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Cornell University
Office of Research Integrity and Assurance
Human Research Participant Protection Program

SOP 12: Informed Consent, Enrollment, and Other Considerations for Research Involving Prisoners

1. Subject of Policy & Procedure

This document sets forth the requirements for obtaining (a) IRB approval of research involving prisoners; and (b) informed consent and enrollment of prisoners in human research.

Under the federal regulations, 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." The definition applies to minors as well as adults. When persons under the age of 18 are involved, the Protocol Principal Investigator (Protocol PI) and the IRB must apply the additional protections outlined in SOP 11: Informed Consent, Enrollment, and Other Considerations for Research Involving Children.

Historically prisoners were often enrolled in research projects because it was a convenient population in which to conduct research. As a result of the inappropriate use of prisoners in research, federal regulations are written in such a way as to require investigators to provide unique justification and in many cases prisoners are automatically excluded from participating. Prisoners are a "vulnerable population," because their lack of physical liberty raises the issue of whether they have the ability to make a truly voluntary and un-coerced decision to participate in research. The respect for persons elaborated in the Belmont Report requires that the decision to participate in research be wholly informed and voluntary. A secondary issue is whether confidentiality of participation and of data can be adequately maintained in the prison facility as well as the risk of other prisoners knowing that the research participant may have unique characteristics (HIV status, mental status, etc). It is essential for the investigator to understand the unique challenges of confidentiality in a prison setting.

Because the research participant is not able to prioritize his or her schedule, the Protocol PI is required to obtain the additional concurrence of prison officials (and, often, to make alternate arrangements) for the participant to be able to meet with the investigative team.

Therefore, when prisoners are involved, the IRB gives special consideration to recruitment methods, oversight of the consent process, confidentiality, privacy, and the completeness of information provided to the prisoners. The extent of protection of the prisoner's rights and welfare considered by the IRB depends on the risk of harm and the likelihood and degree of the benefit to the prisoner from involvement in the study. This policy discusses these special considerations and protections.

Moreover, in order to safeguard prisoners' interests and to protect them from harm, federally-mandated considerations are in place for reviewing research involving prisoners. Adding to the protection provided under the Common Rule (45 CFR 46), federal regulations (45 CFR 46, Subpart C) provide additional protections for prisoners involved in research as well as outlining when research with prisoners would require federal oversight in addition to the protection outlined in the regulations. Each time that the IRB considerers a research activity that involves prisoners, a prisoner representative must provide input into the review and approval process. While these regulations apply only to research supported by the Department of Human Health and Services (DHHS), Cornell University's institutional policy extends the same protection to all research participants regardless of the source of financial support or funding.

Finally, certain prisoners may be members of another vulnerable population (*e.g.*, pregnant or cognitively impaired prisoners). In these instances, the Protocol PI and the IRB should carefully apply, as appropriate, not only this SOP, but also the SOPs pertaining to the second vulnerable population of which the prisoner is a member. The IRB should give special attention to these groups of prisoners who, while they need special protections, should not be denied the opportunity to participate in research, especially research which may benefit them.

2. Scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects conducted by Cornell University faculty, staff, or students or by anyone conducting a research activity supported by Cornell University or where Cornell is considered to be engaged in the research.

3. Terms and Definitions

All parties to whom this policy applies (*e.g.*, faculty, students, staff, IRB members) should consult the IRB Glossary.

4. See Also

Affected researchers and employees should also consult:

1. Cornell University Federalwide Assurance Registration
2. OHRP Guidance: Prisoners

5. Regulations Applicable to Informed Consent

5.1. The Belmont Report

5.2. 45 CFR 46.109(b), (c), & (e): IRB Review of Research, stating that (1) "[a]n IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects;" (2) "[a]n IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117;" and (3) "[a]n IRB shall have the authority to observe or have a third party observe the consent process and the research."

5.3. 45 CFR 46.111(a)(4), (a)(5), & (b): Criteria for IRB approval of research, mandating that (1) informed consent "will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116," and "appropriately documented, in accordance with, and to the extent required by §46.117;" and (2) "[w]hen some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects."

5.4. 45 CFR 46.116: General requirements for informed consent

5.5. 45 CFR 46.117: Documentation of informed consent

5.6. 45 CFR 46, Subpart C, addressing additional protections for prisoners involved as participants in research

5.7. OHRP Guidance on the Involvement of Prisoners in Research, May 23, 2003

6. Requirements for IRB Approval of Research Involving Prisoners

While a person's status as a prisoner does not bar his or her participation in research, such participation and the associated research warrant additional scrutiny by the Protocol PI and the IRB.

