**Public Health Division**
**Prisoner Participation in Research**

When a proposed research project includes prisoners, regardless of funding, the Public Health IRB (PH IRB) elects to apply 45 CFR 46 Subpart C, "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects". 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. Penal institutions include prisons, jails, and juvenile offender facilities in which an individual's ability to leave is restricted. Individuals involuntarily confined or detained to other institutions by court-order, including inpatient treatment facilities, hospitals, or halfway houses are also prisoners. Parolees and probationers living in the community and/or wearing monitoring devices are generally not considered to be prisoners.

It is important to understand that these additional mandated protections are not intended for individuals who have *ever* served time in prison over their lifetime. The protection is in place, rather, for any subject that is a prisoner involved in the research during their incarceration or other court ordered confinement. If the PH IRB finds that there are no particular risks in linking their health data to information regarding their incarceration or conviction and further, there is zero risk that a prisoner in the study would somehow be taken advantage of, abused, or lose something as a result of being a prisoner, then it may determine that Subpart C does not apply.

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 even feasible that the inmate participate in the study, prior to obtaining PH IRB review. 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

**<u>The Review</u>**
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 who are not prisoners";
- apply the Public Health Division "Children Participation in Research" policy and Subpart D if the prisoner is also a minor;
- apply both the general PH IRB policies and procedures as well as any additional rules pertinent to the inclusion of prisoners 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 that capacity;
- ensure a majority of the Board, exclusive of this Prisoner Representative, has no association with the prison(s) involved, apart from their membership on the PH IRB;
- review all research including initial, continuing, amendment requests, and reports of adverse events in which prisoners are the target population or incidentally included; and
- cease all research interactions, interventions, and the obtainment of identifiable private information about incarcerated prisoner-subjects if a human subject participating in an IRB-approved protocol becomes a prisoner after the research has begun.

**Previously Enrolled Subjects**

If an enrolled research participant becomes incarcerated during the course of the research it is the duty of the investigator to report the event to the PH IRB within 5 working days of becoming aware, unless the study was previously approved by the PH IRB for prisoner participation. If this is not the case but investigators assure the PH IRB that research interactions and interventions and/or obtaining identifiable private information will not occur during the subject's incarceration, then approval under Subpart C will not be required.

If, however, investigators wish to pursue research interactions and interventions and/or obtain identifiable private information while the participant is incarcerated, the PH IRB must review the protocol under the prisoner regulations at Subpart C and thus no research activity can occur with this participant until the PH IRB has re-reviewed and approved the research for their inclusion. For federally funded studies this will include secretarial consultation and certification to OHRP which is discussed in greater detail below.

In special circumstances in which the Principal Investigator asserts that it is in the best interest of the subject to remain in the research study while incarcerated, the PH IRB Chair or Vice Chair may determine that the subject may continue to participate in the research before the requirements of Subpart C are satisfied. For example, it would be detrimental to the subject if he/she is undergoing some medical treatment and suddenly must stop the treatment simply because regulations require that such interaction ceases once a subject becomes an incarcerated prisoner-subject. If the PH IRB Chair or Vice-Chair agrees with the P.I.'s assessment, that it is in the best interest of the participant to remain in the research study while incarcerated and prior to the requirements of Subpart C being met, the exception will be made.

**Federally Funded Studies**

Note, for any HHS conducted or supported research involving prisoners, the PH IRB will also certify to the HHS Secretary, through OHRP, that it has reviewed the research and made the seven findings as required by Subpart C. No action may be taken by the research team until these federally mandated steps are complete. For research not conducted or supported by HHS, although Subpart C will be applied, secretarial consultation and certification to OHRP are not required.

**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;
- PH IRB registration number;
- Sites where research involving prisoners will be conducted. If considered engaged in the research, site assurance numbers must be included;
- 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.

*Along with the certification letter, the following material must be sent:*

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

**Routes of Review**

Research involving prisoners must be reviewed by the convened PH IRB unless the project is eligible for expedited review. For initial, continuing, and amendment requests, 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. 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 seven requirements of 45 CFR 46.305 in their research protocol and/or application to the PH IRB and the Board 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 PH 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; and
7) The research under review represents one of the following permissible categories under 45 CFR 46.306(a)(2):
   i. Research on 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 subjects;
   ii. Research on prisons as institutional structures or on prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
   iii. 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 HHS, 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;
   iv. 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 HHS, 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
   v. Research conducted or supported by HHS that meets the *2003 Secretarial Waiver of the Applicability of Certain Provisions of DHHS Regulations for the Protection of Human Subjects for DHHS Epidemiologic Research Involving Prisoners as Subjects*. The sole purpose of such studies must be to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease. In such cases where this waiver may apply, the PH IRB must still review the research under Subpart C and certify to OHRP that 1-6 referenced above apply, the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and the prisoner population is not a particular focus of the research. Until the PH IRB receives confirmation from OHRP that the research appropriately meets the waiver criteria, the research may not proceed.

Applicable Regulations:
45 CFR 46, Subpart C