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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” which it defines as "an individual organism of the species homo sapiens from fertilization until live birth.”  **NOTE:** If the research is not federally-funded/Subpart B does not apply, only Page 2 (PA Statute requirements) should be completed. | | | |
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| § 46.206 Research After Delivery, The Placenta, The Dead Fetus, Or Fetal Material | | | |
| 1) This research proposes to use the following: (Check all that apply) | | | |
| placenta | | the dead fetus | macerated fetal material |
| cells excised from dead fetus | | tissue excised from dead fetus | organs excised from dead fetus |
| Yes  No | 2) Will any information associated with the material identified above be recorded for research purposes in such a manner that living individuals can be identified, directly or through identifiers linked to those individuals?  If “**YES**”, these individuals are considered to be research subjects and all pertinent human subject regulations are applicable to their participation.  If “**NO**”, **PA State Law still regulates this research**. CHOP legal counsel may have to review prior to IRB approval to ensure that the research and the consent process complies PA State Law. | | |

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| § 46.207 Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Human Fetuses, or Neonates. | |
|  | This requires review by the Secretary of the Department of Health and Human Services (DHHS) and posting in the Federal Register for public comments and review. |

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| PA Statute, Title 18 – Crimes and Offenses, Chapter 32 Abortion; § 3216. Fetal experimentation. | | | | | |
| 3) What is the source of the fetal material? (Check all that apply) | | | | | |
| Stillbirth  Miscarriage | | | Ectopic pregnancy  Abortion | | Any other means |
| Yes  No | 4) Confirm that all persons who participate in the procurement, use, or transplantation of fetal material, including the recipients of such material, will be informed as to the source(s) of the particular material as enumerated in (3.0) above. | | | | |
| 5) Who did obtain / will be obtaining the written consent of the mother to procure the material? **NOTE:** If the investigator did obtain / is obtaining consent from the mother, a copy of this consent form must be attached to the eIRB application.  (Check all that apply) | | | | | |
| CHOP investigator | | Individual(s) not on the current research team (e.g. CHOP or outside entity) | | Company | |
| Yes  No | 6) Do the investigators have access to individually identifiable information about the mother and/or fetus? | | | | |
|  | | | | | |
| If the answer to any of the questions (7 - 12) below is "NO", the study is not approvable under PA Law. | | | | | |
| Yes  No | 7) Confirm that written consent was / will be obtained from the mother to procure the material. | | | | |
| Yes  No | 8) Confirm that no consideration of any kind was / will be offered or given for written consent to procure the material. | | | | |
| Yes  No N/A | 9) Confirm that, if the material is derived from abortion, written consent to procure the material was / will be obtained after the decision to abort is made. | | | | |
| Yes  No | 10) Confirm that the individual obtaining consent did not / will not employ the possibility of the use of aborted material as an inducement to a pregnant woman to undergo abortion. **NOTE:** Payment for reasonable expenses occasioned by the actual retrieval, storage, preparation and transportation of the material is permitted. | | | | |
| Yes  No | 11) Confirm that remuneration, compensation, or other consideration was not / will not be paid to any person or organization in connection with the procurement of the material. | | | | |
| Yes  No | 12) Confirm that no person (e.g. the mother) who consents to the procurement or use of any fetal tissue or organ did / will designate the recipient of that tissue or organ, and no other person or organization did / will act to fulfill that designation. | | | | |
| 13) The information in questions 7-12 above was confirmed by: (Check all that apply)  The CHOP investigators  Provider of the fetal tissue or organ (if so, attach provider documentation to the RF with this form) | | | | | |