
Yale University Institutional Review Boards Procedure

Procedure 310 PR.1 Informed Consent in Research Involving Children

Overview	1
Permission of Parents or Guardians.....	1
Assent	1
Emancipated Minors and Waivers of Permission of Parent or Guardian	2
Research Involving Wards of the State or Other Entity.....	3
Research Involving Protected Health Information.....	3

Overview

This procedure describes the steps necessary to obtain legally effective informed consent in studies involving children. In most cases, children cannot provide consent to participate in research. Instead, permission from a parent or appropriate guardian is obtained along with the child's assent.

Permission of Parents or Guardians

1. Permission from parent(s) or guardian(s) is required for all research involving children unless waived by the IRB. The IRB will also determine whether parental permission is required from one or both of the parents as described in the Participation of Children in Research policy.
2. Unless written permission is waived by the IRB in accordance with the policy, permission must be obtained using a permission form which follows the requirements for informed consent.
3. In addition to the information required in an adult consent form, the parental permission form should clearly describe:
 - Aspects of the study that impact the child as well as those that require parental involvement, and
 - Any limitations on parental access to their child's research data or responses.

Assent

1. Assent Requirements:

Assent is defined as "a child's affirmative agreement to participate in research," and should be sought in addition to parental permission when the child is sufficiently mature to understand the nature of his or her participation in a research study. While children are incapable of providing legally effective informed consent, they nevertheless may possess the ability to assent or dissent from participation. The assent process assures the elements of understanding and cooperation, and provides a feeling of inclusion on the part of the child. The process also illustrates the investigator's respect for the rights and dignity of the child in the context of research. In recognition of children's differing rates of intellectual and emotional development, federal regulations do not specify the age for which assent is required. They also do not state what form the assent process should take. Rather, these determinations are left to the judgment of the principal investigator and the IRB. In making such assessments, the principal investigator and the IRB are obligated to examine the ages, maturity and psychological state of the children involved.

2. Assessment of Child's Understanding:

As part of the assent process, the individual obtaining the assent must evaluate the child's ability to understand what's being said in order to provide informed assent. This is usually done through the evaluation of the questions raised by the child and answers given to the questions asked of the child. As part of the assent process, children should be asked open-ended questions about the research in

which yes and no answers do not suffice to determine whether the child recalls and understands what has been explained to him/her. Such questions include:

- “Can you tell me what will happen if you agree to take part in this study?”
- “How will this study help you?”
- “What should you do if you want to stop being in this study? Can you leave this study once it begins?”

3. Elements of Assent

Depending on the assessment of the maturity and cognitive abilities of the children to be enrolled, assent may be written or verbal. Children capable of reading and writing should be provided an assent form written in language appropriate for their cognitive level. The assent process as well as any forms must be approved by the IRB. In general, the following standards will be applied:

Infants and Young Children: If the child is under the age of 7, or found intellectually unable to provide assent, only a parental permission form is required.

Children: If the subject’s intellectual capabilities fall within the range of a normal 7-12 year-old, an assent form is required in addition to the parental permission form.

Adolescents: If the subject is 13-17 years of age, and has age-appropriate cognition and understanding, an adolescent assent form is required in addition to a parental permission form.

Whenever assent is sought from a child, the assent discussion, form, or information sheet should include the following:

- A simplified description of the purpose of the research, including the risks and benefits;
- A description of the procedures and interventions to which the minor subject will be exposed;
- An explanation of any procedures that may hurt and for how long the pain will last;
- An explanation that the child has the right to decide whether or not to participate in the research study;
- An explanation of the research alternatives;
- A description of the level of confidentiality of the data including whether there could be any state mandated reporting such as abuse reporting and whether or not the child’s responses will or will not be shared with their parents;
- A question and answer period in which the researcher should encourage the child subject to ask questions about her/his participation in the study;
- An explanation that the potential subject may withdraw from the research at any time, if applicable.

Assent forms/information sheets should be in a simple format that is appropriate to the child’s maturity and cognitive ability. The use of large type, simple schema, and pictures can facilitate the child’s understanding of the text. Older children, such as adolescents, may be provided with a form which mirrors the parental/guardian permission form in its content and format.

Emancipated Minors and Waivers of Permission of Parent or Guardian

When the IRB has determined that permission from a parent or guardian is not necessary or appropriate for the child’s participation in the research, or when a child has been granted emancipation from a court, the child will be asked to provide informed consent in accordance with the procedure on Informed Consent. Extra care must be taken in these instances to assure that the child participant fully understands the research.

Research Involving Wards of the State or Other Entity

Researchers must be careful when identifying the appropriate parental/guardian figures from whom permission must be obtained in order to enroll the child into the research. Foster parents can not provide consent for foster children to participate in research because they are not considered their legal guardians. However, the foster parent(s) may need to be consulted as the research may require their commitment; for example, driving the child to and from research appointments. In this population, it is typically the protective service worker, or state-appointed case worker, who stands in loco parentis or is the legal guardian from whom parental permission must be obtained. The researcher should consult with the case worker in determining whether additional permissions from other parental figures, e.g., the biological parent, may be necessary. Researchers should note that studies involving medical risks may require a medical history of the child from someone who has a thorough and reliable knowledge of the child's health.

All research protocols designed to enroll children who are wards of the State of Connecticut must obtain approval from the Connecticut Department of Children and Families IRB. (See <http://www.ct.gov/dcf/cwp/view.asp?a=2555&q=314538>.)

Research Involving Protected Health Information

Protocols that will involve the creation, use or disclosure of Protected Health Information (PHI) also must obtain an authorization for the research use in accordance with University Policy 5032, Statement of Policy on Use and Disclosure of Protected Health Information for Research Purposes.