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| **Study Information** | | | | | | | | | | | |
| Title of Study: | | | | | | | | | |  | |
| IRB ID (if known): | | | | | | | | | |  |  |
| Principal Investigator (PI): | | | | | | | | | |  | |
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| **Section 1. Risk: Benefit Category**  From the four categories listed below, choose one that best describes your research by checking the adjacent box. Complete the additional information requested specific to the category selected in the space provided below each item.  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 the ***daily life of a healthy child*** or during the performance of routine physical or psychological exams or tests. | | | | | | | | | | | |
|  | | | | | | **Category 1. Minimal risk research** | | | | | |
| **Risks** – Describe why the research risk is only minimal. | | | | | | | | | | | |
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| **Assent of Child and Consent of Parent/Guardian** – Describe provisions that will be made for obtaining the assent of the children, and the consent of at least one parent/guardian *unless you will be asking for waiver of either or both of these conditions (see Section 2 below)*. Assent means the ability of children to state whether or not they wish to participate in the research. | | | | | | | | | | | |
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| **OR** | | | | | | | | | | |
|  | | | | | | **Category 2. Greater than minimal risk research with the possibility of direct benefit to individual participants** | | | | | |
| **Risks** – Identify the research risks that are greater than minimal (if your research involves more than one group, describe the risks for each group). | | | | | | | | | | | |
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| **Benefits to participants** - (if your research involves more than one group, describe the benefits for each group):  Describe the anticipated benefit to the participants of an intervention or procedure employed in the research. | | | | | | | | | | | |
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| **Risk to Benefit Comparison** – Describe how the relationship of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches. | | | | | | | | | | | |
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| **Assent of Child and Consent of Parent/Guardian** – Describe provisions that will be made for obtaining the assent of the children, and the consent of at least one parent/guardian *unless you will be asking for waiver of either or both of these conditions (see Section 2 below)*. | | | | | | | | | | | |
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| **OR** | | | | | | | | | | |
|  | | | | | | **Category 3. Greater than minimal risk research and no possibility of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition** | | | | | |
| **Risks** – Identify the research risks that are greater than minimal (if your research involves more than one group, consider the risks for each group). | | | | | | | | | | | |
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| **Level of Risk\*** – Describe how the risks for participating in your research represent a minor increase over minimal risk:  \**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.* | | | | | | | | | | | |
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| **Comparison of research to non-research experiences** – Describe how the relationship of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches. | | | | | | | | | | | |
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| **Importance of knowledge to be gained** – Explain why the intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition, and would be of vital importance for the understanding or amelioration of the participants' disorder or condition. | | | | | | | | | | | |
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| **Assent of Child and Consent of Parent/Guardian** – Describe provisions that will be made for obtaining the assent of the children, and the consent of both parents/guardians\*\* *unless you will be asking for waiver of either or both of these conditions (see Section 2 below)*.  \*\* *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.* | | | | | | | | | | | |
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| **OR** | | | | | | | | | |
|  | | | | | | **\*\*\*Category 4. Research that does not fall under Categories 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** | | | | | |
| **Risks** – Identify (list) the research risks that are greater than minimal: | | | | | | | | | | | |
| **Assent of Child and Consent of Parent/Guardian** – Describe provisions that will be made for obtaining the assent of the children, and the consent of at least one parent/guardian: | | | | | | | | | | | |
| \*\*\**NOTE: Contact the IRB Office before proceeding if this category is applicable to your study. If your research is funded by a department of the federal government (e.g., Department of Health and Human Services (DHHS), or is FDA regulated, a report must be sent for review to the appropriate Department office, or Commissioner of FDA. If this category is applicable, the IRB Office will prepare and submit a report of IRB review to the appropriate federal official(s).*   1. *CFR 46.407; 21 CFR 50.54)* | | | | | | | | | | | |
