OHSU Policy

Policy

A. When a protocol involves the use of prisoners as subjects, both the general OHSU IRB policies and procedures apply as well as the additional rules as determined by federal, state, county, and local regulations.

B. The OHSU IRB must review all research in which prisoners are the target population, the subject is a prisoner at the time of enrollment, or when a currently enrolled subject becomes incarcerated and research interventions and interactions would occur during the incarceration period or identifiable private information will be obtained during the incarceration period.

C. The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners.

D. The OHSU IRB will not issue a waiver of consent for participants who are the subject of this policy.

E. When a prisoner is a minor (e.g., an adolescent detained in a juvenile detention facility is a prisoner), the OHSU IRB policy regarding children in research will also apply.

F. OHSU IRB-approved federally-funded research will be submitted for OHRP certification and while OHRP certification is not mandatory for non-DHHS supported research, it is the policy of the OHSU IRB to require investigators to abide by the OHRP certification requirements as stated above.

G. In addition to the requirements of 45 CFR 46 Subpart A, a protocol involving prisoners must meet seven criteria. The Additional Protocol Requirements are as follows:

1. The research under review represents one of the following categories of research permissible under 45 CFR 46.306(a)(2):
   a. 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 and no more than inconvenience to the participants.
   b. A 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.
   c. Research on conditions particularly affecting prisoners as a class (e.g., 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 of DHHS (through OHRP) 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.
   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 of DHHS (through OHRP) 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.

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 prisoner 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 participants 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 participants 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 that 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 IRB 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.

Effective: 4/21/2008

1 “Follow-up examination and care” should be interpreted to include any examination or care that is necessary after the end of a study or after a subject can no longer participate in a study due to release. The primary rationale for the Subcommittee’s belief is its determination that the safety and welfare of all subjects would require consideration of both eventualities: release from custody during the study, or the ending of a study for persons who remain incarcerated.