Albert Einstein College of Medicine

# Pregnant Women, Fetuses, and Neonates

## I. Purpose

This Procedure describes the additional protections that apply when pregnant women, fetuses, and neonates are enrolled as subjects in human research conducted under the auspices of the Einstein Institutional Review Board ("IRB").

## II. Scope

This Procedure applies to all human research involving pregnant women, fetuses, and neonates conducted under the auspices of the Einstein IRB.[1]

## III. Definitions

**Fetus**: the product of conception from implantation until delivery.

**Neonate**: a newborn.

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

**Viable neonate**: a neonate that is able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

## IV. Procedure

When the Einstein IRB considers research that requires the involvement of pregnant women, neonates, or fetuses, it will ensure that all requirements of 45 CFR 46 Subpart B are met prior to approval of the research. Under these regulations, the IRB is required to document specific findings to minimize the potential for risk or harm to the fetus, and additional attention must be given to the conditions for obtaining informed consent.

### Research involving pregnant women or fetuses

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

[1] For information on research involving the dead fetus or fetal material, refer to the "Fetal Tissue Research Procedure."

- 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.
- 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.
- Any risk is the least possible for achieving the objectives of the research.
- The mother may consent for the study 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.
- Both the mother and father must consent for the study if the research holds out the prospect of direct benefit solely to the fetus. 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.
- Each individual providing consent must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
- Children who are pregnant may consent to healthcare procedures related to prenatal care. For more information, refer to the “Enrollment of Children in Research” procedure.
- 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.
- Individuals engaged in the research will have no part in determining the viability of a neonate.

**Research involving neonates**

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

- Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- Individuals engaged in the research will have no part in determining the viability of a neonate.
- The below requirements for neonates of uncertain viability and nonviable neonates have been met, as applicable.

*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 this subpart unless the following additional conditions are met:

- The IRB determines that:
    - 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 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; and

- 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.

*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:

Vital functions of the neonate will not be artificially maintained;

- The research will not terminate the heartbeat or respiration of the neonate;
- There will be no added risk to the neonate resulting from the research;
- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- The legally effective informed consent of both parents of the neonate is obtained, except that the waiver and alteration provisions 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 of this paragraph, 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 of this paragraph.

*Viable neonates*

A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements outlined in the Procedure “Enrollment of Children in Research.”

**Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates**

Research involving pregnant women, fetuses, or neonates that does not meet the above requirements may only be conducted if:

- The Einstein IRB finds that 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; and

- The OHRP, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:
    - That the research in fact satisfies the requirements for research with pregnant women or fetuses, as applicable; or
    - The following:
        - 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;
        - The research will be conducted in accord with sound ethical principles; and
        - Informed consent will be obtained in accord with the informed consent provisions of 45 CFR 46 and all applicable subparts.

## V. Effective Date

June 1, 2020

## VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.