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Research Involving Prisoners

Purpose

Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and non-coerced decision whether or not to participate as subjects in research. This policy provides additional safeguards for the protection of prisoners involved in research with human subjects.

Policy Narrative

DEFINITIONS

A. *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.

B. *DHHS* means the Department of Health and Human Services.

C. *PRISONER* means 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.

D. *MINIMAL RISK* 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.

COMPOSITION OF INSTITUTIONAL REVIEW BOARDS WHERE PRISONERS ARE INVOLVED

When the fully convened Institutional Review Board (IRB) reviews a protocol involving prisoners as subjects, the composition of the IRB must satisfy the following requirements:

1. A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved.
2. At least one member of the Board shall 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 Board only one Board need satisfy this requirement. The prisoner representative may be an alternate member as long as they are serving as a member when the prisoner research is under review.

ADDITIONAL DUTIES OF THE INSTITUTIONAL REVIEW BOARD WHERE PRISONERS ARE INVOLVED

When the IRB is reviewing a protocol in which one or more prisoners are subjects, the IRB must determine that the research represents one of the following categories of research permissible under 45 CFR 46.305(a):

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 the Office of Human Research Protection (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;
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.

In addition to all other requirements for approval, the IRB must also make the following determinations for research in which one or more prisoners are subjects:

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 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;

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; and

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 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.

The IRB will also ensure that any other appropriate safeguards are in place before approving research involving prisoners as subjects.

DOCUMENTATION OF FINDINGS

The IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of research involving prisoners, the IRB documentation will include information justifying that the IRB has made all of the determinations required in the preceding section, as required by 45 CFR 46 Subpart C.

CERTIFICATION OF IRB FINDINGS

For research involving prisoners as subjects which is conducted or supported by DHHS, the institution engaged in the research must certify to the Secretary (through OHRP) that the IRB designated under its assurance has reviewed and approved the research and has made the determinations described in the preceding section of this policy as required under 45CFR 46.305.

The Secretary (through OHRP) must determine that the proposed research falls within one of the above listed categories of research permissible under 45 CFR 46.306(a)2. DHHS conducted or supported research involving prisoners as subjects may not proceed until the OHRP issues its approval in writing to NIU on behalf of the Secretary.

Research involving prisoners which is not conducted or supported by DHHS should not be certified to OHRP.

Procedural History of the Policy

Approved by the convened Institutional Review Board and the VP for Research in January 2021.

