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| **PI Name:** | **Submission #:** |
| **Protocol Title:** | |

**Reviewer Instructions:** Please check applicable boxes and provide explanation, rationale, etc. as necessary in the form below.

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| **Section A: Type of Review** |
| Full Board Initial Review  Full Board Continuing Review  Expedited Initial Review: Category?\*  Expedited Continuing Review: Category?\*  \***For Expedited Reviews:**  Please click [here](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html) for Expedited Review Categories  Confirm the below applicability criteria for expedited review are met:  The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. For continuing review, this applies to current and future procedures and does not include procedures no longer being performed. This does not apply to category 8(b).  The research is not classified. |

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| **Section B: Conflict of Interest Declaration (Check one):**  I do not have a (financial or non-financial) conflict of interest relative to the conduct of this study.  I have a (financial or non-financial) conflict of interest relative to the conduct of this study. *(If this is the case, please notify the Human Subjects Office so that an alternative reviewer may be assigned).* |

**Section C: Summary of the Protocol (include any problems or issues in this section as well):**

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| **Section D: 46.111 Criteria for IRB Approval of Research—in order to approve research covered by this policy, the IRB must determine that all of the following requirements are satisfied:** | |
| 1. **45 CFR 46.111(1):** Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk (for example, using information from interventions already being performed on the subjects for diagnostic or other treatment purposes). | |
| Is there enough information provided in the application materials to reach a conclusion regarding this criterion?  Yes  No | Based on your review of the materials, is this criterion met?  Yes  No |
| Please record your findings as well as your rationale. | |
| 1. **45 CFR 46.111(a)(2)**: Risks to subjects are reasonable in relation to anticipated benefits, if any to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider those risks and benefits that may result from research only. The IRB should not consider possible long-range effects of applying knowledge gained in research (for example, the possible effects of the research on public policy among those research risks that fall within the purview of its responsibility). | |
| Is there enough information provided in the application materials to reach a conclusion regarding this criterion?  Yes  No | Based on your review of the materials, is this criterion met?  Yes  No |
| Please record your findings as well as your rationale. | |
| 1. **45 CFR 46.111(a) (3)**: Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. | |
| Is there enough information provided in the application materials to reach a conclusion regarding this criterion?  Yes  No | Based on your review of the materials, is this criterion met?  Yes  No |
| Please record your findings as well as your rationale. | |
| 1. **45 CFR 46.111(a)(4)**: Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by   [§46.116.](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) | |
| Is there enough information provided in the application materials to reach a conclusion regarding this criterion?  Yes  No | Based on your review of the materials, is this criterion met?  Yes  No |
| Please record your findings as well as your rationale. | |
| 1. **45 CFR 46.111(a)(5)**: Informed consent will be appropriately documented, in accordance with, and to the extent required by  [§46.116.](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116) | |
| Is there enough information provided in the application materials to reach a conclusion regarding this criterion?  Yes  No | Based on your review of the materials, is this criterion met?  Yes  No |
| Please record your findings as well as your rationale. | |
| 1. **45 CFR 46.111(a)(6)**: When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. | |
| Is there enough information provided in the application materials to reach a conclusion regarding this criterion?  Yes  No | Based on your review of the materials, is this criterion met?  Yes  No |
| Please record your findings as well as your rationale. | |
| 1. **45 CFR 46.111(a)(7)**: When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. | |
| Is there enough information provided in the application materials to reach a conclusion regarding this criterion?  Yes  No | Based on your review of the materials, is this criterion met?  Yes  No |
| Please record your findings as well as your rationale. | |
| 1. **45 CFR 46.111(b)**: When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. | |
| Is there enough information provided in the application materials to reach a conclusion regarding this criterion?  Yes  No | Based on your review of the materials, is this criterion met?  Yes  No |
| Please record your findings as well as your rationale. | |

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| **Section E: Additional Required Determinations:** |
| 1. Is a waiver of informed consent OR a waiver of documentation of informed consent proposed? (If yes, please continue; if no, go on to Question 2 in this section)   Yes  No |
| 1. Is a waiver or alteration of consent requested?   Yes (If yes, select approval criteria below)  No  Is it appropriate? All must apply:  Research involves no more than minimal risk  Waiver/alteration will not adversely affect rights and welfare of subjects  Research could not practicably be conducted without the waiver/alteration (note that this is not for convenience)  Whenever appropriate, subjects will be provided additional pertinent information after participation.  The research is NOT subject to FDA regulations |
| 1. Is the PI requesting waiver of the requirement to obtain a documented (signed) consent form?   Yes (If yes, select approval criteria below)  No  If yes, one of the following must apply:  The only record linking the subject to research would be the consent form, and principal risk to the subject would be a potential harm resulting from breach of confidentiality and the research is NOT subject to FDA regulations  The research presents no more than minimal risk of harm to subjects, and involves no written procedures for which written consent is normally required outside of the research context |

