Policy on Research Involving Prisoners

Effective date: 9/20/2019

I. Background
UC Santa Cruz follows the Office of Human Research Protections regulations for any research involving prisoners. OHRP regulations under 45 CFR 46, Subpart C Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects outline additional criteria investigators must meet to conduct research with the prisoner population. This population has limited autonomy and is therefore a vulnerable subject population. This policy describes those regulations as well as additional requirements from the Department of Justice and State requirements.

II. Definitions
a. Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examinations or tests.
b. Prisoner: An individual involuntarily confined or detained in a penal institution. This encompasses 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.

III. IRB Review and Approval of Research Involving Prisoners
a. Additional ethical considerations and regulatory requirements are needed for research involving prisoners to safeguard their interests and to protect them from harm since they are a vulnerable population with limited autonomy. When a protocol involves the use of prisoners as subjects, the additional procedures outlined in this policy must be followed for the IRB to approve the research.
b. Research involving prisoners must be reviewed and approved following UCSC IRB policies and procedures, and must follow federal, state, county, and local regulations for prisoners.
c. California Penal Code 3502 prohibits biomedical research (research relating to or involving biological, medical or physical science) involving prisoners.
d. Note that the definition of minimal risk under Subpart C is different from that under the ordinary Common Rule (Subpart A). (See definition above.)
e. The IRB must review all research in which prisoners are the target population, the subject is a prisoner at the time of enrollment, or when a currently enrolled
participant becomes incarcerated and research interventions and interactions would occur during the incarceration period or if identifiable private information will be obtained during the incarceration period.

f. When the IRB is reviewing a protocol in which a prisoner is a participant, the convened IRB must make seven additional findings under 45 CFR 46.305(a) in addition to requirements under 45 CFR 46, Subpart A, as follows:

   i. The research under review represents one of the following categories of research permissible under 45 CFR 46.306(a)(2) and California Penal Code 3505:

      1. A 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 participants;

      2. A 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 participants;

      3. Research on conditions particularly affecting prisoners as a class (e.g., 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). When the research is funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html), the study may proceed only after the Secretary (through OHRP) 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 participant. When the research is funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html) and the study requires 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 (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics and
Institutional Review Board

published notice, in the Federal Register, of his intent to approve such research

ii. 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 prisoner is impaired;

iii. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

iv. Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Principal Investigator (PI) provides to the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

v. The information is presented in language which is understandable to the participant population;

vi. 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

vii. Where the IRB 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. Waiver of the Applicability of Certain Provisions of DHHS Regulations for the Protection of Human Subjects for DHHS Epidemiologic Research Involving Prisoners as Subjects

a. For a minimal risk epidemiologic study in which prisoners are not the particular focus and the sole purpose of the study is either: to describe the prevalence or incidence of a disease by identifying all cases; or to study potential risk factor associations for that disease.

b. The two Subpart C provisions that are waived are: the requirement that an IRB choose one of the four categories in 45 CFR 46.306(a)(2); and, when the research is funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html
and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html), the requirement that the Secretary (through OHRP) make the final choice of one of the four categories.

c. When the research is funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html), the institution responsible for the conduct of the research must certify in writing to the OHRP: 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-participants and prisoners are not a particular focus of the research.

d. When research involving prisoners is funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html), the research cannot start until the IRB has received approval for the research from OHRP.

V. Composition of IRB when Prisoners are Involved in Research

a. When an IRB reviews a protocol involving prisoners as subjects, the composition of the IRB must satisfy the following requirements of HHS regulations at 45 CFR 46.304 (a) and (b): 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; and 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, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

b. UCSC does not regularly review research that involves prisoners, but will ensure that a regular or alternate member of the IRB is someone that is knowledgeable about and experienced in working with these participants.

c. If a prisoner representative is selected to serve on the IRB Committee, the person must have a close working knowledge, understanding and appreciation of prison conditions from the perspective of a prisoner. Suitable individuals could include present or former prisoners; prison chaplains; prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.

d. A prisoner representative is needed for all types of review, including initial review, continuing review, amendments (except personnel-only
amendments), or reports of unanticipated problems involving risk to participants or others.
e. The IRB must notify OHRP of any change in the IRB roster occasioned by the addition of a prisoner or a prisoner representative. The IRB should be alert to the impact of roster changes on quorum requirements. Specifically, the IRB should: notify OHRP of the name and qualifications of the prisoner representative, if the approved IRB roster does not currently reflect this information; and maintain the CV of the prisoner representative serving on the IRB.

