

An earlier presentation on prisoners as research subjects summarized four types of research that any study involving prisoners must represent in order to receive approval from the IRB, as well as from all appropriate state or federal departments. Those four types, outlined in subpart C of the Department of Health and Human Services' regulations, include research:

- that relates to the causes, effects, or processes of criminal behavior or incarceration;
- that examines prisons as institutions or prisoners as inmates;
- that pertains to conditions common among prisoners;

*and*

- that offers a potential for direct benefit to subjects.

An epidemiological study, however, that examines conditions affecting both prisoners and non-prisoners, and that may offer no direct benefit to subjects, may not represent any of these four types of permissible research.

In 2003, the Department of Health and Human Services adopted a special waiver that allows prisoner involvement in epidemiological research, provided that the study at hand presents “no more than minimal risk and no more than inconvenience to the prisoner-subjects.” DHHS-supported epidemiological studies relating to chronic diseases, injuries, or environmental health may include prisoner involvement if they're designed:

- to describe the prevalence or incidence of a disease by identifying all cases;
- and*
- to study potential risk factor associations for a disease.

As with all research involving prisoners, the Department of Health and Human Services must receive certification of IRB approval. Certification should include the IRB's determination:

- that the study presents no more than minimal risk and no more than inconvenience to prisoner-subjects;
- and*
- that prisoners are not a particular focus of the research.

An HIV study, for example, aimed at determining as yet unidentified risk factors for HIV may be allowed to enroll prisoners as subjects. The Department of Health and Human Services' Center for Disease Control and Prevention collects data about HIV-positive diagnoses throughout the United States. A researcher with access to these data may be allowed to enroll prisoners, provided that the study

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presents no more than minimal risk and no more than inconvenience to prisoner-subjects.

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

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