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| **Section F: 45 CFR 46, Subpart D: Are Children (minors) involved in this study?**  Yes (if yes, move on to below questions)  No (if no, go directly to Section G) | |
| 1. Risk Category | |
| **Minimal Risk**  45 CFR 46.404 (OHRP)  21 CFR 50.51 (if FDA-regulated agents involved)  **More than minimal risk; possibility of direct benefit**  45 CFR 46.405 (OHRP)  21 CFR 50.52 (if FDA-regulated agents are involved)  **(Slightly) More than minimal risk; no possibility of direct benefit\***  45 CFR 46.406 (OHRP)  21 CFR 50.53 (If FDA-regulated agents are involved)  \**For this category, both parents must sign, and no wards of state or foster children may be enrolled unless specifically approved by the IRB and in compliance with the regulations as per 46.409* | |
| 1. Is parent permission being obtained? | |
| Yes  If this is a .404/.51 or .405/.52 study (per your answer above in question 1), is permission from only one parent acceptable?  Yes  No | No  One of the following sets of conditions must be met in order for parent permission to be waived. Do either of the following apply?  Either all of the below:  Research involves no more than minimal risk  Waiver/alteration will not adversely affect rights and welfare of subjects  Research could not practicably be conducted without the waiver/alteration (note that this is not for convenience)  Whenever appropriate, subjects will be provided additional pertinent information after participation.  The research is NOT subject to FDA regulations  **-----------OR------------**  Is the research protocol designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects?  Yes  No |
| 1. Is minor assent being obtained?   Yes  Written  Verbal    No  This study involves a drug or procedure with no standard alternatives available, or the risk/benefit profile of the standard alternatives that are available are such that participation in the protocol would be important to the health or well-being of the children.  The subject population is too young, or the capability of some or all of the children is so limited that they cannot reasonably be consulted. | |
| Age ranges of minors included in this study and any comments or rationale for waiver requests, how will permission/assent be documented, etc.: | |
| **Section G: Are adults who cannot consent for themselves involved in this study?**  Yes (if yes, move on to below questions)  No (if no, go directly to Section H) | |
| 1. Must this population be include in order for the study question to be answered?   Yes  No | |
| 1. What is the risk level of this study?   Minimal Risk  More than minimal Is there a possibility of benefit?  Yes  No | |
| 1. Who is giving permission on behalf of the subject? | |

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| **Section H: Subpart B: Are pregnant women, fetuses or neonates involved in this study?**  Yes (If yes, please complete the questions below)  No (If no, please proceed to Section I) |
| 1. Both of these criteria must be met:   Where scientifically appropriate, previous studies and data are available  Any risk is the least possible for achieving the objectives of the research |
| 1. One of these criteria must be met:   The risk to the fetus is caused solely by interventions or procedures that hold the potential of direct benefit for the woman or fetus  There is no possibility of direct benefit for the woman or fetus, but the risk to the fetus is minimal (*note that if the study is federally funded, there are additional criteria for compliance-please note this so that Human Subjects Office staff can flag this to be discussed at the IRB meeting*) |
| 1. Check one regarding possibility of benefit:   There is the possibility for direct benefit to the pregnant woman only  There is the possibility of direct benefit to the fetus only\*  There is the possibility of direct benefit to both the pregnant woman and the fetus  There is no possible direct benefit for the woman or the fetus, but risk is minimal  \*For this criterion to apply, check study documents to ensure that the study includes paternal consent (unless the father is unable to consent due to unavailability, incompetence, temporary incapacity or the pregnancy resulted from rape or incest) |
| 1. Are viable neonates (separated from the mother and independently functioning) included in this study?   Yes (If yes, these are considered children, so Subpart D applies-Please complete Section F )  No |
| 1. Are non-viable neonates, or neonates of uncertain viability involved in this study?   Yes (If yes, please contact the Human Subjects Office for guidance)  No |

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| **Section I: Subpart C: Are prisoners involved in this study?**  Yes (If yes, please complete the questions below)  No (If no, please proceed to Section J) |
| If research involves prisoners, it must satisfy ***all*** of the below criteria:  Advantages to participation are not coercive  Risks are commensurate with what would be acceptable to non-prisoners  The selection procedures are fair  The information is presented in an understandable language  There is no effect on decisions related to parole  Follow-up provisions are adequately addressed  If all of the above are satisfied, please check one of the following for a determination in connection with [45 CFR 46.306](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.306):  Research on possible causes, effects and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects  Research on prisons as institutional structures or of prisoners as incarcerated persons, provided the study presents no more than minimal risk and no more than inconvenience to the subjects  Research on conditions particularly affecting prisoners as a class, provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts (in medicine, ethics, penology etc) and published notice in the Federal Register of the intent to approve such research  Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subjects  If the research includes the assignment of prisoners to control groups that might not benefit from the research, it may only proceed after the Secretary of the HHS has consulted with appropriate experts and published a note in the Federal Register of the intent to approve the research |

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| **Section J: Is sponsor-required GCP compliance required for this study?**  Yes (If yes, please complete the questions below)  No (If no, please proceed to Section K) |
| 1. Are the following elements present in the consent document?   Yes  No  N/A All payments are prorated  Yes  No Alternatives are provided with risks/benefits assessment  Yes  No  N/A Costs and treatment in case of injury is clearly addressed  Yes  No Subject responsibilities are addressed in a distinct section  Yes  No  N/A Subjects will be given a signed and dated copy of the informed consent document  Yes  No All engaged investigators have documented GCP training |

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| **Section K: Any other special circumstances being requested (waiver for reporting certain adverse events, etc.)** |
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| **Continuing Review Frequency** | **Recommendation (check one):** |
| 12 Months  Other\* List (ie 6 months, etc)  \*If this is selected, include rationale for this choice: | Approve as submitted  Modifications required  Tabled  Disapprove |
| Risk Level (check one)  Minimal Risk\*  Greater than Minimal Risk  *\*****Minimal risk****means that 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 or psychological examinations or tests.* |  |