# 4.3 Research Involving Prisoners

## 1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for review and approval of research involving prisoners.

## 2.0 Policy

- 2.1. It is the policy of the Organization that federally funded research involving prisoners will be reviewed and approved in accordance with the requirements of 45 CFR 46 Subpart C.
- 2.2. It is the policy of the Organization that for non-federally funded research involving prisoners, the Organization will apply equivalent protections. These protections will be based upon the ethical principles in the Belmont Report. In addition, the requirements in 45 CFR 46, Subpart C will be applied to the greatest extent possible in consideration of the nature of the research.

## 3.0 Definitions

- 3.1. Prisoner is defined by HHS regulations at 45 CFR 46.303(c) as "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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

*Note: In accordance with OHRP guidance, application of the regulatory definition of prisoner includes the following: 1) Individuals detained in a residential facility for court-ordered substance abuse treatment; or 2) Individuals with psychiatric illnesses that have been committed involuntarily to an institution as an alternative to criminal prosecution or incarceration.*

*Note: Individuals who are on probation or parole regardless of whether they are required to wear a monitoring device are generally not considered prisoners. Individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness are also not considered prisoners. However, such subjects are vulnerable and, therefore, must be afforded additional appropriate protections as required by 45 CFR 46.111(b).*

- 3.2. Minimal risk in prisoner research is defined by HHS regulations at 45 CFR 46.303(d) as "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."

*Note: The IRB interprets the term "healthy persons" to mean the average healthy person in the general population who is not a prisoner.*

## 4.0 Additional IRB Requirements

- 4.1. When reviewing research involving prisoners, the IRB will satisfy the following additional requirements:
  - 4.1.1. The majority of the members of the IRB will not have an association with the prison involved in the study (excluding the prisoner members).
  - 4.1.2. At least one member of the IRB will be a prisoner or a prisoner representative. The prisoner or prisoner representative must have a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner.
- 4.2. A prisoner or prisoner representative must be involved in all IRB actions pertaining to protocols involving prisoners, including (but not limited to) a) initial review of the protocol, b) continuing review, c) protocol and/or consent changes, d) review of reports of unanticipated problems involving risks to subjects. When research involving prisoners is reviewed by the convened IRB the prisoner representative must be present as part of the quorum and must present his/her review either orally or in writing.

# 5.0 Permitted Research Involving Prisoners

- 5.1. In accordance with HHS regulations at 45 CFR 46.306(a)(2), research may involve prisoners as subjects only if the research falls under one or more of the categories listed below:
  - 5.1.1. 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.
  - 5.1.2. 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.
  - 5.1.3. 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 assault).
  - 5.1.4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
- 5.2. If HHS-funded research fits either category C or D above where prisoners are assigned to control groups which may not benefit from the research, final approval rests with the Secretary of HHS with OHRP acting on behalf of the Secretary. Following IRB approval, the entire research proposal (including the IRB-approved protocol, any relevant HHS grant application or proposal, consent documents, any IRB application forms, and any other information requested or required by the IRB for initial review) will be submitted to OHRP. OHRP will consult with appropriate experts, including experts in penology medicine and ethics, and publish notice, in the Federal Register, of intent to approve such research. HHS, through OHRP, will issue its approval in writing to the IRB.
- 5.3. For research which is not funded by HHS, neither certification to OHRP nor expert review for Categories C and D above is required. The IRB may however, at its discretion convene an equivalent expert review body to review studies classified under those categories.
- 5.4. Waiver of Requirements for Epidemiological Studies
  - 5.4.1. Epidemiologic studies involving prisoners as subjects need not meet the requirements of section 5.1, 5.2 and 5.3 of this policy provided:
    - 5.4.1.1. The sole purpose of the research is (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease.
    - 5.4.1.2. The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
    - 5.4.1.3. Prisoners are not a particular focus of the research. Note: On June 20, 2003, HHS approved a waiver of the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for specified epidemiologic research conducted or supported by HHS. This means that the research under this waiver provision need not fall within the categories specified in Section 5.0 of this policy.

# 6.0 Procedures for IRB Review of Research Involving Prisoners*

- 6.1. If a research protocol will involve prisoners (per section 3.1 of this policy), the IRB

application must also include completion of Addendum C: Research Involving Prisoners as Subjects.
- 6.2. The UNMC IRB will normally not use expedited review for protocols, changes, or continuing review of research involving prisoners.
- 6.3. The UNMC IRB does not allow exemption from IRB review of research involving prisoners.
- 6.4. The UNMC IRB does not allow monetary compensation of prisoners who serve as research participants.

# 7.0 IRB Findings

- 7.1. The IRB will make the following additional findings for research involving prisoners (per 45 CFR 46.305(a)):
  - 7.1.1. The research represents one of the categories permissible under Section 5.0 of this policy.
  - 7.1.2. Any possible benefits 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.
  - 7.1.3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
  - 7.1.4. 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 PI provides to the IRB justification in writing for following some other procedures, control subjects will be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
  - 7.1.5. The information is presented in language which is understandable to the subject population.
  - 7.1.6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in 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.
  - 7.1.7. If 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 prisoner' sentences and for informing participants of this fact.
- 7.2. The IRB may grant a waiver or alteration of informed consent in accordance with HRPP policies 5.2 (Waiver or Alteration of Informed Consent and HIPAA Authorization).
- 7.3. The IRB may grant a waiver of signed consent in accordance with HRPP policy 5.4 (Waiver of the Requirement to Obtain Signed Consent Form).

# 8.0 Documentation of Compliance with Subpart C

- 8.1. For research reviewed by the convened IRB, compliance with Subpart C (or with the equivalent protections described in this policy) will be documented in the letter to the investigator which is part of the meeting minutes.
- 8.2. If the IRB approves research involving prisoners funded by HHS that has been, the IRB will provide written certification to OHRP that it fulfilled the responsibilities described in this policy and in 45 CFR 46 subpart C. Specifically the certifications will include:
  - 8.2.1. The name and address of the institution.
  - 8.2.2. Identification of the research protocol and relevant HHS grant application or protocol.
  - 8.2.3. A copy of all paperwork necessary for IRB initial review (including detailed protocol, relevant HHS grant application or proposal, IRB application, ICF).
  - 8.2.4. Verification of the presence of a prisoner representative during consideration of the study.
  - 8.2.5. Verification of the required findings per section 7.1 of this policy, and 45 CFR 46.305(a).
  - 8.2.6. Determination that the research falls into one of the permitted categories of research per section 5.1 of this policy, and 45 CFR 46.306(a).
- 8.3. For epidemiologic studies described in section 5.4 above funded by HHS, the IRB will provide written certification to OHRP as above, except that it will only verify that the requirements of 45 CFR 46.305(a)(2) through (7) were met.

# 9.0 Special Circumstances

- 9.1. When a previously enrolled subject becomes a prisoner
  - 9.1.1. When a previously enrolled subject becomes a prisoner (as determined by the Executive Chair or designee, in consultation as appropriate with the prisoner representative) and the research was not reviewed and approved by the IRB in accordance with this policy, the PI must report the situation to the IRB immediately. All research activities and interventions for the now incarcerated prisoner-subject must stop until the protocol is reviewed under the requirements of this policy.
    - 9.1.1.1. If the investigator believes that it would be in the best interests of the subject to continue research activities while incarcerated, a request may be made to the IRB.
      - 9.1.1.1.1. If the research is NOT subject to the requirements of 45 CFR 46 subpart C then the IRB Executive Chair (or designee) may grant temporary approval for the subject to continue in the study until the IRB has met and determined that all of the applicable requirements of this policy have been met. The IRB will be notified of the temporary approval at the next convened meeting.
      - 9.1.1.1.2. If the research is subject to the requirements of 45 CFR 46 subpart C then the convened IRB (at either a scheduled meeting, or at a meeting of the RR-IRB) will review to determine whether requirements of 45 CFR 46 subpart C are met. The ORA will provide documentation of compliance with subpart C to OHRP as described in section 8.0 of this policy.
      - 9.1.1.1.3. In either case, if some of the requirements of Subpart C or of this policy cannot be met, but it is in the best interests of the participant to continue the research intervention, the board may decide to keep the participant enrolled (and, if subject to subpart C, inform OHRP of the decision along with the justification), or may remove the participant from the study and keep them on the study intervention under an alternate mechanism such as compassionate use or off label use.
    - 9.1.1.2. If the PI determines that the prisoner should be withdrawn from the study, the PI must make provisions for the continuation of any necessary treatment of the subject. In general, this would entail consultation with prison authorities and transfer of medical records. The IRB should be promptly notified of this subject's withdrawal and plans for continuity of treatment.
- 9.2. When a potential subject is an adolescent detained in a juvenile detention facility
  - 9.2.1. If a potential subject is an adolescent detained in a juvenile detention facility, the individual is both a child and a prisoner. In such a case additional protections for prisoners and children who are research subjects must be provided in accordance with this policy and HRPP policy 4.4 (Research Involving Children).
- 9.3. When the PI indicates that the proposed subject population may have a high risk of incarceration during the course of the study (but currently does not include prisoners)
  - 9.3.1. Any proposed subject population that has a high risk of incarceration during the course of the study is generally considered to be a vulnerable population. Therefore, the IRB must determine that there are appropriate additional protections in accordance with 45 CFR 46.111(b).

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