MCW IRB Committee Procedures

RESEARCH INVOLVING PRISONERS

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

Applies to: Institutional Review Board Committees

PURPOSE:
To outline criteria the IRB Committee should apply when reviewing projects that seek to enroll or that may enroll prisoners. Prisoners are considered to be vulnerable subjects in the context of participation in research. All prisoners are regarded as being vulnerable to coercion or undue influence and therefore need additional safeguards to protect their rights and welfare as research subjects. These additional safeguards are described below

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.

DHHS - the Department of Health and Human Services

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.

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

PROCEDURE:
1. The MCW IRB reviews and approves research involving prisoners in compliance with 45 CFR 46 Subpart C and other applicable regulations and laws.
2. The provisions of Subpart C apply whenever the research targets prisoners as subjects, or whenever a human subject becomes a prisoner after a research project has commenced.
    a. In the case of an adolescent detained in a juvenile detention facility, the provisions of Subpart C apply, and if the adolescent is a child, the provisions of Subpart D apply. An adolescent would be considered to be a child ifthey were less than 18 years old.

IRB REVIEW
1. When reviewing research involving a prisoner, the IRB must ensure the criteria for approval have been satisfied, including the following:

- A majority of the IRB (exclusive of the prisoner representative) shall have no association with the prisoners involved, apart from their membership on the IRB.
- At least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.
    - When the convened IRB reviews research involving prisoners, the prisoner representative receives all documents pertaining to the IRB application, is present at the meeting, and presents their review in writing to the convened IRB.
- The IRB must meet the special composition requirements noted above for all types of review of protocols involving prisoners, including initial review, continuing review, review of protocol amendments, and review of reports of unanticipated problems involving risks to subjects or others.

In addition, the IRB notes that:

- None of the exemption categories in DHHS regulations for research involving human subjects at 45 CFR 46.101(b) apply to research involving prisoners (45 CFR 46.101(i), Footnote 1).
- Prisoners cannot be involved in planned emergency research (OHRP [OPRR] Report 97-01) where the requirement for informed consent has been waived by the Secretary of DHHS under the authority of 45 CFR 46.101(i).

2. The IRB will review research involving prisoners and approve such research only if it finds that each of the seven (7) conditions outlined in 45 CFR 46.306 are met, and documents the protocol-specific findings supporting that conclusion for each condition via the *IRB Member Form: Projects involving Prisoners (subpart C) Checklist.*
    a. The DHHS Secretarial waiver for certain epidemiological research conducted or supported by DHHS. Such research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to project potential risk factor associations for a disease.
    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 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 (through OHRP), the proposed research involves solely one of the above categories of research permissible under §46.306(a)(2).

    [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.]

3. In order to both conclude that the seven (7) required conditions are met and satisfy the requirements of 45 CFR 46 Subpart A, the IRB must be familiar 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).

DOCUMENTATION OF IRB REVIEW

1. The IRB Committee member who serves as the prisoner representative is assigned as the secondary reviewer of the eBridge submission and will complete the *IRB Member Form: Projects involving Prisoners (subpart C) Checklist*.
2. Documentation of their review will be uploaded to the eBridge project workspace within eBridge.
3. The prisoner representative will structure and focus their review of the project around meeting the requirements of Subpart C. The prisoner representative must be present at the convened IRB meeting.

Other Federal Agency Requirements:

1. For projects conducted within the Bureau of Prisons or funded by the National Institute of Justice (NIJ), the additional federal agency requirements are documented via the *IRB Member Form: Additional Federal Agency Requirements Checklist*.
2. For projects supported by Department of Defense, projects involving prisoners of war as human participants is prohibited per regulation. Additionally, projects involving detainees is prohibited, though the prohibition does not apply to projects involvinf investigational drugs and devices when the same product would be offered to US military personnel in the same location for the same condition.

