FRIENDS RESEARCH INSTITUTE, INC.
INSTITUTIONAL REVIEW BOARD
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Supplementary Application for Research Involving Children

Name of Investigator: IRB Study #:
Title of Protocol: Date of Submission:

Please complete this form only if applicable to your research study.

Research involving children is governed by 45 CFR 46 Subpart D. Children are considered a vulnerable research population because their intellectual and emotional capacities are limited.

The regulations specify the following four categories of permissible child research and the requirements that must be met under each category. Please check the applicable category for your research and indicate how this research project addresses the issues listed in that category:

☐	1. 46.404 – Research not involving greater than minimal risk. The following requirements must be met:
	a. Describe how the potential risks are outweighed or balanced by the potential benefits to the subject/participant.
	b. Indicate how adequate provisions have been made for soliciting assent of the children and permission of the parents or guardians.
☐	2. 46.405 – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. The following requirements must be met:
	a. Describe how the risk is justified by the anticipated benefits to the subjects/participants.
	b. Describe how the relation of the anticipated benefit to the risk is at least as favorable to the subjects/participants as that presented by the available alternative approaches.
	c. Indicate how adequate provisions have been made for soliciting the assent of the children and permission of their parents or guardians.
	d. Describe the procedures for minimizing any potential risks. (Where appropriate, discuss provisions for ensuring necessary intervention in the event of an AE to the subject/participant, and the provisions for monitoring the data collected to ensure the safety of the subjects/participants.)
☐	3. 46. 406 – Research involving greater that minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. The following requirements must be met:
	a. Indicate how the risk represents a minor increase over minimal risk.
	b. Indicate how the intervention or procedure presents experiences to subjects/participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations.

	c. Describe how the intervention or procedure is likely to yield generalizable knowledge about the subjects/participants' disorder or condition which is of vital importance for the understanding or amelioration of the subjects/participants' disorder or condition.
	d. Indicate how adequate provisions have been made for soliciting the assent of the children and permission of their parents or guardians.
	e. Describe the procedures for minimizing any potential risks. (Where appropriate, discuss provisions for ensuring necessary intervention in the event of an AE to the subject/participant, and the provisions for monitoring the data collected to ensure the safety of the subjects/participants.)
☐	4. 46.407 – Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children:
	The IRB must submit this category of research to HHS for approval.

PROVIDE THE FOLLOWING INFORMATION IF CHILDREN ARE WARDS OF THE STATE:
1. Is the research related to their status as wards or is it conducted in schools, camps, etc., in which the majority of children are not wards? ☐ Yes ☐ No
2. If yes, provide information on the provisions that have been made for appointing an advocate for the child.