Department:	**UAMS Institutional Review Board**
Policy Number:	**17.9**
Section:	**Special Populations**
Effective Date:	**July 31, 2002**
Revision Date:	**November 18, 2002; August 24, 2004; February 8, 2005; January 24, 2011; August 19, 2015; February 15, 2016; May 26, 2020; October 9, 2020; September 15, 2023; October 15, 2024**

SUBJECT: Prisoners Involved in Research

I. **POLICY**

Prisoners, as a vulnerable population, merit additional protections when included in human subject research. Prisoners' incarceration may limit their ability to make a voluntary and uncoerced decision whether or not to participate in research, and also has implications for their privacy and the confidentiality of their information. Nor must prisoners be expected to shoulder research risks that would be unacceptable to the non-prisoner population. To safeguard prisoners' rights, safety, and welfare, the UAMS IRB will apply additional ethical and regulatory considerations when reviewing research that involves prisoners. These considerations will be based on those described at 45 CFR 46 Subpart C.

II. DEFINITIONS

A. **Minimal Risk.** As used in this policy, "Minimal risk" 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.

B. **Prisoner.** As used in this policy, "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, including juveniles, 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. Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial. When a prisoner is also a minor, such as an adolescent detained in a juvenile detention facility, IRB policy 17.1 regarding Children in Research will also apply.

Common examples of the application of the regulatory definition of prisoner are as follows:

1. Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.

2. Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.

3. Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

4. Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Contact the IRB when questions arise about research involving these populations.

III. PROCEDURE

Research, which involves the use of prisoners as subjects, must meet the requirements of the general IRB Policies and the special ones outlined in this policy. The IRB may not approve research involving prisoners if these special provisions are not met.

Investigators submitting research with the intent to enroll prisoners must show in their application how their proposed study meets each of the elements under Subpart C, as outlined below in Section B.

If a subject becomes a prisoner while enrolled in a study that was not reviewed under Subpart C, follow the procedures outlined below in Section C.

Research involving prisoners cannot be deemed exempt.

Research involving prisoners may only be expedited in limited circumstances as described below in Section D.

A. IRB Composition when Prisoners Are Involved

The IRB's composition must meet the following two requirements when reviewing research involving prisoners:

1. A majority of the IRB Committee shall have no association with the prison(s) involved, apart from their membership on the IRB; and
2. At least one member of the IRB Committee shall be a prisoner representative with appropriate background and experience to serve in that capacity. The prisoner representative may be listed as an alternate on the IRB roster for quorum purposes but is a voting member of the IRB when needed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.

The IRB must meet the special composition requirements for all types of review of the protocol: initial review, major modifications and continuing review unless no subjects have been enrolled. If no subjects have been enrolled, the continuing review may be expedited under category 8.

B. Convened IRB Review Process

Research involving prisoners must be reviewed, and presented at a convened meeting, by a prisoner representative with a focus on the requirements of Subpart C. The prisoner representative will have access through the IRB e-system to all submitted materials and is to present his/her review either orally or in writing.

The IRB will make seven specific determinations when approving research involving prisoners. The determinations will be documented in minutes and/or the online submission system.

1. The research represents one of the permissible categories of research:

   a. 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 subjects;
   b. A 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;
   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). When the research in this category is HHS-conducted or -supported, it 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 or her intent to approve the research; 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 subject. For HHS-funded or -supported research in this category, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research 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 or her intent to approve the research. OHRP interprets control groups which may not benefit from research to include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo;

e. Certain epidemiological research, whether or not conducted or supported by HHS. In this category, the research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. Prisoners must not be a particular focus of the 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 nonprisoner 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 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 that particular research project;

5. The study information is presented in language, which is understandable to the subject population;

6. Adequate assurance exists that the parole board will not take into account a prisoner's participation in the research in making decisions regarding transfer to community supervision, 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.

Note: In order to make some of these seven findings, the IRB must be familiar with the specific conditions in the local prison(s) or jail site(s) that are pertinent to subject protections, before approving the Research.

Research Funded by DHHS: If the proposed research is funded by DHHS, the IRB will certify to OHRP that the IRB reviewed the research and made the seven findings. The research may not begin until OHRP responds with an approval. If OHRP determines that the research does not fit into one of the permissible categories, the research involving prisoners may not proceed. If OHRP disagrees with the IRB's determination of the category of prisoner research, the OHRP determination will prevail.

Federal Bureau of Prisons. The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau of Prisons. The IRB and the research team are to follow the regulations at 28 CFR 512 when reviewing or conducting such research.

C. **Procedure when subjects unexpectedly become Prisoners**

1. **Investigator actions:**
   a. If a subject becomes a prisoner while enrolled in research not reviewed under prisoner requirements, the Investigator will notify the IRB immediately. The report should note whether the study team will terminate the subject's enrollment or have the study re-reviewed under prisoner requirements. If the Investigator believes it is in the best interests of the subject to remain in the research study while incarcerated, the justification for this belief should be submitted to the IRB.
   b. All research interactions and interventions with the now-incarcerated prisoner-subject must cease and no more identifiable private information about the now-incarcerated prisoner-subject may be obtained until the IRB completes its review.
   c. If the now-incarcerated subject is to be removed from the study, all subject interactions, interventions and data collection pertaining to the subject must cease.

2. **IRB actions:**

   a. Re-review the research under the prisoner requirements; or
   b. If the subject's participation in the research is to be terminated, the IRB should consider the risks associated. If the subject's participation cannot be terminated for health or safety reasons, choose one of the following options:
      i. Keep subject active on the study until the prisoner requirements are met. The IRB must promptly re-review the proposal in accordance with the prisoner requirements, send a certification to OHRP if the study requires certification, along with justification for keeping subject enrolled, and wait for a letter of authorization in reply.
      ii. Remove subject from the study but find alternate mechanism to keep subject on study intervention, such as compassionate or off label use.

D. **Expedited Review of Prisoner Research**

1. **Research involving interaction with prisoners.** Research involving interaction with prisoners may only be reviewed under expedited procedures when a determination has been made that the research involves no greater than minimal risk to the prison population being studied. While the normal expedited reviewers may also review, the prisoner representative must review the research and agree with the risk determination. The prisoner representative must also be involved in the review of all modifications and continuing reviews.

2. **Research which does not involve interaction with prisoners (existing data, chart reviews).** Research which does not involve interaction with prisoners but uses identifiable private information about prisoners may only be reviewed under expedited procedures when a determination has been made that the research involves no greater than minimal risk to the prison population being studied. Separate review by the prisoner representative may be requested but is not required. However, if the prisoner representative reviews the initial submission, then he or she must review subsequent modifications and continuing reviews.

IV. REFERENCES

45 CFR 46 Subpart C
28 CFR 512
OHRP Guidance titled "Prisoner Involvement In Research"
OHRP "Prisoner Research FAQs"
AAHRPP elements pertaining to IRB review and/or vulnerable populations: II.1.A; II.2.A; II.2.D; II.2.E; II.4.B; III.1.F
AAHRPP Tip Sheet 18: Review of Research Involving Prisoners and the Role of the Prisoner Representative
OHRP personal communication dated 9.21.20 re research not HHS-funded or –supported.
2003 HHS Secretarial waiver applying to certain epidemiological research