

## I. PURPOSE

The purpose of this standard operating procedure is to describe the requirements for assent and parental permission for research involving children.

The principle of respect for persons requires that the choice of an autonomous person be respected. Under the usual conditions of clinical research, this is accomplished by soliciting the informed consent of the prospective research subject. However, as children are generally unable to consent for themselves, researchers must seek the permission of parent(s) or guardian and the assent of the child.

## II. POLICY STATEMENT

It is the policy to comply with all federal and state regulations that pertain to informed consent, parental permission, and assent. Assent and parental/guardian permission must be obtained in accordance with IRB determinations for research involving children.

When a child who was enrolled in research with parental or guardian permission subsequently reaches the legal age of consent to the procedures involved in the ongoing research (in most instances 18 years of age), the subject's participation in the research is no longer regulated by the requirements regarding parental or guardian permission and subject assent.

## III. SCOPE

These policies and procedures apply to all IRB protocols involving children as research subjects.

## IV. DEFINITIONS

Assent: A child's or other individual's affirmative agreement to participate in research where the child or individual is not eligible by age or impaired decision making ability to provide consent. Mere failure to object by the child or individual should not be construed as assent.

Guardian: Any person designated by Court Order as the Minor's legal guardian or as a person who can otherwise make medical decisions on behalf of the Minor.

Parent: A child's biological or adoptive parent.

Parental Permission: The agreement of parent(s) or guardian to the participation of their child or ward in research.

Recruitment: The process by which an investigator conveys information to a prospective subject to in order to allow the individual to determine whether or not they are interested in participating in the research.

Screening: Involves collection of data through oral or written communication with the prospective subject (or legally authorized representative), and/or collection of identifiable

private information or identifiable biospecimens.

Ward: Any child who has been adjudged dependent by a court and who is under the control of a public official or agency, including Foster children, or any child under the control of DHS in Philadelphia or a County Children and Youth Agency in another county in Pennsylvania; also, children in penal custody or otherwise detained within the criminal justice system.

## V. PROCEDURES

### A. ASSENT

1. The Investigator submits research involving children following **SOP 301** and must provide the IRB with either a description of how assent will be obtained and documented, or requests consideration of a waiver of assent.
2. The IRB reviews the submitted research following **SOP 105** and determines whether adequate provisions are made for soliciting the assent of a child when, in the judgment of the IRB, the child is capable of providing assent.
  - (a) When determining whether children are capable of assenting, the IRB considers the ages, maturity, condition, and psychological state of the children involved. The IRB has the discretion to judge children's capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis.
  - (b) The default age at which solicitation of assent will be 7 years of age but younger or older limits may be chosen based on the nature of the study and the expected capacity for the prospective subject(s) to understand the purpose of the research, the nature of the procedures and the ability to express their voluntary approval or disapproval to participate.
3. The IRB may determine that children's assent is not required in any of the following three types of circumstances:
  - (a) The capability of some or all of the children is so limited that they cannot reasonably be consulted;
  - (b) The intervention or procedure involved in the research holds out a prospect of direct benefit to the health or well-being of the children and is available only in the context of the research;
  - (c) The IRB grants a waiver of assent when the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either 45 CFR 46.116(e) or 45 CFR 46.116(f)(3). See **SOPs 802** and **706**.
4. When the IRB determines that a child's assent is required:

(a) The child shall be given an explanation of the proposed research procedures in language that is appropriate to the child's age, experience, maturity, and condition; and

(b) The IRB shall determine whether and how assent must be documented.

5. A child's dissent to participation in a study, which should normally be respected, may be overruled by the child's parents as specifically approved by the IRB if the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that 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.

## B. PARENTAL PERMISSION

1. The Investigator submits research involving children following **SOP 301** and provides the IRB with either a description of how permission will be obtained and documented, or requests consideration of a waiver of permission.

(a) Documentation of permission from the child's parent(s) or guardian(s) is provided by their signature and date on the Informed Consent document.

(b) All of the requirements for informed consent apply to obtaining parental/guardian permission and all of the appropriate informed consent elements must be included in a written consent document unless otherwise waived by the IRB.

(c) Permission must be obtained before the initiation of any screening processes performed solely for the purpose of research, unless the screening procedures are limited to the collection of data through oral or written communication with the child or the child's parent/guardian, or to the collection of identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

2. If children who are Wards (or foster children) are to be included as research subjects (**SOP 504**), the investigator provides the IRB with information about the proposed permission/assent process, as well as the identity and authority of the individuals who will provide permission for the Ward subjects. A foster parent can never give valid permission for a Ward.

