

<b>Special Considerations: Prisoners</b>	
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## **1. PURPOSE**

- 1.1. Federal regulations require that research involving “vulnerable” populations such as prisoners be reviewed under 45 CFR 46 Subpart C. “Vulnerable” in the context of human subjects research protections does not refer to the susceptibility of harm, but rather the inability or a threat to the ability of an individual to give voluntary informed consent. When some or all the subjects are likely to be vulnerable to coercion or undue influence, the IRB must ensure that additional safeguards are in place to protect the rights and welfare of these subjects.
- 1.2. Research involving prisoners generally requires review by the convened IRB during a full board review and the IRB may only approve research involving prisoners which satisfies the approval criteria described below in addition to any pertinent California regulations. Research conducted in prisons may not qualify for exemption under 45 CFR 46.101(b).

## **2. DEFINITIONS**

- 2.1. *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 which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
- 2.2. *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.

## **3. POLICY and PROCEDURE**

### ***Composition of the IRB***

- 3.1. When the IRB reviews a protocol involving prisoners as subjects, the composition of the committee must satisfy the following requirements:
  - A. A majority of the committee (exclusive of the prisoner member) shall have no association with the prison(s) involved, apart from their membership on the committee.
  - B. At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

### ***Inclusion of Prisoners***

- 3.2. If prisoners will participate in the research, or subjects may reasonably be expected to become incarcerated at some point during the course of the study, the IRB may approve research involving prisoners only if it finds that the following conditions are met:
  - A. The research under review represents one of the permissible categories of research described in Section 3.3 below.
  - B. Any possible advantages accruing to the prisoner through participation in the research, when compared to the general living conditions, medical care, quality of food,

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amenities, and opportunities for earnings in prison, are not of such a magnitude that the prisoner's ability to weigh the risks and benefits of the research in the limited-choice environment of the prison is impaired.

- C. The risks involved in the research are commensurate with risks that would be accepted by non-prison volunteers.
- D. Selection procedures within the prison are fair to all prisoners and immune from arbitrary intervention by prison authority or prisoners. Unless the investigator provides the IRB justification in writing for following some other procedure, control subjects *must* be selected randomly from the group of eligible prisoners for the research project.
- E. Any information given to subjects is presented in language that is appropriate for the subject population.
- F. Adequate assurance exists that parole board(s) 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/her parole.
- G. Where the IRB finds there is a need for follow-up examination of care of subjects after the end of their participation in the research, adequate provisions has been made for such examination or care, taking into account the varying lengths of prisoner sentences, and for informing the subjects of this fact.

#### ***Categories of Permissible Research***

3.3. Research involving prisoners is permissible only if the research involves one or more of the four permissible categories, or if the research meets the criteria described in a DHHS Secretarial waiver that applies to certain epidemiological research (68 FR 36929, June 20, 2003):

- A. The first two categories are (i) the study of possible causes, effects, and processes of incarceration, and of criminal behavior, and (ii) the study of prisons as institutional structures or of prisoners as incarcerated persons. Research in these two categories is permissible only if the study presents no more than minimal risk, and no more than an inconvenience to the subjects.
- B. The third category (iii) is research on conditions particularly affecting prisoners as a class. Examples of such research include vaccine trials and other research on hepatitis, which is more prevalent in prisons than elsewhere, and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults. Research in this category may proceed only after the Secretary has consulted with appropriate experts in the *Federal Register* of his or her intent to approve the research.
- C. The fourth category (iv) is research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In this category, if the IRB-approved proposal is a study in which some of the prisoners will be assigned to a control group and these prisoners may not benefit from their participation in the research, such research may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the *Federal Register* of his or her intent to approve

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the research. OHRP interprets *control groups which may not benefit from research* to include a control group receiving standard of care that the prisoner would otherwise receive, services as usual, or a placebo.

- D. The DHHS Secretarial waiver for certain epidemiological research conducted or supported by DHHS functions as a fifth category (v) of permissible research. The criteria for this category are that the research must have as its sole purpose (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. The IRB must still review the research under the requirements for prisoners described in this procedure and certify to OHRP that an appropriately constituted IRB has reviewed the proposal and made all other required findings. Authorization from OHRP must be received prior to initiating any research involving prisoners.

