1. PURPOSE

The policy describes the requirements concerning review of research that involves prisoners.

2. PROCEDURE

Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and non-coerced decision whether or not to participate in research. To safeguard their interest and to protect them from harm, special ethical and regulatory considerations apply when reviewing research involving this population.

3. DEFINITIONS

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 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.

For Prisoners, "*minimal risk*" means the probability and magnitude of physical or psychological harm that is normally encountered in daily lives or in the routine medical, dental, or psychological examination of a healthy person.

Prisoner representative: A person who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of prisoners. The prisoner representative is an advocate that may be a former prisoner or anyone else who meets the requirements stated here (examples: public defense attorney; prison chaplain; volunteer counselor; member of a community-based prisoner advocacy group).

4. SPECIFIC POLICIES

4.1 IRB Composition

The IRB shall meet the following requirements:

- A majority of the IRB shall have no association with the prison(s) involved, apart from their membership on the IRB.
- A least one person should be known and trained to serve as a prisoner representative with appropriate background and experience to serve in that capacity. This prisoner representative does not need to be an IRB member, and will only voice their professional opinion on studies that specifically have this vulnerable population.

4.2 Additional Duties of the IRB When Reviewing Research with Prisoners

If a PI indicates in the study submission that prisoners will participate in the research, or that human subjects may reasonably be expected to be incarcerated at some time point during the study, the additional requirements will apply to IRB review of the research:

- In addition to all other responsibilities of IRBs under 45 CFR 46 Subpart C, the IRB will include in its minutes that the research falls into one of the four categories of research permissible under 45 CFR 46.306(a)(2).
- If the research involving prisoners is either conducted or supported by DHHS, then the IRB will certify to OHRP that the duties of the IRB have been fulfilled. See "Procedures: Certification" below for additional details on this process.

- Prior to IRB Review, PI is responsible for obtaining necessary approvals with the Department of Corrections or other state departments, as applicable.

When reviewing research involving prisoners, the IRB will follow Subpart C of the DHHS regulations.

- A prisoner representative must be present at the 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 may attend the meeting by phone, video conference, or webinar as long as the prisoner representative is able to participate in the meeting as if they were present in person at the meeting.
- The prisoner representative must present his/her review either orally or in writing at the IRB meeting when research involving prisoners is reviewed.

The IRB reviewer(s) will use the "Research Involving Prisoners Checklist" to determine if the research falls under one of the four categories and is permitted research involving prisoners and meets all the appropriate determinations.

4.3 Level of IRB Review

Initial Review of research involving prisoners is normally reviewed at a convened IRB meeting. However, it may be performed by the expedited process instead of the convened IRB only when the research meets the following:

a. involves no interaction or intervention with prisoners;
b. the research meets the standard criteria for expedited review;
c. the definition of minimal risk as defined for prisoners is adhered to; and
d. the prisoner representative must concur with the determination that the research involves no greater than minimal risk.

Amendments to studies initially reviewed by a convened IRB are reviewed as follows:

a. Minor change: may be reviewed by the expedited process. The reviewer is encouraged to obtain consultation from a prisoner representative. An example of a minor change is to allow a current prisoner to enroll willfully on their own into a research study that is currently open and enrolling.
b. More than a minor change: the full convened IRB must conduct the review and a prisoner representative must participate in the review.

Continuing review must be performed using the same process as the initial review, unless the research qualifies for expedited review.

- If no prisoners have been enrolled, the research may receive continuing review using the expedited procedure.

Local regulations: In addition to meeting federal regulations, the project must comply with local and state requirements for inclusion of prisoners as subjects.

4.4 When Human Subjects Become Prisoners during a Research Protocol

This procedure applies whenever any human subject in a research protocol becomes a prisoner at any time during the protocol, *e.g.,* after the research has commenced. This is necessary because it is unlikely that

review of the research and the consent document contemplated the constraints imposed by the possible future incarceration of the human subject.

