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Research Involving Prisoners

Regulatory Background and Definitions

Because prisoners are a vulnerable research population, the Office of Human Research Protection (OHRP) requires and enforces additional protections (45 CFR 46 Subpart C [1]). OHRP Guidance on the Involvement of Prisoners in Research [2] will be useful to PIs who conduct prisoner research, or those who have enrolled a research participant who subsequently becomes incarcerated.

The California Penal Code (Sections 3500; 3501-3509.5, 3521) [3] outlines provisions for research involving prisoners within the state. IRB policies are consistent with all federal and state regulations.

Definitions:

Prisoner [4] 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.

Minimal risk (prisoners) [4]: 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. Note: This definition differs from the minimal risk definition [5] that applies to research with non-vulnerable populations.

What to do if ...

Prospective participants are in danger of arrest

If the research population includes people who are likely to be jailed during a study ? and whose participation the investigator would like to continue ? the study should be reviewed as prisoner research. This would include studies intending to enroll parolees, street people, addicts and prostitutes because these individuals are more likely to be arrested than the general population.

You should anticipate the likelihood of arrests and discuss what study activities will and will not continue while the participants are in jail. To include these jailed participants, the study must meet the same requirements and review standards as other studies involving prisoners.

Enrolled participant is jailed

If a research participant is incarcerated after enrollment in a study, the participant can continue in the study *only if the IRB reviews and approves the study in accordance with all requirements for research involving prisoners*. If the study is not already approved to include prisoners, immediately contact the IRB at 415-476-1814 and speak with the specialist on prisoner research. The study will need to be modified and must be reviewed by a member of the IRB qualified to represent prisoners? interests.

Permissible Categories of Research Involving Prisoners

Biomedical Research

California law prohibits all biomedical research on prisoners (Section 3502 [6]).

However, prisoner participation in investigational new drug (IND) research may be allowed under certain circumstances.

- The treatment protocol or treatment IND meets the regulatory requirements in 21 CFR 312, regulations enforced by the FDA; and
- The treatment is deemed to be in the prisoner's best medical interest [Section 3502.5(a)], and
- The prisoner-participant has given informed consent [Section 3521].

Behavioral Research

There are four categories of permissible behavioral research.

Below are the four permissible categories defined by State (Section 3505 [6]) and federal regulations [45 CFR 46.306(a)(2) [1]]:

1. Studies of 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. Studies 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 trials and other research on hepatitis which is more prevalent in prisons than elsewhere.
- Research on social and psychological problems (alcoholism, drug addiction, and sexual assaults). The study may proceed only after the HHS Secretary (through OHRP) has consulted with appropriate experts and has published notice of approval in the Federal Register.

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. Non-therapeutic research with a control group must be approved by the IRB and subsequently reviewed by the HHS Secretary. The Secretary?s ruling, informed by consultation with experts, will be published in the Federal Register.

Epidemiologic Research

Prisoners may be included in some research directed towards the prevalence, incidence or risk factors for diseases that might affect prisoners.

By HHS Secretarial waiver (68 FR 36929 [7], June 20, 2003), prisoners may be included in epidemiologic research in which the sole purposes are (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 research must present no more than a minimal risk [8], present no more

than inconvenience to the subjects and prisoners must not be a particular focus of the research.

For more information, call the IRB at 415-476-1814 and ask to speak with the specialist on prisoner research.

Additional Requirements

In addition to all the basic human subject protection requirements (45 CFR 46, Subpart A [9]), the IRB must review prisoner research and find that the research complies with seven additional requirements [45 CFR 46.305(a) [1]]:

1. The study satisfies the criteria for permissible research.

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.

Other Considerations

Investigators conducting prisoner research should carefully consider the following issues:

- Confidentiality: There are several privacy and confidentiality issues to address in the prison environment, such as the availability of private rooms to conduct interviews and involving prison staff in any part of the study.
- Informed consent: Prisoners who are competent have the fundamental right to decide whether or not to participate in research. UCSF requirements for informed consent [10] are consistent with those specified for prisoners in state regulations (Section 3521-3523 [11]).

IRB Composition and Review Process

The IRB must abide by federal requirements for review and approval of research involving prisoners.

IRB membership requirements (including one prisoner representative)

Research involving prisoners must be reviewed by an IRB that fulfills the following membership requirements [45 CFR 46.304 [1]]:

- 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.
- 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

Note: If a research project is reviewed by more than one IRB, only one IRB must satisfy the requirement that at least one member is a prisoner or a prisoner representative.

Federal approval required

The institution responsible for conducting federally-funded prisoner research must provide a Prisoner Certification Letter to the OHRP citing that the IRB has completed its review of permissible research and that the seven additional requirements are met.

Note: The research cannot proceed until OHRP issues written approval to the institution.

Extra review time needed

The availability of qualified reviewers and the requirement for federal approval mean that researchers should allow for at least a month additional time between submission and final approval of an application affecting prisoners.

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Links
[1] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc
[2] http://www.hhs.gov/ohrp/policy/prisoner.html
[3] https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=PEN&division=&title

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