Supplement H

**RESEARCH INVOLVING CHILDREN AS SUBJECTS**

Indicate your responses below and explain your selections in the protocol. Do not provide details in this document.

# Children as Subjects (check all that apply)

## Where will the children participate?

\_\_ NIH Clinical Center

\_\_ Other NIH Site Specify:

\_\_ Home

\_\_ School

#### If yes, have you obtained the necessary permission from the school district?

#### \_\_ Yes \_\_ No *(Attach documentation of permission)*

\_\_ Outside Clinical Site

\_\_ Other, specify:

## b. Are any of the children wards of a State or any other agency, institution, or entity? (see 45 Part 46.409) \_\_ Yes \_\_ No

# Risk/Benefit Assessment and parental permission for participation

Check the boxes below that best represents the degree of risk and benefit to which the children in this study will be exposed based on 45 CFR 46 Subpart D and, if applicable, 21 CFR 50 Subpart D.

**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 the cohort.

1. For each risk category, please select the appropriate permission level.

In general, permission from both parents is required for research involving children 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. For Categories 1& 2, the IRB may find that the permission of one parent is sufficient for compliance with 45 CFR 46 but NIH may require permission of both parents.

Waiver of parental permission for research not regulated by the FDA: The IRB may waive the requirement for obtaining consent from a parent or legal guardian, except when research is regulated by the FDA (21 CFR 50.55), if:

1. The research meets the provisions for waiver in SOP 12 (Informed Consent) or

2. The IRB determines that the research study is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), provided an appropriate mechanism for protecting the children participants is substituted, and that the waiver is not inconsistent with applicable 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.

\_\_ The proposed research poses risk 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) (45 CFR 46.404).

\_\_ Permission will be obtained from both parents unless:

* + 1. One parent is deceased, unknown, incompetent, or not reasonably available; **or**
    2. When only one parent has legal responsibility for the care and custody of the child.

\_\_ Permission from only one parent is being requested

\_\_ A waiver of parental permission is being requested *(Complete Supplement L and provide justification for a waiver in the protocol.)*

\_\_ The proposed research poses a greater than minimal risk with the potential for direct benefit to subjects (45 CFR 46.405).

Address in the protocol, how the benefit to risk assessment is at least as favorable as that presented by alternative approaches.

\_\_ Permission will be obtained from both parents unless:

1. One parent is deceased, unknown, incompetent, or not reasonably available; **or**
2. When only one parent has legal responsibility for the care and custody of the child.

\_\_ Permission from only one parent is being requested

\_\_ A waiver of parental permission is being requested *(Complete Supplement L and provide justification for a waiver in the protocol.)*

\_\_ The proposed research poses a greater than minimal risk with no potential for direct benefit to the individual subjects, but is likely to yield generalizable knowledge about the subjects’ conditions (45 CFR 46.406).

Please address the following in the protocol,

1. How the risk of the protocol presents a minor increase over minimal risk.
2. How the procedure(s) present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected situations.
3. How the knowledge to be gained is of vital importance for the understanding or amelioration of the condition.

\_\_ Permission will be obtained from both parents unless:

1. One parent is deceased, unknown, incompetent, or not reasonably available; **or**
2. When only one parent has legal responsibility for the care and custody of the child.

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 (45 CFR 46.407).

*(Requires approval by Deputy Director for Intramural Research and the Secretary of Health and Human Services and/or the Commissioner of Food and Drugs, as applicable.)*

Address the benefit to risk ratio in the protocol and discuss the ways in which the study presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children.

Permission will be obtained from both parents unless:

1. One parent is deceased, unknown, incompetent, or not reasonably available; **or**
2. When only one parent has legal responsibility for the care and custody of the child.

# 3. Parental Permission in a Group Setting

## What permission will be obtained from the parents if the research is being conducted in a group setting (e.g., a classroom)? (Explain in the protocol what provisions have been made for children whose parents have not given permission for them to participate.)

# 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.

## Please indicate below whether the children you will study are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved.

\_\_ All are capable

\_\_ None are capable (Explain in the protocol)

\_\_ Some are capable (Explain in the protocol)

## Describe in the protocol how assent will be obtained, including what information will be provided to the subjects.