**Questionnaire B2: Subpart B: §46.205: Neonates of Uncertain Viability**

PI:  Protocol #

Completed by Primary Reviewer or Chair:

* *Check the appropriate box for each part as it relates to the proposed research. When shaded box is checked, provide justification as to how the proposed research meets the criteria for that part and go to next part.*
* *Neonates of uncertain viability (viability not ascertained yet) may be involved in research if* ***all*** *of the following conditions [in shaded boxes] are met:*

|  |
| --- |
| **(a)** **Pre-clinical data:** Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. [§46.205(a)(1)]  |
|  **[ ]  No ►** STOP!§46.205 **NOT** met. |  |
|  **[ ]  Yes** |
|  **[ ]  N/A** [i.e. not scientifically appropriate] |
| **(b) Neonate viability:** Individuals engaged in the research will have no part in determining the viability of a neonate. [§46.205(a)(3)]  |
|  **[ ]  No ►** STOP! §46.205 **NOT** met. |  |
|  **[ ]  Yes** (Statement is true) |
| **(c) Risk to neonate:** Which of the following statements applies to the proposed research? [§46.205(b)(1)] |
|  **[ ]**  (i) 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. |  |
|  **[ ]**  (ii) 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. |
|  **[ ]** Neither (i) nor (ii) applies to the proposed research **►** STOP! §46.205 **NOT** met. |
| **(d)** **Consent of parent:** 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 of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. [§46.205(b)(2)] |
|  **[ ]  No ►** STOP! §46.205 **NOT** met. |  |
|  **[ ]  Yes** |
| **(e) Consent includes impact on fetus/neonate:** Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. [§46.205(a)(2)]  |
|  **[ ]  No ►** STOP! §46.205 **NOT** met. |  |
|  **[ ]  Yes** ►Subpart B: §46.204 [for neonates of uncertain viability] met. |
|  **Additional comments:**        **Reviewed By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |