Vulnerable Populations Supplement (Pregnant Women)

Syracuse VA Institutional Review Board

(Syracuse , Canandaigua & Bath VAMC)

**Name of Project:**

**MIRB#**

**PI Name:**

**VA Facility Name:**

**Date:**

***Check to indicate application status****:*

**Initial  Revised**

**I.** **Protections and Safeguards Included in the Protocol**

|  |  |  |  |
| --- | --- | --- | --- |
| ***The investigator must provide a response for each question or statement below.*** | **YES** | **NO** | **N/A** |
| 1. Where scientifically appropriate, have preclinical studies including studies on pregnant animals and clinical studies including studies on non-pregnant women, been conducted and do they provide data for assessing potential risks to pregnant women and fetuses? *A description of such studies should be included in the project application.* |  |  |  |
| *All of the following questions or statements must be answered yes if this vulnerable population is being proposed as participants in this research.* |  |  |  |
| 1. Selection of Participants: Adequate consideration has been given to the manner in which potential subjects are going to be selected. |  |  |  |
| 1. The risk to the fetus is not greater than minimal, **or** is any risk to the fetus which is greater than minimal caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus? |  |  |  |
| 1. Is any risk the least possible for achieving the objectives of the research? |  |  |  |
| 1. There are no inducements included in the research, monetary or otherwise, that will be offered to terminate a pregnancy. |  |  |  |
| 1. Individuals involved in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. |  |  |  |
| 1. Individuals engaged in the research will have no part in determining the viability of a neonate. |  |  |  |

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| If additional protections and safeguards are included in the protocol and are not described above, please detail them below: |

**III. Informed Consent Requirements**

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| ***The investigator should check the appropriate boxes below to indicate how informed consent will be obtained.*** |
| |  |  | | --- | --- | |  | Adequate provision has been made to monitor the actual consent process by procedures such as:  Overseeing the process by which the consent of individuals is obtained either by: Approving enrollment of each individual or Verifying, perhaps through sampling, that approved procedures for enrollment of individuals into the activity are being followed.  Monitoring the progress of the activity and intervening, as necessary, through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen. | |  | Consent of the pregnant women or her legally authorized representative will be obtained since the research meets one of the following criteria: *(Check one)*  The research holds out the prospect of direct benefit to the pregnant woman.  The research holds out the prospect of direct benefit to both the pregnant woman and  the fetus.  The research holds out no prospect of direct benefit to the pregnant woman or fetus but  the risk to the fetus is not greater than minimal and the purpose of the research is the  development of important biomedical knowledge that cannot be obtained by any other  means. | |  | Consent of the pregnant woman and the father, if readily available, will be obtained as the research holds out the prospect of direct benefit solely for the fetus. There are four criteria for relying on the consent of the mother alone:   1. The purpose of the activity is to meet the health needs of the mother, 2. His identity or whereabouts cannot reasonably be ascertained, 3. He is not reasonably available, or 4. The pregnancy resulted from rape. | |

**IV. Investigator Certification**

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| |  | | --- | | ***The principal investigator must check each box and sign and date the form.*** |  |  |  | | --- | --- | |  | I understand my responsibilities to follow all applicable VA And federal requirements to protect the rights and welfare of this vulnerable population. | |  | I understand that the informed consent requirements described in VHA Handbook 1200.05 concerning this vulnerable population are not intended to preempt any applicable federal, state, or local laws that require additional information be disclosed for the informed consent to be legally effective. | |  | I agree to follow all additional protections and safeguards for this vulnerable population as described in this project and as required by the IRB and I will ensure my project team is informed of these protections, safeguards, and requirements. | | | | | |
|  | Signed |  | Date |  |