COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD
POLICY ON RESEARCH WITH PRISONERS

I. BACKGROUND

Since the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects was published in 1979, protections for research subjects in the United States have continued to advance and there has been increased awareness among researchers and the public about the importance of safeguards for special research subject populations. Prisoners constitute one of these special populations as they are considered more vulnerable to coercion than non-incarcerated persons. Incarceration places prisoners under constraints that may affect their ability to make truly voluntary and uncoerced decisions about whether or not to participate as subjects in research. As such, additional protections are warranted.

Special federal regulations provide guidance for conducting research with prisoners. The U.S. Department of Health and Human Services (**DHHS)** regulations (Subpart A of 45 CFR 46 (**Subpart A)**, also known as the Common Rule), sets out the basic human subject research protections, which include informed consent and review by an Institutional Review Board (**IRB).** The University's general policies and procedures relating to informed consent can be found in the Columbia University Institutional Review Board Policy on Informed Consent (the **IC Policy).**

The principal regulations relating to the involvement of prisoners in research are included in Subpart C of 45 CFR 46 (**Subpart C).** Subpart C is applicable to all biomedical and behavioral research supported by DHHS. Through its Federalwide Assurance, Columbia extends the protections of Subpart C to all research conducted by Columbia investigators, regardless of funding source.

II. EFFECTIVE DATE

The effective date of this Policy is February 1, 2026.

III. DEFINITIONS

Certain terms used in this Policy are defined as follows:

Minimal Risk: 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.

Note that the definition of Minimal Risk in Subpart C differs in several ways from the definition of "minimal risk" in Subpart A of the Common Rule. The differences are that the Subpart C definition:

- Refers to “physical or psychological harm”, rather than “harm or discomfort” as in Subpart A;
- Compares the probability and magnitude of harm in the research to the probability and magnitude of those harms normally encountered in daily life, or in “routine medical, dental or psychological examinations”, rather than in daily life or “routine physical or psychological examinations or tests” as in Subpart A; and
- Identifies “healthy persons” who are not prisoners as the comparison group against which the risks of the research should be measured, rather than leaving the comparison group unspecified, as in Subpart A.

OHRP: The Office for Human Research Protections of DHHS.

Prisoner: Any individual involuntarily confined or detained in a penal institution (e.g., a prison, jail or juvenile offender facility). 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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing.

The OHRP Prisoner Research FAQs provide examples of the application of the regulatory definition of prisoner as follows:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are Prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not Prisoners.
- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are Prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not Prisoners.
- Parolees who are detained in a treatment center as a condition of parole are Prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not Prisoners.
- Probationers and individuals wearing monitoring device are generally not considered to be Prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population, and researchers may consult with OHRP.

IV. DHHS REGULATIONS

A. PERMISSABLE RESEARCH WITH PRISONERS

Subpart C provides that biomedical or behavioral research may involve Prisoners as subjects **only if:**

- If the research is supported by DHHS, the institution responsible for the conduct of the research has certified to OHRP that the applicable IRB has reviewed and approved the research, including making the findings described in Section B below; and
- OHRP has determined that the proposed research involves one or more of the following permissible categories:
    - The 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;
    - The study of *prisons as institutional structures or Prisoners as incarcerated persons,* provided that the study presents no more than Minimal Risk and no more than inconvenience to the subjects;
    - Research on *conditions particularly affecting prisoners as a class*, such as vaccine trials and other research on hepatitis, which is more prevalent among Prisoners, or research on social and psychological problems such as alcoholism, drug addiction and sexual assaults, provided that for research supported by DHHS only, OHRP has consulted with appropriate experts (i.e., in penology, medicine or ethics) and has published a notice in the Federal Register of their intent to approve the research (**OHRP Consultation and Notice);**
    - Research on *practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subjects,* provided that for research supported by DHHS only, if Prisoners may be assigned to a control group and may not benefit from the research, OHRP Consultation and Notice is required.

