**Request for Research Involving Pregnant Women**

**PI Name:** **IRB Protocol Number:**

1. **Research involving Pregnant Women:**
   1. **Does this research pose a greater than minimal risk to the:**

**Woman  Yes  No**

**Fetus  Yes  No**

**If either or both is yes, please explain:**

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

**Woman  Yes  No**

**Fetus  Yes  No**

* 1. **Is the research funded by the US Department of Health and Human Services (e.g., NIH)?  Yes  No**

**If Yes, go to the next questions and complete this form.**

**If No and the risk to the fetus is minimal, then no additional protections are required and no further information is required and the form may be submitted.**

* 1. **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 knowledge, which cannot be obtained by any other means.**

**Explain:**

**Note: For research that is funded by HHS, the important knowledge must be biomedical knowledge.**

* 1. **Where scientifically appropriate, have preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, been conducted to provide data for assessing potential risks to pregnant women and fetuses?**

**Yes  No**

**Explain:**

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

* 1. **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.*