MCW Office of Research
Standard Operating Procedure

RESEARCH INVOLVING PRISONERS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
To describe additional protections and procedures required in the protocol and any additional measures required to secure approval to conduct a project involving vulnerable subjects. Prisoners are considered to be vulnerable subjects in the context of participation in a project.

DEFINITIONS:
Prisoner: A person who is 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.

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

Minimal Risk: 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:
Investigator Responsibilities
1. Investigators will indicate within their eBridge PRO SmartForm that prisoners will be a target population for project activities.
2. If the subject population has an increased potential to become prisoners, and the Investigator will be interacting, intervening, or collecting identifiable private information during the incarceration, the Investigator should contact the MCW IRB and ask that the project undergo initial review by the IRB and OHRP for prisoner participation.
3. Investigators are responsible for obtaining and providing documentation of approval from the detention or correctional facility involved (i.e., prisons, jails, workhouses, etc.) to the IRB as part of their initial application.
4. For federally funded projects, Investigators will provide any additional documents or materials required for certification to the Secretary of DHHS (through OHRP) for research involving prisoners.
5. The Investigator may not screen, recruit, or enroll any individual involuntarily confined or detained in a penal institution without written IRB approval. If the biomedical or behavioral project is conducted or supported by HHS, it also requires

review and written approval by the Secretary of DHHS (through OHRP) before any research activities may begin, including screening and enrollment.

Department of Defense (DoD) Supported Research:

1. Research involving prisoners of war as human participants is prohibited per Department of Defense regulations.
2. Research involving a detainee as a human participant is prohibited.
    a. This prohibition does not apply to research involving investigational drugs and devises when the same products would be offered to US military personnel in the same location for the same condition.

Unexpected incarceration of an enrolled subject:

1. If a subject enrolled in ongoing research becomes incarcerated during the course of the project, and the research proposal was not reviewed and approved by the IRB in accordance with Subpart C of 45 CFR part 46, Investigators must promptly notify the IRB of this occurrence see: *IRB SOP: Requirements for Reporting to the IRB*.
2. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be suspended immediately, except as noted below.
    a. OHRP allows one important exception to the requirement that all research activities with the now-incarcerated subject must cease until the regulatory requirements for research involving prisoners are met.
        i. If the investigator asserts that it is in the best interests of the subject to remain in the research project while incarcerated, the IRB Chair may determine that the now-incarcerated subject may continue to participate in the research until the convened IRB can review the request and approve the change in the research protocol and determine the requirements of subpart C are satisfied and the IRB's approval has been reviewed by the Organizational Official and DoD component officer (if applicable).
    b. Note that in these circumstances, some of the findings required by 45 CFR 46.305(a) may not be applicable; for example, the finding required under 45 CFR 46.305(a)(4) regarding the selection of subjects within the prison may not be applicable, if the subject was recruited outside of an incarcerated context.
3. Upon identification that a previously enrolled research subject has become incarcerated, the incarcerated subject must stop participating in the research which includes all research interactions, interventions and/or obtaining identifiable private information until the convened IRB can review the request and change to the research protocol.
    a. Unless the Investigator petitions the IRB Chair as described in step 1a.
4. If the Investigator wishes to have the incarcerated subject continue to participate in the research, the convened IRB will re-review the change to the research protocol in a timely manner and in accordance with the requirements of subpart C, to ensure that the rights and wellbeing of the now-incarcerated subject are not in jeopardy.
    a. The convened IRB should evaluate if the now-incarcerated subject can:
        i. Continue to consent to participate,
        ii. Capable of meeting the research protocol requirements,
        iii. The terms of the now-incarcerated subject's confinement does not inhibit the ethical conduct of the research, and
        iv. There are no other significant issues preventing the research involving human subjects from continuing as approved.
    b. If these elements are found satisfactory, the convened IRB may approved the change to research protocol to allow the now-incarcerated subject to continue to participate in the research. The approval would be limited to the individual

subject and would not allow continued recruitment and enrollment of incarcerated subjects into the research.

c. The institution(s) engaged in the research involving the incarcerated subject must send a certification to OHRP and wait for a letter of authorization in reply.

