

Research with Prisoners

April 16, 2026

Common Rule: Subpart A

§ 46.107 IRB membership:

- “...consideration shall be given to the inclusion of one or more **individuals who are knowledgeable** about and experienced in working with these categories of subjects.”

§ 46.111 Criteria for IRB approval of research:

- “Selection of subjects is equitable. [...] The IRB should be **particularly cognizant** of the special problems of research that involves a category of **subjects who are vulnerable to coercion or undue influence...**”
- “...**additional safeguards** have been included in the study to protect the rights and welfare of these subjects.”

Common Rule: Subpart C

§46.302 Purpose:

Inasmuch as prisoners may be under constraints because of their incarceration which could **affect their ability to make a truly voluntary and uncoerced decision** whether or not to participate as subjects in research, it is the purpose of this subpart to provide **additional safeguards** for the protection of prisoners involved in activities to which this subpart is applicable.

Defining and Documenting

IRB FAQs for Research with Prisoners

How do the regulations define “Prisoner”?

“...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”

1) Penal Institution

Including prison, jail, or juvenile offender facility--ability to leave the institution is restricted

2) Status

May be convicted felons or untried persons detained pending judicial action

How do the regulations define “Prisoner”?

In a **residential facility** for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration

Individuals with psychiatric illnesses who have been **committed involuntarily** to an institution as an alternative to a criminal prosecution or incarceration

Parolees who are detained in a **treatment center** as a condition of parole

Probationers and individuals wearing monitoring devices are generally **not** considered to be prisoners

Are there additional regulatory considerations?

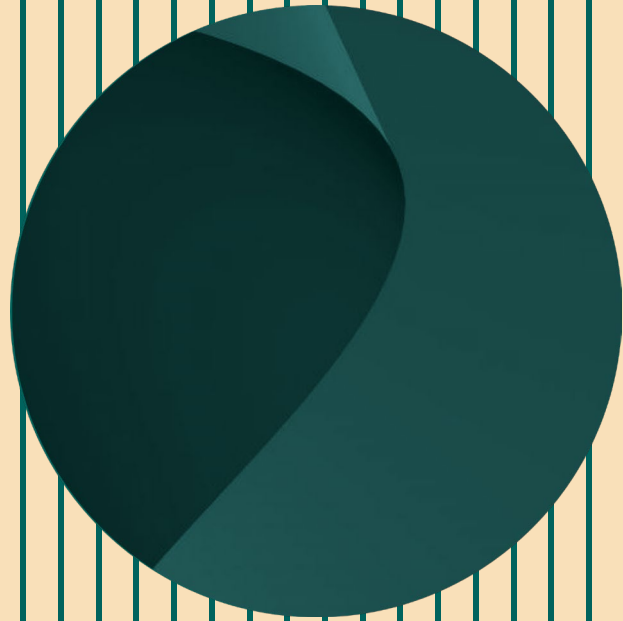


Exemptions do not apply to research involving prisoners

IRB must find research falls into permissible categories of research and make other findings (i.e., determinations guided by Prisoner Checklist)

IRB members not associated with prison involved in the research

IRB must include a prisoner or prisoner representative



What conditions must be met for approval?

- 1) Research falls within category of research permissible
- 2) Magnitude of possible advantages does not impair consent
- 3) Risks commensurate with risks acceptable by nonprisoner
- 4) Selection of subjects is fair and without intervention
- 5) Information is understandable to the population
- 6) Assurance that parole boards will not consider participation; prisoner is clearly informed in advance
- 7) Where follow-up care, adequate provision for such care, given lengths of individual prisoners' sentences

What are the categories for permissible research involving prisoners?

3 Research Involving Prisoners as Subjects (Check if "Yes." All must be checked)

- ☐ The research under review represents one of the following categories of research: **(At least one must be checked)**
- ☐ 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.
 - ☐ 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.
 - ☐ 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).
 - ☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject where one of the following is true: **(One box must be checked)**
 - ☐ All groups may benefit from the research.
 - ☐ Prisoners are assigned to control groups which may not benefit from the research.
 - ☐ Epidemiologic studies in which the sole purpose is to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, the research presents no more than Minimal Risk and no more than inconvenience to the subjects, and Prisoners are not a particular focus of the research¹.

Provide protocol specific findings justifying this determination:

What are the composition requirements for Convened IRB review?

“A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB”

“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 than one IRB, only one IRB need satisfy this requirement”

How do the regulations define “minimal risk” for prisoner research?

