Justice-involved Populations and 45 CFR Subpart C: Interpretation, Process and Protection

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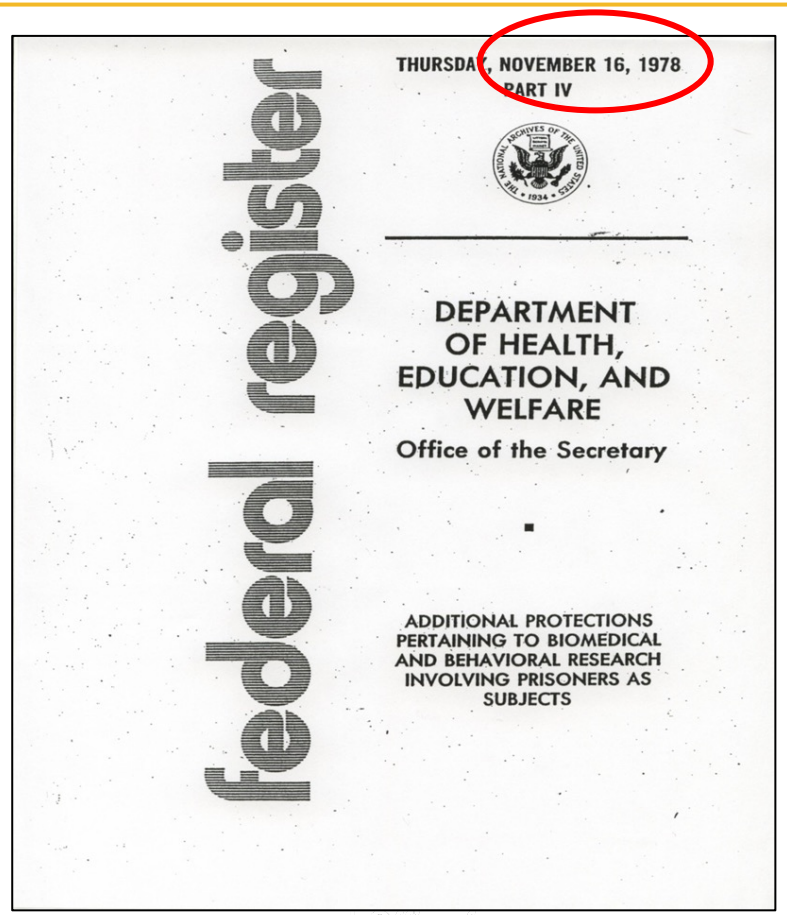
Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.

For a complete and accurate description of the regulatory requirements, please refer to the text of the revised Common Rule available on OHRP's website.

45 CFR Subpart C: Additional Protections for Prisoners



"There are 2 basic ethical dilemmas concerning the use of prisoners as research subjects: whether prisoners bear a fair share of the burdens and receive a fair share of the benefits of research; and whether prisoners are, in the words of the Nuremburg Code, 'so situated as to be able to exercise free power of choice'- that is, whether prisoners can truly give voluntary informed consent to participate in research." *National Commission's Report on Research Involving Prisoners, p5, 1976*

Major Points Regarding Subpart C

1. IRB must have a prisoner representative
2. Emergency waiver of IC not permitted
3. IRB must review §46.305 criteria for consent, risk, coercion considerations, and the research must fit within one of 5 permissible categories.
4. If HHS funded, must submit subpart C certification and receive authorization before starting research: https://www.hhs.gov/ohrp/regulations-and-policy/subpart-c-certification-request-to-ohrp/index.html
5. Triggered anytime there are research interactions/interventions with a prisoner (short incarceration times may not trigger subpart C)
6. Application of the exemptions prohibited except for research that only incidentally includes prisoners – §46.104(b)(2)! **NEW!**

Who's a Subpart C Prisoner Under 45 CFR 46.303(c)?

"Prisoner" means any individual involuntarily confined or **detained** in a penal institution.

- sentenced 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.

See Prisoner FAQS:

www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html

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Possible Subjects Under Subpart C Definition of "Prisoner"

Juvenile Detention

Homelessness

Subpart C

Diminished Mental Capacity

Substance Abuse

HIV/AIDS

Who is *Not* a Subpart C "Prisoner"?

