

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Research Subjects Review Board</b>		<b>Effective Date: 11/27/2019</b>
	<b>Research Involving Prisoners</b>		<b>Policy 603</b>
			<b>Version: 1.2</b>

## POLICY

### 1. Purpose

Define the special ethical and regulatory considerations required by the RSRB that apply when reviewing research involving prisoners.

### 2. Scope

This policy applies to all federally funded research involving prisoners. This policy is invoked when prisoners are an intended population in the protocol and included on the initial study application, or if a subject becomes a prisoner after the RSRB approved research begins. The RSRB routinely applies this policy to non-federally funded research as guidance.

### 3. Definitions

3.1. Prisoner – Includes any individual who is:

- 3.1.1. Involuntarily confined or detained (i.e., ability to leave institution is restricted) in a penal institution (e.g., prison, jail, juvenile offender facility);
- 3.1.2. Detained in other facilities by virtue of statues or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, or is;
- 3.1.3. Detained pending arraignment, trial or sentencing.

Examples of when this regulatory definition of prisoner applies include the following:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration; however, individuals who are undergoing treatment but reside in the community (i.e., are not confined/detained) are not prisoners.
- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration; however, individuals who are voluntarily admitted to an institution for treatment or who have been civilly committed to non-penal institutions are not prisoners.
- Parolees who are detained in a treatment center as a condition of parole.

*Note Exception: Individuals on probation or wearing monitoring devices are generally not considered to be prisoners.*

- 3.2. Minimal Risk (for Prisoner Research) - 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 (non-incarcerated) persons.

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			<b>Version: 1.2</b>

#### 4. References

- 4.1. HHS 45 CFR 46.104(b)(2); HHS 45 CFR 46 Subpart C (46.301 – 46.306); FDA 21 CFR 56.111(b); HHS Federal Register, vol. 68, p. 36929, June 20, 2003
- 4.2. [Policy 302 RSRB Membership and Composition](#);  
[Policy 404 Criteria for Approval of Research](#);  
[Policy 501 Levels of RSRB Review](#)

#### 5. Responsibilities

- 5.1. The RSRB is responsible for applying additional safeguards when reviewing research involving prisoners, who may be under constraints that could affect their ability to make a voluntary and un-coerced decision regarding participation in research.
- 5.2. The RSRB is responsible for the review and approval of research by a board that contains a majority of members having no association with the prison(s) involved, apart from their membership on the board, and that consists of at least one prisoner representative (or prisoner). See *Policy 302 RSRB Membership and Composition*.
- 5.3. The RSRB is responsible for documenting the determinations supporting the approval of research involving prisoners under the requirements listed in section 6.3 of this policy [45 CFR 46.305(a)].
- 5.4. The Investigator is responsible for notifying the RSRB if a subject becomes a prisoner during the course of an RSRB research study not previously approved for inclusion of prisoners.

#### 6. Requirements

- 6.1. **RSRB Composition:** The RSRB must meet the special composition requirements as noted under section 5.2 of this policy for research involving prisoners and undergoing convened board review.
  - 6.1.1. Due to the vulnerability of the prisoner population, research involving prisoners is reviewed by the convened board at the time of initial and continuing review, regardless of risk level.
- 6.2. **Permissible Categories of Research Involving Prisoners:** The RSRB may only permit research involving prisoners if the research falls within one of the following categories [45 CFR 46.306(a)(2)]:
  - 6.2.1. 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 subjects;

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- 6.2.2. 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;
- 6.2.3. 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) and, for studies assigning subjects to a control group that may have no benefit that HHS has documented intention to approve such research;
- 6.2.4. Research on both innovative and accepted practices, which have the intent and reasonable probability of improving the health or well-being of the subject and, for studies assigning subjects to a control group that may have no benefit that HHS has documented intention to approve such research; **or**
- 6.2.5. Epidemiologic research solely directed towards the prevalence or incidence of a disease by identifying all cases, or to study the risk factors associated with a disease, **and** the research presents no more than minimal risk, no more than inconvenience to the prisoner subjects, and prisoners are not a particular focus of the research (DHHS Waiver of Subpart C – Federal Register, vol. 68, p. 36929, June 20, 2003).

*Note:* Per federal regulations 45 CFR 46.104(b)(2), research involving prisoners may not be deemed exempt. The proposed research may qualify for expedited review procedures (see *Policy 501 Levels of RSRB Review*).

- 6.3. **RSRB Findings for Approval:** Prisoners may be involved in research only if the criteria for approval of research are met per *Policy 404 Criteria for RSRB Approval of Research*, as well as the following seven (7) additional findings:
  - 6.3.1. The study satisfies the criteria for permissible research listed under section 6.2 of this policy;
  - 6.3.2. 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;
  - 6.3.3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
  - 6.3.4. 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 Investigator provides to the RSRB 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;

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			<b>Version: 1.2</b>

- 6.3.5. The information is presented in language which is understandable to the subject population;
- 6.3.6. 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**
- 6.3.7. Where the 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 individual prisoners' sentences, and for informing participants of this fact.

