

**Policy Number: 37**

**Title: Prisoners**

**Date of Last Revision: 10/12/07, 11/21/10, 02/16/11, 09/21/12, 01/28/15, 05/01/16, 05/31/19, 06/03/19, 09/28/20, 04/12/22, 08/17/22**

**Introduction to Policy:**

Prisoners are 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. Special precautions aim to assure that their consent to participate in the research is both knowing and voluntary.

**Applicable Definitions:**

**45 CFR 46.303 (HHS – Subpart C): Definition of a Prisoner:** “Prisoner” 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 ([45 CFR 46.303\(c\)](#)). Individuals are 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 may be untried persons who are detained pending judicial action, for example, arraignment or trial. Common examples of the application of the regulatory definition of prisoner are as follows:

1. Individuals detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners.
  - a. Individuals receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.
2. Individuals with psychiatric illnesses committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners.
  - a. Individuals 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, are not prisoners.
3. Parolees detained in a treatment center as a condition of parole are prisoners.
  - a. Individuals living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.
4. Probationers and individuals wearing monitoring devices are generally not prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned participant population. Institutions may consult with OHRP when questions arise about research involving these populations.

**Minimal Risk Definition per 45 CFR 46.303(d):** *Minimal risk* is 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.<sup>1</sup>

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<sup>1</sup> Differs from 2018 Common Rule Definition of Minimal Risk: Minimal risk means that 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 or during the performance of routine physical or psychological examinations or tests.

- I. **UC Irvine (UCI) Institutional Review Board (IRB) Level of Review<sup>2</sup>**
- A. **Full Committee Review: At UCI, the *initial review* of research that involves an interaction with a prisoner requires full committee review.** This includes research that qualifies under categories 45 CFR 46.306 (i) and (ii).
1. Future reviews may occur under the expedited review procedure (subcommittee) **should the *full committee* agree the research involves minimal risk as allowed by the regulations at 45 CFR 46.306.**
  2. The IRB member(s) reviewing the research must include a prisoner or a prisoner representative.
  3. For categories 45 CFR 46.306 (iii) and (iv), full committee review is always required, along with DHHS consultation.
- B. **Subcommittee / Expedited Review: At UCI, for research that involves access to prisoner data with no interaction or intervention with the prisoner population (that coincide with categories 45 CFR 46.306 (i) and (ii)), *initial review may be done at subcommittee.*** The IRB member reviewing the research must include a prisoner or a prisoner representative.
- C. **Subcommittee / Exempt Review:** IRB exemptions do not apply EXCEPT for research aimed at involving a broader subject population that **only incidentally** includes prisoners [45 CFR 46.104(b)(2)].
- II. **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):
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; and
  2. 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.
  3. The prisoner representative 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.
- III. **IRB Review and Approval of Research Involving Prisoners – Federal Criteria**
- A. It is the policy of the UCI IRB to review and approve all research involving prisoners with additional ethical and regulatory considerations applicable to prisoners under 45 CFR 46, Subpart C.
- B. The UCI 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.*
- C. **When the IRB is reviewing a protocol in which a prisoner is a participant, the IRB Committee must make, in addition to requirements under 45 CFR 46, Subpart A, seven findings under 45 CFR 46.305(a). See Table 1 – Federal.**

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<sup>2</sup> For reference, the Department of Health and Human Services (DHHS) regulations allow expedited review of research involving prisoners. The Office for Human Research Protections (OHRP) recommends that the full committee IRB review research-involving prisoners as human subjects. If the research is reviewed under the expedited review procedure, OHRP recommends that the IRB member(s) reviewing the research include a prisoner or a prisoner representative.

