

PREGNANT PERSONS, HUMAN FETUSES, & NEONATES GUIDANCE

Justification of Review Requirements

The HRPP/IRB is responsible for reviewing all procedures and materials to ensure the protection of the rights and welfare of human subjects and equitable participant enrollment. The proposed research must comply with the basic requirements for Protection of Human Subjects outlined in [45 CFR 46 Subpart A](#) and the requirements for Protections for Pregnant Persons, Human Fetuses, and Neonates Involved in Research outlined in [45 CFR 46 Subpart B](#).

Defining Pregnant Persons, Human Fetuses, & Neonates

The following applicable terms are defined in [45 CFR 46.202](#):

- **Pregnancy:** The period of time from implantation until delivery. A person shall be assumed to be pregnant if they exhibit any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
- **Delivery:** Complete separation of the fetus from the pregnant person by expulsion or extraction or any other means.
- **Fetus:** The product of conception from implantation until delivery.
- **Dead fetus:** A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
- **Neonate:** A newborn.
- **Nonviable neonate:** A neonate after delivery that, although living, is not viable.
- **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.

Considerations for Inclusion/Exclusion Criteria

When developing your enrollment inclusion/exclusion criteria, pregnant persons should not be excluded from participations in research unless the science of the project, or the health of the subject(s) will be compromised by their participation. Consider the following regarding the enrollment of pregnant persons in human subject research:

- Will the risks to the pregnant persons be minimal?
- Will the risk to the fetus be minimal?
- Will the result of the research promote or contribute to the safe, effective, and accessible treatment for pregnant persons?
- Will inclusion offer the possibility of direct benefit to pregnant persons and/or fetus that is unavailable outside the research setting?
- Will exclusion result in a failure to establish the dose/dosing regimen, safety, and efficacy of treatments during pregnancy that may compromise the health of pregnant persons and their fetuses?