Vulnerable Population Supplement (IDMC)

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 Project**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Please provide a response for each question or statement below.*** | **YES** | **NO** | **N/A** |
| 1. Does the protocol give a compelling reason why persons with impaired decision-making capacity are necessary to answer the research question? |  |  |  |
| 1. Does the project expose this vulnerable population to significant risks (including tangible and intangible?) |  |  |  |
| 1. If the project is greater than minimal risk, is there at least a greater probability of direct benefit than risk to the participant? |  |  |  |
| 1. If the project proposes the use of institutionalized individuals does it include an adequate justification for their use? |  |  |  |
| 1. Are there procedures detailed in the project for evaluating the mental status of prospective participants to determine whether they are capable of giving informed consent or assent? |  |  |  |
| 1. Does the research project include a description of the informed consent process for those who lack capacity to consent, including reference to state laws that determine who has authority to consent on behalf of the subject? |  |  |  |
| 1. Consent is limited by a legally authorized representative to situations where the prospective subject is incompetent or has impaired decision‑ Making capacity, as determined and documented in the person’s medical record in a signed and dated progress note. |  |  |  |
| 1. If there is any question as to whether a potential adult subject has decision-making capacity, and there is no documentation in the medical record that the individual lacks decision-making capacity, and the individual has not been ruled incompetent by a court of law, the researcher must consult with a qualified practitioner (who may be a member of the research team) about the individual’s decision-making capacity before proceeding with the consent process. |  |  |  |
| 1. If a legally authorized representative gives informed consent, will the subject be asked for assent? |  |  |  |
| 1. If a legally authorized representative gives informed consent and assent of the subject is not sought, is the justification for not getting assent detailed in the project? |  |  |  |
| 1. If there is a potential to enroll participants who have temporary or fluctuating decision-making capability, is there a process detailed in the project describing the requirement for re-consent? |  |  |  |
| 1. Have procedures been included in the project detailing procedures to ensure participant’s representatives are well informed regarding their roles and obligations to protect participants with impaired decision-making? |  |  |  |
| 1. Disclosures to be made to the subject must be made to the subject’s legally authorized representative. |  |  |  |
| 1. The subject’s legally authorized representative must be told that that his or her obligation is to try to determine what the subject would do if able to make an informed decision. If the prospective subject’s wishes cannot be determined, the legally authorized representative must be told that he or she is responsible for determining what is in the subject’s best interest. |  |  |  |
| 1. You/the practitioner must plan to explained the proposed research to the prospective subjects when feasible even when the subject’s legally authorized representative gives consent. |  |  |  |
| 1. You must ensure the study includes appropriate procedures for respecting dissent. Prohibit subject from being forced or coerced to participate in a research study. |  |  |  |
| If additional protections and safeguards are included in the project and are not described above, please detail them below. | | | |

**IV. Investigator Certification**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | | ***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 understand VHA Handbook 1200.05 describes the entities allowed to provide surrogate consent for research purposes unless otherwise specified by applicable state law. | |  | 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 |  |