

Protecting people who participate in research

*CITI Training Study Guide
Research Involving Pregnant Women,
Fetuses or Infants*

**Research Involving Pregnant Women -
Special Guidelines Set Forth by NIH**

Historically, women of childbearing age were excluded from some studies to avoid harm to a developing fetus in an unsuspected pregnancy.

**Research Involving Pregnant Women -
Special Guidelines Set Forth by NIH**

In 1994 to avoid denying the benefits of research to women (e.g. drug-testing only on men whose drug response might differ from women's), NIH issued guidelines to exclude women only when there is compelling evidence that inclusion would be inappropriate to women's health, or to the purpose of the research.

Research Involving Pregnant Women, Fetuses and Non-viable Newborns - Special Rules Set Forth by DHHS

Subpart B of the federal Department of Health and Human Services sets out “Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research.”

Note: Research involving viable (able to survive) newborns is governed by Subpart D pertaining to children.

Research Involving Pregnant Women, Fetuses and Non-viable Newborns - Special Rules Set Forth by DHHS

Subpart B allows research with pregnant women or fetuses only if appropriate studies on animals and non-pregnant individuals have been completed.

If the research is not about meeting the health needs of the mother or fetus, the risk to the fetus must be minimal.

Research Involving Pregnant Women, Fetuses and Non-viable Newborns - Consent

1. Researchers must fully inform parents regarding the possible impact of the research on the fetus.
2. If the research may provide direct benefit to the mother or has minimal risk to the fetus, only the mother's consent is needed.

Research Involving Pregnant Women, Fetuses and Non-Viable Newborns - Consent

3. If the research has the prospect of direct benefit only to the fetus then consent of both the mother and father is required.
4. The father's informed consent need not be secured if his identity or whereabouts cannot reasonably be ascertained, he is not reasonably available, or the pregnancy resulted from rape or incest.

Research Allowed with Newborns (Neonates)

1. If the viability of the neonate is uncertain, research is allowed only if there is no added risk, or the research aims to enhance the possibility of survival.

Research Allowed with Neonates

2. If the neonate is non-viable (it will not survive), research is allowed only if:
 - the infant's vital functions will not be artificially maintained; and
 - experimental activities will not terminate the newborn's heartbeat or respiration; and
 - the research poses no additional risks; and
 - the research will generate important biomedical knowledge that cannot be obtained by other means.
