

Public Health Division
PRISONER PARTICIPATION IN RESEARCH

When a proposed research project includes prisoners, the Public Health IRB (PH IRB) will take into consideration federal regulatory requirements that provide additional protection for prisoners who are involved in research. By regulatory definition, a prisoner is 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. Ankle bracelets/in-home restrictions ordered by the court are considered incarceration. Mental and substance abuse facilities are considered incarceration if someone is mandated to attend in lieu of jail or prison. Probation and parole are usually not considered as incarceration.

When reviewing research involving prisoners, the PH IRB will:

- apply the prisoner specific definition of minimal risk: 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;
- apply the PH IRB policy on children participation in research if the prisoner is also a minor;
- apply both the general PH IRB policies and procedures as well as any additional rules as determined by Federal, state, county and local regulations;
- have at least one PH IRB member be a former prisoner, or a prisoner representative with appropriate background and experience to serve in this capacity;
- have no association with the prison(s) involved, apart from their membership on the PH IRB;
- review all research in which prisoners are the target population, the participant is a prisoner at the time of enrollment, or when a currently enrolled participant becomes incarcerated and research interactions and interventions would occur during incarceration or identifiable private information will be obtained during incarceration; and
- inform investigators that DHHS supported research involving prisoners must first be certified and approved by the Office for Human Research Protection (OHRP) before prisoner research participants may be enrolled.

The Public Health Division will submit for OHRP certification, federally funded research involving prisoners which the PH IRB has reviewed and approved under 45 CFR 46, Subpart C. The PH IRB will apply the same standards and regulations to non-DHHS supported research involving prisoners, except that certification to OHRP will not be necessary.

Research involving prisoners must be reviewed by the convened IRB unless the project is eligible for expedited review. Studies that meet expedited review criteria, in accordance with 45 CFR 46.110(b)(1), will be assigned to the prisoner representative and one additional board member for review. An expedited review may be performed by only the prisoner representative for minor changes to previously approved research or continuing reviews in accordance with 45 CFR 46.110. The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners.

In order to approve research involving prisoners, investigators must address the following requirements in the research protocol or application to the PH IRB and the PH IRB must make these same findings:

- 1) 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;
- 2) The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- 3) 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 PH 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 is presented in language which is understandable to the subject population;
- 5) 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;
- 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 provisions have been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact; and
- 7) The research under review represents one of the following categories of research permissible under 45 CFR 46.306(a)(2):
 - > 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 more than inconvenience to the participants;
 - > 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;
 - > 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 intent to approve such research; or
 - > Research on practices both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. 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 intent to approve such research.

Research that involves epidemiologic studies in which the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or study potential risk factor associations for a disease, may qualify for a waiver of some or all of the provisions of 45 CFR 46, Subpart C. The PH IRB must find that 1) through 6) identified above apply to the research and determine and document that the research presents no more than minimal risk and no more than inconvenience to the prisoner participant and prisoners are not a particular focus of the study. Institutions that propose such studies must certify to the Secretary of DHHS (through OHRP) that these findings have been made.

Measures that must be taken if an enrolled research participant becomes incarcerated:

- 1) The investigator must report the event to the PH IRB within 5 working days of becoming aware of the incarceration unless the study was previously approved by the PH IRB and OHRP for prisoner participation. All research activities pertaining to this participant must cease until the PH IRB has reviewed the following:
 - a. Investigators must clarify and assure the PH IRB that research interactions and interventions or obtaining identifiable private information will NOT occur during the incarceration. If so, PH IRB review and approval under the prisoner regulations will not be required;
 - b. If investigators wish to pursue research interactions and interventions or obtaining identifiable private information while the participant is incarcerated, the PH IRB must review the protocol under the prisoner regulations. No research actions can occur with this participant until the PH IRB has reviewed and approved, **and** the research has been determined by OHRP to be permissible under 45 CFR 46.306(a)(2).
- 2) Participants may continue in the research prior to PH IRB review under the prisoner regulations only if the investigator asserts and the PH IRB Chair or Vice-Chair agrees that it is in the best interest of the participant to remain in the research study while incarcerated.

In order to conduct any research in a correctional facility, investigators must seek and receive approval from that facility to conduct or continue the research. Questions will need to be asked of appropriate authorities to determine whether it's feasible that the inmate participate in the study. Investigators should familiarize themselves with the following regulations pertaining to research with an inmate in the Department of Corrections:

- ORS 421-085
- OAR 291-035-0005 through 0015
- OAR 291-124-0080

Prisoner certification letter to OHRP:

The PH IRB Coordinator will assist investigators in the submission of material to OHRP for certification of federally funded research involving prisoners. The certification letter to OHRP shall include the following:

- Institutional assurance number;

- IRB registration number;
- Names of sites where research involving prisoners will be conducted. If these sites are considered engaged in the research, assurance numbers for those sites are required;
- Title of the DHHS grant and the grant award number;
- DHHS funding agency name;
- DHHS program officer contact information; and
- A chronological listing of IRB meetings where the protocol was considered for approval.

The following material must be sent along with the certification letter:

- IRB approval letter indicating the IRB made the required findings under 45 CFR 46.305(a) and which of the four categories in 45 CFR 46.306(a)(2) is applicable to the study;
- IRB approved protocol and consent forms;
- Any relevant DHHS grant application or proposal;
- Any IRB application forms required by the IRB; and
- Any other information requested or required by the IRB to be considering during its initial review.

Applicable Regulations:

45 CFR 46, Subpart C

21 CFR 50, Subpart D