Research Involving Prisoners

I. Purpose
This policy/procedure applies to all investigators conducting research with prisoners regardless of age. For research projects that involve more than minimal risk, the Institutional Review Board (IRB) may consider whether there is the potential for direct benefit for the individual participant. More than minimal risk research projects in which there is only potential benefit to society or where the prison population is chosen as a convenient study population are not sufficient justifications for the enrollment of prisoners in a research project.

II. Definitions
a. **DHHS** – The Department of Health and Human Services [46.303(b)].

b. **Minimal Risk as Defined for Prisoners** – 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.


d. **Prisoner** – Prisoners are people who are involuntarily being held in a jail, prison, juvenile justice center, treatment or other facility or who have been detained while awaiting arraignment, trial, or sentencing. This includes those prisoners who have been admitted to hospitals, psychiatric centers, alcohol or drug treatment facilities as an alternative to sentencing, or confined to their home under a court order (such as an ankle bracelet with the intent of limiting movement). The term “prisoner” includes individuals sentenced to such an institution under a criminal or civil statute; as well as 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 [46.303(c)]. The definition applies to children, as well as adults. When children are involved, the additional protections outlined in both Subpart C and Subpart D (Children) apply and must be followed.

e. **Secretary** – The Secretary of Department of Health and Human Services (DHHS) and any other officer or DHHS employee to whom authority has been delegated [46.303(a)].

III. Policy

Per the federal regulations, permitted research involving prisoners include:

1. Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as participants only if:
   a. The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under 45 CFR 46.305 of this subpart; and
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b. In the judgment of the Secretary the proposed research involves solely the following:
   i. The research is the study of 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;
   ii. The research involves the study of prisoners as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk (see special definition above) and no more than inconvenience to the participants;
   iii. The research involves the study of conditionsparticularly 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;
   iv. 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.
   v. Secretarial Waiver – The DHHS Secretarial waiver for certain epidemiological research conducted or supported by DHHS functions as a fifth category of permissible research (68 FR 36929, June 20, 2003). The criteria for this category are that the research must have as its sole purpose:
      • to describe the prevalence or incidence of a disease by identifying all cases, or
      • To study potential risk factor associations for a disease.
      • The research presents no more than minimal risk and no more than inconvenience to the prisoner-participants.
      • Prisoners are not a particular focus of the research.

The institution still must review the research under subpart C and certify to OHRP that an appropriately constituted IRB has reviewed the proposal and made all other required findings under HHS regulations at 45 CFR 46.305(a) and receive OHRP authorization prior to initiating any research involving prisoners. All of the other requirements of subpart C apply to research in this category.

vi. Except as provided in paragraph (1) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as participants.

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2. Biomedical or behavioral research not conducted or supported by DHHS may involve prisoners as participants only if it meets other applicable prisoner regulations (Department of Defense, etc) and is reviewed and approved by the IRB.

3. **The VA and Prisoners in Research:** Research involving prisoners may not be conducted by Veterans Administration (VA) investigators while on official duty or at VA-approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer. If the waiver has been granted the research must follow all federal, state, and local regulations and WSU policy (1200.05 47).

4. **For Department of Defense (DoD) regulated research involving prisoners:**
   a. The DoD prohibits research involving prisoners of war.
   b. The IRB must be aware of the definition of “prisoner of war” for the DoD component granting the addendum.

For all research involving prisoners that is supported or conducted by DHHS (only), regardless of category, GRU must certify to the Secretary through OHRP that the IRB reviewed the research and made seven findings as required by the regulations (45 CFR 46.305(a)(1) (see below “What the IRB Must Determine in Order to Approve Prisoner Research”). After the certification request is sent to OHRP, OHRP must then 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. Following certification, OHRP will send a letter to the institution authorizing the involvement of prisoners in the proposed research, if OHRP finds that the research involves one of the permissible categories.

