SUBJECT CHILDREN

0 unresolved comment(s)

SECTION 1. Risk Level

Complete this section and include it with your IRB application submission. *In Kentucky, a child is an individual less than 18 years of age unless the individual is legally emancipated.*

Note: the explanation(s) you are being asked to provide in Section 1 correlate(s) to the risk level you selected in the Risk Level section.

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

FOR FDA REGULATED RESEARCH: Based on the 2013 FDA final rule Subpart D, a placebo control arm of a clinical trial must be approved under either Risk Category 1, Risk Category 3], or Risk Category 4]. FDA does not consider administration of a placebo to offer a prospect of direct benefit to an individual subject under Subpart D, Risk Category 2 [21 CFR 50.52].

Not involve greater than minimal risk.

In the Risk Level section of the IRB Application you indicated your research does not involve greater than minimal risk.

A. Explain why your research does not involve greater than minimal risk:

SECTION 2. Assessment and Evaluation of the Risks

For details, refer to the UK IRB's Policy on Children in Research.

A. Provide justification for the participation of children as research subjects in your study.

B. Has this research been conducted in adults? ○ Yes ○ No

If yes, is there any indication that the proposed research would benefit, or at least not be harmful to children?

C. Indicate how many children you propose to enroll in the study:

Note: Whenever possible, involve the fewest number of children necessary to obtain statistically significant data which will contribute to a meaningful analysis relative to the purpose of the study.

Justify this number:

D. Check all that apply:

- ☐ My research involves children 6 years of age or older.
- ☐ My research involves children under 6 years of age.

Indicate how assent will be solicited by selecting all that apply:

Assent will be solicited from: ○ All Children ○ Sub-group of children ○ None of the children

I am requesting waiver of the requirement for assent from: ○ All Children ○ Sub-group of children ○ N/A

Indicate justification for waiving assent for these children: (Check all that apply)

- ☐ 1. The intervention or prospect involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child/children and is available only in the context of the research.
- ☐ 2. The children are not capable of providing assent based on the age, maturity, or psychological state.
- ☐ 3. The capability of the children is so limited that they cannot reasonably be consulted
- ☐ 4. Other (explain)

** If you checked question 3, please explain:

** If you checked question 4, please explain:

E. Unless you are requesting a waiver of the requirement for assent for ALL children, you must answer “yes” to at least one of the following two statements.

Note: All assent forms or scripts must be attached to the “Informed Consent" section of this application. Be sure to save your responses in this section first.

For Children 6-11:
Assent will be obtained verbally. I have attached an assent script for obtaining verbal assent for IRB review.

○ Yes ○ No

For Children 12-17:
The children will document assent by signing an assent form, or provide assent verbally if approved by the IRB, depending on the circumstances outlined in the application. I have attached an assent form or script for IRB review.

○ Yes ○ No

F. Explain how study personnel will evaluate dissent (e.g., behaviors that would indicate the child does not want to participate such as moving away, certain facial expressions, head movements, etc.). If your study involves only children under 6 years of age, enter “N/A” below.

G. Describe how parental permission will be obtained.

I have attached a parental permission form for IRB review. ○ Yes ○ No

Parental permission forms must be attached in the “Informed Consent" section of this application. Be sure to save your responses in this section first.

Note that for Risk Category 3 or Risk Category 4 where research involves more than minimal risk without the prospect of direct benefit to the individual child, the permissions of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available OR or only one parent has legal responsibility for the care and custody of the child.)

I am requesting

☐ The permission of 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. **(required for Risk Category 3 or Category 4 Research).**

☐ The permission of one parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. **(permitted for Risk Category 1 or Category 2 Research).**

☐ Waiver of the requirement for signatures on parental permission forms. (Complete the “Request for Waiver of Signatures” questions in the in the Informed Consent/Assent Process/Waivers Section)

☐ Waiver of the requirement for parental permission.

Note: Parental/guardian permission cannot be waived for FDA regulated studies that are greater than minimal risk (Risk Categories 2-4).

Parental Permission Waiver Options

○ Complete the "Request for Waiver of Informed Consent Process” questions in the Informed Consent/Assent Process/Waivers Section.

○ Justify that the research study is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable request (e.g., abused children):

Justify:

H. Describe how study personnel will ensure that a parent is present when the child participates in any research activities.
Note: If the nature of the research is such that it is not appropriate to have a parent present (e.g., research into sensitive personal issues, physical examinations of teenagers, etc.), explain why.

I. Describe the study personnel expertise for dealing with children at the ages included and whether they are knowledgeable and sensitive to the physical and psychological needs of the children and their families. Explain how the facility in which the research will be conducted is appropriate in relation to environment and/or equipment accommodating to children.

J. If applicable, provide additional information that may support your request to involve children in research.

SECTION 3. Wards of the State

If you need to activate this section:

- go to the Subject Demographics section;
- select “Wards of State (Children)” in the categories of subjects and controls to be included in your study;
- save that section.

A. 45 CFR 46.409(a)

Please indicate which category describes your research proposal:

- ○ Research is related to subjects’ status as ward of the state.
- ○ Research is conducted in schools, hospitals, or similar setting(s) in which the majority of children involved in the study are NOT wards.

B. 45 CFR 46.409(b)

Federal regulations state that an advocate must be appointed in circumstances where investigators enroll wards of the state for research studies which are greater than minimal risk **specifically risk category 3 or 4**. Please answer the following questions:

a) Will the advocate serve in addition to a guardian or in loco parents?

○ Yes ○ No

b) Check the applicable item:

- ○ Each child will have their own advocate.
- ○ One advocate will serve for all children enrolled in the study.
- ○ N/A

c) Explain why the advocate has the background and experience to serve as an advocate for the study.

d) Federal regulations state that an advocate cannot be associated with the study, investigator or organization. Please provide assurances that the advocate does not meet any of the criteria listed above.

SECTION 4. Children Located Outside the State of Kentucky

Does your study involve children outside the state of Kentucky? ○ Yes ○ No

Provide information regarding the state definition of legally authorized representative, child, or guardian, as applicable to the research and to the federal definitions. [If the research is to be conducted in more than one state outside of Kentucky, provide this information for each state.]:

Guidance on Consent and/or Authorization by a Legally Authorized Representative
Consistent with Kentucky health care decision statutes for choosing a legally authorized representative for children, the following responsible parties in the order of priority listed shall be authorized to make research participation decisions on behalf of the child: (a) the judicially-appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship; (b) the parent of the child.

Definitions
For definitions of “child/children”, emancipated individuals, “legally authorized representative”, “guardian”, “assent”, and “permission”, see the ORI/IRB Informed Consent Standard Operating Procedures (SOP).