



CHECKLIST: Research Involving Children

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The research meets all of the following: (All must be "Yes")

- Yes No The research falls into one of the following categories of research involving children: (Check box that is true)
- CATEGORY 21 CFR §50.51/45 CFR §46.404 (Complete Section 2)
 -

	<input type="checkbox"/> CATEGORY 21 CFR §50.53, 50.54/45 CFR §46.406, 46.407 (Complete Section 6)
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CATEGORY 21 CFR §50.51/45 CFR §46.404 (All must be "Yes")

Yes No

No greater than minimal risk to children is presented.
Provide protocol specific findings justifying this determination:

CATEGORY 21 CFR §50.52/45 CFR §46.405 (All items in the left most columns must be "Yes")

Yes No

The research involves greater than minimal risk¹ to subjects.
Provide protocol specific findings justifying this determination:

Yes No

The research presents the prospect of direct benefit to the individual subjects.
Provide protocol specific findings justifying this determination:

Yes No

One of the following is true. **(Check box that is true)**
 The risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject.
 The risk to children is presented by a monitoring procedure that is likely to contribute to the subject's well-being.
Provide protocol specific findings justifying the checked determination:

Yes No

The risk is justified by the anticipated benefit to the subjects.
Provide protocol specific findings justifying this determination:

Yes No

The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
Provide protocol specific findings justifying this determination:

¹ **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal children or during the performance of routine physical or psychological examinations or tests in normal children.

CATEGORY 21 CFR §50.53/45 CFR §46.406 (All must be "Yes")

Yes No

The research involves greater than minimal risk to children presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject.

Provide protocol specific findings justifying this determination:

Yes No

The risk represents a minor increase over minimal risk. ("Minor increase over minimal risk" means no greater than risk in the daily lives of children with the condition or disorder under study, but still socially acceptable.²)

Provide protocol specific findings justifying this determination:

Yes No

The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

Provide protocol specific findings justifying this determination:

Yes No

The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

Provide protocol specific findings justifying this determination:

² Wendler D. "What is a "minor" increase over minimal risk?" *J Pediatr*; 01-Nov-2005; 147(5): 575-8.

CATEGORY 21 CFR §50.54/45 CFR §46.407³ (All must be "Yes")

Yes No

The research does not meet the requirements of 21 CFR §50.51/45 CFR §46.404, 21 CFR §50.5/45 CFR §46.405, or 21 CFR §50.53/45 CFR §46.406.

Provide protocol specific findings justifying this determination:

Yes No

The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

Provide protocol specific findings justifying this determination:

³ For FDA-regulated research, the research may proceed only after FDA has reviewed and approved the research. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD) the research may proceed only after the Director, Defense, Research and Engineering has reviewed and approved the research.

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Adequate provisions for Soliciting the Permission of Parents or Guardians (Must be "Yes")

Yes No

One of the following is true: (Check box that is true)

- Permission is to be obtained from both parents 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.



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Waiver of Parental Permission (45 CFR §46.408(c)) (All must be "Yes" or "Not Applicable")

<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is not FDA-regulated.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research does not involve non-viable neonates.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: (Check boxes that are true) <input type="checkbox"/> Public benefit or service programs. <input type="checkbox"/> Procedures for obtaining benefits or services under those programs. <input type="checkbox"/> Possible changes in or alternatives to those programs or procedures. <input type="checkbox"/> Possible changes in methods or levels of payment for benefits or services under those programs. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research could not practicably be carried out without the waiver or alteration. <i>Provide protocol specific findings justifying this determination:</i>

Adequate Provisions to Solicit the Assent of Children (Must be "Yes")

Yes No

Assent is required from: (Check box that is true)

All children. (Complete Section 14)

None of the children. (Complete Section 13)

Some children. (Indicate which children below and Complete Section 14)

Assent is required from children who have the maturity and cognitive ability to be consulted.

Assent is required from children meeting these criteria:

Reason Why Assent is Not Necessary (Must be "Yes")

Yes No