Policy Statement

This policy describes the policy and procedures for Institutional Review Board (IRB) review of research involving fetuses, pregnant women, or human in-vitro fertilization. Research involving these groups requires compliance with the federal regulations at 45 CFR 46 Subpart B (45 CFR §46.204, "Research involving pregnant women or fetuses prior to delivery"; 45 CFR §46.205, "Research involving neonates"; 45 CFR §46.206, "Research involving, after delivery, the placenta, the dead fetus, or fetal material").

Reason for Policy

Special regulatory requirements govern the participation of pregnant women in research. Research involving women who are pregnant receives special attention from IRBs because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. IRBs must also determine when the informed consent of the father to the research is required by federal regulations. The involvement of a third party (the fetus) that may be affected but cannot consent justifies the special attention to research involving pregnant women. There is also a need to prevent harm or injury to future members of society.

Research involving the human fetus raises special concerns for IRB reviewers. The fetus has a unique and inextricable relationship to the mother. It cannot consent to be a research subject. These circumstances have aroused lengthy public debate on the ethics of fetal research and led to special federal regulations that guide IRB deliberations about fetal research. The fetus may also be an indirect subject of research when pregnant women participate.

Entities Affected By This Policy

This policy applies to all faculty, staff, and students of the university conducting human subjects research involving fetuses, pregnant women, or human in-vitro fertilization; the IRB committee members and chairs; Research Integrity office staff.

Who Should Read This Policy

- Faculty, staff, and students of the university engaged in human subjects research subject to IRB review and oversight
- New and re-appointed IRB committee members
- New and re-appointed IRB committee co-chairs
- Research Integrity office staff

Responsibilities

Responsible Party	List of Responsibilities
Designated reviewers	Apply this policy when conducting reviews of IRB applications.
Lehigh University faculty, staff, and students submitting human subjects research for IRB review	Read, understand, and follow this policy when preparing applications for submission to the IRB. Read, understand, and follow this policy when conducting human subjects research.
Research Integrity office staff	Process IRB reviews and apply this policy when research involving fetuses, pregnant women, or human in-vitro fertilization.

Principles

For research involving pregnant women, fetuses, or neonates, the IRB will approve the conduct of the research only if it finds that the research meets the regulatory criteria for approval addressed under the federal regulations at 45 CFR 46 Subpart B (45 CFR §46.204, "Research involving pregnant women or fetuses prior to delivery"; 45 CFR §46.205, "Research involving neonates"; 45 CFR §46.206, "Research involving, after delivery, the placenta, the dead fetus, or fetal material").

Procedures

Initial Screening

Upon acceptance of a complete package, the Research Integrity office staff makes a preliminary determination as to whether this policy applies to the study.

Pregnant Women or Fetuses Prior to Delivery (45 CFR §46.204)

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
b) 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;
c) Any risk is the least possible for achieving the objectives of the research;
d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a 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 and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions;
e) 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 in accord with the informed consent provisions, except that the father's 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.
f) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR §46 Subpart D;
h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
i) 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
j) Individuals engaged in the research will have no part in determining the viability of a neonate.

For research involving pregnant women or the fetus prior to delivery, the documented, written informed consent of the pregnant women or her authorized representative will be obtained in accordance with the provisions of 45 CFR §46.204; unless the IRB grants either a waiver of informed consent in accordance with 45 CFR §46.116(d) or a waiver of the requirement to document informed consent in accordance with 45 CFR §46.117(c).

Research Involving Neonates (45 CFR §46.205)

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

a) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
b) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
c) Individuals engaged in the research will have no part in determining the viability of a neonate.

Neonates of uncertain viability

Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the following additional conditions have been met:

1. The IRB determines that:
    a. 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
    b. 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.
2. And that the 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 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.

For research involving neonates of uncertain viability, the documented, written informed consent of either parent or the authorized representative of either parent will be obtained in accordance with the provisions of 45 CFR §46.205; unless the IRB grants either a waiver of informed consent in accordance with 45 CFR §46.116(d) or a waiver of the requirement to document informed consent in accordance with 45 CFR §46.117(c).

Nonviable neonates

After delivery nonviable neonate may not be involved in research covered by this subpart 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, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, 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 to meet the requirements, 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 to meet the requirements.

Research involving, after delivery, the placenta, the dead fetus, or fetal material (45 CFR §46.206)

Research involving, after delivery, 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 and regulations regarding such activities.

If information associated with 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 considered research subjects and are entitled to all applicable research protections and regulations.

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)

For research that does not meet the criteria for approval addressed under 45 CFR §46.204, "Research involving pregnant women or fetuses prior to delivery"; 45 CFR §46.205, "Research involving fetuses after delivery"; or 45 CFR §46.206, "Research involving, after delivery, the placenta, the dead fetus, or fetal material," the IRB must find that:

- the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women or fetuses; and
- the research, if federally supported, will be submitted for review and approval by the Secretary, DHHS, in accordance with the provisions of 45 CFR §46.207, “Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women or fetuses”. If the research study is not federally-supported, the IRB will use a review by a panel of obstetrician/gynecology experts (2 members with expertise in the area who are not currently IRB members) and an ethicist to recommend whether to approve the study as research that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women or fetuses.

Web Address For This Policy

Lehigh University IRB website (IRB Standard Operating Procedures and Policies)

Related Resources

University Policies and Documents
Lehigh University IRB Glossary
External Resources
Code of Federal Regulations 45 Part 46, Protection of Human Subjects
Code of Federal Regulations 45 Part 46, Protection of Human Subjects, Subpart B
Code of Federal Regulations 45 Part 46, Protection of Human Subjects, Subpart D

Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation	Senior Research Integrity Specialist	610-758-2871	https://research.cc.lehigh.edu/contact-us-0