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Subject: Vulnerable Populations
Division: IRB
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IRB Policy 109.2: PRISONERS

Policy

The inclusion of individuals in a research study who are considered “prisoners” involves special ethical considerations and requires meeting additional regulatory requirements to safeguard prisoners’ interests and protect them from harm. Prisoners constitute a research population who are at risk for coercion due to their legal status or confinement.

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. Department of Health and Human Services (HHS) regulations at 45 CFR 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners as subjects.

The provisions of Subpart C apply to any research conducted or supported by FRI in which prisoners are subjects. This includes research that involves individuals who are prisoners at the time of enrollment in the research or individuals who become prisoners after they become enrolled in the research.

Definitions

"Prisoner" is defined by HHS regulations at 45 CFR part 46.303(c) as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution (see below for examples of institutions) under a criminal or civil statute (such as court mandated drug treatment), 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."

Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or those convicted of misdemeanors, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.

Common examples of the application of the regulatory definition of prisoner are as follows:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.

- Individuals with psychiatric illnesses who have been committed involuntarily to a psychiatric institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal 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, including parolees, are not prisoners.

- Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.

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.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

Special Composition of IRB

When the IRB reviews a protocol involving prisoners as subjects, the composition of the IRB will satisfy the following requirements of HHS regulations at 45 CFR 46.304(a) and (b):

- A majority of the IRB (exclusive of prisoner members) will have no association with the prison(s) involved, apart from their membership on the IRB.

- At least one member of the IRB will be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

FRI's IRB has at least one prisoner representative who has a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner. The prisoner representative will be present at every IRB meeting in which a protocol involving prisoners as subjects is reviewed, for all types of review of the protocol (including initial review, continuing review, review of protocol amendments, and review of reports of unanticipated problems involving risks to subjects). The curriculum vitae of the prisoner representative, serving on the IRB is on file in the IRB office.

Permitted Research Involving Prisoners

In order to approve research involving prisoners, the IRB must determine that the proposed research falls into one of the permissible categories of research.

The categories of permissible research involving prisoners under 45 CFR 46.306(a)(2) are the following:

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 (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; 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 (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.

IRB Review of Research Involving Prisoners

Research involving prisoners may not be exempt

Initial Review

At FRI, initial review of research involving prisoners will only be performed at convened IRB meetings.

When the IRB is reviewing a protocol in which a prisoner is a subject, the IRB will make, in addition to other requirements under 45 CFR 46, Subpart A, seven additional findings under 45 CFR 46.305(a), as follows:

1. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2);

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 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;

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 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.

These seven additional findings made by the IRB will be documented in the minutes of the IRB meeting in which the protocol was reviewed as a prison study.

Approval of Research Involving Prisoners Funded by the Department of Health and Human Services

For HHS conducted or supported research involving prisoners two actions must occur:

1. FRI must certify to the Secretary (through OHRP) that the IRB has reviewed and approved the research under 45 CFR 46.305; and

2. The Secretary (through OHRP) must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2).

After a protocol involving prisoners as subjects has been approved by the IRB, the IRB Administrator will send a certification letter that the IRB has made the seven additional findings required under 45 CFR 46.305(a), along with a copy of the research protocol, informed consent document, and Supplementary Application for Research Involving Prisoners to OHRP.

Research involving prisoners as subjects may not proceed until OHRP issues its approval in writing to FRI on behalf of the Secretary under 45 CFR 46.306(a)(2).

Once an approval letter is received from OHRP in the IRB office, a copy of the letter and a non-contingent approval letter from the IRB will be forwarded to the investigator. At this point, and this point only, may an investigator begin to recruit prisoners as subjects.

Research proposals that are not conducted or supported by HHS do not require a Secretarial consultation, nor do they require certification to OHRP. As a result, the investigator may begin to recruit prisoners immediately upon IRB final approval.

Continuing Review

Continuing review of research involving prisoners may not be reviewed via an expedited review procedure unless the following conditions are met:

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 enrolled and no additional risks have been identified; or

3. Where the remaining research activities are limited to data analysis.

If a protocol involving prisoners is designated for continuing expedited review, the FRI IRB prisoner representative member will be involved in the review as appropriate.

Previously Enrolled Research Subjects

When a previously enrolled research subject becomes a prisoner and the relevant research protocol was not reviewed and approved by the IRB in accordance with the requirements of HHS regulations at 45 CFR part 46, Subpart C, the principal investigator will:

1. Promptly notify the IRB of this event, in writing, within one week of the principal investigator being made aware of the incarceration.

2. Cease all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject until the requirements of Subpart C have been satisfied with respect to the relevant protocol.
    - If the principal investigator would like the subject to continue in participation in the research protocol, an amendment must be submitted with revisions to the protocol and consent form to detail how continuation of the prisoner meets applicable criteria under 45 CFR 46 Subpart C.

3. When the principal investigator asserts that continued participation is in the best interest of the subject, the principal investigator must seek the IRB Chair's determination that the subject may continue participation in the study until 45 CFR 46, Subpart C is satisfied.

At the earliest opportunity after receiving notification that a previously enrolled research subject has become a prisoner, the full, convened IRB will re-review the protocol in accordance with the requirements of Subpart C if the principal investigator wishes to have the prisoner subject continue to participate in the research.

NOTE: Notification to the IRB of incarcerations is not required for studies that have been previously approved in accordance with Subpart C.

Applicable Regulations and Guidelines

45 CFR 46, Subpart C
OHRP Guidance on the Involvement of Prisoners in Research (May 23, 2003)
OHRP Guidance: Prisoner Research FAQs
OHRP Guidance: Prisoner Research Certification