Research with Prisoners

Overview

Incarceration places prisoners under constraints that may affect their ability to make truly voluntary and un-coerced decisions about whether or not to participate as subjects in research. Prisoners, therefore, constitute a vulnerable population for which additional protections are warranted.

Definitions

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.

Minimal risk is the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Prisoner Representative may be a current or former prisoner or someone who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner

Regulations

Department of Health & Human Services (DHHS), Subpart C of Part 46 provides additional protections for biomedical and behavioral research involving prisoners as subjects. These additional protections, or provisions, of the federal regulations are intended to assure that 1) prisoners provide voluntary consent to participate in research; 2) prisoner's confidentiality is rigorously protected; 3) and prisoners are not used as subjects in studies for which non-incarcerated subjects are suitable. These provisions apply whether the research involves individuals who are prisoners at the time of enrollment in the research or who become prisoners after they become enrolled in the research.

DHHS also requires that the IRB have among its members:

1. one or more individuals knowledgeable about and experienced in working with prisoners when research, involving prisoners, is to be reviewed;
2. a majority of the Board, exclusive of the prisoner member(s), can have no association with the prison(s) involved apart from their membership on the IRB.

Food & Drug Administration (FDA): The current FDA regulations for the protection of human subjects do not include any specific additional protections for research subjects who are prisoners. However, the FDA does consider prisoners to be a vulnerable subject population for which the IRB must include additional safeguards.

Department of Defense: Provides instructions on the policies and responsibilities for the protection of human subjects in DoD-supported programs

Department of Justice (DOJ): If research is conducted within the Bureau of Prisons, the research must comply with Department of Justice regulations

Massachusetts law
IRB process for research involving prisoners: Provide copy of MA Department of Corrections with application

Permitted research involving prisoners

When an IRB is reviewing a protocol in which a prisoner is a subject, the IRB must make seven additional findings under 45 CFR 46.305 as follows:

1. For DHHS-supported research[1], the research under review must fall within one of the following four categories of research permitted under §46.306(a)(2)
    1. 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 subjects;
    2. 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 subjects;
    3. 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
    4. 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.
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.

IRB review of research involving prisoners

When reviewed by the convened IRB

- An IRB member who qualifies as a prisoner representative must be present at the convened meeting of the IRB and during the presentation, discussion, and vote of any study which involves prisoners.
- A majority of the IRB members (exclusive of prisoner members) must have no association with the prison involved, apart from their membership on the IRBs.

The prisoner representative:

- Must be a voting member of the IRB. (This individual may be listed as an alternative member who becomes a voting member when needed).
- Must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative must receive all review materials pertaining to the research (same as primary reviewer).
- Must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved. Presence may be in-person, by phone, or virtually.
- Must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.

When reviewed using expedited review procedures

Research involving individuals who are incarcerated may be reviewed by an expedited procedure under the following three circumstances:

1. Minor changes in previously approved research (with the exception of protocols funded by the Department of Defense)
2. Continuing review of research previously approved by the convened IRB as follows:

1. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
2. where no subjects have been enrolled and no additional risks have been identified; or
3. where the remaining research activities are limited to data analysis.
4. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Documentation of Subpart C findings

IRB meeting minutes provide a summary of protocols listed on the agenda along with board discussions, IRB stipulations and board action..

Certification letter to OHRP for HHS funded research ONLY

If a study utilizing prisoners as research participants is federally funded, the HRPP office will follow the process to submit the electronic certification to the Office for Human Research Protections (OHRP) indicating it has approved a study that will include prisoners, the category the study fits into as well as how the study satisfies the six criteria noted under the regulations.

A research study is not permitted to commence for DHHS supported research until written approval is received from OHRP on behalf of the DHHS Secretary under the provisions of 45 CFR 46.306(a)(2).

When an enrolled subject becomes incarcerated during their participation

When a human subject involved in ongoing research becomes a prisoner during the course of the study, and the relevant research study was not previously approved by the IRB for the inclusion of prisoners:

- All research procedures with the now-incarcerated prisoner-subject, including interactions and interventions and collection of identifiable private information, must immediately cease.
- If research personnel wish to have the prisoner-subject continue to participate in the research, the study team must submit an amendment to the IRB requesting inclusion of prisoners and the IRB must approve the inclusion in accordance with this policy. The prisoner-subject may continue to participate in research procedures once the amendment is approved.
- If research personnel believe it is in the best interest of the prisoner-subject to continue to receive research procedures before such an amendment can be reviewed, the IRB Chair may determine that the prisoner-subject may continue to participate in the research until the above requirements are met.
- IRB approval for inclusion of prisoners is not required if research procedures will not occur during the incarceration period.

Examples of the definition of prisoner

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration; however, individuals who are receiving nonresidential court-ordered substance abuse treatment and are residing in the community are not prisoners. Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.
- Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, half-way house, including parolees, are not prisoners.
- Probationers and individuals wearing monitoring devices are generally not considered prisoners; however, situations of this kind frequently require an analysis of the particular circumstance of the planned participant population. Examples of those NOT considered a prisoner:
- Parolees who are not detained but living in the community and sentenced to community-supervised monitoring, half-way house, including parolees, are not prisoners.
- Persons who are not "prisoners" when they enroll in the project, however are in jail for short periods of time at a later date if that short period of incarceration does not affect their participation in the project.

What is the IRB reviewer looking for in a protocol?

The IRB has prisoner research reviewers that have experience with this vulnerable population. They will be looking for the researcher to show that they are experienced and knowledgeable about doing research with a prisoner population, the setting, or are working closely with a mentor with this experience and knowledge. Detention facilities are tightly controlled. Routine research protocols and procedures need to be adjusted when using these settings. If you are not experienced in this area, you will need to involve faculty who are, or work with a co-PI mentor that is. The protocol may need to describe routine research procedures in more detail than normal. In the new protocol submission describe:

- Justification for the inclusion of prisoners in the study. If applicable, delineate the procedures to be conducted in the jail, prison, detention center, or treatment facility from the overall project described.
- If and how detention facility staff are involved in conducting the research.
- How the recruitment and selection of prisoner participants will be done.
- How the project will obtain informed consent, and also state in the consent that" participation will not affect any sentencing, parole decisions or judicial outcomes."
- Customary treatment or services at these facilities for the condition being studied.
- Where research procedures will be done within the facility, who will be present (e.g., correctional officer, etc.), how data will be collected, and how data will be protected.
- If any materials will be given to the prisoner and if you are seeking institutional approval of distribution.

- What the incentive is, if applicable, and how it will be distributed. Most facilities will not allow direct payment.
- How the study will protect subject confidentiality from staff and other prisoners.
- Plans for ensuring follow-up examination or care of participants after the end of their participation, if necessary.
- How risks specific to these settings are minimized.
- If travel to a clinic, lab, or another study site outside of the facility is needed for the research. If so, the consent should state how transfer and transportation arrangements will be handled. Consult with the facility prior to submitting your protocol to the IRB to ensure the facility can/will accommodate prisoner transport for the study and who will pay for it.

References

HHS Subpart C: Prisons as Research Subjects

OHRP Guidance on Approving Research Involving Research

Food & Drug Administration

Federal Bureau of Prisons

Department of Defense

Department of Justice