A research protocol that involves prisoners may not qualify for exemption from IRB review.

Where the study carries greater than minimal risk, a potential benefit to society or the convenience of prisoners as a study population is an insufficient justification for their enrollment.

In addition to the approval criteria applicable to all human participant research, the IRB shall approve research involving prisoners only if it meets the following criteria:

1. The research under review represents one of the following permissible categories of research:

    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. 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 (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 HHS Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his intent to approve such research;[1] 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 participants. In cases where those studies require the assignment of prisoners, in a manner consistent

[1] The focus of the research needs to be specifically on the effect of the condition on the prison population and not on the condition itself.

with protocols approved by the IRB, to control groups that may not benefit from the research, the study may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of the 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 prison is impaired. Involvement in a research protocol cannot be considered during a parole hearing for any prisoner who has agreed voluntarily to be a research participant;

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 Protocol PI provides to the IRB 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 participants in that particular research project;

5. The information is presented in language that 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.

7. Responsibilities of the Protocol PI

The Protocol PI must discharge all of the following responsibilities, in the following order, before commencing a research study involving prisoners:

7.1. Obtain Initial Approval from Penal Facility:

Because the prison or other imprisoning facility is responsible for the care of the prisoner, it must participate to some degree in the implementation of the protocol. Therefore, after deciding to enroll prisoners in a protocol, the Protocol PI must obtain initial approval from the penal facility. This approval should be documented in the protocol application.

7.2. Obtain IRB Review and Approval before Enrollment of Prisoners:

Next, the Protocol PI should complete and submit the protocol application for IRB review and approval. If the protocol has previously received approval, the Protocol PI should submit an amendment requesting approval to enroll prisoners. The Protocol PI also should develop for the potential prisoner participant(s) a separate consent form that takes into account the additional risks and uniqueness of being a member of this vulnerable population. This prisoner consent form must be used for all prisoners and it cannot be used for any prospective non-prisoner participants in the study. The prisoner consent form, too, must be approved by the IRB before use. It should be submitted to the IRB as part of the protocol or amendment application, along with any other consent documentation and the approval letter from the penal facility.

1. If the Protocol PI requests approval to enroll prisoners in a research project exclusively or in addition to other research participants, he or she must obtain IRB review and approval of the protocol and prisoner enrollment *before* enrollment may begin.

2. If the Protocol PI did not intend originally to enroll prisoners in a research protocol but subsequently finds that a prisoner qualifies for enrollment, the Protocol PI shall first request IRB approval to enroll prisoners in the protocol via an amendment application. *See* SOP 3: Initial and Continuing Review by the IRB: Requirements for Submission of Applications, Approval Criteria, and Expedited and Convened Committee Review Procedures, Section 11.

3. If a Protocol PI enrolls a non-prisoner participant who subsequently becomes a prisoner, the Protocol PI will remove the participant from the study or the Protocol PI will obtain IRB approval for enrolling prisoners in the protocol, as set forth below in Section 8.

7.3. Obtain Formal Agreement with Penal Facility:

After the protocol has been approved for prisoner enrollment by the IRB, the Office of Research Integrity and Assurance (ORIA) shall enter into a formal agreement with the penal facility concerning the facility's responsibilities in a research project conducted by Cornell personnel. The Protocol PI shall provide ORIA with all assistance and information necessary to procuring this agreement. All documentation relating to the penal facility agreement will be kept by both the Protocol PI and ORIA as part of the protocol file.

7.4. Obtain DHHS Approval:

If it approves the protocol, the IRB will refer the protocol to the Director of ORIA and ORIA to determine whether DHHS Secretary approval is required (*see above* Section 6, categories (1)(c) & (d)). The Director of ORIA will not consider a request to obtain the approval of the DHHS Secretary until the protocol has received an approval by the IRB which states only one condition – approval by the Secretary of DHHS. If the Director of ORIA and ORIA determine that DHHS Secretary approval is required, ORIA shall submit the protocol and related documents, including the penal facility agreement, for federal approval.

ORIA, on behalf of Cornell, shall certify to the Secretary of DHHS, in such form and manner as the Secretary may require, that the duties of the IRB under Sections 6 and 9 of this SOP

have been fulfilled. A copy of the IRB-approved protocol application and any relevant grant application or proposal should be sent to the OHRP. The study, if supported by DHHS, cannot be initiated until OHRP determines that the proposed research involves at least one of the categories of permissible research set forth in Section 6(1). OHRP will issue its approval or disapproval in writing to Cornell on behalf of the Secretary under 45 CFR 46.306(a)(2).

