

**Valdosta State University**  
**Institutional Review Board (IRB)**  
**for the Protection of Human Research Participants**

**Guidance on Review of Research Involving Prisoners**

Valdosta State University's Institutional Review Board (IRB) provides additional protections to prisoners participating in research as specified in 45 CFR 46, Subpart C. The purpose of Subpart C is stated as follows: "Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable." Additionally, Subpart C recognizes that research involving prisoners may be limited or barred by state or local law that takes precedence.

"Prisoner" is defined as "any individual involuntarily confined or detained in a penal institution. 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 penal institution, and individuals detained pending arraignment, trial, or sentencing."

Subpart C provides a modified definition of "minimal risk" that is applied to research involving prisoners. For protocols involving prisoners, "minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons."

Subpart C also requires at least one member of the IRB to be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity. Additionally, a majority of the Board, exclusive of prisoner members, can have no association with the prison(s) involved apart from their membership on the IRB.

Although research involving prisoners cannot be exempted from IRB review, expedited review is allowed. However, because of the vulnerability of prisoners, the Office of Human Research Protections (OHRP) recommends that all research involving prisoners be reviewed by the convened IRB. If the research is reviewed under the expedited review procedure, OHRP recommends that the IRB member(s) reviewing the research include a prisoner or prisoner representative. The VSU IRB will conduct convened reviews of all protocols involving prisoners unless an emergency warrants expedited review, in which case the prisoner representative will be involved in the review.

In addition to the general requirements for human participant research protocols, special criteria must be met for research involving prisoners. Specifically, the research must represent one of the following four categories of research determined permissible under 45 CFR 46, Subpart D:

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;

3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research, such as on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.

The that the Secretary of the United States Department of Health & Human Services must also approve federally funded studies that meet the third or fourth categories.

Additionally, research protocols involving prisoners as participants must meet all of the following eight criteria in order to be approved:

1. A letter from each prison where participants will be recruited, printed on the penal institution's letterhead and signed by the warden or chief correctional officer, giving the researcher permission to conduct research at the prison must be provided to the IRB. *(See items e. and f. for additional information that should be included in the letter.)*
2. Any possible advantages accruing to the prisoner through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, must not be of such a magnitude that the prisoner's ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison would be impaired.
3. The risks involved in the research must be commensurate with risks that would be accepted by non-prisoner volunteers.
4. The procedures for the selection of subjects within the prison must be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the researcher provides written justification for following some other procedure, control group participants in quantitative study designs must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
5. Information about the study must be presented in language that is understandable to the subject population.
6. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision must be made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact. *(Medical, psychological, and/or counseling services that are available to participants through the prison should be documented in the permission letter from the chief correctional officer [see item a.], stated in the consent process, and documented in the consent form.)*
7. There must be adequate assurance that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole. *(This may be documented in the letter from the prison.)*
8. Each prisoner must be clearly informed in advance that participation in the research will have no effect on his or her parole. *(This should be stated during the consent process and documented in the consent form.)*

The researcher should also note that, although not a regulatory requirement, the IRB will be cognizant of researcher safety and may provide some comment on this aspect of the proposed study.