

Children's
Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board

Policy Number: IRB-20

Effective Date: June 20, 2005

POLICY TITLE:

PARENTAL PERMISSION AND CHILD ASSENT

POLICY:

When children are involved as research participants, permission for the child to take part in the research activity is obtained from the child's parents or legal guardian. In addition, the assent of the child shall be obtained when in the judgment of the IRB the children are capable of providing assent.

DEFINITIONS:

"Children" are persons who have not attained the legal age for consent to treatment or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.402 (a)].

"Assent" means a child's affirmative agreement to take part in research. Mere failure to object, absent affirmative agreement, is not to be construed as assent [45 CFR 46.402 (b)].

"Permission" means the agreement of parent(s) or guardian of the child or ward to take part in the research [45 CFR 46.402 (c)].

"Parent" means a child's biological or adoptive parent [45 CFR 46.402 (d)].

"Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care [45 CFR 46.402 (e)].

PROCEDURE:

Parental permission

20.1 Permission from the child's parent or legally authorized representative is required for the participation of children involved in research.

- 20.2 The permission of one parent is sufficient when the research involves minimal risk to the child (45 CFR 46.404 and 21 CFR 50.51) or the research involves greater than minimal risk but offers the prospect of direct benefit to the child (45 CFR 46.405 and 21 CFR 50.52). [45 CFR 46.408 (b) and 21 CFR 50.55 (e) (2)].
- 20.3 The permission of both parents is required when the research involves greater than minimal risk and no prospect of direct benefit to the child but the research is likely to yield generalizable knowledge about the child's disorder or condition (45 CFR 46.406 and 21 CFR 50.53). However, if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has legal responsibility for the care and custody of the child, then the child may be enrolled in this category of research activity with the permission of one parent [45 CFR 46.408 (b) and 21 CFR 50.55 (e) (2)].
- 20.4 For research activities involving children that fall into the category of research not otherwise approvable which present an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children, the research may be forwarded to the designated federal officials for review under the regulations 45 CFR 46.407 and 21 CFR 50.54. If approved, the permission of both parents is required when enrolling children in research activities conducted under 45 CFR 46.407 or 21 CFR 50.54, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has legal responsibility for the care and custody of the child, then the child may be enrolled in this category of research activity with the permission of one parent [45 CFR 46.408 (b) and 21 CFR 50.55 (e) (2)].
- 20.5 The term "not reasonably available" applies to situations when it is not possible with reasonable efforts to contact the parent, e.g., when the second parent is stationed overseas in military service, or the whereabouts and contact information for the second parent are not known to the first parent. "Not reasonably available" would not apply in situations when the second parent is on a business trip, or the second parent is at work.
- 20.6 Permission of parents or the child's legally authorized representative is documented by having the parent(s) or legal guardian sign and date the written consent form after the research has been explained to them and their questions answered. [45 CFR 46.408(d) and 21 CFR 50.55 (f)].
- 20.7 The requirement to obtain the permission of parents to enroll children in research is based on the underlying presumption that parents are acting in the best interest of their children and that parental permission provides protections to children who are considered a vulnerable research population.

20.8 The federal regulations [45 CFR 46.408 (c)] allow the IRB to waive the requirement for obtaining parental permission when it is not a reasonable requirement to protect the child, as in the example of research involving abused or neglected children. When the IRB determines that parental permission is not a reasonable requirement for protecting the child, the IRB shall require the researcher to provide an alternative mechanism to substitute for parental permission. In most cases, this would involve the appointment of advocates who have appropriate experience and training.

20.9 Any such waiver of parental permission as described in 20.8 must be consistent with Federal, State, and local law.

Assent

20.10 The ethical principle of respect for persons applies to children involved in research. Under this principle, the developing decision making capacity of the child is respected by the process of obtaining informed assent.

20.11 When determining whether children are capable of providing assent to take part in a research activity, the IRB will take into account the age, maturity, physical and psychological state of the children to be involved in the proposed research. The IRB may make the determination for all children to be enrolled or if it deems appropriate, for each child on a case by case basis. [45 CFR 46.408 (a) and 21 CFR 50.55 (b)].

20.12 The IRB may determine that assent is not required if the capability of some or all of the children is so limited they cannot reasonably be consulted or the research holds out the prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research. [45 CFR 46.408 (a) and 21 CFR 50.55 (c) (1) and (2)].

20.13 As a general rule, Children's IRB will require assent from all adolescents 14 – 17 years of age when enrolled in research that holds out the prospect of direct benefit that is important to their health and well-being and the treatment or intervention offered is available only in the context of research, even though waiver of assent is allowed under the federal regulations (item 20.12). This general rule is based on the acknowledgement that by age 14 most adolescents have acquired adult decision making capacity and not seeking assent would be contrary to the ethical principle of respect for persons.

20.14 The IRB may waive the requirement for assent in accordance with 45 CFR 46.408(a) and 21 CFR 50.55 (d). The IRB must determine that the research involves no more than minimal risk; the waiver will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver; and when appropriate, research participants

will be provided with additional, pertinent information after participation.

- 20.15 When the IRB requires assent for children to take part in research, the child's decision is binding and must be respected by the researchers and parents.
- 20.16 When the IRB requires assent for children, as a general rule the IRB requests that parental permission be sought first and only after parental permission is obtained, that the assent of the child is sought.
- 20.17 When the IRB determines that the assent of a child is required, it will also determine that the provisions for obtaining and documenting assent are adequate [45 CFR 46.408 (e) and 21 CFR 50.55 (g)].
- 20.18 In general the IRB applies the rule of seven in determining the requirements for documenting assent. For children under 7 years of age, no written assent is required. The IRB will still expect the researcher to explain to the child what is happening. The IRB may request the researchers develop an oral assent script to be read to children under 7 years of age or use the simple written assent form to read to the children. For children 7-13 years of age, the IRB will ask for written assent to be documented in a simple, written assent form. Adolescents 14-17 years of age may indicate written assent by signing the consent form approved for the research, which is co-signed by their parent(s) or legal guardian.
- 20.19 The IRB has developed a sample assent form template for researchers to use in developing a simple written assent form for 7-13 year old children. Appendix 13.A. The assent template outlines the basic information the IRB expects researchers to provide to the children during the assent process. The assent form must be written in age appropriate language and generally at a reading level of 2nd -3rd grade.
- 20.20 The consent form for the research activity is to be written at an 8th grade reading level or lower (IRB Policy 19). As long as the adolescent can read at this reading level and understands the language of the consent form, the adolescent may document their assent to take part in the research activity by signing and dating the consent form.

Submitting Committee: Institutional Review Board

Approved by: Douglas S. Dehema 6/20/05
 Chair Date

Elizabeth Tros 6/20/05
 Manager Date