

## Policies and Procedures

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### 1. PURPOSE

This policy describes additional protections for prisoners. The regulations specify additional protections for prisoners [45 CFR 46 subpart C (DHHS)]. The review of prisoner research shall be limited to the review by the Social-Behavioral Board (IRB-02); however, under special circumstances the Biomedical Board (IRB-01), with the prisoner representative present, may review specific projects to maintain a subject on a research protocol for his/her health and safety.

### 2. PRISONERS IN RESEARCH

- 2.1. Prisoners are considered vulnerable because they are in a restrictive, institutional environment. The National Commission for the Protection of Human Subjects found that prisoners often volunteer for medical research as a means to gain access to competent medical, social service, or psychological care.
- 2.2. Because their autonomy is limited, prisoners may participate only in certain categories of research, and special precautions are needed to ensure that their consent to participate in the research is both knowing and voluntary.

### 3. DEFINITION OF A PRISONER

- 3.1. *Prisoner* is defined by HHS regulations 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 which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing” (45 CFR 46.303(c)).
- 3.2. Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, residential correctional facility, or juvenile offender facility, and/or their ability to leave the institution is restricted. Prisoners may be convicted felons or untried persons who are detained pending judicial action (e.g., arraignment or trial).
- 3.3. Common examples of the application of the regulatory definition of prisoner are as follows:

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- 3.3.1. Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners
- 3.3.2. Individuals who have psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; 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
- 3.3.3. 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
- 3.3.4. Probationers and individuals wearing monitoring devices generally are not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population
- 3.3.5. Individuals who are incarcerated while on a research project, but who do not require interaction or intervention while incarcerated, are not considered prisoners under Subpart C

## 4. CATEGORIES OF RESEARCH IN WHICH PRISONERS MAY PARTICIPATE

- 4.1. Prisoners may participate in the following kinds of research:
  - 4.1.1. Studies of the possible causes, effects, and processes of incarceration and criminal behavior, if those studies present no more than minimal risk or inconvenience to the subjects
  - 4.1.2. Studies of prisons as institutions, or of prisoners as incarcerated persons, if those studies present no more than minimal risk or inconvenience to the subjects

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- 4.1.3. Research on conditions affecting prisoners as a class (e.g., hepatitis, drug addiction, sexual assaults, and other conditions more prevalent in a prison population than elsewhere), but only after the Secretary of the Department of Health and Human Services has consulted with experts in medicine, ethics, and penology and published a notice approving the proposed research in the *Federal Register*
  - 4.1.4. Research on practices that are intended and reasonably likely to enhance the well-being of the subjects; however, if some of the prisoners will be assigned to control groups that will not benefit from the research, the study must first be approved by the Secretary of the Department of Health and Human Services, after consultation with appropriate experts as described above
  - 4.2. The Secretary of DHHS has waived the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:
    - 4.2.1. In which the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease, and
    - 4.2.2. In which the institution responsible for the conduct of the research certifies to the Office for Human Research Protections, DHHS, acting on behalf of the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a) (2)– (7) and determined and documented that the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and prisoners are not a particular focus of the research
  - 4.3. All prisoner research that is funded by DHHS shall be reviewed by the Office for Human Research Protection (OHRP) after IRB review but prior to the initiation of the project.
- 5. DEFINITION OF MINIMAL RISK FOR RESEARCH INVOLVING PRISONERS (45 CFR 46.303(D))**
- 5.1. *Minimal risk* is defined 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**.

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5.2. For research involving prisoners, the definition of minimal risk requires reference to physical or psychological harm, as opposed to harm or discomfort, from risks normally encountered in the daily lives, or routine medical, dental or psychological examination, of healthy persons.

