Research involving Vulnerable Populations: Pregnant Individuals, Fetuses, Neonates, Fetal Material

Place a check in the box beside the category that best fits your proposed research and answer the questions that immediately follow:

Section A. Research Involving Pregnant Individuals or Fetuses (§ 46.204)

1. Is there supportive data to assess potential risks **to pregnant individuals and fetuses** from any pre-clinical studies on pregnant animals and/or any clinical studies with non-pregnant individuals?

No 🡪 *The research is not approvable.*

Yes 🡪 Please describe or reference the section of the protocol where this information can be found:

Not applicable (not scientifically appropriate) 🡪 Please explain:

1. Please provide an assessment of the anticipated risks and benefits:

|  |  |  |
| --- | --- | --- |
| 1. Does this research hold the prospect of **direct** benefit to the pregnant individual AND/OR the fetus? | | |
| Yes, **direct** benefit to the pregnant individual  Please explain:  *Informed consent must be obtained from the pregnant individual or their legally authorized representative as required in 45 CFR 46.116 & 117.* | Yes, **direct** benefit to the fetus\*\*  Please explain:  *\*\*If this research holds the prospect of direct benefit* ***solely to the fetus****,* *consent must be obtained from the* ***pregnant individual and the other parent*** *as required in 45 CFR 46.116 & 117.*  *Exception may be made from obtaining the other parent’s consent if they are unable to consent because of unavailability, incompetence, or temporary incapacity, or the pregnancy resulted from rape or incest.* | No, this research does not hold the prospect of direct benefit for the individual or the fetus  *Informed consent must be obtained from the pregnant individual or their legally authorized representative as required in 45 CFR 46.116 & 117.*  **NOTE: Under Pennsylvania law, any non-therapeutic medical procedure performed upon a fetus is prohibited and may be considered to be a third degree felony per 18 Pa.Con.Stat Section 3216(a). Non-therapeutic means that which is “not intended to preserve the life or health.”**  **Consultation with the Office of General Counsel may be recommended by the IRB.** |
| 1. Please provide an assessment of the anticipated risk to the fetus:   Greater than minimal risk 🡪 Is the risk to the fetus caused solely by interventions or procedures that hold prospect of direct benefit?  No 🡪 *The research is not approvable.*  Yes  Not greater than minimal   1. Provide rationale for the above risk assessment: | | 1. Please provide an assessment of the anticipated risk to the fetus:   Greater than minimal risk 🡪 *The research is not approvable.*  Not greater than minimal 🡪   1. Is the purpose of the research to develop important biomedical knowledge that cannot be obtained by any other means?   No 🡪 *The research is not approvable*.  Yes 🡪 Please explain how the knowledge cannot be obtained by other means: |
| 1. Please explain how the risk is the least possible for achieving the objectives of the research: | | |
| 1. Does the informed consent form include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus?   No 🡪 *The research is not approvable.*  Yes | | |

1. Does this research involve participants who are pregnant and meet the definition of “children” as defined in 45 CFR 46.402?

No

Yes 🡪 ***If ”Yes”, please also submit the Vulnerable Population Supplemental Form for Children with your application.***

*NOTE: PA and NJ state law allow pregnant minors to consent for themselves IF:*

* *They are legally emancipated, or*
* *The research involves the provision of medical care or treatment, (including care or treatment deemed to be experimental).*

*If the above 2 criteria are not met, under federal regulations assent from the pregnant minor and permission from their parent or legal guardian must be obtained in accordance with the provisions of 45 CFR 46, Subpart D.*

1. Will there be any inducements, monetary or otherwise, offered to terminate a pregnancy?

No

Yes 🡪 *The research is not approvable.*

1. Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?

No

Yes 🡪 *The research is not approvable.*

1. Will individuals engaged in the research have any part in determining the viability of a fetus?

No

Yes 🡪 *The research is not approvable.*

Section B. Research Involving Neonates (§ 46.205)

1. Does this research involve neonates (newborn child)?

No 🡪 *Skip to Section C*

Yes, viable neonates 🡪 *Please complete the “Vulnerable Population Supplemental Form for Children.”*

Yes, neonates of uncertain viability

Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by Subpart B unless the following conditions are met:

1. Is there supportive data to assess potential risks **to neonates** from any pre-clinical studies on pregnant animals and/or any clinical studies?

No 🡪 *The research is not approvable.*

Yes 🡪 Please describe or reference the section of the protocol where this information can be found:

Not applicable (not scientifically appropriate) 🡪 Please explain:

1. Will individuals engaged in the research have any part in determining the viability of a neonate?

No

Yes 🡪 *The research is not approvable.*

1. Place a check in the appropriate box as it applies to this research:

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

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.

