UNIVERSITY OF CALIFORNIA
SANTA CRUZ
Institutional Review Board

Policy on Research Involving Children

Effective date: 9/20/2019

I. Background

For research funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html), the Office for Human Research Protections expects human subjects research involving children to comply with additional regulatory protections under 45 CFR 46 Subpart D.

II. Definitions

a. *Assent:* a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent.
b. *Children:* persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable state or local law where the research will be conducted.
c. *Guardian:* an individual who is authorized under applicable state or local law to consent on behalf of a child.
d. *Minors:* (UC Irvine) In California, individuals under the age of 18 years old are considered minors. However, California allows minors to consent to some research procedures for themselves. Therefore, not all "minors" are considered "children" under the federal regulations.

III. IRB Review and Approval of Research Involving Children

In addition to the criteria for approval of research under 45 CFR 46, the IRB must also apply 45 CFR 46 Subpart D to approve research involving children when the research is funded by a Common Rule department or agency (see above). The Subpart requires the IRB to determine which category the research falls under (see section 4 below). The categories are based upon level of risk and benefit.

IV. Research Categories Involving Children

a. **Research not involving greater than minimal risk.** The IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 45 CFR§46.404.
b. **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects**. The IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual

subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that: the risk is justified by the anticipated benefit to the subjects; 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 adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.405.

c. **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.** The IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that: the risk represents a minor increase over minimal risk; the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.406.

d. **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.** If the IRB does not believe a study meets the requirements of §46.404, §46.405, or §46.406, the study can be approved under §46.407 only if: The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or all of the following: (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) The research will be conducted in accordance with sound ethical principles; (iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

V. Requirements for permission by parents or guardians and for assent by children.

a. In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. 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, the assent of the children is not a necessary condition for proceeding with the research. 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 in accord with §46.116 of Subpart A.
b. In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission 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.
c. In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon 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.
d. Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.

e. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

VI. Wards

a. Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is: related to their status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
b. If the research is approved under paragraph (a) of this section, 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. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

VII. Department of Education Requirements When Involving Minors in Research

a. The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. ¬ß 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.
b. The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. ¬ß 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED). PPRA is intended to protect the rights of parents and students.
c. Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.
d. No student shall be required, as part of any program specified in 98.1 (a) or (b), to submit without prior consent to psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following: Political affiliations or beliefs of the student or the student's parent; Mental and psychological problems potentially embarrassing to the student or his or her family; Sex behavior and attitudes; Illegal, anti-social, self-incriminating and demeaning behavior; Critical appraisals of other individuals with whom the student has close family relationships; Legally recognized privileged and analogous relationships, such as those of lawyers, physicians,

and ministers; Religious practices, affiliations, or beliefs of the student or student's parent or; Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

e. Prior Consent means: Prior consent of the student, if the student is an adult or emancipated minor; or Prior written consent of the parent or guardian, if the student is an unemancipated minor.
f. For certain types of research projects not directly funded by the United States (U.S.) Department of Education and conducted in a school that receives funding from the U.S. Department of Education, the IRB will ensure compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following: The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student; A procedure for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
g. Arrangements to protect study privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items); Political affiliations or beliefs of the student or the student's parent; Mental and psychological problems potentially embarrassing to the student or his or her family; Sex behavior and attitudes; Illegal, anti-social, self-incriminating and demeaning behavior; Critical appraisals of other individuals with whom the student has close family relationships; Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers; Religious practices, affiliations, or beliefs of the student or student's parent or; Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.
h. The right of a parent of a student to inspect, upon the request of the parent or guardian, any instructional material to be used as part of the educational curriculum for the student. Instructional material may include teacher's manuals, films, tapes or other supplementary instructional material, which will be used in connection with any research or experimentation program or project. Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques. Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.

i. The administration of physical examinations or screenings that the school or agency may administer to a student.
j. The collection, disclosure or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure or use. The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student and any procedure for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

VIII. Environmental Protection Agency Requirements When Involving Minors in Research

a. Research requirements when supported by the EPA:
    i. The EPA prohibits research involving the intentional exposure of children to any substance.
    ii. The EPA requires application of 40 CFR 26 Subpart D to provide additional protections to children as participants in observational research, i.e., research that does not involve intentional exposure to any substance.
b. EPA policy requires submission of IRB determinations and approval to the EPA Human Subjects Research Review official for final review and approval before the research can begin.
c. Research not supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including the prohibition of the intentional exposure of children to any substance.

IX. References

a. 45 CFR 46 Subpart D Additional Protections for Children Involved as Subjects in Research
b. UC Irvine Human Research Protections Standard Operating Policies and Procedures *Children*