1. **As part of the seven findings, the first finding requires confirmation of which permissible research category the study represents.**

IV. **IRB Review and Approval of Research Involving Prisoners – California Criteria**

- A. **The California Department of Corrections and Rehabilitation (CDCR) must approve research involving state prisoners.** Note that county or local jails may detain state prisoners.
  1. **CDCR Link: <https://www.cdcr.ca.gov/research/research-requests/>**
  2. **It is the investigator's responsibility to identify and meet these and other related CDCR requirements.**
- B. **Committee for the Protection of Human Subjects (CPHS) approval may apply to prisoner research.** CPHS is the institutional review board (IRB) for all of the departments under the California Health and Human Services Agency (CHHSA). CPHS is also the IRB required to review all research-related requests for state personal information to the University of California and non-profit educational institutions. (CPHS must also approve research requests for release of data relating to birth and death certificated from the California Department of Public Health.)
  1. **CPHS Link: <https://www.chhs.ca.gov/cphs/>**
  2. **It is the investigator's responsibility to identify and meet these and other related CPHS requirements.**
- C. **As applicable, researchers 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.
  1. **It is the Lead Researcher's responsibility to identify and meet CA penal code requirements, as applicable.**
  2. **Notable California Considerations:**
    - i. CA Penal Code 3502 prohibits the conduct of biomedical research on prisoners except when a physician treating a prisoner has determined that access to a drug or treatment available only under a treatment protocol or treatment IND is in the best medical interests of the prisoner and the prisoner has provided consent per CA penal Code Section 3521.
    - ii. In addition, per CA Penal Code 3504, any physical or mental injury of a prisoner resulting from the participation in behavioral research, irrespective of causation of such injury, shall be treated promptly and on a continuing basis until the injury is cured.
    - iii. CA Penal Code 3505 states behavioral research shall be limited to studies of the possible causes, effects and processes of incarceration and studies of prisons as institutional structures or of prisoners as incarcerated persons which present minimal or no risk and no more than mere inconvenience to the subjects of the research. Informed consent shall not be required for participation in behavioral research when the California Department of Corrections determines that it would be unnecessary or significantly inhibit the conduct of such research. In the absence of such determination, informed consent shall be required for participation in behavioral research.
    - iv. CA Penal Code 3515 states that in any biomedical or behavioral research, the California Department of Corrections must determine the following:
      1. That the risks to the prisoners consenting to research are outweighed by the sum of benefits to the prisoners and the importance of the knowledge to be gained;

2. That the rights and welfare of the prisoners are adequately protected, including the security of any confidential personal information;
  3. That the procedures for selection of prisoners are equitable and that subjects are not unjustly deprived of the opportunity to participate;
  4. That adequate provisions have been made for compensating research related injury;
  5. That the rate of remuneration is comparable to that received by non-prisoner volunteers in similar research;
  6. That the conduct of the activity will be reviewed at timely intervals; and
  7. That legally effective informed consent will be obtained by adequate and appropriate methods.
- v. CA Penal Code 3521 states that a prisoner shall be deemed to have given their informed consent only if each of the following conditions has been satisfied:
1. Consent is given without duress, coercion, fraud, or undue influence;
  2. The prisoner is informed in writing of the potential risks or benefits, or both, of the proposed research;
  3. The prisoner is informed orally and in writing in the language in which the subject is fluent of each of the following:
    - a. An explanation of the biomedical or behavioral research procedures to be followed and their purposes, including identification of any procedures which are experimental;
    - b. A description of all known attendant discomfort and risks reasonably to be expected;
    - c. A disclosure of any appropriate alternative biomedical or behavioral research procedures that might be advantageous for the subject;
    - d. The nature of the information sought to be gained by the experiment;
    - e. The expected recovery time of the subject after completion of the experiment;
    - f. An offer to answer any inquiries concerning the applicable biomedical or behavioral research procedures; and
    - g. An instruction that the person is free to withdraw their consent and to discontinue participation in the research at any time without prejudice to the subject.
4. CA Penal Code 3522 states that at the time the prisoner is informed in writing of the potential risks or benefits, or both, of the proposed research, they must also be given information as to
- a. the amount of remuneration they will receive for the research, and
  - b. the manner in which the prisoner may obtain prompt treatment for any research-related injuries. The amount of remuneration must be comparable to that which is paid to non-prisoner volunteers in similar research.
- vi. CA Penal Code 3508 states behavioral modification techniques shall be used only if such techniques are medically and socially acceptable means by which to modify

