IRB Checklist – Children

Regulations at 45 CFR 46, Subpart D require that children involved in research be afforded additional safeguards. This checklist provides guidance on the specific provisions of Subpart D, and other laws and regulations affecting children involved in research.

Part A – Background Information

A Child shall be an individual who has not attained the legal age for consent to treatments or procedures involved in the research in the jurisdiction in which the research is to be conducted.

Child participant age range: _____

Has information specifying the legal age of consent to treatments or procedures involved in the research under the applicable jurisdiction(s) been submitted to the IRB by the PI?

- No
- Yes
- Not Applicable – there are no treatments or procedures that require consent

Are the children involved in this research wards of the State AND is there greater than minimal risk to participants?

- No (Go to Part B)
- Yes (continue)

For research involving wards of the State where there is greater than minimal risk to participants, all of the following criteria must be met (please check all that apply):

- The research is related to their status as wards, or conducted in settings in which the majority of subjects are not wards, AND
- An advocate has been appointed for each ward/child/subject, in addition to any other individual acting on behalf of the child as guardian or in loco parentis.
- The advocate will 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.
- The advocate will not be 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.

Comments:
Part B – Category Determination

Instructions: Please check/select the one category that best describes the risk, benefits, and appropriate consent requirements for the study. Within the selected category, review the listed criteria and check to indicate that all criteria are met. Provide any comments as needed at the end of this section.

- Category 1 – 45 CFR 46.404 – Research involving risk that is no greater than minimal:
  - The research is not greater than minimal risk; and
  - Permission is obtained as determined in Part C, below, and
  - Assent of the child will be obtained as appropriate (see Section C, below).

- Category 2 – 45 CFR 46.405 – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants, in which:
  - The risk involved is justified by anticipated benefit to the participant; and
  - The increased risk is anticipated when presented by an intervention or procedure that holds out the prospect of direct benefit for the individual participant, or by a monitoring procedure that is likely to contribute to the participant’s well being, and
  - The benefit to risk ratio is at least as favorable as that presented by alternative approaches, and
  - Permission is obtained as determined in Part C, below, and
  - Assent will be obtained, if appropriate, unless the benefit is not available outside the research. See Section C, below.

- Category 3 – 45 CFR 46.406 – Research involving greater than minimal risk but presenting no prospect of direct benefit to the individual participant:
  - The research will likely yield vitally important generalizable knowledge about the participants’ disorder or condition, and
  - The elevated risk anticipated is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual participant, or by a monitoring procedure that is not likely to contribute to the well being of the participant.
  - Risk represents a minor increase over minimal risk; and
  - The research presents experiences reasonably commensurate with those inherent in participants’ actual or expected medical, dental, psychological, social or educational settings;
  - Permission of both parents will be obtained (see Part C below) unless one of the parents has sole legal responsibility for the care and custody of the child, or one of the parents is deceased, unknown, incompetent to provide permission, or not reasonably available.

- Category 4 – 45 CFR 46.407 – Research not otherwise approvable:
  - The IRB does not believe the research meets the requirements of Categories 1-3.
The research presents a reasonable opportunity to further the understanding, alleviation, or prevention of a serious problem affecting the health and welfare of children.

The DHHS Secretary has approved the research under 45 CFR 46.407 criteria.

Before research procedures begin, permission of both parents will be obtained unless one of the parents has sole legal responsibility for the care and custody of the child, or one of the parents is deceased, unknown, incompetent to provide permission, or not reasonably available.

Comments:

Part C – Permission and Assent Procedures

Assent means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

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

Guardian means an individual who is authorized under applicable state or local law to act on behalf of a child.

Type of Permission Required: If Category 1 or Category 2 was selected above, determine which of the following consent requirements is appropriate:

- The permission of both parents is required if both parents are alive, known, competent, reasonably available, and have legal responsibility for the care and custody of the child. Otherwise, the permission of one parent is required.
- The permission of one parent is sufficient, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

Waiver of Permission is granted because:

- The research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), and
- The PI has provided an appropriate substitute mechanism for protecting the children, and
- The waiver is not inconsistent with Federal, state or local law.

Waiver of Assent is granted because:

- The capability of some or all of the children is so limited that they cannot reasonably be consulted,
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 participants are capable or assenting, but the assent is waived under circumstances as set forth under section 46.116 of Subpart A.

Assent shall be obtained from:

☐ All Children
☐ Some Children
☐ No Children

If “Some Children” has been checked, document below which children are not required to assent:

Assent shall be obtained (check one of the following, if applicable):

☐ In writing, using an assent form
☐ In writing, using a signature block on the informed consent form
☐ Orally

Comments:

Part D – Privacy Issues Related to Family Educational Rights and Privacy Act (FERPA) and Protection of Pupil Rights Amendment (PPRA)

This section pertains to obtaining permission to access/use a child’s educational records only. This is separate from parental permission to participate in the study.

Without regard to the permissibility of research under 45 CFR 46, additional restrictions on data gathered or used under FERPA (34 CFR 99) and/or PPRA (34 CFR 98) or their state law equivalents may apply when the research generates or utilizes Educational Records pertaining to the participants.

Educational Records shall mean records that pertain to a child attending an educational institution when that institution receives funds from, or is under the jurisdiction of, the Department of Education.

If the research involves either of the two conditions below, this section must be completed.

☐ Yes ☐ No participants being enrolled primarily because they are attending classes at a cooperating publicly financed school or other educational institution, or
☐ Yes ☐ No educational records provided by a publicly financed school or other educational institution.
IF EITHER OF THE ABOVE IS CHECKED, THIS PART MUST BE COMPLETED.

FERPA

☐ Waiver of parental (or qualified student) permission under FERPA is granted because educational records containing personal identifiers are being used to conduct studies to:
  ☐ Develop, validate or administer predictive tests
  OR
  ☐ Improve instruction, AND
  ☐ The studies are conducted in such a way as to prevent identification of students or parents by individuals other than authorized representatives of the record-holding institution, AND
  ☐ The records are destroyed when no longer needed to fulfill the purposes of the study.

☐ Waiver is not granted

PPRA

☐ Waiver of parental permission under PPRA is granted because the following types of information will not be collected under the study (All of the 7 elements below must be checked to qualify for the waiver under the PPRA):
  ☐ Political affiliations;
  ☐ Mental and psychological problems potentially embarrassing to the student and his/her family;
  ☐ Sex behavior and attitudes;
  ☐ Illegal, anti-social, self-incriminating and demeaning behavior;
  ☐ Critical appraisals of other individuals with whom respondents have close family relationships;
  ☐ Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; or
  ☐ Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

☐ Waiver is not granted