

**Protecting people who participate in research**

*CITI Training Study Guide  
Research Involving Prisoners*

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**Research Involving Prisoners -  
Special Rules Set Forth by DHHS**

Subpart C of the federal Department of Health and Human Services regulations says, in a nutshell:

**the only research that may be conducted with prisoners as subjects is research directly relevant to the lives of prisoners.**

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**Research Involving Prisoners -  
Special Rules Set Forth by DHHS**

Prison research funded by the U.S. Department of Health and Human Services (including NIH) must be certified by the Office of Human Research Protections.

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**Four Types of Allowable Research**

1. Studies of possible causes, effects and processes of incarceration, and studies of criminal behavior, so long as the study presents no more than minimal risk and no more than inconvenience to the subjects.

(Minimal Risk = "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.")

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**Four Types of Allowable Research**

2. Studies 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.

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**Four Types of Allowable Research**

3. Research on conditions that particularly affect prisoners (such as hepatitis, alcoholism, drug addiction or sexual assault).

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**Four Types of Allowable Research**

- 4. Research on practices aimed at improving the health or well-being of prisoners.

Note: if a study requires “control groups” such that some prisoners may not benefit from the research procedures, the research may require federal review.

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**Use of Incentives**

The IRB must take extra care that the incentives to be provided are not excessive, and thus coercive.

An excessive incentive would be one that is not within the prisoner’s normal power to obtain (while a prisoner), or that pays them more than a couple days’ worth of wages (in many states, \$1/day is the maximum wage).

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**Issues in Assessing Risk**

- Prisoners may have a limited support system for processing feelings.
- Some categories of crimes are more “acceptable” in prison than others – if the purpose of a study addressing less acceptable crimes becomes known, participants may face severe consequences from fellow prisoners.
- Some health conditions are especially stigmatized (e.g. HIV). A study’s real intentions may require disguise.

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### **Required Composition of the IRB**

- A majority of the IRB members must have no association with the prison(s) involved.
- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience.

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### **Required IRB Findings**

- The research must fit one of the four allowed categories.
- Benefits of participation must not impair the prisoner's ability to weigh the risks.
- The risks are equivalent to risks that would be acceptable to non-prisoner volunteers.
- Procedures for selection of subjects are fair to all prisoners.
- Information is presented in understandable language.
- Prisoners are informed the research will have NO effect on their parole.
- Prisoners are informed of the availability of follow-up care.

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### **When a Participant Becomes a Prisoner**

The IRB must be notified if a research participant becomes a prisoner during the study and research with that subject must be suspended until the IRB certifies it may continue under Subpart C.

The only exception to this rule is if it is in the best interests of the subject to remain in the study.

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