**This form should be used when pregnant women/neonates/fetuses are a targeted study population.**

* **Pregnant Women:** Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
* **Neonate:** A newborn.
* **Nonviable Neonate**: A neonate after delivery that, although living, is not viable.
* **Viable Neonate:** Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.
* **Fetus**:the product of conception from implantation until delivery.

To be given the correct regulatory category, language must be documented, reviewed, and approved as part of the IRB materials. Provide protocol specific justification for each item to assist the IRB with their review.

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| **Basic Information** | | |
| **Title of Study:** | |  |
| **Short Title:** | |  |
| **Principal Investigator Name:** | |  |
| **Section 1: General Information** | | |
| What activities will pregnant individuals be completing for the research study?  Explain: | | |
| Will the study procedures place subjects at any risk?**Once a neonate is determined to be viable, they are considered children; also complete the *Appendix for Children/Wards* for viable newborns.**  Explain: | | |
| Will any of the pregnant individuals be a minor (17 years old and younger)?  No Yes  **If Yes, also complete the *Appendix for Children/Wards*** | | |
| Will a waiver of consent be obtained for the pregnant women or neonates?  No Yes  **If Yes, also complete the *Appendix for Waiver or Alteration of Consent/PHI*.** | | |
| **Section 2: Pregnant Women (45 CFR 46.204)**  **All must be checked YES to include pregnant women in the research** | | |
| Yes | Research where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses | |
| Yes | The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means | |
| Yes | Any risk is the least possible for achieving the objectives of the research | |
| Yes | If the research holds out the prospect of direct benefit to the pregnant women, the prospect of direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal risk and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, the woman's consent is in accord with the informed consent provisions of the regulations. | |
| Yes | If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained\*  ***\*Except that the father’s consent needs not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.*** | |
| Yes | Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate | |
| Yes | No inducements, monetary or otherwise, will be offered to terminate a pregnancy | |
| Yes | Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy | |
| Yes | Individuals engaged in the research will have no part in determining the viability of a neonate | |
| **Explain how the proposed study meets the elements above to include pregnant women in the research:** | | |
| **Section 3: Neonates (45 CFR 46.205(a))**  **All must be checked YES to include neonates in the research** | | |
| Yes | Research that where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates | |
| Yes | Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate | |
| Yes | Individuals engaged in the research will have no part in determining the viability of a neonate | |
| **Explain how the proposed study meets the elements above to include neonates in the research:** | | |
| **Complete Subparts A and B if applicable**  **Subpart A: Neonates of Uncertain Viability (45 CFR 46.205(b))**  **All must be checked YES to include neonates of Uncertain Viability in the research** | | |
| Yes | 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 | |
| Yes | The purpose of the research is the 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 | |
| **Explain how the proposed study meets the elements above to include neonates in the research:** | | |
| **NOTE: Parental permission from either parent or their LAR is required for Neonates of Uncertain Viability.** | | |
| **Subpart B - Nonviable Neonates (45 CFR 46.205(c))**  **All must be checked YES to include Nonviable neonates in the research** | | |
| Yes | Vital functions of the neonate will not be artificially maintained | |
| Yes | The research will not terminate the heartbeat or respiration of the neonate | |
| Yes | The purpose of the research is the 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 | |
| **Explain how the proposed study meets the elements above to include neonates in the research:** | | |
| **NOTE: Parental permission of BOTH parents or their LAR is required for Nonviable Neonates.** | | |
| **Section 4: Placenta, dead fetus, or fetal material (45 CFR 46.206)** | | |
| Yes | Research involving, after deliver, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws.\*  **\*Note: Research on aborted fetuses is not permitted in Arizona per state law.** | |
| **Explain the applicable laws:** | | |
| **Section 5: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates (45 CFR 46.207)** | | |
| Yes | The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. | |
| **Explain:** | | |