3. If a person other than a parent signs an Informed Consent/Permission Document, the investigator obtains documentation from that individual that he or she is legally authorized to consent for the child, or in the case of Wards, that a governmental agency or public official has guardianship of the child.

4. The IRB reviews the research submission following **SOP 105** and determines,

to the extent that consent is required, that adequate provisions are made for soliciting the permission of parents or guardians of each child involved in a research study.

5. The IRB makes the following additional determinations, which will be documented in the IRB meeting minutes for full Board determinations and in the initial IRB Correspondence for determinations made using expedited review procedures:

- (a) Whether the permission of both parents is required;
- (b) Whether the permission of one parent is sufficient;
- (c) Whether the parental permission process is waived because the research is not subject to FDA regulations and meets the requirements of 45 CFR 46.116(e), 45 CFR 46.116 (f)(3) or 45 CFR 46.408(c).

6. The IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 (§50.51) or §46.405 (§50.52). When research is to be conducted under §46.406 (§50.53) and §46.407 (§50.54) permission must be obtained from both parents, 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.

7. The IRB may alter or waive the requirement for obtaining parental or guardian permission if it determines that:

- (a) The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either 45 CFR 46.116(e) or 45 CFR 46.116(f)(3); or
- (b) The relevant research protocol is designed to study conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children); provided that an appropriate mechanism is in place to protect the children, provided that the research is not FDA-regulated, and provided that the waiver is not inconsistent with federal, state, or local law, or CHOP policy. 45 CFR 46.408(c); or
- (c) The research satisfies all of the requirements for an Exception to the General Requirements (for informed consent) as specified in 21 CFR 50.23 including:
  - (1) the prospective subject is confronted with a life-threatening situation necessitating the use of a test article;
  - (2) informed consent (parental permission) cannot be obtained because of inability to communicate or unavailability of the parent/guardian;

- (3) time is insufficient to obtain consent from the subject's legal representative; and
- (4) there is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

**C. Children Who Reach the Legal Age of Consent While Enrolled in a Study**

- 1. When a child who was enrolled in research with parental or guardian permission subsequently reaches the legal age of consent the Investigator seeks and obtains the legally effective informed consent for the now-adult subject for any ongoing interactions or interventions with the subjects.
- 2. The IRB considers, if appropriate, a waiver under 45 CFR 46.116(f)(3) of the requirements for obtaining informed consent in order for the subjects to continue their participation in the research.

**D. Signatures**

- 1. The IRB provides the consent form template with an assent section at the end of the document. This section is to be completed by the individual obtaining assent. If subjects are ages 12-17 years, their signature may be obtained on the form, but their signature is optional. Children who voluntarily choose to sign the consent document are permitted to do so.

**VI. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.408, 45 CFR 46.116	21 CFR 56.408, 21 CFR 56.116
45 CFR 46 Subpart D	21 CFR 50 Subpart D
	21 CFR 50 Subpart B

## VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105: IRB Review Processes	SOP 705: Waiver of Informed Consent for Planned Research Conducted in Emergency Settings
SOP 301: Research Submission Requirements	SOP 706: Waiver of Elements of Consent and Waiver of Written Authorization
SOP 504: Research Involving Children	SOP 802: Emergency Use Of Unapproved Drugs, Biologics, Or Devices
SOP 505: Minors Who Are Not Children in the Research Context	

## VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for establishing and periodically reviewing and modifying (as appropriate) the consent form template.
Chair, CPHS	Responsible for periodically reviewing the consent form template and requesting modifications (as appropriate).

## IX. ATTACHMENTS:

The IRB website has information on Assent of Children at:  
<https://www.research.chop.edu/services/assent-of-children>

## X. REVISIONS:

6-10-10	Revised for clarity and remove redundant information found in other SOPs and to add a link to the reference material on the IRB website.
7-7-10	Revised to reflect AAHRPP's recommendations.
8-14-18	Revised to updated definitions and referenced SOPs.
1-22-19	Revised to update the regulatory citations to reflect the changes to the Common Rule.
12-22-22	Minor administrative edits.

**XI. APPROVAL:**

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/22/22  
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS