

| SYRACUSE UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM STANDARD OPERATING PROCEDURES | | | |
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| TITLE: SPECIAL CATEGORIES OF RESEARCH: PRISONERS | | DOCUMENT NUMBER: 022 | |
| REVISION NUMBER | REVISION DATE (SUPERSEDES PRIOR VERSION) | EFFECTIVE DATE | PAGE NUMBER |
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Title: SPECIAL CATEGORIES OF RESEARCH: PRISONERS

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the responsibilities as mandated by the Federal regulations when prisoners are involved as participants in research.

2.0 Policy:

It is the policy of the Syracuse University (SU) Institutional Review Board (IRB) to review and approve all research involving prisoners with additional ethical and regulatory considerations applicable to prisoners under 45 CFR 46, Subpart C, *Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Participants*.

The IRB provides extra scrutiny of research involving vulnerable populations who, by virtue of their situations, are susceptible to exploitation or may have difficulties exercising informed consent. The IRB pays special attention to the risks and benefits of research, incentives for participation, and the informed consent process on research involving vulnerable populations.

The special vulnerability of prisoners makes consideration of involving them as research participants particularly important. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as participants in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners. Therefore, if a protocol involves the use of prisoners as participants, both the general IRB policies and procedures apply as well as the additional ones outlined in this policy.

- 2.1** The IRB may approve research involving prisoners by following the Checklist for Studies Involving Prisoners.
- 2.2** The IRB will have a prisoner representative as a member.
- 2.3** When an IRB reviews a protocol involving prisoners as participants, the composition of the IRB must satisfy the following requirements of 45 CFR 46.304 (a) and (b):
 - 2.3.1** A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB; and
 - 2.3.2** At least one member of the IRB must be present at the meeting and be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB only one IRB need satisfy this requirement.
- 2.4** The prisoner representative selected to serve on the IRB Committee must have a close working knowledge, understanding and appreciation of prison conditions from the perspective of a prisoner. Suitable individuals could include present or former prisoners; prison chaplains; prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.
- 2.6** The IRB must meet the special composition requirements for all types of review for the protocol: initial review, continuing review, review of protocol amendments, review of reports of unanticipated problems involving risk to participants or others, or in the event an individual becomes a prisoner while participating in a research protocol.

- 2.7 The IRB must notify OHRP of any change in the IRB roster occasioned by the addition of a prisoner or a prisoner representative. The IRB should be alerted to the impact of roster changes on quorum requirements. Specifically, the IRB should:
 - 2.7.1 Notify OHRP of the name and qualifications of the prisoner representative, if the approved IRB roster does not currently reflect this information; and
 - 2.7.2 Maintain the CV of the prisoner representative serving on the IRB.
- 2.8 If a participant becomes a prisoner after enrolling in a research study, the Investigator is responsible for immediately reporting the event in writing to the IRB. This is not required if the study was previously approved by the IRB for prisoner participation.
- 2.9 If research interactions and interventions or obtaining identifiable private information will not occur during the incarceration, IRB review and approval is not required.
- 2.10 If the study was not previously reviewed and approved by the IRB in accordance with the requirements, all research interactions and interventions with the participant, and acquisition of identifiable private information, must cease until the requirements are satisfied unless the IRB determines that there is an over-riding safety concern or ethical issue involved such that it is in the best interests of the participant to continue participating in the research interventions or interactions.
- 2.11 The full, convened IRB Committee is to review the current research protocol in which the participant is enrolled, taking into special consideration the additional ethical and regulatory concerns for a prisoner involved in research.
- 2.12 For research conducted or supported by HHS to involve prisoners, two actions must occur:
 - 2.12.1 The institution engaged in the research must certify to the Secretary (through OHRP) that the IRB designated under its assurance of compliance has reviewed and approved the research under 45 CFR 46.305; and
 - 2.12.2 The Secretary (through OHRP) must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2).
- 2.13 If an Investigator wishes to engage in non-HHS supported research, certification is not required. However, the IRB should apply the standards of this policy and the Federal regulations in reviewing the research.
- 2.14 If either of the following is true, the research should only proceed after the IRB has consulted with the appropriate experts, as determined by the IRB:
 - 2.14.1 The research involves conditions particularly affecting prisoners as a class; or
 - 2.14.2 The research does not satisfy the stipulations above.
- 2.15 When a prisoner is also a minor (e.g. an adolescent detained in a juvenile detention facility is a prisoner), *SOP 021* will also apply.
- 2.16 Expedited review of research involving prisoners is not allowed. The full, convened IRB Committee must review research involving prisoners as human participants.
- 2.17 Exemption from review of research involving prisoners is not allowed. Research that would otherwise be exempt from the requirement that it receive IRB approval is not exempt when the research involves prisoners.

