NOTE: Investigators, please include this form with the IRB application if your research involves children. In Alabama a child is an individual less than 18 years of age unless the child is legally emancipated. If your research involves children with more than one vulnerability (e.g., children who are pregnant, incarcerated, or cognitively impaired) attach the supplementary form for that vulnerable population as well.

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.

Section I.

Select and complete the category that applies to your research.

☐ 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 both parents or the legal guardian. (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). Justify reason(s) if seeking permission from only one parent.

☐ 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. *(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). Justify reason(s) if seeking permission from only one parent.*

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<th>Category 3 (45 CFR 46.406; 21 CFR 50.53)</th>
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<td>My research involves greater than minimal risk, and no prospect of direct benefit to individual subject, but likely to yield generalizeable 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 *(i.e., 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 to 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 generalizeable 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). Justify reason(s) for seeking permission from only one parent.*
### 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 Compliance will prepare and submit a report of IRB review to the appropriate federal official(s).

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<tr>
<td>a)</td>
<td>My research falls under this category because:</td>
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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. <em>(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).</em> Justify reason(s) if seeking permission from only one parent.</td>
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### Section II.

In order to effectively assess and evaluate the risk of your proposed research to children, the IRB requires the following information. Respond to all items.

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<td>a)</td>
<td>Provide justification for the participation of children as research subjects in your study.</td>
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| 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 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)*. |
| d) | Describe how assent of a child will be obtained and documented *(if applicable)*. If not applicable, explain why. |
I am requesting waiver of the requirement for assent. □ Yes □ No

Justify:

OR

I have attached an assent form/assent script for IRB review. □ Yes □ No

e) 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...)).

f) Describe how parental permission will be obtained. [Note: If you propose to waive the requirement for parental permission (i.e., getting parental permission may be against the best interest of the child, i.e., a study of abused or neglected children), describe what measures will be taken to protect the rights and welfare of the children.]

I am requesting waiver of the requirement for parental permission. □ Yes □ No

Justify:

OR

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

g) Describe measures that will be taken to ensure that a parent is present when the child participates in any research interventions or procedures. [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...) please explain why.]

h) 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.

i) If applicable, provide any additional information that may support your request to involve children in this research.