Common Rule: Part A

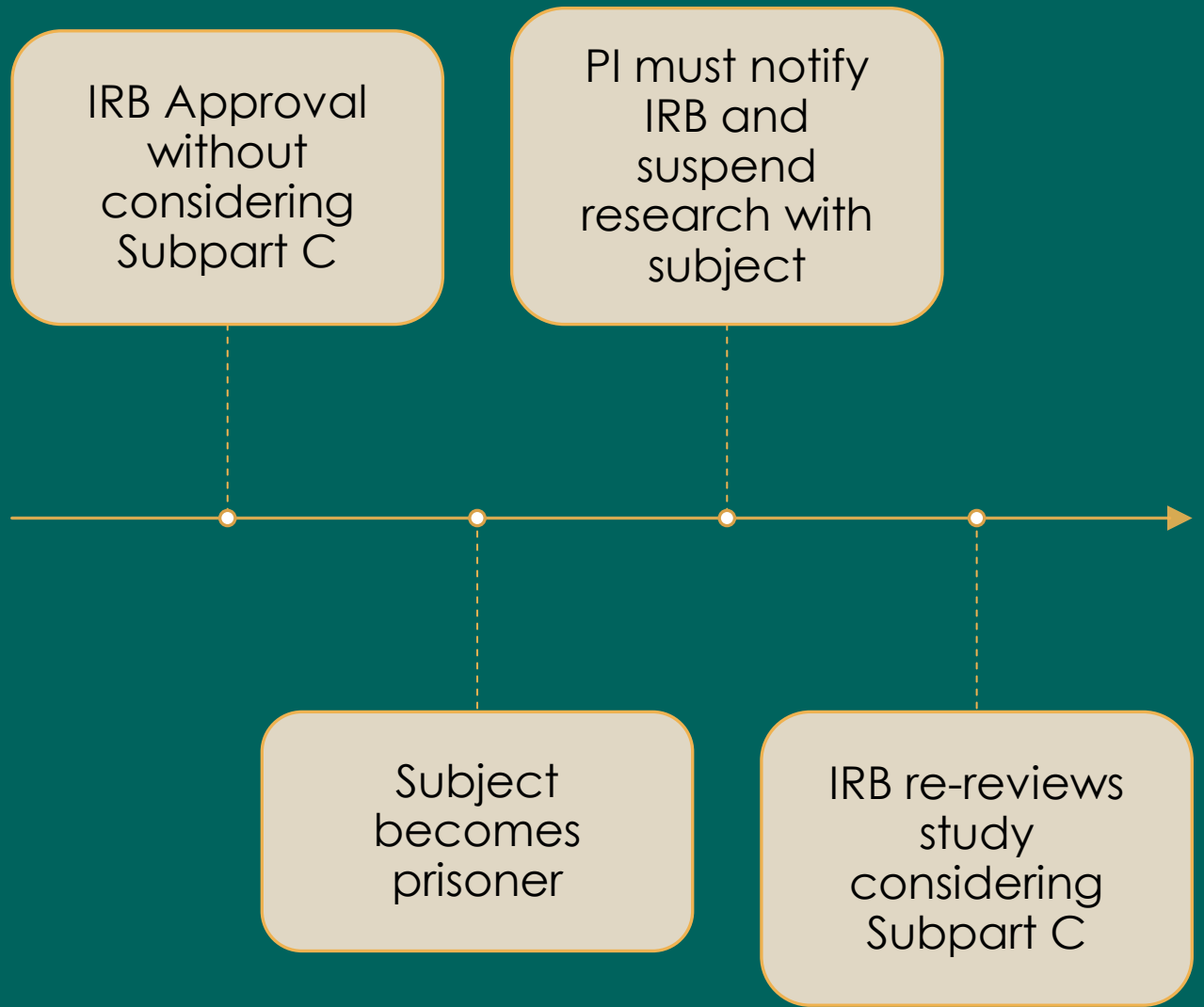
“*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”

How do the regulations define “minimal risk” for prisoner research?

Common Rule: Part C

“*Minimal risk* is 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**”

What happens if a human subject becomes a prisoner during a study?



Can the IRB consider Subpart C anticipating subjects will become prisoners?

Yes!

Note, some key findings may not be applicable. For example:

- If subjects are not recruited from within a prison
- If there is no particular parole board involved yet
- The IRB should document these findings accordingly (i.e. Prisoner Checklist)

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Questions?