

12.1 THE PROTECTION OF VULNERABLE POPULATIONS IN HUMAN SUBJECTS RESEARCH

All human subjects warrant protection from the risks of participation in research. However, certain populations of subjects, those who are termed “vulnerable,” require additional, special protection. Federal regulations indicate, “The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.”

Special subparts have been included in the Code of Federal Regulations (CFR) to address special protections for three populations in particular - pregnant women, human fetuses and neonates (45 CFR 46 Subpart B), prisoners (45 CFR 46 Subpart C), and children (45 CFR 46 Subpart D and 21 CFR 50 Subpart D). However, there exist other classes of subjects who may be subject to other vulnerabilities, for example, HIV positive people, that must be considered by the IRB during the review of a protocol.

12.2 PROTECTIONS FOR PREGNANT WOMEN, HUMAN FETUSES, AND NEONATES

Subpart B of 45 CFR 46 applies to research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates.

Definitions:

Pregnancy encompasses the period from implantation until delivery.

Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Fetus means the product of conception from implantation until delivery. *Dead fetus* means a fetus that does not exhibit a heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord.

Neonate means a newborn (first four weeks of life, i.e. less than 28 days of age).

Viable neonates are regulated under Subpart D of 45 CFR 46 (research involving children). Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

A. Inclusion of Pregnant Women or Women of Childbearing Potential in Research

In accordance with the principle of justice described in the Belmont Report, pregnant women must not be excluded from research without appropriate medical or scientific justification. During the course of a clinical study, pregnant women or women of childbearing potential may be encountered coincidentally as potential subjects. Alternatively, pregnant women and fetuses may be the target study population(s). Federal regulations do not distinguish between research in which pregnant women or fetuses are a target population, versus research in which pregnant women or fetuses may be only incidental subjects.

- i. Conducting research where pregnant women are not the target population