# Introduction

The following information is based upon the Code of Federal Regulations (CFR). Additional duties are required for the Human Research Ethics Board (HREB) when prisoners are involved in the research. Because prisoners might be under constraints that could affect their ability to make a truly voluntary and uncoerced decision to participate in research, the guidelines provide additional safeguards for the protection of prisoners involved in activities to which these guidelines apply. Even if the research is not federally sponsored, investigators need to follow these guidelines.

## A. Definition of “prisoner” and “minimal risk”

According to [45CFR46.303](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.303),

***Prisoner:*** *Any individual involuntarily confined or detained in a penal institution. The term encompasses 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.*

***NOTE***: The Office for Human Research Protections (OHRP) has indicated that probationers, parolees, persons ordered by the court to attend non-residential community programs, and individuals released from prison to halfway houses would *not* meet the Subpart C definition of prisoner. [[1]](#footnote-1)

Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial. Examples of this definition:

* Substance abuse treatment. Individuals detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners. Individuals receiving non-residential court-ordered substance abuse treatment are residing in the community are not prisoners.
* Psychiatric institutionalization. Individuals with a psychiatric illness who have been committed involuntarily to an institution as an alternative to criminal prosecution or incarceration are prisoners. Individuals who have been voluntarily institutionalized or have been civilly committed to non-penal institutions for treatment are not prisoners.
* Parole. Parolees detained in a treatment center as a condition of parole are prisoners. Persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.
* Probation; monitoring devices. Probationers and individuals wearing monitoring devices are generally not considered prisoners. However, situations of this kind frequently require an analysis of the particular circumstances. Consult with HSD management, who may consult with OHRP.

***Prisoner Minimal Risk Definition****: 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****: This definition differs from the* [*minimal risk definition*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102) *that applies to research with non-vulnerable populations.*

## B. Categories of permitted research involving prisoners (i.e., studies that target a prisoner population)

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided the study presents no more than minimal risk and no more than inconvenience to the subjects.
2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided the study presents no more than minimal risk and no more than inconvenience to the subjects.
3. Research on conditions particularly affecting prisoners as a class (e.g., 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). The study may proceed only after the HHS Secretary (through OHRP) has consulted with appropriate experts and has published notice of approval in the Federal Register.

or

1. 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 HREB 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.

***NOTE****: If the proposed research involving prisoners as subjects does not fit within categories (1), (2), (3) or (4) above, research receiving federal funding may only be conducted with the permission of the Secretary of DHHS after seeking a waiver under* *[45 CFR § 46.101(i).](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html%22%20%5Cl%20%2246.101)*

**In addition, prisoners may be included in some research directed towards the prevalence, incidence or risk factors for diseases that might affect prisoners.**

By HHS Secretarial waiver ([68 FR 36929](http://www.gpo.gov/fdsys/pkg/FR-2003-06-20/pdf/03-15580.pdf), June 20, 2003), prisoners may be included in epidemiologic research in which the sole purposes are (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factors for a disease. The research must present no more than a [minimal risk](http://irb.ucsf.edu/#minimal), present no more than inconvenience to the subjects, and prisoners must not be a particular focus of the research.

The HREB may also prospectively review under Subpart C a non-prison study that involves a study population at risk for incarceration, such as probationers or substance abusers.1

## C. Research involving subjects who become prisoners while enrolled in an HREB approved protocol

If a participant becomes a prisoner during the course of their participation on a research study, the investigator must inform the HREB as soon as possible because the Subpart C regulations are applicable.

The investigator must provide the HREB with the following information:

* If it is in the subject’s best interest to continue in the study as a prisoner, and whether the subject’s status as prisoner affects the risks of participation in the study or the potential benefits from continued participation;
* If the subject wishes to continue as a participant, and what the re-consent process will be;
* If there are practical complications of subject continuation in the study,
* If there is any other factor that is important for the HREB to consider when determining whether the subject should continue as a participant in the study.

The HREB must make the final determination of whether the subject may continue in the study.  If the HREB determines that the participant may continue, the HREB must review the study under the criteria on research involving prisoners.

