**Questionnaire B3: Subpart B: §46.205: NonViable Neonates\***

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.*
* *Non-viable neonates\* may be involved in research if* ***all*** *of the following conditions [in shaded boxes] are met:*
  + \* *§46.202(e): “Nonviable neonate means a neonate after delivery that, although living,is not viable.”*

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| --- | --- | --- |
| **(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) Artificial maintenance:** Vital functions of the neonate will not be artificially maintained. [§46.205(c)(1)] | | |
| **No ►** STOP! §46.205 **NOT** met. |  | |
| **Yes** (Statement is true) |
| **(d) Heartbeat & respiration:** The research will not terminate the heartbeat or respiration of the neonate. [§46.205(c)(2)] | | |
| **No ►** STOP! §46.205 **NOT** met. |  | |
| **Yes** (Statement is true) |
| **(e)** **Additional risks:** There will be no added risk to the neonate resulting from the research. [§46.205(c)(3)] | | |
| **No ►** STOP! §46.205 **NOT** met. |  | |
| **Yes** (Statement is true) |
| **(f) Purpose:** The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. [§46.205(c)(4)] | | |
| **No ►** STOP! §46.205 **NOT** met. |  | |
| **Yes** (Statement is true) |
| **(g)** **Parental consent:** The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A, except that the waiver and alteration provisions of Sec. 46.116(c) & (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 of (c)(5), 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 of this paragraph. [§46.205(c)(5)] | | |
| **No ►** STOP! §46.205 **NOT** met. |  | |
| **Yes** (Statement is true) |
| **(h) 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: §46.205 [for non-viable neonates] met. | |
| **Additional comments:**  **Reviewed By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | |