

SPECIAL POPULATIONS: RESEARCH WITH CHILDREN

In order to develop medical treatments that benefit children as a group, it is necessary to involve them in research studies. However, research involving children may pose difficult ethical dilemmas. Children are vulnerable and incapable of giving informed consent. The health and well-being of each child involved in the research study must also be protected. The government has put into place special regulations and guidelines regarding children in research.

THE REGULATIONS

Subpart D of Title 45, Part 46 of the Code of Federal Regulations classifies research with children into four categories based on the level of risk to the child. Federal regulations permit an IRB to approve a research project involving children if it satisfies the conditions of one of the first three categories. The categories are:

- (1) No greater than minimal risk.
- (2) Greater than minimal risk with the possibility of direct medical benefits to the child.
- (3) Minor increase over minimal risk with no direct medical benefits to the child but results are important for understanding the child's disorder or condition.
- (4) If not qualified for approval in the first three categories, the project can be approved by the Secretary of the Department of Health and Human Services upon consultation and public hearings.

When reviewing studies involving children, the IRB must determine into which category the research falls. The IRB must also determine that adequate provisions are made to obtain and document the permission (consent) of the child's parent or authorized representative. In general, the permission of one parent is required for categories (1) and (2), and the permission of both parents is required for categories (3) and (4), unless one parent is deceased, unknown, incompetent,

or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

CONSENT AND ASSENT

Consent

Consent is a legal concept, and, as such, it must be obtained from the child's authorized representative. In studies involving minors, the authorized representative is the parent or court-appointed guardian. In the state of Iowa, a minor is anyone under 18 years old.

The Informed Consent Document

The Informed Consent Document is used to document the parent or guardian's permission for the child to participate in the study. The Informed Consent Document template includes signature lines for the subject, the person who obtained consent, and a parent or guardian (<http://research.uiowa.edu/hso/docs/consent01.doc>). If the study involves the recruitment of minors age 13-17 and the Informed Consent Document is written at an appropriate level, both the minor and the parent/guardian may sign the Consent Document. The teen's signature indicates knowledgeable agreement to participate (assent), and the parent/guardian's signature indicates legal consent.

Assent

To enroll a child in a research study, the regulations require an investigator to obtain the assent of the child in addition to the consent of the parent(s)/guardian(s). *Assent* is a knowledgeable agreement to participate in the study. Adequate provisions should be made for soliciting the independent, non-coerced assent of minors. In general, the IRB recommends that children age 7 and older be given the opportunity to give assent. If the child from whom assent is sought refuses, s/he should not be enrolled, even if the parent/guardian gives permission. Alternatively, if the child from whom assent is sought agrees to participate, s/he may not be enrolled if the parent/guardian does not

give permission. The IRB may make an exception to obtaining assent in studies of children with life-threatening illnesses who are eligible for research treatment protocols. If the study involves children under age 7, consent from the parent is the sole requirement.

The Assent Document

The Assent Document is used to document the child's knowledgeable agreement, or assent, to participate in the study. The IRB recommends that this form be used with children in the 7-12 age range, but it may also be used with teenagers to enhance their comprehension if the study involves complicated procedures. An Assent Document template is available on the "Forms/Templates" page of the Human Subjects Office web site, <http://research.uiowa.edu/hso/docs/assentdo.doc>.

THE IRB APPLICATION

Recruiting children requires that researchers provide information about the study at a level understood by both the child and his/her parent(s) or guardian(s). When filling out the New Project Application, remember:

- (1) To check the "Minors" box on the first page of the application, and fill in the age range of the subjects. Subjects under the age of 18 cannot be incidentally enrolled into a study unless the IRB has approved the study for enrollment of minors.
- (2) To provide details about how and in what order consent and assent will be obtained.
- (3) For studies in which some children in a group will be participating in the research and some will not (e.g., a special classroom project), give details of the processes used to separate the participating children from the non-participating ones.
- (4) For studies involving children age 7-12, include an Assent Document with the application. If using Word, use Tools/Options/Spelling & Grammar, check "show readability statistics," then spell-check the Assent document to make sure it's at a 2nd or 3rd grade reading level.
- (5) Subjects age 13-17 may sign the Informed Consent Document if the language used in the document is clear and straightforward, and written at an age-appropriate level. The Informed Consent Docu-

ment should include a signature line for the subject and a line for the subject's parent or guardian. The form should also include the boxed statements on the first page of the consent template concerning teens/parents.

Glossary

Minimal risk: *The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.*

Minors: *Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Iowa, a minor is someone who has not reached his/her 18th birthday.*

UPCOMING EVENTS

Brown Bag Lunch Wednesday, January 14, noon - 1 in the Ziffren Conference Room, 1502 JCP. Tips on writing an Informed Consent Document, and a walk-through critique of two actual Consent Documents, with a "before" and "after" comparison.

Lecture Series Marjorie Speers, Executive Director of the Association for the Accreditation of Human Research Protection Programs, will give two lectures on January 21 from 8:30 - noon in the Medical Alumni Auditorium, 301 GH. The talks are titled: "The Status of Human Research Protections: What's Working and What's Not," and "Putting Research Participants in Harm's Way: Do IRBs Identify and Minimize Risks?"

The Human Subjects Office

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