5. If the Investigator solicits or obtains information from the parents or spouse, rather than the incarcerated subject, for information about the incarcerated subject's behavior and attitudes for the research project. This activity would constitute "obtaining identifiable private information about" the incarcerated subject, and would invoke subpart C and would be require review and approval from the IRB if it was not originally reviewed and approved under subpart C.
6. During detention, the incarcerated subject does not have to be formally withdrawn; as long as there is no interaction, intervention or obtaining data with the subject while incarcerated (see above) subpart C is not invoked. Therefore, there is no need to withdraw and re-enroll. If the investigator can wait until the person is no longer incarcerated, subpart C is never an issue.
7. Data that had been acquired prior to incarceration may continue to be analyzed.

CRITERIA THAT MUST BE SATISFIED:

1. The IRB will review research involving prisoners and approve such research only if it finds that each of the following seven (7) conditions is met and documents the protocol-specific findings supporting that conclusion for each condition. Therefore, the Investigator must provide information addressing each of the following criteria:
   a. The research under review represents one of the categories of research permissible under §46.306(a)(2) or 68 FR 36929, June 20, 2003:
      i. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the project presents no more than minimal risk (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) and no more than inconvenience to the subjects;
      ii. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the project presents no more than minimal risk (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) and no more than inconvenience to the subjects;
      iii. 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 project 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
      iv. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject, but not studies involving control groups which may not benefit from the research. In cases in which the project requires the assignment of prisoners to a control group that may not benefit from the research, the project 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.

v. The DHHS Secretarial waiver for certain epidemiological research conducted or supported by DHHS. Such research must have as its sole purpose:
    - to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease.
    - The research presents no more than minimal risk
    - The research presents no more than an inconvenience to the subjects

Note that if any of the above research is to be conducted or supported by DHHS, it may involve prisoners as subjects only if the MCW Institutional Official (IO) or their designee has certified* to the Secretary of DHHS (through OHRP) that the IRB has approved the research under §46.305, and in the judgment of the Secretary of DHHS (through OHRP), the proposed research involves solely one of the above categories of research permissible under §46.306(a)(2).

i. Note that research proposals in category c. or d. that are not conducted or supported by DHHS do not require a Secretarial consultation, nor do they require certification to OHRP.

b. 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;
c. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
d. 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 with 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;
e. The information is presented in language which is understandable to the subject population;
f. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the project 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
g. Where the IRB finds there may be a need for follow-up examination or care of subjects 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 subjects of this fact.

2. Investigator must provide the IRB with the specific conditions in the local prison or jail site(s) where the research will be conducted before approving the research for implementation at the site(s).

AMENDING AN ACTIVE PROTOCOL APPROVED FOR THE INCLUSION OF PRISONERS

If a project involving prisoners previously authorized by OHRP is amended, the IRB does not have to recertify with DHHS. However, if there is a fundamental change in the research that alters the applicability of the approved category under 45 CFR 46.306, OHRP should be notified.

PROCEDURES:

1. Investigators must complete and submit their projects to the IRB for review and indicate their eBridge SmartForm subjects which fall under the definition of prisoners will be included in the research project.
    a. If the Investigator is amending their project to include this population, an amendment must be submitted and approved prospectively. Refer to *IRB SOP: Amendments* for more information.
2. Investigators are responsible to include any additional information as noted above in this policy with their eBridge SmartForm.

REFERENCES:

45 CFR 46 Subpart C
45 CFR 46.305
45 CFR 46.306
68 FR 36929

SUPPORTING DOCUMENTS:

IRB SOP: Amendments
IRB SOP: Requirements for Reporting to the IRB

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