UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
REVIEW OF RESEARCH –
ADDITIONAL PROTECTIONS FOR PRISONERS

I. PURPOSE

To document the policy and procedures used by University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) regarding the review of clinical studies involving prisoners.

II. SCOPE

This SOP applies to the IRB administrative staff, IRB members and investigators.

Personnel Responsible:

UTGSM IRB administrative staff, IRB members, investigators

III. BACKGROUND

Insofar as incarceration places prisoners under constraints that may affect their ability to make truly voluntary and un-coerced decisions about whether or not to participate as subjects in research, they constitute a vulnerable population for which additional protections are warranted. In addition to the responsibilities outlined in SOP 03 (Review of Research), UTGSM IRB shall determine whether proposed studies with prisoners also satisfy the conditions enumerated at 45CFR46, Subpart C, "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects." These provisions of the federal regulations are intended to assure that prisoners provide voluntary consent to participation in research, that their confidentiality is rigorously protected, and that prisoners are not used as subjects in studies for which non-incarcerated subjects are suitable. They apply whether the research involves individuals who are prisoners at the time of enrollment in the research or who become prisoners after they become enrolled in the research. DHHS also requires that the IRB have among its members one or more individuals knowledgeable about and experienced in working with prisoners when research involving prisoners is to be reviewed. The current FDA regulations for the protection of human subjects, 21 CFR 50, 56, do not include any specific additional protections for research subjects who are prisoners. However, the FDA does consider prisoners to be a vulnerable subject population for which the IRB must include additional safeguards.

In Accordance With:

45 CFR 46 Subpart C; OHRP Guidance on Written IRB Procedures, 07/01/2011.

Prisoner Research Certification

http://www.hhs.gov/ohrp/policy/populations/prisoncertlet.html

OHRP Guidance on the Involvement of Prisoners in Research

http://www.hhs.gov/ohrp/policy/prisoner.html

Prisoner Research – FAQs

http://answers.hhs.gov/ohrp/categories/1568

Research Involving Vulnerable Populations (Video)

http://www.hhs.gov/ohrp/education-and-outreach/online-education/videos/

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

Definitions:

Prisoner means an individual involuntarily confined or detained in a penal institution, including persons: (1) sentenced to such an institution under a criminal or civil statute; (2) detained pending arraignment, trial or sentencing; and (3) detained in other facilities (e.g. for the treatment of drug detoxification or alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution, and (4) individuals detained pending arraignment, trial, or sentencing (45 CFR 46.303(c)).

Individuals are prisoners if they are in any kind of penal institution, such as prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.

Examples of the regulatory definition of prisoner:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.
- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.
- Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

- Probationers and individuals wearing monitoring devices are generally not considered prisoners; however, situations of this kind frequently require an analysis of the particular circumstance of the planned subject population.

Minimal risk means 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.

IV. PROCEDURES

1. For research conducted or supported by DHHS to involve prisoners, the following conditions must occur:
   a. The institution engaged in the research must certify to the Secretary of HHS (through OHRP) that the proposed research falls within the categories of research permitted under 45 CFR 46.306(a)(2).
   b. The Secretary must determine that the proposed research falls within one of the categories of permissible research specified in 45 CFR 46.306(a)(2).
   c. The IRB letter to OHRP will include:
      1. Name and address of the institution;
      2. OHRP Assurance #;
      3. Date(s) of the IRB meeting(s) in which the protocol was considered, including a brief chronology that encompasses date of the initial IRB review and date of Subpart C review;
      4. The IRB approved protocol;
      5. Any relevant HHS grant application or proposal, including relevant grant number;
      6. Any IRB application forms required by the IRB; and
      7. Any other information requested or required by the IRB to be considered during the initial review;
      8. Notification of the name and qualifications of the prisoner representative if the approved IRB roster does not already reflect this information.
      9. The IRB's determination regarding the seven additional findings under 45 CFR 46.305 and the specific category under which the research is authorized according to 45 CFR 46.306.
      10. A brief description of the research sufficient to allow OHRP to determine whether or not to concur with the IRB; and whether OHRP needs to consult with appropriate experts and publish a Federal Register Notice.
   d. Prisoner research certification letters will be mailed to:

      Attention: OHRP Prisoner Research Contac Person
      Office for Human Research Protections
      Department of Health and Human Services
      The Tower Building
      1101 Wooten Parkway, Suite 200
      Rockville, MD 20852

e. The IRB will keep a copy of this letter in the files for the study.