In June 2003, DHHS added the additional category of epidemiological research on specific diseases (a) to describe the prevalence or incidence of a disease by identifying all cases, including Prisoner cases, and (b) to study of potential risk factor associations for a disease. The DHHS indicated that this exception would apply to, for example, epidemiological research relating to chronic disease, injuries and environmental health that uses epidemiologic methods, such as interviews and collection of biologic specimens. The institution responsible for the conduct of the research must certify to OHRP that the IRB has approved such research and has determined and documented that one of the two above conditions has been met and that the research involves no more than Minimal Risk and no more than inconvenience to the Prisoner subjects and that Prisoners were not a particular focus of the research.

Note: As indicated in the OHRP Prisoner Research FAQs:

- The above certification and Consultation and Notice requirements are required only for DHHS-supported research, regardless of whether the institution responsible for the conduct of the research has chosen to extend the applicability of its FWA and Subpart C to all research.
- Each institution engaged in a multicenter research study involving Prisoners must certify to OHRP as indicated above unless (a) an institution relied upon the review of an IRB operated by another institution engaged in the research, and (b) such IRB or the other institution certified to OHRP on behalf of both institutions.

B. REQUIREMENTS WITH RESPECT TO THE IRB

1. Prisoner Representatives

In addition to the other regulatory requirements with respect to the composition of the IRB, when an IRB reviews a proposal involving Prisoners as subjects:

- A majority of the IRB (exclusive of Prisoner members) may not have any association with the prison(s) involved, apart from their membership on the IRB; and
- At least one member of the IRB must be a Prisoner, or a Prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research proposal is reviewed by more that one IRB, only one IRB need satisfy this requirement.

  Note: OHRP recommends that a Prisoner representative have a close working knowledge and understanding and appreciation of prison conditions from the Prisoner's perspective.

2. Studies Eligible for Expedited Review

OHRP recommends that all research involving Prisoners be reviewed by a convened IRB. However, it does not object to expedited review in certain circumstances. The Columbia IRB believes that the following guidelines that it has adopted are in line with OHRP's regulations:

- Research involving interaction with Prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than Minimal Risk for the prison population being studied.
    - The Prisoner representative must concur with the determination that the reseach involves no greater than Minimal Risk.
    - The Prisoner representative must review the research as a sole or additional reviewer, designated by the IRB Chair, or consultant.
    - Review of modification and continuing review must use the same procedures as for initial review.

- Research that does not involve interaction with Prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than Minimal Risk for the prison population being studied.
    - Review by a Prisoner representative is not required.
    - The Prisoner representative may review the research as a reviewer or consultant if so designated by the IRB Chair.
    - Review of modification and continuing review must use the same procedures as initial review.

3. Exempt Research

It is University policy that any research study subject to Subpart C may not be categorized as exempt research, other than research that involves a subject population that only incidentally includes Prisoners.

Note: Any research believed to be exempt must nonetheless be submitted in Rascal so that the IRB can determine whether an exemption is appropriate under the DHHS regulations.

4. REQUIRED FINDINGS OF THE IRB FOR PRISONER RESEARCH

Subpart C provides that the applicable IRB may approve research with Prisoners **only if** it finds that:

- The research under review falls into one of the permitted categories of research described in Section A above;
- The possible advantages accruing to the Prisoner 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;
- The risks involved in the research are commensurate with risks that would be accepted by volunteers who are not Prisoners;
- Procedures for the selection of subjects within the prison are fair to all Prisoners and immune from arbitrary intervention by prison officials or other Prisoners; control subjects must be selected randomly;
- The information about the research is presented in language which is understandable to the subject population;
- Each Prisoner is clearly informed in advance that participation in the research will have no effect on their parole; and
- Adequate provision has been made for follow-up examination or care is there is a need for such.

