



Protocol No.

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I. BACKGROUND

The ethical mandate of an IRB is to protect the rights and welfare of human research subjects. IRBs are obliged to ensure that research studies do not endanger the safety or well being of human subjects or undermine public confidence in the conduct of research. The special vulnerability of children makes consideration of involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are in place for reviewing research involving children. Title 45 CFR Part 46, Subpart D provides for "Additional Protection for Children Involved as Subjects of Research." Research that is contrary to the rights and welfare of child subjects is prohibited.

II. IRB CONSIDERATIONS

A. Justification

Please provide written justification that documents the benefits that are likely to accrue to each child participating in the project. The statement should include information gathered on adults if it exists or an explanation about why it does not exist.

B. Basic Protocol Information

Risk/Benefit Assessment:

Both the FDA and OHRP define **minimal risk** as "a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily experienced in daily life or during the performance of routine physical or psychological examinations or tests." For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination.

In your opinion, the research presents (check one and follow the applicable instructions):

- No greater than minimal risk to the subject. *(Complete Section C.)*
- Greater than minimal risk but presents the prospect of a direct benefit to the subjects. *(Complete Section D.)*
- Greater than minimal risk with no prospect of a direct benefit to the subjects but likely to yield generalizable knowledge about the subject's disorder or condition. *(Complete Section E).*

C. Research Involving No More Than Minimal Risk

Consent and/or Assent of Subject Participation:

1) Are you requesting waiver of consent? Yes No

If yes, please indicate that you have provided the IRB with **one** of the following:

- written justification of waiver for **each** of the four regulatory requirements (see page 15 of the submission form); or
- written documentation indicating to the IRB that the research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (i.e., abused or neglected children). Additional mechanisms for protecting the subject have been substituted.

2) If a waiver of consent is not being requested:

(a) Does the consent form include provisions for parental/guardian consent?

Yes No*

*Please include a provision for consent of at least one parent or guardian.

(b) Does the consent form include provisions for assent of the subject?

Yes No**

If "no" and the age, maturity and psychological state of the children renders them fully capable of assenting, the IRB requires that an explanation be given for not securing the assent of the children (in the state of Illinois, the age of 7 is commonly believed to be the age at which a child gains capacity to assent). In circumstances where the subject is fully capable of assenting, the IRB will waive the assent of the child only if (i) the intervention or procedure involved holds out the prospect of direct benefit that is important to the health or well-being of the child **and (ii) this direct benefit is available only in the context of the research.

D. Research Involving Greater than Minimal Risk But Presenting the Prospect of Direct Benefit to Subjects

- 1) Have the direct benefits been described in the submission form, protocol, and consent form? Yes No*
- 2) Are the anticipated risks justified by the anticipated benefits to the subjects? Yes No*
- 3) Is the anticipated risk/benefit ratio at least as favorable to the subjects as that presented by available alternative approaches? Yes No*

*If "no" to **any** of the above risk assessment questions, the IRB may be prohibited from approving the study.

Consent and/or Assent of Subject Participation:

- 1) Are you requesting waiver of consent? Yes* No

*Note: The IRB requires written documentation indicating to the IRB that the research protocol is designed for conditions or a subject population for which parental or guardian permission is not reasonable requirements to protect the subjects (example: neglected or abused children). Additional mechanisms for protecting the subjects have been substituted.

- 2) If a waiver of consent is not being requested:

- (a) Does the consent form include provisions for parental/guardian consent? Yes No*

*Please include a provision for consent of at least one parent or guardian.

- (b) Does the consent form include provisions for assent of the subject? Yes No**

If "no" and the age, maturity and psychological state of the children renders them fully capable of assenting, the IRB requires that an explanation be given for not securing the assent of the children (In the state of Illinois, the age of 7 is commonly believed to be the age at which a child gains capacity to assent). In circumstances where the subject is fully capable of assenting, the IRB will waive the assent of the child only if (i) the intervention or procedure involved holds out the prospect of direct benefit that is important to the health or well-being of the child **and (ii) this direct benefit is available only in the context of the research.

E. Research Involving Greater Than Minimal Risk With No Prospect of Direct Benefit to Subjects But Likely to Yield Generalizable Knowledge About the Subject's Disorder or Condition

1) Does the risk represent a minor increase over minimal risk?

Yes No*

2) Does the intervention or procedure present experiences to subjects that are reasonable and commensurate with those inherent in their actual or expected medical, dental, psychological, social, or education situations?

Yes No*

3) Is the generalizable knowledge yielded by the intervention or procedure of great vital importance for the understanding or amelioration of the subjects' disorder or condition?

Yes No*

*If "no" to **any** of the above risk assessment questions, the IRB may be prohibited from approving the study.

Consent and/or Assent of Subject Participation:

1) Are you requesting waiver of consent?

Yes* No

*Note: The IRB requires written documentation indicating to the IRB that the research protocol is designed for conditions or a subject population for which parental or guardian permission is not reasonable requirements to protect the subjects (example: neglected or abused children). Additional mechanisms for protecting the subjects have been substituted.

2) If a waiver of consent is not being requested:

(a) Does the consent form include provisions for parental/guardian consent?

Yes No*

*If no, please include a provision for consent of **both** parents unless one parent is deceased, unknown, or not reasonably available, or when one parent has legal responsibility for the care and custody of the child.

(b) Does the consent form include provisions for assent of the subject?

Yes No**

If "no" and the age, maturity and psychological state of the children renders them fully capable of assenting, the IRB requires that an explanation be given for not securing the assent of the children (in the state of Illinois, the age of 7 is commonly believed to be the age at which a child gains capacity to assent). In circumstances where the subject is fully capable of assenting, the IRB will waive the assent of the child only if (i) the intervention or procedure involved holds out the prospect of direct benefit that is important to the health or well-being of the child **and (ii) this direct benefit is available only in the context of the research.