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Investigator Guidance:
Child Assent and Permission by Parents or Guardians

Research with children involves more complex considerations with respect to assuring the voluntary participation of research participants than research with adults. As described below, there are issues of assent, consent, and parental permissions that must be considered. Federal regulations do not provide many specifics but they do include parental permission requirements, also discussed below. The Federal regulations also charge that "adequate provisions [be] made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent... [taking] into account the ages, maturity, and psychological state of the children involved" [*45 CFR 46.408*].

How Does Assent Differ from Consent?

Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate or not. They may also provide a written assent if they are older. Circumstances in which a child's assent may be unnecessary or inappropriate are discussed later in this guidance document.

Process for Obtaining Child Assent and/or Parental/Guardian Permission

The Process

The process for obtaining oral and/or written consent for children and minors is similar to that of obtaining consent for adults. An effective informed consent process involves at minimum these elements:

- Conducting the process in a manner and location that ensures participant privacy,
- Giving adequate information about the study in a language understandable to the participant,
- Providing adequate opportunity for the participant to consider all options,
- Responding to the participant's questions,
- Ensuring the participant has understood the information provided,
- Obtaining the participant's voluntary agreement to participate, and
- Continuing to provide information as the participant or research requires.

A complicating factor for the children and adolescents assent is the requirement to also consider parental permission—discussed below.

Assent from Children or Minors

Researchers should carefully consider and propose adequate provisions for obtaining the assent of children prior to their participating in research. The IRB application should address whether the intended subject population of children would be capable of understanding the nature of their participation in the research, and if so, whether or how assent will be obtained.

- In determining whether children are capable of assenting, the ages, maturity, and psychological state of the children involved should be taken into account. This determination may be made for all children and adolescents to be involved in research under a particular protocol, or for each child, as appropriate. An assent process that takes into account the child's experience and level of understanding, assures an element of cooperation and a feeling of inclusion on the part of the child, and also illustrates the investigator's respect for the rights and dignity of the child in the context of research.
- Out of respect for children as developing persons, they should be provided with essential information and asked whether or not they wish to participate in the research, particularly if the research: (a) does not involve interventions likely to benefit them; and (b) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

Permission from Parents or Guardians

Adequate provisions must also be made for soliciting the permission of each child's parent(s) or legally authorized representative or guardian, as noted below. At a minimum, the federal requirements for consent indicated below must be met. However, the researcher or the IRB may determine that more stringent requirements are appropriate.

Regulatory Category of Permitted Research with Children	One Parent's or Both Parents' Permission Required?
Minimal Risk [*45 CFR 46.404, 21 CFR 50.51*]	**One parent**/legal guardian *may* be sufficient.
Greater than Minimal Risk, Direct Benefit to Subject [*45 CFR 46.405, 21 CFR 50.52*]	**One parent**/legal guardian *may* be sufficient but IRB must determine whether one or two is required.
Greater than Minimal Risk, No Direct Benefit to Subject, but Likely to Yield Generalizable Knowledge about Subject's Condition [*45 CFR 46.406, 21 CFR 50.53*]	**Both parents**/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.
Greater than Minimal Risk, No Direct Benefit to Subject, but Results May Alleviate Serious Problems of Children's Health or Welfare [*45 CFR 46.407, 21 CFR 50.54*]	**Both parents**/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.

> ***IMPORTANT NOTE:*** *When there is only one living parent or guardian or one parent has sole custody after a divorce, the investigator and/or IRB may determine that single-parent or single-guardian permission is sufficient.*

When Parents Disagree

If there are two parents available to give permission but they disagree about allowing their child to participate in the study, *the child may not be enrolled unless that disagreement can be resolved*. This applies to all permissible categories--even if only one parent's signature is required, when both parents are involved in the decision, they must agree for the child to be enrolled. If a parent who was not involved or available for the original consent later becomes involved or available, the two parents must then agree.

Documentation of Assent and/or Parental Permission

Assent and/or Parental Permission should be documented according to the table and standards below, although the IRB may modify the standards based on age, maturity, developmental status or other considerations that may determine the appropriateness of a given approach. Parental Permission should be obtained with the use of a modified Adult Consent Form, based on the UM consent template.

Discussion of Guidelines, and Signature and Documentation Requirements

For children under 7: *Only parental permission is required.*

- In certain cases, the investigator may deem a child in this age range is capable of being involved in the assent process. If so, make sure the child is given a simple verbal explanation of what will happen to him or her or what he or she will be asked to do. Document this discussion on the parental permission form or in the study records.
- Use a consent form, referring to the subject throughout as "your child" or "your infant."
- If parents are also part of the study, one consent/permission form may be used to describe the study procedures for both the child as well as the parent(s).