5. SPECIAL CIRCUMSTANCES

A. When an Individual Becomes a Prisoner After Enrollment in a Study That Has Not Met the Requirements of Subpart C

If a subject in a research study becomes a Prisoner after enrollment in a Study that has not met the requirements of Subpart C, the Principal Investigator (**PI)** must notify the IRB immediately. Upon notification, the IRB must re-review the protocol with reference to the requirements of Subpart C and except in the special circumstance described below, all research interactions and interventions with, and obtaining identifiable private information about, the now incarcerated Prisoner must cease until all of the requirements of Subpart C have been satisfied.

OHRP has permitted one exception to the foregoing requirement: if the PI asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the applicable IRB Chair may determine that the subject may continue to participate in the research until the requirements of Subpart C are satisfied.

B. When an Individual Is Temporarily Incarcerated After Enrollment in a Study

If an individual becomes temporarily incarcerated while enrolled in a study that has not been reviewed in light of the Subpart C requirements, and the temporary incarceration has no effect on the study, such individual may remain enrolled as a study participant. If the individual becomes permanently detained or involuntarily confined to a penal institution, they should be removed from the study until the study is re-reviewed with reference to the requirements of Subpart C unless required to avert immediate risk of harm to the individual.

C. When Individuals are Targeted Subjects or Anticipated Subjects

If the research population includes individuals who are likely to be incarcerated during a study, such as studies intending to enroll parolees, street people, addicts and prostitutes, the PI may request that the protocol be reviewed prospectively as Prisoner research. Although all of the requirements of Subpart C may not be met in such a situation, the IRB, after consultation with the Principal Investigator, may make the determination that the proposed research is permissible for Prisoners so long as certification is made to OHRP and OHRP authorizes the research study.

D. When Prisoners are Minors

Adolescents who are detained in a juvenile detention facility are considered to be Prisoners even if they are minors. In such a case, both Subpart C and Subpart D would be applicable. See the Columbia University Institutional Review Board Policy on Research Involving Children for further information on Subpart D requirements.

V. OTHER REGULATIONS

A. FDA

Although FDA regulations contain a Subpart D governing children as research subjects, the FDA regulations do not include the specific Subpart C safeguards for prisoners. The FDA adopted a final rule in 1980 applicable to Prisoner research, but because of a federal suit brought by certain prisoners, the regulations were indefinitely suspended. Nonetheless, it is safe to assume that the FDA does consider prisoners to be a vulnerable research population for which the IRB must include additional protections.

B. DEPARTMENT OF JUSTICE, BUREAU OF PRISONS

The federal Bureau of Prisons (**BOP)** is responsible for all federal prisons and the care, custody and control of federal prisoners. The Department of Justice (**DOJ)** has promulgated regulations (28 CFR 512) relating to research with prisoners in the custody of the BOP due to specific concerns about the types of research that should be conducted with prisoners and the confidentiality of Prisoners' personal information in the prison environment. All research with BOP prisoners must follow the requirements of 28 CFR 512, including:

- The research project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- The research design must be compatible with both the operation of prison facilities and the protection of human participants.
- All research must be reviewed and approved by the BOP IRB.
- Except as noted in the consent statement to the participant, the research must not provide research information that identifies a participant to any person without that participant's prior written consent and may not be admitted as evidence or used for any other purpose in any judicial, administrative or legislative proceeding, provided that confidentiality may not be guaranteed as to information that indicates that the subject intends to commit a crime, harm themselves or others or leave a facility in which they are incarcerated.
- Incentives may not be offered to help persuade inmate subject to participate in the research project, other than soft drinks and snacks to be consumed at the test setting.
- Except for computerized data records maintained at an official DOJ site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

See 28 CFR 512 for additional details.

C. OTHER AGENCIES

Most Federal agencies (other than those indicated above) have adopted Subpart C or other Prisoner-related regulations. The Department of Defense (**DOD)** requires notification to the DOD if a subject enrolled in DOD-funded research becomes a Prisoner and prohibits research involving detainees of prisoners of war. Any investigator who plans to involve Prisoners as research subjects in a non-DHHS-funded study should contact the IRB for further information on possible applicable regulations.