3.0 References and Reference Documents:

45 CFR 46 Subpart C

OHRP Guidance Document "OHRP Guidance on Involvement of Prisoners in Research," May 23, 2003
SOP 021, Special Categories of Research: Children

4.0 Procedure:

4.1 Investigator Responsibilities.

- 4.1.1 The Investigator will submit the application for initial review and check under special populations that prisoners are a member of the participant group. If the participant population has an increased potential to become prisoners, and the Investigator will be interacting, intervening, or collecting identifiable private information during the incarceration, the Investigator may choose to have the proposal reviewed initially by the IRB and OHRP for prisoner participation.

- 4.1.2 The Investigator must report in writing to the IRB immediately when a participant becomes a prisoner after enrollment in research activities. If the research was not reviewed and approved by the IRB and OHRP in accordance with 45 CFR 46 Subpart C, the Investigator must notify the IRB in writing of the event. All research interactions and interventions with, and obtaining identifiable private information about, the now incarcerated prisoner-participant must cease until all requirements have been satisfied with respect to the relevant research activities. *NOTE: The IRB Chair may determine that the participant may continue to participate in the research until all requirements are satisfied in special circumstances in which the Investigator asserts that it is in the best interests of the participant to remain in the research study while incarcerated.*
- 4.1.3 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.
- 4.1.4 The Investigator will provide any additional documents or materials required for certification to the Secretary (through OHRP) for federally funded research involving prisoners.
- 4.1.5 The Investigator may not screen, recruit, or enroll any individual involuntarily confined or detained in a penal institution without written IRB approval. If the behavioral research is conducted or supported by HHS, it also requires review and written approval by the Secretary (through OHRP) before any research activities may begin, including screening and enrollment.

4.2 IRB Responsibilities.

- 4.2.1 The IRB Committee must review the proposed research taking into consideration all applicable SU policies, as well as additional requirements for prisoners to participate in research as described in 45 CFR 46, Subpart C.
- 4.2.2 The Committee may not review or make determinations regarding studies involving prisoners as a target population unless the Committee has a member who is a prisoner or a prisoner representative with a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner. Documentation of expertise is provided by the curriculum vitae of the prisoner or prisoner representative serving on the IRB.
- 4.2.3 The IRB will review the proposed research, consents, and applicable documents to determine whether the study meets criteria 45 CFR 46.111 for approval. In order to provide written documentation of these criteria, the IRB Committee must complete the Checklist for Studies Involving Prisoners detailing how each of these criteria is met. All seven criteria for approval must be met and documented individually.
- 4.2.4 When a research participant becomes a prisoner, and the IRB has not previously reviewed the proposal for prisoner populations, the IRB will conduct a review of the research proposal in accordance with Subpart C and make one of the following determinations:
 - 4.2.4.1 IRB review and approval is not required if the research interactions and interventions or obtaining of identifiable private information will not occur during the incarceration period; or
 - 4.2.4.2 Approve withdrawal of the participant(s) from the study if withdrawal will not place the participant at undue harm or risk; or
 - 4.2.4.3 Approve research participation for non-prisoner participants but approve pending for prisoner-participants if the seven required findings in 45 CFR 46.305(a) have been met but the IRB is still waiting on the receipt of the Secretary's determination (through OHRP) that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2). All interactions and interventions with, and obtaining identifiable private information must cease for these prisoner-participants until the requirements of Subpart C have been satisfied with respect to the relevant protocol. *NOTE: OHRP has allowed one important exception. In special circumstances in which the Investigator asserts*

that it is in the best interests of the participant to remain in the research study while incarcerated, the IRB Chair may determine that the participant may continue to participate in the research until the requirements of Subpart C are satisfied; or