| **Section 2. Additional Information (Required for ALL studies involving children)** | | | | | | | | | | |
| **2.1** Provide justification for the participation of children as research participants in your study. | | | | | | | | | | | |
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| **2.2** Has this research been conducted on adults? | | | | | | | | | | | |
| Yes | | | | | |
| **If yes, is there any indication that the proposed research would benefit, or at least not be harmful to children?** | | | |
| No | | | | | |
| **2.3** Are you requesting a waiver of assent? | | | | | | | | | | | |
| Yes  **If yes, justify the waiver by selecting all that apply.** | | | | | |
| The children are not capable of assenting because: | | | |
| The research holds out a prospect of direct benefit that is important to the health or well-being of the children **and** the  treatment/intervention is available only in the context of the research because: | | | |
| Other (explain): | | | |
| No | | | | | |
| **2.4** Explain what methods will be used for evaluating dissent by a child (i.e., description of behaviors that would indicate child does not want to participate such as moving away, certain facial expressions, head movements, etc.). | | | | | | | | | | | |
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| **2.5** Parental Consent | | | | | | | | | | | |
| The following is a description of how parental consent (permission) will be obtained. | | | | | |
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| **OR** | | | | | | | |
| This study is requesting waiver of the requirement for parental consent. | | | | | |
| Describe the reason why you are requesting a waiver of parental consent (i.e., getting parental permission may be against the best interest of the child as in a study of abused or neglected children). | | | |
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| Describe what measures will be taken to protect the rights and welfare of the children | | | |
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| Describe the expertise of the research staff/study personnel in dealing with children of the age range included in your study and whether they are knowledgeable and sensitive to the physical and psychological needs of those children and their families.  Describe the appropriateness of the facility in which the research will be conducted as it relates to environmental conditions and/or equipment accommodating to children. | | | |
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| If applicable, provide additional information that may support your request to involve children in research. | | | |
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| **Section 3. Wards of the State**  **This section is only applicable for studies:**   1. Involving wards of the state, **AND** 2. The research risk to benefit comparison was classified as either Category 3 or 4 in Section 1 above. | | | | | | | | | | | |
| **N/A – This study is NOT enrolling children under category 3 or 4 in Section 1 above**. | | | | | | | | | | |
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| **3.1**  **Indicate which category describes your research proposal as it relates to the inclusion of wards of the state.** | | | | | | | | | | |
| The research is related to participant’s status as a ward of the state. | | | | | | |
| The research is conducted in schools, hospitals, or similar setting(s) in which the majority of children involved in the study are **NOT** wards of the state. | | | | | | |
| Neither of the above. | | | | | | |
| **3.2** **Federal regulations require that an advocate must be appointed in circumstances where the investigator enrolls a ward of the state for research studies under categories 3 or 4 in Section 1.**  **Answer the following questions:** | | | | | | | | | | |
| **3.2a**  Will the advocate serve in addition to a guardian **or** in place of parents? ***(Select one)*** | | | | | | | | | | |
| Advocate will serve in addition to a guardian. | | | | | | |
| Advocate will serve in place of parents. | | | | | | |
| **3.2b** Will each child have their own advocate **or** will one advocate serve for all children enrolled in the study? ***(Select one)*** | | | | | | | | | | |
| Each child will have their own advocate. | | | | | | |
| One advocate will serve for all children. | | | | | | |
| **3.2c** Explain how the advocate has the background **and** experience to serve as an advocate for the study: | | | | | | | | | | |
| **3.2d**  Federal regulations state that an advocate cannot be associated with the study, investigator or organization. Please provide assurances that the advocate meets these restrictions. | | | | | | | | | | |
| **Certification** | | | | | | | | | | |
| **By submitting this form, investigator acknowledges and confirms compliance with "INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)" throughout the conduct of the study.** | | | | | | | | | | |
| * For DHS, EPA, HHS, or VA research the applicable official is the Department Secretary. For DOD research, the applicable official is the Director, Defense, Research, and Engineering. For federal research, the meeting is announced in the Federal Register. * The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition. | | | | | | | | | | |