**VULNERABLE POPULATION ASSESSMENT FORM**

***Please see associated guidance document for information pertaining to this assessment form.***

**Principal Investigator:** Click or tap here to enter text.

**Study Number:** Click or tap here to enter text.

|  |  |
| --- | --- |
| **Vulnerable Population Targeted** | |
| Children |  |
| Pregnant Women, Fetuses or Neonates |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section I: Studies Involving Children, 45CFR46, Subpart D** | | | |
|  | **Research not involving greater than minimal risk.** | One parent required for consent. | 45CFR46.404 |
|  | **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.** | One parent required for consent. | 45CFR46.405 |
|  | **Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject’s disease or condition.** | Both parents are required for consent unless meeting criteria set forth in CFR46.408(b). | 45CFR46.406 |
|  | **Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.** | Both parents are required for consent unless meeting criteria set forth in CFR46.408(b). | 45CFR46.407 |
| **Section II: Studies Involving Pregnant Women, Fetuses or Neonates, 45CFR46, Subpart B** | | | |
|  | **Research involving pregnant women or fetuses.** | Consent must be obtained in accordance with 45CFR46.204(d-g). | 45CFR46.204 |
|  | **Research involving neonates.** | One parent required for consent for neonates of uncertain viability, except as set forth in 45CFR46(b)(2); both parents required for consent for nonviable neonates, except as set forth in 45CFR46.206(c)(5). | 45CFR46.205 |
|  | **Research involving, after delivery, the placenta, the dead fetus or fetal material.** |  | 45CFR46.206 |
|  | **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.** | Consent to be obtained in accordance with 45CFR46.207(b) (2)(iii). | 45CFR46.207 |

By submitting this document, the Principal Investigator agrees to comply with all regulatory guidelines for vulnerable populations as required by 45CFR46, Subpart D for children as research subjects and Subpart B for women, fetuses, or neonates as research subjects.