

P&P: SC 502 Version No: 1.2 Effective Date: 6/1/2018	PRISONERS AS A VULNERABLE POPULATION	Supersedes: CPHS Policies and Procedures 10/1/2009
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1. POLICY

The use of the term “vulnerable” in the context of human research protections does not refer to 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 subjects are likely to be vulnerable to coercion or undue influence the IRB must ensure that additional safeguards have been included in the study to protect the rights and welfare of these subjects. Prisoners, individuals involuntarily confined or detained in a penal institution, as a population are considered vulnerable because the constraints of incarceration may affect an individual’s ability to give voluntary, informed consent. Therefore, the IRB may only approve research involving prisoners which satisfies the applicable criteria below in addition to the requirements delineated in RR 401 – Initial Review.

Important Note: This policy applies to research involving prisoners as subjects conducted or supported by the Department of Health and Human Services (DHHS). For any HHS-conducted or -supported research involving prisoners, CPHS must certify to the Secretary (through the Office for Human Research Protections, or OHRP) that the convened committee reviewed the research and made the seven findings required by the regulations (45 CFR 46.305(c) and 46.306(a)(1)), as detailed below. CPHS approval is contingent upon OHRP’s determination that the study involves one of the permissible categories of research involving prisoners and subsequent authorization to CPHS. Research not conducted nor supported by DHHS may not be subject to all the requirements listed below. CPHS will determine which requirements apply.

Specific Policies

1.1 Important Definitions

- 1.1.1 ***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.
- 1.1.2 ***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. It is important to note that this definition of minimal risk differs from the definition included in RR 402 – Expedited Review.
- 1.1.3 ***Secretary*** means 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.

1.2 Composition of the IRB

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 prisoner members) 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.

1.3 Inclusion of Prisoners

If prisoners will participate in the research, or subjects may reasonably be expected to become incarcerated at some time point during the course of the study, the IRB may approve research involving prisoners only if it finds that the following conditions are met and, if DHHS supported or conducted, certifies the IRB's findings to the Secretary (via OHRP):

- A. The research under review represents one of the permissible categories of research described in section 1.4 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, amenities, and opportunity 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 procedures, 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 or care of subjects after the end of their participation in the research, adequate provision has been made for such examination or care, taking into account the varying lengths of prisoner sentences, and for informing subjects of this fact.

1.4 Categories of Permissible Research

Research involving prisoners is permissible only if:

- (1) The institution responsible for the conduct of the research has certified to the Secretary that the IRB has approved the research under the above-referenced criteria; and

(2) In the judgment of the Secretary, the proposed research involves one of the following:

(i) the 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) 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 subjects;

(iii) Research on conditions particularly affecting prisoners as a class. Examples of such research include 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. Research in this category 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 the research; OR

(iv) 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 prisoners will be assigned to a control group and these prisoners may not benefit from their participation in 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 the research. OHRP interprets *control groups which may not benefit from research* to include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.

The DHHS Secretarial waiver for certain epidemiological research conducted or supported by DHHS functions as a fifth category 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 policy 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.

1.5 When Subjects Become Prisoners

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. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must be suspended 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 requirements for research involving prisoners. The IRB should also review the consent document and process in consideration of constraints imposed by incarceration. Upon this review, the IRB can either (a) approve the involvement of the prisoner-subject in the research in accordance with this policy 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 interests of the subject to remain in the research study while incarcerated, the subject may continue to participate in the research until the IRB can re-review the study in accordance with the requirements for research involving prisoners. In these circumstances, some of the findings required by section 1.3 may not be applicable. For example, the finding required under 1.3D 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.

1.6 Additional Considerations

- 1.6.1 *Informed Consent:* Due to low literacy rates within the prisoner population, consent form language should be presented in simple, straightforward terms and at a reading level appropriate for the given subject. Care should be taken to make sure the potential subject understands all elements of informed consent before deciding whether to participate.
- 1.6.2 *Children:* When a prisoner is a minor (e.g., an adolescent detained in a juvenile facility is a prisoner), SC503 – Children as a Vulnerable Population also applies.
- 1.6.3 *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.
- 1.6.4 *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.
- 1.6.5 *Non-DHHS Supported Research:* If an investigator wishes to engage in non-HHS supported research, certification to the Secretary is not required.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

The OPHS Director and/or IRB Assistant Director is responsible for maintaining up-to-date review tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines. The Assistant Director is also responsible for ensuring the IRB members are apprised of new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

The IRB Chair/Designee is responsible for providing IRB members with ongoing guidance and leadership.

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

4. PROCESS OVERVIEW

When proposed research involves vulnerable populations, the IRB must take special precautions to ensure research participants' rights, safety, and welfare. In all cases involving vulnerable populations, the IRB Chair(s) and members must be cognizant of the subjects' needs when evaluating the protocol and are responsible for determining any additional protective stipulations to be applied to the research.

When proposed research involves prisoners, the OPHS Director, Assistant Director, and/or IRB Administrator will ensure that a prisoner representative is selected to be a primary or secondary reviewer for the protocol.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 Subpart C

45 CFR 46.111

21 CFR 56.111

OHRP Guidance on Involvement of Prisoners in Research
(May 2003)

OHRP IRB Guidebook

OHRP FAQs

The Belmont Report