

<b>Michigan State University Human Research Protection Program</b>	
<i>Subject: Special Categories of Research Subjects</i>	
<i>Sub-Topic: Prisoners</i>	
<i>Section: 6-8-B</i>	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by: IRB, URC, UGC, MSU Legal Counsel</i>	<i>Approved by: Vice President of Research and Graduate Studies, 3-3-2005</i>
<i>Related Sections:</i>	

## **Policy**

Because prisoners may be under constraints as a result of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether to participate as subjects in research, it is important to provide additional safeguards for the protection of prisoners (45 CFR 46.302).

Research that involves prisoners may not undergo an expedited review procedure; applications must be taken to the full board for review and discussion. In addition, the Institutional Review Board (IRB) staff should assign the IRB member prisoner advocate as the primary reviewer.

## **Definitions**

“**Prisoner** means 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.” (45 CFR 46.303(c))

“**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.” (45 CFR 46.303(d))

## **Categories**

The following are the only categories (from 45 CFR 46.306(a)(2)) in which it is permissible to use prisoners as research subjects:

“(A) study of the possible causes, effects and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk or inconvenience to the subjects;”

“(B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk or inconvenience to the subjects;”

- “(C) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research 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) provided that the study may proceed only after the Secretary 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; or”
- “(D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.”

### ***Additional Criteria for Approval***

In order to approve projects involving prisoners the IRB must satisfy itself that the following standards (from 45 CFR 46.305) are met:

- “(1) the research under review represents one of the categories of research permissible under §46.306 (a)(2);”
- “(2) any possible advantages accruing to the prisoner through his or 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, 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 prison is impaired;”
- “(3) the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;”
- “(4) procedures for the selection of 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 Board 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;”
- “(5) the information is presented in language which is understandable to the subject population;”
- “(6) adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and”
- “(7) 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, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.”

## **Documentation**

The criteria for approving the project must be documented in the IRB minutes, including the protocol specific information justifying such findings. A standard form will be used to assist in the documentation.