VI. Measures that are to be Taken When a Current Research Participant Becomes a Prisoner

a. If a participant becomes a prisoner after enrolling in a research study, the Investigator is responsible for immediately reporting the event in writing to the IRB. This is not required if the study was previously approved by the IRB for prisoner participation.
b. If research interactions and interventions or obtaining identifiable private information will not occur during the incarceration, IRB review and approval under Subpart C is not required.
c. If the participant is temporarily incarcerated while enrolled in the study, the temporary incarceration has no effect on the study, and the subject may remain enrolled, IRB review and approval under Subpart C is not required.
d. If the temporary incarceration has an effect on the study, review will be handled as outlined below:
   i. If the study was not previously reviewed and approved by the IRB in accordance with the requirements of Subpart C, the IRB will consider the risks associated with terminating the subject’s participation in the study and either,
      ii.
         1. Terminate the subject’s participation until the requirements of Subpart C have been satisfied; or
         2. In special circumstances in which it is in the best interests of the subject to remain in the research study while incarcerated, allow the subject to continue until the requirements of Subpart C are satisfied.
   iii. The full, convened IRB Committee will review the current research protocol in which the participant is enrolled, taking into special consideration the additional ethical and regulatory concerns for a prisoner involved in research.
   iv. If some the requirements of Subpart C cannot be met, but it is in the best interests of the participant to remain in the study, the IRB may
decide to keep the participant enrolled and inform OHRP of the decision along with the justification.

v. If in the best interest of the participant, the IRB may decide to remove the participant from the study but keep them on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.

VII. Research Conducted or Supported by Common Rule Departments or Agencies
For research involving prisoners conducted or supported by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html), two actions must occur: the institution engaged in the research must certify to the Secretary (through OHRP) that the IRB designated under its assurance of compliance has reviewed and approved the research under 45 CFR 46.305; and the Secretary (through OHRP) must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2). The research cannot start until the IRB has received approval for the research from OHRP.

VIII. Federal Bureau of Prisons (Department of Justice)
a. When Human Research is conducted with the federal Bureau of Prisons (Department of Justice), the organization relies on the Bureau Research Review Board to ensure compliance with 28 CFR 512;
   i. The project must not involve medical experimentation, cosmetic research or pharmaceutical testing.
   ii. The research design must be compatible with both the operation of the prison facilities and protection of human participants. Researchers must observe the rules of the institution or office in which the research is conducted.
   iii. Any researcher who is a non-employee of the Bureau must sign a statement that the researcher agrees to adhere to the requirements of 28 CFR 512.
   iv. All research proposals will be reviewed by the Bureau Research Review Board.
b. The Federal Bureau of Prisons 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:
   i. The researcher shall prepare reports of progress on the research and at least one report of findings.
ii. At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation (ORE), with a report on the progress of the research.

iii. At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board (BRRB), the regional director, and the warden of each institution which provided data or assistance. The researcher shall include an abstract in the report of findings.

iv. A researcher may publish in book form and professional journals the results of any research project conducted under this subpart.

v. In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.

vi. The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.

vii. Prior to submitting for publication, the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

c. California Penal Code 3500-3523 specify additional requirements for prospective researchers to obtain conduct research within the California penal system.

IX. Additional Considerations

a. When a prisoner is also a minor (e.g., an adolescent detained in a juvenile detention facility), additional regulations regarding children in research will also apply. (See Policy on Research Involving Children)

b. The convened IRB Committee must initially review research involving intervention or interaction with prisoners as human subjects. If the research involves minimal risk to subjects and meets the federal criteria for expedited review (45 CFR 46.110 and 21 CFR 56.110), the IRB Committee may authorize continuing expedited review of the research.

c. Exempt review research involving prisoners is only acceptable for research aimed at involving a broader subject population that only incidentally includes prisoners.

X. References

a. UC Irvine HRPP Policy on Prisoners
b. DHHS: 45 CFR 46.111 Subpart C
c. DOJ: 28 CFR 512
d. CA Department of Corrections, Prisoners in Biomedical and Behavioral Research, Penal Code 3500-3523