**Guidance: Prisoner Research**

INTRODUCTION

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.

DEFINITIONS

**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.[[1]](#footnote-2)

[**45 CFR 46.303 (HHS – Subpart C)**](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46)**: 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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.303)). 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.
	1. 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.
	1. 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.
	1. 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.

LEVEL OF REVIEW

**Full Committee Review[[2]](#footnote-3):** 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). 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.

The IRB member(s) reviewing the research must include a prisoner or a prisoner representative.

For categories 45 CFR 46.306 (iii) and (iv), full committee review is always required, along with DHHS consultation.

**Subcommittee / Expedited Review:** 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***.***

Again, the IRB member reviewing the research must include a prisoner or a prisoner representative.

**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)].

IRB COMPOSITION

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:

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.

IRB REVIEW CONSIDERATIONS

**Federal Criteria:** The UCI IRB will review all research involving the targeted enrollment of prisoners with additional ethical and regulatory considerations applicable to prisoners under 45 CFR 46, Subpart 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**.

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

**California Criteria:** The California Department of Corrections and Rehabilitation (CDCR) must approve research involving state prisoners.Note that county or local jails may detain state prisoners. It is the Principal Investigator’s (PI) responsibility to identify and meet these and other related CDCR requirements.

* [CDCR Link](https://www.cdcr.ca.gov/research/research-requests/)

**The 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 delating to birth and death certificated from the California Department of Public Health.) It is the PI’s responsibility to identify and meet these and other related CPHS requirements.

* [CPHS Link](https://www.chhs.ca.gov/cphs/)

**Researchers must *also* comply with the additional limitations and requirements in** [**California Penal Code Sections 3501 – 3523**](https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=PEN&division=&title=2.1.&part=3.&chapter=&article=)**.** It is the PI’s responsibility to identify and meet CA penal code requirements, as applicable, and document these requirements within in the UCI IRB submission.

Notable California Considerations:

1. 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.[[3]](#footnote-4)
2. 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.
3. **Department of Health and Human Services Supported Research (DHHS):** For any DHHS conducted or supported research involving prisoners, the institution(s) engaged in the research must certify to the Secretary (through the Office of Human Research Protections (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)). OHRP then will determine whether the proposed research involves one of the categories of research permissible under [45 CFR 46.306(a)(2)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.306), and if so which one. The research cannot start until the IRB has received approval for the research from OHRP.

**Waiver of the Applicability of Certain Provisions of DHHS Regulations for the Protection of Human Subjects for DHHS Epidemiologic Research Involving Prisoners as Subjects:** 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.

The two [Subpart C](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html) 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.

**When a Current Research Participant Becomes a Prisoner:** If a participant becomes a prisoner after enrolling in a research study, the PI 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.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.

If the incarceration has an effect on the study, and Subpart C review has not yet occurred, proceed as follows:

1. Consider terminating the enrollment of the participant. The PI 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.
2. If the participant cannot be terminated for health or safety reasons: 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 *or*
3. 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 # 2.

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.

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.

**Additional Approvals: Federal Bureau of Prisons:** The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau of

Prisons under [28 CFR 512.](https://www.ecfr.gov/current/title-28/chapter-V/subchapter-A/part-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.

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.

**Additional Considerations: Department of Defense**

The Department of Defense (DoD) does not allow for an expedited IRB review of prisoner research.

The DoD prohibits research with Prisoners of War.

**Additional Considerations: Outside California**

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.

**Additional Considerations: Minors**

When a prisoner is also a minor (e.g., an adolescent detained in a juvenile detention facility is a prisoner), DHHS [Subpart D](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html) / [FDA Subpart D](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-D) will also apply.

**References:**
DHHS: [45 CFR 46.111](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.111)

DOJ: [28 CFR 512](https://www.ecfr.gov/current/title-28/chapter-V/subchapter-A/part-512)

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](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/prisoner-research-ohrp-guidance-2003/index.html)”, 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> 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/faq/prisoner-research/index.html>

UC Davis Checklist: Prisoners: HRP-415

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

**Table 1. Federal Requirements for Prisoner Research[[4]](#footnote-5)**

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| --- | --- | --- | --- | --- | --- | --- |
| 1. **CFR 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)** |
| The research under review represents **one of the four following categories of research permissible** under [45 CFR 46.306(a)(2)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1306) which are as follows:Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents *no more than minimal risk* and no more than inconvenience to the subjects; Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents *no more than minimal risk* and no more than inconvenience to the subjects;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 *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*Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. *In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary 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.* | 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; | The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers; | 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; | The information is presented in language which is understandable to the subject population; | 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 | 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. |

1. 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. [↑](#footnote-ref-2)
2. 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. [↑](#footnote-ref-3)
3. 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*. Additional requirements apply. [↑](#footnote-ref-4)
4. 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](http://www.gpo.gov/fdsys/pkg/FR-2003-06-20/pdf/03-15580.pdf)). [↑](#footnote-ref-5)