4.2.4.4 Approve research participation for non-prisoner participants but defer for prisoner-participants if the seven required findings in 45 CFR 46.305(a) have not been met to the satisfaction of the IRB. All interactions and interventions with, and obtaining identifiable private information must cease for these prisoner-participants until the requirements of Subpart C have been satisfied with respect to the relevant protocol. *NOTE: OHRP has allowed one important exception. In special circumstances in which the Investigator asserts that it is in the best interests of the participant to remain in the research study while incarcerated, the IRB Chair may determine that the participant may continue to participate in the research until the requirements of subpart C are satisfied.*

4.2.5 For DHHS supported research, the institution must certify to the Secretary (through OHRP) that the IRB designated under its assurance of compliance has made the seven findings required under 45 CFR 46.305(a) and a statement indicating that the IRB chose one of the four permissible categories of research in 45 CFR 46.306(a)(2).

4.2.5.1 It is sufficient to include a statement that indicates that the IRB made the required findings under 45 CFR 46.305(a). OHRP does not require that the prisoner letter include a specific listing or rationale behind the IRB findings. The institution may wish to include a brief, protocol-specific explanation of the IRB's rationale for each finding.

4.2.5.2 The institution must indicate in the certification letter which of the four categories of permissible research involving prisoners in 45 CFR 46.306(a)(2) is applicable to the proposed research. Research involving prisoners can proceed only if the research fits under a category of permitted research under 45 CFR 46.306(a)(2). OHRP will make its own determination, based on the information in the prisoner certification letter, the protocol materials and the grant application as to whether any of the four categories apply to the proposed research. OHRP may or may not concur with the IRB's choice of category.

4.2.5.3 The institution may wish to include a statement that indicates that the IRB was constituted as per the requirements in 45 CFR 46.304. OHRP does not require that the prisoner certification letter include information about the manner in which the IRB fulfills the requirements of 45 CFR 46.304. The institution may wish to provide the name of the prisoner representative.

4.2.5.4 In addition to the prisoner certification letter, the following information must also be sent to OHRP:

4.2.5.4.1 The protocol application (which includes the protocol and any IRB submission materials including the ICDs); and

4.2.5.4.2 The grant application (including any grant award updates).

4.2.5.5 OHRP encourages the inclusion of the following information with the prisoner certification letter:

4.2.5.5.1 OHRP Assurance Number;

4.2.5.5.2 IRB Number for Designated IRB;

4.2.5.5.3 Site(s) where research involving prisoners will be conducted;

4.2.5.5.4 If prisoner research site is "engaged in research," provide OHRP Assurance Number;

4.2.5.5.5 DHHS Grant Award Number;

4.2.5.5.6 DHHS Funding Agency Name;

4.2.5.5.7 Funding Agency Grants/Program Officer Name and Telephone Number;

4.2.5.5.8 Title of DHHS Grant;

- 4.2.5.5.9** Title of Protocol (if the same as the title of the grant, indicate as such);
- 4.2.5.5.10** Version date of the ICD to be used with prisoners;
- 4.2.5.5.11** Date(s) of IRB Meeting(s) in which the protocol was considered and provide a chronology of:
 - 4.2.5.5.11.1** Date of initial IRB review; and
 - 4.2.5.5.11.2** Date of Subpart C reviews including:
 - 4.2.5.5.11.2.1** Type of IRB review (initial, amendment, addendum, continuing review); and
 - 4.2.5.5.11.2.2** Special IRB review for prisoner issues.
- 4.2.5.5.12** Principal Investigator; and
- 4.2.5.5.13** Reason for IRB review (choose the applicable reasons):
 - 4.2.5.5.13.1** Non-prison study (not previously reviewed and certified under Subpart C) in which participant has become incarcerated (or otherwise fits the definition of prisoner in 45 CFR 46.303(c)) and the PI wishes to continue the individual’s participation in the study;
 - 4.2.5.5.13.2** Non-prison study with at-risk population (i.e., probationers, substance abusers);
 - 4.2.5.5.13.3** Non-prison study, majority of study population are non-prisoners but PI seeks to enroll some prisoners (as defined in 45 CFR 46.303(c));
 - 4.2.5.5.13.4** Minimal risk DHHS conducted or supported epidemiologic research, majority of study population are non-prisoners but PI seeks to enroll some prisoners (prisoners are not the focus of the study) and the sole purpose of the study is either:
 - 4.2.5.5.13.4.1** To describe the prevalence or incidence of a disease by identifying all cases; or
 - 4.2.5.5.13.4.2** To study potential risk factor associations for a disease.
 - 4.2.5.5.13.5** Initial Subpart C review of study designed to be conducted in a prison or using prisoners as defined in 45 CFR 46.303(c), the PI seeks to enroll already incarcerated participants.
- 4.2.6** The prisoner certification letter must contain the following information, if applicable:
 - 4.2.6.1** Justification for the use of prisoners in the study. If applicable, delineate the protocol to be conducted in the prison from the overall project described in the grant application;
 - 4.2.6.2** Study objectives or study aims;
 - 4.2.6.3** Brief summary of study procedures;
 - 4.2.6.4** Customary treatment or services at the prison (or alternative to incarceration) research site(s) for the condition being studied;
 - 4.2.6.5** Description of how risks specific to a prison (or alternative to incarceration) setting are minimized;
 - 4.2.6.6** Whether the prison site(s) are “engaged in research” and whether they have obtained an assurance with OHRP;
 - 4.2.6.7** Whether a Certificate of Confidentiality was obtained by the PI for the study;

- 4.2.6.8 Describe recruitment procedures in the specific prison (or alternative to incarceration) setting; and
- 4.2.6.9 Describe how the consent form was altered for use with a prison population or specific prisoner and whether the subsequently incarcerated participant will be reconsented.
- 4.2.7 All prisoner research certification letters should be mailed to:
OHRP Prisoner Research Coordinator
Office for Human Research Protections (OHRP)
Department of Health and Human Services
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
- 4.3 The IRB Committee may approve the research for non-prisoner populations until all the criteria in Subpart C are satisfied.
- 4.4 The IRB must inform the Investigator in writing that no prisoner-participants can be enrolled or involved until the IRB/institution receives a letter from OHRP that acknowledges receipt of the prisoner certification and indicates the Secretary's (through OHRP) determination that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2).
- 4.5 ORIP Responsibilities.**
 - 4.5.1 The ORIP Director or designee will verify that the supplemental form for "Vulnerable Populations: Prisoners" is completed as part of the initial study documents.
 - 4.5.2 The ORIP Director or designee will verify that the Committee reviewing the research involving a prisoner has at least one member who is a prisoner or prisoner representative in attendance.
 - 4.5.3 To adequately document the IRB review of the research:
 - 4.5.3.1 The curriculum vitae of the prisoner or prisoner representative serving on the IRB will be on file in the IRB;
 - 4.5.3.2 The "Checklist for Studies Involving Prisoners" will be placed in the IRB file; and
 - 4.5.3.3 The discussion and determinations of the IRB regarding the seven additional findings required under HHS regulations at 45 CFR 46.305(a) will be documented in the minutes.
 - 4.5.4 For HHS studies the ORIP Director will assist in preparing documents for the certification letter and prepare a draft certification letter to the Secretary (through OHRP) which will be signed by the appropriate institutional official listed on SU's FWA.

SOP 022: SPECIAL CATEGORIES OF RESEARCH: PRISONERS

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