Policy on Research Involving Pregnant Women, Fetuses, and Neonates

Effective date: 9/20/2019

I. Background
The Office of Human Research Protections (OHRP) regulations under 45 CFR 46, Subpart B provide additional protections for pregnant women, human fetuses, and neonates of uncertain viability, or nonviable neonates. This policy outlines what researchers conducting research funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html) must consider when conducting research involving subjects from this vulnerable population.

II. Definitions
a. Dead Fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
b. Delivery: complete separation of the fetus from the woman by expulsion or extraction or any other means.
c. Fetus: the product of conception from implantation until delivery.
e. Nonviable Neonate: a neonate after delivery that, although living, is not viable.
f. Pregnancy: the period of time from implantation until delivery.
g. Viable: being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

III. Social Behavioral Educational Studies Incidentally Including Pregnant Women
The Principal Investigator (PI) and the IRB must decide when a pregnant woman’s participation in a study would pose a risk either to herself, to the fetus, to a neonate of uncertain viability, or nonviable neonates. The majority of studies at UCSC are social behavioral studies that do not specifically target pregnant women and pose no risk to fetuses or neonates covered by Subpart B. For this reason, the UCSC IRB does not consider such studies to involve pregnant women, fetuses or neonates for the purposes of complying with Subpart B. Alternatively, if a researcher is specifically targeting women who are pregnant, or there are risks affecting pregnant women specifically or their fetuses (e.g., use of MRI or other biomedical procedures), then the additional criteria must be met.
IV. IRB Review and Approval of Research Involving Pregnant Women, Fetuses, Neonates

a. In order for the IRB to approve studies with this population, or for the research to be determined exempt, all the criteria below must be met:

i. 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;

ii. 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;

iii. Any risk is the least possible for achieving the objectives of the research;

iv. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

v. For children who are pregnant, assent and permission are obtained in accord with IRB child assent and parent permission guidelines;

vi. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

vii. 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

viii. Individuals engaged in the research will have no part in determining the viability of a neonate.

ix. 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 IRB informed consent guidelines;

x. 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 IRB informed consent guidelines, 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.
V. **Viable Neonates as Children**
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 of 45 CFR 46. Investigators should pay special attention to additional protections for children involved as subjects in research as detailed in Subpart D.

VI. **References**
- UC Berkeley Guidance Pregnant Women, Fetuses, and Neonates in Research
- 45 CFR 46 Subpart B
- 45 CFR 46 Subpart D