- Each institution engaged in a multi-center research study must certify to the OHRP that DHHS regulations at 45 CFR 46.305© and 46.306(a)(1) have been met unless an institution relied on the review of an IRB operated by another institution engaged in the research, and that IRB or the other institution certified to OHRP on behalf of both institutions.
- If research is not conducted or supported by DHHS, WSU does not need to submit any certification to OHRP.
- Research proposals that are supported or conducted by DHHS and are in category 3, 4, or 5, require a Secretarrial consultation, in addition to certification to OHRP. OHRP, on behalf of the Secretary of DHHS, will consult with appropriate experts with respect to the applicable category. When applicable, OHRP will also publish a notice of intent to approve such research in the FEDERAL REGISTER. Research can proceed only after receiving an authorization letter from OHRP.
- When approval from OHRP and/or the Secretary of DHHS is required before prisoners can be enrolled in research, the GRU Institutional Official for Human Subjects Research will be responsible for submitting the protocol and related documents for certification and consultation.
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Conditions for Enrollment of Prisoners:

- Prisoners may not be enrolled in a research project involving a placebo unless the standard of care for the disease or condition is “no treatment” and the procedures for using the placebo are the same as the “no treatment” option.
- Secretarial waiver of informed consent in certain emergency research is not applicable to research involving prisoners (61 FR 51531).
- None of the exemption categories in the DHHS regulations for research [45 CFR 46.101(b)] apply to research involving prisoners [45 CFR 46.101].
- Research that qualifies for exemption from IRB review may not enroll prisoners. Research that requires expedited or full board review for non-prisoners may enroll prisoners in a research protocol if reviewed and approved by all the following: (1) one of the GRU IRBs at a full board meeting; and (2) after administrative review by the Institutional Official.
- If a Principal Investigator (PI) has requested approval to enroll prisoners in a research project in addition to other research participants, the enrollment of other research participants may be started after IRB review and approval. The enrollment of prisoners may not begin until after the additional approval of: the Institutional Official, and (2) after review and approval of OHRP for all DHHS supported research.
- Participants who later become prisoners: This process applies also if a PI enrolls a participant in a research protocol who subsequently becomes a prisoner. When this occurs:
  - The individual’s participation in the research must stop unless the PI determines that withdrawing the participant will cause harm to the participant and the PI notifies the IRB Chair of this and the IRB Chair concurs.
  - The PI must notify the IRB immediately for instructions on how to proceed in obtaining IRB and administrative approval for enrolling prisoners in a research protocol.
- Because the prison or penal institution or other facility responsible for the care of the prisoner must participate in the implementation of the research protocol, the PI is responsible for obtaining the initial approval of the prison or penal institution. The letter of support must contain:
  - A general statement of support for the PI to conduct the research in their institution;
  - An assurance that the prisoner will not be given any advantages from participation when compared to the other prisoners who do not participate;
  - An assurance that participation in the research will not influence the parole board and its decisions; and
  - A statement that the protocol meets the local standards for the ethical treatment of prisoners.
- Once initial approval of the prison or penal institution administrative unit has been obtained and the protocol has been approved by the IRB for the enrollment of prisoners in the research project, the GRU Institutional Official for Human Subjects Research shall review the file for final approval. If the project is supported by or conducted by DHHS, then the project will also require the review and certification by the Secretary of DHHS prior to beginning for the prisoner participants.
- A separate informed consent form that takes into account the additional risks and uniqueness of being a vulnerable population shall be developed by the PI for the enrollment of prisoners,
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approved by one of the GRU IRBs at a full board meeting. That informed consent form must be used for all prisoners but cannot be used for individuals who are not prisoners.

- For Department of Defense (DoD) regulated research involving prisoners:
  - The DoD prohibits research involving prisoners of war.
  - The IRB must be aware of the definition of “prisoner of war” for the DoD component granting the addendum.

IRB Review of Research with Prisoners:

Composition of Institutional Review Boards When Prisoners are Involved:

- A majority of the Board (exclusive of prisoner or prisoner representative IRB members) shall have no association with the prison involved, apart from their membership on the Board.
- At least one member of the IRB shall be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity, except that when more than one IRB reviews a particular research project, only one IRB need satisfy this requirement.

