

Date:
CPHS#:

**OPHS WORKSHEET - 45 CFR 46.205
RESEARCH INVOLVING NEONATES**

I. Viable Neonates

A Viable Neonate is a newborn that is, after delivery, able to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. A neonate that has been determined to be viable may be included in research only to the extent permitted by and in accordance with SC503 – Children as a Vulnerable Population, and RR401 – Initial Review.

II. Neonates of Uncertain Viability

Neonates of uncertain viability may not be involved in research until it has been ascertained whether or not a neonate is viable or the Committee for Protection of Human Subjects has determined that all of the following conditions are met:

- A. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

Protocol-specific comments:

- B. Individuals engaged in the research will have no part in determining the viability of a neonate.

Protocol-specific comments:

- C. The Committee determines that either of the following conditions has been met:
- i. The research holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research.
 - ii. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research.

Protocol-specific comments:

- D. The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accordance with IC701 – General Requirement and Documentation of Informed Consent, unless altered or waived in accordance with IC702 – Informed Consent Waivers.

Protocol-specific comments:

- E. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

Protocol-specific comments:

III. Nonviable Neonates

A nonviable neonate may not be involved in research *unless* the Committee determines that all of the following conditions are met:

- A. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

Protocol-specific comments:

- B. Individuals engaged in the research will have no part in determining the viability of a neonate.

Protocol-specific comments:

- C. Vital functions of the neonate will not be artificially maintained.

Protocol-specific comments:

- D. The research will not terminate the heartbeat or respiration of the neonate.

Protocol-specific comments:

- E. There will be no added risk to the neonate resulting from the research.

Protocol-specific comments:

- F. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

Protocol-specific comments:

- G. The legally effective informed consent of both parents of the neonate is obtained in accordance with IC701; however, the waiver and alteration provisions of do not apply here. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a

nonviable neonate will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to replace the consent of the parent.

Protocol-specific comments:

- H. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

Protocol-specific comments: