

## Guidance: Special Subject Populations: Prisoners (last updated April 30, 2013)

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### Introduction

Prisoners are considered vulnerable because they are in a restrictive, institutional environment that affords little opportunity for making choices, earning money, communicating with outsiders, or obtaining medical care. Because their autonomy is limited, prisoners may participate only in certain categories of research, and special precautions are needed to assure that their consent to participate in the research is both knowing and voluntary.

California state law<sup>1</sup> prohibits the conduct of biomedical research<sup>2</sup> on any prisoners in this state, except when a physician treating a prisoner has determined that access to a drug or treatment available only under a Treatment IND is in the best medical interests of the prisoner and the prisoner has provided consent.<sup>3</sup>

### Definitions

**Minimal Risk:** Risk of physical or psychological harm that is no greater in probability and severity than that ordinarily encountered in the daily lives, or in the routine medical, dental or psychological examinations of healthy persons [[45 CFR 303\(d\)](#)].

**Prisoner:** An individual involuntarily confined in a penal institution, including persons:  
(1) sentenced under a criminal or civil statute;  
(2) detained pending arraignment, trial, or sentencing; and

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<sup>1</sup> California Penal Code § 3502

<sup>2</sup> "Biomedical research" means research relating to or involving biological, medical, or physical science.

<sup>3</sup> California Penal Code §3502.5. See [OHRPP Guidance & Procedure: Use of Drugs and Biologics in Clinical Research And Treatment](#).

(3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [[45 CFR 46.303\(c\)](#)].

Correspondence from DHHS dated March 19, 2004 indicates that OHRP does not interpret [45 CFR 46.303\(c\)](#) to include subjects living in the community and receiving court mandated drug treatment.

## Special Considerations for Research Involving Prisoners

### Federal Criteria for Approval

[45 CFR 46.305\(a\)](#) requires that when an IRB reviews a protocol in which a prisoner is a participant, the IRB must make, in addition to other requirements under [45 CFR 46, subpart A](#), the following seven findings:

1. The research under review represents one of the categories of research permissible under [46.306\(a\)\(2\)](#);
2. Any possible advantages accruing 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;
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
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 principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. The information is presented in language which is understandable to the subject population;
6. Adequate assurance exists that parole boards 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 or her parole; and
7. Where the Board 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 prisoners' sentences, and for informing participants of this fact.

## State of California Criteria for Approval

**California Penal Code §3515** requires the following determinations be made before approving behavioral research projects that involve California prisoners as participants:

1. That the sum of the benefits to the prisoners and the value of knowledge gained outweigh the risks to the participants.
2. That the rights and welfare of the prisoners are adequately protected, including the security of any confidential personal information.
3. That the selection process is equitable and the rate of remuneration for participation is comparable to that received by non-prisoner volunteers in similar research.
4. That provisions have been made to compensate any research-related injury.
5. That research activity will be reviewed regularly.
6. That legally effective informed consent will be obtained by adequate and appropriate methods.

## Categories of Research In Which Prisoners May Participate

### Federal Categories

When an IRB reviews a protocol in which a prisoner is a subject, the IRB must determine whether that research falls within one of the following four categories allowed under [45 CFR 46.306\(a\)](#) in order to approve the protocol:

- 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;
- 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;
- Research on conditions particularly affecting prisoners as a class (for example, vaccine trials<sup>4</sup> 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) provided that the study may proceed only after the Secretary [of DHHS] has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

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<sup>4</sup> California state law overrides federal regulation and prohibits biomedical research with prisoners in California, except as noted in Section I above. [California Penal Code § 3502]

- Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary [of DHHS] has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

### State of California Categories

If research involves prisoners in a California facility, researchers and the IRB must **also** comply with the additional limitations and requirements in [California Penal Code Sections 3501 – 3523](#). These provisions limit the types of biomedical research that may be conducted and place additional requirements on other types of research.

- **Prohibition of Biomedical Research:** California law prohibits the conduct of biomedical research on any prisoners in this state, except when a physician treating a prisoner has determined that access to a drug or treatment available only under a Treatment IND is in the best medical interests of the prisoner and the prisoner has provided consent.
- **Allowable Behavioral Research:** California Penal Code §3505 specifies allowable behavioral research as limited to studies of:
  - the possible causes, effects and processes of incarceration,
  - prisons as institutional structures, and
  - prisoners as incarcerated persons.
 Research must present minimal or no risk to the subjects of the research, and no more than mere inconvenience.