2. During the review of any study involving the potential for enrollment of prisoners, in addition to normal review procedures, UTGSM IRB will consider the following:
   a. IRB Membership: The composition of the IRB must satisfy the requirements of HHS regulations at 45 CFR 46.304 for IRB review of a protocol involving prisoners as subjects that is conducted or is supported by HHS which include the following:
      i. 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;
      ii. At least one IRB member must be a prisoner, or a prisoner representative with appropriate background, experience or working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner to serve in that capacity. The IRB will retain documentation of the prisoner or prisoner representative serving on the IRB.
      iii. The prisoner representative must be present at the meeting where a study involving this population will be reviewed, must review the study, and must present his/her review either orally or in writing at the meeting. Where a particular research project is reviewed by more than one IRB< only one IRB need satisfy this requirement.
      iv. These requirements must be met during all types of protocol review including initial review, continuing review, review of protocol revisions and review of reports of unanticipated problems involving risks to subjects.
   b. The IRB must notify OHRP of any change in the IRB roster occasioned by the addition of a prisoner or a prisoner representative as required by 45 CFR 46.103(b)(3).
   c. Applicable State Laws: UTGSM IRB will consider applicable state laws in the review of these studies.

3. Additional duties of the IRB where prisoners are involved.
   a. When the IRB reviews a protocol in which a prisoner is a subject, the IRB must make and document, in addition to other requirements under 45 CFR 46, subpart A, seven additional findings under 45 CFR 46.305(a), as follows:
      i. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2);
      ii. 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;
      iii. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

iv. 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 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;
v. The information is presented in language which is understandable to the subject population;
vi. 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
vii. 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.

4. Permitted research involving prisoners must fall into one of the following categories:
   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 subjects; *(Note that the definition of minimal risk for prisoner research at 45 CFR 46.303(d) differs from the definition of minimal risk for other research, contained in 45 CFR 46, subpart A, 45 CFR 46.102(i))*
   b. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
   c. 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 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 subject. 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.

5. When a previously enrolled research subject becomes a prisoner and the relevant research protocol was NOT reviewed and approved by the institutional review board (IRB) in accordance with the requirements of HHS regulations at 45 CFR46, subpart C, the principal investigator should promptly notify the IRB of this event. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol.

   NOTE: OHRP has allowed one important exception. In special circumstances in which the principal investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.

6. Upon receipt of notification that a previously enrolled research subject has become a prisoner, the IRB should promptly re-review the protocol in accordance with the requirements of subpart C if the principal investigator wishes to have the prisoner subject continue to participate in the research. The IRB will notify the investigator in writing that, except in the special circumstances noted above, all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease until all of the requirements of subpart C have been satisfied with respect to the relevant protocol.

7. Following receipt of the certification letter and research proposal, OHRP will determine if the proposed research meets any of the four categories of research permissible under HHS regulations at 45 CFR 46.306(a)(2). If OHRP determines that the research involves a category of research requiring Secretarial consultation with appropriate experts (see 45 CFR 46.306(a)(2)(iii) and (iv)), OHRP will notify the institution that the Secretary must consult with experts regarding the proposed research before a determination is made as to whether the research may involve a prisoner as a subject. When applicable, OHRP also will publish in the Federal Register a notice of intent to approve such research. HHS conducted or supported research involving prisoners as subjects may not proceed until OHRP issues its approval in writing to the institution on behalf of the Secretary under 45 CFR 46.306(a)(2) and informs the institution that the research involving the prisoner as a subject may proceed.

8. The full Board will review all new applications involving prisoners. However, the IRB may utilize an expedited review procedure for continuations and revisions related to research involving prisoners, provided that the decision to utilize expedited review is in accord with SOP: IRB Expedited Review. Applications (new, continuation, and revision) for research involving prisoners do not qualify for exempt review.

9. The IRB may approve a request for waiver or alteration of consent for research involving prisoners when it meets the conditions specified in SOP: Informed Consent.

Any request for waiver or alteration of consent for research involving prisoners must be reviewed by the full Board.

10. All correspondence will be kept in the study files for the investigation.