ORIA will notify the Protocol PI whether the study has been approved or disapproved. All documentation relating to the HHS approval will be kept by both the Protocol PI and ORIA as part of the protocol file.

7.5. Obtain Consent of the Prisoner:

After obtaining IRB approval of the enrollment of prisoners in the protocol and, if necessary, DHHS approval, the Protocol PI may begin to enroll prisoners as participants.

As stated previously, the Protocol PI shall develop for the potential prisoner participant(s) a consent form that takes into account the additional risks and uniqueness of being a member of this vulnerable population. This form shall be approved by the IRB before use. This form must be used for all prisoners, but it cannot be used for any prospective non-prisoner participants in the study.

7.6. Maintain Confidentiality of Data:

The Protocol PI must maintain the confidentiality of the identity and other private identifying information of the prisoner-participant before, during, and after the research project concludes. When the consent form represents privacy concerns, the IRB needs to weigh the importance of the documentation of informed consent and where the consent form should be maintained so that it is available on reasonable demand by the research participant but not available to other individuals (prisoners and staff) associated with the facility.

8. Procedures for when a Participant Becomes a Prisoner during a Research Study

To be clear, the regulatory protections in this SOP are applicable to all prisoner-participants, regardless of their status at the time of their enrollment in the study. Therefore, this SOP applies at any time during the study when a participant becomes a prisoner, including after the research has commenced. The application of this SOP — particularly, Section 8 — is necessary, because it is unlikely that the original IRB review of the protocol and the consent document(s) contemplated the constraints imposed by the possible future incarceration of participants.

8.1. Upon learning that a participant has become a prisoner after enrollment in the research, the Protocol PI must halt any research interactions and interventions with the participant and cease obtaining private identifying information from/about him or her. The Protocol PI must report the incarceration in writing to the IRB immediately upon learning of it.

8.2. The IRB Chair and the Director of ORIA should review the protocol to determine initially whether the continued participation of a prisoner in the research is appropriate under the regulations, *i.e.*, the requirements set forth above in Section 6. The Protocol PI should be instructed by ORIA, as appropriate, to submit an amendment for IRB review and approval or to remove the participant from the study.

8.3. If the protocol is appropriate for prisoner enrollment, ORIA will determine whether the amendment is appropriate for expedited or convened committee review. *See* SOP 3: Initial and Continuing Review by the IRB, Section 11. The Protocol PI must submit the amendment application for review and approval, including a prisoner consent form and documentation of the penal facility's initial approval. If a convened committee review is required, ORIA will place the protocol on the agenda for a future meeting of the convened IRB.

8.4. In special circumstances where the Protocol PI asserts that it is in the best interests of the participant to remain in the research study while review of the amendment is taking place, the IRB Chair may determine that the participant may continue to participate in the research pending review and approval, assuming that the Protocol PI has obtained initial approval from the penal facility.

8.5. The IRB can either (a) approve the involvement of the prisoner-participant in the research in accordance with this SOP or (b) determine that this participant must be withdrawn from the research. The IRB should take special consideration of the conditions of being a prisoner and the difficulty of maintaining confidentiality and privacy.

8.6. Additionally, the IRB should confirm that, when appropriate, the informed consent includes information regarding subsequent incarceration which may result in termination of the participant's participation without regard to the participant's consent.

9. Special Considerations for IRB Review and Approval of Research Involving Prisoners

If a Protocol PI indicates in the protocol application that prisoners will participate in the research or that participants may reasonably be expected to be incarcerated at some point during the study, the following additional requirements apply to IRB review of the protocol:

9.1. Composition of the IRB: In approving research involving prisoners, the IRB shall meet the following additional requirements regarding its composition:

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.

2. At least one member of the IRB shall 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. In addition to meeting federal requirements, the project must comply with local and state requirements for inclusion of prisoners as participants. *See* SOP 18: New York State Laws Affecting Human Research. ORIA will consult with Cornell counsel as necessary.

If approved, the IRB will refer the protocol to the Director of ORIA to determine whether DHHS Secretary approval is required. *See above* Section 7.4.

9.2. Review Process: As stated previously, protocols involving prisoners may not be exempted from IRB review. However, the inclusion of prisoners does not, in and of itself, necessitate

convened committee review. The level of risk involved must be considered in making this determination. The IRB may invite members or consultants with special expertise and competency related to the protocol involving prisoners to participate in the protocol review. The IRB Administrator or other ORIA member will document clearly in the minutes the outcome of any IRB discussion related to the enrollment of prisoners in the protocol, including but not limited to:

1. Federally required considerations per 45 CFR 46, Subpart C
2. Consent process
3. Special precautions regarding the confidentiality of the prisoner(s)' participation and personally identifying data