

Part one of this presentation looked at federal regulations governing research involving prisoners as subjects. Next, we summarize the certifications that a researcher must obtain before prisoners may take part in a study, as well as the role of the IRB.

A researcher who wishes to enroll prisoners should identify prisoners as a subject population within the eResearch application. In its review, the IRB must examine a study closely to make sure it meets seven special criteria.

1. The study must represent one of the permissible categories of research involving prisoners, according to federal regulations; the first part of this presentation outlined these permissible categories;
2. the attractiveness of possible benefits of study participation must not present undue influence in prisoners' decision whether to join the study;
3. the study's risks must not be of greater magnitude for prisoners than for non-prisoners;
4. the process of selecting prisoner subjects must be fair and free of the influence either of prison staff or of other inmates;
5. as with all human subjects research, study documents and discussions must be in language that subjects and potential subjects understand; this may involve special measures when communicating with members of a prison population;
6. the researcher must make sure that a prisoner's study participation will have no bearing on a parole board's decisions to grant or deny that prisoner parole; the researcher must make this clear to all prisoner subjects during informed consent discussions and in the informed consent document;
7. finally, if the study involves any follow-up procedures, the researcher must have adequate provisions in place to carry out these procedures while the subject is incarcerated, and must make sure that the prisoner understands the follow-up arrangements.

When approving any research involving prisoners as subjects, the IRB must document clearly that the study meets all seven of these special criteria.

After receiving initial study approval from the IRB, the researcher must go on to seek further approval from the federal, state, or local department that operates the prison facility where potential subjects are detained, as well as from the party responsible for the facility, such as a prison warden.

U-MIC TRANSCRIPT

Prisoners as Research Subjects

(Part Two)

If the study is federally funded, the Department of Health and Human Services' Office of Human Research Protections must review and certify the proposed research before prisoners may take part. The IRB will work directly with the Office of the Vice President for Research to request this additional certification on the researcher's behalf.

If in its review process OHRP concludes that the IRB incorrectly applied the categories of permissible research—outlined in part one of this presentation—OHRP may notify the institution that it has chosen to re-categorize the study. If OHRP determines that the research does not fit any of the permissible categories of research involving prisoners, the researcher will not be allowed to enroll prisoners in the study.

If the study is not federally funded, the Office of the Vice President for Research must still provide its own certification before the researcher will be allowed to enroll prisoners.

The IRB may grant a waiver or alteration of informed consent in research involving prisoners, provided that study meets the usual regulatory criteria. Even with a waiver or alteration of consent, however, the researchers must clearly inform subjects in advance that their study participation will have no effect on the decisions of a parole board.

Note, as well, that none of the exemption categories for human subjects research, as outlined in the federal regulations, apply to research involving prisoners.

Although the regulations permit IRBs to approve research involving prisoners by expedited review, federal guidance recommends that all research involving prisoners be reviewed by a convened Board. If the study does undergo expedited review, federal guidance recommends that the IRB member reviewing the research be a prisoner or prisoner advocate.

Contact the IRB for more information about prisoners as subjects in research.

Posted: 8/22/2012