

Research Involving Prisoners

The federal regulations governing human subjects in research 45 CFR 46, Subpart C provide additional safeguards for the protection of research subjects who are prisoners because the constraints associated with incarceration may affect the individual's ability to make a truly voluntary and uncoerced decision regarding participation in research. The additional protections apply to research subjects who are prisoners at the time of enrollment in the research as well as research subjects who become prisoners after they enroll in the research.

Prisoner is defined in the regulations as "any individual involuntarily confined or detained in a penal institution." OHRP extends the definition to "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." Of note, research studies that involve adolescents detained in a juvenile detention facility are subject to these additional protections as well as the additional protections for children.

IRB Review of Research that Involves Prisoners as Subjects

IRB Membership

In order for an IRB to review and approve research that involves prisoners, the membership of the IRB must include at least one member who is or has been a prisoner, or a prisoner representative (someone who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner). Since the Partners Human Research Committee (PHRC) does not meet these special membership requirements, Partners has executed an IRB Authorization Agreement with the Harvard School of Public Health that allows the PHRC to utilize the HSPH IRB for review of research involving prisoners. When a protocol involving prisoners as subjects is being reviewed by more than one IRB because the protocol is being conducted at multiple sites, only one IRB must satisfy the special membership requirements for research involving prisoners as subjects.

Expedited Review

Research involving prisoners may be reviewed through the expedited review procedure if the research is no more than minimal risk and meets the criteria for expedited review found at 45 CFR 46.110 and 21 CFR 56.110. However 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).

For research involving prisoners, "minimal risk" is defined at 45 CFR 46.303(d) as follows: "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**." The HSPH IRB is responsible for determining whether the research is minimal risk and whether the research is eligible for review through the expedited review procedure.

Research Exempt from the Requirements of 45 CFR 46

The exemptions at 45 CFR 46.101(b) do **not** apply to research involving prisoners. For more information, refer to <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>.

Submission of Research Studies that Include Planned Enrollment of Prisoners as Subjects

When the study population includes prisoners, the study must undergo review by the HSPH IRB. Investigators must complete and submit the following to the Partners Human Research Office:

- Partners Human Research Committee required forms and documents, and
- Harvard School of Public Health's [Vulnerable Subjects Worksheet](#)

The Partners Human Research Office will forward the submission to the HSPH IRB with a request to review on its behalf. The HSPH IRB is responsible for the initial and continuing review of the study, and for notifying the principal investigator and the Partners HRC of IRB review actions.

When changes to an ongoing PHRC-approved protocol include extending the study population to include prisoners, investigators must follow the PHRC procedures for submitting proposed changes (amendments) for PHRC approval. The amendment submission must include the following:

- PHRC amendment form;
- Revised PHRC Protocol Summary;
- Revised detailed protocol;
- Harvard School of Public Health's [Vulnerable Subjects Worksheet](#) and
- Other revised documents, as applicable, to the amendment.

As with new submissions, the PHRC will forward the amendment and related review materials to the HSPH IRB for review. Once the study is approved to include enrollment of prisoners as subjects, the HSPH IRB becomes the IRB of record for the study. The HSPH is responsible for continuing review of the study, and for notifying the principal investigator and the Partners HRC of IRB review actions.

When A Subject Becomes a Prisoner While Participating in an IRB-approved Research Study

When a subject becomes a prisoner while participating in a research study approved by the PHRC, all research interactions and interventions with the subject and/or collection of identifiable private information about the subject must cease until the requirements of the federal regulations have been satisfied with respect to the relevant protocol unless the principal investigator asserts and the IRB Chairperson agrees that it is in the best interests of the subject to remain in the research study while incarcerated. In such cases, the subject may continue in the research until the requirements of the federal regulations are satisfied.

When a subject becomes a prisoner, the investigator must notify the PHRC immediately of the situation. The notification should be in writing and should include whether the subject's participation will end as a result of his/her incarceration or whether permission is being requested for the subject to continue in the research because it is in his/her best interests.

When requesting permission for the subject to continue in the research, address the following:

- the prospect of direct benefit to the individual subject;
- the importance of the intervention or procedure to the individual subject's health or well-being
- the availability of the intervention or procedure outside of the research context; and
- how the intervention or procedure can be performed safely while the individual is a prisoner.

The investigator must follow the amendment process described above to include the prisoner as a subject in the research. Once approved, the HSPH IRB will become the IRB of record for the study.