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

Definitions:

Policy:  
It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to review and approve all research involving prisoners with additional ethical and regulatory considerations applicable to prisoners under 45 CFR 46, Subpart C, “Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.”

I. IRB Review and Approval of Research Involving Prisoners  
Prisoners are considered vulnerable because their autonomy is limited and consideration of involving them as research subjects is particularly important. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners. Therefore, if a protocol involves the use of prisoners as subjects, both the general IRB policies and procedures apply and the additional ones outlined in this policy. The IRB may approve research involving prisoners only if these special provisions are met.

A. Research involving prisoners as participants must be reviewed and approved by both UCI IRB policies and procedures, and additional considerations for prisoners as determined by Federal, State, County, and local regulations.

B. California Penal Code 3502 prohibits biomedical research involving prisoners. Biomedical research is defined by CA law as, “research relating to or involving biological, medical or physical science.”

1. In 2016, CA state regulations (CA Penal Code 3500-3524) were amended to grant an exception to the existing prohibition on biomedical research on prisoners by permitting records-based biomedical research, using existing information.

2. Specifically, the regulations say the following:
   a) Biomedical research shall not be conducted on any prisoner in this state.
   b) Notwithstanding subdivision (a), records-based biomedical research using existing information, without prospective interaction with human subjects, may be conducted consistent with this title. 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.)
With this change, the California Department of Corrections and Rehabilitation (CDCR) has to approve the research if the research involves state (as opposed to county or local) prisoners.

i. Note: The Operations Manual states that specifically excluded from the definition of behavioral research is the accumulation of statistical data in the assessment of the effectiveness of programs to which inmates are routinely assigned such as, but not limited to, education, vocational training, productive work, counseling, recognized therapies, and programs which are not experimental in nature.

C. For research involving prisoners, the definition of minimal risk differs from the definition of minimal risk in the 2018 Common Rule.

1. 2018 Common Rule Definition: 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.

2. Subpart C (Prisoner) Definition: 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.

D. 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.

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

1. 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:
   a) 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;
   b) 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;
   c) 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) provided that 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
   d) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. 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 (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.
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 prisoner 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 participants 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 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;
5. The information is presented in language which is understandable to the participant 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 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.

II. 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. When the research is conducted or sponsored by DHHS, the institution responsible for the conduct of the research must certify in writing to the OHRP:
   1. The IRB approved the research and fulfilled its duties under 45 CFR §46.305(a)(2)–(7) and determined and documented that:
      a) The research presents no more than minimal risk and no more than inconvenience to the prisoner-participants.
      b) Prisoners are not a particular focus of the research.
D. For DHHS-funded research involving prisoners, the research cannot start until the IRB has received approval for the research from OHRP.
III. **Composition of IRB when Prisoners are Involved in Research**

A. If an IRB regularly reviews research that involves prisoners, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these participants.

B. 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.

   a) 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.

C. As a result of Section B above, the overall composition of the IRB Committee might need to change if a number of individuals are associated with the prison or if a prisoner or prison representative is added.

D. The IRB must meet the special composition requirements for all types of review for the protocol: initial review, continuing review, review of a significant modification, review of reports of unanticipated problems involving risk to participants or others, or in the event an individual becomes a prisoner while participating in a research protocol.

IV. **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 or if the participant is temporarily incarcerated while enrolled in the study, IRB review and approval under Subpart C is not required if the temporary incarceration has no effect on the study, keep the participant enrolled.

   1. If the temporary incarceration has an effect on the study, handle as outlined below.

C. If the study was not previously reviewed and approved by the IRB in accordance with the requirements of Subpart C, terminate enrollment or review the research study under Subpart C if it feasible for the participant to remain in the study.

D. Before terminating the enrollment of the incarcerated participant the IRB should consider the risks associated with terminating participation in the study.

E. The full, convened IRB Committee 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.

F. If the participant cannot be terminated for health or safety reasons:

   1. Keep the participant enrolled in the study and review the research under Subpart C.

      a) 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, keep the participant enrolled and inform OHRP of the decision along with the justification.
2. Remove the participant from the study and keep the participant on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.

