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Jocelyn Downie

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Information/Consent/Authorization for Minors' Participation in Research

Jocelyn Downie

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1 Following the workshop described in the previous article "Children and Decision-Making in Health Research," I decided to "operationalize" the approach taken to the issue of minors and consent/authorization. What follows is a proposed set of instructions for investigators that could be provided by REBs to investigators to facilitate the process of applying for ethical approval for research involving minors and to ensure respect for minors who are participating in research.

Instructions for Investigators

I. Preamble

2 Research involving minors raises a number of challenges. One of the most difficult of these (morally, legally, and pragmatically) is how to involve children in decisions about research participation. There is no standard approach taken to this issue in Canada and some investigators only seek authorization from parents or guardians of minors, others seek authorization from parents or guardians as well as assent from minors, still others seek consent from mature minors. In an effort to respond to this challenge and to establish a standard approach to be taken by all investigators in the institution, the REB has adopted the following instructions for presenting a research project for ethical approval.

II. Definitions

"minor" - under the age of majority

"mature minor" - a minor capable of understanding the nature and consequences of the decision to participate in the particular research protocol

"sufficient decisional capacity" - the capacity of an adult considered capable of making the decision to participate in the particular research protocol

III. Information Sheets And Consent/Authorization Forms

3 The following information sheets and consent/authorization forms are required when the following categories of minors may be involved in the research:

1. For minors with no language comprehension and no decisional capacity
 - information sheet directed to the minor's parent/legal guardian
 - authorization form to be signed by the parent/legal guardian
2. For minors with some language comprehension and no or some decisional capacity
 - information sheet directed to the minor's parent/legal guardian
 - authorization form to be signed by the parent/legal guardian

- statement on authorization form (just before the signatures) to the effect that the research has been explained to the minor in a manner appropriate for his/her level of understanding

3. For minors with good language comprehension and sufficient decisional capacity

a. In General

- information sheet directed to the minor and parent
- consent form to be signed by the minor
- authorization form to be signed by parent/legal guardian

b. Exceptions

4 In circumstances in which a case has been made successfully to the REB for making an exception to the general rule (i.e., where the minor does not wish the parent/legal guardian involved or the parent/legal guardian is opposed to the research participation and where the parent/legal guardian's signature is not legally required for participation and the parent/legal guardian's participation is not required as a participant in the trial or as a facilitator of the minor's participation):

- information sheet directed to the minor
- consent form to be signed by the minor

IV. Research Summary

5 For research involving minors, the investigator(s) must address the following issues in the research summary:

1. Competency

6 Briefly describe the process for assessing the language comprehension and decisional-capacity of the minors

2. Consent/Authorization

7 Describe the process for informing the parents and/or the minors about the research (i.e., who will be told what and from whom consent/authorization will be sought)

- follow the process set out in the instructions re:
information sheets and consent/authorization forms

- Describe the process for dealing with an immature minor protesting to the research

- the research should not proceed if the minor protests and an unfavourable harm/benefit ratio would result from involuntary participation in the research

8 Describe the process for dealing with absence of parent/legal guardian and disagreement between a mature minor and parent/legal guardian

- if the mature minor does not wish to participate and the parent/legal guardian wishes the mature minor to participate, then the mature minor should not be enrolled in the trial

- if the mature minor wishes to participate and the parent/legal guardian's signature is not available (either because the minor does not wish the parent/legal guardian involved or because the parent/legal guardian is opposed to the research participation) and where the parent/legal guardian's signature is legally required for participation and/or the parent/legal guardian's participation is required (as a participant in the trial or as a facilitator of the child's participation, for example, driving the minor to the Health Centre), then the minor should not be enrolled in the trial.

- if the mature minor wishes to participate and the parent/legal guardian's signature is not available (either because the minor does not wish the parent/legal guardian involved or because the parent/legal guardian is opposed to the research participation) and where the parent/legal guardian's signature is not legally required for participation and the parent/legal guardian's participation is not required (as a participant in the trial or as a facilitator of the child's participation, for example, driving the minor to the Health Centre), then the researcher should make the case for enrollment of the minor without parental information or authorization and the REB will make a case-by-case assessment (this assessment will be made with reference to, for example, the potential harms of the research, the potential benefits of the research, the potential harms of parental involvement, and the potential harms of parental exclusion).

- Use forms that are specific to the appropriate decision-maker (i.e., not "you/your child")

3. Confidentiality

9 Describe what information will be given to the parents/legal guardians and what will be kept from them even when they are involved in the decision-making process re: research participation (e.g., pregnancy test results where pregnancy is an exclusion criterion).

10 Describe the process for ensuring that such information will not be inadvertently given to the parents/legal guardians.

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