- behavior and if such techniques do not inflict permanent physical or psychological injury.
- vii. CA Penal Code 3509 notes that nothing in this title is intended to diminish the authority of any official or agency to adopt and enforce rules pertaining to prisoners, so long as such rules are not inconsistent with this title.
  - viii. Informed consent shall not be required for participation in behavioral research when the department determines that it would be unnecessary or significantly inhibit the conduct of such research. In the absence of such determination, informed consent shall be required for participation in behavioral research.
  - ix. CA Penal Code 3521 specifies conditions in which informed consent of the prisoner may be satisfied.
  - x. *Clarification: Per University of California Office of the President (UCOP) advice, where "Department" is referenced in CA Penal Code 3515, this does not refer to the IRB. Per UCOP "Department" refers to CDCR.*

- D. Exception to Biomedical Research: In 2016, California amended state regulations (CA Penal Code 3500-3524) to grant an exception to the existing prohibition on biomedical research on prisoners by permitting records-based biomedical research, *using existing information*.** The use or disclosure of individually identifiable records pursuant to this subdivision shall only occur after both of the following requirements have been met:
- 1. The research advisory committee established pursuant to Section 3369.5 of Title 15 of the California Code of Regulations approves of the use or disclosure.
  - 2. The prisoner provides written authorization for the use or disclosure, or the use or disclosure is permitted by Section 164.512 of Title 45 of the Code of Federal Regulations. (Amended by Stats. 2016, Ch. 197, Sec. 2. (SB 1238) Effective January 1, 2017.)
  - 3. See Section IV A above regarding additional approvals.

**V. IRB Review and Approval of Research Involving Prisoners – Department of Health and Human Services Supported Research**

- A. **For any HHS conducted or supported research involving prisoners, the institution(s) engaged in the research must certify to the Secretary (through OHRP) that the IRB reviewed the research and made seven findings as required by the regulations (45 CFR 46.305(c) and 46.306(a)(1)).**
- B. The certification request may be sent to OHRP via email.
- C. OHRP then will 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.
- D. Following its review of the certification, OHRP will send the institution a letter authorizing the involvement of prisoners in the proposed research, if OHRP determines that the research involves one of the permissible categories.
- E. OHRP will consult with appropriate experts with respect to certain research that falls under paragraphs (iii) and (iv) of 45 CFR 46.306(a)(2). When applicable, OHRP (on behalf of the Secretary of HHS) also will publish a notice of intent to approve such research in the Federal Register.
- F. If OHRP determines that the proposed research does not involve one of the permissible categories, it will state in the letter to the institution that such research involving prisoners cannot proceed.
- G. The research cannot start until the IRB has received approval for the research from OHRP.

- H. If an Investigator wishes to engage in non-HHS supported research, certification is not required. However, the IRB should apply the standards of this policy and the Federal regulations in reviewing the research.

**VI. 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:
  - 1. To describe the prevalence or incidence of a disease by identifying all cases; or
  - 2. To study potential risk factor associations for that disease.
- B. The two Subpart C provisions that are waived are:
  - 1. *The requirement that an IRB choose one of the four categories in 45 CFR 46.306(a)(2); and*
  - 2. *The requirement that the Secretary (through OHRP) make the final choice of one of the four categories.*
- C. The institution responsible for the conduct of the research certifies to the Office for Human Research Protections, DHHS, acting on behalf of the Secretary, that
  - 1. The IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and
  - 2. Determined and documented that
    - a) The research presents *no more than minimal risk* and no more than inconvenience to the prisoner-subjects, and
    - b) Prisoners are not a particular focus of the research.

