

**Institutional Review Board (IRB)**

**GUIDLEINES FOR RESEARCH INVOLVING NEONATES**

**1. Introduction**

Federal regulations (45 CFR 46.201, also “Subpart B”) require additional safeguards when approving research involving neonates. The purpose of these guidelines is to assist investigators conducting research with neonates by outlining the special considerations for such research.

**2. Definitions**

**Subpart B** refers to regulations that apply to research involving neonates as subjects. Subpart B is found in 45 CFR 46 (DHHS).

**Neonate** refers to newborn infants.

**Viable**, as it pertains to a neonate, means being able to survive after delivery, given the benefit of available medical therapy, to the point of independently maintaining heartbeat and respiration as determined by a physician who is not engaged in the research.

**Nonviable Neonate** is a neonate that (although alive after delivery) is not capable of surviving to the point of sustaining life independently, even with the support of available medical therapy, as determined by a physician who is not engaged in the research.

**3. Additional Protections for the Inclusion of Neonates in Research**

To approve research involving neonates, the IRB must determine that the research provides the additional protections described in 45 CFR 46 Subpart B in addition to meeting the regulatory criteria for approval for all human subjects research.

The IRB must consider the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the neonate in order to determine whether the study is approvable under federal regulations. The IRB can approve studies involving neonates only if the research meets the following criteria, according to the viability of the neonate.

Research Involving Viable Neonates

A neonate, after delivery, that has been determined to be viable may be included in the research according to the federal regulations for children. The regulations governing research involving children are outlined in 45 CFR 46 (DHHS) and 21 CFR 50 (FDA) as Subpart D. Requirements for including minors in research are described in the SLU IRB “Guidelines for Research Involving Minors.”

Research Involving Neonates of Uncertain Viability

If the viability of the neonate will not be determined in the course of the study, the IRB may approve the study involving neonates only if the research fits into one of the following categories and meets additional considerations 1-3, below:

**Category One:**

The research holds the prospect of enhancing the probability of survival of the neonate to the point of viability. Any risk to the neonate is the least possible for achieving the objective of enhancing the probability of survival of the neonate to the point of viability.

**-Or-**

**Category Two:**

The research will not result in additional risk to the neonate and the purpose of the research is the development of important biomedical knowledge, which cannot be obtained by other means.

**-And-**

**Additional Considerations (1-3):**

1. Where scientifically appropriate, preclinical studies and clinical studies have been conducted and provide data for assessing potential risks to neonates;
2. The individual(s) providing consent will be fully informed regarding the reasonable foreseeable impact of the research on the neonate;
3. The individuals conducting the research are prohibited from determining the viability of the neonate.

Research Involving Nonviable Neonates

After delivery, nonviable neonates may be included in the research if all of the following conditions are met:[[1]](#footnote-1)

* Where scientifically appropriate, preclinical studies and clinical studies have been conducted and provide data for assessing potential risks to neonates;
* The individual(s) providing consent will be fully informed regarding the reasonable foreseeable impact of the research on the neonate;
* The individuals conducting the research are prohibited from determining the viability of the neonate;
* Vital functions of the neonate will not be artificially maintained;
* The research will not terminate the heartbeat or respiration of the neonate;
* There will be no added risk to the neonate resulting from the research;
* The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

**4. Obtaining Consent for Research Involving Neonates**

Informed consent must be obtained from the necessary individuals as described below.

Research Involving Viable Neonates

Permission from a parent or guardian is required. Requirements for parental permission are described in SLU IRB “Guidelines for Research Involving Minors.”

Research Involving Neonates of Uncertain Viability

Consent from either parent of the neonate is required. If consent cannot be obtained from either parent because of unavailability, incompetence, or temporary incapacity, a legally authorized representative for the parent(s) may give consent. See SLU IRB “Guidelines for Use of Legally Authorized Representatives.”

Research Involving Nonviable Neonates

Consent from both parents of the neonate is required. If consent cannot be obtained from one parent because of unavailability, incompetence, or temporary incapacity, consent from one parent will suffice. If neither parent can give consent, the neonate may not be included. Consent from the father is not required if the pregnancy resulted from rape or incest.

See the SLU IRB “Guidelines for Research Involving Pregnant Women and Fetuses” for special considerations when obtaining consent from pregnant women, including women in labor.

**5. Research involving Neonates that does not meet the protections found in Subpart B**

Research involving neonates that does not meet the conditions for approval described by the federal regulations may be conducted only if all of the following conditions are met:

* The IRB finds that the research presents a reasonable opportunity to further in pertinent understanding, prevention, or alleviation of a serious problem affecting the health or welfare of neonates;
* The Secretary (DHHS), after consultation with a panel of experts in pertinent disciplines (e.g. science, medicine, ethics, law, etc.) and following opportunity for public review and comment (including a public meeting announced in the *Federal Register*), has determined either of the following:
* The research satisfies the regulatory conditions for approval
* The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of neonates; the research will be conducted consistent with sound ethical principles; and informed consent will be obtained in accordance with the regulatory requirements pertaining to neonates.

**6. References**

45 CFR 46.205

AAHRPP, Inc. Elements II.3.F, II.4.A

1. Meets the criteria listed in 45 CFR 46.205 [↑](#footnote-ref-1)