Vulnerable Population Supplement (Prisoners)

 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**

|  |  |  |  |
| --- | --- | --- | --- |
| ***The investigator must provide a response for each question or statement below. All responses must be answered as “Yes” or “N/A” if this vulnerable population is to be included as participants in the project.*** | **YES** | **NO**  | **N/A** |
| 1. Are there any possible advantages to the prisoner from his/her participation in the research when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison that would impair the participant’s ability to weigh the risks of the research against the value of such advantages?
 | [ ]  | [ ]  | [ ]  |
| 1. Are the risks involved in the research commensurate with the risks that would be accepted by non-prisoner volunteers?
 | [ ]  | [ ]  | [ ]  |
| 1. Are procedures for selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities and are these procedures described in the project?
 | [ ]  | [ ]  | [ ]  |
| 1. If control groups are going to be used, will the control participants be randomly selected?
 | [ ]  | [ ]  | [ ]  |
| 1. Is the information presented in a language understandable to the general prison population?
 | [ ]  | [ ]  | [ ]  |
| 1. Does the informed consent document clearly state that participation in the research will not affect parole decisions and has the investigator trained prison authorities in this requirement?
 | [ ]  | [ ]  | [ ]  |
| 1. If there is a need for follow-up examinations or care of participants after the end of their participation in the research, has adequate provision been made for such examinations or care considering the length of the individual prisoner sentences and are these provisions described in the protocol?
 | [ ]  | [ ]  | [ ]  |

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

**III. Category of Permissible Prisoner Research**

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| ***The investigator should check the appropriate box below to indicate the category of permissible prisoner research to which the study pertains*** |
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|  |  |
| --- | --- |
| **[ ]**  | The research is minimal risk and no more than an inconvenience to the participants. It involves the possible causes, effects, and processes of incarceration and of criminal behavior. |
| **[ ]**  | The research is minimal risk and no more than an inconvenience to the participants. It involves a study of prisons as institutional structures or of prisoners as incarcerated persons. |
| **[ ]**  | The research is a study on conditions particularly affecting prisoners as a class, i.e., social and psychological problems such as alcoholism and drug addiction. |
| **[ ]**  | The research is a study on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health and/or well being of the participants. |
| **[ ]**  | This is an epidemiologic study. The sole purpose of the project is to describe the prevalence or incidence of a disease or condition by identifying all cases or to study the potential risk factors associated with a disease or condition. The research presents no more than minimal risk and no more than an inconvenience to the participants. Prisoners are not a particular focus of the research. |
| **[ ]**  | The research involves a project participant that became incarcerated after enrollment in the Project. It is to the benefit of the project participant to remain enrolled in the project.If yes, please justify:       |

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**IV. Investigator Certification**

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| ***The principal investigator must check each box and sign and date the form.*** |

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| [ ]  | I understand my responsibilities to follow all applicable VA and federal requirements to protect the rights and welfare of this vulnerable population. |
| [ ]  | I will ensure all the project team members are trained in the additional protections and safeguards that are to be afforded this vulnerable population as stipulated in this supplement and as may be further mandated by the VA Central IRB. |
| [ ]  | I understand that I must receive a waiver from the Chief Research and Development Officer per VHA Handbook 1200.05 for conducting research with prisoners as participants after I have obtained approval from the IRB and the R&D committee prior to beginning any research on prisoner participants. The only exception is if the IRB Chair approves the continued participation of a participant who becomes a prisoner after enrollment in a project if it is determined to be in the best interests of the participant until the IRB had made a decision on the amendment. |

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|  | Signed |  | Date |  |