Persons who are:

- Court-adjudicated to attend non-residential treatment programs as alternative to incarceration while living in the community
- Voluntarily entered treatment
- Civilly committed due to danger to self or others
- Released from prison to halfway houses
- Handcuffed
- Electronic monitoring (generally)

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Subpart C Protections 45 CFR 46.305(a)(1)-(4)

1. Must fit a permissible category of research (Risk)
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 (Coercion)
3. The risks are commensurate with risks that would be accepted by non prisoners (Risk)
4. Selection of subjects within the prison is fair and immune from arbitrary intervention by prison authorities or prisoners (Recruitment)

Subpart C Protections §46.305(a)(5)-(7)

5. The information is presented in language which is understandable to the subject population (IC)
6. Assurance exists that parole boards will not consider research participation in parole decisions; prisoners are informed in advance that participation in the research will not affect parole (IC)
7. Adequate provision has been made for follow-up care (Risk)

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Prisoner research must fit a §46.306(a)(2) category

Category (i)

Study of possible causes, effects, and processes of incarceration and of criminal behavior

Category (ii)

Study of prisons as institutional structures or of prisoners as incarcerated persons

Category (iii)

Research on conditions particularly affecting prisoners as a class

Category (i) and (ii) require no more than minimal risk

No risk ceiling, but requires a Secretarial consultation

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Prisoner Research Must Fit a §46.306(a)(2) Category

Category (iv)

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 ***assignment of prisoners*** in a manner consistent with protocols approved by the IRB to ***control groups which may not benefit from the research***, the study may proceed only after the Secretary has consulted with appropriate experts…

No risk ceiling, but may require a Secretarial consultation.

OHRP Interpretation of §46.306(a)(2)(iv) "Control Group"

Control group = standard of care, services as usual, or placebo.

If a study is greater than minimal risk, randomization of prisoners to a control group "which may not benefit from the research" will require a Secretarial consultation and approval before the study can proceed.*

Randomization of prisoners to two or more active arms can be approved by OHRP without a Secretarial consultation.

***That doesn't mean it can't be done.**

What Exactly is a Secretarial Consultation?

Similar to subpart D §46.407 review: see FDA/OHRP joint draft guidance
hhs.gov/ohrp/news/announcements-and-news-releases/index.html

Study must be referred to OHRP for review:

1. Complete protocol, consent forms, IRB minutes, any other informative documentation is placed in a docket for public comment
2. A panel of relevant experts is selected to review materials
3. A public meeting is held to discuss the proposed research and expert recommendations are posted in a docket for public comment
4. OHRP develops an opinion for the ASH, which may include changes to the research protocol
5. ASH, on behalf of the Secretary, issues a final determination

What's the Timeline?

Reasonable to expect

6-9 months

Your Study Will Not Trigger a Sec Consultation If:

1. Prisoners are not randomized to a placebo, standard of care or services as usual arm
   - ✓ Keep in mind that prisoners CAN be randomized to a standard of care "+" arm
2. Subjects become prisoners only *after* enrollment (subsequently incarcerated)
3. Subjects were prisoners, but are recruited *after* release
4. Study is minimal risk and satisfies categories §46.306(a)(2)(i) or (ii)

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Office-based Methadone Versus Buprenorphine to Address Retention in Medication for Opioid Use Disorder Treatment – A Randomized Pragmatic Hybrid Effectiveness/Implementation Trial

This is a randomized control trial that will examine the comparative effectiveness of two FDA-approved medications for the treatment of opioid use disorder (OUD). The study examines whether office-based methadone with pharmacy administration and/or dispensing, or office-based buprenorphine (BUP) results in greater treatment retention in approximately 600 patients with OUD. As part of the trial, researchers will identify implementation barriers, facilitators and acceptability at the patient, provider and health-systems level for office-based methadone with pharmacy administration and/or dispensing.

Individuals who are currently in jail, prison or other overnight facility will not be recruited. In the event a participant becomes incarcerated during the course of the study, the research team will collect follow-up assessments.

