Guidance - Children and Consenting Minors and Assent

This guidance includes parental and guardian permission, when a child may consent for themselves, types of surrogate decision makers for children and their authority, and required documentation.

Definitions:

Assent: A child's affirmative agreement to participate in research. Absent affirmative agreement, mere failure to object is not assent.

Children:

[DHHS and FDA] 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. Subpart D of the DHHS must be applied only if an individual involved in the research meets this definition.

[Pennsylvania law] The legal age for consent to treatments or procedures involved in research is generally 18, but there are important exceptions.

Minors: Persons under 18 years of age. Because some minors can consent for themselves to some research procedures, not all "minors" meet the federal criteria for being "children."

"Emancipated" Minors must meet one of the following requirements:

a. have entered into a valid marriage whether or not it has been dissolved, or
b. be on active duty with the armed forces, or
c. have received a court declaration of emancipation.

Guardian: An individual or official appointed through a state or local law, a court order, or upon the death of a parent through the parent's will to have custody of a child, either temporarily or permanently, with the associated rights to make decisions on behalf of the child. (Normally, the authority of a parent ceases upon the court appointment of a guardian).

In Pennsylvania a guardian has the authority to consent on behalf of a child to general medical care (and therefore meets the DHHS and FDA definition of "guardian") when his or her court issued letters of guardianship include the authority to consent on behalf of a child to general medical care.

Ward: (defined by FDA) a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

Waiver of Parental or Guardian Permission

- FDA regulated research is not eligible for waivers (unless the emergency exception applies.)
- For non-FDA regulated research, the IRB may waive parental or guardian permission if:
  a. regular conditions for waiver of consent are met (see 45 CFR 46.116(c) or 46.116(d)); or

b. parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted; for example, if the study:
    - focuses on a condition or is a study of such a private and sensitive nature that it is not reasonable to require permission, (for example, adolescents in studies concerning treatment of sexually transmitted disease); or
    - involves a subject population such as abused or neglected children. [45CFR 46.408(c)]

- A request for a waiver (or partial waiver) will be considered for research conducted *in a classroom*, if the research is minimal risk and meets the other waiver requirements.
- Research is ***generally not suitable for a waiver*** if it involves:
    - mental or psychological problems,
    - sexual behavior or attitudes,
    - illegal/antisocial/self-incriminating behavior,
    - appraisals of other individuals with whom the minor has a familial relationship,
    - relationships legally recognized as privileged (lawyers, doctors, clergy), or
    - religious affiliations or beliefs.

Assent

The IRB must determine whether researchers have adequate provisions to solicit assent, when the children are capable of providing it. The researcher must inform the IRB how the affirmative assent of the child will be documented, e.g., by signature on assent form, documented by the researcher, or other. A researcher for an experimental drug study must normally obtain the assent of any child participant 7 years or older. For studies involving children *7 to 17 years*, the IRB recommends that researchers document the child's willingness to participate with a signed assent document. A child's capacity to assent must be evaluated on an individual basis.

Assent Document

- Include any information that can affect a child's decision to participate - an explanation of the proposed research procedures (procedures that are not part of the child's care should be described as optional), the research purpose, and any discomforts.
- Use language that is geared to the cognitive level of participating children. The language used in the parental consent document might also be suitable for an older teen.
- Might more appropriately be obtained orally (omission of signature) for younger children (younger than 7 years but old enough to be consulted about participating in research).

See Assent Form Template on the Human Subjects Research website.

Assent Not Required or Waived

At the request of a researcher, the IRB may determine no assent is required in one or more of the following circumstances (including FDA regulated protocols):

- Children are not capable of assenting, after taking into account the ages, maturity, and psychological state of the children involved, either for all the children or for each child.
- 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.

- Customary conditions for waiver or alteration of consent are satisfied (45 CFR 116 or 21 CFR 50.55 (d)).

Special Circumstances:

1) Parents or Guardian Are Unavailable

Generally, a researcher may not involve a child in research if the parent(s) or guardian are not available to provide permission and the IRB has not waived parental or guardian permission.

2) Children Who Are Wards

- Laws limit research with children who are "wards" of the State or other agency, institution or entity.
- The IRB may approve a protocol that involves wards and research involving greater than minimal risk with no prospect of direct benefit to participants (under 45 CFR 46.406 or 21CFR 50.53) or not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (under 45CFR 46.407 or 21 CFR 50.54) only if the study is:
  1) related to their status as wards, or
  2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the participating children are not wards.

  If the research is approved under the above conditions, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child in a study.

  ***Note*:** The above does not apply for research approved under 46.404 or 405, 50.51 or 52.

  Who may be an advocate?

  An advocate: i) has the background and experience to act in (and agrees to act in) the best interest of the child for the duration of the research, and ii) is not associated in any way with the research (except as an advocate, or member of the IRB), the researchers, or any guardian association.

  - Researchers are responsible for: i) informing the IRB when the study intends to include children who are wards; and ii) compliance with any relevant requirements of the competent court, agency, institution, or entity of which the child is a ward.
  - For *research involving medical care* for wards of a court, an order from the judge is often required, in addition to permission from the person charged with the care of the child.

3) Guardians – Restrictions on Authority

Medical Care (no research involved)

In Pennsylvania, a guardian normally has the same authority with respect to the child as a parent having legal custody, except as limited by statute or court order (e.g. the legal document establishing the guardianship).