|  |  |
| --- | --- |
|  | **IRB REVIEWER CHECKLIST FOR****Subpart B-Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research** |
| The purpose of this required worksheet is to supplement the “Reviewer Remarks” form to document the IRB determinations in accordance with federal regulations. Sections marked with (\*) are required. |
| **Project Title** Enter text. | **IRB#:** Enter text. | **Principal Investigator:** Enter text. |

|  |  |
| --- | --- |
| **If Non-Federally Regulated Minimal Risk Research (Check if “Yes”. All must be checked)**[ ] The research is NOT conducted, funded, or otherwise subject to regulation by DHHS, Environmental Protection Agency (EPA), or Veterans Administration (VA).☐ The research involves no more than Minimal Risk to pregnant women and fetuses.☐ The research is not funded by Department of Defense or does not involve interventions/invasive procedures to the woman or fetus and does not involve fetuses or neonates as subjects.**If all the above was checked, stop here.** |  |
| **If Federally funded or More than Minimal Risk Research, answer the following:** |  |
| **Question 1.** \* Will the investigator enroll pregnant women and/or human fetuses?  |  |
|  | [ ]  | **Yes** *Answer Question 2.* | [ ]  | **No.** |
| **Question 2.** The only involvement of human subjects will be in one or more of the following categories:  |  |
| **Criteria for 204: Research involving pregnant women or fetuses.**  |  |
|  | Pregnant women or fetuses may be involved in research if all of the following conditions are TRUE: |  |
|  |[ ]  \* Where scientifically appropriate, 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. |  |
|  |[ ]  \* The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means. |  |
|  |[ ]  \* Any risk is the least possible for achieving the objectives of the research. |  |
|  |[ ]  \* If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part. |  |
|  |[ ]  \* If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of [subpart A](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subparta) of [this part](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#part46), 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. |  |
|  | [ ]  | \* Each individual providing consent under paragraph [(d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.204(d)) or [(e)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.204(e)) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. |  |
|  | [ ]  | \* For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part. |  |
|  | [ ]  | \* No inducements, monetary or otherwise, will be offered to terminate a pregnancy. |  |
|  | [ ]  | \* Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. |  |
|  | [ ]  | \* Individuals engaged in the research will have no part in determining the viability of a neonate. |  |
|  | [ ]  | **Yes.** All the above \*statements are true. The project meets the criteria for Subpart B 204.On the “Reviewer Remarks” section, describe the protocol specific findings in the recommendation for Subpart B. | [ ]  | **No.** The **project does not meet the criteria** for Subpart B 204. |  |  |
| **Criteria for 205: Research involving neonates.*** Research may involve Neonates of Uncertain Viability if a and b are true.
* Research may involve Nonviable Neonates if a and c are true.
* Research may involve Viable Neonates if d is true.
 |  |
|  |[ ]  (a) Neonates of uncertain viability and 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. |  |
|  |  |[ ]  \* Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate. |  |
|  |  |[ ]  \* Individuals engaged in the research will have no part in determining the viability of a neonate. |  |
|  |  |[ ]  \* The requirements of paragraph (b) or (c) of this section have been met as applicable. |  |
|  | [ ]  | (b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met: |  |
|  |  | [ ]  | \* The IRB determines that: |  |
|  |  |  |[ ]  (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, or |  |
|  |  |  |[ ]  (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. |  |
|  |  |[ ]  \* 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. |  |
|  |[ ]  (c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met: |  |
|  |  | [ ]  | \* Vital functions of the neonate will not be artificially maintained. |  |
|  |  | [ ]  | \* The research will not terminate the heartbeat or respiration of the neonate. |  |
|  |  | [ ]  | \* There will be no added risk to the neonate resulting from the research. |  |
|  |  |[ ]  \* The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. |  |
|  |  | [ ]  | \* The legally effective informed consent of both parents of the neonate is obtained in accord with [subpart A](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subparta) of [this part](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#part46), except that the waiver and alteration provisions of [§46.116(c)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116) and [(d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116) 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 this paragraph (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 (c)(5). |  |
|  | [ ]  | (d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part. |  |
|  | [ ]  | **Yes.** The project meets the criteria for Subpart B 205.On the “Reviewer Remarks” section, describe the protocol specific findings in the recommendation for Subpart B. | [ ]  | **No.** The **project does not meet the criteria** for Subpart B 205. |  |  |
| **Criteria for 206: Research involving, after delivery, the placenta, the dead fetus or fetal material.** |  |
|  | [ ]  | (a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities. |  |
|  | [ ]  | (b) If information associated with material described in paragraph [(a)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.206) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of [this part](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#part46) are applicable. |  |
|  | [ ]  | **Yes.** The project meets the criteria for Subpart B 206.On the “Reviewer Remarks” section, describe the protocol specific findings in the recommendation for Subpart B. |[ ]  **No.** The **project does not meet the criteria** for Subpart B 206. |  |  |
| **Criteria for 207: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.**   |  |
|  |  The Secretary will conduct or fund research that the IRB does not believe meets the requirements of §46.204 or §46.205 only if: |  |
|  | [ ]  | (a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and |  |
|  | [ ]  | (b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either: |  |
|  |  | [ ]  | (1) That the research in fact satisfies the conditions of §46.204, as applicable; or |  |
|  |  | [ ]  | (2) The following: |  |
|  |  |  | [ ]  | \* (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; |  |
|  |  |  | [ ]  | \* (ii) The research will be conducted in accord with sound ethical principles; and |  |
|  |  |  | [ ]  | \* (iii) Informed consent will be obtained in accord with the informed consent provisions of [subpart A](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subparta) and other applicable subparts of [this part](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#part46). |  |
|  | [ ]  | **Yes.** The project meets the criteria for Subpart B 207.On the “Reviewer Remarks” section, describe the protocol specific findings in the recommendation for Subpart B. | [ ]  | **No.** The **project does not meet the criteria** for Subpart B 207. |  |  |
| **IMPORTANT!** * If none of the above criteria are met, the project is not eligible to enroll pregnant women, fetuses, nor neonates. If the protocol intends to enroll this population and not enough information was provided to meet the above criteria, on the “Reviewer Remarks” document, describe what modifications or additional information is needed for the protocol to meet the criteria.
 |

Reviewers remarks: Click or tap here to enter text.