocities committed in the name of medical research during World War II in Germany; the Tuskegee Syphilis experiments on African-American men in the United States where the research subjects were prevented from getting effective treatment while participating in a study on syphilis long after a cure was discovered for the disease; the Willowbrook studies where mentally ill children were injected with hepatitis; the Jewish Chronic Hospital Disease Study in Brooklyn in which the

patients hospitalized with debilitating chronic diseases were injected with live cancer cells without their consent; and the Cameron experiments where electric shock experiments were tested on mentally ill patients in Canada.[1] The more recent controversies surrounding the Zidovudine trials in several developing countries in the late 1990s have once more brought to the fore fears about the risks in research involving humans.[2]

A number of developing countries have recently developed, or are in the process of developing, new instruments for guiding and regulating research involving humans. These instruments form the basis of governance of research in these countries, and this seems an appropriate time, therefore, to consider the governance of health research in developing countries. The aim of the thesis is to examine analytically the system for governing health research involving humans in a developing country, Nigeria.

1.2 Structure and Arrangement

The thesis consists of eight chapters. Apart from the introduction and the structure and arrangement of the thesis, Chapter One describes the background and a rationale for this study. It then engages in an identification of the need for,

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[1] See a detailed review of some historical cases in J. Katz, *Experimentation with Human Beings* (New York, Russell Sage Foundation, 1972). Other experiments have also been described by Henry K. Beecher, "Ethics and Clinical Research" (1966) 274: 24 N. Engl. J. Med. 1354.

[2] Paquita De Zulueta, "Randomised Placebo-Controlled Trials and HIV-Infected Pregnant Women in Developing Countries: Ethical Imperialism or Unethical Exploitation?" 15: 4 Bioethics 290 at 293-296. See also, G. Annas "Human Rights and Maternal-Fetal HIV Transmission Prevention Trials in Africa" (1998) 88 Am. J. Pub. Health 560, Marcia Angell, "The Ethics of Clinical Research in the Third world (1997) N. Engl. J. Med. 847-849 and Abdool Q. Karim, et al., "Informed Consent for HIV Testing in a South African Hospital: Is it Truly Informed and Truly Voluntary?" (1998) 88 Am. J. Pub. Health 637.

and the benefits of, health research involving humans, both generally and specifically in developing countries. Further, this chapter discusses the need for domestic governance systems in developing countries. Lastly, this chapter introduces Nigeria, which is examined in the thesis as an example of a developing country that has recently taken steps to establish a research governance system.

Chapter Two examines governance as a useful analytical framework for the work to be undertaken in thesis. It attempts to clarify the concept of governance, distinguishing it from the terms "regulation" and "law." It examines the applicability of governance to health research involving humans, discussing the concept as a theoretical framework, identifying different forms of governance, and providing a rationale for employing a hybrid framework of governance. It identifies the goals of the governance of health research involving humans and the criteria by which a research governance system can be assessed. It also discusses how the hybrid governance framework proposed will be used in subsequent discussion in the thesis.

The third chapter attempts to identify and examine the components of research governance systems, examining the ethical and institutional frameworks. For this examination, it draws from the research governance systems of various countries around the world.

The fourth chapter inquires into the role of law in research governance in developing countries. It argues that developing countries should consider developing comprehensive legislation as part of their research governance

system. It identifies what should be the basic content of such legislation. It also argues for greater recognition of the interrelationship between an ethical framework, a legal framework and the institutional framework.

The fifth chapter provides specific context and background on Nigeria. Nigeria is a developing country which provides a good case study for studying research governance for several reasons. These reasons include its high population, its great need for health research, and the steps it has taken recently to develop a research governance system. This chapter describes context for research governance in Nigeria, including, the political organization of the country, the legal environment for regulation and governance, and the operation of the health system. It also describes the types of research that take place in Nigeria. It examines the history of research governance in Nigeria, including some allegations of unethical research. These allegations of unethical conduct of research in Nigeria indicate the necessity for research governance, and the findings from the history indicate issues that must be taken into consideration as Nigeria develops a research governance system.

The sixth chapter analyses the current arrangements for research governance in Nigeria. It discusses the components of the research governance system in Nigeria, the ethical, legal and institutional frameworks. It analyses these frameworks and identifies gaps, weaknesses, and potential problems. Based on available evidence, it assesses Nigeria's research governance system in line with the criteria identified in the second chapter.

The seventh chapter makes recommendations for improvement to the Nigeria's system of research governance.

The eighth chapter concludes the thesis with a brief summary of the entire work.

1.3 Research Background, Rationale, and Aims

In recent years, there has been, and there continues to be, considerable interest in health research involving humans in developing countries. One part of the discussion centers on the insufficient proportion of health research conducted in developing countries. Many developing countries lack adequate resources, expertise, and infrastructure for conducting health research,[3] and frequently depend on developed country sponsors, including international organizations and government organizations in developed countries to conduct research in required areas of healthcare.[4] Still, even with such dependence, there is concern that many diseases that occur principally in developing countries are not receiving sufficient attention in research.[5]

The increasing awareness of the difference in the circumstances of developing countries and developed countries, the higher burden of disease, and the higher level of vulnerability of persons in developing countries to exploitation have, at the same time, prompted concerns about the ethical conduct

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[3] Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries* (London: Nuffield Council on Bioethics, 2002) at 6.
[4] Sonia Shah, "Globalization of Clinical Research in the Pharmaceutical Industry" (2003) 33:1 International Journal of Health Services 29 at 30-31.
[5] See Section 1.5

of research involving humans in these countries. The conduct of external researchers in developing countries has been criticised for failing, in many cases, to meet the ethical standards which such researchers would have been compelled to adopt in developed countries. There have also been a number of claims that multinational pharmaceutical companies have conducted unethical trials in developing countries, endangering and sometimes damaging the lives of the research participants involved in such trials.[6] The other part of recent debate on research in developing countries thus focuses on the regulation of research in these countries. Although there are certain linkages between the two sides of this debate – the proportion of research conducted and the regulation of such research – the thesis is principally concerned with the latter, which is, the governance and regulation of health research in developing countries.

Research in this area has focused mainly on examining the ways in which the economic inequalities and disparity in access to healthcare between developing countries and developed countries have affected the types of research conducted in developing countries by external sponsors, and who dictates the research agenda, including the types of research to be conducted. Research has also focused on how these inequalities, and the difficulties in applying the international ethical guidelines, give rise to ethical concerns and controversies. Recent literature has therefore focused on several ethical concerns in research in developing countries, including the adequacy of informed consent procedures in developing countries, the standard of care to be offered to persons involved in randomised clinical trials, access to the benefits of the research, and the

[6] The case of Pfizer trials in Nigeria, discussed in detail in Chapter Five, is a good illustration.

inadequacy of ethics review in developing countries.[7] To provide a context for the discussion that follows in the thesis, these ethical concerns are laid out briefly below. Although no attempt is made to address these concerns in great detail or to answer the troubling questions which arise with respect thereto (this not being the main focus of this thesis), these concerns, however, remain relevant in the context of governance of research in developing countries because the governance systems in these countries will have to grapple with these issues which raise particular concerns in these settings.

Informed consent is now accepted as key in every research project involving human participants. The requirement for informed consent is firmly established in many international guidelines, [8] national guidelines and regulations [9] as well as international human rights law [10] as a fundamental prerequisite in research involving humans. It is considered to be one of the most important safeguards required to protect research participants from exploitation. [11] While there is general agreement about the necessity for informed consent in which research is conducted, obtaining informed consent in

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[7] See the Nuffield Council on Bioethics, 2002: *The Ethics of Research Related to Healthcare in Developing Countries* (London: Nuffield Council on Bioethics, 2002) online: <http://www.nuffieldbioethics.org/fileLibrary/pdf/errhdc_fullreport001.pdf> (October 17, 2007).

[8] These include the *Nuremberg Code* 1947, World Medical Association (WMA) *Declaration of Helsinki: Ethical Principles for Research Involving Human Subjects*, adopted by the 18th WMA June 1964, latest amendment latest amendment made by the 59th WMA General Assembly, Seoul, October 2008. Council of International Organisation of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* adopted 1993 and revised 2002.

[9] For instance Article 2.1 of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* applicable in Canada.

[10] Article 7 of the *International Covenant on Civil and Political Rights* G.A. res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, *entered into force* Mar. 23, 1976.

[11] Ruth Macklin, *Double Standards in Medical Research in Developing Countries* (Cambridge: Cambridge University Press, 2004) (hereinafter Macklin (2004) at 131.

developing country settings may be especially challenging. The challenges are usually the result of such factors as low literacy rates, higher burden of diseases and limited healthcare options, gender differences and inequalities, language differences and translation difficulties, lack of familiarity with scientific research, different understanding of the concepts of health and disease, high regard for medical professionals, and conflict between cultures and accepted ethical guidelines.[12] The economic disparities between countries pose a particular challenge to obtaining true informed consent. Many of the potential research participants in many developing countries are poor, have little access to the poor healthcare systems available and inadequate access to effective medicines in many of these countries. In light of these challenges, people may be more willing to participate in research with a belief that they may get free healthcare services and medicines which would not otherwise be available. As such, there appears to be a greater level of vulnerability, particularly when poverty and other factors such as illiteracy, belief systems that are not necessarily compatible

[12] Nuffield Council on Bioethics, supra note 7 at 39. In that report it is noted that"Sickness or death may be attributed to witchcraft or sorcery rather than biomedical explanations evoking infectious agents, genetic predispositions, or weak immune systems—explanations central to the western biomedical model of disease." See Patricia, A Marshall, *Ethical Challenges in Study Design and Informed Consent for Health Research in Resource-Poor Settings* (Geneva: World Health Organisation, 2007), online: <http://www.who.int/tdr/publications/publications/pdf/ethical_challenges.pdf> (December 10, 2007) at 12. Language and translation difficulties also affect the comprehension of information, a vital part of the informed consent process Terms like 'research" "placebo" and "randomization," may not easily be translated to local languages. See Patricia A Marshall, "Informed Consent in International Health Research" (2006) 1 Journal of Empirical Research on Human Research Ethics 25 at 26. V. Adams, *et al.*, "The Challenge of Cross-Cultural Clinical Trials Research: Case Report from the Tibetan Autonomous Region, People's Republic of China" (2005) 19:3 Medical Anthropology Quarterly 267; N. Kass , S. Maman and J. Atkinson, "Motivations, Understanding, and Voluntariness in International Randomized Trials" (2005) 27:6 IRB: Ethics and Human Research 1.; R. R Love and N.C. Fost, "Ethical and Regulatory Challenges in a Randomized Control Trial of Adjuvant Treatment for Breast Cancer in Vietnam" 45:8 Journal of Investigative Medicine 423. NBAC, 2001; Nuffield Council on Bioethics, 2002.

with western biomedicine, lack of political power and frequent human rights violations in some developing countries are combined. A lack of options may lead to undue inducement, arising from false expectations and inadequate understanding of the risks of participation in research and may compromise the informed consent process.[13] The Pfizer trial which took place in Northern Nigeria during a meningitis epidemic in 1996 was suggestive of inadequate understanding of information because the poor parents of the children enrolled in the trial may well have assumed that the children would receive treatment.[14] This case is discussed in detail in Chapter Five.

Although these challenges are well recognized and the need to balance ethical requirements and socio-cultural differences is understood, there is little consensus on precisely how they are to be addressed by researchers in practical situations.[15] The literature continues to address very important issues which underlie much of the research conducted by developed country sponsors in developing countries. For instance, when, if ever, is it appropriate to deviate from international ethical guidelines? Does cultural relativity justify ethical

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[13] Ibid. Undue inducement is prohibited by some guidelines including the CIOMS Guidelines. Guideline 7 of CIOMS Guidelines deals with payment to research participants and in this context prohibits payments which may be too large, or extensive medical services which would serve as undue inducement. See also, Ezekiel Emmanuel, Xolani E. Currie and Allen Heman, "Undue Inducement in Clinical Research in Developing Countries: Is It A Worry?" (2005) 366 Lancet 336. E. Tafesse, E. and Murphy, T. (1998) "Ethics of Placebo-Controlled Trials of Zidovudine to Prevent the Perinatal Transmission of HIV in the Third World," New England Journal of Medicine, 338: 838. See also, David B. Resnik, "Biomedical Research in the Developing World: Ethical Issues and Dilemmas" in Ann Smith Iltis, *Research Ethics* (New York: Routledge, 2006).

[14] See Macklin (2004) supra note 11 at 100.

[15] Some commentators even argue that there is little data to show that the difficulties surrounding informed consent are peculiar to developing countries. See, Christine Pace, Christine Grady & Ezekiel J. Emanuel, "What We Don't Know About Informed Consent" (2003) SciDevnet, online: SciDevNet <http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierreaditem&dossier=5&type=3&itemid=189&language=1> (accessed September 19, 2009).

relativism?[16] Is ethical relativism permissible in particular instances? Does it constitute "ethical imperialism" to impose the requirements of the international ethical guidelines regardless of differing circumstances, or is a universal standard the only justifiable standard? These questions also have great relevance for concerns surrounding the standard of care issue, another ethical concern that has received much attention in the literature.

The standard of care[17] issue can rightly be stated to be the issue which thrust ethical issues in research involving humans in developing countries into the limelight in recent years. It is perhaps the most hotly debated issue in internationally-sponsored research in developing countries. This concern revolves mostly around the nature of the care and treatment provided during research, including all the preventive or therapeutic treatment that ought to be provided to participants in the course of the research. As Macklin succinctly notes, the ethical issue focuses on "what is ethically acceptable to provide to a control group in research with the standard of care in the developing country –

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[16] Macklin (2004), supra note 11 at140. See generally, David B. Resnik, "Biomedical Research in the Developing World: Ethical Issues and Dilemmas" in Ann Smith Iltis, *Research Ethics* (New York: Routledge, 2006) at 141. D. Resnik, "Exploitation in Biomedical Research," (2003) 12 Theoretical Medicine and Bioethics, 197–224. See also, Ruth Macklin, *Against Relativism: Cultural Diversity and the Search for Universals in Medicine,* New York: Oxford University Press, 1999).

[17] Although it is employed profusely in the literature, several different meanings may be attributed to the phrase, "standard of care." Some of these include the ethical standards generally that should apply in health research involving humans in different countries, "the types or level of treatments provided to patients in the clinical setting, but it might not serve as a justification for what *ought* to be provided to participants in research" See National Bioethics Advisory Commission *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries Volume1- Report and Recommendations of the National Bioethics Advisory Commission* (Bethesda, Maryland: National Bioethics Advisory Commission, 2001), (hereafter NBAC)at 13 (emphasis mine); See also, A.J. London. "The Ambiguity and the Exigency: Clarifying 'Standard of Care' Arguments in International Research" (2000) 25 J Med Philos. 379; "the nature of the care and treatment that will be provided to participants in research" (see the Nuffield Council on Bioethics, supra note 6 at 86.); and the term might mean, what actually obtains in a particular setting. See, NBAC, at 13.

whatever is routinely provided to people in that country with that medical condition? Or must a control group be provided with the best treatment available elsewhere – the 'standard of care' in the sponsoring country?"[18]

The standard of care debate originates from the basic ethical requirement that participants in research should not be exploited. But how this basic ethical requirement is to be translated in actual practice, especially in developing countries, which have more limited healthcare options, has created heated debate in the literature. Several broad issues arise with regard to standard of care in research. In view of the limited healthcare options available in many developing countries, what standard of care should be offered participants in the control arm of clinical research? Should this differ in any respect from the standard of care offered within similar research elsewhere in the world, particularly in developed countries? Should the same ethical standards apply across borders, irrespective of the different context including, poverty and poor healthcare systems? Is a different standard justifiable on the grounds that the results of the research will ultimately benefit wider populations in developing countries?[19]

Some argue that it is unethical to conduct trials in developing countries which would never be conducted in developed countries for fear of harm to participants and that doing so creates a double standard, one for the rich and another for the poor,[20] and creates room for exploitation.[21] The opponents of

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[18] Macklin (2004), supra note 11 at 34.
[19] Ibid at 36.
[20] P. Lurie and S. M Wolfe, "Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human /Immunodeficiency Virus in Developing Countries" (1997) 337 New Eng. J. Med. 853.
[21] See Marcia Angell, "Investigators' Responsibilities for Human Subjects in Developing Countries" (2000) 342:13 New England Journal of Medicine 967.

this argument counter that this would simply not be feasible in many cases due, among other things, to the poor healthcare systems in many developing countries, and the expensive prices of some of the interventions which, in any case, would be unaffordable for many people in developing countries. Further, they argue that a strict interpretation of the requirement for the universal standard of care as opposed to a local standard of care is unrealistic and may have the devastating effect of preventing research into certain diseases in these countries.[22] It has also been argued that providing effective treatment to participants in the control arm of a clinical trial, where such treatment is not readily obtainable elsewhere in the country, may compel prospective participants to enroll in the study, thus serving as an undue inducement.[23]

The debates surrounding the issue of standard of care were ignited by the 1997 article of Lurie and Wolfe in the *New England Journal of Medicine.*[24] In it, they objected to the unethical nature of clinical trials conducted by the US National Institutes of Health (NIH) and the Centre for Disease Control (CDC) for the prevention of perinatal transmission of HIV involving HIV positive women in South Africa, Uganda, Thailand and other developing countries. The

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[22] For a summary of some of these arguments in relation to the HIV research in developing countries, see generally Paquita De Zulueta, "Randomised Placebo-Controlled Trials and HIV-Infected Pregnant Women in Developing Countries: Ethical Imperialism or Unethical Exploitation?" 15: 4 Bioethics 290 at 293-296. See also, G. Annas "Human Rights and Maternal-Fetal HIV Transmission Prevention Trials in Africa" (1998) 88 Am. J. Pub. Health 560, Marcia Angell, "The Ethics of Clinical Research in the Third world (1997) N. Engl. J. Med. 847-849 and Abdool Q. Karim, et al., "Informed Consent for HIV Testing in a South African Hospital: Is it Truly Informed and Truly Voluntary?" (1998) 88 Am. J. Pub. Health 637.

[23] See generally, Jack Killen *et al*, "Ethics of Clinical Research in the Developing World" (2002) 2 Nature 210. See also *ibid.* See NBAC, supra note 17 at 26.

[24] See Lurie and Wolfe, *supra* note 20. There were responses to the article by Lurie and Wolfw, in which others tried to show that these trials were not unethical. H. Varmus and D. Satcher, "Ethical Complexities of Conducting Research in Developing Countries" (1997) 337 New Eng. J. Med. 1003.

women were not provided antiretroviral treatment, thereby arguably allowing many infants to contract HIV unnecessarily. The trials were argued to be against international ethical guidelines, notably the Helsinki Declaration, which at that time required that "every patient, including those of a control group, if any ... should be given the best proven diagnostic and therapeutic method."[25] The object of the trial was to discover a more affordable means of administering the expensive drug zidovudine (AZT), which had proven effective in treating HIV in developed countries, so that it could be more accessible in developing countries. Commentators, like Angell, likewise insisted that since the use of a placebo would have been unethical in the United States, the use of placebos in zidovudine trials in these developing countries was also unethical.[26] Critics argued that the long-course treatment of AZT could have been used rather than using no treatment at all, reducing the number of babies who became infected with HIV in the trials while still achieving sound scientific results.[27] There were countering responses to the article by Varmus and Satcher.[28] They tried to show that these trials were very much needed in developing countries to produce affordable treatment for HIV. The placebo-controlled trials were necessary to produce faster, clearer and more reliable results than would otherwise be obtained through the use of active controls, which would be more expensive and less efficient. The trials were not unethical, they argued, mainly because of the

[25] Principle 30 of the 1996 Amendment.
[26] Marcia Angell, "The Ethics of Clinical Research in the Third World (1997) N. Engl. J. Med. 847-849.
[27] Lurie and Wolfe, supra note 22.
[28] H. Varmus and D. Satcher, "Ethical Complexities of Conducting Research in Developing Countries" (1997) 337 New Eng. J. Med. 1003.

special context of the trial and the limited circumstances which obtained in the countries in which the trials took place. Other commentators agreed, calling it "ethical imperialism" to impose the standards obtaining in developed countries on developing countries with very different circumstances.[29] These debates drew attention to the problems relating to the use of placebos and the provision of standard treatment to research subjects involved in randomized clinical trials.[30] There have been other cases, for instance, the proposed Surfaxin trials in several Latin American countries in which a placebo was to be used although effective treatment was available in the United States. [31]

Thus, despite the provisions of the international ethical guidelines on these issues, there continues to be controversy in this area and a diversity of thinking on the issues. Is a global and universal standard of care the only acceptable ethical standard? Does this amount to ethical imperialism? Is a local standard of care (treatment based on the standard available in the local or regional context) permissible in some cases, allowing local circumstances and existing conditions to be taken into consideration? Or does this amount to exploitation? Is there a midway between a universal standard of care and a local standard of care? What

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[29] Letter by Edward K. Mbidde (Chaiman of the AIDS Research Committee of the Uganda Cancer Institute, to the director of the NH, 8 May 1997.

[30] S, G. Annas, "Human Rights and Maternal-Fetal HIV Transmission Prevention Trials in Africa" (1998) 88 Am. J. Pub. Health 560.

[31] See James V. Lavery et al, (ed.), *Ethical Issues in International Biomedical Research: A Casebook*, (Oxford: Oxford University Press, 2007) at 151-159. See Macklin 2004, *supra* note 17 at 17-18; or the Hepatitis A vaccine trials conducted in Thailand in 1991 (see R Lie, "Justice and International Research," in R. Levine, S. Gorovitz, and J. Gallagher, (eds.) *Biomedical Research Ethics: Updating International Guidelines* (Geneva: CIOMS-WHO, 2000) at 27-40.). For differing views on the exploitative nature of the Surfaxin trials, see Robert J. Temple, "Benefit to the Trial Participants or Benefit to the Community? How Far Should the Surfaxin Trial Investigators' and Sponsors' Obligations Extend? in Lavery, *supra* note 19 at 155- 159; and Peter Lurie and Sidney Wolfe, "The Developing World as the Answer to the Dreams of Pharmaceutical Companies: The Surfaxin Story" in Lavery, ibid. at 159- 168.

is the role of the international ethical guidelines? Are they a descriptive standard of what is to be done, or an aspirational ideal?[32] Even more broadly, the debates address the disparity between the economic circumstances and healthcare options in developed and developing countries and what justice, equity, and equality mean in terms of health research involving humans in developing countries. Different views on these issues are articulated in the still-growing body of literature.[33]

The other major ethical concern in the developing world context relates to the benefits to be derived from the research to be conducted. This is also directly linked to avoiding exploitation of research participants and research communities. In developing countries where research is mainly sponsored by external entities, research is often driven by economic or academic interests that may not reflect the needs of these countries.[34] Two issues, therefore, arise with regard to benefits. First, is externally-sponsored research justifiable in developing countries, that is, would the research benefit the participants and the wider population? Secondly, what happens with regard to any potential benefit derived from the research after it is over? The Helsinki Declaration[35] and the International Ethical Guidelines for Biomedical Research Involving Human

[32] Macklin (2004), supra note 11.
[33] For more recent articles which deal with this issue, see for example: David Wendler et al, "The Standard of Care Debate: Can Research in Developing Countries Be Both Ethical and Responsive to Those Countries' Health Needs?" (2004) 94:6 American Journal of Public Health 923. A.A. Hyder and L. Dawson, "Defining Standard of Care in the Developing World: The Intersection of International Research Ethics and Health Systems Analysis" (2005) 5 Developing World Bioethics 142; Halley S. Faust, "Is a National Standard of Care Always the Right One?" (2007) 7:1 Developing World Bioethics 45. Hans-Jörg Ehni and Urban Wiesing, International Ethical Regulations on Placebo-Use in Clinical Trials: A Comparative Analysis" (2007) Bioethics Online Early Article.
[34] Nuffield Council on Bioethics, supra note 7.
[35] Principle 17 of the Helsinki Declaration (2008).

Subjects of the Council for International Organisation of Medical Sciences (CIOMS Guidelines)[36] require that health research conducted in any country must be beneficial to the participants in the research project and responsive or relevant to the country's needs, respectively.

Like the standard of care issue, the issue of benefits is fraught with divergent views, some of which have to do with defining exactly what "benefits" consist of, others based on the broader issue of inequities between different countries and how best to address them, and yet others based on different conceptions of justice.[37] Considerable attention has also been devoted in the literature to this issue.[38]

These debates around these ethical concerns in the literature have drawn attention to the wider problem of employing ethical standards in developing countries that differ from the standards used in developed countries. Further, these debates have highlighted the difficulty in the application of ethical principles as may be contained in international ethical guidelines such as the *Helsinki Declaration.*[39]

Beyond the ethical concerns and the difficulties in applying the international guidelines, however, a major concern is whether regulation or

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[36]Guideline 10 of the CIOMS Guidelines.
[37] Macklin (2004) *supra* note 11 at 94.
[38] See for example, Shapiro and Meslin, *ibid.*;; Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries, "Fair Benefits for Research in Developing Countries". (2002) 298 Science 2133; C. Weijer and E.J. Emanuel, "Protecting Communities in Biomedical Research" (2000) 289 Science 1142. Segun Gbadegesin and David Wendler, "Protecting Communities in Health Research from Exploitation" (2006) 20:5 Bioethics 248; Leonard H. Glantz, George J. Annas, Michael Grodin and Wendy K. Mariner, "Research in Developing Countries: Taking Benefits Seriously" (1998) 28 Hastings Center Report 38.
[39] World Medical Association (WMA) *Declaration of Helsinki: Ethical Principles for Research Involving Human Subjects*, adopted by the 18th WMA June 1964, latest amendment made by the 59th WMA General Assembly, Seoul, October 2008. Online: <http://www.wma.net/e/policy/b3.htm>

oversight is keeping pace with the increase in research in developing countries. It would appear that insufficient attention has been paid to the regulation of research involving humans in developing countries as evidenced, for instance, by findings that some developing countries do not have research ethics review boards.[40] In 2001, the Regional Committee for Africa of the World Health Organization (WHO) observed that studies involving humans in the Africa Region were not subjected to ethics review.[41] One study has found that among members of ethics review committees in African countries, "knowledge of local legal frameworks governing research was inconsistent and unclear."[42] This may be as attributable to a lack of comprehensive legal frameworks relating specifically to research involving humans, as to a lack of adequate training about them. Others have noted with specific regard to biomedical research that "many developing countries lack regulatory mechanisms and a legal framework for biomedical research."[43]

Moreover, much of the literature relating to research involving humans in developing countries focuses mainly on the ethics of externally-sponsored research, that is, research sponsored by developed countries or international organisations in developing countries. Much of the literature, while shedding light on this important subject, thus fails to address the ethics and regulation of

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[40] Cheryl Cox Macpherson, "Ethics Committees Research Ethics: Beyond the Guidelines" (2001) Developing World Bioethics 57.

[41] J. Kiriga, C. Wambebe and A. Baba-Mousa, "Status of National Bioethics Committees in the WHO African Region" (2005) 6 BMC Med Ethics E10, online: BMC < http://www.biomedcentral.com/1472-6939/6/10> (April 3, 2007).

[42] See Cecilia Milford, Douglas Wassenaar, and Catherine Slack, "Resources and Needs of Research Ethics Committees in Africa: Preparations for HIV Vaccine Trials" (2006) 28: 2 IRB: Ethics & Human Research 1 at 9.

[43] Alimuddin Zumla and Anthony Costello, "Ethics of Healthcare Research in Developing Countries" (2002) 95 (6) J R Soc Med. 275

indigenous research.[44] For instance, the National Advisory Bioethics Council set up by President Clinton in 2000, produced an important and wide-ranging report on the ethics of research in developing countries in 2001: *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (Volumes 1 and 2).[45] While this report draws attention to the problems of ethics review in developing countries, it focuses mainly on how American researchers and researchers sponsored by institutions in the United States can conduct research ethically in developing countries.

Another report emanating from the United States titled: "The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects"[46] focused on assessing the capacity of the United States Food and Drug Administration (FDA) to protect research participants in foreign clinical trials from which data is generated for the purpose of obtaining FDA approval. It provided a summary of current oversight available in the United States regarding protections for research participants in countries outside the United States, particularly developing countries.

Other insightful texts have been produced on the subject of health research in developing countries in recent years. The Nuffield Council on Bioethics, an independent organization created in 1991 to consider ethical issues in medicine,

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[44] See Zulfiqar Ahmed Bhutta, "Ethics in International Health Research: A Perspective from the Developing World" (2002) 80:2 Bulletin of the World Health Organisation 114 at 115.

[45] National Bioethics Advisory Commission *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries Volume1- Report and Recommendations of the National Bioethics Advisory Commission* (Bethesda, Maryland: National Bioethics Advisory Commission, 2001), (hereafter NBAC).

[46] Department of Health and Human Services, Office of the Inspector General, "The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects" (2001), available online at: <oig.hhs.gov/oei/reports/oei-01-00-00190.pdf> (September 22, 2007)

based in the United Kingdom and funded partly by the United Kingdom Medical Research Council,[47] also produced an in-depth report on health research in developing countries in 2002: *The Ethics of Research Related to Healthcare in Developing Countries*. The stated purpose of the report was to "examine the ethical issues raised when research related to healthcare is carried out in developing countries and funded by sponsors from developed countries."[48] In this light, it discussed extensively the major ethical concerns of informed consent, standard of care, and post-trial obligations. It went further to examine the problems of ethics review in developing countries and how to deal with these problems in practical ways. It recommended, amongst other things, that all countries should establish an effective system for the ethical review of research, which includes the establishment and maintenance of research ethics committees independent of governments and sponsors. It did not, however, engage in a detailed examination of research governance within developing countries.

A book by Ruth Macklin titled: *Double Standards in Medical Research in Developing Countries*,[49] possibly the first book wholly devoted to the subject of research involving humans in developing countries, discusses issues relating to the ethical concerns in internationally-sponsored research in developing countries. This timely book discusses in detail the reasons why employing double ethical standards in medical research in developing countries does not

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[47] See Nuffield Council on Bioethics <www.nuffield bioethics.org> (November 9, 2008).
[48] Nuffield Council on Bioethics, 2002: *The Ethics of Research Related to Healthcare in Developing Countries* (2002), online: < http://www.nuffieldbioethics.org/fileLibrary/pdf/errhdc_fullreport001.pdf> (October 17, 2008), at xv.
[49] Ruth Macklin, *Double Standards in Medical Research in Developing Countries* (Cambridge: Cambridge University Press, 2004).

stand up to scrutiny. It focuses on "the ethical controversies that have surrounded the design and conduct of international medical research sponsored by industrialized countries or industry, and carried out in developing countries." [50] There are several illuminating illustrations of allegations of exploitative research in developing countries and a detailed analysis of the international ethical guidelines and their interpretation and application in developing countries and the difficulties associated with them. However, the book's objective did not include analysis of the governance of research involving humans in developing countries – which this thesis directly engages.

A more recent book on research involving humans in developing countries is *Ethical Issues in International Biomedical Research: A Casebook.* [51] It contains articles and commentaries from several authors who have written extensively about health research in developing countries. It self-describes as "the definitive book on the ethics of research involving human subjects in developing countries."[52] The book's special strength and contribution is the use of several actual case studies to explore and address the thorny ethical issues that arise in conducting research in developing countries. It also attempts to broaden the scope of ethical concerns that arise in the context of research in these countries. Two of the case studies deal with ethics review and regulations. Although arguably implicated in its discussions, there is little discussion of legal frameworks in developing countries.

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[50] See p. i.
[51] James V. Lavery et al, (ed.), *Ethical Issues in International Biomedical Research: A Casebook*, (Oxford: Oxford University Press, 2007).
[52] See Preface.

Several articles have, however, examined emerging ethics review systems in developing countries, including countries in Africa and Latin America.[53] These articles have put forth information about the establishment and the challenges facing ethics review systems in developing countries. Many of them have called for more attention and more studies on ethics review committees in developing countries. While they are certainly a welcome addition to the burgeoning literature in this area, there is still room for further examination.

It is important to note that academic discourse, with its main focus on ethical issues in conducting research in developing countries has, understandably, taken place mainly within a bioethics context. Thus, there has been relatively little analysis from a legal perspective. There is much discussion of ethical principles, and the interpretation, application, and the inadequacies of the international ethical guidelines which contain provisions on these issues. The international ethical guidelines have thus been the subject of a great deal of debate about the principles behind the guidelines, as well as the application of these principles in practice. While this is a good place to start, much remains

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[53] See Nancy Kass *et al*, "The Structure and Function of Research Ethics Committees in Africa: A Case Study" PLoS Med 4:1:e3 See also, R R Love and N Fost, "A Pilot Seminar on Ethical Issues in Clinical Trials for Cancer Researchers in Vietnam" (2003) 25 IRB 8–10; A Hyder, S. Wali, A Khan, N Teoh , N Kass, et al. "Ethical Review of Health Research: A Perspective from Developing Country Researchers" (2004) 30 J Med Ethics 68–72; B. Arda, "Evaluation of Research Ethics Committees in Turkey" (2000) 26 J Med Ethics 26: 459– 461; Jonathan Camp et al, "Challenges Faced by Research Ethics Committees in El Salvador: Results from A Focus Group Study" (2009) 9:1 Developing World Bioethics 11; C C Macpherson, "Ethics Committees, Research Ethics: Beyond the Guidelines" (2001) 1 Developing World Bioethics 57–68; D. Elsayed, "The Current Situation of Health Research and Ethics in Sudan" (2004) 4 Developing World Bioethics 154–159; R Rivera and E Ezcurra, "Composition and Operation of Selected Research Ethics Review Committees in Latin America" (2000) 23 IRB 9–12; R. Coker and M McKee, "Ethical Approval for Health Research in Central and Eastern Europe: An International Survey" (200) 1 Clinical Medicine 197–199; WHO South East Asian Regional Office, *Ethics in Health Research*, (New Delhi: World Health Organization, 2001); J.M Kirigia, C Wambebe, and A Baba-Mousa, "Status of National Research Bioethics Committees in the WHO African Region" (2005) BMC Medical Ethics 6.

unexplored in terms of the regulation of health research within developing countries.

What is missing in the literature on research oversight in developing countries, then, is a broader analysis from a governance and legal perspective which critically examines the structure and adequacy of any existing governance systems and the potential effect of these systems on the protection of human participants in these countries. In this respect, assemblages of research participants' protections such as contained in the *International Compilation of Human Research Protections* compiled by the Office for Human Research Protections (OHRP) in the United States Department of Health and Human Services,[54] and the *Global Research Ethics Map*,[55] a resource prepared by the Harvard School of Public Health, provide important information. However, these resources do not provide, and indeed are not intended to provide, in-depth analysis of research participants' protections in developing countries.

The major argument that this thesis makes and attempts to explore, therefore, is that there is need to take a more comprehensive and systemic view of the regulation of research involving humans in developing countries. There is a need to expand the focus on research involving humans in developing countries to include a consideration of not only the ethical issues, but also fuller examinations of the existing and emerging governance structures and arrangements in developing countries.

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[54] OHRP, *International Compilation of Human Research Protections, 2010* online: <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf> (May 30, 2010).
[55] Harvard School of Public Health, *Global Research Ethics Map* online: <https://webapps.sph.harvard.edu/live/gremap/index_main.cfm?CFID=2273289&CFTOKEN=35907300> (May 30, 2010).

The importance of the governance and regulation of research cannot be overemphasized. Health research involving humans poses physical, social, economic and psychological risks, some of which are amply illustrated in the early historical cases.[56] These risks emphasise the need to ensure that research is ethical and as safe as possible. There is therefore need for oversight of such research. Moreover, researchers require a secure regulatory environment in which to conduct research with the knowledge of what the rules and standards are and, perhaps, the greater possibility of producing research which is socially beneficial to the wider community. Balancing these sometimes competing priorities (ensuring the safety of research participants on one hand, and providing a stable environment for research on the other) requires a governance system. The central objectives of research governance therefore include the promotion of socially beneficial research and improving the quality of any research and any outcome, protecting and safeguarding the interests of persons on whom research is conducted and building, and maintaining public trust.[57]

Governance of research involving humans has thus been defined as "a framework through which institutions are accountable for the scientific quality, ethical acceptability and safety of the research they sponsor or permit."[58]

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[56] A detailed review of some historical cases is contained in J. Katz, *Experimentation with Human Beings* (New York, Russell Sage Foundation, 1972). See also Introduction for some examples.

[57] See A. Samanta and J. Samanta, "Research Governance: Panacea or Problem?" Clin Med. 2005 May-Jun;5(3):235; M. McDonald (ed.), *The Governance of Health Research Involving Human Subjects* (Ottawa: Law Commission of Canada, 2000) at 4; Marie Hirtle, "The Governance of Research Involving Human Participants in Canada" (2003) 11 Health L. J. 137 at 144; Jocelyn Downie and Fiona McDonald, "Revisioning the Oversight of Research Involving Humans in Canada" (2004) 12 Health Law Journal 159 at 160.

[58] M H Walsh, J J McNeil, K J Breen, "Improving the Governance of Health Research" Med J Aust 2005; 182: 468-471. Others define it as: the system of administration and supervision

Further, according to the United Kingdom Research Governance Framework for Health and Social Care, research governance: "sets out principles, requirements and standards; defines mechanisms to deliver them; describes monitoring and assessment arrangements; improves research and safeguards the public by enhancing ethical awareness and scientific quality, promoting good practice reducing adverse incidents and ensuring lessons and forestalling poor performance and misconduct."[59] To summarise in a definition that brings together the process of governance and its objectives in relation to research involving humans, research governance refers to, "the systems in place for ensuring that ... research on human beings is safe [or as safe as possible], conforms to ethical standards and is likely to contribute to scientific understanding."[60] Thus, a research governance system is comprised of mechanisms based on ethical standards, employed to protect research participants and the public, and to ensure that research is potentially beneficial.

Governance issues, as Michael McDonald rightly observes, arise with respect to the proper division of responsibilities for the protection of research participants amongst the agencies and organizations that conduct, sponsor, and regulate research.[61] Extrapolating from this, research governance requires an

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through which research is managed, participants and staff are protected, and accountability is assured. This definition however deemphasizes, wrongly in my view, the ethical foundation for research governance. Sara Shaw, Petra M Boynton and Trisha Greenhalgh, "Research Governance: Where Did it Come From, What Does it Mean?" (2005) 98 Journal of the Royal Society of Medicine 496.

[59] United Kingdom, Department of Health, *Research Governance Framework for Health and Social Care* (Second Edition) (United Kingdom, 2005) at 1.

[60] Victoria Armstrong et al, *Public Perspectives on the Governance of Biomedical Research: A Qualitative Study in a Deliberative Context* (United Kingdom: Wellcome Trust, 2007) at 4.

[61] Michael McDonald, "Canadian Governance of Health Research Involving Human Subjects: Is Anybody Minding the Store?" (2001) 9 Health L. J. 1 at 4, online:

examination of the scope and structure of the system, the responsibilities and composition of the institutions within the system, accountability and compliance mechanisms within the system, all of which have implications for ensuring the protection of participants and promoting beneficial research. Research governance systems (which may be formal or informal), may include overarching legislative/regulatory frameworks and policy framework. Thus, in discussing research governance, one may perhaps choose to focus on a legal perspective examining, for instance, the legal framework for the protection of research participants in developing countries. However, an examination of governance systems in the particular context of research involving humans, as this thesis intends to engage in, appears more encompassing than a strictly legal perspective. This more comprehensive perspective allows a broader, less reductionist analysis of the linkages that come together to form the research governance system, including law.

Research governance is a broad concept focusing on interactions between different actors, state and non-state actors, and encompassing principles and standards on the one hand, and systems defined by accountability mechanisms on the other. The standards straddle different disciplines. As has been rightly noted, "standards that underpin effective research governance exist in the domains of ethics and law, science, information protection, health and safety, intellectual property and commercialisation, financial management, and public relations."[62] An analysis of research governance thus seems necessarily to entail a discourse on a broad range of subjects and even separate disciplines.

[62] Walsh et al, supra note 58 at 469.

However, my focus is mainly on analysing regulatory systems and structures, rather than on inquiring deeply into the ethics of research or into scientific methodologies and outcomes, although these clearly present some of the reasons for the existence of the governance systems. In this thesis, I propose to examine the different components of governance system, including an ethical framework, a legal framework, and institutional mechanisms, using a hybrid framework of governance.

There is increasing interest in the area of health research involving humans and in its governance in developing countries, with many recent publications considering ethics review systems in developing countries.[63] But there are comparatively few publications that examine the governance of research in these countries in a comprehensive way, including the specific role of government or the legal system in regulating research. For instance, with specific respect to law relating to research participants' protection, a recent article observes in relation to such law in West Africa that:

> One difficulty in researching human research subjects laws in West Africa when using law reviews, research journals, and similar sources is that the majority of the articles focus less on actual laws, and more on the need for laws and ethical issues in this area.[64]

In another instance, with specific regard to ethics review committees, an acknowledged component of research governance, Kass *et al*, note that:

> Most literature examining RECs [Research Ethics Committees] comes from wealthier

[63] See note 53.

[64] László M. Szabó and Tamara J. Britt, "Guide to Researching Human Research Subjects Laws in West Africa" (2007) 2:4 Journal of Empirical Research on Human Research Ethics 93 at 100.

> countries... However, there has been little research examining procedures, strengths, and challenges of RECs in developing countries.[65]

Macklin adds that:

> Among the countries known to have regulations or guidelines requiring prior ethical review of research by an independent committee are Uganda, India, Nepal, Thailand, Zimbabwe, Zambia, and South Africa. Less is known about the actual operation of these committees—their membership requirements, terms of reference, and operating procedures.[66]

This vacuum has also been noted by others, including Bhutta, who also observes the relative lack of input by researchers from the developing world. He notes that:

> Recently, there has been considerable debate about the ethical conduct and reviewing of health research, but this debate has largely taken place among ethicists and researchers in

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[65] They further note that: "Additional information on how African RECs function, including their staffing, operating procedures, strengths, and challenges would be useful for African and international researchers working within Africa, and for growing efforts to enhance ethics capacity on this vast continent." See Nancy Kass *et al*, "The Structure and Function of Research Ethics Committees in Africa: A Case Study" PLoS Med 4:1:e3, online: <http://medicine.plosjournals.org/archive/1549-1676/4/1/pdf/10.1371_journal.pmed.0040003-S.pdf> (June 9, 2007). The authors list a number of articles describing issues relating to ethics review committees in developing countries: R R Love and N Fost, "A Pilot Seminar on Ethical Issues in Clinical Trials for Cancer Researchers in Vietnam" (2003) 25 IRB 8–10; A Hyder, S. Wali, A Khan, N Teoh , N Kass, et al. "Ethical Review of Health Research: A Perspective from Developing Country Researchers" (2004) 30 J Med Ethics 68–72; B. Arda, "Evaluation of Research Ethics Committees in Turkey" (2000) 26 J Med Ethics 26: 459– 461; C C Macpherson, "Ethics Committees, Research Ethics: Beyond the Guidelines" (2001) 1 Developing World Bioethics 57–68; D. Elsayed, "The Current Situation of Health Research and Ethics in Sudan" (2004) 4 Developing World Bioethics 154–159; R Rivera and E Ezcurra, "Composition and Operation of Selected Research Ethics Review Committees in Latin America" (2000) 23 IRB 9–12; R. Coker and M McKee, "Ethical Approval for Health Research in Central and Eastern Europe: An International Survey" (200) 1 Clinical Medicine 197–199; WHO South East Asian Regional Office, *Ethics in Health Research*, (New Delhi: World Health Organization, 2001); J.M Kirigia, C Wambebe, and A Baba-Mousa, "Status of National Research Bioethics Committees in the WHO African Region" (2005) BMC Medical Ethics 6.

[66] Ruth Macklin, "After Helsinki: Unresolved Issues in International Research" (2001) 11 Kennedy Institute of Ethics Journal 17 at 25.

> industrialized countries. The views of public health practitioners and researchers from developing countries have been underrepresented.[67]

With increasing publications on research ethics and governance by developing country researchers,[68] this may be changing. However, there is certainly room, and need, for greater representation.

As for regulatory agencies that approve new drugs in developing countries, these have been largely overlooked in the literature. It is not clear how effective they are in protecting any research participants who participate in trials for drugs. Luna points out that this may be because, in fact, they rely on already completed studies in developed countries.[69] However, trials are currently being undertaken in several developing countries for various new drugs and vaccines not yet approved in developing countries, including vaccines for HIV/AIDS. The Pfizer incident which generated much controversy and allegations of harm, discussed later in the thesis, was a trial of a drug in a hospital in Nigeria.[70]

Further, although ethics and ethical issues are at the core of the need for the governance of research, and one can therefore not realistically divorce completely the ethical concerns from the governance of research, there is a vacuum with regard to governance and regulation in the literature that needs to be more fully explored. This gap in the literature is understandable given that

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[67] Bhutta supra note 45 at 114.

[68] A significant number of articles were published within the period that this doctoral thesis was written between 2007 and 2010. See for example, Wen Kilama and Aceme Nyika (ed.), Health Research in Africa: Ethical and Practical Challenges Volume 112, Supplement 1, Pages S1-S102 (November 2009) .

[69] Florencia Luna, "Research in Developing Countries" in Bonnie Steinbock, *The Oxford Handbook of Bioethics* (Oxford: Oxford University Press, 2007) at 329-330.

[70] This case is discussed in more detail in Chapter Four.

many developing countries have, until recently, lacked mechanisms for the protection of research participants, including ethics review committees. For instance, in a study commissioned by the United States National Bioethics Advisory Committee, some researchers expressed frustration over the failure of "national governments to regulate research and to enforce ethical guidelines for all research projects implemented within national boundaries."[71] Bhutta further notes that,

> While the tradition of ethical review committees is well established in developed countries, and the selection and training of members is relatively well organised, this is not the case in developing countries. Indeed, until recently, the concept of local ethics committees – especially established 'standing' committees – was unfamiliar.

Increasingly, however, many developing countries, including African countries, are taking steps to address gaps in the oversight of research and to provide protection for participants in research by establishing or formalizing domestic regulatory regimes and governance structures. These steps include establishing national ethics review boards, and enacting, or amending previously existing guidelines, and even legislation governing research involving humans. Nigeria is one example. At the end of 2006, it produced a national code for ethics in health research.[72] Other developing countries have taken steps to develop new or update old guidelines, revive old ethics review committees or establish ethics

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[71] See also, Nancy Kass and Adnan Hyder, "Attitudes and Experiences of US and Developing Country Investigators Regarding US Human Subjects Regulations" in NBAC volume 2, supra note 17 at B-105.

[72] NHREC, *National Code for Health Research Ethics* (2006), online: <http://www.nhrec.net/nhrec/index.html> (February 7, 2008).

review systems to address existing vacuums in this area. They include Brazil (1996)[73] Uganda, (1997)[74] India (2000)[75] Nepal (2001),[76] Malawi (2002),[77] South Africa (2004)[78] Tanzania (2002)[79] and Kenya (2004).[80] Others like Bangladesh are in the process of developing national guidelines.[81] Still others have taken steps to develop regional associations of ethics committees such as the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP),[82] the Latin American Forum of Ethics Committees in Health Research (FLACIES),[83] and the Pan-African Bioethics Initiative (PABIN).[84] A Pan-African registry is currently being developed for clinical trials conducted in Africa.[85] These are exciting and important developments. Some commentators

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[73] The National Ethics of Research Committee (CONEP) was established by the Brazilian National Health Council (CNS) in 1996 (Resolution 196/96).

[74] Uganda, *Guidelines for the Conduct of Health Research Involving Human Subjects in Uganda* (National Consensus Conference 1997). See S. Loue and D. Okello "Research Bioethics in the Ugandan Context II: Procedural and Substantive Reform" (2002) 28 Journal of law, Medicine and Ethics 165-173.

[75] Indian Council of Medical Research (ICMR), "Ethical Guidelines for Biomedical Research on Human Subjects" (2000), online: <http://www.icmr.nic.in/ethical.pdf> (March 29, 2007).

[76] Nepal Health Research Council, *National Ethical Guidelines For Health Research in Nepal* (2001), online: < http://www.nhrc.org.np/guidelines/nhrc_ethicalguidelines_2001.pdf> (February 7, 2008).

[77] National Research Council of Malawi, *Procedures and Guidelines for the Conduct of Research in Malawi* (2002).

[78] National Health Research Ethics Council, Ethics in Health Research: Principles, Structures and Processes Guidelines. (Pretoria: Department of Health, 2004).

[79] Tanzania set up a national ethics review committee in 2002. See J.K.B. Ikingura, M. Kruger and W. Zeleke, "Health Research Ethics Review and Needs of Institutional Ethics Committees in Tanzania" (2007) 9: 3 Tanzania Health Research Bulletin 154.

[80] National Council for Science and Technology, *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya* (2004); Ministry of Health: *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines* (2005) *Science and Technology Act* (2001).

[81] Harun-Ar-Rashid, "Regional Perspectives in Research Ethics: A Report from Bangladesh" (2006) 12: 1 East Mediterranean Health Journal S66.

[82] http://www.fercap-sidcer.org/

[83] Foro Latino Americano de Comités de Ética en Investigacion en Salud, online: <http://www.flaceis.org>

[84] See online: <http://www.pabin.net/>

[85] The Pan African Clinical Trials Registry, online: <http://www.atmregistry.org/> (September 17, 2009).

have suggested that the emerging policies are comparable, in theory if not practice, to the older systems in developed countries.[86] This is not surprising, given that while these more recent guidelines may be more wide-ranging and may operate more broadly than the older systems found in some developed countries, they have probably drawn on experiences in those countries while also drawing on local context.

Understanding the governance arrangements currently in place in developing countries seems particularly important at this time because of these recent steps taken by many developing countries, including African countries. This need is not lessened by the fact these systems are relatively recent and, it may thus be argued, allowing insufficient time to analyse in any great detail their adequacy and effectiveness in protecting research participants. The potential of these emerging systems and their possible strengths and weaknesses are, in fact, perhaps best analysed at this point when the arrangements are fluid enough to allow for amendments, improvements, and developments in different directions. Certainly some weaknesses may present after a long period of operation. However, instead of choosing to repair a broken system many years from now, this may be the best time to point out possible and early identifiable mistakes and gaps in these new arrangements which could then be corrected from the outset. Such evaluation is also especially crucial because developing countries without governance systems or in the process of establishing governance

[86] See S B Bhat and T T Hegde, "Ethical International Research on Human Subjects Research in the Absence of Local Institutional Review Boards" (2006) 32 J. Med. Ethics 535 at 535 referring to India's guidelines note that, "Indian policy on biomedical clinical trials originating outside the country, although not necessarily effective in practice, is fairly well defined, and in theory comparable with the systems in developed nations."

systems may want to adopt the procedures and systems now in use in developing countries that have taken early steps in this respect.[87]

Examining these systems from a governance perspective is also important not only because such examination provides much-needed descriptive information on the emerging governance systems in developing countries, but because it moves the discourse from identification of issues to proffering of solutions. The discussion about ethical concerns is important because it addresses the ways in which the conduct of research affects participants. To put these concerns into a context in which action can be taken, however, there is a need for domestic governance structures and systems, including policy guidelines, legislation and ethics review mechanisms.

As earlier pointed out, much of the literature on research involving humans in developing countries focuses on internationally-sponsored research in developing countries. Discussions on the ethics of international research or research supported by developed country sponsors in developing countries and particular ethical concerns remain important, not least because they address important issues of global equity and the practical application of ethical principles. However, the literature fails to address the ethics and regulation of indigenous or domestic research,[88] that is, research sponsored by entities within developing countries. The current emphasis on global economic, health and knowledge disparities is not misplaced, and this has undoubtedly had a positive

[87] For instance, Nigeria appears to be borrowing some of South Africa's concepts, including enacting legislation similar to South African legislation and establishing a national ethics review committee.

[88] See Zulfiqar Ahmed Bhutta, "Ethics in International Health Research: A Perspective from the Developing World" (2002) 80:2 Bulletin of the World Health Organisation 114 at 115.

impact on recent regulatory developments in developing countries. But there is little consideration of how indigenous research is governed or regulated in developing countries or how research participants in this type of research (no matter how little) are protected. An understanding of domestic governance systems is especially important therefore because such systems govern all research involving humans, not only internationally-sponsored research but also indigenous or domestically-sponsored research.

In a similar vein, there is some focus in the literature on the provision of equivalent protections by developed countries when their citizens or companies sponsor or conduct research in developing countries.[89] These are undoubtedly important and even morally desirable. But discussion of domestic governance systems allows room for consideration of developing countries' ownership in the protection of their citizens who become research participants. This shift in focus could also allow for more participation of researchers from the developing world in these important debates.

Examining research involving humans from a governance perspective is also helpful because it allows one to ask the crucial question: What regulatory tools and institutions are required to effectively govern research involving humans? The first tool that typically comes to mind is ethics review. Ethics review is a process by which research projects and protocols are evaluated by a

[89] See for example, United States, Department of Health and Human Services, 'Report of the Equivalent Protections' (2003), available at: _http://www.hhs.gov/ohrp/international/EPWGReport2003.pdf (5 April, 2007). See also, "Biomedical Research Projects in Developing Countries" (Denmark) (2006), online: <http://www.cvk.im.dk/cvkEverest/Publications/cvkx2Eimx2Edk%20x2D%20dokumenter/English/20061130095326/CurrentVersion/ulandssagerENG.pdf> (April 3, 2007).

committee of persons independent of the researchers to assess the ethical acceptability of the projects.[90] These committees are required to safeguard the rights, safety, and well-being of the research participants.[91] Ethics review is now a central part of the research governance systems of many countries and the ethics review system may therefore be mistakenly considered the governance system.

The literature tends, therefore, to examine mainly the work of ethics review committees, particularly in developed countries where they have been established for a longer period. However, a broader and more inclusive view of research governance systems may include other components apart from the ethics review system, such as a legal framework, including formal legislation and other forms of law; national and international ethics guidelines; professional associations and codes of conduct; national regulatory bodies such as the ones which regulate pharmaceutical production and the use of human participants, departments of health (of which the drug regulatory agency may be a part); civil

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[90] An ethics committee has been defined as: " An independent body ... consisting of healthcare professionals and non-medical members, whose responsibilities it is to protect the rights, safety, and wellbeing of human subjects involved in a trial and provide public assurance of that protection by, among other things, expressing an opinion on the trial protocol, the suitability of the investigator and the adequacy of the facilities, and on methods and documents to be used to inform trial subjects and obtain their informed consent." See Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001. *Official Journal of the European Communities* 1 May 2001. L121/34. <http://eudract.emea.eu.int/docs/Dir2001-20_en.pdf> (8 Mar 2007). The independence of ethics review committees has been questioned in the literature, especially where they operate within an institutional context and there is a possibility of conflicts of interest as in Nigeria and South Africa and many other countries. See for example, Ezekiel J Emmanuel *et al*, "Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals" (2004) 141: 1 Annals of Internal Medicine 282, online: <http://www.annals.org/cgi/reprint/141/4/282.pdf> (May 24, 2007) at 283. See also, Carl H. Coleman and Marie Bousseau, "Strengthening Local Review of Research in Africa: Is the IRB Model Relevant?" (2006), online: <http://www.bioethicsforum.org/ethics-review-of-medical-research-in-Africa.asp> (June 22, 2007).

[91] See Commentary to Guideline 2 of the CIOMS Guidelines.

society, including non-governmental organizations which promote patients' rights; the general public, the research participants themselves, and the interactions between these entities.[92] An examination of different jurisdictions will show that these tools and institutions are employed in the governance of research in varying degrees.

There is need, therefore, to expand the focus on health research involving humans in developing countries to include a consideration of not only the ethical issues, but also more detailed examinations of the emerging governance structures in developing countries. An analysis of these emerging domestic regulatory and governance regimes is necessary to understand the context for the local application of ethical principles, to provide information on these recent developments, and as mentioned earlier, to proactively identify and draw attention to national systems and practices, and the potential issues, weaknesses and problems that may arise in these new regimes. And, in so doing, one could indicate concerns that developing countries may want to take into consideration in establishing or building on their domestic governance mechanisms. Hence, the main aim of this thesis is to set forth a more comprehensive and systemic view of the governance and regulation of research involving humans in developing countries. For this purpose, my thesis will focus on a case study of a developing country: Nigeria.

A word is perhaps necessary here on the use of the term "developing countries." Although the main focus of the thesis is on an analysis of the

[92] See Ann Strode, Catherine Slack, Muriel Mushariwa, "HIV Vaccine Research – South Africa's Ethical-Legal Framework and Its Ability to Promote the Welfare of Trial Participants" (2005) 95: 8 South African Medical Journal 598.

Nigerian system of research participants' protection, I make reference to 'developing countries' as part of the contextual framework which provides the rationale for the thesis and within which I pursue my analysis. With particular regard to research involving humans, understanding the context within which such research takes place is important for a proper appreciation of some of the peculiar issues that may arise in analysing the need for oversight and the obstacles that may beset the governance systems. I also address the issues from the perspective of a scholar originating from one of such countries. Further, this research targets developing countries as some of its main audience, for whom I hope this work may serve a useful purpose.

So, what are 'developing countries'? The term 'developing countries,' although a widely-used term does not have a strict definition, is frequently used rather loosely,[93] and "lacks precision and explanatory power."[94] However, it refers principally to an economic level which is lower than that of some other countries.[95] Other features include widespread poverty in both rural and urban

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[93] Mitsuo Matsushita et al., *The World Trade Organization* (Oxford: Oxford University Press, 2003) at 374. Even within important international agreements, such as the World Trade Organisation agreements which sometimes require differential treatment of developing countries, the term is not defined.

[94] Robert J. Griffiths (ed.), *Developing World 95/96* (Sixth Edition) (Connecticut: The Dushkin Publishing Group, 1995) at 4.

[95] The World Bank which categorises countries using gross national income (GNI) per capita as the main criterion, classifies developing countries into low-income economies (that is, countries with an income per capita of $735 or less). These include countries like India, Nigeria, Afghanistan, Bangladesh, Uganda, Zambia, and Zimbabwe, lower middle-income economies (countries with an income per capita of $736 to $2,935). These include countries like South Africa, China, Egypt, Thailand, Philippines. The countries which fall into these income brackets are generally referred to as developing countries. The UN also designates forty-nine countries as "least developed countries (LDCs)." This designation is based on such indices as low income, weak human assets, a high level of economic vulnerability and a population of less than 75 million The low income per capita criterion employed by the World Bank places all developing countries in one category in spite of the wide diversity that exists between these countries including socio-cultural and political dissimilarities as well as differences in population, size, ownership of natural resources, wealth distribution, and ethnic diversity among other things.

areas, massive migration from rural to urban areas, uneven distribution of wealth and unequal opportunities for education, employment and access to health care.[96] Although they are not a homogenous group, and important differences exist between developing countries, even in terms of economic development and health research capacity,[97] there are important similarities which make a group analysis possible and appropriate. These include the inadequacy of resources to meet the needs of their citizens, widespread poverty, low standards of living, high rates of population growth, and general economic and technological dependence on developed countries, relatively poor health care systems, high birth and death rates and low life expectancy, as well as the relative lack of access to knowledge and information about research.[98] Macklin notes that it may be appropriate to address developing countries together especially with respect to analysis on the subject of research involving humans. According to her:

See World Bank, "Country Classification" online: World Bank <http://www.worldbank.org/data/countryclass/countryclass.html> (December 8, 2007). United Nations Conference on Trade and Development (UNCTAD), *The Least Developed Countries Report 2002: Escaping the Poverty* Trap (Geneva, UNCTAD, 2002) at ii. Online: <http://www.unctad.org/en/docs//ldc2002_en.pdf> (December 8, 2007).

[96] Griffiths, supra note 94.

[97] Macklin notes accurately that: "there is a continuum along which countries typically called "developing" fall with regard to the above characteristics. Most of the countries in sub-Saharan Africa are desperately poor, have little or no manufacturing capability, and have few highly trained and experienced biomedical researchers. South Africa is the key exception, with Uganda, Kenya and Nigeria ranking somewhat above most other countries in these respects. A look at South America reveals that Brazil and Argentian boast many highly trained and experienced biomedical researchers. These countries have had an industrial infrastructure for many years. Yet Brazil is the country with the widest gap between the richest and poorest members of the population, and Argentina has slid from being a First World country (at the beginning of the twentieth century) to occupying the financial status of a Third World country (at the beginning of the twenty-first century). Among Asian countries, Thailand, India, and China all have highly trained and experienced biomedical researchers and all also have the capability to manufacture drugs." See Macklin (2004), supra note 11 at 10-11.

[98] Martin Bulmer and Donald P Warwick, *Social Science Research in Developing Countries: Surveys and Censuses in the Third World* (London: UCL Press, 1993) at 1- 2.

> It depends on the specific features of a country that bear on the research enterprise. It is appropriate to lump together countries that are resource-poor, since neither the government nor the majority of citizens can afford medical treatments that become largely available to residents of wealthier countries once research is concluded. It is appropriate to lump together countries that have few trained scientists and little experience of conducting biomedical research. And it is appropriate to lump together countries that lack ethical guidelines for research and have little or no capacity for conducting ethical review of research conducted there by industry or by scientists from industrialised countries.[99]

The regulatory capacity of many developing countries in many areas including, as Macklin points out, health research involving humans, is weak.[100] This is evident in the paucity of ethics review committees and limited capacity for effective ethics review. Apart from limited financial resources, the expertise needed for ethics review is frequently inadequate and the need for training in research ethics, which is currently lacking in many developing countries, has been noted elsewhere.[101] Further, generally speaking, regulation and governance take place against a backdrop of, in many cases, relatively new democracies in which regulatory institutions are still in the process of development.[102] The analysis undertaken in the thesis discusses governance

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[99] See Macklin (2004), supra note 11 at 10.

[100] J Stern, "Electricity and Telecommunications Regulatory Institutions in Small and Developing Countries" (2000) 9 Utilities Policy 131 at 136, observing in relation to utilities regulation that there is a problem of ensuring an adequate supply of regulatory staff and skills which are critical for establishing effective reforms in developing countries.

[101] Nuffield Council on Bioethics, supra note 7 at 8.

[102] Both Nigeria and South Africa have relatively new democracies, 1996 and 1999 respectively, although the stage of institutional development in the two countries may differ.

within this context. The group analysis that creates the background for the thesis is, however, nuanced and made more specific by a focus on Nigeria.

The thesis is descriptive, analytic, and prescriptive. Part of the aim in conducting this analysis is to describe and set out in detail the emerging governance systems in developing countries, specifically, Nigeria. The descriptions are then employed in assessing and evaluating the adequacy of the systems in place in Nigeria and to make suggestions for further improvement. Several questions are raised and an attempt is made to answer them in this thesis. Such questions include: Why are research governance systems needed in developing countries? How is research involving humans currently governed in the country under analysis, Nigeria? What are/ought to be the values underlying these emerging systems of governance? What is the role of law, if any, in these systems, and what are the implications of this role or lack thereof on the protection of research participants? What ought to be the role of law? What are the strengths and weaknesses of the governance system currently under development in Nigeria? How can the system be improved to ensure better protection of research participants in Nigeria?

In conducting the analysis, reference is made to the existing oversight systems of other countries. Such references are not in-depth discussions but are necessarily limited to particular contexts in order to ensure proper focus on Nigeria and to keep the thesis within manageable limits. The aim of such reference will not only be to draw useful contrasts and comparisons, but to draw lessons from these countries in terms of what governance and regulatory

arrangements truly work and what arrangements would be unworkable for Nigeria and other developing countries.

It is anticipated that this work will to some extent address the existing vacuum in the literature, namely an exposition and analysis of the governance arrangements for health research involving humans in developing countries. It is also hoped that it would contribute to the burgeoning literature on health research involving humans in developing countries. It would hopefully be of value to scholars, research sponsors, researchers and regulators in developed and developing countries who need to understand research governance and regulation in different jurisdictions, particularly the emergent governance regimes of developing countries.

1.4 The Need for Health Research

While it is important to ensure that research is governed in such a way as to ensure the safety of research participants, it is reasonable to ask the questions: What is health research? Why is it needed in developing countries? Below I consider briefly what health research means, the need for health research generally, and then examine in the next subsection the need for health research specifically in developing countries.

Health research involving humans may be described as research that seeks by systematic investigation to produce generalisable knowledge about the

health of human beings.[103] In effect, it is a process in which social and scientific investigations are undertaken with human beings as subjects, and which has as its goal generalisable knowledge with the potential to improve human health. Different types of health research are carried out in all countries (on different levels and scales) for the purposes of, among others, preventing and treating new diseases, including through the development of new and better means of diagnosis, therapeutic and preventive medicines and delivery systems. In addition to aiding the discovery of new treatments, health research also helps to determine the actual effectiveness of already accepted treatments.[104] It also involves research seeking to answer medical questions regarding the history, causes (including socio-economic roots) and progression of diseases. Testing new treatments, in particular, may require the conducting of clinical trials to determine the merits of different treatments and interventions. Such clinical trials often entail research on human beings and materials drawn from human beings[105] and is usually aimed at providing generalisable knowledge for the health benefits of a wide group of people. In this sense, clinical research is different from therapy, which may also be carried out concurrently with such

[103] This extrapolates the definitions of 'research' found in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998) available online at Interagency Advisory Panel on Research Ethics <http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm> (August 11, 2007); in the United States Department of Health and Human Services regulations: 42 CFR 52.5.

[104] See Jocelyn Downie, "Contemporary Health Research: A Cautionary Tale" (2003) Health Law Journal (Special Edition) at 1.

[105] Baruch A. Brody, *The Ethics of Biomedical Research: The Ethics of Biomedical Research: An International Perspective* (New York, Oxford University Press) 1998 at 2.

research.[106] Other types of health research investigate social determinants of disease and the effect of behavioural patterns on health.

Health research thus includes clinical research, social and behavioural research, basic research, laboratory and operational research as well as feasibility studies, epidemiological research, and health systems research. [107] But not all these types of research require participation by human subjects. Feasibility studies, for instance, may be carried out to evaluate the practicability of integrating certain methods of inspection into existing health care facilities. Health systems research may be carried out to assess the suitability of health care facilities in delivering care to patients. These may, however, not necessarily require participation by human subjects.

An important caveat to mention at this juncture is research involving complementary and alternative medicine (CAM) and traditional medicine. While this may involve human participants, and while this may raise issues particularly relevant to many developing countries in which CAM and traditional medicine are employed widely, this thesis focuses on research on conventional or orthodox medical practices and social investigations related therewith. References to drugs are as understood in orthodox biomedicine. There are several reasons for excluding this type of research, the most important of which is that much of the emerging regulatory guidelines in developing countries do not specifically refer to the governance of CAM. And, while it

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[106] See Kathleen Cranley Glass and Trudo Lemmens, "Research Involving Humans" in Jocelyn Downie et al, (eds.), *Canadian Health Law and Policy*, 2nd ed. (Ontario, Butterworths, 2002) at 460.

[107] See Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries* (London: Nuffield Council on Bioethics, 2002) at 25-26.

would be a worthwhile venture to explore the governance of CAM involving humans, in order to limit the scope of this thesis to manageable proportions within the limited timeframe, I do not focus specifically on the governance of research involving humans in CAM and traditional medicine.

It is important to note that, although there tends to be a focus in the literature, and even in research governance systems, on biomedical or clinical research (perhaps because of the more obvious physical risk involved in such research), health research involving humans is not restricted to such research. Health research involving humans also extends to social science or behavioural research and research in the humanities in which humans are the subjects and which may have health implications. For instance, the example of the Tudor study in which it was sought to determine if children could be induced to stutter by being labeled stutterers may, strictly speaking, not be considered clinical research and yet it caused harm to children.[108] Other examples may include a study of the effect of sexual violence on women during genocide, or a study of stigmatization as a result of infection with leprosy, mental illness or HIV, or studies on sexual behaviours of persons who have undergone HIV testing and counseling,[109] aimed at reducing high risk sexual behaviour, or studies of the health effects of domestic violence and emotional abuse against women.[110] Such research also includes studies involving children with learning disabilities or cognitive impairments or studies involving access to records of personal or

[108] Nicoline Grinager Ambrose & Ehud Yairi, "The Tudor Study: Data and Ethics" (2002) 11:2 Am. J. Speech-Language Pathology 190.
[109] Nuffield Council on Bioethics, supra note 7 at 25.
[110] See Lavery, supra note 33 at 347-358.

confidential information, including genetic or other biological information, concerning identifiable persons. [111] These scenarios can all, in a broad understanding of "health," be considered health research involving humans. In these kinds of research, there is also the possibility of harm. For instance, failure to obtain informed consent or disclosure of private information obtained in the course of the research may cause harm to research participants. Other harms may also include psychological stress, or an experiencing of anxiety or humiliation.

As Downie points out, and as the examples above show, research risks are not so neatly identified with disciplines. [112] The discipline, by itself, does not determine the presence or absence of ethical considerations, but rather whether or not the methodology employed (which is not determined by the discipline) results in the research having a direct impact on human beings.[113] Moreover, with the increasingly interdisciplinary nature of investigations of health accompanying the recognition that the determinants of health come not only from health therapies and technologies but are also dependent on social and economic factors, focusing governance only on biomedical research seems

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[111] Economic and Social Research Council, "Research Ethics Framework" at 8, online: <http://www.esrc.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf> (March 3, 2010).

[112] Jocelyn Downie, "The Canadian Agency for the Oversight of Research Involving Humans: A Reform Proposal" (2006) 13 Accountability in Research 75 at 83. Social Science Research Ethics in Developing Countries and Contexts" (2004) ESRC Research Ethics Framework, <http://www.york.ac.uk/res/ref/docs/REFpaper3_v2.pdf> (April 26, 2007). See also, Brenda Louw and Rina Delport, "Contextual Challenges in South Africa: The Role of a Research Ethics Committee" (2006) 4:4 Journal of Academic Ethics 39-60. See Kevin D. Haggerty, "Ethics Creep: Governing Social Science Research in the Name of Ethics" (2004) 27: 4 Qualitative Sociology at 399.

[113] Michael Owens, "Engaging the Humanities? Research Ethics in Canada" (2002) 33:3 Journal of Research Administration 5 at 6.

faulty.[114] In any event, many institutions and countries have adopted the gradation of risk, including the concept of "minimal risk"[115] in an attempt to provide a system where research is reviewed according to the intensity of the risk.

With respect to risks, Waring and Lemmens classify the risks accompanying health research involving humans into two broad categories: risks to persons and risks to social values. Risks to the person might be physical, such as death or injury resulting from interventions or unexpected responses to environmental, genetic, pharmacological, or environmental factors. Risks to the person might also be psychological harms including psychological stress, or an experiencing of anxiety or humiliation. Risks to social values include risks to the objectivity and scientific integrity of research that are posed by conflicts of interest and to public trust in the ethical conduct of research. Research risks may also be collective in the sense that research may potentially harm a community instead of an individual. The results of research may cause

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[114] Increasingly, therefore, oversight is being extended to social science research involving humans. In Australia and Canada, for example, major guidance covers biological sciences, social sciences and the humanities. See Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 1998 (with 2000, 2002 and 2005 amendments). See NHMRC, *National Statement on Ethical Conduct in Human Research* 2007, online: <http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf> (June 20, 2007). See generally, "Purpose, Scope and Limits of this Document" at p.7.This is not always viewed favorably. See for example, Haggerty, supra note 114. See, C. Kristina Gunsalus, "Human Subject Protections: Some Thoughts on Costs and Benefits in the Humanistic Disciplines" in Arthur Galston, and Christiana Peppard (eds.) *Expanding Horizons in Bioethics* (Dordrecht: Kluwer Academic Publishers, 2005). See also, Giving Voice to the Spectrum: Report of the Social Sciences and Humanities Research Ethics Special Working Committee to the Interagency Advisory Panel on Research Ethics (June 2004), online: <http://www.pre.ethics.gc.ca/english/workgroups/sshwc/SSHWCVoiceReportJune2004.pdf> (October 19, 2007).

[115] These include countries like the United States and Canada.

significant harm in the community, for instance, where the results are used to justify discrimination against or within a community, or support harmful stereotypes or social perceptions. Such harm is of particular issue in already vulnerable and disadvantaged communities in various countries, including developing countries.[116] These risks are the main reason why health research involving humans requires regulation by effective governance mechanisms. They can also occur in different types of health research. All told therefore, it may not be wise to draw a strict line between the types of research, biomedical research or social science research which has health implications, particularly since there are risks in these types, (although the risks are perhaps more conspicuous in biomedical research and less easy to assess in social and behavioural research[117]), and this strict demarcation is avoided in this thesis.

Even with the risks, health research involving human participants has many benefits, including the promotion of health and understanding of human behaviour. Steady progress in biomedical research in particular has, in recent years, yielded a larger store of effective medicines and sophisticated

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[116] Duff R Waring and Trudo Lemmens, "Integrating Values in Risk Analysis of Biomedical Research: The Case for Regulatory and Law Reform (2004) 54:3 University of Toronto Law Journal 249 at 251. See also Baruch A. Brody, Laurence B. McCullough, Richard R. Sharp, "Consensus and Controversy in Clinical Research Ethics" (2005) 294: 11 Journal of the American Medical Association 1411 at 1412. See also, Sherry I. Brandt-Rauf et al, "Ashkenazi Jews and Breast Cancer: The Consequences
of Linking Ethnic Identity to Genetic Disease" (2006) 96:11 American Journal of Public Health 1979.
With respect to conflict of interest, Waring and Lemmens note that: "Conflicts of interest, for example, may have a conscious or unconscious impact on the way researchers represent risks or on other behaviour of research staff during the recruitment process or during the research itself. In areas where there are problems with the understanding and transmission of risk information to participants, there is greater concern about the impact of conflicts of interest and more reason to develop a fully independent review of risks." See p. 251

[117] Susan M. Labott and Timothy P. Johnson, "Psychological and Social Risks of Behavioral Research" (2004) 26:3 IRB: Ethics and Human Research 11.

technologies for curing diseases and improving health outcomes than has ever been available. Moreover, the clear linkages between health and development,[118] and health and human rights,[119] mean that research into factors, including socio-economic factors, which promote good health remains vital, particularly in developing countries. Consequently, health research involving humans is carried out in all countries (on different levels and scales) for the purposes of, among other things, preventing and treating new diseases, exploring social behaviours, attitudes, and values which may have practical benefits, including providing information for policy-making as well as promoting health.

1.5 The Need for Health Research in Developing Countries

In developing countries where eighty percent of the world's population live, there is a high burden of disease and high levels of poverty, including communicable diseases and very low levels of life expectancy.[120] In these countries, health research is particularly important to find ways of reducing that burden and, where possible, by the least expensive means. Research into the

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[118] See Global Forum for Health Research, 10/90 Report on Health Research 2003-2004, online: <http://www.globalforumhealth.org/Site/002__What%20we%20do/005__Publications/001__10%2090%20reports.php> (November 3, 2008) at pp.3-6, for an exposition of the linkages, with several examples in different countries. See also, See for example, World Bank, *World Development Report 1993: Investing in Health* (Geneva: World Bank, 1993), online: World Bank <http://www-wds.worldbank.org/servlet/WDS_IBank_Servlet?pcont=details&eid=000009265_3970716142319> (September 15, 2008) at 17-19, discussing the impact of health on economic growth and development in developing countries.

[119] See for example, Paul Hunt, Rébecca Steward, Judith Bueno de Mesquita and Lisa Oldring, "Neglected diseases: A Human Rights Analysis" Social, Economic and Behavioural Research. Special Topics No.6, TDR Research Publications (2007), online: < http://www.who.int/tdr/svc/publications/tdr-research-publications/neglected-diseases-human-right-analysis> (November 12, 2008), examining the linkages between neglected diseases and human rights in developing countries.

[120] Nuffield Council on Bioethics, supra note 7 at 6.

factors that determine good health is also important. Although many of the diseases in developing countries require simple interventions that do not perhaps necessitate extensive health research, such as improved sanitation, adequate nutrition and clean water, the high incidence of diseases such as HIV/AIDS and malaria means that continued health research remains crucial.[121] Also, therapies that have already proven effective elsewhere may need to be tested specifically in developing countries because of genetic and environmental differences.[122]

Research undertaken in the past in many developing countries into diseases such as malaria, yellow fever, and trypanosomiasis has contributed immensely to knowledge about the prevention and treatment of these diseases.[123] Clinical trials in developing countries conducted in developing countries have contributed to public health knowledge and practice in both developing and developed countries.[124] The HIV/AIDS epidemic in particular — with an estimated 33 million people infected worldwide, the majority of these people living in developing countries, especially sub-Saharan Africa[125] — emphasizes the need for research. HIV/AIDS research has made it possible to discover the cause of the disease and interventions such as antiretroviral drugs that have

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[121] Nuffield Council on Bioethics, *The Ethics of Clinical Research in Developing Countries* (London: Nuffield Council on Bioethics 1999) at 2.
[122] Nuffield Council on Bioethics, supra note 7 at 15.
[123] Nuffield Council on Bioethics, supra note 7 at 6. For instance, the Rockfeller Foundation Yellow Fever Commission undertook research on yellow-fever in 1920s in West Africa. See Olajide Ajayi, "Health Research in Nigeria." Online: Oxford Research Forum <http://www.oxfordresearchforum.i12.com/editorials/nigeria.htm> (March 3, 2004).
[124] See David Mabey, "Importance of Clinical Trials in Developing Countries" (1996) 348 Lancet 1113 for examples of trials in developing countries that have influenced clinical and public health practice in the developed world.
[125] Joint United Nations Programme on HIV/AIDS (UNAIDS), *2008 Report on the Global AIDS Epidemic* (Geneva: UNAIDS, 2008), online: <http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp> (November 5, 2008) at 32.

made the disease a manageable condition rather than a death sentence. Continued research in developing countries is necessary to discover better preventive methods, a cure, or preventive vaccine.

Despite the obvious need for health research in developing countries, resources for undertaking such research are sadly lacking. Developing countries lack trained researchers, infrastructure, and sufficient resources to allocate to health research. They may also lack the political will to devote the resources available to them to health research.[126] There is a high level of dependence, therefore, on foreign sponsors in the developed world. Governmental organizations such as the National Institutes of Health (NIH), and the Centers for Disease Control (CDC) in the United States, the Canadian International Development Agency (CIDA), the International Development Research Centre (IDRC), the Canadian Institutes of Health Research (CIHR), the United Kingdom Medical Research Council (MRC) and the UK Department for International Development (DfID), France's Agence Nationale de Recherches sur le Sida (ANRS) and the European-Developing Countries Clinical Trials Programme (EDCTP); international organizations such as the World Health Organisation (WHO) and United Nations Development Programme/World

[126] The Commission on Health recommended a programme of essential national health research, a concept for identifying research priorities for each developing country to address problems specific to each country as well as global problems. It also recommended that at least 2 per cent of national health expenditure should be invested in the programme and that at least 5 per cent of all grants should go to research. Not many developing countries have heeded these recommendations. At present, some developing countries, including South Africa, Thailand, Pakistan and Tanzania, have adopted the Essential National Health Research (ENHR) strategy. However, progress in implementing the ENHR strategies has been "slow and uneven." See Nuffield Council on Bioethics, *supra* note 72 at 27. See Global Forum on Health, Equitable Access: Research Challenges for Health in Developing Countries (Geneva: Global Forum on Health, 2008), online: <http://www.globalforumhealth.org/Site/002__What%20we%20do/005__Publications/009__Forum%20Reports.php> (November 7, 2008) at 17.

Bank/WHO 'Special Programme for Research and Training in Tropical Diseases' (TDR); or non-profit organisations originating in developed countries such as the Wellcome Trust and the Bill and Melinda Gates Foundation, sponsor research on areas such as HIV/AIDS, tuberculosis, malaria, diabetes, hypertension, cardio-vascular disease, and sexual and reproductive health in many developing countries.[127]

Pharmaceutical companies also sponsor research into new drugs in developing countries. The development of new drugs may be targeted for the needs of developing countries or may simply be undertaken for the development of new interventions for diseases which may not necessarily be prevalent in developing countries. The dependence on foreign sponsors creates its own problems, raising questions about the motives of such sponsors,[128] research priorities and how responsive research projects are to the health needs of the population, who sets the agenda for research in the developing world,[129] as well

[127] See generally the Nuffield Council on Bioethics, *supra* note 72; see also Global Forum on Health, The 10/90 Report on Health Research 2003-2004 (Geneva: Global Forum on Health, 2004), particularly Chapter 9.

[128] The motives of foreign sponsors are arguably varied, ranging from altruistic to self-interested reasons. As the NBAC notes: "The studies in question might simply be one way of helping the host country address a public health problem, or they might reflect a research sponsor's assessment that the foreign location is a more convenient, efficient, or less troublesome site for conducting a particular clinical trial. They might also represent a joint effort to address an important health concern faced by both parties." See NBAC, supra note 17 at i. Some authors have questioned the motives of multinational pharmaceutical companies in conducting drug research in developing countries, especially when the resulting drugs may be unaffordable for people in these countries. See Macklin (2004), supra note 11 at 6-9. Reduced costs, legislative and regulatory vacuum resulting in fewer delays and requirements, the availability of more willing and treatment naïve participants, foreign market development have been identified as possible motivations for multinational pharmaceutical companies' interest. See David M. Carr, "Pfizer's Epidemic: A Need for International Regulation of Human Experimentation in Developing Countries" (2002) 35 Case W. Res. J. Int. L. See also Shamoo, *supra* note 9 and Shah, *supra* note 8, *Globalization of Clinical Trials*, *ibid.*

[129] Nuffield Council on Bioethics, supra note 7.

as whether or not developing countries benefit adequately from such research efforts.

However, even with the resources provided by sponsors in the developed world, there is still a wide gap in the resources for, and therefore the level of, health research conducted in developing countries. Previous studies, particularly the study published by the Commission on Health Research for Development in 1990, [130] had shown that only ten percent of the resources available globally are devoted to diseases that account for ninety percent of global diseases, principally affecting poor people in developing countries – the "10/90 gap."[131] In recent years, there has been an increase in the volume of research in these countries, a trend frequently referred to as the "globalization of research."[132] For example, a report by the Office of the Inspector General in the United States Department of Health in 2001 noted a sharp 16-fold increase in

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[130] Commission on Health Research for Development, *Health Research: Essential Link to Equity in Development* (New York: Oxford University Press, 1990) reporting the great disparity between the amounts spent on research in developed and developing countries and noting that only 5 percent of monies available were devoted to research in developing countries which bear over 90 percent of the burden of diseases. See generally also, Global Forum for Health Research, *The 10/90 Report on Health Research, 2001–2002* (Geneva: The Forum, 2002), online: Global Forum <http://www.globalforumhealth.org/Site/002__What%20we%20do/005__Publications/001__10%2090%20reports.php> (September 15, 2007). As well, health issues in the developing world appear to be under-represented in medical literature around the world. See for example, A Langer, Diaz-Olavarieta, C K Berdichevsky and J Villar "Why is Research from Developing Countries Underrepresented in International Health Literature, and What Can Be Done about It?" (2004) 82:10 Bulletin of the World Health Organisation. Bernard Lown and Amitava Banerjee, "The Developing World in The New England Journal of Medicine" (2007) Globalization and Health, online: <http://www.globalizationandhealth.com/content/2/1/3> (October 10, 2007).

[131] World Health Organization, *Investing in Health Research and Development: Report of the Ad Hoc Committee on Health Research Relating to Future Intervention Options* (Geneva, WHO, 1996).

[132] "Social Science Research Ethics in Developing Countries and Contexts" (2004) ESRC Research Ethics Framework, <http://www.york.ac.uk/res/ref/docs/REFpaper3_v2.pdf> (April 26, 2007), describes this as research becoming a broadly distributed process, with many different actors across the globe. See also, Seth W Glickman et al, "Ethical and Scientific Implications of the Globalization of Clinical Research" (2009) 360:8 New England Journal of Medicine 816.

foreign research conducted for the approval of drugs in the United States.[133] Much of this increase has been reported in countries in Eastern Europe, Latin America, and Asia.[134] This increase in global research, particularly in developing countries, is attributable to several factors, including the interest of non-profit organizations like the Bill and Melinda Gates Foundation in these countries, the increase in international collaboration and public-private partnerships such as the Medicines for Malaria Venture (MMV).[135] The pharmaceutical industry's interest in the availability of treatment naïve participants and in foreign market development, as well as the prevalence of HIV/AIDS and other diseases in some developing countries and the ensuing search for vaccines, are also possible reasons for the increase in global health

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[133] Office of the Inspector General, "The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects" (2001), available online at: <oig.hhs.gov/oei/reports/oei-01-00-00190.pdf> (September 22, 2007) at 6. (Hereafter, *Globalisation of Clinical Trials.)* Others cite an increase in the volume of research from personal experience with research or researchers: See Godfrey B. Tangwa, "Research with Vulnerable Human Beings" (2009) 112 (Suppl. 1) Acta Tropica S16 at S17.

[134] Mary Jo Lamberti, Susanna Space and Sara Gambrill, "Going Global" (2004) 13 Applied Clinical Trials 84., online: Applied Clinical Trials <http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=98387> (September 26, 2005). See also, *Globalization of Clinical Trials, supra* note 8 at 8.

[135] See Jill Wechsler, "New Research Models Spur Third-World Efforts" (September 1, 2006) Applied Clinical Trials, online: <http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=370343&&pageID=2> noting that the private-public partnership (PPP) model promoted by the Bill and Melinda Gates Foundation has brought about an increase in interest in research into drugs for neglected diseases in developing countries. See, Andrés de Francisco and Stephen Matlin (eds.), Monitoring Financial Flows for Health Research 2006: The Changing Landscape of Health Research for Development (2006), online: http://www.globalforumhealth.org/Site/002__What%20we%20do/005__Publications/004__Resource%20flows.php> (April 21, 2007). See also, Global Forum for Health Research, 10/90 Report on Health Research 2003-2004, online: <http://www.globalforumhealth.org/Site/002__What%20we%20do/005__Publications/001__10%2090%20reports.php> (October 16, 2007).

research. HIV vaccine research is currently taking place in countries like Uganda, Kenya, South Africa, Botswana, and Nigeria.[136]

But the amount of research in developing countries trails behind research in developed countries and is still very much below optimal levels.[137] The Global Forum on Health Research in its 2004 report notes that, "Many diseases and risk factors accounting for a high level of burden in terms of morbidity and mortality suffer from very low levels of funding for research. These include, in particular, acute respiratory infections, diarrhoeal diseases, TB, tropical diseases, perinatal conditions and HIV/AIDS."[138] International efforts such as the Tropical Diseases Research (TDR)[139] have been hampered by a lack

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[136] See Cecilia Milford, Douglas Wassenaar, and Catherine Slack, "Resources and Needs of Research Ethics Committees in Africa: Preparations for HIV Vaccine Trials" (2006) 28: 2 IRB: Ethics & Human Research 1 at 2, David P. Fidler, ""Geographical Morality" Revisited: International Relations, International Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries" (2001) 42 Harv. Int'l. J. 299 at 301-302, noting that one of the strategies for addressing the HIV/AIDS problem in developing countries is to develop cheap HIV vaccines and therapy regimes that are easy to implement and that this requires clinical trial research in developing countries which will remain an attractive venue for such research. Shamoo summarises the reasons behind the growth of clinical research in developing countries, noting that : "The increase in clinical trials in developing countries is fueled by the recent push for global commerce. Trends include the pharmaceutical industry's interest in new drugs; new emerging markets; emerging infrastructure from investigators in developing countries in the newly found, home-grown pharmaceutical services corporations; inability to conduct such research in developed countries; and the less costly and less restrictive regulatory environments found in developing countries." See Adil E. Shamoo, "Debating Moral Issues in Developing Countries" (Jun 1, 2005) Applied Clinical Trials, online: Applied Clinical Trials <http://www.actmagazine.com/appliedclinicaltrials/article/articleDetail.jsp?id=165484> (September 26, 2007).

[137] See Global Forum for Health Research, *10/90 Report on Health Research 2003-2004* (Geneva: Global Forum for Health Research, 2004), online: < http://www.globalforumhealth.org/Site/002__What%20we%20do/005__Publications/001__10%2090%20reports.php> (December 8, 2007) at 122.

[138] Ibid.

[139] TDR is a joint effort of the WHO, World Bank and the United National Development Programme (UNDP), which seeks to "promote public-private partnerships, and to assist pharmaceutical companies in the late stage of product development. Acting as a broker linking academia, governments, industry, health professionals and affected communities, TDR has been involved in the implementation of field trials and the licensing out of new products, or new uses for existing products." Nuffield Council on Bioethics, *supra* note 72 at 27.

of funds and support.[140] Expenditures on diseases such as malaria, which affects mainly people in the developing world and which has claimed even more lives than HIV/AIDS,[141] remain paltry in comparison to expenditures on diseases that affect people in the developed world.[142] New drugs are needed to reduce morbidity and mortality from malaria and to deal with the increasing incidence of resistance to older drugs, but many developing countries lack the necessary resources for the needed research, (an estimated US$ 2 billion per year in Africa and US$ 1 billion per year for other malaria-endemic areas)[143] and the resources provided by the public and private sectors in developed countries remain insufficient.[144]

With respect to new drugs, there is an inadequacy of effective, safe and affordable medicines to control infectious diseases that cause high morbidity and mortality in developing countries.[145] Where treatments exist, they are often old, toxic and difficult to administer and unsuitable for the challenging conditions in developing countries.[146] Although there appears to be, in recent years, an increase in drug development in developing countries, pharmaceutical

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[140] James Orbinski and Solomon Benatar, "Drug Development for Visceral Leishmaniasis: A Failure of Market and Public Policy" in Lavery, supra note 20 at 92.

[141] According to the Global Forum on Health Research, "Malaria kills over 1 million people a year, mainly children under five and pregnant women. It is estimated that there are between 300 and 500 million cases of malaria every year in sub-Saharan Africa, Asia and South America." See the Global Forum on Health Research, The 10/90 Report on Health Research 2003-2004, supra note 103 at 215. R W Snow et al, "Estimating Morbidity, Mortality and Disability Due to Malaria among Africa's Non-pregnant Population" (1999) 77 Bulletin of the World Health Organisation 624–40.

[142] Ibid at 123 and 215. See Nuffield Council on Bioethics, supra note 7 at 23.

[143] Global Forum on Health, supra note 103 at 247, (these are 2004 figures).

[144] Recent initiatives include the WHO, UNICEF and UNDP's, Roll Back Malaria Partnership, and the Medicines for Malaria Venture (MMV). However,

[145] P. Trouiller et al, "Drug Development for Neglected Diseases: A Deficient Market and A Public Policy Failure" (2002) 359: 9324 Lancet 2188.

[146] See Beatrice Stirner, "Stimulating Research and Development of Pharmaceutical Products for Neglected Diseases" (2008) 15 European Journal of Health Law 391 at 394.

companies have largely ignored diseases that occur in these countries because investment in research and development in these countries would yield only poor, if any, returns. One study pointed out that of 1393 new chemical entities marketed between 1975 and 1999, only 16 were for tropical diseases and tuberculosis, and observed that there is a 13-fold greater possibility of bringing a drug for central-nervous-system disorders or cancer to the market than for a neglected disease.[147] The state of drug development in developing countries arguably shows both a failure of public policy (governments in both developing and developed countries have paid insufficient attention to this issue, including providing the necessary support and funding) and a shirking of ethical responsibility (pharmaceutical companies have consistently placed profit ahead of the lives of the poor).[148]

Further, health research in developing countries is particularly important with the realization that dependence on health research conducted in developed countries may not be sufficient for the purposes of developing countries in some instances. For example, research findings in developed countries, where more resources are expended on research, may not easily be transferable to developing country settings for various reasons, including the fact that communicable diseases which are prevalent in developing countries are not typically prevalent and thus are not the focus of research in the developed world, socio-cultural and economic circumstances differ, and interventions developed in the developed world do not always work as effectively in the developing

[147] Ibid.
[148] See Lavery, supra note 20 at 87-85.

world.[149] Genetics, cost factors, and climatic conditions may require different interventions to be developed for developing countries.

Although some increase in resources and in the volume of health research has been noted, as the discussion above indicates, the disequilibrium in resources devoted to health research in developing countries persists. In the discussion that follows regarding the governance of research in developing countries, one cannot lose sight of the fact that there is need for more health research in developing countries. More research remains necessary to address public health needs, improve health outcomes, increase life expectancy and promote human rights and economic development. Hopefully, the growing trend in health research in developing countries will continue, and will extend to African countries and to neglected diseases.

It is hoped, however, that the need for more research in developing countries will not hinder adequate oversight in developing countries.[150] One is also hopeful that as more resources become available and more research projects are undertaken, there will be adequate oversight of such research. This will help to ensure the safety, and preserve the trust of research participants in developing countries, which might in turn facilitate greatly needed health research in those countries.

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[149] Global Forum on Health Research, *supra* note 103 at 124-125.

[150] There have been speculations that some developing countries have, in the past, willfully neglected to address the regulation of research because of concerns that this may limit resources for research from rich countries. See R. N. Nwabueze, 'Ethical Review of Research Involving Human Subjects in Nigeria: Legal
and Policy Issues' (2003-3004) 14 Ind. Int'l & Comp. L. Rev. 87 at 89.

1.6 The Need for Research Governance Systems in Developing Countries

Much of the discussion of health research involving humans in developing countries has focused on ethical principles, standards, and the discussions and dissensions that have occurred with respect to these, particularly in the context of research conducted in developing countries by external sponsors. But several important questions may occur in the consideration of these issues. What are the domestic contexts of these discussions? What are, and what should developing countries be doing in terms of protecting their citizens who may participate in research? Should all the discussion about the ethical conduct of research in developing countries be conducted at the international level, especially in view of the great impact of externally-sponsored research in developing countries? This particular question can be answered firmly in the negative. For one thing, the domestic context for the governance of health research in developing countries is important not least because it effectively engages the parties that need to be involved in any serious discussion of the protection of participants in health research in developing countries. For another, governance of health research in developing countries would encompass all research conducted in developing countries – externally-sponsored research and domestically-sponsored research.

