

When Does Human Research Involve Neonates?

A study is considered to include neonates when a newborn baby (viable or non-viable) is enrolled in a study (including chart reviews).

Requirements for Inclusion of Neonates in Human Research

Investigators must provide protocol specific justification to the Institutional Review Board (IRB), so that the IRB may make a determination that the enrollment of neonates in the research is justified. Submit the *Appendix for Pregnant Women, Neonates, and Fetuses* for the IRB to make a determination.

Definitions ([45 CFR §46.202](#))

- *Neonate* means a newborn.
- *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. The Secretary of Health and Human Services (HHS) may from time to time, considering medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of the pre-2018 Requirements or the 2018 Requirements, as applicable, and [subpart D](#).
- *Nonviable neonate* means a neonate after delivery that, although living, is not viable.

Categories of Research Involving Neonates

Until it has been ascertained if a neonate is viable, a neonate may not be involved in research unless additional conditions have been met. See regulatory categories related to the involvement of a Neonate in research:

1. Research involving neonates (viable, nonviable, and unknown viability) ([45 CFR §46.205](#)).
2. Research involving, after delivery, the placenta, the dead fetus or fetal material ([45 CFR §46.206](#)).
3. 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 contact the HSPP office ([45 CFR §46.207](#)).

Requirements Regarding Parental Permission ([45 CFR §46.205](#))

1. For viable neonates or neonates of uncertain viability, parental permission from either parent of the neonate is permissible. If neither parent is able to consent because of unavailability, incompetence, or incapacity, the legally effective informed consent of either parent's legally authorized representative (LAR) is permissible. The consent of the father or his LAR is not required if the pregnancy resulted from rape or incest.
2. For nonviable neonates, the informed consent of **BOTH** parents must be obtained. **There is no waiver provision for one or both parents or LARs for inclusion of nonviable neonates in research, unless one parent is unavailable, incompetent, or incapacitated or if the pregnancy resulted from rape or incest.**