# **APPENDIX B: Children**

|  |  |
| --- | --- |
| **IRB Study Number:** | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Complete the questions below to request inclusion of participants who are considered children. The inclusion of children as participants in research requires that the investigator comply with the additional protections provided in [***45 CFR 46 Subpart D***](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html) and [***21 CFR 50 Subpart D***](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-D) .  Children/Child — Person(s) who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Individuals under 18 years of age are considered children in Indiana unless they meet the definition of emancipated minors.  **Review the HRP-416 - CHECKLIST - Children to ensure that you have provided sufficient information.** | | |
|  | | |
| 1. Select one of the following options and address the criteria below for how they are met: | | |
|  | | **Minimal Risk** |
|  | | 1. Provide rationale for why the intervention is not greater than minimal risk (i.e., 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 exams or tests).   Click or tap here to enter text. |
|  | | **Greater than minimal risk with the prospect of direct benefit to participants** |
|  | | 1. Describe how the research involves greater than minimal risk to participants.   Click or tap here to enter text.   1. Specify how the research presents the prospect of direct benefit to the individual child.   Click or tap here to enter text. ￼   1. Explain how the risk is justified by the anticipated benefit to the individual child.   Click or tap here to enter text.   1. Explain how the relation of the anticipated benefit to the risk is at least as favorable to the child as that which would be presented by available alternative approaches (e.g., other treatments).   Click or tap here to enter text. |
|  | | **Greater than minimal risk without the prospect of direct benefit but likely to yield generalizable knowledge** |
|  | | 1. Describe how the research involves greater than minimal risk to participants.   Click or tap here to enter text.   1. Explain how the risk represents a minor increase over minimal risk by addressing each of the following:    1. The increase in the probability and magnitude of harm is only slightly more than minimal risk.   Click or tap here to enter text.   * 1. Any potential harms associated with the procedure will be transient and reversible in consideration of the nature of the harm (restricted to time of procedure or short post-experimental period).   Click or tap here to enter text.   * 1. There is no, or an extremely small probability, that participants will experience severe pain, discomfort, stress, or harm associated with the procedure.   Click or tap here to enter text.   1. Explain how the intervention or procedure presents experiences to children that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.   Click or tap here to enter text.   1. Explain how the intervention or procedure is likely to yield generalizable knowledge about the child's disorder or condition that is of vital importance for the understanding or amelioration of the child's disorder or condition.   Click or tap here to enter text. |
|  | | **Not otherwise approvable** |
|  | | 1. Explain how the research does not meet the requirements of previous options above.   Click or tap here to enter text.   1. Explain how the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.   Click or tap here to enter text. |
|  | | |
| 1. Is there a possibility that any of the research participants will be wards of the state or any other agency or institution?   Yes à Proceed to question #3  No à Proceed to question #6 | | |
| 1. If yes, does the research involve greater than minimal risk without the prospect of direct benefit?   Yes à Proceed to question #4.  No à Proceed to question #6 | | |
| 1. Children who are wards may be included in research involving greater than minimal risk without the prospect of direct benefit only if one of the following conditions applies. Select the appropriate condition for this research:   The research is related to their status as wards.  The research will be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards. | | |
| 1. If children who are wards of the state may be included in research that is more than minimal risk without the prospect of direct benefit, an advocate must be appointed (see the HRP-416 CHECKLIST- Children for more information). Address the following statements regarding the assigned advocate:   An advocate will 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.  Click or tap here to enter text.  The advocate will have the background and experience to act in, and will agree to act in, the best interests of the child for the duration of the child’s participation in the research.  Click or tap here to enter text.  The advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.  Click or tap here to enter text. | | |
|  | | |
| 1. Assent will be obtained from: | | |
|  | All children | |
|  | Some children  Indicate why (select one):  Child participants are not capable of providing assent based on age, maturity, or psychological state  Some of or all the participants’ capability is so limited that they cannot reasonably be consulted | |
|  | No children  Indicate why (select one):  Child participants are not capable of providing assent based on age, maturity, or psychological state.  Some of or all the participants’ capability is so limited that they cannot reasonably be consulted.  The intervention or procedure involved in the research holds out a prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.  Other: Click or tap here to enter text. | |
|  | Assent will be waived using the same criteria as for waiver of informed consent  Address the following:  The research involves no more than Minimal Risk to the participant.  Click or tap here to enter text.  The waiver or alteration will not adversely affect the rights and welfare of the participants.  Click or tap here to enter text.  The research could not practicably be carried out without the waiver or alteration  Click or tap here to enter text.  Whenever appropriate, the participants will be provided with additional pertinent information after participation.  Click or tap here to enter text.  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. Note: I**f research is FDA regulated, is subject to Pre-2018 Requirements OR if does not use identifiable private information or biospecimens, please enter N/A.**  Click or tap here to enter text. | |
| 1. Provide information about the participants that will provide assent (e.g., age range, cognitive ability)?   Click or tap here to enter text. | | |
| 1. Describe the method(s) and documentation for assent process(es) (e.g., verbal script, online script, assent form).   Click or tap here to enter text. | | |
| 1. Explain the process of obtaining assent/parental permission from children and their parents (e.g., will parents and children be approached separately or together, will parents or guardian be present with the child during discussions of the research?).   Click or tap here to enter text. | | |
| 1. Will parental permission be obtained?   Yes à Proceed to question #11  No à Complete Appendix R: Waiver of Parental Permission Process and proceed to question #12 | | |
| 1. Are both parents required to provide permission 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?   Yes  No | | |
| 1. Will incentives be offered to the research participants?   Yes. Incentives will be offered to:  Child  Parent/guardian  No | | |
| 1. Will sensitive or private information (e.g., questionnaires, test results) be shared with the parents/guardian?   Yes. Explain: Click or tap here to enter text.  No  N/A | | |
| 1. If participation is to continue beyond the time that the child is the age of majority, describe the process to be used to obtain consent from the participant. Note: Maintaining identifiable materials for ongoing research purposes (e.g., repository) requires consent from the participant.   Click or tap here to enter text. | | |