Further, addressing some of the thorny ethical issues in a domestic context, with domestic policies and guidelines may be useful in resolving these issues to some extent in a practical way, and in a manner which engages developing countries more effectively in the debates surrounding the ethics of

health research. These domestic policies and guidelines would, of course, be part of the steps that developing countries will be taking to address issues relating to human participants' protection, and be part of a domestic governance system. In this regard, Johnson and others succinctly argue that:

> [A]s the current controversies in ethics predominantly involve research in developing countries, it is vital that these countries are partners in decisions and consensus building in bioethics, and that discussion of key contemporary ethics problems are not predominantly taking place in medical journals and by Western researchers but are actively considered by national bodies in all countries which sponsor or host health research.[151]

In addition, the debates emphasise the necessity of establishing or further developing domestic governance systems to prevent unethical conduct in research in developing countries. As well, the development of domestic research governance systems can also curb total dependence on ethics review carried out externally by sponsor agencies or countries that are unfamiliar with the social, health, and economic realities of developing countries.[152]

Even apart from the controversies surrounding some of the provisions of the international ethical guidelines, as has been rightly pointed out elsewhere, they operate under a voluntary adoption model.[153] The domestic governance

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[151] Sonali Johnson et al, "Ethics, Justice and Public Trust: Promoting Research Ethics Governance at National Level" (2008), online: < http://www.tropika.net/specials/bamako2008/background-documents/tuesday/Ethics-Background-paper-for-circulation.pdf> (/December 12, 2008).

[152] Ibid.

[153] James Lavery, "The Challenge of Regulating International Research with Human Subjects" (June, 2004) Science and Development Network, online: <http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&policy=52&section=265&dossier=5> (December 9, 2008). Some have therefore argued that this model fails to protect

system thus becomes even more relevant when one considers the voluntary nature of the major guidelines, which are typically not directly enforceable in domestic law and, which cannot, strictly speaking, be considered as part of international law. The Helsinki Declaration and the CIOMS Guidelines, while widely accepted, are not binding international law, and contain no provisions for legal enforcement. This means that countries are not under any legal obligation to comply with, or implement the requirements of the international ethical guidelines. Moreover, there are hardly any rules in international law which regulate the activities of multinational pharmaceutical companies or even generally provide for research ethics.[154] The ethical standards set out in the international and national guidelines, though important because they underpin the governance system, are not the same as, and should not be conflated with the governance system – which include legal regulation and other non-legal guidance and the role of institutions – and its functioning.

Further, the international guidelines and the new national guidelines will be ineffective without the appropriate mechanisms for their implementation in a domestic setting.[155] Issues of implementation and enforcement necessitate

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research participants in developing countries and that persons from these countries be excluded from biomedical research on the basis of inadequacies of the international ethical guidelines. See for instance, R. R. Kishore, "Biomedical Research and Mining of the Poor: The Need for their Exclusion" (2006) 12:1 Science and Engineering Ethics 175.

[154] See generally Kevin M King, "A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects" (1994) 34 Stan. J. Int'l L. 163, for a discussion of the different international law rules which apply to research, including international humanitarian law against torture, and the ICCPR which contains the requirement for informed consent (Article 7), *International Covenant on Economic, Social and Cultural Rights* 16 December 1966, 993 U.N.T.S 3, (entered into force 3 January 1976) which contains a right to benefits of scientific research.

[155] See Susan Bull, "Introduction: Ethics of Research" (2002) SciDev, online: < http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierfulltext&Dossier=5> (November 7, 2007).

that developing countries set up governance systems that can operate effectively in a local context to protect research participants while allowing socially desirable health research to take place. In other words, even where countries choose to comply with the requirements of the international guidelines domestically, ethical principles, rules and guidelines require domestic structures, mechanisms and agents for their implementation. Ethics review, an important mechanism of research governance, typically operates within particular domestic systems. Thus, as some commentators have rightly noted, the international guidelines are by themselves "no substitute for a substantive system of research governance entrenched at the national level."[156] The international guidelines require localisation, application, and enforcement in the context of developing countries' domestic policies, laws and regulations. Developing countries can therefore not simply rely completely on the international guidelines to provide oversight of health research but need to develop domestic governance systems.

The point also has to be made that many developed countries have domestic systems of research governance to provide oversight of health research. This may be in addition to the international ethical guidelines or even despite the international guidelines. These governance systems are designed primarily to allow health research to be undertaken within safe parameters. Several developed countries have attempted to address protections for research

[156] J Ford and G Tomossy, 'Clinical Trials in Developing Countries: The Plaintiff's Challenge', Law, Social Justice & Global Development Journal, online: <http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/ford/> (April 4, 2007). See also, George F. Tomossy and Jolyon Ford, "Globalisation and Clinical Trials: Compensating Subjects from Developing Countries" in B. Bennett and G.F Tommossy (eds.), *Globalization and Health: Challenges for Health Law and Bioethics* (Springer: Dordretcht, 2006) at 30, noting that, despite the difficulties of limited resources "a substantive system of research governance entrenched at the national level would be the ideal solution."

participants in developing countries where research is sponsored by such developed countries.[157] These domestic systems are, however, aimed primarily at the protection of the citizens of these countries and there may be competing motives. For instance, political developments in a developed country, as Dickens observes, might create a possibility that populations in developing countries may find their interests compromised by policies in the developed country.[158]

Also, as Dickens and Cook note with specific respect to submissions of research projects to be conducted in developing countries for review in developed countries, and the need for ethics review committees in developing countries:

> The claim that a committee will not approve greater risks to members of another country's population than it will approve to its own is usually well-intentioned and honorable, but may deny members of the other country's population choice and autonomy, be insensitive to the other country's own view of its priorities, and be paternalistic. It is not submission to an irresponsible 'anything goes' type of ethical relativity to recognize that ethical principles and priorities can differ between countries, and that what is

[157] See, for example, "Biomedical Research Projects in Developing Countries" (Denmark) (2006), online: <http://www.cvk.im.dk/cvkEverest/Publications/cvkx2Eimx2Edk%20x2D%20dokumenter/English/20061130095326/CurrentVersion/ulandssagerENG.pdf> (April 3, 2007). For an insightful exposition of the concept of equivalent protections in relation to the United States, see Bernard Dickens, "The Challenge of Equivalent Protection" in NBAC volume 2, supra note 16. See § 46.101(h) of Title 45 Code of Federal Regulations. See also, United States, Department of Health and Human Services, 'Report of the Equivalent Protections' (2003), available at: _http://www.hhs.gov/ohrp/international/EPWGReport2003.pdf (5 April, 2007).

[158] B. Dickens, "The Challenge of Equivalent Protection" in NBAC volume 2, supra note 17 at A-10.

> unacceptable in one country may be acceptable in another, and vice versa.[159]

They note also that:

> Despite the many challenges and occasional doubts, with training and appropriate resources, committees can be brought to a level of reliable structure and effective functioning, in developing and developed countries alike.[160]

Developing countries need domestic systems that put their needs, priorities and the safety of their citizens first. For instance, in 2008 the United States FDA decided to allow using data from foreign clinical trials in new drug applications even if the trials only compare new products to placebos instead of best available treatments, thus ceasing to apply the 1989 version of the Helsinki Declaration, previously the standard, in foreign clinical trials.[161] While some commentators have expressed concern about how this might affect participants in developing countries,[162] where a developing country has a standard similar to the latest version of the Helsinki Declaration or even stricter, and takes steps to enforce these standards, researchers from other countries will nevertheless have to maintain these standards when they come to do research in such country.

The major argument which could be raised against the establishment of domestic governance systems in developing countries is that of cost and priorities. The point can perhaps realistically be made that regulatory and

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[159] B M Dickens and R J Cook, "Challenges of Ethical Research in Resource-Poor Settings" (2003) 80 International Journal of Gynecology and Obstetrics 79 at 84.
[160] Ibid.
[161] "FDA Scraps Helsinki Declaration on Protecting Human Subjects," online: <http://www.cspinet.org/integrity/watch/200805051.html#2> (December 19, 2008).
[162] See for example, Jonathan Kimmel, Charles Weijer, Eric Meslin, "Helsinki Discords: FDA, Ethics, and International Drug Trials" (2009) 373: 9657 Lancet 13.

governance structures, including appropriate training for regulators, infrastructure and technology, and adequate remuneration for those employed in this area, amongst other things, cost money. Developing countries have many challenges, including pressing health problems such as those relating to reducing maternal and infant mortality, tackling malaria and HIV/AIDS, building new and maintaining old and dilapidated health infrastructure, dealing with brain drain of health workers, and addressing poverty and poverty-related diseases, with only limited resources to meet them. It may be argued therefore that the regulation of health research may not be an area to which many developing countries should choose to devote resources given other pressing needs. This line of argument assumes that since developing countries lack capacity, they can do little to prevent unethical conduct of research and to create governance structures which protect research participants. This assumption may be based on practical realities, including limited resources in developing countries. Indeed, a close look at the attitude of developing countries in the past regarding the governance of health research reflects this perspective.

Nonetheless, while developing countries may be handicapped in terms of available resources to monitor research, there are certainly steps that they can reasonably take to ensure the safety of their citizens who participate in it. Moreover, given the urgent need for increased health research in developing countries, the lacuna in the regulation of health research that currently exists both domestically and internationally and what this means in terms of the protection of research participants, research risks, and the allegations of abuses

that have occurred in several developing countries in recent years, a more urgent issue arises: Can developing countries afford *not* to put in place effective governance systems? Examples such as the Pfizer incident in Nigeria, where basic procedures such as the requirement for ethics approval for the clinical trial were not clear, met, or enforced, indicate the need for effective regulatory and governance systems in developing countries. Governance of health research is clearly a priority in developing countries, alongside the need for increased research on neglected diseases in developing countries. External help from developed countries and international organisations may be necessary to address issues of costs and gaining increased understanding of regulatory and governance systems from countries which have had them longer. Such external help recognises the fact that developed countries have an interest in disease eradication in developing countries because many diseases do not respect geographic boundaries. Diseases such as HIV/AIDS require research, which should realistically occur in many developing countries as there is a greater burden of that disease in such countries. Yet such research would benefit developed countries too as they seek to provide treatments and cures to their own citizens. Effective regulation of such research in developing countries would therefore benefit developed countries. As will become clear in the discussions that follow, some external assistance from foreign countries has been forthcoming and is increasingly a key component of the steps that some developing countries have taken in regards to the domestic governance of research.[163] All told, however, the issue of costs and priorities does not negate

[163] These include research ethics capacity-building programs developed by the Fogarty

the need for domestic governance systems. In addition, some of the critical health problems which developing countries face require research, and such research would occur more safely within a regulated environment which takes into consideration the peculiarities of the developing world context already discussed.

It would of course be naïve to ignore or gloss over global inequalities and how these may affect the steps that developing countries are willing to take to protect their citizens while encouraging beneficial health research to be undertaken. Thus, the need for increased health research in developing countries, in an increasingly competitive global research environment may prompt some countries to refrain from putting in governance structures or may cause them to merely adopt, without due consideration, governance arrangements approved in developed countries. In this regard, although there is little empirical data in support, some commentators have observed that developing countries may, in fact, avoid putting in place governance mechanisms in place to regulate research, since this might limit necessary research by external sponsors, which these countries have limited resources to undertake.[164] However, even if this is true and, even apart from the negative implications of expediently putting the lives, safety and welfare of citizens at risk in order to achieve certain (perhaps even laudable) objectives, one could counter that argument as not well-founded. Implicit in such an argument is a lack of understanding of the relationship between the two sides of the debate, that is, that there is conceivably a

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International Center of the United States National Institutes of Health, and the European-based European and Developing Countries Clinical Trials Partnership (EDCTP).

[164] Nwabueze, supra note 150.

relationship between the need for increased resources for beneficial research in developing countries and the regulation of such research. It can be argued that appropriate governance structures may create more room to undertake, and manage, such research. To explain further, there is the possibility that such structures may ensure that such research operates within safe, clearly established parameters. This, in turn, may help create trust between researchers and research participants and the wider community, thus potentially making increased room for research that is more likely to be beneficial to the target population. This way, everyone stands to gain - researchers, research participants and the wider community. As rightly observed by Johnson and others, "Research governance regulations and mechanisms at national level, are necessary not only for maintaining credibility and a high quality of research but also for maintaining public trust in the purpose and conduct of health research."[165]

Trust is a particularly important factor to consider in the developing world context. This is because the erosion of trust affects not only the potential participation in health research; it may also affect participation by the general population in important and beneficial health programmes. For instance, the rejection in 2004 of the polio vaccine in Northern Nigeria (a disease that has largely been eradicated in many countries around the world) has been attributed, in part, to the fears engendered by the Pfizer incident.[166] The unanticipated costs

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[165] Johnson et al, supra note 147.

[166] See A. S. Jegede, 'What Led to the Nigerian Boycott of the Polio Vaccination Campaign?' 4(3) PLoS Med (2007): e73 available at: _doi:10.1371/journal.pmed.0040073_ (3 April 2007). See also, Ebenezer Obadare, A Crisis of Trust: History, Politics, Religion and the Polio Controversy in Northern Nigeria" (2005) 39:3 Patterns of Prejudice 265 at 278-279.

of failure to establish effective governance structures may therefore exceed the costs of proper governance.

As for merely adopting governance arrangements approved in developed countries, in a process that has been termed "bioethical colonialism" or "ethical imperialism," this is a major concern, especially if one accepts like I do, that external assistance may be necessary to help developing countries. To counter this problem at the international level, some commentators like Dickens have suggested that not only should research sponsors in developed countries invest in developing research capacity in poorer countries, but that they engage in developing research ethics capacity. Such research ethics capacity would be helpful in allowing more authentic international collaboration in the development process of the international guidelines.[167] Such research ethics capacity would also be helpful in developing national systems of governance.

Attention must, of course, be paid to the potential for "bioethical colonialism" and that external sponsors who choose to promote research ethics capacity in developing countries must constantly reevaluate their programs in this respect. But it does not negate the need for, and in fact emphasises, the need for greater participation by developing countries in the regulation of health research involving participants from these countries. Such involvement does not, in my opinion, include re-inventing the wheel. In other words, mechanisms that may be helpful in the governance of research, such as ethics review, cannot be

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[167] Dickens, supra note 158 at A-17. See also James Lavery, "The Challenge of Regulating International Research with Human Subjects" (June, 2004) Science and Development Network, online: <http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&policy=52&section=265&dossier=5> (December 9, 2008).

discarded on the basis of avoiding "bioethical colonialism." But paying attention to domestic contexts is necessary. Thus, there may be other mechanisms that may not necessarily apply in some developed countries that may be necessary. This may include addressing controversial ethical issues in domestic ethical guidelines. It may also include the use of comprehensive legislation as I suggest in the following chapters.

In sum, there are strong arguments for domestic systems in developing countries and that these systems would be beneficial for health research in developing countries as well as for the safety of research participants. The steps that several developing countries are taking in this respect are therefore a welcome development.[168] Descriptions and analyses of these developments as this thesis and the growing literature on research governance in developing countries provide are also welcome to identify ways to improve these emerging systems.

1.7 Research Governance in Nigeria: An Introduction

Although the thesis addresses the governance of research involving humans in developing countries, it focuses specifically on Nigeria as a case study. Below I give a brief background on the Nigeria.

Nigeria is Africa's most populous nation, with a population estimated at about 150 million people and accounting for about 47 percent of the population

[168] See section 1.3 for some examples of these steps.

of West Africa.[169] It is an influential player in African affairs.[170] It has recently established a peaceful transition to a democratic government, adopting a new constitution in 1999. Prior to 2006 when it established a national code for research ethics, the research oversight mechanisms in Nigeria consisted of a spectrum of formal and informal mechanisms including regulation by the federal government through agencies created for that purpose, review by ethics review bodies in research institutions and self-regulation by medical practitioners. There were no policy guidelines or law relating specifically to research involving humans, or requiring the existence of ethics review committees in research institutions, setting down their structure or composition and functions or even requiring that research protocols must pass through ethics review. In late 2006, Nigeria established a National Health Research Ethics Committee as well as a *National Code for Health Research Ethics* designed to provide oversight for research.[171]

There are several reasons for focusing on Nigeria. First, I have chosen Nigeria because of my personal connection to that country (I am Nigerian), and my personal interest in research governance in that country which arose initially from allegations of unethical conduct of research in that country (like the Pfizer incident which made headlines around the world). But I have also opted to study Nigeria, an African country, because developing countries in Africa have

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[169] World Bank, "Nigeria: Country Brief," online: <http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/AFRICAEXT/NIGERIAEXTN/0,,menuPK:368906~pagePK:141132~piPK:141107~theSitePK:368896,00.html> (February 8, 2008).

[170] Ibid.

[171] National Health Research Ethics Committee: <http://www.nhrec.net/nhrec/> (January 14, 2010).

some of the most pressing problems of poverty and health challenges, such as malaria and HIV/AIDS and other neglected diseases which require much research. Many of them also, until recently, lacked governance mechanisms for research involving humans. Others still do not have any organized mechanisms for regulating research involving humans. In focusing on Nigeria I am focusing on an African country which has considerable influence in the region, politically and economically.

Nigeria, a major oil exporting country, also plays an influential role in African affairs. It is the eighth largest oil exporter in the world.[172] The BBC notes that "Nigeria is the economic powerhouse of West Africa, contributing nearly 50% of regional GDP.[173] The Economist, in an even broader statement, observes that, "Nigeria remains crucial to the future of Africa: the continent's most populous country and its largest economy after South Africa, with which it jostles for continental leadership."[174] It has acted as a mediator in many African conflicts and provided military assistance to many peacekeeping efforts in the continent, including in Liberia, Eritrea and Sierra Leone.[175] It is currently a non-permanent member of the United Nations Security Council.

With its multi-ethnic and multi-cultural population, past history of colonization, military rule, recent transition to democratic rule, many squandered opportunities to raise the standard of living of its citizens, and rural/urban

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[172] BBC, "Nigeria: Facts and Figures" online: <http://news.bbc.co.uk/2/hi/africa/6508055.stm?lsf> (June 26, 2009).
[173] Ibid.
[174] Richard Synge, "The Role of Nigeria in the Evolution of West African Regional Security and Democratisation: Contradictions, Paradoxes and Recurring Themes" (1999) 13: 1 Cambridge Review of International Affairs 55.
[175] 'Capping the Well-Heads of Corruption" *The Economist*, 21 October 2006.

disparities, it shares the challenges that many developing countries face, including leadership and democratic challenges as well as poverty and health-related problems. In addition, Nigeria is also an interesting context to look at research governance because of its great burden of disease, vast population, and high human resource potential in terms of potential high numbers of researchers, all of which present great need and opportunities for health research. Past allegations of unethical conduct of research further cement this great need. Also, from an economic standpoint, Nigeria has economic challenges but also the economic potential to provide a workable, if not perfect, governance system for health research.

It has taken steps recently towards improving the governance of health research, and it is hoped that many developing countries in the African continent can learn from its governance experience. Detailed analysis of Nigeria's context and research governance efforts are undertaken in Chapters Five and Six, and recommendations for improvements are made in Chapter Seven.

It is hoped that the analysis of the research governance regime in Nigeria will prove helpful in identifying ideas that may be helpful to the country as its governance system evolves. It is also anticipated that these ideas will prove more easily transferable to other developing countries with similar socio-economic and political contexts and challenges which are in the process of establishing research governance systems.

Chapter Two

Governance as an Analytical Framework for Health Research Involving Humans

2.1 Introduction

Health research involving humans in developing countries has been the subject of much ethical analysis, particularly in the area of biomedical research. But Chapter One identified a vacuum in our understanding and analysis of this important area - not much work has been done with respect to taking a broad look at the emerging regulatory systems in these countries and linking the various parts of the governance of research into a comprehensive whole. This chapter explores one way to address this vacuum by taking an in-depth look at governance.

Governance and regulation have become very relevant and interesting areas of consideration for scholars in recent years. Concerns about overregulation, inefficiency of regulating institutions, legalism, inflexibility and costs of regulation, and arguments in favour of deregulation gained ground in recent years. Much has thus been made of the concept of 'new" governance which allows greater participation of private actors in social regulation. The idea of regulation as the state's top-down control of behaviour through certain means, including the enactment and enforcement of legal rules, had increasingly given way to a growing reliance on private actors and non-legal rules. But

recent events[176] have once more brought to the fore questions about regulation and governance, and the appropriate role of government in not only economic regulation but also in social regulation.

Health research involving humans is one area of human endeavour in which the areas of governance and regulation have particular relevance. As explained briefly in Chapter One, formal and informal mechanisms are employed in the regulation of research involving humans, to ensure, among other things that research is conducted within ethically acceptable and safe parameters. This chapter seeks then to analyse health research involving humans using a governance analytical framework.

The focus on governance raises several interrelated questions: First, what specifically is governance? This is necessary because the term "governance" is applied liberally with respect to research involving humans. Sometimes it is used interchangeably with the related term "regulation." Do they mean the same thing? Can they mean the same thing in the particular context of regulating the conduct of research involving humans? Second, what is a governance analytical framework? Third, are there other possible alternative analytical frameworks? If there are, why use a governance framework? Fourth, how will the governance framework be used?

I answer these questions in different sections below. In the second section, I define the term 'governance' and examine its relationship to regulation

[176] Such as the recent global economic crisis which caused frantic state interventions in several Western countries to minimize the impact of the crisis on the world's troubled financial markets, or the recent oil spill in the United States, billed as the most catastrophic environmental disaster since the Exxon Valdez incident.

and to law. In the third section, I discuss governance as a valuable and functional analytical framework for research involving humans, considering its theoretical aspects, its current manifestations in the literature and the hybrid framework which I am adopting. I explain the rationale for choosing to apply a governance lens to the subject of research involving humans in developing countries generally and in particular, Nigeria. I also describe briefly how this framework will be employed.

2.2. What is Governance?

'Governance' is a term now used liberally not only in relation to regulation or organisational management, but in political administration internationally and domestically, as well as in the field of development. As a concept, it appears to be subject to many interpretations. And the increasing recognition of 'new' governance arrangements has added to confusion as to the meaning of the term. In particular, these "new" governance arrangements have spurred whole schools of thought devoted to understanding the concept of governance within political and social science.[177]

The concept of governance has been used in academic and other literature in various ways. In discussions about states in general, and developing countries in particular, governance is frequently employed in discussions relating to democracy and the rule of law and the challenges that developing

[177] Kees Van Kersbergen and Frans Van Waarden, "'Governance' as a Bridge between Disciplines: Cross-Disciplinary Inspiration Regarding Shifts in Governance and Problems of Governability, Accountability and Legitimacy" (2004) 43 : 1 European Journal of Political Research 141. See also, Oliver Treib, Holger Ba¨hr and Gerda Falkner, "Modes of Governance: Towards a Conceptual Clarification" (2007) 14:1 Journal of European Public Policy 1.

countries face in these areas.[178] The reference to democracy and rule of law may allow us to view this idea of governance as "democratic governance." It is therefore not surprising that some define governance as including: "the processes by which governments are chosen, monitored, and changed; the systems of interaction between the administration, the legislature, and the judiciary; the ability of government to create and to implement public policy; and the mechanisms by which citizens and groups define their interests and interact with institutions of authority and with each other."[179]

Apart from the democratic nature of any specific government, governance is also used in reference to the responsibilities of governments. The World Bank thus defined governance in 1997 as: "the manner in which power is exercised in the management of a country's economic and social development"[180] and more recently in 2006 as: "the manner in which the state acquires and exercises its authority to provide public goods and services."[181] The United Nations Development Programme (UNDP) similarly defines governance as: "the exercise of political, economic and administrative authority to manage a nation's affairs. It is the complex mechanisms, processes and institutions through

[178] See for instance, USAID, "Sub-Saharan Africa: Democracy and Governance," online: <http://www.usaid.gov/locations/sub-saharan_africa/sectors/dg/> (February 5, 2009).
[179] Peter McCawley, "Governance in Indonesia: Some Comments" (2005) ADBI Research Policy Brief No 17: Governance, online: < http://www.adbi.org/files/2006.04.rpb17.governance.indonesia.comments.pdf> (June 7, 2008).
[180] World Bank, *Governance*: *The World Bank's Experience*, (World Bank: Washington D.C., 1994).
[181] World Bank, *Strengthening World Bank Group Engagement on Governance & Anticorruption,* (World Bank, Washington DC, 2006)..

which citizens and groups articulate their interests, exercise their legal rights and obligations, and mediate their differences."[182]

These descriptions of governance have prompted the term "good" governance, used especially by international financial and development agencies such as the World Bank and the UNDP in relation to developing countries, that is, the extent to which the government uses its power to produce and sustain development for its citizens. In promoting the idea of good governance, these institutions have taken steps to encourage democracy, free-market reforms, promote institutional and regulatory reforms, shifting power from the public sector or government to the private sector, and engaging civil society in the process of achieving public goals in an efficient manner. This usage of governance draws together strands from the political, administrative, and economic values of legitimacy and efficiency. [183] In short, with the concept of "good governance," these organisations, as Rhodes points out, have combined the principles of new public management and liberal democracy.[184]

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[182] UNDP, *Reconceptualising Governance* (New York: UNDP, 1997), online: <http://www.pogar.org/publications/other/undp/governance/reconceptualizing.pdf> at 9.

[183] See Cynthia Hewitt de Alcantra, "Uses and Abuses of the Concept of Governance" (1998) 50: 155 International Social Science Journal 105 at 106. de Alcantra notes that the increasing reliance of international development agencies on the concept of governance signifies an intellectual shift from complete reliance on free market policies to a more social and development-oriented approach. She points out that: "By talking about 'governance' – rather than 'state reform' or 'social and political change – multilateral banks and agencies within the development establishment were able to address sensitive questions that could be lumped together under a relatively offensive heading and usually couched in technical terms, thus avoiding any implications that these institutions were exceeding their statutory authority by intervening in the internal political affairs of sovereign affairs." See also, George Philip, "The Dilemmas of Good Governance: A Latin American Perspective," (1999) 34:2 Opposition and Government 226.

[184] R A W Rhodes, "The New Governance: Governance without Government" (1996) 44 Political Studies 652 at 656.

More recently, the term "governance" has also been used particularly in academic literature in referring to the changes associated with transformations in the regulatory landscape, the different roles now adopted by governments (or the state), and private and non-state actors. In this sense, governance, also described as "new" governance, refers to: "a basically nonhierarchical mode of governing, where non-state, private corporate actors (formal organizations) participate in the formulation and implementation of public policy,"[185] "the investigation of a plurality of sites of non-state regulatory activity"[186] or as concerning "activities related to public purposes that are undertaken jointly by multiple actors, including those 'beyond government,' or at the very least beyond the organizational boundaries of a single government,"[187] It has also been employed to describe implementation of public policy by self-organising networks and sometimes as synonymous with the "new public management." [188] This conception of governance involves several core ingredients including: the accomplishing of public goals through collaboration with other organizations, including private-sector and nonprofit organizations and employing non-hierarchical, informal, and extra-constitutional means.[189] This understanding is

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[185] Renate Mayntz, "From Government to Governance: Political Steering in Modern Societies," Paper presented at the Summer Academy on IPP: Wuerzburg, September 7-11, 2003, online: <http://www.ioew.de/governance/english/veranstaltungen/Summer_Academies/SuA2Mayntz.pdf > (February 26, 2008). See also,

[186] Peter Swan, "Governing at a Distance: An Introduction to Law, Regulation and Governance," in Michael Mac Neil, Neil Sargent, and Peter Swan, *Law, Regulation, and Governance* (Ontario: Oxford University Press, 2002) at 10.

[187] Rhodes, supra note 9 at 653.

[188] Ibid. at 653 and 655.

[189] Karen Mossenberger, "The Many Meanings of Governance: How Should We Develop Research and Theory?" (2007) Draft Paper prepared for the Conference: "A Global Look at Urban and Regional Governance: The State-Market –Civic Nexus" January 18-19, 2007, online: <http://www.halleinstitute.emory.edu/governance/conference2007/THE%20MANY%20MEANINGS%20OF%20GOVERNANCE%20(mossberger).pdf> (February 4, 2009) at 2.

different from what may be referred to as the "old" or traditional governance which denotes a process of steering and controlling activities in the economy and the society in which the state plays a central role.[190]

The concept of governance is thus a loose one – ranging from how power is acquired (democratic governance) to what actors exercise control over public policy (old and new governance) – to which several specific meanings can be attached, and of which there may be different types and which may be connected to different potential theories, and different empirical and normative concerns.[191] Theoretically, as subsequent discussion in this chapter will show, many authors currently employ the term "governance" only in the new governance sense (discussed in more detail later in the chapter), and fail to distinguish between it and governance as a generic term.

Beyond any specific understanding of the concept, however, governance has a generic meaning which underlies the different understandings held in particular fields of thought. In this sense, according to Mossenberger, it is simply the process of governing.[192] de Alcantra points out that:

> In the English speaking world, 'governance' is a word routinely used over the course of many centuries to refer to the exercise of authority within a given sphere. It has often been employed as a synonym for the efficient management of a broad range of organisations and activities, from the modern corporation (corporate governance) or university (the

[190] Jon Pierre, "Introduction: Understanding Governance ," in Jon Pierre (ed.) *Debating Governance* (Houndmills, Basingstoke, Hampshire: Palgrave Macmillan, 2000) at 3.
[191] Ibid. at 3.
[192] Mossenberger, supra note 14 at 13.

> governance of Vassar College) to the ocean depths.[193]

Thus, the term "governance," is used widely and is applicable to regulation and management activities in a variety of institutions and organisations, including governments, companies (hence, corporate governance), and in discourse relating to world affairs (hence, global governance). For the purpose of the analysis undertaken in this thesis, it is important to go back to this generic understanding of governance.

In this respect, according the University of Ottawa Centre on Governance, governance is broadly speaking, "about the processes by which human organizations, whether private, public or civic, steer themselves."[194] Governance also generally refers to the "processes and structures that an organization uses to direct and manage its general operations and program activities."[195] Similarly, Rosenau defines governance as "systems of rule, as the purposive activities of any collectivity that sustain mechanisms designed to ensure its safety, prosperity, coherence, stability, and continuance."[196] In a description that presents a holistic conception of governance, a Law Commission of Canada study explains the concept of governance as pertaining

> not only to organizations, but also to the complex ways in which private, public and social organizations interact and learn from one another, the manner in which citizens

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[193] de Alcantra, supra note 8 at 105.
[194] Quoted in M. MacDonald, *The Governance of Health Research Involving Human Subjects* (Ottawa: Law Commission of Canada, 2000).
at 22.
[195] Ibid.
[196] J N Rosenau, "Change, Complexity and Governance in Globalizing Space" in J. Pierre (ed.), Debating Governance: Authority, Steering and Democracy (Oxford: Oxford University Press, 2000) at 171.

> contribute to the governance system, directly and indirectly, through their collective participation in civil, public and corporate institutions; and the instruments, regulations and processes that define the 'rules of the game.'"[197]

The study of governance therefore involves an examination of the distribution of rights, obligations and power that support the organisational system, the patterns of coordination that support its activities and sustain coherence, and establishing benchmarks, and sharing knowledge to ensure restoration when there are signs that the system requires repair.[198]

These generic descriptions of governance, which are applicable to any activity that requires some control, perhaps explain the liberal use of the term with particular regard to research involving humans, and are helpful for the purpose of analysis in this thesis. It also explains in part why the concept may be seen by some as allowing some form of control over activities, without necessarily requiring governmental input or intervention. On the other hand, as exemplified by its usage in the context of democratic governance or even the idea of good governance, the role of the state in the process of governance cannot simply be ignored. It is important to state that the generic understanding of governance is pivotal to the analysis conducted in the thesis, even though I draw also from specific understandings of governance in trying to develop a suitable and useful framework for analyzing the systems that regulate research involving humans in developing countries.

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[197] Ibid. at 4.
[198] *Ibid.*

2.2.1 Governance and Regulation: An Examination of Relationship

The terms "governance" and regulation are frequently used interchangeably, and sometimes together. Do they mean the same thing? A review of the literature on regulation and governance does not present a clear answer as many authors writing in this area assume an understanding of the terms and do not set out to define them or describe specifically how they choose to use the terms. Having described governance above, I now consider the related term "regulation."

Regulation is, broadly speaking, a process of imposing order and prescribing acceptable conduct.[199] The term, like governance, is also used in a variety of situations, but is more often than not understood as the command - and - control techniques by which the state, typically through the use of legally-backed sanctions, prescribes acceptable conduct. Regulation is conceived, by traditionalists, as a product of the state or government. This concept of regulation locates its basis in the theory of legal positivism.[200] Thus one could, as Majone does, define regulation as: ". . . sustained and focused control exercised by a public agency, on the basis of a legislative mandate, over activities that are generally regarded as desirable to society" or as Hood and others do, "the use of public authority to set and apply rules and standards."[201]

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[199] See Christine Parker, Colin Scott, Nicola Lacey, John Braithwaite (eds.), "Introdduction" in *Regulating Law* (Oxford Oxford University Press, 2004) at 4. See also, Anthony Ogus, Regulation: Legal Form and Economic Theory (Oxford: Clarendon Press, 1994) at 1.

[200] See discussion in Roderick MacDonald, "The Swiss Army Knife of Governance" in Pearl Eliadas, Margaret Hill & Michael Howlett, *Designing Government: From Instruments to Governance,* (Montreal & Kingston: McGill-Queens University Press, 2005), hereafter *Designing Government.*

[201] G. Majone, *Regulating Europe*, (London: Routledge, 1996) at 9. C. Hood, et al, *Regulation inside Government: Waste-Watchers, Quality Police and Sleaze- Busters* (Oxford: Oxford

This understanding of regulation is associated with, and mostly, limited to law in the form of formal legislation or legal regulations or a set of authoritative rules, often administered by a governmental agency, for monitoring and enforcing compliance.

Regulation as rulemaking and rule-enforcement by governments, according to King, has its roots in the early stages of modern statehood and is a function undertaken by all states.[202] However, although this view of regulation has been predominant (especially in legal circles), it is becoming increasingly outdated as many begin to accept the notion of regulation as a wider activity encompassing more than command-and-control. Indeed, regulation is widely acknowledged as including different types of regulation, including regulation by law, economic or fiscal regulation (for example, through the use of taxes or licensing or the manner in which private firms are restrained from anticompetitive behaviour), market regulation (or regulation by market forces) or self-regulation within a particular industry or profession (which may be acknowledged by law). Further, different disciplines have different conceptions of regulation. For instance, for economists, regulation may be the means by which private firms are compelled to adopt anti-competitive behaviour. Some therefore view economics, law and politics as intertwined, while some distinguish between economic regulation and social regulation.[203]

University Press, 1999) at 3. See also, Julia Black, "Critical Reflections on Regulation" (2002) 27 Australian Journal of Legal Philosophy 1at 11-12.

[202] Roger King, *The Regulatory State in an Age of Governance: Soft Words and Big Sticks* (Houndmills, Basingstoke, Hampshire: Palgrave Macmillan, 2007) at 13.

[203]See Macgregor observing that regulation is "a process in which economics, politics and law are inextricably intertwined." L. McGregor, T. Prossert, and Villiers (eds.), *Regulation and Markets Beyond* Aldershot, Ashgate, 2000) at 3. See also, M. Minogue, "Governance-Based

A more modernist and arguably more comprehensive and appropriate view of regulation includes both state and non-state actors, legislation and other non-formal forms of law and social rules. [204] This understanding of regulation identifies more closely with the understanding of the "new governance," described in detail in sections below. One definition of regulation thus views it as "all mechanisms of social control or influence affecting behaviour from whatever source, whether they are intentional or not."[205] This definition is broader than those stated above, but as Black rightly observes, it is rather diffuse, having little or no definitional boundaries and consequently leaving little room for analysis.[206] It may therefore be more fruitful to consider regulation as an intentional attempt to control, order, or influence the behaviour of others.[207] Indeed, some consider regulation as always intentional, even though its results and outcomes may be unintended.[208] In this sense, regulation is not limited to state intervention in the economy or society or targeted rules, and it includes the basic prerequisites for a regulatory regime, namely, the setting of standards; processes for monitoring compliance with the standards; and mechanisms for enforcing standards. [209]

Analysis of Regulation" (2003) Annals of Public and Cooperative Economics 649. See generally, R Baldwin, C Scott and C Hood, *A Reader on Regulation* (Oxford University Press, 1998).

[204] Fiona McDonald, "Patient Safety, Governance and Regulation: JSD Thesis Proposal" (Unpublished manuscript submitted to Dalhousie University, 2005) at 13.

[205] Julia, Black, "Critical Reflections on Regulation" (2002) 27 Australian Journal of Legal Philosophy 1 at 11. R Baldwin, C Scott and C Hood, *A Reader on Regulation* (Oxford University Press, 1998).

[206] Black, ibid.

[207] Ibid.

[208] Alan Hunt, *Explorations in Law and Society: Toward a Constitutive Theory of Law* (New York: Routledge, 1993) at 315.

[209] See Parker et al, supra note 24.

The view of regulation as controlling of conduct or imposing order leads to thinking that regulation may only be an aspect of governance which emphasises a wide variety of actors and coordination of different mechanisms in managing a policy sphere. This is particularly true if one considers regulation as a product of the state. For instance, Swan observes that: "governance defined as any strategy, process, procedure, or program for controlling, regulating, or exercising authority over animate or inanimate objects or populations, is regarded as being much broader than the conception of state-centred regulation."[210] A review of the literature shows that although some may still regard regulation as 'what states do,' increasingly, governance is used to indicate the fact that non-state bodies do something similar (particularly in the context of the 'new' governance). Many authors then extrapolate from this to employ governance as the overarching term and 'regulation' as a sub-set of governance.[211]

As only an aspect of governance, regulation may not completely capture all the activities or all the actors which a governance framework anticipates, including, for instance, citizens and their participation in the process. Governance may therefore be a higher order or more encompassing activity that includes regulation (involving the setting of standards; processes for monitoring compliance with the standards; and mechanisms for enforcing standards.), but also many other kinds of actions, policy options and approaches.[212] Indeed,

[210] Swan, supra note 11 at 11.
[211] Thanks to Professor Julia Black of the London School of Economics for her helpful attempt to clarify these terms.
[212] Thanks to Prof Lahey for this concise summary.

some describe governance broadly as "the regulation of social activities utilizing a variety of modes and mechanisms of societal regulation,"[213] and as, "all the forms of regulation that are neither market nor state: it is civil society minus the market ... plus local political society."[214] The governance of research involving humans could thus be argued to include all regulatory activities affecting such research. Conceived in this way, then, regulation is subsumed in, and is only, a component of governance. Agreeing with this view, Braithwaite, Coglianese, and Levi-Faur describe 'governance' as a broader term than 'regulation.' To them: "Governments and governance are about providing, distributing, and regulating. Regulation can be conceived as that *large subset of governance* that is about steering the flow of events and behavior, as opposed to providing and distributing. Of course, when regulators regulate, they often steer the providing and distributing that regulated actors undertake as well."[215] Lobel adds that regulation as a concept carries with it the problematic issues of boundaries and predetermined solutions, but that the concept of governance is "open, dynamic, and diverse with a built-in temporal dimension."[216] Braithwaite and Parker further point out that, "Governance is a more general theoretical domain than regulation in that governance is also about allocating resources in ways that are

[213] Volker Schneider and Johannes M. Bauer, "Governance: Prospects of Complexity Theory in Revisiting System Theory" (2007) Paper presented at the annual meeting of the Midwest Political Science Association, Palmer House Hotel, Chicago, IL, Apr 12, 2007, online: < http://www.quello.msu.edu/images/uploads/wp-07-01.pdf> (February 27, 2008)
[214] Bob Jessop, "The Regulation Approach, Governance and Post-Fordism: Alternative Perspectives on Economic and Political Change?" 24 Economy and Society 307 at 313 Georges Benko, and A Lipietz, R. Boyer, 'De la Régulation des Espaces aux Espaces de Régulation', *Théorie de la Régulation: L'état des Savoirs*, (Paris: La Découverte, 1994)293-303.

[215] John Braithwaite, Cary Coglianese, David Levi-Faur, "Can Regulation and Governance Make a Difference?" (2007) 1:1 Regulation and Governance 1 at 3, (emphasis mine).
[216] Orly Lobel, "The Renewal Deal: The Fall of Regulation and the Rise of Governance (2004) 89 Minnesota Law Review 342 at 348.

not intended to steer the flow of events," and that "regulatory theory is becoming an increasingly central part of the theory of governance."[217] However, others, particularly those who view governance only from the perspective of "new" governance, see governance as being narrower than regulation. In this vein, Vincent-Jones notes that:

> Thus, there is sufficient common ground in regulation and governance theories to suggest that a synthesis is possible and may be useful in the analysis of central-local relations. However, while the approaches share a concern with processes of social control, direction and influence, there are fundamental differences in the form of inquiry and scope of explanation. In the regulation approach, the motivating force is the state as a 'purposeful actor.' Governance theorists studying the exercise of political power through governmentality, on the other hand, address the *narrower* issue of what authorities of various sorts want to happen, in relation to problems defined how, in pursuit of what objectives, and through what strategies and techniques.[218]

However, even if one does not assume that regulation is an activity engaged in only by the state in a top-down, command-and- control fashion, but an activity which involves a controlling of conduct by other actors, governance could still be argued to be a broader domain. This is because, perhaps more than regulation, it allows for a wide range of actors and institutions, permits the examination of the distribution of rights, obligations and power that support the organisational

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[217] John Braithwaite and Christine Parker, "Conclusion" in Christine Parker et al, *Regulating Law* (Oxford: Oxford University Press, 2004) at 288.
[218] Peter Vincent-Jones, "Values and Purpose in Government: Central-local Relations in Regulatory Perspective" (2002) 29 Journal of Law and Society 27 at 31.

system, the patterns of coordination that support its activities and sustain coherence, and establishing benchmarks, and sharing knowledge to ensure restoration when there are signs that the system requires repair.[219]

In any event, whatever views one holds, there is certainly a significant correlation between governance and regulation. To make the distinction between governance and regulation thus seems difficult, and to some, may even appear to be a matter of mere semantics or simply unnecessary given that, fundamentally speaking, the two concepts refer to controlling or directing behaviour, persons and organisations. That difficulty persists given that in some understandings or approaches, both governance and regulation do not necessarily emanate from the state, and both draw on such important criteria as effectiveness. And yet to others such an argument would amount to drawing "a simple-minded equation of regulation and governance."[220] What, then, is the significance of attempting to define these terms? A basic understanding of the terms, governance and regulation, as attempted here is important because, as the above discussion clearly shows, these are terms that may be used differently,

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[219] *Ibid.*

[220] Jessop, supra note 39 at 330. For a detailed analysis of the differences and similarities of governance theory and regulatory theory, see Jessop, supra note ... However, he goes on to note that: "Indeed there could well be sound theoretical reasons for combining the two notions or paradigms in dealing with specific issues. Several possibilities exist here: they could be seen as semantically different but conceptually identical approaches with exactly the same coverage (e.g., Lipietz 1993: 8n); as equivalent conceptual approaches which are, however, relevant to different analytical domains (e.g., integral economics vs integral politics); as super- and subordinate concepts within an abstract-concrete hierarchy (e.g., governance as an abstract concept, regulation as its concretization in the economic domain); as more and less encompassing concepts respectively along a general-particular continuum (e.g., the Benko and Lipietz view of local governance as a rather heterogeneous residual category within the regulation approach); or as non-equivalent but possibly complementary conceptual approaches relevant to different domains (e.g., regulation pertaining to structural forms and governance to inter-organizational relations)."

depending frequently on the context or the discipline.[221] It is therefore essential to consider basic definitions of these terms generally and also specifically with respect to how they are employed in this thesis.

I understand and employ the term 'governance' in this thesis as involving regulation (with the ingredients of standard-setting, compliance-monitoring, and standards enforcement) as a core element. Regulatory theory is therefore drawn on significantly in the analysis undertaken in this thesis. It is, however, convenient to employ primarily the term (and framework of) governance, especially given that the term 'governance' is used quite frequently in the literature dealing with research involving humans. But beyond this convenience, the generic understanding of governance, the different meanings which one can attach to the term, as well as the literature on the 'new governance,' which I employ in my analysis below, affords broad room for understanding, analysing, and making recommendations on, the emerging research governance systems in developing countries.

2.2.2 Governance and Law

It may also be necessary to distinguish law from governance (which in this thesis includes regulation as a core element) because law, however conceived, also deals with controlling of behaviour, both in a normative and positivist sense. Considered in the positivist sense advocated by Hart, law represents rules articulated and enforced by an institutionalized

[221] For a lawyer, for instance, regulation and governance may mean legislation or other types of legal regulation.

authority which regulate conduct or behaviour.[222] In this sense, law, as an official product of the state and as a set of rules articulated by the state and usually backed by sanctions (hard law) is a critical part of the much-maligned command-and-control regulation. The state, then, is clearly an actor (perhaps the most important actor) in regulation and governance. As I will argue in the following subsections, in some circumstances, despite the increasing acknowledgement of the role of other actors in regulation and governance, the state (with its function of developing formal law) remains a very important actor. Whether or not one views regulation as broader than the positivist view of the top-down use of state authority to control conduct, law performs some regulatory and instrumental functions (which Black refers to as "regulatory law"[223]). It is a mechanism or one of the policy options envisaged by governance. Law, then, is a lever of action with the object or purpose of changing or controlling behaviour with prescriptions.[224] The concerns attached to seeing law as a tool of governance in the form of legislation and legal regulations would thus relate to how the state seeks to achieve compliance and may also include creating mechanisms in legislation or legal regulations for allowing self-regulation by the persons or organisations which need to be regulated.

In a normative sense, law is clearly broader than the positivist view of law "as made and judged by the legislative and judicial branches of

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[222] Julia Black, "Law and Regulation: The Case of Finance" in Parker et al, supra note 24 at 34.
[223] Ibid.
[224] Roderick A. Macdonald, "The Swiss Army Knife of Governance," in Pearl Eliadis, Margaret M. Hill, and Michael Howlett, et al, *Designing Government: From Instruments to Governance* (McGill-Queen's University Press, 2001) at 219.

state-government then enforced by the policing agencies of the executive."[225] Scott's definition of regulation identifies the relationship between law in a normative sense and regulation. Regulation, as he defines it, may be "any process or set of processes by which norms are established, the behaviour of those subject to the norms monitored or fed back into the regime, and for which there are mechanisms for holding the behaviour of regulated actors within the acceptable limits of the regime (whether by enforcement action or by some other mechanism)."[226] These norms may be in this case legal norms operating within a legal framework with legal enforcement mechanisms, such as penal sanctions. Lange further argues that from a postmodernist point of view, law could be considered as operating progressively more through norms, and that it is no longer inevitably connected to the powers of a central sovereign state.[227] As the work on the new governance indicates, non-state normative orders are also components of regulation and governance in the present day. In a normative sense, law acts not only in a positivist fashion as one of the mechanisms of regulation and governance, but also provides the context in which governance and regulation take place. Further, because of its standard-setting potential, law can also influence the course of governance.[228] It can also mediate between other actors involved in governance.

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[225] Kelvin Walby, "Contributions to a Post-Sovereigntist Understanding of Law: Foucault, Law as Governance, and Legal Pluralism" (2007) 16 Social and Legal Studies 551 at 552.
[226] Colin Scott, "Analyzing Regulatory Space: Fragmented Resources and Institutional Design" (2001) Public Law 329 at 331.
[227] Bettina Lange, "Regulatory Spaces and Interactions: An Introduction," (2003) 12 Social and Legal Studies 111 at 112.
[228] See Angus Corbett and Stephen Bottomley, "Regulating Corporate Governance" in Parker et al, *supra* note 87 at 63.

Since it regulates conduct, it is obvious that there is a close relationship between law, governance, and regulation. This relationship is perhaps clearer to socio-legal scholars, who consider law in social contexts, than legal scholars who take an internal view of law and focus on doctrine.[229] For socio-legal scholars, then, the linkages between law, governance, and regulation are not limited to the objective of controlling conduct in order to achieve certain social goals. In this regard, looking at law through a regulatory lens may also involve understanding the interactions between hard law and soft law, doctrines and legislation, public and private law, as well as the effect that common law doctrines may have on the operation of statutory law intended to regulate conduct and vice versa.[230] It would also involve looking at the ways in which legal norms affect the regulatory environment.

At any rate, it is arguable that whether understood in a positivist sense or in a normative sense, law by no means covers all the terrain that governance does, given that governance involves different actors and mechanisms. Law entails "complex, reciprocal, multiple, and overlapping modes of regulations" and provides only some, but not all, of the major mechanisms through which governance is implemented.[231] However, law, understood broadly, particularly in a normative context, as providing the background and support for governance (for example, in the context of the rule of law) and may also be argued by some to be broader than regulation and governance.

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[229] Ibid at 37.
[230] Parker, supra note 24 at 5.
[231] Walby, supra note 50 at 557. Hunt supra note 33 at 306.

What is clear is that even though there may be areas of overlap, it is easier not only to see law and governance as distinct from each other (than perhaps it is to distinguish regulation from governance), but to view law as one of the options that governance utilizes, and which may play a central role in governance. Indeed, scholars who favour the "law as governance" approach (or the law as a constitutive mode of regulation approach) see a symbiotic relationship between law and governance.[232] They suggest a "modest role for law where law is conceived as connectively situated among a multiplicity of other constitutive modes of regulation."[233] Further, focusing on law in a normative or positivist sense addresses mainly legal regulation and legal institutions but does not necessarily allow proper focus on other institutions or policy mechanisms or the interactions between these mechanisms. A governance approach offers a broader analysis. In subsequent sections of this chapter and in the following chapter, I consider the role of law in the governance of research involving humans in developing countries.

2.3 Governance as an Analytical Framework for Research Involving Humans

Health research involving humans, given its nature and the issues connected therewith, has been the subject of much ethical analysis. There is certainly a preoccupation in the literature with research ethics and institutional and research practice. Although this is not out of place, understanding the subject of health research involving humans not only in terms of the ethical

[232] Hunt, ibid at 331.
[233] See generally, Walby, supra note 50 at 553.

standards or even the work of ethics review committees requires a broader perspective. Analysing this subject comprehensively from the perspective of controlling and managing it requires a broader framework of analysis than a strictly ethical framework, or even a legal framework, or one that considers only an organisational framework. It requires a framework that is able to marry these different angles effectively to provide a broad and wide-ranging analysis and offer an encompassing account of the regulation of health research in developing countries. For the purposes of this thesis, governance (specifically a hybrid form of governance discussed in subsequent pages) seems more useful for understanding and making recommendations on the research governance systems emerging in developing countries.

It may seem somewhat circular to consider the governance and regulation of research involving humans by employing a governance framework. One could, however, ask what would be a better way to look at governance systems than by adopting a framework of governance, especially when one considers that governance, aside from being an activity, has also increasingly begun to be regarded as a theoretical field worth studying in the social sciences. In essence, then, I am applying a theoretical framework of governance to the activity of governance. The reasoning behind this position is discussed in greater detail below.

Below I consider governance as a theoretical field. I explain why I consider governance to be a useful framework of analysis. I discuss the application of governance as a framework for analysing health research

involving humans and, the goals of governance in the context of health research involving humans.

2.3.1 Governance as Theory

I have described above the various meanings that can be ascribed to governance but can governance be viewed as a theory capable of providing a lens through which to examine fruitfully a policy field such as health research involving humans? The different meanings assigned to governance indicate that viewing governance as a coherent theoretical field able to generate hypotheses may be problematic. In this respect, Mossenberger argues that: "Any general theory of governance is likely to be so abstract that it has little explanatory value in specific instances."[234] Frederickson and Smith also argue that, "Lacking a universal definition, governance is currently more an acknowledgement of the empirical reality of changing times than it is a body of coherent theory."[235] They, however, admit that there is an emerging field of governance theory.[236] Others go so far as to question if it should count even as a concept, noting its notorious slipperiness,[237] and arguing that it is merely another rhetorical device which adds nothing of substance to the object of study.[238]

While recognising the validity of the concerns surrounding governance as a theoretical concept, it is not inconceivable that the different

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[234] Mossenberger, supra note 14 at 13.
[235] H. George and Kevin B. Smith, *The Public Administration Theory Primer (*Boulder, CO: Westview Press, 2003) at 209.
[236] Ibid.
[237] Pierre, supra note 15 at 7.
[238] Peter Leisink and Richard Hyman, "Introduction: The Dual Evolution of Europeanization and Varieties of Governance" (2005) 11: 3 European Journal of Industrial Relations 277 at 279-280.

definitions of the term may mean, not that there is not "a theory" of governance, but that there are varying theoretical understandings of, or approaches to governance. Moreover, going by the different definitions discussed above, governance is clearly a concept describing certain processes, even though it may lack some precision. As Bevir and Rhodes point out, however, most concepts are vague when taken on their own; they require determination of their compositional ingredients.[239] Conceptual frameworks, such as governance, "provide a language and frame of reference through which reality can be examined and lead theorists to ask questions that might not otherwise occur. The result, if successful, is new and fresh insights that other frameworks or perspectives might not have yielded. Conceptual frameworks can constitute an attempt to establish a paradigm shift."[240] Thus, even if there is not as yet a cohesive theory of governance (and this is, of course, debatable), as a concept it is valuable as a means of understanding the processes that come within its confines, and affords a valuable lens through which to consider certain types of activities and regulatory arrangements.

Some authors therefore describe theories of governance in different contexts.[241] Maynzt states that governance theory "began by being concerned

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[239] M Bevir and R Rhodes,A Decentered Theory of Governance: Rational Choice, Institutionalism, and Interpretation" Working Paper 2001-10 (Institute of Governmental Studies, University of California, Berkeley, 2001) online: <http://repositories.cdlib.org/cgi/viewcontent.cgi?article=1016&context=igs> (February 7, 2008).
[240] D Judge, G Stoker, and H Wolman, "Urban Politics and Theory: An Introduction" in D. Judge, G. Stoker and H. Wolman, *Theories of Urban Politics* (London: Sage, 1995) at 3.
[241] See for example, Burkard Eberlein, Dieter Kerwer, "New Governance in the European Union: A Theoretical Perspective," (2004) 42: 1 Journal of the Common Market 121 – theoretical perspectives in the context of the European Union. See also, Renate Maynzt, "New Challenges to Governance Theory" in Henrik Paul Bang (ed.), *Governance as Social and Political Communication* (Manchester: Manchester University Press, 2003) at 27. Vasudha Chhotray and

with the steering actions of political authorities as they deliberately attempt to shape socio-economic structures and processes."[242] Governance theory has now extended from concern with steering in the political sphere to being, at its broadest perhaps, about "the practice of collective decision-making."[243] Jessop provides a general description of governance theories and what they offer as an analytical framework. He states that:

> One could define the general field of governance studies as concerned with the resolution of (para-)political problems (in the sense of problems of collective goal-attainment or the realization of collective purposes) in and through specific configurations of governmental (hierarchical) and extra-governmental (non-hierarchical) institutions, organizations, and practices.[244]

These commentators consider governance theories not only as organising frameworks or frameworks that merely identify the changes now occurring in the ways in which public goals are achieved (as much of recent literature on governance does), but also as theories offering propositions regarding modes for achieving public goals with public and private actors. These theories have different expressions in, and implications for, different disciplines, including law, public administration, political science, development studies, international relations, and environmental studies. The theories extend analytical frames as

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Gerry Stoker, *Governance Theory and Practice: A Cross-Disciplinary Approach* (Palgrave Macmillan, 2008). See generally, Jessop, supra note 39.

[242] Maynzt, ibid.

[243] Vasudha Chotray and Gerry Stoker, supra note 66 at 3.

[244] Jessop, supra note 39 at 318.

deficiencies are identified,[245] and also offer advice as to "what might be" (how the functioning and operation of governance arrangements may be made better) as opposed to merely stating "what is" [246] (for example, how governance arrangements are chosen (intentionally or unintentionally), how they are maintained or how they are changed). [247] Such theories, it is argued, offer "a valuable and challenging dimension to our understanding of our contemporary social, economic, and political world."[248]

The theoretical understandings of, or the approaches to, governance that have been discussed extensively in the literature include those relating to governance by command-and-control, governance by networks,[249] the neo-liberal theory of governance which is related to rational choice theory,[250] collaborative governance, [251] as well as sustainable governance. [252] Others include global governance theory, [253] the multi-level theory of governance observed particularly in the European Union system of governance, [254] conceptualizations of democratic governance and related theories of good

[245] See generally Maynzt, ibid.
[246] Vasudha Chhotray and Gerry Stoker, supra note 66 at 4-5.
[247] Ibid. at 6.
[248] Chotray and Stoker, supra note 66 at 1.
[249] Rhodes, R.A.W., *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability* (Buckingham/Philadelphia: Open University Press, 1997).
[250] Bevir and Rhodes, supra note 64.
[251] Chris Ansell and Alison Gash, "Collaborative Governance in Theory and Practice" (2008) 18:4 Public Adm Res Theory 543. See also,John Donahue, "On Collaborative Governance," (2004) Corporate Social Responsibility Initiative Working Paper No. 2, John F. Kennedy School of Government, Cambridge: Harvard University), online: <http://www.hks.harvard.edu/m-rcbg/CSRI/publications/workingpaper_2_donahue.pdf> (May 16, 2009).
[252] Kernaghan Webb, "Sustainable Governance in the Twenty-First Century: Moving beyond Instrument Choice" in Pearl Eliadis et al, *Designing Government: From Instruments to Governance* (McGill-Queen's University Press, 2001) (hereafter *Designing Government*).
[253] Martin Hewson and Timothy J. Sinclair, "The Emergence of Global Governance Theory," in Martin Hewson and Timothy J. Sinclair, *Approaches to Global Governance Theory* (Albany, NY: State University of New York Press, 1999).
[254] Ian Bache and Matthew Flinders (eds.) *Multi-level Governance* (Oxford: University Press, 2004).

governance employed by international organisations.[255] It is beyond the scope of this thesis to delve into each of these approaches to governance. I discuss instead the common bases which these understandings have and, in the next section, the broad understandings of the traditional and the new governance, which encompass generally, and in different combinations, the ingredients of the different understandings of governance now explored in the literature.

The contents of these theoretical understandings have certain commonalities and overlap to a large extent. For one thing, they relate to the achievement of public objectives and policy goals, through regulation, the provision of fiscal incentives, and other means of social control. For another, they tend to be actor-centred and instrument-centred, identifying the actors that are, and that should be, involved in the achievement of these goals and the instruments or tools that should be utilised in reaching these objectives. Traditional approaches to governance, as I discuss in fuller detail below, clearly acknowledge the role of the state as an actor in governance, while other approaches may view the state as only one of the actors in the activity of governance. Traditional or "old" governance clearly acknowledges the government as the central actor, such that governance is simply what government does, and is in many ways synonymous with government.

But the understanding of the state as only one actor (sometimes a minimal actor) is captured particularly in the new governance (discussed below) and its variants, including good governance, collaborative governance, sustainable governance and, governance by networks. Mossenberger notes that

[255] See UNDP, supra note 7.

recent usage (in the new governance understanding) has emphasized "the need to coordinate the actions of multiple actors to realize public purposes." [256] This approach unpacks the state in terms of sundry processes of governing requiring the active participation of different groups in civil society.[257] It emphasises a participatory, pluricentric[258] or collective[259] approach in which different actors and institutions play important roles. The UNDP's conceptualisation of good governance, for instance, includes certain characteristics: freedom of association and participation and freedom of the media. It also includes application of the rule of law, transparency, sustainability, and accountability in the functioning of bureaucracies, promotion of equity and equality and diverse perspectives, efficient and effective in the use of resources. In addition it involves the ability to define and take ownership of national solutions, freely available and valid information, effective and efficient public sector management, and cooperation between governments and civil society organisations, and is enabling and facilitative, regulatory rather than controlling.[260] Good governance systems, according to the UNDP, are participatory, involving all members of governance institutions or actors – the state, the private sector and civil society – in

[256] Mossenberger, supra note14 at 13.
[257] Mark Bevir and Frank Trentmann, "Introduction: Consumption and Citizenship in the New Governance" in Mark Bevir and Frank Trentmann, *Governance, Consumers, and Citizens: Agency and Resistance in Contemporary Politics* (New York: Palgrave Macmillan, 2007) at 7.
[258] Kees Van Kersbergen and Frans Van Waarden, "'Governance' as a Bridge between disciplines: Cross-Disciplinary Inspiration Regarding Shifts in Governance and Problems of Governability, Accountability and Legitimacy," (2004) 43 European Journal of Political Research 143 at 151.
[259] Thus to Chhotray and Stoker, governance theory is about the practice of "collective decision-making." Vasudha Chhotray and Gerry Stoker, *Governance Theory and Practice: A Cross-Disciplinary Approach* (New York: Palgrave Macmillan, 2008) at 3.
[260] See UNDP, supra note 7 at 19.

influencing decision-making.[261] Sustainable governance, an offshoot of the new governance, with its emphasis on the value of harnessing the energies, experience, expertise, and advantages of multiple actors (including state and private actors), instruments, institutions, and processes,[262] also underscores the participatory nature of these understandings of governance and the state as only one of the actors in the activity of governance and regulation.[263] So, too, does collaborative governance, with its emphasis on collaboration between private and public sectors.[264] Network governance, in addition to its other features (such as the asymmetric interdependencies and self-referentiality of the actors)[265] also stresses this participatory nature of governance, allowing that public goals are met by networks of government or the state, private actors, including business entities and voluntary or non-profit actors, although there may also be times when the networks consist only of non-state actors.[266]

The descriptions of the part these actors play in many of the approaches are empirical in the sense that they describe present realities. They are also considered in a prescriptive sense, recommending an ideal with different

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[261] Ibid.
[262] Kernaghan Webb, "Sustainable Governance in the Twenty-First Century: Moving Beyond Instrument Choice" in Pearl Eliadis et al, *Designing Government: From Instruments to Governance* (McGill-Queen's University Press, 2001) (hereafter *Designing Government*) at 271.
[263] Gerry Stoker, "Governance as Theory: Five Propositions" (1998) 50: 155 International Social Science Journal 17-28 at 17.
[264] See John Donahue, "On Collaborative Governance," (2004) Corporate Social Responsibility Initiative Working Paper No. 2, John F. Kennedy School of Government, Cambridge: Harvard University), online: <http://www.hks.harvard.edu/m-rcbg/CSRI/publications/workingpaper_2_donahue.pdf> (May 16, 2009).
[265] Lester M Salomon, "The New Governance and the Tools of Public Action : An Introduction" (2001-2002) 28 Fordham Urb. L.J. 1611 at 1613 at 1631.
[266] Kees Van Kersbergen and Frans Van Waarden, "'Governance' as a Bridge between disciplines: Cross-Disciplinary Inspiration Regarding Shifts in Governance and Problems of Governability, Accountability and Legitimacy," (2004) 43 European Journal of Political Research 143 at 149-151.

analyses as to what part they could play in the governance process.[267] The actors involved in governance typically act and interact within an institutional framework.[268] In this respect, governance has been described as a theoretical perspective which attempts to address systems and emphasise the actors (with their own rationales and motivations) who perform within an institutional setting which shapes, but does not necessarily determine, every option.[269] As a theoretical domain, therefore, governance draws broadly from institutional theory and systems theory.[270]

Institutional theory has been depicted as attending to:

> the deeper and more resilient aspects of social structure. It considers the processes by which structures, including schemas, rules, norms, and routines, become established as authoritative guidelines for social behavior. It inquires into how these elements are created, diffused, adopted, and adapted over space and time; and how they fall into decline and disuse.[271]

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[267] Ibid. at 152.

[268] Maynzt, supra note 66 at 37.

[269] Bjoern Niehaves, Karstern Klose, Joerg Becker, "Governance Theory Perspectives on IT Consulting Projects: The Case of ERP Implementation" (2006) 5:1 E-Service Journal 5 at 9.

[270] *Ibid.* See Mathieu Deflem, "The Boundaries of Abortion Law: Systems Theory from Parsons to Luhmann and Habermas" (1998) 76: 3 Social Forces 775 at 776-778. Governance theory demonstrates that the regulation of systems occurs primarily within the system itself. See Bjoern Niehaves, Karstern Klose, Joerg Becker, "Governance Theory Perspectives on IT Consulting Projects: The Case of ERP Implementation" (2006) 5:1 E-Service Journal 5 at 5-7.

[271] See W. Richard Scott, "Institutional Theory: Contributing to a Theoretical Research Program" online: <http://www.si.umich.edu/ICOS/Institutional%20Theory%20Oxford04.pdf> (February 7, 2008). W. Richard Scott, "Institutional theory" in George Ritzer (ed.), *Encyclopedia of Social Theory*, (California: Sage Publications, 2004) at 408-14. See B. Guy Peters, "Institutional Theory: Problems and Prospects" (2000) 69 Political Science Series, Institute for Advanced Studies, Vienna, online: < http://www.ihs.ac.at/publications/pol/pw_69.pdf> (February 7, 2008). Institutional theory is employed in examining systems, and is therefore closely related to systems theory. See Scott, "Institutional Theory: Contributing to a Theoretical Research Program" at 2. See also, Jenny Stewart and Russell Ayres, "Systems Theory and Policy Practice: An Exploration" (2001) 34: 1 Policy Sciences 79 at 80.

Some commentators describing this theory observe that social reality is a human construction created through interactions which eventually become institutions. [272] Institutions are therefore seen as "collections of standard operating procedures and structures that define and defend interest." [273] In this way, institutions explain the political actions of individuals and constitute political actors in their own right. More succinctly, institutions have been described as "formal rules, compliance procedures, and standard operating practices that structure relationships between individuals in various units of the polity and the economy."[274] The process by which behaviours are replicated and conferred with the same meaning by human beings (who interact to create social reality) is referred to as institutionalisation and institutionalised rules "provide a framework for the creation and elaboration of formal organizations," or institutions.[275] Institutional theory is employed in examining systems, and is therefore closely related to systems theory.[276]

Systems, according to Parsons, refer to "a whole consisting of interrelated parts that perform specific functions in relation to each other and

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[272] See B. Guy Peters, "Institutional Theory: Problems and Prospects" (2000) 69 Political Science Series, Institute for Advanced Studies, Vienna, online: < http://www.ihs.ac.at/publications/pol/pw_69.pdf> (February 7, 2008). Scott's popular definition captures the essence of institutions as the shaping of social reality: "Institutions consist of cognitive, normative and regulative structures and activities that provide stability and meaning to social behaviour."

[273] James March and Johan Olsen, "The New Institutionalism: Organizational Factors in Political Life," (1984) 78 The American Political Science Review 734 at 738.

[274] Peter Hall, *Governing the Economy: The Politics of State Intervention in Britain and France* (Cambridge: Polity Press, 1986 at 19-20.

[275] Ibid.

[276] See R Scott, "Institutional Theory: Contributing to a Theoretical Research Program" *supra* note 110 at 2. Jenny Stewart and Russell Ayres, "Systems Theory and Policy Practice: An Exploration" (2001) 34: 1 Policy Sciences 79 at 80.

contribute to the maintenance of the whole."[277] Modern society, according to him, consists of autonomous systems: the economy, the political system, the societal community and the fiduciary or values system, each of which performs special functions but which interact with each other, with law (and the legal system) playing an integrative role.[278] A system, according to Stewart and Ayres, consists of interrelated parts, specified relations between the parts and specified boundaries. They add that: "The word 'system' is often used to describe the assembly of organisations to be found in a given policy field, and to suggest the interconnections between them as in 'health system' or 'research system.'"[279] They observe further that: "As a methodology for the social sciences, systems approaches build on an understanding of the phenomena of interest to the investigator as a sub-set of more general processes and relationships," with the investigator treating the subject of investigation as a whole which has interrelated parts.[280]

As an analytical framework, then, governance (particularly the new governance perspective and its variants) takes a systems approach, permitting the discussion of steering of activities in terms of the interrelated parts of that activity, that is, the institutions and organisations involved in a

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[277] See Talcott Parson, *Social Systems and the Evolution of Action Theory* (New York: Free Press, 1977) at 177-203. See Mathieu Deflem, "The Boundaries of Abortion Law: Systems Theory from Parsons to Luhmann and Habermas" (1998) 76: 3 Social Forces 775 at 776-778. Governance theory demonstrates that the regulation of systems occurs primarily within the system itself, and therefore "challenges the assumption of a dichotomy between the system-external regulator (e.g., political power) and the regulated system (e.g., a policy field) which often results in implementation problems." See Niehaves et, al, supra note 94 at 5-7.

[278] Ibid.

[279] See Jenny Stewart and Russell Ayres, "Systems Theory and Policy Practice: An Exploration" (2001) 34: 1 Policy Sciences 79 at 81.

[280] Ibid.

particular policy field. It recognises the institutions within a system and all the actors in the policy field, including those being regulated, as potentially active actors in the governance process.[281] Thus it allows for the study of the configuration of particular institutions, organizations and agencies, involved in various ways in a system (such as the research governance system) and the interactions of, and relationships between these bodies.[282]

The commonalities in the different approaches to governance are captured effectively in the generic definition which I have adopted for this thesis: "the processes by which human organizations, whether private, public or civic, steer themselves,"[283] with a core element of regulation and control to achieve certain goals. Similarly, according to Chotray and Stoker, "Governance, within the socio-legal frame, is an overarching concept to describe the complex and multi-faceted social processes – official and unofficial, intended and unintended, visible and invisible – that together mediate social behaviour and conduct."[284] Thus, governance as a theoretical construct has been described as "a system of rules in action (i.e. applied by social actors) by which desired societal states of affairs are approached (positive control), and undesired states avoided (negative control)."[285] Further, from that generic perspective, governance is not only about achieving goals and objectives through positive and negative control, it also includes the provision of policies, facilities, processes, instruments (such

[281] Niehaves et al, *supra* note 94.
[282] McDonald, *supra* note 19 at 22.
[283] From the University of Ottawa Centre on Governance, quoted in M. McDonald, ibid.
[284] Chhotray and Stoker, supra note 66 at 14.
[285] Volker Schneider and Johannes M. Bauer, "Governance: Prospects of Complexity Theory in Revisiting System Theory" (2007) Paper presented at the annual meeting of the Midwest Political Science Association, Palmer House Hotel, Chicago, IL, Apr 12, 2007, online: < http://www.quello.msu.edu/images/uploads/wp-07-01.pdf> (February 27, 2008) at 10.

as statutes and policy mandates) available resources, institutions, and institutionalised rules and norms by which these goals are to be realised.[286]

The contribution of the governance perspective to theory, argues Stoker, is not at the level of causal analysis, nor does it offer a new normative theory. Instead, its significance lies in serving as an organising framework, and providing a framework for understanding changing processes of governing.[287] As a theoretical framework, it is rather broad, and thus may be considered too wide as an analytical framework.[288] However, this breadth might be seen as a weakness in terms of depth. But it is also its strength, especially as a framework for investigating a system such as that of health research involving humans which consists of different actors, systems and institutions. As Schneider and Bauer assert, the major advantage of governance is "that it provides a rather abstract frame in order to cover a broad array of institutional arrangements and mechanisms by which the coordination, regulation and control of social systems and subsystems can be conceptualized."[289]

Further, as a concept, governance focuses on the tools or instruments employed in achieving public objectives. Thus beyond the perspective taken on governance – whether traditional or new – many theories of governance focus on the tools or instruments of governance. Each theoretical understanding may favour or emphasise a different set of tools for achieving

[286] Macdonald, supra note 49 at 208. See also Frederickson and Smith, *supra* note 60 at 214.
[287] Stoker, supra note 88 at 18.
[288] Schneider and Bauer, *supra* note 110 at 3-4.
[289] *Ibid.* at 3.

public objectives.[290] Several tools are generally used in the governance of research involving humans, including ethics review committees, a legal framework that may include legislation, and a policy framework that may include ethics guidelines and guidelines for the operation of ethics review committees. For my purposes, the question would be: What tools or instruments are required to effectively govern research involving humans in developing countries? If one accepts certain actors and tools in governance as necessary, the question arises: Against what criteria can the actors and tools be measured?

The different understandings of the forms of governance and recent ideas about them, which I describe below, are useful in this examination. I will employ the literature on the new governance to raise and attempt to answer questions on the role of government and other actors, as well as the role of formal legislation and national guidelines in the governance of research involving humans in Nigeria. Below I consider the different forms of governance – traditional and new – and where the focus should rest in an examination of research involving humans in developing countries.

2.3.2 Governance – 'Old,' 'New,' and 'Hybrid'

Discourse on governance has gained currency within recent conceptualizations of the "new governance." Governance, in particular 'new governance,' reflects recent ideas of implementing public policies not only through government bureaucracies but also through private actors and public-

[290] See generally Salomon, supra note 90.

private partnerships. Prior to this, the focus was on governance as done in a top-down, hierarchical fashion, which I describe here as traditional or "old" governance.[291]

Traditional governance or "old" governance [292] involved the government at the centre directing all other actors, playing the role of main regulator, but also acting as a service provider, job creator, property owner and employer.[293] The state was viewed as essential to achieve public objectives. Indeed, "The traditional use of 'governance' and its dictionary entry define it as a synonym for government."[294] Traditional governance involved a hierarchical or legislator's perspective to policy development and implementation, with a firm bias for a vertical command-and-control regulatory model.[295] The state set rules or standards through the legislature (creating legislation), or agencies delegated power by the legislature (creating regulations), and private actors had to comply with those rules. These rules were enforced through the mechanisms of inspection, judicial enforcement[296] and other means, sometimes with the assistance of private attorneys general.[297] The state remained the central actor in

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[291] This should not be mistaken for its other usage as the authority of traditional chiefs in certain societies. See for example, Albert C. Peeling, "Traditional Governance and Constitution Making among the Gitanyow" (2004) online: <http://www.fngovernance.org/pdf/Gitanyow.pdf> (June 2, 2009).
[292] B. Guy Peters, "Governance and Comparative Politics" in Pierre, supra note 15 at 39-41.
[293] G. Majone, "The Rise of the Regulatory State in Europe" (1994) 17 West Eur. Pol. 77.
[294] Gerry Stoker, "Governance as Theory: Five Propositions" (1998)
[295] Maynzt, supra note 66 at 29.
[296] Joanne Scott and Susan Sturm, "Courts as Catalysts: Re-thinking the Judicial Role in New Governance" (2007) 13 Colum. J. Eur. L. 565 at 567.
[297] Jason M Solomon, "Law and Governance in the 21st Century Regulatory State," (2008) 86 Texas Law Review 819 at 822.

governance and regulation even if it met with resistance from regulated groups,[298] operating in an adversarial manner instead of collaboratively.

Research in this area, however, revealed policy and regulatory failures arising from this governance perspective. Strong arguments against state control, focusing on issues of inefficiency, ineffectiveness, overregulation, legalism, and inflexibility have led to an increasing shift to governance which involves all the stakeholders in the governance process.[299] Scholars in different fields, including economics, international relations, and political science, became disenchanted, and expressed growing dissatisfaction, with what Jessop describes as "the conventional realist distinction between the domestic political hierarchy organized under the dominance of a sovereign state and the international anarchy formed through inter-state relations in international relations, and in political science, a rigid public-private distinction in state-centred analyses of politics and its associated top-down account of the exercise of state power."[300]

"New" governance is understood, in recent literature in political science and public administration, as pushing conventional arrangements in the traditional governance towards delegated self-regulation, through persuasion, informal networks and norms, benchmarking and experimental deliberation.[301] Government or the state has been observed to be overburdened and therefore

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[298] Maynzt, supra note 66 at 29.
[299] Solomon, supra note 122.
[300] Jessop, supra note 39 at 310.
[301] Jelle Visser, "Beneath the Surface of Stability: New and Old Modes of Governance in European Industrial Relations" (2005) 11: 3 European Journal of Industrial Relations 287. See also, Maynzt, supra note 66 at 27.

unable to cope effectively and adequately with the myriad societal problems facing it. The need arises, therefore, to engage other actors in dealing with some of these problems. In the new governance, areas that were previously taken to be the sole province of the state, the regulation of which were considered the exclusive prerogative of government, are now increasingly viewed as general problems that can be undertaken and solved by other actors and institutions, sometimes in conjunction with the state. This understanding took root as a reaction to past events, including the fiscal crises in western democracies in the 1980s and the move from earlier ideas of nationalization, public corporations and central planning toward privatization, deregulation and globalization, all of which were considered to be more effective in stimulating economic growth, productivity and innovation.[302] The appeal of governance thus derives largely from the reforms of the public sector promoted by neoliberal governments in Britain and the United States in the 1980s, with an understanding of governance as more likely to bring about increased efficiency in the public sector than state bureaucracy.[303] (As the recent recession, and even the recent oil spill in the Gulf of Mexico have shown,[304] however, leaving much power in private hands has its own problems). In any event, these movements have, it is argued, eroded the

[302] Renate Mayntz, "From Government to Governance: Political Steering in Modern Societies" Summer Academy on IPP: Wuerzburg, September 7-11, 2003, online: <http://www.ioew.de/governance/english/veranstaltungen/Summer_Academies/SuA2Mayntz.pdf > (June 1, 2009).

[303] See Mark Bevir and R. A. Rhodes, "A Decentered Theory of Governance: Rational Choice, Institutionalism, and Interpretation" Working Paper 2001-10 (Institute of Governmental Studies, University of California, Berkeley, 2001) online: <http://repositories.cdlib.org/cgi/viewcontent.cgi?article=1016&context=igs> (February 7, 2008).

[304] "Size of Spill in Gulf of Mexico Is Larger than Thought" *New York Times*, April 29, 2010, page A14.

traditional authority of the state, and caused the limitations of that authority, with regard to governance and regulation, to become more evident.

Much of the literature dealing with the new governance, in attempting to define this concept, thus identifies and elaborates an increasing de-emphasis on hierarchical regulation by the state through strictly command-and-control methods, to governance through partnerships between the government and private entities, with the aim of achieving public goals. It describes the increasingly networked nature of the actors in governance, the proliferation of different tools in governance, and governments acting more indirectly, shifting lawmaking and other regulatory processes from a command-and-control framework to a more responsive approach tailored to local circumstances. It also describes the use of less traditional regulatory instruments and more creative means to achieve public objectives, including robust public participation, benchmarking and information sharing to solve public problems. [305] Partnerships between the state, industry, and civil society, are thus one of the main hallmarks of the new governance.[306]

Within the "new governance" concept, traditional ways of achieving regulatory goals yield not only to participative approaches but also to innovative approaches. These include voluntary approaches under which regulators work with industry associations to develop practice codes, information sharing practices, sharing of best practices, self-auditing that involves evaluation of compliance by regulated entities or third parties,

[305] Solomon supra note 121 at 822. (This project was being written at the time of the BP 2010 Gulf of Mexico Oil Spill said to be the biggest environmental crisis in American history.
[306] Lobel, supra note 41 at 374 - 375.

management-based systems that entail firm responsibility for adhering to plans that limit regulated harms, and performance-based approaches that put emphasis on regulation for results.[307] In terms of regulation in the new governance, "the scope of regulation as command shrinks while the parameters of regulation as self-governance unfold."[308] New governance systems may therefore include, in certain respects, systems of self-regulation, that is, systems where private actors, such as professional associations, regulate their members on issues delegated to them directly or indirectly by government.[309] Such self governance typically takes place in the "shadow of hierarchy" (the state).[310] New governance tools or instruments also include soft law, that is, guidelines, benchmarks and standards that have no formal sanctions, rather than hard law, such as legislation (which in a positivist sense can be regarded as a top-down projection of state authority)[311] as key components of governance.[312]

Law (both in a broad sociological and normative sense, as well as in the positivist, functional and formal sense) in the new governance context could be described as operating as a facilitating vehicle, recognising, permitting and ratifying the implementation of voluntary and other approaches and forms of ordering employed in the new governance. In the new governance, law becomes

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[307] Peter J. May, "Regulatory Regimes and Accountability" (2007) 1 Regulation & Governance 8 at 8.
[308] Swan, supra note 11 at 14.
[309] In such cases, state involvement is indirect if self-regulation takes place as a response to threats by government that if nothing is done, state action will follow. See Robert Baldwin and Martin Cave, *Understanding Regulation: Theory, Strategy, and Practice* (New York: Oxford University Press, 1999) at 126. See also Maynzt, *supra* note 126 at 4.
[310] Maynzt, supra note 66.
[311] Macdonald, supra note 26 at 209.
[312] See Louise G. Trubek, "New Governance and Soft Law in Health Care Reform" (2006) 3 Indiana Health Law Review 139 at 158.

"softer, less coercive, less hierarchical, more revisable, more flexible, more experimental, more inclusive of nontraditional actors, less reliant on courts and formal legislation."[313] The use of sanctions and coercive methods are attenuated, and attempts are made instead to "maintain incentives and opportunities to elaborate robust norms in context."[314] In this regard, it has been observed that some approaches to the new governance retreat from the idea of specific rights established by formal legal bodies and enforced by judicially imposed sanctions. Less coercive sanctions, with the potential for flexibility in implementation and compliance (such as a reporting requirement) are preferred to hard legal rules (with penalties such as fines or imprisonment).[315]

Further, with its preference for soft law (that is, open-ended guidance as opposed to rules, and no formal sanctions) new governance places responsibility for law-making in deliberative processes which are to be continually revised by participants taking experience into account. Lawmaking thus moves from a top-down, command-and-control structure, (which has been criticized as being sometimes underinclusive and undereffective, other times overeffective and leading to overregulation and overlegalisation, or becoming captured by powerful interests)[316] to a cooperative, reflexive approach tailored to local circumstances.[317] Accountability is provided mainly through transparency

[313] Neil Walker and Grainne De Burca, "Reconceiving Law and New Governance," (2007)13 Columbia Journal of European Law 519 at 525.
[314] Scott and Sturm, supra note 121 at 568.
[315] Lobel, supra note 41 at 391.
[316] Lobel supra note 41 at 363.
[317] Lobel supra note 35 at 345.

and peer review rather than democratic institutions of state and formal legal processes.[318]

As Salomon points out, these systems are not necessarily new as the term implies, but recognition of the concept and interest in the ways in which government works to achieve public goals may be more recent.[319] Likewise, Trubek notes that the word "new" refers to the "widespread and explicit use of nonconventional forms of governing," rather than its novelty[320]and in the sense of being different from traditional mode of governing. Lobel, for her part, considers the "newness" of the new governance approach to be an essential feature of this emerging approach, a dynamic innovation that allows the regime to constantly renew itself.[321]

In any event, such governance aspires to being more open-textured, flexible, and participatory, involving all stakeholders in the regulatory process and responsive to contribution from those being regulated. Thus Salomon notes that "the upshot is an elaborate system of third party government in which crucial elements of public authority are shared by a host of non-governmental or other-governmental actors, frequently in complex collaborative systems...."[322] Lobel adds that, "The adoption of governance-based policies redefines state-society interactions and encourages multiple stakeholders to share traditional roles of governance."[323] At the centre of the concept of new

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[318] Scott and Sturm, supra note 121 at 565.
[319] See Lester M Salomon, "The New Governance and the Tools of Public Action: An Introduction" (2001-2002) 28 Fordham Urb. L.J. 1611.
[320] Trubek, *supra* note 137.
[321] Lobel, supra note 41 at 354.
[322] Salomon supra note 144 at 1613.
[323] Lobel, supra note 41 at 344-345.

governance, therefore, is the recognition that government is not the sole actor in the policy sphere and that there is a spectrum of public and private actors, domestically and internationally, that make significant contributions to the governance process, creating relationships between governments and private organizations which Salomon has described as "collaborative."[324] The new governance has been applied, in its different approaches, to diverse areas such as

[324] Salamon supra note 129. The "new regulatory state" which also comes up frequently in the literature on the new governance shares a similarity with the new governance (and also with the new public management) but is not the same. The new regulatory state denotes "a shift by governments away from command and control regulation to a reliance on new institutions that set and enforce market rules at arm's length.... Institutionally, the regulatory state is characterized by a set of agencies, commissions, and special courts that governments have created to define, monitor, and enforce market rules." See David Bach and Abraham L. Newman, "The European Regulatory State and Global Public Policy: Micro-institutions, Macro-influence" (2007) 14: 6 Journal of European Public Policy 827 at 828 and 830. Like the new governance, the regulatory state, (the growth of which in many accounts is linked to the rise of marketization) is dependent upon, an array of civil and non-governmental groups and networks. However, the new governance is broader than market-supporting rules as envisaged under the new regulatory state, which is arguably only a form of governance. New governance is also less about what the increasingly regulatory state does (which is act by regulation instead of through providing as in the welfare state), and more about what other actors do. For instance, the new regulatory state, having ceased to be the all-round provider, allows companies in through privatization and then sets up regulatory agencies to regulate the privatization process and the companies' performance. The use of hierarchy (albeit not in a bureaucracy) is a central characteristic of the regulatory state. See Colin Scott, "Regulation in the Age of Governance: The Rise of the Post Regulatory State in Jacint Jordana, and David Levi-Faur, (eds.) *The Politics of Regulation: Institutions and Regulatory Reforms for the Age of Governance* (Cheltenham, UK: Edward Elgar Publishing, 2004) 145-174. The new governance does share some of the challenges of the new regulatory state, including those of legitimacy and accountability. The broader definition of the regulatory state given by King is perhaps more helpful: "In one sense, the notion of 'the regulatory state' may refer fairly straightforwardly to the changing administrative form of the state, such as increased reliance by governments on standards-setting and enforcement agencies, or on the shedding of operational responsibilities for the delivery of public services by government departments to executive bodies that are controlled by Ministers through broad framework agreements. It may also, in these meanings, include reference to the rise of 'regulation inside government' – the sleaze-busters and wastewatchers ... – or to the increasing interpenetration of the national state by supranational regulatory bodies, such as the EU and the European Court of Justice (ECJ). However, 'the regulatory state' as a mode of governance is characterized as much by its relationships with non-state actors and by an increasing variety of regulatory norms, instruments and controllers, as it is by changes in its administrative architecture." See Roger King, *The Regulatory State in an Age of Governance: Soft Words and Big Sticks* (Houndmills, Basingstoke, Hampshire: Palgrave Macmillan, 2007) at 5. Michael Moran, "Understanding the Regulatory State" (2002) 32 Brit. J. Pol. Sci. 391; J. Braithwaite, "Accountability and Governance under the New Regulatory State" (1999) 58:1 Aus. J. Pub. Admin. 90; Michael Moran, "The Rise of the Regulatory State in Britain" (2001) 54 : 1 Parliamentary Affairs 19; and John Braithwaite, "The New Regulatory State and the Transformation of Criminology" (2000) 40: 2 British Journal of Criminology 222.

environmental law,[325] policing, information technology, occupational health[326] and medical error.[327]

For some, the new governance may represent an acknowledgement of the failure of the state.[328] But, as Pierre observes, this may be an overstatement.[329] The emergence of the new governance, Pierre points out, should not be taken merely as proof of the decline of the state, but should be understood as the state's ability to adapt to external changes.[330] Moreover, as Swan points out, some of the new approaches to governance do not necessarily assume that state power is in decline but instead suggest that contemporary governance and regulation is more complex and is being transformed.[331] Government is adopting a different role, from a more hands-on-approach to a more indirect approach.

Still much has been made of the seemingly diminishing role of government as the provider of regulation and control in a lot of the literature on

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[325] Kernaghan Webb, "Sustainable Governance in the Twenty-First Century: Moving beyond Instrument Choice" in Pearl Eliadis et al, *Designing Government: From Instruments to Governance* (McGill-Queen's University Press, 2001).
[326] Lobel, supra note 41.
[327] David M. Trubek and Louise G. Trubek, "New Governance and Legal Regulation: Complementarity, Rivalry, and Transformation," (2007)13 Colum. J. Eur. L. at 547.
[328] See for instance, Andrew Jordan, "The Rise of the New Policy Instruments in Comparative Perspective: Has Governance Eclipsed Government?" (2005) Political Studies 477 at 490, noting that "most scholars associate governance with a decline in central government's ability to steer society."
[329] Pierre, supra note 15 at 5. Maynzt, supra note 115 at 6.
[330] Pierre, supra note 15 at 3.
[331] Swan, supra note 11 at 1-16. Rosenau and E.- O. Czempel similarly note that: "The role of governments is certainly not obsolete, but other organizational structures are appearing alongside them, driven by new social actors, to take over those functions that public administrations appear incapable of discharging satisfactorily." See J. N. Rosenau and E.- O. Czempel, *Governance without Government Governance without Government: Order and Change in World Politics,* (Cambridge: Cambridge University Press) at 250.

the new governance.[332] While such a framework recognises clearly the limitations of the state or government, and the deficiencies of a strictly command-and-control type of governance (such as legalism and rigidity), one of the issues a new governance framework raises is the apparent minimisation of the role of government and the usefulness of the command-and-control approach, which is necessarily one of the most important regulatory instruments of government. There appears to be a "tendency" to expel the state and "ignore consideration of state power."[333] Indeed the term "governance" appears employed increasingly in place of, and at the expense of, the concept of government[334] and has been described as "governance without government."[335] This is true particularly where governance is seen as a fundamentally non-hierarchical, interactive process in which no one actor enjoys more effective authority than the others.[336] Thus it has been pointed out that:

> The language of governance rather than government in itself signals a shift away from the monopoly of traditional politico-legal institutions, and implies either the involvement of actors other than classically governmental actors, or indeed the absence of any traditional

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[332] Jordan, supra note 151.Rhodes, supra note 9 at 652-653, pointing out the frequent usage of governance in place of government. See generally Swan, supra note 10 at 1-3. See also, Alan Hunt, *Explorations in Law and Society: Toward a Constitutive Theory of Law* (New York: Routledge, 1993) at 312. Governance, "is supposed to permit collective projects to be carried through without the formal authority and concrete sanction of governments." Pierre de Senarclens, Governance and the Crisis in the International Mechanisms of Regulation (1998) 50: 155 International Journal of Social Science 91 at 94.

[333] Ibid.

[334] Ibid. at 13.

[335] This comes from the title of a prominent book: See J. N. Rosenau and E.- O. Czempel, *Governance without Government Governance without Government: Order and Change in World Politics* supra note 129.

[336] See generally, Jan Kooiman, in Pierre, supra note 15 at 8.

> framework of government, as is the case in the EU and in any trans-national context.[337]

While this approach to governance may resonate well in a system like that of the European Union, it may not apply more generally. Pierre thus observes that many approaches to the new governance appear to have very little to say with respect to government's role in society more generally.[338] In this regard also, Jachtenfuchs has suggested that, "the governance approach . . . has a strong bias towards effective and efficient problemsolving and almost completely ignores questions of political power."[339]

It is useful, then, to question what government brings to the governance table, and where and how law, often considered a product of state, fits in. Does the new governance mean a replacement of law by non-legal normative orders? Further, is the new governance approach necessarily transformative of law or does it create a hybrid approach?[340] Should law only operate as a legal framework or background for new governance and an encourager of the regulatory facilities of organisations or should there remain a more extensive role for law? These are very broad questions which cannot be answered completely within the scope of this thesis. In any event, according to Salomon:

> The new governance acknowledges that command and control are not the appropriate administrative approach in the world of

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[337] Graínne de Búrca and Joanne Scott, "New Governance, Law and Constitutionalism," online: <http://www.ucl.ac.uk/laws/clge/docs/govlawconst.pdf> (June 9, 2009) at 3.
[338] Pierre, supra note 15.
[339] M. Jachtenfuchs, 'The Governance Approach to European Integration," (2001) 39:2 Journal of Common Market Studies 245 at 258.
[340] Jason M Solomon, "Law and Governance in the 21st Century Regulatory State," (2008) 86 Texas Law Review 819.

> network relationships that increasingly exists. Given the pervasive interdependence that characterizes such networks, no entity, including the state, is in a position to enforce its will on the others in the long run. In these circumstances, negotiation and persuasion replace command and control as the preferred management approach, not only in the setting of policy but in carrying it out.[341]

It is important to ask whether this view applies equally in all contexts. There are arguably contexts in which the command-and-control function of government remains useful and even necessary as a means of coercing other parties involved in the governance process and therefore ensuring that public objectives are met and that public values are protected. Should law then continue to operate with sanctions, while specifically detailing and protecting the rights of those unable to do so for reasons including their relative powerlessness? As further discussion will show, I answer this question in the affirmative.

With the potential, if not actual, displacement of the state comes also the problematic issues of accountability. While new governance promises greater effectiveness as well as increased efficiency in meeting regulatory goals, a number of concerns arise such as: how can private actors who are not elected by the general public be held accountable for actions taken in the interest of the public? Also, there is sometimes an implicit assumption of equality of power between all the actors in the governance sphere, [342] which is emphasised by frequent references to horizontal and hierarchical actions in describing the new

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[341] Salomon, supra note 142 at 133.
[342] Garson D, "Governance Theory" (2006) online: <http://www2.chass.ncsu.edu/garson/pA765/governance.htm> (February 1, 2008).

governance. As I discuss below, this is one the reasons why a hybrid form of governance would be more effective than a strict new governance framework.

Aside from these issues, the other matter that rears its head with regards to the application of the new governance, and is of particular interest in this thesis, is its workability in the context of developing countries. In this respect, one of the major criticisms of the new governance approach, is that it appears essentially technocratic and somewhat apolitical (or perhaps more accurately, as Hirst calls it, post political).[343] Peters accurately captures this concern when he states that:

> These various versions of governance also appear to present something of a travelling problem .... This hazard appears primarily as we think about the 'new governance' approach as it functions in different societies. On the one hand in those societies in which civil society has not been seen to be sufficiently developed to sustain effective governance, the question appears to be how to build a strong society and to do so for reasons of building the capacity of government to govern. On the other hand, in more developed societies, the existence of a strong civil society appears to become a barrier to effective governance.[344]

Although it is difficult to see how a strong civil society could be an obstacle to effective governance, (indeed a strong civil society appears essential to effective governance), Peters identifies the issue that arises with applying the new governance in certain developing countries where the civil society may not be strong, the bureaucracies may not be functional or accountable and many

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[343] Paul Hirst, "Democracy and Governance," in Pierre, supra note 15 at 24.

[344] B. Guy Peters, "Governance and Comparative Politics" in Pierre, supra note 14 at 42. See also, Maynzt supra note 115 at 5 6. See also King summarizing the different ways in which the regulatory state functions in different countries. King, supra note 149 at 9- 10.

consider the governments to be captured by commercial or ethnic interests. Moreover, in terms of application, the concept of new governance and decentralization is more established in developed countries than in developing countries, where a dependency on government support and reliance on centralized government still exists.[345] However, this is gradually changing, allowing for the consideration of the new governance in developing countries.[346] Also, instances in which developing country governments allow the use of vigilante groups to combat crime in place of ineffective police forces,[347] or the contributions made by private companies to health management through workplace policies and programmes[348] and the adoption of public-private partnerships in different policy areas, and the active participation of new governance actors such as non-governmental organisations in different policy areas also point toward the fact that strategies similar to new governance strategies are not alien to developing countries.

Still, many approaches to the new governance as now detailed in the literature have little room for dealing with the sorts of issues that may arise

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[345] See Klaas Schwartz, "The New Public Management: The Future for Reforms in the African Water Supply and Sanitation Sector?" (2008) 16 Utilities Policy 49 at 56, noting the new public management reforms implemented in three African countries but observing that there is still a significant level of dependency on government and donor support so that it becomes difficult to measure the actual impact of the new management reforms.

[346] See Dele Olowu, "Governance in Developing Countries: The Challenge of Multi-Level Governance" paper presented at the Seventh International Seminar on Geo-Information Science (GIS) in developing countries, 15-18 May, Enschede, the Netherlands, 2002, online: <http://www.gisdevelopment.net/proceedings/gisdeco/sessions/key_olowu.htm> (January 19, 2008).

[347] Johannes Harnischfeger, "The Bakassi Boys: Fighting Crime in Nigeria" (2003) 41: 1 The Journal of Modern African Studies 23. Questions of legitimacy and accountability have, however, arisen in the face of extra-judicial killings and allegations of human rights abuses.

[348] Such as those relating to HIV/AIDS in South Africa. See for example, Gavin George and Tim Quinlan, "Health Management' in the Private Sector in the Context of HIV/AIDS: Progress and Challenges Faced by Company Programmes in South Africa" (2009) 17 Sustainable Development 19.

in developing countries, since they make the assumption that these approaches will take place in a liberal democracy, with a strong civil society, and functioning bureaucratic institutions. In developed countries, these assumptions may arguably be overstretched,[349] but they are even more so in the context of many developing countries with considerably different democratic and regulatory narratives. However, as I pointed out in the previous subsection, the concept of governance can also be identify *what ought to be* rather than only *what is*. But even beyond addressing normatively governance in a developing country environment, any approach taken with respect to governance in any particular field in developing countries must also take into consideration the context. In other words, one must tread the line between the practical and the ideal, the descriptive and the normative, and using what is to achieve what ought to be.

In my view, therefore, a hybrid form that takes into account the specific context of developing countries as well as the strengths of the various approaches to governance is necessary. In this regard, I agree with Maynzt's view that, "In modern governance, hierarchical control and civic self-determination should not be opposed to, but combined with each other. Theoretically, this combination can be more effective than either of the "pure" forms."[350] In fact, as Schneider and Bauer point out, it is difficult to imagine a scenario where either one or the other is in exclusive operation. They observe that:

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[349] See for instance, Hirst, supra note 166; Maynzt, supra note 66 at 6.
[350] Maynzt, supra note 126 at 6. See also, Jordan, et al, supra note 151 at 483-485. See also,

> In many areas of inquiry, where the governance concept is used to analyse the functioning of political systems or the performance of public policies by governmental and nongovernmental actors, there is currently this danger of over-simplification. For instance, it is sometimes argued that modern societies are in a transition from hierarchical to network governance. Although there is a grain of truth in this statement, it would not make much sense to assume that societies are only governed by hierarchies, or networks, or markets. Concrete societies are based on combinations of these generic and many other mechanisms, which we perhaps do not fully understand at the moment.[351]

Or, as Sinclair insightfully states with respect to environmental regulation:

> If conventional wisdom is rejected, and absolute distinctions between self-regulation and command and control regulation are viewed as being essentially arbitrary and misleading, then, in many instances, regulatory differences will merely be a question of emphasis. It may be more accurate and productive, therefore, to envisage the range of environmental policy instruments as being on a regulatory continuum, with idealized forms of "pure" self-regulation and "strict" command and control regulation at opposing ends... In the vast majority of circumstances, neither pure self-regulation nor strict command and control regulation will be appropriate; rather, some combination of the two will provide the optimal regulatory solution. By recognizing this truth, policymakers will be in a much

[351] See Schneider and Bauer, supra note 110 at 23. See also, Trevor Purvis, "Regulation, Governance, and the State: Reflections on the Transformation of Regulatory Practices in Late-Modern Liberal Democracies," in MacNeil, Sargent and Swan, supra note 10 at 28-31, noting that a more complex and sophisticated account is required to explain transformations in state-society interactions. And see Oliver Treib, Holger Ba¨hr and Gerda Falkner, "Modes of Governance: Towards a Conceptual Clarification" (2007) 14: 1 Journal of European Public Policy 1 at 9, noting that there is no empirical evidence pointing to the use of one form without the other.

> stronger position to adapt regulation to suit a range of circumstances.[352]

Although new governance does not wholly reject the application of traditional governance methods and tools like formal legislation, certain approaches within the new governance do deemphasise them, favouring instead voluntary agreements, soft law, and self regulation, operating in the distant shadow of hierarchy. The state, as Lobel describes it, becomes a facilitator, rather than a regulator and controller, while the law becomes a shared problem solving process rather than an ordering activity.[353] The preference for soft law in the new governance (such as guidelines), according to Lobel, signifies not that law is unnecessary but that law can operate in different normative ways.[354]

As practical as this may appear, these new roles for government and law may not be sufficient in all situations, particularly in areas where certain populations are vulnerable and direct government input may be necessary. Law, then, cannot only be a facilitator, or a coordinator, or a harmonizing influence between different subsystems,[355] it should also act as prospective protector of rights and enforcer of responsibilities. In my view, government and formal law (understood not only normatively as a background support but also as a command-and-control technique) can still operate in a productive way to address important public policy issues, while utilizing other creative approaches which involve the private sector and the citizenry more fully in regulation and decision-

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[352] Darren Sinclair, "Self-Regulation versus Command and Control? Beyond False Dichotomies" (1997) 19 Law and Policy 529 at 532-533.
[353] Lobel, supra note 41 at 377.
[354] Lobel, supra note 41 at 379.
[355] Lobel, supra note 41 at 404.

making. In this regard, Webb observes in a discussion of the concept of sustainable governance that:

> To recognize some of the limits of the state and the importance of nonstate actors is not to suggest that state institutions will not remain the central actor in public policy or that conventional instruments of governing will not remain of central importance. But it is to suggest that governments can and should work more systematically with others to develop and implement sustainable approaches to governing – that is, governance approaches that, because they integrally involve other actors have the potential to be more robust, responsive, efficient, effective, and flexible than conventional, state-imposed regulatory approaches.[356]

The sustainable governance concept, an offshoot of the new governance,[357] is characterized by an acknowledged place for government action and law, but which extends beyond the command-and-control methods of traditional regulation to recognise the role of other actors and institutions outside of government. Similarly, May notes that the reforms of new governance have not "wholly or even widely supplanted traditional regulation that emphasizes enforcement of rules by governmental agencies and penalties for noncompliance with the rules." [358] Moreover, as King rightly notes, certain notions of "governance without government," in which states create little more than legal

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[356] Kernaghan Webb, "Sustainable Governance in the Twenty-First Century: Moving Beyond Instrument Choice" in Pearl Eliadis et al, *Designing Government: From Instruments to Governance* (McGill-Queen's University Press, 2001) (hereafter *Designing Government*) at 242-243. The concept of sustainable governance is therefore particularly helpful in that the role of the government is not completely minimized or even altogether discarded, but I go even further in giving the government an enhanced role in my hybrid framework.

[357] Webb describes the concept of sustainable governance as "attempts to recognize and draw on the largely untapped potential of the private sector, the third (voluntary) sector, and individual citizens to assist in governing in the public interest." See Webb, *ibid.* at 243.

[358] May, supra note 130.

frameworks within which networks function, fail to take into account four key state governance functions, (or, at any rate, the function which states ought to exercise) namely: "articulating a common set of priorities for society; having consistent and coordinated goals that provide coherence across a large range of policy sectors; steering, including new instruments such as the use of the private sector; and accountability, which is especially important for democratic governance, and which is a particular weakness for non-governmental actors in the governance process."[359]

Understanding the role of different actors is perhaps more critical in developing countries where the state's regulatory capacity is typically weak, and governments and public institutions may be weak or corrupt. Yet in a still centralized atmosphere, the state may remain the major regulatory body usually having the most resources at its disposal. As Minogue and Carino assert, "many factors in developing country political and economic systems demonstrate a propensity for regulation *inside* government."[360]

However, some would argue that while these arguments in favour of a broader role for the state and the law than may otherwise currently exist may sound strong, in practice they may not stand at all. It could therefore be argued in relation to other policy issues that devising stricter rules and more elaborate laws do little in the face of high levels of corruption, non-compliance and non-enforcement of these rules and laws. In fact these rules may even

[359] King, supra note 149 at 21.
[360] Martin Minogue and Ledivina Carino, "Introduction" in *Regulatory Governance in Developing Countries* (Cheltenham, United Kingdom: Edward Elgar Publishing Limited, 2006) at 3.

contribute to more corruption. Yet, as Polidano discusses in the context of new public management, (which is akin to, but not the same as, the new governance)[361] there are also contexts in which an active government role and increased rules alongside public reforms have worked effectively and yielded beneficial outcomes. He concludes that political and administrative leadership make a huge difference in the implementation of certain reforms.[362] A generalisation as to the situation in developing countries may therefore not be appropriate. As I argue in greater detail in the next chapter, a broad role for law is important, especially in the interest of research participants and the general public in developing countries.

In other words, it needs to be recognised that government, with all the challenges that may be attached to that institution in developing countries, remains an actor in the governance and regulation of different policy spheres. This recognition allows for a pragmatic approach that takes practical realities into account, and around which more realistic possibilities in improving governance can be built. Thus, we can argue for the active involvement of the state but also for complementary in-put from other sectors such as civil society and non-governmental organizations, as well as arms-length processes, which would be necessary for adequate oversight. It may not be wise to minimise the essential role of the state to that of simply facilitating other forms of regulation,

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[361] Charles Polidano, The New Public Management in Developing Countries" online: <http://unpan1.un.org/intradoc/groups/public/documents/APCITY/UNPAN014322.pdf> (June 5, 2009).

[362] Polidano, ibid. at 24-32, citing examples from Ghana and Brazil. See also, Christian von Drachenfels, "The Call for the "Regulatory State": Challenges for Developing Countries" (2009) online: Vox <http://www.voxeu.org/index.php?q=node/2987> (June 8, 2009).

particularly in a developing country context, but other actors and tools are needed for greater effectiveness.

The aim, then, is not to return to an era of complete command and control (if it ever truly existed in that manner), nor to employ the state and the law only as facilitative instruments for the work of other actors and institutions. The intention is instead to point out that a framework that emphasises and utilises the strengths of all actors and institutions, (especially in the specific context of health research), is likely to be more helpful. A hybrid approach between the all-powerful state and autonomous, hierarchical, self-organising private and societal actors is thus necessary.[363]

With specific regard to a sensitive area such as research involving humans, the subject under consideration, agendas may differ in terms of what counts as beneficial research and how to facilitate it. Also, the vulnerability of

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[363] In the helpful analysis of Trubek and Trubek, hybrids consisting of traditional governance (which they call legal regulation), consisting of fixed statutes and detailed rules and judicial enforcement on the one hand, and new governance approaches, consisting of other flexible approaches such as policy guidelines, may operate in different ways with different outcomes. They could be *complementary*, existing side by side. They could be competing such that the two approaches are utilised and in the end only one form survives, and Trubek and Trubek call this *rivalry*. They could also be *transformational* of each other where the two become fused or integrated such that none can function without the other. See Trubek and Trubek, supra note 152 at 543- 544 and 560. de Búrca and Scott also identify different type of hybrid approach namely: 'baseline or fundamental normative hybridity', 'functional/developmental hybridity', and 'default hybridity (or 'governance in the shadow of law). They note that "Of the three variants of hybridity, baseline hybridity is arguably the most restrained or even cautious in its insistence on a robust role for a traditional legally grounded framework.... The rise of experimental governance and new problem-solving approaches has generated profound scepticism and unbridled enthusiasm alike, and an insistence on the co-existence of the familiar (traditional, legally and constitutionally grounded regulation) with the new (experimental governance) sets a limit to the risks posed by an excessive faith in new governance... A more positive version of fundamental or baseline hybridity claims not merely a continuing parallel role for traditional law and regulation, but also that new governance mechanisms may even serve to enhance the effectiveness of law's traditional role." See de Búrca and Scott supra note 136 at 12 and 13. As the discussion shows, I favour both these approaches. See also, Jordan et al, supra note 151 at 481, describing the different ways in which the traditional governance interacts with the new governance – coexistence, fusion, competition, and replacement.

research participants, particularly in the developing world context to potential exploitation is palpable. Self-regulation by professional organisations of physicians and medical researchers may be helpful in determining the manner in which research should be conducted. However, professional organizations regulate members who may have other interests that conflict fundamentally with the interests of those who subject themselves to such research. Funding agencies' requirements may also be helpful. But since these requirements could vary from one funding agency to the next, and from one funded organisation to another, these requirements will not only be non-comprehensive in facilitating research and setting appropriate parameters, they can only offer at best patchy and incomplete protection to research participants.

Thus, in an area such as I describe below which had previously been dominated by non-state actors, the mediating role of the government as a protector of its citizens remains essential still. Given that governments should ideally work for the citizens' best interests, they may, if they actively exercise appropriately the powers at their disposal, be a more effective negotiator on behalf of the citizens. This does not suggest that the government itself is not an interested party – it may, for instance, be interested in attracting foreign research and the accompanying jobs and monies, an interest that may conflict with the paramount objective of ensuring the safety of participants in research. Indeed, although there have been no empirical studies to support this, some have accused developing world governments of refusing to adopt legal regulations in

order to retain the interest of research sponsors.[364] And it is not unusual in a developing country context that the state may be run by a corrupt government. As I mentioned in the Chapter One, economic constraints may mean that the scarce resources are devoted to myriad problems. Leadership challenges, where the state fails to lead in providing basic amenities, may abound, [365]such that other actors, such as non-governmental organisations are becoming more relevant in providing basic services, including healthcare. [366] The relevant capacity for reviewing and monitoring research, important aspects of research governance, may not be found within developing country bureaucracies. As I discuss in subsequent chapters, Nigeria has many of these issues. For some, therefore, the weaknesses of the state, especially in a developing country context, may mean that a system without the active input of the government, except perhaps in some kind of facilitative role may be best.

However, other actors that may be involved in the research governance systems are not necessarily free from some of these concerns.[367] More importantly, my arguments in Chapter One regarding the importance of a domestic context and the need to create national governance systems also feed

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[364] See for example R. N. Nwabueze, "Ethical Review of Research Involving Human Subjects in Nigeria: Legal and Policy Issues" (2003–2004) 14 Ind. Int'l & Comp. L. Rev. 87

[365] Kenneth L. Leonard, "When Both States and Markets Fail: Asymmetric Information and the Role of NGOs in African Health Care" (2002) 22 International Review of Law and Economics 61 at 62, noting the various challenges associated with governments in Africa.

[366] Ibid.

[367] See for example, with respect to non-governmental organisations, Raymond C. Offenheiser, "Enhancing NGO Effectiveness in Africa: Re-Evaluating the Potential for Genuine Partnerships 7 Oxfam America, Working Paper No. 4, 1999), noting that African NGOs are viewed as lacking amongst other things, legitimacy, and may be prone to cronyism. See also, Henry Zakumumpa, "Are NGOs the New Colonial Power in Africa?" Daily Monitor, June 3, 2009, online: <http://www.monitor.co.ug/artman/publish/opinions/Are_NGOs_the_new_colonial_power_in_Africa_85863.shtml> (June 19, 2009). Yet others argue in relation to the delivery of health care services in Africa that NGOs offer better services. See Leonard, ibid.

into my arguments here about the importance of the state in an area such as that of health research involving humans. The active involvement of the state in the governance of health research would, in my view, result in a more organised, less fragmentary system. Reliance only on funding requirements or conditions in employment contracts or institutional ethics review committees which are not coordinated in any fashion and which face inherent conflict of interest issues, or on drug regulatory authorities which are typically government agencies, will not be comprehensive and may be inadequate. In any event, to dismiss an actor with perhaps the most resources, however imperfect, especially in a developing country is, in my view, unhelpful and counterproductive. Instead of dismissing the state, it is necessary to seek ways to clearly delimit the authority of the state and to encourage its active and effective input, if only to add legitimacy to the system (for instance, through the creation of a national ethics review system, set up by government but not a part of government bureaucracy).[368] Also necessary are ways to build the necessary expertise and capacity in specific areas such as ethics review and encouraging advocacy by interested groups.

Further, mechanisms for providing inducement, checks, and balances, are needed. Creating relevant arms-length processes, addressing issues relating appointments into, and the composition of the relevant bodies created by the state, are all avenues through which the independence, integrity, and

[368] Some have therefore argued, for instance, with respect to national research ethics review committees in the developing world, that an attachment to the ministry of health would be more effective and legitimate. See Carl H. Coleman and Marie Bousseau, "Strengthening Local Review of Research in Africa: Is the IRB Model Relevant?" (2006), online: <http://www.bioethicsforum.org/ethics-review-of-medical-research-in-Africa.asp> (June 22, 2007).

ultimately the effectiveness of the system can be ensured. To these would be added the active participation of other actors such as civil society, including research participants, patients' rights organisations and even institutions such as the media, which may not have a formal or explicit role in research governance. They should complement and act as a check on government, boosting the effectiveness of the governance process. Indeed, they may actively induce the state or government to perform and utilise the appropriate resources. These steps emphasise that a strictly top-down framework will not suffice (and, as I discuss further in this chapter, is increasingly not the case even in developing countries), and that other actors are necessary, but in addition to the state.

Additionally, a formal legal framework is an instrument which the government should ideally bring to the governance table. The legal framework should establish a system of governance (facilitative) that details the obligations of all parties involved in the process. But it should go further, even beyond the protections that could be provided through the retrospective decisions of courts, and the possible administrative law applications to the work of ethics review committees, to offer prospective and specific safeguards for participants and sanctions for noncompliance (protective and regulative). In addition, allowing for guidelines (soft law) in areas where specificity could be elusive, potentially offers not only more legitimacy but a greater level of accountability than would otherwise be the case. One could reasonably argue that law is an important underpinning for the governance of research involving humans, not least because law, more often than not, implies a role for government, is wide-

ranging, thus potentially regulating and imposing accountability on all the actors in the governance systems, including the government. It confers a certain legitimacy on public actions, including governance systems and choice of governing instruments. This legitimacy arises when law operates in a democratic context such that resulting legislation and or regulations have indirect input from the citizens who place representatives in government.[369] Further, the threat of sanctions in this context may serve as an incentive for complying not only with the legislation but also with the guidelines.[370]

Consequently, rather than seeing the governance context in these countries as simply a command-and-control condition or a situation in which the government has minimal role, it is perhaps more useful to draw on both traditional governance (by which I mean state control) and the new governance (the newer recognition of a partnership between all the stakeholders). This relates to the sustainable governance concept or the good governance approach mentioned above: governance would be carried out with an explicit role for government as well as a space in which private actors could contribute to governance.[371] One could then reasonably ask such important questions as how the characteristics of traditional governance (including formal or hard law) can be fruitfully blended with, or be complementary to, less traditional forms of governance, (such as soft law or increased civil society participation), for greater effect where necessary. One could also ask what benefits the different actors –

[369] See generally Pierre Issalys, "Choosing Among Forms of Public Action: a Question of Legitimacy" in *Designing Government*, supra note180 particularly at 169-171.
[370] Trubek and Trubek, supra note 152 at 8.
[371] The good governance approach recognizes the important role of the state and the rule of law, while emphasizing the importance of the private sector and the civil society.

government, research sponsors, researchers, professional bodies, and research participants – bring to the table and how these can be more effectively managed to ensure better governance of research.

In this way, new governance, with its emphasis on utilising all the actors and institutions along with taking cognisance of multiple sites of regulation and addressing the relationship between state intervention and societal autonomy, in combination with traditional approaches by the state, becomes helpful in creating an effective framework in the context of health research involving humans in developing countries. While this may obviously not have the same purchase in all settings, or be suitable for all situations requiring governance, a hybrid framework that adopts a generic understanding to which both traditional and new governance contribute their strengths, harnesses the synergies of different actors and institutions, and takes into account the political and socioeconomic contexts and also the best interests of developing countries is needed in such countries as Nigeria.

In employing this hybrid, it is important to admit that I am making some assumptions, the most important of which is that governance will take place within a democracy, no matter how imperfect, such that any resulting legislation is the product (however indirectly) of the people's wishes. Fortunately, this is the case in Nigeria. But it may limit the applicability of such a framework in other contexts where this may not be so. Thus, there would, of course, be more difficulties in an undemocratic setting. It is also not possible within the scope of this thesis to examine big questions relating to the challenges

that law presents in the sense that, as described by Hunt, it can be both a mechanism that contributes to social domination (as in, for instance, law enacted in a military regime), and as a mechanism that contributes to the potential of human emancipation.[372] I am clearly dwelling more on the positive aspects of law, but I address in more particular detail the role of law and any possible objections in the context of research governance in the Chapter Four. Again, the political context in terms of the division of authorities and the organisation of the legal system also matter. I will dwell on the political and constitutional context of Nigeria in Chapter Five and Chapter Six. As these chapters will show, the hybrid presented here, in my view, is likely to be feasible in the legal and political contexts of this country.

In the following subsections, I employ this hybrid version as the analytical framework for the subject of regulation of health research involving humans. I also argue for its potential effectiveness when used appropriately. This is not difficult to do since, even though this is hardly articulated in the literature,[373] some systems of health research governance, as a subsequent section shows, currently operate certain versions of this hybrid. The liberal use of "governance" in describing the management of structures and mechanisms in research involving humans may also, although not always clearly articulated in the literature, arise from this recognition of the different instruments and actors involved in such management.

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[372] Hunt, supra note 33 at 327.

[373] An important exception is the Canadian report *The Governance of Health Research Involving Human Subjects*, which dwells on the concept of governance). See M. MacDonald (ed.), *The Governance of Health Research Involving Human Subjects* (Ottawa: Law Commission of Canada, 2000).

This framework would be incomplete, however, without a consideration of what the goals of governance for research should be, and the criteria by which to measure the attainment of those goals. I consider this in the following subsection.

2.3.3 Goals and Criteria for Governance of Health Research Involving Humans

In the application of any kind of framework to the subject of research governance in developing countries, it is important to question: What are the goals of the governance of research involving humans? Although this is addressed summarily in Chapter One, it bears reiteration here.[374] Downie and Mcdonald carefully list the main objectives of the governance of health research involving humans. In their insightful review, the goals of governance arrangements are to:

> •Respect the dignity and rights of research participants
> • Protect the safety of all research participants, as much as it is possible to do so
> •Build and maintain trust between the researchers, research institutions, research participants, and society as a whole
> •Promote potentially beneficial research
> •Promote safe and effective research
> •Analyse, balance and distribute harms and benefits
> •Pursue all of the above in a way that is administratively and financially efficient and fair.[375]

[374] See page 14 of Chapter One.
[375] Jocelyn Downie and Fiona McDonald, "Revisioning the Oversight of Research Involving Humans in Canada" (2004) 12 Health Law Journal 159 at 160.

These can be summarised as yielding three main goals, namely: first, the goal of ensuring that research is potentially beneficial and, second, that while inherent risks exist in the process, efforts are made to minimise them and to protect the safety, dignity and wellbeing of research participants. A third important goal is the maintenance of trust between the research community and society as a whole, which flows from the first two goals.[376]

Thus, the major reason for conducting research is that it has the potential to provide benefits, whether in terms of providing effective (or more effective) therapeutic interventions for diseases or information which influences health policies. In the developing world, as I discussed in Chapter One, the need for health research and the potential benefits attached therewith cannot be overstated.

In the process of obtaining these benefits, the safety of research participants must be actively ensured. Research participants who volunteer themselves for research for the purpose of potentially obtaining benefits for the society deserve to have their safety, rights and welfare protected to the greatest extent possible. Research ethics as articulated in the international guidelines makes this abundantly clear. Where there are conflicts between these goals, the goal of ensuring the safety of the participants and minimizing any risk to them clearly takes precedence. The Helsinki Declaration clearly states that: "In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests." [377] The

[376] McDonald, Governance of Health Research Involving Humans in Canada, at 51.
[377] Article 6 of the Helsinki Declaration, 2008.

precedence of research participants in the scale of priorities represents an important value. The normative goals for research governance can then be framed thus: There is value in ensuring that the health of people in general is improved. The protection of the rights, safety, dignity and welfare of research participants is, however, of greater value. In ensuring the rights of research participants, the trust of the community is preserved, and in turn more the potential for more beneficial research is made possible.

All the governance arrangements and structures put in place therefore have to achieve these goals and reflect these values, respecting the paramount importance of not jeopardizing the health and well-being of research volunteers. Furthermore, the governance arrangements, as Downie and McDonald rightly note, need to be operated in an efficient manner, which in the final analysis, will affect the effectiveness of the arrangements.

If the goals of research governance are clear, what about the criteria by which the attainment of these goals are measured? Governance literature is also very helpful in this regard. Salomon discusses several criteria, some of which are particularly helpful in my analysis, namely, effectiveness, efficiency, equity, manageability, and legitimacy and political feasibility.[378] Others have proposed such criteria as clear mission; responsibility; accountability; transparency; stewardship; flexibility; succession; representation; and simplicity.[379] From the good governance approach, which fundamentally links democracy, development and health promotion, we have such criteria as

[378] Salomon, supra note 142 at 1647-1649.
[379] MacDonald, supra note 19 at citing *The Canadian Institutes for Health Research (CIHR) Public Report on Governance.*

participation, consensus orientation, accountability, transparency, responsiveness, effectiveness, equity and respect for the rule of law.[380] Hirtle links the good governance criteria to health research involving humans, observing that: "To address research ethics issues from the perspective of public governance is to focus on elements of good governance. These include accountability, oversight and transparency, clear government roles and responsibilities, clear relationships, structures and standards, and public processes, mechanisms and participation."[381]

From these various discussions, I derive eight criteria, which encapsulate the above prescriptions. The criteria are: effectiveness, legitimacy, clarity, comprehensiveness, efficiency, adequacy, uniformity, and simplicity. I discuss the criteria against which the actors, instruments and mechanisms applied in attaining the goals of health research involving humans can be assessed respectively below.

Effectiveness, as Salomon points out, is the most fundamental and basic measure for assessing the success of public action. "It essentially measures the extent to which an activity achieves its objectives."[382] The criterion of effectiveness in the context of the governance of health research thus raises the question of whether the objectives of the system are being met – promoting beneficial research and protecting research participants. Questions of

[380] Helmut Brand, "Good Governance for the Public's Health" (2007) 17:6 European Journal of Public Health 561, citing the United Nations Economic and Social Commission for Asia and the Pacific (UNESCAP) at 1.
[381] Marie Hirtle, "The Governance of Research Involving Human Participants in Canada" (2003) 11 Health L. J. 137 at 138-139. See Stephanie J Poustie et al, "Implementing a Research Governance Framework for Clinical and Public Health Research" (2006) 185 The Medical Journal of Australia 623.
[382] Salomon, supra note 144 at 1647.

compliance also fall under the criterion of effectiveness. This criterion therefore applies to all the tools or instruments and institutions employed in governance of health research involving humans. All the other criteria are important only to the extent that they contribute to meeting this criterion. Thus, while I engage in an examination of each of the other criteria in examining specific mechanisms of research governance, the criterion of effectiveness runs through all the examination and will be an intrinsic part of the analysis of each of the tools. In other words, I will be asking if the degree of uniformity or clarity or comprehensiveness of standards, actors, tools and institutions involved in research governance is effective in meeting the goals of promoting socially beneficial research and protecting research participants in developing countries, specifically in Nigeria.

Working within a governance framework, therefore, the thesis will consider what tools ought to be employed in the research governance system and examine their potential effectiveness in achieving the goals of research governance in Chapter Three. The assessment of effectiveness is certainly not easy, even in this case where the goals are fairly clear. Systems are usually shown to be ineffective when an incident occurs, (in the case of research governance, research participants die or are harmed). It is perhaps more accurate to state that what we are concerned with here is both actual and potential effectiveness. In other words, what potential does the system in Nigeria have to work effectively?

Within the criterion of effectiveness also comes the related criterion of legitimacy which is also a criterion that runs through each of the rest of the criteria. Legitimacy raises issues of rights, obligation and power, and of acceptance of authority. In a general sense, legitimacy has been described as being about:

> the moral grounding of power and therefore involves social and cultural norms and expectations concerning proper behaviour of those that govern, the social relationship between rulers and ruled, the role of trust, reputation and force, and the balance between authority and obeisance. Such norms and expectations vary across time and space. They can refer to the output or input of policymaking, to the procedures or legality of decision making or to its content, to the performance or to the status of rulers, and to limited or ultimate criteria of justice.[383]

Thus legitimacy refers not only to power and authority but also to the internal and external processes of exercising that authority in a policy sphere. Legitimacy is crucial to garner wide support for the measures taken to govern a particular activity, in this case health research involving humans, and thus ensure its effectiveness. A legitimate tool is more likely to be accepted and to be effective in achieving its ends. Thus Issalys frames the issue of the choice of governance tools in terms of legitimacy. He observes that legitimacy "resides in the acceptance both of an authority and of the rules laid out by this authority, it has obvious repercussions for the effectiveness and even for the efficiency of

[383] NWO Research Programme, "Shifts in Governance: Problems of Legitimacy and Accountability" (The Hague: Netherlands Organisation for Scientific Research, 2004).

any mechanism of public intervention."[384] Effectiveness and efficiency of governance actions are therefore closely linked to legitimacy, as are public participation, accountability and transparency. [385]

Questions about the independence, transparency, and credibility or conflicts of interest in ethics review committees thus provoke questions about legitimacy. Several issues addressed in this thesis are by implication questions of legitimacy. For instance, questions about the origins of research governance in developing countries such as whether recent research governance systems are being established for the principal purpose of receiving research funding from developed countries, involve an examination of legitimacy. Questions about the sufficiency of public participation in research governance, or questions about the role of law in research governance or the role of government generally or even in the context of national ethics review committees, necessarily engender an examination of legitimacy. Thus, like effectiveness, questions of legitimacy implicitly undergird much of the discussion that follows in analysing the mechanisms of research governance in Nigeria.

The other criteria raise specific issues as to the organisation and operation of the research governance system. Clarity in the context of research governance requires that the roles, responsibilities, rights of all the stakeholders in the research governance system, including research sponsors, research funders,

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[384] Pierre Issalys, "Choosing Among Forms of Public Action: a Question of Legitimacy" in *Designing Government*, describing the various perspectives adopted in discourse relating to the criteria for choosing the tools for public action, particularly with respect to legitimacy at 154.
[385] Baldwin and Cave also referring to legitimacy point out the benchmarks for regulation namely: legislative mandate, accountability, due process, expertise, and efficiency. Baldwin and Cave, *supra* note 128 at 77-84. These criteria are similar to those laid out by Issalys, ibid. at 171.

research institutions, professional bodies, research regulators and research participants, and lines of accountabilities be clear and unambiguous to ensure greater effectiveness.

Related to this is the need for uniformity or consistency and adequacy. The legal and ethical standards applied within the research governance system must be both adequate and consistent, and not dependent, for instance, on the institution in which research is taking place or the organisation which is funding the research. Adequacy is also important in the consideration of the authority of the different institutions. They must have adequate independence, adequate resources, and adequate authority to operate and carry out tasks within the research governance system, including standard setting, and standards implementation.

The system also needs to be comprehensive, including the whole spectrum of actors and different types of health research involving humans, provide protections for a wide scope of research participants, and should be encompassing in terms of the relevant issues. It should include not only ethical standards and legal regulations, but prescriptions relating to other factors (for instance, the training of researchers or the creation of clinical trial registries), which may affect the conduct of health research. These should be addressed comprehensively within the various legal and policy instruments which govern research. As Downie and McDonald note, non-comprehensive systems (for instance, in terms of what kinds of health research are covered, or what receives ethics review) pose threats to research participants, may impose increased costs

on society, increase adherence or compliance problems and put public trust in the research process at risk.[386]

The system needs to be efficient. Efficiency is a criterion that considers the balance of results against costs.[387] It questions how best to achieve results with minimum financial, human, and time resources. Particularly in the context of a developing country, the available resources, financial, infrastructural and human resources must be utilised efficiently. These should permit seamless relationships between different actors and instruments and proper coordination between structures, and allow no duplication and waste of scarce resources. Efficiency, however, can only be contributory to the effectiveness of the system; it cannot be a goal in itself, otherwise the protection of research participants may be jeopardised.

Despite the wide range of actors involved in what is increasingly a complex activity, the organisation of the governance system and the processes employed therewith, although there are underlying complexities, should aim to permit a relative ease of operation and the clarity of roles and lines of accountability earlier mentioned. In subsequent chapters of the thesis, and in the specific context of the research governance systems of Nigeria, I will be making assessments using these criteria.

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[386] Downie and McDonald, supra note 199 at 8.
[387] Salomon, supra note142 at 1648.

2.3.4 Rationale for a Governance Framework

The term "governance" has been used, in recent times, quite liberally in relation to health research involving humans and other ethics-related issues. Much of the usage occurs without specificity and with an assumption that the meaning and the reason for such use is clear. This has caused a commentator like Ruth Chadwick, a bioethicist, to speculate as to the reason for this profusion in use:

> The controversies about ethics and Bioethics in particular, however, surely constitute one factor in the increasing popularity of talking about 'governance' in addition to or even in preference to ethical oversight. The hope and promise of good governance is reassuring, and might be thought to be stripped of the suggestion of 'moralising' that could be associated with 'ethics' for some, on the one hand, while it might also appear to imply more critical distance, on the other.[388]

Although I disagree that governance eliminates "moralising," (indeed, as I argued in Chapter One, and as I point out in the application of the framework in section 2.6 below, ethics is an important building block of the governance framework applied here), it may be, as Chadwick suggests, that governance as a concept allows some distance and measured or deliberate judgment in addressing the subject of health research involving humans. However, beyond the presumed objectivity which governance might offer or its current fashionable usage, my main argument is that it offers a comprehensive frame within which to consider the regulation of what is a beneficial, yet potentially risky, activity.

[388] Ruth Chadwick, "Bioethics and Governance" (2007) 21: 4 Bioethics (Editorial).

I examine this argument in more detail below and discuss the reasons why a governance framework is not only helpful but necessary.

Governance of research involving humans in developing countries is, as I have previously pointed out, an area not yet sufficiently researched. Governance, as is clear from discussions above, can also be used as an analytical framework. Using governance as an analytical framework seems to flow, then, as a natural consequence of my consideration of this topic. My specific framework, a generic understanding of governance, includes all the actors, including the government, research sponsors and citizens as active participants in the process, and finds merit in a hybrid form that includes the strengths of both traditional and new governance.

To begin with, the problems arising from research involving humans in the developing world are problems of governance. The fundamental questions that this thesis attempts to answer in the specific context of Nigeria are clearly questions of governance, namely: How ought health research involving humans, a clearly beneficial and public activity which also has risks, to be managed? By what criteria ought the current systems to be assessed? In what ways can the systems be improved? The preceding discussion shows the clear value of governance as a means for understanding the controlling of activities in order to achieve public goals and objectives. The issues that arise in the context of these questions, for instance, the consistency of ethical and legal standards,

the comprehensiveness of any regulatory standards, compliance with those standards, and effectiveness of any regulations, are all issues of governance.[389]

Furthermore, as observed elsewhere, the importance of governance as an analytical framework is that it is "more comprehensive and encompassing than traditional approaches to political analysis, because it refers to more actors and levels of authority than national governments and includes informal and non-institutionalized as well as formal and institutionalized procedures and processes."[390] It will also be recalled that governance as an analytical framework "covers a broad array of institutional arrangements and mechanisms by which the coordination, regulation and control of social systems and subsystems can be conceptualized." [391] One could certainly focus on a specific actor such as the state or the government, or the impact of the judicial system or medical institutions or ethics review committees. But health research involving humans is an activity managed by different institutions and mechanisms, and which has effects beyond the specific group managed by a specific medical institution or a specific research sponsor.

Further, as McDonald observes, "governance issues arise with respect to the appropriate division of responsibilities for the protection of human subjects amongst the agencies and organizations that conduct, sponsor, and regulate research."[392] Extrapolating from this, research governance requires an

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[389] See Jocelyn Downie, "Contemporary Health Research: A Cautionary Tale" (2003) Health Law Journal (Special Edition) 1 at 5, describing several governance issues.
[390] Leisink and Hyman, supra note 63 at 280.
[391] Schneider and Bauer, *supra* note 109 at 3-4.
[392] Michael McDonald, "Canadian Governance of Health Research Involving Human Subjects: Is Anybody Minding the Store?" (2001) 9 Health L. J. 1 at 4.

examination of the scope and structure of the system, the responsibilities and composition of the institutions within the system, accountability and compliance mechanisms within the system, all of which have implications for ensuring the protection of participants and promoting beneficial research, and all of which come clearly under the umbrella of governance.

Additionally, a consideration of national systems as engaged in here requires a comprehensive systemic approach. Moreover, in my view, there is value in considering the processes as well as the desired outcomes and goals or objectives of ensuring that health research involving humans is conducted in a particular manner, that is, in the safest way possible and with the greatest possibility of achieving beneficial results. If considered in this way, a holistic and systemic approach which considers all the actors and institutions involved in the processes and in achieving these outcomes and reaching these objectives will prove not only useful but necessary.[393]

As an analytical framework, then, governance has descriptive, explanatory, organising and normative value that allows us, in my view, to examine not only the policy response to any particular field of activity, in this case, health research involving humans. It also compels us to think more broadly in terms of the systems governing that field, the constellation of actors and institutions that come together to make up the systems, and to question what the appropriate relationships and interactions between them should be. Governance is thus a very useful analytical framework for health research involving humans because of the importance of the comprehensive systems perspective. It offers a

[393] Chotray and Stoker, supra note 66 at 6.

macro perspective (or what Mcdonald calls a 'second-order' perspective)[394] on the actors, institutions, mechanisms, rules and processes that are involved in, and manage, health research involving humans. It helps to analyse broadly and in a less reductionist fashion the linkages that come together to form the research governance system, including law. A hybrid governance framework, as employed here, acknowledges that the oversight of research includes not only the active role of formal government but also takes account of other components which may not always be dependent on government and law.

Taking the comprehensive perspective afforded by the governance framework also allows an evaluation of what these instruments convey about the nature of the relationships between all the policy actors and institutions, including such actors and institutions as the government and the legal system, civil society and patients rights' organisations, researchers and ethics review committees, and research participants. It thus affords, for example, freedom to examine law in the context of different disciplines that bear on research involving humans, such as biomedicine and social science. It permits an inquiry into not only the role and place of law in the system (for instance, is it facilitative?), but also its relationship with other components and key institutions frequently employed in the oversight of research involving humans, such as ethics review committees (for instance, does it create legal obligations for these institutions) in achieving the public policy objectives of enabling beneficial research while ensuring the safety and dignity of research participants. It is necessary also to locate and evaluate the place of ethics review

[394] Mcdonald supra note 19 at 23.

alongside other components and instruments, including the ethical framework, the legal framework and institutional mechanisms such as drug approval agencies, departments of health, professional organisations and also civil society, including non-governmental organizations which promote patients' rights.[395]

Thus, within the perspective of a hybrid framework of governance one could fruitfully ask whether, based on available evidence, these institutions, and actors work separately or together and if so how harmoniously. In many countries, developed and developing, the systems of research participants' protection (with respect to standards, structures, regulations and policies) are not necessarily ordered as a coherent, cohesive and organized structure and consist of fragmented institutions and policies involved in the governance process.[396] To explain this point further, the different actors in research governance may employ different forms of governance. For example, funding agencies may have separate criteria for funding eligibility different from those utilized in research institutes which may themselves have no coercive control over researchers. The universities may also have different guidelines and ways for ensuring compliance, including clauses in researchers' employment contracts, which may be different from those employed by self-regulating professional bodies which may exercise significant influence and control over their members, which may also differ from the powers exercised by departments of health.

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[395] See Ann Strode, Catherine Slack, Muriel Mushariwa, "HIV Vaccine Research – South Africa's Ethical-Legal Framework and Its Ability to Promote the Welfare of Trial Participants" (2005) 95: 8 South African Medical Journal 598.

[396] See Jocelyn Downie, The Canadian Agency for the Oversight of Research Involving Humans: A Reform Proposal" (2006) Accountability in Research 75 where she points out that in Canada "Numerous bodies are tasked with various aspects of what can really only loosely be called a "system."

The normative weight of international organizations such as the World Medical Association and the guidance they provide, as well as how these have influenced the development of the governance systems in developing countries also provide a source of governance.[397] What are the contributions of these different bodies to the research governance system? And how do these different sources of regulation affect how adequately research participants are protected? Do they work cohesively or not and how does this affect the effectiveness and adequacy of the system? A governance framework helps to identify and analyse these sources and determine how the interplay between the different players and the forms of governance and how harnessing these subsystems could provide greater effectiveness in research governance. One could then reasonably attempt to answer such important questions as how the characteristics of traditional governance (including formal or hard law) can be fruitfully blended with, or be complementary to, less traditional forms of governance, (such as soft law or increased civil society participation), for greater effect where necessary. One could also try to determine what benefits the different actors – government, research sponsors, researchers, professional bodies, and research participants – bring to the table and how these can be more effectively managed to ensure better governance of research.

Further, I am of the view that employed appropriately, and without overstretching what might be considered an already diffuse concept, governance does not only have an explanatory and organising value, it also has

[397] See Adèle Langlois, "The UNESCO Universal Declaration on Bioethics and Human Rights: Perspectives from Kenya and South Africa," (2008) 16:1 Health Care Analysis 39.

prescriptive value. In this regard, one can consider simply the organisation of the system and the actors within that system, or how the system is changing to accommodate different types of actors, instruments and processes (as much of the recent literature in governance does). But one can also go beyond that to question whether the system is working effectively, which then requires us to question what the system, (whether organised coherently or cohesively or not) is set up to achieve, and even further what the system should achieve. One can also ask whether the right interests are involved in decision-making in research governance. One can also question if the right instruments or tools are being utilised, a central concern in governance literature. We could also question if the current governance arrangements in any country help the delivery of better outcomes. In other words, governance as an analytical framework also allows us to inquire normatively as to what the goals of regulation and governance should or ought to be, the necessary actors and instruments or tools, and the criteria by which to evaluate governance.

Just as importantly, the actors, institutions, instruments and processes involved in research governance work within a socio-political context which may affect their effectiveness. A hybrid governance framework allows not only the evaluation of these contexts, but also permits one to address normatively the ideal context for the institutions, actors and processes to function effectively. A governance framework is also helpful in raising important questions relating to legitimacy of governance actions within any given socio-political context, for example, in determining the source(s) of

authority for relevant matters such as law-making and production of national guidelines.

Although I am adopting a framework of governance, there are several other possible analytical frameworks that could be fruitfully employed in investigating health research involving humans in developing countries. These include a strictly bioethical framework, international relations theory, tort law, criminal law, or a human rights framework. A strictly bioethical framework would be useful in examining and making recommendations about the relevant ethical concerns that arise in the context of health research in developing countries. International relations theory (including regime theory)[398] may provide an understanding of the complex relationships that exist at the international level and their impact on the international organisations which regulate research internationally and which provide the guidelines that are applied in some domestic contexts. It may even address the global inequalities that exist internationally, the part that different states may play in fostering such inequalities, and how these may affect domestic governance regimes. A tort law framework may provide answers to questions about the judicial role in research governance in developing countries and the legal obligations of researchers and research sponsors to research participants. So, too, could a criminal law framework, which may also analyse the impact of legal sanctions on prohibited

[398] Regime theory aims at explaining the political forces which drive international co-operation between states and how the distribution of global public goods is affected. According to Abbott, the theory "incorporates information and ideas as well as power and interests, and acknowledges significant roles for private and supranational actors and domestic politics." See Kenneth W Abbott, "International Relations Theory, International Law, and the Regime Governing Atrocities in Internal Conflicts" (1999) 93:2 The American Journal of International Law 361 at 367. See Andreas Hasenclever, Peter Mayer and Volker Rittberger (eds.), *Theories of International Regimes*, (Cambridge University Press, 1997).

behaviours arising from health research involving humans. A human rights framework could address the rights of research participants and the obligations arising therewith - a discourse focused on rights, duties and related institutional arrangements. None of these frameworks, however, has the comprehensive reach of a governance framework which, by description, encompasses elements of these theories. In addition, given the stated vacuum in this area, the stated goals of this thesis, and the importance of a systems perspective already pointed out, a governance framework seems most suitable.

2.4 Application of Governance as an Analytical Framework for Health Research Involving Humans

To undertake a systemic analysis as anticipated in this thesis, one has to consider broadly the actors and institutions involved in the research governance system. To do this, an examination of the value bases for the system (which are principally located within research ethics) as well as the instruments (the guidelines, legal regulations) and the regulating institutions which attempt to accomplish these value-based objectives is necessary. The analytical framework of the thesis therefore takes a three-pronged approach, consisting of ethical, legal and performance approaches, to the investigation of research governance arrangements and mechanisms in Nigeria. These are discussed respectively below, and then applied in the rest of the thesis.

2.4.1 Research Governance: Ethics and Values

Research governance and ethics are inextricably linked. The international ethical guidelines, including the Helsinki Declaration, the CIOMS Guidelines and the *Good Clinical Practice: Consolidated Guideline*, ICH Harmonized Tripartite Guideline, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and, more recently, the UNESCO Declaration on Bioethics and Human Rights, have therefore been primary instruments for regulating research involving humans. While they have no formal legal character and cannot, by themselves, be considered law, these guidelines may be incorporated into domestic law.[399] But, even where they are not so incorporated, they contain some provisions that may bind researchers and research institutions requiring them to adopt certain standards. While these international guidelines have provided a form of governance, national guidelines, mostly recent, play a crucial role in research governance in many countries, including Australia,[400] the United Kingdom,[401] Canada,[402] and developing countries such as Uganda,[403] India,[404] Nepal,[405] South

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[399] See, A.C Campbell and K.C Glass, "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research" (2001) 46 McGill L.J. 473 at 478.
[400] Australia: NHMRC, *National Statement on Ethical Conduct in Human Research* 2007, online: <http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf> (June 20, 2007).
[401] Department of Health, *Research Governance Framework for Health and Social Care* (Second Edition) (United Kingdom, 2005), online: <http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4122427.pdf> (June 19, 2007).
[402] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 1998 (with 2000, 2002 and 2005 amendments) online: <<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm> (August 11, 2007).
[403] Uganda, *Guidelines for the Conduct of Health Research Involving Human Subjects in Uganda* (National Consensus Conference 1997).

Africa,[406] and Nigeria.[407] Some of these more recent national guidelines appear, in varying degrees, to be more exhaustive than the international guidelines. This is not surprising given that they are inspired by, and are building on, the foundations already established by these guidelines. The thesis therefore discusses also the ethical framework provided by the guidelines and the role they play in the governance of research in Nigeria.

To analyse these guidelines and their impact on the research governance system, one must be able to situate them in context and understand their origins. The analysis of paradigm shifts in the understanding of ethical protections for research participants and research oversight by Emmanuel and Grady in a recent article is helpful in this regard. They note that research oversight has undergone four major paradigm shifts.[408] These paradigm shifts have occurred as a result of different events signifying the risks of research and embody different perspectives on the value of research and its potential hazards and different conceptualizations of the objectives of oversight. According to them, "Each period also advances a different underlying ethical principle guiding the protections of research participants, empowers different institutions to implement the protections, and has its own way of balancing protection of

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[404] Indian Council of Medical Research (ICMR), "Ethical Guidelines for Biomedical Research on Human Subjects" (2000), online: <http://www.icmr.nic.in/ethical.pdf> (March 29, 2007).
[405] Nepal Health Research Council, *National Ethical Guidelines For Health Research in Nepal* (2001), online: < http://www.nhrc.org.np/guidelines/nhrc_ethicalguidelines_2001.pdf> (February 7, 2008).
[406] National Health Research Ethics Council, *Ethics in Health Research: Principles, Structures and Processes Guidelines*. Pretoria: Department of Health, 2004 online: <http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/> (June 19, 2007).
[407] NHREC, *National Code for Health Research Ethics* (2006), revised 2007.
[408] Ezekiel J. Emmanuel and Christine C. Grady, "Four Paradigms of Clinical Research and Research Oversight" (2006) 16 Cambridge Quarterly of Healthcare Ethics 82 at 82.

research participants against other important values in biomedical research."[409] Thus they categorise these four periods, which though distinct may sometimes overlap, as: researcher paternalism, regulatory protectionism, participant access and community partnerships. These different periods could also be linked to the changes in governance from the old to the new, as discussed above.

Researcher paternalism, the paradigm operating during and immediately after World War II,[410] denotes a period in which a utilitarian approach, an ethical approach which justifies individual sacrifice for the greater good of society, was adopted. In that milieu, the ethical principle guiding research and research oversight was social value: "Individual sacrifice was necessary for research and justified by the tremendous good it would produce for all of society."[411] Emphasis was therefore placed more on the value of research rather than on the safety of participants. It is not surprising, then, that the major mode of research oversight was through self-regulation by researchers, who took on the paternalistic role of determining what was ethical and useful, "weighing social value over individual risk–benefit assessments when they were in tension."[412] Such paternalism corresponded with the prevailing medical ethics

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[409] *Ibid.*

[410] Jonathan D. Moreno, "Goodbye to All That: The End of Moderate Protectionism in Human Subjects Research" (2001) 31: 3 Hastings Center Report 9 at 10.

[411] Emmanuel and Grady, supra note 233 at 84.

[412] *Ibid.* at 85. Louis Lasagne's statement quoted in Emmanuel (*ibid*), summarises this position succinctly:

Society frequently tramples on the rights of individuals in the "greater interest." . . . [T]he good of the individual and the good of society are often not identical and sometimes mutually exclusive. I submit that the successful development of such an ethical conscience, combined with professional skill, will protect the patient or experimental subject much more effectively than any laws or regulations. . . . I believe it is inevitable that the many will continue to benefit on occasion from the contributions—sometimes involuntary—of the few. The problem is to know when to say "Halt!" Louis Lasagne, "Some Ethical Problems in Clinical Research" in E

at that time – the doctor-knows-best mind-set.[413] Professional ethics, codes, and oaths established by physicians, such as the Hippocrates Oath, served as normative standards. Although peer review of research took place in several institutions, it was by no means mandatory.[414] As was made clear by the scandals exposed in articles and books, researcher paternalism far from protecting research participants, in fact, exposed participants to harm. There was with little regard for informed consent and the deception of participants was justified on the basis of the good of society.[415]

The scandals, including the Tuskegee Syphilis trial on African-American men, led to a paradigm shift to a model of regulatory protectionism or what Moreno refers to as "strong protectionism,"[416] which was essentially a minimisation of the discretion of researchers in governing their conduct of research involving humans,[417] and formal introduction of the state into research governance. This paradigm shift led to such regulatory steps as the enactment in the United States of the National Research Act in 1974 and the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which drew up the Belmont Report which states the ethical principles which should provide the basis for all research involving humans, as

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Mendelsoh, J P Swazey, and I Taviss, (eds.) *Human Aspects of Biomedical Innovation* (Cambridge, Mass: Harvard University Press, 1971), 98–110, at 108, 110.

[413] Ibid.

[414] Moreno, supra note 235 at 11.

[415] The misconduct of researchers became open with such incidents as the publication of Henry Beecher's landmark article in 1966 in which he detailed some of the unethical practices taking place in the name of research and such incidents as the Tuskegee Syphilis Study in the United States and Jewish Chronic Disease Hospital.

[416] Moreno, supra note 235.

[417] Ibid.

previously mentioned.[418] Further, independent ethics review committees and government regulators such as the Federal Drug Agency (FDA) in the United States became important mechanisms for governing the conduct of research on the basis of the principles elaborated in the Belmont Report. The utilitarian approach thus gave way to an approach of principlism. Principlism avoids comprehensive ethical theories but adopts midlevel principles that are common to, and can be justified and agreed upon by, multiple ethical theories, especially utilitarianism and deontology or virtue theory. The ethical principles of respect for persons/autonomy, beneficence/non-maleficience, and justice, stipulated in the Belmont Report, originated from this approach. This approach has gained wide approval and is much employed within bioethical circles.[419] This may be classified as the period which most relates to the era of traditional governance with strong government intervention.

According to Ezekiel and Grady, there has been another paradigm shift from regulatory protectionism to participant access mainly as a result of the HIV/AIDS epidemic, beginning in the early eighties. Participants now see regulatory protectionism as somewhat paternalistic and demand the right to be involved in the decision-making process, most particularly with regards to the right to participate in research which they think will be useful in finding cures to

[418] These ethical principles originated from principlism, subsequently formalised by Childress and Beauchamp in their seminal work *Principles of Biomedical Ethics.* It has however been criticised for being somewhat paternalistic and for its restrictive approach to research involving certain populations, including prisoners and women. Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* (Oxford: Oxford University Press, 2001) (Fifth Edition). See Ezekiel, supra note 233.

[419] See for example, Aurora Plomer, *The Law and Ethics of Medical Research: International Bioethics and Human Rights* (Oxford: Cavendish Publishing, 2005) at 8-10, describing the role of principlism in the work of national bioethics committees.

diseases such as HIV/AIDS which as yet have no cure. McDonald acknowledged this paradigm observing that:

> In some cases, articulate interest groups with strong agendas have formed to lobby for research in areas affecting their health, e.g., people with AIDS or those with or at risk of hereditary forms of breast cancer. This has also complicated the picture we currently have of the ethics of research involving humans, so that it is no longer just a question of protecting research subjects from the potential harms of research (as would have been seen to be a principal task of research ethics processes in the 1970's and 1980's).[420]

Hence, as summarised by Ezekiel and Grady, "Individuals did not need to be protected by regulation; rather they should be entrusted to know their own good and interests and be free to pursue them."[421] The core ethical principle during this period was, then, the right to autonomy. Scholars of governance may see this as part of the move to the new governance era described above.

This move is emphasised even more with the shift which Ezekiel and Grady conclude with, a shift from the participant access paradigm to a paradigm of collaborative partnership (reminiscent of Salomon's description of collaborative governance). Involvement of communities is now argued to be a necessary part of the research approval process. Collaborative partnership recognizes the importance of the social framework in determining both research agendas and priorities, and in negotiating better protections for research

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[420] M McDonald, "The Current Context of the HRIHS in The Governance of Health Research Involving Human Subjects (HRIHS), in McDonald, supra note 19 online: <http://www.ethics.ubc.ca/people/mcdonald/lccmacdonald.pdf> (November 24, 2007) at 89.
[421] Ezekiel and Grady, supra note 233.

participants. Interestingly, this is a trend clearly observed in obtaining approval for biomedical research in developing countries currently. Only recently, a microbicide clinical trial being conducted in Thailand had to stop, partly due to protests by community activists that the communities were not sufficiently involved in the process of approving the research.[422] As Ezekiel and Grady note: "One frequently recommended response to the need to protect developing country communities from exploitation was to develop partnerships with the community in which the research was being conducted."[423] In developing countries, ethics review committees now frequently have the role of ensuring that benefits are made available to the communities as well as protecting the individual participants of research. Arguments for the research participants' representation on ethics review committees, which are increasingly made in the literature,[424] can clearly be categorised as falling into this paradigm. It is important to note that these paradigm shifts overlap to a certain extent and two paradigms may exist at the same time.

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[422] A. Chua, N. Ford, D. Wilson and P. Cawthorne, "The Tenofovir Pre-Exposure Prophylaxis Trial in Thailand" (2005) 2: 10 PloS Medicine 346.

[423] Ezekiel and Grady, supra note 228. See for example, E Emanuel, D Wendler, J Killen, C Grady, "What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research" (2004) 189 Journal of Infectious Diseases 930; C Weijer, G Goldsand, E J Emanuel, "Protecting Communities in Research: Current Guidelines and Limits of Extrapolation" (1999) 23 Nature Genetics 275–80; C Weijer, E J Emanuel, "Protecting Communities in Biomedical Research" (2000) 289 Science 1142–4; P E Cleaton-Jones "An Ethical Dilemma: Availability of Antiretroviral Therapy after Clinical Trials with HIV Infected Patients Are Ended" (1997)314 British Medical Journal 887–8; P. Wilmshurst, "Scientific Imperialism: If They Won't Benefit from the Findings, Poor People in the Developing World Shouldn't Be Used in Research" (1997) 314 British Medical Journal 840–1; L H Glantz and G J, Annas, M A Grodin and W K Mariner, "Research in Developing Countries: Taking 'Benefit' Seriously (1998) 28:6 Hastings Center Report 38–42.

[424] See for example, Michael Hadskis, "Giving Voice to Research Participants: Should IRBs Hear From Research Participant Representatives?" (2007) 14: 3 Accountability in Research 155.

The descriptions of these paradigm shifts focus on biomedical research and on western countries, in particular the United States. However, Ezekiel and Grady's characterisation of these paradigm shifts in research oversight illustrates regulatory movements in research governance from self-regulation to increased government role and the use of command-and-control techniques to a collaborative partnership increasingly involving all stakeholders in the research process, including ordinary citizens and research participants. These shifts appear to show a movement towards the new governance paradigm described above, still including the regulatory presence of the United States government in publicly funded research. As I have argued, a strong government presence in addition to increased participant involvement in governance processes, amongst other steps, may yield more effective results in developing countries.

Ezekiel and Grady's characterization of these movements is also useful for the purposes of identifying relevant issues that need to be addressed in the governance systems that currently exist in developing countries. For instance, what are the origins of research governance in developing countries? Have they developed in reaction to adverse events or external funding requirements or to replicate developments in other jurisdictions? And how have these origins affected the path their development has taken – the route of voluntary guidelines or a more regulated approach, including the enactment of relevant legislation? In the United States, for instance, the legislative approach was adopted with respect to federally funded research in response to reports of

unethical conduct. Has this been the case in developing countries? Answers to such questions are examined in the specific context of Nigeria in Chapter Four. Other questions also arise such as: What are the values at stake in research governance generally, and in developing countries particularly? And how are these reflected in the types of research governance systems and the mechanisms currently emerging in developing countries? Finally, the categorisation also raises the question: What implications do these systems have for the protection of the rights and safety of research participants? These are examined in detail in subsequent chapters.

2.4.2 Research Governance: Legal Context

Apart from the ethical foundations of the governance of research involving humans, law and legal analysis have not been absent from the area of research involving humans. Much current analysis in the legal context focuses on risk and on determining the legal responsibilities of stakeholders in the research enterprise. Such analysis considers from that perspective, liability under the law of torts, including what actions by researchers, such as failure to obtain informed consent leading to injury, may constitute or be actionable as trespass, (that is, assault, battery) or negligence. Law thus regulates researchers' conduct. Legal analysis may also focus on the duty of care owed to research participants by others in the governance arena, including the researchers, the government, and the ethics review committees may also be reflected upon within

a legal framework of analysis.[425] Such matters as the legal status of the emerging guidelines and the legal protections available to research participants, may also be determined within this framework.

Given the history of regulating research involving humans in many countries, law may not be the centrally dominant regulatory institution, but yet it is not insignificant to research governance. Law appears to be a purposive instrument, a regulatory tool of oversight, but this is by no means generally applicable. Indeed, law appears in many countries not to have direct application in the research governance systems and, in the apt words of Bernard Dickens in relation to the Canadian system of governance, law frequently "applies almost inadvertently" to the research enterprise.[426]

With respect to the governance perspective adopted in this thesis, the main question that arises is: What is the appropriate role for law in the research governance system? Can it go beyond the rules of tort to a more specific, extensive role such as direct legislation? Accordingly, one of the central issues which the thesis examines broadly is the role of law as a social control, the place of law in governance arrangements, and the limits of law in an evolving, dynamic and special area such as the area of health research involving humans. In other words, the jurisprudential significance of the analysis of research governance systems which the thesis proposes to undertake is, to determine the role that law should play in the particular governance systems of

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[425] See Susan V Zimmerman, "Translating Ethics into Law: Duties of Care in Health Research Involving Humans" (2005) 13 Health Law Review 13. See *Reibl v. Hughes* (1980), 114 D.L.R. (3d) 1 (S.C.C.).

[426] Bernard M Dickens, "Governance Relations in Biomedical Research" in *The Governance of Health Research Involving Human Subjects supra* note 19 at 98-99.

developing countries. Indeed, this is the main rationale for adopting a governance framework – that is, to examine the role of law alongside other governance mechanisms or instruments. Generally speaking, law can establish, authorize, and legitimate decision-making and oversight processes. Law may thus regulate research involving humans and, normatively, through its standard-setting aspects, contribute to the promotion of ethics standards. In my view, therefore, research governance or oversight should have a legal context, and law, as I argue in Chapter Four must go beyond a facilitative role and extend to a protective one.

In the rest of the thesis I ask such questions as: What role ought law to play in the governance of health research in developing countries? What types of legal instruments are currently employed in research governance and, what are the reasons behind this choice of instruments?[427] What is, and what ought to be, the role of law in research governance in Nigeria? Does this role relate to only specific issues (for example, facilitation of research through the creation of research institutes, or protection of research participants via provisions on confidentiality or privacy issues or informed consent)? Or does it affect governance arrangements more generally?[428] What role do private actions in tort play and to what extent do such actions, and arising case law, currently govern research in developing countries and specifically in Nigeria? More

[427] These questions were raised in a more specific way in a study focusing on research governance in Canada titled: *The Governance of Health Research Involving Human Subjects* commissioned by the Law Commission of Canada, See *The Governance of Health Research Involving Human Subjects supra* note 19.
[428] Bernard M Dickens, "Governance Relations in Biomedical Research" in *The Governance of Health Research Involving Human Subjects supra* note 19.

importantly, how should the role of law expressed – through legislation, case law, common law concepts or contractual arrangements – and what should such law cover? The thesis thus examines the existing legal arrangements which may form part of the governance framework and whether or not these arrangements have the potential to promote socially beneficial research and provide better protection of research participants in these countries. In doing this, it examines also the political and social contexts of law in these countries, and more specifically in Nigeria.

2.4.3 Research Governance: Institutional Context

Good governance requires that collective moral intentions (or values) be translated into effective and accountable institutional actions.[429] It is important, then, to examine the institutions that actually implement the rules and guidelines contained in legal and non-legal instruments. What form does the institutional framework take and what is the organisational structure of research governance in Nigeria?

One of the key institutions in the governance of research in all countries is the ethics review committee which may be established by institutions like universities or research institutes or by governments. Government departments of health are also another institution involved in research participants' protection. Legal institutions such as judicial institutions (discussed in the legal context) also play a role in research governance. Another

[429] McDonald, supra note 19 at 149.

is the drug regulatory agency which gives approval for new drugs and regulates the use of human participants in the testing of those drugs.

I examine these different institutions but illustrate here the issues that may arise in the context of ethics review committees. Ethics review is central to most research governance systems, including that of Nigeria. Several questions arise within the context of a governance framework with specific regard to ethics review and include: What form does the ethics review committee structure take? Is the ethics review committee an arm's length review body that is independent and objective in terms of membership, processes, and reporting relationships? Who does the ethics review committee report to? Who appoints its membership? Are the interests of prospective research participants adequately represented on the committee and how? Are there lay or community representatives? Are there transparent and effective accountability relationships to those who set standards? Who, if anyone, addresses gaps and inconsistencies in standards and processes and how?[430] Is there any requirement for any specific expertise, (for instance, ethics expert, legal expert, statistics or clinical research expert) and for lay representation? Do the committees provide approval before, during and after research commences? In other words, is there ongoing monitoring and oversight?

While these questions specifically relate to ethics review committees, the same questions can be raised in relation to other institutional structures involved in research involving humans, such as drug approval

[430] Mcdonald, supra note 19 at 63.

agencies – the institutions that bear responsibility for the drug approval processes in these countries – and departments of health and professional organisations such as medical associations. I investigate whether, based on available evidence, these governance issues are adequately addressed or have the potential to be so addressed. An investigation of these institutions is also required to determine if they work together in a systematic, co-ordinated fashion to effectively protect research participants while creating a stable environment for research.

2.4.4 Performance of the System

Beyond gaining an understanding of the ethical framework of the governance system, the legal context and the institutional instruments of governance, another important issue that requires consideration is the current and potential functioning of the systems for research governance in Nigeria. How well is the system working in practice and what potential does it have to work well?

Based on available evidence, the thesis considers in the chapters that follow issues relating to legitimacy, effectiveness, comprehensiveness, clarity, efficiency, simplicity, consistency and adequacy. Questions that will be asked in this section with respect to the different actors and instruments include: How comprehensive is the system? What aspects of research does it cover? How much public participation is there in the processes? What provisions are

made within the system for important matters such as standards, compliance, and education? Does the system make for simplicity or is it a convoluted process in which there is no certainty of what the standards are, or clarity of structures? Are the rights and responsibilities of actors in the governance system clear? How is the system financed? How efficient is it? Are the conduct and enforcement of oversight adequate and effective? Is there an adequacy of resources and expertise for effective governance? The answers to these questions will go beyond the descriptive to the normative, from what currently is, to what ought to be.

2.5 Conclusion

The governance of health research involving humans in developing countries requires a more comprehensive analysis than has hitherto been undertaken. The aim of this chapter has been to discuss the analytical framework within which a detailed examination of this subject can be undertaken. In the foregoing pages, I have attempted to set out a governance framework which, in my view, will allow the comprehensive and wide-ranging analysis required here. The framework draws considerably from work already done by scholars of regulation and governance, but attempts to set out a hybrid framework which I consider to be more suitable for the purposes of the thesis. I have addressed the rationale for adopting this framework. I have also, in the foregoing pages, indicated how this framework will be applied in the rest of the

thesis. The subsequent chapters will provide more details and put this framework further in the specific context of Nigeria.

Chapter Three

Components of Research Governance Systems: Ethical and Institutional Frameworks

3.1 Introduction

The governance of health research involving humans is a wide-ranging subject. In many countries, research governance typically operates through different institutions, instruments, and processes, all of which I term "components of research governance." As will become obvious in the discussion that follows, the number and diversity of actors and instruments which come together to form the components of governance requires a hybrid framework of analysis such as I suggested in Chapter Two. These components may include drug regulatory authorities; funding agencies; a legal framework; the ethics review system; and policy guidelines that detail the ways in which research should be conducted.

Three main questions may arise in examining the components and tools of research governance, namely: What are the components of research governance currently in use in countries around the world, and how do they operate to govern health research? What should be the components of governance of health research in developing countries? Do these components act, and should they act in a coordinated fashion?

In this chapter, I answer the first question, namely, what are the components of research governance systems currently in use around the world? The objectives of this chapter are therefore to identify and describe two components of research governance systems widely accepted both in the

literature and in actual operation, namely: the ethical framework and the institutional framework. In my view, these are important components and there is no need to re-invent the wheel in developing countries. In essence, these components are also essential in developing countries.

However, while there is clear understanding in the literature and in the actual operation of governance systems that these are necessary components for the governance of health research, there may be some debate about their content. Thus, for instance, there is broad acceptance of the need for an ethical framework but there may be disagreement about the content of domestic or international ethical guidelines or how they should be implemented in developing countries.

Another example of a widely accepted component, both in the literature and in the actual operation of governance systems, is the central role of ethics review committees. Even though widely accepted, there are systemic issues that may limit their functionality and effectiveness in protecting research participants. I identify these systemic issues and the specific issues that have been of concern in developing countries.

Less articulated in the literature is the inclusion of non-governmental organisations or research participant advocacy groups in the institutional framework. Non-governmental organisations are omitted in most accounts of the components of research governance. This is understandable because these organisations may be argued not to be, strictly speaking, part of the formal research governance system. But in light of the hybrid framework proposed in

Chapter Two, the balancing purpose that such organisations can serve, and the need to provide a more complete picture of research governance components, as this thesis proposes, I argue here that such organisations are a necessary component of the institutional framework.

In providing a description of the institutional framework, I identify systemic issues that may limit the effectiveness of the different organisations involved in research governance in different countries, many of which are articulated in the literature on research governance. It is necessary to identify these concerns because they are matters that need to be addressed in research governance systems, including the emerging governance systems of developing countries. These systemic issues are then considered in more detail in the specific context of Nigeria in subsequent chapters. Descriptions undertaken in this chapter are drawn from various jurisdictions around the world, particularly, Australia, Canada, Denmark, Nigeria, South Africa, the United Kingdom, and the United States.

The discussion is undertaken with the macro perspective discussed in Chapter Two in mind, allowing for breadth of analysis rather than specificity. Thus, although some specific issues are identified, it is not intended to be a detailed description of *all* the specific issues and concerns that arise in the context of an ethical framework or an institutional framework. In essence, no one country has a perfect system. The problematic issues identified in the discussion undertaken here indicate some of the issues that need to be addressed in the contexts of developing countries like Nigeria.

The chapter commences with this introduction as the first section. The second section comprises three subsections. The first considers the ethical framework, examining the role of national and international guidelines in creating an ethical framework for the governance of health research involving humans. It notes that establishing domestic guidelines in developing countries may be one way to address issues that have been controversial in the international ethical guidelines. The second subsection considers the role of different institutions and organisations involved in the governance of research involving humans, particularly ethics review committees. It identifies some of the systemic issues that have been problematic in developed countries, and also issues that may pose difficulties in developing countries. The third subsection concludes the chapter.

3.2 Ethical Framework

Research governance and bioethics are inextricably linked. The ethical framework of the governance of research involving humans is a vital and foundational component of research governance system. Indeed, an ethical framework should be a core part of the governance of research involving humans. It is within the ethical framework that the true goals and objectives of research governance are located – the goals of ensuring beneficial research and protecting the safety of research participants. Thus governance involves not only procedures and processes but the underlying values that require the adoption of these procedures. And although governance and regulatory

structures are important active aspects of protecting research participants, their procedural aspects and institutional mechanisms must be built on an ethical foundation. This ensures that there are not merely governance mechanisms operating formalistically without any ethical directions, or compliance with procedural requirements divorced completely from the ethical principles which necessitate the governance structures to begin with. As Slowther and others acknowledge:

> Recognizing and responding to the ethical dimension of research is a fundamental part of the research governance process. Ethical codes of practice and regulatory frameworks reflect concern about actual or potential examples of unethical research.[1]

Hence, ethical standards and principles have been an important underpinning for research governance both internationally and locally. Any serious discussion of the governance of research must therefore consider ethical foundations and values and begin with the discussion of the ethical framework.

The ethical framework, as discussed here, consists of the research ethics principles which may be located in the international ethical guidelines and in the national ethical guidelines. Many of these guidelines are amended at intervals in light of evolving understanding of ethical issues. The ethical framework may also derive from values articulated in other important national sources, such as constitutions of countries. For the purposes of this chapter, I will consider international ethical guidelines and research ethics principles

[1] Anne Slowther, Petra Boynton, and Sara Shaw, "Research Governance: Ethical Issues" (2006) 99 J R Soc Med 65 at 65.

which are specifically dedicated to the ethics of research involving humans around the world. I will consider any national sources in the specific context of Nigeria in Chapters Five and Six.

This section undertakes, therefore, a brief description of some research ethics principles and then an overview of the international ethical guidelines. As discussed below, although commonly recognised as the ethical framework, there is nonetheless disagreement as to their universality. One way to address that thorny issue would be for developing countries to adopt national ethical frameworks which are cognizant of general ethical issues and local contexts.

3.2.1 Research Ethics: Ethical Principles

There is a clear understanding that research has to be conducted in an ethical manner, even though there may be disagreement in certain situations as to what is ethical or not. Much of the debate relating to ethical concerns surrounding research involving humans in developing countries assumes an understanding of research ethics, ethical principles, and the international ethical guidelines. Ethical principles have been adopted in several countries, including the United States, to provide a general framework for analysis, which can subsequently be applied to a specific ethical problem to arrive at a resolution. These principles provide guidance as to what may be ethical, and can be used in

evaluating appropriate behaviour in the conduct of research.[2] They therefore make a valuable contribution to the ethical framework which applies in the research governance systems of countries around the world. A consideration of these ethical principles may be a good starting point for the examination of the ethical framework underpinning research governance systems. Given the considerable attention that these principles have received (and continue to receive) in research ethics literature, as well as the scope of this thesis, only a brief examination is undertaken here.

Below, I describe briefly the ethical principles which have been considered by some to be foundational in the governance of health research, namely: respect for persons, beneficence, and justice. I then consider briefly the arguments against the general applicability of these principles and arguments against their application as an adequate underpinning for research governance systems in all contexts, especially in the developing world context. I point out that, given that these principles are not necessarily uncontested, there needs to be a local contextual adaptation of these and, possibly, the inclusion of other principles. I also conclude that national guidelines and policies, (already adopted in a few developing countries) which take into consideration the contexts and the values of different countries may be one way of resolving dilemmas around determining what the appropriate ethical underpinnings of research governance systems in these countries ought to be.

[2] As is noted in the Canadian Tri-Council Policy Statement (Article G): "In their best uses, principles serve as short-hand reminders of more complex and context-specific moral reflection."

The most prominent of these ethical principles can be located in the Belmont Report. The Belmont Report was produced by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research created under the 1974 National Research Act to address the ethical concerns arising from the revelations of the Tuskegee Syphilis Study, the Willowbrook studies, and the Jewish Chronic Hospital Disease Study, among others.[3] The report enunciated three guiding principles for research involving humans namely, respect for persons, beneficence, and justice.[4] Below, I describe the understanding of these guiding principles in major research ethics literature.

The first principle, respect for persons, is associated in much of the literature on research ethics with the concept of autonomy. The principle of respect for persons requires that everyone is regarded with respect, with interests that have to be taken into account, and not merely the means to an end. In other words, people are not to be used as objects, without interests, feelings or dignity, in a research study. Further, there is a presumption that persons are the best guardians of their own interest and must therefore be involved in any decision which may affect them.[5] According to Beauchamp and Childress, "personal autonomy is an extension of political self-rule to self-governance by the individual: personal rule of the self while remaining free from both controlling

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[3] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda, Md.: The Commission, 1978) at 1-8 [*Belmont Report*].
[4] Ibid.
[5] Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries* Nuffield Council of Bioethics (2002) at 51.

interferences by others and personal limitations, such as inadequate understanding, that prevent meaningful choice."[6] The requirement for informed consent in research involving humans is derived from this principle. The other part of the principle of respect of persons, according to the Belmont Report, requires that persons with diminished autonomy (by reason of mental incapacitation, or incarceration) require protection.

The second principle, beneficence, according to most understandings of the term in literature, requires not only that persons are respected but that efforts are made to secure their safety and welfare. "Beneficence ensures that the risks of the act of research are kept within the essential context of the commitment to do the good for the benefit of others."[7] Given that there is always the possibility of risk in research involving humans, it requires investigators to give thought to the maximization of benefit and the reduction of risk to participants in research. In the Belmont Report, beneficence requires not only the positive obligation to ensure the good of participants in research, but also the negative obligation to refrain from harming participants. This negative obligation, known as non-maleficience, is sometimes dealt with separately by bioethicists.[8]

The last principle, justice, requires the just distribution of the benefits of research and the avoidance of undue imposition of burdens. The

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[6] Tom L. Beauchamp and James Childress, *Principles of Biomedical Ethics*, (New York: Oxford University Press, 2001) (5th Edition) at 68. See also, Robert J. Levine, *Ethics and Regulation of Clinical Research* (Second Edition) (Baltimore: Urban and Schwarzenberg, 1986) at 11-18. It must, however, be noted that while the above-stated view of autonomy predominates in research ethics, there are other understandings of autonomy, such as, relational autonomy.

[7] Edward F. Gabriele, "The Belmont Ethos: The Meaning of the Belmont Principles for Human Subjects Protection" (2003) 34: 2 Journal of Research Administration 19 at 21.

[8] See Beauchamp and Childress, supra note 11.

principle requires that the risks of research cannot be allowed to sit unfairly and unevenly on a specific population. Like beneficence and respect for persons, it requires that persons who are disadvantaged and vulnerable are protected from carrying the burdens and risks of research. The other side of this principle requires that the benefits are distributed fairly and that these benefits do not become the sole province of the advantaged.[9]

These principles, subsequently discussed more extensively by Beauchamp and Childress in their pioneering work *Principles of Biomedical Ethics*,[10] were the attempt of the Commission to summarise the basic ethical precepts that it identified during its deliberations. Certainly, the Nuremberg Code and the Helsinki Declaration which preceded the Belmont Report provided a statement of several ethical principles to guide researchers. However, the Belmont Report engaged in a more detailed exploration of the ethical foundations of research involving humans.[11] The adoption of principles, as found in the Belmont Report, in defining guidance for the ethical conduct of research involving humans, (often referred to as principlism) avoids comprehensive ethical theories. Instead this approach adopts midlevel principles that are common to, and can be justified and agreed upon by, multiple ethical

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[9] See the Belmont Report.
[10] Tom L. Beacuchamp and James F. Childress, *Principles of Biomedical Ethics* (5th Edition) (New York: Oxford University Press, 2001). The first edition was published in 1978. See also, Robert J. Levine, Ethics and Regulation of Clinical Research (Second Edition) (Baltimore: Urban and Schwarzenberg, 1986 at 11-18.
[11] Albert R. Jonsen, "On the Origins and Future of the *Belmont Report*" in James F. Childress, Eric M. Meslin and Harold T. Shapiro, *Belmont Revisited: Ethical Principles for Research with Human Subjects* (Washington DC: Georgetown University Press, 2005) at 3.

theories, especially utilitarianism and deontology or virtue theory.[12] The ethical principles therefore draw from different ethical theories, but discussion of these ethical theories is beyond the scope of this work.

Many of the challenges that arise in health research involving humans are usually dealt with by reference to the principlism approach. These include, but are by no means limited to, issues such as: What is the right balance between the benefits of research and the risks to the individual? (concerns about beneficence and maleficience) Can a research participant truly understand the risks and benefits to participation in research? (that is, concerns about autonomy) How should the burdens of research be fairly distributed? (that is, concerns about justice).[13] Thus, issues of informed and voluntary consent, minimization of risk and ensuring a favourable risk/benefit ratio, equitable non-exploitative selection of participants, and privacy and confidentiality of participants, are dealt with by reference to the principles described above.[14]

This approach has gained wide approval and is much employed within bioethical circles and is entrenched in various guidelines and regulations for research involving humans.[15] Further, the principles inform and are reflected in the work of many international agencies that have great influence internationally with regards to the regulation of research involving humans, such

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[12] See Beauchamp and Childress, supra note 10 at 51. See also, Eric M. Meslin et al, "Principlism and the Ethical Appraisal of Clinical Trials" in George F. Tomossy and David N. Weisstub, Human Experimentation and Research (Hants: Ashgate Publishing Company, 2003) at 77.-78.

[13] Janet L. Dolgin and Lois L. Shepherd, "Law, Medicine, and Philosophy" in Janet L. Dolgin and Lois L. Shepherd, *Bioethics and the Law* (New York: Aspen Publishers, 2009) at 402.

[14] Baruch A Brody, *The Ethics of Biomedical Research: An International Perspective* (New York: Oxford University Press, 1998) at 36.

[15] Meslin, supra note 17 at 77.

as the World Health Organisation (WHO), the Council for International Organisations of Medical Sciences (CIOMS) and the United Nations.[16] What is more, the inclusion of the concept of informed consent, derived from the principle of respect of persons, in the *International Convention on Civil and Political Rights* also allows the consideration of such concepts not only as ethical values but also as fundamental human rights. Moreover, as Meslin and others point out, "the advantage offered by the principles is that they do, in fact, provide a generally accepted framework of values within which individual contextual considerations may be evaluated."[17] These guiding ethical principles – respect for persons, beneficence, and justice – serve as the basis for the US federal regulations for research involving humans.[18]

The principlism approach, though widely adopted, has faced several criticisms. These include that reliance on principlism limits more robust moral discourse and appears to suggest that ethical matters can be quantified in a more or less mathematical manner.[19] It is also argued by some that principlism obscures and confuses moral reasoning by its random and varied use of moral theory.[20] Other arguments are even more critical of the way in which the principles have developed. For commentators like Rhodes, the derivation of the

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[16] Monica Konrad, "Norms, Values and Transcultural Medical Ethics," in European Group on Ethics in Science and New Technologies to the European Commission, *The Ethical Aspects of Biomedical Research in Developing Countries: Proceedings of the Round Table Debate* (2003), online: <http://ec.europa.eu/european_group_ethics/publications/docs/tb1oc_en.pdf> (December 2, 2008) at 14.

[17] Meslin, supra note 17 at 81.

[18] Office for the Protection of Research Subjects, "History of Research Ethics" online: <http://research.unlv.edu/OPRS/history-ethics.htm> (November 24, 2008).

[19] See John H. Evan, "Max Weber Meets the Belmont Report: Toward a Sociological Interpretation of Principlism" in Childress et al, *supra* note 122 at 229.

[20] K. Danner Clouser and Bernard Gert, "A Critique of Principlism" (1990) 15: 2 The Journal of Medicine and Philosophy 219.

principles from the Nazi trials of prisoners in World War II not only presented a backward way of developing principles for regulating health research involving humans, but also created an essentially paternalistic model for the governance of research involving humans.[21] Other critical arguments address the limited scope of the principles, including that the principles focus on individuals and thus do not adequately address communities participating in research.[22] The emphasis on individualism, it also argued, obscures "the importance of a nexus of human relationships indispensable to traditional decision-making in much of the world."[23] Feminist critiques make similar arguments against principlism's elevation of so-called rational principles over relational values such as relational autonomy, care, empathy and mutuality.[24] Moreover, the principles, while possibly offering clarity with respect to the values that they represent, do not offer a precise or even usable guide for action in difficult situations[25] and they may require broader interpretation than given in the Belmont Report context to

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[21] Rosamonde Rhodes, "Rethinking Research Ethics" (2005) 5: 1 American Journal of Bioethics 7. Others argue, however, that this paternalism is justifiable for the purposes of protecting research participants. See Franklin G. Miller and Allan Wertheimer, "Facing Up to Paternalism in Research Ethics" (2007) 37 Hastings Center Report 24.

[22] See Aurora Plomer, *The Law and Ethics of Medical Research: International Bioethics and Human Rights* (Oxford: Cavendish Publishing, 2005) at 8-10, describing the role of principlism in the work of national bioethics committees and in major reports such as the Nuffield Council on Bioethics report, *supra* note 5. However, Meslin and others note that many criticisms against principlism are especially relevant to principlism if considered as a substitute for moral theory. See Meslin, supra note 17 at 81.

[23] Norio Fujiki and Darryl R. J. Macer (ed.), *Bioethics in Asia* (Bangkok: Eubois Ethics Institute, 2000) at 77-80.

[24] Ibid. See also, Sue Sherwin, "Whither Bioethics? How Feminism Can Help Reorient Bioethics" (2009) 1:1 International Journal of Feminist Approaches to Bioethics 7, discussing relational autonomy and global bioethics.

[25] See for example, K. Danner Clouser and Bernard Gert, "A Critique of Principlism," (1990) 15 Journal of Medicine and Philosophy 219 at 220. Among their criticisms of the principlism approach is the argument that the principles do not necessarily provide a specific directive or guidance for action. See also, R B Davis, "The Principlism Debate: A Critical Overview" (1995) 20: 1 Journal of Medicine and Philosophy 85, arguing that there is no conclusive evidence in favour of, or against, principlism in academic debate because most scholarly research is biased in favour of its adopted position based on prior epistemological commitments.

deal with complex concerns, such as those arising in the context of developing countries.

Arguments against the applicability of the ethical principles in the developing world context point out that the conceptual framework underlying the ethical principles are of Western origins and orientation (or even more specifically American origins). As such, even when de-contextualised, they are not necessarily accommodating of other non-Western cultures with different values. For instance, the principle of respect of persons, it is argued, arises from the individualist values of Western cultures and may not work in precisely the same way in some developing country contexts.[26] Konrad summarises this concern succinctly when she states:

> Principlism and the '4-principles approach' developed by Beauchamp and Childress (1994) with its stress on the respect for persons through (1) autonomy (2) beneficence (3) nonmaleficence and (4) justice, including equity, was not originally formulated with the explicit remit of tackling the socio-political effects of multiculturalism - either within the USA or elsewhere. Nor, in its founding conceptualisation, was it particularly sensitive to the challenges facing cross-cultural field research in international health. Nonetheless, it is these very principles that have provided general guidance for many regulatory bodies involved in formulating ethical guidelines for biomedical research.[27]

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[26] N. Yasemin Oguz, "Research Ethics Committees in Developing Countries and Informed Consent: With Special Reference to Turkey" (2003) 141:5 Journal of Laboratory Clinical Medicine 292. Lukas Kaelin, "Contextualizing Bioethics: The UNESCO Declaration on Bioethics and Human Rights and Observations about Filipino Bioethics" (2009) Eubios Journal of Asian and International Bioethics 42.

[27] Konrad *supra* note 21 at 13.

Plomer further argues that recourse to fundamental ethical principles "can create an illusion of consensus and at its worst act as a poor substitute for democratic procedures and processes to find agreement and practical compromises between different moral cultures in pluralist societies."[28] But others disagree with these views, arguing that beyond the differences in context and circumstances, the ethical principles affirm the value of every human being and that certain ethical principles are applicable across cultures. Beauchamp notes, for instance, that "Belmont's principles are so woven into the fabric of morality in morally sensitive cultures that no responsible research investigator could conduct research without reference to them."[29] Yet others argue, for instance, that the principle of respect of persons as revealed in the requirement for informed consent is individualist and therefore Western in orientation.[30]

These arguments indicate that the general applicability of these principles is by no means uncontested. It is obvious that there are no easy answers on issues regarding the universality or otherwise of the ethical principles, not least because these issues reflect a broader controversy about how to deal with global differences, inequalities, and disparities that go beyond the ethics of health research. It is also apparent that while on the surface there

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[28] Plomer, *supra* note 27 at 2.
[29] Tom L. Beauchamp, "The Origins and Evolution of the Belmont Report" in Childress et al, *supra* note 124 at 15.
[30] Lisa Newton, "Ethical Imperialism and Informed Consent" (1990) 12:3 IRB: A Review of Human Subjects Research 11. However, others have pointed out that appeals to cultural sensitivity frequently rely on "limited and often dated anthropologic literature that does not reflect the rapid cultural changes brought about by colonialism and independence, warfare, and urbanization." C. Ijsselmuiden, C. and R. Faden, "Images in Clinical Medicine" (1990) 326 New England Journal of Medicine 833 at 833.

appears to be some consensus on ethical principles there are troubling issues that suggest that this might not be an entirely accurate picture.

In my view, looking at ethics and governance in a local context may prove helpful in addressing these conflicting views. In this respect, instead of accepting wholesale and without reflection the ethical principles used elsewhere, developing countries can acknowledge that there are divergent views and begin to address these issues thoughtfully in their national policies and guidelines. Thus, instead of adopting a strictly "local" ethic built only on local values, a "universal" ethic which may be considered imperialist, a "mid-way" which recognises local values, local needs, and circumstances but which also adopts the protections offered by the ethical principles underlying the international ethical guidelines, may be more helpful. This may mean addressing problematic issues in national policies, bearing in mind the need to minimize the possibility of exploitation, a particular concern in resource-challenged countries. Also, since cultural challenges cannot be generalized to all developing countries,[31] addressing such issues in a way that defines what the national position on these challenges is may be useful. As well, legal requirements vary from one country to the next. Addressing some of the ethical issues in a local context may allow the different legal and ethical requirements to be brought into harmony, where appropriate.

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[31] See for instance, Emmanuel R. Ezeome and Patricia A. Marshall, "Informed Consent Practices in Nigeria," (2008) Developing World Bioethics, Early View Article at 2. Patricia A Marshall, "The Individual and the Community in International Genetic Research" (2004) 15: 1The Journal of Clinical Ethics 76. See Anant Bhan, Mina Majd, Adebayo Adejumo, "Informed Consent in International Research:
Perspectives from India, Iran and Nigeria" (2006) 3 Medical Ethics 36; See Ruth Macklin, "Informed Consent for Research: International Perspectives" (2000) 55 JAMWA 290 at 291, describing cultural divergences in informed consent issues in developing countries.

Additionally, if one sees the three principles of respect for persons, beneficence/maleficience, and justice as only starting points, one can move to expanding the borders of ethical values as some commentators have done.[32] Several countries have adopted this approach also. The Australian National Statement on Ethical Conduct in Human Research, for example, notes that research has to be conducted according to certain values and principles, the major ones being, respect for human beings, research merit and integrity, justice, and beneficence.[33] The current edition of Canada's Tri- Council Policy Statement on Ethics takes a more detailed approach, including such ethical principles as respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for justice and inclusiveness, balancing harms and benefits and maximizing benefits.[34] Other organisations that deal with bioethics have adopted similar, but not identical, principles. For instance, in its report on the ethics of healthcare in developing countries, the Nuffield Council on Bioethics identified four applicable principles: alleviation of suffering, respect for persons, and sensitivity to cultural differences, and the duty

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[32] Emmanuel and others, for example, have proposed several principles and benchmarks for the ethical conduct of clinical trials (which could conceivably be extended to other types of health research), including such principles as solidarity. Ezekiel J. Emanuel, David Wendler, Jack Killen, and Christine Grady, "What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research," (2004) 189 The Journal of Infectious Diseases 930.

[33] Australia: NHMRC, *National Statement on Ethical Conduct in Human Research* 2007, online: <http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf> (June 20, 2007) at 10.

[34] Section C: "Guiding Ethical Principles," Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 1998 (with 2000, 2002 and 2005 amendments) online: <<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm> (August 11, 2007). These have been distilled in the latest draft forthcoming edition into three principles, - respect for dignity, moral worth of every person, and minimisation of harm.

not to exploit the vulnerable.[35] The European Group on Ethics in Science and New Technologies (EGE) has also identified ethical principles to which it adheres, including: the principle of respect for human dignity, individual autonomy, justice, beneficence and non-maleficience and proportionality.[36]

Apart from the inadequacies of the international ethical guidelines, (some of which are considered necessary partly because many developing countries lack domestic ethics policies)[37] determining the ethical principles that form the bedrock of the governance of research requires an understanding of the domestic context. Others have suggested the addition of new ethical values which have particular significance in the context of internationally-sponsored research, such as solidarity, and communitarianism, to other widely accepted values. [38] And some argue that the ethical principles underlying international projects, for instance in population genomics research, include respect for persons, but also center on the values of solidarity and equity.[39] These values can be built into the national guidelines and the domestic governance systems of

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[35] Nuffield Council on Bioethics, supra note 5 at 49.

[36] The European Group on Ethics in Science and New Technologies (EGE): "Opinion Number 17 on the Ethical Aspects of Clinical Research in Developing Countries," (2003), online: <http://ec.europa.eu/european_group_ethics/docs/avis17_en.pdf> (November 18, 2008) at 12.

[37] Howard Wolinsky, "Bioethics for the World" (2006) 7:4 European Molecular Biology Organization Reports 354 -358.

[38] See for instance, Shawn H. E. Harmon, "Solidarity: A (New) Ethic for Global Health Policy" (2006) 14 Health Care Analysis 215.

[39] Bartha Maria Knoppers, "Challenges to Ethics Review in Health Research," (2009) 17: 2 and 3 Health Law Review Bartha Maria Knoppers and Ruth Chadwick, "Human Genetic Research: Emerging Trends in Ethics" (2005) 6 Nature Reviews Genetics 75; Human Genome Organization (HUGO) Ethics Committee, "Statement on Human Genomic Databases" (2003) Eubios Journal of Asian and International Bioethics 99. "Asian Experts Want Bioethics Incorporate Asian Values" online: <http://www.unescobkk.org/fileadmin/user_upload/library/OPI/Documents/UNESCO_in_the_news/0808Aug12AsianExperts.pdf> (February 23, 2010).

developing countries. What is called for, therefore, is careful reflection on the issues arising, the values of the country in question, and the context.

I have described generally the main ethical principles adopted as part of ethical frameworks. As described above, this is not necessarily an uncontested area, and the principles may vary between countries and organisations. I have pointed out that national ethical guidelines and policies may be necessary to address problematic areas. The inadequacies of the principles adopted in the United States and elsewhere require that developing countries make a concerted effort to develop national guidelines that address ethics and values in addition to developing procedural guidelines. In essence, then, in developing countries there must be continued reflection in light of their specific contexts on what ethical principles work best to protect research participants. These must then be addressed in national ethical guidelines. In the Chapter Five, I consider the ethical principles which inform, and provide the ethical framework of, the domestic governance system of Nigeria.

3.2.2 Research Ethics: Ethical Guidelines

Beyond the underlying principles and values discussed above, international ethical guidelines have specific requirements for the ethical conduct of research. Moreover, the international ethical guidelines play an important role in the domestic governance systems of many countries, operating as soft law in the regulation and governance of health research. The governance approach of these guidelines fits well into the new governance approach because

these international ethical guidelines provide, to a large extent, open-ended guidance as opposed to rules, and very little formal sanctions.[40] Further, the origin, development, and effect of these guidelines are prototypical examples of the new governance approach.

Many countries either employ these guidelines directly, or indirectly, drawing upon them in national regulations, policies and guidelines.[41] A brief overview of the international ethical guidelines is therefore necessary. More importantly, I argue that developing countries should consider developing national guidelines to address any areas of weakness in the international ethical guidelines and to provide the national position on issues in the international ethical guidelines that may be controversial.

The overview of current international ethical guidelines begins with the Nuremberg Code. Although, the principles enunciated in the Code were part of the judgment at the Nuremberg Trials[42] and were therefore not intended to be a code of medical research ethics, the Code is of major historical

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[40] O. Lobel, "The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought" (2004) 89 Minnesota Law Review 342 at 363.

[41] See Delon Human and Sev S. Fluss, "The World Medical Association's Declaration of Helsinki: Historical and Contemporary Perspectives" (2001) World Medical Association, online: <http://www.wma.net/e/ethicsunit/pdf/draft_historical_contemporary_perspectives.pdf> (April 4, 2007).

[42] The origins of modern international bioethics can be traced to the abuse of research participants in concentration camps in the Second World War and the subsequent enunciation of the *Nuremberg Code*, the first international declaration of ethical standards for research outlined by the judges at the Nuremberg trials of Nazi doctors in 1947 at the Nuremberg 'Doctors Trials' in 1947. See generally G.J. Annas and M. A. Grodin, *The Nazi Doctors and the Nuremberg Code: Human Rights in Experimentation* (New York, Oxford University Press, 1992). Evelyne Shuster, "Fifty Years Later: The Significance of the Nuremberg Code" (1997) 337 N Engl. J. Med 1436; Jochen Vollman, "Informed Consent in Human Experimentation before the Nuremberg Code" (1996) 313 BMJ 1445; Pascal Arnold and Dominique Sprumont, "The 'Nuremberg Code': Rules of Public International Law" in Ulrich Trohler and Stella Reiter-Theil (eds.), *Ethics Codes in Medicine: Foundations and Achievements of Codification Since 1947* (Aldershot: Ashgate Publishing Ltd., 1998).

importance. It codified the ethical tenets governing scientific research on human beings[43] and marked the beginning of a larger consciousness of the need to establish standards for the ethical conduct of human research. It brought the issue of the ethical conduct of research involving humans to wider awareness.[44]

The Nuremberg Code has therefore been described by some commentators as the most important document in the history of medical research ethics.[45] It is widely cited as influential in the development of international and national guidelines for research involving humans, including the Helsinki Declaration.[46] It was largely responsible for the inclusion of a provision on the need for informed consent in human experimentation in the *International Covenant on Civil and Political Rights*.[47] Some have even argued, perhaps due to its origins as part of a court judgment, and also the moral force of its principles, that the Nuremberg Code is part of customary international law binding on states.[48] But, as has been pointed out by some authors, the requirements of customary international law include evidence of general state practice and *opinio juris*, (that is evidence that the practice of states is informed by a sense of legal obligation,) which may arguably not be present in regard to

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[43] Annas and Grodin, *ibid.*

[44] See Sharon Perley *et al.*, "The Nuremberg Code: An International Overview" in Annas and Grodin ibid at 152- 155.

[45] Evelyne Shuster, "Fifty Years Later: The Significance of the Nuremberg Code" (1997) 337 N Engl. J. Med 1436.

[46] See for example, Hans-Martin Sass, "Reischrundschreiben 1931: Pre-Nuremberg Germany Regulations Concerning New Therapy and Human Experimentation," (1983) 8 Journal of Medicine and Philosophy 99. Perley et al, supra note 44 at 154.

[47] G.A. res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, *entered into force* Mar. 23, 1976. See Perley *et al., ibid* at 153.

[48] See Pascal Arnold and Dominique Sprumont, "The 'Nuremberg Code': Rules of Public International Law" in Ulrich Trohler and Stella Reiter-Theil (eds.), *Ethics Codes in Medicine: Foundations and Achievements of Codification Since 1947* (Aldershot: Ashgate Publishing Ltd., 1998).

the application of the international ethical guidelines discussed here. But some of their requirements may be considered part of international law. For instance, a United States court decided in 2009 that violation of the requirement for informed consent in human experimentation was a violation of customary international law.[49]

The Nuremberg Code`s major contribution to contemporary research ethics is its requirement for informed consent, now widely accepted as a core requirement for research involving humans.[50] Its requirements are evidently concerned with respect of persons, and beneficence/maleficience, (not as much with justice), although this is not specifically stated.

Despite its contributions to the development of research ethics, the Nuremberg Code has been criticised for its absolutist informed consent requirements and failure to make any exceptions in this regard, the narrow context in which it was drawn up which limited the scope of the code, and for the responsibilities it places on investigators or researchers, without any safeguards to ensure that those responsibilities are carried out. [51]

Although it remains an influential document, the Nuremberg Code has, however, largely been superseded in practical application by the

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[49] See Markus Schott, "Medical Research on Humans: Regulation in Switzerland, the European Union, and the United States" (2005) 60 Food and Drug L. J. 45. See *Rabi Abdullahi v. Pfizer, Inc Docket* Nos. 05-4863-cv (L), 05-6768-cv (CON), 2009 WL 214649 (2d Cir January 20, 2009).

[50] See Jay Katz, "The Consent Principle of the Nuremberg Code: Its Significance Then and Now" in Annas and Grodin, supra note 40 at 227-238. Pascal Arnold and Dominique Sprumont, "The 'Nuremberg Code': Rules of Public International Law" in Ulrich Trohler and Stella Reiter-Theil (eds.), *Ethics Codes in Medicine: Foundations and Achievements of Codification Since 1947* (Aldershot: Ashgate Publishing Ltd., 1998).

[51] Perley, supra note 42 at 157.

Helsinki Declaration.[52] Since 1964 when it was adopted, the severally revised *Helsinki Declaration* has provided the primary guiding principles for regulating medical research involving human participants for the purpose of guiding physicians and others conducting biomedical research involving humans.[53] It contains a number of requirements for the ethical conduct of research, such as provisions requiring informed consent from participants in medical research, which reflects the value of respect of persons.[54] It has modified the principle of informed consent as found in the Nuremberg Code in allowing for, and requiring proxy consent where the potential research subject is incapable of consenting.[55] One of the most controversial requirements in the Declaration in recent years in the context of research involving humans in developing countries has been the requirement relating to the standard of care to be provided to participants in randomized clinical trials. It currently provides that the effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods.[56] Another requirement which has raised concerns in the developing world context is the requirement that medical research can only ethically be justified where there is a reasonable likelihood that the populations in which the research is conducted stand to benefit from the results.[57]

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[52] Ibid at 150.
[53] See Introduction, para. A of the Helsinki Declaration.
[54] Principle 22 and 24.
[55] This has been criticised by several authors who allege that this has watered down the effect of the principle. See for Jay Katz, *Experimentation with Human Beings* (New York, Russell Sage Foundation, 1972)..
[56] Principle 32.
[57] Principle 19.

The Helsinki Declaration is widely applied and referenced in different national and international guidelines.[58] It has not only been instrumental to the governance and regulation of biomedical research by providing guiding principles, it has also been influential in the establishment of ethical review committees, a key component of research governance.[59] In establishing a requirement for independent ethical review committees in the 1975 amendment and requiring that reports of experimentation violating the Declaration's ethical principles not be accepted for publication, it gave teeth to substantive standards through procedural mechanisms.[60] But, as Dickens notes, it remains procedurally undeveloped.[61]

The issues that have arisen with the Helsinki Declaration, particularly in the context of the developing world, have been issues of interpretation and application in the special circumstances that may arise in that context. Charges of ethical imperialism leveled against the ethical standards set in the Helsinki Declaration, and opposing arguments about ethical relativism, have raised questions about the universality of the principles contained in the Declaration and whether or not the Declaration can truly represent a broad and international spectrum of opinion on ethical standards such as would be

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[58] See Snezana Bosnjak, "The Declaration of Helsinki- The Cornerstone of Research Ethics" (2001) 9:3 Archive of Oncology 179.
[59] World Medical Association, "WMA History: Declaration of Helsinki" online: <http://www.wma.net/e/history/helsinki.htm> (November 24, 2008). See Principle 13.
[60] James F. Childress, "Nuremberg's Legacy: Some Ethical Reflections" 43:3 Perspectives in Biology and Medicine 347 at 351.
[61] Bernard Dickens, "The Challenge of Equivalent Protection" in National Bioethics Advisory Commission *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries Volume II- Report and Recommendations of the National Bioethics Advisory Commission* (Bethesda, Maryland: National Bioethics Advisory Commission, 2001 at A-3.

necessary to guarantee its legitimacy.[62] The clarifications which have been added to the Declaration in recent years as a result of these concerns have, according to some commentators, threatened to weaken the authority of the principles contained therein.[63]

Further, although it has set procedural and substantive standards for the ethical conduct of biomedical research and carries great moral and normative authority, the scope of the Declaration is limited by the fact that it is binding only on medical researchers. Its legal status in many countries is also uncertain.[64] However, where guidelines, such as the Helsinki Declaration, are adopted by legislation, they become legally binding. Moreover, courts may also consider it in examining the standard of conduct which may be expected from researchers. For instance, the Quebec Supreme Court in Canada referred to the Helsinki Declaration in *Weiss v. Solomon*, in trying to determine the standard of care required of a researcher and a hospital through the approval of the protocol by the hospital's ethics review committees[65] The Helsinki Declaration has also informed legislation, and has been incorporated in the regulations and guidelines of some countries.[66]

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[62] See Plomer, supra note 27 at 4.
[63] See for example, "Dismantling the Helsinki Declaration" (2003) 169:10 CMAJ Editorial.
[64] See the Nuffield Council on Bioethics, supra note 5 at 64. Plomer, supra note 27 at 5.
[65] W*eiss v. Solomon* (1989) 48 CCLT 280 (Que Sup Ct). The researcher was found liable for not adequately disclosing the risks of involvement in a biomedical research project, in which the research participant subsequently died.
[66] See, Fluss and Human, supra note 45. See S Gevers, "Medical Research Involving Human Subjects: Towards an International Legal Framework?" (2001) European Journal of Health Law 293 at 294, noting the indirect legal significance of the Helsinki Declaration. See Angela Campbell & Kathleen Cranley Glass, "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research" (2001) 46 McGill L.J. 473.

Despite being influential in the development of national and international ethical guidelines and legal regulations, Plomer notes that "the legal force of the Helsinki Declaration is severely limited by local, procedural and substantive rules."[67] An uncertain legal status in various countries notwithstanding, the Helsinki Declaration, as previously stated, is a primary reference document with regards to ethical standards in health research. This uncertainty, however, indicates that a national ethics policy may be more useful as a guidance document in developing countries, especially when supported directly or indirectly by domestic law.

The Council for International Organisation of Medical Sciences (CIOMS)[68] in conjunction with the World Health Organisation has also adopted guidelines for ethical research, the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*[69] (CIOMS Guidelines). They were first drafted in 1982 to propose ways in which the principles set out in the Helsinki Declaration could be effectively applied in developing countries.[70] The guidelines have historical foundations in the Helsinki Declaration.[71] They were most recently revised in 2002, following the intense debates about the standard

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[67] See Plomer, supra note 27 at 5.

[68] The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organization established jointly by WHO and United Nations Scientific and Cultural Organization (UNESCO) in 1949. See online: <www.cioms.ch> (March 8, 2008).

[69] The Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* adopted 1993 and revised 2002.

[3]3 The "Background Note" of the 1993 edition of the CIOMS Guidelines stated as their main purpose was: "...to indicate how the ethical principles...as set forth in the Declaration of Helsinki, could be effectively applied, particularly in developing countries, given their socioeconomic circumstances, laws and regulations, and executive and administrative arrangements."

[71] Ibid.

of care issue (briefly discussed in Chapter One).[72] They are designed to be useful to countries in defining national policies on the ethics of biomedical research involving human subjects. They contain ethical guidelines and standards which apply specifically to the circumstances of developing countries. For instance, the guidelines state that the ethical justification of biomedical research is the prospect of discovering new ways of benefiting people's health, and can only be ethically justifiable if it is carried out in ways that respect, protect, are fair to, and morally acceptable within the communities in which the research is conducted.[73] It also requires that all research be submitted to an ethics review committee which must be independent of the research team.[74] It contains specific provisions relating to establishing or improving ethical review mechanisms, particularly within developing countries, taking into consideration the lack of resources and other peculiar conditions.[75]

Other ethical guidelines deal with specific issues in research. They draw from, and build on, the major guidelines described briefly above, primarily the Helsinki Declaration. These include the *Operational Guidelines for Ethics Committees that Review Biomedical Research* drawn up by the WHO and the *Ethical Considerations in HIV Preventive Vaccine Research* drawn up by UNAIDS, which applies to HIV vaccine research, (most of which is currently taking place in developing countries), and the more recent UNESCO Declaration

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[72] See Trudo Lemmens *et al*, "CIOMS' Placebo Rule and the Promotion of Negligent Medical Practice" (2004) 11 European Journal of Health Law 153.
[73] Guideline 1.
[74] Guideline 2.
[75] See the CIOMS Guidelines Preamble, online: <http://www.cioms.ch/frame_guidelines_nov_2002.htm> (March 4, 2004).

on Bioethics and Human Rights. [76] They also include the International Conference on Harmonisation's *Harmonised Tripartite Guidelines for Good Clinical Practice* (GCP)[77] which aims to "provide a unified standard for the European Union, Japan and the United States to facilitate the acceptance of clinical data by the regulatory authorities in these jurisdictions."[78] The GCP establishes scientific and ethical quality for drug trials internationally.[79] The existence of the GCP reflects increasing recognition of the need for a harmonization of rules between countries to ensure easier facilitation of ethical review of research, as well as increased foreign market access for pharmaceuticals.[80] The GCP contains mainly regulatory and administrative procedures, but also addresses such ethical issues as informed consent. Many countries, including developing countries, now require compliance with the GCP as part of their drug approval processes.[81]

These international ethical guidelines aim to provide general guidance for ethical conduct of research in countries around the world. They

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[76] Tropical Disease Research and World Health Organisation, *Operational Guidelines for Ethics Committees that Review Biomedical Research*, online: WHO <http://www.who.int/tdr/publications/publications/ethics.htm> (September 19, 2008). James Lavery, "The Challenge of Regulating International Research with Human Subjects" (June, 2004) Science and Development Network, online: <http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&policy=52&section=265&dossier=5> (December 19, 2008).

[77] International Conference on Harmonisation of Technical Requirements for Registration of Pharamceuticals for Human Use, ICH Harmonised Tripartite Guideline – *Guideline for the Good Clinical Practice* (ICH-GCP Guideline) (Geneva: 1996).

[78] Ibid.

[79] Paragraph 3.

[80] Adriana Petryna, "Ethical Variability: Drug Development and Globalizing Clinical Trials" (2005) 32: 2 American Ethnologist 183 at 185.

[81] See Marie Hirtle et al, "A Comparative Analysis of Research Ethics Review Mechanisms and the ICH Good Clinical Practice Guideline" (2001) 7 European Journal of Health Law 265 at 265-266. It has been argued that the WHO is the more appropriate international organization to set international standards related to pharmaceuticals, rather than the ICH.

provide a new governance approach to the regulation and governance of health research, with the attendant benefits of a voluntary model of adoption, and of flexibility. As guidelines, they are flexible and so can address a wide variety of issues in a broad manner. They provide soft law guidance rather than hard law regulation. Instead of penal sanctions, there are other methods of enforcement, including, for instance, non-publication by journals where a research project clearly violates a requirement of the guidelines.[82] As discussed in Chapter Two, such flexibility, voluntariness, and lack of penal sanctions would appeal to proponents of the new governance. In a complex enterprise, comprising diverse perspectives held by different stakeholders, with often conflicting interests, the guidelines may be argued to provide a basic standard. In my view, their moral authority, particularly the Helsinki Declaration, provides a form of governance and regulation which may go beyond obedience to black-letter laws.

However, views on their practical application are divergent. Their provisions can sometimes conflict.[83] Moreover, since compliance with the guidelines is mainly voluntary, uniformity in practice is not guaranteed, which may lead to less protections for research participants in some countries. Further, the same flexibility which allows room for addressing issues broadly means that there is little precision in the guidance that they give and application in practice may sometimes prove difficult.

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[82] See for instance, Article 30 of the Helsinki Declaration which requires researchers to report research results, including sources of funding, conflicts of interest, and institutional affiliations. See Human and Fluss, supra note 45.

[83] Lemmens et al, supra note 72. See also Howard Wolinsky "The Battle of Helsinki" (2006) 7:7 European Molecular Biology Organization Reports 670.

As Plomer observes, the increasing globalisation of medical research brings to light the tension between the aspiration to universality of the ethical principles in the international guidelines and the reality of the plurality of cultures.[84] As the ethical concerns in developing countries described briefly in Chapter One clearly show, even though the international guidelines, particularly the Helsinki Declaration, carry great normative weight and have informed national policies and guidelines for research involving humans around the world, it is not always clear what is required to satisfy the rules in these guidelines. It has also been argued that they provide insufficient consideration of issues of global inequality, social justice, and inclusion of all groups in the benefits and burdens of research,[85] thus limiting their legitimacy. In this respect, Lavery observes that:

> The process by which international guidelines are developed is critical to their legitimacy and authority, particularly since the main guidelines function under a voluntary adoption model. During recent revisions of the Declaration of Helsinki and the CIOMS Guidelines, the issue of whose perspectives were taken into account emerged as a critical challenge. In particular, questions were raised over whether there was sufficient developing-country representation during the drafting process, and also whether there was sufficient transparency with respect to the influence of powerful research interests to ensure an appropriate balance between protecting research participants and facilitating important scientific research.[86]

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[84] Plomer, supra note 22 at 13.

[85] See Lisa Eckenweiler et al, "The Declaration of Helsinki through a Feminist Lens," (2008) 1:1 International Journal of Feminist Approaches to Bioethics 162.

[86] Lavery, supra note 81 at 204. See Jonathan Kimmel, Charles Weijer, Eric Meslin, "Helsinki Discords: FDA, Ethics, and International Drug Trials" (2009) 373: 9657 Lancet 13.

Also, Lemmens and others point out the contradictions in the guidelines (with specific respect to the use of placebo in biomedical research) and note that it may affect the weight that might be accorded them by domestic courts. According to them:

> These contradictions are sufficient to warn researchers and research ethics committees against a mere reliance on these documents as setting binding research standards. Although such incompatibility could be viewed as undermining their moral authority and jeopardizing their usefulness, we rather suggest that it indicates the limitations of these guidelines. They are the reflection of an on-going ethical debate and political struggle within their respective organizations. The contradictions between the different rules and the process by which they were established indicate why these ethics guidelines cannot be considered as creating binding norms. They also make it hard to claim that national courts could look to these documents for guidance to determine what constitutes appropriate and widely accepted research practice.[87]

In addition, as noted in Chapter One, the United States, in 2008, decided to cease applying the Helsinki Declaration in foreign clinical trials if used to support applications for registration of products in the United States, relying instead on the ICH-GCP. This effectively permits the greater use of placebos in foreign clinical trials.[88] The decision raises questions about general applicability of the

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[87] Lemmens, supra note 72 at 156.

[88] "FDA Scraps Helsinki Declaration on Protecting Human Subjects," online: <http://www.cspinet.org/integrity/watch/200805051.html#2> (December 19, 2008). See also, Jonathan Kimmel, Charles Weijer, Eric Meslin, "Helsinki Discords: FDA, Ethics, and International Drug Trials" (2009) 373: 9657 Lancet 13. Michael E Goodyear, Trudo Lemmens, Dominique Sprumont and Godfrey Tangwa, "Does the FDA have the Authority to Trump the Declaration of Helsinki?" (2009) 338 BMJ 1559.

international ethical guidelines, but even more so, about what developing countries should do to take ownership of the protection of research participants in those countries.

One way to address the complex concerns about ethical principles, and the contents and legitimacy of the international guidelines, may be an engagement between all interested agents and parties in continuous dialogue, negotiation, and reflection in an open, transparent way.[89] Moreover, collective consideration and acceptance of standards by countries generally will prevent accusations of hegemony which may arise where one country imposes its own standards and procedures, even where such standards and procedures are effective in protecting the rights of research participants.[90] The recent debates about the ethics of externally-sponsored research in developing countries and subsequent attempts at revision and clarification of both the CIOMS and Helsinki Declaration, if not entirely successful, indicate a willingness to consider different perspectives. In this respect, it would be helpful to include more representatives and perspectives from developing countries in the process of creating and amending these guidelines, as well as in developing research protocols to be employed in developing countries.

But going beyond these suggestions, national ethics policies or guidelines, in my view, are especially necessary to address areas that have proved contentious in the international guidelines. National guidelines and

[89] Konrad, supra note 22 at 13. See also, Michael D E Goodyear, Karmela Krleza-Jeric, Trudo Lemmens, "The Declaration of Helsinki: Mosaic Tablet, Dynamic Document, or Dinosaur?" (2007) 335 BMJ 625 at 626.

[90] See Godfrey Tangwa, "Moral Agency, Moral Worth and the Question of Double Standards in Medical Research in Developing Countries," (2001) 1:2 Developing World Bioethics 156 at 67.

policies can also ensure that any gaps in the international guidelines are specifically addressed in a national context. It is thus necessary for developing countries to establish national policies and guidelines which address in more depth the specific contexts and ethical issues which arise in these countries. This does not suggest that the international ethical guidelines have no further use. Their moral authority, (particularly the Helsinki Declaration) remains considerable. But, in view of the limitations discussed above, and the potential benefits of domestic guidance, national guidelines are essential.

Some developing countries are already taking this route. Developing countries which have taken this step include South Africa,[91] Kenya, Uganda,[92] Nepal,[93] and India.[94] These countries have adopted national guidelines that are "tailored to their national contexts, with specific provisions addressing the vulnerabilities that may have enabled past abuses."[95] For instance, the South African national ethics guidelines adopt a broad meaning of the term "standard of care" and state exceptions in which the use of placebos may be allowed in arguably more specific terms than the Helsinki Declaration.[96] In Kenya, the guidelines make special provisions concerning research with underdeveloped

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[91] National Health Research Ethics Council, *Ethics in Health Research: Principles, Structures and Processes Guidelines.* (Pretoria: Department of Health, 2004)

[92] Uganda, *Guidelines for the Conduct of Health Research Involving Human Subjects in Uganda* (National Consensus Conference 1997).

[93] Nepal Health Research Council, *National Ethical Guidelines for Health Research in Nepal (2001)*

[94] Indian Council of Medical Research (ICMR), *"Ethical Guidelines for Biomedical Research on Human Subjects" (2000).* See also, Nandini Kumar et al, "The Indian Experience" (2008) 6:4 Journal of Academic Ethics.

[95] Adèle Langlois, "The UNESCO Universal Declaration on Bioethics and Human Rights: Perspectives from Kenya and South Africa" (2008) 16:1 Health Care Analysis 39 at 43-44.

[96] National Health Research Ethics Council, Ethics in Health Research: Principles, Structures and Processes Guidelines. (Pretoria: Department of Health, 2004)online: <http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/> (December 15, 2008). See Paragraphs 2.14 and 2.15.

communities, prisoners, married women in rural areas and pregnant or lactating women.[97] Other countries like Ghana,[98] and Pakistan,[99] however, still do not have national guidelines.

Apart from addressing contentious issues and gaps, national guidelines and policies can also provide specific requirements regarding the structure and organisation of the governance system. They may also set out the actors in the governance system, their responsibilities and a system of accountability. The United Kingdom's *Research Governance Framework for Health and Social Care,* is an example. This framework applies to research conducted under the National Health Service (NHS),[100] and specifies the responsibilities of research participants, research sponsors and ethics review committees. In like manner, Canada's Tri-Council Policy Statement specifies, among other things, the operation of ethics review committees, including the conditions under which an expedited review may take place, the requirement for institutions to establish a standing committee to hear appeals when a researcher is dissatisfied with an ethics review committee's decision, matters that are not addressed in the Helsinki Declaration, for instance. Both ethical principles and procedural or structural matters may be contained in the same guidance

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[97] National Council for Science and Technology, *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya* (NCST No. 45, 2004). See paragraph 9-13.

[98] See Paulina Tindana and Okyere Boateng, "The Ghana Experience" (2008) 6: 4 Journal of Academic Ethics, noting that "The major challenge in Ghana is the lack of national ethics guidelines governing the conduct of research with human subjects." See also, Harvard School of Public Health, "Global Research Ethics Map: Ghana" online: <https://webapps.sph.harvard.edu/live/gremap/view.cfm?country=Ghana> (June 11, 2010).

[99] Harvard School of Public Health, "Global Research Ethics Map: Pakistan" online: < https://webapps.sph.harvard.edu/live/gremap/view.cfm> (June 11, 2010).

[100] Department of Health, *Research Governance Framework for Health and Social Care* (Second Edition) (United Kingdom, 2005), online: <http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4122427.pdf> (June 19, 2009), Section 1.2.

document,(such as is the case with the Tri-Council Policy Statement and the Australian the *National Statement on Ethical Conduct in Human Research* 2007),[101] or in separate documents. Given the gaps that exist in the international guidelines and the procedural matters that need to be attended to, there is need to provide for both substantive ethical matters and organizational or structural issues and procedural issues and processes, in domestic policy documents.

Finally, national policies can provide a further layer of protection for research participants, beyond any protections offered by the international ethical guidelines. This may be by clarifying the application of certain ethical principles in the local context and by specifying appropriate procedural mechanisms. Developing countries therefore need to consider creating national guidance, where not already in place, to allow for clear and unambiguous application.[102]

In a hybrid framework of governance as proposed in Chapter Two, such national policy guidance will retain the positive attributes of a new governance approach (including flexibility and ease of amendment) while operating within a domestic context. Such flexibility is important because of changes that may need to be made in line with international developments, ongoing evolution in research ethics, and changes in domestic circumstances. With wide consultations between stakeholders in the research enterprise, these guidelines could also promote legitimacy. As I argued in Chapter Two, allowing for guidelines (soft law) in areas where specificity could be elusive, potentially

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[101] NHMRC, *National Statement on Ethical Conduct in Human Research* 2007. The UK's Research Governance Framework for Health and Social Care focus mainly on processes and procedural matters.

[102] Nuffield Council of Bioethics, note 10 at 66.

offers not only more legitimacy but a greater level of accountability than would otherwise exist. However, national guidelines, like international guidelines typically lack enforcement mechanisms, relying instead on moral suasion in developing countries. (Developed countries typically rely on withdrawal of funding). Thus, as I argue in the next chapter, hard law is also necessary, given the need to protect research participants in developing countries. Certain basic requirements, in my view, need to be enforceable in law. Still, some controversial ethical issues, like the standard of care issue, may best be dealt with in national guidelines rather than legislation because of the evolving understanding of such issues. In the following chapters, I consider in greater detail the national guidelines that have recently been adopted in Nigeria, and its impact on research governance.

3.3 Institutional Framework

Beyond the ethical standards detailed in the ethics guidelines described above, an institutional framework is required, and has developed in countries around the world, to provide a system of governance. Different institutions act as the active mechanisms which implement the ethical framework. Principal among these institutions is the ethics review committee. Other institutions such as the national drug regulatory authorities and professional associations also play an active role in the implementation of ethical standards and principles.

Below I describe briefly the institutions that govern health research involving humans in countries around the world. The account given of these institutions is by necessity condensed to provide only the most essential details. Also, while this subsection addresses some of the issues that arise in the deployment of these institutions in research governance, the analysis undertaken here is necessarily broad. However, the identification of systemic issues which affect the functioning and effectiveness of these institutions is necessary for an understanding of issues that may arise in developing countries like Nigeria. An in-depth analysis is conducted in the context of Nigeria in Chapters Five and Six.

3.3.1 Ethics Review Committees

Ethics review is a fundamental part of the research governance systems of many countries and is now widely recognised as a necessary safeguard and a formal mechanism for the protection of research participants. A detailed history of the origins of ethics review is outside the scope of this thesis and has been engaged in by others.[103] McNeill, for instance, traces the history of ethics review committees in several countries,[104] and it is unsurprising that, particularly in the United States where they first began as a system of peer review,[105] these committees were established in response to several unethical

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[103] Paul M. McNeill, *The Ethics and Politics of Human Experimentation* (Cambridge: Cambridge University Press, 1993) at 53-84. See also, Ruth R. Faden and Tom L. Beauchamp, *A History of Informed Consent* (New York and Oxford: Oxford University Press, 1986).
[104] The United States, Britain, Ireland, Australia, New Zealand and Canada.
[105] See Charles McCarthy, "The Institutional Review Board: Its Origins, Purpose, Function and Future" in David N. Weisstub, *Research on Human Subjects: Ethics, Law and Social Policy* (Oxford: Elsevier Science Ltd., 1998) at 307.

experiments involving humans. Such experiments include the 1963 Jewish Chronic Disease Hospital incident, where chronically ill patients were injected with cancer cells without their knowledge or consent.[106] Below, I reflect briefly on the ethics review process and its significance in research governance. From a systems perspective, I also describe briefly some of the issues that affect its effectiveness as a crucial part of research governance, including composition, structure and financial support, with illustrations from different countries. I then consider, briefly, ethics review in developing countries.

The ethics review process is one of the principal means of ensuring that any proposed research is ethical.[107] It requires that investigators or researchers submit the proposed research project or protocol to a committee, which inquires into its ethical acceptability. Thus it is different from, (though it may include) peer review of the scientific aspects of research.[108] The ethics review committee is charged with assessing the risks and benefits of the proposed research, ensuring that the potential benefits of the proposed research outweigh any foreseeable risks attached thereto, and in this process weighing the interests of the research participants, the society, and the investigators. Ethics review committees review proposed research to make sure that it complies with

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[106] See McNeill, for a fuller history of origins of the ethics review system. See McNeill, supra note 103 at 57.

[107] Along with informed consent, ethics review is considered by many to be the other major safeguard by which research participants are protected in health research. See for instance, Ruth Macklin, *Double Standards in Medical Research in Developing Countries* (Cambridge: Cambridge University Press, 2004) (hereinafter Macklin (2004). See also McNeill, supra note 103 at 1.

[108] Richard Ashcroft, "The Ethics and Governance of Medical Research: What Does Regulation Have to Do with Morality?" (2003) 1:1 New Review of Bioethics 41 at 48.

ethical standards as articulated in international and domestic guidelines. The functions of ethics review committees thus include,

> identifying and weighing up the risks and potential benefits of research; evaluating the process and materials (printed documents and other tools) that will be used for seeking participants' informed consent; assessing the recruitment process and any incentives that will be given to participants; evaluating risks to participants' confidentiality (and the related risk of discrimination) and the adequacy of confidentiality protections ; and examining any other issues that may affect the ethical acceptability of the research. In international research, the committee represents the interests of the local population.[109]

In carrying out these functions, they provide a means of accountability, and boost public trust and confidence in the research enterprise. In this way, these committees also play an important role in facilitating research.

Ethics review committees typically have authority to decide whether research proposals are reasonable and ethically acceptable and can proceed, or whether they are not and should therefore not proceed, or whether they can proceed with some modification, or if research has already commenced, whether it is to be terminated. The extensive powers of ethics review committees have attracted criticisms from many researchers and commentators, including complaints that they sometimes prevent and delay beneficial research, unnecessarily limit academic and research freedom, and that the process is

[109] WHO, *Research Ethics Committees: Basic Concepts for Capacity-building* (Geneva: WHO, 2009) at 14.

expensive.[110] However, even though negotiating the balance between promoting socially beneficial research and protecting research participants is not always easy, ethics review is, and is likely to continue being, a critical part of research governance because the ethics review committee is the component of research governance which directly oversees research protocols and can most directly regulate researchers' conduct.

Many of the international ethical guidelines require that health research involving humans must pass through the ethics review process. The Helsinki Declaration, for instance, requires that "The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins."[111] The committees that carry out such review (referred to here as ethics review committees[112]) are now regarded as key in most countries for the purpose of providing independent ethics assessment of research protocols and protecting research participants. Some countries, like Denmark[113] and South Africa,[114] have even taken the additional step of making

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[110] M. Schuman, "Clinical Trials: The Balance between Protecting Participants and Promoting Drug and Product Development" (2009) 180: 6 CMAJ 603; D S Wald, "Bureaucracy of Ethics Applications" (2004) 329 BMJ 282–4 ; Alysun M Jones, Bryony Bamford, "The Other Face of Research Governance" (2004) 329: 7460 BMJ 280 (September 16, 2009); C.K. Gunsalus et al., "Mission Creep in the IRB World", (2006) 312 Science 1441; Norman Fost and Robert J. Levine, "The Dysregulation of Human Subjects Research" (2007) 298 JAMA: Journal of the American Medical Association 2196; Jon Nicholls, "The Ethics of Research Ethics Committees" (2000) 320: 7243 BMJ 1217.

[111] Article 15. Helsinki Declaration 2008.

[112] Different countries have different nomenclature: Institutional Review Boards in the United States, Research Ethics Boards (REB) in Canada, Health Research Ethics Committees (HREC) in Nigeria and South Africa. But all have basically the same functions.

[113] See Section 1 and Section 8 of the *Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects.*

[114] Section 73 of the *National Health Act.* Sweden also legally mandates ethics review of research involving Humans. See *The Swedish Ethical Review Act,*(Lag (2003:460) om etikprövning av forskning som avser människor) issued 5 June, 2003 (SFS no 2003:460), implemented in January 2004 and amended in 2008, online: <http://www.riksdagen.se/webbnav/index.aspx?nid=3911&bet=2003:460> (September 11,

it a legal requirement that all health research, with certain specified exceptions, pass through ethics review. Other countries, including the United States, Canada, and the United Kingdom, legally require ethics review specifically for clinical trials of drugs. Research governance, for the most part then, is built around the committees which carry out ethics review, ensuring amongst other things that research is conducted in an ethical manner and that the rights, safety and welfare of research participants are protected. Even systems which lack a formal legal underpinning typically consist of institutional ethics review committees as the centre-piece of such systems.

The requirements of most research sponsors, and international journals, particularly journals which publish biomedical research, that ethics review approval must be obtained for funding or publication,[115] further cements the centrality of ethics review in research governance. These mechanisms – funding requirements and publications – are soft law mechanisms favoured in new governance thinking, and are thus part of the hybrid framework proposed in this thesis for effective governance of health research involving humans.

The decisions taken during review by these committees, whether to approve, disapprove a proposed research protocol, or terminate an ongoing project, are influenced by international, national, and institutional policy and guidelines, by law, institutional culture and also, significantly, by the views,

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2009).
The Swedish ethical review act was revised in 2008 (SFS 2008:192).

[115] International Journal of Medical Journal Editors, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Protection of Human Subjects and Animals in Research" online: <http://www.icmje.org/ethical_6protection.html> (September 30, 2009).

values and decision-making processes of individual members.[116] Further, as Schuppli and Fraser point out, "Aspects of committee structure and process—committee composition, deliberation, process, group dynamics and training—can also affect decisions." Thus, from a systemic perspective, the composition or membership of committees, and the structure and organisation of ethics review committees, and the financial support that the committees receive to undertake their work as a fundamental part of the research governance system, are some of the factors which can affect their functioning. I consider these briefly below.

The composition of ethics review committees is one of the factors that have an effect on their functioning. As McNeill accurately observes, "It is very important therefore that the body evaluating the ethics of a research study is appropriately constituted and competent to decide the issue. Otherwise, ethics committees could do the opposite of what they are intended to do and, in effect, act as sponsors of unethical experimentation."[117] The adequacy of ethics review is, for the most part, dependent on the expertise of the members.[118] The adequacy of review depends, in significant ways, also on the discretionary judgments and personal values of members of the committee,[119] making the composition of the ethics review committee a very crucial issue in research

[116] C.A. Schuppli and D. Fraser, "Factors Influencing the Effectiveness of Research Ethics Committees" (2007) 33 Journal Medical Ethics 294.
[117] McNeill, supra note 103 at 6.
[118] See Jocelyn Downie and Fiona McDonald, "An International Comparative Review of Research Ethics Review Bodies" (2003) 3 Clinical Researcher 14 at 21.
[119] Carl H Coleman and Marie-Charlotte Bouësseau,"How Do We Know That Research Ethics Committees Are Really Working? The Neglected Role of Outcomes Assessment in Research Ethics Review" (2008) 9:6 BMC Medical Ethics; C H Coleman, "Rationalizing Risk Assessment in Human Subject Research (2004) 46:1Arizona Law Review 1.

governance. There is therefore need to have a broad membership. Such membership should include adequate expertise necessary to appropriately evaluate the soundness and scientific validity of research protocol, capability to examine research projects for ethical soundness, and ability to take into account the values of the community in which the research is to take place.

The composition of committees varies in different countries, ranging from at least five members in countries like Canada,[120] the United States,[121] South Africa[122] and Nigeria,[123] to at least seven members in Denmark[124] and the United Kingdom,[125] and eight members in Australia.[126] There is general recognition that there should be members that are familiar with the research methods that are being proposed.[127] It is also now recognised that, in order to achieve a diversity of values and perspectives, and to counter any predisposition by institutional members towards research or institutional interests, the committee should be comprised not only of members drawn from the institution (in an institutional ethics committee), but also that there should be lay members. These members represent the community in which the research is to take place and also research participants.[128] In this regard, they are necessary to advance

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[120] Section 1, Article B- 1.3- Membership of REBs of the TCPS.
[121] Department of Health and Human Services. Protection of Human subjects. 1991; Title 45 CFR & 46.45 CFR 46.107.
[122] South Africa - Section 4.1 of *Ethics in Health Research: Principles, Structures and Processes* (Composition).
[123] NHREC, *National Code for Health Research Ethics* (2006), Section D.
[124] Section 3.
[125] Section 6 of the Department of Health, *Governance Arrangements for NHS Research Ethics Committees* London, UK: The Stationery Office, 2001.
[126] Chapter 5.1. 29 of the National Statement.
[127] See for instance, Canada - Section 1, Article B- 1.3 (TCPS)- Membership of REBs.
[128] See for instance, South Africa - Section 4.1 of *Ethics in Health Research: Principles, Structures and Processes* (Composition). Section 6 of the United Kingdom *Governance Arrangements for NHS Research Ethics Committees*, which requires that at least a third of the

dialogue with, and accountability to, local communities.[129] In the United Kingdom, at least a third of the membership is required to be "lay" members who are independent of the National Health Service (NHS), and whose primary personal or professional interest is not in a research area.[130] In Denmark, half of the regional committee is required to be drawn from lay members.[131] These may include non-medical clinical staff who have not practiced as such for at least five years, and at least half of the lay members must be persons who are not and have never been involved in carrying out research on humans.[132] In a hybrid governance framework, lay membership, that is, membership drawn from outside the institution, and from the community, enhances accountability and responsiveness. Inclusion of such members in ethics review is therefore beneficial.

Questions continue to be raised in the literature, however, regarding whether ethics review members should be part-time volunteers or dedicated

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membership should be "lay" members who are independent of the NHS, and whose primary personal or professional interest is not in a research area. These may include non-medical clinical staff who have not practiced as such for at least five years and at least half of the lay members must be persons who are not and have never been involved in carrying out research on humans.

[129] TCPS – Article 1.3 (see discussion).

[130] Section 6 of the *Governance Arrangements for NHS Research Ethics Committees*

[131] McNeill, supra note 103 at 102. Holm notes that, in practice, committees have between seven and fifteen members, each with a majority of lay members. The professional members are appointed by the Danish Health Sciences Research Council, and the lay members are appointed by the County Councils. He observes further that although the lay members are politically appointed, they do not represent their respective political parties in the REC and that the lay members are not usually lawyers, clergy or philosophers, but "true" lay people. Soren Holm, "The Danish Research Ethics Committee System—Overview and Critical Assessment in NBAC, *Ethical and Policy Issues in Research Involving Human Participants Commissioned Papers and Staff Analysis* (Washington: NBAC, 2001) at F-10.

[132] Section 6 of the *Governance Arrangements for NHS Research Ethics Committees.*

professionals,[133] the need for ethicists on ethics review committees,[134] the need for representation of research participants on ethics review committees,[135] and what lay membership really means, especially given that what is considered lay membership varies in each jurisdiction. Is a lay member merely one with no scientific expertise, or one with no connection to the institution?[136]

Questions also arise regarding the role that lay persons can and should play in the ethics review process, and whether or not lay persons can effectively contribute to the process, especially in the absence of a certain level of education and training in matters of research and research ethics.[137] Some commentators have suggested that lay persons on committees have difficulty in participating fully in the review process.[138] Others have observed that the roles of lay members need to be more clearly defined as they lack the authority or knowledge to challenge the interpretation of research by other knowledgeable

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[133]"Choosing a Research Ethics Committee System Amongst the Existing Models? Critical Decision of a Middle Income Country(Chile)" <http://www.gfbronline.com/PDFs/Eighth_Casestudy1.pdf> (September 14, 2009).

[134] Nathan Emmerich, "On the Ethics Committee: The Expert Member, the Lay Member and the Absentee Ethicist" (2009) 5:1 Research Ethics Review 9; Downie and McDonald, supra note 118.

[135] Hadskis, Michael, "Giving Voice to Research Participants: Should IRBs Hear From Research Participant Representatives?" (2007) 14: 3Accountability in Research 155; McNeill, supra note 103 at 7.

[136] Denise Avard, et al, "Research Ethics Boards and Challenges for Public Participation" (2009)17: 2-3 Health Law Review 66 at 67, describing the vagueness of the definition of lay membership in the Canadian TCPS. What is considered lay membership varies in each jurisdiction. In the United Kingdom, for instance, it is the persons who are not related to the NHS as employees or in a non-executive role, but they can be non-medical clinical staff who have not practiced their profession for five years. See Section 6 of the *Governance Arrangements for NHS Research Ethics Committees*. In South Africa, two lay persons are required. Lay persons are defined as who have no affiliation to the institution, are not currently involved in medical, scientific or legal work and are preferably from the community in which the research is to take place." Section 4.1 of the *Ethics in Health Research: Principles, Structures and Processes Guidelines*.

[137]Avard, ibid;

[138] McNeill, supra note 103 at 185-187.

and scientific members.[139] Lay persons are nevertheless needed to bring a balanced perspective to such reviews and reduce conflicts of interest. [140] Apart from lay participation, some jurisdictions require an ethics expert,[141] others require a lawyer,[142] while others underscore the desirability of gender balance in the composition of such committees.[143] Other related issues include provision of education and training for ethics review committee members in the different disciplines, methodologies, approaches, and ethical issues implicated in health research. There are more detailed discussions of these issues in other literature.[144] A fuller description and discussion in the context of Nigeria follows in Chapters Five and Six.

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[139] Sarah Dyer, "Rationalising Public Participation in the Health Service: The Case of Research Ethics Committees" (2004) 10 Health and Place 339. See also, P E Bauer, "A Few Simple Truths about Your Community IRB Members" (2001) 23 IRB 7.

[140] This need to reduce potential conflict of interest has been noted in the United States where the current requirement is that there be one non-institutional and one nonscientific member on a board, a requirement that can be met with the selection of one individual who meets both requirements. 45 CFR 46.107. The Office of the Inspector General has therefore recommended increased representation on IRBs of nonscientific and non-institutional members. Office of the Inspector General, *Institutional Review Boards: A Time for Reform* (Washington, D.C.: Department of Health and Human Services, 1998) at 17-18. In the Danish system, Holm notes that the lay majority works well. However, he adds that there may be little access to the required expertise in research methodology and may therefore have problems in evaluating certain kinds of projects. Holm, *supra* note 131. This lack of relevant expertise has also been noted in the United Kingdom. See Stauch *et al*, *supra* note 31 at 553. For this reason, I would not advocate a lay *majority*, especially in a developing country. However, there should be a good number of lay persons, by which I mean, persons with non-medical or scientific background or background in the kind of research being considered to bring a balanced perspective to ethics review.

[141] Canada - Section 1, Article B- 1.3- Membership of REBs.

[142] South Africa - Section 4.1 of *Ethics in Health Research: Principles, Structures and Processes* (Composition). See also Canada, ibid. The lawyer, however, is required only in the cases of biomedical research. The second edition, which is still under consultation, however, makes no distinction between biomedical and other types of research. Both editions state that the lawyer is not to give legal advice or serve as counsel to the committee but to address the legal issues that arise in connection with the proposed research.

[143] See the United States: 45 CFR 46.107;

[144] See generally McNeill, supra note 103, Hadskis, Michael, "Giving Voice to Research Participants: Should IRBs Hear From Research Participant Representatives?" (2007) 14: 3Accountability in Research 155; Raymond de Vries and Carl Forsberg, "Who Decides? A Look at Ethics Committee Membership" (2002) 14:3 HEC Forum 252; Henry B. Dinsdale, "The Composition of Research Ethics Boards" online: <http://www.chrcrm.org/main/modules/pageworks/index.php?page=015&id=231> (September

The structure of the ethics review system is another factor that impinges on the effectiveness of the ethics review process because it has implications for the integrity and independence of the system, and also for its efficiency. Two main types of structures of ethics review systems – the institutional system of ethics review or the regional system of ethics review exist. These may operate in a centralised or decentralised system. The institutional system of ethics review involves ethics review committees in different institutions in which health research takes place. The US model of Institutional Review Boards (IRBs) represents the pioneering approach of "local" review of research, that is, conducting review within the institutions in which the research will take place.[145] The strength of the institutional model lies, then, in the ease of conducting local review, taking into consideration the local context, values, and issues, including cultural issues.

Regulation, as provided by institutional ethics review committees is, effectively, self-regulation.[146] In this respect, institutional committees are typically composed of a majority of members who are drawn from the

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9, 2009); Sohini Sengupta & Bernard Lo, "The Roles and Experiences of Non-affiliated and Non-scientist Members of Institutional Review Board" (2003) 14 Academic Medicine 212; Emily E. Anderson, "A Qualitative Study of Nonaffiliated, Non-scientist Institutional Review Board Members" (2006) 13 Accountability in Research 135; Joan P. Porter, "How Unaffiliated /Non-scientist Members of Institutional Review Boards See Their Roles" (1987) 9:6 IRB: Ethics & Human Research 1; C.A. Schuppli & D. Fraser, "Factors Influencing the Effectiveness of Research Ethics Committees" (2007) 33 Journal Medical Ethics 294; P E Bauer, "A Few Simple Truths about Your Community IRB Members" (2001) 23 IRB 7; Denise Avard, Michèle Stanton- Jean, Roberta L. Woodgate,. Daryl Pullman & Raphael Saginur "Research Ethics Boards and Challenges for Public Participation" (2009) 17: 2-3 Health Law Review 66.

[145] "Choosing a Research Ethics Committee System amongst the Existing Models? Critical Decision of a Middle Income Country(Chile)" <http://www.gfbronline.com/PDFs/Eighth_Casestudy1.pdf> (September 14, 2009).

[146] For the advantages of self-regulation, see generally, Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (New York: Oxford University Press, 1992) at 103.

institutions. Institutional ethics review committees, with many members from the institution, typically have members with expertise in different fields and in methodologies that may be used in health research. And, as mentioned above, they can conduct review taking into account the local context, values and issues, including cultural issues. Also, institutional ethics review committees can closely monitor ongoing studies.[147] Further, an institutional system makes it easier to locate the responsibility for ethical review close to where the research is conducted. [148]

However, many committees are funded by the institutions within which they operate. The institutions themselves frequently depend on research funding from external sources. Inherent conflict of interest issues thus arise from a structure where the institution which seeks to attract research is in some ways the same institution which will review the research, albeit through an ostensibly independent ethics committee.[149] Members of ethics review committees, even in the absence of financial conflict of interest, may have secondary interests, such as approving research in their own area of specialty or disapproving research which may draw research participants from their own research.[150]

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[147] Ayres and Braithwaite, ibid at 104, noting that self-regulation can achieve greater inspectorial depth.

[148] M H Walsh, J J McNeil JJ, K J Breen, "Improving the Governance of Health Research" (2005) 182 Med J Aust 468.

[149] Ezekiel J Emmanuel *et al*, "Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals" (2004) 141: 1 Annals of Internal Medicine 282 at 283. In these countries, ethics review committees can also be independent from the institutions and provide ethics review in exchange for payment.

[150] Eric Campbell, "Concerns about IRBs in the Enterprise of Clinical Research" (2004) 4 Lancet Oncology 326. Downie describes these situations comprehensively and succinctly in the Canadian context. See

Thus, the possibility of regulatory capture increases significantly under the institutional system of ethics review. In this respect, the direct regulators of research, that is the ethics review committees, may be directly or indirectly interested in attracting research funds to the institution. Such interest creates a greater possibility of capture by the researchers and research sponsors whom they are supposed to regulate. The inherent conflicts of interest issues arising from self-regulation in the context of institutional systems of ethics review, thus calls into question the independence of committees. Actual, potential or perceived conflict of interest permits regulatory capture. This not only endangers the safety of participants, it has the potential of marring the promotion of health research by eroding public confidence and trust in the research process.

A regional ethics review committee, on the other hand, is a model of committee review that is not based solely at the local institutional level, such as in a hospital or in a university. These broader regional systems are typically responsible for "a distinct region, a distinct group of research subjects, a distinct disease, or projects related to a distinct funding agency."[151] A country may, therefore, have institutional committees, but also specialised regional committees that review specialised research.[152] Other countries, like Denmark,[153]have regional systems which are typically responsible for a distinct

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Jocelyn Downie, "Contemporary Health Research: A Cautionary Tale" (2003) Health Law Journal (Special Edition) at 12.

[151] Alison Shea, "Regional Research Ethics Boards: Canadian and International Models" (2004), online: via < www.nshrf.ca> (June 23, 2007) at 3.

[152] For example, Canada. Shea, ibid.

[153] And other Scandinavian countries, like Sweden and Norway.

region and all the research conducted in that region are reviewed by one regional committee.

The regional model, as employed in countries like Denmark,[154] would appear to be free from the criticisms of the institutional model because members are drawn region-wide and there is less likelihood of the conflict of interest issues arising in the context of the institutional model. As has been argued in detail elsewhere the "local context" is not lost by regionalization.[155] As well, there may be more balance between local insight and the necessary distance from personal prejudice. Riis has therefore noted that, "It is more appropriate – and a clear advantage for countries having the chance to start from scratch – to create a *regional* system instead of an institutional one from the very beginning." [156] Where appropriately set up, a regional system may be more manageable and efficient and ensure more uniformity of standards and thus more protection of research participants. This is because there will be less ethics review committees and less chance of duplication and inconsistency in reviews.

Both institutional and the regional committees may operate in a centralised or decentralised atmosphere, or in a dual system that combines both.[157] A centralised system,[158] consisting frequently of a national committee,

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[154] The regional model is also employed in other Scandinavian countries: Sweden and Norway. See European Network of Research Ethics Committees (EUREC), "National Information: Sweden" online: <http://www.eurecnet.org/information/sweden.html> (September 11, 2009).
[155] Downie, *supra* note 150 at 93-94.
[156] Povl Riis, "Ethical Review of Biomedical Research in Europe: Suggestions for Best National Practices" (1998), online: < http://www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/Activities/Biomedical_research/CDBI-INF(1998)6E-ManualDebra.pdf> (June 22, 2007) at 4.
[157] Maureen H. Fitzgerald and Paul A. Phillips, "Centralized and Non-Centralized Ethics Review: A Five Nation Study" (2006)13 Accountability in Research 47.

is recommended by some commentators to address issues which institutional or regional committees may be inadequate to deal with. These include the increase in applications for review and multi-site or multi-jurisdictional research and the need to ensure faster, more efficient, consistent, ethics review processes, the need to ensure co-ordination between different institutional or regional ethics review committees, and standardisation of the ethics review process.[159] The functions of auditing ethics review committees and providing guidelines and standards, hearing appeals from the local committees which national ethics review committees typically have, are helpful in creating a uniform system of research governance with clear reporting relationships and accountability. Such national committee would essentially provide what Ayres and Braithwaite call "enforced self-regulation"[160] or regulation of self-regulation. In other words, institutional or regional committees may develop their own policies and function independently. A national or central committee would serve as an "enforcer," monitoring institutional or regional committees to ensure that they function as

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[158] Fitzgerald and Philips describe a centralised system: "In the centralized system all applications, other than possibly undergraduate research, would go to a centralized committee or an overarching national body, and the review process would be conducted by committees associated with and administered by this body. In this system, the committee that reviews the application may or may not be located within the geographical region where the researcher is located. " See Fitzgerald and Phillips, ibid at 63.

[159] See Walsh MH, McNeil JJ, Breen KJ, "Improving the Governance of Health Research" (2005) 182 MJA 468 at 470; Z J Penn and P J Steer, "Local Research Ethics Committees: Hindrance or Help?" (1995) 102 Br J Obstet Gynaecol 1-2; Department of Health, *Ethics Committee Review of Multi-centre Research* (London: Department of Health, 1997); Blunt, J., Savulescu, J., and Watson, A. J. M. (1998). Meeting the challenges facing research ethics committees: Some practical suggestions, *British Med J*, 316: 58–61; Maureen H. Fitzgerald and Paul A. Phillips, "Centralized and Non-Centralized Ethics Review: A Five Nation Study" (2006)13 Accountability in Research 47. D C Whiteman, PM Webb, D M Purdie, and AC Green, "National Ethics Committee Urgently Needed" (2003) 178 MJA 187. M C Christian, al. "A Central Institutional Review Board for Multi-Institutional Trials. (2000) 346 N Engl J Med 1405.

[160] Ayres and Braithwaite, supra note 147.

required. Some commentators have, however, suggested that centralised systems may exacerbate the burden on researchers and ethics committees by adding another level of bureaucracy, and that their effectiveness has yet to be determined.[161]

It is uncommon for countries to run a fully centralised system, in which all administrative systems and review activities are centralised.[162] It is more common for countries to operate either a dual system or a decentralised system. Thus, some developed countries like Denmark, and developing countries like Nigeria and South Africa operate a dual system and therefore have a national ethics review committee. The national ethics review committee may, amongst other things, audit the institutional committees (in the case of Nigeria and South Africa) or regional committees (as in Denmark), act as an appeal body, and also review some types of research. [163] Similarly, others like the United Kingdom and New Zealand operate a dual system, with multiregional and institutional committees and a central committee that vets multisite research protocols (in the case of New Zealand) and a committee for ensuring co-ordination between the different regions (in the case of the United Kingdom).[164]

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[161] Davina Ghersi, ``Research Ethics Committees and the Changing Research Environment`(2005) 5 Lancet Oncology 325;K Alberti, "Multicentre Research Ethics Committees: Has the Cure Been Worse Than the Disease?" 320 (2000) BMJ 1157–58.

[162] Fitzgerald and Philips, cites the example of Tasmania in Australia. Some developing countries until recently also had systems where research was reviewed by the national ministry of health and which could thus be considered a centralised system. See Fitzgerald and Philips, supra note 157.

[163] Denmark has a national ethics review committee: the Danish National Committee on Biomedical Research Ethics. See section 24 of the Act for its functions. See also online: <http://www.cvk.sum.dk/CVK/Home/English.aspx> (June 21, 2009), see also Holm, *ibid.* Sweden operates a similar system. See EUREC, supra note 154.

[164] In the United Kingdom, there is no one national ethics committee that undertakes research review as in the three countries discussed above. Instead, there is a centrally-administered system of regional ethics committees that operate within the framework of the NHS assess any

However, some countries with institutional committees, such as Australia,[165] Canada[166] and the United States,[167] although there may be certain specialised ethics review committees, operate in a mostly decentralised atmosphere with the institutional ethics review committees reporting only to their home institutions and multisite or multi-centre research is reviewed by different institutional committees. What is clearly important is that whatever structure chosen should be one that is geared to meet the goals of ethics review and of research governance namely: to protect research participants and to promote socially beneficial research.

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research on humans that uses NHS patients, resources, or that accesses participants through the NHS. Local Research Ethics Committees are established under the Health Authorities and review research proposals according to where the research is due to take place. The National Research Ethics Service launched on 1 April 2007 supersedes the Central Office of Research Ethics Committees (COREC) and takes over COREC's responsibility of coordinating RECs and providing operational support and advice to the RECs. Further, the United Kingdom Ethics Committee Authority (UKECA) is responsible for establishing, recognizing, accrediting and monitoring ethics committees in the United Kingdom in accordance with the Clinical Trials Regulations and allows them to review clinical trials applications. The United Kingdom, with its current system of "recognized" and "authorized" ethics committees would appear to be somewhat complicated as opposed to the simple and, perhaps, more efficient regional model in Denmark with the eight regional RECs and the national ethics review committee. A Hedgecoe, *et al*, "Research Ethics Committees in Europe: Implementing the Directive, Respecting Diversity" (2006) 32 JME 484. See generally, Maureen H. Fitzgerald and Paul A. Phillips, "Centralized and Non-Centralized Ethics Review: A Five Nation Study" (2006)13 Accountability in Research 47.

[165] In Australia, HRECs function within institutions. Although it also has a national ethics committee, the Australian Health Ethics Committee (AHEC), a principal committee of the NHMRC, this does not act as a national ethics review committee as in South Africa, Nigeria and Denmark. AHEC is established under sections 35 and 36 of the *National Health and Medical Research Council Act* 1992 and is required to oversee the operation of the HREC system. (National Statement 1999 Principles 2.46–2.48). AHEC does not act as an overall review body and does not audit HRECs or review particular projects like the NHREC in Nigeria. Further, it has no power to impose sanctions on non-compliant HRECs or researchers.

[166] In Canada, REBs operate within individual institutions such as universities and within Health Canada. There is no national ethics review committee. Newfoundland has set up its own Health Research Ethics Authority for Newfoundland and Labrador which appoints an REB and approves other research ethics bodies. Some REBs also function on a regional basis such as the Ontario Research Cancer Board. See Downie and McDonald, *supra* note 118 at 6. Section 3 (1), 7 and 8 of the NewFoundLand Health Research Ethics Authority Act, 2006. See Alison Shea, "Regional Research Ethics Boards: Canadian and International Models" (2004), online: via < www.nshrf.ca> (June 23, 2007) at 4.

[167] In the United States, IRBs operate within institutions. The *National Research Act* 1974 requires each institution conducting federally supported research involving human subjects to establish an IRB to review the ethical aspects of all research protocols within the institution.

Ethics review systems can be costly, including expenditures for documentation, necessary equipment, training, project monitoring and site visits. They must therefore have adequate financial support. Denmark stands out from the other jurisdictions in detailing in law a system of funding for ethics review committees within its legislation.[168] In this regard, McDonald and Downie note that:

> Funding for administrative support is important to facilitate the smooth running of the committee and to allow the members to concentrate on protocol review. It also allows review bodies to access additional support or expertise, for example, if considering a particularly complex or emerging issue. For researchers, it may affect the speed of the review process. For the public, it may affect the adequacy of the review and consequently the safety of the project.[169]

With the notable exception of Denmark, many countries do not legally require that ethics review committees be provided with adequate funding to carry out their work. It is obvious that a lack of funding and administrative support jeopardise the protection of participants with which ethics review committees are charged. Given the paucity of resources in developing countries, this issue is of particular concern.

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[168] *Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects* 2003 (as amended)online: <http://www.cvk.sum.dk/English/actonabiomedicalresearch.aspx> (November 6, 2009), section 28.

[169] Downie and McDonald, supra note 118 at 24.

With regard to developing countries, the concept of ethics review, while relatively new in many such countries,[170] is rapidly gaining ground.[171] While some developing countries have a relatively long history of ethical review of studies involving human participants,[172] some earlier studies noted the absence of ethics review committees in some countries.[173] In 2001, for instance, the Regional Committee for Africa of the World Health Organization (WHO) pointed out that about a quarter of the studies involving humans in the Africa Region were not subjected to ethics review.[174] Other studies undertaken by the NBAC on research in developing countries found that some research undertaken by researchers from the United States in developing countries had not undergone

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[170] Zulfiqar A. Bhutta, "Building Capacity for Ethical Review in Developing Countries" (June 2004) SciDevNet, online: <http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&dossier=5&policy=53> (October 15, 2007).

[171] See Chapter One. See also, A. Nyika et al, Composition, Training Needs and Independence of Ethics Review Committees across Africa: Are the Gate-Keepers Rising to the Emerging Challenges?" (2009) 35 J Med Ethics 189.

[172] These include countries like South Africa.

[173] Cheryl Cox MacPherson, "Research Ethics: Beyond the Guidelines" (2001) 1 Developing World Bioethics 57–68, noting that some Caribbean countries lacked ethics review committees. See Alimuddin Zumla and Anthony Costello, "Ethics of Healthcare Research in Developing Countries" (2002) 95: 6 Med. J R Soc 275, noting that Myanmar and Laos did not have functional ethics review committees as recently as 2002. See also, K. Ahmad, "Developing Countries Need Effective Ethics Review Committees" (2003) 362 Lancet 2003 627–628.

[174] A A Hyder et al, "Ethical Review of Health Research: A Perspective from Developing Country Researchers" (2004) 30 Journal of Medical Ethics 30. J. Kiriga, C. Wambebe and A. Baba-Mousa, "Status of National Bioethics Committees in the WHO African Region" (2005) 6 BMC Med Ethics E10, online: BMC < http://www.biomedcentral.com/1472-6939/6/10> (April 3, 2007). Ruth Macklin, *Double Standards in Medical Research in Developing Countries* (Cambridge: Cambridge University Press, 2004) at 150-151, with two examples of studies conducted by US researchers in developing countries, for which no ethics approval was obtained. In another study, a little less than 90 percent of published clinical trials conducted in 2004 did not report having undergone ethics review. D Zhang et al, "An Assessment of the Quality of Randomized Controlled Trials Conducted in China" (2008) 9 Trials 22. See also, Abbas, E E "Industry-Sponsored Research in Developing Countries" (2007) 28: 6 Contemporary Clinical Trials 677.

any ethics review in the host countries.[175] But, as discussed in Chapter One, with the establishment of some form of ethics review and sometimes even formalized national systems, this situation seems to be changing in many developing countries, including African countries. Increasingly, studies are now being undertaken of the functioning of ethics review committees in developing countries.[176]

However, as important as ethics review and ethics review committees clearly are in research governance, and even as many ethics review committees are being developed in developing countries, they face many challenges. Ensuring adequate ethical review is crucial. Requiring ethics review of research protocols and establishing ethics review systems, while steps in the right direction, do not, by themselves, ensure that the risks attendant to

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[175] See also, Nancy Kass and Adnan Hyder, "Attitudes and Experiences of US and Developing Country Investigators Regarding US Human Subjects Regulations" in NBAC volume 2, supra note 131 at B-103. Hyder et al, NBAC volume 2, supra note 131 at 69.

[176] Examples of recent studies on ethics review committees in developing countries include: Jonathan Camp et al, "Challenges Faced by Research Ethics Committees in El Salvador: Results from A Focus Group Study" (2009) 9:1 Developing World Bioethics 11; P. Effa, A. Massougbodji, F. Ntoumi, "Ethics Committees in Western and Central Africa: Concrete Foundations" (2007) 7 Developing World Bioethics 136; ; J.K.B. Ikingura, M. Kruger and W. Zeleke, "Health Research Ethics Review and Needs of Institutional Ethics Committees in Tanzania" (2007) 9: 3 Tanzania Health Research Bulletin 154; D. Elsayed and Nancy Kass, "Assessment of the Ethical Review Process in Sudan" (2007) 7: 3 Developing World Bioethics 148; Nancy Kass *et al*, "The Structure and Function of Research Ethics Committees in Africa: A Case Study" PLoS Med 4:1:e3; Milford, Cecilia, Wassenaar, Douglas and Slack, Catherine, "Resources and Needs of Research Ethics Committees in Africa: Preparations for HIV Vaccine Trials" (2006) 28: 2 IRB: Ethics & Human Research 1; J.M Kirigia, C Wambebe, and A Baba-Mousa, "Status of National Research Bioethics Committees in the WHO African Region(2005) 6 BMC Med Ethics 10; D. Elsayed, "The Current Situation of Health Research and Ethics in Sudan" (2004) 4 Developing World Bioethics 154–159; A Hyder, S. Wali, A Khan, N Teoh , N Kass, et al. "Ethical Review of Health Research: A Perspective from Developing Country Researchers" (2004) 30 J Med Ethics 68–72; B. Arda, "Evaluation of Research Ethics Committees in Turkey" (2000) 26 J Med Ethics 26: 459– 461;; R Rivera and E Ezcurra, "Composition and Operation of Selected Research Ethics Review Committees in Latin America" (2000) 23 IRB 9–12; R. Coker and M McKee, "Ethical Approval for Health Research in Central and Eastern Europe: An International Survey" (200) 1 Clinical Medicine 197–199; WHO South East Asian Regional Office, *Ethics in Health Research*, (New Delhi: World Health Organization, 2001).

health research involving humans are completely eliminated or even minimised in the face of inadequate structures or reviews.

Thus, as the amount of research conducted in the developing world increases, concerns have also arisen with regard to the existence, functioning, effectiveness and independence of ethics review committees in developing countries. Studies have suggested that some research conducted by indigenous researchers did not undergo ethics review.[177] Other studies have suggested that even where conducted, ethics review may not be rigorous, due to lack of capacity and infrastructure. Recent studies have thus identified problems, including lack of standardization, insufficient funding, inadequate facilities and equipment for work, understaffing[178] imbalance in composition,[179] conflict of interest, lack of transparency, and inadequate training and capacity to review research,[180] inadequate or non-existent post-approval monitoring systems,[181] as well as inactivity in the ethics review committees in developing countries.[182] Given such issues as possible political interference, the understandable yet inappropriate desire of some committees to attract funding and other perceived

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[177] Kass and Hyder, *supra* note 175 at B-109. Elsayed and Kass, ibid. at 148.
[178] J.K.B. Ikingura, M. Kruger and W. Zeleke, "Health Research Ethics Review and Needs of Institutional Ethics Committees in Tanzania" (2007) 9: 3 Tanzania Health Research Bulletin 154.
[179] Keymanthri Moodley and Landon Myer, "Health Research Ethics Committees in South Africa 12 years into Democracy" (2007) 8 BMC Medical Ethics 1.
[180] See Milford *et al, supra* note 5. See also, Nancy Kass *et al*, "The Structure and Function of Research Ethics Committees in Africa: A Case Study" PLoS Med 4:1:e3, online: <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040003> (May 3, 2009).
[181] Kass and Hyder, *supra* note 163 at B-109.
[182] "A Rapid Assessment of Strategic Information Systems for Lesotho's HIV/AIDS Programme" (June, 2005)
online:
<http://www.rhap.org.za/resources/240.pdf?PHPSESSID=c765d08831c119ea0b51da8863412bf2> (April 11, 2008) at 40, noting the inactive state of the ethics review board.

benefits to the community from proposed research projects, ad-hoc establishment of committees to satisfy foreign requirements,[183] and the dependence of some ethics review committees on foreign funding for meeting routine costs, the independence of ethics review committees in developing countries has also been questioned.[184]

In the African context, a recent study on the structure and function of ethics review committees found that conflicts of interest arose in the context of reviewing the protocols of departmental colleagues and protocols which would bring money into the institutions. In such cases, questions were sometimes not raised to allow the projects to proceed quickly.[185] Given the paucity of resources in institutions in such countries, the likelihood of conflict of interest and the harm that could result from such conflict are amplified. Such conflict of interest issues would affect the independence of the committee and consequently the protection of participants with which the committee is charged. Some commentators therefore argue against the wholesale adoption of the institutional models operated in some developed countries.[186] The alternative would be for developing countries to consider their circumstances and study different systems around the world to determine if a regional model would work better in their specific contexts.

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[183] See Kass and Hyder, *supra* note 314 at B-108.
[184] Nuffield Council on Bioethics, *supra* note 5 at 104-106; Macklin (2004), *supra* note 17; Lavery, *supra* note 19 at 233-237.
[185] Nancy Kass *et al*, "The Structure and Function of Research Ethics Committees in Africa: A Case Study" PLoS Med 4:1:e3.
[186] Carl H. Coleman and Marie Bousseau, "Strengthening Local Review of Research in Africa: Is the IRB Model Relevant?" (2006), online: <http://www.bioethicsforum.org/ethics-review-of-medical-research-in-Africa.asp> (June 22, 2007).

Many of these recent studies also point to the need for more studies to identify better the problems that ethics review committees face, including, for example, what the costs of running an effective ethics review committee are, and the training needs of ethics review committees.[187] In one study in Sudan, it was found that ethical reviews were carried out mainly as part of the requirements for obtaining funding from international agencies, and that some of the researchers could not explain what an ethics review committee was.[188] It is, therefore, crucial to determine why more ethics review committees are being established in developing countries and how this might affect independent, effective, ethics review in such countries. For instance, some commentators have pointed out that, "It is generally felt that collaboration with international research centres or with industry will remain closed to African researchers until appropriate structures for the ethical review of clinical trials are in place and functioning on the national level."[189] Are these new ethics review systems being developed, therefore, merely to satisfy foreign requirements and attract research funding? It is also essential to consider how recent developments in research governance in developing countries affect the structuring of the system of ethics review committees, the composition of the committees, the process of appointing members into the committees, the functions of the committees, the adequacy of their powers and authority and, ultimately, their effectiveness in

[187] Nyika et al, supra note 171 at 191-3.
[188] D. Elsayed and Nancy Kass, "Assessment of the Ethical Review Process in Sudan" (2007) 7: 3 Developing World Bioethics 143.
[189] P. Effa, A. Massougbodji, F. Ntoumi, "Ethics Committees in Western and Central Africa: Concrete Foundations" (2007) 7 Developing World Bioethics 136.

carrying out their assigned functions. I consider these issues in more detail in the context of Nigeria in subsequent chapters.

In sum, however, ethics review is a central and critical component of research governance. In the foregoing pages, I have considered its uses and some of the systemic issues that arise generally, and specifically in developing countries.

3.3.2 National Drug Regulatory Agencies

National drug regulatory agencies or authorities are institutions that protect public health through regulating the efficacy and safety of drugs consumed by people, implementing legislation, generating rules, and developing enforcement strategies with regards thereto. They are typically a national creation, established by legislation. Their functions are usually dictated by the statute that establishes them. These functions may include developing appropriate standards for the manufacture, import, supply, promotion and use of drugs. Their functions may also include facilitating access to drugs, inspection of manufacturing facilities and distribution channels and monitoring adverse drug reactions. More relevant for the purpose of this thesis, national drug regulatory authorities typically evaluate the safety of clinical trials.[190]

Thus, with specific regard to research governance, drug regulation and drug regulatory authorities are an important component because the drug development process requires that new drugs be tested on human beings in

[190] Andy Gray, *Resource Guide on Drug Regulation in Developing Countries* (London: DFID Health Systems Resource Centre, 2004), online: <www.dfidhealthrc.org/publications/atm/Gray.pdf> (September 19, 2009).

clinical trials prior to approval for general use.[191] Clinical research poses risks and must therefore be regulated. Such regulation is usually undertaken by a national regulatory authority, pursuant to domestic legislation and regulations. These detail legal requirements for the conduct of clinical trials, and typically include Good Clinical Practice (GCP) requirements, such as ethics review approval, recruitment requirements, consent procedures, the qualifications of investigators and the duties of sponsors. The duties of sponsors include reporting of adverse reactions to an intervention during a clinical trial to ethics review committees and the regulatory authority.[192] These requirements aim to ensure that clinical trials are credible and that research participants are protected.[193]

All functions relating to drug regulation may come under a single agency[194] which may or may not be part of a country's department or ministry of health.[195] Whether or not it is an independent agency is a significant factor because "if a national drug regulatory authority (DRA) is an arm of an existing

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[191] These clinical trials are typically conducted in four phases, with each phase consisting of testing in increasing number of humans. Supornchai Kongpatanakul and Brian L. Strom, "Pharmacoepidemiology and Drug Evaluation," in Chris J. Van Boxtel, Budiono Santoso, and I. Ralph Edwards, (eds.), *Drug Benefits and Risks: International Textbook of Clinical Pharmacology* (Second Edition) (Amsterdam: IOS Press, 2008) at 30.

[192] The ICH-GCP has been adopted in many countries around the world. See Segev Shani and Zohar Yahalom, "The Role of the Pharmaceutical Industry in Disseminating Pharmacovigilance Practice in Developing Countries" (2008) 63 Food & Drug L.J. 701 at 709; Krishan Maggon, "Investigator and site selection and performing GCP clinical studies in India" (2004) 25 Controlled Clinical Trials 366; Hirtle, supra note 81.

[193] Robert H Rowland, "How Are Drugs Approved? Part 3. The Stages of Drug Development" (2008) 46: 3 Journal of Psychosocial Nursing 17 at 18.

[194] Nigeria – National Agency for Food and Drug Administration and Control; South Africa – Medicines Council; and United States – Food and Drug Agency.

[195] Australia – Therapeutic Goods Administration (Department of Health and Ageing); United Kingdom (Medicines and Healthcare Products Regulatory Agency – a part of the Department of Health) and Canada (Therapeutic Products Directorate, Health Canada). In many African countries, such as Ghana, Botswana, Uganda, Kenya and so on, the Ministry of Health conducts review of clinical trials.

ministry, its director may not be able to make major policy decisions on his/her own. It may well be that many drug regulation activities are carried out by another agency with overlapping jurisdictions and functions."[196]

However organised, the role of national regulatory authorities is essential, especially in light of the fact that the interests of the pharmaceutical companies which usually sponsor clinical trials for new drugs may sometimes diverge significantly from the interests of those who participate in research, public health, and public interests.[197] National regulatory authorities regulate the procedures for the commencement and the implementation of clinical trials. These authorities monitor the clinical trial process, with the aim of not only ensuring the safety of medicines but the safety of trial participants. These authorities typically have to give approval before the commencement of clinical trials.[198] Drug regulatory authorities may also regulate the manner in which ethics review committees operate in regard to review of clinical trials.[199] They may also conduct inspections of trials to ensure that appropriate safety and ethical standards are maintained. They are also usually required to maintain records of clinical trials data submitted by research sponsors.

Several systemic issues arise with respect to the governance of drug research involving humans, mostly revolving around the effectiveness of such

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[196] WHO, *The World Medicines Situation* (Geneva: World Health Organisation, 2004), at 14.
[197] John Abraham, "The Pharmaceutical Industry as a Political Player" (2002) 360 Lancet 1498 at 1500.
[198] See for instance, United Kingdom - MHRA, "Medicines and Medical Devices Regulation: What You Need to Know" online: <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf> (September 18, 2009).
[199] See Trudo Lemmens, "Federal Regulation of REB Review of Clinical Trials: A Modest But Easy Step Towards An Accountable REB Review Structure in Canada" (2005) 13: 2 and 3 Health Law Review 39.

authorities in carrying out their mandate, including the protection of research participants. Whether or not drug regulatory authorities in a given country play a sufficiently active role in research governance is dependent on such factors as sufficient political and legislative support; the possibility of regulatory capture of national regulatory authorities by some interested parties; funding of such agencies; the relationship of the national drug regulatory authorities and the other interested stakeholders such as the department of health, or any other related governmental body such as a national ethics body and the ethics review committees; and how well they regulate sponsors of clinical trials and ethics review committees; in relation to clinical trials of drugs and devices.

With regard to developing countries, as already pointed out in Chapter One, a dramatic increase in research in these countries, especially clinical trials conducted by multinational pharmaceutical companies, has been noted.[200] Amidst the advantages for multinational pharmaceutical companies of cost reduction, shorter timelines for testing, and the availability of a greater number of treatment-naïve participants and, very significantly, lesser regulatory hurdles, questions have arisen about the possible exploitation of research participants in developing countries.

The work of drug regulatory authorities in developing countries is therefore becoming even more essential with respect to providing a system for the availability of safe drugs, while ensuring the safety of research participants

[200] See Chapter One, section 1.6. See also, Sarita Rai, "Drug Companies Cut Costs with Foreign Clinical Trials" *New York Times*, February 24, 2005, online: <http://www.nytimes.com/2005/02/24/business/24clinic.html> (September 19, 2009). Seth W Glickman et al, "Ethical and Scientific Implications of the Globalization of Clinical Research" (2009) 360:8 New England Journal of Medicine 816.

in this era of globalisation. Yet a WHO study found several limitations in regulatory authorities in developing countries, noting that a good number lacked well-developed drug regulation capacity.[201] Drug regulatory authorities in developing countries face many challenges including, "operating in an environment with insufficient political support, resulting in inadequate legislative mechanisms, inadequate financial resources, inconsistent application processes and corruption of an appropriate regulatory culture."[202]

In addition to inadequate political and legislative support, drug regulatory authorities in developing countries frequently lack sufficient resources as well as access to the high levels of scientific expertise necessary for the effective assessment or registration of drugs.[203] Indeed many developing countries' drug agencies, in addition to charges to pharmaceutical companies,[204] depend on foreign aid in order to function.[205] The limited resources available have to be expended to attend to other problems with which developing countries are besieged, including limiting supplies of counterfeit drugs.[206]

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[201] WHO, *Use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce* (Geneva, World Health Organization, 1995) quoted in the *World Medicines Situation*, supra note 196 at 94.
[202] Suzanne Hill and Kent Johnson, "Emerging Challenges and Opportunities in Drug Registration and Regulation in Developing Countries" (2004) DFID Health Systems Resource Centre, online: <http://www.dfidhealthrc.org/publications/atm/Hill.pdf> at 40.
[203] Ibid.
[204] Ibid, at 14. See also, Warren A Kaplan and Richard Laing, "Paying for Pharmaceutical Registration in Developing Countries" (2003) 18: 3 Health Policy and Planning 237.
[205] See, for instance, Charles Wendo, "Uganda's Drug Regulatory Agency Faces Financial Crisis" (2001) 358: 9280 Lancet 482.
[206] Which is a cause of concern given that there are little or no restraints to purchasing drugs and many (if not all) drugs can be bought over the counter Kongpatanakul and Strom, supra note 192 at 33. See also, Shani and Yahalom, supra note 192

Drug approval processes in developing countries also tend to be less sophisticated than in developed countries.[207] The inadequacies of developing countries have serious implications in light of the increase in clinical trials exportation by multinational pharmaceutical companies. The financial power and influence of multinational pharmaceutical companies, the resource constraints of developing countries, and dependence on user fees to maintain regulatory processes make regulatory capture a serious concern in the context of these countries.[208]

Some have therefore argued that developing countries when considering applications for new drugs, should, and in many cases do,[209] rely on the assessments of drug regulatory authorities in developed countries, including those in the Europe and the United States.[210] Others have argued for more regional co-operation between developing countries. Examples of poorly studied drugs exist, indicating that mere reliance on drug approval processes in developed countries does not always guarantee the safety of drugs.[211] Further, such arguments while relevant and helpful in the promotion of drug research in developing countries provide little help with respect to how to effectively protect research participants, a clear responsibility of drug regulatory authorities.

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[207] Drug regulatory authorities in developed countries are often only required to consider the quality of clinical trial data and the safety of drugs entering their domestic markets. Thus, they typically have little information on the manner of research conducted in developing countries, whether ethical or unethical.Glickman, supra note 200 at 818.

[208] See John Abraham, "The Pharmaceutical Industry as a Political Player" (2004) Lancet, discussing the regulatory capture by pharmaceutical companies in the context of the United States. See also, Hill and Johnson, supra note 202.

[209] Shani and Yahalom, supra note 182 at 709.

[210] Gray, supra note 182 at 2. Piero L. Olliaro et al, "Drug Studies in Developing Countries" (2001) 79:9 Bulletin of the World Health Organisation 894.

[211] See the example of Norplant described in *The World Medicines Situation*, supra note 196 at 99.

In sum, drug regulatory authorities are a crucial part of the governance of research involving humans because they directly regulate clinical trials. In subsequent chapters we focus on the specific systemic issues that arise with respect to their work in Nigeria.

3.3.3 Policymaking Structures

Other institutions involved in the governance of research are what could be considered as domestic policymaking structures. These may be government departments or ministries of health. Thus, in the United Kingdom for example, the Department of Health has created the major policy guidance - *Research Governance Framework for Health and Social Care*[212] – which governs research conducted under the National Health Service.

Apart from government departments, the policymaking structure may be a national ethics review committee with a mandate to provide research ethics policy, as well as an ethics review function as, for example, in Nigeria. The policymaking structures may also be a national policymaking body specifically established for that purpose, which may or may not have a statutory base, and may or may not have direct regulatory functions.[213] Thus, for instance, in Australia, the Australian Health Ethics Committee (AHEC), established under the *National Health and Medical Research Council Act* 1992

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[212] Department of Health, *Research Governance Framework for Health and Social Care* (Second Edition) (United Kingdom, 2005), online: <http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4122427.pdf> (June 19, 2009), Section 1.1.

[213] For instance, national ethics review committees may audit and accredit local committees, but also make national guidelines, thus combining regulatory and policy making functions.

is mandated to issue guidelines for human research.[214] In South Africa, the National Health Research Ethics Council has a clear policy-making role as well. It has the mandate to determine guidelines for the functioning of health research ethics committees and set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials.[215] In Canada, the Interagency Advisory Panel on Research Ethics, created by the three major federal funding agencies helps develop, interpret and implement the *Tri-Council Policy Statement on Research on Ethical Conduct of Research Involving Humans*, Canada's major research ethics policy.[216] While it has a direct role in policy-making, preparing draft policies with input from various stakeholders, it is not independent from the government funding agencies, which have the final say on the policies.

These policy structures may be active policymaking bodies in the sense that they have the mandate to devise or create policies that govern health research involving humans and other areas of bioethics. The policies made either by these bioethics policy bodies or government ministries of health may have a direct impact on the way research is conducted and regulated. However, there may also be national bioethics advisory councils or commissions, whose

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[214] Section 35 (3) (b). According to Dodds and Thomson, "Other than the specific reference to medical research involving humans, there is no provision relating to the sources from which AHEC can derive issues for its work. AHEC can be said, then, to have a specific responsibility to develop national policy governing. Susan Dodds and Colin Thomson, "Bioethics and Democracy: Competing Roles of National Bioethics Organisations (2006) 20:9 Bioethics 326 at 330.

[215] National Health Research Ethics Council, online: <http://www.doh.gov.za/nhrec/index.php> (October 29, 2009). Other advisory bodies include the Belgian Advisory Committee on Bioethics, the Finnish National Advisory Board on Health Care Ethics, the French National Consultative Ethics Committee for Health and Life Sciences, and the Portuguese National Council of Ethics for the Life Sciences. See Dodds and Thomson, ibid at 329.

[216] Panel on Research Ethics, "About Us: Terms of Reference" online: <http://pre.ethics.gc.ca/eng/panel-group/about-apropos/reference> (October 15, 2009).

impact on research governance may be more indirect and limited. These advisory councils or commissions are typically mandated to make policy recommendations to the government, including policies and guidelines on research involving humans. Acting in such an advisory capacity, the government may or may not follow their recommendations on policy options to adopt, allowing them only an indirect role on research governance as, for example, in Denmark. The Danish Council of Ethics is an independent body established under statute which advises the Danish Parliament and raises public debate about ethical problems in the field of biomedicine, including biomedical research relating to human beings.[217] Countries such as the United States have had several successive bioethics advisory councils, which typically exist at the pleasure of the executive in power. A recent example is the recent disbandment[218] of President George W Bush`s President`s Council on Bioethics, which advised President George W. Bush on bioethics issues,[219] including research ethics. This has been replaced by the new Presidential Commission for the Study of Bioethical Issues, established by President Barack Obama.[220]

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[217] Danish Council on Ethics (Det Etiske Råd), <http://www.etiskraad.dk/sw293.asp> (September 8, 2009). The legislation is *The Act on The Danish Council of Ethics*, Act No. 440 of 9 June 2004. See particularly Section 2 of the Act.

[218] Nicholas Wade, "Obama Plans to Replace Bush's Bioethics Panel" *New York Times*, June 17, 2009, online: <http://www.nytimes.com/2009/06/18/us/politics/18ethics.html?ref=global-home> (September 20, 2009).

[219] See The President's Council on Bioethics, online: <http://www.bioethics.gov/> (September 8, 2009). There have been other bioethics commissions in the United States, including National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research established in 1974 and the National Bioethics Advisory Commission (NBAC) established in 2001.

[220] "President Obama Establishes New Presidential Commission for the Study of Bioethical Issues, Names Commission Leadership" online: <http://www.whitehouse.gov/the-press-office/president-obama-establishes-new-presidential-commission-study-bioethical-issues-nam> (May 6, 2010).

Such advisory councils may help create policy, although this may not be their direct function.

Policy structures assist in articulating, and elaborating on issues and divergent views, permitting the reaching of consensus on areas where there may be scientific and moral uncertainty and controversy.[221] The establishment of such policymaking structures brings the state into the arena of research governance and helps define the role that the state has chosen to play in such governance. In a manner that is clearly part of the new governance approach, such policies may also provide conditions for funding,[222] and may even influence legislation.[223] And, in countries where no research-related legislation has been enacted, the policies made by such organizations may be the only substantive guide that sets parameters for health research involving humans. Deliberations by such bodies, and any publications put forth, also assist in keeping the public informed on issues arising in research ethics and governance. These deliberations may also signal the directions which government regulation or policy-making more broadly may take, and shape the ultimate policy even where the council or commission is only advisory because members of such committees tend to be persons regarded as experts in research ethics and governance issues.[224]

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[221] But some argue that bioethics commissions can sometimes prevent a serious debate about issues by putting on the appearance of reaching a false consensus. See Jonathan D. Moreno, "Do Bioethics Commissions Hijack Public Debate?" (1996) 26: 3 The Hastings Centre Report 47.
[222] Dodds and Thomson, supra note 214 at 329.
[223] See Moreno, supra note 221.
[224] Weiman Rei and Jiunn-Rong Yeh, "Steering in the Tides: National Bioethics Committee as an Institutional Solution to Bio-politics?" in *Asian Bioethics in the 21st Century* (2003) Eubios, online: < http://www.eubios.info/ABC4/abc4363.htm> (October 29, 2009).

Some of the systemic issues which arise with respect to policy structures and their role in research governance in both developed and developing countries include issues around legitimacy, community engagement or public participation, transparency, accountability, representation and effectiveness. For instance, in terms of legitimacy, accountability, representation, and community engagement, broad-based consultation of the public are necessary. What is the nature of public participation in the development of research ethics policies?[225] How broad are attempts to ensure public participation and how much influence does such participation have on the resulting policies? Are there inherent conflicts of interest issues that may undermine the effect of the policies developed and, more generally, research governance? As an example, in Canada, it has been argued that an inherent conflict of interest exists with respect to the creation of an ethics guideline by the major funding agencies whose major purpose is to promote research, and who have also created the Interagency Panel Advisory Panel on Research Ethics, the policy-making body.[226] These issues have an impact on the effectiveness of these policymaking bodies, the resulting policies developed and, ultimately, on research governance.

These issues also arise specifically in such areas as the process of appointment into such bioethics councils. Who appoints members of these councils? Does membership of these councils or committees reflect a broad

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[225] Charles Weijer, "Book Review: *Society's Choices: Social and Ethical Decision Making in Biomedicine*" online: < http://www.ncehr-cnerh.org/english/communique/npubs_e.html> (March 12, 2008).
[226] See Downie supra note 150.

range, or diversity, of persons? And how does this affect the work that the councils do? In the United States, for example, President Bush appointed members of the President's Council on Bioethics, who were viewed by some as mainly researchers who supported his conservative views on stem cell research, and whose recommendations were considered to be therefore ideological rather than objective.[227]

In terms of effectiveness, particularly with respect to advisory councils or commissions, how much do they really affect the direction of policy towards promoting research and protecting research participants, especially if established for political purposes?[228] And are they granted sufficient resources to carry out their mandate?

These systemic issues arise in different countries, developed and developing, but perhaps more so in developing countries with less established democracies. Specifically in developing countries, policies should be made with an understanding of the context of resource challenges, global inequities, the limited awareness of rights by many who may participate in research, and the effect of these on the promotion of research and on the protection of research

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[227]Elizabeth Blackburn and Janet Rowley, "Reason as Our Guide" (2004) PLos Biol 2(4). This was disputed by others. Elizabeth Blackburn, "Bioethics and the Political Distortion of Biomedical Science" (2004) 350: 14 New England Journal of Medicine 1379. See Paul Elias, "Scientists Rally around Stem Cell Advocate Fired by Bush" *Associated Press*, March 18, 2004, online: <http://www.usatoday.com/tech/news/2004-03-18-eliz-blackburn_x.htm> (September 20, 2009). President Obama subsequently issued an order in March 2009 to lift the ban on federal funding of embryonic stem cell research may be argued to advance his more liberal approach to bioetechnology, particularly stem cell research.

[228] See, for example, James W. Fossett and Michelle N. Meyer, "Bioethics Panel's Role May Be Small on Policy, Big on Issues" (July, 2009) The Nelson Rockefeller Institute of Government, online: <http://www.rockinst.org/observations/fossettj/2009-07-next_presidents_council_bioethics.aspx> (October 19, 2009), arguing that bioethics commissions in the United States play a very limited role in policy development around bioethics issues.

participants. Are these policymaking structures sufficiently empowered with the necessary mandate, resources, and expertise, to take these factors into account in crafting research ethics policies? I consider the place of policy-making structures and the arising systemic issues in Nigeria in subsequent chapters.

3.3.4 Other Institutional Actors: Universities, Research Institutes, Research Sponsors, Professional Associations

In addition to the institutions described above, other institutions such as universities and research institutes are also involved in the governance of health research. The role that the institutions described here play (or should play) indicates that they have to be a part of the governance framework, and this adds further justification for the necessity for a hybrid governance framework that recognises the activity of different actors in analysing the governance of health research in developing countries.

Many universities, teaching hospitals, and research institutes have research ethics policies that govern the ethical conduct of research. These policies may require ethics review of research and prescribe the manner in which ethics review committees are organised, administered, and funded. In some cases, these policies are a requirement from research sponsors who sponsor research in those institutions. For instance in Canada, where the major research ethics policy is a product of the federal funding agencies, institutions are required to draw up policies in line with the TCPS.[229] The inherent conflict of

[229] CIHR, NSERC, SSHRC, *Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards*, online: <http://www.nserc-

interest issues arising from institutional requirements for and efforts to obtain funding and the possible impact on ethics review in these institutions have been discussed above.

In other cases, research sponsors, which may include government funding agencies, pharmaceutical companies, and non-governmental organizations, draw up policies and provide funding conditions to ensure the ethical conduct of research. Under those conditions, research sponsors typically require compliance with the conditions for continued funding eligibility.

Professional organisations also regulate research conducted by their members, not only in terms of ensuring quality assurance, establishing professional standards, educating and certifying their members,[230] but in establishing specific requirements regarding ethical conduct of research. "Rules of conduct or ethical codes," notes Bernard Dickens, "are often considered to be characteristic of professions, as opposed to craft and trade associations."[231] According to him, they are particularly common within health care professions, where they set guidelines for how professionals should act in dealings with their patients and with each other in, among other things, in experimental studies involving animals, humans, and social or population groups.

Professional associations' responsibilities to regulate research may originate from a statutory basis, a duty to maintain professional standards and

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crsng.gc.ca/NSERC-CRSNG/Policies-Politiques/MOURoles-ProtocolRoles/index_eng.asp> (November 23, 2009).

[230] Henry Dinsdale, "Professional Responsibility and the Protection of Human Research Subjects in Canada" (2005) 13: 2 and 3 Health Law Review 80 at 80.

[231] Bernard Dickens, "Codes of Conduct and Ethics Guidelines" in Lester Breslow, *Encyclopedia of Public Health* (New York: Macmillan, 2002) at 224 – 227.

promote public trust and confidence, or fiduciary obligations.[232] In Canada, for instance, the Alberta College of Physicians and Surgeons, requires physicians and surgeons in that province to submit their research activities for ethics review and has set up a centralized Research Ethics Review Committee to oversee such activities.[233] The College of Physicians and Surgeons of Manitoba has also put in place a similar measure.[234] In Nigeria, the Medical and Dental Council of Nigeria, a professional association of doctors and dentists, has drawn up a code of ethics which includes requirements for the ethical conduct of research.[235]

Systemic issues arise with respect to each of these institutions, including the limitations of scope of the research governed by them, which is necessarily determined by the scope of their authority and interest. Some pertinent issues and some kinds of research may thus fall outside their scope. In the case of professional associations, while there is an opportunity to regulate some kinds of research that may fall outside the scope of other policies, for instance research that takes place in doctor's offices, they cannot provide comprehensive protections for all health research.[236] Also, there may be inadequate interest in research governance and a limited understanding of the potential role of the professional association in research governance.[237]

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[232] See Timothy Caulfield *et al.*, "Research Ethics and the Role of the Professional Bodies: A View from Canada" (2004) 32 Journal of Law Medicine & Ethics 365.
[233] See Ibid.
[234] College of Physicians and Surgeons or Manitoba (CPSM). (2005), online: <http://www.cpsm.mb.ca/> (June 21, 2007).
[235] Online: <http://www.mdcn.org/functions.htm> (April 1, 2009).
[236] See Caulfield, supra note 232.
[237] See, for instance, Dinsdale, supra note 230 at 82 describing the inadequacy of professional associations' interest in research governance in Canada.

In the case of research sponsors, their requirements may conflict with the interests of research participants. Such conflict of interest also arise in universities, which may be desirous of facilitating research and require continued research funding, but also have to protect research participants within university-affiliated research. The death of a research participant in the United States, Jesse Gelsinger, in a gene therapy trial, exposed such conflict of interest issues. In that instance, the principal investigator and the university had an undisclosed financial interest in the outcome of the trial. The university benefited substantially from donations made by the research sponsor to its gene therapy programs.[238] Similarly, the case of Dr. Nancy Olivieri, a researcher at the University of Toronto whose contract with a research sponsor, Apotex, precluded publication of adverse findings during a trial and who did not receive appropriate support from the university, highlights concerns about conflicts of interest.[239] These concerns are, of course, exacerbated in the resource-challenged settings of developing countries.

3.3.5 Non-Governmental Organisations

In the hybrid framework that I proposed in Chapter Two, I discussed the possibility that non-governmental organisations may serve as checks on other actors in governance. Although they may lack the type of legitimacy and

[238] See D. R. Waring and T. Lemmens, 'Integrating Values in Risk Analysis of Biomedical Research: The Case for Regulatory and Law Reform' University of Toronto Law Journal (2004) 249 ; W M Kong, "Legitimate Requests and Indecent Proposals: Matters of Justice in the Ethical Assessment of Phase 1 Trials Involving Competent Patients (2005) 31 Journal of Medical Ethics 205. See also, Barry Schwartz, "Safety in Human Research: Past Problems and Current Challenges from a Canadian Perspective" (2008) 20: 3 HEC Forum 277.
[239] Downie, supra note 150.

accountability required of government or state entities, they may bring a balance to the research governance system that would otherwise be lacking. They may also, as watchdogs, serve as the voice of research participants, and possibly prevent regulatory capture which can jeopardise the interests of research participants and the general public. Thus, from the perspective of new governance or my hybrid governance framework, non-governmental organisations could – along with community and lay participation in ethics review committees – serve as the entry point for non-state actors, including those on behalf of whom governance arrangements are employed. In this section, I consider these organisations as a potential and important constituent of research governance.

Under the umbrella of non-governmental organisations come organizations such as patients' rights groups, consumer organizations, and community groups. Although they typically do not feature in accounts of the institutional framework of research governance and may not be considered a formal part of the framework, in my view, they are particularly necessary because they provide an avenue for past and potential research participants, and citizens to participate in research governance in an organised fashion. They also provide an important means of providing checks and balances on other institutions through, among other things, publicizing unethical research (in other words, naming and shaming). They are also particularly essential in developing countries where weak or fledgling democracies and corruption are major concerns.

In developed countries, many patients' rights organizations are focused mainly on advocacy for funding for clinical research on different diseases, on gaining access to clinical trials and speeding up drug approval processes.[240] These types of organisations have very often

> expressed an enthusiasm for 'the bright side' of research, and a willingness to assume risk, that many scientific investigators did not share... These advocates have tended to avoid REBs that examine the risks faced by research participants. They have regarded ethics review as a paternalistic distraction from the main goal of promoting benefits to patients.[241]

But there are others, such as the Alliance for Human Research Protection[242] in the United States, whose main focus is the protection of participants in research.[243] This organisation is a "network of lay and professional people with a mandate to advance ethical research practices; to ensure that the human rights, dignity, and welfare of research participants are protected; and to minimise the risks associated with such endeavours."[244] Another such organisation is the Citizens for Responsible Care and Research,[245] whose mission is to raise the level of ethical and professional conduct of research involving humans,

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[240] An example of such an organization is the Abigail Alliance for Better Access to Developmental Drugs, see online: < http://abigail-alliance.org/> Another example is AIDS Coalition to Unleash Power (ACT UP). See Mark Harrington, "Community Involvement in HIV and Tuberculosis Research" (2009) 52 (S1) Journal of Acquired Immune Deficiency Syndrome S63.

[241] Waring and Lemmens at 238.

[242] Alliance for Human Research Protection, online: <http://www.ahrp.org/cms/content/view/18/87/>(October 31, 2009).

[243] Another example is the Public Citizen's Health Research Group, also based in the United States, which was one of the organisations that raised concerns about the standard of care issue in the zidovudine trials in developing countries mentioned in Chapter One. See P. Lurie and S. M Wolfe, "Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human /Immunodeficiency Virus in Developing Countries" (1997) 337 New Eng. J. Med. 853. The authors are members of the Public Citizen's Health Research Group.

[244] Waring and Lemmens, supra note 224 at 281.

[245] Citizens For Responsible Care and Research (CIRCARE), online: <http://www.circare.org/>

especially with respect to the protection of vulnerable participants, like the mentally challenged, and children.[246]

In developing countries, non-governmental organizations typically act as a buffer between the government and citizens, acting as the voice of the latter, including in areas such as human rights. The activist and advocacy efforts of such organisations have assisted in the changing of old laws, and the enactment of new legislation. Such efforts have brought the need to accommodate consultations with civil society groups in such legislative processes to the fore.[247] Such organisations may deliver healthcare services. They may also engage in activism around health issues including, but not limited to, activities such as promoting access to essential medicines for HIV/AIDS, reducing disease-related stigma and discrimination, and liaising with international organizations such as the WHO in health-related activities.

With respect to research governance, non-governmental organisations in developing countries have been engaged in presenting community views on ethical issues in health research, and are increasingly consulted in designing research protocols.[248] In South Africa, civil rights

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[246] Ibid.

[247] See for example, Obiora Chinedu Okafor, "Modest Harvests: On the Significant but Limited Impact of Non-Governmental Organisations on Legislative and Executive Behaviour in Nigeria" (2004) 48:1 Journal of African Law 23 at 24.

[248] In Thailand, community groups consisting of sex workers and their representatives, and drug users protested the trial of tenoforvir, a microbicide, in 2004, on the grounds that participants were not afforded enough protections, including provision of treatment in the event that they got infected. See Seree Jintarkanon *et al*, "Unethical Clinical Trials in Thailand: A Community Response" (2005) 365: 9471 The Lancet 1617; JA Singh and EJ Mills "The Abandoned Trials of Pre-exposure Prophylaxis for HIV: What went Wrong?" (2005) 2:9 PLoS Med 234; and A. Chua, N. Ford, D. Wilson and P. Cawthorne, "The Tenofovir Pre-Exposure Prophylaxis Trial in Thailand" (2005) 2: 10 PloS Medicine 346.

organizations have successfully challenged government research policies through legal action.[249]

Non-governmental organisations can assist in the very essential work of educating research participants at the grassroots levels where most research activities take place, and where the burden of research is most felt.[250] At such grassroots level, there is less likelihood of education and awareness of the rights of participants. They could also engage in advocacy to strengthen regulations, establish, and implement research governance policies and legislation. NGOs may be well placed to act in respect of drawing attention to the requirements of justice and access to benefits contained in many ethical guidelines.

Even though I am of the view that non-governmental organisations may be helpful in the governance of health research in developing countries, this does not mean that they are entirely free of any concerns. Some of the systemic issues, particularly in developing countries, are that there are too few of these organisations, and that where they do exist, sufficient resources in terms of funding and training on the relevant issues may be lacking. Conflict of interest and regulatory capture issues may also arise where such organisations are involved in advocacy not only for the ethical conduct of research, but also advocacy for access to participation in research, two potentially conflicting goals. The possibility also exists of their being captured by other stakeholders whose interests may not necessarily be aligned with those of research

[249] For prominent examples, see Jerome Amir Singh, "Using the Courts to Challenge Irrational Health Research Policies and Administrative Decisions" (2009) 112 Suppl 1 Acta Tropica S76.
[250] Temidayo O Ogundiran, "Enhancing the African Bioethics Initiative" (2004) 4 BMC Medical Education 21.

participants, including the interests of patients who have few alternatives and therefore seek faster approval processes, or pharmaceutical companies who may want to circumvent existing ethical and procedural requirements.[251] In developing countries, where the adequacy of resources in any sector, including the non-profit sector, is almost always a concern, the possibility of capture of advocacy groups raises serious potential issues. A continuous evaluation and appraisal of their functions is therefore necessary.

3.4 Conclusion

To set the stage for the application of the hybrid governance framework proposed in Chapter Two, I have sought, in the foregoing pages, to identify and discuss many of the processes, institutions, and mechanisms employed in the governance of health research involving humans. I have categorised these processes, actors, and mechanisms into ethical and institutional frameworks. In doing so, I have pointed out that developing countries who do not already have domestic ethics policies may need to put such in place. These should address the gaps in the international ethical guidelines. National guidelines also retain the positive attributes of the new governance approach.

I have identified systemic issues that have been of concern in institutional components in different countries. Emerging governance systems have to address these concerns. One of such matters is the appropriate ethics review structure. In this respect, I have noted that an appropriate structure

[251] See for example, Sharon Batt, "Marching to Different Drummers: Health Advocacy Groups in Canada and Funding from the Pharmaceutical Industry" (2005), online: <http://www.whp-apsf.ca/pdf/corpFunding.pdf> (July 23, 2010).

(whether institutional or regional, centralised or decentralized), in my view, cannot be one that is set up merely to attract research funding or be one that adopts foreign structures wholesale. An appropriate structure will be the result of a reasoned and wide-ranging discussion, take into consideration the local context and local challenges, and focus on the protection of research participants in a particular country. I have also discussed the input of drug regulatory agencies, policy-making structures, universities, professional associations, and research sponsors in the governance of health research, and the potential systemic issues that they may face. I have also pointed out that non-governmental organisations may be a beneficial constituent of the components of research governance in developing countries.

The number and diversity of actors and instruments described in this chapter make obvious the need for a governance framework such as I suggested in Chapter Two, and convey the necessity for my focus on governance. In the next chapter I argue that a legal framework is also an essential component of research governance.

Chapter Four

The Case for Legislation and the Need to Recognise the Relationship between Ethical, Legal and Institutional Frameworks

4.1 Introduction

In my analytical framework, discussed in detail in Chapter Two, I argued that law (a tool wielded by the state) brings something important to the table of governance. Amid other components of research governance, discussed in Chapter Three, a legal framework is, I argue, a crucial component of research governance.

The first objective of this chapter, therefore, is to argue for the need for specific and comprehensive domestic legislation on research governance in developing countries. In this regard, while ethical and institutional frameworks are widely accepted in research governance and articulated in the literature, legislation on research governance is still a contested matter, or one which has not been given sufficient thought in several countries, including developing countries. Some developed countries like Denmark, [1] the Netherlands, [2] and Spain[3] have specific legislation on research governance. Developing countries like South Africa[4] and Chile[5] also have legislation dealing with aspects of research governance. But many other developing countries do not yet have comprehensive legislation addressing research governance. In the sections below, I provide an account of the possible

[1] *Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects 1992.*
[2] *Medical Research Involving Human Subjects Act, 1999,* as amended.
[3] *Law on Biomedical Research, Law 14/2007*
[4] *National Health Act, no 16 of 2003.*
[5] *Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning, Law No. 20.120.*

impact of the law on research governance, and argue for a comprehensive legislative basis to provide a foundation for research governance in developing countries. I also consider the basic content of such legislation.

The second objective is to argue for the need for the recognition of the relationship between the three frameworks: the ethical, the institutional and the legal frameworks. As I discussed in Chapter Two, governance takes a systems approach, permitting the discussion of steering of activities in terms of the interrelated parts of that activity, in this case, health research involving humans.[6] As discussed in Chapter Two, governance as an analytical framework allows us to study the configuration of particular institutions, instruments, and processes, and the interactions and relationships between them.[7] In this chapter, I argue for the importance of the recognition of linkages between a domestic legal framework, an institutional framework, and an ethical framework, and contend that such recognition will be helpful with respect to achieving the stated goals of research governance.

This chapter commences with this introduction. The second section examines the legal framework for research governance, discusses generally the role law plays in the governance of health research and argues for a real role for law in the form of formal legislation in domestic governance systems in developing countries. The third section points out the need for better recognition of the relationship that exists, and should exist, between the ethical, legal and institutional frameworks. The fourth section concludes the chapter.

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[6] Bjoern Niehaves, Karstern Klose, Joerg Becker, "Governance Theory Perspectives on IT Consulting Projects: The Case of ERP Implementation" (2006) 5:1 E-Service Journal 5 at 9.

[7] M. MacDonald (ed.) *The Governance of Health Research Involving Human Subjects* (Ottawa: Law Commission of Canada, 2000) at 22.

4.2 The Legal Framework

It is clear that the ethical framework, discussed in Chapter Three, is a foundational component of research governance, as is an institutional framework which actuates the ethical framework. Similarly, a legal framework is an important component of research governance because of the special characteristics of law which differentiate it from ethics or bioethics, the broader domain of research ethics.

While both law and ethics aim to define acceptable and unacceptable conduct,[8] there are differences however in these two normative systems in terms of their goals and methods.[9] A major difference is that whereas ethics may only be aspirational, law sets mandatory minimum standards. In setting minimum standards, law performs a more restricted function than ethics, identifying and regulating those kinds of conduct about which there is general agreement.[10] These mandatory standards set by law may bring about legal liability if infringed.[11] The weapon of legal liability assists in bringing in line the conduct of persons involved in research, or as Scott so aptly puts it, "Law packs ethics with the 'punch' of potential sanctions."[12] Further, as some authors have rightly observed, and as discussed in Chapter Two, law is usually considered the product of authoritative law-making institutions associated with the nation state. Ethical principles, in contrast, may be grounded in a wider range of sources with no obligatory connection to the state.

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[8] Judith Hendrick , "Legal Aspects of Clinical Ethics Committees" (2001) 27: 1 Journal of Medical Ethics 50. See also, Bethany Spielman, "Invoking the Law in Ethics Consultation (1993) 3 Cambridge Quarterly of Healthcare Ethics 457 at 464.

[9] Bethany J. Spielman, *Bioethics in Law* (Humana Press, 2007) at 2.

[10] Thus, for instance, the law will most likely not regulate areas that are ethically controversial. However, the law is most likely to regulate an area like informed consent where there is, to a large extent, general agreement. Charity Scott, "Why Law Pervades Medicine: An Essay on Ethics in Health Care" (2000) Notre Dame Journal of Law and Public Policy 245 at 259.

[11] Hendrick, supra note 8.

[12] Scott, supra note 10 at 258.

Moreover, in addition to their different sources, they may occasionally reach different conclusions on the same issues.[13] With respect to their goals, the general objectives of law, including in dispute resolution and in standard-setting, typically differ from the more immediate concerns of bioethics.[14]

But there are also connections in the two fields that allow both to influence each other, and to provide value in the specific area of research governance.[15] In this regard, the law (in part)[16] reflects society's idealism, morality, and some consensus, at any given point in time, of what society views as acceptable, ethically appropriate behavior.[17] In a socio-legal sense, law's most important reason for existing is as a communal resource[18] which society imbues with power (including coercive power) to express and regulate the basic values that society holds important. Bioethics (and ethics more generally) is concerned with such values as autonomy, equity, fairness and justice. To achieve these lofty ideals, society chooses the vehicle of law, which acts as an enforcer of social values.[19] Thus law in its role as the principal instrument for protecting and upholding human rights, ought to promote (although there have been instances where it has fallen short of promoting) equity,

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[13] John Dawson, 'An Introduction to the Law of Research,' in John Dawson and Nicola Peart, (eds.), *The Law of Research* University of Otago Press (2003), 14- 25 at 25.
[14] Carl E Schneider, "Bioethics in the Language of Law" (1994) 24:4 Hastings Centre Report 16.
[15] Ibid. See also, Hendrick, supra note 8.
[16] Legal positivists would argue differently – morality is separate from law. However, law while not simply equated with morality must show to some extent a reflection of the morality of the society.
[17] Scott, supra note 10 at 245.
[18] Roger Cotterrell, "Subverting Orthodoxy, Making Law Central: A View of Sociolegal Studies" (2002) 29: 4 Journal of Law and Society 632 at 642-3.
[19] Scott, supra note 10 at 257.

fairness, and justice.[20] Law is also a principal means of enforcing policies, including health policies, and a crucial medium for deciding differences about public policy.[21]

In general, then, law may be considered, as Schneider so concisely summarises it:

> essentially a device for social regulation. It is the means by which society through its government seeks to establish a framework for human interactions. This framework helps set minimum standards for human behavior (criminal law and tort law exemplify this function), helps establish and support the institutions and practices people use in organizing their relations with each other (this is what contract and commercial law, for instance, do), and helps people resolve their disputes (which is a primary function of civil courts). In this century, the law has broadened that framework by providing some minimum assurances of human well-being (what we call the welfare state).[22]

Governance and regulation through law thus has several uses, including facilitating certain socially and morally acceptable actions, setting norms and protecting citizens, including, through setting penalties and sanctions for unacceptable action or behaviour and regulating or declaring standards thus providing clarity and certainty in handling controversial areas.[23] Formal regulation by means of statutes is particularly useful where the interests of the weak and vulnerable are at stake.[24]

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[20] Ibid at 246.

[21] B.R. Dworkin, *Limits: The Role of Law in Bioethical Decision-Making* (Indiana: Indiana University Press 1996) at 2.

[22] Schneider, supra note 14 at 16. Another useful definition for the purposes of this thesis is the one given by Dworkin, who describes law in terms of procedure and processes for correcting or refusing to correct social ills, for the purpose of deciding whether to intervene, who should intervene and in what way in relationships between persons and the government. See Dworkin, ibid. at 8.

[23] Linda Nielsen, 'From Bioethics to Biolaw' in Cosimo Marco Mazzoni (ed.), *A Legal Framework for Bioethics* (The Hague: Kluwer Law International, 1998) at 42.

[24] *Ibid.* at 44.

In the case of health research involving humans, ethical concerns relate principally to the safety and welfare of research participants, an area in which the law can play, and has played a crucial role. The legal framework of research governance in different jurisdictions typically consists of common and civil law principles in the areas of tort and criminal law, but may also include formal, specific legislation. While few jurisdictions have specific legislation governing research, some have legislation governing specific aspects of research such as clinical trials, while in many others (including developing countries such as Jamaica, Bolivia, and Vietnam) formal legislation governing many aspects of research involving humans is absent.

In this section, I begin by describing briefly how the law currently operates in the context of research governance. I then consider the potential role that law could play in research governance in developing countries, and argue for the potential benefits of specific legislation in an area requiring both the promotion of research, and the protection of those who participate in such research.

4.2.1 Law and Research Governance

In many countries around the world, the law impacts governance of health research involving humans in various ways. As Jaffe observes, the law "is a system of decisional organs and their formal and informal products: the legislature (statutes), the executive administrative (regulations and adjudication), and the courts (adjudication)."[25] This system, in its entirety – through statute, regulations, and case law – regulates health research involving humans. Below, then, I provide a brief

[25] Louis L. Jaffe, "Law as a System of Control" (1969) 98: 2 Daedalus 406 at 407.

descriptive account of the impact of the law on the governance of health research involving humans.

The ethical obligation to secure free and informed consent for participation in human research is a key requirement entrenched in the law of many countries. The law may also influence the conduct of research, and therefore research governance in relation to competence to provide free and informed consent, addressing the age of majority, mental competence, and provisions for research involving mentally disabled persons or children, and who may act as an authorised representative. These requirements may be found in a variety of pertinent sources of law, including common law, civil law, legislation, regulations, and even constitutional law.

Privacy and confidentiality are other areas in which the law may play a significant role. Personal data may be protected by specific legislation, and the right to privacy is widely regarded as a fundamental right.[26] But law may also require the reporting of information obtained in the course of research in order to protect the health, safety, or life of a research participant or third party, including information about child abuse, sexually transmitted diseases, intent to murder, or suicidal thoughts.

Constitutional law may contain basic requirements for health research involving humans such as informed consent (as in South Africa[27]), and fundamental rights which impact health research, such as the right to privacy. Importantly, constitutional law in most countries also articulates the delineation or distribution of

[26] Hazel Biggs, *Healthcare Research Ethics and the Law: Regulation, Review and Responsibility* (Oxford: Routledge Cavendish, 2010) at 97.
[27] (Section 12(2)(c) of *the Constitution of South Africa* 2003.

powers of different authorities, determining which level of government (especially in a federal system of government) can exercise legislative and regulatory powers.[28]

Specific legislation or legal regulations may exist on the conduct of clinical trials, including the creation of drug regulatory agencies as described above and containing a requirement for ethics review approval. Legislation, as is the case in Denmark,[29] may also establish the research governance structure, including the national ethics review committee, its mandate, and the place of ethics review committees. Ethics review committees may operate directly or indirectly, under legislated mandate.[30]

Further, the law's impact on research governance can be felt through common and civil law addressing the liability of researchers and research institutions, including the law of torts, specifically the law on negligence, the law on battery, and the law on fiduciary duties. In the common law, a claim in negligence requires the proving of a duty of care, in this case owed by a researcher to a research participant, the breaching of that duty, and that harm or injury resulted from that

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[28] See for instance, Jennifer Llewellyn, Jocelyn Downie & Robert Holmes, "Protecting Human Research Subjects: A Jurisdictional Analysis" (2003) Special Edition, Health Law Journal 207.

[29] *Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects 1992.* This is also the case in France, Spain and the Netherlands. France - Biomedical Research (Loi Huriet-Sérusclat), Articles L1121-1 to L1126-7 (2004) (French), available at: <http://www.legifrance.gouv.fr/> Decree No. 97-555 Concerning the National Consultative Ethics Committee for Health and Life Sciences (1997): available at: <http://www.ccneethique.fr/english/start.htm> ; Protection of Persons who Participate in Biomedical Research (Public Health Code, Regulatory Section, Additional Book II, Articles R.2001 to R.2053); Spain - Medicaments Law 1990; Netherlands- Medical Research Involving Human Subjects Act 1999, Netherlands, as amended by Decree of 5 March 1999 (Stb. 150) promulgating rules with regard to the central assessment of medico-scientific research involving human subjects (Decree on the central assessment of medico-scientific research involving human subjects). Decree of 3 January 2006 (Stb. 39) amending the Decree on the central assessment of medico-scientific research involving human subjects (extension of the range of medico-scientific research requiring central assessment)Staatsblad van het Koninkrijk der Nederlanden, 1999; Law of 20 June 2002 (Stb. 338) promulgating rules governing medical research.

[30] Michael Hadskis and Peter Carver, "The Long Arm of Administrative Law: Applying Administrative Law Principles to Research Ethics Boards" (2005) 13: 2 and 3 Health Law Review 19.

breach.[31] The research participant who is harmed in the course of research, whether through non-disclosure of the harm that could result from participation or the researcher's failure to meet requisite standards for informed consent, can thus argue that a duty of care owed by a researcher (or researchers) was breached and resort to an action in domestic courts for compensation. In the Canadian case of *Halushka v University of Saskatchewan*, a student at the University of Saskatchewan was offered fifty dollars to participate in a clinical trial, in the course of which he suffered cardiac arrest. The student had been told that a catheter would be inserted into a vein in his arm but was not told that it would be advanced to and through his heart. The court found that the researcher had not informed the student of the purpose of the research and associated procedures. It held that, "the subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and options which a reasonable man might be expected to consider before giving his consent."[32] An ethics review committee may also face legal liability on the grounds that the approval of a study was provided in a negligent way. In the Canadian case of *Weiss v Solomon*, the ethics review committee was found liable for non-disclosure of material information which caused harm to the research participant (which liability was to be borne by the hospital which established the ethics review committee).[33]

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[31] See EH Morreim, "Medical Research Litigation and Malpractice Tort Doctrine: Courts on a Learning Curve" (2003) 4:1 Houston Journal of Health Law and Policy 1.

[32] *Halushka v University of Saskatchewan*, (1965), 53 D.L.R. (2d) 436 (Sask. C.A.). See also *Grimes v. Kennedy Krieger Institute Inc*, 782 A.2d 807. See Susan M. Wolf, Jordan Paradise, and Charlisse Cagaanan, "The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties" (2008) 36:2 J Law Med Ethics. 184.

[33] *Weiss v. Solomon* (1989) 48 CCLT 280 (Quebec Supreme Court).See Benjamin Freedman and Kathleen Cranley Glass, "*Weiss v. Solomon:* A Case Study in Institutional Responsibility for Clinical Research" (1990) 18: 4 Law, Medicine & Health Care 395. See also, Jennifer L. Gold, "Watching the Watchdogs: Negligence, Liability, and Research Ethics Boards" (2003) 11 Health Law Journal 153.

The research participant can also claim that battery occurred against her if the research took place without her consent. This situation may arise particularly in cases where the research participant is undergoing therapeutic treatment and during the course of the treatment research involving her is conducted without her knowledge.[34] Similarly a claim of fraud may be brought against the researcher or research sponsor where she acts as a result of a misrepresentation by the researcher or the researcher sponsor.[35] The research participant can also claim that a fiduciary relationship exists between the researcher(s) and the research participant, which required the researcher to take special care not to harm the research participant, a claim that would be stronger if a doctor-patient relationship also existed between the researcher and the research participant. In the United States case of *Grimes v. Kennedy Krieger Institute Inc,*[36] where the parents of minor children brought a negligence action against a research institute affiliated with Johns Hopkins University for lead-related injuries allegedly suffered by their children participating in a study concerned with lead abatement in housing, the Appellate Court found that, as a general rule, a special relationship exists in the research context between researchers and participants. In the specific context of clinical trials, which typically entail a doctor-patient relationship, the general law that doctors have a duty to act in the best interests of their patients, also applies in many

[34] Ian Kennedy and Andrew Grubb, *Medical Law* (Third Edition) (Oxford: Oxford University Press, 2005) at 1710.
[35] Ibid. See also Jaffe supra note 25 at 407-408.
[36] *Grimes v. Kennedy Krieger Institute Inc* 782 A.2d 807. *Grimes*, 782 A.2d 807, at 846. In the US, a court has found that a special relationship exists between researcher and research participant, regardless of whether a doctor-patient relationship existed. See *Blaz v. Michael Reese Hosp. Found.*, 74 F. Supp. 2d 803 (N.D. Ill. 1999).

jurisdictions.[37] It must, however, be noted that the strict rules of tort would place the burden of proof on the plaintiff, who may be powerless to produce the required evidence.[38] It may also not be an easy matter to prove causation or the relevant standard of care.[39]

Criminal law, especially in regard to assault and criminal negligence, also regulates research involving humans. Where a researcher applies force intentionally and without the consent of the research participant, a researcher may be criminally liable. Also, where a researcher is under a legal duty under common law or statute, and acts in reckless disregard for the life and safety of a research participant, the researcher may be criminally liable. Improper possession of human tissue samples, for example by possessing them without appropriate consent, may also constitute theft.[40]

Administrative law, comprising a set of common law principles that govern the exercise of public power, understood as "the making of authoritative decisions affecting the rights or interests of persons in civil society,"[41] is also applicable in the research governance context.[42] In the United Kingdom, the courts have extended judicial review to include non-statutory bodies and functions where the body is providing a public function as ethics review committees undoubtedly

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[37] Ian Kennedy and Andrew Grubb, *Medical Law* (Third Edition) (Oxford: Oxford University Press, 2005) at 1708.
[38] See J. K. Mason and R. A. McCall Smith, *Law and Medical Ethics* (Butterworths, 1994) p.365.
[39] Margaret Brazier, "Liability of Ethics Committee and Their Members'" (1990) PN 186 quoted in Kennedy and Grubb, supra note 37 at 1702.
[40] Bernard M Dickens, "Governance Relations in Biomedical Research" in M. McDonald (ed.), *The Governance of Health Research Involving Human Subjects* (Ottawa: Law Commission, 2000) at 97.
[41] Hadskis and Carver, supra note 30 at 19.
[42] Ibid.

do.[43] The situation would be even more clearly the same where there is a statutory basis for the operation of ethics review committees. Some administrative law principles therefore apply to review by an ethics review committee - such as the rules of natural justice – a fair opportunity to be heard, an explanation of opinions and decisions, a fair chance of rebuttal, and good grounds for decisions.[44] These principles may also apply to the work carried out by bioethics commissions, such as the policy structures described in Chapter Three, especially when created under a legislative mandate conferring on them powers to exercise certain functions.

Other common and civil law principles found in intellectual property law, contract, and labour law also have an impact of research governance. Intellectual property laws dictate the intellectual property rights derivable from research. Contract law and labour law have an impact on research governance, for instance, in cases where researchers employed by universities are required under their employment contracts to conduct research according to certain policies or to comply with certain ethical guidelines. Breach of such contract is actionable in law.[45] In the Olivieri case mentioned in Chapter Three, the sponsor, Apotex, entered into contracts with the investigator, some of which required her to keep confidential certain information for a period of time, including information about adverse events discovered during the trial. Apotex threatened to pursue legal remedies against Dr. Oliveri for breach of this contractual obligation. This case indicates an area in which the law (in this case contract law), can conceivably conflict with ethical duties. The

[43] See *R v Panel on Take Overs and Mergers ex p Datafin plc* (1987) QB 815. See Kennedy and Grubb, supra note 264 at 1705-6.
[44] Kennedy and Grubb, ibid.
[45] Dickens supra note 38 at 99.

matter did not proceed to court, so there is no precedent on how a court would rule in such a situation, including whether or not the contract would be upheld as valid (in which case Dr. Olivieri would have been in breach of her contract with Apotex) or whether the contract would be held null and void for being against public policy.[46]

Law can also operate in research governance through laying down rules for entry into relevant professions, and the incorporation of a professional norm by legislation, thus giving professional guidelines the force of law. Campbell and Glass point out that courts are empowered to go beyond guidelines to establish legal norms. More often, however, they refer to the guidelines in determining the legal standard of care, in the absence of other legislation.[47] As discussed in Chapter Three, these guidelines may be considered soft law, instruments favoured under new governance arrangements. Similarly, under tort law, courts can refer to, and adopt, the standards set out in international guidelines such as the Helsinki Declaration or the Nuremberg Code, giving them some legal force.[48] In essence, therefore, new governance mechanisms like soft law may interact with the hard law when enforced by the courts.

Further, decisions made by courts may be applicable in a research context, even where not specifically relating to a claim arising out of a research

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[46] W J Sullivan, "The Law and the Physician as Principal Investigator in Sponsored Clinical Trials" (2003) 50:5 Canadian Journal of Anesthesia 436 at 439.

[47] Campbell and Glass note that: 'Where legislation explicitly incorporates a professional norm and refers to it as the standard of care, guidelines will carry the force of law. Otherwise, they will bear no definite legal authority and will not be considered legally binding.' See Campbell and Glass, in Downie, Jocelyn et al (ed.), Canadian Health Law and Policy (Second Edition) (Ontario: Lexis NexisInc., 2002). at 485.

[48] The Grimes court, for instance, referred to the Nuremberg Code in identifying the duties of researchers to those who participate in research. See 82 A.2d 807, at 849. See the Hazel Glenn Beh,"The Role of Institutional Research Boards in Protecting Human Subjects: Are We Really Ready to Fix a Broken System?" (2002)26 Law and Psychology Review 1 at 18.

context.[49] In the United States case of *Abigail Alliance for Better Access to Developmental Drugs v Eschenbach*, for example, the court held that there was no constitutional duty to provide terminally ill patients the right of access to experimental drugs that have passed limited safety trials but have not proven safe and effective. In essence, then, though this case was about access to experimental drugs, it would apply more widely to other cases, in this instance, indicating the need for more trials before drugs are made more widely available. The legal duties of researchers identified in such decisions help define the parameters within which researchers, host institutions, and research ethics committees must operate and are thus a crucial part of research governance systems.

The foregoing is by no means an exhaustive account of the law's impact on research governance. It is, however, obvious that law plays a significant role, if sometimes indirect, uncoordinated and unplanned role in research governance. In this respect Dickens writing about the Canadian context observed that:

> Biomedical research involving human subjects remains governed in Canada by law that is primarily directed to other purposes. Law applies *almost inadvertently* to the enterprise of biomedical research. Not only does legislation pay little regard to biomedical research, but may deliberately exclude it from coverage.[50]

Similarly, in many countries around the world, the law provides oversight to research, but in a manner that is:

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[49] *Abigail Alliance for Better Access to Developmental Drugs v Eschenbach* 495 F. 3d 695 (2007).
[50] Bernard M Dickens, "Governance Relations in Biomedical Research" in M. McDonald (ed.), *The Governance of Health Research Involving Human Subjects* (Ottawa: Law Commission, 2000) at 98-99. (My emphasis).

> piecemeal, uncoordinated, haphazard, issuing from various federal and state courts applying constitutional and common law and from federal and state legislatures and regulatory bodies creating statutory and regulatory schemes. By the very nature of how courts work – that is, accepting those cases brought before them by litigants – courts have responded issue by issue, and jurisdiction by jurisdiction, so that the law of one state on a particular bioethics issue may be opposite that of another, while a third has not yet considered the issue at all. Legislatures, in theory at least, have more freedom to set their own agendas and create comprehensive statutory schemes, but they have also tended to react on an issue-by-issue basis, especially in response to news events or public interest in an issue.[51]

As I argue, however, in the next section, this is a situation that needs to change, especially in developing countries. Legislation can and should play a larger, more intentional and specific role in developing countries' research governance systems.

4.4.3 The Case for Legislation in Developing Countries

While there is increasing interest in the governance of health research in many developing countries, and while common and civil law principles and some legislation may have direct and indirect impact on research governance, most do not have specific legislation as part of the governance mechanisms regulating such research. Further, even though some developing countries currently have legislation dealing with clinical trials for drugs, and some have legislation which encompass many health matters including establishing ethics review committees (as, for instance, in South Africa and Nigeria), many lack comprehensive legislation devoted

[51] Janet L. Dolgin and Lois L. Shepherd, "Law, Medicine, and Philosophy" in Janet L. Dolgin and Lois L. Shepherd, *Bioethics and the Law* (New York: Aspen Publishers, 2009) at 7.

to health research involving humans.[52] It is pertinent therefore to ask broadly again as I did in Chapter Two: Should law only operate as a legal framework or background for new governance and an encourager of the regulatory facilities of organisations or should there be a more extensive role for law in research governance? My answer, discussed in greater detail below, is that there should be an extensive role for law in the form of legislation on research governance in developing countries.

In this section, then, I argue that legal regulation ideally should operate to protect citizens, preserve their welfare and dignity, and potentially prevent harm as well as provide an enabling environment for acceptable conduct in research in developing countries. I contend that specific legislation on health research involving humans can play a crucial role in the protection of research participants through providing a legal basis for comprehensive governance systems and addressing specific issues around which there is some agreement. A comprehensive legal structure that catches most, if not all, research within its ambit, which extends protections to all research participants, and which puts in place the basic requirements is needed in many developing countries. Comprehensive legislation, in my view, represents the best practical response, providing the protections one can reasonably expect without sacrificing all the gains that an important activity such as health research involving humans offers.[53] In addition, drawing on my hybrid

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[52] See the Harvard School of Public Health, "Global Research Ethics Map" online: < https://webapps.sph.harvard.edu/live/gremap/index_main.cfm?CFID=1294829&CFTOKEN=50159247> (November 9, 2009). Indeed, many developed countries such as Canada and the United Kingdom also lack such legislation. But countries such as Spain and Denmark have more comprehensive legislation devoted to biomedical research.

[53] Dworkin, supra note 21 at 155, in relation to the United States regulations.

framework of governance, comprehensive legislation does not displace other components of research governance and does not act in isolation. Instead, it provides a stable, legitimate, and effective foundation within which they can perform effectively. Below, I make the case for such comprehensive legislation. I begin by considering the benefits of legislation vis-à-vis other governance mechanisms. I then consider the need for legislation specifically in developing countries. I also discuss the possible content of such legislation.

To begin with, why would legislation, understood here as "law made by elected representatives who may be informed by a large number and wide variety of sources"[54] be preferable to any other kind of legal instrument or indeed policy guidelines? Why not place sole reliance on the institutional framework, in particular the ethics review committee? Why not rely on common law and civil law to continue to right the wrongs that may arise in the course of health research involving humans? The answer is that legislation is prospective (in that, by comparison to the common law, it can address issues before they arise), it has the capacity to be more comprehensive, and perhaps most importantly, it embodies all the authority of law (unlike guidelines) and has the capacity to protect vulnerable citizens.

Legislation, even where it is only created in reaction to a scandal, can address issues which have yet to arise in addition to problems that have already arisen. Thus, although it may lack the flexibility of the common or civil law, legislation has the capacity to be prospective and it can be comprehensive, addressing a whole range of relevant issues. By contrast, courts can only, generally speaking, address the issues that arise before them and matters relating to health

[54] Ibid. at 10.

research involving humans may be addressed in a spasmodic manner.[55] Further, the common law of tort is reactive and applies only after the harm has been done, and is thus only indirectly prospective, that is, only with respect to past court decisions serving to deter harmful conduct. "The common law," writes Dworkin, "is ill suited to comprehensive, systematic lawmaking. It develops in fits and starts and at any one time it is likely to contain more holes than fabric."[56] He notes further that common law courts have neither the staff nor authority to regulate behavior in detail nor to supervise ongoing activities,[57] matters which can reasonably be provided for in legislation. The common law undoubtedly has its uses. But reasoned, comprehensive, systematic lawmaking, instead of piecemeal, inconsistent, fragmented lawmaking, in my view, may provide a sounder basis for research to proceed. Such legislation will not only provide legal protection to research participants, but will also provide researchers clear parameters within which research can be conducted in these countries.

In addition, legislation, the direct fruit of a democratic process, offers more accountability, uniformity and a more open process for debating issues, and therefore enjoys more legitimacy. Waring and Lemmens observe that:

> [L]egislation is debated openly, its provisions are publicized, and the legislative process provides accountability.... legislators are subject to the electoral process and parliamentary debates on legislative proposals are subject to public scrutiny. Legislation promotes uniformity and enforceability and can contain clarifications about the conditions

[55] Jaffe, supra note 25. As Dworkin observes in the federal context of the United States, where state courts make common law, "for most purposes common law is unlikely to provide uniform, national resolutions of issues." See Dworkin, supra note 21 at 8.
[56] Dworkin, ibid. at 9.
[57] Ibid at 13.

> under which vulnerable persons can legally be participants in research. In short, 'legislation has all the advantages that have been claimed for guidelines, and none of the disadvantages.'[58]

These attributes add to the moral authority of legislation. Legislation is typically enacted to reflect societal values, and in many ways imbues moral authority in actions and consequently legitimacy.[59]

Policy guidelines and professional guidance are useful and certainly have a place in dealing with the kinds of situation which may not always be appropriately dealt with in law, for instance, where there is continuing controversy and things are likely to change very rapidly. However, as useful and persuasive as guidance from national guidelines and professional codes may be, they may not, or may only indirectly, have the legal, binding and authoritative force that legislation boasts. Even then, policy guidelines are often offshoots of the legislative process. With specific respect to professional codes, they may not be as comprehensive since they typically only regulate the conduct of researchers that are members of the specific profession. The Nuffield Council on Bioethics notes, rightly in my view, that:

> Most of the existing guidance, however, has merely persuasive force and is only enforceable through sanctions imposed on members of the profession or group which was responsible for the particular guidance. The Declaration of Helsinki, produced by the WMA, only binds physicians. Similarly, the CIOMS guidelines only bind members of the

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[58] Duff R Waring and Trudo Lemmens, "Integrating Values in Risk Analysis of Biomedical Research: The Case for Regulatory and Law Reform (2004) 54:3 University of Toronto Law Journal 249 at 286-287 quoting liberally from Bernard Starkman, 'Models for Regulating Research: The Council of Europe and International Trends' in David N. Weisstub, (ed.), *Research On Human Subjects: Ethics, Law and Social Policy* Elsevier Science, (1998) 264 at 274.

[59] As Schneider rightly points out, "But law is not just a structure of regulation backed by force. Law also enjoys social and moral authority. Laws are often obeyed because people believe they should obey the law. And people are subtly but truly influenced by the law's expressive capacity (which exploits the law's power to impart ideas through words and symbols) and by the social force (the force of familiarity, custom, and legitimacy) acquired by institutions the law supports." Schneider, supra note 14 at 20.

> signatory organisations. Many involved in research related to healthcare today, however, are not members of the medical profession and thus may not be accountable under these guidelines.[60]

The accountability and legitimacy that should be part of the legislative process is also largely absent in the development of these guidelines.

Ethics review committees remain important as the part of an institutional framework that directly considers research protocols. However, they also lack a comprehensive reach since they must necessarily proceed on a case-by case basis. Moreover, legislation can provide a legal basis for ethics review, making it a legal requirement and creating different ethics review bodies. The significance of such legislative underpinning has been further underscored elsewhere:

> However hard they work, however thorough their examination of research protocols on a case-by-case basis, however much better constituted and trained, and however well supported they may be administratively, unless they have the power to ensure that all research is submitted to them and to stop research that they regard as unethical, they will not be taken sufficiently seriously. For these reasons and others... there should be proper legislation.[61]

I have considered the benefits of legislation in research governance generally, but what about legislation in research governance in developing countries specifically? One of the most important reasons why legislation as a basis for research governance in developing countries may be especially necessary is lack of

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[60] Nuffield Council on Bioethics, 2002: *The Ethics of Research Related to Healthcare in Developing Countries* (London: Nuffield Council on Bioethics, 2002) at 65.

[61] S. Verdun-Jones and D .N. Weisstub, 'The Regulation of Biomedical Research Experimentation in Canada: Developing An Effective Apparatus for the Implementation of Ethical Principles in a Scientific Milieu' 28 Ottawa L. Rev. (1996) 297 at 316, quoting Neuberger. See J. *Neuberger, Ethics and Healthcare: The Role of Research Ethics Committees in the United Kingdom Research Report* (London: King's Fund Institute, 1992) at 13.

resources. Funding is employed in western countries to ensure that researchers comply with ethical guidelines. For instance, the Canadian Tri-Council Policy Statement (TCPS) requires that researchers and research institutions who seek funding from the three major funding bodies must comply with the TCPS.[62] The United States "Common Rule" has similar enforcement mechanisms.[63] While some research is funded domestically, many resource-poor developing countries also rely heavily on foreign funding of research. Although there are usually requirements for the ethical conduct of research which accompany such funding, this is regulation from the perspective of the funders and not from the perspective of country in which the research is to be conducted. As part of a hybrid framework of governance, such funding requirements provide some sort of regulation. However, much difficulty is experienced by developing countries in controlling the types of research that may be conducted and ensuring that such research is responsive to local needs.[64] There are sometimes differing priorities of external researchers and indigenous researchers and there is legitimate concern about the power of researchers over research participants in the resource-challenged contexts of developing countries. As well, there is inherent tension in producing scientific benefits and protecting research participants. These circumstances require that there be an authoritative independent mechanism,

[62] See Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 1998 (with 2000, 2002 and 2005 amendments).
[63] Protection of Human Subjects: Department of Health and Human Services Regulations, Title 45, Code of Federal Regulations, (CFR) Part 46. The Federal Policy for the Protection of Human Subjects. See §46.
[64] See M.T. White, 'Reframing International Research Ethics: From Paternalism to Partnership' (2006), available at: <http://www2.gsu.edu/~wwwphl/ethics/africa_conference/papers/White.pdf> (accessed 16 March 2007).

separate from funding requirements, for the protection of participants in research in developing countries.

In addition, these countries cannot rely on funding as a means of regulation as some rich countries do since, to a large extent, they cannot offer or withhold funding. Moreover, reliance on regulation by funding agencies is not a comprehensive basis for governance; different kinds of research may be regulated differently, some may not be regulated at all. There would be no base standard for engaging in health research involving humans, or comprehensive protection for all participants. Further, in the absence of a legislative framework for research involving humans, there may be inadequate protections for participants in such research and unclear means for enforcement of compliance with the international guidelines or any existing domestic guidelines.

Another reason why such legislation is necessary is that, in many developing countries, legislation is lacking on some of the specific issues that arise in research. For instance, many developing countries, such as Nigeria, do not have any legislation on privacy and confidentiality, or the rights of minors, areas in which many developed countries have legislation. Comprehensive legislation would therefore address these and other issues, providing clear legal requirements, rights, and responsibilities. The contexts of developing countries, therefore, provide reasonable grounds for arguments for legislation.

Also, governments of developing countries need to exercise a sense of ownership with regard to protecting their citizens. In view of the sovereignty of each nation and the resulting problems for any sponsoring developed country that is

concerned with in protecting the citizens of host developing countries where their nationals conduct research in developing countries, national legal regulation on the part of the developing country may be the best way to protect participants in research.[65] Each country's national laws apply within its territory and principally to its own citizens. Laws with extraterritorial effect are mainly enacted for activities widely condemned such as pedophilia.[66] Thus, Skene notes that:

> It is rare for countries to have laws directly preventing their nationals doing research overseas that would not be permitted at home, or even bringing back the products of such research, unless they pose a safety risk, such as importing genetically manipulated organisms created overseas.[67]

As such, even though some developed countries may wish to provide equivalent protections for people in developing countries, domestic legislation remains necessary to protect vulnerable citizens, and the existence of such legislation reflects a state that is concerned for the welfare of its citizens.

One of the problems that may arise in the area of regulating research involving humans is that a profusion of ethical guidelines and policies may be developed. Such profusion may produce confusion instead of providing clarity to researchers and research participants. In developing countries, where research governance is still a relatively new endeavour, the dialogue that necessarily precedes

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[65] See William DuBois, "New Drug Research: The Extraterritorial Application of FDA Regulations, and the Need for International Cooperation" (2003) 36 Vand. J. Transnat'l L. 161; see also, G. F. Tomossy and J Ford, Globalisation and Clinical Trials: Compensating Subjects from Developing Countries in in B. Bennett and G.F Tommossy (eds.), *Globalization and Health: Challenges for Health Law and Bioethics* (Springer: Dordretcht, 2006) at 30, noting that, despite the difficulties of limited resources 'a substantive system of research governance entrenched at the national level would be the ideal solution.'

[66] L. Skene, 'Undertaking Research in Other Countries: National Ethico-Legal Barometers and International Ethical Consensus Statements,' *PLoS Med* 4(2) (2007) e10.

[67] Skene *ibid.*, argues,"in the great majority of cases, there are no ethical reasons to prevent scientists from doing research abroad or using the research results at home, even if the research does not comply with local laws."

legislation will improve clarity, with discussions by key stakeholders of the ways to govern research in such a way as to create an enabling environment for research, delineate the responsibilities of stakeholders in the research enterprise and protect research participants.

In addition, policies tend to be more short-lived and less likely to be adopted by successive governments. It has been observed generally, in relation to health policies in developing countries, therefore, that:

> Many developing countries have adopted health policies on an ad hoc or informal basis, with the result that policies are not memorialised in legislation and therefore have no force of law. Enacting policies with no underlying legislation often means policy initiatives are short-lived and can be easily repudiated by successive governments. Even where a country is firmly committed to its policies, rule of law and existing international agreements, it is not bound by a policy, much less programmes, that has not been enacted in appropriate and enforceable legislation.[68]

To implement relevant policies and plans, and to ensure stability, consistency and sustainability, legislation is necessary. Legislation can also beneficially serve to articulate, codify and consolidate values, as well as strengthen and support the goals and objectives articulated in national policies.

In a similar vein, it is important for there to be a legislative and thus more legitimate foundation for the work of ethics review committees in developing countries, which may otherwise operate from a weak position. Ethics review committees in developing countries operate in challenging political and socio-

[68] Health Partners International, "Health Policy, Legislation and Biomedical Ethics" online: < http://www.healthpartners-int.co.uk/our_expertise/health_policy_legislation_and_ethics.pdf> (November 9, 2009).

economic contexts. They are required to consider general, problematic issues that accompany health research involving humans but also the special issues that arise in these contexts, for instance: issues relating to post-trial access to benefit; determining whether a particular research will benefit the wider community or whether a different study will be more beneficial to the community given the specific needs of that community; or the appropriate standard of care to be provided in a challenging socio-economic context.[69] Ensuring the independence and legitimacy of these committees requires that they operate within a statutory framework, not merely national ethical guidelines.[70]

The case I make here for employing legislation may, however, attract opposing views. Legislation (and the legislative process) is not without its flaws. Dworkin details some of these in his book, *Law: The Role of Law in Bioethical Decision Making*,[71] where he describes the ways in which politics interferes with, and influences the legislative process sometimes negatively, with politicians undertaking political negotiations between themselves, relying on lobbyists for expert information, which do not necessarily ensure sound legislation. In developing countries, particularly those with fledgling democracies, these challenges are of course greater in magnitude, where electoral malpractice and the failure of elected

[69]C H. Coleman and M Bouesseau, "Strengthening Local Review of Research in Africa: Is the IRB Model Relevant?" (2006), online: <http://www.bioethicsforum.org/ethics-review-of-medical-research-in-Africa.asp> (June 22, 2007).

[70] Even the international ethical guidelines, like the *Helsinki Declaration*, recognise that ethics review committees should be in conformity with the laws and regulation of the country, arguably recognising the necessity of a legal framework for the work of such committees. See Article 13 of the Helsinki Declaration.

[71] B.R. Dworkin, *Limits: The Role of Law in Bioethical Decision-Making* (Indiana: Indiana University Press 1996) at 2..

leadership to pay attention to matters relevant to their citizenry, amongst other things, may result in flawed legislation, or no legislation or overall policy direction.

The arguments made above in favour of specific legislation in developing countries governing health research involving humans may thus raise questions about the limits of law in such countries. In these countries, the more important question may not be whether law can have an impact on research governance, but whether in the specific context of developing countries law is of any use at all. Are laws generally complied with in developing countries? Are there adequate means to enforce legislation in such countries? What about corruption and abuse of power?

One cannot cursorily dismiss the challenges that the rule of law faces in developing countries or the political and socio-economic realities of such countries. As I pointed out in Chapter Two, the hybrid framework adopted in this thesis, including my proposal for legislation-driven governance of research requires some sort of functional or functioning democracy and a desire by developing countries' governments to better the lives of their citizens. There may be no viable alternative to this for, as discussed in Chapter Two, the government and the law remain formidable repositories of resources and authority.

The potential challenges of enforcement, political commitment, adequate resources, functioning institutions, in developing countries' contexts, do not, in my view, obviate the need for a comprehensive legal basis for research governance in developing countries. In terms of political commitment, it must be said that a number of developing countries have begun to tackle, even if imperfectly, some of the challenging issues. Nigeria, which I focus on as a case study in this thesis,

recognises the power of law and, as I discuss in subsequent chapters, is moving in the direction of employing law, although inadequately in my opinion, in the governance of health research. Countries like Chile,[72] and South Africa,[73] have also adopted legislation as a basis for the governance of health research in these countries. But many other developing countries, including Bolivia, Jamaica, and Vietnam, have not enacted legislation to govern health research involving humans.[74] In terms of enforcement, even under imperfect conditions such as exist in developing countries, legislation creates legal obligations and provides a rallying point for individuals and organisations. Individuals and organisations would be better able to pressure and compel the state to meet its obligations to protect research participants by enforcing compliance. In developing countries such as Nigeria and South Africa, non-governmental organisations have had some success in compelling governments to meet their obligations under the constitution, different legislation, and human rights instruments. More broadly, addressing the matter of research governance legislatively provides the opportunity to build the broader governance capacity of democratic institutions. The potential of the law to improve research governance in developing countries should therefore not be exaggerated but neither should the significant good that it can do in these contexts be overlooked.

Creating basic legal requirements for research would not only provide protections for research participants but would establish an enabling environment for

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[72] *Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning, Law No. 20.120.*

[73] *National Health Act, Act No. 16 2003.*

[74] See OHRP, *International Compilation of Human Research Protections, 2010* online: <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf> (May 30, 2010), which lists many developing countries and the regulations, guidelines and legislation governing health research involving humans.

researchers, who would be equipped with the knowledge of the regulatory structures, procedures and requirements. Verdun-Jones and Weisstub also note that providing a legislative basis for the operation of ethics review committees may provide a defence to a negligence action brought against a researcher where she has acted in good faith according to a research protocol for which she obtained approval from an ethics review committee.[75] Compliance with the law thus offers protections for researchers and facilitates beneficial research. Legislation could also act as a means of securing resources, for instance, funding for ethics review committees. In this way, legislation would act as a facilitative mechanism as well as a protective mechanism.

The use of legislation will therefore not displace the need for other components of research governance. It does not, for instance, substitute for effective self-regulation at the institutional level (institutional ethics review committees or professional associations). But legislation has the potential to strengthen these components of governance and provide a solid foundation for their functioning. Legislation can address the fundamental weakness of voluntary self-regulation, which as Ayres and Braithwaite observe, is the possibility that self-regulating actors will be unwilling to regulate effectively.[76]

In addition to the challenges of the legislative process and the socio-political environments of developing countries, a counter argument against legislation may be that although it is a prospective tool of law, legislation may not necessarily foresee all the problems and issues that may arise with research involving humans, an area which is constantly evolving. As such, a legislative approach may

[75] Verdun-Jones and Weisstub, supra note 61 .
[76] Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (New York: Oxford University Press, 1992) at 106.

not be feasible for all the issues that arise. As rightly noted, "changing values, advances in science, and unanticipated situations combine to create the possibility that prospective, comprehensive lawmaking will be fundamentally flawed."[77] This is a legitimate argument. However, it is doubtful that a legal vacuum or an atmosphere of fragmented and incomplete legal protections for research participants, is better than enacting a possibly flawed legislation that attempts to protect research participants, because the legislation does not anticipate all future events. Such an argument does not detract from the importance of legislation as a crucial tool for protecting vulnerable research participants, nor does it rebut the argument that legislation can act as a comprehensive and authoritative basis for research governance. In any event, as I discuss further below, the type of legislation envisaged, is one which addresses the core and basic requirements for the ethical conduct of research. One of such core requirements may be the requirement for regulatory authorities to undertake developments as things evolve in certain instances.

Likewise, the prospective nature of legislation may not necessarily allow for the evolving nature of fields such as research governance and ethics. Thus it may be feared that legislation would generate a rigidity which would stifle the conduct of research, creating worry for researchers who may be concerned about litigation and penalties.[78] However, where the legislation is not too detailed as to be too restrictive, particularly in relation to the powers of the ethics review committees,[79] and articulates basic standards for the conduct of research, the advantages of legally

[77] Dworkin, note 21 at 12. See also, Campbell and Glass, note 47 at 486.
[78] Verdun-Jones and Weisstub, supra note 61 at 329.
[79] See Verdun-Jones and Weisstub, *ibid.*

enforceable protections for research participants, clarity and comprehensiveness of responsibilities and a secure environment within which researchers can conduct research outweigh the possible disadvantages. In any event, broad public consultation prior to enacting such legislation or regulations would be necessary. The need for any sanctions or penalties[80] and the extent to which certain controversial ethical issues, such as those around access to post-trial benefits or standard of care, should be addressed in legislation, can be addressed in such consultations.

Rigidity need not be an insurmountable obstacle. While it may be burdensome to amend legislation, particularly with respect to time, financial and human resources, it is necessary to recognise that amendments may need to be made to legislation. Indeed, room must be made for such amendments to occur to take into account changing circumstances, advances in the field of health research, and greater understanding in research ethics. In other words, such legislation "should not be viewed as an event, but as an ongoing process that evolves with time."[81] A mandatory review period provided for in such legislation (as contained for instance in the Assisted Human Reproduction Act in Canada) would allow the flexibility needed in an evolving area such as the governance of health research involving humans. Certain matters, however, particularly controversial issues on which opinions revolve on a frequent basis, may not be appropriate matters for the

[80] See B. K. Sovacool, 'Using Criminalization and Due Process to Reduce Scientific Misconduct' 5: 5 American Journal of Bioethics (2005) W1–W7, advocating the use of criminal legislation for the protection of research participants and to reduce intentional research misconduct.
[81] WHO, *WHO Resource Book on Mental Health, Human Rights and Legislation* (Geneva: WHO, 2005) at 7.

legislation. Such matters can, and should be dealt with in policy or regulatory guidelines that derive their authority from legislation.

Another argument against comprehensive legislation may be that, although legislation is said to provide clarity, the uncertainties of and vagaries of language limit such clarity.[82] However, some of the limitations of legislation, as Dworkin notes, can be remedied by paying special attention to them.[83] This would apply especially to the issues of language and proper drafting.

A different opposing argument would be that with regard to research governance in developing countries, the major issues that arise would be how to fund the governance system, provide adequate expertise for conducting thorough ethics review and ensure the independence of the committees. These are important but different concerns. But again, these do not detract from the argument for comprehensive legislation. Indeed, the argument that I make here is that, amongst other things, there should first be a proper foundation for ethics review, preferably a legal foundation, guaranteeing the important role and function of ethics review committees. How to ensure that such ethics review is properly carried out is a separate matter, which does not detract from the need for good legislation, but will in fact become a more pressing issue to tackle where it is addressed by such legislation. For instance, as mentioned above, legislation may create a funding scheme, imposing obligations on the government to create such a scheme, and requiring that research sponsors pay a small fee to a fund from which ethics committees may be funded.

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[82] Dworkin, supra note 21 at 13.
[83] Ibid at 14.

Obviously, legislation, by itself, does not make people or organisations ethical. Researchers must be committed to ethical conduct, and a culture of ethical conduct in research is a necessity. However, a lack of legislation does not ensure ethical conduct, but leaves room for exploitation and unethical practices. Legislation, particularly in the absence of any other strong compliance mechanisms, may also act as a deterrent against unacceptable conduct.

4.4.4 Content of Legislation

Having made a case for legislation in research governance in developing countries, several issues may arise, including issues relating to content. One question that may arise is: what should well-conceived, comprehensive legislation contain? In my opinion, specialised or dedicated legislation on the governance of health research involving humans may be best because it is easier to enact than a mixed-model legislation comprising other matters. There is a greater likelihood that all the essential aspects of the research governance are addressed, it eliminates the need for multiple amendments to existing laws, and the process of enacting it provides an opportunity to raise public awareness about the relevant issues relating to health research involving humans.[84] Still, legislation that contains other unrelated matters, but is comprehensive in its provisions on research governance may suffice.

The Danish legislation on biomedical research: *Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research*

[84] WHO, supra note 305.

Projects[85] is a good example of a legislation dedicated to biomedical research. Although it covers only biomedical research (thus not including other types of research covered in the wider umbrella of health research), it provides details of the organization of the research governance system, the funding of the system, but also addresses many other issues, including, for instance, conflicts of interest issues.[86] It could therefore provide a possible starting point for developing countries interested in enacting similar legislation. Below I summarise the main matters that such legislation must deal with. I must emphasise that this is just a broad sketch of what the legislation should contain. Developing countries may decide to expand the contents of such legislation, but the requirements below are, I suggest, basic requirements that should be contained in such legislation. Such legislation must also fit within the constitutional frameworks of such countries.

To start with, such legislation should govern all health research involving humans and stipulate certain basic formal legal requirements. (It should in fact cover all research involving humans, but since this thesis is focused on health research and has made arguments regarding health research only, I will focus here on legislation on health research involving humans). It would thus go beyond drug regulatory processes which many developing countries may have. The legislation should not be limited to clinical research, although this may cause more immediate harm than other types of research such as behavioural research. But, as pointed in Chapter One, even these types of research may result in harm and it would be wise to

[85] *Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects* 2003 (as amended)online: <http://www.cvk.sum.dk/English/actonabiomedicalresearch.aspx> (November 6, 2009).
[86] Section 14.

provide protections for participants in any research and to ensure that no health research is unregulated.

The basic requirements would include the requirement for all health research involving humans to undergo ethics review. As some studies have revealed,[87] not all research conducted in developing countries pass through ethics review. It is therefore necessary to make it explicit in law and even criminalise failure to seek such review, creating sanctions for such behaviour. In Denmark, for instance, it is illegal, and punishable by up to four months imprisonment or the imposition of a fine, to commence a biomedical research project without the approval of an ethics review committee or to implement substantial changes in the research project after commencement without the approval of an ethics review committee.[88]

Such legislation should require the establishment of ethics review committees. It should state which type of organisational structure, whether institutional or regional committees.[89] It should state that research protocols must be submitted to these committees and elucidate general methods of operation. It should grant these committees power to review research, to approve or reject research protocols, propose modifications to research protocols, monitor research, and to order the discontinuation of research where found to be unethical or unsafe. The legislation should aim to provide consistency in the rules for the creation, organization, composition, powers and operation of the ethics committees,[90] as well

[87] See Section 3.2.1 above.
[88] Section 29 of the Act.
[89] In my opinion, a regional structure may work best for developing countries. I discuss this in subsequent chapters.
[90] Dannie Di Tillio-Gonzalez and Ruth L. Fischbach, 'Harmonizing Regulations for Biomedical Research: A Critical Analysis of the US and Venezuelan Systems" (2006) Developing World Bioethics 1471-1481.

as provide secure resources for ethics review committees by addressing sources of funding, particularly for a national ethics review committee. The provision of secure resources for ethics review committees in legislation is necessary to ensure the independence and sustainability of such committees. In Denmark, for instance, the costs of the regional committees are required to be paid by the county councils, which in turn can charge a fee payable by research sponsors and research institutions, thus providing a stable source of funding for the ethics review committees. It even provides for the reimbursement of members who serve on the regional committees.[91] Payment for research review might raise ethical questions regarding whether such payment may undermine the independence of ethics review committees. But particularly in resource-constrained developing countries, there may be no viable alternative. I discuss this in my recommendations for Nigeria.

Thus, in addition to making ethics review a legal requirement, such legislation should create or recognize other specific institutions, including national ethics committees and policymaking structures and specify their powers of such committees, such as the power to create guidelines. Legislation should create national ethics review committees, which as discussed earlier, are particularly helpful in easing bureaucratic issues such as those involved in multi-centre research. The significance of empowering the national ethics review committees to make guidelines by law is that, depending on the manner in which this provision is couched, compliance with such guidelines may become mandatory, having a

[91] See section 28 of the Act.

derivative force in law.[92] The establishment of these national guidelines would also be helpful in assuring uniformity of practice among the regional, or institutional research ethics committees. Such committees should be required to provide public reports of their activities from time to time, for example, annually.

The law should also provide time limits within which ethics review committees must reach a decision about whether or not a research project can proceed. The Danish law has similar provisions.[93] This is obviously helpful for researchers, and is one example of a situation in which the law undertakes a facilitative action. It should also provide a complaints mechanism through which researchers and research sponsors can present complaints, perhaps to a national committee where these limits are exceeded. Additionally, the law should delineate appeal processes for researchers who have submitted projects to ethics review committees.

It should also define clearly the relationship between the drug regulatory agency and the ethics review committees to ensure that there is harmony, no unnecessary duplication of responsibilities or loopholes, and to assist researchers and research sponsors in understanding what the requirements are.[94] Similarly, the proposed legislation should address the place of other existing guidelines, international or domestic, either by incorporating them or by explicitly recognising their application or non-application in the country. The legislation should also have

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[92] Bernard Starkman, supra note 58 at 268. Commenting in respect of the legislative approach taken by the United States, Starkman argues that "[t]he legal basis of the regulations provided an important rationale for insisting on responsible cooperation with the research review process."

[93] See section 10.

[94] See section 15.

a mandatory review period, for instance, every ten years, to take into consideration any changes in the area of health research involving humans.

With respect to substantive provisions, at the minimum, I suggest that informed consent, widely recognized as mandatory for the ethical conduct of research, should be one of the statutory requirements. The details of how to obtain informed consent should, ideally, be a part of the legislation. It should also include how to obtain consent in less than ideal situations, such as in emergencies. The law should also provide penal sanctions for non-compliance with informed consent provisions.

Such legal regulations should address such issues as legal capacity to participate in research, legal representation of minors and the protections that must be available to such vulnerable groups as children, the mentally challenged, developmentally disabled, and prisoners. The Pfizer incident, which I discuss in the following chapters, involved children. In the absence of clear legal rules regarding what constitutes informed consent in the case of children, and who can give such consent, the safety of children involved in research may be jeopardised. Additional specific legal protections are needed for vulnerable groups and these should be provided in legal regulations or legislation.[95] As well, it should address the legality or otherwise of all biomedical research, but particularly non-therapeutic biomedical research involving children and the mentally challenged, and other persons in vulnerable situations.

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[95] See G. Dworkin, Law and Medical Experimentation: Of Embryos, Children and Others with Limited Capacity 13 Monash ULR (1987) 189, noting that: "There seems to be a strong case for general legislative consideration, and clarification of the power to give proxy consent for the purposes of research on children."

Further, such legislation should deal with privacy and access to information issues. It should also provide for issues relating to adequate health insurance for research participants and compensation for injury or harm to participants. Given the additional protection that research participants require and the fact that many developing countries lack public health insurance schemes, this should be an area that should be covered in legislation. A compensation scheme should be provided for by such legislation such that healthy volunteers in clinical trials will receive compensation for any injury resulting from participation in such trials.[96] According to Burris, such compensation scheme is a structural reform that does not depend on virtue or participant autonomy to prevent harm, but recognises that some harms will occur in any case.[97] But he also questions whether a fault-based system would repeat the malpractice system's combination of under-and-over-claiming, and if a compensation scheme is worth the effort and cost, given that the research participants volunteered and harm from research is arguably rare.[98] It is debatable that a compensation scheme is not needed because a research participant volunteered; indeed it could be argued that this is the very reason why such a scheme is necessary. Research-related injury may be rare but may be devastating when it does occur. A compensation scheme provides potential participants with protections, but also the public with confidence that research volunteers will be adequately taken care of in the event of any harm.

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[96] S. C. Chima, 'Regulation of Biomedical Research in Africa" (2006) 332 BMJ 848-851.
[97] Scott Burris, "Regulatory Innovation in the Governance of Human Subjects Research: A Cautionary Tale and Some Modest Proposals" (2008) 2:1 Regulation and Governance 65 at 82.
[98] Ibid.

Conflict of interest issues should also be addressed in such legislation. The Olivieri case provides an example of a situation where legislation would have been useful. In that case, if legislation had made it clear that all adverse events must be reported by law, then any contract with a research sponsor stating otherwise would have been illegal in that respect. It should be made statutorily mandatory for adverse events discovered in the course of research to be reported to participants, the drug regulatory authority, and the ethics review committee which approved the trial. Where this is a clear legal requirement, a research sponsor would be unable to legally insert a clause in a contract with an investigator or researcher not to provide such a report to the relevant persons. Whistle-blower protections should also be provided under these laws, so that an investigator or any person who makes a confidential report about unethical practices in research receives clear protection under the law. Beyond these, the law should also provide for a mechanism that is increasingly accepted around the world as necessary in ensuring ethical conduct in health research, namely, registration of trials in clinical trial registries.[99] The law should mandate the establishment of such a registry, and make it compulsory for all clinical trials to be registered in such registry to ensure that it is known at any given time what trials are ongoing in the country, and be better able to monitor these trials.

Such legislation should also address issues that will begin to arise as ethics review becomes more entrenched in developing countries, including issues relating to the legal liability of ethics review committees and insurance for ethics review committees. In the absence of any law creating ethics review committees and

[99] J L Gold and D M Studdert, `Clinical Trials Registries: A Reform That is Past Due,` (2005) 33:4 J Law Med Ethics 811.

defining their responsibilities and their legal liability, certain difficulties arise for research participants in establishing the liability of these committees.[100] Difficulties may also arise for members of these committees in defending themselves in the absence of any statutory limitations on the degree of possible liability. A system of liability created by legislation may be more appropriate, both for ethics review committees whose role is to protect research participants, and for research participants who require protection.

The foregoing is, as stated at the outset, only a broad sketch of what such legislation should cover. Legislation on research governance in developing countries could therefore go beyond the matters proposed here. Developing countries must take into consideration their contexts and their peculiar challenges in enacting such legislation. Broad-based consultations with key stakeholders in which vigorous debate is permitted and an understanding of what other jurisdictions have done in these areas will obviously be a necessary precursor to a successful enactment of legislation that has the potential of being effective in promoting health research and protecting research participants in such research. Enactment of such legislation would also have to fit within the framework of a country's constitutional distribution of powers and be consistent with other law in place, including for instance, human rights laws.[101]

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[100] See M. Brazier, 'Liability of Ethics Committee and Their Members' *PN* (1990) 186, quoted in Ian Kennedy and Andrew Grubb, *Medical Law* (Third Edition) (New York: Oxford University Press, 2005) at 1702. These arise from difficulties in establishing the legal status of ethics review committees.
[101] See Dickens, in the Canadian context, supra note 50.

4.3 Recognition of the Relationship between the Ethical, Legal and Institutional Frameworks

In Chapter Two, I argued that a hybrid governance framework, as articulated in this thesis, can be helpful in determining whether current governance arrangements, including different mechanisms and frameworks, in any country is likely to help the delivery of better outcomes. In Chapter Three, I described generally many of the mechanisms within the ethical and institutional components employed in governing research in different countries. And above, I argued for the use of legislation as a foundation for research governance in developing countries. However, as I have described in those chapters, each of these components has systemic challenges, whether from their non-existence, from lack of proper use, or from lack of the mandate or authority to operate more broadly, or from the challenging context in which they have to operate, particularly in developing countries. None of the components, it seems, can work by itself to achieve effective governance of health research involving humans.

It is important to recognise that each of the components brings something important to the governance of health research involving humans – ethics lays the value foundation and gives the reason for governance, the legal framework regulates behavior and lends the "punch" of legal force, and the institutional framework actuates both the legal and the ethical frameworks. It seems to me, then, that to put the different components of research governance in silos, whether in scholarship, or in the actual operation of these components in different jurisdictions, without realising that they may be more effective when they work together, is

counterproductive. For instance, the issue of ethics review committees, which I have categorized under the institutional framework, has received so much attention in the literature that they may therefore be mistakenly considered *the* governance system. McDonald describes accurately this tendency to reduce the governance system to ethics review, observing that:

> [T]he ethics review process by the REB has come to be, in the minds of the major institutional actors and their constituents, a surrogate for a comprehensive ethical approach to research involving human subjects. In effect, countries around the world have put in place a social system that loads on to the REB approval process almost the total burden of ethical responsibilities for human subjects research. That is, all the major actors (including research sponsors, institutions, and regulators) behave as if REB approval is all that there is to the ethical conduct of research involving human subjects. The REB process (and with it the focus on the research proposal and the consent form) has become the reification of the sum total of responsibilities and accountabilities for researchers, research institutions, research sponsors, and research regulators. In effect, this rationalizes the avoidance of major responsibilities that arise before, after and on the peripheries of the REB review process. [102]

The literature has tended to focus mainly on the work of ethics review committees. However, for scholars interested in the governance of health research, researchers involved in health research, research sponsors, and perhaps most importantly for research regulators, to see the linkages between the different components of governance is to take a view of the big picture. These frameworks have to work together to effectively achieve the objectives of research governance.

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[102] McDonald, *supra* note 68 at 9. See also Susan V. Zimmerman, "Translating Ethics into Law: Duties of Care in Health Research Involving Humans" (2005) 13 Health Law Review 13 at 13.

Recognition of these components assists in identifying instances in which some issues may not be addressed effectively or do not fall within the ambit of any legal, policy or institutional framework, or inadequacies in sponsor requirements (such as reporting of adverse events within a clinical trial or disseminating research findings). Such identification helps then to find the appropriate mechanisms to deal with such matters.

An acknowledgement of the possible relationship and the interactions between these components allows us not only to identify possible gaps and weaknesses in a particular framework, but to determine if such gaps or weaknesses can be remedied within that framework or, whether a better remedy can be found in the context of another framework where appropriate. In the foregoing sections, I have discussed the systemic issues affecting different mechanisms of the institutional component, and the limitations of law in a developing country context. A specific issue in the governance of research may therefore be more effectively dealt with by addressing it in the context of that particular component, or in the context of all three components. For instance, the issues of conflict of interest or reporting adverse events, may be dealt with not only in the domestic ethics policy, but in legislation, with researchers and ethics review committees then required to carry out their obligations under both the ethical and legal framework. A funding mechanism may be mandated in legislation to ensure that ethics review committees have the necessary resources to effectively carry out their functions. Employed appropriately, the work of non-governmental organisations may be helpful in articulating community concerns and in promoting the enforcement of legislation.

Moreover, legislation is a type of legal framework, particularly well-suited to establishing the connections between the frameworks (including other parts of the legal framework, such as tort) and to facilitating collaborative functioning between the components. It is by its nature a "meta-governance" tool. It can, however, only be deployed in this way if it is designed in new governance ways, with much consultation, and with the need for responsiveness and effectiveness at the forefront of legislators' minds.

Finally, the recognition of the possible relationships between these frameworks may help streamline the legislation, policies and guidelines and assist in defining the sources of authority for governing the ethical conduct of health research which, especially in the case of the developing countries may be myriad and yet insufficient. In doing this, an investigation of the relationships between institutions which conduct research and the relationships between the institutions which regulate research becomes possible. This would in turn help researchers in navigating the regulatory requirements and ultimately result in better governance of health research. A systematic approach that recognises the relationships between all three frameworks, both in scholarship and in the actual operation of these frameworks would be beneficial.

4.3 Conclusion

In my hybrid framework, I argued that law, as a policy option of the state, brings something important to research governance. In the foregoing pages, I have argued that developing countries may need to enact specific legislation devoted

to health research involving humans. Such legislation does not operate in isolation nor does it substitute for other components of research governance, including those which operate as self-regulation. Legislation may, however, provide a firmer, more legitimate basis for the functioning of other components of research governance. Legislation inherently incorporates aspects of other components of research governance, conferring on then legal affirmation and authority, creating appropriate sanctions not guaranteed within other governance frameworks. I have also described some of the areas that, in my view, should be covered by such legislation.

I have also argued that the systemic challenges, and the weaknesses in the operation of each of the frameworks requires that there be better recognition of the possible relationships that exist and should be present in the operation of these frameworks.

Having set the stage in this chapter and in the three chapters that preceded it, in the chapters that follow, I will address specifically governance arrangements in Nigeria.

Chapter Five

Research Governance in Nigeria: Context and History

5.1 Introduction

Nigeria is a low-income developing country in Sub-Saharan Africa. It is Africa's most populous country, with an estimated population of over a hundred and fifty million people, approximately a quarter of Africa's population.[1] It is also the eighth most populous country in the world.[2] Nigeria is the eighth largest oil exporting country in the world and the largest oil producer in Africa.[3] Although blessed with oil, and a large human population, Nigeria has been besieged by political instability, weak leadership, military rule, human rights abuses, ethnic and tribal conflicts, corruption, mismanagement, and many squandered opportunities to effectively utilise its relatively vast resources to provide a high standard of living for its many citizens. Notwithstanding these weaknesses Nigeria remains, a "sub-regional hegemon,"[4] "crucial to the future of Africa: the continent's most populous country and its largest economy after South Africa,"[5] "Africa's greatest contradiction

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[1] World Bank, *World Development Indicators 2008* (New York: World Bank, 2008). The Central Intelligence Agency (CIA), World Factbook: Nigeria, online: < https://www.cia.gov/library/publications/the-world-factbook/geos/ni.html> (December 27, 2009).
[2] Central Intelligence Agency, "Country Comparison: Population" in the World Factbook, online: <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2119rank.html> (March 2, 2010).
[3] BBC, "Nigeria: Facts and Figures" online: <http://news.bbc.co.uk/2/hi/africa/6508055.stm?lsf> (June 26, 2009). US Energy Information Administration: Independent Statistics and Analysis, "Nigeria: Oil" online: <http://www.eia.doe.gov/emeu/cabs/Nigeria/Oil.html> (March 2, 2010).
[4] L. Bergholm, "Who Can Keep the Peace in Africa?" (2007) 16: 442 African Affairs 147 at 151.
[5] Richard Synge, "The Role of Nigeria in the Evolution of West African Regional Security and Democratisation: Contradictions, Paradoxes and Recurring Themes" (1999) 13: 1 Cambridge Review of International Affairs 55

... at once the continent's greatest hope and its biggest danger,"[6] and, because of its vast oil and human resources, significant on the world stage.

Nigeria has recently taken several steps with respect to research governance and provides an interesting context within which to study research governance in a developing country. In addition, there are significant possibilities for health research. In this regard, it has a large population, thus providing a large pool of potential research participants, and also a significant and growing number of potential researchers. It also has a significant burden of disease, and thus a great need for health research. With the great need for health research and a large pool of potential research participants, there is a corresponding need to ensure that whatever health research takes place occurs within clearly defined parameters.

Despite its oil wealth, Nigeria also has many economic challenges and myriad problems, including high levels of poverty. Politically, its democracy is still at a nascent stage. And with respect to health, there is a significant burden of disease and a weak health system. These characteristics are emblematic of many other developing countries, particularly in Africa. In these respects, Nigeria provides a good case study. Its actions with respect to research governance have the potential to influence other developing countries in their research governance efforts. The efforts of other countries will, of course, have to be tailored to fit their contexts more precisely.

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[6] W. Wallis, "Africa's Greatest Hope—And Danger" *Newsweek* (February 11, 2002) at 24.

The objective of this chapter is to provide background information on Nigeria, and the history of research governance efforts in the country. It aims to describe the context in which the governance of health research involving humans in Nigeria takes place. In this chapter, I provide a description of health research in Nigeria, the health system in which this takes place, and the political and legal context in which this system operates. I consider the historical background of research governance in Nigeria. The history provided here is drawn from bits of information from various sources, and presents a more comprehensive and detailed picture of the history of research governance in Nigeria than is currently available. As part of this history, I consider also the major instance of unethical conduct of research in Nigeria, the Pfizer incident. This incident has received much attention in the literature and has become a conspicuous example of the potential room for exploitation that exists in many developing countries. The discussion of the context and the history of research governance will reveal some of the issues that need to be addressed as the emerging governance system is developed.

This chapter is broadly divided into two main parts. The first provides information on the political and legal context, and on the health system in Nigeria. The second part provides a history of research governance. The chapter is composed of seven sections. The first section is this introduction. The second section describes the political background and the legal context. The third section describes Nigeria's health profile and health system. The fourth section provides a description of health research in Nigeria. The fifth section attempts to construct a history of research governance in Nigeria. It also considers allegations of unethical research in a bid to

create an appropriate context for the need for research governance in Nigeria and to identify gaps in research governance and regulation in Nigeria. The sixth section draws some conclusions from the history of research governance and the discussion of the Nigerian context and identifies issues that arise from Nigeria's history of research governance. The seventh section concludes the chapter.

5.2 Political and Legal Context

Nigeria is a former British colony which will celebrate fifty years of independence in October 2010. Nigeria is a democratic federal republic with a multi-party political system. After thirty nine-years of independence, twenty-nine years of which were spent under military rule, it has, starting in 1999, operated as a new democracy.[7] Although democracy in Nigeria is still very much a work-in-progress, it remains clear that to many Nigerians, and in light of some achievements under the democratic regime since 1999, a flawed democracy is better than authoritarian military rule.[8] Many hope, therefore, that the days of military rule will remain in Nigeria's historical past. One of the achievements of this recent

[7] This is Nigeria's longest experience of democracy. Although the general elections in 2007 resulted in the first ever handover of political power from one civilian government to another in Nigeria's history, the elections were criticised by domestic and international observers for pervasive vote-rigging and fraud. Rotimi T Suberu, "Nigeria's Muddled Elections" (2007) 18:4 Journal of Democracy 95.

[8] Many surveys indicate that Nigerians like and support the idea of democracy. Michael Bratton and Robert Mattes, "Africans' Surprising Universalism" (2001) 12:1 Journal of Democracy 107 at 112. And according to Bradley, "The research on attitudes toward democracy in Nigeria looks favorable in terms of citizens wanting and demanding it. For example, Lewis and Bratton (2000) found that in general Nigerians have a fervent attachment to democratic values and electrifying optimism about the benefits of democracy." Matthew Todd Bradley "Civil Society and Democratic Progression in Postcolonial Nigeria: The Role of Non-Governmental Organizations" (2005) 1:1 Journal of Civil Society 61.

democratic period may be the recognition of the need for new legislation to deal with various recent concerns such as the governance of health research involving humans.

Under the Constitution of the Federal Republic of Nigeria 1999 (hereafter, the 1999 Constitution),[9] Nigeria operates a presidential system of government in a federal state, with powers divided between the federal, state and local governments.[10] The country comprises 36 states[11] and a Federal Capital Territory, and 774 local government areas.[12] Each of the states is administered by a governor (the head of the executive branch), and has a House of Assembly, the legislative arm of government and a judicial arm of government comprising state courts. The federal government is headed by a President. The bicameral National Assembly (comprising the Senate and the House of Representatives), whose members are elected from federal senatorial districts and constituencies, makes federal laws. The judicial system is comprised of several courts, the highest of which is the Supreme Court.[13] Each local government area is administered by an elected executive chairman. There is also an elected local legislative council, with members from electoral wards.

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[9] *Constitution of the Federal Republic of Nigeria, 1999* (CFRN). Yusuf notes that: "it has been accepted that only a federal polity can ensure equity and protect the rights of hundreds of minority groups amalgamated by colonial power into a nation state." See Hakeem O. Yusuf, "The Judiciary and Political Change in Africa: Developing Transitional Jurisprudence in Nigeria" (2009) 7:4 International Journal of Constitutional Law 654 at 669.

[10] Section 2 (2) of the Constitution states that the country shall be a "Federation consisting of States and a Federal Capital Territory."

[11] Politically, the country is divided into six geo-political zones – North West, North East, North Central, South East, South South, and South West.

[12] Adetunji Labiran et al, *Health Workforce Profile for Nigeria* (Federal Ministry of Health, 2008), online: <http://www.afro.who.int/hrh-observatory/country_information/fact_sheets/Nigeria.pdf > (January 25, 2010) at 13.

[13] See Section 6 of the Constitution.

In theory, although state are designed to remain fairly autonomous, following years of military rule in which power was concentrated in the federal government, the federal government holds much power and resources. According to Yusuf,

> The federal government has acquired so many powers that it has come to exercise control over virtually every aspect of day-to-day governance. It not only controls foreign affairs, the security agencies, the armed forces, and currency, it also exclusively controls or oversees commerce and trade, social security, labor, weights and measures, and vital aspects of land policy within the states. It has effectively taken over the arena of "ordinary governance," extending well beyond the regular spheres contemplated for a central government within a regular federation. Predictably, this dominance by the federal government has secured for it a disproportionate share of the country's resources. [14]

The dominance of the federal government in practice alongside the constitutional distribution of powers is relevant to note in the discussion of governance and regulation of health research involving humans in Nigeria. This is because of the concurrent nature of the powers of the federal and state governments in matters of health, research, and education as I discuss briefly below and also in Chapter Six. It is also important to underscore this because, as the history of research governance in Nigeria indicates, the federal government has taken steps to regulate health research,

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[14] See Yusuf, supra note 27 at 667, noting that . See also, Said Adejumobi, "Civil Society and Federalism in Nigeria" (2004) 14: 2 Regional and Federal Studies 211. See generally, Crisis Group, "Nigeria's Faltering Federal Experiment" Africa Report Number 119 (October 2006), online:<http://www.crisisgroup.org/library/documents/africa/west_africa/119_nigerias_faltering_federal_experiment.pdf> (January 20, 2010), particularly from 2-4. See also generally Olowu, supra note 21, discussing the centralised federal government system that Nigeria runs.

whereas the states have not. I discuss the arising concerns in this regard in Chapter Six.

With respect to the legal context, an assortment of different types of law, including the common law (which is the result of its English colonial heritage), customary law which recognise the customary practices of different ethnic groups, Islamic law, many statutes, and, most importantly, the constitution, operate in the country.

In the 1999 Constitution, there is no clear-cut delineation of responsibilities with respect to health, between the federal, state and local governments. Rather, health is on the concurrent legislative list in the Nigerian Constitution.[15] Thus, health is a matter in which the federal and state governments have concurrent powers, with the state subordinate to the federal government in any area of health in which the federal government has made a generally applicable law. It has been noted, in this regard, that the concurrent responsibilities of all the levels of government – federal, state and local – in the provision of health care has led to "chaotic coordination and communication, poor accountability, and considerable disparities throughout the country."[16]

With regard to health research, the federal government through the National Assembly may make laws to regulate or co-ordinate scientific research, including health research involving humans.[17] In addition, matters relating to drugs

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[15] See the *Constitution of the Federal Republic of Nigeria, 1999* (CFRN), Second Schedule. The concurrent legislative list also provides that the functions of the local government council shall include the "provision and maintenance of health services." Fourth Schedule of the Constitution.
[16] Sally Hargreaves, "Time to Right the Wrongs: Improving Basic Health Care in Nigeria" (2002) 359 The Lancet 2030 at 2030.
[17] Section 21, Second Schedule, Part II of the CFRN.

are within the exclusive powers of the federal legislative body, the National Assembly.[18] This does not prevent the state legislature (the House of Assembly) from establishing institutions or making any arrangements for the purpose of scientific research.[19] Also, under the Revised National Health Policy 2004, which contains Nigeria's policy on health, the federal government is responsible for policy formulation, guidance, coordination, supervision, monitoring and evaluation.[20]

In the area of health, and specifically in the area of research governance, then, the federal government can set uniform minimum standards, allowing the states to legislate, provided that such state law does not conflict with the basic federal law. As discussed more fully in the subsequent pages, it would appear that the federal government has been more active in the area of regulating research than the states, mainly through the creation of a national regulatory body for new drug approvals, the National Administration for Food and Drug Administration (NAFDAC), and a national ethics review committee, the National Health Research Ethics Committee. While a strong federal government may have its problems in other areas, its current role appears to make room for a national and uniform system of research governance which, as I discuss a little further below, is beneficial for Nigeria.

In addition to the creation of a national drug regulatory agency and the national health research ethics committee, a federal bill is currently going through the legislative process to provide a comprehensive health approach for the country,

[18] Section 26, Schedule 2, Part I, of the CFRN.
[19] Section 22, Schedule 2, Part II of the CFRN. The Federal Government has created the Ministry of Science and Technology which oversees research in Nigeria.
[20] See, Federal Republic of Nigeria, *Revised National Health Policy*, (Abuja, Federal Ministry of Health, 2004).

defining the roles and responsibilities of the three tiers of government and other stakeholders in the system. This process had begun with the last administration, following the recognition in the Revised National Health Policy 2004 that:

> One of the major weaknesses in the health sector currently is the non-existence of some important health legislations [sic] and the outdatedness, contradictions and ambiguities of some existing health laws. For example, the 1999 Constitution fell short of specifying what roles the various levels of government must play in the national health care delivery system. Therefore, one of the important health legislations [sic] that need to be put in place is the National Health Act which shall define the national health system and spell out the health actions of each level of government, among other things. Indeed, such an Act is necessary in order to give legal backing to this revised policy.[21]

The National Health Bill was passed by the National Assembly in May, 2010.[22] It has, however, not yet being signed into law by the President.[23] The aim of the Bill is to "provide a framework for the regulation, development and management of a national health system and set standards for rendering health services in the federation, and other matters connected therewith."[24] It is enacted primarily to define the roles and responsibilities of the federal, state and local governments in the national health system and ensure effective linkages between the three levels of government. It will also provide a legal basis for the operation of the National Health Policy. More relevant for the purpose of this thesis, the Bill also provides for the establishment, composition, tenure and functions of the National Health Research

[21] Chapter 10, section 1 of the Revised National Health Policy.
[22] Adibe Emenyonu, "Withhold Assent on National Health Bill, Lab Scientists Tell Jonathan" *Thisday*, June 1, 2010.
[23] Federal Republic of Nigeria, *National Health Bill*, 2009.
[24] See Long Title of Bill.

Ethics Committee and the establishment and functions of health research ethics committees. I examine these provisions in more detail in Chapter Six.

Aside from the Constitution and domestic legislation, Nigeria is a signatory to international human rights instruments that have implications for the rights of persons who participate in health research. Such human rights instruments include the *International Convenant on Civil and Political Rights*[25] which provides in its Article 7 for the requirement of informed consent as a prerequisite to participation in medical research.[26]

One of the main problems that may affect governance and regulation efforts in Nigeria is corruption. Systemic corruption in Nigeria has been written about extensively elsewhere.[27] Corruption is a serious problem because it reduces the resources available to tackle problems, including health-related problems that affect the citizenry. Corruption could also subvert regulatory controls, allowing private interests to capture public lawmakers and administration who develop regulations or regulatory agencies that implement such regulations, to the detriment of the public. It may put the lives of the citizenry in jeopardy by allowing unsafe practices by the private sector for profit motives, (such as, permitting the importation

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[25] *International Covenant on Civil and Political Rights,* G.A. res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, (entered into force March 23, 1976).

[26] Nigeria, however, operates a dualist system of law and thus requires the domestication of international treaties for domestic operation in the country. Nigeria has not domesticated the International Covenant on Civil and Political Rights.

[27] In 2003, Transparency International ranked Nigeria the most corrupt country out of 133 countries. In 2005, Nigeria was ranked the sixth most corrupt country out of 186 countries. See James T. Gire, "A Psychological Analysis of Corruption in Nigeria" (1999) 1: 1 Journal of Sustainable Development in Africa 1.; S.T. Akindele, "A Critical Analysis of Corruption and its Problems in Nigeria" (2005) 7: 1 Anthropologist 7. R. S. O. Wallace, 'Growing Pains of an Indigenous Accountancy Profession: The Nigerian Experience" (1992) 2:1 Accounting, Business and Financial History. Transparency International, *Global Corruption Report 2009: Corruption in the Private Sector* (London: Pluto Press, 2009) at 4, 201-203.

and sale of counterfeit drugs as has occurred in Nigeria).[28] With respect to research governance, corrupt behaviour could potentially permit unsafe and unethical practices in the course of health research involving humans.

The ongoing efforts to root out corruption in Nigeria have met with mixed results and, frequently, a questioning of motives, zeal, credibility, legitimacy, and efficacy.[29] Yet there have been some successes, particularly in the health area. In this regard, Nnamuchi notes that:

> With the demise of military dictatorship in 1999 came new expectations and rekindled hope for a change in status quo. Perhaps, as a result, the democratically-elected administration introduced several innovative policy initiatives some of which are presently being implemented at the different levels of government. The aim of these initiatives is to restructure and revamp the health system, and concomitantly realize the goals of the recently revised National Health Policy and health-related goals of the Millennium Development Goals (MDGs). Although the process has been far from perfect, the development and implementation of these programmes represent a significant departure from the errors and deficiencies of the past.[30]

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[28] Dora Akunyili, "The Fight against Counterfeit Drugs in Nigeria" in Transparency International, *Global Corruption Report: Corruption in the Private Sector, 2006* (London: Pluto Press, 2006), at 96-100.

[29] See Shola J. Omotola, "Through A Glass Darkly': Assessing the 'New' War against Corruption in Nigeria" (2006) 36: 3-4 Africa Insight 214. See also, Osita N. Ogbu, "Combating Corruption in Nigeria: A Critical Appraisal of the Laws, the Institutions and the Political Will" (2008) 14 Annual Survey of International & Comparative Law 99. Recent efforts include the passing of the *Corrupt and Other Related Offences Act No.5 of 2000 (ICPC Act)*, the establishment of the Economic and Financial Crimes Commission (EFCC) under the *Economic and Financial Crimes Commission Act,* 2004, the *Nigeria Extractive Industries Transparency Initiative Act 2007* which aims to facilitate transparency in the extractive industries, which account for more than 80 per cent of Nigeria's foreign earnings, and the enactment of the *Public Procurement Act 2007*, which aims to ensure more transparency in procurement, increases the fines for corruption and abuse of public funding, and creates the new Bureau for Public Procurement.

[30] Obiajulu Nnamuchi, "The Right to Health in Nigeria" ('Monitoring the Right to Health: a Multi-Country Study', University of Aberdeen), online: <http://www.abdn.ac.uk/law/documents/Nigeria_%20210808.pdf> (January 26, 2009).

Recent efforts such as those by Nigeria's drug regulatory agency against counterfeit drugs,[31] and the creation of different initiatives under democratic regimes to tackle the problem of HIV/AIDS after years of neglect by military governments,[32] suggest that corruption can be mitigated[33] and that the necessary political will to undertake requisite reforms can be found. Recent reforms, as I discuss further below, have also included steps to create a legislative basis for research governance in Nigeria.

It would be easy to throw one's hands up in the face of Nigeria's many problems and fledgling democracy. One could engage in a justified polemic about the challenges Nigeria faces, particularly with regard to democratic governance. It would be naïve if not impossible, then, to proceed with any analysis of research governance as though there were no obstacles in the way. Context is important. However, taking refuge in extreme cynicism and resignation is unhelpful and unlikely to solve any problems, including those of ensuring the promotion of necessary and beneficial health research and how to regulate such research.

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[31] The government has recorded successes in recent years in the efforts to eliminate the sale of fake and adulterated drugs, estimated to have been about 70 percent of all drugs in the country, at one time. The NAFDAC, "hitherto an inept, moribund and corrupt institution, has launched an elaborate campaign seeking to restore integrity to the pharmaceutical industry. In furtherance of its campaign, the agency has shut down many local pharmaceutical businesses and blacklisted several foreign-based manufacturers of counterfeit drugs, mostly in India and China. NAFDAC's resurgence and clampdown on peddlers of adulterated drugs have spurred a growth in local production, reported to have surged to 35% in 2002 and currently stands at 40%. Another positive outcome has been a drastic reduction in the volume of fake drugs in circulation, reportedly 10% in 2001." See Obiajulu Nnamuchi, "The Nigerian Social Health Insurance System and the Challenges of Access to Healthcare: An Antidote or a White Elephant?" (2009) Medicine and Law, Akunyili supra note 28. Owen Dyer, "New Report on Corruption in Health" (2006) 84:2 Bulletin of the World Health Organisation 84 at 85.

[32] These include the creation of the National Agency for the Control of AIDS (NACA) in 2000, and government initiatives to provide access to antiretrovirals.

[33] Transparency International ranked Nigeria 147th out of 179 countries surveyed in a recent report, an improvement from its 2001 report, 90th of 91countries. See, Transparency International, "*Corruption Perception Index 2007*, online: <http://www.transparency.org/policy_research/surveys_indices/cpi/2007> (January 27, 2010).

Further, given the difficulties facing the Nigerian polity, the governance of health research may be argued to be low on the list of challenging concerns that must be tackled. I have already argued in the first chapter, but it bears reiterating here that developing countries like Nigeria need health research and that governance of such research is necessary to retain public trust and prevent unethical behaviour. To argue that other challenges must be taken care of before seeking to regulate health research in Nigeria is unhelpful, given that health research continues to be conducted in Nigeria in the face of other challenges that exist. More importantly, even greater levels of health research are needed to gain an understanding of, and to provide treatments for the many diseases afflicting the Nigerian population. Moreover, recent efforts in Nigeria with respect to research governance show that arguments against regulating research would be belated, if not without merit.

Government input in research governance in Nigeria is necessary. Yet it is also true that the most basic problems of Nigeria are lack of good and effective political leadership.[34] There is obviously, then, much to be said for – and much that has been said about – good political governance in Nigeria and other developing countries. Still, practically, the government, for all its flaws and weaknesses, remains the possessor of the largest resources, the vehicle for lawmaking, the interpreter and enforcer of law, the actor in whom responsibility lies for making crucial decisions about health, and on whom lies the obligation for providing protections for citizens including in health research. The many calls for better political governance in Nigeria in various forums and literature implicitly recognise

[34] Chinua Achebe, *The Trouble with Nigeria* (Oxford: Heinemann, 1983) at 3.

this. Further, good political governance can perhaps best be nurtured through effective governance on important specific policy issues such as the governance of health research. With respect to the concerns of this thesis, it is unarguable, even from a human rights perspective, that the government ought to be concerned with both the facilitation of health research, but also, more importantly, for the safety of the public. Further, the fact that the government has been a crucial actor in some of the research governance initiatives puts it squarely in the middle of any analysis on developing the research governance arrangements in Nigeria.

But the weak legitimacy and accountability of the government means that placing total reliance on the government with respect to building research governance structures and arrangements is insufficient, if not impossible, and that other actors such as the professional associations, research sponsors, and non-governmental organisations, are crucial. These actors are necessary to provide a check on political actors. These actors, however, lack the inherent political legitimacy that accrues to government as well as a comprehensive reach. They may also not necessarily be free from the concerns that arise with respect to the government. Nor can they provide a uniform and comprehensive system of governance.

In analysing and making recommendations for improvements in research governance in Nigeria, then, what is needed is a positive approach which recognises and does not belittle, but is also not resigned to, the enormity of the challenges. In addition, a synergistic approach, which effectively employs different sectors of the Nigerian polity to ensure effective governance of health research, is required.

Further, it is also necessary to develop ideas to ensure that the structures that have already been put in place work as effectively as possible in the Nigerian context to provide protections for research participants and with as little duplication of efforts and resources as possible. A hybrid framework of analysis as proposed in this thesis seems therefore apposite for examining and making recommendations for research governance in Nigeria, and this chapter and the next two chapters proceed with this understanding.

5.3 Health in Nigeria

In this section, I engage in a brief, general description of Nigeria's health profile, permitting me to lay the groundwork for establishing health research, and its governance, as a priority for Nigeria. I begin by describing briefly health challenges in Nigeria. I then describe the organization of Nigeria's health system. This brief description is helpful to provide some information on several of the key institutions involved in health and, consequently, in research governance in Nigeria. The aim of these descriptions is to create a broad context for the discussion of health research involving humans in Nigeria.

