**DO NOT DELETE OR ALTER ANY PART OF THIS FORM**

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| **Principal Investigator:** | [REQUIRED FIELD] |
| **Study Title:** | [REQUIRED FIELD] |
| **IRB #:** |  |

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| **ADDENDUM: RESEARCH WITH CHILDREN OR WARDS OF THE STATE** |

**Instructions:**

* Read the guidance provided below before answering the questions.
* Do not leave questions/[REQUIRED FIELD] blank; write or check "**N/A**" if not applicable.

**Guidance:**

* By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally, the law considers any person under 18 years old to be a child.
* The HHS regulations at 45 CFR part 46, subpart D permit IRBs to approve 1-3 categories of research involving children as subjects. The fourth category of research requires a special level of HHS review beyond that which is provided by the IRB.

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| **SECTION 1. RESEARCH PRESENTS NO GREATER THAN MINIMAL RISK** |

1. **Is this research considered no greater than minimal risk to the children?**

**☐ No**

**☐ Yes**

***If yes****,* ***complete (a-b).***

***PLEASE NOTE:***

*To approve research in this category* ***all*** *the conditions (a-b) below must be satisfied.*

1. **Explain how the research presents no greater than minimal risk to the children:** [REQUIRED FIELD]
2. **Explain how adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at** [**45 CFR 46.408**](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#46.408)**:** [REQUIRED FIELD]

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| **SECTION 2. RESEARCH INVOLVING GREATER THAN MINIMAL RISK WITH** **PROSPECT OF DIRECT BENEFIT** |

1. **Is this research considered greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research?**

**☐ No**

**☐ Yes**

***If yes****,* ***complete (a-c).***

***PLEASE NOTE:***

*To approve research in this category all the conditions (a-c) below must be satisfied.*

*Signatures of both parents may be required.*

* 1. **Explain how the risk is justified by the anticipated benefits to the subjects:** [REQUIRED FIELD]
  2. **Explain how the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches:** [REQUIRED FIELD]
  3. **Explain how adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at** [**45 CFR 46.408**](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#46.408)**:** [REQUIRED FIELD]

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| **SECTION 3. RESEARCH INVOLVING GREATER THAN MINIMAL RISK WITHOUT PROSPECT OF DIRECT BENEFIT** |

1. **Is this research considered 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 subject's disorder or condition?**

**☐ No**

**☐ Yes**

***If yes****,* ***complete (a-d).***

***PLEASE NOTE:***

*To approve research in this category all the conditions (a-d) below must be satisfied.*

*Signatures of both parents may be required.*

* 1. **Explain how the risk of the research represents a minor increase over minimal risk:** [REQUIRED FIELD]
  2. **Explain 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:** [REQUIRED FIELD]
  3. **Explain how the intervention or procedure 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:** [REQUIRED FIELD]
  4. **Explain how adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at** [**45 CFR 46.408**](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#46.408)**. the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children:** [REQUIRED FIELD]

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| **SECTION 4. RESEARCH**  **NOT OTHERWISE APPROVABLE** |

1. **Is this research not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children?**

**☐ No**

**☐ Yes**

***If yes****,* ***complete (a).***

***PLEASE NOTE:***

*Research falling into this category can be approved only after the Secretary of Health and Human Services (HHS), in consultation with a panel of experts, determines that the research satisfies applicable conditions under* [*§46.407*](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#46.407)*.*

1. **Explain how the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children:** [REQUIRED FIELD]