

 Office of Research Integrity - Human Subjects			SOP #: ORI(HS)-7.02
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Approved by: Biomedical Chair	Signature on file	Date:	
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SOP 7.02 –Vulnerable Subjects: Prisoners

1. Objective

The purpose of this SOP is to describe considerations for conducting research with prisoners. Prisoners are considered a vulnerable population in need of additional protections because their incarceration could affect their ability to make a truly voluntary decision whether or not to participate as subjects in research. 45 CFR 46 Subpart C outlines additional considerations for biomedical and behavioral research involving prisoners as subjects. Except as provided in this SOP and 45 CFR 46 Subpart C, biomedical or behavioral research conducted or supported by the US Department of Health and Human Service shall not involve prisoners as subjects.

2. General Description

Prisoners and other vulnerable populations with impingements on their freedom, such as parolees and probationers, persons court-ordered to attend nonresidential treatment programs, and persons residing in halfway houses, should also be afforded additional protections.

Adolescents detained in juvenile detention facilities are also considered prisoners. When a research subject is both a prisoner and a minor, Subpart D (Additional protections for children involved as subjects in research) also applies (see SOP 7.01).

When investigators anticipate that some of the subjects in a planned research study population are likely to be prisoners or become prisoners during the course of the study (for example, subjects on parole, probation, under electronic monitoring, or in substance abuse treatment studies) the IRB may review the research prospectively for prisoner involvement in accordance with the requirements of 45 CFR part 46 Subpart C.

Definitions

Prisoner - is defined to include any individual involuntarily confined or detained in a penal institution (45 CFR 46.303.c). 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.

Secretary - means the Secretary of the Department Health and Human Services (US DHHS) and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

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3. Roles & Responsibilities

Execution of SOP: Principal Investigators (PI)/Study Personnel (SP), IRB Chair, IRB, Office of Research Integrity – Human Subjects (ORI-HS) Staff.

It is the responsibility of ORI-HS to ensure that at least one member of the IRB who is a prisoner representative participates in the review of the project.

The IRB will carefully review the inclusion of prisons as research subjects to ensure that additional protections are in place for this vulnerable population.

If the research is supported by federal funds, the IRB Chair must certify the research to the DHHS Office of Human Research Protection (DHHS OHRP). In that case, the investigator must contact UNLV ORI-HS to discuss the situation. ORI-HS will address the matter on a case-by-case basis. The investigator will be informed that she or he must wait for notification from the IRB that the federal OHRP has authorized the research study prior to initiating any interaction or intervention with or before obtaining identifiable private information about prisoners.

If an investigator wishes to enroll prisoners as subjects in a research study, the protocol proposal form must clearly describe which of the four permissible categories of research the research study falls within discussed in this SOP section 4(1)(ii).

If a research participant becomes a prisoner after enrolling in a research study, and the investigator wishes for research interactions and interventions or the collection of identifiable private information to continue while a participant is incarcerated, the investigator is responsible for promptly reporting the event in writing to the IRB. This is not required when the study was previously approved by the IRB for the participation of prisoners. The investigator must promptly secure approval from the State of Nevada Department of Corrections and/or any other involved entity before conducting research procedures with prisoners.

4. Procedures

All prisoner research at UNLV is reviewed by a fully convened IRB with a prisoner representative present. There are seven additional requirements that provide specific protections for prisoners as research subjects, and these must be satisfied before the IRB can approve the study. The following are the seven requirements specified in Subpart C.

1. The research under review must fall within one of the permissible categories listed below:
 - i. The institution responsible for the conduct of the research has certified to the Secretary that the IRB has approved the research under §46.305; and
 - ii. In the judgment of the Secretary the proposed research involves solely the following:
 - 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;

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- 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 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.
 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 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.
 5. The information is presented in language which is understandable to the subject 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.
 7. 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.

The Board shall carry out such other duties as may be assigned by the Secretary.

The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the IRB under this section have been fulfilled.

5. References

45 CFR 46 Subpart C
45 CFR 46 Subpart D
SOP 7.01 Children