

REVIEWER CHECKLIST
RESEARCH INVOLVING NEONATES

IRB REVIEWER: Please answer and follow the directions for each of the three required (asterisked) questions. Then complete the Final Determination question below.

1) The research involves neonates where it will not be ascertained whether a neonate is viable: True
 False [Clear](#)

If False, please skip to the next section below.

The following statements must be true to approve the research involving neonates of uncertain viability:

True	False	Clear	Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
True	False	Clear	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
True	False	Clear	Each individual engaged in the research will have no part in determining the viability of a fetus.
True	False	Clear	Either of the following is true: The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability and any risk is the least possible for achieving that objective. 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.
True	False	Clear	Either of the following is true: The legally effective informed consent of either parent of the neonate will be obtained. (Exception: the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.) 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 will be obtained. (Exception: the consent of the father's legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.)

Requested Revisions/Clarifications: Provide more information if you answered "False" to any statements above or if you are unable to make a determination. Please indicate your final determination at the end of this checklist.

2) The research involves neonates ascertained to be non-viable: True False **Clear**

If False, please skip to the next section below.

The following statements must be true to approve the research involving non-viable neonates:

True	False	Clear	Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
True	False	Clear	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
True	False	Clear	Individuals engaged in the research will have no part in determining the viability of a neonate.
True	False	Clear	Vital functions of the fetus will not be artificially maintained.
True	False	Clear	The research will not terminate the heartbeat or respiration of the fetus.
True	False	Clear	There will be no added risk to the fetus resulting from the research.
True	False	Clear	The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.
True	False	Clear	The legally effective informed consent of both parents will be obtained. (Exception: the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.) The informed consent of one parent will suffice if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity. (The consent of a legally authorized representative of either or both of the parents of a nonviable neonate is not permitted.)

Requested Revisions/Clarifications: Provide more information if you answered "False" to any statements above. Please indicate your final determination at the end of this checklist.

3) The research involves neonates ascertained to be viable: True False **Clear**

The following statements must be true to approve the research involving viable neonates:

True	False	Clear	The research meets the regulatory requirements (please see the Children's Checklist).
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Requested Revisions/Clarifications: Provide more information if you answered "False" to any statements above. Please indicate your final determination at the end of this checklist.

FINAL DETERMINATION

The proposed involvement of neonates is Approvable.

The proposed involvement of neonates cannot be determined at this time and needs further clarification noted above in the appropriate section(s).

The proposed involvement of neonates is Not Approvable.

[Clear](#)

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