**HUMAN USE RESEARCH**

**RESEARCH INVOLVING PREGNANT WOMEN, HUMAN FETUSES AND/OR NEONATES**

For studies involving pregnant women, human fetuses and/or neonates, check the box beside the section that best fits your research, and address the issues that immediately follow as they apply to your research by typing in the line provided.

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|  | **Section 1. Research Involving Pregnant Women or Fetuses [**[**45 CFR 46.204**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.204)**]** | | | | | | |  | **[Section 1 does not apply.]** |
|  | Limitations on research involving pregnant women or fetuses - 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, or procedures used to terminate a pregnancy; and Individuals engaged in the research will have no part in determining the viability of a neonate.  Check this box to confirm your understanding of these limitations | | | | | | | | |
| **A.** | **Prior research related to risks for pregnant women or fetuses**  Describe any pre-clinical studies on pregnant animals and any clinical studies conducted on non-pregnant women that have been conducted that are useful for assessing potential risks to pregnant women and fetuses or rationale why this information is not needed (scientifically appropriate). (If already described in a Sponsor’s Protocol or Investigator Brochure, provide Section number      ) | | | | | | | | |
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| **B.** | **Risk to the fetus** – the IRB can only approve research that meets one of the two risk criteria listed – if neither of these is accurate, contact the IRB Office before proceeding.  Check the box next to the item that best describes the anticipated risk to the **fetus**: | | | | | | | | |
| 1) |  | | [Minimal risk](https://www.uthscsa.edu/vpr/services/glossary#Minimal-Risk); | | | Special circumstance in minimal risk research: indicate here if there are  no risks to the fetus (e.g., only risk of the research is breach of confidentiality for the pregnant women) | | | |
|  | | | **or** | | |  | | | |
| 2) |  | | Greater than minimal risk and 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. | | | | | | |
| **C.** | Provide a rationale for the anticipated risk to the fetus selected in section B: | | | | | | | | |
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| **D.** | Explain why any risk is the least possible for achieving the objectives of the research: (For further clarification see the definition of [minimizing risk](https://www.uthscsa.edu/vpr/services/glossary#Minimizing-Risk)): | | | | | | | | |
| 1) |  | Yes | |  | No | Are there alternative procedures that pose less risk than those proposed in the study? | | | |
|  | If **yes**, explain why the alternatives are not being used: | | | | | | | | |
| 2) |  | Yes | |  | No | Are you using procedures already being performed on the subjects for diagnosis or treatment? | | | |
|  |  | Yes | |  | No | If no, are the study procedures the least number necessary to answer the research question? | | | |
|  | If **no**, explain why: | | | | | | | | |
| **E.** | Check the appropriate boxes to determine who is required to sign the consent document: | | | | | | | | |
| 1) |  | Yes | |  | No | The research activities involving pregnant women hold out the prospect of a direct benefit to the pregnant woman; | | | |
| 2) |  | Yes | |  | No | The research activities involving pregnant women hold out the prospect of a direct benefit **both** to the pregnant woman and the fetus; or | | | |
| 3) |  | Yes | |  | No | The research activities involving pregnant women do not hold out the prospect a of direct benefit for the woman or the fetus, but the risk to the fetus is 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. | | | |
| *If “Yes” to any of the above in “E.”, informed consent must be obtained from the pregnant woman or her legally authorized representative as required in* [*45 CFR 46.116 & 117*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116)*; but consent from the father is not required. The informed consent should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus.* | | | | | | | | | |
| 4) |  | Yes | |  | No | The research activities involving pregnant women hold out the prospect of a direct benefit solely to the fetus. | | | |
| *If “Yes”, informed consent must be obtained from the pregnant woman and the father as required in 45 CFR 46.116 & 117. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus.*  *NOTE: The father's informed consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.* | | | | | | | | | |
| 5) |  | Yes | |  | No | | The research activities involving pregnant women will involve individuals under the age of 18 who are pregnant and are not considered [emancipated](https://www.uthscsa.edu/vpr/services/glossary#Mature-Minor) minors. | | |
| *If ”Yes”, assent from the pregnant child and consent from her parent or legal guardian must be obtained in accordance with the provisions of 45 CFR 46, Subpart D.* | | | | | | | | | |