A Comparative Effectiveness Trial of Sublingual Versus Extended-release Buprenorphine with Individuals Leaving a Carceral Setting

This study is a randomized controlled trial of XR-B vs. SL-B in a large metropolitan jail. An open-label design will randomly assign 240 adults with moderate-to-severe OUDs who are soon-to-be-released to either XR-B or SL-B treatment in jail, followed by 6-months of post-release buprenorphine treatment, a 7-month safety visit, and final long-term follow-up at 12-months. Subjects will also receive overdose prevention education in jail and at each follow-up.

Following release from jail, the study will provide participants with a card specifying the address of the community treatment provider who will be providing 6-months of study medication treatment. Office-based medical management post-release will be conducted at each monthly research visit. Medical management will focus on 1) medication adherence and side-effects, 2) non-study opioid abstinence; 3) accessing psychosocial/mental health counseling and treatment and 4) monitoring and addressing potential SL-buprenorphine diversion.

Long-acting Injectable Antiretroviral Treatment to Improve HIV Treatment Among Justice-involved Persons Being Released to the Community

This study is a single arm open label feasibility trial that will assess the use of long-acting injectable (LAI) antiretroviral treatment (ART) for HIV in persons being released from prison. Up to ten participants will be enrolled and will transition from daily oral ART to the first FDA-approved injectable ART regimen consisting of cabotegravir and rilpivirine (CAB/RPV) within one month of release, with continuation by community providers after release. Participants will be followed for three months after release, and assessments will be conducted at baseline (after enrollment) in prison, and then at one-month and three-months after release from prison.

Unlocking Access to Infectious Diseases Testing and Vaccination in Jails: Stakeholder Engagement

The overall objective of this project is to identify barriers and facilitators towards delivery of infectious disease care in jails. The central hypothesis is that there are missed opportunities for providing infectious diseases care (testing, treatment, vaccination) to inmates that are related to patient and systems factors which will be revealed through in-depth interviews with people involved in healthcare delivery in the jail, and that opt-out testing is a feasible strategy to overcome these missed opportunities

OHRP recategorized from 46.306(a)(2)(iii) to (ii)

Assessing Needs and Advancing Dignity-Conserving Care for Hospitalized, Incarcerated Older Adults: Cohort Study

This study will examine temporal trends and associations between antecedent factors, hospitalization experiences and adverse health outcomes among incarcerated persons aged ≥ 55 years. This project is a retrospective chart review of incarcerated patients receiving care at any Mayo Clinic hospital in the states in which Mayo Clinic operates. Researchers will identify incarcerated patients with a hospitalization of more than 24 hours to analyze those whose conditions necessitated admission for acute care services. Coded data will be stored in Mayo Clinic's internal, HIPAA-compliant REDCap database, organized by study numbers assigned to the subjects. The review will analyze patient antecedent factors, hospitalizations, adverse health outcomes, and variables related to ethics and dignitary harms.

Confidentiality and Privacy Considerations

Confidentiality and Privacy Considerations for Protecting Vulnerable Subjects in Research

Utilize encrypted laptops for surveys rather than oral interviews

- ✓ Use methods to prevent eavesdropping

Limit access to identifiable data, e.g.,

- ✓ Store research records in locked cabinets; encryption; codes rather than identifiers

Be aware of mandatory reporting requirements: communicable diseases, suicidal ideation, child abuse

Educate research staff about research context! Possible issues:

- ✓ Asking if subjects can read
- ✓ Prison administration controlling communications to prisoners
- ✓ Questions about follow-up contacts

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Typical Locator Form Language

Following the consent, a study team member will complete a locator form. The locator form obtains information on the living and housing plans of participants once released, as well as their prior places of residence. Contact information of relatives and friends will be gathered; locations of hang out spots, places of employment, and a basic physical description are also documented. This form will be kept in the consent study files.

Undue Influence/Coercion for a Prisoner Population

45 CFR 46.305(a)(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.**

Concerns about Payment and Undue Influence

- Exploitation
- Payment advertising
- Payment-induced deception
- Completion bonuses
- Taxation issues

Concerns can lead to payment conservatism ("better safe than sorry!")

