

## PRISONERS AS RESEARCH PARTICIPANTS

*This guidance document is intended for researchers planning to involve prisoners as subjects. Should you need additional assistance, please contact OPHS at 510-642-7461 or [ophs@berkeley.edu](mailto:ophs@berkeley.edu).*

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**A. General Information:** As a population, prisoners are considered vulnerable because the constraints of incarceration may affect an individual's ability to make a truly voluntary decision about whether or not to participate as a subject in research. For this reason, federal regulations and California State regulations include additional protections for this population.

Research involving prisoner subjects generally requires review by the convened committee, that is the full board, and CPHS may only approve research involving prisoners which satisfies the approval criteria described below in addition to other applicable requirements under 45 CFR 46 and any pertinent California regulations (see Part E for California regulations).

Note: Authorization from the Department of Health and Human Services, Office for Human Research Protections (OHRP) must be obtained prior to the initiation of any *federally funded* research involving prisoners.

**B. Definition of a Prisoner:** Federal regulations (45 CFR 46.303(c)) define a "prisoner" 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. This means that individuals are considered prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or untried persons who are detained pending judicial action, for example, arraignment or trial.

Examples of individuals who are prisoners:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration.
- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration.
- Parolees who are detained in a treatment center as a condition of parole.

**C. Parolees, Probationers and Persons Wearing a Monitoring Device:** The definition of “prisoner” excludes those on probation, parole or wearing a monitoring device unless there is a condition of confinement that places restrictions on their freedom of movement. For example, 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. Although parolees, probationers and persons wearing monitoring devices are not considered prisoners, situations of this kind typically require careful consideration of the circumstances for the inclusion of the subject population in the research so as to minimize the potential for coercion or undue influence. (See also Part F for information about what must happen when a subject becomes a prisoner during the course of an ongoing study)

Examples of individuals who are not prisoners:

- Individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community.
- 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.

**D. Approval Criteria for Inclusion of Prisoners in Research:** As set forth in federal regulations at 45 CFR 46 Subpart C, the CPHS may approve research involving prisoners if all of the criteria below are met. *These rules are complex; please contact OPHS if you have any questions.*

1. Any possible advantages that the prisoner would gain through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, must not be of such a magnitude that the prisoner’s ability to weigh the risks and benefits of the research in the limited-choice environment if the prisoner is impaired.
2. The risks involved in the research must be commensurate with risks that would be accepted by non-prison volunteers.
3. Selection procedures within the prison must be fair to all prisoners and immune from arbitrary intervention by prison authority or prisoners. Control subjects must be selected randomly from the group of eligible prisoners for the research project *unless* the researcher provides the CPHS with justification in writing for a different procedure.
4. Any information given to subjects must be presented in language that is understandable to them.
5. The CPHS must be provided with adequate assurance that parole board(s) will not take into account a prisoner’s participation in the research when making decisions regarding parole, and each prisoner must be clearly informed in advance (e.g. in the consent form) that participation will have no effect on his/her parole.
6. When there is a need for follow-up examination or care of subjects after the end of their participation in the research, adequate provision must be made for such examination or care, taking into account the varying lengths of prisoner sentences, and for informing subjects.
7. The research must fit into one or more of the *five permissible categories* described below.

- a. *Categories 1 and 2* – The first two categories are: (1) the study of the possible causes, effects, and processes of incarceration, and of criminal behavior, and (2) 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 inconvenience to the subjects.

<sup>1</sup>*Minimal risk for prisoners* 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.”

- b. *Category 3* is 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.
- c. *Category 4* 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 CPHS-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. *Control groups which may not benefit from research* include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.
- d. *Category 5* – 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. CPHS must certify to OHRP that an appropriately constituted committee has reviewed the protocol and found that it meets the criteria for approval of research involving prisoners.

**E. Prisoners in California:** The State of California has provisions regarding research with prisoners in addition to federal regulations. 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.

Except for specific exceptions, biomedical research may not be conducted on any prisoner in a state prison (PC §3502). “*Biomedical research*” means research relating to or involving biological, medical or physical science. Directives from the Secretary of the Youth and Adult Correctional Agency and the Director of the Youth Authority also prohibit the conduct of biomedical research on wards. This applies to research relating to or involving biological, medical, or physical science. The only exceptions are for research that is specifically codified in statute and approved by the Director of the Department, the Secretary of the Youth and Adult Correctional Agency, and the Governor’s Office.

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<sup>1</sup> The definition of minimal risk in federal regulations is different for prisoners than for other subject populations.

For more information, visit the [California Department of Corrections \(CDCR\) Website](#)

**F. When Subjects Become Prisoners:** If a participant in ongoing research becomes a prisoner during the course of the study, and the relevant protocol was not reviewed and approved by the CPHS in accordance with the requirements for research involving prisoners, the researcher must promptly notify OPHS. All research interactions and interventions with, and obtaining identifiable private information about, the now-prisoner-subject must be suspended immediately, except as noted below. If the researcher wishes to have the prisoner subject continue to participate in the research, the following steps must be taken:

1. CPHS must at the earliest opportunity, after receiving the investigator's notice, re-review the protocol in accordance with the criteria for research involving prisoners described above. The consent document and process will be reviewed in consideration of constraints imposed by incarceration. Upon this review, the Committee 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.
2. If the research is funded by DHHS, CPHS 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.
3. In special circumstances in which the investigator is in communication with CPHS and the Committee 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 criteria for inclusion or prisoners may not be applicable. For example, the criterion regarding the selection of subjects within the prison may not be applicable if the subject was recruited outside of an incarcerated context.

If the researcher anticipates that some of the subjects in a planned research study population are likely to be prisoners or become prisoners during the course of the study, CPHS may review the research prospectively for prisoner involvement in accordance with the requirements of subpart C of 45 CFR part 46.

**G. Additional Information:** For additional information on research involving prisoners, please visit the links below and/or contact the Office for the Protection of Human Subjects.

[DHHS Office for Human Research Protections \(OHRP\) - Frequently Asked Questions](#)

[OHRP Guidance on the Involvement of Prisoners in Research](#)