

P&P: IC 703 Version No: 1.1 Effective Date: 10/1/2009	ASSENT AND PARENTAL / GUARDIAN PERMISSION	Supercedes: CPHS Policies and Procedures 9/1/2007
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1. POLICY

Special ethical and regulatory considerations apply when research involves children as subjects. Children are inherently more vulnerable than adults, thus requiring a higher level of protection, and are also legally incapable of giving valid informed consent. The IRB will apply the requirements and guidance found in federal regulations 45 CFR 46, Subpart D, “Additional Protections for Children Involved as Subjects in Research” (see SC 503, “Children as a Vulnerable Population”). This includes provisions for obtaining *assent* from the child or minor and *permission* from the parent(s) or guardian.

Specific Policies

1.1 Definitions (as per federal regulations at 45 CFR 46.402)

- 1.1.1 *Children* are 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

(Note: In California, the legal age for such consent is usually 18 years old, but some exceptions apply under state law (see below). These or applicable laws of other states or countries where the research is being conducted will be considered.

"Children" vs. "Minors": Under California law, both terms—“children” and “minors”—are used to refer to people who are under 18 years of age. However, some people under 18 years of age can consent for themselves to certain research procedures (e.g., self-sufficient minors, emancipated minors, those seeking medical care related to the prevention or treatment of pregnancy). Therefore, not all “minors” meet the federal criteria for being “children” (*as defined above*). Only people who are “children” under the federal regulations are covered by the additional protections described in Subpart D of 45 CFR 46 and 21 CFR 50. *Thus, these policies and procedures will be applied in all cases involving minors who are also considered "children" under the federal regulations. In some cases, the IRB may choose to apply them to minor subjects who are not considered children under the federal definition as well, depending on the specific research.*)

- 1.1.2 *Assent* means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- 1.1.3 *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.
- 1.1.4 *Parent* means a child’s biological or adoptive parent.
- 1.1.5 *Guardian* means an individual who is authorized under applicable State or local law to consent on before of a child to general medical care.

1.2 Assent

In instances where the subject is not legally capable of giving informed consent, the IRB must find that adequate provisions are made for obtaining the assent of the subject when in the judgment of the IRB, the subject should be capable of providing assent.

- 1.2.1 In determining whether subjects are capable of assenting, the IRB shall take into account the age, maturity, and psychological state of the subject involved. This judgment may be made for all subjects to be involved in research under a particular protocol, or for each subject, as the IRB deems appropriate.
- 1.2.2 When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.
- 1.2.3 In most cases, seeking assent and documenting such assent in writing will be required if the subjects are at least seven years old. (Note: California State law requires obtaining assent from minors to participate in research, and for certain types of medical research specifies that consent [assent] be obtained from the subject if he/she is “seven years of age or older”).
- 1.2.4 Assent forms shall be written at the appropriate educational and maturity level of the youngest prospective subject in the age range. Depending on the age range of the minors involved, multiple assent forms may be required for different reading comprehension levels. For older children, one document may be developed to serve as a joint assent/permission form, with signatures to be obtained from both the child and the parent(s) or guardian on the same document.
- 1.2.5 The IRB has authority to require assent from children younger than seven if they are likely to comprehend and appreciate what it would mean to volunteer to participate in a given study.

1.3 Waiver of Assent

- 1.3.1 If the IRB determines that the capability of some or all of the subjects 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 subject and is available only in the context of the research, the assent of the subject is not a necessary condition for proceeding with the research.
- 1.3.2 Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived (see IC 702, “Waivers of Informed Consent”).

1.4 Parental/Guardian Permission

- 1.4.1 The IRB shall determine that adequate provisions are made for soliciting the permission of each child’s parent(s) or guardian. Where parental permission is to be obtained, the IRB will require permission from one or both parents in accordance with specifications relating to the four categories of permissible research with children, as described in 45 CFR 46 (see SC 503, “Children as a Vulnerable Population”).

- 1.4.2 Permission by parents or guardians shall be documented in accordance with 45 CFR 46.117 (see IC 701, “General Requirements and Documentation for Informed Consent”).

1.5 Waiver of Parental/Guardian Permission

- 1.5.1 In accordance with 45 CFR 46.408, the IRB may waive the requirements for obtaining parental or guardian permission for research involving children if EITHER of the following sets of conditions is met:
- A. The IRB makes and documents the required findings under either 45 CFR 46.116(c) or 46.116(d) (see IC 702, “Waivers of Informed Consent,” 1.1.a or 1.1.b); OR
 - B. The IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), and also finds that: (i) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; and (ii) the waiver is not inconsistent with federal, state, or local law.

The choice of an appropriate substitute mechanism will depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

- 1.5.2 A request for waiver of parental permission will not necessarily require Full Committee review. The Chair and one other Committee member with appropriate expertise may review and approve such a request for waiver (as described above in 1.5.1A and 1.5.1B) on an expedited basis if they deem this appropriate.

1.6 Wards

- 1.6.1 Children who are wards of the state or any other agency, institution, or entity can be included in research approved under 45 CFR 46.406 or 46.407 only under certain conditions (see SC 503, “Children as a Vulnerable Population”). If the research is approved, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individuals acting on behalf of the child as guardian or in loco parentis.
- 1.6.2 IRB decisions regarding assent/permission requirements will therefore take the above into consideration in addition to other relevant regulations and guidance.
- Note:* Waiver of informed consent (including assent and/or permission) under 45 CFR 46.116 and 46.408 will not apply to any research which falls under the jurisdiction of the FDA, as FDA regulations do not provide for waiver of consent except in specific emergency circumstances (see IC 702, “Waivers of Informed Consent”).

2. SCOPE

These policies and procedures apply to all research submitted to the UC Berkeley IRB.

3. RESPONSIBILITY

The IRB Staff are responsible for screening/pre-reviewing all informed consent documents and for communicating with Investigators to bring documents into compliance, before and/or after full Committee/ IRB Chair review. The IRB, IRB Chair, and/or IRB member designee is responsible for final determination of whether assent is indicated, and if so, whether and how assent must be documented. Likewise, the IRB, IRB Chair, and/or IRB member designee is responsible for final determination of whether parental/guardian permission is appropriate and that stipulations for obtaining or waiving permission are met.

4. PROCESS OVERVIEW

When children are to be included as participants, the Investigator should include discussion of special consent issues involved, and parental/guardian permission forms and child assent forms as appropriate (or request for waiver thereof), with the research application.

An OPHS staff member will pre-review the assent and/or permission documents to assess whether they are appropriate and adequate. Staff will notify the Investigator of any omissions or necessary corrections before and/or after review, as appropriate, by the full IRB (for applications requiring full Committee review) or IRB Chair or designee (for applications or responses requiring expedited review.)

The assent and/or permission documents will be evaluated on the basis of both the CPHS Informed Consent Guidelines and the respective research protocol, including special attention to such issues as readability, age-appropriate language, and completeness of relevant information. The IRB members and/or IRB Chair or designee will subsequently confirm, reject, or add to this evaluation, and will give final approval as per the type of application.

After the application is approved, all approved informed consent, parental permission, and assent documents (English and foreign language) will be approval stamped and made available to the Investigator along with the protocol approval letter.

In addition to relevant information provided in the Informed Consent Guidelines posted on the CPHS website, OPHS staff are available to advise investigators on the informed consent process, in particular regarding special circumstances that may be involved with vulnerable subject populations such as these.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 Subpart D