Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: IX.B
Section: Vulnerable Populations
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Special Categories of Research: Prisoners

Definitions:
1. DHHS: The Department of Health and Human Services.
2. Minimal Risk for Prisoners: 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 examinations of healthy persons.
3. Prisoner: 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. Probation and parole are treated the same and are usually NOT considered as incarceration. Ankle bracelets/in home restrictions are considered as incarceration. Mental and substance abuse facilities are considered incarceration if someone is mandated to attend in lieu of jail or prison however, an individual in such a facility is NOT considered incarcerated if they voluntarily commit themselves.
4. Secretary: 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.

Policy:
It is the policy of the Human Research Protections Program (HRPP) to review and approve all research involving prisoners with additional ethical and regulatory considerations applicable to prisoners under 45 CFR 46, Subpart C, “Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.”

I. IRB Review and Approval of Research Involving Prisoners.
The special vulnerability of prisoners makes consideration of involving them as research subjects particularly important. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners. Therefore, if a protocol involves the use of prisoners as subjects, both the general HRPP policies and procedures apply and the additional ones outlined in this policy. The IRB may approve research involving prisoners only if these special provisions are met.

A. Research involving prisoners as participants must be reviewed and approved by both HRPP policies and procedures, and additional considerations for prisoners as determined by federal, state, county, and local regulations.

B. For research involving prisoners, the definition of minimal risk differs from the definition of minimal risk in the Common Rule. The definition for prisoners requires reference to physical or psychological harm as opposed to harm or discomfort, to risks normally encountered in the daily lives, or routine medical, dental or psychological examination of healthy persons. See definition above.

C. The IRB must review all research in which prisoners are the target population, the subject is a prisoner at the time of enrollment, or when a currently enrolled participant becomes incarcerated and research interventions and interactions would occur during the incarceration period or if identifiable private information will
be obtained during the incarceration period.

D. When the IRB is reviewing a protocol in which a prisoner is participant the full convened IRB Committee must make, in addition to 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 following categories of research permissible under 45 CFR 46.306(a)(2):
   a) A 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 participants;
   b) A study of prisons as institutional structures or of prisoners as incarcerated person, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
   c) 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 (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
   d) 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 (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.
   e) Epidemiologic Research: The Secretary of DHHS has waived the applicability of 45 CFR 46.305(a)(1) and 46.305(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies in which the sole purposes are (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease, and where the institution responsible for the conduct of the research certifies to the Office for Human Research Protections DHHS, acting on behalf of the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)-(7) and determined and documented that (i) the research present no more than minimal risk and no more than inconvenience to the prisoners-subjects, and (ii) prisoners are not a particular focus of the 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 prisoner is impaired.

3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
4. 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.

II. Composition of IRB when Prisoners are Involved in Research

A. If an IRB regularly reviews research that involves prisoners, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these participants.

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

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

2. At least one member of the IRB must 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.
   
a) If a prisoner representative is selected to serve on the IRB Committee, the person must have a close working knowledge, understanding and appreciation of prison conditions from the perspective of a prisoner. Suitable individuals could include present or former prisoners, prison chaplains; prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.

C. As a result of Section B above, the overall composition of the IRB Committee might need to change if a number of individuals are associated with the prison or if a prisoner representative is added.

D. The IRB must meet the special composition requirements for all types of review for the protocol including initial review, continuing review, review of protocol amendments, review of adverse events or unanticipated problems involving risk to participants or others, or in the event an individual becomes a prisoner while participating in a research protocol.

E. The IRB must notify OHRP of any change in the IRB roster occasioned by the addition of a prisoner or a prisoner representative. The IRB should be alert to the impact of roster changes on quorum requirements. Specifically, the IRB should:

1. Notify OHRP of the name and qualifications of the prisoner representative, if the approved IRB roster does not currently reflect this information; and

2. Maintain the CV of the prisoner representative serving on the IRB.
III. Measures that are to be Taken When a Current Research Participant Becomes a Prisoner
A. If a participant becomes a prisoner after enrolling in a research study, the Investigator is responsible for immediately reporting the event in writing to the IRB. This is not required if the study was previously approved by the IRB for prisoner participation.
B. If research interactions and interventions or obtaining identifiable private information will not occur during the incarceration, IRB review and approval under Subpart C is not required.
C. If the study was not previously reviewed and approved by the IRB in accordance with the requirements of Subpart C, all research interactions and interventions with, and obtaining identifiable private information must cease until the requirements of Subpart C are satisfied. This is necessary because it is unlikely that review of the research and the ICD contemplated the constraints imposed by the possible future incarceration of the participant.
D. The full, convened IRB Committee is to review the current research protocol in which the participant is enrolled, taking into special consideration the additional ethical and regulatory concerns for a prisoner involved in research.

IV. Research Conducted or Supported by HHS.
A. For research conducted or supported by HHS to involve prisoners, two actions must occur:
   1. The institution engaged in the research must certify to the Secretary (through OHRP) that the IRB designated under its assurance of compliance 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).
B. If an Investigator wishes to engage in non-HHS supported research, certification is not required. However, the IRB should apply the standards of this policy and the Federal regulations in reviewing the research. If either of the following are true, the research should only proceed after the IRB has consulted with the appropriate experts, as determined by the IRB:
   1. The research involves conditions particularly affecting prisoners as a class as explained in Section ID.1.c above; or
   2. The research does not satisfy the stipulations at Section ID.1 above.

V. Additional Approvals.
A. The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau of Prisons under 28 CFR 512. The provisions under 28 CFR 512 specify additional requirements for prospective researchers (both employees and non-employees) to obtain approval to conduct research within the Bureau of Prisons (Bureau) and responsibilities of Bureau staff in processing proposals and monitoring research projects.
B. Tennessee Department of Correction (TDOC) Policy #114.02 outlines the procedures for acquiring research approval within the department. These “Submittal Instructions for Research Applicants” outline the guidelines as established by policy [#114.02 (VI)(C)(1)] for proposing and conducting research within TDOC facilities. The research process within the TDOC is consistent with American Correctional Association (ACA) standards referenced in Standards for Adult Correctional Institutions, 3rd Edition. Specific ACA standards pertaining to research activities within the Department of Correction include 3-4105, 3-4106, 3-4107, 3-4108, 3-4109, 3-4110, and 3-4373.

VI. Additional Considerations.
A. When a prisoner is also a minor (e.g., an adolescent detained in a juvenile detention facility is a prisoner), HRPP Policy IX.A regarding children in research will also apply.
B. Expedited review of research involving prisoners is not allowed. The full,
convened IRB Committee must review research involving prisoners as human subjects.

C. Exemption from review of research involving prisoners is not allowed. Research that would otherwise be exempt from the requirement that it receive IRB approval is not exempt when the research involves prisoners.

References:
45 CFR 46 Subpart C
28 CFR 512