Reviewer Checklist - Research Involving Neonates

Instructions:
Mark the appropriate category.

- *Determine whether the research is approvable under one of the three categories listed below.*
- *A subsequent checklist will be required based upon the following selection. Comments, revisions, or clarifications can be identified in the area provided on the subsequent pages.*

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.

The Children Checklist will be required.

Research involving neonates of uncertain viability
Use this category for research where the viability of the neonate will not be determined during the course of the study.

Research involving nonviable neonates
The definition of a "nonviable neonate" is a neonate after delivery that, although living, is not viable.

Clear

Reviewer Checklist - Research Involving Neonates of Uncertain Viability

Please determine whether the research is approvable under this particular category. Please provide any comments, revisions, or clarifications in the area provided below.

All three of the following questions must be answered "Yes" or "N/A" in order to approve the research under this category:

○ Yes ○ No ○ N/A Clear	Have preclinical and clinical studies (including studies on pregnant animals) been conducted and provide data for assessing potential risks to neonates? *N/A if not clinically/scientifically appropriate.*
○ Yes ○ No Clear	Will the individual(s) providing consent be fully informed of the reasonable foreseeable impact of the research on the neonate?
○ Yes ○ No Clear	Are individuals engaged in the research prohibited from determining the viability of a neonate?

Neonates Risk Assessment:
Select one

- ○ 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.
- ○ 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.

Clear

Consent Process:

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.

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

Specific Concerns: If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolution to Concerns: Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

Reminder: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

Determination: Is the proposed involvement of neonates of uncertain viability approvable?

- ○ Yes.
- ○ Yes, if the above stipulation is met.
- ○ No.

Clear

Reviewer Checklist - Research Involving Nonviable Neonates

Please determine whether the research is approvable under this particular category. Please provide any comments, revisions, or clarifications in the area provided below.

All three of the following questions must be answered "Yes" or "N/A" in order to approve the research under this category:

○ Yes ○ No ○ N/A Clear	Have preclinical and clinical studies (including studies on pregnant animals) been conducted and provide data for assessing potential risks to neonates? *N/A if not clinically/scientifically appropriate.*
○ Yes ○ No Clear	Will the individual(s) providing consent be fully informed of the reasonable foreseeable impact of the research on the neonate?
○ Yes ○ No Clear	Are individuals engaged in the research prohibited from determining the viability of a neonate?
○ Yes ○ No Clear	Are individuals engaged in the research prohibited from artificially maintaining the vital functions of the neonate?
○ Yes ○ No Clear	Are individuals engaged in the research prohibited from terminating the heartbeat or respirations of the neonate?
○ Yes ○ No Clear	Is there additional risk to the neonate resulting from the research?
○ Yes ○ No Clear	Is the purpose of the research to develop important biomedical knowledge that cannot be obtained by other means?

Consent Process:
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 with appropriate documentation. 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.

Specific Concerns:
If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolution to Concerns:
Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

Reminder: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

Determination: Is the proposed involvement of nonviable neonates approvable?

- ○ Yes.
- ○ Yes, if the above stipulation is met.
- ○ No.

Clear