

## **PROTECTION OF PRISONERS IN RESEARCH**

The regulations in this policy are derived from SubPart C of The Code of Federal Regulations Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protections of Human Subjects, and are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services and The University of Texas at Tyler involving prisoners as subjects.

Nothing in this policy shall be construed as indicating that compliance with the procedures set forth in this policy will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable state or local laws.

Any protocol involving prisoners as subjects shall be conducted only through a full board review process.

The requirements of this policy are in addition to those imposed under the Common Rule, Basic HHS Policy for Protection of Human Research Subjects (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subparta>)

### **I. Purpose**

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 (Subpart C) to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

### **II. Definitions**

(a) *Secretary* means 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.

(b) *DHHS* means the Department of Health and Human Services.

(c) *Prisoner* means 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 (forensic psychiatric clients or persons ruled incompetent to stand trial) which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) *Minimal risk* is 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.

### **III. Composition of Institutional Review Boards Where Prisoners Are Involved**

In addition to satisfying the requirements in [§46.107](#) which involves IRB membership as it relates to research regarding prisoners, the UT Tyler IRB carrying out responsibilities under this part\* with respect to research covered by this subpart, shall also meet the following specific requirements:

- (a) A majority of the UT Tyler IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the UT Tyler IRB.
- (b) At least one member of the UT Tyler IRB shall be a prisoner, or a prisoner representative/advocate with appropriate background and experience to serve in that capacity.

### **IV. Additional Duties of the UT Tyler IRB Where Prisoners Are Involved**

(a) In addition to all other responsibilities prescribed for the UT Tyler IRB under this part, the UT Tyler IRB shall review research covered by this subpart and approve such research only if it finds that:

- The research under review represents one of the categories of research permissible under Section V of this policy, (a)(2<sup>nd</sup> bullet);
- 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;
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- 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 UT Tyler 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;

- The information is presented in language which is understandable to the subject population;
- 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
- Where the UT Tyler 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.

(b) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the UT Tyler IRB under this section have been fulfilled. Federally funded, IRB-approved research involving prisoners must be reviewed by the Office for Human Research Protections (OHRP) before the study may be initiated. In addition, research that falls into categories 3 or 4 described above requires federal consultation and approval. If research is not conducted or supported by HHS, these requirements do not apply.

(c) The UT Tyler IRB shall carry out such other duties as may be assigned by the Secretary.

## **V. Permitted Research Involving Prisoners**

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

- The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under Section IV of this policy; and
- In the judgment of the Secretary the proposed research involves solely the following:

(i) 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;

(ii) 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;

(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 study may proceed only after the Secretary 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. 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 has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

## **VI. Specific Items to include in the IRB Application**

- A. A statement to indicate the research involves one of the following:
1. The study of the possible causes, effects, or processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than an inconvenience to the participants.
  2. The 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 participants.
  3. Research on the conditions particularly affecting prisoners as a class of people (for example, 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). [HHS

funded or conducted research in this category may proceed only after the Secretary (through OHRP) has consulted with the appropriate experts including experts in penology, medicine, and ethics, and published notice in the Federal Register, of the intent to approve such research. For research that is not HHS funded or conducted, the need to convene an expert panel will be determined on a protocol per protocol basis.]

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. [In cases in which the study protocol design is such that it is required to assign prisoners to control groups which may not benefit from the research, HHS funding of conducted research may proceed only after the Secretary (through OHRP) has consulted with the appropriate experts including experts in penology, medicine, and ethics, and published notice in the Federal Register, of the intent to approve such research. For research that is not HHS funded or conducted, the need to convene an expert panel will be determined on a protocol per protocol basis.]
- B. A statement describing the correctional facility(ies) where the research will occur. Include the name, type of facility, and indicate if it is a local, state, or federal facility.
  - C. A description of the criteria that was used in selecting the correctional facility(s).
  - D. A description of the procedures for the selection of participants. The selection process within the correctional facility must be fair to all prisoners and not expose participants or non-participants (those declining to participate) to stigmatization, harassment, prejudice, or retaliatory treatment. Assurance that the procedures for assignment to various groups (e.g. experimental, control) within the research should also be designed to be fair.
  - E. A description of the possible advantages for prisoners if they participate. Advantages must not be of the magnitude that they will unduly influence the prisoner's ability to weigh the risks of the research against the value of such advantages.
  - F. A description of the risks to prisoners involved in the research and compare the similarities and differences to the risks that would be likely be deemed minimal or reasonable by non-prisoner volunteers.
  - G. Description of how the PI will ensure there is no arbitrary influence or intervention by prison authorities regarding the selection, assignment, and withdrawal of prisoners during the study.

- H. Description of the provisions made to ensure that parole board will not have access to information related to the prisoners' participation in the research. If the parole board will have access to the information, the PI must verify that the parole board will not use the information when considering the prisoners' parole.
- I. A statement concerning whether the PI anticipates the need for follow-up examinations or care for participants after the end of their participation; even if a prisoner does not complete the study (e.g. psychological counseling). Also, describing the provisions for the follow-up examinations or care after participation has ended (e.g. how often, how long will the care be available, and under what conditions).
- J. Describe the protocol for prisoners that are released, transferred, or moved from the primary research site during their research participation and before completing the study. (For example, would there be follow-up, would data continue to be collected?)

*Investigators must become certified through the Secretary to conduct DHH funded research. For assistance with this, contact the Office of Research & Scholarship or the IRB Chair.*