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I. PURPOSE

The regulations governing federally funded research, 45 CFR 46 Subpart B provide for special considerations and protections to be afforded to pregnant women and fetuses for their participation research. Pennsylvania Law severely restricts research on the fetus. It is illegal under the Abortion Control Act for any person to perform "non-therapeutic experimentation" upon any unborn child/fetus or upon any child born alive during the course of an abortion.

Pregnant women, fetuses and neonates are considered to be potentially vulnerable in the research context. They may be under constraints because of their status, which could affect their ability to make truly voluntary, uncoerced decisions. It is the purpose of this standard operating procedure to confirm that The Children's Hospital of Philadelphia IRBs provides all required additional safeguards for the protection of these populations.

The Children's Hospital of Philadelphia's Institutional Review Boards (IRBs) follow written policies and procedures for determining the risks to vulnerable populations, in particular pregnant women, fetuses and neonates of uncertain viability and nonviable neonates, as defined in applicable federal and state regulations.


II. POLICY STATEMENT

It is the policy of the IRB that federally funded research involving pregnant women, human fetuses, neonates of uncertain viability and non-viable neonates must comply with the special protection considerations described under 45 CFR 46 Subpart B, and in this policy, in order to receive and maintain IRB approval. The CHOP IRB will document the determinations required by the regulations along with protocol specific findings justifying those determinations.

For studies without federal funding, where the applicable research procedures are not greater than minimal risk, 45 CFR Part 46, Subpart B will be used as a guide, but determinations of approval for inclusion of pregnant women will predominantly be made by assuring that risks to the fetus are not greater than minimal and that all criteria for approval (§46.111 or §56.111) are met. The IRB may require additional protocol-specific safeguards based on the potential risks to the woman or the fetus.

III. SCOPE

These policies and procedures apply to all IRB staff, IRB members, and researchers and their staff who propose and conduct research involving pregnant women, fetuses and neonates.

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IV. DEFINITIONS

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

Delivery: Complete separation of the fetus from a pregnant woman by expulsion or extraction or any other means.

Fetus: The product of conception from implantation until delivery.

Neonate: An infant in their first month of life.

Nonviable neonate: A neonate after delivery that, although living, is not viable.

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.

Primary and Secondary Reviewer: An IRB member or alternate selected for each full board protocol review (including Initial, Amendment, Reportable Event, and Continuing Review) who is responsible for providing an in depth review of all submitted materials (described in SOP 301) prior to the meeting, documenting the review on the appropriate evaluation form, presenting the review to the full board, highlighting potential issues for IRB consideration, and making a recommendation for action by the IRB.

Reviewer: The Chair, CPHS or their designee who is responsible for providing an in-depth review of all submitted materials (described in SOP 301), documenting the review on the appropriate evaluation form, and taking an action on behalf of the IRB. The reviewer can must be an experienced IRB member/alternate.


Secretary: Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

Viable: As it pertains to the neonate, means potentially 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.

V. PROCESS

A. Research Involving Pregnant Women and Fetuses:

1. When federally funded research involves pregnant women and fetuses, the

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primary reviewer or expedited reviewer (IRB reviewer) will ensure that the reviewer checklists applicable to pregnant women and fetuses are completed and that the research complies with the requirements of 45 CFR 46.204.

2. In addition to the research review procedures described in the **SOP 105** (IRB Review Process), the IRB approves federally funded research involving pregnant women and fetuses as participants only if it finds that the research under review satisfies the requirements of Subpart B.

3. When research is not federally funded, the IRB will not apply Subpart B protections to research, if the risk of the procedures, as they apply to the pregnant woman and for the fetus (e.g., review of medical records), are not greater than minimal even where the overall risks of the research are greater than minimal (e.g., a drug trial).

(a) 45 CFR Part 46.204 will serve as a guide for the IRB's determinations.