IRB Membership for Subpart C Review 46.304

- At least one prisoner representative
- A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board

Question: *Our IRB oversees research at 10 different state hospitals, and patients may be coming from multiple regions. Should we replace 'prison' with 'state hospital' or 'state hospital system', or does this refer to strictly the prison a state hospital patient may be associated with? The concern is whether we need to limit our IRB membership associations with the state hospital system or state agency that oversees the state hospital system.*

IRB Membership for Subpart C Review

"Associated" in 46.304(a) is similar in intent to "affiliated" in 45 CFR 46.107(c)

Affiliation - An employee or agent of the organization registering the IRB (or a member of that person's immediate family) is considered affiliated. Affiliated members include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB. An individual that has no affiliation with the organization registering the IRB, other than as an IRB member, is considered unaffiliated with the entity operating the IRB. Unaffiliated members may include people whose only association with the institution is that of a patient, subject, or former student at that institution. Paying unaffiliated members for their services would not make the member "otherwise affiliated" as stated in the regulations, or cause the member to have a conflicting interest.

Regulations +
Decision Charts +
Guidance +
Requests for Comments
Informed Consent Posting +
Single IRB Exception Determinations +
Subpart C Certification Request to OHRP
Regulations & Policy Archived Materials

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Subpart C Certification Request to OHRP

An institution that intends to conduct HHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2) or meets the criteria for the Epidemiological Waiver. Epidemiological Waiver - PDF. To send a subpart C certification request to OHRP, the institution must submit this submission form: https://oash.force.com/ohrpwebforms/s/prisoner-web-form in conjunction with a copy of the research proposal. The term "research proposal" includes:

- the IRB-approved protocol, including consent forms;
- any IRB application forms required by the IRB; and
- any other information requested or required by the IRB to be considered during IRB review.

Note: If an IRB considers the grant application during its review of the study, only submit portions of the grant application relevant to subpart C review.

Questions regarding Subpart C and certification should be sent to subpartc@hhs.gov

Feedback

U.S. Department of Health and Human Services (HHS)

Subpart C Certification Form

OMB No. 0990-0473

Approved for use through October 31, 2026

In compliance with 45 CFR 46.305(c), an institution that intends to conduct HHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2).

OHRP requires the electronic submission of Subpart C certification requests. If an institution is unable to submit information electronically, please call 240-453-8141 or email subpartc@hhs.gov to discuss an alternative submission process.

Do not print and scan the certification form for submission. Fill the form out electronically, and email a copy of the electronically filled-out form as an attachment.

To submit a subpart C certification request to OHRP, the institution must submit a completed copy of this certification form in conjunction with a copy of the research proposal in order to determine whether the appropriate findings have been made. The term "research proposal" includes:

- the IRB-approved protocol, including consent forms;
- any IRB application forms required by the IRB; and
- any other information requested or required by the IRB to be considered during IRB review.

Note: If an IRB considers the grant application during its review of the study, only submit the portions of the grant application relevant to subpart C review for the purposes of subpart C certification.

Administrative Information

* Name of Institution: *(Name of the Institution that Operates the IRB of Record, or the Non-institutional IRB that Serves as the IRB of Record)*

* Address of the Institution that Operates the IRB of Record, or the Non-institutional IRB that Serves as the IRB of Record:

IRB that Serves as the IRB of Record

* Name(s) of Institutions Relying on the IRB of Record:

sIRB for multiple institutions?

Contact Information for the Individual Submitting the Certification:

* Contact First Name

* Contact Last Name

* Contact Title

OHRP Resources

- Prisoner FAQs

http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html

- Prisoner Research Certification Submission

https://www.hhs.gov/ohrp/regulations-and-policy/subpart-c-certification-request-to-ohrp/index.html

- May 23, 2003 OHRP Prisoner Research Guidance

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/prisoner-research-ohrp-guidance-2003/index.html

Contact

- Contact us or submit your questions to OHRP@hhs.gov
- Visit OHRP website at www.hhs.gov/ohrp