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|  | **Section 2. Research Involving** [**Neonates**](https://www.uthscsa.edu/vpr/services/glossary#Neonate)[**§** [**46.205**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.205)**]** | |  | **[Section 2 does not apply.]** |
|  | After delivery, there must be a determination as to whether the neonate is viable (viable means being able to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.  **There are three possible determinations:**  **1) \*Neonate is nonviable, 2) \*\*Neonate has uncertain viability, or 3) \*\*\*Neonate** **is viable.**  **Limitation on determining viability of neonates** - individuals engaged in the research will not have any part in determining the viability of a neonate being considered for inclusion in the study.  Check this box to confirm your understanding of these limitations | | | |
|  | **\*Complete sections A & B if the research involves neonates of uncertain viability.**  **\*\*Complete sections A & C if the research involves nonviable neonates.**  **\*\*\*Complete** [**Form W – Research Involving Children for research**](https://www.uthscsa.edu/sites/default/files/Services/forms/form_w.docx) **involving viable neonates.** | | | |
| **A.** | **Scientific justification for inclusion of** **Neonates of Uncertain Viability AND Nonviable Neonates** | | | |
|  | Explain why the proposed research is scientifically appropriate to include neonates. Include descriptions of any pre-clinical studies that have been conducted which provide data for assessing potential risks to neonates or rationale why this information is not needed (scientifically appropriate). (If justification can be clearly cited in background refer to page and paragraph.) | | | |
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| **B.** | **Neonates of Uncertain Viability** - the IRB can only approve research that meets one of the two criteria listed – if neither of these is accurate, contact the IRB Office before proceeding. Place a check in the appropriate box as it applies to your research. | | | |
| 1) |  | 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, **or** | | |
| 2) |  | The research has the main purpose of 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 the procedures that will be used to obtain legally effective informed consent of either parent of the neonate.  ***NOTE:***  *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 will be obtained as required by* [*45 CFR 46.116 & 117*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116)*.* ***These procedures must assure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate. The father's informed consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.*** | | | |
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| **C.** | **Nonviable Neonates: After delivery nonviable neonate may not be involved in research unless all of the following additional conditions are met:**  (1) Vital functions of the neonate will not be artificially maintained;  (2) The research will not terminate the heartbeat or respiration of the neonate;  (3) There will be no added risk to the neonate resulting from the research;  (4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and  (5) The legally effective informed consent of both parents of the neonate is obtained (waiver or alteration of consent is not allowed). However, there are some exceptions.    Check this box to confirm your understanding of these limitations | | | |
|  | Explain the procedures that will be used to obtain legally effective informed consent of both parents of the neonate in the recruitment section of your protocol.  *Note: 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. 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.* ***These procedures must assure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate.*** | | | |
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|  | | **Section 3. Research Involving After Delivery, The Placenta, The Dead Fetus, Or Fetal Material** [**§** [**46.206**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.206)**]** | | | | | | | | | |  | | **[Section 3 does not apply.]** |
| **A.** | | This research proposes to use the following: (Check all that apply) | | | | | | | | | | | | |
|  | |  | Placenta | | | | | |  | The dead fetus |  | | Macerated fetal material | |
|  | Cells excised from dead fetus | | | | | |  | Tissue excised from dead fetus |  | | Organs excised from dead fetus | |
|  | |  | Other  Describe **🡪:** | | | |  | | | | | | | |
| *NOTE: The use of any of the above must be conducted in accordance with any applicable Federal, State, or local laws, regulations, and institutional policies regarding such activities.* | | | | | | | | | | | | | | |
| **B.** |  | | | Yes |  | No | | Will any information associated with the material identified above be recorded for research purposes in such a manner that living individuals can be identified, directly or through identifiers linked to those individuals? | | | | | | |
|  | If “Yes”, provide a rationale for the recording of identifiable information [*Note: those individuals are considered to be research subjects and all pertinent human subject regulations are applicable to their participation.*]: | | | | | | | | | | | | | |
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|  | | **Section 4. Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Human Fetuses, or Neonates**  [**§** [**46.207**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.207)**, § 46.208, § 46.209, § 46.210]** |  | **[Section 4 does not apply.]** |
| **A.** | If the study is Department of Health and Human Services (HHS) funded, or funding by HHS is sought, review by the Secretary of HHS and posting in the *Federal Register* for public comments and review is required. If this category is applicable, the OIRB will prepare and submit a report of IRB review to the appropriate HHS official. | | | |