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.
    - x 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

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.”
    - x OHRP recommends that the “practic

- 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