#### ***When Subjects Become Prisoners***

3.4. If a human subject involved in ongoing research becomes a prisoner during the course of the study, and the relevant research proposal was not reviewed and approved by the IRB in accordance with the requirements for research involving prisoners, the investigator must promptly notify the IRB when they are made aware of this change. All research interactions and interventions with and obtaining identifiable private information about, the now-incarcerated prisoner-subject must be stopped immediately, except as noted below. Upon receipt of the investigator's report that a previously enrolled research subject has become a prisoner, if the investigator wishes to have the prisoner subject continue to participate in the research, the following steps must be taken:

- A. The IRB must at the earliest opportunity, after receiving the investigator's notice, re-review the protocol in accordance with the Subpart C. The IRB should also review the consent process and document consideration of constraints imposed by incarceration. Upon this review, the IRB can either (a) approve the involvement of the prisoner-subject in the research or (b) determine that this subject must be withdrawn from the research.
- B. The IRB must send a certification to OHRP and wait for a letter of authorization in reply. Otherwise the prisoner-subject must stop participating in the research, except as noted below.
- C. In special circumstances in which the investigator is in communication with the IRB and the IRB or Chair determines that it is in the best interest of the subject to remain in the research study when incarcerated, the subject may continue to participate in the research until the IRB can re-review the study in accordance with 45 CFR 46 and Subpart C. In these circumstances, some of the findings required by Section 3.3 above may not be applicable. For example, the finding required under Section 3.3.D. regarding the selection of subjects within the prison may not be applicable if the subject was recruited outside of an incarcerated context. The IRB should document findings of non-applicability accordingly.

3.4.1. If the research anticipates that some of the subjects in a planned study population are likely to be prisoners or become prisoners during the course of the study, the

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IRB may require the research prospectively for prisoner involvement in accordance with the requirements of 45 CFR 46 Subpart C.

### ***Additional Considerations***

3.5. *Children*: When a prisoner is a minor (e.g., an adolescent detained in a juvenile facility as a prisoner), HSC SOP – *Special Considerations: Children* also applies.

*Prisoners in California*: The state of California has provisions regarding research with prisoners that deviate from the federal regulations. Except for specific exceptions, biomedical research may not be conducted on any prisoner (PC §3502) “*Biomedical research*” means research relating to or involving biological, medical, or physical science. Research with prisoners in California is governed by the Research Review Process for the California Department of Corrections and Rehabilitation (CDCR). This review process is applicable to research involving prisoners in state prisons, but not research with prisoners in county or municipal detention. Arrangements to access prisoners in a county or municipal facility must be made at the local level.

*Additional Approvals*: Additional approvals may be required depending on the rules of the prison system (e.g., California Department of Corrections). It is the investigator’s responsibility to identify and meet these requirements.

*Non-DHHS Supported Research*: If an investigator wishes to engage in non-HHS supported research, certification to the Secretary is not required. However, the IRB will apply the standards of this document and the Federal Regulations when reviewing the research.

- 3.6. Investigators must take into account risks, such as breaches of confidentiality, coercion and undue influence on the prisoner’s decision to participate in the research.
- 3.6.1. The decision to use incentives must be appropriate to the research setting. For example, incentives that may seem trivial could be significant within a prison setting which could result in undue influence to participate in the research.
  - 3.6.2. Investigators must clearly communicate the limits of confidentiality when consenting prisoner-subjects in the research study. Investigators must distinguish between what information cannot be kept confidential in a prison (e.g., harm to others) and what can be kept confidential.
  - 3.6.3. Investigators must also assess whether the questions they ask the participants would place the prisoner-subjects at risk of harm from others, especially within focus groups. For example, within prisons, some crimes are deemed more “acceptable” than others and identifying a prisoner-subject that participated in an “unacceptable” crime could place them at risk of harm with other prisoners within the institution.

## **4. SCOPE**

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These policies and procedures apply to all non-exempt human subjects research conducted by investigators affiliated with UCSB.

## **5. RESPONSIBILITY**

The investigator is responsible for ensuring appropriate procedures for obtaining informed consent are followed when enrolling prisoners as research participants.

The IRB staff are responsible for an initial review of all new and continuing research protocol applications as described in HSC SOPs 014 and 017 – *Initial Review* and *Continuing Review*.

The IRB staff and Research Integrity Office are responsible for ensuring that IRB members are apprised of new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting discussion leaders with appropriate expertise to conduct the reviews of such research.

The IRB reviewers are responsible for conducting an appropriate review of research planned for vulnerable populations, including an assessment of potential coercion, in consultation with any appropriate experts and resources as needed.

## **6. PROCESS OVERVIEW**

- 6.1. Proposed research involving vulnerable populations must take special precautions to ensure that the research participants' rights, safety, and welfare are safeguard against any risks.
- 6.2. IRB members must take in consideration Subpart C of the federal regulations and any other applicable federal, state, or local laws when reviewing research involving prisoners.
- 6.3. When evaluating the proposed research, the IRB members will ensure that the protocol contains the appropriate informed consent processes and will identify any additional potential risks and safeguards needed to protect the participants' rights, safety, and welfare.
- 6.4. The IRB staff will communicate any requests for revisions or clarifications requested by the IRB before final approval of the research application.
- 6.5. The IRB staff shall prepare and maintain adequate documentation of IRB activities involving prisoners per OHRP guidance.

### **References:**

45 CFR 46 Regulations  
UC Berkeley Policies and Procedures  
Belmont Report – Ethical Principles and Guidelines for the Protection of Human Subjects Research  
OHRP Guidance on the Involvement of Prisoners in Research