Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 204: Special Populations - Prisoners

POLICY
The HHS regulations for the protection of human subjects in research at 45 CFR 46 include five subparts. Here we will focus on Subpart C. This subpart provides additional protections pertaining to biomedical and behavioral research involving prisoners as subjects.

PURPOSE
Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

DEFINITIONS

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.

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.*

Additional duties of the Institutional Review Boards where prisoners are involved.
(a) The Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under §46.306(a)(2);

(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 prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner participants;

(4) 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;

(5) The information is presented in language that is understandable to the subject 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 Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provisions have been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

Permitted research involving prisoners

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and

(2) In the judgment of the Secretary, the proposed research involves research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. *Study interventions that involve a pill or tablet will disqualify this patient population (a prisoner) because medical furlough is only allowed for treatment involving IV infusions for purposes of this policy.*

SCOPE

This SOP applies to all research subjects who become prisoners during the course of their participation in a clinical trial, and the IRB committee.