

Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #16	Research Involving People Who Are Incarcerated	
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I. PURPOSE

This document details Appalachian State University's IRB's standard for research with human subjects who are incarcerated. Studies involving people who are incarcerated must comply with varying requirements that do not apply to other types of human subjects' research. These requirements are designed to address contextual vulnerability of participants who are incarcerated compared with other research. The requirements that apply to research with people who are incarcerated are described below.

II. AUTHORITY

In accordance with [45 CFR 46](#), the HHS Policy for the Protection of Human Research Subjects, pertinent federal and State laws or applicable regulations that provide additional protections for human subjects must be followed. All non-exempt or contractually obligated human subjects' research studies that involve people who are incarcerated must adhere to the additional regulations found at [Subpart C of 45 CFR 46](#).

III. RESPONSIBILITY

1. Research personnel are responsible for complying with all federal, state, and local laws pertaining to research with human subjects for any location where those research activities take place. Research personnel are expected to provide accurate information in the IRB application about the inclusion of people who are incarcerated; plan for appropriate informed consent procedures that minimize undue influence and coercion while promoting participant welfare, safety, and voluntariness; provide a scientific justification for why people who are incarcerated are targeted for the research; and provide all necessary supplemental documentation to the IRB for review.
2. Research protections (RP) staff and the IRB are responsible for ensuring the proposed research protocol has addressed all regulatory requirements of 45 CFR 46 and the additional requirements for inclusion of people who are incarcerated in Subpart C. Research protections (RP) staff may request changes or clarifications from the investigators about any component of the research protocol to enable the study's compliance with federal law prior to granting approval. RP staff should consult with advocates and experts for incarcerated people as required by 45 CFR 46 throughout the protocol review process.

IV. DEFINITIONS

1. Minimal Risk (in the context of research with incarcerated persons)
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 (see [45 CFR 46.303\(d\)](#)).
2. Person who is Incarcerated
A person who is incarcerated is 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 (see definition of *prisoner* under [45 CFR 46.303\(c\)](#)).

3. Incarcerated Persons Representative

An Incarcerated Persons Representative is an individual who is currently or formerly a person who is incarcerated or an individual who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the person who is incarcerated (e.g., prison chaplain, prison social worker, prison health care worker).

4. Undue Influence

Undue influence occurs through an offer of an excessive or inappropriate reward, or overture in order to obtain compliance or participation. In addition to undue influence that can arise with the offering of rewards, undue influence also can be subtle because influence is contextual.

- a. Undue influence may come about due to the participant's environment or circumstance as a person who is incarcerated or detained.
- b. Undue influence may come about due to people with real and perceived authority over the possible participant and promise of favor, opportunity, or reward.
- c. Undue influence may come about due to conflicts of interest.
- d. Undue influence may come about due to peer and familial relationships resulting in the feeling of pressure to participate in the research due to benefits the family may receive.
- e. Undue influence may come about due to compensation or incentives. These issues range from type of compensation for participation, amount of compensation participation, and to whom the compensation is given.

5. Coercion

Coercion is an overt or implicit threat of harm or negative consequence that is intentionally presented by one person to another in order to obtain compliance. This can occur when an authority within the prison requests participation or a peer with power asserts their power over the participant telling them to be in the study.

6. Exploitation

Exploitation is when a participant is taken advantage of due to their contextual vulnerability and can occur when:

- a. the relationship between researcher and participant is asymmetrical.
- b. the participant needs a resource that the researcher supplies.
- c. the participant depends upon the researcher or the research activities for the needed resources.
- d. the researcher enjoys discretionary control over the resources that the participant needs.

V. PROCEDURES

This standard applies to all research activities completed by Appalachian State University researchers involving people who are incarcerated as participants in research. Research involving people who are incarcerated is only permitted if the research addresses the possible causes, effects, and processes of incarceration, and of criminal behavior; the study of prisons as institutional structures or of people who are incarcerated as incarcerated persons; conditions particularly affecting people who are incarcerated as a class; or is on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.

A. Ethical Considerations for Research with People Who are Incarcerated

People who are incarcerated are an especially vulnerable population that face unique circumstances when participating in research. Given that this is a captive population with diminished autonomy, ensuring that research is conducted without coercion or exploitation presents many challenges to the research community and the Appalachian State University IRB.

1. In addition to the protections outlined in Subpart C of the federal regulations for research with

human subjects, special attention must be paid to the following concerns when including people who are incarcerated in research activities:

- a. Privacy – When protecting the privacy of participants in a prison setting, there may be obstacles. It may be difficult to secure a private setting during recruitment, consent, and the data collection process. Additionally, researchers must be careful to not reveal to other people who are incarcerated that their peer is a participant in a research study.
- b. Justice – Research targeting or involving people who are incarcerated should only be completed if the research is relevant to the people who are incarcerated or their situation. Research involving participants who are incarcerated should only be approved when it cannot reasonably be conducted without their participation. Their participation in research should never be justified based simply on their availability, compromised position, or the convenience for the researcher. When reviewing research involving people who are incarcerated, the IRB considers whether targeting or including people who are incarcerated is in alignment with the aims of the study and representative of those who will benefit from the research.
- c. Respect for Persons – Researchers must protect the autonomy of all people who participate in research, subsequently treating participants with respect and providing the opportunity for proper and thorough informed consent. The incarcerated population inherently has limited autonomy and may be susceptible to coercion or exploitation of circumstances, leading to limited capacity for voluntary informed consent. People who are incarcerated can feel pressured to participate due to fear of punishment for not participating in the study, in hopes of being treated better, or having access to treatments or experiences otherwise not afforded to them. Additionally, being offered an opportunity to leave a cell or to meet new people during research activities may present undue influence for participation or exploitation of circumstance.

B. Participants who are Considered People Who are Incarcerated

1. A person who is incarcerated is any individual involuntarily confined or detained in a penal institution. The federal regulations at 45 CFR 46 also use the term “prisoner” for the same purpose.
2. The term “people who are incarcerated” is intended to encompass:
 - a. individuals sentenced to a penal institution under a criminal or civil statute;
 - b. individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution; or
 - c. individuals detained pending arraignment, trial, or sentencing.
3. Individuals are people who are incarcerated 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.
4. People who are incarcerated may be convicted of a crime or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
5. Common examples of the application of the regulatory definition of a person who is incarcerated (also called a “prisoner” in 45 CFR 46) are as follows:
 - a. Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are people who are incarcerated; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not people who are

incarcerated.

- b. Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are people who are incarcerated; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others, are not people who are incarcerated.
- c. Parolees who are detained in a treatment center as a condition of parole are people who are incarcerated; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not people who are incarcerated.
- d. Those on probation and/or wearing monitoring devices are generally not considered to be people who are incarcerated; however, situations of this kind frequently require an analysis of the particular circumstances of the planned participant population. Institutions may consult with the [Office for Human Research Protections](#) (OHRP) when questions arise about research involving these populations.

C. Permitted Research Involving People Who are Incarcerated

The regulations governing research with human subjects permit the following types of research activities involving people who are incarcerated. These are limited to:

- 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 participants.
- 2. Study of prisons as institutional structures or of people who are incarcerated as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants.
- 3. Research on conditions particularly affecting people who are incarcerated 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 of the Department of Health and Human Services (DHHS) has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the *Federal Register*, of their intent to approve such research.
- 4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of people who are incarcerated in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the study may proceed only after the Secretary of DHHS has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the *Federal Register*, of their intent to approve such research.

D. Investigator Responsibilities When Completing Research with People Who are Incarcerated

- 1. The investigator will indicate within the initial IRB submission, or through an amendment, that people who are incarcerated will be a target population for project activities while articulating the necessity for the involvement of people who are incarcerated.
- 2. Investigators are responsible for obtaining and providing documentation of approval from the

detention or correctional facility involved (i.e., prisons, jails, workhouses, etc.) to the IRB.

3. The investigator will provide any additional documents or materials required for certification to the Secretary of DHHS for federally funded research involving people who are incarcerated.
4. The investigator may not recruit, consent, or enroll any individual involuntarily confined or detained in a penal institution without IRB approval. If the research is conducted or supported by DHHS, this research also requires review and written approval by the Secretary of DHHS before any research activities may begin. Refer to Section E.8 below.
5. The investigator is responsible for adhering to all local, state, and federal laws regarding completing research with people who are incarcerated.
6. If at some point while participating in a research project a participant becomes incarcerated, it is the responsibility of the principal investigator (PI) to notify the IRB. The protocol will then be re-reviewed according to Subpart C or the person who is incarcerated will be withdrawn from the research.
 - a. All research interactions, interventions, and obtaining identifiable, private information about the now-incarcerated person who is an incarcerated-participant must be suspended immediately.
 - b. Upon receipt of the investigator's report that a previously enrolled research participant has become a person who is incarcerated, if the investigator wishes to have the person who is incarcerated continue to participate in the research, the IRB must promptly re-review the proposal in accordance with the requirements of subpart C.
 - c. If the study is federally funded, the institution(s) engaged in the research involving the person who is incarcerated must send a certification to OHRP and wait for a letter of authorization in reply. Otherwise, the person who is an incarcerated participant must stop participating in the research
 - d. OHRP allows one important exception to the requirement that all research interactions or interventions with, and obtaining identifiable private information about the now-incarcerated participant, must cease until the regulatory requirements for research involving people who are incarcerated are met.
 - i. In special circumstances in which the investigator asserts that it is in the best interest of the participant to remain in the research study while incarcerated, the participant may continue to participate in the research until the requirements of subpart C are satisfied.
 - ii. The investigator must promptly notify the IRB of this occurrence so that the IRB can re-review the study.

E. Responsibilities of the Institutional Review Board

1. Research Reviewers
 - a. When reviewing research involving people who are incarcerated at the convened committee, the IRB must meet the following composition requirements:
 - i. A majority of the IRB must have no association with the prison(s) involved, apart from their membership on the IRB.
 - ii. At least one member of the IRB must be a person who is/was incarcerated or is an Incarcerated Persons Representative, with appropriate background and

experience to serve in that capacity.

- iii. The Incarcerated Persons Representative must be a voting member of the IRB. A comment may be added to the roster indicating that the Incarcerated Persons Representative will only count towards quorum when they attend and review studies covered by [Subpart C of 45 CFR 45](#).

2. Research Approval Criteria

- a. The research under review represents one of the categories of research permissible under [45 CFR 46.306\(a\)\(2\)](#).
- b. Any possible advantages accruing to the person who is incarcerated through their 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.
- c. The risks involved in the research are commensurate with risks that would be accepted by those research volunteers who are not incarcerated.
- d. Procedures for the selection of participants within the prison/jail are fair to all people who are incarcerated and immune from arbitrary intervention by prison authorities or other people who are incarcerated. Unless the PI provides (to the IRB full board) a justification in writing for following some other procedures, "control" participants must be selected randomly from the group of available people who are incarcerated who meet the characteristics needed for that particular research project.
- e. The information is presented in language that is understandable to the participant population.
- f. Adequate assurance exists that parole boards will not take into account a person's participation in the research in making decisions regarding parole, and each person who is incarcerated is clearly informed in advance that participation in the research will have no effect on their parole.
- g. Where the IRB full 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 individuals who are incarcerated' sentences, and for informing participants of this fact.
- h. The IRB full board shall carry out other duties as may be assigned by the Secretary of DHHS.
- i. The institution shall certify to the Secretary of DHHS, in such form and manner as the Secretary may require, that the duties of the full board under this section have been fulfilled. Refer to Section E.8. below.