CATEGORY-SPECIFIC INFORMATION FOR PERMISSIBLE RESEARCH

1. **If the IRB chose category (i) or (ii),** (after determining that the project satisfied the threshold condition for the category), OHRP recommends that the IRB provide the rationale for determining that the project is no more than the Subpart C definition of minimal risk.
2. **If the IRB chose category (iii), thus triggering the requirement for Secretarial consultation with appropriate experts,** OHRP recommends that the IRB provide the rationale for the choice of category and formally request that consultation in the letter.
3. **If the IRB chose category (iv),** OHRP recommends that the IRB provide the rationale for determining that the project is "research on practices....which have the intent and reasonable probability of improving the health and well-being of the subject."
    - OHRP recommends that the "practice" be described; typically it will be an intervention being studied.
    - If the project is an extension project or is a free-standing follow-up project to another project that involves an intervention, OHRP recommends that the IRB describe the relationship between this project and the project with the intervention.
4. **Regarding category (iv), describe whether the project involves assigning prisoners to control groups which may not benefit.**
    - If all subjects will be recruited and assigned to groups (including a control group) ***prior*** to incarceration, then "prisoners" will not be assigned to a control group. Therefore, if the IRB is being asked to review a project under Subpart C because a previously enrolled subject now meets the Subpart C definition of "prisoner" and PI wishes to continue the participation of this prisoner-subject, there will be no trigger for a Secretarial consult if the IRB finds that the project fits under category iv.
    - If the project DOES involve assigning persons that meet the Subpart C definition of "prisoner" to a control group "which may not benefit from the research", the requirement for Secretarial consultation with appropriate experts is triggered.
5. **Explanation of category (iv) phrase "control groups which may not benefit from the research":**
    - If there is an arm that provides treatment-as-usual, services-as-usual or the standard medical care that would be available to the prisoner whether or not he/she participated in the project, this type of arm would be considered a "control group" under Subpart C, category iv (45 CFR 46.306(a)(2)(iv)).
    - The presence of a control group to which persons meeting the Subpart C definition of "prisoner" may be assigned triggers a Secretarial consultation with experts, which must occur after OHRP receives the prisoner certification and ***prior*** to the involvement of any "prisoners" in the project.

- If there is an arm that provides an intervention *in addition to* treatment-as-usual, or services-as-usual or standard medical care, OHRP would probably not consider this type of arm a Subpart C category iv "control group".

Information about the June 20, 2003 Waiver of the Applicability of Certain Provisions of DHHS Regulations for the Protection of Human Subjects for DHHS Epidemiologic Research Involving Prisoners as Subjects:

- For a minimal risk epidemiologic project in which prisoners are not the particular focus and the sole purpose of the project is either:
  1) To describe the prevalence or incidence of a disease by identifying all cases; or
  2) To study potential risk factor associations for that disease.
- The two Subpart C provisions that are waived are:
  1) The requirement that an IRB choose one of the four categories in 45 CFR 46.306(a)(2); and
  2) The requirement that the Secretary (through OHRP) make the final choice of one of the four categories.
- An institution/IRB must certify in writing to OHRP, even if the June 20, 2003 Subpart C epidemiological waiver applies.
- The prisoner certification letter for an epidemiological project that falls under the waiver must contain the following statements:
  1) The IRB fulfilled its duties under 45 CFR 46.305(a)(2)-(7);
  2) The research is no more than minimal risk or inconvenience; and
  3) Prisoners are not the particular focus of the project.
- When possible, the letter should contained a statement as to the sole purpose of the project, as described in the protocol and/or grant application materials.

ADDITIONAL CONSIDERATIONS: IF A SUBJECT BECOMES A PRISONER

1. If a human subject involved in ongoing research becomes a prisoner 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, the investigator must promptly notify the IRB as described in *IRB SOP: Requirements for Reporting to the IRB*.
   - All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must be suspended immediately, except as noted below.
2. Upon receipt of the Investigator's report that a previously enrolled research subject has become a prisoner, if the investigator wishes to have the prisoner subject continue to participate in the research, the IRB must promptly re-review the proposal in accordance with the requirements of subpart C, and the institution(s) engaged in the research involving the prisoner subject must send a certification to OHRP and wait for a letter of authorization in reply. Otherwise, the prisoner subject must stop participating in the research, except as noted below.
3. OHRP allows one important exception to the requirement that all research interactions or interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease until the regulatory requirements for research involving prisoners are met. In special circumstances in which the investigator asserts that it is in the best interests of the subject to remain in the research project while incarcerated, the subject may continue to participate in the research while the IRB reviews the project under subpart C or, the subjects may be removed from the research but remain on the research intervention under an alternate mechanism such as off-lable use, etc., if one exists. The investigator must promptly notify the IRB of this occurrence, so that the IRB can re-review the project.

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. The IRB should document findings of non-applicability accordingly.

4. Soliciting information from the parents or spouse, rather than the incarcerated subject, for information about the subject's behavior and attitudes would constitute "obtaining identifiable private information about" the incarcerated subject, and would invoke subpart C.
5. During detention, the subject does not have to be formally withdrawn; as long as there is no interaction/intervention/obtaining 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.
6. Data that had been acquired prior to incarceration may continue to be analyzed.

REFERENCES:
45 CFR 46 Subpart C
OHRP Guidance Document: “OHRP Guidance on Involvement of Prisoners in Research”, May 23, 2003.

SUPPORTING DOCUMENTS:
IRB SOP: Requirements for Reporting to the IRB
IRB Member Form: Projects involving Prisoners (subpart C) Checklist
IRB Member Form: Additional Federal Agency Requirements Checklist

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