5.3.1 Nigeria's Health Profile

In Nigeria, average life expectancy is estimated to be around forty-seven years, indicating a poor health profile. [35] There is a prevalence of infectious, endemic, emerging, and re-emerging diseases. Malaria is the most significant cause of morbidity.[36] There are also frequent epidemic outbreaks of infectious diseases such as cholera, cerebrospinal meningitis, measles, tuberculosis, yellow fever and Lassa fever.[37] Nigeria remains one of the few countries in the world where polio is yet to be eradicated.[38]

While malaria remains the most prevalent disease, the incidence of morbidity and mortality from HIV/AIDS is high. It is estimated that about 4.4 percent of the population is infected with HIV, making Nigeria the third in the world after India, and South Africa, in terms of prevalence.[39] There is a high prevalence of tuberculosis in the country, with Nigeria having the world`s fifth largest tuberculosis burden – an estimated 450,000 new cases each year.[40] The incidence of maternal mortality is one of the highest in the world.[41] Child mortality also remains high,

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[35] See the Central Intelligence Agency (CIA), World Factbook: Nigeria, online: <https://www.cia.gov/library/publications/the-world-factbook/geos/ni.html> (December 27, 2009).
[36] WHO, "Malaria", online: <http://www.who.int/countries/nga/areas/malaria/en/index.html> (January 26, 2010).
[37] WHO, "WHO Country Cooperation Strategy: Federal Republic of Nigeria, 2002-2007" at 6, available at <http://www.who.int/countries/nga/about/ccs_strategy02_07.pdf> (January 25, 2010) (Hereafter, WHO Country Strategy) at 4.
[38] David L Heymann and Bruce Aylward, "Eradicating Polio" (2004) 351:13 New England Journal of Medicine 1275.
[39] WHO Country Office Nigeria, "Annual Report 2007," online: <http://www.who.int/countries/nga/reports/who_2007_annual_report.pdf> (January 26, 2010) at 10.
[40] Patrick O Erah and Winifred A Ojieabu, "Success of the Control of Tuberculosis in Nigeria: A Review (2009) 2:1 International Journal of Health Research 3 at 10; WHO, "Global Tuberculosis Control: A Short Update to the 2009 Report," (Geneva: WHO, 2009), online:<http://whqlibdoc.who.int/publications/2009/9789241598866_eng.pdf> (March 3, 2010).
[41] WHO, *World Health Statistics 2007* (Geneva: WHO, 2007) at 26.

Nigeria being one of the five countries in the world that contribute to about half of all childhood deaths of children under the age of five.[42]

Although efforts are currently being made to meet the 2015 Millennium Development Goals (MDGs),[43] which include reducing child mortality, improving maternal health, combating HIV/AIDS, tuberculosis, and other diseases, much remains to be done in these and other areas. There is also a growing incidence of chronic and non-communicable diseases, such as hypertension, coronary heart disease, diabetes and cancer.[44] Nigeria is one of the 23 countries in the world which account for 80 percent of the deaths from non-communicable or non-infectious diseases worldwide.[45]

In sum, then, as noted elsewhere, "the health profile of Nigeria is characterised by twin epidemics of communicable diseases such as malaria, tuberculosis and HIV/AIDS and non-communicable diseases like obesity, hypertension, diabetes, cancers, and mental health disorders. In this respect, it is similar to most other developing countries."[46] These diseases present challenges that can be dealt in part through better knowledge obtainable only by research.[47]

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[42] WHO, "Child and Adolescent Health", online: <http://www.who.int/countries/nga/areas/cah/en/index.html> (January 26, 2010).

[43] United Nations, Resolution Adopted by the General Assembly: United Nations Millennium Declaration, Resolution55/2, 8 September 2000, online: <http://www.un.org/millennium/declaration/ares552e.htm> (January 26, 2010)

[44] WHO, "WHO Country Cooperation Strategy: Federal Republic of Nigeria, 2002-2007" at 6, available at <http://www.who.int/countries/nga/about/ccs_strategy02_07.pdf> (January 25, 2010) (Hereafter, WHO Country Strategy). See also, WHO, "The Impact of Chronic Disease in Nigeria" online: <http://www.who.int/chp/chronic_disease_report/media/nigeria.pdf> (February 4, 2010).

[45] WHO, *Report and Development: Coordination and Financing - Report of the Expert Working Group* (Geneva: WHO, 2010) at 2.

[46] Clement A. Adebamowo et al, "Developing Ethical Oversight of Research in Developing Countries: Case Study of Nigeria" in Olayiwola Erinosho (ed.), *Ethics for Public Health Research in Africa* (Proceedings of an International Workshop in collaboration with the Special Programme for Research

5.3.2 Nigeria's Health System

The National Health Policy, first introduced in 1988, and last revised in 2004[48] provides the main policy for health in Nigeria. The policy contains provisions on seven key areas, one of which is health research.[49] One other key area is the health system and its management. In this respect, the policy provides for a system, at the apex of which is the National Council on Health, comprising the Minister of Health and the Minister of State for Health and the State Commissioners for Health.[50]

The National Health Policy also provides that the federal government, operating primarily through the Federal Ministry of Health, is responsible for disease surveillance, essential drugs supply, and vaccine management.[51] In addition, it provides specialized health care services at tertiary health institutions namely, university teaching hospitals (associated with medical schools) and federal medical centres. Recently, some of the federal university teaching hospitals have been named "centres of excellence," specialising in treatment of, and research on, specific health issues, cardiac diseases, cancer, infectious diseases, and dentistry.[52] More relevant

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and Training in Tropical Diseases (TDR) of the World Health Organisation, with the support of the Federal Ministry of Health, Abuja, Nigeria, April 21-23, 2008) (Ibadan: Social Science Academy of Nigeria, 2008) at 15.

[47] Anthony C. Ikeme, "Nigeria's Clinical Trials Scene" (2008) Applied Clinical Trials.

[48] Federal Ministry of Health, *National Health Policy and Strategy to Achieve Health for all Nigerians* (Lagos, Nigeria: FMH, 1988); Federal Ministry of Health, *Revised National Health Policy*, 2004.

[49] See Chapter Ten. The other areas are: National Health System and its Management; National Health Care Resources; National Health Interventions and Services Delivery; National Health Information Systems; Partnership for Health Development; and Health Research and Health Care Laws.

[50] See Revised National Health Policy.

[51] Ibid.

[52] These are the Ahmadu Bello University Teaching Hospital, Zaria (Cancer), University of Nigeria Teaching Hospital, Enugu (Cardiac disorder),Lagos University Teaching Hospital (LUTH), Lagos (Dentistry), University of Maiduguri Teaching Hospital, (UMTH)Maiduguri (Infectious Diseases) and

for the purpose of this thesis, the federal government is also responsible for policy formulation, strategic guidance, coordination, supervision, monitoring and evaluation at all levels. The federal government can therefore make major policies relating to health and health research as is evident in the National Health Policy.

The federal tertiary institutions also serve as referral institutions for the secondary health facilities operated by the states through the state ministries of health. These include general hospitals and comprehensive health centres. The local governments are responsible for primary health centres which make referrals to state-run general hospitals. Aside from referrals, there are different interrelationships between all three levels of government in the operation of the health system. In this regard the WHO notes that:

> Operationally, the decentralized health structures of the federal government are in the states, while those of states are in the LGAs. Some states build and operate tertiary facilities or specialist hospitals. While the federal government is responsible for the management of teaching hospitals and medical schools for the training of doctors, the states are responsible for training nurses, midwives and community health extension workers (CHEWs). The LGAs provide basic health services and manage the PHC facilities which are normally the first contact with the health system. [53]

In essence, then, the federal and state governments operate differently and have authority over different institutions in which health research might occur.

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the University of Ibadan Teaching Hospital (UCH) Ibadan (Oncology). See Chris Ajaero, "Centres of Decay" Newswatch, May 17, 2009, online: <http://www.newswatchngr.com/index.php?option=com_content&task=view&id=951&Itemid=1> (March 17, 2010).

[53] "WHO, "WHO Country Cooperation Strategy: Federal Republic of Nigeria, 2002-2007" at 6, available at <http://www.who.int/countries/nga/about/ccs_strategy02_07.pdf> (January 25, 2010).

In addition, there are several independent agencies and parastatals of the Federal Ministry of Health created to deal with various areas of health, which are part of the Nigerian public health system. These include the National AIDS Control Agency, National Primary Health Care Development Agency, National Programme on Immunization Agency, Population Activities Fund Agency, the Department of Community Development and Activities, the National Health Insurance Scheme, and more relevant for the purpose of this thesis, the National Agency for Food and Drug Administration and Control, and the Nigerian Institute for Medical Research.[54] With regard to these health system arrangements, the World Health Organisation has noted that:

> Overall, the roles of the different parastatals of the public sector are not well delineated, and activities need to be coordinated in order to avoid overlapping of efforts. As in other sectors, the federal governance arrangement constrains the leverage that the Federal Ministry of Health (FMOH) has over the State Ministry of Health (SMOH). For instance, FMOH cannot compel SMOH to implement some health policies and programmes. This makes stewardship of the health sector very challenging. Consequently, the gap between policy formulation by the FMOH and implementation by states and LGAs is wide."[55]

This suggests that the challenges of overlapping, variability in implementation, and duplication must also be addressed in any research governance efforts. Further, the authority of each level of government over separate institutions and the possibility that research may take place at any institution, indicates that research governance

[54] See Nkoli I Aniekwu, "Health Sector Reform in Nigeria: A Perspective on Human Rights and Gender Issues" (2006) 11:1 Local Environment 127 at 131.
[55] WHO Country Cooperation Strategy, supra note 53 at 6.

efforts must be implemented not only at one level, for instance at the federal level, but at all levels of government.

Apart from the government-run health facilities, there are many private-run health facilities, including for-profit private sector institutions, mission hospitals and facilities run by faith-based and community-based organisations and other non-governmental organisations.[56] Non-governmental organisations and donors play a vital role in Nigeria's health system. Health care delivery is funded from the monies made available under the national budget, but also frequently with aid and technical assistance from international aid organizations and development partners like the World Bank, United States Agency for International Development (USAID), the Canadian International Development Agency (CIDA), the United Kingdom's Department for International Development (DfID), Japan International Cooperation Agency (JICA), the Global Drug Facility, and the World Health Organisation.[57] Many donors, including the USAID, the DFID, the World Bank, and CIDA contribute towards specific health system initiatives and projects. However, as has been noted elsewhere, state ownership or buy-in into initiatives sponsored by donors or carried out by non-governmental organisations is important not only for greater legitimacy but also for effectiveness.[58] Indeed, it has been noted that in Nigeria (which because of its oil exportation activities is not aid-dependent), international

[56] I.O. Orubuloye and J.B. Oni, "Health Transition Research in Nigeria in the Era of the Structural Adjustment Programme" (1996) 6 (Suppl) at 304.
[57] DFID, "Nigeria: Country Health Briefing Paper" (2000), online: <http://www.dfidhealthrc.org/publications/Country_health/Nigeria.pdf> (January 25, 2010). See the Revised National Health Policy 2004., Section 8.4.
[58] Health and Fragile States Network, "Health System Reconstruction: Can It Contribute to State-Building?" (2008), online: <http://www.healthandfragilestates.org/index2.php?option=com_docman&task=doc_view&gid=32&Itemid=38> (January 20, 2010).

donors have limited influence on shaping behaviour.[59] What it means, then, is that alliances and partnerships with the government have to be carefully built and nurtured.[60]

Nigeria's health care system was ranked 187th out of 191 members of the WHO in 2000, making it one of the worst health systems in the world. Many have suggested that the lack of coordinated efforts by the different levels of governments and development agencies in the execution of health programs has seriously impeded improvements in health care delivery in Nigeria and led to duplication of efforts and waste of resources.[61] Similarly, the WHO has attributed the poor state of the health system in Nigeria to several factors, namely: organisation, stewardship, financing and provision of health services. These factors are compounded by other socioeconomic and political factors in the Nigerian environment.[62] As I discuss below, some of these same factors, particularly, stewardship, coordination, organisation and financing, are key challenges for research governance in Nigeria.

There is some evidence that the government is taking action regarding the dismal state of affairs in Nigeria's health system, through various initiatives and programs. These include the initiation of the Health Sector Reform Plan of Action, which is to guide investments and actions by all levels of government, the private

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[59] Ibid. at 37.
[60] It has been noted therefore that: "Most development partners in Nigeria are aware that short-term support for service delivery can contribute to undermining state capacity, particularly if it bypasses government. Consequently many have adopted long-term, strategic approaches aimed at building institutional capacity and fostering longer term sustainability. The major donor-funded health programmes in Nigeria do appear to contribute to state-building, and are designed and implemented with core governance objectives in mind." Ibid. at 40 -41.
[61] See Hargreaves, supra note 16; Nnmauchi, supra note 30 at 6.
[62] WHO Country Strategy, supra note 53 at 9.

sector, donors and all development partners in health.[63] With respect to epidemic preparedness, a National Epidemic Preparedness Committee was set up in 2009.[64] Several policies have been developed or revised in recent years including the National Health Policy (revised in 2004), and the National Child Health Policy (developed in 2006).[65] Although belated, there is evidence of political will in tackling the challenge of HIV/AIDS in the country. Evidence of this commitment includes the establishment of the National Agency for the Control of AIDS (NACA) and the initiatives to provide access to antiretroviral treatment, beginning in 2001,[66] and the recent move to renew the strategic plan for continuing these initiatives, the National Strategic Framework.[67] The WHO notes, also, that:

> In recent years, Nigeria has responded positively to global initiatives such as Roll Back Malaria (RBM), HIV/AIDS control, Polio Eradication Initiative (PEI), directly-observed treatment short-course (DOTS) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Notable progress has been made towards eradication of guinea-worm disease, resulting in a decrease in the number of cases from over 600,000 in 1989 to about 13,000 per year in the late 1990s. In addition, Nigeria has reached the WHO leprosy elimination target of less than one case per 10,000 population.[68]

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[63] Ibid. at 6.

[64] "Healthcare: Our Steps So Far, By Minister" *The Guardian* (October 11, 2009), online: <http://www.ngrguardiannews.com/sunday_magazine/article10/indexn3_html?pdate=111009&ptitle=Healthcare:%20Our%20Steps%20So%20Far,%20By%20Minister&cpdate=293008> (February 20, 2010).

[65] See Federal Ministry of Health, Policies Archives, online: <http://www.fmh.gov.ng/PoliciesArchive.html#> (March 2, 2010).

[66] U.S. Center for Disease Control and Prevention (CDC), "The Emergency Plan in Nigeria", online: <http://www.cdc.gov/nchstp/od/gap/countries/Nigeria.htm>, (March 2, 2010); Avert, "HIV & AIDS in Nigeria", available at <http://www.avert.org/aids-nigeria.htm> (September 2, 2009).

[67] UNAIDS, "Nigeria to Accelerate Universal Access Efforts in HIV Response" February 23 2010, online: < http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2010/20100223_Nigeria_2.asp> (March 17, 2010).

[68] WHO Country Strategy, supra note 53 at 6.

The recent efforts with regard to developing governance arrangements in Nigeria, which I describe below, can be counted as some evidence of increasing political commitment to matters relating to health. Many challenges described above, however, remain, including challenges in the area of health research.

5.4 Health Research in Nigeria

In this section, I begin with a short history of health research in Nigeria. I then consider the need for health research in Nigeria and Nigeria's current policy on health research. I point out that, despite the government's low level of commitment to health research, a significant amount of health research continues to take place in Nigeria, including health research involving humans, creating a need for the proper governance of research.

5.4.1 A Brief History of Health Research and the Ongoing Need for Health Research in Nigeria

Health research in Nigeria has a long history predating Nigeria's independence from the British colonial regime in 1960. In this respect, the descriptions of this history by Ajayi and Nwabueze are helpful. [69] Although recent by western standards, medical research has been undertaken in Nigeria for many

[69]Olajide Ajayi, "Health Research in Nigeria." Online: Oxford Research Forum <http://www.oxfordresearchforum.i12.com/editorials/nigeria.htm> (March 3, 2004). See also, Adetokunbo O. Lucas, "Health Research in Africa: Priorities, Promise, and Performance" (1989) Volume 569 Biomedical *Science and the Third World: Under the Volcano*, at 17. See also, Remigius N. Nwabueze, 'Ethical Review of Research Involving Human Subjects in Nigeria: Legal and Policy Issues' 14 Ind. Int'l & Comp. L. Rev. (2003-2004) 87.

decades beginning with the establishment of the Rockfeller Foundation Yellow Fever Commission in 1920. The Yellow Fever Foundation, as it was popularly called, built a Research Unit in Yaba, Lagos in 1925 where research on yellow fever was conducted. It is not clear from available sources whether this was meant to benefit Nigerians. But this is unlikely, following Ochonu's hint that:"Colonial medicine was about keeping British colonial personnel healthy."[70]

In 1952, the British government established the University College Hospital (UCH) at the University College Ibadan. The UCH had been a campus of the University of London since 1948. The UCH was mandated, amongst other things, to conduct medical research.[71] In 1957, a facility for clinical research was commissioned at the University of Ibadan.

In 1954, the British colonial government made provisions for research funding in colonial territories, leading to the formation of the West African Council for Medical Research for the West African territories of Nigeria, Ghana, Gambia, and Sierra Leone.[72] According to the Ordinance which established it,[73] its functions included organising medical research in the territories and providing information obtained therewith to the British government. The West African Council for Medical Research consisted of four research units dedicated to helminthiasis, virology, hot climate physiology, and haematological research. With the establishment of

[70] Moses Ochonu, "'Native Habits are Difficult to Change': British Medics and the Dilemmas of Biomedical Discourses and Practice in Early Colonial Northern Nigeria" (2004) 5:1 Journal of Colonialism and Colonial History.
[71] *University College Hospital Act, Laws of the Federation of Nigeria and Lagos, 1958*, Chapter 215, section 3. As Nwabueze observes, other teaching hospitals established subsequently have also been mandated likewise. Nwabueze, supra note 69.
[72] Ajayi, supra note 69.
[73] *West African Council for Medical Research Ordinance*, Laws of the Federation of Nigeria and Lagos, Cap. 215 (1958).

universities in Nigeria, like the University of Ibadan and the University of Lagos, the West African Council for Medical Research, whose activities had previously extended to other West African British colonies like Ghana, was dismantled in 1962.

The Medical Research Council of Nigeria, established by military decree in 1972,[74] took over the responsibilities of the West African Council for Health Research. In 1977, the *National Science and Technology Development Agency Decree* repealed the decree which established the Medical Research Council of Nigeria, and instituted the National Science and Technology Development Agency. The Agency's mandate was to advise the federal government on matters relating to scientific research and development. The responsibilities and assets of the Medical Research Council of Nigeria were subsequently transferred to the National Institute for Medical Research established by the *Research Institute's Order of 1977.*[75]

It is clear from the history described above that interest in health research has existed for a long time in Nigeria, and even predates Nigeria as an independent country. Today, with the many diseases that plague the Nigerian population, there remains a clear need for health research. As discussed in Chapter One, ten percent of global research funding is devoted to research in developing countries (like Nigeria) which bear ninety percent of the diseases,[76] a very inequitable distribution. There is

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[74] Medical Research Council, Decree No 1.

[75] *Research Institute's (Establishment etc) Order of 1977*, Annual Volume of the Laws of the Federal Republic of Nigeria (1977). See The Nigerian Institute of Medical Research, About NIMR" online: <http://www.nimr.gov.ng/aboutus.php?page=an> (February 22, 2010).

[76] Commission on Health Research for Development, *Health Research: Essential Link to Equity in Development* (Oxford: Oxford University Press,1990). See the Nuffield Council on Bioethics, *The*

relatively little drug research into neglected diseases. As I pointed out in that chapter, there is great need for health research in developing countries.

In the context of Nigeria, the HIV/AIDS epidemic is a significant threat and is one area in which health research remains necessary and appropriate. The disproportionate burden of HIV infection borne by persons in Nigeria (and other developing countries) relative to many other countries in the world requires the development of new interventions and technologies to aid prevention efforts, provide more effective treatments, and perhaps a cure in the not so distant future. The National HIV/AIDS Prevention Plan indicates that there is inadequate research on prevention methods, and limited research on sexually transmitted infections. [77] More research is also required for better treatment methods for HIV-related or opportunistic diseases such as tuberculosis. Research is also needed on other issues not directly related to treatment and prevention. These include issues such as social problems like stigma, or the effect of sexual and domestic violence on prevalence rates, or the social factors contributory to the spread of HIV and other sexually transmitted diseases in specific populations or communities or risk prevalence, and attitudinal risk factors, such as vehicular accidents and road safety.

Other common diseases in Nigeria like malaria (which continues to be the most significant health issue in the country) and infectious diseases such as trypanosomiasis (sleeping sickness) require further research to provide more effective, less drug-resistant, less expensive treatments and vaccines. Non-infectious

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Ethics of Research Related to Healthcare in Developing Countries (1999) at 21-23, describing the substantial difference in the levels of research between developed and developing countries.

[77] National HIV/AIDS Prevention Plan at 16, 20.

diseases such as diabetes, cancer, and heart disease, which are affecting an increasing number of Nigerians, also need to be studied. Apart from treatments, research needs to be undertaken to provide better disease prevention behaviours and methods (some of which might be established from studies on environmental and genetic determinants of non-infectious diseases), and more cost-effective devices. These diseases could be studied in other countries. However, genetic differences, such as among the Yorubas of Nigeria who have a high twinning rate, may make Nigeria not only attractive to researchers, but even necessary for the development of some interventions.[78] Further, to provide cost-effective interventions would necessitate research in a resource-constrained setting like Nigeria. This would also be the case with interventions that may be easier to use in a country like Nigeria.

Further, the potential benefits of health research could include other related benefits to the country. These would include, for example, the improvement of the quality of health care services offered to the population, an increase in the country's capacity to participate in the international research enterprise and a possible contribution to economic development and growth by providing employment, equipment, training and income for local researchers and their institutions, transferring skills and retention of talented individuals who may be otherwise lost to the country.

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[78] For instance, Nigeria is a part of a six-country consortium involved in the HapMap project, which is a significant project because of the potential information it could provide about the human genome and the effect it could have on the rest of the world. Yorubas from Ibadan, Nigeria were recruited for the project. See The International HapMap Consortium, "The International HapMap Project" (2003) 426 Nature 789. Elizabeth G. Phimister, "Genomic Cartography – Presenting the HapMap" (2005) 553:17 New England Journal of Medicine 1766. See A. Akinboro, M. A Azeez, and A A Bakare, "Frequency of Twinning in Southwest Nigeria" (2008) 14:2 Indian Journal of Human Genetics 41.

Apart from diseases specific to Nigeria, health research conducted in Nigeria could also be beneficial to other countries around the world. Mabey notes that many examples exist of trials in developing countries, like Nigeria, which have influenced clinical and public health practice, even in the developed world.[79] One of the examples he cites is of a trial of chloramphenicol sponsored by the United Kingdom Medical Research Council in Zaria, Northern Nigeria in 1973 and carried out by researchers at the Ahmadu Bello University, Zaria. This trial showed that, for the treatment of group A meningococcal meningitis, a single therapy of chloramphenicol was more effective than sulphonamides. It was also as effective, simpler to use, and much cheaper than large and frequent doses of penicillin, the standard drug at the time.[80] This was at a time when combination therapy was the norm in many industrialised countries.[81] Today, HIV trials, for example, could provide potential sources of information beneficial to Nigeria but also to other countries around the world.

Given the clear need for health research in Nigeria, what is the current policy for health research? The current policy on health research in Nigeria is embodied in several policies, including the *National Health Policy*, most recently revised in 2004, the *National Drug Policy*,[82] most recently revised in 2005, and the *National Child Health Policy*, 2006.[83]

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[79] David Mabey, "Importance of Clinical Trials in Developing Countries" (1996) 348 Lancet 1113.
[80] H C Whittle et al, "Trial of Chloramphenicol for Meningitis in Northern Savanna of Africa" (1973)3 BMJ 379.
[81] Mabey, supra note 79.
[82] Federal Ministry of Health, *National Drug Policy* (Abuja, Federal Ministry of Health, 2005).
[83] The Federal Ministry of Health, *National Child Health Policy* (Abuja, Federal Ministry of Health, 2006).

The National Health Policy recognises that a good health system is the result, amongst other things, of the appropriate utilisation of health research. In this respect, it states that: "The health system shall, reflect the economic conditions, socio-cultural and political characteristics of the communities as well as the application of the relevant results of social, biomedical, health system research and public health experience."[84] The objectives of the health research policy are to:

> i. Establish the criteria for identifying priorities;
> ii. *Provide the operational guidelines for health research (ethical, institutional, social, legal, monitoring and evaluation etc);*
> iii. Provide the framework for the coordination of health research;
> iv. *Identify the roles and functions of various actors and institutions and empower them*;
> v. Establish a sustainable mechanism for capacity development and enhancement of health research;
> vi. Establish the mechanism for funding;
> vii. Build consensus on health research outcomes through advocacy;
> viii. Disseminate information on health research outcomes widely; and
> ix. Promote the use of health research outcomes in addressing major health issues and problems.[85]

The policy further states that the Federal Ministry of Health in collaboration with the Federal Ministry of Education and the Federal Ministry of Science and Technology, the Federal Ministry of Justice, and other related Ministries shall set and review the priorities for health services and biomedical research in Nigeria; the scope, location, capacity and content of activities in the field of biomedical and health services research at academic and other institutions. Matters that are considered to be of high priority include: co-ordinating the activities of scientists, researchers and institutions,

[84] Revised National Health Policy, 2004, section 4.3.
[85] Section 9.1 of the Revised National Health Policy (emphasis mine).

and training of research scientists, technicians and other support staff especially in the priority disciplines where there are marked shortages, such as epidemiology, medical biologists, and health care law specialists. Also of importance under the policy are the strengthening of Ministries of Health and other institutions to enhance their capabilities to undertake relevant research, and the establishment and sustainability of a programme that will encourage private sector participation in health research activities. It also states that the government shall provide more resources including tax exemptions and rebates for research in the health sector and encourage the private sector, especially companies that engage in health related activities, to sustain research activities that enhance health.[86] The policy also provides for the allocation of resources for relevant drug research, including traditional remedies.[87]

In addition, the *National Child Health Policy* requires the Federal Ministry of Health to initiate and support research relevant to child development in collaboration with different organisations. It also requires that ministries of health and other institutions be supported in order to enhance their capability to undertake relevant research in child survival, development, protection and participation.[88]

As will become clear in Chapter Six, the National Health Bill has assigned some of the responsibilities of the Federal Ministry of Health related to research governance under the National Health Policy to other bodies created under

[86] Section 9.3.
[87] Section 5.14 (e). See also the *National Drug Policy.*
[88] Sections 3.5 and 4.16 of the Child Health Policy, supra note... at 14 and 46. Local government councils have a similar mandate under the policy.

that Bill. And when it is signed into law, the National Health Policy will only operate in relation to matters not contained in the National Health Bill.

5.4.2 The Current State of Health Research in Nigeria

Health research in Nigeria, as in many developing countries, is a complex issue with different angles. These angles include the fact that Nigeria needs health research but not enough is currently taking place. Another angle is that the government has directed insufficient resources for health research in Nigeria. Yet another angle is that external sponsors, as in many developing countries, support a significant amount of health research. Further, there is the challenge of setting national health research priorities, ensuring that those priorities are met, and that all of the research that does take place is effectively regulated. I address these different angles in explaining the current state of health research in Nigeria briefly below.

With more than twenty medical schools,[89] eleven of which have public health programmes,[90] there are a significant (though underutilised) number of avenues for health research, including research involving humans.[91] Health research is conducted in all the medical schools (which have affiliated teaching hospitals) in Nigeria. The University of Ibadan and the University of Lagos are, however,

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[89] See MDCN, Medical Schools in Nigeria, online: <http://www.mdcnigeria.org/MedSchools.htm> (March 17, 2010).

[90] CB IJsselmuiden et al, "Mapping Africa's Advanced Public Health Education Capacity: the AfriHealth Project" (2007) 85:12 Bulletin of the World Health Organization 914 at 916.

[91] Dianne Miller et al, "Knowledge Dissemination and Evaluation in a Cervical Cancer Screening Implementation Program in Nigeria" (2007) 107 Gynecologic Oncology S196 at S197.

particularly active in this respect.[92] These universities are some of the earliest established universities, are located in cosmopolitan cities, and host many externally-sponsored research projects. Generally speaking, the government provides much of the funding for different kinds of research that takes place in Nigerian universities, including health research.[93]

The federal government also funds some research through research institutes such as the Nigerian Institute of Medical Research, a parastatal of the Federal Ministry of Health, which carries out research on parasitic, infectious and non-infectious diseases.[94] The National Institute for Pharmaceutical Research and Development was established by the government principally to advance indigenous pharmaceutical research and development and enhance development and commercialization of pharmaceutical raw materials, drugs, and biological products.[95] The Institute has recently produced a drug for the treatment of sickle cell disease.[96] Another is the National Institute for Trypanosomiasis Research, which conducts

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[92] The University of Ibadan has a Postgraduate Institute for Medical Research and Training (PIMRAT). FAHAMU Oxford, *Healthcare Training and Internet Connectivity in Sub-Saharan Africa, A Report for Nuffield Department of Medicine and Department for Continuing Education University of Oxford*, October 2002, online: <http://tall.conted.ox.ac.uk/globalhealthprogramme/report/Nuffieldwebreport.pdf> (January 29, 2010) at 84.

[93] See P. A Donwa, "Funding of Academic Research in Nigerian Universities" online <http://portal.unesco.org/education/en/files/51642/11634301905Donwa-EN.pdf/Donwa-EN.pdf > (March 2, 2010).

[94] Established by the Federal Government under the *Research Institute (Establishment etc) Order 1977*, pursuant to the *National Science and Technology Development Agency Decree* (No 5) of 1977, it succeeded the Medical Research Council of Nigeria created in 1972. The *National Science and Technology Development Agency Decree* repealed the *Medical Research Council Decree of 1972.* The Clinical Science division of the NIMR has the mandate to conduct research into "human health problems in Nigeria."

[95] National Institute for Pharmaceutical Research and Development online: <http://www.niprd.org/niprdceovoices.htm> (February 2, 2010).

[96] Adole Hassan, "Nigeria Takes over Sickle Cell Drug" (2009) SciDev.net, online: <http://www.scidev.net/en/science-and-innovation-policy/research-ethics/news/nigeria-takes-over-sickle-cell-drug.html> (March 28, 2009).

research into the pathology, immunology and methods of treatment of trypanosomiasis or sleeping sickness. Twenty research institutes operate as parastatals under the umbrella of the Federal Ministry of Science and Technology. Also involved in research is the Nigerian Natural Medicine Development Agency, a parastatal under the Federal Ministry of Science and Technology,[97] whose main mission is to collate, document, research, preserve, develop, and promote traditional medicine practices and products in Nigeria.[98]

However, there is still an inadequate level of health research in Nigeria. This may, as some commentators suggest, be partly a result of potential participants' scepticism and mistrust, and limited technical knowledge and expertise.[99] But this has also largely been attributed to lack of government commitment to health research, even given the limited resources available. [100] Although, my extensive research provided little information on exact amounts spent by the Nigerian government on health research in more recent years due to lack of data, a WHO study on health research expenditures in Nigeria for the year 2001 provides some clue. This study estimated government expenditures on health research to be about 0.1 percent of around 2-3 percent of the national budget, the latter being the total

[97] It is mandated by statute to formulate, promote administer, monitor, coordinate and review science and technology policies and activities including research in the health sciences.
[98] Nigerian Natural Medicine Development Agency, "About NNMDA" online: <http://nignaturemed.net/index.php> (February 10, 2010). Some but not all of these institutes require human participants in carrying out their areas of research, for instance, the Nigerian Natural Medicine Development Agency, does not carry out research involving humans.
[99] See for example, Darren Roblyer et al, "Objective Screening for Cervical cancer in Developing Nations: Lessons from Nigeria" (2007) 107 Gynecologic Oncology S94 at S96.
[100] See also, Christina Scott and Abiose Adelaja, "Key African Countries 'Not Keeping Health Research Promises'" SciDev.net November 18, 2008, online: <http://www.scidev.net/en/news/key-african-countries-not-keeping-health-research-.html> (February 22, 2010).

government expenditure on health.[101] The 2-3 percent is much less than the ten to fifteen percent recommended by the WHO to be devoted to health[102] or the 15 percent of the annual budget to which Nigeria committed itself in the *Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Diseases.*[103] Much of the 2-3 percent allocated to health is spent on health care delivery, obviously leaving very little for health research, as evidenced by the WHO study.

Insufficient political commitment to health research is also evident from inadequately funded research institutions, inadequate facilities, poor infrastructure, ill-developed policies as well as significant brain drain in the medical field,[104] and poor support and funding for essential health research.[105] This situation was especially evident during military rule, but remains so today. In this regard, Ajayi rightly notes that:

> It is not often credible to accept the official excuse of unavailability of funds side by side with glaring financial abuse by military and other types of dictatorship. With what may have been available in human and material terms, there has been a lack of co-ordination between policy-makers, National

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[101] WHO, Regional Office for Africa, "Expenditures on Health Research in African Countries:" 2008 Algiers Ministerial Conference on Research for Health in the African Region (2008), online: <http://www.tropika.net/specials/algiers2008/technical-reviews/paper-3-en.pdf>(March 9, 2010). See Adedoyin Soyibo, "National Health Accounts of Nigeria, 1998-2002, Report Submitted to the WHO, 2005, online: <http://www.who.int/nha/country/Nigeria_Report_1998-2002.pdf> (February 8, 2010).

[102] WHO, "Proposal on Innovative Sources of Funding to Stimulate Research and Development Related to Diseases that Disproportionately Affect Developing Countries` online: <http://www.who.int/phi/Nigeria.pdf> (March 23, 2010). A study has also pointed out that all the research funding provided by the government to Nigerian universities did not exceed0.03 percent of the GDP. See Donwa, supra note 93 at 3.

[103] *Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Diseases* OAU/SPS/ABUJA 3.

[104] Ajayi, supra note 69. See also, Nwagwu, supra note 109 at 21. However, some commentators have pointed out that the absence of directories of research activities tends to minimize the amount of research that actually takes place. Temidayo O Ogundiran, "Enhancing the African Bioethics Initiative" (2004) 4 BMC Medical Education 21.

[105] See for example, National HIV/AIDS Prevention Plan, supra note 77 at 22.

> Health Research Council administrators, and research institutes whether related to health or not.[106]

The lack of a health research council, whose mandate would include funding health research in the country, is also evidence of insufficient understanding by the government of the necessity for health research in the Nigerian context. A National Health Research Committee is one of the bodies to be established by the *National Health Bill*. It is unarguable that the government could, and ought to, commit more resources to health research, given the need for, and the potential benefits of, health research.

In 2006, African governments in a High Level Ministerial Meeting on Health Research in Africa convened by the Federal Ministry of Health in Nigeria and the Ministry of Health in Ghana, through their Ministers of Health and Heads of Delegation agreed, amongst other things,:

> To strive to ensure the allocation of 2% of the national health budget and to further mobilize other resources from national and international sources for health research.[107]

This suggests that African governments, including the Nigerian government, understand the need for health research. It remains to be seen, however, if this will actually be implemented.

Although the proportion of health research conducted in Nigeria remains inadequate, the recent political shift to democracy has played, and continues to play,

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[106] Ajayi, supra note 69.

[107] See Communique, High Level Ministerial Meeting on Health Research in Africa, Abuja, Nigeria, March 8-10, 2006, online: <http://whocc.who.ch/countries/nga/reports/Health_Research_meeting_Communique.pdf>(March 2, 2010).

a role in boosting health research activities in Nigeria. Nwagwu, analysing empirical evidence on biomedical research literature in Nigeria since independence, points out that "judging by the pattern of growth, biomedical research in Nigeria has proceeded rather slowly since 1967 [when the Civil War began] but made more rapid advances in 1998–2002 attributable probably to the civilian administration that came into power in June 1999."[108] Democracy has also brought a greater flow of resources from international sources.[109] Others have argued that, despite infrastructural and personnel limitations, Nigeria remains an attractive venue for health research, including clinical trials. Ikeme, for instance, notes that:

> Because of relative lack of access to medical treatment and medications, participating in a clinical trial is a unique and beneficial opportunity for many patients. Rapid recruitment is thus an advantage for conducting a clinical trial in Nigeria when compared to the Western countries. Despite these compelling qualities, a lot of myths still exist about the country's capacity for [clinical] trials.[110]

Thus, there is both need and ample room for growth in health research, to provide the necessary knowledge to improve health in Nigeria.

Apart from the small and inadequate proportion of health research funded domestically, a significant amount of health research is, as in most African

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[108] Williams Nwagwu, "Mapping the Landscape of Biomedical Research in Nigeria Since 1967" (2005) 18: 3 Learned Publishing 200 at 204.

[109] Nwagwu notes elsewhere that: "The relative peace and freedom in the new government and the introduction of new favourable policies could account for the increase in scientific publications in the field during 1999-2002. During this period, most of the embargoes placed on Nigeria by the various international communities were lifted; foreign aid, most of which had been withdrawn during the period, was restored." See Williams E Nwagwu, "Patterns of Authorship in the Biomedical Literature of Nigeria" (2007) 17: 1 Libres 1 at 23.

[110] Anthony C. Ikeme, "Nigeria's Clinical Trials Scene" (2008) Applied Clinical Trials, online: <http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/CRO%2FSponsor+Articles/Nigerias-Clinical-Trial-Scene/ArticleStandard/Article/detail/522051> (February 2, 2010).

countries, funded by foreign sponsors, including multinational pharmaceutical companies, foreign governments, and foreign-based non-governmental organisations.[111] Several studies, including clinical trials, epidemiological studies and social science health-related studies are, and continue to be, funded by external sponsors such as the WHO Special Programme for Research and Training in Tropical Diseases and the United States National Institutes of Health (NIH).[112] Other foreign development initiatives which partner with developing countries, such as the European and Developing Countries Clinical Trials Partnership, have been very active in promoting clinical trials in Nigeria and other developing countries.[113] The Family Health International, a non-governmental organization, has sponsored many HIV prevention trials, including microbicides trials.[114] Further, cooperative groups such as the International Breast Cancer Study Group and the International Breast Cancer Research Foundation have established collaborating centers in

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[111] See Temidayo O Ogundiran, "Enhancing the African Bioethics Initiative" (2004) 4: 21 BMC Medical Education.
See the National Institute for Medical Research, online: <http://www.nimr-ng.org/> (October 4, 2008).

[112] Among some of the studies funded by external sources are the NIH-sponsored studies of the social, environmental and genetic determinants of hypertension in African populations, studies in breast cancer genetics, and studies in the genetic and environmental determinants of diabetes type 2. Patricia Marshall, "The Relevance of Culture and Informed Consent in U.S-Funded International Health Research in NBAC, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*, Volume II (Commissioned Papers and Staff Analysis) (Bethesda, Maryland, 2001) at C-11.

[113] P Olliaro and P G Smith, "The European and Developing Countries Clinical Trials Partnership" (2004) 9 J. HIV Ther 53. See also, "HIV/AIDS, Tuberculosis, and Malaria Research and Programs in Sub-Saharan Africa" online: < http://researchafrica.rti.org/index.cfm?fuseaction=home.country_view&country_id=14> for examples of some research funded by different international organizations in Nigeria.

[114] These include the vagina gel, SAVVY, and Tenoforvir, a microbicide, both of which have been discontinued. The SAVVY Trial was discontinued in 2007 for safety reasons. See P J Feldblum et al, "SAVVY Vaginal Gel (C31G) for Prevention of HIV Infection: A Randomized Controlled Trial in Nigeria" (2008) 3:1 PLoS ONE 3(1): e1474. Until 2005 when the controversial trials were stopped, Family Health International conducted clinical trials of Tenoforvir, a drug for the prevention of HIV infection, in Nigeria among sex workers. Jon Cohen, "More Woes for Novel HIV Prevention Approach" (2004) 307: 5716 Science 1808. See also, Jerome A. Singh, Edward J. Mills, "The Abandoned Trials of Pre-Exposure Prophylaxis for HIV: What Went Wrong?" (2005) PLoS Med 2(9): e234.

Nigeria, thereby providing access to cancer clinical trials for patients with cancer.[115] Another key research project conducted in Nigeria is the Human Genome and the International Haplotype Mapping Project (HApMAp). Nigeria is part of a six-country consortium involved in HapMap project which is significant because of the potential information it could provide about the human genome and the effect it could have on the rest of the world.[116]

Additionally, although the level of drug research in developing countries is much lower than necessary, multinational pharmaceutical companies have conducted, and continue to sponsor, clinical trials for the purpose of testing new drug interventions in Nigeria.[117] Clinical trials currently ongoing include, for instance, trials of probiotics for urogenital infections.[118] Nigeria's drug regulatory agency, NAFDAC, periodically publishes some of information on its website

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[115] Clement A Adebamowo, "Cancer in Nigeria" (April 2007) Asco News and Forum, online: <http://pda.asco.org/anf/Past+Issues/April+2007/Cancer+in+Nigeria?cpsextcurrchannel=1> (February 28, 2010).

[116] The purpose of the HapMap project is to find out the common patterns of DNA sequence variation in the human genome and to make this information freely available in the public domain. Such information will allow the discovery of sequence variants that affect common disease, and will facilitate the development of diagnostic tools, and improved methods of treatment. This project, amongst other things, "fulfills the need for a new approach to ferreting out genes that participate in complex multigenic disorders such as diabetes mellitus."Yorubas from Ibadan, Nigeria were recruited for the project. See The International HapMap Consortium, "The International HapMap Project (2003) 426 Nature 789. Elizabeth G. Phimister, "Genomic Cartography — Presenting the HapMap" (2005) 353: 17 New England Journal of Medicine 1766.

[117] See for instance, B N Okeahialam et al, "Lacidipine in the Treatment of Hypertension in Black African People: Antihypertensive, Biochemical and Haematological Effects" (2000) 16: 3 Current Medical Research and Opinion 184.

[118] Kingsley Anukam, "Oral use of probiotics as an adjunctive therapy to fluconazole in the treatment of yeast vaginitis: A study of Nigerian women in an outdoor clinic" (2009) 21: 2 Microbial Ecology in Health and Disease 72. Natarajan Ranganathan, et al, "Probiotic Dietary Supplementation in Patients with Stage 3 and 4 Chronic Kidney Disease: A 6-month Pilot Scale Trial in Canada" (2009) 25: 8 Current Medical Research and Opinion 1919 at 1919. See also, "Use of Oral Probiotics as an Adjunctive Therapy to Fluconazole in the Treatment of Yeast Vaginitis" online: < http://clinicaltrials.gov/ct2/show/NCT00479947> (April 26, 2010).

regarding clinical trials.[119] In addition to sponsoring drug-related research, multinational pharmaceutical companies have in the past donated medical equipment and drugs. In 2008, for example, the government commissioned the first centre dedicated solely to clinical trials, donated by the multinational pharmaceutical company, GlaxoSmithKline, at the Lagos State University College of Medicine.[120]

Externally funded research is essential to the growth of knowledge about the prevention and treatment of diseases in Nigeria and forms a substantial part of the health research which occurs in the country. But in this regard, Ogundiran notes that:

> Collaborative research with colleagues from the developed countries is often externally funded. ... Of particular ethical concern in collaborative research is the fact that external sponsors may differ in their motives for conducting research and there may be limited applicability of research benefits to the country or local community.[121]

Thus intertwined with the need for greater levels of health research in Nigeria and the role of external sponsors in meeting that need are the related themes of research priorities and research governance. As discussed in Chapter One, there has been concern in the literature about how research agendas are set, and who sets the research agenda in developing countries such as Nigeria. There has also been concern about the conduct of research in developing countries like Nigeria which

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[119] NAFDAC notes on its website that five drugs are currently undergoing clinical trials (as at February 2010), although it does not name the specific drugs or the companies conducting the trials NAFDAC, Registration and Regulatory Affairs Directorate, online: <http://www.nafdac.gov.ng/index.php?option=com_content&view=article&id=84&Itemid=117#p26> (February 4, 2010).

[120] Zakariyya Adaramola, "Nigeria: Country Gets its First Clinical Trial Site," (November 2, 2008) *Daily Trust.*

[121] See Ogundiran, supra note 111.

will not ultimately benefit the population for reasons including the non-affordability of the resulting intervention or the ineffectiveness of the research results in the developing country context. These concerns are clearly pertinent in the Nigerian context. For instance, in a research survey undertaken by the UK Department for International Development, many respondents were of the view that funding provided by donors was mainly driven by donor priorities rather than national priorities.[122] The Pfizer incident, discussed below, is an example of research funded by a multinational pharmaceutical company which, because of the potential high costs of the resulting intervention, would not have been of significant relevance to the Nigerian public. These are issues that require continued government attention and engagement with research sponsors. They are also issues that need to be taken into consideration in establishing governance arrangements.

In sum, health research has a long history in Nigeria, dating back to the colonial era. At present, there is a significant, if inadequate, amount of health research currently conducted in Nigeria, with much of it sponsored by external sponsors. There continues to be need for health research in Nigeria. The Revised National Health Policy recognises this need. In light of the increasing health research activities in Nigeria, and the recognition in national policies of the necessity for even more health research, it is necessary to ensure that there are adequate arrangements to regulate current and potential health research involving humans in

[122] DFID, "DFID Research Strategy, (2008-2013) Consultation – Africa: Country Report for Nigeria" (2007), online: http://www.research4development.info/PDF/Outputs/Consultation/NigeriaCountrypaperFinal.pdf>(February 10, 2010).

Nigeria. Allegations of unethical research, some of which are described below, emphasise this need even more.

5.5 A Brief History of Research Governance in Nigeria

One of the aims of this thesis is to detail recent developments in research governance in a specific developing country context like Nigeria. Examining the origins of these new developments in this area will, as I pointed out in Chapter One, allow for the identification of gaps, weaknesses, and areas for potential improvement. In other words, a description and analysis of where Nigeria has been, will be helpful in determining where Nigeria now needs to go with respect to research governance, and perhaps how it should get there.

Although, as I described above, health research involving humans has been conducted in Nigeria since colonial times, there has been very little effort to document the history of research governance in Nigeria. What follows, therefore, is an attempt to piece this history together from fragments of information available in the public domain. I consider this necessary because as research governance arrangements are developed in Nigeria, it is important to learn what challenges existed in establishing and operating such arrangements in the past and then to take steps to address them in current and future arrangements. In this section, then, I provide a brief history of research governance in Nigeria. This description includes accounts of alleged unethical practices in Nigeria which indicate the necessity for effective research governance in Nigeria.

The history of research governance in Nigeria can be roughly divided into two broad stages: pre- 2006 before the establishment of the National Code on Health Research Ethics and post 2006 when the most recent and more concerted efforts were made to formalise governance arrangements in a national and country-wide manner. In the first subsection, I recount the history of research governance from the earliest available accounts. Many of the allegations of unethical research fall into the pre-2006 era. I describe them in a subsection after the description of the pre-2006 era. In doing so, I underscore the need for effective research governance. I describe the period from 2006 briefly. A more in-depth analysis of current research governance arrangements is conducted in the next chapter.

5.5.1 Research Governance in Nigeria Prior to 2006

While health research was conducted during the colonial era pre-1960, there are no documented attempts to establish mechanisms for research governance in Nigeria during the colonial times.[123] Nor are there any documented efforts to establish such mechanisms in the post-independence era until 1980 when the first attempts to create a formal regulatory structure began.

However, in a 1980 article,[124] Ajayi proposed a three-tier structure for research governance in Nigeria. This would consist of a National Ethical Committee, comprising biomedical researchers and social scientists, which would

[123] See Nwabueze, supra note 69.
[124] O. O. Ajayi, "Taboos and Clinical Research in West Africa" (1980) 6 Journal of Medical Ethics 61 at 62.

determine the relevance of proposals for research on large populations, articulate national health research priorities, and ensure that the source and funding of such programmes do not conflict with political goals and policies. The second tier was to be Peer Review Committees to be situated in a hospital, communities, or research institutes, which would review research proposals according to ethics standards. The third tier would be a sub-committee situated in individual research departments or laboratories to determine scientific validity and technical competence.

Ajayi's suggestions appear, at least in part, to have been adopted. A national ethics review committee, was established sometime afterwards in 1980. However, it became non-functioning as a result of lack of funding and lack of political interest.[125] According to Adebamowo and others:

> The earliest attempts to set up a national ethics regulatory infrastructure in Nigeria took place in 1980. However, this effort faltered largely because of lack of sustained interest and funding. Subsequent attempts were also unsuccessful because the decades of the 1980s and 1990s were marked by military misrule and socio-economic dislocation.[126]

From my research, there appears to have been no significant activities with respect to research governance at the national level until 2002. Until 2002, there was no functioning national ethics review committee. Any reviews conducted at the national level were done through the Directorate of Clinical Services, Research, and Training

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[125] EDCTP, "Support for Ethics Review Boards: Strengthening the National Health Research Ethics Committee of Nigeria (NHREC)" online: < http://www.edctp.org/uploads/tx_viprojects/Project_Profile_-_CB_Ethics-Review_41302_Clement_Adebamowo.pdf> (February 25, 2010).

[126] Adebamowo et al, supra note 64 at 16.

in the Federal Ministry of Health.[127] The Federal Ministry of Health, as described earlier, has been the key health policymaker in Nigeria. It had the mandate to make policies, including research ethics policies, but did not make any general research ethics policies that applied in every situation and to all institutions.

There were also several ethics review committees in different institutions, particularly the teaching hospitals attached to some federal universities. Some of them had been established in the 1980s, have since been reconstituted severally and only became truly functional in recent years.[128] The University of Ibadan in Nigeria is a good example. According to a recent article written by the current chairperson of the University College Hospital Ethics Committee at the University of Ibadan, Professor Adeyinka Falusi, and others:

> In 2002, we reviewed the status of the University College Hospital, University of Ibadan Ethics Board that had been in existence since 1980. We found that the Board had not been active and was poorly organized with no constitution or written standards or policies in place to guide the review of research proposals. There was no established infrastructure such as a designated secretariat, staff, or records of previous IRB reviews and approvals. Meetings were held as needed, or as infrequently as every 6 months, as there was very little research at the University due to pervasive academic strikes and the dire economic condition of the country. The Director of the Institute for Medical Research and Training (IMRAT) who ultimately approved all institutional research studies made the selection of suitable reviewers for each submitted protocols. On occasion, the Director gave executive approvals after review of the protocol without the benefit of a full

[127] Adefolarin O. Malomo et al, "The Nigeria Experience" (2009) 6:4 Journal of Academic Ethics 305.
[128] See Networking for Ethics on Biomedical Research in Africa (NEBRA): Final Report, online: <http://elearning.trree.org/file.php/1/NebraReport/FinalReport-2006-english.pdf> (February 22, 2010) at 69-70.

> committee. Despite the importance of this essential review process for promotion of research activities within the University, there was no budget allocation to support the activities of the ethics board. Predictably, there was little or no awareness of the existence of an IRB by faculty and staff and not surprising; there was no international registration or recognition of the existence of a duly constituted IRB.[129]

The above is especially interesting because University College Hospital, Ibadan is a pioneer medical establishment in Nigeria, and much of the externally-sponsored health research which occurs in the country is conducted there. As described by Ajayi in the following subsection, the public had a negative perception of research practices in the hospital. A situation in which researchers and staff at the University did not know of the existence of an ethics review committee in the institution clearly suggests the dire conditions of research governance at the University in which a significant portion of health research in the country took place. The situation was unlikely to have been different in other institutions with even less research. Indeed, according to Nwabueze, it appeared that the few Nigerian institutions with ethics review committees which functioned at all provided ethics review of mainly collaborative studies (especially those conducted in collaboration with United States-based institutions). Apart from any other reservations that one might have to this ad-hoc manner of functioning, it could be argued as Nwabueze does, that research participants were likely to be denied "the protections afforded by the existence of a regular, functional, and competent ethics committee."[130]

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[129]Adeyinka G Falusi, Olufunmilayo I. Olopade and Christopher O. Olapade, "Establishment of a Standing Ethics/Institutional Review Board in a Nigerian University: A Blueprint for Developing Countries" (2007) Journal of Empirical Research on Human Research Ethics 21 at 22.
[130] Nwabueze, supra note 69 at 104.

According to a survey[131] conducted between 2003 and 2005, there were thirty ethics review committees in institutions in Nigeria in the early 2000s. These institutions were mainly in federal institutions including the major teaching hospitals, some of the federal hospitals and the major research centres like the NIMR. These ethics review committees were variously called the Institutional Review Board (as in the United States), the Institutional Review Committee, the Ethical Review Committee.[132] However, many state hospitals did not have ethics review committees.[133] As the Pfizer incident which occurred in 1996 shows, this did not mean that research never took place in them, or that such a possibility did not exist. Many of the existing committees, as described in the case of the ethics review committee at the University of Ibadan above, were grossly underfunded and lacked the necessary expertise to carry out their duties.[134] Many of them had no significant activity.[135]

In 2002, the National Ethics Review Board was created.[136] Its mission was to promote "good ethical practice in Nigerian scientific research, safeguard the dignity, right, safety and well-being of all actual or potential research participants' through the auditing and accreditation of ethics review committees, and the training

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[131] Networking for Ethics on Biomedical Research in Africa (NEBRA): Final Report, online: <http://elearning.trree.org/file.php/1/NebraReport/FinalReport-2006-english.pdf> (February 22, 2010).
[132] Ibid.
[133] A few state hospitals but not all state hospitals have ethics review hospitals. See Ogundiran, supra note 111.
[134] Ogundiran, ibid.
[135] Ibid.
[136] See Malomo et al., supra note 127 at See National Ethics Review Board, *Draft National Ethical and Operational guidelines for Research on Human Subjects*, Nigeria, online: <http://elearning.trree.org/file.php/1/NebraReport/nebra-Annex-15.pdf> (February 24, 2010).

of ethics review members, and advising the government on ethical matters.[137] The Board was never recognised either legally or in a government policy and it has now been by replaced by another national body.[138] A draft national guideline: *Draft National Ethical and Operational Guidelines for Research on Human Subjects*,[139] was prepared but never took effect.

In 2005, another national committee, called the National Ethics Committee of Nigeria, was established by the Chairman of the National AIDS Control Agency. Its mandate was to coordinate and provide oversight for institutional ethics review committees. This national committee was also not legally recognised and had no financial support from the government. It existed for a time alongside another national committee, the National Health Research Ethics Committee, established by the Federal Ministry of Health, which is currently functioning.[140] This indicated the challenges of duplication of functions, and the lack of clarity about which government department could legally establish a national ethics review committee.

Prior to 2006, there were no national domestic ethics guidelines providing guidance, either in terms of substantive ethical standards or with regard to procedures and compositions of ethics review committees. Marshall, in a 1999 study commissioned by the United States National Bioethics Advisory Commission, noted

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[137] Ibid. at

[138] It has been replaced by the National Health Research Ethics Committee created in 2006.

[139] National Ethics Review Board, *Draft National Ethical and Operational guidelines for Research on Human Subjects*, Nigeria, online: < http://elearning.trree.org/file.php/1/NebraReport/nebra-Annex-15.pdf> (February 24, 2010).

[140] Information provided by Professor Femi Soyinka, the former chairman of the National Ethics Committee. See also, WHO, "National Bioethics Committees in the African Region" <http://www.who.int/ethics/committees/afro/en/> (June 2, 2010).

that there was considerable variation in the implementation of the process of ethical review between institutions, especially in terms of their composition.[141] Nwabueze also noted that some of the existing ethics review committees operated not consistently, but on an ad hoc basis.[142] For guidance on ethical standards, the defunct NERB described above relied on different documents, including the Constitution, the Helsinki Declaration, the CIOMS Guidelines, the WHO/TDR Guidelines, the ICH-GCP Guidelines, the Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* among others.[143] Some institutional ethics review committees employed the Helsinki Declaration as their main reference document, or the CIOMS Guidelines, while others used internal guidelines developed by the institutions.[144]

Apart from the ethics review structure, the National Agency for Food and Drug Administration and Control (NAFDAC) was established by the National Agency for Food and Drug Administration and Control Act in 1993. NAFDAC is a parastatal of the Federal Ministry of Health and is responsible for ensuring drug safety and compliance with approved specifications and quality and regulates the importation, exportation, and manufacture, registration, and marketing of drugs. Its functions also include the regulation of clinical trials for drugs. In regard to research for pharmaceutical production, NAFDAC drew up a set of guidelines around 2002

[141] Patricia Marshall, "The Relevance of Culture and Informed Consent in U.S-Funded International Health Research in NBAC, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*, Volume II (Commissioned Papers and Staff Analysis) (Bethesda, Maryland, 2001) at at C-11-C-12.
[142] Nwabueze, supra note 69.
[143] NERB, supra note 136 at 15.
[144] Ibid.

for the purposes of regulating clinical trials of drugs in Nigeria (NAFDAC Guidelines).[145] The application of the NAFDAC Guidelines is limited, however, to drug research and does not apply more generally to all health research involving humans. Thus, the guidelines could not be regarded as providing general protections for participants in health research in Nigeria.

With regard to legal regulation of health research involving humans, although there were common law principles that could be argued to have provided some sort of legal framework for research, there was no direct legislation to regulate health research involving humans. Prior to 2006, there was also no law requiring the existence of ethics review committees in research institutions, or setting down their structure or composition and functions or even requiring that research protocols must pass through ethics review. However, NAFDAC, the drug regulatory agency, which had previously drawn up guidelines as described above, drew up draft Clinical Trials Regulations 2004,[146] which were never passed. Among other requirements, according to the NAFDAC Guidelines, clinical trials of drugs now have to pass through ethics review and meet other procedural requirements.

Apart from legal regulation, self-regulation by professional association is, as discussed in Chapter Three, another potential means of regulating health research involving humans. The Medical and Dental Council of Nigeria is the professional regulatory body, established by statute,[147] which determines the standards for educating medical and dental professionals and makes rules for

[145] The Guidelines, which I have on file is undated. However, according to a NAFDAC official from whom the document was obtained in 2004, at the time, the document had been prepared recently.
[146] I have these on file. NAFDAC has now drawn up a new set of guidelines based on the ICH-GCP.
[147] *Medical and Dental Practitioners' Act Cap 221 Laws of the Federation of Nigeria* (LFN) 1990.

maintaining universally acceptable professional standards of practice and conduct. Although there is not much literature on the Medical and Dental Council of Nigeria's regulation of the conduct of health research by its members, it took a step in that direction in the 2004 revision of the code of ethics,[148] entitled: Code of Medical Ethics. This most recent edition of the Code provides amongst other things that, "Every Teaching Hospital or Medical Research Institute MUST constitute an Ethical Review Committee composed of competent individuals to examine the research protocol of every researcher in the institution."[149] The Council imposes penalties for the infringement of standards or bad conduct. However, no researcher, from my research, has been punished for not adhering to the standards laid down by the Medical and Dental Council of Nigeria.

Governance of health research involving humans in Nigeria is, as the foregoing discussion in Nigeria suggests, not a recent phenomenon, having begun formally in 1980. Research governance in Nigeria prior to 2006 consisted of a spectrum of formal and informal mechanisms with little formal or comprehensive engagement with, and oversight of the conduct of, health research involving humans on a national level, with the exception of drug-related health research. There was no direct legal regulation except for drug research regulation, beginning in 1993 with the creation of NAFDAC. Existing regulations were hardly implemented, as the Pfizer incident described below, shows. As I describe below, this state of affairs

[148] The edition of the code which preceded the current edition was titled: Rules of Professional Conduct for Medical and Dental Practitioners in Nigeria. The code of ethics was first put in place in 1963. The 2004 edition replaced the MCDN, *Rules of Professional Conduct for Medical and Dental Practitioners in Nigeria, 1995.* See MDCN, History of Medical and Dental Council of Nigeria, online: http://www.mdcnigeria.org/Historyframe.htm> (February 2, 2010).
[149] Section 31 (C), Medical and Dental Council of Nigeria, Code of Medical Ethics, 2004, online: <http://www.mdcnigeria.org/Downloads/CODE%20OF%20CONDUCTS.pdf> (February 20, 2010).

allowed much room for exploitation and unethical practices and left participants with minimal options for legal redress.

Further, research governance appears to have proceeded in a very haphazard, fragmentary fashion, with little coordination between the various bodies involved in regulating health research involving humans. For instance, a cursory look at the different guidelines and regulations, including the NAFDAC Guidelines, the Medical Dental Council of Nigeria, Code of Medical Ethics, National Ethics Review Board, and the *Draft National Ethical and Operational Guidelines for Research on Human Subjects*, Nigeria, shows that they provide varying requirements for the conduct of health research involving humans. There are different requirements for the composition and structure of ethics review committees, and somewhat different substantive ethical standards. Moreover, ethics review committees, both nationally and institutionally, have been non-functional over the years.

The early 2000s, however, signalled a new direction in research governance in Nigeria, with the establishment of national ethics review committees, the drawing up of guidelines for clinical trials by NAFDAC, the preparation of the *Draft National Ethical and Operational Guidelines for Research on Human Subjects* (which was never adopted), and the Medical and Dental Council of Nigeria revision of the Code of Ethics to include requirements for the ethical conduct of health research involving humans. These events paved the way for a potentially more comprehensive, nation-wide, scheme for research governance. Prior to this scheme, however, research participants in Nigeria experienced several instances of unethical

research, including the Pfizer incident which has been discussed widely in the literature.

5.5.2 Unethical Conduct of Research in Nigeria Prior to 2006

Prior to 2006, there were several allegations of unethical research, many of them revolving around lack of informed consent and failure to obtain approval from an ethics review committee prior to marketing drugs. Some of these allegations were based on anecdotal evidence, and although not independently verified, nevertheless affected public perception and trust in some cases. For example, Ajayi in a 1999 paper, points out that:

> [The] University College Hospital, Ibadan has not lived down the perception of the local population that unethical human experimentation went on in the hospital. The selection of cases for admission (often linked to the severity of illness and types that could not be handled outside a tertiary centre) were misunderstood to be related to research interests. Mortality in the very ill patient was often ascribed to injections given for research purposes.[150]

Similarly, Anya, a physician, detailed his experiences as a medical student in Nigeria in the 1990s, noting in the Lancet that:

> Training to be a doctor in Nigeria a decade ago included little more than cursory attention to either clinical or research ethics: a single hour-long lecture on ethics and professional practice, delivered close to the final examinations, sufficed. As a house officer at a major teaching hospital, it was not unusual to be instructed to take samples for a

[150] Ajayi, supra note 69.

> research project without any research protocols or consent forms being provided. Ethics committees were weak or non-existent at most hospitals.[151]

Another example, although not strictly about the conduct of research, was a 1999 controversy involving the marketing of HIV/AIDS drug and vaccine which highlighted the vacuum in Nigeria's regulatory procedures. In that incident, a Nigerian doctor, Dr. Jeremiah Abalaka, claimed to have found the cure for HIV/AIDS as well as a vaccine to prevent the diseases.[152] At this time, there was very little access to antiretroviral treatment in Nigeria. Several infected persons received treatment from the doctor at exorbitant costs. The drug and vaccine received support from top army officers who proceeded to make it available to soldiers suffering from AIDS.[153] Dr. Abalaka claimed to have performed clinical trials (involving testing the drug on himself) before making the drug available to the general public. However, in 2000, after much opposition from different scientific bodies, including the Nigerian Medical Association (NMA) and the Nigerian Academy of Science, the Federal Ministry of Health banned the drug and vaccine.[154] The Nigerian Academy of Science had criticised the methods of Dr. Abalaka, on the grounds that the drug and vaccine had not passed through any clinical trials or ethics review procedures. They could not, however, refer to any domestic legislation or

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[151] Ike Anya and Rosalind Raine, "Strengthening Clinical and Research Ethics in Nigeria—An Agenda for Change" (2008) 372 Lancet 1594.
[152] Barnaby Phillips, "Nigerian Doctor finds HIV Cure" *BBC News* May 8, 2000. Online: BBC News <http://news.bbc.co.uk/1/hi/world/africa/740523.stm> (April 3, 2010).
[153] *Ibid.* See also, "Nigeria-AIDS: Nigerian Army Again Backs Claims of HIV/AIDS Cure" Agence-France Press July 4, 2000. Online: Agence-France <http://www.aegis.com/news/afp/2000/AF000713.html> (April 3, 2010).
[154] Khabir Ahmad, "Public Protests as Nigeria Bans Use of Untested HIV Vaccine" (2000) 356 The Lancet 493.

policy that required these steps because none existed at this time.[155] Accusations of political machinations were made by the doctor and his supporters against the government and different associations of medical doctors. The lack of clear regulatory procedures meant there was no impartial domestic standard against which to judge such claims.[156]

Beyond the anecdotal evidence described above, studies have noted that many research projects were conducted in Nigeria without ethical review.[157] The Pfizer incident which occurred in 1996 is a prime example. That incident encapsulates many of the problematic issues in research governance in Nigeria in the past, underscores Nigeria's challenging context, and has had consequences beyond the arena of health research. An account of the history of research governance in Nigeria is thus incomplete without a discussion of the Pfizer incident.

In 1996, there was an outbreak of a meningitis epidemic in Kano, a state in the northern part of Nigeria. About 250,000 people were infected during the epidemic and about 15,000 people died.[158] Humanitarian organisations such as the Medicins Sans Frontier went to Kano and began providing the cheap and effective antibiotic, chloramphenicol (which interestingly had been tested in the Northern part

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[155] Ibid.

[156] Lumumba C. Achilonu, "The Politics of Abalaka's Vaccines" *Thisday*, February 9, 2001, online: <http://www.thisdayonline.com/archive/2001/02/09/20010209com01.html> (March 10, 2010). Barnaby Phillips, "Nigerian Doctor Finds HIV 'Cure'" BBC News May 8, 2000 online: <http://news.bbc.co.uk/2/hi/africa/740523.stm> (March 10, 2010).

[157] NEBRA, supra note 156 at 72.

[158] Emmanuel R Ezeome and Christian Simon, "Ethical Problems in Conducting Research in Acute Epidemics: The Pfizer Meningitis Study in Nigeria" (2010) 10: Developing World Bioethics 1. Other sources put the death toll at 15,000. See The BBC has a figure of 15,000 people. "Nigerians Sue Pfizer Over Test Deaths" *BBC News* (30 August 2001). Available at: <http://news.bbc.co.uk/1/hi/business/1517171.stm> (22 January 2007).

of Nigeria about twenty years earlier).[159] At the same time, Pfizer, an American multinational pharmaceutical company, sent in staff to conduct a trial of an antibiotic, Trovafloxacin (commonly called Trovan).[160] The Kano Infectious Diseases Hospital, where the trials took place, was reported to be at the time, a poor, dirty hospital with few beds, poor power supply, and no clean water.[161]

Pfizer's main reason for conducting the clinical trials in Kano was to obtain approval for the drug from the United States Food and Drug Agency.[162] The trial was to investigate whether the oral form of Trovan was more effective and efficient in treating children infected with meningitis than other existing treatments, including Ceftrixacone, the gold standard treatment. Later, when charges of unethical conduct were made, Pfizer also alleged that another major reason for conducting the trials was to provide humanitarian services to the infected victims who were obviously in need of medical assistance at the time.[163] Sometime after the trial had ended, several allegations were made regarding the unethical manner in which Pfizer conducted the trials. These were first publicised by the *Washington Post* in a series of investigative articles on the conduct of clinical trials by developed country researchers in developing countries. [164]

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[159] See Whittle, supra note 80.

[160] WHO, 'Cerebral Meningitis in Nigeria- Update in Disease Outbreaks Reported' (7 March 1996). Online: WHO <http://www.who.int/disease-outbreak-news/n1996/mar/n7mar1996b.html> (16 April 2007).

[161] Joe Stephens, 'The Body Hunters (Part 1): As Drug Testing Spreads, Lives Hang in the Balance' *Washington Post* (17 December 2000) at p. A01.

[162] Ibid.

[163] See Remigius N. Nwabueze, 'Ethical Review of Research Involving Human Subjects in Nigeria: Legal and Policy Issues' 14 Ind. Int'l & Comp. L. Rev. (2003-2004) 87 at 98.

[164] This was a series of six articles containing stories on clinical trials in developing countries. See, J Stephens, The Body Hunters (Part 1): As Drug Testing Spreads, Lives Hang in the Balance" *Washington Post* (17 December 2000) at p. A01. Available at: Washington Post

Pfizer's Trovan had not been previously tested in children. However, about 200 children, aged between 1 and 13 and infected with meningitis were enrolled in the Kano trials. 100 of the children were thus put on the Trovan while another 100 were put on the Ceftrixacone.[165] Out of the enrolled number, it was alleged that 11 died in the trials,[166] 5 of whom were on the experimental drug, Trovan, given orally, while the other 6 were on injections of the standard drug Cetrifaxone.[167] It was also reported that other children involved in the trials suffered seizures, or became paralysed.[168] It was also reported that at least one child was not taken off the experimental drug and given the standard drug when it was clear that her condition was not improving, which was clearly unethical.[169] The trials were conducted within three weeks and Pfizer left Kano immediately.

The allegations made against Pfizer include that there was no informed consent, and no follow-up of the children after conclusion of the trial. The parents of the children alleged that they had not been adequately informed about the trial and would not have subjected their children to it had they been informed that their children were participating in a trial rather than simply receiving treatment. No written consent was obtained, although Pfizer had prepared an informed consent form. Due to the illiteracy of the parents, only verbal consent was obtained after oral

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<http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&contentId=A11939-2000Dec15&notFound=true> (March 3 2007).

[165] Ibid.

[166] S Bosely, New Drug 'Illegally Tested on Children': Pfizer Accused of Irregularities during Clinical Trials in Nigeria *The Guardian* (London), (17 January 2001) at 19.

[167] Stephens, supra note 162.

[168] Ibid.

[169] Washington Post, ibid. See also Jacqui Wise, Pfizer Accused of Testing New Drug without Ethical Approval" (2001)322 BMJ 194, online : <http://www.bmj.com/cgi/content/full/322/7280/194> (March 2, 2010).

explanations had been made to the parents of the children in English and Hausa (the language of the participants).[170] Also, there was no follow-up of the children partly because many of them did not show up after leaving the hospitals, and also because Pfizer reportedly did not send people to check up on them.[171] It is necessary to note that Nigeria had no direct policy on research involving children, although commonsense suggests that obtaining informed consent from poor and illiterate parents, whose children were in danger of dying in an epidemic, would be a difficult matter.[172]

A puzzling issue was why Pfizer would choose to conduct a trial during an epidemic in a poor area when other organisations were seeking to provide assistance. Was it ethically permissible to conduct tests for a drug that would, if things went well, yield huge profits for Pfizer during an epidemic? Was it ethically acceptable to conduct a trial in a developing country like Nigeria, which had minimal chances of actually being used in that country due to its exorbitant costs?[173] Pfizer defended itself on the grounds that acute epidemics of meningitis are rare in developed countries, that drug response may differ from one setting or population to another, and that it is necessary to determine what kinds of drugs will be most

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[170] Ibid. Barnaby Phillips, Nigeria's Drug Trial Fears *BBC News* 14 March 2001. Available at: BBC News <http://news.bbc.co.uk/1/hi/world/africa/1220032.stm> (1 September 2005).

[171] As was alleged, many of the affected children were "rural people with no address." Stephens, supra note 162.

[172] See generally, Ayodele S Jegede, "Understanding Informed Consent for Participation in International Health Research" (2009) 9:2 Developing World Bioethics 87. See also Ezeome and Thomson, pointing out that: "People may mistake research activities as compulsory elements of public health intervention being directed at the epidemic. Therapeutic misconception is almost inalienable from research endeavors in this setting. This may explain why the Pfizer study reported a one hundred percent participation rate among patients that were approached for enrollment."

[173] Hauke Goos, "Using Africans as Guinea Pigs: Nigeria Takes On Pfizer over Controversial Drug Test" (2008) Spiegel Online International, online: <http://www.spiegel.de/international/world/0,1518,517805,00.html> (March 16, 2010).

effective in an epidemic situation.[174] According to a press statement it made in 2006: "At the time of the epidemic - the largest in the country's history, according to health officials - Pfizer believed that Trovan would provide a life-saving treatment for meningococcal meningitis that was afflicting tens of thousands of Nigerians. The goal of the study was simple - to find an effective treatment for a disease that was having a devastating effect on the people of sub-Saharan Africa."[175] Also, in its statement of defence in a case eventually filed against it by the Nigerian government, Pfizer stated that it had donated over 18 million naira to Kano State (about 180,000 dollars) in medicine equipment and materials to fight the concurrent epidemics.[176]

There were also apparent procedural defects, for instance, proper records of the trials were not kept as required in such trials.[177] Further, there was no approval of the research protocol by an independent ethics review committee. Pfizer stated that it had obtained the necessary approvals from NAFDAC, the Federal Ministry of Health, and the Kano State Ministry of Health.[178] When the incident was publicized by the Washington Post, Pfizer also stated that it had received approvals from an ethics review committee in the hospital. But, there was no ethics committee

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[174] Ezeome and Thomson, supra note 157 at 5.
[175] Pfizer, "Pfizer Statement – 1996 Trovan Clinical Study in Nigeria" online: <http://www.pfizer.ca/english/newsroom/press%20releases/default.asp?s=1&year=2006&releaseID=193> (March 14, 2010).
[176] Pfizer Inc., "Trovan, Kano State Civil Case – Statement of Defense Summary" New York, NY: Pfizer Inc, online: <http://www.pfizer.com/files/news/trovan_statement_defense_summary.pdf>(March 2, 2010). However, as Ezeome and Thomson rightly note, "research cannot be paraded as a form of emergency relief at the cost of taking appropriate steps to protect affected individuals." Ezeome and Thomson, supra note 157.
[177] Ruth Macklin, *Double Standards in Medical Research in Developing Countries* (Cambridge: Cambridge University Press, 2004) at 101.
[178] Pfizer, Summary: Trovan, Kano State Civil Case – Statement of Defense, online: <http://www.pfizer.com/files/news/trovan_statement_defense_summary.pdf> (March 11, 2010).

in the hospital at the time of the trial[179] and no evidence exists that any ethics review committee in Nigeria examined the research protocol before the trial commenced.[180] A purported letter of approval was not given at the time of the incident and was backdated by at least a year.[181] It may be stated, however, that there were no domestic regulations or guidelines in Nigeria, at the time of the trials, requiring Pfizer to obtain any such approval. Pfizer in its statement of defence sought to rely on this gap in Nigerian law and policy, stating:

> Pfizer contends that there was no regulation or law in Nigeria requiring ethical committee approval before conducting a clinical trial or investigative study. Therefore, there was no need to obtain what the law did not require. In addition, there was no formal ethics committee sitting at either Kano's IDH or at the nearby Bayero Teaching Hospital. There were, however, numerous other forms of approval by local physicians and government officials authorizing the study to go forward including, but not limited to, the head of the IDH and Dr. Idris Mohammed. At no time was patient care compromised in any way.[182]

However, the requirement for ethics review approval was also a requirement of the international ethical guidelines, such as the Helsinki Declaration. There were also questions as to whether the foreign physicians used by Pfizer in the

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[179] See also, Phillips, supra note 151. Bosely, supra note 165.
[180] B Ukwuoma, "Pfizer Official, Others Summoned to Kano over Drug" *The Guardian* (January 12, 2001).
[181] Bosely, supra note 165. See also, Joe Stephens, "Doctors Say Drug Trial's Approval Was Backdated" *Washington Post* (December 17, 2000) at p. A01 Available at: Washington Post <http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&node=&contentId=A63515-2001Jan15&notFound=true> (March 3, 2007).
[182] Pfizer Statement of Defense, supra note 177.

study were licensed by the Medical and Dental Council of Nigeria to treat patients in Nigeria.[183]

The drug was approved by FDA in 1997, a year after the trials in Nigeria. One of the grounds of the approval was the beneficial impact of the drug as manifested in the clinical trials conducted in Kano.[184] Later, in 1999, the FDA issued a public health advisory limiting the use of the drug to certain categories of patients and restricting its use because it was shown to cause fatal liver damage.[185] The European Union also withdrew the drug from the market in 1999 because of liver problems.[186] The drug was not registered or marketed in Nigeria since it was too expensive and therefore not affordable.[187]

The parents of the children involved in the trials brought action in the Federal High Court in Nigeria alleging lack of informed consent, and seeking compensation from Pfizer.[188] This case was dismissed in 2002. Another suit was filed by thirty families in a District Court in the United States in August, 2001 while the case filed in Nigeria was pending, seeking punitive damages against Pfizer under the United States *Aliens' Tort Claims Act*,[189] alleging that Pfizer had violated the law

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[183] T. Soniyi. "Pfizer's Drug Trial Illegal – FG Panel" Punch (Lagos, Nigeria) October 22, 2007, online: <http://www.punchng.com/Articleprint.aspx?theartic=Art200710223534214 > (May 2, 2008).
[184] Sonia Shah, "Globalization of Clinical Research in the Pharmaceutical Industry," 33:1 International Journal of Health Services 29 at 33.
[185] US Food and Drug Administration/ Centre for Drug Evaluation and Research, Public Health Advisory: Trovan ((Trovafloxacin/Alatrofloxacin Mesylate): Interim Recommendations 09 June 1999. Available at: <http://www.fda.gov/cder/news/trovan/> (accessed 1 September 2005).
[186] Tinker Ready, 'Pfizer in Unethical Trial Suit' (2001) 7 Nature Medicine 1077.
[187] B Ukwuoma, 'Pfizer Official, Others Summoned to Kano over Drug' *The Guardian* (12 January 2001).
[188] *Zango v. Pfizer Inc.* No. FHC/KCS/2001.
[189] The *Aliens Tort Claims Act* 28 USC 1350 empowers the District Court in the United States to decide on any civilian action brought by non-citizens of the United States on allegations of violation of the law of nations or a treaty of the United States and has been famously applied in the case of *Filartiga v Pen-Irala* 630 F.2d 876 (2d Cir. 1980). See a history of the Act in Marisa Anne

of nations due to its alleged non-conformity with international ethical standards for research.[190] The plaintiffs in this case sought to rely on internationally recognised guidelines for ethical clinical research, the Helsinki Declaration and the Nuremberg Code and the ICCPR. The suit was later dismissed by the District Court on the grounds of *non forum conveniens* finding that, despite acknowledged problems of corruption and bias, Nigerian law recognises medical malpractice, negligence and personal injury claims and Nigerian courts thus afforded an adequate forum for trying the matter.[191] The plaintiffs appealed. The suit was remanded to the District Court by the Court of Appeals in October, 2003.[192] This appeal was also dismissed in August, 2005 on similar grounds, with the court stating that Nigeria was the proper forum for action.[193] In that case, the judge noted that language used in the instruments relied on by the plaintiffs was merely 'aspirational' language which could not be characterized as creating well-defined and universally accepted legal obligations under international law to sustain an action under the *Aliens Tort Claims Act*.[194] However, in January 2009, the Court of Appeals for the Second Circuit, in a decision remarkable for its potential impact not only on US law but on international law and multinational companies' liability, held that the District Court had jurisdiction under the *Alien Torts Claims Act* for a violation of the norm of customary international law prohibiting medical experimentation on non-consenting

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Pagnattaro, "Enforcing International Labor Standards: The Potential of the Alien Torts Claims Act" (2004) 37 Vand.erbilt Journal of Transnational Law 203 at 211-214.

[190] *Abdullahi v. Pfizer, Inc.*, 2002 WL 31082956 (S.D.N.Y. 17 Sep 2002).

[191] *Ibid.*

[192] *Abdullahi v. Pfizer, Inc.* 77 Fed. Appx. C.A(2nd Cir.(N.Y.), 2003, WL 22317923 October 8, 2003.

[193] *Abdullahi, et al. v. Pfizer Inc.*, No. 01 Civ. 8118, SDNY; 2005.

[194] Ibid.

human participants.[195] In June 2010, the United States Supreme Court dismissed an appeal by Pfizer against the Court of Appeals ruling, effectively allowing the case to proceed further in the US court system.[196]

The Nigerian government, now under a democratic regime, opened an inquiry of the incident in 2001, five years after the trial took place. The findings of the panel of inquiry were not made public until the *Washington Post* obtained a leaked copy in May 2006.[197] The panel found, among other things, that Pfizer had not obtained the informed consent of the participants in the trial since they were not informed that they were engaged in a trial and that no ethics approval was obtained.[198] The panel also criticised NAFDAC, the Nigerian drug regulatory agency, and the Federal Ministry of Health, for failure to take action after the chairman of the task force for the epidemic made complaints to them about the trial.[199]

In June 2007, the Kano State government and federal government instituted civil[200] and criminal proceedings against Pfizer, respectively.[201] These

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[195] *Rabi Abdullahi v. Pfizer, Inc* Docket Nos. 05-4863-cv (L), 05-6768-cv (CON), 2009 WL 214649 (2d Cir January 20, 2009).

[196] BBC, "US Supreme Court Rejects Pfizer Nigeria Lawsuit Appeal"*BBC News*, June 29, 2010, online <http://www.bbc.co.uk/news/10454982> (July 27, 2010).

[197] J Stephens, "'Panel Faults Pfizer in '96 Clinical Trial In Nigeria Unapproved Drug Tested on Children" (2006) *Washington Post* Sunday, 7 May 2006; A01, available at: <http://www.washingtonpost.com/wp-dyn/content/article/2006/05/06/AR2006050601338_pf.html> (accessed 19 March 2007).

[198] The purported letter of approval was not given at the time of the incident and was backdated by at least a year. *Ibid.*

[199] Soniyi supra note 188.

[200] *Attorney General of Kano State v Pfizer Inc and Others* SUIT No: K/233/2007. N. Ugochukwu. "FG Makes N876.3bn Claims from Pfizer over Tests" *Businessday* Online (Lagos, Nigeria) 4 June: 1. Online:<http://www.businessdayonline.com/print.php?a=13687 March 4, 2010).

[201] See Joe Stephens, 'Pfizer Faces Criminal Charges in Nigeria' *Washington Post* Wednesday 30 May 2007 p.A10, available at <http://www.washingtonpost.com/wp-dyn/content/article/2007/05/29/AR2007052902107.html> (February 11 2008). Heidi Vogt, "Pfizer

legal actions were settled out of court in 2009, with no admission of liability by Pfizer. [202] The settlement amounted to 75 million dollars in total. Under the terms of the settlement with Kano State, Pfizer agreed to establish a Healthcare/Meningitis Fund from which study participants can receive financial support. Pfizer also agreed to finance several healthcare initiatives selected by the Kano State government that benefit the people of Kano State, amounting to US$30 million over a period of two years and reimburse Kano State for US$10 million in legal costs associated with the litigation. The Healthcare/Meningitis Fund would pay out a maximum of 35 million dollars to be divided amongst persons who could show that they participated in the Trovan clinical trial.[203] The settlements do not, however, resolve the claims brought by the trial participants in the United States since the government actions were not brought on behalf of these participants.

The Pfizer incident raised troubling questions about the motives of research sponsors, particularly pharmaceutical companies, in conducting research in developing countries like Nigeria, possible corruption in developing countries in the area of health research, and the vulnerability of participants in these countries to exploitation. It also raised questions about the existence, and adequacy of domestic legal, ethical, and policy requirements and governance structures for the conduct of

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Facing 4 Court Cases in Nigeria" Associated Press August 11, 2007 online: <http://www.washingtonpost.com/wp-dyn/content/article/2007/08/11/AR2007081100435.html> (March 2, 2010).

[202] Pfizer, "Pfizer, Kano State Reach Settlement of Trovan Case" (2009) online: <http://mediaroom.pfizer.com/portal/site/pfizer/index.jsp?ndmViewId=news_view&newsId=20090730005769&newsLang=en> (March 15, 2010). Joe Stephens, "Pfizer Reaches Settlement In Nigerian Drug-Trial Case" *Washington Post*, April 4, 2009, online: <http://www.washingtonpost.com/wp-dyn/content/article/2009/04/03/AR2009040301877.html> (March 15, 2010).

[203] Ibid.

research in Nigeria. The incident further called into question the government's role in ensuring the protection of research participants in Nigeria.

Further, as some research has suggested, the trial was partly responsible for a boycott of polio vaccine immunisation from 2003 to 2004 in the Northern part of Nigeria, where polio has been endemic.[204] This is particularly significant because Nigeria is one of only six countries in the world where polio has remained endemic.[205] The continued survival of the polio virus in Nigeria has been cited as potentially jeopardizing the global efforts to eradicate polio.[206] Political and religious leaders in the Northern states specifically alluded to the Pfizer incident in support of their stance against polio immunisation. In a statement in 2004, Dhatti Ahmed, the Secretary of the Supreme Council of Sharia (SCSN) said that:

> [t]he SCSN harbours strong reservations on the safety of our population, not least because of our recent experience in the Pfizer scandal, when our people were used as guinea pigs with the approval of the Federal Ministry of Health, and the relevant UN agencies.[207]

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[204] Maryam Yayha, "Polio Vaccines – "No Thank You" Barriers to Polio Eradication in Northern Nigeria (2007) 106: 423 African Affairs 185. See also, Ebenezer Obadare, "A Crisis of Trust: History, Politics, Religion and the Polio Controversy in Northern Nigeria" (2005) 39:3 Patterns of Prejudice 265.

[205] David L Heymann and Bruce Aylward, "Eradicating Polio" (2004) 351:13 New England Journal of Medicine 1275. There is evidence more recently that progress is being made to eradicate polio in Nigeria. See Stephanie Nebehay, "Nigeria Makes Gains in Polio Eradication" Reuters, March 6, 2010).

[206] See Lancet, "Vaccine-Derived Poliomyelitis in Nigeria" (2007) 370 Lancet 1394.

[207] Abiodun Raufu, "Polio Vaccine Plans May Run Into Problems in Nigeria" (2004) 327 British Medical Journal 380.

Thus, although there were other factors, the rejection of the polio vaccine in the Northern states of Nigeria has been attributed in part to the fears engendered by the Pfizer incident.[208]

In conclusion, Nigeria's history of health research and research governance includes instances of unethical conduct, some documented, and others only anecdotal. These instances, as the Pfizer incident shows, damage public trust in a context where health research is very much needed. These instances, particularly the Pfizer incident, also exposed the vacuum that existed in Nigeria's research governance arrangements prior to 2006.

5.5.3 Research Governance in Nigeria Since 2006

The recent move towards a domestic ethical framework and a new national regulatory structure, as discussed above, began around 2002. The impetus for this move came from both domestic and international events. As I discuss below, international interest in research governance in developing countries like Nigeria, the Pfizer incident, and growing domestic interest in health research and research ethics, appear to have been contributory to increased national attention to research governance in Nigeria.

In 2000, the Fogarty International Centre of the National Institutes of Health in the United States, through the International Bioethics Education and Career

[208] See Bolu Olusanya, "Polio-Vaccination Boycott in Nigeria" (2004) 363 Lancet 1912. A S Jegede, What Led to the Nigerian Boycott of the Polio Vaccination Campaign? PLoS Med (2007) 4(3): e73.

Development Award, began to train several researchers in research ethics and ethics review.[209] These researchers have been influential in the recent developments in the ethics review infrastructure in Nigeria. According to Adebamowo and others, by 2004, several Nigerians had graduated from the Fogarty-funded training programme in the United States, Canada, and South Africa, and set out to assist their institutions in setting up ethics committees where none previously existed, to strengthen existing ones and to provide local bioethics training. [210] In addition, the need to meet requirements of foreign sponsors, particularly government institutions in United States, was contributory.[211] Moreover, the Pfizer incident, as described above, exposed the vacuum that existed in Nigeria's governance arrangements for health research involving humans.

The international interest (particularly from the United States) and the Pfizer incident generated a desire among local researchers to engage the government in efforts to develop a national structure for research governance. According to Adebamowo, several researchers advocated at the national level to encourage the federal government to develop a national structure. The government subsequently established the National Health Research Ethics Committee in 2005.[212] Further, during a 2006 Presidential Retreat on the Health of Nigerians, the fact that Nigeria

[209] See Adnan A. Hyder et al, "A Case Study of Research Ethics Capacity Development in Africa" (2007) 82:7 Academic Medicine 675.
[210] Adebamowo, supra note 64 at 18.
[211] See for example, Falusi et al, supra note 127 noting the importance of gaining the FWA in the University of Ibadan. For instance, the United States National Institutes of Health, requires that any research institution in the world that receives US government funds for research must have a certification known as the Federal Wide Agreement (FWA) showing that the standards of current United States human subjects' regulation have been met.
[212] Eyitayo Lambo, Address of the Federal Minister of Health, Prof. Eyitambo Lambo at the Inaugural Ceremony of the National Health Research Ethics Committee, Held at Conference Hall of the Federal Ministry of Health, Abuja on 5th October 2006, online: < http://nhrec.net/nhrec/news2.html> (March 2, 2010). See also the National Health Research Ethics Code at 3.

needed domestic regulatory structures to meet its Millennium Development Goals targets was strongly emphasised.[213] In addition, a High-level Ministerial meeting was convened by the Nigerian Federal Ministry of Health and the Ghana Ministry of Health in March 2006, at which health research and the need for good systems of research participants' protection was discussed.[214]

The federal government through the Federal Ministry of Health then signed a technical cooperation agreement with the West African Bioethics Training Programme, a programme funded by the Fogarty International Centre. According to the agreement, the West African Bioethics Training Program was to provide training and support for members of the National Health Research Ethics Committee and several members of staff of the Federal Ministry of Health. The West African Bioethics Training Program was also required under the agreement to assist the Federal Ministry of Health in drafting a national code for health research ethics, develop standard operating procedures for ethics committees, and other relevant documents, with the aim of strengthening health research ethics in Nigeria. The West African Bioethics Training Program developed the National Code on Health Research Ethics, according to Adebamowo, taking into account the Nigerian Constitution, the federal structure of the country, relevant laws, the history of research and research ethics in Nigeria as well as the needs of local and international researchers.

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[213] Adebamowo, supra note 64 at 18.

[214] See Communique, supra note.107 and see the Preface to the National Code on Health Research Ethics.

Adebamowo and others note that: "Previous bioethics needs' assessment studies had indicated that the potential for bureaucratic delays, corruption and obstructionism were the most important concerns that biomedical researchers in Nigeria have about a national ethics committee."[215] The committee within West African Bioethics Training Program which drafted the National Code were therefore required to pay attention to these matters as it developed the National Code. The draft code developed by West African Bioethics Training Program was submitted to the National Health Research Ethics Committee in 2006 and it was adopted by the Federal Ministry of Health after consultations and amendments.[216]

Thus, in 2006, the government of Nigeria established the National Health Research Ethics Committee as well as a *National Code for Health Research Ethics* (the National Code) designed to provide oversight for research.[217] According to the Preface to the National Code written by the then Minister of Health, Professor Eyitayo Lambo,

> The National Code of Health Research Ethics represents the collective concern of the government and the people of Nigeria to ensure the protection of human participants in scientific research to the highest ethical standard that is possible.[218]

The National Code applies to "all health research involving human participants, conducted, supported or otherwise subject to regulation by any institution in

[215] Adebamowo, supra note 64 at 18.
[216] Federal Ministry of Health, National Code on Health Research Ethics: <http://www.nhrec.net/nhrec/> (January 14, 2010) at 3.
[217] Federal Ministry of Health, National Code on Health Research Ethics: <http://www.nhrec.net/nhrec/> (January 14, 2010).
[218] Ibid. See Preface.

Nigeria."[219] It therefore provides overarching governance for health research in Nigeria and is not limited to drug research like the NAFDAC Guidelines or the NAFDAC Clinical Trials Regulations. The National Code contains several substantive ethical and procedural requirements for the conduct of health research involving humans in Nigeria. I discuss some of these requirements in Chapter Six.

The National Health Research Ethics Committee operates at the national level. The National Health Research Ethics Committee has the responsibility for registering Health Research Ethics Committees, updating, revising, editing and modifying the Code, providing oversight of functions of the Health Research Ethics Committees, including registering and auditing them. It can also mete out penalties against persons found to be in violation of any norms and standards, or guidelines, set for the conduct of research under the National Code. It also has the responsibility of advising the federal and state ministries of health on any ethical issues concerning research. The Department of Planning, Research and Statistics in the Federal Ministry of Health serves as the secretariat of the National Health Research Ethics Committee.[220]

Health Research Ethics Committees, operating at the institutional level in the different states, conduct actual reviews of protocol and report to the National Health Research Ethics Committees.[221] These committees are now required to register with the National Health Research Ethics Committee. All institutions that

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[219] Section B.
[220] Federal Ministry of Health , "Department of Planning Research and Statistics" online: <http://www.fmh.gov.ng/Organisation-PRS.htm> (March 8, 2010).
[221] See Section C (a) of the National Code for Health Research Ethics. See also, NHREC, online: <http://www.nhrec.net/nhrec/about.html> (February 2, 2007).

seek to conduct health research must establish Health Research Ethics Committees. These committees must be registered with the National Health Research Ethics Committee. Clinical trials of drugs still have to pass through the requirements of NAFDAC, the drug regulatory agency. Medical and dental practitioners still have to abide by the Medical and Dental Council of Nigeria's Code of Medical Ethics. I discuss these matters in more detail in Chapter Six.

However, there is still no overarching legislation on health research involving humans. Hope, however, is close on the horizon. A National Health Bill, which will provide the statutory basis for the establishment of the NHREC, was passed by the National Assembly in May 2010. It now awaits the President's assent.[222]

The influence of the Pfizer incident on development of the Bill is not expressly documented anywhere but the provisions of the Bill suggest that the incident may have had some influence. In this regard, the Bill makes provisions for informed consent, including what constitutes informed consent in the case of a minor participating in research. However, the Bill is much narrower than the scope of legislation discussed in Chapter Four. Also, because of constitutional divisions in the federation, the application of the Bill may not necessarily be as wide in scope as may be assumed from its provisions. These matters are analysed in greater detail in Chapter Six.

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[222] Speaker's Office, "2008 to 2009" Acts, online: <http://www.speakersoffice.gov.ng/resources_acts_2009.pdf> (March 2, 2010). See also, Emmanuel Ogala, "Finally, Federal Lawmakers Pass a Bill" *Next*, March 14, 2010, online: <http://234next.com/csp/cms/sites/Next/News/Metro/Politics/5539991-147/finally_federal_lawmakers_pass_a_bill.csp> (March 14, 2010).