6.4. **Prisoner Certification to OHRP:** For research funded by an agency/office of the Department of Health and Human Services (HHS), the University of Rochester will certify to the Office for Human Research Protection (OHRP) that the RSRB completed its review of permissible research and that the seven additional requirements are met (see Appendix 1 for template letter).

6.4.1. Research activities may not proceed until OHRP issues written approval of the study through published notice in the Federal Register and notice to the UR.

6.5. **Incarceration After Enrollment:** All research interactions and data collection activities must cease for a subject who becomes incarcerated after enrollment.

6.5.1. Once confirmed that the subject meets the definition of prisoner upon receipt of report from the Investigator, the RSRB will re-review the study under the requirements of sections 6.1 – 6.4 of this policy if the Investigator plans to continue the prisoner subject's participation in the study. For federally supported research, study activities involving that subject may not be conducted until written letter of authorization is received from OHRP. Otherwise, the subject must be withdrawn from the study after the risks of withdrawal are considered, except as noted below.

6.5.1.1. The Investigator may provide justification that it is in the best interest of the subject to remain in the study while incarcerated for health or safety reasons, in which case the RSRB Chair will determine that the subject may continue to participate in study activities until the requirements of 45 CFR 46 subpart C are satisfied. If any of the findings required under subpart C cannot be met, this must be documented in the certification to OHRP. Alternatively, if a treatment intervention is used in the study, the subject may be removed from the research study and treated under standard of care measures.

6.5.2. If the RSRB determines that the subject doesn't meet the definition of prisoner, follow up activities may resume per protocol.

*Note:* If a subject is temporarily (i.e., for a period of time in between study visits) incarcerated after enrollment, the RSRB will confirm that the incarceration has no effect

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on the conduct of the study overall or future protocol visits for the subject and whether the subject may remain enrolled.

- 6.6. **Potential Prisoner Enrollment:** If the study population includes people who are likely to be incarcerated during enrollment (i.e., individuals/sub-populations more likely to be arrested than the general population), and whose participation the Investigator would like to continue, the RSRB will review the study as prisoner research under the review requirements in sections 6.1 – 6.4 of this policy.

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**Appendices:**

Appendix 1: Template Prisoner Research Certification to OHRP

**Revision History:**

06/2016: Add hyperlinks to references, add Sect 6.1.1, add reference to 6.2.5  
11/27/2019: Update regulatory citation for updated Common Rule, editorial changes, and update signatories.

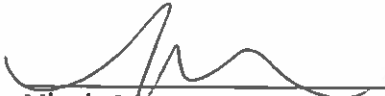
**Supersedes Date:**

08/01/2016

**Approved By:**

  
\_\_\_\_\_  
Kelley A. O'Donoghue  
Director, OHSP

11/27/2019  
Date

  
\_\_\_\_\_  
Nicole Mason  
Executive Director, RSRB

12/2/2019  
Date

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	<b>Research Subjects Review Board</b>		<b>Effective Date: 11/27/2019</b>
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			<b>Version: 1.2</b>

**Appendix 1: Template Prisoner Research Certification to OHRP**

[Note: Add RSRB letterhead and mail to OHRP via FedEx]  
[DATE]

[Contact Name]  
Division of Policy and Assurances  
Office for Human Research Protections (OHRP)  
The Tower Building  
1101 Wootton Parkway, Suite 200  
Rockville, MD 20852

Re: Study Title: [INSERT]  
RSRB #: [INSERT]  
Principal Investigator: [INSERT]

Dear [Insert Name]:

Attached please find the following documents related to a study that was approved under subpart C to include prisoners at the University of Rochester:

- RSRB Approval Letter dated [INSERT]
- RSRB Application
- Protocol dated [INSERT]
- Measures completed during the study, if applicable
- Description of the program, if applicable
- RSRB Approved Study Consent dated [INSERT]
- RSRB Approved Prisoner Consent dated [INSERT]
- [Insert any additional documents as applicable]

[Insert a brief description of any additional information that may be relevant. If the study will not target prisoners, but rather the enrollment of prisoners is possible given the study population, this should be stated here.]

Please note the following information to facilitate your review:

- FWA00009386 (exp. [INSERT DATE]) – University of Rochester Federalwide Assurance Number
- IRB[insert IRB #] U of Rochester IRB #XP - IRB Number for the designated IRB
- [INSERT DEPARTMENT AND AGENCY GRANT NUMBER] Sponsored Grant Number
- [Program officer name and contact information (phone and email)]

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This study was approved by the full board at the [INSERT DATE] meeting. At that time, subpart C was reviewed and determined by the board [Insert risk determination and category of approval permissible under 45 CFR 46.306(a)] due to [Insert rationale for determination].

Thank you for your time and attention to this matter.

Sincerely,

Nicole Mason,  
 Executive Director  
 Research Subjects Review Board  
 University of Rochester