(b) Research involving pregnant women and fetuses will be considered approvable, provided that the risks to the woman and the fetus are not greater than minimal and the research meets all criteria for approval under 21 CFR 50 or 45 CFR 46, Subpart A.

(c) On a case-by-case basis, the IRB may require additional protections, depending on the potential for harm to the woman or fetus.


4. Regardless of funding source research conducted in Pennsylvania must comply with Pennsylvania statute. If applicable, CHOP Legal Counsel will provide their determination in writing.

B. Research Involving Non-Viable Neonates or those of Uncertain Viability

1. Regardless of funding source, when the research involves non-viable neonates or neonates of uncertain viability, the IRB reviewers will ensure that the Subpart B: §46.205 Neonates of Uncertain Viability checklist is completed and that the research complies with the requirements of 45 CFR 46.205.

2. A viable neonate may be included in federally funded research only to the extent permitted by and in accordance with the requirements of **SOP 504** (Research Involving Children).

3. In addition to the research review procedures described in the **SOP 105**, the IRB approves federally funded research involving non-viable neonates or neonates of uncertain viability as participants only if it finds that the research under review satisfies the requirements of Subpart B.

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C. Research Involving After Delivery, the Placenta, the Dead Fetus or Fetal Materials


1. For federally funded research, the mother will be considered the subject of research involving the placenta. The IRB reviewers will complete Subpart B: §46.206 Research involving After Delivery, Placenta, Dead Fetus or Fetal Material checklist to ensure and document that the research complies with the requirements of 45 CFR 46.206. Regardless of funding source research conducted in Pennsylvania must comply with Pennsylvania statute.
2. When federally funded research involves the dead fetus or fetal materials the IRB reviewers will complete Subpart B: §46.206 Research After Delivery: Placenta, Dead Fetus or Fetal Material checklist to ensure and document that the research complies with the requirements of 45 CFR 46.206.
 - (a) Research involving the dead fetus; or macerated fetal material (cells, tissue, organs from a dead fetus), shall be conducted only in accord with any applicable Federal, State, or local laws regarding such activities.
 - (b) When information associated with this material is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and Subpart A of 45 CFR 46 and the applicable CHOP IRB's SOPs related to human subjects protections apply.
3. When research involving after delivery, the dead fetus or macerated fetal materials is not federally funded, the subjects of the research will be considered to be decedents and 45 CFR 46.206 will not apply.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.204, 45 CFR 46.205, 45 CFR 46.206	18 PCS §3216 - Fetal Experimentation
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VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105: IRB Review Process	SOP 301: Research Submission Requirements
SOP 504: Research Involving Children	SOP 501: Vulnerable Subjects

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VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for ensuring that the applicable Subpart B Checklist is completed prior to the IRB making a determination regarding research involving pregnant women, fetuses and neonates (non-viable and uncertain viability) and fetal materials and the products of conception.
Chairman, CPHS	Responsible for ensuring the IRB applies the appropriate regulations and makes the required determinations regarding pregnant women, fetuses and neonates (non-viable and uncertain viability) and fetal materials and the products of conception.


IX. ATTACHMENTS

IRB Reviewer Checklists:

- Subpart B §46.204: Research involving pregnant women or fetuses
- Subpart B §46.205: Research involving neonates (of uncertain viability)
- Subpart B §46.206: Pennsylvania Statute: Research involving after delivery, the placenta, the dead fetus, or fetal material

X. REVISIONS:

8-1-2006	Addition of Form FTO
6-10-2010	Revised for clarity and minor grammatical updates, updates the names of the relevant IRB reviewer forms and updated links to the IRB's website.
01-11-2013	Removed references to the regulations that are contained in the identified sections of the IRB reviewer forms and updates needed as a result of "un-checking the box" on CHOP's FWA.
09-25-2018	Revised to make minor grammatical changes and edits to accurately reflect subpart paragraph numbers and titles.

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XI. APPROVAL:

Director, Human Subjects Research

Date

Chair, Committees for the Protection of Human Subjects

Date