RESEARCH INVOLVING NEONATES

Definitions

Subpart B: This term refers to the regulations which apply to research involving neonates as subjects. Subpart B is found in 45 CFR 46 (DHHS).

Neonate: Newborns from the time of delivery up until 28 days old.

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.

Federal Research Regulations

Federal regulations require additional safeguards when approving research involving neonates. These special protections are found in Subpart B. The IRB may approve research involving neonates only if the research meets the criteria outlined in Subpart B, provided that the research also meets the general criteria for approval.

Description

The IRB must consider the general criteria for IRB approval for all studies, including those that involve neonates. In determining whether the general criteria for approval are met, the IRB may have additional considerations for the research that would generally not be of concern in an adult population.

Risks
Risks that may be considered minimal when dealing with adults (e.g. blood draw) may be more risky when applied to a neonate population. Efforts should be made to minimize any potential harm.

Additional Protections for the Inclusion of Neonates in 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 the federal regulations. The standard of review is conducted consistently, regardless of full board or expedited review. The IRB may approve studies involving neonates only if the research meets the following criteria, according to the viability of the neonate:

(1) 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 both 45 CFR 46 (DHHS) and 21 CFR 50 (FDA) as Subpart D. Requirements for including children in research are described in the Investigator Guidance Series: Research Involving Children (see links at the end of this document).

(2) Research Involving Neonates of Uncertain Viability
If the viability of the neonate will not be determined during the course of the study, the IRB may approve the study involving neonates only if the research fits into either category 1 or 2 below and also meets all of the following considerations 1-3:

Category 1:
The research holds out 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.

Category 2:
The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.

Additional Considerations (1-3):

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;
2. Each individual providing consent is fully informed regarding the reasonable foreseeable impact of the research on the neonate;
3. Individuals engaged in the research will have no part in determining the viability of a neonate.

(3) Research Involving Nonviable Neonates
After delivery, nonviable neonates may be included in research if the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;
2. Each individual providing consent is fully informed regarding the reasonable foreseeable impact of the research on the neonate;
3. Individuals engaged in the research will have no part in determining the viability of a neonate;
4. Vital functions of the neonate will not be artificially maintained;
5. The research will not terminate the heartbeat or respiration of the neonate;
6. There will be no added risk to the neonate resulting from the research;
7. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

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 the Investigator Guidance Series: Parental Permission (see links at end of this document).

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. Requirements for legally authorized representatives are described in the Investigator Guidance Series: Research Involving Individuals with Decisional Impairment (see links at the end of this document).

Consent from the father need not be obtained if the pregnancy resulted from rape or incest.

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 in the research.

Consent from the father need not be obtained if the pregnancy resulted from rape or incest.

Additional Considerations

VA Research: VA research involving neonates must follow the Office of Research & Development's (ORD) requirements for research involving neonates as described in VHA Directive 1200.05, Paragraph 19. VA Medical Facility Director certification is required for neonatal research. ~~The VASLCHCS is authorized to care for veterans and to conduct research that supports the mission of the Veterans Health Administration (VHA) and that enhances the quality of health care delivery to veterans.~~

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

~~**Therefore, research involving children (and neonates) must not be conducted by VA investigators while on official duty or at the VA or approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer.** If the waiver is granted, the research must be in accordance with applicable Federal regulations pertaining to children as research subjects.~~

Points to Address

New Study Application:	1. **Participants page**: a) Check the box indicating participants under the age of 7 will be enrolled. b) Indicate the exact age of participants, including neonates. c) Select Neonates as a vulnerable population. The Vulnerable Population page will be automatically populated as you continue through the application. d) When describing the *Characteristics of Participants/Inclusion* Criteria, state whether viable or nonviable neonates will be included in the research. If the viability of the neonates will be unknown during the research study, please state. Describe the process to which viability will be determined for the purposes of the study, including any medical conditions that may be relevant. 2. **Vulnerable Populations page**: Complete this page justifying the inclusion of neonates as a vulnerable population. 3. **Consent Process page**: Complete this page, indicating that consent/parental permission will be obtained according to the appropriate regulatory requirements listed above. Describe the process in detail.
Consent/Parental Permission Documents:	1. Include consent and/or parental permission documents that will be used in the study. Include the appropriate signature lines for the parent(s), according to the appropriate regulatory requirements listed above.

References & Links

Additional Protections for the Inclusion of Neonates in Research (OHRP): 45 CFR 46, Subpart B, 46.205	*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.205*
Investigator Guidance Series: Children	*http://irb.utah.edu/guidelines/investigator.php*
Investigator Guidance Series: Parental Permission	*http://irb.utah.edu/guidelines/investigator.php*
Investigator Guidance Series: Research Involving Cognitively Impaired Individuals	*http://irb.utah.edu/guidelines/investigator.php*

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