

# Research with Prisoners

In order to conduct research with prisoners, researchers must adhere to additional regulations beyond the basic requirements for research with human subjects (45 CFR 46).

Research with prisoners is governed by federal regulations that classify prisoners as a “vulnerable population” (45 CFR 46 Subpart C) because their ability to make an informed and voluntary decision to participate in research is compromised.

Certain forms of research with prisoners are permissible but often require review and approval from several agencies. The IRB should be contacted during the design of any research protocols intended to involve prisoners.

## Definition of Prisoner

A prisoner, as defined by Federal Regulation (45 CFR 46.303 (c)) is any individual involuntarily confined or detained in a penal institution, including:

- 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
- individuals detained pending arraignment, trial, or sentencing

## When a Subject Becomes Incarcerated After Study Enrollment

If a study requires a follow-up visit with a subject who has become incarcerated during the course of research, the advised course of action is to delay re-contacting the subject until they have been released. If a study necessitates visiting a subject while they are incarcerated a detailed amendment must be submitted to the IRB.

## Permitted Prisoners Research

For research conducted or supported by HHS to involve prisoners, two actions must occur:

1. The IRB must review and approve the research under 45 CFR 46.305; and

2. OHRP must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2). The categories of permissible research are the following:
- 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; (Note that the definition of minimal risk for prisoner research at 45 CFR 46.303(d) differs from the definition of minimal risk for other research, contained in 45 CFR 46, subpart A, 45 CFR 46.102(i))
  - 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) provided that the study may proceed only after OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of their intent to approve such research;  
or
  - 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 IRB to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of their intent to approve such research.

### **Prohibited Prisoner Research**

Detention centers generally reserve the right to disallow a research activity from going forward at their facility. For research conducted in the California Department of Corrections and Rehabilitation proposed studies are reviewed by the **CDCR Office of Research**.

Certain forms of research such as medical experimentation, cosmetic research, or pharmaceutical testing are prohibited within the Bureau of Prisons (**28 CFR 512.11**).