

Checklist for Research Involving Children

Principal Investigator (Last, First):

Protocol # (XX-XX-XXXX):

Project Title:

1. Does the research involve greater than minimal risk?

Yes No

(If "No," skip to question #4)

2. If "Yes," complete sections "A" or "B" or "C" below to determine under which category the research may be approvable.

A. There is the prospect of direct benefit for the individual subject.

Is the risk justified by the anticipated benefits to the subjects?

Yes No

Is the relation of anticipated benefits to the risk at least as favorable to the subjects as that presented by available alternative approaches?

Yes No

If all answers are "Yes," skip to question 4.

B. The research holds no direct benefit to the individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.

Does the risk represent a minor increase over Minimal risk?

Yes No

Does the intervention or procedure present experiences to the subjects that are reasonably similar to those to be expected from their actual or expected medical, dental, psychological, social, or educational conditions

Yes No

Is the intervention or procedure likely to yield generalizable knowledge about the subject' disorder or condition that is of vital importance?

Yes No

C. The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children generally.

Does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children?

Yes No

Will the research be conducted in accordance with sound ethical procedures

Yes No

3. Are any wards of the State to participate in the research?

Yes No

If "Yes,":

REQUIREMENT #1:

Is the research related to their statuses as wards?

Yes No

OR

Is the research conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved are not wards?

Yes No

AND

REQUIREMENT #2:

Has an advocate been appointed 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?

Yes No

4. Parental Informed Consent and Child Assent

A. Does the research adequately provide for soliciting the permission of both of the child's parents or guardians?

Yes No

If "No," will the permission be sought from one parent only?

Yes No

If "Yes," is the research minimal risk or greater than minimal risk but presenting the prospect of direct benefit to the subjects?

Yes No

B. Does the research provide for obtaining assent from children 7-18 years of age?

Yes No

If "No," is a waiver of assent being requested?

Yes No

If "Yes," does the research protocol explain and provide the rationale for appropriate alternative mechanisms for protecting the children who participate?

Yes No