Adebamowo and others, point out the role democracy has played in encouraging the development of a national ethics review structure in Nigeria. They note that, "[t]he advent of civilian democracy in Nigeria in 1999 coincided with a period of increased international attention to the problems of unethical health research that occurred particularly in developing countries."[23] Apart from sponsoring research, as described above, several foreign bodies are involved in promoting research ethics capacity building in Nigeria. One of these is the Fogarty awards which, as described above, have had a direct impact on the development of research governance structures in Nigeria. Another is the European Developing Country Clinical Trials Partnership, which has funded several research ethics programs in Nigeria, including the Research Ethics Capacity Building Programme at the Nigerian Institute of Medical Research and the European Developing Country Clinical Trial Partnership Research Ethics Capacity Building Collaboration, which aims to train Nigerian researchers and members of ethics review committees in Nigeria.[223]

On the whole, there is now a formal, more comprehensive, national system of ethics review in Nigeria. There is also more clarity about research governance structures in Nigeria. Many of these developments can be attributed to the recent democratic regime in the country, increased international attention to health research and to regulation, and to instances of unethical research in Nigeria.

[223] "Research Ethics Capacity Building Programme, "About Us" online: < http://www.recbp.org/about_recbp.htm> (February 28, 2010).

5.6 Conclusions and Issues Arising

What salient points, apart from background information, can be gleaned from this brief discussion of the general context of Nigeria and the history of research governance in Nigeria? Have gaps, weaknesses and areas for potential improvement been revealed? How are these likely to impact research governance in Nigeria today? Below I point out some of these essential points and potential problem issues. I analyse them more fully in Chapter Six, and propose solutions in Chapter Seven.

First, while democracy has brought a few positive changes, including generally in health, the area of health research is one which has yet to receive all the attention it deserves. Yet, there continues to be significant need for health research in Nigeria. Major national policies recognise this need. On the other hand, there has been an increase in health research activities in Nigeria, particularly from external sponsors, under the recent democratic regime. In light of this increase and the recognition in national policies of the necessity for even more health research, it is crucial to make sure that there are sufficient arrangements to regulate current and potential health research involving humans in Nigeria. The instances of unethical research serve to call even more attention to this need. The federal government which, as described above, is responsible for policy formulation, strategic guidance, coordination, supervision, monitoring and evaluation at all levels in the country, has taken the lead in establishing a system of research governance in Nigeria.

Further, research governance efforts, particularly with respect to development of ethics review structures at the national and institutional levels, have

been long in the making, beginning in 1980. There have been many fits and starts along the way, with ethics review committees at all levels failing and being reestablished over the years. The issues of sustainability and political commitment are therefore matters that have great relevance in the Nigerian context. In developing current research governance arrangements in Nigeria, it is necessary to consider also the potential for these new arrangements to be sustained.

The development of research governance structures have somewhat but not strictly followed the pattern of the paradigm shifts described by Emmanuel and Grady, discussed in Chapter Two. Regulatory movements in research governance in Nigeria appeared to have moved from the self-regulation of doctors to a national ethics review to institutional ethics review and now to an increased government role. However, enabling research participants and ordinary citizens to be part of research governance is, as I describe in the next chapter, still a work in progress, as is the effective use of command-and-control techniques like formal legal regulation. As I argued in my analytical framework in Chapter Two, a strong government presence in addition to increased participant involvement in governance processes, amongst other steps, may yield more effective results in a developing country like Nigeria. Indeed, this is hardly debatable in the Nigerian context, where ethics review in institutions floundered partly as a result of insufficient support from the government. As I argue further in the next Chapter, there is still room for the Nigerian government to work more effectively in its role in research governance in Nigeria.

Also, as both anecdotal evidence and actual documented incidents of unethical research indicate, there is need for effective research governance in Nigeria

not only to protect research participants but to preserve the trust and confidence of the Nigerian population in health research activities and institutions. Such confidence is necessary also, perhaps more crucially, for the uptake and effectiveness of basic, beneficial health programs in a challenging health context (like immunization programmes). The incidents of unethical conduct of research described here also emphasise the existence of several socio-economic factors, such as illiteracy and poverty, which render potential research participants more vulnerable to exploitation and thus emphasise the need for effective governance of research.

Further, the Pfizer incident which was heavily publicized in domestic and international media might cause research sponsors to be wary about conducting relevant and essential research in Nigeria. Clear and effective governance arrangements which delineate the parameters for the ethical and responsible conduct of research in Nigeria (which were lacking during the Pfizer incident) can, however, counter such wariness.

Related to the above, the positive impact of democracy is another issue that must be borne in mind. During the years of military rule, there was very little progress on research governance. Although Nigeria's democracy has not necessarily brought all the dividends that the Nigerian citizenry would have hoped for, and remains very much a work-in-progress, it appears that democracy has been good for the needed growth in health research activities in Nigeria as well as for research

governance efforts.[224] During this current democratic era, more efforts have been made to develop and improve research ethics structures in Nigeria than had been made in previous years. There has also been greater support in this area from foreign agencies in developed countries, particularly the United States and the European Union. Democracy, it seems, has not only encouraged more political commitment from the Nigerian leadership but has encouraged foreign assistance in research governance initiatives. Research governance in Nigeria is likely to benefit from continued efforts to retain and build a more democratic government.

Related to this impact of democracy, it would appear that research governance efforts in Nigeria have been significantly impacted by initiatives developed in other countries – from the institutional ethics review committee to the ethical values underlying these arrangements – and from all indications are likely to continue to do so. [225] Much of what Nigeria might do in terms of research governance thus appears likely to be constrained by the current culture of research governance in the countries from which the research funding is coming. Although this means that not all the initiative for establishing governance structures in Nigeria has been indigenous or domestic, this may not necessarily be a negative thing, at least by comparison to the previously existing vacuum. In any case, it is only partly true, given that key research governance structures like ethics review committees had previously been in place, if not necessarily effectively utilized or sustained.

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[224] Adebamowo et al supra note 64. Even the research participants in the Pfizer incident benefited from steps taken by the government during the democratic era.

[225] For instance, the National Code, the primary document for research governance in Nigeria, was drafted with funding from the Fogarty International Centre of the NIH although it remains a document emanating from the Federal Ministry of Health.

Also, foreign support may provide some of the resources required for the working of research governance arrangements. However, it does raise the concerns that have been articulated elsewhere, such as potential bioethical colonialism.[226] It also raises potential serious conflict of interest issues, the possibility of adoption of arrangements that may possibly not be workable in the Nigerian context, and issues of sustainability. Foreign support of research governance also raises the issue of the degree of political commitment to the research governance process. Is the Nigerian government merely rubberstamping initiatives developed by donors and sponsors of research? To what degree are the new research governance arrangements geared towards domestic concerns? Is it reasonable or even possible to sustain the governance of health research in Nigeria mainly through foreign support? And given limited resources and other challenges requiring attention, how can resources be provided domestically for the maintenance of research governance arrangements? I address these issues in the next chapter.

Another salient point is that, with the creation of a national code and a national ethics review committee, there is now a national context for research governance. A more concrete and predictable system for governing research is emerging. This national system of governance will apply everywhere, irrespective of geographical location or even prevailing conditions of knowledge and resources. As the Pfizer incident showed, health research involving humans can take place anywhere and in any hospital, even in previously unusual instances. A national

[226] Ogundiran, supra note 130.

system makes room for the same principles to apply in all cases and thus affords the same protections to every potential participant in research in Nigeria.

There are several other bodies involved in research governance, including NAFDAC, the Medical and Dental Council of Nigeria, the National Health Research Ethics Committee. There are also different guidelines and regulations. Thus, while major steps towards a national, comprehensive structure have been taken, there is still a potential risk of duplication, overlap, and inefficient coordination. These are already challenges experienced in the health system as a whole, as discussed earlier. And this has been experienced in research governance in the past, with two national ethics review committee operating concurrently.

On the other hand, the history of research governance in Nigeria indicates that, apart from the federal government, other institutions and organisations have not been very active in research governance. As I have argued in previous chapters, a hybrid framework of governance requires that different mechanisms, institutions or organisations are involved in research governance for greater effectiveness.

A different point is that research governance arrangements in Nigeria appear to have focused on ethics review which is certainly a crucial and central piece in research governance. However, as I argued in Chapter Three and Chapter Four, there should be recognition that there other components to research governance, including a well-developed ethical framework, a comprehensive legal and

institutional framework. The next chapter delves deeper into this issue and argues that these frameworks need further development in the Nigerian context.

Finally, the discussion of the political and legal background, and the health profile of Nigeria, indicates the fact that these recent research governance arrangements will operate within a challenging milieu. For instance, how are critical issues in research governance, such as conflict of interest, to be dealt with where poverty is widespread, the health system is poor, pharmaceutical companies donate clinical trials centers, and major research governance endeavours are undertaken with foreign funding?

In sum, the history of research governance in Nigeria indicates that there are likely to be challenges in research governance in Nigeria, including systemic, operational, and contextual challenges. There are also likely to be challenges in the areas of the sustainability and political commitment to implement and enforce relevant law and policy. As I discuss in Chapter Five and Six, these challenges are not insurmountable.

5.7 Conclusion

In recent years, Nigeria has established (and re-established) research governance policies and arrangements. For developing countries intent on doing the same, Nigeria's experience might be a point of reference, if not wholesale adoption.

In this chapter, I have sought to describe the broader political and legal context in which this has taken place. I have also attempted to describe the health context of Nigeria, including diseases requiring research in the Nigerian context, Nigeria's health system, and Nigeria's policies on health and health research.

There is a significant need for health research in Nigeria. With this need comes the responsibility to ensure that not only is health research promoted, but that research participants, many of whom might be poor, illiterate and vulnerable in other ways, are protected. The Pfizer incident shows that this is a responsibility that must be taken seriously by all actors in research governance in Nigeria.

The best research governance arrangements in Nigeria would be, in my view, arrangements that take into consideration the context and challenges of Nigeria. This would include its federal structure, its history of ethnic strife, its limited resources, the problem of corruption, and the need for transparency. The next chapter focuses on a detailed analysis of current research governance arrangements in Nigeria and addresses the issues highlighted by the history of research governance in Nigeria.

Chapter Six

Research Governance in Nigeria: Analysis and Assessment of Current Governance Arrangements

6.1 Introduction

Research governance in Nigeria, as I explained in Chapter Four, formally began on a national level in 1980. It has, however, since 2006, entered a phase of renewed attention and commitment. The aim of this chapter is to analyse and evaluate the current arrangements for research governance in Nigeria. The analysis is based on a need for a comprehensive view of research governance, using a hybrid framework of governance, the groundwork of which has been laid in previous chapters.

To reiterate, this hybrid framework recognises the necessity of harnessing the synergies of different actors (such as policymaking bodies, drug regulatory authorities, institutional ethics review committees, non-governmental organisations), and policy mechanisms, such as ethical guidelines, but also a formal legal framework. This framework involves an explicit role for government, as well as a space in which private actors, including non-governmental organisations, could contribute to research governance. And, as I argued in Chapter Four, for research governance arrangements to be truly effective, there is need to recognise, and take advantage of, existing and potential interrelationships between the different frameworks and actors in research governance. The discussion of the Nigerian context in Chapter Five indicated that there exists the beginnings of an institutional framework. It also showed that an ethical framework exists with a new national code of research ethics established in 2006. The developments in Nigeria also show that the government plays a significant role in the

governance of research. The role of law as a significant mechanism to facilitate other mechanisms and to ensure accountability is beginning to gain acknowledgement, particularly with the development of the *National Health Bill.* A universal and comprehensive system involving different actors appears to be emerging. As I will show below, the lines of responsibilities and accountability are becoming more apparent, even though this is still a work in progress. Yet several questions remain: Are the existing arrangements adequate? If they are not, what is missing? This chapter attempts to answer these questions.

In this chapter, then, I undertake two main tasks. The first task is to describe and analyse in greater detail all the different components of research governance in the Nigerian context – the ethical framework, the legal framework, and the institutional framework. It is important to undertake this description because of the paucity of literature describing the current landscape of research governance in Nigeria. In my analysis, I identify within each framework, current and potential problems, gaps, and weaknesses. I draw from previous discussion in Chapter Three of the concerns that have arisen in other jurisdictions, especially within the institutional components of research governance, and also from Chapters Four and Five, dealing with the legal framework and the Nigerian context respectively. The weaknesses and gaps identified include systemic, operational and contextual issues.

In light of the discussion and analysis, I then undertake the second task which is to assess the current research governance arrangements and the potential they have of performing the required functions. I examine this through the criteria identified in

Chapter Two namely: effectiveness, legitimacy, clarity, comprehensiveness, efficiency, adequacy, uniformity, and simplicity.

This chapter is divided into six parts. The first is this introduction. The second is a two-pronged discussion of the ethical framework. It considers the general values of the country as an entry point and a basis for research governance. It then examines the specific ethical principles for health research involving humans in Nigeria. The third section discusses the legal framework of research governance in Nigeria, exploring the legal structure offered by common law concepts and legislation which have direct implications for research governance. The fourth section considers the institutions involved in research governance in Nigeria – the ethics review committees, the drug regulatory authority, policy structures, other institutions, and the potential role of non-governmental organisations. The fifth section examines the potential of current arrangements in Nigeria to meet the goals of research governance based on several criteria discussed in Chapter Two. The sixth section concludes the chapter.

6.2 The Ethical Framework of Research Governance in Nigeria

The ethical framework of research governance, as discussed in Chapter Three, provides the foundation and the value basis for research governance, and the true goals and objectives of research governance. The international ethical guidelines, such as the Helsinki Declaration, provide the basic international standard for the ethical conduct of health research involving humans. These international ethical guidelines may also influence conduct within countries or be formally adopted as national guidance. As will

become clear in the discussion that follows, even with the establishment of a new national code on research ethics, the Helsinki Declaration, in particular, retains a large influence in Nigeria.

Within a national context, however, there may be several other domestic sources from which ethical values may be drawn. In Nigeria, ethical values relevant for health research involving humans may be identified, generally speaking, from basic and fundamental sources such as the Constitution, which describe broadly how people ought to be treated in Nigeria. For instance, under the fundamental objectives and directive principles of the Constitution, it states that:

> ....(2) In furtherance of the social order- ...
>
> (b) the sanctity of the human person shall be recognized and human dignity shall be maintained and enhanced;
>
> (d) exploitation of human or natural resources in any form whatsoever for reasons, other than the good of the community, shall be prevented; ...[1]

The sanctity of the human person and human dignity are concepts which can be hard to define, and there are different controversial ways in which these terms may be used.[2] But in the Nigerian context, where different kinds of abuses of human rights have occurred in the past, these terms, though not justiciable, articulate important national values. They also have important implications, particularly with respect to how persons ought to be treated by the government and other persons. This clause also

[1] Chapter II section 17 (2)
[2] Abortion, cloning, embryonic stem cell research, and euthanasia are some examples.

articulates a value which has important implications for health research involving humans.

With respect to health research involving humans, Spears articulates an arguably straightforward explanation of the value of the sanctity of human life, stating that:

> The sanctity of the human person is derived from Immanuel Kant's philosophical restatement of the Golden Rule: Always treat other persons as ends and not as means only. This means that while we may at times use persons as a means, we always recognize their inherent dignity as human beings. While we may use patients in our clinical research studies, we do so only after informing them of the possible harms and benefits and after obtaining their informed consent.[3]

In other words, a person who is to participate in health research must be treated with respect, and not merely as an object or a means to an end. The Constitution thus restates a basic value – the fundamental worth of persons, including persons who participate in research in Nigeria.

In the same vein, exploitation of human beings is also not permitted in the Nigerian context. However, the addition of the clause "other than the good of the community" creates concern in the context of health research involving humans that the good of the community may override the good of the individual volunteering herself for participation in research. To make sense in the specific context of health research involving humans, therefore, the clause dealing with the prevention of exploitation of

[3] Karen Spear, "Response to 'On the Ethics of the Therapeutic Cloning'" (2003) 12 Journal of Hematotherapy and Stem Cell Research 135 at 135.

human resources has to be read in conjunction with the clause as to sanctity of the human person and human dignity.

In addition, the Constitution also includes the value of respect for human rights. Specific rights are therefore protected by the Constitution, reflecting the important value of persons, including participants in research, in the Nigerian context. Specific rights such as the right to privacy[4] and the right of every person to the dignity of his or her person,[5] further reflect the importance of the person. The core value articulated in the Constitution, the fundamental law of the land, is thus the fundamental importance of the human person, including persons who volunteer to participate in research. Research governance arrangements in Nigeria must therefore reflect, and protect, this essential value.

Ethical values in Nigeria can also be drawn from the Revised National Health Policy.[6] The Policy lists several "Underlying Principles and Values."[7] The most relevant values for research governance as provided in the Policy are: social justice, equity, accountability, effective partnership with actors in health, and gender

[4] Section 37 of the Constitution.

[5] Section 34. The term "dignity" is a controversial concept. Some argue that it is too loose a concept to mean anything. According to Macklin, it is no more than respect for persons and their autonomy. See Ruth Macklin, "Dignity is a Useless Concept" (2003) 327 British Medical Journal 1419. To others, however, "dignity " has a specific meaning. Thus according to Jordan, "'Human dignity' refers to a collection of intangible, distinctively human goods. To affirm that there is such a thing is to affirm that genuine human flourishing requires at least the following: moral virtue, appreciation of beauty, awareness of oneself as a unique individual, participation in human community, receptivity, and personal agency." See Matthew Jordan, "Bioethics and 'Human Dignity" (2010) 35 Journal of Medicine and Philosophy 180 at 184. See also, S. Killmister, "Dignity: Not Such A Useless Concept" (2010) 36 Journal of Medical Ethics 160. See, Thomas De Koninck, "Protecting Human Dignity in Research Involving Humans" (2009) 7 Journal of Academic Ethics 17.

[6] See Federal Ministry of Health, *Revised National Health Policy* (Abuja: Federal Ministry of Health, 2004).

[7] See Section 3.2 of the Revised National Policy.

sensitivity.[8] These values ought therefore to guide the development of the research governance system. For instance, the system must be designed to be accountable to the Nigerian people and should therefore include clear reporting lines. Gender sensitivity would be crucial in areas such as inclusion of women as participants in research, and in the membership of national and regional or institutional review committees. Effective partnership would require ensuring good interrelationships between different levels of government in research governance, and effective linkages with other stakeholders in research governance. Interestingly, these values also reflect some of the strengths of the new governance approach, in particular, effective partnership with other actors, indicating the need for recognition of the different actors and instruments in research governance. They also reflect some of the criteria developed in Chapter Two, in particular, effectiveness and legitimacy. Below, I assess the emerging research governance system in Nigeria using these criteria.

In addition to the general values of the Nigerian state as provided under the Constitution and documents such as the National Health Policy, the ethical framework of Nigeria can be deciphered more specifically from the provisions of the National Code for Health Research Ethics ("the National Code).[9] As I noted in Chapter Three, national guidelines and policies, such as the National Code, which take into consideration the contexts and the values of different countries may be one way of resolving the existing ethical dilemmas of conducting research in developing countries. As soft law, favoured under the new governance approach and adopted in my hybrid framework, it offers

[8] Ibid.
[9] Federal Ministry of Health, *The National Code for Health Research Ethics* (Abuja, Federal Ministry of Health, 2007).

greater potential for flexibility, responsiveness and participation. The establishment of the National Code in Nigeria is therefore a significant achievement, of great importance, and potential benefit.

As well as the National Code, other instruments contain ethical guidance. These include the Code of Medical Ethics made by the Medical and Dental Council of Nigeria, which regulates medical and dental practitioners in Nigeria, and the regulations and guidelines made by the National Administration for Food and Drug Control (NAFDAC). I discuss and analyse the provisions of these instruments below.

6.2.1 The National Code for Health Research Ethics

The National Code defines health research as being a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalisable knowledge. Such investigation may consist of therapeutic procedures, including interventions administered with the intent of providing direct benefit to the research participant. It may also consist of non-therapeutic procedures, and interventions only intended to answer scientific questions.[10] There are, however, some types of research exempted from the requirements of the National Code, including ethics review. These include research on the effectiveness of or comparison between teaching methods, curricula or classroom management methods, research involving the evaluation of outcomes of procedures, programs and services

[10] Section A.

designed to produce information leading to improvement in delivery, and so on.[11] The definition of research in the National Code is therefore broad, encompassing clinical trials but also other types of health research.

The National Code applies to all health research conducted in Nigeria. It states that: "Health research that is conducted anywhere in Nigeria must comply with all sections of this code."[12] Thus, the National Code has broad coverage, both geographically, and with regard to the types of health research covered. Its provisions, including the ethical principles contained therein, thus apply to all kinds of health research in Nigeria.

The National Code, taking a different approach from the Belmont Report, distils the ethical principles that provide guidance for ethics review committees in reviewing research into ten principles.[13] While many of the principles might be considered to fit into the Belmont framework of respect for persons, beneficience, and justice, a broader set of principles allows for the capturing of many moral considerations. These include considerations that might have specific implications in a developing country context like Nigeria, particularly in the area of community engagement, and with respect to issues with implications for vulnerability in resource-challenged settings.

[11] Section B.
[12] Section A.
[13] Under the section titled: "Ethical Principles and Guidelines for HREC's Approval of Research," it states: "In order to approve research covered by this code the HREC, shall determine a balance between the various principles guiding the ethical conduct of research, some of which are outlined below. Since some of these will inevitably conflict, judgement and consensus are essential in determining whether a research should be conducted." Researchers, research sponsors, and research institutions are thus not expressly required to ensure the application of these principles in health research. Instead, it is implied that these principles should guide the conduct of research by researchers by the fact that all research must pass through ethics review as required under the Code, but this should have been made explicit.

The first principle is that research must have social or scientific value to either participants, the population they represent, the local community, the host country *or* the world, in order to justify the use of finite resources and risk of harm to participants.[14] While this is generally good, it would have been more helpful to specify that research undertaken in Nigeria should be relevant to local needs (*and* the world). Simply stating that research must have value for the host country *or* the world leaves room for the possibility of research which may have value for the rest of the world but perhaps not for Nigeria. An example is research on developing expensive medication that may not be affordable in Nigeria after the research. One could contrast this with a similar principle in South Africa's guidelines which provides that researchers in South Africa have an ethical responsibility to ensure that their research is relevant both to the broad health and development needs of the country and to individual needs. The South African guidelines specifically require that research findings must be translatable into mechanisms for improving the health status of South Africans.[15]

The second principle is the requirement for scientific validity.[16] Thus, it must have clear scientific objectives, use valid methodology, have equipoise in the case of

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[14] Section F (a). (Emphasis mine).

[15] Section 2.2 of the National Health Research Ethics Council, *Ethics in Health Research: Principles, Structures and Processes Guidelines*. (Pretoria: Department of Health, 2004). The Kenyan Guidelines contain similar provisions, requiring that "Externally sponsored research designed to develop a therapeutic, diagnostic or preventive product must be responsive to the health needs of Kenya. That means the research to be conducted must address health problems that are important in Kenya." National Council for Science and Technology (NSCT), *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya*, NCST no. 40 (Nairobi, NCST, 2004) 3(hereafter, "Kenyan Guidelines"). The National Code does, however, require that in international collaborative studies, research should be accompanied by "comprehensive capacity building, technology transfer and health care delivery strategies that address significant local health problems and add value to local participants of research, including researchers, institutions, communities and the country." Section F(a).

[16] Section F (b).

clinical trials, have adequate operationalising plans within the context of the environment in which the study is to take place, have a plausible data analysis plan, including a specific role for Data and Safety Monitoring Boards in clinical trials, and it must use correct measurement for outcomes. In the absence of these requirements, a research project is deemed unethical.

The third principle is that there must be fair selection of participants based on the scientific objective(s) of the research while minimizing any attendant risk.[17] However, it goes on to state that this should not be construed to allow the exclusion of groups such as women, children, groups of people disadvantaged in any way, and other vulnerable people especially from research that would benefit them without explicit reasons for doing so, but specific safeguards are required to protect the vulnerable. This is a very useful principle, especially in a context that remains to a large extent paternalistic. Further elaboration of this principle beyond the brief, general discussion contained in the National Code would have been helpful.[18] For instance, while it can be argued that under the National Code, pregnancy is not, by itself, a ground for exclusion from health research (as, for instance, in the Kenyan Guidelines),[19] the principle could have been couched in more specific terms, with respect to pregnancy and reproductive capacity. Might these be considered sufficient reason for exclusion and why? What other grounds could constitute good reasons (or insufficient reasons) for excluding

[17] Section F(c).
[18] See, for instance, a discussion if this principle in the Australian context: Angela J Ballantyne, Wendy A Rogers on behalf of the Australian Gender Equity in Health Research Group, "Fair Inclusion of Men and Women in Australian Clinical Research: Views from Ethics Committee Chairs" (2008) 188: 11 Medical Journal of Australia 653.
[19] See for instance, the Kenyan Guidelines, section 14 which deals with research involving pregnant women.

persons from participating in research? It would have been helpful if examples of reasonable grounds for any exclusion were provided in the National Code.

The fourth principle[20] requires that there must be valid attempts to minimize risks and maximize health related benefits for participants to ensure a favourable risk and benefit ratio. These benefits are distinguished from risks and benefits of therapies that participants would be exposed to even if they were not participating in research or incidental risks or benefits. In the weighing of risks, the principle requires that risks and benefits should be considered at the level of both individual participants and community. It does not delineate specifically how such risk should be weighted. (For instance, if the risk to the community is minimal but the risk to the individual is higher, what happens?).

The fifth principle requires that for research to be ethical it must undergo independent review. It states that independent review, through a system of ethical review and oversight of such systems provides assurance that reasonable attempts have been made to minimise the potential impact of the conflicting interests of the different parties involved in health research including participants, researchers and sponsors of research, and ensures balanced judgement.

The sixth principle is informed consent. It states that informed consent is a prerequisite for the ethical conduct of research. It delineates the process for obtaining informed consent in Nigeria. Consent forms are to be no longer than 8 pages and should not contain unnecessary jargon and legalisms. Importantly, it also requires that

[20] Section K (d).

all consent activities be documented and where written consent is not possible, witnessed thumb-printing or witnessed audio-recording may be acceptable if approved by the ethics review committee.[21] It permits verbal consent and states that information about the research is to be provided at an educational level no higher than for individuals with 9 years of education in Nigeria. This is essential in the Nigerian context because of the considerable degree of illiteracy in certain parts of the country.[22] Translation of documents may be required in other situations. Consent in instances such as research involving persons with diminished autonomy, children, and other extraordinary instances are to be provided in other guidance documents issued by the National Health Research Ethics Committee. These documents have yet to be produced but are clearly essential, especially in light of the Pfizer incident.

The National Code emphasises procedural requirements and the informed consent form. However, the focus on crucial substantive issues is, in my view, much less than desirable. For instance, it provides the size of the paper documenting informed consent (A4), the font, the font size, spacing and margins.[23] Substantively speaking, it does require that "adequate information"[24] be provided to research participants but does not specifically state what constitutes adequate information. This is a matter that would have benefited from a clearer discussion in a country like Nigeria, with its diverse

[21] Section F (f) (9)
[22] See UNESCO, *Education For All (EFA) Global Monitoring Report 2010: Reaching the Marginalised* (Oxford: Oxford University Press, 2010). Ben Chuks Okeke, "Literacy/Numeracy and Vocational Training among Rural Women in Nigeria for a Good Livelihood and Empowerment" (2004) 23:3 International Journal of Lifelong Education 287.
[23] Section K (f) (2) and 9.
[24] Section K (f) (1).

circumstances.[25] For instance, it has been noted that in some parts of Nigeria, a strict disclosure of all possible risks as required in many developed countries may unnecessarily frighten potential participants and may cause huge difficulties in enrolling research participants.[26] This cannot be generalized, however, as many educated Nigerians would prefer to have as much information as possible. Although it requires a statement of all the risks and benefits in the discussion of another principle, clearly stating that in the section dealing with *informed consent*, would have been very helpful. Fadare and Porteri note that it would also have been appropriate to discuss the dependent relationship between researchers (who are often physicians acting in the dual role of doctor and researcher) and research participants. They contend that, in a paternalistic context where doctors are still often regarded as having all the knowledge, it would have been appropriate for the National Code to emphasise or itemise the rights of research participants even within such relationships.[27] In such a relationship, it may be best for informed consent process to be conducted by a physician not directly in charge of the potential participant's care and treatment.[28]

Related to the above point, although parts of informed consent issues are dealt with in the discussion of other principles (including respect for persons, maintaining of

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[25] Elsewhere, the Code requires the consent processes to include explicit information about the researchers, their affliation, qualification and contact details that will allow research participants or ethics review committees to contact them. But this cannot be all the information required in the informed consent process. See Section S (1) (i).

[26] Ezeome and Marshall, supra note 222 at 3. Are there circumstances in which it could be ethically appropriate to withhold any information and what effect would this have on the validity of any consent obtained for participation in the research project? This question would have been answered by a clearer definition of informed consent than is currently contained in the National Code.

[27] Joseph O Fadare and Corinna Porteri, "Informed Consent in Human Subject Research: A Comparison of the International and Nigerian Guidelines" (2010) Journal of Empirical Research on Human Research Ethics 67 at 71.

[28] This is required by the Helsinki Declaration and the Code of Medical Ethics, 2004, s.31.

trust relationships), there is no clear definition of informed consent. Nor is there any discussion of related concepts such as voluntariness, coercion, incentives, and undue inducement. There is, instead, a requirement for some of these matters to be contained in the informed consent document. Presumably, it is assumed that everything contained in the informed consent document would be discussed by the ethics review committee. The committee may, however, focus exclusively and erroneously on the document rather than the process. Moreover, these issues are vital in health research involving humans, and have particular relevance in a developing country context like Nigeria, as discussed in Chapter One. They deserve to be articulated in fuller and clearer terms in the Code, especially in light of the circumstances of the Pfizer incident.[29] It appears to me that there is room for elaborating further on informed consent in the Code.

The seventh ethical principle under the Code is that there must be respect for potential and enrolled research participants from the commencement to the end of the research project. According to the Code, this requires that their right to privacy may not be compromised, their involvement is voluntary, and that they can withdraw at any time. However, it makes an exception to the ability to withdraw at any time, stating: "However, data, samples, etc. already contributed to the research up to that point may not *needlessly* be withdrawn as this may jeopardise the scientific validity of the research, unjust to those who remain in the study and all or part of their sample or data may have been used or modified into different form(s), including presentation at

[29] The Kenyan Guidelines, for instance, state that undue inducement is not to be permitted. It will be recalled that one of the issues that arose in the Pfizer incident discussed in Chapter Four was that the parents alleged that they had inadequate understanding of information because they assumed that the children would receive treatment.

meetings or publications by the researchers."[30] This provision has particular significance in light of other research that has occurred in Nigeria, including the HapMap project mentioned in Chapter Five. The use of the word "needlessly" is troubling, if not inappropriate. Who determines what is "needless" – the ethics review committee, the researcher, or the participant who submitted the sample or data and the community?

The current statement in the seventh ethical principle thus needs revision as it is tantamount to unduly limiting the rights of research participants and communities. What is required is clear guidance on when it would be possible or not permissible to withdraw data.[31] A revision is necessary, especially given that the National Code states elsewhere that a Materials Transfer Agreement required for samples and biological materials does "not vitiate the right of research participants or communities to request that their samples be withdrawn from research according to the terms of the informed consent process."[32] For instance, it would be better to state that data can be withdrawn at any time except, when the data has been modified or is impossible to extricate from other data (such as when it has been anonymised).

In like manner, the requirement for privacy is treated rather cursorily with the National Code stating that: "Their right to privacy may not be needlessly compromised."[33] While it requires the informed consent document to contain a section

[30] Section F(g).
[31] For a discussion of this issue, see generally, OECD, *Creation and Governance of Human Genetic Research Database* (Organisation for Economic Cooperation and Development, 2006) at 95.
[32] Section N.
[33] Section F (g).

on confidentiality[34], the National Code does not address what might comprise "needless" interference with privacy, or needful limitation of privacy. Nor does it address possible mechanisms for maintaining privacy.

Respect for participants also requires that participants be informed of the progress of the research and any finding that may have a potential effect on their health and wellbeing and their continued participation in the research. This would ostensibly include any adverse events. Thus, in a situation such as arose in the Olivieri incident in Canada, described in Chapter Three, a researcher would be under an ethical duty to inform research participants of any adverse events.

The respect principle also includes engagement with the community where the research is to take place. According to the National Code, community consultations or assent may have to precede research activities so as to ensure community acceptance and to respect the socio-cultural values of the community and its institutions. The community "may" also be informed of the progress of the research, relevant findings that may influence their health and well-being, and the outcome of the research. The use of the word "may" indicates that this is not mandatory. One would have thought that it would be mandatory to inform communities of relevant findings that may influence their health and well-being. Further, there is, although implied, no explicit emphasis on the continued importance of individual consent. The Kenyan Guidelines, for instance, note that due to cultural reasons married women in some rural areas may not be allowed to give their consent to participation without the express permission of

[34] Section K (f) (5 (x).

their husbands. However, the Kenyan guidelines also emphasise that in such instances, the woman must still give her consent.[35] Such emphasis is also present in the Canadian guidelines with respect to Aboriginal participants in research.[36] The Nigerian context is pluralistic, making more direct guidance useful. In a study on informed consent practices in Nigeria, it was observed that: "Nigeria, like most nations in Africa, is too pluralistic in its culture and social norms for any of the factors to uniformly apply, and most significant generalizable factors are shaping informed consent practices in Nigeria along a Western model."[37] Another study on informed consent to genetic epidemiological research on hypertension and breast cancer in Nigeria noted that women in rural areas in Nigeria were more likely to state that they needed spousal permission to participate in research than women in urban areas.[38] In Nigeria, where communities, particularly in rural areas, play crucial roles in the lives of their members and women in some areas may require permission from their husbands, or where parents seek endorsement of adult children on important matters, an emphasis on the continued necessity of the individual's informed consent would have been appropriate. This would be in line with the fundamental value of each person in Nigeria, a value articulated in the Constitution.

The eighth principle in the National Code states that for research to be ethical the trust relationship between researchers and research participants must in no way be

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[35] Kenyan guidelines, section 6.
[36] *CIHR Guidelines for Health Research Involving Aboriginal People* (Ottawa: CIHR, 2008), Article 4.
[37] Emmanuel R. Ezeome and Patricia A. Marshall, "Informed Consent Practices in Nigeria," (2009) 9:13 Developing World Bioethics 138 at 140.
[38] Patricia A Marshall, "The Individual and the Community in International Genetic Research" (2004) 15: 1The Journal of Clinical Ethics 76. See Anant Bhan, Mina Majd, Adebayo Adejumo, "Informed Consent in International Research: Perspectives from India, Iran and Nigeria" (2006) 3 Medical Ethics 36.

undermined. This also requires transparency between researchers, participants and communities, including an explanation of goals, risks, benefits.[39] Like the principle of respect for persons, the trust principle also encourages the engagement of individual participants and communities, respect for local socio-cultural values, and the provision of relevant and timely feedback to communities.

The ninth principle[40] states that for research to be ethical, the interest of participants, researchers, sponsors, and communities must be protected. This principle requires the transfer of technology where appropriate, capacity building and respect for socio-cultural and other differences. It also requires that intellectual property, indigenous knowledge and contributions of all parties must be taken into consideration, adequately protected, and compensated particularly where research leads to tangible or intangible benefits. Satisfactory parameter(s) that shall determine sharing of commercial and other benefits should be clearly articulated. Where appropriate, benefit sharing agreements, materials transfer agreements, patent rights, intellectual property and royalty distribution agreements should be signed before the commencement of the research project. In light of the controversy that has arisen with respect to the distribution of benefits in developing countries, this is an important principle. Unfortunately, it does not state what happens where the interests of participants and

[39] It also includes explanations of and "alternatives to participation and voluntariness." The phrasing here is confusing.
[40] Section K (i).

others conflict. It would have been appropriate to state explicitly that the interests of participants are paramount, in the event of a conflict.[41]

The tenth principle[42] requires that for research to be ethical, it must be conducted according to the principles of good clinical and laboratory practices. Any clinical trial conducted in Nigeria has to be conducted according to the principles articulated in the National Code, relevant laws, the provisions of guidelines or regulations set periodically by the Federal Ministry of Health, the provisions of the current *Harmonized Tripartite Guideline for Good Clinical Practice* (ICH-GCP E6) and the provisions of the current ISO 14155-1, 14155-2 (2003): *Clinical Investigation of Medical Devices for Human Subjects.*

In addition to the ethical framework, the Code also provides for the specific responsibilities of the ethics review committees, sponsors, host institutions, and researchers.[43] The National Code also includes procedures for institutional ethics review committees to register with the National Health Research Ethics Committee.[44] I discuss these below.

The ethical framework provided in an instrument such as the National Code should provide an ethical foundation for the operation of the research governance system. This would include providing coherent guidance for ethics review committees reviewing research. It should also provide specific protections for research participants.

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[41] Ibid. In one of several confusing provisions, it also states: "Risks, benefits, and responsibilities of research must be shared during the development, planning, conduct, dissemination of *results*." It is not clear what is meant by this clause.
[42] Section K (f).
[43] Section S.
[44] Section C.

The National Code attempts to meet these expectations. It articulates guidance for ethics review committees in Nigeria. It provides a ready reference source for researchers conducting research in Nigeria, thus covering the gap that previously existed. It applies to all health research conducted anywhere in Nigeria, thus providing broad protections for all research participants in Nigeria.[45]

Health research anywhere in Nigeria, according to the National Code "*must* comply with all sections of this code."[46] It also uses mandatory words in describing several of the responsibilities of sponsors, researchers, and ethics review committees, thus making it clear that these cannot be waived. The use of strong language is commendable, as is the reach of the National Code, that is, health research conducted anywhere in Nigeria. The National Code thus creates ethical standards but also creates obligations. In so doing, it elevates protections for research participants, while creating parameters for other parties involved in health research in Nigeria.

Moreover, the National Code addresses several issues that have much significance in the developing world, especially matters relating to distributive justice. Thus the ethical framework provided by the National Code includes the principle of a trust relationship, which invokes the concept of fiduciary relationship between researchers and research participants, but also between researchers, research sponsors and communities. Issues such as conflicts of interest, which evoke divided loyalties, would be antithetical to such a relationship. Further, in many of the principles, the need to bring communities into the research process, a matter that is of great significance in a

[45] Section A.
[46] Section A (emphasis is mine).

developing context like Nigeria, is emphasised. As well, the need to ensure that research benefits communities in which a project takes place is highlighted.[47]

However, in my opinion, there are important areas in the National Code that would benefit from fuller discussion, especially in view of the Nigerian context. These include the areas of informed consent and privacy. Particularly with regard to informed consent, the National Code leans towards procedural matters rather than substantive issues. For example, it lists what needs to be contained in the informed consent document but does not even define the concept. Nor does the National Code engage in a comprehensive discussion of issues arising in informed consent and how they should be addressed by researchers and ethics review committees in the Nigerian context. There are similar issues with the concept of privacy as dealt with in the National Code.

As stated above, use of words, such as "Code"[48] and "must" throughout the National Code, indicate that the responsibilities of researchers, sponsors and ethics review committees are mandatory. However, what may have been sacrificed in the pursuit of such directness is the provision of guidance in areas that have proved controversial in research ethics in developing country contexts like Nigeria. Thus, issues that have caused controversy in research in developing country settings, such as the use of placebos, standard of care, undue inducements, and paying research

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Section S(6) (iv) further provides that: "The investigator must provide assurances that reasonable efforts shall be made to ensure that the benefits of research is made available to the community where the research was conducted. Details of any arrangement to ensure this shall be worked out by the researchers, sponsors, HREC, community leaders and Community Advisory Committees."

[48] The word "Code" in some legal traditions indicates that a document is legally binding. See Bernard Dickens, "Codes of Conduct and Ethics Guidelines" in Lester Breslow (ed.), *Encyclopedia of Public Health* (New York: Macmillan Reference, 2002) at 226. As I explain further, the National Code is not yet legally binding but will be if the National Health Bill is signed into law.

participants, do not, unfortunately, receive specific or significant attention in the Code.[49] These matters are very relevant in the Nigerian context. For instance, with regard to undue inducements and paying research participants, Marshall, in a study commissioned by the United States National Bioethics Advisory Commission, records the apparent limitations in choices that prospective research participants face as a result of poverty and lack of education. She reports a Nigerian physician as stating that:

> Because of the scarcity of everything [in Nigeria], to be talking about a choice [is questionable]...in the United States, you can ask questions, you can ask for a second opinion, but that doesn't happen here. We are challenged by [our] culture, by poverty, by lack of literacy, by education of what basic rights a person has... [the] power [of these factors] is too awesome."[50]

Thus, the Nigerian context demands specific guidance as to what might constitute undue inducement. As Dickens and Cook suggest, payments to research participants may not necessarily be considered "undue inducement" in every instance, and in some circumstances payment may be ethically acceptable.[51] But specific guidance would have been helpful.

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[49] This contrasts with the provisions in other developing countries' guidelines like South African and Kenyan research ethics guidelines. See for example, section 2.14 of the South African Guidelines.

[50] Patricia Marshall, "The Relevance of Culture for Informed Consent in U.S.-Funded International Health
Research" in National Bioethics Advisory Commission *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries Volume1- Report and Recommendations of the National Bioethics Advisory Commission* (Bethesda, Maryland: National Bioethics Advisory Commission, 2001) 212 at C-26 to C-27.

[51] B M Dickens and R J Cook, "Challenges of Ethical Research in Resource-Poor Settings" (2003) 80 International Journal of Gynecology and Obstetrics 79 at 80.

In the case of the use of placebos and standard of care, old articles show that placebos have been used in trials in Nigeria when there was effective treatment.[52] The National Code provides that an investigator "must ensure that the investigational product and any comparator products are of appropriate quality and are subject to quality assurance procedures. This information must be accurate and adequate to justify the nature, scale, and duration of the clinical trial."[53] This does not, however, address whether the use of placebos is appropriate or in what circumstances. It could, of course, be argued that the use of placebos with respect to drug trials is addressed in the Code because the National Code requires compliance with the ICH-GCP, which allows the use of placebos under certain circumstances.[54] As some commentators[55] have pointed out, however, the ICP-GCP's stance on placebo use in drug trials is permissive by comparison to other international guidelines such as the Helsinki Declaration (which

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[52] See for instance, L. A. Salako, A. O.Falase, and A. Fadeke Aderounmu, "Placebo-Controlled, Double-blind Clinical Trial of Alprenolol in African Hypertensive Patients" (1979) 6 Current Medical Research Opinion 356.

[53] Indian Council of Medical Research, *Ethical Guidelines for Biomedical Research on Human Subjects* (New Delhi: ICMR, 2000) at 21..

[54] See International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonised Tripartite Guideline: Choice of Control Group and Related Issues in Clinical Trials E-10 (Geneva: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2000), online: <http://www.ich.org/LOB/media/MEDIA486.pdf> (April 1, 2010).

[55] See for instance, Ruth Macklin, "The Declaration of Helsinki: Another Revision" (2009) 6:1 Indian Journal of Medical Ethics 2; Heather Sampson, Charles Weijer and Daryl Pullman, "Research Governance Lessons from the National Placebo Initiative"(2009) 17:3 Health Law Review See Patricia Huston & Robert Peterson, "Withholding Proven Treatment in Clinical Research" (2001) 345 New Eng. J. Med. 912. See "FDA Abandons Declaration of Helsinki for International Clinical Trials" (2008), online: < http://www.socialmedicine.org/2008/06/01/ethics/fda-abandons-declaration-of-helsinki-for-international-clinical-trials/> (May 5, 2010). Adriana Petryna, *When Experiments Travel: Clinical Trials and the Global Search for Human Subjects* (Princeton, NJ:Princeton University Press; 2009). The ICH-GCP, itself, notes that: "Whether a particular placebo controlled trial of a new agent will be acceptable to subjects and investigators when there is known effective therapy is a matter of investigator, patient, and institutional review board (IRB)/independent ethics committee (IEC) judgment, and acceptability *may differ among ICH regions*." (My emphasis). See *The ICH E-10 Guideline: Choice of Control Group and Related Issues in Clinical Trials.*

has been revised severally on this point).[56] This suggests that this is an area which needs to be debated domestically and addressed in greater detail in domestic guidelines. Also, as I discuss below, the Medical and Dental Council's Code of Medical Ethics adopts a different standard. It would have been appropriate, therefore, to specifically address the use of placebos and standard of care in the National Code.

There are other matters, such as informed consent in studies involving children[57] and the mentally ill, which have been left out deliberately, and which the National Code states are to be tackled in other guidance.[58] These are important matters, especially in light of the Pfizer incident, which involved children. It is not clear why these matters were not dealt with in the National Code, which deals with many other issues, and there appears to be no good reasons for not providing protections for children, the mentally ill, and other vulnerable persons within the National Code. This is especially significant because the National Code states that it supersedes other guidance and sub-codes, and is therefore the principal instrument for health research and other

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[56] *The ICH E-10 Guideline: Choice of Control Group and Related Issues in Clinical Trials* indicates that placebo use is permitted, except when there "is proven effective treatment [that] is life-saving or known to prevent irreversible morbidity." Thus the effective treatment need not be the "best" treatment, and apart from fatal diseases or extensive harm, no other exceptions appear to be made. Elsewhere it states that: ""Even when the primary purpose of a trial is a comparison of two active agents or assessment of dose-response, the addition of a placebo provides an internal standard that enhances the inferences that can be drawn from the other comparisons." On the other hand, Article 32 of the current version of the Helsinki Declaration states that: "The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the *best current proven intervention*, except in the following circumstances: The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option." The Helsinki Declaration is clearly stricter than the ICH –GCP.

[57] Other trials have included children in the past. See for instance, H. B. Jibril, A. S. Ifere, D. U. Odumah, "An Open, Comparative Evaluation of Amoxycillin and Amoxycillin plus Clavulanic Acid ('Augmentin') in the Treatment of Bacterial Pneumonia in Children" (1989) 11: 9 Current Medical Research and Opinion 585.

[58] Section (f)13.

issues.[59] Consequently, any gap in respect of these and other issues in the National Code is problematic, and potentially exposes participants to harm and researchers and research sponsors to confusion. Further, as I argued in Chapter Three, domestic ethical codes and guidance, such as the National Code, can have more positive impact than the international ethical guidelines, if they go beyond such guidelines and address any problematic or controversial issues more clearly. They would thus create room for easier implementation in domestic contexts, and offer greater protections to research participants. The National Code has done this only partially.

Related to the above, the National Code does not expressly address the place of other guidelines, such as the Helsinki Declaration and the CIOMS Guidelines (with the exception of the ICH-GCP in respect of drug trials) in research governance in Nigeria. It does state, however, that all health research in Nigeria must comply with the National Code.[60] Thus, it would appear that the National Code would, at the very least, be the first reference point for health research involving humans in Nigeria. And, at the most, the National Code rules out the application of other guidelines. As will become clear shortly, this is problematic mainly because other instruments in Nigeria that provide guidance for health research involving humans essentially require compliance with the Helsinki Declaration. These include the Clinical Trial Guidelines[61] which currently provide guidelines for drug trials in Nigeria, and the Code of Medical Ethics, which regulates medical and dental practitioners in Nigeria. This creates potential room for debate and confusion.

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[59] See p. 68 of the National Code.
[60] Section A.
[61] Section 3 (b) of the NAFDAC Regulations.

According to the provisions of the National Code, the National Health Research Ethics Committee is required to update, revise, edit, and modify the National Code in accordance with international research ethics and local laws, and at its discretion.[62] The National Health Research Ethics Committee may also provide additional guidelines in sub-codes, although the National Code takes precedence when there is a conflict between it and a sub-code. It is hoped that gaps in the discussion of the ethical principles will be addressed either in a revision of the National Code in the near future or in the development of additional guidelines.

6.2.2.2 Code of Medical Ethics and the NAFDAC Guidelines

In Nigeria, the Medical and Dental Council of Nigeria is the regulating professional council which regulates medical and dental practitioners. It has drawn up a *Code of Medical Ethics in Nigeria*, which provides rules, including rules relating to the ethical conduct of biomedical research. The coverage of the *Code of Medical Ethics in Nigeria* is therefore more limited than the National Code, as the former regulates medical and dental practitioners and covers only biomedical research.[63] In addition to the ethical implications discussed here, it also has legal implications considered later in this chapter.

The *Code of Medical Ethics in Nigeria* lays down certain ethical principles derived from the Helsinki Declaration of 1996. One principle requires that informed

[62] Section P.
[63] MDCN, *Code of Medical Ethics in Nigeria*, 2004.

consent be obtained from research participants.[64] It requires that every subject of biomedical research must be informed of the aims, methods, potential benefits and hazards of the research. Where the research is conducted by the physician treating the subject, informed consent must be obtained by another physician.

Amongst other things, the *Code of Medical Ethics in Nigeria* also requires that the importance of the objective be in proportion to the inherent risk to the research participant, and that physicians must cease trials if the harm outweighs the risk. Further, precautions must be taken to protect the privacy of the research participant, and to minimize the impact of the research on the physical and mental integrity, and personality of the participant. In addition, it requires that biomedical research must be conducted only by scientifically qualified persons under the supervision of a clinically competent person. It requires informed consent to be obtained prior to participation in research. It requires that the privacy of persons participating in research be protected. The physician must ensure that potential benefits outweigh potential risks. Further, it requires that the research must conform to generally accepted scientific principles and be based on well-conducted animal experimentation and knowledge of scientific literature.[65]

Also, in medical research combined with medical treatment, it states that the potential benefits and hazards of a new method should be weighed against the advantages of the best diagnostic and therapeutic methods.[66] Since the principles are

[64] Section 31 (vii) – (xi),
[65] Section 31 (B).
[66] Section 31 (B).

drawn verbatim from the 1996 version of the Helsinki Declaration, it requires that: "The patient must be assured of the best-proven diagnostic and therapeutic method. This does not exclude the use of placebo in studies where no proven diagnostic or therapeutic methods exist."[67] As I discussed briefly in Chapter One, this is an area that has caused much controversy. This particular provision has been revised severally since the 1997 controversy surrounding the placebo-controlled trials of AZT in several developing countries.[68] Further, the standard of the "best-proven diagnostic or therapeutic method" is not the standard required under the National Code which, as I described above, requires compliance with the ICH-GCP in clinical trials of drugs, which requires "effective treatment". There could, therefore, potentially be conflict between the two codes with respect to what the standard of care should obtain in biomedical research.

Further, it requires that in the event of legal incompetence, informed consent must be obtained as prescribed under relevant legislation. And, in the event of mental incapacity or in the case of a minor, the consent of a "responsible relative replaces that of the subject."[69] These latter provisions raise some concerns. Who is a "responsible relative"? Moreover, the word "replaces" is problematic as it gives the impression of

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[67] Section 31 (B) (iii).

[68] Principle 32 of the Helsinki Declaration (2008) in its entirety now reads: "The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances: • The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or • Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option." See also, R. K. Lie, E. Emmanuel, C. Grady, and D. Wendler, "The Standard of Care Debate: the Declaration of Helsinki versus the International Consensus Opinion" (2004) Journal of Medical Ethics 190. See also, Zulfiqar A. Bhutta, "The "Standards of Care Debate": Some Perspectives from the Developing World <http://www.microbicides2004.org.uk/abstract/oral/sc_02.html> (August 25, 2005). BMJ, "Beyond Helsinki: A Vision for Global Health Ethics" (2001) 322 BMJ 747.

[69] Section 31.

disrespect for the potential research participant and paints a picture of objectification. Again, it will be recalled that this is an area in which the National Code does not provide any guidance.

The issue of informed consent and who might be a "responsible relative" in the Nigerian context is an illustration of the general problem with the *Code of Medical Ethics in Nigeria* – one comes away with the impression that the ethical concerns have not been carefully deliberated on, nor has much attention been devoted to the Nigerian context. As such, there is no discussion of community engagement, nor is there any emphasis on research priorities, or on how research might benefit the community (matters dealt with in the National Code). This is not surprising as the principles are taken verbatim from the Helsinki Declaration of 1996 (which has since been revised severally).[70]

6.2.4 The NAFDAC Guidelines

Guidelines drawn up by the National Administration for Food and Drug Administration and Control (NAFDAC) also contain certain requirements for drug trials, including informed consent and the requirement of ethics review. Under the "Clinical Trials of Drugs in Nigeria: Guidelines, Procedures and Protocols" (NAFDAC

[70] See R. K. Lie, E. Emmanuel, C. Grady, and D. Wendler, "The Standard of Care Debate: the Declaration of Helsinki versus the International Consensus Opinion" (2004) Journal of Medical Ethics 190. See also, Zulfiqar A. Bhutta, "The "Standards of Care Debate": Some Perspectives from the Developing World <http://www.microbicides2004.org.uk/abstract/oral/sc_02.html> (August 25, 2005). BMJ, "Beyond Helsinki: A Vision for Global Health Ethics" (2001) 322 BMJ 747.

Guidelines),[71] "all novel drugs must undergo clinical studies in Nigeria before being granted marketing authorization in Nigeria."[72] The guidelines require independent ethics review of clinical trials by an independent ethics committee. The independent ethics committee is required to review objectively the suitability of investigators, facilities, protocol, the eligibility of trial subject groups, and the adequacy of informed consent and confidentiality.[73] Like the Code of Medical Ethics in Nigeria, the guidelines also have legal implications considered later in the thesis.

With regard to ethical standards and protection of participants in trials, the guidelines state that: "The *current* revision of the Declaration of Helsinki is the accepted basis for clinical trial ethics, which must be fully known and followed by all engaged in research on human beings."[74] This would put the Guidelines in potential conflict with both the National Code and the *Code of Medical Ethics in Nigeria* (which replicates the 1996 version of the Helsinki Declaration) in different respects, including areas that have been amended, such as the appropriate use of placebos. Unlike the National Code, however, both the *Code of Medical Ethics in Nigeria* and the NAFDAC Guidelines are limited in applicability – to the regulation of medical and dental practitioners, and to clinical trials of drugs respectively.

6.3 Legal Framework

[71] National Agency for Food and Drug Administration and Control, "Clinical Trials of Drugs in Nigeria: Guidelines, Procedures and Protocols" (NAFDAC Guidelines), on file with me.
[72] Introduction, NAFDAC Guidelines.
[73] Article 1.6.
[74] Article 1.1 of the NAFDAC Guidelines, p.11 (My emphasis).

As described in Chapter Three, the law may impact research governance in a number of ways. The law may provide requirements relating to privacy, confidentiality, legal competence to make choices and decisions, informed consent, mandating ethics review, and disclosure of information among other things. As in many developing countries, there is currently no specific legislation on health research involving humans in Nigeria. However, it is anticipated that there will soon be legislation dealing with different aspects of research governance. The legal framework of research governance in Nigeria currently consists primarily of the common law, judicial precedents, and statutes.[75] Below I describe the current legal framework and identify problematic issues. I also discuss the National Health Bill, which though not as yet law, will have significant implications for research governance in Nigeria when it becomes law.

6.3.1 The Common Law and Judicial Decisions

Various aspects of the common law in Nigeria such as the law of torts (negligence, battery, privacy, informed consent), equity, (fiduciary relationships), administrative law and judicial review, have implications for research governance. Actions could be brought in Nigerian courts on matters related to health research involving humans such as breach of confidentiality, breach of contract, violation of privacy, and product liability.[76]

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[75] Another source of law is the customary law, but this is not one of the areas implicated in research governance.

[76] See Fay Rozovsky and Rodney K Adams, "Medical Malpractice Liability in Human Research" (2007) 3:9 Journal of Clinical Research Practices 1.

At present, no cases specifically relating to health research involving humans have been decided by the Nigerian courts.[77] The Pfizer case would have been the first decided case specifically on facts relating to health research involving humans. It was, however, settled out of court. Even so, in the event that any such cases should arise, Nigerian courts would draw on cases on related matters to reach a decision. For instance, in the case of *Medical and Dental Council Tribunal v Okonkwo*,[78] the Supreme Court of Nigeria held that a person can refuse treatment, and in such a case, the physician must respect such refusal. While this was a case on the right of a Jehovah's witness to refuse a specific treatment (requiring blood transfusion), the requirement for informed consent is clear, even in a life-threatening situation as was the case in this matter. It would be even more so where a person is participating in research as a volunteer. Lack of informed consent may also ground actions in battery, as decided by the Supreme Court in *Okekearu v Tanko*.[79] In that case, the court also held that consent must be sought from the person whose body is involved in a treatment procedure. This position would no doubt apply to research.

Similarly, there is as yet no negligence case brought in the specific context of health research involving humans. However, a few cases have been decided on the basis of the tort of negligence in Nigeria.[80] These include cases related to professional

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[77] See Jill Cotterell, "The Functions of the Law of Torts in Africa" (1988) 31 Journal of African Law 161 at 167. The Pfizer incident yielded three main cases which never came to conclusion –

[78] *Medical and Dental Practitioners Disciplinary Tribunal v Okonkwo* (2001) 7 NWLR 206.

[79] *Okekearu v Tanko*, [2002] 15 N.W.L.R. 657, 660, 665-67 (S.C.).

[80] See generally, Jill Cotterell, "The Tort of Negligence in Nigeria" (1973) 17:1 Journal of African Law 30.

negligence involving a doctor-patient relationship.[81] Negligence, with the basic ingredients of a duty of care owed by one party to another, where both parties have a relationship, such as a researcher-research participant relationship,[82] a breach of that duty, and harm suffered as a direct or foreseeable consequence of the breach[83] could thus ground an action against a researcher or an ethics review committee. The standard of care required from a researcher may also be affected by whether or not a doctor-patient relationship existed between the researcher and the research participant. A physician would be required under the law to act in the best interests of their patients. In this case, the court is likely to refer, as they have done in several cases, to the Code of Medical Ethics.[84] Failure to comply with the requirements of the Code of Medical Ethics, some of which specifically address biomedical research, could be considered by the court in determining the existence of a duty or a standard of care and whether or not such duty or standard was breached. Ethics review committees could also be found liable for failure to exercise reasonable care in the discharge of their duties. As I mentioned in Chapter Four, the burden of proof rests on the plaintiff, which may not be easy to discharge.

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[81] *Medical and Dental Practitioners Disciplinary Tribunal v Okonkwo* 7 NWLR 206; *University of Ilorin Teaching Hospital v Akilo* (2000) 22 WRN 117, *Ajegbu v. Etuk* (1962), 6 E.N.L.R. 196; *Igbokwe v. Board of Governors of University College Hospital* [I96I] W.N.L.R. 173.

[82] There must be a relationship between the parties, including a contractual relationship, fiduciary relationship as in certain professional relationship like doctor-patient, or researcher-research participant relationship. Such a person would be a "neighbour" as articulated by Lord Atkin in *Donoghue v Stevenson*.

[83] As articulated by Lord Atkin in *Donoghue v Stevenson* . This has been cited with approval by the Nigerian courts. See H A Olaniyan, "Liability for Medical Negligence in Nigeria" (2005) 4:2 Nigerian Journal of Health and Biomedical Sciences 165 at 166. Hazel Biggs, *Healthcare Research Ethics and Law: Regulation, Review and Responsibility* (Oxford: Routledge-Cavendish, 2010) at 61.

[84] *Medical and Dental Practitioners Disciplinary Tribunal v Okonkwo*7 NWLR 206.

Moreover, as the Supreme Court has decided in cases like *Adigun v A G Oyo State (No.2),*[85] and *Araka and Egbue,*[86] foreign decisions are persuasive, save for when there are rightly decided Nigerian cases on the same point. Since there are no decided cases on informed consent in the research context in Nigeria, other cases from common law jurisdictions dealing with health research involving humans, would be of great persuasive authority in Nigerian courts. Thus, cases such as the Canadian case of *Halushka v University of Saskatchewan*[87] and the United States case of *Kus v. Sherman Hospital,*[88] (both deciding that liability would lie against the physician and the hospital if informed consent was not obtained from the research participant), could be persuasive in Nigerian courts. Cases such as *Grimes v. Kennedy Krieger Institute*[89] (United States), discussed in Chapter Four, which decides that a special fiduciary relationship exists in the research context between researchers and participants, could also have similar effect.

Apart from domestic and foreign judicial precedents, employment contracts drawn up between researchers and research institutions, or contracts between researchers and research sponsors, which may include requirements as to the conduct of all parties in health research, could also ground actions for breach of contracts in

[85] *Adigun v A G Oyo State* (No. 2) (1987) 2 NWLR pt 56 at 197.
[86] *Araka v Egbue* (2003) 17 NWLR 1 at 1 at 22 per Tobi, JSC: ""Of course, this court will not hesitate to use any foreign decision if it is correct, even though contrary to our decision; if the court comes to the conclusion that its decision is wrong, In such case, this court will, in the light of the foreign decision which is correctly given." However, foreign decisions are persuasive not binding on Nigerian courts. See *Adetoun Oladeji (Nig.) Ltd. V Nigerian Breweries Plc* (2007) 5 NWLR 415 at 423, paragraph 11.
[87] *Halushka v. University of Saskatchewan et al.* (1965), 53 D.L.R. (2d) 436, 52 W.W.R. 608 (Sask. C.A.).
[88] *Kus v. Sherman Hospital* 644 N.E. 2d 1214 (Ill. App. 2 Dist. 1995). In this case in which a research participant was not fully informed of the risks of the research, the court held that a physician as well as the hospital (which had instituted an ethics review committee to ensure that informed consent was obtained), were liable for failure to obtain such consent.
[89] *Grimes v. Kennedy Krieger Institute Inc*, 782 A.2d 807.

Nigerian courts where one party fails to comply with the agreed requirements. This will, however, be to the extent permitted by law. In other words, the contract will be invalid if it requires one party to do an act in contravention of any law. For instance, to breach the privacy of a research participant, where not required by law, or to require confidentiality from a researcher on issues that are required by law to be reported to an ethics review committee, would be void and unenforceable under Nigeria law.[90]

Administrative law and the law relating to judicial review are other arenas in which the common law as it operates in Nigeria, and judicial decisions, would affect research governance. Again, there have not been specific cases decided on health research involving humans involving the legal ramifications of the work done by ethics review committees. However, there are other administrative law cases from which the courts may draw in deciding on matters such as the legal liability of ethics review committees, or the members of such committees, or institutions.

In sum, the courts in Nigeria have not decided any cases on health research involving humans. There are, however, cases on other matters, and also foreign decisions on health research involving humans, which the courts may rely on. As I pointed out in Chapter Three, judicial response to health research involving humans does not provide a comprehensive framework or clear parameters for research. This is especially so in Nigeria, where that response is currently absent and can only be surmised by analysing decisions in other instances and foreign decisions. The absence of judicial response is largely because much litigation has not occurred in the area of

[90] *Pans Bisbilder (Nig.) Ltd. V First Bank* Nigeria (2000) 1 NWLR 684.

health research. This suggests the need for comprehensive legislation as I argued for in Chapter Four to address any gaps.

6.3.2 Legislation

Aside from the instances under which the common law and judicial decisions apply, legislation is an important source of law, and is regarded as superior to other kinds of law (excepting the Constitution).[91] There is as yet no specific statute such as the one I argued for in Chapter Three, but several pieces of legislation cover areas of health research involving humans, in ways that are often not cohesive. A bill is awaiting Presidential assent. Much of the statutory law in Nigeria applies indirectly, that is, they were not written with the specific intention of covering health research, thus they apply to other things as well. Others, like the *Medical and Dental Practitioners Act* confer powers that authorise the Medical and Dental Council of Nigeria to establish the *Code of Medical Ethics in Nigeria*. Others apply to specific areas of health research, such as regulations on clinical trials for drugs. Below I discuss the Constitution, the Child Rights Act, the Code of Medical Ethics in Nigeria, the NAFDAC Guidelines, the draft NAFDAC Clinical Trials Regulations and, lastly, the National Health Bill which, it is anticipated, is to become law soon and which will have a significant impact on research governance in Nigeria.

[91] See the Supreme Court decision, in *ARCON* v *Fassassi (No. 4)* (1987) 2 NWLR (Part 59) 42; 45 – 46, where it was noted that a decision of the court can only be overturned by a legislation. In addition, legislation may abolish customary law, and is required in Nigeria to make international treaties applicable within the country.

6.3.2.1 The Constitution

The Constitution is the *grund norm*, or the fundamental law of the land.[92] It also delineates the division of responsibilities for the Nigerian federation. This demarcation of authority has important consequences for research governance in Nigeria. It also contains other specific provisions on human rights which have implications for the rights of research participants and thus research governance.

As described in Chapter Four, matters relating to drugs are within the exclusive powers of the federal legislative body, the National Assembly.[93] This would include the regulation of clinical trials of drugs which, as I describe below, comes within the remit of NAFDAC, the federal drug regulatory agency. However, health, scientific research, and education fall under the concurrent legislative list.[94] The governance of health research therefore comes within the powers of both the federal and state governments.[95]

However, under the doctrine of "covering the field," the federal government can legislate on any matter on which it has legislative competence.[96] As

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[92] In *Daniel Orhiunu v. Federal Republic of Nigeria*, Suleiman Galadima J.C.A said: "The Constitution is what is called the grund norm and fundamental law of the land. All other legislations in the land take their hierarchy from the provision of the Constitution. By the provisions of the Constitution, the laws made by the National Assembly come next to the Constitution; followed by those made by the House of Assembly of a State. By virtue of section 1(1) of the Constitution, the provisions of the Constitution take precedence over any law enacted by the National Assembly even though the National Assembly has power to amend the Constitution itself." *Daniel Orhiunu v. Federal Republic of Nigeria* (2005) 1 NWLR, Part 906 55 – 56, paragraphs H- B.

[93] Section 26, Schedule 2, Part I, of the CFRN.

[94] See the *Constitution of the Federal Republic of Nigeria, 1999* (CFRN), Second Schedule., Section 21, 22, 27 and 28.

[95] Section 21, Second Schedule, Part II of the CFRN, Section 26, Schedule 2, Part I, of the CFRN, Section 22, Schedule 2, Part II of the CFRN.

[96] See section section 4(5) of the Constitution, provides that: "If any Law enacted by the House of Assembly of a State is inconsistent with any law validly made by the National Assembly, the law made by the National Assembly shall prevail, and that other Law shall, to the extent of the inconsistency, be void."

emphasized by the Supreme Court in the 2002 case of *Attorney General of Abia State versus Attorney General of the Federation*,[97] and in other cases before it, under that doctrine any state law which conflicts with a federal legislation on a subject-matter on which both governments have concurrent legislative powers, and on which the federal legislature has enacted a law, or which law can be taken as evincing an intention to cover the field, shall to the extent of its inconsistency, be void.[98] The state is thus subordinate to the federal government in any area of health or scientific research in which the federal government has made a law of general application.

What this means, then, is that the federal government can create a generally applicable law on research governance, as it has done (partially) with the development of the National Health Bill. The states may also make laws to regulate health research, including addressing any issues omitted in the federal legislation, so long as the state law does not conflict with the federal law.

Practically speaking, it would also be easier for the tier of government which has exclusive authority over drugs and related matters, such as clinical trials, and which has also enacted law to regulate professionals in the area of health research, to make law regarding all health research involving humans. Further, as rightly stated in the National Code:

> The Federal Government of Nigeria acting through any of its organs and establishments has the overall duty of protecting the welfare of the citizens of Nigeria. It may therefore exercise all the powers of protecting citizens according to the law, including

[97] *AG Abia State v Ag Federation* (2002) 6 NWLR (pt 763) 264.
[98] See *AG Abia State v Ag Federation* (2002) 6 NWLR (pt 763) 264; *AG of Ogun State and Anor. v AG of the Federation* (1982) 1-2 SC 13, 1982 13 NSCC 1. See NA Inegbedion and E Omoregie, "Federalism in Nigeria: A Reappraisal" (2006) 4:1 Journal of Commonwealth Law and Legal Education 69.

> citizens participating in research. In addition, some agencies of state in discharge of their duties according to law may also exercise regulatory functions within the research environment.[99]

Similarly, under National Health Policy, one of the roles of the government is to coordinate efforts in order to ensure a coherent, nationwide health system.[100] An active role by the federal government, in my opinion, offers the possibility of a uniform set of standards for health research involving humans for the country. A uniform set of standards in turn offers the same protections for research participants across the country. It permits clarity of responsibilities and roles for other actors in research governance, thus potentially promoting health research, which is needed in Nigeria.

Apart from the division of powers, there are specific matters that come within the umbrella of research governance, which may be covered generally under the Constitution. An example of such a matter is privacy. The right to privacy is a fundamental right protected under the Constitution. Section 37 of the Constitution provides that, "The privacy of citizens, their homes, correspondence, telephone conversations and telegraphic communications is hereby guaranteed and protected." The phrase, "the privacy of citizens" could be inferred to cover various aspects of a citizen's life. In *Medical and Dental Practitioners Disciplinary Tribunal v Okonkwo*, the Supreme Court, per Ayoola, JSC, noted that the constitutional right of privacy includes the right of a competent, mature adult to refuse life-prolonging treatment.[101] One could logically infer from this decision that a right to privacy includes the right to

[99] Section M of the National Code.
[100] See Revised National Health Policy, section 3.5.
[101] *Medical and Dental Practitioners Disciplinary Tribunal v Okonkwo* (2001) 7 NWLR 206 at 245-246.

refuse consent to participate in research (which is, essentially, a voluntary activity). Also, the protection of health information, and information collected in the process of health research, could reasonably come within the scope of that right, which would be applicable generally to all research.

In addition to the right of privacy, the Constitution also provides under section 34 that: "Every individual is entitled to respect for the dignity of his person."[102] Accordingly, the section continues, "No person shall be subjected to torture or to inhuman or degrading treatment."[103] A broad construction of this provision could be argued to include debasing or humiliating psychological treatments in pursuit of scientific knowledge, mental harm, or unnecessary bodily harm in the course of research.

Fundamental rights can be enforced by applying to a State or Federal High Court for redress.[104] And a claim relating to the violation of rights of a research participant can be made both under the common law and the Constitution as decided by the Supreme Court in *Minister of Internal Affairs and others v. Shugaba Abdurrahaman Darman*.[105] Thus, persons who claim that they were compelled to participate in research may bring a claim in battery[106] or a claim under the right to dignity of their persons.

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[102] Section 34.
[103] Section 34(1).
[104] Section 46(1) of the Constitution. A High Court is a superior court of record in Nigeria. A claim can also be filed in the Federal High Court. See Zakari v IGP (2000) 8 NWLR (pt.670) 666.
[105] *Minister of Internal Affairs v Shugaba Abdurrahaman Darman* (1982) 3 NCLR 915 at p. 927
[106] See *Medical and Dental Practitioners Council v Okonkwo.*

Further, the Constitution applies to all bodies – public and private. Thus, following the Court of Appeal's decision in *Onwo v. Oko and Others*,[107] a fundamental rights claim can be brought not only against the state but against an individual researcher or a research sponsor.

6.3.2.2 The *Child Rights Act*

The *Child Rights Act*,[108] enacted in 2003, does not have any direct provisions on the involvement of children in health research. But it does have certain provisions that may have implications for health research involving children. For instance, section 1 of the Act, provides that in any actions concerning a child, undertaken by an individual, public or private body, institutions or service, court of law, or administrative or legislative authority, the best interest of the child shall be the primary consideration. Thus, researchers, research sponsors, ethics review committees must consider whether any research involving children would be in their best interest. Section 33 of the Act also provides that a person who exploits a child in any other form not already mentioned in the Act, in a manner prejudicial to the welfare of the child commits an offence and is liable to a fine of five hundred thousand naira or imprisonment to a term of five years. Exploitative practices in the course of research arguably come within this provision. The National Health Bill contains specific provisions on obtaining informed consent for the participation of children in research. I consider that in a subsection below.

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[107] *Theresa Onwo V Nwafor Oko and 12 Others* (1996) 6 NWLR pt456 584.
[108] *Child Rights Act*, Act No.26, 2003.

6.3.2.3 *Medical and Dental Practitioners' Act* and the Code of Medical Ethics

The *Medical and Dental Practitioners' Act*[109] is another statute that has significance for research governance in Nigeria. It establishes the Medical and Dental Council of Nigeria as a statutory body.[110] Medical and dental practitioners, who wish to practice in Nigeria, are required to register with the Medical and Dental Council of Nigeria.[111] The Act also establishes the Medical and Dental Practitioners Disciplinary Tribunal, which tries cases brought by the Medical and Dental Practitioners Investigation Panel also established under the Act.[112]

One of the responsibilities of the Medical and Dental Council of Nigeria, as provided in the Act, is to prepare and review from time to time a statement on the code of conduct for the practice of the medical and dental professions in Nigeria.[113] Under this power, the Medical Dental Council of Nigeria has drawn up rules for the conduct of medical practitioners, which it has reviewed over the years. The most recent revision of the rules is the *Code of Medical Ethics in Nigeria*, (hereafter *Code of Medical Ethics*) drawn up in 2004.[114] I have discussed the Code of Medical Ethics as part of the ethical framework. The discussion that follows dwells on the legal nature of the Code of Medical Ethics and its requirements with respect to biomedical research. I consider the Medical and Dental Council of Nigeria also under the institutional framework.

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[109] *Medical and Dental Practitioners' Act* Cap M8, Laws of the Federation of Nigeria, 1990, as amended.
[110] Section 1 of the *Medical and Dental Practitioners' Act.*
[111] Section 6 of the MDCN, *Code of Medical Ethics in Nigeria*, 2004.
[112] Section 15 of the *Medical and Dental Practitioners' Act.*
[113] Section 1 (c) of the *Medical and Dental Practitioners' Act.*
[114] Medical and Dental Council of Nigeria, *Code of Medical Ethics in Nigeria*, 2004.

The *Code of Medical Ethics* is subsidiary legislation. The *Interpretation Act* defines subsidiary legislation as "any order, rules, regulations, rules of court or bye-laws made either before or after the commencement of this Act in the exercise of powers conferred by an Act."[115] Thus, because of its establishment under the power granted the MDCN by section 1 of the *Medical and Dental Practitioners' Act*, the *Code of Medical Ethics* is regarded as subsidiary legislation, albeit applying specifically to medical and dental practitioners in Nigeria. Furthermore, similar rules, such as the *Rules of Professional Conduct in the Legal Profession* made pursuant to the *Legal Practitioners' Act*[116] have been ruled by the Supreme Court in *Fawehinmi v. Nigerian Bar Association (No.2)*[117] to be subsidiary legislation. The significance of this is that, as decided by the Supreme Court in *Abubakar v. Bebeji Oil and Allied Products Ltd.*, subsidiary legislation, such as the *Code of Medical Ethics*, has the force of law.[118] However, as decided in *Olarenwaju v. Oyeyemi*,[119] as subsidiary legislation, its scope, validity, and authority cannot go beyond the scope of the enabling statute from which it derives its authority, in this instance, the *Medical and Dental Practitioners Act*.

The legal status of the *Code of Medical Ethics* has significant implications for research governance in Nigeria. First, it moves medical and dental practice and research from merely professional self-regulation to the domain of legal regulation. The provisions of the Code of Medical Ethics have legal force, to the extent that they do not go beyond the remit permitted under the enabling statute under which the rules were

[115] Section 37 of the *Interpretation Act, 1964*.
[116] *Legal Practitioners' Act,* 1962.
[117] *Fawehinmi v Nigerian Bar Association (No.2)* (1989) 2 NWLR (pt. 105) 558.
[118] *Abubakar v Bebeji Oil and Allied Products Ltd.*, (2007) NWLR (pt. 1066) 319, at 385, paragraph E.
[119] *Olarenwaju v Oyeyemi and Others* (2001) 2 NWLR (pt 697)229 at p.255-256. *Din v A G Federation* (1988)4 NWLR (pt. 413) 292.

made.[120] Any requirements regarding biomedical research involving medical practitioners and dental practitioners are therefore legal requirements. And, as a legal instrument, it can ground actions in Nigerian courts.[121] The movement of medical research into the legal domain indicates a role for the state which, as discussed in Chapter Two, is the main wielder of the weapon of law.

This does not, of course, mean a complete displacement of self-regulation, since the professional disciplinary bodies are still the primary custodians of authority, except when a medical or dental practitioner's activities are a criminal offence.[122] Self-regulation thus remains a central reality for medical and dental practitioners in Nigeria, including in the area of biomedical research. In the hybrid framework adopted by this thesis, such self-regulation is still an important piece of the puzzle of research governance, and is complementary to other types of regulation, including legal regulation. In this regard the *Code of Medical Ethics*, like many professional codes, provides certain legal protections for medical and dental practitioners who act within its boundaries,[123] thus facilitating research within professionally agreed confines. But, it also, if employed effectively, protects the interests of patients and research participants who can hold medical and dental practitioners to the standards articulated in the code.

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[120] See ibid. See also *Ishola v Ajiboye* (1994) 6 NWLR pt. 352 at 506; *Governor of Oyo v Folayan* (1995) 8 NWLR (pt 413) 292.

[121] See for instance, *Okatta v The Registered Trustees of Onitsha Sports Club* (2008) 13 NWLR (pt 1105) 632, decided on the basis of the Legal Practitioners Rules.

[122] The Supreme Court ruled in *Denloye v Medical and Dental Practitioners' Disciplinary Committee* that the disciplinary body of the Medical and Dental Council of Nigeria cannot decide criminal matters. Such matters are dealt with through the normal venues for criminal matters, namely the courts. *Denloye v Medical and Dental Practitioners' Disciplinary Commitee* (1968) 1 All NLR 306.

[123] See Angela Campbell and Kathleen Cranley Glass, "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research" (2001) 46 McGill Law Journal 473 at 477.

The Code of Medical Ethics makes specific provisions regarding "biomedical research involving human subjects."[124] Biomedical research is a subset of health research involving humans, and thus the application of the *Code of Medical Ethics* is more limited than the National Code. However, unlike the National Code, (which does not yet have any legal basis in law until the National Health Bill is passed) the *Code of Medical Ethics* does have legal force over the conduct of biomedical research in Nigeria.

It provides that the basic principles of the Helsinki Declaration, which it lists, have to be respected by medical and dental practitioners involved in biomedical research. Thus, while the status of the Helsinki Declaration in international law may still be debatable,[125] in the Nigerian context, the principles of the 1996 version of the Helsinki Declaration, as contained in the Code of Medical Ethics, have legal force, and are binding on medical and dental practitioners in Nigeria.[126] Following from this point, it is important to emphasise that the Code of Medical Ethics does not indicate that the Helsinki Declaration, as amended, should be followed. Instead, it lists the principles culled verbatim from the 1996 version. This may seem to be a minor point, except that the Helsinki Declaration has been revised severally since then, most recently, in 2008. As discussed earlier, some of the revisions are significant, especially in light of

[124] Section 31.
[125] The US Court in the Pfizer case appeared to consider the requirement for informed consent under diverse instruments such as Nuremberg Code, the Helsinki Declaration, domestic law to be a norm of customary international law, allowing the appellants to bring a claim under the Aliens Torts Claims Act. See George J. Annas, "Globalized Clinical Trials and Informed Consent" (2009) 360: 20 New England Journal of Medicine 2050.
[126] Campbell and Glass supra note 119 at 475.

controversies about the conduct of internationally sponsored research in developing countries.

The *Code of Medical Ethics* articulates certain basic principles[127] which I have described under the ethical framework, including requirements relating to informed consent, privacy, that the potential benefits outweigh the risks, and the circumstances under which using a placebo would be acceptable.[128] It is important to note that these requirements have legal force as previously stated. They would, therefore, take precedence in law over any opposing requirements under other documents that do not have legal force including, for instance, the National Code (although this is expected to change soon).

The Code of Medical Ethics, following the Helsinki Declaration, also states that protocols must be submitted for "consideration, comment, and guidance to a specially appointed committee independent of the investigator and the sponsor, provided that the independent committee is in conformity with the laws and regulations of the country."[129] The Code of Medical Ethics applies this principle by requiring that every teaching hospital and medical research institute must constitute an Ethical Review Committee, which should be composed of competent individuals to examine the research protocol of every researcher in the institution.[130] It thus seems to require an institutional system of ethics review.

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[127] Section 31 (A) (1) – (xii)
[128] See p. above.
[129] Section 31(iii).
[130] Section 31 (C) i.

However, it also requires that in the case of research which has a "state outlook," every State Monitoring Committee of the Medical and Dental Council of Nigeria must be able to constitute within a short notice a "State Ethical Review Committee" which will be an ad-hoc committee, to consider the research proposal.[131] It does not define what "state outlook" means, but it may be inferred that this refers to multisite or multicentre trials within the same state. Further, it also states that the Directorate of Research of the Federal Ministry of Health must constitute an ethical review committee to consider proposals that have a "national outlook." Again, it does not define "national outlook" but this may be inferred to mean multisite or multicentre research in different states and the Federal Capital Territory. Essentially, these requirements, if complied with, would create a hybrid system of both regional and institutional ethics review. This would differ from the requirements of the National Code, which as I discuss later under the institutional framework, adopts a national system of ethics review, with institutional committees reviewing research on the local level.

Requiring the creation of ethics review committees may seem outside the responsibility of making a "code of conduct which the Council considers desirable for the practice of the professions in Nigeria."[132] However, the Medical and Dental Practitioners' Act confers power under the Act to "do anything which in its opinion is calculated to facilitate the carrying out of its activities under this Act."[133] A broad reading of this power would arguably include the requirement for ethics review

[131] Section 31 (C) ii.
[132] Section 1 of the *Medical and Dental Practitioners Act.*
[133] Section 3 of the *Medical and Dental Practitioners' Act.*

committees in institutions, or in states, for the purpose of ensuring that medical and dental practitioners involved in biomedical research can submit their protocols to these committees. On a narrower reading, however, it is debatable if the powers of the Medical and Dental Council of Nigeria under the *Medical and Dental Practitioners' Act* can be construed to extend to compelling the federal government through the federal ministry of health to create an ethics review committee in the federal ministry or to compel state ministries of health to do likewise. This is important to note because some of the requirements of the Code of Medical Ethics are somewhat different from those contained in the National Code, particularly with respect to the requirements of ethics review committees, but also with respect to substantive ethical matters such as standard of care and the use of placebos. This creates room potentially for confusion. However, as I have stated previously, the Code of Medical Ethics has legal force (to the extent permitted under its enabling statute), while the National Code does not as yet have any legal force.

In any event, even if the Code of Medical Ethics goes too far in mandating ethics review committees at state and federal level, it does indicate the need for ethics review committees in the country, however constituted. However, especially in view of its non-implementation so far, the Code of Medical Ethics is not effective in this respect and indicates the need for other legislation in respect of research governance.

In the case of drug trials, the Code of Medical Ethics also contains provisions on new drug investigations, requiring among other things that such investigations must be approved by an ethics review committee, the Federal Ministry of Health, and

NAFDAC, the drug regulatory agency, in a manner reminiscent of collaborative governance.[134] The ethics review committee of the Federal Ministry of Health must consider the Investigation of New Drug Application (INDA) within six weeks.[135] Among other requirements, progress reports on ongoing clinical trials must be submitted annually to the Federal Ministry of Health. NAFDAC, the drug regulatory agency, must also approve or disapprove a New Drug Applications within a maximum of six months.[136] There are no time limits in the NAFDAC's regulations. However, these are matters that fall squarely within NAFDAC's authority. In this particular instance, regulations and guidelines made by NAFDAC would take precedence in law, because as I discuss below, this is the specific province of NAFDAC under statute.

The Code of Medical Ethics is an important component of the legal framework for research governance, including elements of both self-regulation and legal regulation. However, there are gaps, weaknesses and problems that limit its usefulness as an instrument for governance of research. First, its applicability is limited to medical and dental practitioners in Nigeria.[137] Thus, it would not apply to other researchers, such as social scientists or domestic entities, who may sponsor research, or to external research sponsors. Second, it does not address several key issues, including conflict of interest. Third, the *Code of Medical Ethics* does not provide specific penalties for failure to comply with the requirements. In this respect, section 26 provides that failure to adhere to the Rules 1 to 25, including requirements for registration and various facets

[134] Section 31 (D).
[135] Section 31 (D).
[136] Section 31 (E).
[137] This would include medical and dental practitioners from other countries, who are required by the Code of Medical Ethics to register with the Medical and Dental Council of Nigeria, in order to practise in Nigeria. See Section 6 of the *Code of Medical Ethics*.

of practice, may amount to infamous conduct. If the Medical and Dental Practitioners Tribunal, a tribunal of the same standing as a High Court, finds the practitioner guilty of such conduct, it may suspend or strike him off the register of medical and dental practitioners in Nigeria, and render him legally unable to practice medicine and dentistry in Nigeria. Presumably, if the practitioner is negligent in the treatment of a patient who is also involved in research, then the practitioner may be disciplined by the Tribunal. There is, however, no specific penalty for failure to comply with the sections on biomedical research under sections 31, for instance, failure to submit a research proposal for ethics review. Furthermore, some of its provisions may conflict with provisions in other instruments regulating health research, potentially leading to confusion.

In sum, a more comprehensive legal framework than that afforded by the Code of Medical Ethics is needed.

6.3.2.4 *National Agency for Food and Drug Administration Act* and Regulations

Other legislation with implications for research governance are the *National Agency for Food and Drug Administration And Control Act 1993* (the NAFDAC Act), and the *Drug and Related Products (Registration, Etc.) Act 1993*,[138] both federal laws. The NAFDAC Act establishes National Agency for Food and Drug Administration and Control (NAFDAC), which regulates food and drugs in Nigeria.

[138] Section 1, *National Agency for Food And Drug Administration And Control Act 1993 (NAFDAC Act)*, Cap N1.

The *Drug and Related Products (Registration, Etc.) Act 1993* provides that clinical trials for the importation, manufacture, or supply of a sample of drug, or a drug product, can only be undertaken after a permit has been granted by NAFDAC, which would issue a valid clinical trial certificate for that purpose.[139] Applications for a clinical trial certificate are to be made as prescribed by regulations provided by NAFDAC and clinical trials are to be conducted under regulations made by NAFDAC.[140]

Pursuant to powers conferred on it by the NAFDAC Act, NAFDAC has drawn up guidelines for regulating drug trials in Nigeria.[141] The NAFDAC Guidelines states that: "The current revision of the Declaration of Helsinki is the accepted basis for clinical trial ethics, which must be fully known and followed by all engaged in research on human beings."[142] It also requires that "The principles of informed consent in the current revision of the Helsinki Declaration should be implemented in each clinical trial."[143] These requirements essentially indicate that the Helsinki Declaration is the standard for the conduct of clinical trials of drugs currently in Nigeria. As described above, there are areas of potential conflict between the National Code and the Helsinki Declaration, particularly with respect to matters like the use of placebos in clinical trials. There also areas of conflict between the National Code and the Guidelines including, for instance, the process for obtaining informed consent from a person who is unable to provide verbal or written informed consent. In this respect, the National Code

[139] Section 1(2) and 5 of *Drug and Related Products (Registration, Etc.) Act 1993.*
[140] Section 5(2) of the *Drug and Related Products (Registration, Etc.) Act 1993.*
[141] Section 29 *NAFDAC Act. NAFDAC Guidelines,*
[142] See p. 11, section 1 of the NAFDAC Guidelines.
[143] Section 3.2, p.13.

requires a record such as audio-recording or witnessed thumb-printing, and this must be approved by an ethics review committee.[144] The NAFDAC Guidelines, on the other hand, state that where it is impossible to obtain verbal or written informed consent, the researcher should merely document the reasons why it is impossible to do so. While it is understandable that there would be differences in the requirements of both documents given that they were produced at different times, the divergences in both documents are worrisome because they may create confusion for researchers and research sponsors.

Perhaps to remedy this matter, NAFDAC has recently prepared a new set of regulations which have not yet come into force – the Good Clinical Practice Regulations, 2009.[145] These draft regulations will presumably replace the NAFDAC Guidelines currently in use. These draft regulations are drawn from the ICH-GCP. This is not surprising, especially since many countries have adopted the GCP as the basis for clinical trials of drugs. It is expected that every clinical trial of drugs in Nigeria must comply with these regulations when they are passed.[146] As provided in the ICH-GCP, the regulations reiterate the importance of the Helsinki Declaration stating: "Clinical trials shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with the requirements of these regulations."[147] This may be construed to mean ethical principles in any other guidelines that are of the same import as the Helsinki Declaration, which may arguably include the National Code, although the draft regulations do not refer specifically to the National

[144] Section F(f) of the National Code.
[145] Good Clinical Practice Regulations, 2009, made under the National Agency for Food and Drugs Administration, 1993.
[146] Section 8 (a).
[147] Section 6 (s).

Code. The draft regulations provide requirements for many matters, including matters not contained in the National Code, including requirements for obtaining a minor's consent for participation in clinical trials, and the consent of adults incapable of giving consent.[148] It would be appropriate to ensure that the requirements of the draft regulations are in line with the National Code to provide clarity for researchers and research sponsors.

6.3.2.5 The National Health Bill

As mentioned in Chapter Four, a National Health Bill has been passed by the National Assembly. Although the National Health Bill has yet to be signed into law, and is therefore not strictly part of the legal framework of Nigeria yet, I consider it here because, when it becomes law (after the Presidential assent), it will have significant impact on research governance in Nigeria.

The National Health Bill establishes a National Health Research Committee whose responsibilities include ensuring that the health research agenda and the resources available for research focus on priority health areas.[149] It also confers power on the Minister of Health to establish the National Health Research Ethics Committee,[150] whose functions include registering and auditing health research ethics committees in Nigeria and setting norms and standards for conducting research on

[148] Section 9 and 10.
[149] Section 31 of the National Health Bill.
[150] Section 33 of the National Health Bill.

humans and animals, including clinical trials.[151] The import of the Minister creating the committee is that the committee is not a juristic body, although it is recognized by law. It can, therefore, not sue or be sued.

The Bill also requires that every institution in which health research is conducted must establish or have access to a health research ethics committee. The functions of the health research ethics committees in Nigeria include reviewing, approving, or disapproving of health research protocols.[152]

Aside from creating these bodies, it makes informed consent a legal requirement, and requires the informed consent of a parent or guardian in the case of a minor.[153] Surprisingly, however, it does not expressly state that all health research must pass through ethics review or provide penalties for failure to submit research projects for approval. In view of the Pfizer incident, this is a crucial provision, which should be expressly stated, not merely deciphered from other provisions in the Bill or from subsidiary legislation. The National Code which contains that requirement will, however, become subsidiary legislation if the National Health Bill is passed. But until the National Health Bill is passed, the National Code remains a policy, subordinate to other instruments which have legal force such as the Code of Medical Ethics, and the NAFDAC Regulations and NAFDAC Guidelines. As a federal policy, institutions created under state law can arguably not be compelled under law to comply with the

[151] Section 33(6) of the National Health Bill.
[152] Section 34 of the National Health Bill.
[153] Section 32 of the National Health Bill.

provisions of the National Code. Signing the National Health Bill, when necessary amendments are made, and as soon as practicable, is therefore necessary.

Clearly, the National Health Bill has a potentially significant and beneficial impact on research governance in Nigeria. If and when the Bill is passed, it will provide a formal, legislative basis for the governance of all health research in Nigeria. It will confer legal force on the National Code which contains many vital provisions lacking in other legal instruments, and which has a wider reach and coverage. It will clarify the responsibilities of many key actors in research governance in Nigeria.

However, there are gaps in the Bill which should be remedied before the Bill is passed. For instance, the National Health Bill does not contain a requirement for ethics review. In my opinion, just like the requirement for informed consent, this requirement is so fundamental that it should be contained in the principal legislation. While the National Code contains such a requirement, there are no sanctions for failure to meet such basic requirement, as I suggested in Chapter Four. Also, the Bill does not establish a compensation scheme for research participants. Further, it does not contain a mandatory requirement for registration of a clinical trial in a clinical trial registry, nor does it mandate the creation of a clinical trials registry. No penal sanctions are provided for failure to comply with the Bill. The Bill is therefore not sufficiently comprehensive in its provisions on research governance.

There are also areas of potential conflict with existing legislation. In this respect, the Bill confers power on the National Health Research Ethics Committee to make guidance for clinical trials. As described above, NAFDAC has powers under the

NAFDAC Act to make regulations for drugs, including clinical trials. While the National Code requires that there should be compliance with both the NAFDAC regulations and the National Code,[154] it does not make it clear what would happen in the event of a conflict between any guidance promulgated by the National Health Research Ethics Committee, such as the National Code, and any regulations on clinical trials made by NAFDAC. It would be helpful if the National Health Bill would include a provision stating that the guidance provided by the National Health Research Ethics Committee supersedes all other regulations in the event of a conflict.

Given the gaps pointed out above, it is necessary that the Bill be amended to address them as soon as practicable before Presidential Assent.

6.4 Institutional Framework for Research Governance in Nigeria

In the foregoing pages, I have considered the ethical and legal frameworks of research governance in Nigeria. Below I consider the institutional framework which actually implements the ethical and legal frameworks. Following the outline laid out in Chapter Three, I consider ethics review committees, the drug regulatory authority, NAFDAC, policymaking structures in Nigeria, and non-governmental organisations. I examine their functioning in the past, and the systemic issues identified in Chapter Three that have affected such functioning, and which should be addressed in the emerging institutional framework.

[154] Section M (a).

6.4.1 Ethics Review Committees

In the foregoing discussions of the ethical and legal frameworks of research governance in Nigeria, the fundamental prerequisite of ethics review is emphasized in the different instruments. Below, I recapitulate very briefly the main points about the past functioning of ethics review committees already discussed under the history of research governance in Chapter Four. I then describe and analyse the requirements of ethics review committees under the National Code, drawing from the systemic issues discussed in Chapter Three. Such systemic issues include the composition or membership of committees, the structure and organisation of ethics review committees, capacity and funding issues.

The major function of ethics review committees in Nigeria, as in many countries around the world, is to approve research which meets ethical standards and disapprove research which does not meet such standards. The requirement to submit research protocols to ethics review was not a formal requirement under domestic instruments until 2004 when it was required for biomedical research in the Code of Medical Ethics. As the Pfizer incident showed, there were instances where research projects did not undergo ethics review. I have described the inconsistent, and ad-hoc, manner in which several of the ethics review committees operated in Chapter Five. Many of them suffered gross underfunding, and lacked the expertise to carry out their functions. In some institutions, researchers were not even aware of the existence of ethics review committees As discussed in Chapter Five, at various times national committees were established and then became non-functional. And, at certain points,

there were two national committees in operation. Financial support, stability, and sustainability are therefore key concerns with respect to the functioning of ethics review committees in Nigeria.

