

Federal regulations define a *prisoner* as “any individual involuntarily confined or detained in a penal institution.” This includes anyone, either convicted of a crime or awaiting trial, confined to a jail, prison, or juvenile facility, as well as any individual confined to a residential substance abuse facility or psychiatric institution as an alternative to criminal prosecution or incarceration. Parolees detained in treatment facilities as a condition of their parole are also considered prisoners.

Federal guidance clarifies, however, that the regulatory definition of prisoners does not include those:

- receiving court-ordered non-residential substance abuse treatment;
- residing in psychiatric institutions, whether voluntarily or involuntarily, for reasons not connected with an arrest or conviction;
- or
- living in the community while on parole.

Although in most cases a probationer ordered to wear a monitoring device (or electronic tether) while living in the community is not considered a prisoner, researchers should work with the IRB before enrolling any subject ordered to wear such a device, to ensure that prisoner regulations do not apply.

Due to the limits on prisoners’ personal autonomy, the regulations present a special definition of *minimal risk* that applies only to research involving prisoners. When referring to non-prisoners in research, the regulations state:

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.

When referring to prisoners, however, the regulations define minimal risk as:

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.

Regulations also specify the types of research in which prisoners may participate as subjects. A researcher may, after receiving certification from the appropriate government agencies, be allowed to enroll prisoners if the study at hand:

- examines causes, effects, and processes of criminal behavior and incarceration, *and* presents no more than minimal risk, according to the special definition applicable to prisoners;
- examines prisons as institutional structures or prisoners as incarcerated persons, *and* presents no more than minimal risk;

# U-MIC TRANSCRIPT

## Prisoners as Research Subjects

### (Part One)

- examines conditions likely to affect prisoners as a group (such as the study of vaccines to treat illnesses especially common among prisoners), *and, if the study is federally funded, only after* the Department of Health and Human Services has consulted with the appropriate experts;  
or
- involves new or standard practices that are likely to improve the health or well-being of the subject; if the study is federally funded, and prisoners may be assigned to study control groups that do not receive potentially beneficial treatment, the Department of Health and Human Services must consult with appropriate experts before the researcher will receive permission to enroll prisoners as subjects.

Part Two of this presentation will focus on special considerations and procedures for IRBs, as well as necessary certifications, for reviewing and approving research involving prisoners as subjects.

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