## IRB Member Requirements

For research involving prisoners as participants, the IRB must meet the special composition requirements of [45 CFR 46.304](#) for all types of review of the protocol, including initial review, continuing review, review of protocol amendments, and review of reports of unanticipated problems involving risks to subjects. *(The Administrator for each IRB is responsible for ensuring that composition of the IRB satisfies the requirements.)*

### Convened IRB Review

When a convened IRB reviews a protocol involving prisoners as participants, the composition of the IRB must satisfy the following requirements:

- A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB. [\[45 CFR 46.304\(a\)\]](#)
- At least one member of the IRB present at the meeting 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. [\[45 CFR 46.304\(b\)\]](#)

## Expedited IRB Review

DHHS regulations allow expedited review of research involving prisoners. However, OHRP recommends that the convened IRB review research involving prisoners as human subjects. In the event that a submission qualifies for expedited review, a prisoner representative will be one of the designated reviewers.

## When a Current Research Participant Becomes a Prisoner

When a previously enrolled research participant becomes a prisoner and the relevant research protocol was **not** reviewed and approved by the institutional review board (IRB) in accordance with the requirements of HHS regulations at 45 CFR part 46, [Subpart C](#), the principal investigator should promptly notify the IRB of this event. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-participant must cease until the requirements of 45 CFR 46 [Subpart C](#) have been satisfied with respect to the relevant protocol.

Upon receipt of notification that a previously enrolled research participant has become a prisoner, the IRB should promptly re-review the protocol in accordance with the requirements of 45 CFR 46 [Subpart C](#) if the principal investigator wishes to have the prisoner participant continue to participate in the research.

## Restrictions and Additional Approvals

The **Federal Bureau of Prisons** places special restrictions on research that takes place within the Bureau of Prisons under [28 CFR 512](#). The provisions under [28 CFR 512](#) specify additional requirements for prospective researchers (both employees and non-employees) to obtain approval to conduct research within the Bureau of Prisons (Bureau) and responsibilities of Bureau staff in processing proposals and monitoring research projects.

**Department of Defense** (DOD) prohibits research with Prisoners of War (POW). See the [OHRPP DOD checklist](#) for details.

There may be other approvals required depending on the rules of the prison system (e.g., **California Department of Corrections and Rehabilitation (CDCR)** requirements under [Title 15](#), Article 9.1 of the California Code of Regulations).

***It is the investigator's responsibility to identify and meet these requirements.***

## Minors

When a prisoner is also a minor (e.g., an adolescent detained in a juvenile detention facility is a prisoner), [OHRPP Guidance: Research Involving Children and Minors](#) will also apply.

## Outside California

If research activities under the jurisdiction of the UCLA IRB will involve prisoners held outside of California, the investigator is responsible for identifying and ensuring compliance with the laws

and regulations of the applicable jurisdiction(s). The IRB application should specify the jurisdictions involved.

## Remuneration

Under [Section 3523 of the California Penal Code](#), the amount of remuneration provided to prisoners shall be comparable to that paid to non-prisoner volunteers in similar research. The IRB must therefore consider the amount and mode of compensation to prisoner participants in light of both this requirement and the unique limits on prisoner autonomy.

## Regulations & References

### *Department of Health and Human Services (DHHS)*

- 45 CFR 46 [Subpart C](#) (DHHS)
- Office for Human Research Protections (OHRP) guidance: "[OHRP Guidance on the Involvement of Prisoners in Research](#)," May 23, 2003.
- Office for Human Research Protections (OHRP) guidance: [Prisoner Research – FAQs](#).
- Office for Human Research Protections (OHRP) guidance: [Prisoner Research Certification](#).

### *Department of Justice (DOJ)*

- [28 CFR 46](#)
- [28 CFR 512](#)

### *California Code*

- California Penal Code, [Sections 3500-3524](#)
- California Code of Regulations, [Title 15](#), Article 9.1, "Research of Inmates/Parolees."
- California Department of Corrections and Rehabilitation (CDCR) guidance: [Research Involving Wards, Inmates & Staff](#).
- California Department of Corrections and Rehabilitation (CDCR) guidance: [Research Project Approval Guidelines](#).

### *OHRPP Guidance*

- [DOJ checklist](#)