Chapter 4.2: Children and young people

Introduction

Research involving children and young people raises particular ethical concerns about:

- their capacity to understand what the research entails, and therefore whether their consent to participate is sufficient for their participation;
- their possible coercion by parents, peers, researchers or others to participate in research; and
- conflicting values and interests of parents and children.

These considerations apply to all research involving children and young people. However, they assume special prominence in educational and health research, where there are particular tensions between not placing children at risk in studies of new interventions and the need for knowledge about how such interventions are best used for children.

Researchers must respect the developing capacity of children and young people to be involved in decisions about participation in research. The child or young person’s particular level of maturity has implications for whether his or her consent is necessary and/or sufficient to authorise participation. Different levels of maturity and of the corresponding capacity to be involved in the decision include:

- a. infants, who are unable to take part in discussion about the research and its effects;
- b. young children, who are able to understand some relevant information and take part in limited discussion about the research, but whose consent is not required;
- c. young people of developing maturity, who are able to understand the relevant information but whose relative immaturity means that they remain vulnerable. The consent of these young people is required, but is not sufficient to authorise research; and
- d. young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian.

It is not possible to attach fixed ages to each level – they vary from child to child. Moreover, a child or young person may at the one time be at different levels for different research projects, depending on the kind and complexity of the research. Being responsive to developmental levels is important not only for judging when children or young people are able to give their consent for research: even young children with very limited cognitive capacity should be engaged at their level in discussion about the research and its likely outcomes.

Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement. The guidelines and headings below show how those values, principles and themes apply specifically in research that is the subject of this chapter.

Guidelines

Research merit and integrity

4.2.1 The research and its methods should be appropriate for the children or young people participating in the research.

4.2.2 In the research design researchers should:

- a. specify how they will judge the child’s vulnerability and capacity to consent to participation in research;
- b. describe the form of proposed discussions with children about the research and its effects, at their level of comprehension; and
- c. demonstrate that the requirements of this chapter will be satisfied.

4.2.3 In educational research, discussion with the school community should be built into the research design.

Justice

4.2.4 When children and young people are not of sufficient maturity to consent to participation in research, it is justifiable to involve them only
when:
   a. it is likely to advance knowledge about the health or welfare of, or other matters relevant to, children and young people; or
   b. children's or young people's participation is indispensable to the conduct of the research.

**Beneficence**

4.2.5 The circumstances in which the research is conducted should provide for the child or young person's safety, emotional and psychological security, and wellbeing.

**Respect**

4.2.6 Researchers should be attentive to the developmental level of children and young people when engaging them in understanding the nature and likely outcomes of research, and when judging their capacity to consent to the research.

4.2.7 Except in the circumstances described in paragraphs 4.2.10 and 4.2.11, specific consent to a child's or young person's participation in each research project should be obtained from:
   a. the child or young person whenever he or she has the capacity to make this decision; and
   b. either
      i. one parent, except when, in the opinion of the review body, the risks involved in a child’s participation require the consent of both parents; or where applicable
      ii. the guardian or other primary care giver, or any organisation or person required by law.

4.2.8 An ethical review body may approve research to which only the young person consents if it is satisfied that he or she is mature enough to understand and consent, and not vulnerable through immaturity in ways that would warrant additional consent from a parent or guardian.

4.2.9 A review body may also approve research to which only the young person consents if it is satisfied that:
   a. he or she is mature enough to understand the relevant information and to give consent, although vulnerable because of relative immaturity in other respects;
   b. the research involves no more than low risk (see paragraph 2.1.6);
   c. the research aims to benefit the category of children or young people to which this participant belongs; and
   d. either:
      i. the young person is estranged or separated from parents or guardian, and provision is made to protect the young person’s safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5). (In this case, although the child’s circumstances may mean he or she is at some risk, for example because of being homeless, the research itself must still be low risk); or
      ii. it would be contrary to the best interests of the young person to seek consent from the parents, and provision is made to protect the young person's safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5).

**Standing parental consent**

4.2.10 'Standing parental consent' enables parents to give standing consent (for example at the beginning of each school year) to their child’s involvement in certain types of research in the school setting during that year. Under standing consent, parents are notified of each project, but are not required to give further consent for each project. They should be reminded with each notification that they may withdraw their consent for that project, and also may withdraw their standing consent at any time.

4.2.11 Schools may arrange for standing parental consent to be given for a child's participation in research that:
   a. is for the benefit of children; and
   b. comprises no more than overt observation in school classrooms or anonymous or coded (potentially identifiable) questionnaires or surveys on subject matters not involving sensitive personal information or personal or family relationships.

4.2.12 For any other research, except under the conditions described in paragraphs 4.2.8 and 4.2.9, specific parental consent is needed for each project.

**Best interests of the child**

4.2.13 Before including a child or young person in research, researchers must establish that there is no reason to believe that such participation is contrary to that child’s or young person’s best interest.

4.2.14 A child or young person's refusal to participate in research should be respected wherever he or she has the capacity to give consent to that same research (see levels of maturity (C) and (D) in the Introduction to this chapter). Where a child or young person lacks this capacity, his or her refusal may be overridden by the parents' judgement as to what is in the child’s best interest.