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| Protocol Information | |
| **Project Title**: | |
| Subpart B Protections under 45 CFR 46 | |
| Federal regulations provide additional protections in Subpart B for research that involves (1) pregnant women, (2) fetuses, (3) neonates of uncertain viability and non-viable neonates and (4) research involving after delivery, the placenta, the dead fetus or fetal material. PA law prohibits non-therapeutic research involving an “unborn child”. PA law defines and unborn child as "an individual organism of the species homo sapiens from fertilization until live birth.” | |
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| § 46.204 Research Involving Pregnant Women or Fetuses | |
| Yes  No  Yes  No  Yes  No  Yes  No | 1) The proposed **research is scientifically appropriate**. Included in the protocol and submitted materials:  a) Descriptions of any pre-clinical studies on pregnant animals; and  b) Data from clinical studies conducted on non-pregnant women; and  c) Data is provided for assessing potential risks to pregnant women and fetuses. |
|  | 2) The **risk to the fetus** |
|  | Not greater than minimal;  Greater than minimal risk and 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. |
| Yes  No | 3) The risks have been minimized and are the least possible for achieving the objectives of the research |
| Consent Requirements | |
| 4a) If “Yes” to any of the 3 questions below, informed consent must be obtained from the pregnant woman or her legally authorized representative as required in 45 CFR 46.116 & 117. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus*.* | |
| Yes  No | This research holds out the **prospect of a direct benefit** to the **pregnant woman**; |
| Yes  No | This research holds out the **prospect of a direct benefit** ***both*** to the **pregnant woman and the fetus**; or |
| Yes  No | This research **does not hold out the prospect of direct benefit** for the woman or the fetus, but the 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. |
| 4b) If the answer to the question below is “Yes”, informed consent must be obtained from the pregnant woman and the father as required in 45 CFR 46.116 & 117. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus. | |
| Yes  No | This research holds out the **prospect of a direct benefit solely to the fetus**. |
| 4c) If the answer to the question below is ”Yes”, assent from the pregnant child and permission from her parent or legal guardian must be obtained in accordance with the provisions of 45 CFR 46, Subpart D. | |
| Yes  No | This research will involve participants who are pregnant and meet the definition of “children” as defined in 45 CFR 46.402.  **NOTE**: PA law permits pregnant minors to consent for their own treatment and therefore, under most circumstances, they would not meet the definition of “children” under 45 CFR 46. |
| Yes  No | 5) Will there be any inducements, monetary or otherwise, offered to terminate a pregnancy? |
| Yes  No | 6) Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy? |
| Yes  No | 7) Will individuals engaged in the research have any part in determining the viability of a fetus? |
| **NOTE: If the answer to either 5, 6, or 7 is “Yes”, the research is not approvable** | |