

*Office Use Only:*

**IRB Protocol #:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date Received**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Integrity & Compliance
Institutional Review Board
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Children in Research Attachment

1. **CHILD CATEGORIES:**
2. [ ]  45 CFR 46.404 - Research not involving greater than minimal risk to the children:
	1. Explain how the research risk will be no more than minimal:

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*‘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 or during the performance of routine physical or psychological examinations or tests.”*

* 1. Explain how written permission of the parent(s)/guardian(s) and assent\* of the child will be obtained (\*as applicable).

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[ ]  N/A, Waiver requested, complete the relevant sections below.

1. [ ]  45 CFR 46.405 – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.
	1. Describe any potential risks, and how they are justified by the anticipated benefits to the individual child participants:

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* 1. Explain how the risk/benefit ratio of the research is at least as favorable to the subjects as that provided by available alternative approaches.

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* 1. Explain how written permission of the parent(s)/guardian(s) and assent\* of the child will be obtained (\*as applicable).

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[ ]  N/A, Waiver requested, complete the relevant sections below.

1. [ ]  45 CFR 46.406 – Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subjects disorder or condition.
	1. Describe any potential risks, and how they are justified by the anticipated benefits to the individual child participants:

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* 1. Describe how the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;

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* 1. Describe how the intervention or procedures is likely to yield generalizable knowledge about the subject’s disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition:

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* 1. Explain how the assent of the children will be obtained (providing they are capable\*):

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* 1. Explain how the written permission of both parent(s) or guardian(s) will be obtained\*:

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* 1. If written permission will be solicited from only one parent or guardian, indicate whether:

[ ]  one parent is not reasonably available, or [ ]  only one parent has legal custody

Explain:

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*\*If requesting to waive youth/child assent and/or parental permission, complete relevant section below.*

1. [ ]  45 CFR 46.407 - Research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children:
	1. The research may proceed only if the Secretary, HHS, or his or her designee, after consulting with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, determines either: (1) that the research in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406, or (2) the following:
	* the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
	* the research will be conducted in accordance with sound ethical principles; and
	* adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.
2. **WARDS OF THE STATE:**

***Complete this section for research under categories 3 or 4 above that may involve wards of the state.*** **[ ]  N/A**

1. Children who are wards of the state or any other agency, institution, or entity can be included in research approved under 46.406 or 46.407 only if such research is:
	* Related to their status as wards, or
	* Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

An advocate must be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child’s participation in the research, and who is not associated in any way with the research, the investigator(s), or the guardian organization.

Describe how the research will satisfy these requirements:

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1. **REQUEST FOR WAIVER OF CHILD ASSENT:** **[ ]  N/A**

***The IRB may approve a waiver of the requirement to obtain a child’s assent only under one or more of specific conditions. Indicate which section is applicable, and explain how the conditions will be satisfied.***

[ ]  1. The children will not be capable of providing their assent; explain:

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[ ]  2. The intervention or procedure involved in the research or clinical investigation holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research:

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[ ]  3. The research or clinical investigation will satisfy all of the following conditions:

1. The research involves no more than minimal risk to subjects.
2. The research could not practicably be carried out without the requested waiver or alteration
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

**Explain how the research or clinical investigation will satisfy each of these conditions:**

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1. **REQUEST FOR WAIVER OF PAERNT/GUARDIAN PERMISSION:** **[ ]  N/A**

***The IRB may approve a waiver of the requirement to obtain signed permission from parent(s) or guardian(s) only under certain conditions. Not available for FDA-regulated clinical investigations.***

***Check one as applicable and explain how the research will satisfy these conditions:***

[ ]  1. The research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the subjects (i.e., neglected or abused children).

* An appropriate mechanism for protecting the children is substituted, and
* The waiver would not be inconsistent with Federal, state, or local law.

Explain how the research will meet these criteria:

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[ ]  2. Minimal risk research, if all of the following conditions are met:

1. The research involves no more than minimal risk to subjects.
2. The research could not practicably be carried out without the requested waiver or alteration
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

**Explain how the research will meet these criteria:**

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[ ]  3. Public benefit or service programs, if all of the following conditions are met:

* 1 - The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; **or**

(iv) possible changes in methods or levels of payment for benefits or services under those programs; AND

* 2 - The research could not practicably be carried out without the waiver or alteration.

**Explain how the research will meet these criteria:**

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[ ]  4. State law permits minors to consent for: treatment for sexually transmitted disease, alcoholism, or drug abuse (14 years of age or older), or to receive emergency treatment, pregnancy testing and prenatal care without parental permission (research project must relate to these services).

**Explain how the research will meet these criteria:**

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**\*Note\*** *Research in schools may be subject to additional laws or policies that require written parental permission (i.e., FERPA for use of academic records). In addition, third-party student surveys involving collection of sensitive information (e.g. political affiliations, mental and physiological problems potentially embarrassing to the student and his/her family, sexual behavior and attitudes; illegal, anti-social, self-incriminating and demeaning behavior, critical appraisals of other individuals with whom respondents have close family relationships, legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers, or income) also require written parental permission (Protection of Pupil Rights Amendment - PPRA).*