Human Research Protections (HRP) strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the ZOT IRB application process, email OR-Web-Support@uci.edu for assistance.

 INSTRUCTIONS

This information is necessary for the IRB to determine if the criteria for approval at [45 CFR Part 46 Subpart B](https://www.ecfr.gov/current/title-45/part-46/subpart-B) and [21 CFR 56.111(b)](https://​/%E2%80%8Bwww.ecfr.gov/%E2%80%8Bcurrent/%E2%80%8Btitle-21/%E2%80%8Bpart-56/%E2%80%8Bsection-56.111#p-56.111(b)) (as applicable) are satisfied for [pregnant people, fetuses, and neonates](https://www.ecfr.gov/current/title-45/section-46.202). For more information, visit: [Vulnerable Populations](https://research.uci.edu/human-research-protections/subject-enrollment/vulnerable-populations/).

Answer all questions succinctly using non-technical language as much as possible.

* If a question is a numbered list, respond with a corresponding numbered list.
* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

 1. STUDY INFORMATION

**Short Title:** Specify the short study title.

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| Click or tap here to enter text. |

 2. INCLUSION OF PREGNANT PEOPLE OR FETUSES

[ ]  *This section is not applicable.*

[**§46.204**](#46.204)**: Pregnant people or fetuses may be involved in research if all of the following conditions are met. *If all conditions are not met, also complete section 3.***

**Rationale:**

1. Describe any preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant people, have been conducted and provide data for assessing potential risks to pregnant people and fetuses.
2. Justify that any risk is the least possible for achieving the objectives of the research.

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**Benefit to Participants:** Specify if there is a prospect of a direct benefit to the pregnant person or the fetus and provide protocol specific justification.

[ ]  Risk to the fetus is caused solely by interventions or procedures that hold out the prospect of a direct benefit to the pregnant person or to the pregnant person and the fetus. The pregnant person’s consent is obtained.

[ ]  Risk to the fetus is caused solely by interventions or procedures that hold out the prospect of a direct benefit to solely to the fetus. The pregnant person and the father's consent are obtained. The father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or if the pregnancy resulted from rape or incest.

[ ]  There is no such prospect of direct benefit. Risk to the fetus not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means. The pregnant person’s consent is obtained.

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**Consent/Assent**:

1. Explain how each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus.
2. Specify if the research will include [children](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.402) who are pregnant and if so, verify that assent and **parents/guardians permission are obtained. Alternatively, explain** whether this study will enroll people under the age of 18 who are able to legally consent to treatment or procedures involved in research and if so, provide the legal citation (i.e. state regulation).

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**Assurance:** Provide assurance that all the following are true.

[ ]  No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

[ ]  Individuals engaged in the research will have no part in any decisions as to the timing, method, and procedures used to terminate the pregnancy; and

[ ]  Individuals engaged in the research will have no part in determining the viability of a neonate.

 3. INCLUSION OF NEONATES

[ ]  *This section is not applicable.*

[**§46.205**](#46.205)**: Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met.** ***If all conditions are not met, also complete section 3.***

**Preliminary Data:** Provide a description of any pre-clinical and clinical studies that have been conducted which provide data for assessing potential risks to neonates.

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**Assurance:** Provide assurance that the following is true.

[ ]  Individuals engaged in the research will have no part in determining the viability of a neonate.

**Neonates of Uncertain Viability:** Specify if there is a prospect of a direct benefit to the neonate and provide protocol specific justification.

[ ]  The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective. Consent of either parent of the neonate is obtained.\*

[ ]  The purpose of the research development of important biomedical knowledge, which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research. Consent of either parent of the neonate is obtained.\*

[ ]  Not applicable, this research does not involve neonates of uncertain viability.

\* If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

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**Nonviable Neonates:** Provide assurance that all the following are true.

[ ]  Vital functions of the neonate will not be artificially maintained;

[ ]  The research will not terminate the heartbeat or respiration of the neonate;

[ ]  There will be no added risk to the neonate resulting from the research; and

[ ]  The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. Provide protocol specific justification. Consent of both parents of the neonate is obtained (waivers do not apply).\*

[ ]  Not applicable, this research does not involve nonviable neonates.

\* If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.

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**Consent:** Explain how each individual providing consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate.

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 4. RESEARCH NOT OTHERWISE APPROVABLE

[ ]  *This section is not applicable, end of form.*

[**§46.207**](#46.207)**: Requirements of**[**§46.204**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html#46.204)**or**[**§46.205**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html#46.205)**are not met.**

**Rationale:** Explain why the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of neonates.

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| Click or tap here to enter text. |

**Ethical Principles:** Explain how the research will be conducted in accordance with sound ethical principles.

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| Click or tap here to enter text. |