UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

FACT SHEET

STUDIES INVOLVING CHILDREN AS RESEARCH SUBJECTS

A. GENERAL INFORMATION

The federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects such as children. It is the ethical as well as regulatory mandate of the IRB to ensure that the research does not endanger the children's safety or well-being. **Title 45 CFR Part 46, Subpart D** provides for "Additional Protections for Children Involved as Subjects of Research." Research that is contrary to the rights and welfare of child-subjects is **prohibited**.

B. SUBMISSION REQUIREMENTS

The research plan should provide sufficient detail so that the IRB can make the determinations as listed below. In addition, parental/guardian consents and assents (adolescents and/or child) are normally required. If this study will be conducted at the VA, please review the VA requirements regarding research involving children.

C. DETERMINATIONS

The IRB is required to find that the proposed project meets one of the following categories, in order to approve research with children.

1. **46.404**: The research is NOT greater than minimal risk: the IRB must ensure that there are adequate provisions for soliciting the assent of the child and permission of the parents or guardian;
2. **46.405**: The research poses more than minimal risk to the child where the intervention or procedure holds out the prospect of direct benefit for the child, or by a monitoring procedure, is likely to contribute to the subjects well-being, the IRB must determine:
    a. the risk is justified by the anticipated benefit to the child;
    b. the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
    c. adequate provisions are made for soliciting the assent of the child and the permission of the parent or guardian.
3. **46.406**: The research poses greater than minimal risk with no prospect of direct benefit to the child, but is likely to yield generalizable knowledge about the child disorder or condition, the IRB must determine:
    a. the risk represents a minor increase over minimal risk;
    b. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
    c. the intervention/procedure is likely to yield generalizable knowledge about the child's disorder or condition; and
    d. adequate provisions are made for soliciting assent of the child and permission of the parent or guardian.

The IRB is responsible for ensuring that adequate provisions are made for soliciting the permission of each child's parents or guardians. Where parental permission is to be obtained, the IRB may find the permission of one parent is sufficient for research under **46.404** or **405**. Under **406**, where permission is to be obtained from parents, both parents must give their permission unless one parents is deceased, unknown, incompetent or not reasonably available, or when one parent has legal responsibility for the care and custody of the child. A waiver of permission is possible under **46.408(c)**.

D. DEFINITIONS

Assent: A child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent [**45 CFR 46.402(b)**].

Benefit: A valued or desired outcome; an advantage.

Children: Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of jurisdiction in which the research will be conducted [**45 CFR 46.402(a)**]. California law is under age 18.

Guardian: An individual who is authorized under applicable state or local law to give permission in behalf of a child to general medical care [**45 CFR 46.402(3)**].

Minimal Risk: **T**hat the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [**45 CFR 46.102(i)**].

D. FURTHER INFORMATION

For further information or clarification regarding the above, please contact the Human Research Protections Program at (858) 657-5100 or visit the website at irb.ucsd.edu.