



RESEARCH INVOLVING PRISONERS

Definitions

Subpart C: This term refers to the regulations which apply to research involving prisoners as subjects. Subpart C is found in 45 CFR 46 (DHHS).

Prisoner: A *prisoner* means any individual involuntarily confined or detained in a penal institution, including individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of status or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This includes situations where a human participant becomes a prisoner after the research has commenced.

Minimal Risk: *Minimal risk* as it applies to the IRB's review of research involving prisoners 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.

Description

The IRB reviews all research involving prisoners using the expertise of a prisoner representative (with no association to the prison involved in the research) and who is a member of the IRB. New study submissions indicating prisoners as potential research participants are reviewed by the convened IRB and cannot be reviewed under expedited procedures. Subsequent review of amendment and continuing review applications may also be reviewed by a convened board, but expedited review procedures may be allowed. Expedited review procedures for continuing review applications will be conducted by a prisoner representative of the IRB. If a study wishes to enroll prisoners after initial review and approval is received, an amendment must be submitted and reviewed by the convened IRB.

Allowable Categories of Prisoner Research

The IRB may approve studies involving prisoners only if the research falls into one of the following categories:

1. The research proposes to study the possible causes, effects, and processes of incarceration, and of criminal behavior. The study must be no more than minimal risk and no more than inconvenience to the participants. [45 CFR 46.306(a)(2)(i)]
2. The research proposes to study prisons as institutional structures or to study prisoners as incarcerated persons. The study must be no more than minimal risk and no more than inconvenience to the participants. [45 CFR 46.306(a)(2)(ii)]
3. The research proposes to study the conditions particularly affecting prisoners as a class. (For example: A vaccine trial and other research on hepatitis, which is much more prevalent in prisons than elsewhere or research on social and psychological problems such as alcoholism, drug addiction and sexual assaults.) Studies that fit into this category may only proceed after the Secretary of the Department of Health and Human Services has consulted with appropriate experts in penology medicine and ethics. The Secretary must also publish notice in the Federal Register of his/her intent to approve the research. [45 CFR 46.306(a)(2)(iii)]
4. The research proposes to study the practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participants. The study may be designed for prisoners only or may have the option to include prisoners. In studies where prisoners may be assigned to a control group and may not benefit from the research, the study may not be approved for the inclusion of prisoners until the Secretary of the Department of Health and Human Services has consulted with appropriate experts in penology medicine and ethics. The Secretary must also publish notice in the Federal Register of his/her intent to approve the research. [45 CFR 46.306(a)(2)(iv)]
5. Epidemiologic studies when the research proposes to study the prevalence or incidence of a disease by identifying all cases or to study the potential risk factors associations for disease. The study must be no more

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than minimal risk, no more than an inconvenience to the participants, and prisoners cannot be the particular focus of the study. [Federal Register, Vol. 68, No. 119, pp. 36929-36931, Friday, June 20, 2003]

NOTE: Research proposals in categories 3(iii) or 4(iv) that are not conducted or supported by DHHS do not require a Secretarial consultation, nor do they require certification to the Office for Human Research Protections (OHRP) that the approval criteria for prisoner research are met (see below for approval criteria for prisoner research).

Approval Criteria for Prisoner Research

The University of Utah IRB must consider the general criteria for IRB approval for all studies, including those that involve prisoners. Additionally, the University of Utah IRB must consider the following specific protections when research involves prisoners regardless of funding or regulatory oversight. [45 CFR 46.305(a)]

1. The research must fall into one of the allowable categories of prisoner research (see above).
2. To avoid coercion when recruiting and enrolling prisoners for research, participants must not be presented with possible advantages to participation that would be greater in magnitude than the normal limited-choice environment of the prison. For example, the participants should not be presented with better living conditions, medical care, quality of food, amenities, and opportunities for earnings than is normal provided in the prison environment.
3. The risks of participating in the research must not be greater than the risks that would be accepted by non-prisoner volunteers within the context of the study.
4. Selection procedures for enrolling must be fair to all prisoners. Selection of participants must not be subject to arbitrary intervention by prison authority or other prisoners. If the study proposes the use of a control group, control subjects must be selected randomly from the group of eligible prisoners, unless the investigator provides the IRB with sufficient justification in writing for following some other procedures.
5. As with any study, the information given to participants verbally or via the consent document must be presented in a language that is appropriate for the prisoner population, allowing for an adequate response to questions and concerns and giving the participants the ability to provide informed consent.
6. There must also be adequate assurance that parole board(s) will not take into account a prisoner's participation in research when making decisions regarding parole. Each prisoner must be clearly informed in advance that participation in the research will have no effect on his/her parole.
7. If there is a need for a follow-up examination or further care of the participants after the end of their participation in the research, the investigator must make adequate provision for such examination or care. In determining these provisions, the investigator should take into account the varying lengths of prisoner sentences. Participants should be informed of these provisions.

