

## Appendix D: PREGNANT WOMEN, HUMAN FETUSES, AND NEONATES

45 CFR 46 Subpart B regulates research activities involving this protected population. There are very specific criteria that must be met in order to allow the IRB to approve research involving pregnant women, human fetuses, or neonates. Please indicate whether your proposed research involves:

\_\_\_\_\_ Pregnant women

\_\_\_\_\_ Human fetuses

\_\_\_\_\_ Neonates

1. **45 CFR 46.204 provides information on the criteria that must be met to approve research involving pregnant women or human fetuses.**

- a. Have appropriate studies on animals and nonpregnant humans been conducted and provide data for assessing potential risks to pregnant women and fetuses?
- b. If there is no prospect of direct benefit to the woman or the fetus, the risk to the fetus must not be greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means. Describe whether any risk to the fetus caused solely by the intervention or procedure holds out the prospect of direct benefit to the woman or the fetus.
- c. Is the risk to the fetus the least possible consistent with the research objectives?
- d. Special consent requirements; If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father must be obtained, unless the father is unavailable, incompetent, or temporarily incapacitated, or if the pregnancy resulted from rape or incest. In all other cases, only the consent of the woman is required.
  - i. Will the individual(s) providing consent be adequately informed of the potential risk to the fetus and of alternative treatments and their risks and benefits?
  - ii. Will any inducements, monetary or otherwise, be offered to terminate a pregnancy?
  - iii. Will anyone engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?
  - iv. Will anyone engaged in the research have any part in determining the viability of a neonate?

2. **45 CFR 46.205 provides very detailed information on the criteria that must be met to approve research involving neonates, depending on their viability.**

- a. If the project involves nonviable neonates or neonates of uncertain viability:
  - i. Have scientifically appropriate, preclinical and clinical studies been conducted that provide data for assessing potential risk to neonates?
  - ii. Have all persons required to provide consent been informed of the reasonable foreseeable impact of the research on the neonate?
  - iii. Will anyone engaged in the research have any part in determining the viability of the neonate?

- b. For projects involving neonates of uncertain viability, consent may be typically be obtained from either parent or their legally authorized representative. For these projects, the following questions must also be addressed:
    - i. Describe how the research may enhance the probability of survival of the neonate to the point of viability.
    - ii. Is the risk to the neonate the least possible for achieving that objective?
    - iii. Is the purpose of the research to develop important biomedical knowledge that cannot be obtained by other means?
    - iv. Will there be any added risk to the neonate resulting from the research?
  - c. For projects involving nonviable neonates, consent must typically be obtained from both parents or their legally authorized representatives. For these projects, the following questions must also be addressed:
    - i. Will the vital functions of the neonate be artificially maintained?
    - ii. Will the research terminate the heartbeat or respiration of the neonate?
    - iii. Will there be any added risk to the neonate resulting from the research?
    - iv. Is the purpose of the research to develop important biomedical knowledge that cannot be obtained by other means?
3. For studies of lactating women, is the supply and content of breast milk adequately protected?
4. For studies of conception or contraception, are the risks, benefits, reversibility, and alternatives adequately explained? In contraceptive studies, is there adequate explanation of possible failure and of the options available for dealing with unintended pregnancies?