THE UNIVERSITY OF ARIZONA Research & Partnerships

Research Involving Prisoners

When Does Human Research Involve Prisoners?

A study is considered to include prisoners when the intent of the research is to conduct research with prisoners, and the researcher intends to interact or intervene with the prisoner or to obtain the identifiable information about the prisoner.

A study may not initially intend to involve prisoners, but a subject may become a prisoner during the course of a research study. The investigator must promptly notify the Institutional Review Board (IRB) and all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner subject must stop. If it is not in the best interest of the prisoner to stop research activities, the investigator must request a special exception due to subject safety until the IRB can determine that the regulatory requirement for research with prisoners are met.

If the investigator wishes to have the prisoner subject continue to participate in the research, the IRB must promptly review the proposal to determine if the requirements for involvement of prisoners has been met.

Requirements for Inclusion of Prisoners in Human Research

Investigators must provide protocol specific justification to the IRB and submit the *Appendix for Prisoners* in eIRB, so that the IRB can determine that the enrollment of prisoners in the research is justified.

Research involving prisoners may be deemed Exempt if the research involves a broader subject population that only incidentally includes prisoners.

Research may be deemed Expedite if the research involves no greater than minimal risk for the prison population. Modifications to research may be reviewed per the guidance *Modifying Approved Research*. Modifications involving significant changes or increased risk as determined by the IRB Chair must use the same procedures for initial review including review by the prisoner representative.

Continuing review of prisoner research involving no greater than minimal risk may follow the same procedure for initial review without the responsibility of the prisoner representative, unless the research identifies increased risk to the prisoner population as determined by the IRB Chair.

For research that does not involve interactions with prisoners (e.g., existing data, records reviews), the research may be reviewed via the expedite procedure. Review by the prisoner representative is not required unless it is designated by the IRB Chair.

Definitions (45 CFR §46.303)

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. For prisoners, “minimal risk” means 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.

Categories of Research Involving Prisoners (45 CFR 46.306(a)(2))

1. 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;

   For epidemiological research, the sole purposes must be to: (1) describe the prevalence or incidence of a disease by identifying all cases; or (2) study potential risk factors associations for the disease. Prisoners must also not be a particular focus of the research.

2. 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;

3. 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

4. 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.

Expansion of Research Involving Prisoners

The University of Arizona (UA) has adopted flexible procedures for projects that are not federally funded, supported, or otherwise subject to the federal rules. Projects that meet the requirements of the Flexible Policy may be eligible for increased research activities involving prisoners.

1. Unfunded or non-federally funded research is not required to get approval from the Secretary at the Department of Health and Human Services (HHS).
2. Research using data, samples or materials that involve prisoners or that may involve prisoners may qualify for review under the flexible procedures.
3. Individuals incarcerated during participation in research may continue participation in non-federally funded projects without an IRB re-review involving the prisoner representative if the intent of the study is not to study incarcerated individuals. The research procedures must not continue in the prison facility (e.g., a subject is enrolled in the emergency room, and all study procedures will be completed prior to the prisoner leaving the facility).

4. Modifications to prisoner research do not require re-review by the prisoner representative unless the changes are significantly altering the risk of the prisoner population as determined by the IRB Chair.
5. Continuing review of prisoner research, if appropriate, may follow the same procedure for initial review without the responsibility of the prisoner representative, unless the research identifies increased risk to the prisoner population as determined by the IRB Chair.
6. The UA Human Subjects Protection Program (HSPP) will not consider persons in transitional custody whose liberty is restricted such as half-way houses, electronic monitoring, probation, or house arrest, to meet the federal definition of prisoner. For those individuals, the criteria at 45 CFR 46.111 offer sufficient protection for their level of vulnerability.
7. Data analysis of information collected from court records may be deemed exempt.

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IRB Requirements for Approval of Research with Prisoners

1. The research under review represents one of the categories of research permissible under 45 CFR §46.306(a)(2);

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; **and**

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 HSPP Director will certify to the Office of Human Research Protections the duties of the IRB have been fulfilled for HHS-funded or supported research.