PI: **Click or tap here to enter text.** Protocol # **Click or tap here to enter text.**

* *Check the appropriate box for each part as it relates to the proposed research. When a white box is checked, provide justification as to how the proposed research meets the criteria for that part.*
* *Pregnant individuals or fetuses may be involved in research if* ***all*** *of the following conditions within the white boxes are met, and the study does not violate PA state law.*

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **(a) Pre-clinical data available:** Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant individuals, have been conducted **and** provide data for assessing potential risks to pregnant individuals and fetuses [Data is available to assess risks to pregnant individuals & fetuses] [§46.204(a)] | | | | | | | | | |
| **No ►** STOP!§46.204 **NOT** met. | | | | | | **Click or tap here to enter text.** | | | |
| **Yes** | | | | | |
| **N/A** [i.e. not scientifically appropriate] | | | | | |
| **(b) Risk/Benefit ratio:** Does the research hold out the prospect of **direct benefit** for the **pregnant** **individual 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. | | **Click or tap here to enter text.** |
| **Yes 🡪 NOTE:** Under PA law, any non-therapeutic (that which is “not intended to preserve the life or health”) medical procedure performed upon a fetus is prohibited and may be considered to be a third degree felony. **Consider whether consultation with the Office of General Counsel is necessary.** | |
| **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 individual OR fetus? | | | | | | **No ►** STOP! §46.204 **NOT** met. | | **Click or tap here to enter text.** |
| **Yes** | |
| **(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. | | | | | | **Click or tap here to enter text.** | | | |
| **Yes** | | | | | |
| **(d) Consent of individual:** Consent of the pregnant individual is obtained in accordance with the informed consent provisions of subpart A. [§46.204(d)] | | | | | | | | | |
| **No ►** STOP! §46.204 **NOT** met. | | | | | | **Click or tap here to enter text.** | | | |
| **Yes** | | | | | |
| **(e) Consent of other parent:** *If the research holds out the prospect of direct benefit solely to the fetus* then the consent of the *pregnant individual and the other parent* is obtained in accord with the informed consent provisions of subpart A of this part, except that the other parent's consent need not be obtained if they are unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. [§46.204(e)] | | | | | | | | | |
| **No ►** STOP!§46.204 **NOT** met. | | | | | **Click or tap here to enter text.** | | | | |
| **Yes** | | | | |
| **N/A** [i.e. research benefits pregnant individual or direct benefit solely to fetus does not apply] | | | | |
| **(f) Consent includes impact on fetus/neonate:** Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. [§46.204(f)] | | | | | | | | | |
| **No ►** STOP! §46.204 **NOT** met. | | | | | | **Click or tap here to enter text.** | | | |
| **Yes** | | | | | |
| **(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 this part. [§46.204(g)] | | | | | | | | | |
| **No ►** STOP!§46.204 **NOT** met. | | | | | | **Click or tap here to enter text.** | | | |
| **Yes** | | | | | |
| **N/A ►** *Children are not enrolled, OR the minors are legally emancipated (PA/NJ), OR the research involves the provision of medical care or treatment (PA/NJ)* | | | | | |
| **(h) Inducements:** No inducements, monetary or otherwise, will be offered to terminate a pregnancy [§46.204(h)] | | | | | | | | | |
| **No ►** STOP! §46.204 **NOT** met. | | | | **Click or tap here to enter text.** | | | | | |
| **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. | | | | **Click or tap here to enter text.** | | | | | |
| **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. | | | | | | | | **Click or tap here to enter text.** | |
| **Yes** (Statement is true)►Subpart B: §46.204 [for pregnant individuals or fetuses] met. | | | | | | | |
| Additional comments: **Click or tap here to enter text.** | | | | | | | | | |