Traditionally, ethics review committees in Nigeria have been organised on an institutional basis, sometimes with a national committee in operation. As described in Chapter Five, these institutions were established mainly in federal institutions, including the major teaching hospitals, and the major research centres like the Nigerian Institute of Medical Research. Although each institution could have established guidance and operating procedures for ethics review committees, many had none. Governance at the institutional level was therefore practically non-existent, except where external sponsors specified certain requirements. On the national level, there was no set guidance for the composition of such committees or how they were to be funded. There was no clear way of ensuring that members were educated and had the necessary expertise and diversity to provide balanced reviews.

The National Health Bill confers power on the Minister of Health to create a national committee known as a National Health Research Ethics Committee, and requires institutions to create their own Health Research Ethics Committee. [155] The National Health Research Ethics Committee has the responsibility for registering Health Research Ethics Committees;[156] updating, revising, and editing the Code;[157] auditing Health Research Ethics Committees.[158] It also has the responsibility of advising the

[155] Sections 32 and 34.
[156] Section C.
[157] Section O of the National Code for Health Research Ethics.
[158] Section L.

federal and state ministries of health on any ethical issues concerning research. Further, the National Health Research Ethics Committee has the power to sanction any researcher that commits a violation of an ethical or professional rule by referring such researcher to the relevant statutory council prescribing penalties against any person found to be in violation of any norms and standards, or guidelines, set for the conduct of research under this Act.[159]

The National Code also requires that all institutions that seek to conduct health research must have a Health Research Ethics Committee, which must be registered with the national research ethics committee.[160] The National Code provides the manner for registering Health Research Ethics Committees with the National Health Research Ethics Committee, and requires that such registration must be renewed after two years.[161] Part of the requirement for registering Health Research Ethics Committees is that the institution provides a statement committing itself to taking responsibility for members' actions. All members of the proposed Health Research Ethics Committee must have completed training programs in research ethics approved by the National Health Research Ethics Committee and copies of the certificates of completion of such programs must be submitted along with the application. The institution setting up the Health Research Ethics Committee must provide resources for such training. The institution must also agree to comply with the National Code in the discharge of its responsibilities for protecting the rights and welfare of human participants of research conducted at or sponsored by the institution. The institution

[159] Section N.
[160] Section C.
[161] Section C (b).

must also commit to providing meeting space of sufficient quality, office and storage space, sufficient staff and funds to support the Health Research Ethics Committee in its review and recordkeeping duties. It also requires that the line of reporting authority should be from the chairperson of the Health Research Ethics Committee to the Chief Executive of the institution.[162]

Health Research Ethics Committees (HRECs) review research proposals and protocols in order to ensure that research conducted by institutions, will promote health, contribute to the prevention of diseases or disability or result in cures for diseases. They have the power to approve, disapprove, suspend, and terminate research protocols in accordance with the requirements of the National Code. [163] To address circumstances where an institution may not be able to meet the requirements for establishing an ethics review committee, the National Code requires that an institution that has no ethics review committee may enter into an agreement with another institution that has such a committee to provide ethics review of any research which would take place in such an institution.[164] Such agreement may only exist between institutions in the same state or in the same geopolitical zone.[165] Where the research involves more than three sites, the NHREC may review such research or may mandate another research committee to do so on its behalf.[166] In the case of international

[162] Section C (a) (1) – (6). According to the website of the National Health Research Ethics Committee, there are currently 19 ethics review committees from various health institutions registered with the National Health Research Ethics Committee (NHREC). See NHREC, "Registered HREC Database," online: <http://www.nhrec.net/nhrec/hrec_db.php> (May 2, 2010).
[163] See *National Health Bill*, section 34. National Code, section E.
[164] Section C (f).
[165] Section C (f). In the absence of an institution that has an ethics review committee in the same state or geopolitical zone, an institution is required to refer the national ethics review committee for guidance.
[166] Section C (n).

collaborative research, a HREC may adopt the approval of another HREC or that of any other local or international ethics review committee provided that such approvals comply with the requirements of the Code and take account of local circumstances.[167] HRECs are also required to monitor already reviewed research at intervals appropriate to the degree of risk involved in participation in the research. HRECs may initiate the oversight process in the event of receipt of any complaints or information from any source.[168]

To promote efficiency, the National Code requires that HRECs must review and provide decisions within three months. Where the HREC is unable to provide a decision in three months, it must refer it to the NHREC, which may reallocate the review to another HREC. Where the HREC does not provide a decision within the specified period and does not refer it to the NHREC, the researcher may make a report to the NHREC which may sanction the HREC.[169] The National Code also provides the procedure for reviewing multi-centre trials.[170] Further, among other procedural rules, HRECs are required to keep records of proceedings and maintain such records for ten years.[171]

Conflict of interest is addressed in different provisions of the National Code. These include provisions requiring that any conflict of interest of any members, including employment, ownership of stock, and receipt of honoraria, or grants from

[167] Section E (3) (b).
[168] Section E (e).
[169] Section E (d).
[170] See p.18.
[171] Section E (d).

potential research sponsors, be indicated to the NHREC at the time of registration.[172] It also requires that a member must not participate in the review of a project in which she has a conflicting interest.[173] Also, the director of a medical institution in which clinical trials is to be conducted must ensure that there is no conflict of interest in conducting the trial at the medical institution between the sponsoring company and the researcher who is an employee of the medical institution.[174] The informed consent form should also contain information on any apparent or actual conflict of interest.[175]

In terms of composition, according to the *National Health Bill*, the National Health Research Ethics Committee is to consist of 15 members from different fields of endeavour, appointed by the Minister of Health. They would include a Chairman; a Medical Doctor; a Legal Practitioner; a Pharmacist; a Nurse; at least two Religious Leaders, one each from the Christian and Muslim religions; a Community Health Worker; one Researcher in the Medical Field; one Researcher in the Pharmaceutical Field; three other persons, one of whom must be a woman, all of whom in the opinion of the Minister are of unquestionable integrity.[176] The members are appointed for an initial period of three years. There may be a renewal of another three years, after which that member can no longer serve on the NHREC.[177] A member of the NHREC is

[172] Section C.
[173] Section D.
[174] Section O (8).
[175] Section F (f).
[176] Section 33 of the *National Health Bill.*
[177] Section 33 (3).

required to vacate her office if she resigns, or is requested in the public interest by the Minister to do so.[178]

Health Research Ethics Committees are required to have at least five members. The National Code lists several criteria for choosing members of the committee, namely, experience, expertise and diversity of its members, age, gender, socio-cultural backgrounds, religion, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of researchers and research participants. Members are also required to have varying academic and professional backgrounds to promote complete and adequate review of health research. It also requires the membership of a lawyer "whenever feasible." The National Code does not specifically require lay membership, but it requires at least one scientific member and one non-scientific member. Further, if the HREC wishes to review research that involves vulnerable participants, such as children, prisoners, pregnant women, physically and psychologically disabled persons, the HREC is to appoint one or more individuals knowledgeable about, and experienced in, working with such participants for the review process. However, these individuals are not allowed to vote.[179]

To conduct ethics review effectively adequate financial support, including expenditures for documentation, administrative support and necessary office equipment, training, project monitoring, site visits, any honoraria for ethics review committee members, other direct and indirect costs, is essential. In this respect, the National Code

[178] Section 33(4).
[179] Section D.

provides that HRECs may charge fees for any or all of their activities, at its discretion, and in consultation with the principal officers of the institution. The fees must be commensurate with anticipated expenses required for adequate oversight of research.[180] The National Code further provides that as part of its oversight functions, the NHREC shall review the commitment of institution(s) to provide resources for proper functioning of HRECs.[181] There are no provisions for remunerating members of either the NHREC or the HRECs.

Another key systemic issue is the development of capacity for ethics review. This would include knowledge about the requirements of relevant policies and guidelines for the ethical conduct of health research in Nigeria.[182] The National Code's requirements for registration with the NHREC include a prerequisite for the members of the HREC to undergo NHREC-approved training programmes. Most NHREC-approved training programmes are provided through the West African Bioethics Training Programme, a program affiliated with the University of Ibadan and supported by a National Institute of Health grant, the Fogarty International Center, and the National Human Genome Research Institute.[183]

In terms of ensuring compliance, the National Code provides that in international collaborative research, NHREC shall report its findings of misconduct against researchers, sponsors and collaborators to the national ethics regulatory agency

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[180] Section E (r).
[181] Section L (c).
[182] See Jocelyn Downie, "The Canadian Agency for the Oversight of Research Involving Humans: A Reform Proposal" (2006) 13 Accountability in Research 75 at 80.
[183] West Africa Bioethics Training Programme, online: <http://www.westafricanbioethics.net/wabcms/index.php?option=com_content&task=view&id=50&Itemid=1> (May 30, 2010).

of the country of origin of the researcher.[184] This step does not prevent the institution or participants from taking appropriate legal action against such researchers and their representatives in Nigeria, thus allowing room for participants and other interested parties to seek legal redress outside the ethics review system. More generally, the NHREC has powers to undertake other punitive action against researchers found guilty of unethical practices, including barring them from conducting research for variable periods of time depending on the severity of findings of misconduct. The National Code also provides that NHREC shall recommend disciplinary action against researchers, report all cases of fraud, deception, infamous conduct, plagiarism, fabrication, falsification to the appropriate regulatory authorities, including the police, and NHREC shall bar researchers from conducting research for variable periods of time depending on the severity of findings of misconduct.[185]

Thus, a national system of research governance is emerging in Nigeria, with a national overseeing committee at the top of the structure and an institutional system of ethics review below. The adoption of a national ethics committee as part of the ethics review system in Nigeria provides a potentially uniform and comprehensive system of research governance, clear reporting relationships, and, arguably, greater accountability. As well, the NHREC's requirements for registering and auditing Health Research Ethics Committees, particularly with respect to education and training of members, will also be helpful for developing much needed expertise in ethics review in Nigeria. The NHREC has recently obtained the United States Federal Wide Assurance so that "when the

[184] Section N (f).
[185] Section N (a) to (f).

NHREC functions as an ethics committee according to the National Code and reviews protocols, such protocol review meets the requirements of United States Federal Government funded research."[186] Thus, the establishment of different components of research governance in the country may also facilitate research.

However, at present, the basis and authority on which the NHREC is functioning is not clear. Is it a legal body at present? It would appear not. Is it functioning as a committee set up by the Minister? It would appear so. It is anticipated that the National Health Bill will soon be signed into law, but, as things stand, it does not have legal authority to compel institutional ethics review committees, including those created under state laws to register with it or to oversee these committees, or to create the National Code or require compliance with the National Code. Still, as articulated in the National Health Policy, the federal government can make health policies, such as contained in the National Code. But such policy is arguably not a statute binding on states and state institutions. Given the importance of the national committee, a legislative basis for such committee would ensure its legitimacy, effectiveness, and sustainability. Without a legislative basis, a new Minister of Health may decide to discontinue its operation, jeopardizing its sustainability. Moreover, without a legislative basis, there really is no compelling compliance mechanism to ensure that institutions respect and comply with the National Code emanating from the NHREC. Signing the National Health Bill into law after the necessary amendments and as soon as possible is therefore essential.

[186] Culled from the website of the NHREC, see online: <http://www.nhrec.net/nhrec/> (May 2, 2010).

As described in Chapter Three, the institutional system of ethics review comes with certain challenges. These include inherent conflict of interest issues because the ethics review committee is housed within an institution that is typically intent on attracting research funds. In a developing country setting like Nigeria where resources are limited, this is a great concern. One way to tackle this potential problem is to ensure that membership of such committees includes persons from outside the institution. In the past, most members were drawn from the institution.[187] As I describe below, this position has not changed significantly as the National Code does not specifically require that members must be drawn from outside the institution.

Moreover, the National Code attempts to tackle the matter of the potential inability of some institutions to establish a Health Research Ethics Committee by requiring them to adopt the Health Research Ethics Committee of another institution. There is likely, however, to still be a multiplicity of ethics review committees in Nigeria, if all institutions establish an ethics review committee. This is a problem mainly because of limited resources. In my opinion, it might be better to have fewer ethics review committees organised in a regional system. These ethics review committees could then provide ethics review for all the institutions in a particular state or geo-political zone. In this way, the main strength of institutional review would still not be lost as such regional committees would still be able to take into account the local context, which would not vary significantly being within the same state or geo-political zone. This would limit the resources expended both locally and nationally since there

[187] Jean-Paul Rwabihama, Catherine Girre, Anne-Marie Duguet , "Ethics Committees for Biomedical Research in some African Emerging Countries: Which Establishment for which Independence? A Comparison with the USA and Canada" (2010) 36 J Med Ethics 243 at 244.

would be fewer ethics review committees. It would also ensure that ethics review is available for all states and all institutions. This will be helpful should the kind of situation that arose in Pfizer occur again. Thus, even where an institution does not ordinarily conduct health research and therefore has no cooperative agreement with another institution, but unexpectedly has to permit some sort of health research involving humans, there will be a ready ethics review committee in the state to review such research.

Given the need to ensure the independence and effectiveness of such a national committee, the membership of, and the appointment process into, the committee are key factors to consider. An analysis of the composition of the NHREC as provided in the National Health Bill, shows a concentration of persons in the health field, which would reflect the focus of ethics review in Nigeria. But it also means that people with other backgrounds are very much in the minority and may not bring the necessary diversity and balance for proper consideration of the issues raised in ethics review. There is also no requirement for gender balance. In a country where women remain underrepresented in many sectors, the mandatory requirement for only one woman is, in my view, insufficient. Further, while Moslems and Christians are in the majority, an argument could be made that other religions, including traditional religions, are left out unjustifiably.

Additionally, the appointments process for the national ethics review committees also has implications for the independence of the national committee and consequently, the protection of participants. An open and transparent system is thus

essential. There is much that is good about the appointment process outlined in the National Health Bill, including a specific tenure, and a requirement that removing a member can only be on grounds of "public interest," reducing potential political interference. However, a situation where the Minister, appoints all the members of the NHREC, out of whom three are simply persons whom he considers to be of high integrity, may not be the most transparent way to appoint persons into a committee with huge responsibilities or to secure the independence of such committee. The South African system where the Minister calls for nominations, after consultation with the National Health Research Council (which determines research priorities) and consultation with interested parties out of which she or he makes appointments may be a more transparent means,[188] and, as new governance proponents would argue, encourage more participation in the process. Such interested parties could be the Medical and Dental Council of Nigeria, other professional associations, non-governmental organisations, community advisory bodies, and so on.

Regarding the composition of the HRECs, the National Code could, in my view, have been more direct in its requirements with regard to membership of ethics review committees. Merely listing several criteria, as the National Code does, leaves the institution with the discretion to meet some but not necessarily all the criteria.

Further, drawing from the new governance approach in my hybrid framework, participation by those on behalf of whom regulation is undertaken is essential. Surprisingly, with the emphasis on community participation in the ethical

[188] Section 72 of the *National Health Act, 2003*.

framework outlined in the National Code, there is no specific requirement for a community member or a requirement for the inclusion of research participants. Nor does it expressly require that the institution must go outside to seek members. An institution could therefore argue that they have met the requirements, even if all the members come from the same institution, which would usually be a university. A survey of several African countries, including Nigeria, showed that before 2002, all committee members were fulltime employees of the institution, except in South Africa.[189] There has therefore been a propensity for using only institutional employees in these committees. With the way the requirements are couched, such a tendency is likely to continue. There is also no requirement for gender balance as is the case in South Africa,[190] the United Kingdom,[191]and Canada.[192] Further, the requirement for consultation of someone familiar with working with vulnerable persons without an accompanying requirement that such persons be allowed to vote (as is the case in South Africa and the United States) seems incongruous and may adversely affect the protection of such persons as research participants. Perhaps, this is because such

[189] Jean-Paul Rwabihama, Catherine Girre, Anne-Marie Duguet , "Ethics Committees for Biomedical Research in some African Emerging Countries: Which Establishment for which Independence? A Comparison with the USA and Canada" (2010) 36 J Med Ethics 243 at 244.

[190] The composition of HRECs in South Africa is different from the Nigerian requirements. The main guidance Ethics in Health Research: Principles, Structures and Processes requires that there should be at least nine members with sixty percent quorum including members who are representative of the communities it serves and, increasingly, reflect the demographic profile of the population of South Africa; members of both genders, although not more than 70% should be either male or female. See s.4.1.

[191] Section 6 of the *Governance Arrangements for NHS Research Ethics Committees.* The US regulations also require that although effort should be made to include members include those whose interests are in scientific areas and those whose concerns are in nonscientific areas of both genders but no selection is to be made on the basis of gender. 45 CFR 46.107

[192] Section 1, Article B- 1.3- Membership of REBs. , the TCPS requires that the REB shall be composed of at least five members, including both men and women, of whom at least two members have broad expertise in the methods or in the areas of research that are covered by the REB, at least one member is knowledgeable in ethics and another in law for biomedical research, and at least one member has no affiliation with the institution, but is recruited from the community served by the institution.

persons with familiarity with vulnerable persons may not have undergone the training required for regular members. But this means that vulnerable persons, or a professional who is familiar with their situation, are effectively excluded from actual decision-making on the HRECs. Accountability, the need for balance and diversity, and the necessity to prevent inherent conflict of interest, require that the compositional requirements of ethics review committees be revisited.

Further, the provisions on financial support for Health Research Ethics Committees sound good on paper and attempt to cover all possible loopholes. For example, if an institution intends to conduct research, it must commit to provide resources and if the resources are not provided, the NHREC may revoke its registration. But past experience has shown that institutions have often failed to provide resources for ethics review committees. Governments, too, have also failed to provide resources for ethics review committees. As Falusi and others note with respect to the ethics review committee at the University of Ibadan, a federal institution, "Despite the declared interest in fostering research, the University of Ibadan has never had sufficient resources from the Federal Government to operate an IRB."[193] Interestingly, the ethics review committee in that university resorted to a "public/private partnership" in order to obtain resources. In this partnership, The University of Chicago through a generous grant from the Ralph and Marion Falk Medical Research Trust provided $40,000 in grant support.[194] With the funds the committee was provided with basic necessities for

[193] Adeyinka G Falusi, Olufunmilayo Olopade, and Christopher O Olopade, "Establishment of a Standing Ethics/Institutional Review Board in a Nigerian University: A BluePrint" (2007) Journal of Empirical Research on Human Research Ethics 21 at 23.
[194] Ibid.

running. It is not clear how the committee will continue to be funded when the grant support runs out, and if the institution intends on continuing to seek grants to support the ethics review committee.

Further, even though the National Code requires fees from research sponsors to be commensurate with the anticipated expenses of the review, charging fees raises the spectre of conflict of interest and regulatory capture in a resource-limited setting like Nigeria. Yet, it may be difficult for institutions, which are already straining under the burden of limited funds to provide resources, independent of such fees, for ethics review committees. In addition, it may not be desirable to charge fees for all types of research, including research conducted by students, projects for expedited review, and non-funded research. Perhaps, a better approach might be to establish a scheme through which ethics review committees in Nigeria, including the National Health Research Ethics Committee, are funded. Such scheme, which would be independent of the institutions, apart from providing resources for the functioning of ethics committees, will also ensure greater independence than would otherwise be the case. I discuss this scheme further in my recommendations in Chapter Seven.

Conflict of interest and the related concomitant of regulatory capture are serious concerns for the governance of health research in countries around the world. In a telling observation, a survey on ethics review in African countries, observed that, "No committee has rejected a research protocol."[195] Of course, this may be because each protocol reviewed met the requisite ethical standards. But it is also a reminder that

[195] Rwabihama et al, supra note 189 at 244-245.

many institutions in all countries, but especially institutions in the developing world and specifically in African countries like Nigeria, have many reasons to desire to attract the resources represented by research, especially externally sponsored research.

There are various provisions on conflict of interest in the National Code as I described above. There are requirements that HREC members must not vote on matters in which they have a conflict of interest, and for directors of medical institutions to ensure that no conflict exists between researchers and research sponsors. There are, however, no direct injunctions on what should happen in other cases. Instead, there is a requirement for any potential conflicts of interest to be indicated to the NHREC at the time of registration, and for informed consent forms to contain an indication of any conflicts of interest. It does not state what indicating such potential conflict of interest would mean for either registration with the NHREC or what the ethics review committee should do if the informed consent form indicates that a researcher has a conflict of interest.

More generally, the provisions do not address institutional conflicts of interest, that is, circumstances in which an institution would benefit from proposed research projects, and therefore has an interest in ensuring that the project is approved. Presumably the establishment of an "independent" HREC would take care of this circumstance. Nevertheless, the potential for such conflict becomes even more significant, given the wording of the membership requirement in the National Code that allows members to be drawn solely from the institution. There is therefore, an increased potential for perceived, if not actual, conflict of interest. Further, as already described,

many institutions rely on foreign funding for maintaining ethics review committees. The peculiarities of the establishment of some of these committees in the past also contribute to a perceived lack of independence. As Rwabihama and others describe it in the African context,

> fault may lie in the peculiarity of the origin of these committees. The establishment of the first African ethics committees is connected to the need of conducting Western research projects in developing countries. While African scientists are managing to conduct local research in order to solve some endemic or tropical diseases in the region, ethics committees are still working with the dependences of Western agencies. Committees are not independent enough, according to the history of their creation and the socio-economic context.[196]

The creation of a national system of governance has the potential to deal with the problematic beginnings of ethics review as described by Rwabihama and others, especially if it takes into account these challenges. Given its importance, and the adoption of an institutional system (where members of ethics review committees could include members of the same department as a researcher or previous or potential collaborators on research projects), a specific section on conflicts of interest, would have been helpful in the National Code. Such section could include a detailed expatiation on what may constitute conflict of interest in different circumstances, and how institutions, ethics review committees, research sponsors and researchers should deal with such conflicts.

[196] Rwabihama, et al, supra note 189 at 249.

With respect to the powers of the NHREC to compel compliance with the National Code, it can impose several sanctions. However, as things stand currently, it cannot legally enforce compliance because it is not yet a legally established body. Even when the National Health Bill is passed, the sanctions which the NHREC can impose are limited. Particularly in relation to external researchers, it may be argued that the sanctions in the National Code are insufficient, since these researchers may not face any direct penalties for any unethical conduct. This would be different, however, if there were penalties, especially for basic infractions, such as failure to obtain informed consent, or failure to submit projects for ethics review.

In sum, there is significant progress in the development of a uniform ethics review system in Nigeria. There is currently a desire to establish and register functional ethics review committees in Nigeria. But the history of research governance in Nigeria shows that sustainability is crucial and has been lacking in the past. Efforts to establish or re-establish committees must therefore proceed in a manner that takes this into account. Even with these developments, then, several important issues remain, including the continued lack of a legislative basis for both the NHREC and the National Code with its attendant effect on the sustainability of the emerging ethics review system in Nigeria. And, of course, it remains to be seen how rigorous the implementation of the National Code's requirements for ethics review committees will be.

6.4.2 Drug Regulatory Authority: NAFDAC

Established in 1993, NAFDAC is the principal regulator of drugs in Nigeria.[197] I have already discussed the guidelines that NAFDAC has developed, and the regulations it is currently developing, pursuant to its powers under the NAFDAC Act. [198]

In recent years, NAFDAC has engaged in a public, and by many accounts, largely successful, war against the importation, production, and sale of counterfeit and substandard drugs in Nigeria.[199] In this respect, it has enforced the registration of drugs, confiscated large amounts of counterfeit drugs, and prosecuted offenders. Its work in this respect has been lauded widely, and referred to as a model for other developing countries that have the same problem.[200]

However, very little is known about NAFDAC's current work as the main regulator of clinical trials. But its past left much to be desired. In this respect, there have been contradictory accounts of whether or not Pfizer received permission from

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[197] Section 5 of thee *NAFDAC Act.*
[198] Section 29 *NAFDAC Act*
[199] Owen Dyer, "New Report on Corruption in Health" (2006) 84: 2 Bulletin of the World Health Organisation 84. 12. 24. A I Raufu, "Nigeria Leads Fight Against "Killer" Counterfeit Drugs" (2006) 84:6 Bulletin of the World Health Organization 685. The National Agency for Food and Drug Administration and Control (NAFDAC) "NAFDAC Destroys N10B Fake Drugs in 4 Years" (2006) 1: 10 NAFDAC News 4.
[200] Ibid.

NAFDAC for its infamous clinical trial in 1996.[201] Even after the trials, NAFDAC has provided no clear answers. The panel of inquiry that investigated the Pfizer incident criticised the NAFDAC for failing to take action after the chairman of the task force made complaints about the trial.[202]

NAFDAC clearly has the legislative authority required to carry out the mandate of regulating clinical trials of drugs. Since 2001, it has also enjoyed significant political support in carrying out reforms, particularly with respect to reducing the infiltration of counterfeit and substandard drugs in Nigeria. Its success in that respect is a major indicator that governance and regulation, as well as law, can be effective in Nigeria. There is now need for NAFDAC to broaden its efforts to include effective regulation of clinical trials. The new draft regulations based on the ICH-GCP, as described above, indicate that NAFDAC is aware of its regulatory role with respect to clinical trials. These new regulations must be carefully pondered and put in place as soon as possible. It is heartening that they were made available for public comment on NAFDAC's website, suggesting a desire to engage and involve the public in the process.

However, NAFDAC's regulatory role must be coordinated properly with other actors, including national and institutional review committees, in research governance in Nigeria in order to provide comprehensive protections for participants in health research and to prevent potential confusion for research sponsors. Greater

[201] Sam Eferaro, "NAFDAC Okayed Pfizer's Trovan Trials" *Vanguard* 8 January, 2001.
[202] See Chapter Five.

uniformity in the provisions of the regulations provided by NAFDAC and other documents such as the National Code is desirable. Further, as the Pfizer incident indicates, NAFDAC must take its role as a regulator of clinical trials of drugs in Nigeria seriously.

Aside from the regulations of NAFDAC, Garuba, Kohler, and Huisam, in a recent survey of the work of NAFDAC (regarding registration, procurement, inspection, and distribution of drugs), noted that there have been significant improvements over the years. These include on-the-job training for officials of NAFDAC, and public availability of some information. However, several weaknesses remain. These include an inadequate number of trained staff, a lack of conflict of interest guidelines, inconsistency in the documentation of procedures, and lack of public availability of such documentation.[203] These are systemic issues that will also impact adversely on the proper regulation of clinical trials of drugs in Nigeria if they are not dealt with. For instance, an adequate number of trained staff is necessary to monitor trial sites, and review documentation among other things. An investment of resources by the Nigerian government is clearly necessary to assist NAFDAC in its regulatory functions. Thus, with respect to NAFDAC, adequacy of resources, implementation, accountability, and uniformity of regulatory requirements are key issues as research governance develops.

[203] Habibat A Garuba, Jillian C Kohler, and Anna M Huisman, "Transparency in Nigeria's Public Pharmaceutical Sector: Perceptions from Policy Makers" (2009) 5: 14 Globalization and Health . See also, Hart O Awa and Christen A Nwuche, "Cognitive Consistency in Purchase Behaviour : Theoretical and Empirical Analyses (2008) International Journal of Psychological Studies 44 at 50.

6.4.3 Policy-Making Structures

According to the National Health Policy, the federal government, through the Federal Ministry of Health, is the main policymaker for the country on health-related matters, although states may make policies within the state health system. Until the establishment by the Minister of the National Health Research Ethics Committee, therefore, the Federal Ministry of Health was in charge of making policies relating to health research.

The current policy for health research is articulated in the National Health Policy drawn up by the Federal Ministry of Health. However, the National Health Bill, when signed into law will confer policymaking powers on the National Health Research Committee which is to make research policies. The core of any policies emanating from this committee would be to ensure that the research conducted in the country would be research which meets Nigeria's priorities. As discussed in Chapter Four, the determination of research priorities in developing countries like Nigeria is crucial to prevent exploitation of research participants in Nigeria. The establishment of a committee charged with this responsibility will therefore be a welcome development.

The National Health Bill will also legally empower the National Health Research Ethics Committee (NHREC) to make policies for research governance in Nigeria. Indeed, that committee, inaugurated by the Minister of Health, has already begun to develop policies such as contained in the National Code.

Recently, the creation of a "National Bioethics Committee" in Nigeria, with the support of the United Nations Educational Scientific and Cultural Organisation (UNESCO), has been under contemplation.[204] There are thus several policymaking bodies in Nigeria either currently functioning or in the process of being established.

As I pointed out in Chapter Three, legitimacy, community engagement and public participation, transparency, accountability, representation and effectiveness, are key concepts in my hybrid framework of governance (drawn from new governance) important systemic issues for policy structures like those listed above. To these issues may be added a clear delineation of roles and responsibilities to prevent duplication. In the Nigerian context, legitimacy strictly in terms of a statutory basis is clearly a problem currently, although that it expected to change soon. The NHREC which is already operating and providing policies has no clear basis in law. In terms of representation, especially as described under the section on ethics review committees, there is room for improvement. Independence, plurality, diversity and multi-disciplinary focus are necessary.

With respect to transparency and public participation, the National Health Research Ethics Committee currently has a website on which it has posted the latest version of the National Code and the list of Health Research Ethics Committees registered with the national committee. These steps are clearly steps in the right direction. However, it is stated in the National Code that the NHREC may revise the

[204]UNESCO, UNESCO Assisting Bioethics Committee: Meeting to Discuss the Establishment of the National Bioethics Committee, online: <http://unesdoc.unesco.org/images/0018/001847/184765e.pdf> (May 2, 2010).

National Code at any time. In the three years since I began my research, various changes, some minor and others major, have been made to the document.[205] It has been difficult to obtain information on how much public consultation there was prior to the establishment of the National Code. But the provision that the NHREC may revise the National Code at any time clearly suggests that broad engagement of stakeholders in health research is not a priority. This in turn undermines the legitimacy of the document, and may affect compliance with, and respect for, the document. Further, it potentially creates a strict top-down governance approach (instead of a new governance or a hybrid governance approach) that does not lend itself to responsiveness and effectiveness.

It remains to be seen if, and when, the other policymaking structures will become active. It is important, however, that the mandates for each of these bodies are clearly mapped out and that there is no duplication in authority or roles. Not only would any duplication result in policies which may be potentially confusing for researchers, it would be inefficient and a waste of limited resources. Given limited resources, it must be determined clearly if a National Bioethics Committee is really needed alongside a National Health Research Committee and a National Health Research Ethics Committee or if one can be subsumed within the other. If it is determined that all three are required, a clear delineation of roles is necessary. Further, political support is necessary to ensure the effectiveness of these bodies. Sufficient resources are also necessary to ensure effective functioning of the research.

[205] I have various versions of the National Code on file.

6.4.4 Universities, Research Institutes, Research Sponsors, Professional Associations

Prior to the recent developments in research governance in Nigeria, regulation took place mainly at the institutional level, that is, in Nigerian universities, teaching hospitals, and research institutes. However, from the history of research governance discussed in Chapter Five, the institutional framework of governance was non-functional. During this period, much of the governance that existed emanated mainly from the requirements of research sponsors. Research funded by international organisations such as the World Health Organisation and the United Nations Joint Programme on HIV/AIDS (UNAIDS) or national organisations such as the United States National Institutes of Health or Wellcome Trusts therefore had to meet the ethical requirements of these organisations.

Universities, research institutes, research sponsors and professional associations lack the wide remit and authority to ensure a comprehensive framework of research governance. However, to permit a truly functional hybrid governance framework as contemplated in this thesis, it is important for these institutions, including universities and research institutes, to have and implement regulatory frameworks governing research within their authority. The National Code has now provided standards for the ethical conduct of research, which institutions must adopt. But it also allows institutions to "elaborate guidelines for the conduct of research in accordance with their enabling law and consistent with the need for maintenance of the highest

ethical and scientific standard as outlined in this code."[206] Thus, institutions can still create guidelines that are in line with the National Code. They can also create other guidelines on specific issues such as conflict of interest.

Research sponsors can, and will, most likely, continue to employ their own guidance, using their own means for ensuring compliance, which is typically the threat of withdrawing funding. However, they must also comply with the requirements of the National Code and ensure that their contractual and ethical requirements of researchers and research institutions do not conflict with requirements under the National Code. Pharmaceutical companies, in particular, must ensure that contracts drawn up with researchers do not conflict with the National Code's requirements.

With respect to professional associations, the Medical and Dental Council of Nigeria, as already discussed under the legal and ethical frameworks above, regulates medical and dental practitioners in Nigeria, under a statutory framework. Medical doctors, should they be found to have violated the Code of Medical Ethics, would thus be liable under mechanisms authorised under the law. However, while the Medical and Dental Council has established a Code of Medical Ethics which contains requirements for ethical research by medical and dental practitioners, as already discussed, that code is limited in scope and application.

More importantly, self-regulation is a crucial part of the framework of professional regulation. In this respect, both the Nigerian Medical Association, an association of all medical and dental practitioners in Nigeria,[207] and the Medical and

[206] Section M.

[207] Any medical or dental practitioner registered under the Medical and Dental Practitioners' Act has a right of membership of the Association.

Dental Council of Nigeria, which is a statutory body, operate to provide such self-regulation. The Nigerian Medical Association, which is the largest medical association in West Africa[208]with over 35,000 members, is recognised under the *Medical and Dental Practitioners Act.*[209] It nominates eleven members of the Medical and Dental Council of Nigeria. It is consulted on an ad-hoc basis by the federal government and contributes to health policies. It also provides continuing education to medical and dental practitioners. [210]

The Medical and Dental Council of Nigeria still has to ensure that medical and dental practitioners comply with the code, and must be willing to take measures against practitioners who fail to comply. However, both the Medical and Dental Council of Nigeria and the Nigerian Medical Association have not, in my view, been sufficiently active in ensuring proper research governance in Nigeria. There is, for instance, no evidence that either has tried to push for the establishment of ethics review committees at the institutional and state levels as required in the Code of Medical Ethics. As another example, neither body publicly condemned or took any actions against the doctor who reportedly provided a backdated letter to Pfizer in the 1996 trial. Interestingly, one of the sanctions that the National Health Research Ethics Commitee can apply against an erring researcher is to report her to the appropriate professional council.[211] If the professional council shows no interest in disciplining erring members, this sanction becomes merely illusory. Such inadequate professional interest is, as I

[208] NMA, "About Us" online: <http://www.nigeriannma.org/aboutus.htm> (May 2, 2010).
[209] Section
[210] About Us, supra note 223.
[211] National Health Bill, section 33.

discussed in Chapter Three, one of the systemic issues that adversely affects research governance in many countries.[212]

Also, although medical and dental practitioners are required to know and comply with the requirements of the code, there is not much public awareness of the code, and many potential participants in Nigeria have little knowledge of their rights and the obligations of medical and dental practitioners.[213]

At present, other professional associations have yet to develop frameworks for the ethical conduct of health research involving humans. It would be appropriate for these professional associations to, at the least, formally adopt the National Code and require their members to comply with it on pain of sanction by the professional association. The trust that the public places in professional associations, and the interest of these associations in maintaining that public trust, require that they begin to show greater interest in the ethical conduct of research by their members.[214]

It is important that universities, research sponsors, and professional associations engage more actively in ensuring that health research involving humans conducted within their realms of authority meet high ethical standards. Even though their scope of authority is limited, regulating effectively within their domains, and actively participating in the national effort, will provide non-governmental governance of research, and allow a hybrid, potentially more complete, and thus more effective

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[212] Henry Dinsdale, "Professional Responsibility and the Protection of Human Subjects of Research in Canada" 2 and 3 Health Law Review 80 at 82.
[213] Han de Vries, Paul Sanderson, Barbara Janta, *International Comparison of Ten Medical Regulatory Systems: Egypt, Germany, Greece, India, Italy, Nigeria, Pakistan, Poland, South Africa and Spain* (California: Rand Corporation, 2009) at 11.
[214] Timothy Caulfield, Trudo Lemmens, Douglas Kinsella and Michael McDonald, "Research Ethics and the Role of Professional Bodies: A View From Canada" (2004) 32:2 Journal of Law, Medicine and Ethics 365 at 367.

model of governance, to emerge in Nigeria. At present, the degree of accountability and community engagement is inadequate as is effectiveness, particularly in relation to professional associations.

6.4.5 Non-Governmental Organisations

As I have explained in other chapters, while non-governmental organisations (NGOs) are not a typical component in many accounts of research governance, they are particularly essential in the hybrid framework that I think is necessary both in gaining an understanding of, and in creating, effective research governance systems in developing countries. As I argued in Chapters Two and Three, a government role is crucial but these NGOs can serve to increase the responsiveness of government, and hopefully as a voice for research participants. And NGOs who work to promote the rights and welfare of research participants could be particularly beneficial in the specific context of Nigeria as described in Chapter Four.

Non-governmental organisations (NGOs) have provided many services in Nigeria, including in the areas of democratic governance, public participation, civil liberties and human rights, and health.[215] As in many developing countries where the state may not always meet the expectations of the people, NGOs often attempt to fill the gap or advocate for changes in the state's actions, policies or proposals. While their achievements in some respects may only be modest, their impact in Nigeria has been significant. For instance, Okafor observes in a very interesting study on the impact of human rights NGOs on legislation, lawmaking and executive actions in Nigeria that:

[215] Matthew Todd Bradley "Civil Society and Democratic Progression in Postcolonial Nigeria: The Role of Non-Governmental Organizations" (2005) 1:1 Journal of Civil Society 61.

> One remarkable feature of the state-NGO relationship in Nigeria is that even during the darkest days of military rule in that country, NGOs were still able to exert a modest measure of influence on legislation and legislative action in Nigeria. Laws were repealed or modified by various military regimes in part as a result of sustained campaigns launched by many of these NGOs. The legislative process itself was also positively affected. NGOs have also been able to achieve the same modest measure of success during the period of civilian rule between 1999 and 2001.[216]

In the health sector, NGOs have been actively involved in different aspects of health delivery, advocacy and education.[217] For instance, NGOs have been closely involved with advocating for human rights of people afflicted with the disease, assisting the development of policies for HIV/AIDS prevention and treatment in Nigeria, soliciting support from other countries and international organisations, and with educating the public about the disease.[218] NGOs could also play such roles in the context of research governance by promoting awareness of issues surrounding health research and research governance, and by participating in related policymaking. Many of them work at the grassroots level, allowing them significant access to, and opportunities in, communities in which research may take place.[219]

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[216] Obiora Chinedu Okafor, "Modest Harvests: On the Significant but Limited Impact of Human Rights NGOs on Legislative and Executive Behaviour in Nigeria (2004) 48:1 Journal of African Law 23 at

[217] Kenneth L. Leonard, "When Both States and Markets Fail: Asymmetric Information and the Role of NGOs in African Health Care" (2002) 22 International Review of Law and Economics 61.

[218] Davidson Umeh and Florence Ejike, "The Role of NGOs in HIV/AIDS Prevention in Nigeria" (2004) 28: 3–4 Dialectical Anthropology 339; Eudora Chikwendu, "When the State Fails: NGOs in Grassroots AIDS Care" (2004) 28: 3–4 Dialectical Anthropology 245.

[219] M G Olujide, "Non-Govermental Organisations Self-Evaluation: Issue of Concern in Nigeria" (2005) 11:1 The Journal of Agricultural Education and Extension 63.

Currently, there are few NGOs which provide different services with respect to research governance. These include the Association for Good Clinical Practices in Nigeria (AGCPN) and The New HIV Vaccine and Microbicide Advocacy Society. The Association for Good Clinical Practices in Nigeria was founded in 2006 and has over 200 members, including physicians, nurses, pharmacists, and biomedical scientists.[220] Its goal is to build up the infrastructure for biomedical research in Nigeria by increasing the number of physicians and institutions capable of conducting clinical research. It also trains researchers in good clinical practices for clinical research. The New HIV Vaccine and Microbicide Advocacy Society advocates for the use and availability of new prevention technologies such as microbicides in Nigeria.[221] The work of these organisations touches on research governance, but is also focused on research promotion. While vital, research facilitation or promotion sometimes conflicts with research regulation aimed principally at protecting research participants.

There is, however, presently no NGO currently whose work focuses solely on research governance and on the rights, safety, and welfare of research participants. Such an organization would be a welcome addition to the research governance landscape of Nigeria. An NGO focused on the rights and welfare of research participants could advocate for the passing of relevant legislation, formulation of policies that take into account the needs of communities in which research takes place, and advocate for practical implementation of legislation and policies. It may educate research participants about their rights and the risks and benefits of participation in

[220] Information obtained from website. The website is currently non-functional but I have the information on file.
[221] Ibid.

research. It could liaise with, and act as a bridge between different stakeholders, some of whom may be primarily involved in conducting or sponsoring research and communities. It may also, as has occurred in South Africa, take legal action to challenge government or sponsors' actions or policies.[222] It may also act as a whistleblower on issues relating to research governance, including obvious cases of conflict of interest, corruption, or government inaction. The Pfizer incident, for example, would have benefited from the presence of such an organization. Such an organization would have kept the matter in the public eye and perhaps it would not have taken as long as it did for participants and their families to receive justice. In short, such an organization could potentially act as a check on the emergence of a lumbering bureaucracy that may lose sight of the main issues, and potentially keep other actors in research governance accountable by different means.

NGOs are nevertheless not completely free of systemic problems that may limit their positive impact on research governance. Concerns about NGOs in Nigeria and other African countries have been raised about their accountability, legitimacy, lack of autonomy, utility, and efficacy.[223] NGOs which ordinarily ought to keep governments accountable have sometimes failed to be accountable themselves. These are important concerns, necessitating a constant reappraisal of any NGOs that eventually fill the current gaps in this area. Yet, there is also evidence that there are

[222] New HIV Vaccine and Microbicide Advocacy Society, online: < http://www.nhvmas-ng.org/> (May 30, 2010).
[223] See Ebenezer Obadare, "Religious NGOs, Civil society and the Quest for a Public Sphere in Nigeria" (2007) 1 African Identities 135; Julie Hearn, "African NGOs: The New Compradors?" (2007) 38:6 Development and Change 1095.

NGOs which live up their responsibilities.[224] Moreover, these concerns do not vitiate the potential usefulness of an organization that can challenge, persuade, and support other institutions involved in research governance.

In any event, it would be impossible and unhelpful to rely completely, or even primarily, on NGOs to provide all that is necessary for effective research governance. This is not their role. Still, given the specific challenges of Nigeria, there is a distinct possibility that NGOs can, as they have on other issues, act as voices for research participants.

6.5 Assessing Nigeria's Governance Arrangements

In Chapter Two, I discussed a number of criteria distilled from various sources that could be used to measure assess whether the goals of research governance are being, or have the potential to be met. The values drawn from various sources in Nigeria, including the National Code, indicate that the goals discussed in that chapter remain the same – the facilitation of socially beneficial research, the maintenance of public trust in research and, most importantly, the protection of the welfare, safety, and rights of research participants. The criteria discussed in that chapter were Clarity, Comprehensiveness, Efficiency, Adequacy, Uniformity, and Simplicity. Through each of these criteria run the criterion of effectiveness (can the current arrangements meet the objectives) and the criterion of legitimacy (do current arrangements emanate from the right authority and do they show the right degree of public participation, transparency

[224] Hearn, ibid.

and accountability). In the specific context of Nigeria, current research governance systems are at an emergent or nascent stage, which makes it difficult to provide a detailed assessment. Even so, the potential for these arrangements to meet these criteria can be assessed, and hopefully will be helpful in addressing any gaps and weaknesses moving forward.

With respect to clarity, the National Code is clear about the roles, responsibilities and rights of stakeholders, to an appreciable degree. Without recounting all that has been already discussed, it will suffice to say that the National Code specifically addresses the roles of ethics review committees at the national and institutional levels, the responsibilities of sponsors and investigators. However, some issues remain. For one thing, until the National Health Bill is signed into law, the clarity provided by the National Code remains in doubt, especially given that other legal instruments have different provisions. For instance, the Code of Medical Ethics requires that there should be ethics review committees at the state level; the National Code requires only institutions in which research is to take place to establish ethics review committees. For another, until the National Health Bill is passed, it is not clear that the National Code can compel state institutions by any consequential means to comply. In addition, it is also not clear, as the Code of Medical Ethics appears to anticipate, that the states have any role in research governance. But while the National Health Bill will provide a national system and promote uniformity, state legislation will aid implementation of the National Code.

Regarding uniformity and adequacy, the National Code provides a considerable degree of uniformity in terms of the ethical standards its sets. The potential consistency that the National Code represents is, to my mind, the strongest feature of the emerging governance system in Nigeria. However, as I have described, there remains an issue of legitimacy and authority because the National Code, as it stands today, is, at best, a policy of the Federal Ministry of Health. That issue (in terms of a statutory basis) will hopefully be addressed when the President assents to the National Health Bill.

Current legal requirements are also inconsistent in some respects. Much of the legal framework in Nigeria arises inadvertently and by inference and implication. Judicial decisions and common law, as I have previously pointed out, are necessarily fragmentary in nature, since issues are decided on a case by case basis. Thus, many important aspects of research governance may not be articulated in the existing law as decided by the courts. In the Nigerian context, where no case specifically on health research involving humans has been decided, the gaps, especially with respect to the structures of governance (such as ethics review) are even more conspicuous. Related to this point, reliance on the common law in the development of research governance would require litigation by parties in Nigeria, which is not as frequent as in most developed countries. It would therefore take a long time, if ever, to develop research governance systems by such means.[225] Some commentators like Cotterell also suggest that the law of torts in the context of Nigeria and other African countries appears to cater more to the needs of the elite rather than poor persons, who are in the majority.

[225] Cotterell, "The Functions of the Law of Torts in Africa" supra note 77 at 182-184.

Without going into the merits of this observation, the necessity for equal protections for every potential research participant in Nigeria requires that a prospective tool, like legislation, be enacted.

There are some varying requirements in other instruments with legal force including the Code of Medical Ethics and the NAFDAC Guidelines. If all existing instruments are enforced strictly, the potential confusion will impede rather than facilitate research, and may hinder the protection of research participants. This will consequently result in a failure to meet the important goals of research governance. This necessitates a more comprehensive framework, such as the one arguably provided by the National Health Bill. However, even if the National Health Bill is signed into law, it would have to make it clear that regulations emanating from the National Health Research Ethics Committee override other regulations. And even after the National Health Bill is signed into law, these instruments would still have to be amended to bring them in line with the National Code. The uniformity of standards and requirements for research governance is still in need of improvement.

The passing of the National Health Bill also affects the National Health Research Ethics Committee's adequacy of independence, resources, and authority to operate. The matter of resources will require close attention and practical solutions, given the history of research governance in Nigeria. In this respect, even if the National Health Bill is passed in its current form, several provisions in the National Code will have to be revisited.

It is too early to determine if the system in place is efficient. In my view, however, efficiency might best be achieved with having fewer instead of more ethics review committees. This may limit costs, thus maintaining sustainability, and consequently, protecting research participants in the long term.

In terms of comprehensiveness, the current research governance arrangements as articulated in the National Code address all health research involving humans in Nigeria, regardless of the funding source and geographical location. There are, however, matters which do not receive consideration which remain important. These include ethical issues such as undue inducement, standard of care, the consent of children and mentally challenged individuals, or accountability issues such as creation of clinical trial registries, or legal issues such as providing sanctions for infractions of certain basic requirements. There are also ethical issues which require a rethink as discussed above, including the approach to privacy, or which are insufficiently addressed, such as conflict of interest. Aside from these, the legal underpinning of the National Code is also a problem in this respect, given varying requirements under other legal instruments which do not have a comprehensive scope.

Regarding equitable distributions of harms and benefits, all the instruments which govern research in Nigeria require fair selection of participants. More generally, if the National Code is properly implemented and is provided legal authority, it will provide equitable benefits and risks for most research participants, with the important exception of children and mentally challenged individuals. It also has the potential to

be efficient if seamless relationships between institutional and national ethics review committees are maintained.

Even in a fledgling democracy such as Nigeria's, legitimacy remains crucial. As Issalys observes, legitimacy or the appropriate derivation of authority has obvious consequences for both effectiveness and efficiency of any mechanism of public intervention.[226] As is clear from the foregoing discussion, major issues remain with regard to legitimacy. This is not only with respect to passing the National Health Bill, although this is an essential part of that legitimacy. In other words, legality and the force of law (and I have explained why this is necessary) is only a part of the necessary legitimacy, in my view. In this respect, there are questions regarding public participation in the processes. At the moment, the National Code can be (and has been) revised by the National Health Research Ethics Committee at will, and without any sort of public consultation or formal consultation with other institutions involved in research governance. The National Health Research Ethics Committee is chosen by the Minister, who has very wide latitude in doing so. There are currently no provisions in any of the instruments requiring an accounting to the government (the National Assembly) of any activities relating to research governance.

With regard to effectiveness, other institutions such as professional associations, research sponsors and universities would have to become active regulating their spheres of authority. This would allow not only a top-down approach from the

[226] Pierre Issalys, "Choosing Among Forms of Public Action: a Question of Legitimacy" in Pearl Eliadas, Margaret Hill & Michael Howlett, *Designing Government: From Instruments to Governance,* (Montreal & Kingston: McGill-Queens University Press, 2005) at 154.

national level, but also a bottom-up approach to the governance of research, allowing a hybrid framework which is potentially more effective. Unfortunately, this has not often been the case because many of these institutions have not been active in regulating research. Further, there are currently no organisations, such as the NGOs suggested here, which might act as checks and thus encourage these institutions to remain accountable. These issues may adversely affect effectiveness. Beyond these matters, practical implementation is crucial for effectiveness. The history of research governance suggests that this, in addition to uniform policies, had been lacking in Nigeria, and requires close attention now.

6.6 Conclusion

The ethical framework of health research involving humans in Nigeria, includes domestic sources that provide ethical values such as the Constitution, the most essential of these values being the fundamental value of the human person in Nigeria. The ethical framework is, however, more specifically articulated in the National Code. It contains a set of ethical principles which are to guide the conduct of health research involving humans.

There are, however, gaps and issues in the National Code that would benefit from a review by the National Health Research Ethics Committee. Moreover, there is room for potential conflict, and confusion, as other documents that provide ethical guidance in Nigeria draw principally from the Helsinki Declaration, which has different requirements in certain respects. This is a situation, however, that could be readily

managed within national systems of governance, and is indeed one of the reasons why a national or domestic system of governance is advocated in this thesis.

A legal framework for research governance exists in Nigeria. But that framework is currently incomplete. The common law is, by its manner of development, deficient. Other aspects of the legal framework which focus squarely on research governance, namely the Code of Medical Ethics and the NAFDAC Clinical Trial Regulations, are limited in scope and applicability. While each instrument is necessary in research governance, neither of these instruments provides comprehensive protections for research participants and complete parameters for researchers and research sponsors. Important aspects of research governance are not provided for, for instance, the composition of ethics review committees. In addition, they do not have uniform requirements in all respects. While it may be argued that each of these instruments provides a form of regulation, there is bound to be confusion for researchers trying to comply with all the requirements, some of which may conflict. Thus, in my view, the narrow remit of the Medical and Dental Council of Nigeria and the Code of Medical Ethics, indicate the need for a more comprehensive, and overriding legislation. The National Health Bill may be argued to be such legislation. However, as I have discussed, there are currently several gaps that need to be remedied.

With respect to the institutional framework, the National Code has articulated requirements for ethics review committees at the institutional level, with a national committee acting as an overseeing authority. There are also other institutions such as NAFDAC, professional associations, research sponsors and research institutions which

regulate research. I have identified issues in the National Code, and contextual and operational systemic issues which have the potential to impact research governance adversely. I have also discussed the need for a non-governmental organization whose work would focus on the protection of research participants.

To conclude, a national research governance system is emerging. There are, however, still issues with respect to clarity, comprehensiveness, uniformity, and adequacy, as well as legitimacy and effectiveness. In the next chapter I make recommendations to improve research governance in Nigeria, taking into consideration the context, analyses and assessments discussed in Chapter Five and this chapter.

Chapter Seven

Moving Forward: Some Recommendations for Research Governance in Nigeria

7.1 Introduction

Nigeria is a developing country with much need for health research. It also has a large population, offering a great potential for researchers and research sponsors. Recently, it has established research governance arrangements to ensure that the rights and welfare of research participants are protected while creating clear parameters for researchers. These recent arrangements, discussed in Chapters Five and Six, may serve as a guide for other developing countries which may be considering establishing research governance structures. The major question in this chapter, therefore, is: How can the emerging governance arrangements in Nigeria be improved and made to work?

It is necessary to begin by acknowledging that Nigeria has taken some laudable steps towards better governance of research. With respect to the political context, the current democratic dispensation in Nigeria is more likely to provide a sustaining environment for research governance. There is likely to be more political interest, interest by other actors, and international assistance, in addressing the continuing need for health research, and for such research to be conducted ethically.

Generally, Nigeria has taken considerable steps, and appears to be on the right track, to establishing a good system which will protect research participants and facilitate research. In this respect, Nigeria has adopted a framework of governance with a strong government role, particularly at the federal level. This is appropriate, given that the federal government, both constitutionally and practically, has the powers, the mandate, and greater resources than other actors, to ensure a good system of governance for health research in the country. However, as I recommend below, the active input of other actors is necessary to ensure effectiveness.

Further, the ethical framework of the National Code and other relevant documents recognise the important values of the fundamental worth of persons in Nigeria (which includes autonomy and respect for persons and the need to protect the wellbeing of persons including research participants), the need for research relationships built on a foundation of trust, and the need to engage with the communities in which research is to take place.

By establishing a national code on ethics at the federal level, a uniform standard appears to be emerging for the entire country with regard to health research sponsored by any organization, public or private, and research conducted in all parts of the country. The creation of a national committee is also a significant achievement. Its functions include providing uniform standards, auditing ethics review committees, and acting as a central ethics review committee registry. There is likelihood that it will provide a more uniform system of governance and better oversight of research than has hitherto been the case. There is also now a greater

potential for delineation of roles and responsibilities, and accountability, than had previously existed. Although this remains a work-in-progress, there is also an emerging recognition of the need for the interaction of the ethical, legal and institutional frameworks in Nigeria.

However, as the discussion in the preceding chapters indicates, several gaps, weaknesses, and potential problems remain. These include problems arising from the Nigerian context such as limited resources, issues arising from the configuration of current arrangements such as different requirements in instruments with varying legal force, and systemic issues such as ensuring adequate accountability. More steps could be taken to provide the emerging system with greater legitimacy and authority. More could also be done to improve the emerging arrangements in terms of comprehensiveness, clarity, uniformity, adequacy, and efficiency, all in an effort to make these arrangements more effective than they currently are. More could also be done by other non-governmental actors to improve governance within their realms of authority.

Below, I make some recommendations to improve the emerging research governance arrangements, in order to ensure better protection of participants, maintain public trust, create clearer parameters for researchers and, consequently, facilitate more research in Nigeria. I make several recommendations below.

In making these recommendations, I take into consideration the findings from the previous discussion of the Nigerian context and history of research governance in Chapter Five, and the potential gaps and weaknesses from the analyses

and assessment in Chapter Six. I have made a number of suggestions in my analyses in Chapter Six, such as adding some sections to the National Code or revising some sections, but I focus here on more macro-level matters. Further, the need for a hybrid framework for developing countries flows through these recommendations because I believe that this will ensure better governance in Nigeria. In this regard, what appears certain is that there is no one magic pill for ensuring functional and effective governance system in Nigeria. As I stated in Chapter Two, in a developing world context like Nigeria, and with Nigeria's peculiar challenges described in Chapter Five, it is necessary to tread the line between the practical and the ideal, the descriptive and the prescriptive, and using what is to achieve what ought to be. In this respect, because of the inherent and operational weaknesses of different actors – the government, research institutions, research sponsors, non-governmental organisations – it is imperative that the strengths of all actors, institutions, and systems are fully utilised. A strong government role (as is becoming apparent in Nigeria), without the accompanying effectiveness of other actors will mean a return to traditional or "old" governance, with all the attendant problems of inflexibility, legalism, unresponsive bureaucracy, and a government with still limited capacity in governance generally. On the other hand, active steps by other actors without a strong government role will result in a non-comprehensive, inconsistent, potentially inadequate, unaccountable and unclear system which may jeopardise research participants' welfare.

Below, then, I suggest several steps to improve the emerging system of research governance in Nigeria. For consistency, I have made recommendations on

the three major components of research governance, that is, the ethical, legal, and institutional frameworks, addressing the potential issues arising from the context, as discussed in Chapter Five, and the gaps and weaknesses identified in Chapter Six.

7.2 Ethical Framework: Revising the National Code

In Chapter Three, I suggested that one way of dealing with the controversial issues that have arisen in the interpretation and application of the international ethical guidelines would be to address such issues in domestic guidelines. The National Code on Health Research Ethics (the National Code), has attempted to do this. But there are still gaps and areas that require a review as I pointed out in Chapter Six. Important ethical issues such as standard of care and undue inducement which have been controversial and the subject of much debate require attention and clarification. Other matters that were addressed inadequately, such as informed consent require more substantive attention. Other gaps such as research with children and the mentally challenged should also be addressed. Gaps in areas requiring clearer guidance, such as privacy, and conflict of interest, require a review. Finally, there is currently no mandatory review period in the National Code. A mandatory review period is necessary to ensure continuous development.

7.3 Legal Framework

7.3.1 Enacting Federal Legislation on Research Governance or Amending the National Health Bill

Earlier in the thesis, I made the case that law in a facilitative, regulative and protective role brings something important to the governance table. More specifically, I have contended that comprehensive legislation is needed for health research involving humans. My arguments for legislation regarding the advantages of comprehensiveness, clarity, accountability, and legitimacy, are applicable to the Nigerian context. Indeed, Nigeria recognises the need for new health legislation, and has developed the *National Health Bill* which includes some specific provisions on health research involving humans. Even the Medical and Dental Council of Nigeria, which regulates medical and dental practitioners, operates under law. The crucial issue, therefore, is not whether law, in the form of formal legislation, might be useful in Nigeria or whether law can be recognized in Nigeria as a crucial part of research governance. This is already acknowledged in the health sphere, as is articulated in the *National Health Bill*, and in other policy spheres.[1] The important question would be how effective legislation might be in Nigeria. In other words, can legislation be effective not merely in theory and on paper but in reality in a fledgling, democratic society like Nigeria?

While it would be an overstatement to say that legislation is frequently effectively enforced in Nigeria, there are certainly instances in which law has been

[1] Legislation has been passed in this democratic dispensation to govern important policy spheres, including most recently, the *Oil and Gas Industry Content Development Act,* the *Pensions Act.*

effective in Nigeria. Drawing from an example in the health sphere, the National Administration for Food and Drug Control in Nigeria (NAFDAC) has made remarkable progress in the war against the sale of counterfeit drugs in Nigeria since 2001.[2] NAFDAC has been aided in this work by the powers granted it under legislation and by political commitment. This suggests that legislation can, and does, work in the Nigeria, and that corruption need not be an insurmountable problem. There is, however, a greater chance of success where there is political commitment.[3] But political commitment and support without the necessary legislative support (for instance, using the example of NAFDAC, legal power to seize counterfeit drugs, to prosecute offenders, and for the courts to impose punishments of fines or imprisonment) would have been insufficient. Thus legislation is necessary.

Given other successes in the health sphere, including in the struggle to eliminate counterfeit drugs, and the equally admirable efforts to provide access to antiretroviral drugs in Nigeria,[4] I am optimistic that the necessary political commitment to implement legislation can be found. Indeed, given the history of research governance in Nigeria discussed in Chapter Five, the priority given to the issue by the government (even if influenced by incidents like the Pfizer incident and

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[2] Owen Dyer, "New Report on Corruption in Health" (2006) 84: 2 Bulletin of the World Health Organisation 84. 12. 24. A I Raufu, "Nigeria Leads Fight Against "Killer" Counterfeit Drugs" (2006) 84:6 Bulletin of the World Health Organization 685. The National Agency for Food and Drug Administration and Control (NAFDAC) "NAFDAC Destroys N10B Fake Drugs in 4 Years" (2006) 1: 10 NAFDAC News 4.

[3] Ibid.

[4] .S. Center for Disease Control and Prevention (CDC), "The Emergency Plan in Nigeria", online: <http://www.cdc.gov/nchstp/od/gap/countries/Nigeria.htm>, (March 2, 2010); Avert, "HIV & AIDS in Nigeria", available at <http://www.avert.org/aids-nigeria.htm> (September 2, 2009).

foreign initiatives) indicates some level of commitment. Without such legislation, however, there would be little point in speaking of enforcement or effectiveness.

It is important to recall that in my hybrid framework, legislation does not displace other components. It does not, for instance, act as a substitute for effective self-regulation by the Medical and Dental Council of Nigeria. It does not replace policymaking structures. It does not detract from the fact that ethics review committees in institutions need to be properly constituted to provide effective review of research protocols. Institutions and research sponsors can still provide their own requirements for ethical research, which may be stricter but not less stringent that the basic standards mandated by law.

What legislation provides is a more authoritative foundation for these other components to function effectively, and a legal system of accountability. It can also clarify the roles of different actors and the legal confines within which research can be undertaken. For instance, one of Pfizer's defenses was that ethics review of research protocols was not a legal requirement in Nigeria at the time of its Trovan trial. One could, of course, argue that this was an ethical requirement as stated in international ethical guidelines, and that Pfizer's stance in employing such a defense was unethical. However, this is a loophole that can easily be plugged by legislative means, consequently protecting research participants in Nigeria from similar unethical research.

Further, beyond the direct benefits of legislation, there are indirect advantages. Legislation provides a potential advocacy tool for institutions like

pressure groups or non-governmental organisations to promote the interests of research participants, to pursue legal actions in court where appropriate and to put pressure on the government. The *National Health Bill* is itself partly a result of advocacy from civil society groups and international aid agencies in Nigeria. Political commitment can, therefore, result from enacting legislation, because it gives other parties an instrument for pressuring the state.

In addition, the history of research governance in Nigeria indicates that sustainability, an important component of effective governance, has been a major concern. At present, both the National Health Research Ethics Committee and the institutional ethics review committees are operating without a legislative mandate, creating doubts about their legitimacy and sustainability. As things stand currently, a new Minister of Health may decide not to establish the National Health Research Committee. But legislation would help to ensure the continued existence of these committees, and impose a legal obligation on any minister of health to constitute the committee. It would also prevent duplication, ensuring that there is clarity on who can constitute such a committee, and that two national committees (as had previously occurred) would not be in operation at the same time.

The varying requirements under different existing subsidiary legislation are another good reason for legislation in Nigeria. Comprehensive legislation, especially one that is specifically focused on health research, would be generally applicable. It would override other subsidiary legislation, and therefore ensure uniform requirements, reducing potential confusion.

The *National Health Bill*, which has just been passed by the National Assembly and which is now only awaiting the President's assent, can be argued to be such legislation, even though it includes other unrelated matters. Very importantly, the National Health Bill provides a legal basis for a National Health Research Committee which determines priorities for health research and advises the Minister of Health. It also provides a legal basis for the National Health Research Ethics Committee, and gives it the power to make guidelines for the conduct of health research in Nigeria.

However, there are several important matters that are not addressed either in the National Health Bill or in the National Code. For instance, the National Health Bill does not contain the basic requirement for ethics review. While the National Code contains such a requirement, there are no sanctions in the Bill for failure to meet such basic requirement, as I suggested in Chapter Three. Nor is there any sanction for failing to obtain informed consent, even though this is the only substantive ethical requirement contained in the National Health Bill. A sanction of fines, at least, would have been appropriate. There is no mandatory requirement for registration of a clinical trial in a clinical trial registry, nor is the creation of a clinical trials registry mandated under the National Health Bill or the National Code. These are basic requirements which demand penal sanctions in the form of fines and imprisonment for failure to comply.

Further, a means for providing resources for the ethics review committees, both at the institutional and national levels, is not provided. There is no provision for

a compensation scheme for research participants. A new law on health research involving humans, or an amendment of the National Health Bill, would thus be necessary to take into account these important elements that are currently lacking.

7.3.2 Establishing Uniform Standards and Requirements

Uniform standards provide participants with the same protections and researchers with clarity about ethical and legal requirements. The National Health Bill or specific legislation on research governance should address the place of other existing instruments, such as the Clinical Trials Regulations, and the Code of Medical Ethics. It could do this by explicitly stating that guidance provided by the National Health Research Ethics Committee overrides other guidance, where there is a conflict. Moreover, it would be appropriate for a harmonization of instruments to occur between the NAFDAC and the National Health Research Ethics Committee, particularly as NAFDAC considers a new set of draft regulations on clinical trials. NAFDAC should also consider amending the draft regulations on clinical trials to reflect the place of the National Code and the NHREC. It would be appropriate for NAFDAC and National Health Research Ethics Committee to come together to address these matters.

7.4 Institutional Framework

7.4.1 A Regional System or Institutional Ethics Review System?

At present, the institutional system of review is operated in Nigeria with a national committee at the top. However, it is important to consider whether a regional system would be more effective. The arguments of Coleman and Bouësseau offer an insight into the need to reconsider the institutional ethics review committee system in African countries. They observe that:

> The structure of the American IRB system is a poor fit for African countries. The IRB system is premised on the importance of "local" review of research (i.e., review in the institution in which the research will take place), as well as a separation between IRBs and the agencies that regulate them. In many African countries, however, institutional-level committees that exist independently of regulatory authorities may lack sufficient legitimacy to be effective. In addition, they may find it difficult to reject research protocols, or to insist on substantial changes that might lead sponsors to reconsider working with the institution, if foreign research is an institution's primary means of financial support. By contrast, a centralized committee housed within a government agency may be in a better position to take strong positions and ensure that those decisions are respected. In addition, creating a single centralized committee is likely to be simpler, and less costly, than attempting to create separate committees at every research institution in the country.[5]

I agree with much of their observation, including the need for a national committee and that such a committee would have greater legitimacy than merely institutional

[5] Coleman, Carl H. and Bousseau, Marie, "Strengthening Local Review of Research in Africa: Is the IRB Model Relevant?" (2006), online: <http://www.bioethicsforum.org/ethics-review-of-medical-research-in-Africa.asp> (June 2, 2010).

committees. Indeed, Nigeria has established such a national committee which provides oversight of institutional ethics review committees – the National Health Research Ethics Committee. Their arguments relating to a single centralized national ethics review committee raise very important issues of conflicts of interest, intricacy, and costs where separate institutions each have committees. However, it seems to me that a centralized national committee may be overburdened with reviewing every single research protocol. What may be more helpful would be retaining a national committee, but perhaps creating fewer regional committees as opposed to many institutional committees.

A regional system of ethics review would situate ethics review committees out of hospitals or universities but provide reviews for research protocols in these institutions. A regional system, as I explained in Chapter Three, has a greater potential to reduce conflict of interest because it is situated outside the institution, which typically is intent on attracting research funds. As previously discussed, such conflict of interest is a serious concern in many countries, but particularly in a resource-limited setting such as Nigeria where institutions are in great need of funding and other benefits that may come with execution of a research project.

A regional committee, by its nature, is also more likely to draw members from the community and from different institutions, further increasing the potential for independence. As discussed in Chapter Five, currently most if not all members of institutional committees in Nigeria are drawn from the institution, and as

discussed in Chapter Six, the provisions of the National Code do not suggest that this is likely to change. A regional committee is more likely to be independent as, by its very definition, members have to be drawn in a region-wide manner. Moreover, the adoption of a regional system could result in less ethics review committees, which in turn would be limit costs, a great concern in a resource-constrained setting like Nigeria.

The Medical and Dental Council of Nigeria's Code of Medical Ethics appears to anticipate the creation of a mixed system of ethics review, with both institutional and state (which can be considered "regional") ethics review committees in operation. The state ethics review committees would review projects with a "state outlook" which appears to mean multisite projects within a state. These would, however, operate on an ad-hoc basis,[6] eliminating the benefits of predictability.

Others like Jegede have suggested the creation of ethics review committees in different local governments. These ethics review committees would be funded by the local government councils.[7] These would also operate like regional ethics review committees since they would be situated outside the institutions. The positive aspect of this suggestion is that such committees would be situated outside institutions and they would include community members, thus reducing the inherent conflict of interest that afflicts institutional ethics review committees. The problematic aspect of this suggestion is that there would be a multiplicity of ethics review committees given that there are currently 776 local government councils in

[6] Section 31(IV) of the *Code of Medical Ethics in Nigeria.*
[7] A S Jegede, "What Led to the Nigerian Boycott of the Polio Vaccination Campaign?" PLoS Med (2007) 4(3): e73

Nigeria. This would potentially increase costs and even variations in the application of standards.

If a regional system were to be adopted, in my opinion, it might be better to consider establishing regional committees along geo-political lines, which would result in six ethics review committees. These would be funded by an independent scheme which I propose a little further below. Alternatively, in line with the federal structure that obtains in Nigeria, a committee could be established in each of the thirty-six states and in the Federal Capital Territory. These committees may be formally affiliated with the state ministries of health, but will be registered with, and audited by, the national committee. Proposals for research projects to be undertaken in any institutions in that state would be submitted to those committees. These would also be funded by the independent scheme. Members would be drawn state-wide, from institutions and from the community.

Even if these suggestions are not accepted, it is necessary to reconsider the institutional system now in place. Membership must be drawn more widely, including members from outside the institution. Institutions must put in place conflict of interest guidelines, which must then be actively implemented.

7.4.2 A Funding Scheme for Ethics Review Committees

It is also important to consider a scheme from which ethics review committees in Nigeria, whether regional, institutional, or national, may be funded.

From the history of ethics review committees in Nigeria and from information obtained from several individuals involved in ethics review in Nigeria, funding for ethics review committees is a major concern. Other studies on developing countries, including African countries, have identified the lack of financial support as a key concern.[8]

Although the National Code requires institutions to support ethics review committees, it is not clear that this will ensure that ethics review committees actually receive the needed resources to do the important work for which they are established. The National Code also permits ethics review committees to charge fees for ethics review. However, this may result in conflicts of interest issues, where an institution places too much reliance on such fees. In any event, even if an ethics review committee charges strictly for the expenses for a specific research project, there will be other ongoing general expenses, including expenses for administrative personnel, maintenance of equipment, and internet access.

As Nwabueze suggests, a central fund into which all research sponsors may pay in may be a good alternative.[9] In the scheme I propose, however, both the federal government and the state government would be required to contribute specific amounts each year. In this way, governments will take greater ownership of the need to protect research participants in Nigeria and curtail complete dependence

[8] See for instance, See Cecilia Milford, Douglas Wassenaar, and Catherine Slack, "Resources and Needs of Research Ethics Committees in Africa: Preparations for HIV Vaccine Trials" (2006) 28: 2 IRB: Ethics & Human Research 1.

[9] Remigius N Nwabueze, "Ethical Review of Research Involving Human Subjects in Nigeria" in Angela Long et al, *The Regulation and Organisation of Research Ethics Review: Report of a Comparative International Workshop Held at the Faculty of Law, University of Toronto, June 16-18, 2005* (Toronto, Canada: Brown Book Company Limited, 2006) at 66.

on foreign support for the operation of the ethics review system. While foreign support of ethics review committees provides necessary assistance in a resource-limited setting like Nigeria, there is no guarantee that such funding will continue in perpetuity. Further, there is also the matter of independence. The perception, if not reality, that regulation and ethics in developing countries like Nigeria, are merely an endeavour funded and determined by foreign entities undermines the independence that is a necessary part of research governance in these countries.

Institutions will also be required to contribute to the fund annually. Foreign programs which support ethics review systems, such as the Fogarty Program in the National Institutes of Health which currently supports different ethics-related programs, may contribute to the scheme. In addition, certain researchers could be exempted from the requirement to pay into this fund, including non-funded researchers and student researchers. This funding scheme would be administered by an independent body which would report to the Federal Minister of Health. This body being separate from the National Health Research Ethics Committee would permit that committee to focus on its oversight functions and reduce the conflict that may arise in exercising the dual functions of auditing Health Research Ethics Committees and funding them. Such a scheme would also be given legal backing in new legislation on research governance or in an amended National Health Bill and any state legislation, thus imposing legal obligations on the parties that must contribute to the scheme.

The major challenge of such a fund lies in implementation, that is, the possibility that such a scheme will be ill-managed. This is a real possibility. However, the alternative (that is, institutions providing ethics review committees with funding), has not been effective. In conversations with several researchers in Nigerian universities, some suggested that the funding problem could only be solved with foreign funding since many institutions would be unable to provide support, given limited resources. This suggestion raises the issue of the degree of independence that can reasonably be exercised under such circumstances. I believe that the scheme I propose may provide not only resources for the ethics review system in Nigeria, but will ensure legitimacy, independence and sustainability, and should, at least, be considered.

7.4.3 Development of Capacity for Ethics Review

Apart from the need for resources, the lack of expertise for ethics review in developing countries like Nigeria has been noted in several studies on ethics review systems in developing countries.[10] The National Code already contains a requirement for the training of ethics review committee members. It is necessary to ensure that such training actually occurs.

In Nigeria, there are few programs which provide training to members of ethics review committees. The main one is the Fogarty-supported West African

[10] See for instance, Milford et al, supra note 5. See also, Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries* (London: Nuffield Council on Bioethics, 2002) at 25.

Bioethics Training Program, which is the approved training program of the National Health Research Ethics Committee, which also runs degree programs in bioethics at the University of Ibadan. The Fogarty program has also supported several scholars in bioethics programs in universities in Canada and the United States.[11] There is also the Nigerian Bioethics Initiative, one of outcomes of the Pan-African Bioethics Initiative (PABIN) founded in 2001 at a workshop organised by the World Health Organisation. It organises multidisciplinary bioethics workshops in Nigeria and participates in African continental and regional bioethics networks.[12]

More programs are necessary. These programs should provide ethics training to researchers and ethics review members. Training must be provided on the regulations in place, including the National Code. Such training could include in-person training by research ethics experts and online courses. It could include the sort of online tutorials offered in countries like Canada,[13] which typically includes case studies which test the principles set out in the regulatory documents. This would be helpful particularly in areas with internet access.

The government must consider sponsoring some of these programs to ensure the development of adequate ethics review capacity in Nigeria. This would be one way of taking greater ownership of its responsibility to preserve the welfare

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[11] Sue Eckstein, "Efforts to Build Capacity in Research Ethics: An Overview" (2004) SciDevnet, online: < http://www.scidev.net/en/middle-east-and-north-africa/policy-briefs/efforts-to-build-capacity-in-research-ethics-an-ov.html> (May 30, 2010). See also, A J Ajuwon, N Kass "Outcome of a Research Ethics Training Workshop among Clinicians and Scientists in a Nigerian University"(2008) 9:1 *BMC Med Ethics*

[12] See PABIN, online: <http://www.pabin.org/home.aspx> (June 1, 2010).

[13] See the Interagency Panel on Research Ethics,*Tri-Council Policy Statement Tutorial* online: <http://www.pre.ethics.gc.ca/english/tutorial/> (June 2, 2010).

of Nigerians, including research participants. While foreign assistance in this area is welcome, government support would also enhance the sustainability of these programs.

7.4.4 Developing Expertise in Ethics and Including an Ethics Component in Medical Schools' Curriculum

In addition to training members of ethics review committees, it is important to include an ethics or bioethics component in the curriculum of medical schools in Nigeria. Anya's observation about the "little more than cursory attention to either clinical or research ethics" in "a single hour-long lecture on ethics and professional practice, delivered close to the final examinations"[14] succinctly captures the need for more thorough bioethics education for medical students. Other students in other fields that may be involved in health research also require more bioethics education. As Anya further points out:

> When ethics is on the curriculum, it has mostly been restricted to a brief overview of clinical ethics, with little mention of issues related to ethical practice in research. Within the nursing profession, the curriculum issued by the Nigerian Nursing and Midwifery Council mentions ethics just once, within the context of quality.[15]

There is currently no requirement for expertise in ethics or bioethics in the membership of both the National Health Research Ethics Committee and the Health

[14] Ike Anya and Rosalind Raine, "Strengthening Clinical and Research Ethics in Nigeria—An Agenda for Change" (2008) 372 Lancet 1594.
[15] Ibid. at 1595.

Research Ethics Committees. The reason may be because there is very little expertise in ethics or bioethics in the country.

It is suggested, therefore, that both the National Universities Commission and the Medical and Dental Council of Nigeria, which regulate medical education in Nigeria, should make ethics a mandatory component of the medical curriculum. Such ethics training must be more thorough and rigorous. The National Code should also be required reading for students in medical schools and in other fields of study which involve health research, including in the social sciences. The West African Bioethics Training Program has recently established a degree program in bioethics at the University of Ibadan.[16] More of such programs are needed in other universities.

7.4.5 Developing Expertise in Regulation and Governance

Apart from developing expertise in ethics, developing better knowledge in other disciplines implicated in research governance, including law, policy analysis, regulatory theory and practice, and governance, is important. Persons involved in research governance, including in the NHREC and NAFDAC should be provided with training in these areas and exposure to the research governance systems of other countries. This may include courses in foreign universities or training provided in Nigeria with experts from around the world.

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[16] West African Bioethics Training Program supported MSc, MPhil/PhD program in Bioethics at the University of Ibadan, online: <http://www.westafricanbioethics.net/wabcms/index.php?option=com_content&task=view&id=14&Itemid=60> (May 30, 2010).

7.4.6 Enhancing Transparency, Public Participation, and Accountability

The hybrid framework of governance includes important components drawn from the concept of good governance and the new governance, including transparency, participatory, reflexive and inclusive processes, responsiveness, accountability, and public awareness and engagement.[17] Enhancing transparency requires clarity of roles, responsibilities, and processes. As things stand currently, the National Code can be revised without any public or even stakeholder input. This jeopardises transparency and puts power into the hands of few people with no checks. It is also worrisome that the Minister has wide latitude in choosing the persons who serve on the National Health Research Ethics Committee.

It is suggested therefore that public consultations would be helpful in any revisions of important policy documents such as the National Code. The provisions of the National Code should therefore be revised to accommodate greater public consultation.[18] Such consultations should also be announced in newspapers and in other media to ensure wide coverage.

In addition, the National Health Research Ethics Committee should provide annual reports of its activities on its website, as well as any policies developed. Currently, there are no public records of health research. As Ogundiran has pointed out, the absence of directories of research activities in African countries

[17] See generally, Victoria Armstrong et al, "Public Perspectives on the Governance of Biomedical Research: A Qualitative Study in a Deliberative Context" (United Kingdom: Wellcome Trust, 2007).
[18] There is precedent for public consultations in drafting regulations. For instance, the draft Good Clinical Practice Regulations drawn up by NAFDAC were put up on its website for a public consultation.

like Nigeria tends to minimize the amount of research that is actually conducted.[19] Such directories in the Nigerian context would provide policymakers and research sponsors with information about existing gaps. It is necessary to create a clinical trial registry and a registry for other ongoing health research projects to encourage transparency and accountability.[20] With respect to clinical trials, "The virtue of [a requirement of registration in a clinical trial registry] notes Macklin, "is that it makes transparent just which clinical trials fail to reach a successful conclusion, either because of demonstrated lack of safety or absence of efficacy."[21] Such records will also encourage access to important information and assist researchers in identifying potential problems and weaknesses in the research governance system which could then be addressed. I have suggested that the creation of such clinical trial registry and the requirement for registration of trials should be provided in any legislation on research governance. Alternatively, mandating registration in a regional registry such as the Pan-African Clinical Trials Registry[22] may suffice.

Transparency also means avoiding any semblance or perception of conflict of interest and maintaining the integrity and independence of the review process. This is particularly important if institutional committees are retained. Transparency includes creating specific provisions addressing conflicts of interest in the National Code, as I discussed in Chapter Five. Such provisions should include a

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[19] Temidayo O Ogundiran, "Enhancing the African Bioethics Initiative" (2004) 4 BMC Medical Education 21.

[20] An example of a domestic clinical trials registry is the South African registry. See South African National Clinical Trials Register, online: <http://www.sanctr.gov.za/> (July 28, 2010).

[21] Ruth Macklin, "The Declaration of Helsinki: Another Revision" (2009) 6:1 Indian Journal of Medical Ethics 2 at 3.

[22] Pan-African Clinical Trials Registry, online: <http://www.pactr.org/> (July 28, 2010).

clear definition of conflict of interest. It should address both institutional and members' potential conflict of interest. It should address potentially problematic situations such as how reviews should be conducted when an institution (if institutional committees are retained) has previously accepted a major donation from a research sponsor (such as the donation of a clinical trial centre), which subsequently seeks to conduct research in the institution. In such circumstances, the National Health Research Ethics Committee may perform the review, or the National Code may preclude institutional administrators from participating in ethics review. The National Code should also address an existing lacuna in the current provisions by stating clearly what happens in cases where members declare a potential conflict of interest at the time of registration with the National Committee. It should require institutions to put in place conflict of interest policies. It should also state clearly the penalties for non-compliance with the conflict of interest provisions.

Transparency, inclusion, and responsiveness also require drawing members of national committees and programs widely. For instance, it may raise the spectre of conflict of interest where members of the National Health Research Ethics Committee run training programs which typically require institutions or members of ethics review committees to pay fees for such training. There should be a clear separation of functions such that members of the National Health Research Committee cannot serve in other roles which may suggest a conflict of interest. I have already suggested in Chapter Six that the conflicts of interest provisions in the National Code need to be revised.

Similarly, it is crucial that the membership of the National Health Research Ethics Committees which is determined by the Minister of Health should be drawn broadly and with all attention to the need for transparency, accountability, participation, and effectiveness. It is suggested that nominations should be drawn from different stakeholder groups in appointing members of the National Health Research Ethics Committee and that the National Health Bill be amended accordingly. Members of institutional ethics review committees (if regional committees are not adopted) must also include members drawn from outside the institution to enhance transparency and limit any potential conflict of interest.

7.4.7 Ensuring a Grassroots and Broad-based Spread of Governance Efforts

At the moment, much of the initiatives appear to be focused at the national level. The National Health Research Ethics Committee appears to be functioning and it has a website (although it has not been updated in a year).[23] These initiatives must, however, filter down to the institutional level (or the regional level if that is adopted) in order to be effective.

In addition, any initiatives must target not only a few institutions (or regions) but must encompass a broad spectrum of institutions. From my research, certain institutions, in particular the University of Ibadan, the West African Bioethics Institute, the Nigerian Institute of Medical Research, have also been at the forefront

[23] NHREC, online: <http://www.nhrec.net/nhrec/> (July 28, 2010).

in the emerging governance system.[24] This is understandable, given that much externally sponsored research is undertaken in these institutions.[25] Furthermore, many persons who have been crucial to research ethics development in Nigeria work in these institutions.[26] It is important, however, that governance efforts are spread throughout the country, and that more institutions (if the institutional system is continued) are engaged actively in the process. This would mean drawing membership of national committees broadly around the country. It would also entail site visits by the National Health Research Ethics Committee.

It also requires ensuring greater public awareness of the rights of research participants, and education about the potential benefits and risks of research and the regulatory roles and responsibilities of ethics review committees, NAFDAC, and other regulatory bodies. This information will build public confidence and trust, and allay anxieties about the research enterprise, which may in turn help to facilitate research. Such information is still lacking.

Moreover, for the governance system to retain a hybrid flavor, it is important that other actors in addition to institutions and government are involved in the process. I focus on this below.

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[24] See for instance, Adeyinka G Falusi, Olufunmilayo I. Olopade and Christopher O. Olapade, "Establishment of a Standing Ethics/Institutional Review Board in a Nigerian University: A Blueprint for Developing Countries" (2007) Journal of Empirical Research on Human Research Ethics 21; Adefolarin O. Malomo et al, "The Nigeria Experience" (2009) 6:4 Journal of Academic Ethics 305.

[25] Ibid.

[26] Ibid.

7.4.8 Strengthening NAFDAC

NAFDAC has been lauded for its war against the sale of counterfeit drugs in Nigeria. It must now devote greater attention to its role in regulating clinical trials in Nigeria, which is one of its legal responsibilities.

As discussed in Chapter Six, NAFDAC currently lacks trained personnel among other things. Particularly in this era of globalisation of clinical trials, it is necessary that the Nigerian government invest more resources into addressing these inadequacies in NAFDAC to ensure greater regulatory effectiveness and better protection of research participants. Such resources could be devoted to training personnel, monitoring trial sites, maintaining records and clinical trial data submitted by research sponsors, providing up-to-date information on ongoing clinical trials, and other related activities.

Maintaining open channels of communication between NAFDAC and the National Health Research Ethics Committee is also crucial. As discussed above, it is essential for purposes of clarity that regulations developed by NAFDAC on clinical trials should not diverge significantly from guidance provided by the National Health Research Ethics Committee. NAFDAC must ensure that it utilises only health research ethics committees registered with the National Health Research Ethics Committee. These matters will require communication and an ongoing relationship between the two bodies.

7.4.9 Clarifying Roles in Policy-Making

In addition, it is important to define clearly the remit of the different policy structures that are currently emerging. As discussed in Chapter Five, one of the problems in the functioning of the health system has been duplication and lack of clarity of the responsibilities of different sectors and actors. It is crucial, therefore, that policymaking structures have clearly defined authority. It should be clear, for instance, that the National Health Research Committee (which defines and addresses priorities in health research) does not interfere with the work of the National Health Research Ethics Committees. The National Health Bill defines the remit of these bodies and should be strictly complied with. Both committees report to the Federal Minister of Health. The Federal Ministry of Health must, however, not interfere with the functioning of these committees.

More importantly, with the ongoing discussions regarding the creation of a National Bioethics Committee, consideration must be given to the possibility of overlap and duplication of functions as well as to costs.

7.4.10 Active Involvement of Professional Associations, Universities, and Research Sponsors

Professional associations in Nigeria have a legal and ethical duty to act in the public interest. This requires becoming more active in research governance efforts. Self-regulation is a crucial component of the hybrid framework of governance advocated in this thesis. In this regard, professional associations should

educate their members on the necessity for ethical conduct in research. Statutory councils must be prepared to investigate and penalize members found to have breached codes of conduct in relation to health research involving humans. They can also act as a check on the powers of government with respect to the governance of health research.

In the specific case of the Medical and Dental Council, it would be appropriate to revisit the Code of Medical Ethics in Nigeria to bring it in line with national requirements, for instance, with respect to the requirements of informed consent and the requirements of ethics review. It should also revise the code to ensure that the sanctions for ethical misconduct in biomedical research are clear. Furthermore, it should address other issues not currently covered by the code, especially the issue of conflict of interest. It should also create more public awareness of the code, the rights of patients and research participants, and the duties of medical and dental practitioners.

The Medical and Dental Council of Nigeria and the Nigerian Medical Association should also participate actively in efforts to govern health by providing its input on research ethics policies to the National Health Research Ethics Committee and to the Minister of Health. In this respect, it could bring more balance to regulatory efforts. The Council, and other professional associations involved in health research involving humans, such as the Nursing and Midwifery Council and the Nigerian Anthropological-Sociological Association, should adopt the National Code, require their members to comply with it, and participate in policymaking.

Federal universities, state universities, and research institutes will need to comply with legislation and policies on health research. Even if a regional system of ethics review is adopted, it will still be necessary that these institutions become more actively involved in research governance by developing internal policies. Privately owned universities must likewise commit to the regulation of health research within their realms of authority. Universities must require an extensive study of, and engagement with regulation, governance and ethics in health research-related fields. Moreover, it would be helpful for universities to contribute to the policymaking efforts of the national committees by providing comments on new and impending policies.

Research sponsors, domestic and external, will, in all probability, continue to regulate how research funded by them should be conducted. But they must seek information on regulatory requirements in the developing countries in which they sponsor research. And they must ensure that any agreements or guidelines do not conflict with domestic laws and policies.

7.4.11 Development of Non-Governmental Organisations

I have argued in previous chapters that a non-governmental organisation focused on the rights and welfare of research participants may contribute positively in keeping other actors involved in research governance accountable. This does not suggest that these organisations are always wholly free of problems, including problems relating to accountability and effectiveness. But there is a role for external

actors such as NGOs to help keep other actors accountable, provide a voice for research participants, and provide surveillance over Nigeria's research governance landscape. The integration of such organisation in the research governance system will keep it from being a strict top-down arrangement and draw on the advantages of a hybrid framework in a fragile political and economic environment. Currently, no NGOs focusing on research governance exist in Nigeria. It would be helpful and beneficial for the emerging research governance system in Nigeria if that vacuum was filled.

Such organisation would educate and engage with communities in which health research is to be conducted and educate potential research participants about their rights and obligations in health research, participate in policymaking by making representations to the National Health Research Ethics Committees, and act as a whistleblower should concerns arise about a study or the conduct of a regulatory body.

7.5 Conclusion

The above suggestions will, hopefully, improve research governance in Nigeria. Practical implementation is, however, crucial for the success of emerging governance efforts. The Nigerian government, and other actors such as universities, research sponsors, researchers, and any interested NGOs, must implement, and comply with any legislation and policies made.

Assistance from international sources remains helpful, but such assistance must also respect the domestic policies and the need for the development of a domestic system of research governance. The Nigerian government must take greater ownership of, and invest in, research governance in Nigeria by devoting resources to this very important policy matter, and bringing pending efforts in this regard to fruition. A periodic assessment of the research governance system is also necessary to ensure its smooth functioning and to identify and address problems as they arise.

The need to protect research participants and prevent unethical conduct of health research involving humans, which has occurred in Nigeria in the past, require all actors in research governance to take the necessary steps.

Chapter Eight

Conclusion

The ethics of health research conducted in developing countries has been, and continues to be, a topical issue. Concern about the welfare of participants in research particularly in the resource-limited circumstances of many developing countries, the arguably increased vulnerability of research participants in these countries, and the potential for exploitation has generated much discussion. The economic disparities between developed and developing countries, the impact of such disparities on global health, and on the continuing need for research in these countries is likely to continue to draw attention from researchers. However, although much of the literature has focused on the ethical issues, this thesis has emphasised the need for an expanded focus which would include the emerging governance and regulatory systems in developing countries. Most literature in the past has pointed out the regulatory vacuum that exists in developing countries with respect to regulating health research involving humans. But several developing countries have recently put, or are in the process of putting in place, regulatory mechanisms to protect research participants.

These recent developments need to be understood, especially because other developing countries may seek to consider, and perhaps even replicate these systems. In addition, any gaps and weaknesses may be corrected in these early stages. Domestic governance systems also allow developing countries to take greater ownership of the protection of participants in health research, whether

domestically or internationally sponsored. I have argued in the preceding chapters that, while international research governance efforts are important, developing countries need to address research governance domestically. Issues of implementation and enforcement, among other reasons, make it necessary for developing countries to set up domestic systems of research governance.

The aim of this thesis has therefore been to present a comprehensive and systemic approach to the governance and regulation of health research involving humans in developing countries. It has focused on Nigeria as an example of a developing country which has taken recent steps to regulate health research involving humans.

To assist my analysis in this thesis I adopted the analytical framework of governance. Governance, generally speaking, takes a systems approach, permitting the discussion of steering or managing of activities in terms of the interrelated components of that activity including the values, institutions, organisations, processes, and goals. Further, it recognises the institutions within a system and all the actors in the policy field, including those being regulated, as potentially active actors in the governance process. Governance is about achieving goals and objectives through positive and negative control.

To achieve the aim of presenting a comprehensive and systemic approach to the regulation of health research involving humans in developing countries, I employed a hybrid framework of governance, which drew from the different understandings of governance – generic, "good" "sustainable" "traditional," "new" –

and from regulatory theory. My hybrid framework of governance recognises that the state is a crucial actor in research governance, being the major source of formal law, but that other actors, including private actors, are also essential in research governance. Thus, the framework requires the active involvement of the state and the complementary in-put from other sectors such as civil society and non-governmental organizations. In discussing the analytic framework, I described the main goals of research governance, namely the promotion of socially beneficial research and the protection of research participants (and by extension communities, and the public trust). I also established nine criteria by which a research governance system may be measured. While this framework has its limitations and may not apply equally in all settings and policy spheres, a hybrid framework that adopts a generic understanding of governance to which both traditional and new governance approaches contribute their strengths, harnesses the synergies of different actors and institutions, and takes into account the political and socioeconomic contexts may be a strong framework for research governance in developing countries like Nigeria. This framework, in my opinion, is useful both to understand and to critically grapple with the governance of health research in developing countries. It is also forward-looking and helpful for countries seeking to develop and improve systems of governance. The breadth of the framework offers a macro perspective rather than a detailed analysis of specific legal or ethical issues, and is suited to the specific purposes of this thesis.

This framework in mind, I have addressed different components of research governance, dividing the mechanisms, institutions and processes, into the

legal, ethical and institutional frameworks. I have considered national and international ethics guidelines; professional associations and codes of conduct; ethics review committees; national regulatory bodies such as the ones which regulate pharmaceutical production and the use of human participants, departments of health (of which the drug regulatory agency may be a part); civil society, including non-governmental organizations which promote patients' rights; the general public, research participants themselves, and the interactions between these entities. I have also considered the potentially beneficial role that law can play in research governance systems, arguing that comprehensive legislation regulating health research involving humans is essential in developing countries.

To undertake more specific analysis, I focused on Nigeria, a developing country in Africa, as a case study. Nigeria has taken some positive steps in recent years towards developing a national system of research governance. Other developing countries with the same challenges as Nigeria may examine its emerging research governance arrangements for useful lessons. I have described the context in which these emerging governance arrangements will operate. I have also provided a history of research governance in Nigeria, highlighting specific issues that need to be addressed as Nigeria moves forward in implementing the emerging governance arrangements. The history of research governance in Nigeria includes instances of unethical conduct of research in the country which make effective research regulation imperative.

I have engaged in a detailed analysis of current research arrangements in Nigeria, identifying areas that need to be improved in relation to, inter alia, comprehensiveness, legitimacy, uniformity, clarity, and adequacy. I have also made recommendations, arising from the research findings, that may be helpful in ensuring the effectiveness of the governance arrangements with respect to protecting research participants, protecting public confidence in the research enterprise and facilitating research. These recommendations require the active input of all actors in research governance, including the government, professional associations, research sponsors, and non-state actors.

Finally, the aim of this thesis was to address health research involving humans in developing countries from a governance perspective, including the role of the law in research governance. It is hoped that this thesis will encourage other efforts to analyse the emerging governance systems in developing countries. More empirical and qualitative research is needed to identify areas and means of improvement. A consideration of the role of law in the emerging governance arrangements of developing countries is also necessary. It is hoped that more research will assist in the development of robust and effective research governance systems in developing countries, provide information to regulators in various countries and, most importantly, promote the protection of research participants in those countries.

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