



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

FACT SHEET

CHILD'S ASSENT

The special vulnerability of children makes consideration of involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are in place for reviewing research involving children. Title 45 CFR 46, Subpart D provides for "Additional DHHS Protections for Children Involved as Subjects in Research." Research that is contrary to the rights and welfare of child-subjects is prohibited. *All research involving children regardless of risk must be submitted for review by the FULL COMMITTEE.*

"**ASSENT**" means a child's affirmative agreement to participate in research. *Mere failure to object should not, absent affirmative agreement, be construed as consent.* [45 CFR 46.202(b)]

"**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. [45 CFR 46.202(a)]

When children or minors are involved in research, the regulations require the **assent** of the child or minor and the **permission** of the parent(s) or legally authorized representatives, in place of the consent of the subjects. While children may be legally incapable of giving informed consent, they nevertheless may possess the ability to **assent** to or dissent from participation. Out of respect for children as developing persons children should be asked whether or not they wish to participate in research, particularly if the research: (1) does not involve interventions likely to be of benefit to the subjects; and (2) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

The federal regulations do not require that assent be sought from children starting at a specific age, however California law does (see following paragraph regarding state law), but that their assent should be sought when, in the judgement of the IRB, the children are capable of providing their assent. The IRB will take into account the ages, maturity, and psychological state of the children involved [45 CFR 46.408(a)]. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Investigators who engage in medical research should take note of California State Law 26668.4: **Consent if subject is minor**; drugs to which applicable (a) ...if the subject is a minor, consent shall be provided by a parent or guardian of the subject and **shall also be provided by the subject if the subject is seven years of age or older.** (b) Consent given pursuant to this section shall *only be for the prescribing or administering of an experimental drug which is related to maintaining or improving the health of the subject or related to obtaining information about a pathological condition of the subject.*

The child's assent (in addition to the parent's consent) should be an explanation of the proposed research procedures **in a language that is appropriate to the child's age, experience, maturity, and condition.** **This explanation should include a discussion of any discomforts and inconveniences, in non-technical terms, the child may experience if she or he agrees to participate.**

Research involving children is classified into one of four categories under the federal regulations:

1. Research not involving greater than minimal risk [45 CFR 46.404].
2. Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual subject. Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the subject; and (b) the relationship or risk to benefit is at least as favorable as any available alternative approach [45 CFR 46.405].
3. Research involving greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. Research in this category is approvable provided: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to subjects that are reasonable commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and (c) the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition [45 CFR 46.606].
4. Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

In all cases, the IRB will review the project to determine that adequate provisions have been made for soliciting the assent of children and the permission of their parents or guardians [45 CFR 46.408].

When involving children in research, investigators should consider the following issues, and provide a clear explanation of the scientific and ethical basis for the proposed research plan:

- Does the research have an identifiable prospect of direct benefit to the individual child participant?
- Can that benefit be achieved through alternative means?
- Does the research have an identifiable prospect of risk to the individual child participant?
- What safeguards are proposed to minimize these risks? When procedures involving greater than minimal risk to children are anticipated, investigators should provide convincing scientific and ethical justifications.
- Is the inclusion of normal volunteers justified?
- Will older children be enrolled before younger ones?
- Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?
- Are mechanisms in place to ensure that children are involved as research subjects in ways that do not undermine their dignity as young persons? Are provisions made that show respect for the developing rights of children, such as: (a) obtaining their assent, and, where appropriate, honoring their dissent; and (b) protecting their need for privacy and the confidentiality of information regarding them?
- Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?
- Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?
- If conditions present in children have implications for other family members' health statuses, are appropriate mechanisms proposed for dealing with the larger family unit (e.g., genetic risks or HIV infection)?
- Are proposed subjects to be very young?
- Are the procedures involved painful?
- Must subjects stay overnight in the hospital when they otherwise would not have to?