



Office of Human Research Ethics Training Tips

Prisoner Research, SOP 34

Definition: A *prisoner* is defined as a person who is **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. **Includes house arrest, if detained and not free to move about, are a prisoner.** [45 CFR 46.303(c)]

The regulations covering research involving prisoners apply not only to research that targets prisoners or the prison setting, but also to **subjects who become incarcerated following their enrollment or subjects for whom their incarceration is coincidental with their research involvement**, (e.g., a prisoner with cancer enrolled in a treatment-oriented study that involves no other prisoners).

All prisoners are regarded as being vulnerable to coercion or undue influence and therefore need additional safeguards to protect their rights and welfare as research participants.

1. Full Board Required with prisoner representative present
 - a. For initial, amendment and renewal reviews
 - b. Exception: Minimal risk, meets expedited categories & review done by Prisoner Representative **OR**
 - c. Research involves no interaction with prisoners (e.g. existing data, record review) **does not** require prison rep
2. Cannot enroll prisoners in Emergency Research
3. Studies with adolescents (unless they are married, emancipated or over 18) must meet Sub Part D **and** Prisoner regulations -- Sub Part C
4. Waivers of consent must meet same criteria as any other study
 - a. Care about inducements to be in research are not coercive -- Know that participation will not affect parole possibilities.
5. Targeted Research vs. Research where a subject becomes a prisoner (Accidental Prisoner)
6. **Targeted Research:**
 - a. Are prisoners needed for this research?
 - b. Must have prisoner rep there
 - c. Must meet all 7 requirements below (SOP 34.3 Required findings)

When an IRB is reviewing a protocol in which a prisoner is a subject, the IRB must make, in addition to other requirements under 45 CFR 46, subpart A, seven additional findings under 45 CFR 46.305(a), as follows:

- i. the research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2) listed below in the next section;
- ii. 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;
- iii. the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- iv. 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 IRB 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;

- v. the information is presented in language that is understandable to the subject population;
- vi. 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
- vii. where the IRB 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.

d. Must go to Secretary of Health & Human Services for certification (45 CFR 46.306(a)(2))

(i) **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)) **(See box below)**

(ii) **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;

(iii) **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 the Secretary (through OHRP)** has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the Secretary's intent to approve such research; or

(iv) **research on practices, both innovative and accepted, that 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 that may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and **published notice, in the Federal Register, of the Secretary's intent to approve such research.**

(v) an additional fifth category of permissible research is provided by HHS Secretarial waiver for certain **epidemiological research conducted or supported by HHS.** The criteria for this category are that the research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. The institution still must review the research under subpart C and certify to OHRP that an appropriately constituted IRB has reviewed the proposal and made all other required findings under HHS regulations at [45 CFR 46.305\(a\)](#) and receive OHRP authorization prior to initiating any research involving prisoners. All of the other requirements of subpart C apply to research in this category.

7. Accidental Prisoner

- a. Stop research on that person
- b. Can analyze data previously collected
- c. Must review study with prisoner rep
- d. IRB will look at this research to see if:
 - i. It is possible to continue the subject on the study
 - ii. Will the prison allow research staff into the prison
 - iii. Care that participation in the research does not create a risk for the subject

<p>Definition of Minimal Risk in Prisoner Research 45 CFR 46.303(d)</p>	<p>Definition of Minimal Risk in 45 CFR part 46, subpart A, 45 CFR 46.102(i)</p>
<p>"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.</p>	<p>"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.</p>