

OHRS Information Sheet Requirements to Involve Prisoners as Participants in Research

Individuals who are incarcerated – “prisoners” – may not be enrolled in research unless the IRB has granted approval for the inclusion of these individuals. In order for research to involve individuals who are incarcerated or detained, the IRB review must include a prisoner advocate representative at the IRB meeting at which the particular research is reviewed and approved; and, the IRB must make specific findings required by the Federal regulations for research involving prisoner participants (45 CFR 46, Subpart C). This applies to new enrollments and to the continuation of current participants who become incarcerated or detained.

The purpose of the regulations is to afford additional protections for prisoners, who are a vulnerable population due to the constraints of incarceration. Issues of concern for this population include:

- restricted ability to make voluntary and uncoerced enrollment decisions;
- possible inability to decide to continue research interventions and to keep research visits once incarcerated; and
- coordination of access to treatments and compliance with the study procedures between visits.

A prisoner who participates in research and because of that, is permitted to spend time at the prison hospital and enjoy certain benefits, may actually find him/herself at some risk within the institution.

There are practical issues as well for the investigator such as how to manage access to the prisoner.

The Federal Regulations define a ‘prisoner’ as any individual 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. 45 CFR Part 46, Subpart C.

What if a current participant becomes incarcerated?

1. If a currently enrolled participant in research becomes incarcerated after enrollment, the investigator must notify the IRB immediately and all interactions and interventions and collection of protected health information (PHI) must cease until the regulatory requirements have been satisfied for the research. This means that the research must be re-reviewed in the context of including prisoners and making the additional regulatory determinations.

Exception: The principal investigator may submit an amendment to the IRB to justify that it is in the best interest of the individual to remain in the research and request IRB approval to continue the involvement of the participant while the regulatory requirements are being met.

If compliance will not be sought for this research, discontinue the prisoner participant from the research and recommend standard care, if applicable.

Please call OHRS for further information relating to the inclusion of prisoners in research.