MUSC
Medical University of South Carolina

# IRB Reviewer Checklist
# Special Subject Populations
# Children (Complete Only One Category)

Reviewer: PRO #: PI:

**This checklist must be completed by an IRB member with sufficient expertise. In order to approve the use of children, responses must be "yes" unless not applicable:**

**Category 1: Not greater than minimal risk:**

a. Adequate provisions have been made for soliciting the assent of the children; and ○ Yes ○ No

b. Adequate provisions have been made for soliciting parental/guardian permission: ○ Yes ○ No

☐ The permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonable available, or when only one parent has legal responsibility for the care and custody of the child; **or**

☐ The permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shared legal responsibility for the care and custody of the child.

**Category 2: Greater than minimal risk but of direct benefit to individual subjects:**

a. Risk is justified by anticipated benefit; ○ Yes ○ No

b. Relation of the benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and, ○ Yes ○ No

c. Adequate provisions have been made for soliciting parental/guardian permission ○ Yes ○ No

☐ The permission of both parents is required 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; **or**

☐ The permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shared legal responsibility for the care and custody of the child.

**Category 3: Greater than minimal risk, no direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition:**

a. Risk represents a minor increase over minimal risk; ○ Yes ○ No

b. Procedure presents experiences to the subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; ○ Yes ○ No

c. Intervention/procedure is likely to yield generalizable knowledge about the subjects' condition which is of vital importance for understanding or amelioration of the subjects' disorder; and, ○ Yes ○ No

d. Adequate provisions have been made for soliciting parental/guardian permission. (The permission of both parents is required 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.) ○ Yes ○ No

**Category 4: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children** ○ Yes ○ No

a. 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

b. The Secretary, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of Categories 1-3, as applicable, or

(2) 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

**"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Daily life refers to the daily life of normal children.**

## Wards of the State or Another Agency

When research in Category 3 or 4 involves wards of the state or another agency and the 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, the IRB requires 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 *in loco parentis,.*

**Does the protocol adequately address Wards of the State or Another Agency?** ◯ Yes ◯ No ◯ NA

## Waiver of Parental Permission [45 CFR §46.408(c)]

In addition to the provisions for waiver contained in §46.116 of Subpart A, the IRB may waive the consent requirements in Subpart A of this part and paragraph if the IRB determines that all of the following are Yes:

- 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). ◯ Yes ◯ No ◯ NA
- An appropriate mechanism for protecting the children who will participate as participants in the research is substituted ◯ Yes ◯ No ◯ NA
  - 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 participants, and their age, maturity, status, and condition.
- The waiver is not inconsistent with Federal, state or local law. ◯ Yes ◯ No ◯ NA
- The research is not FDA-regulated ◯ Yes ◯ No ◯ NA

## Assignment of a Child Subject Advocate when parental consent is waived

In circumstances where the convened IRB waives parental consent, a child subject advocate must be assigned to protect the children who would participate as participants in the research.

- The advocate is 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 is not associated in any way (except in the role as investigator(s)), or the guardian organization.

**Does the protocol adequately address Assignment of a Child Subject Advocate?** ◯ Yes ◯ No ◯ NA

## Child Assent: (MUSC Policy states that child assent is only applicable for children between the ages of 12 and 17, inclusive and as appropriate.)

- Will assent be a requirement of
  ◯ All Children ◯ Some Children ◯ None of the Children
- When assent is not a requirement of some or all children:
  - ☐ The children are not capable of providing assent based on the age, maturity, or psychological state.
  - ☐ The capability 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 assent can be waived using the criteria for waiver of the consent process.
- When assent is a requirement, will assent be documented ◯ Yes ◯ No
- When assent is documented, describe the process to document assent:

## Research funded by the Department of Education OR performed in schools

**Does the research involve (Check as applicable)** ◯ Yes ◯ No ◯ NA

- ☐ Participants being enrolled primarily because they are attending classes at a cooperating publically financed school or other educational institution or,
- ☐ educational records provided by a publically financed school or other institution.

If Yes, complete the IRB Reviewer Checklist – Federal Funding Department of Education Addendum