Title: SARMC Institutional Review Board: Vulnerable Populations - Research Involving Prisoners

Policy Statement: If investigators plan to include members of this vulnerable population in their research, the IRB will take additional steps to meet the regulations described below. The regulations detail special protections for research involving prisoners, who due to their incarceration may have a limited ability to make voluntary and un-coerced decisions about whether or not to participate as subjects in research.

Research that involves prisoners must be taken to full board review to ensure heightened scrutiny. Although the research may qualify for expedited review, the weight of a review and subsequent approval will not be placed upon one reviewer given the unique circumstance. Therefore, expedited review procedures will not be utilized and the exempt category will not be used for research involving prisoners.

Projects that are primarily focused on collecting de-identified data for aggregate analysis may be considered for expedited approval. Such projects must provide care that does not deviate from the standard of care.

Procedure:

I. Definition of a Prisoner

Prisoner means any individual involuntarily confined or detained in a penal institution/prison. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a prison, and individuals detained pending arraignment, trial, or sentencing.

Any individual who participates in research while involuntarily confined or detained in a prison (or its equivalent) is considered a prisoner under the DHHS regulations. This is the case even when an individual becomes incarcerated subsequent to enrollment (for example, a subject in a study or an extended treatment trial becomes incarcerated after the research begins but before it ends). In such cases, the investigator must notify the IRB immediately upon learning that the participant has become a prisoner. Further research involving the prisoner-participant must be suspended until the IRB has reviewed the research at its earliest opportunity and determined whether the research is suitable for the involvement of prisoners under the criteria described in the categories of research as indicated in this policy. If the research is suitable for prisoners, the participation of the prisoner-participant may continue uninterrupted. If the research is not suitable for prisoners, the prisoner-participant may not enroll in the study during the period of incarceration.
II. IRB Authority and Responsibility

A. In order to consider research involving prisoners, IRBs must:
   1. Have a majority of its members not otherwise associated with a prison.
   2. Adequately represent the interests of prisoners by including a prisoner or a prisoner advocate on the board membership, unless the research has already been reviewed by an IRB that included a prisoner advocate. This representative will perform primary or secondary review of the research protocol. Documentation to substantiate the review that included a prisoner advocate must be provided and retained in the IRB meeting agenda and meeting minutes.

B. Under DHHS regulations, prisoners may participate in the following categories of research:
   1. Studies (involving no more than minimal risk or inconvenience) of the possible causes, effects, and processes of incarceration and criminal behavior.
   2. Studies (involving no more than minimal risk or inconvenience) of prisons as institutional structures or of prisoners as incarcerated persons.
   3. Research on particular conditions affecting prisoners as a class provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice in the Federal Register of his intent to approve such research.
   4. If the research involves possible assignment of a prisoner to a research control group, which may not be of benefit, the study may proceed only after the Secretary of DHHS has consulted with appropriate experts including experts in penology medicine and ethics, and published notice in the Federal Register, of his intent to approve such research.

C. To approve research involving prisoners the IRB must document that the following standards are met:

   1. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared with the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the penal institution, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the penal institution is impaired.
   2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
   3. Procedures for selecting subjects within the prison are fair to all prisoners, and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures,
control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

4. The information and consent is presented in language that is understandable to the prisoner population. Consent must be voluntary and presented without coercion. Prison staff such as a warden and/or health care professional may not sign or physically consent for an inmate/prisoner.

5. Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research when making decisions regarding parole. Each prisoner must be informed in advance and provided documentation that participation in the research will have no effect on his or her parole.

6. Where the board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, while taking into account the varying lengths of individual prisoner's sentences, and for informing participants of this fact.

Once a determination by the IRB has been rendered, the meeting minutes will document the category that permits the conduct of the research. The category for approval will also be communicated to the principal investigator in the initial approval letter.

III. Prisoners and Minors

Research that includes a participant that is both a prisoner and a minor require that the additional protections for children apply. An adolescent detained in a juvenile detention facility would be considered a prisoner.

The IRB will take a conservative approach when considering research that includes this vulnerable population. The principal investigator must provide additional written justification for including this population and address how participants will be provided protections that will mitigate risks before the IRB will conduct review of the research.

Related Policies: Vulnerable Populations.


References:

Code of Federal Regulations. (Last revised January 15, 2010). Title 45A – Department of Health and Human Services; Part 46 – Protection of Human Subjects; Subpart C -Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html