**VII. 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 reporting the event in writing to the IRB upon learning of the event. 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. The participant may stay enrolled.
  - 1. If the incarceration has an effect on the study, and Subpart C review has not yet occurred, proceed as follows:
    - a) Option 1: Consider terminating the enrollment of the participant.
      - (1) The Investigator should consider the risks associated with terminating participation in the study. The Investigator is encouraged to contact the IRB Office to discuss with HRP Staff or the IRB Chair/s.
- C. If the participant cannot be terminated for health or safety reasons:
  - a) Follow requirements for Option 2 (below) or
  - b) Remove the participant from the study and keep the participant on the study intervention under an alternate mechanism such as expanded access. If expanded access applies, follow requirements for Option 2.
  - c) Option 2: Submit a modification to the study requesting that the IRB review the research study under Subpart C for the participant to remain in the study.
- D. If some the requirements of Subpart C cannot be met, but it is in the best interest of the participant to remain in the study, the investigator may keep the participant enrolled and inform the IRB. The IRB will then inform OHRP of the decision along with the justification.
- E. The IRB is to 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.

**VIII. Additional Approvals: Federal Bureau of Prisons**

- 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. When Human Research is conducted with the Federal Bureau of Prisons the organization relies on the Bureau Research Review Board to ensure compliance with 28 CFR 512.

- IX. **Additional Considerations: Department of Defense**
  - A. **The Department of Defense (DoD) does not allow for an expedited IRB review of prisoner research.**
  - B. The DoD prohibits research with Prisoners of War.
  
- X. **Additional Considerations: Outside California**
  - A. If research activities under the jurisdiction of the UCI 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 jurisdictions.** The UCI Protocol Narrative should specify the jurisdictions involved and measures to ensure compliance.
  
- XI. **Additional Considerations: Minors**
  - A. When a prisoner is also a minor (e.g., an adolescent detained in a juvenile detention facility is a prisoner), IRB Policy 36 regarding children in research will also apply.

**References:**

DHHS: [45 CFR 46.111](#)

DOJ: [28 CFR 512](#)

IRB Policy 36, "Vulnerable Populations - Children"

CA Department of Corrections, Prisoners in Biomedical and Behavioral Research, Penal Code 3500-3523

Section 3369.5 of Title 15 of the California Code of Regulations

OHRP Guidance Document: "[OHRP Guidance on Involvement of Prisoners in Research](#)", May 23, 2003

Information on CDCR approval processes can be found in the agency's Operations Manual (Article 19), online at

[https://www.cdcr.ca.gov/Regulations/Adult\\_Operations/docs/DOM/DOM%202019/2019-DOM.pdf](https://www.cdcr.ca.gov/Regulations/Adult_Operations/docs/DOM/DOM%202019/2019-DOM.pdf) and on the agency's website at <https://sites.cdcr.ca.gov/research/>.

<https://oshpd.ca.gov/data-and-reports/data-resources/cphs/>

OHRP "Prisoner Research FAQs": <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/fag/prisoner-research/index.html>

UC Davis Checklist: Prisoners: HRP-415

UCLA Office of the Human Research Protection Program Guidance: Special Subject Populations: Prisoners



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**Procedure Number: 37.A**

**Title: Procedure for Review of Research Involving Prisoners**

**Procedure:**

This procedure outlines the responsibilities as mandated by the Federal regulations when prisoners are involved as participants in research.

