Form W
Include in IRB Application For Research Involving Children

Section 1.
For studies involving children, complete this form 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.

Indicate the category that best describes your research by checking the appropriate box below, and explain in the space provided why your research falls under that category.

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.

NOTE FOR FDA REGULATED RESEARCH: Based on 2013 21CFR50 Subpart D Final Rule, a placebo control arm of a pediatric clinical trial must be categorized under either Category 1, 3, or 4 below. FDA does not consider administration of a placebo to offer a prospect of direct benefit to an individual subject under Subpart D, Category 2 [21 CFR 50.52].

☐ Category 1 (45 CFR 46.404; 21 CFR 50.51)
My research does not involve greater than minimal risk.

a) My research falls under this category because:

b) Describe what provisions will be made for soliciting the assent of the children, and the permission of at least one parent/guardian in Section 2 (d), (e), and (g) below.

☐ Category 2 (45 CFR 46.405; 21 CFR 50.52)
My research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects.

a) My research falls under this category because:

b) Justify the risk(s) by explaining the anticipated benefit to the subjects:

c) Explain how the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches:

d) Describe what provisions will be made for soliciting the assent of the children, and the permission of at least one parent/guardian in Section 2 (d), (e), and (g) below.
<table>
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<tr>
<th>Category 3 (45 CFR 46.406; 21 CFR 50.53)</th>
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<tr>
<td>My research involves greater than minimal risk, and no prospect of direct benefit to individual subject, but likely to yield generalizable knowledge about the subject’s disorder or condition.</td>
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a) My research falls under this category because:

b) Describe how the risks for participating in your research represent a minor increase over minimal risk *(e.g., the children being recruited have a disorder or condition that would place them in a group other than an average healthy child; therefore, the research qualifies as a minor increment over minimal risk. This risk is slightly more than what the average healthy child would experience, but is reasonable for these participants because it is not more than they would experience or expect given their condition.)*.

c) Describe how the research intervention(s)/procedure(s) present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations:

d) Explain why 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:

e) Describe what provisions will be made for soliciting the assent of the children, and the permission of both parents/guardians (permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child) in Section 2 (d), (e), and (g) below.
## Category 4 (45 CFR 46.407; 21 CFR 50.54)

My research does not fall under Category 1, 2, or 3 listed above, however, the research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

**NOTE:** If your research is funded by, or funding has been sought from the Department of Health and Human Services (DHHS), Department of Education, or is FDA regulated, a report must be sent for review to the DHHS Secretary, Secretary of the US Department of Education, or Commissioner of FDA. If this category is applicable, the Office of Research Integrity will prepare and submit a report of IRB review to the appropriate federal official(s).

<table>
<thead>
<tr>
<th>a)</th>
<th>My research falls under this category because:</th>
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<tr>
<td>b)</td>
<td>Describe what provisions will be made for soliciting the assent of the children, and the permission of both parents/guardians (permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child) in Section 2 (d), (e), and (g) below.</td>
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### Section 2.

In order to effectively assess and evaluate the risk of your proposed research to children, the IRB requires the following information. For details, refer to “UK IRB’s Policy on Children in Research” [https://www.research.uky.edu/office-research-integrity/vulnerable-populations-children].

<table>
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<tr>
<th>a)</th>
<th>Provide justification for the participation of children as research subjects in your study.</th>
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<tr>
<td>b)</td>
<td>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?</td>
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<td>c)</td>
<td>Indicate how many children you propose to enroll in the study and justify this number (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).</td>
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<td>d)</td>
<td>For children 6 years of age or older, describe how assent will be solicited. If under 6 years of age, skip to item “g”.</td>
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Assent will be solicited from:

□ All children

□ A sub-group of children (request waiver of assent)

□ None of the children (request waiver of assent)

I am requesting waiver of the requirement for assent from:

□ All children

□ A sub-group of children (request waiver of assent)

Indicate justification for waiving assent for these children:

(Check all that apply)

□ 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.

- The children are not capable of providing assent based on the age, maturity, or psychological state.
- The capability of the children is so limited that they cannot reasonably be consulted because: ________________________________.
- Other: (explain):

| e) | Unless a waiver of the requirement for assent is being requested for all children, complete “e”:
| --- | --- |
| 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. I have attached an assent form for IRB review.  
- Yes  
- No |

| f) | Explain what methods will be used for evaluating dissent [i.e., description of behaviors that would indicate child does not want to participate (such as moving away, certain facial expressions, head movements, etc…)]. |

| g) | Describe how parental permission will be obtained. |

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

|  | 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.
- 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.  
(Note that for research that involves more than minimal risk without the prospect of direct benefit to the individual child, that the permissions of both parents are required 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.)

|  | I am requesting waiver of the requirement for parental permission.  
- Yes  
- No |
Note: Parental/guardian permission cannot be waived for FDA regulated studies that are greater than minimal risk (Categories 2-4)

If yes (select one):
- [ ] Complete and attach Form E;
- [ ] OR
- [ ] 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):

**h)** Describe measures that will be taken to ensure that a parent is present when the child participates in any research interventions. [Note: If the nature of the research is such that it is not appropriate to have a parent present (i.e., research into sensitive personal issues, physical examinations of teenagers, etc...), provide an explanation about why.]

**i)** Describe the expertise of the research staff/study personnel 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. Describe the appropriateness of facility in which the research will be conducted 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.
For studies involving **Wards of the State**, also complete this 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. Please answer the following questions:
<p>| | |</p>
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<tr>
<td><strong>Principal Investigator:</strong></td>
<td><strong>Date:</strong></td>
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<tr>
<td><strong>Study Title:</strong></td>
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| a) | Will the advocate serve in addition to a guardian or *in loco* parents? |
| b) | Will each child have their own advocate or will one advocate serve for all children enrolled in the study? |
| 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.**

For research involving **children outside the state of Kentucky**, also complete this section.

| a) | 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.] |

**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 Procedure which is available on the ORI [website](https://www.research.uky.edu/office-research-integrity/policies-guidance).

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Form W-Research Involving Children  
University of Kentucky  
7/31/17