	INVESTIGATOR GUIDANCE: Research Involving Prisoners				
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1 PURPOSE


- 1.1. This guidance describes the processes for conducting research with prisoners.

2 BACKGROUND

- 2.1. "Prisoner" means:
- 2.1.1. Any individual involuntarily confined or detained in a penal institution (e.g., jail, state prison, federal prison, or a detention center). 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.
 - 2.1.2. The term "prisoner" does not include individuals court-ordered to reside at residential re-entry centers, community release centers, or those on probation or parole.
- 2.2. The ability of prisoners to make a free, unbiased and uncoerced decision about whether or not to participate in research is limited because of their status as incarcerated individuals. In the history of research in the United States and abroad, prisoner populations have been exploited because of their convenience: they provided large groups of subjects located in one place largely observing the same routines and receiving roughly the same standard of care. These criteria remain largely the same today. It is therefore incumbent upon this institution and its research community to ensure that prisoners are safeguarded appropriately, to ensure that they have the ability to voluntarily determine whether they choose to participate in research.

3 GUIDANCE

- 3.1. In addition to all other IRB responsibilities prescribed in this document, the board shall review research involving prisoners and approve such research only if it finds that:
- 3.1.1. Prisoners may be involved in research if the research falls into one of the following categories permissible under 45CFR46.306(a)(2):
 - 3.1.1.1. 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;
 - 3.1.1.2. 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;
 - 3.1.1.3. 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); *or*
 - 3.1.1.4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
 - 3.1.2. 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 their ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
 - 3.1.3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

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- 3.1.4. 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; **and**
- 3.1.5. 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.
- 3.2. In addition to these requirements, research involving incarcerated minors is subject to Federal regulations Title 45, Part 46, Subpart D and FAU Investigator Guidance 406, "Research Involving Minors".
- 3.3. In addition to these requirements, research involving incarcerated pregnant women is subject to Federal regulations Title 45, Part 46, Subpart B and FAU Investigator Guidance 404, "Research Involving Pregnant Women, Fetuses, and Neonates".
- 3.4. It is the responsibility of the PI to assess the likelihood of non-prisoner subjects becoming prisoners during the course of a research study. The PI should determine the likelihood that a subject could be reclassified as a prisoner subject in the middle of the research (e.g., in a study involving parolees with a high likelihood of re-offense) and whether that subject will remain in the study or be withdrawn. In the former case, the PI should make sure the research is initially reviewed and approved as prisoner research by the IRB if possible. If a subject in a research protocol becomes a prisoner during the time in which he or she is actively participating in the study and the protocol has not been approved for the inclusion of prisoners then the following steps must occur:
 - 3.4.1. The PI must immediately notify the IRB in writing of the subject's status change, and whether the subject was withdrawn or remains in the study.
 - 3.4.2. If the PI requests that the subject remain in the study, the IRB must re-review the protocol in accordance with the policy as written in the above sections.
 - 3.4.3. If the IRB determines that the research is not approvable as prisoner research then the subject must be withdrawn from the study.

4 REFERENCES

- 4.1. 45 CFR 46 Subpart C
- 4.2. 45 CFR 46 Subpart B
- 4.3. 45 CFR 46 Subpart D