|  |  |  |  |
| --- | --- | --- | --- |
| Study ID |  | PI |  |

**Neonates of uncertain viability** 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?*

|  |
| --- |
|  |

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?*

|  |
| --- |
|  |

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

*Why does the research meet this criterion?*

|  |
| --- |
|  |

Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the following additional conditions have been met:

The IRB determines that (select applicable criteria)

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.

*Why does the research meet this criterion?*

|  |
| --- |
|  |

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.

*Why does the research meet this criterion?*

|  |
| --- |
|  |

The legally effective informed consent of either parent of the neonate or, 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 is obtained in accord with subpart A (45 CFR 46), except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

*Why does the research meet this criterion?*

|  |
| --- |
|  |

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