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| Study ID |  | PI |  |

**Nonviable neonates** may be involved in research if all of the following conditions are met:

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

*Why does the research meet this criterion?*

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

*Why does the research meet this criterion?*

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

*Why does the research meet this criterion?*

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After delivery nonviable neonate may not be involved unless all of the following additional conditions are met:

Vital functions of the neonate will not be artificially maintained.

*Why does the research meet this criterion?*

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

*Why does the research meet this criterion?*

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

*Why does the research meet this criterion?*

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

*Why does the research meet this criterion?*

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The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A (45 CFR 46), except that the waiver and alteration provisions of Sec. 46.116(c) and (d) do not apply. However, 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 to meet the requirements, 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 meet the requirements.

*Why does the research meet this criterion?*

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| IRB determination made by: | | | | | | | | | |
| Expedited reviewer | | Name: |  | | Date: |  | |  | |
|  | | | | | | | | | |
| Full board | Name of individual completing this form: | | |  | | | Meeting date | |  |
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