## D. Level of HREB review

* ***Initial review*** will be conducted by the full HREB as well as a board member who is a prisoner advocate must participate in the review. A decision will be made about how continuing review will be handled.

***Prisoner Advocate:*** An HREB member who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of prisoners. The prisoner advocate 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). The prisoner advocate cannot be an employee of a correctional system.

* ***Continuing review* may be performed** by the full HREB or by the HREB chair or chair designee. The level of continuing review needed for the particular protocol should be determined at the initial review.
* ***Modifications*** to studies initially reviewed by a full HREB are reviewed as follows:
	+ ***More than a minor change:*** *the full HREB including a prisoner advocate must conduct the review.*
	+ ***Minor change:*** may be reviewed by the HREB chair or chair designee. The reviewer is encouraged to obtain consultation from a prisoner advocate, as needed.

## E. Certification Letter to OHRP

***NOTE: The HREB will follow OHRP’S federal certification criteria ONLY for DHHS-supported research.***

The following federal agencies have adopted Subpart C of the federal human subjects regulations at 45 CFR 46.

* Health and Human Services
* Department of Defense
* Department of Homeland Security
* Central Intelligence Agency
* Department of Energy

If any of the above are selected, prisoner certification and authorization must be obtained from OHRP.

The HREB must submit a Certification Letter to OHRP following review of DHHS-supported research involving prisoners. The purpose of this letter is to certify to the Secretary that the HREB approved the research under 45 CFR 46.305.

The Certification Letter to OHRP will be **constructed by the HREB** and must include:

Name and address of the institution;

Specifically identified research protocol in question;

Copy of the HREB application and all relevant materials reviewed and approved by the Board;

Any relevant HHS grant application of protocol;

HREB specific findings of 45 CFR 46.305

Prisoner research certification letters should be mailed to:

Attention: OHRP Prisoner Research Contact Person

Office for Human Research Protections

Department of Health and Human Services

The Tower Building

1101 Wootton Parkway, Suite 200

Rockville, MD 20852

## F. Additional Requirements

In addition to all the basic human subject protection requirements ([45 CFR 46, Subpart A](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subparta)), the HREB must review prisoner research and find that the research complies with seven additional requirements [[45 CFR 46.305(a)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc)]:

1. The study satisfies the criteria for permissible research.

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 subjects 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 Board 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.

5. The information is presented in language which is understandable to the subject population.

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 HREB 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.

## G. Other Considerations

Investigators conducting prisoner research should carefully consider the following issues:

* Confidentiality: There are several privacy and confidentiality issues to address in the prison environment, such as the availability of private rooms to conduct interviews and involving prison staff in any part of the study.
* Informed consent: Prisoners who are competent have the fundamental right to decide whether or not to participate in research.
* Researchers must indicate in the consent form who will have the right to review the data and other limitations to confidentiality.
* Researchers in the informed consent must indicate that participation in the research project will have no effect on consideration of sentencing, length of sentence, or parole.
* ***The Federal Bureau of Prisons*** has adopted extensive regulations for researchers seeking to use federal prisoners as research subjects. Among other things, these regulations prohibit use of prisoners within federal facilities for “medical experimentation, cosmetic research, or pharmaceutical testing.” 28 C.F.R. 512.11(a)(3). In addition, strict limitations are imposed on incentives to prisoner/participants, and researchers may not promise confidentiality to subjects who reveal a future intent to engage in criminal behavior.

## H. References

*Click on the links to access the websites of the reference materials.*

[Code of Federal Regulations, Subpart C (45 CFR §46.303-306)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc)

[Office for Human Research Protections (OHRP) Prisoner Guidance May 2003](http://www.hhs.gov/ohrp/policy/prisoner.html),

[Secretary’s Advisory Committee on Human Research Protections (SACHRP) recommendations about defining who is and who is not a prisoner (4/18/2005)](http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2005-july-28-letter-appendix-a/index.html)

1. [Secretary’s Advisory Committee on Human Research Protections (SACHRP) recommendations about defining who is and who is not a prisoner (4/18/2005)](http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2005-july-28-letter-appendix-a/index.html) [↑](#footnote-ref-1)