G. Consistent with California Penal Code 3502.5, access to an investigational drug or treatment may be provided by a physician who provides medical care to prisoners only through a treatment protocol or treatment IND if the physician determines that access to that drug is in the best medical interest of the patient and the prisoner has provided informed consent.

V. 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 (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 (through OHRP) must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2).

B. The research cannot start until the IRB has received approval for the research from OHRP.

C. If either of the following are true, the research should proceed only after the IRB has consulted with the appropriate experts, as determined by the IRB:
   1. The research involves conditions particularly affecting prisoners as a class as explained in Section I.E.1.c above; or
   2. The research does not satisfy the stipulations at Section I.E.1 above.

VI. Additional Approvals
A. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the organization relies on the Bureau Research Review Board to ensure compliance with 28 CFR 512;
   1. The project must not involve medical experimentation, cosmetic research or pharmaceutical testing.
   2. 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.
   3. 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.
   4. All research proposals will be reviewed by the Bureau Research Review Board.

B. 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. Pertinent restrictions are as follows:
   1. The researcher shall prepare reports of progress on the research and at least one report of findings.
   2. 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.
   3. 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.
4. A researcher may publish in book form and professional journals the results of any
research project conducted under this subpart.
5. In any publication of results, the researcher shall acknowledge the Bureau's
participation in the research project.
6. The researcher shall expressly disclaim approval or endorsement of the published
material as an expression of the policies or views of the Bureau.
7. 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. The provisions under this Penal Code specify
additional requirements for prospective researchers to obtain conduct research within the
California penal system.

VII. Additional Considerations
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.
B. The full, 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. Per the 2018 Common Rule, 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)].

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
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
and on the agency’s website at https://sites.cdcr.ca.gov/research/.
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 submit the “Vulnerable Populations: Prisoners” (Appendix C) with any new study submission in which prisoners will be a target population for research activities. 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 for prisoner participation.

B. The Investigator must report in writing to the IRB immediately 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, the Investigator must notify the IRB in writing of the event. 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.

C. The IRB Chairperson may determine that the subject 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 subject to remain in the research study while incarcerated and the provisions of CA Penal Code 3500 -3523 have been met.

D. Lead Researchers are responsible for obtaining and providing documentation of approval from the detention or correctional facility involved (i.e., prisons, jails, workhouses, etc.) to the IRB.

E. The LR will provide any additional documents or materials required for certification to the Secretary (through OHRP) for federally funded research involving prisoners.

F. The LR may not screen, recruit, or enroll any individual involuntarily confined or detained in a penal institution without written IRB approval. If the biomedical or behavioral research is conducted or supported by HHS, it also requires review and written approval by the Secretary (through OHRP) before any research activities may begin, including screening and enrollment.

G. For research conducted within the Bureau of Prisons,

1. The research must comply with all the additional DOJ requirements under 28 CFR 812, including:
   a) 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.
   b) The applicant must provide a summary which includes the following information:
      (1) 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.
      (2) Indication of risk or discomfort involved as a result of participation.
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.

Specific resources required from the Bureau of Prisons.

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.

Description of steps taken to minimize any risks.

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.

Description of any anticipated effects of the research study on organizational programs and operations.

Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

A statement regarding assurances and certification required by 28 CFR 46, if applicable.

c) 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 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 and 21 CFR 56.111 for approval. In order to provide written documentation of these criteria, the Primary and Secondary Reviewers must complete the “IRB Reviewer’s Checklist” detailing how each of these criteria is met. In addition, the IRB will discuss the additional protections necessary for this population as outlined in the federal regulations, Subpart C and Appendix C, with the latter being completed by the LR. Should the IRB not agree with the version of Appendix C as submitted, the IRB must require the LR to revise Appendix C as per the final IRB determination per subpart C.

D. For research involving interaction with prisoners reviewed by the expedited procedure:

1. Research involving interaction with prisoners may be reviewed by the expedited review process, if a determination is made by the convened IRB that the research involves no greater than minimal risk for the prison population being studied.

2. The prisoner representative must concur with the determination that the research involves no greater than minimal risk.

3. The prisoner representative must review the research as a reviewer, designated by the chair, or consultant. This may be the sole reviewer or in addition to another reviewer, as appropriate.
4. Review of modification and continuing review must use the same procedures for initial review using this expedited procedure including the responsibility of the prisoner representative.

E. For research that does not involve interaction with prisoners (e.g. existing data, record review) reviewed by the expedited procedure:
   1. Research that does not involve interaction with prisoners may be reviewed by the expedited procedure, if a determination is made by the convened IRB that the research involves no greater than minimal risk for the prison population being studied (one exception is allowed – see item “F” below).
   2. Review by a prisoner representative is not required.
   3. The prisoner representative may review the research as a reviewer or consultant if designated by the IRB Chair.
   4. Review of modifications and continuing review must use the same procedures as initial review.

F. Research involving the use of the California Department of Corrections and Rehabilitation (CDCR) database allows for the identity of subjects to be disclosed. As there is no direct interaction or intervention with prisoners, if researchers agree to redact identifiers or double code the data, the study poses minimal risk to subjects and may be initially reviewed at subcommittee level.
   a) If researchers will not redact identifiers or double code the data, the study must be initially reviewed at full committee (a convened meeting).

G. Minor modifications to research may be reviewed using the expedited procedure described above, based on the types of modification (i.e., involving interaction or no interaction with prisoners).

H. Significant Modifications reviewed by the convened IRB must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting. See Section III for Prisoner Representative Responsibilities.

I. Continuing review involves the same procedures for initial review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting. See Section III for Prisoner Representative Responsibilities.
   1. If no participants have been enrolled and no additional risks have been identified, the research may receive continuing review using the expedited procedure under expedited category # 8b.

J. 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 in writing to the IRB. This is not required if the study was previously approved by the IRB for prisoner participation.
   2. If research interactions and interventions or obtaining identifiable private information will not occur during the incarceration or if the participant is temporarily incarcerated while enrolled in the study, IRB review and approval under Subpart C is not required if the temporary incarceration has no effect on the study, keep the participant enrolled.
      a) If the temporary incarceration has an effect on the study, handle as outlined in Policy 37, Section IV.

K. For DHHS 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. It is sufficient to include a statement that indicates that the IRB made the required findings under 45 CFR 46.305(a). OHRP does not require that the prisoner letter include a specific listing or rationale behind the IRB findings. The institution may wish to include a brief, protocol-specific explanation of the IRB’s rationale for each finding.

2. The institution must indicate in the certification letter which of the four categories of permissible research involving prisoners in 45 CFR 46.306(a)(2) is applicable to the proposed research. Research involving prisoners can proceed only if the research fits under a category of permitted research under 45 CFR 46.306(a)(2). OHRP will make its own determination, based on the information in the prisoner certification letter, the protocol materials and the grant application as to whether any of the four categories apply to the proposed research. OHRP may or may not concur with the IRB’s choice of category.

3. The institution may wish to include a statement that indicates that the IRB was constituted as per the requirements in 45 CFR 46.304. OHRP does not require that the prisoner certification letter include information about the manner in which the IRB fulfills the requirements of 45 CFR 46.304. The institution may wish to provide the name of the prisoner representative.

4. In addition to the prisoner certification letter, the following information must also be sent to OHRP:
   a) The IRB application (which includes the protocol narrative and any IRB submission materials including the ICDs); and
   b) The grant application (including any grant award updates).

5. OHRP encourages the inclusion of the following information with the prisoner certification letter:
   a) OHRP Assurance #;
   b) IRB # for Designated IRB;
   c) Site(s) where research involving prisoners will be conducted;
   d) If prisoner research site is “engaged in research”, provide OHRP Assurance #;
   e) DHHS Grant Award #;
   f) DHHS Funding Agency Name;
   g) Funding Agency Grants/Program Officer Name and Telephone #;
   h) Title of DHHS Grant;
   i) Title of Protocol (if the same as the title of the grant, indicate as such);
   j) Version date of the ICD to be used with prisoners;
   k) Date(s) of IRB Meeting(s) in which the protocol was considered and provide a chronology of:
      (1) Date of initial IRB review; and/or
      (2) Date of Subpart C reviews including:
         (a) Type of IRB review (initial, amendment, addendum, continuing review); and
         (b) Special IRB review for prisoner issues.
   l) Principal Investigator; and
   m) Reason for IRB review (choose the applicable reasons):
      (1) Non-prison study (not previously reviewed and certified under Subpart C) in which participant has become incarcerated (or otherwise fits the definition of prisoner in 45 CFR 46.303(c)) and the PI wishes to continue the individual’s participation in the study;
      (2) Non-prison study with at-risk population (i.e., probationers, substance abusers);
      (3) Non-prison study, majority of study population are non-prisoners but PI seeks to enroll some prisoners (as defined in 45 CFR 46.303(c));
(4) Minimal risk DHHS conducted or supported epidemiologic research, majority of study population are non-prisoners but PI seeks to enroll some prisoners (prisoners are not the focus of the study) and the sole purpose of the study is either:
   (a) To describe the prevalence or incidence of a disease by identifying all cases; or
   (b) To study potential risk factor associations for a disease.
(5) Initial Subpart C review of study designed to be conducted in a prison or using prisoners as defined in 45 CFR 46.303(c), the PI seeks to enroll already incarcerated subjects.

6. It would be helpful (but not required) if the prisoner certification letter contained the following information:
   a) Justification for the use of prisoners in the study. If applicable, delineate the protocol to be conducted in the prison from the overall project described in the grant application;
   b) Study objectives or study aims;
   c) Brief summary of study procedures;
   d) Customary treatment or services at the prison (or alternative to incarceration) research site(s) for the condition being studied;
   e) Description of how risks specific to a prison (or alternative to incarceration) setting are minimized;
   f) Whether the prison site(s) are “engaged in research” and whether they have obtained an assurance with OHRP;
   g) Whether a Certificate of Confidentiality will be obtained by the PI for the study;
   h) Describe recruitment procedures in the specific prison (or alternative to incarceration) setting; and/or
   i) Describe how the consent form was altered for use with a prison population or specific prisoner and whether the subsequently incarcerated participant will be reconsented.
   j) All prisoner research certification letters should be mailed to:
      OHRP Prisoner Research Coordinator
      Office for Human Research Protections (OHRP)
      Department of Health and Human Services
      The Tower Building
      1101 Wootton Parkway, Suite 200
      Rockville, MD 20852

L. The IRB Committee may approve the research for non-prisoner populations until all the criteria in Subpart C are satisfied.
M. The IRB must inform the LR in writing that no prisoner-subjects can be enrolled or involved until the IRB/institution receives a letter from OHRP that acknowledges 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).

III. **Prisoner Representative Responsibilities**
For research involving prisoners reviewed by the convened IRB:
A. 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.
B. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C.
C. The prisoner representative must receive all review materials pertaining to the research (same documents as the primary reviewer).

D. The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
   1. 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 as if they were present in person at the meeting.

E. The prisoner representative must present his / her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.

IV. IRB Administrator Responsibilities

A. The Administrator will verify that the “Vulnerable Populations – Prisoners” (Appendix C) is completed by the LR as part of the initial 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 subjects 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 Committee reviewing the research involving a prisoner has at least one member who is a prisoner or prisoner representative in attendance.

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. The “Supplemental Reviewer's Checklist for Prisoners" will be placed in the IRB file; and
   3. The discussion and determinations of the IRB regarding the seven additional findings required under HHS regulations at 45 CFR 46.305(a) will be documented in the minutes.

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:
DHHS 45 CFR 46.111 and Subpart C
28 CFR 512
CA Penal Code 3500 -3523