1. Explain the procedures that will be used to obtain legally effective informed consent of **either parent** of the neonate (OR 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).

*NOTE: 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 other parent's informed consent need not be obtained if they are unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.*

Yes, nonviable neonates

After delivery, a nonviable neonate may not be involved in research covered by Subpart B **unless all of the following additional conditions are met**:

1. Will the vital functions of the neonate be artificially maintained?

No  Yes 🡪 Please describe:

1. Does the research include procedures to terminate the heartbeat or respiration of the neonate?

No  Yes 🡪 Please describe:

1. Will there be any added risk to the neonate resulting from this research?

No  Yes 🡪 Please describe:

1. Is the sole purpose of the research for the development of important biomedical knowledge that cannot be obtained by other means?

No  Yes 🡪 Please explain:

1. Explain the procedures that will be used to obtain legally effective informed consent of **both parents** of the neonate (OR 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 other parent 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*).

*NOTE: 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.*

Section C. Research Involving Post-delivery material, the placenta, fetal material, etc. [§ 46.206 & 18 Pa.C.S.A. 3216(b)]

1. 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 |

1. 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?

No

Yes 🡪 *Those individuals are considered to be research subjects and all pertinent human subject regulations are applicable to their participation.*

1. Will the pregnant individual be asked to provide written consent before donating the fetal tissue, organ or material for use in the research or experimentation? 18 Pa.C.S.A. 3216(b)

No 🡪 *The research is not approvable.*

Yes

1. If the research involves fetal tissue, organs or material derived from abortion, will the pregnant individual’s written consent to use the fetal material in research be obtained before, or after, the decision to undergo the abortion was made? 18 Pa.C.S.A. 3216(b)

Before 🡪 *The research is not approvable.*

After

Not applicable because the fetal tissue, organ or materials will not be derived from abortion

1. Will consideration of any kind be offered or given in order to obtain the pregnant individual’s consent to procure or use the fetal tissue, organ or material in the research or experimentation? 18 Pa.C.S.A. 3216(b)

No

Yes 🡪 *The research is not approvable.*

NOTE: Under Pennsylvania law, you may not offer or give consideration (money or other value) in order to obtain the pregnant individual’s consent or pay any portion of the costs of any abortion. However, you may be able to pay for reasonable expenses occasioned by the actual retrieval, storage, preparation and transportation of the fetal material for the research or experimentation.

NOTE: Informed consent waiver and alteration provisions may not be applied.

1. Will the possibility of the use of aborted fetal tissue, organs or material in research be used as an inducement to a pregnant individual to undergo an abortion? 18 Pa.C.S.A. 3216(b)

No

Yes 🡪 *The research is not approvable.*

1. Will any consideration (money or other value) be paid to any person or organization in connection with the procurement of the fetal tissue, organ or materials? 18 Pa.C.S.A. 3216(b)

No

Yes 🡪 *The research is not approvable.*

NOTE: Under Pennsylvania law, you may not pay anyone for procuring the fetal materials for your research. However, you may be able to pay someone for the reasonable expenses occasioned by the actual retrieval, storage, preparation and transportation of the fetal material for the research.

1. Will all individuals participating in the procurement, use, or transplantation of fetal tissue, organs, or materials, including the recipients of such tissue or organs, be informed as to whether the tissue, organs or materials were procured as a result of stillbirth, miscarriage, ectopic pregnancy, abortion, or any other means? 18 Pa.C.S.A. 3216(b)

No 🡪 *The research is not approvable.*

Yes

1. Will any person who consents to the procurement or use of fetal tissue, organs or materials for research or experimentation be able to designate a recipient for the fetal tissue, organ or materials? 18 Pa.C.S.A. 3216(b)

No

Yes 🡪 *The research is not approvable.*

Section D. Research Not Otherwise Approvable. (§ 46.207)

This research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant individuals, human fetuses, or neonates.

Please explain:

*Note: This requires review by the Secretary of the Department of Health and Human Services (DHHS) and posting in the Federal Register for public comments and review.*

Guidance

**Definitions**

Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Delivery means complete separation of the fetus from the individual by expulsion or extraction or any other means.

Fetus means the product of conception from implantation until delivery.

Neonate means a newborn.

Nonviable neonate means a neonate after delivery that, although living, is not viable.

Pregnancy encompasses the period of time from implantation until delivery. An individual will be assumed to be pregnant if they exhibit any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

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. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.