Prisoner Research

Purpose

The purpose is to outline the policy and procedures for the inclusion of prisoners in human research.

Definitions

Prisoner means any individual involuntarily confined or detained in a penal institution and encompassing 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. Those detained in court-mandated residential programs, where the ability to leave is restricted, are considered prisoners (e.g. juvenile detention centers, mandated residential drug and alcohol treatment in lieu of incarceration, etc.).

Minimal risk (for prisoners) 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.

Policy

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, additional safeguards have been implemented for this population under regulations at 45 CFR 46, Subpart C.

In order to review prisoner research, the IRB membership includes at least one member who is a prisoner or a prisoner representative with the appropriate background and experience to serve in that capacity. A majority of the IRB, exclusive of the prisoner member, shall have no association with the prison(s) involved, apart from their membership on the Board.

Unless research is aimed at a broader subject population of non-prisoners which only incidentally includes prisoners, such as with secondary research use of information or biospecimens, prisoner research is prohibited from exemption, and must be reviewed by a convened IRB (full review).

Additional Duties of the IRB in Reviewing Prisoner Research

When an IRB reviews prisoner research, it must make seven additional findings under 45 CFR 46, subpart A as listed below. Note that the Secretarial consultation mentioned in 1(iii) and 1(iv) is not required unless research is conducted or supported by Federal agencies which apply Subpart C.

1. The research represents one of four permissible categories, which studies the following:
    1. 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;
    2. 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 subjects;
    3. 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
    4. 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 his intent to approve such research.

2. Any possible advantages accruing to the prisoner through participation, 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. The 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 which is understandable to the participant 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.

Other State and Federal Laws

In Pennsylvania, the Department of Corrections has issued Policy Statement 2.1.2 which effectively bans the use of state prisoners in any medical experiments, cosmetic experiments, or pharmaceutical testing, with the exception for some testing involving treatment for AIDS and HIV infection. If a study utilizes prisoners

from a state prison in PA, approval from the Research Review Committee of the Commonwealth of Pennsylvania, Department of Corrections is required.

The Federal Bureau of Prisons has adopted extensive regulations for use of federal prisoners as research subjects. These regulations prohibit them from “medical experimentation, cosmetic research, or pharmaceutical testing” [28 C.F.R. 512.11(a)(3)]. In addition, strict limitations are imposed on incentives, and researchers may not promise confidentiality to subjects who reveal a future intent to engage in criminal behavior.

Parole and Probation

Because individuals on parole or probation do not meet the prisoner definition, the IRB is not required to make the seven, additional prisoner findings during its review. However, such individuals may still be vulnerable and experience increased risks due to their situation. As such, the IRB must ensure that adequate protections are in place for these individuals.

The IRB requires a recruitment permission letter from an authority at each site, and such permission should include a statement addressing the fact that the subjects are not considered prisoners under OHRP's federal definition. The permission letter, as well as the consent form, must state that the decision whether or not to participate will not affect parole or probation.

Subject Becoming a Prisoner During Research

If approved research did not propose the inclusion of prisoners, but one its subjects becomes a prisoner during the study’s duration, the investigator must notify the IRB immediately. All interactions, interventions and the collection of identifiable information about the prisoner-subject must cease, unless the

Director of Human Participants Protection and Research Compliance, with consultation of the IRB Chairperson if necessary, determines otherwise in the best interest of the prisoner-subject. At the earliest opportunity, the IRB may have to re-review the research materials in accordance with prisoner requirements. The IRB will decide if:

- The prisoner-subject may continue in the research
- The prisoner-subject must be withdrawn and fully informed of the reason
- Any other revisions are deemed necessary

Official IRB re-review is not usually required if research activities will not occur during the prisoner-subject's incarceration period. However, the investigator must file an Adverse Event/Unanticipated Problem report form with the IRB.

Procedures

The investigator meets all of the IRB's usual submission requirements. In addition, the investigator must:

1. Include in the informed consent form (voluntary nature section) a statement that the decision whether or not to participate will not affect parole or probation.
2. Obtain a recruitment permission letter, hand-signed and on letterhead, from the Warden or Director of the facility. This letter must include adequate assurance that the decision whether or not to participate will not affect parole or probation.
3. Meet any additional requirements of the prison or facility, such as submission to its IRB, if applicable.

Related Policies

- Mandatory Reporting
- Revisions to Approved Research

History

02/07/2017 – Added OHRP's recommendation about review type
07/18/2019 – Updated as a result of the Revised Common Rule