**I. Lead Researcher (LR) Responsibilities**

- A. The LR will address the criteria for the inclusion of prisoners with any new study or amendment submission in which prisoners will be a target population for research activities.
- B. If the participant population has an increased potential to become prisoners, and the LR will be interacting, intervening, or collecting identifiable private information during the incarceration, the LR may choose to have the proposal reviewed initially by the IRB and OHRP (if necessary) for prisoner participation.
- C. As soon as they are made aware, the LR must report in writing to the IRB when a participant becomes a prisoner after enrollment in research activities if the research was not reviewed and approved by the IRB and OHRP in accordance with 45 CFR 46 Subpart C. All research interactions and interventions with, and obtaining identifiable private information about, the now incarcerated prisoner-participant must cease until the requirements of Subpart C have been satisfied with respect to the relevant research activities.
- D. The IRB Chairperson may determine that the participant may continue to participate in the research until the requirements of Subpart C are satisfied in special circumstances in which the LR asserts that it is in the best interests of the participant to remain in the research study while incarcerated and the provisions of CA Penal Code 3500-3523 have been met.
- E. The LR is responsible for obtaining and providing documentation of approval from the detention or correctional facility involved (i.e., prisons, jails, workhouses, etc.) to the IRB.
- F. The LR will provide any additional documents or materials required for certification to the Secretary (through OHRP) for HHS supported research involving prisoners. The IRB Office will help support this submission process.
- G. The LR may not screen, recruit, or enroll any individual involuntarily confined or detained in a penal institution without written IRB approval (and certification to the Secretary (through OHRP) for HHS supported research involving prisoners).
- H. For research conducted within the Bureau of Prisons,
  - 1. The research must comply with all the additional DOJ requirements under 28 CFR 512. This includes:
    - i. When submitting a research proposal to the Bureau, the applicant must demonstrate academic preparation or experience in the area of study of the proposed research.
    - ii. The applicant must provide a summary which includes the following information:
      - a) A summary which includes: names and current affiliations of the researchers; title of the study; purpose of the study; location of the study; methods to be employed; anticipated results; duration of the study; number of participants (staff or inmates) required and amount of time required from each.
      - b) Indication of risk or discomfort involved as a result of participation.
      - c) A comprehensive statement, which includes: review of related literature; detailed description of the research method; significance of anticipated results and their contribution to the advancement of knowledge.
      - d) Specific resources required from the Bureau of Prisons.

- e) Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
  - f) Description of steps taken to minimize any risks.
  - g) Description of physical or administrative procedures to be followed to: ensure the security of any individually identifiable data that are being collected for the study; destroy research records or remove individual identifiers from those records when the research has been completed.
  - h) Description of any anticipated effects of the research study on organizational programs and operations.
  - i) Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
  - j) A statement regarding assurances and certification required by 28 CFR 46, if applicable.
- iii. The applicant/researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant or subcontractor to the researcher.

## II. IRB Committee Responsibilities

- A. The IRB Committee (full committee or subcommittee) must review the proposed research taking into consideration all applicable UCI policies and procedures, as well as the additional requirements for prisoners to participate in research as described in 45 CFR 46, Subpart C and CA Penal Code 3500 -3523.
- B. The Committee may not review or make determinations regarding studies involving prisoners as a target population unless the Committee has a member who is a prisoner or a prisoner representative with a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner. Documentation of expertise is provided by the curriculum vitae of the prisoner or prisoner representative serving on the IRB. *See Section III for Prisoner Representative Responsibilities.*
- C. The IRB Committee will review the proposed research, consents, and applicable documents to determine whether the study meets criteria 45 CFR 46.111 for approval. Written documentation of these criteria is detailed in the final IRB approved version of the IRB application.
- D. In addition, the IRB will discuss the additional protections necessary for this population as outlined in the federal regulations, Subpart C and State requirements.
- E. When a research participant becomes a prisoner, and the IRB has not previously reviewed the proposal for prisoner populations, the IRB will conduct a review of the research proposal in accordance with Subpart C and make one of the following determinations:
  - 1. If a participant becomes a prisoner after enrolling in a research study, the Investigator is responsible for immediately reporting the event (upon learning of the event) in writing to the IRB. This is not required if the study was previously approved by the IRB for prisoner participation.
  - 2. See Policy 37, Section VII above.
- F. For categories 45 CFR 46.306 (iii) and (iv) (regardless of funding): Research may not begin until DHHS has been notified and has performed their consultation with applicable experts. The IRB Office will help to facilitate this notification and process.
- G. For HHS supported research, the institution must certify to the Secretary (through OHRP) that the IRB designated under its assurance of compliance has made the seven findings required under 45 CFR 46.305(a) and a statement indicating that the IRB chose one of the four permissible categories of research in 45 CFR 46.306(a)(2).
  - 1. In addition to the prisoner certification letter, the following information must also be sent to OHRP:

- i. The IRB application (which includes the protocol narrative and any IRB submission materials including the ICDs); and
  - ii. The grant application (including any grant award updates).
  - iii. IRB Teams may refer to the internal share folder for examples of prior certifications: (\\ad.uci.edu\uci\OR\RA\Files\RP\IRB\Common Files -- IRB\HHS Prisoner Certification)
- H. The IRB may approve the research for non-prisoner populations if all the criteria in Subpart C are satisfied. **UCI prisoner research cannot start until the IRB has received approval for the research from OHRP.**
- I. The IRB must inform the LR in writing that no prisoner-subjects can be enrolled or involved until the IRB/institution receives the approval letter from OHRP.
  - 1. The OHRP approval letter will acknowledge receipt of the prisoner certification and indicates the Secretary's (through OHRP) determination/approval that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2).
  - 2. The OHRP approval letter will be provided to the LR and maintained in IRB records.

### III. **Prisoner Representative Responsibilities**

For research involving prisoners reviewed by full committee or subcommittee:

- A. The IRB must include a prisoner or prisoner representative.
- B. The prisoner representative must be a voting member of the IRB. The prisoner representative may be listed as an alternative member who becomes a voting member as needed.
- C. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C.
- D. The prisoner representative must receive all review materials pertaining to the research (same documents as the primary reviewer).
- E. *At full committee (convened IRB):*
  - 1. The prisoner representative must be present at the full committee when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
  - 2. The prisoner representative may attend the meeting by phone, video-conference or webinar, as long as the representative is able to participate in the meeting.
  - 3. The prisoner representative must present his / her review either orally or in writing at the full committee.

### IV. **IRB Administrator Responsibilities**

- A. The Administrator will verify that all requisite sections of the IRB application have been completed by the LR as part of the initial or amended study documents.
- B. The Administrator will conduct a pre-review and take into consideration the requirements under 45 CFR 46, Subpart C and CA Penal Code 3500 -3523, under which prisoners may participate in human participants research.
- C. The Administrator will e-mail the LR with any questions or needed clarification in regard to the prisoner population.
- D. The Administrator will verify that the IRB Member/ Full Committee reviewing the research involving a prisoner includes at least one member who is a prisoner or prisoner representative.
- E. To adequately document the IRB review of the research:
  - 1. The curriculum vitae of the prisoner or prisoner representative serving on the IRB will be on file in the IRB;
  - 2. and
  - 3. The discussion and determinations of the IRB regarding findings required per federal and state regulations and noted in Policy 37 Sections III, IV, V above.
- F. For HHS supported research, the Administrator will assist in preparing documents for the certification letter and prepare a draft certification letter to the

Secretary (through OHRP) which will be signed by the appropriate institutional official listed on UCI's FWA.

**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.

California Committee for the Protection of Human Subjects

**Table 1. Federal Requirements for Prisoner Research<sup>3</sup>**

45CFR 46.305 (a)(1)	45 CFR 46.305 (a)(2)	45 CFR 46.305 (a)(3)	45 CFR 46.305 (a)(4)	45 CFR 46.305 (a)(5)	45 CFR 46.305 (a)(6)	45 CFR 46.305 (a)(7)
<p>The research under review represents <b>one of the four following categories of research permissible</b> under <a href="#">45 CFR 46.306(a)(2)</a> which are as follows:</p> <ul style="list-style-type: none"> <li>i. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents <i>no more than minimal risk</i> and no more than inconvenience to the subjects;</li> <li>ii. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents <i>no more than minimal risk</i> and no more than inconvenience to the subjects;</li> <li>iii. Research on conditions particularly affecting prisoners as a class (for example, 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) provided that <i>the study may proceed only after the Secretary 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</i></li> <li>iv. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. <i>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 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.</i></li> </ul>	<p>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;</p>	<p>The risks involved in the research are commensurate with risks that would be accepted by non prisoner volunteers;</p>	<p>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;</p>	<p>The information is presented in language which is understandable to the subject population;</p>	<p>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</p>	<p>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.</p>

<sup>3</sup> See Policy 37, Section VI for additional considerations for epidemiologic research. Also: Research that meets the criteria described in an HHS Secretarial waiver that applies to certain epidemiological research ([68 FR 36929, June 20, 2003 \(PDF\) - PDF](#)).