

Institutional Review Board

SUPPLEMENT C – RESEARCH INVOLVING CHILDREN

Principal Investigator:	
Study Title:	

Please complete if your research involves children (individuals who have not yet reached the age of 21).

1. Children as Subjects

a. What is the age range of the children in this research?

Click here to enter text.

b. Where will the children participate?

☐ Home

☐ School

☐ University lab/office

☐ Other – Specify

Click here to enter text.

c. Will any of the research take place in school settings? ☐ Yes ☐ No

If yes, have you obtained the necessary permission from the school district? ☐ Yes ☐ No
(Attach documentation of permission)

d. Are any of the children wards of the State or any other agency, institution, or entity? ☐ Yes ☐ No

If yes, provide details:

Click here to enter text.

2. Allowable Categories

Check the category below that best represents the degree of risk and benefit to which the children in this study will be exposed. Note: more than one category may be indicated such as when a protocol involves both a study group and a control group; in these cases, please specify.

a. ☐ **Category 1:** The proposed research poses risks no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk).

b. ☐ **Category 2:** The proposed research poses a greater than minimal risk with the potential for direct benefit to subject.

c. How is the benefit to risk assessment at least as favorable as that presented by alternative approaches?

Click here to enter text.

CCC-UPR Institutional Review Board

- d. ☐ **Category 3:** The proposed research poses a greater than minimal risk with no potential for direct benefit to individuals, but likely to yield generalizable knowledge about the subjects' conditions.

- e. How is the risk of the protocol a minor increase over minimal risk?

Click here to enter text.

- f. How does the procedure present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected situations?

Click here to enter text.

- g. How is the knowledge to be gained of vital importance for the understanding or amelioration of the condition?

Click here to enter text.

- h. ☐ **Category 4:** The proposed research does not meet the criteria in the above categories but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children.

- i. Provide justification for why this research should be approved:

Click here to enter text.

3. Parental Permission

- a. What permission will be obtained from the parents?

In general permission from both parents is required for research involving children unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. For Categories 1 & 2, however, the IRB may find that the permission of one parent is sufficient.

Permission will be obtained from both parents, where possible

Permission from only one parent is being requested

A waiver of parental permission is being requested. Provided justification for a waiver:

Click here to enter text.

- b. If the research is being conducted in a group setting (e.g., a classroom), explain what provisions have been made for children whose parents have not given permission for them to participate:

Click here to enter text.

4. Assent from Children

Adequate provisions must be made for soliciting the assent of children when in the judgment of the IRB the children are capable of providing assent and for soliciting the permission of their parents or guardians.

- a. Please indicate whether the children you will study are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved. Please be specific:

☐ All are capable.

☐ None are capable. Explain:

Click here to enter text.

Some are capable. Explain:

Click here to enter text.

- b. Describe how assent is will be obtained, including what information will be provided to the subjects:

Click here to enter text.

- c. Describe how assent will be documented. Attach copies of all assent forms, if any.

Click here to enter text.