## 6. ADDITIONAL DUTIES OF THE IRB

- 6.1. When the IRB reviews research that will involve prisoners, it shall first confirm that the proposed study fits within the permissible categories of research described above. It then shall determine whether:
- 6.1.1. Any advantages that prisoners will realize as a result of participation in the research, when compared to general living conditions, medical care, quality of food, amenities, and opportunities for earnings within the prison, are not so great as to impair the prisoner's ability to weigh the risks and benefits of participation and freely choose
  - 6.1.2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers (usually demonstrated by enrolling non-prisoner subjects from the community, as well)
  - 6.1.3. Procedures for selecting subjects within the prison are fair and free from arbitrary manipulation by prison authorities or other prisoners. Control subjects will be selected randomly from among the group of eligible volunteers, unless the Principal Investigator justifies a different procedure
  - 6.1.4. The information presented during recruitment and consent procedures is in a language, and level of complexity, understandable to the subject population
  - 6.1.5. The governing body will not take research participation into account when making decisions about parole or release and each prisoner is informed in advance that participation will have no effect on the possibility of parole or release
  - 6.1.6. Adequate provision is made for medical follow-up necessary to protect the health and welfare of the subjects, taking into account the varying lengths of prisoners' sentences

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6.1.7. For DHHS-funded research, the individual is indicated (by title of position) who certifies to OHRP the duties of the IRB have been fulfilled.

## 7. RESEARCH CONDUCTED IN THE FEDERAL BUREAU OF PRISONS

7.1. The Federal Bureau of Prisons has adopted extensive regulations for researchers seeking to use federal prisoners as research subjects. Among other things, these regulations prohibit use of prisoners within federal facilities for “medical experimentation, cosmetic research, or pharmaceutical testing” [28 CFR 512.11(a)(3)]. In addition, strict limitations are imposed on incentives to prisoner subjects, and researchers may not promise confidentiality to subjects who reveal a future intent to engage in criminal behavior.

## 8. REGULATORY REQUIREMENTS

8.1. Research involving prisoners shall be reviewed by the convened IRB-02 committee, which has one member who is a prisoner representative that must review all materials pertaining to the research. The prisoner representative must present his/her review either orally or in writing at the convened IRB meeting when research involving prisoners is reviewed. The majority of the IRB (exclusive of prisoner members) have no association with the prison involved, apart from their membership on the IRB. This shall include initial review, continuing review, full board modifications, and reportable unexpected or unanticipated problems, unless the following apply:

- 8.1.1. Research involving archival records only (if not funded by the DHHS) may be approved expedited if no identifiers are recorded. Two members will review and one reviewer must be the prisoner representative. Expedited review will be allowed for both initial review and ongoing continuing review
- 8.1.2. Research involving materials (e.g., data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). This would be considered secondary research
- 8.1.3. Modifications that would otherwise be approvable by expedited review may be expedited as long as the prisoner representative receives a copy of the modification and concurs that it does not adversely affect the prisoners

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- 8.1.4. IRB Document, “IRB Member Checklist for Research Involving Prisoners” shall be completed and placed in the file for documentation that all additional duties of the IRB have been fulfilled
- 8.2. If a subject becomes a prisoner after enrollment in a research study, the investigator shall notify the IRB immediately and research contact with the study subject shall cease, unless under special circumstances the investigator asserts that it is in the best interest of the subject to continue to participate until the IRB reviews. The prisoner-subject shall be withdrawn from study participation, or the IRB shall, at the earliest opportunity, re-review the research protocol and consent form in accordance with the listed requirements. The IRB can either:
- 8.2.1. confirm that the participant meets the definition of a prisoner and approve the involvement of the prisoner-subject in the research, or
  - 8.2.2. determine the risks associated with terminating participation in the study and whether termination would have an effect on participant’s health and safety prior to determining whether this subject shall be withdrawn from the research. Note that if the subject-prisoner is withdrawn from study participation, s/he must be fully informed of the reason for such action
  - 8.2.3. remove the participant from the study and keep the participant on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.
  - 8.2.4. If this occurs in a biomedical project reviewed by IRB-01, the IRB-01 must re-review the project at a convened meeting with a prisoner representative in attendance. A prisoner representative shall be on the IRB-01 roster (as well as the IRB-02 roster) but shall only be counted as quorum on IRB-01 when protocols requiring review under Subpart C are reviewed. The prisoner representative must present his/her review either orally or in writing at the convened IRB meeting when research involving prisoners is reviewed. The majority of the IRB (exclusive of prisoner members) have no association with the prison involved, apart from their membership on the IRB. While the subject is a prisoner and remains on study, all modifications and continuing reviews shall be reviewed at a convened meeting with a prisoner representative in attendance. If the project has a modification that does not usually require review at a convened meeting, the change may be reviewed using the expedited review by the Chair or designee and a prisoner representative.