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| | OHR-27  5/2011 | | --- | | Research Involving Pregnant Women, Human Fetuses or Neonates | |
| **Principal Investigator:** |
| **Protocol Title:** |
| * *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.* * *Pregnant women, fetuses, or neonates may be involved in research if* ***all*** *of the following conditions [in shaded boxes] are met:* |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **(a) Pre-clinical data:** Preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted **and** provide data for assessing potential risks to pregnant women and fetuses . [§46.204(a)] | | | | | | | | | |
| **No ►** STOP!§46.204 **NOT** met. | | | | | | **Provide rationale:** | | | |
| **Yes,** briefly describe | | | | | |
| **N/A** [i.e. not scientifically appropriate] | | | | | |
| **IRB REVIEWER COMMENT(S)** | | | | | | | | | |
| **(b) Risk/Benefit ratio:** Does the research hold out the prospect of direct benefit for the woman OR fetus? [§46.204(b)] | | | | | | | | | |
| **No ►** | Is the risk to fetus greater than minimal? | **No ►** | Is the purpose of the research for the development of important biomedical knowledge which cannot be obtained by any other means? | | | | **No ►** STOP! §46.204 **NOT** met. | | **Provide rationale:** |
| **Yes** | |
| **Yes►** STOP! §46.204 **NOT** met. | | | | | | |
| **Yes►** | Is the risk to the fetus caused *solely* by interventions or procedures that hold out the prospect of direct benefit for woman OR fetus? | | | | | | **No ►** STOP! §46.204 **NOT** met. | |
| **Yes** | |
| **IRB REVIEWER COMMENT(S)** | | | | | | | | | |
| **(c) Least possible risk:** Any risk is the least possible for achieving the objectives of the research. [§46.204(c)] | | | | | | | | | |
| **No ►** STOP! §46.204 **NOT** met. | | | | | | **Provide rationale:** | | | |
| **Yes** | | | | | |
| **IRB REVIEWER COMMENT(S)** | | | | | | | | | |
| **(d) Consent of woman:** Consent of pregnant woman will be obtained in accord with the informed consent provisions of subpart A (as embodied in the OHR-8, Informed Consent Template, and the OHR-2.. [§46.204(d)] | | | | | | | | | |
| **No ►** STOP! §46.204 **NOT** met. | | | | | |  | | | |
| **Yes** | | | | | |
| **(e) Consent of father:** If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father will be obtained in accord with the informed consent provisions of subpart A of the code of federal regulations, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. [§46.204 | | | | | | | | | |
| **No ►** STOP!§46.204 **NOT** met. | | | | | **Provide rationale:** | | | | |
| **Yes** | | | | |
| **N/A** [i.e. research benefits woman or direct benefit solely to fetus does not apply] | | | | |
| **IRB REVIEWER COMMENT(S) on (d) and (e)** | | | | | | | | | |
| **(f) Consent includes impact on fetus/neonate:** Each individual providing consent under paragraph (d) or (e) of this section will be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. [§46.204(f)] | | | | | | | | | |
| **No ►** STOP! §46.204 **NOT** met. | | | | | |  | | | |
| **Yes** | | | | | |
| **IRB REVIEWER COMMENT(S)** | | | | | | | | | |
| **(g) Pregnant children:** For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of the code of federal regulations. [§46.204(g)] | | | | | | | | | |
| **No ►** STOP!§46.204 **NOT** met. | | | | | |  | | | |
| **Yes (if YES, fill out and submit form OHR-26** | | | | | |
| **N/A** [i.e. children not enrolled] | | | | | |
| **IRB REVIEWER COMMENT(S)** | | | | | | | | | |
| **(h) Inducements:** No inducements, monetary or otherwise, will be offered to terminate a pregnancy [§46.204(h)] | | | | | | | | | |
| **No ►** STOP! §46.204 **NOT** met. | | | |  | | | | | |
| **Yes** (Statement is true) | | | |
| **(i)** **Pregnancy termination:** Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. [§46.204(i)] | | | | | | | | | |
| **No ►** STOP! §46.204 **NOT** met. | | | |  | | | | | |
| **Yes** (Statement is true) | | | |
| **(j)** **Neonate viability:** Individuals engaged in the research will have no part in determining the viability of a neonate. [§46.204(j)] | | | | | | | | | |
| **No ►** STOP! §46.204 **NOT** met. | | | | | | | |  | |
| **Yes** (Statement is true)►Subpart B: §46.204 [for pregnant women or fetuses] met. | | | | | | | |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature, Principal Investigator Date** | | | | | | | | | |
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| **FOR IRB USE ONLY Other comments:**  **Reviewed By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of irb meeting:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | |