Human Research Protections (HRP) strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the ZOT IRB application process, email [OR-Web-Support@uci.edu](mailto:OR-Web-Support@uci.edu) for assistance.

INSTRUCTIONS

This information is necessary for the IRB to determine if the criteria for approval at [45 CFR Part 46 Subpart C](https://www.ecfr.gov/current/title-45/part-46/subpart-C), and [21 CFR 56.111(b)](https://​/​www.ecfr.gov/​current/​title-21/​part-56/​section-56.111#p-56.111(b)) (as applicable) are satisfied for [prisoners](https://www.ecfr.gov/current/title-45/part-46/subpart-C). For more information, visit: [Vulnerable Populations](https://research.uci.edu/human-research-protections/subject-enrollment/vulnerable-populations/).

Answer all questions succinctly using non-technical language as much as possible.

* If a question is a numbered list, respond with a corresponding numbered list.
* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

1. STUDY INFORMATION

**Short Title:** Specify the short study title.

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| Click or tap here to enter text. |

2. INCLUSION OF PRISONERS

[**Prisoners**](https://www.ecfr.gov/current/title-45/part-46/subpart-C)**:** Describe how the target population meets **the definition of prisoners**.

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[**Minimal Risk**](https://www.ecfr.gov/current/title-45/part-46/section-46.303#p-46.303(d))**:** Describe how the research **meets the definition of minimal risk for prisoners**.

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| Click or tap here to enter text. |

**Inconvenience to Participants:** Describe how the research will pose no more than inconvenience to the subject.

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| Click or tap here to enter text. |

3. STATE REQUIREMENTS

**CALIFORNIA**

**Assurance:** Provide assurance that the following are true. Select all that apply.

Study team will identify and comply with the applicable requirements for conducting research involving prisoners within California. This includes a prohibition of biomedical research, with limited exceptions.

Study team will identify and comply with [California Department of Corrections and Rehabilitation](https://www.cdcr.ca.gov/research/research-requests/) (CDCR) requirements for research involving state prisoners. Note that county or local jails may detain state prisoners.

Study team will identify and comply with [Committee for the Protection of Human Subjects (CPHS**)**](https://oshpd.ca.gov/data-and-reports/data-resources/cphs/) requirements for research involving state prisoners. Note that CPHS approval is required to review all research requests for state personal information to the University of California and non-profit educational institutions. CPHS must also approve research requests for birth and death data from the California Department of Public Health.

Study team will identify and comply with [California Penal Code 3500-3524](https://leginfo.legislature.ca.gov/faces/codes_displayexpandedbranch.xhtml?tocCode=PEN&division=&title=2.1.&part=3.&chapter=&article=) requirements for research involving state prisoners.

**Type of Research:** Specify whether the research is biomedical or social-behavioral in nature (see [Code 3500](javascript:submitCodesValues('3500.','6.4.1','2016','197','1',%20'id_76e0db79-c636-11e6-a742-84f150336b2e'))) and provide protocol specific justification.

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**Informed Consent:** Informed consent Is not 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 is required for participation in behavioral research ([CA Penal Code 3505](https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=3505.&lawCode=PEN)).Specify the consent process.

Obtain consent using a consent document and process compliant with [CA Penal Code 3521](https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=3521.&lawCode=PEN)

Waiver or alteration of consent

**OUTSIDE CALIFORNIA**

**Assurance:** Provide assurance that the following is true.

Study team will identify and comply with the applicable requirements for conducting research involving prisoners outside California.

4. PERMITTED RESEARCH

[**45 CFR 46.306**](https://www.ecfr.gov/current/title-45/section-46.306)**: Permitted Research Involving Prisoners.**

**Category: Select the description that applies and** address the required action, as applicable.

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|  | **Category of Research** | **Required Action** |
| ​​☐​ | **46.306(a)(2)(i):** Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study is no more than minimal risk and no more than inconvenience to the participants. | N/A |
| ​​☐​ | **46.306(a)(2)(ii):** Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study is no more than minimal risk and no more than inconvenience to the participants. | N/A |
| ​​☐​ | **46.306(a)(2)(iii):** Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and 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). | 1. Explain the condition/s that will be studies and provide the rationale. 2. The study may proceed only after the DHHS 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. |
| ​​☐​ | **46.306(a)(2)(iv):** Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. | 1. Explain the research practices used in this study and how they are intended to improve the health and well-being of the subjects. 2. In cases in which those studies required 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 [of the DHHS] 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. |
| ​​☐​ | **Epidemiological research conducted or supported by HHS:** Epidemiological research, that has as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. The study must post no more than minimal risk and present no more than an inconvenience to prisoner participants; prisoners must not be a specific focus of the research. | 1. Describe the epidemiologic research. 2. Specify the type of epidemiologic research:   ☐​ To describe the prevalence or incidence of a disease by identifying all cases  ☐​ To study potential risk factor associations for a disease that the research meets this category |

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**Justification:** Provide protocol specific justification to support the above selection.

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| Click or tap here to enter text. |

**\*Control group:** If the study includes a prisoner control group that may not benefit from the research address the following:

1. Provide justification for the study design including a control group that may not benefit from the research.
2. Specify if control participants are selected randomly from the group of available prisoners who meet the characteristics needed for this study.
   1. If the participants for the control group in this study *are not selected randomly*, provide justification for the proposed selection of control participants.

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5. CONDITIONS REQUIRED FOR IRB APPROVAL

[**45 CFR 46.305**](https://www.ecfr.gov/current/title-45/section-46.305)**: Research must meet the following conditions for IRB approval.**

**Assurance:** Provide assurance that all the following are true.

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 participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

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

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.

**Follow-Up:** If follow-up examination or care of prisoners after their participation has ended, appropriate, describe the provisions that have been made for consider the varying lengths of their sentences and how they will be informed.

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