**Dartmouth College •**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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**CPHS – RESEARCH INVOLVING PREGNANT WOMEN and FETUSES**

**Please complete: CPHS# PI:**

The questions below reflect the regulatory conditions contained in 45 CFR 46 Subpart B.

**1. Research involving Pregnant Women and Human Fetuses:**

a. Does this research pose a greater than minimal risk to the:

Woman  **No  Yes**

Fetus  **No  Yes**

If either is yes, explain:

b. Does the research hold out the prospect of direct benefit for the:

Woman  **No  Yes**

Fetus  **No  Yes**

c. For research that does not hold out the prospect of direct benefit to the fetus, explain how the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

d. Where scientifically appropriate, have preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, been conducted to provide data for assessing potential risks to pregnant women and fetuses?  Yes No

Explain:

e. Explain why the level of risk is the least possible for achieving the objectives of the research and provide justification for your explanation:

f. Describe how you will ensure that individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus:

NOTE: if the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father must be obtained, 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. Otherwise, the consent of the mother is sufficient.

g. Check off that the Principal Investigator assures that:

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; and

Individuals engaged in the research will have no part in determining the viability of a neonate.