NOTE: There may be circumstances under which not all of the criteria listed here applies. The IRB assesses and documents non-applicability accordingly.

When Participants become Prisoners after Enrollment in Research

If a participant becomes a prisoner after enrollment in research, the investigator is responsible for reporting this information to the IRB promptly via a Report of Information in the ERICA system. To include the incarcerated participant in the research, the investigator must submit an amendment to add prisoners as a participant population.

All research interactions and interventions with the incarcerated participant, including the collection of identifiable private information, must cease until the convened IRB has determined that research can be conducted on this population. In special circumstances in which the investigator asserts that it is in the best interest of the participant to remain in the research study while incarcerated, the IRB Chairperson (or designee) may determine that the subject may continue to participate in the research until the convened board determination is officially made.

If the study is being conducted or funded by DHHS, Subpart C must be assessed. If the requirements of Subpart C cannot be satisfied, though inclusion in the research is in the best interest of the incarcerated participant (e.g., no acceptable, alternative treatments exist), the IRB may determine that the subject may continue to participate in the research, and OHRP

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must be informed of this decision and justification. If the incarceration is temporary and has no impact on the study procedures, the participant may remain enrolled.

In all cases, the research will be referred to the soonest available convened IRB where a prisoner representative is present. The IRB may require that the prisoner be consented via a consent form that addresses specific concerns related to the prisoner population. The prisoner consent should be submitted with the amendment to add the prisoner population and should address the approval criteria listed above.

NOTE: This is an example of a circumstance when the finding required under 45 CFR 46.305(a)(4) regarding the selection of subjects within the prison may not be applicable, if the subject was recruited outside of an incarcerated context. The IRB should document findings of non-applicability accordingly.

Additional Considerations

VA Research: Veteran’s Administration Salt Lake City Health Care System (VASLCHCS) Prisoners are considered a vulnerable population because both their incarceration and the constraints imposed on them during their incarceration may render them unable to make a truly informed and voluntary decision regarding whether to participate as subjects in research. **Therefore, research involving prisoners must not be conducted by VA investigators while on official duty or at the VA or approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer (CRADO).** If the waiver is granted, the research must be in accordance with applicable Federal regulations pertaining to prisoners as research subjects (VA Directive 1200.05).

DHHS-supported Prisoner Research: For prisoner research supported by DHHS, the IRB must notify OHRP and certify that the requirements for prisoner research have been met. OHRP will review the IRB’s determination. Only if OHRP concurs, the research may proceed. If research is not DHHS-conducted or -supported, the University of Utah IRB does not need to submit any certification to OHRP.

Points to Address

Application:

1. **Participants Page:** Select “Prisoners” as a participant population.
2. **Vulnerable Populations Page:** Complete this page, justifying the inclusion of prisoners in the study.
3. **Risks and Benefits Page:** Describe the foreseeable risks and benefits to the participants, taking into account the participants’ status as prisoners and ensuring that any potential benefits are not coercive with regard to the environment of the prison.
4. **Documents and Attachments Page, Other Documents Section:** Attach a letter of cooperation from the correctional facility/facilities where the prisoners are housed.

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Consent Document:

1. **Study Procedures:** Include the provisions for follow-up examinations or care following participation in the study.

2. **Study Procedures:** Please state that the participant will not be presented with possible advantages to participation that would be greater in magnitude than the normal limited-choice environment of the prison. For example, you may state that the participant will not receive better living conditions, medical care, quality of food, amenities, or opportunities for earnings than what is normally provided in the prison environment.

3. **Study Procedures:** If participation in the study requires the participants to travel to a clinic, lab, or other study site outside of the prison, the consent should state how transfer and transportation arrangements will be handled. **The researcher must consult with the correctional facility prior to drafting this section to ensure the facility can/will accommodate prisoner transport for the study.**

4. **Voluntary Participation:** Include a statement that participation in the research will have no effect on parole determinations.

References & Links

*OHRP Guidance on the
Involvement of Prisoners in
Research*

<http://www.hhs.gov/ohrp/policy/prisoner.html>

OHRP Prisoner Research FAQs

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html>

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