3. Administrative Review Processes

- a. None of the exemption categories for research involving human subjects at 45 CFR 46.104(d) apply to research involving people who are incarcerated unless they are incidentally included in the research.

- b. Research involving people who are incarcerated must be reviewed via Expedited procedures or by the convened full board, except as indicated in V.E.3.a above.
 - c. The Incarcerated Persons Representative must review research involving people who are incarcerated, focusing on requirements in Subpart C.
 - d. The Incarcerated Persons Representative must receive all review materials pertaining to the research.
- 4. Expedited Review
 - a. Research involving people who are incarcerated may be reviewed by the expedited procedure, if a determination is made (by the IRB staff or full board member and the Incarcerated Persons Representative) that the research involves no more than minimal risk for the incarcerated person population being studied, and the research falls within the categories eligible for expedited review. The representative for the people who are incarcerated may determine that a convened full board review is required.
 - b. The Incarcerated Persons Representative must agree with the determination that the research involves no more than minimal risk for the study to receive expedited review.
 - c. The Incarcerated Persons Representative must review the research as a reviewer, designated by the IRB chair, or as a consultant. This may be as the sole reviewer or in addition to another reviewer, as appropriate.
 - d. Review of amendments, other than minor personnel changes, must use the same procedures as the initial review.
- 5. Convened Full Board
 - a. The Incarcerated Persons Representative must present their review either orally or in writing at the convened meeting of the IRB when the research involving people who are incarcerated is reviewed.
 - b. Annual approval renewal must use the same procedures as the initial review, including the responsibility of the Incarcerated Persons Representative to review the renewal materials and to participate in the meeting.
 - c. The IRB may require increased oversight of the research based on the type of research. This may include approval renewal at a frequency of more than once a year.
- 6. Amendments
 - a. Amendments to research that was initially reviewed via expedited procedures, may be reviewed using expedited procedures unless the amendment changes the risks/benefits ratio or procedures in a way that requires full board review.
 - b. Amendments to research that was initially reviewed via the full board, must be reviewed by the full board unless the amendments are minor.
 - c. Amendments to research that was approved by the full board that involve more than a minor change must use the same procedures as the initial review.
- 7. Annual Renewals for Full Board Studies
 - a. The continuing review of the research must use the same procedures as the initial

review.

- b. The Incarcerated Persons Representative must be present and participate in the convened full board meeting to review and approve the renewal materials. For expedited research, the Incarcerated Persons Representative must have the opportunity for input and review before approval.
8. Department of Health and Human Services (DHHS) Certification
- a. For any DHHS-conducted or supported research involving people who are incarcerated, the institution(s) engaged in the research must certify to the Secretary that the IRB reviewed the research and made seven findings as required by the regulations ([45 CFR 46.305\(a\)](#)).
 - b. For Appalachian State University research, this applies only to federally funded research activities or research that involves the DHHS as a collaborator.
 - c. The certification request must be forwarded to OHRP.
 - d. OHRP then will determine whether the proposed research involves one of the categories of research permissible under [45 CFR 46.306\(a\)\(2\)](#), and if so, which one. OHRP will consult with appropriate experts with respect to certain research that falls under paragraphs (iii) and (iv) of [45 CFR 46.306\(a\)\(2\)](#). When applicable, OHRP will also publish a notice of intent to approve such research in the *Federal Register*. Research involving people who are incarcerated may proceed only after receipt of the OHRP authorization letter.
 - e. Following its review of the certification, if OHRP determines that the research involves one of the permissible categories, OHRP will send the institution a letter authorizing the involvement of people who are incarcerated in the proposed research.
 - f. Following its review of the certification, if OHRP determines that the proposed research does not involve one of the permissible categories, it will state in the letter to the institution that such research involving people who are incarcerated cannot proceed.
 - g. If research is not DHHS-conducted or supported, the institution does not need to submit any certification to OHRP.