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| **HSC**  |

For studies involving **children**, complete this form and include it with your IRB application submission. *In Texas, a child is an individual less than 18 years of age unless the individual is an* [*emancipated minor*](https://www.uthscsa.edu/vpr/services/glossary#Mature-Minor) *or is of legal age for consent to medical treatment involved in the research. See IRB policy on Consent for more information. For the purposes of DHHS regulations viable* [*neonates*](https://www.uthscsa.edu/vpr/services/glossary#Neonate) *are considered children and are protected under section A and D of 45 CFR 46. Neonates of uncertain viability or nonviable neonates require additional protections see* [*Form U.*](https://www.uthscsa.edu/sites/default/files/Services/forms/form_u.docx)

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| Section 1: Inclusion of children**For all studies involving children, complete this section.** |
| **a)** Provide justification for the participation of children as research subjects in your study. |
|        |
| **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)** Describe measures that will be taken to ensure that a parent is present when the child participates in any research interventions.  *[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.), provide an explanation about why.]* |
|       |
| **d)** 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. |
|       |
| **e)** If applicable, provide additional information that may support your request to involve children in research. |
|       |
| **f)** Will children who are participating in the research study become adults during their participation? [ ]  Yes [ ]  No |
| If Yes, describe process for re-consenting subject when he/she reaches 18 years of age:       |

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| Section 2: 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.**  |

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| [ ]  | **Category 1 Minimal risk research** *Note:* [*Minimal risk*](https://www.uthscsa.edu/vpr/services/glossary#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.***(**[**45 CFR 46.404**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.404)**;** [**21 CFR 50.51**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.51)**)** |
| **Risks** - Describe how the risk of the research is only minimal: (if enrolling more than one population, consider risks of all groups) |
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**OR**

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| [ ]  | **Category 2 Greater than minimal risk research with the prospect of direct benefit to the individual subjects.****(**[**45 CFR 46.405**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.405)**;** [**21 CFR 50.52**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.52)**)** |
| **a) Risks** - Identify the research risks that are greater than minimal: (if enrolling more than one population, consider risks of each group) |
|       |
| **b) Benefits to subjects** (if enrolling more than one population, consider benefits of each group) |
| (1) Explain the anticipated benefit of an intervention or procedure to the subjects: |
|       |
| (2) Explain the anticipated benefit from a monitoring procedure that is likely to contribute to the subject's well-being: |
|       |
| **c) Risk:Benefit Comparison** - 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: |
|       |

**OR**

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| [ ]  | **Category 3 Greater than minimal risk research and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition****(**[**45 CFR 46.406**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.406)**;** [**21 CFR 50.53**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.53)**)**  |
| **a) Risks** - Identify the research risks that are greater than minimal: (if enrolling more than one population, consider risks of each group) |
|       |
| **b) Level of Risk** - 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) Comparison of research to actual situation** - Describe how the research intervention(s)/procedure(s) present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations: |
|       |
| **d) Importance of the knowledge to be gained** - Explain why the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder or condition: |
|       |

**OR**

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| [ ]  | **Category 4 Research that 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: 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).* [**45 CFR 46.407**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.407)**;** [**21 CFR 50.54**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.54) |
| **Risks** - Identify the research risks that are greater than minimal: |
|       |

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| Section 3: Assent |
| **a)** Are you requesting a waiver of assent? [ ]  Yes [ ]  No, ***skip to Section 3: Assent b)***  |
| If Yes, justify 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)       |
| **b)** Describe what provisions will be made for soliciting the assent of the children, and the consent of at least one parent/guardian: |
|       |
| **c)** 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.)]. |
|       |

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| Section 4: Parental Permission |
| **a)** For Category 1 Minimal Risk Research & Category 2 Greater than minimal risk research with the prospect of direct benefit, **provide a description of how parental consent (permission) will be obtained for at least one parent/guardian**: |
|       |
| **b)** Category 3 Greater than minimal risk research and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition & Category 4 Research that 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 **provide a description of how parental consent (permission) will be obtained for at least both parents/guardians**:*Note: 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 and the method of determination has been documented.* |
|       |
| **OR** |
| **c)** This study is requesting waiver of the requirement for parental consent.  |
|  | Describe the reason why you are requesting waiver [i.e., getting parental permission may be against the best interest of the child (i.e., a study of abused or neglected children)]: |
|  |       |
|  | c) Describe what measures will be taken to protect the rights and welfare of the children : |
|  |       |

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| Section 5: Wards of the State**This section is only applicable for studies:**1. involving wards of the state, **AND**
2. the research risk:benefit was classified as either Category 3 or 4 in Section 2 above.
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| [ ]  | **N/A** – This study is not enrolling children under category 3 or 4 in Section 1 of this form. |
| **B. Indicate which category describes your research proposal in relation to the inclusion of wards of the state:** |
| [ ]  | The research is related to subjects’ 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. |
| [ ]  | None of the above |
| **B. Federal regulations require that an advocate must be appointed in circumstances where the investigator enrolls a ward of the state for research studies under category 3 or 4 in Section 1.** **Answer the following questions:** |
|  | **a)** 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 |
|  | **b)** 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 |
|  | **c)** Explain why the advocate has the background **and** experience to serve as an advocate for the study. |
|  |       |
|  | **d)** Federal regulations state that an advocate cannot be associated with the study, investigator or organization. Please provide assurances that the advocate meets these restrictions. |
|  |       |