- If a human subject becomes a prisoner after enrollment in research, the PI is responsible for reporting this situation in writing to the IRB immediately.
- At the earliest opportunity after receiving the PI's notice or otherwise becoming aware of the prisoner status of a human subject, the IRB should review the protocol again with a prisoner representative as a member of the IRB. The IRB should take special consideration of the conditions of being a prisoner.
- Prior to IRB Review, PI is responsible for obtaining necessary approvals with the Department of Corrections or other state departments, as applicable.
- Upon this review, the IRB can either (a) approve the involvement of the prisoner human subject in the research in accordance with this policy or (b) determine that this human subject must be withdrawn from the research.
- If involvement of the prisoner human subject is approved, a special addendum to the consent document may be created that informs the prisoner human subject of the impact incarceration may have on his or her continued participation.

If a human subject becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C:

- Before terminating the enrollment of the prisoner, the IRB should consider the risks associated with terminating participation in the study.
- If the human subject cannot be terminated for health or safety reasons
    - Keep the human subject enrolled in the study and review the research under Subpart C.
        - If some requirement of Subpart C cannot be met, but it is in the best interest of the human subject to remain in the study, keep the human subject enrolled and inform OHRP (if applicable) of the decision along with the justification.
    - Remove the human subject from the study and keep the human subject on the study intervention under an alternative mechanism such as compassionate use, off label use, etc.

5. Procedures: Certification

Prisoner research supported by any federal agency that adopted the 45 CFR 46, Subpart C regulations must meet two additional requirements. Research involving prisoners not conducted or supported by HHS does not need to submit any certification to OHRP.

1. Certification: The IRB must certify to OHRP that one of its IRBs has reviewed and approved the research in compliance with the applicable regulations, and
2. Authorization: The OHRP must determine that the proposed research falls within the categories of permissible prisoner research and that the IRB review has met the special requirements for prisoner research. The research cannot begin until the IRB has received OHRP's authorization letter.

Certification Materials to be sent to OHRP include: IRB Approved Protocol, any relevant grant material that was submitted to funding agencies (such as the NIH) within the DHHS, all IRB approved materials, and a letter to the OHRP from the IRB. The letter should include a statement that the IRB has reviewed the research under regulations 45 CFR 46, subpart C and has made the findings required under 45 CFR 46.305(a). The letter should also include the OHRP Assurance number (FWA number), Name, address and

IRB registration number of the IRB that performed the review, and other study-specific details. A copy of the letter is sent to the researcher for their files.

Authorization by OHRP: OHRP determines whether the proposed research involves one of the permissible categories of prisoner research, and if so which one. Following its review of the certification packet, OHRP sends the IRB a letter with its determination and decision. A copy of the OHRP determination letter is then provided to the PI, indicating that the research with prisoner(s) may proceed.

Modifications to an approved and certified study do not require re-certification with OHRP unless there is a fundamental change in the research that alters the applicability of the approved prisoner research category.

6. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report
45 CFR 46: Subpart C
45 CFR § 46.305 - Additional duties of the Institutional Review Boards where prisoners are involved
21 CFR 56.111
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html#4175

7. REFERENCED DOCUMENTS

Research Involving Prisoners Checklist

REVISION HISTORY

Revision Number	Version Date	Approved By Date Approved
2.1	10/2/2020	Avera Institutional Official, 10/2/2020
• Clarified that the prisoner representative does not have to be an actual IRB member, but must be an appropriate person to represent the prisoner population. • Added an example of a minor amendment which is Expeditable, such as when a study is already open and enrolling, and the site wants to enroll a current prisoner into a study. • As a clarification, added that research involving prisoners not conducted or supported by HHS does not need to submit any certification to OHRP. • Added another prisoner FAQ link from the HHS website		
2.0	3/12/2019	Avera Institutional Official, 4/8/19
• Added definitions of a Prisoner and prisoner representative. • Clarified that the prisoner representative will be an alternate IRB member, and will vote only on the studies that have this vulnerable population. • Added in that the PI is responsible for obtaining necessary approvals with the Dept. of Corrections or other state departments. • Clarified the level of IRB review needed for initial approval, modifications, and continuing review. • Added in the Certification and Authorization requirement with OHRP if the research is supported by any federal agency • Updated applicable regulations		
1.0	August 2016	Director HSRP / August 2016