Review of “Greater Than Minimal Risk” Research Involving Prisoners:

For research reviewed by the convened IRB (research that is greater than minimal risk), involving prisoners:

- The prisoner representative must be a voting member of the IRB and can be an alternate.
- The prisoner representative must review any research involving prisoners
- The prisoner representative must be present at the convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
- The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.
- Minor modifications may be reviewed using the expedited procedure described below, using either of the two procedures described based on the type of modification.
- Substantial modifications reviewed by the convened IRB must use the same procedures for initial review including the responsibility of the prisoner representative.
- Continuing review of research involving prisoners must use the same procedures for initial review, including the responsibility of the prisoner representative.

Review of “Minimal Risk” Research Involving Prisoners:

For research reviewed by the expedited procedure (minimal risk) involving interaction with prisoners (including obtaining consent from prisoners):

- Research involving prisoners, involving interaction with prisoners (including obtaining consent from prisoners) may be reviewed by the expedited procedure if a determination is made that

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the research is minimal risk (see special definition) for the prison population being studied or included.

The prison representative must concur with the determination of minimal risk.

- The prison representative must review the research as a reviewer. Review of modification and continuing review must use the same procedures for initial review using this expedited process, including the responsibility of the prison representative. If no one is enrolled, the prison representative does not need to review at the point of continuing review.

Review of research that does not involve interaction with prisoners:

For research reviewed by the expedited procedure that does not involve interaction with prisoners (e.g., existing data, record review):

- Research involving prisoners that does not involve interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research is minimal risk for the prison population being studied or included. The Prisoner or Prisoner Representative must concur with the risk level.
- Review by the prison representative is not required for studies with no direct interactions with prisoners.

Review of modification and continuing review must use the same procedures for initial review using this expedited process including the responsibility of the prison representative.

What the IRB Must Determine in Order to Approve Prisoner Research:

When an IRB is reviewing a protocol in which a prisoner is a subject, the IRB must make, in addition to other requirements under 45 CFR 46, Subpart A, seven additional findings under 45 CFR 46.305(a), as follows:

1. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2); The specific category must be noted in the record or minutes.
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 participants 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 participants 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;

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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 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.

IV. Process for Enrolling Prisoners in a Research Protocol

1. The PI determines that he/she would like to enroll prisoners in a research protocol or the PI determines that a previously enrolled participant has become a prisoner.

2. The PI obtains initial approval in writing form the prison or penal institution concerning the enrollment of one or more prisoners in a research project.

3. The PI checks “Prisoner” in the Subject Selection section of Core Data Form and completes the Protocol Specific Determinations for Prisoners supplemental form. If a previously approved protocol is changed to now request enrollment of prisoners as research participants, the PI must revise the Core Data Form to indicate prisoners as a population and complete the Protocol Specific Determinations for Prisoners supplemental form, for IRB review.

4. The PI prepares a separate consent form for the enrollment of prisoners in a research protocol.

5. The Core Data Form, protocol, informed consent form, penal institution approval letter, protocol, and accompanying documentation are submitted to one of the GRUIRBs.

6. The IRB Administrator of the IRB committee or other office staff notifies the IRB Office Director, IRB Administration, and the IRB Chair of the prisoner protocol as soon as this is known.

7. It is recommended that the Chair consider inviting the PI to the IRB meeting in order to answer any questions that may arise. This will facilitate the lengthy process of review that the prisoner protocol will undergo as an extremely vulnerable subgroup for those studies that are supported or conducted by DHHS.

8. The study must be assigned to a Prisoner or Prisoner Representative as one of the reviewers, even if it is expedited.

9. The IRB then discusses and reviews the protocol. If approved, the IRB shall indicate that the protocol must obtain: (a) Administrative review and approval by the Institutional Official for Human Subjects Research and (b) review and certification by OHRP, if it is DHHS research.

10. After obtaining: (a) the approval of one of the WSU IRBs to enroll human participants in a research protocol; (b) Institutional Official for Human Subjects Research approval to enroll prisoners, and (c) certification from OHRP if it is DHHS supported research, (d) then the PI is notified that he/she is authorized to enroll prisoners in a research protocol.

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