

Guidance and Procedures Number: 23
Title: Special Subject Populations: Prisoners
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I. 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 law¹ prohibits the conduct of biomedical research² 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.³

II. Definitions

- A. **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)].
- B. **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 (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.

III. Special Considerations for Research Involving Prisoner Subjects

When an IRB reviews a protocol in which a prisoner is a subject, the IRB must make, in addition to other requirements under 45 CFR 46, subpart A, seven findings under 45 CFR 46.305(a), as follows:

¹ California Penal Code § 3502

² “Biomedical research” means research relating to or involving biological, medical, or physical science.

³ California Penal Code §3502.5. See [HRPP Guidance & Procedure # 34: FDA Requirements](#) for information regarding Treatment INDs.

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 nonprisoner 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.

IV. Categories of Research in Which Prisoners May Participate

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:

1. 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;
2. 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;
3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials⁴ and other research on hepatitis which is much more prevalent in prisons than

⁴ 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]

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

4. 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.

V. Composition of the IRB

- A. For research involving prisoners as subjects, 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.

1. The Administrator for each IRB is responsible for ensuring that composition of the IRB satisfies the requirements.

- B. When an IRB reviews a protocol involving prisoners as subjects, the composition of the IRB must satisfy the following requirements:

1. 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)]
2. 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)]

VI. Additional Guidelines for Research Conducted or Supported by DHHS

- A. For research conducted or supported by DHHS to involve prisoners, two actions must occur:

1. The institution engaged in the research must certify to the Secretary [of DHHS] (through OHRP) that the IRB designated under its assurance of compliance has reviewed and approved the research under 45 CFR 46.305; and
2. The Secretary [of DHHS] (through OHRP) must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2).

- B. Under 45 CFR 46.305(c), the institution responsible for conducting research involving prisoners that is supported by HHS shall certify to the Secretary [of DHHS] (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a). The institution must send to OHRP a certification letter to this effect, which should also include the name and address of the institution and specifically identify the research protocol in question and any relevant HHS grant application or protocol. HHS conducted or supported research involving prisoners as subjects may not proceed until OHRP issues its approval in writing to the institution on behalf of the Secretary [of DHHS] under 45 CFR 46.306(a)(2).
- C. Under its authority at 45 CFR 46.115(b), OHRP requires that the institution responsible for the conduct of the proposed research also submit to OHRP a copy of the research proposal so that OHRP can determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so, which one. The term "research proposal" includes the IRB-approved protocol, any relevant HHS grant application or proposal, any IRB application forms required by the IRB, and any other information requested or required by the IRB to be considered during initial IRB review.
- D. If an investigator wishes to engage in non-HHS supported research, certification is not required. However, the IRB will apply the standards of this guidance and the Federal regulations in reviewing the research.

VII. Measures to be Taken When a Current Research Subject Becomes a Prisoner

When a previously enrolled research subject 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-subject must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol.

Upon receipt of notification that a previously enrolled research subject has become a prisoner, the IRB should promptly re-review the protocol in accordance with the requirements of subpart C if the principal investigator wishes to have the prisoner subject continue to participate in the research.

VIII. Additional Approvals

- A. 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.
- B. There may be other approvals required depending on the rules of the prison system (e.g., California Department of Corrections and Rehabilitation 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.

IX. Additional Considerations

- A. When a prisoner is also a minor (e.g., an adolescent detained in a juvenile detention facility is a prisoner), [HRPP Guidance & Procedure # 21: Special Subject Populations: Children](#) will also apply.
- B. 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.
- C. 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 subjects in light of both this requirement and the unique limits on prisoner autonomy.

X. Expedited Review of Research Involving Prisoners

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.

Regulations:

45 CFR 46 Subpart C

28 CFR 46

28 CFR 512

California Penal Code, Sections 3500-3524

California Code of Regulations, Title 15, Article 9.1

References:

OHRP Guidance Document: "OHRP Guidance on the Involvement of Prisoners in Research," May 23, 2003. <http://hhs.gov/ohrp/humansubjects/guidance/prisoner.pdf>

OHRP, *Human Research Questions & Answers: Prisoner Research*. <http://www.hhs.gov/ohrp/faq.html>