For children 7-12 years of age: *In most cases, children this age will be able to participate in the assent process, using a simplified assent form. A separate, more detailed permission form will be needed for the parents or guardians.*

- Create two documents: a simplified child assent form and a separate parental consent form.
- The assent form should be brief and study specific, with subheadings or numerical paragraphs, and contain language that is both appropriate to the child's development and age. The assent form should have a simple format that is easy to read and when possible, limited to one page. The use of larger type, simple schema, and pictures will facilitate the child's understanding of the text.
- Children may not be required to sign the assent form, but investigators are required to document in the research record that child assent has been obtained either on the parental permission form or retained separately within the study records.
- If parents are also part of the study, a consent/permission form may be used to describe the study procedures for both the child as well as the parent(s), though the child would also have an assent form.

For children 13-17 years of age: *Children this age are able to participate in the assent process, Federal regulations do not require substantial revision of the adult consent form, however the assent document must be written in language at an appropriate level of readability and should discuss whether parents will have access to sensitive data that may be part of the study (drug use, sexual activity, etc.), if applicable.*

- Use clear, straightforward language written at the 8th grade reading level.
- Only the adolescent is asked to sign the assent form.

IMPORTANT NOTE: *In some research projects, it may be necessary to use two assent forms written to accommodate subjects at either end of the age range or to accommodate different maturity levels of the participants.*

Re-Assent and Consent at Youth and Adult Milestones

The researcher and the IRB should consider whether re-assent of children who are participating in longitudinal research or **written consent of children who turn 18 years of age during study participation is required**.

- When appropriate, the researcher and the IRB need to determine that adequate provisions are made for soliciting the assent of children who reach seven years of age during study participation.
- When appropriate, the researcher and the IRB need to ensure an ongoing assent process with continuing subjects by requiring the re-assent of subjects who turn 14 years of age.
- The researcher and the IRB need to ensure that adequate provisions are made for soliciting the consent of children who turn 18 years of age during study participation. If the child participated in a study in which the only remaining procedures are data analysis, consent may not be required.

Waiver of Child Assent

Even in cases in which the researcher and the IRB determine that the children are capable of assenting, the IRB may grant a waiver of the assent requirement in accordance with 45 CFR 46.116(d). Such waiver of the assent requirement by the IRB is also allowed under 21 CFR 50.55(d) for research subject to FDA regulations.

Alternatively, if either of the following are true then the assent of the children is not a necessary condition for proceeding with the research:

- The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

In such circumstances as a child's dissent, which should normally be respected, the dissent may be overruled by the child's parents. This should be discussed in the eProst application and will be considered by the IRB. When research involves the provision of experimental therapies for life-threatening diseases such as cancer, however, researchers should be sensitive to the fact that parents may wish to go to extremes, even when the likelihood of success is marginal and the probability of extreme discomfort is high. Should the child not wish to undertake such experimental therapy, and if, for example, the child is a mature adolescent and death is imminent, the child's wishes should be respected.

Waiver of Parental Permission

In certain cases, research may be designed for conditions or for a subject population for which parental permission for inclusion in research is not a reasonable requirement to protect the subjects (e.g., neglected or abused children).

For FDA-Regulated Studies

FDA regulations [*21 CFR 50*] lack the provision for waiver of parental permission. This is because the FDA does not believe it oversees studies for which such a waiver is appropriate. Researchers who believe it appropriate to include selected groups of adolescents in research involving FDA-regulated articles should consider the section below titled Legal Exceptions Permitting Certain Minors to Consent.

For Non-FDA-Regulated Studies

The IRB may waive parental/guardian permission provided “an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law” [*45 CFR 46.408*].

APPLICATION NOTE: *In such cases, the PI may propose a waiver of parental consent/permission under 45 CFR 46.408(c) or 45 CFR 46.116 in the study protocol uploaded to the eProst application.*

The IRB will consider all other requests for waiver of parental permission on a protocol-by-protocol basis.

Examples where parental permission *MAY* be waived

- Research on child abuse or neglect, or research that is reasonably likely to elicit information identifying child abuse or neglect, where there is serious doubt as to whether the parents' interests reflect the child's interests. [*45 CFR 46.408(c)*].

  This type of study is difficult to pursue and thus rarely comes before the IRB. Since the federal regulations specifically refer to "research on neglected or abused children" as an instance where "parental or guardian permission is not a reasonable requirement to protect the subjects," the IRB would be likely to waive parental permission in such a case, provided the other requirements of the regulations 45 CFR 46.408(c) are met.

- Research on people under 18 who are in circumstances where they are clearly outside of parental influence or control.

  The IRB would evaluate each study carefully to determine whether parental permission is not a reasonable requirement to protect the subjects.

  Researchers also should be aware that some people under 18 who are living independently may not fit the federal definition of "children" and are able to consent for themselves without a waiver of parental permission.

  APPLICATION NOTE: *Investigators should address all such consent concerns for research with minors, including arguments for waiver of standard consent procedures in the eProst Application.*

Legal Exceptions Permitting Certain Minors to Consent in Florida

In Florida, minors (those under 18 years of age) generally may not consent to medical care or treatment, or research involving medical care or treatment, without a parent or legal guardian's consent. However, the Florida statutes regarding the removal of "Disability of Nonage of Minors" (Title XLIII, Chapter 743) describe conditions when the requirement(s) for parental consent are waived by law.