Research on Pregnant Women, Fetuses, and Neonates

Pregnant women, fetuses, neonates, placentas

Additional regulatory considerations located at 45 C.F.R. 46.201 – 207 (Subpart B) apply for reviewing research involving pregnant women, human fetuses, neonates of uncertain viability, nonviable neonates, or placentas after delivery conducted or supported by the DHHS, unless the exemptions located at 45 C.F.R. 46.101(b)(1)-(6) apply. All exempt categories for approval of research at 45CFR46 are applicable to research on pregnant women, fetuses, and neonates.

Where clinically appropriate, information from preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, that have been conducted and provide data for assessing potential risks to pregnant women and fetuses should be included in the study protocol. Research on fetuses and/or pregnant women should only be done if:

- The research is not greater than minimal to the fetus, OR
- any risk to the fetus that is greater than minimal is caused solely by interventions or procedures that offer the prospect of direct benefit for the mother or fetus

If the anticipated benefit of the research is ONLY to the fetus, both the mother and father must provide informed consent (unless the father is unavailable, undetermined, or the pregnancy resulted from rape/incest.) If there the possibility of direct benefit to the pregnant woman, consent of the father is not required.

The protocol should be inclusive of the following considerations:

- No inducements, monetary or otherwise, will be offered to terminate a pregnancy
- Individuals engaged in research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy
- Individuals engaged in research will have no part in determining the viability of the fetus

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

If the research is not otherwise approvable, HHS approval to conduct the research may be requested (45CFR46 Subpart B, 207.).

- The Secretary will conduct or fund research that the IRB does not believe meets the requirements of § 46.204 or § 46.205 only if:
- **(a)** The 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

- **(b)** The Secretary, 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:
- **(1)** That the research in fact satisfies the conditions of § 46.204, as applicable; or
- **(2)** The following:
- **(i)** 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;
- **(ii)** The research will be conducted in accord with sound ethical principles; and
- **(iii)** Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Research on neonates of uncertain viability

For research on neonates of uncertain viability, consent of either parent is required. If neither parent is available to consent because of unavailability, incompetence, or incapacity, the legally effective consent of either parent's legally-authorized representative is required. Consent of the father or his legally-authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Research on non-viable neonates

For research on non-viable neonates, consent from both parents is required, except:
If either parent is unable to consent because of unavailability, incompetence, or incapacity, consent of one parent is required. Consent of the father need not be obtained if the pregnancy resulted from rape or incest. Consent from a legally-authorized representative is not allowed.

Placenta / cord blood collection

Cord blood and/or placenta may be collected at the time of delivery for research purposes with the consent of the mother. Woman's IRB provides a consent template for cord blood / placenta collection if this collection is not part of a larger research study (e. g., for practice of cord blood / placenta sampling techniques). If a study participant consents to donate cord blood / placenta more than three months prior to delivery, it is recommended that she reaffirm her consent closer to her estimated delivery date.

Consenting women in labor

The IRB will consider the level of risk and aims of the study when the enrollment process includes consenting pregnant women at admittance and while in labor. Care should be taken to obtain and document informed consent at the most appropriate time; the timing of consent will be determined by the nature of the study and the likelihood of the event that would make a

woman eligible for recruitment. Opportunity should be given for the woman and her partner to discuss the study and have any questions answered before informed consent is obtained.

In Vitro fertilization

Under Louisiana law, the use of a human ovum fertilized in vitro is solely for the support and contribution of the complete development of human in utero implantation. No in vitro fertilized human ovum will be farmed or cultured solely for research purposes or any other purposes. The sale of a human ovum, fertilized human ovum, or human embryo is expressly prohibited. Embryonic stem cell research in Louisiana is prohibited by Revised Statute §9:122.