

HUMAN RESEARCH AFFAIRS
RESEARCH INVOLVING PRISONERS

The federal regulations governing human participants in research 45 CFR 46, Subpart C provide additional safeguards for the protection of research participants 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 participants who are prisoners at the time of enrollment in the research as well as research participants 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 Participants

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 Mass General Brigham IRB does not meet these special membership requirements, Mass General Brigham will utilize the Harvard School of Public Health (HSPH) IRB for review of research involving prisoners. When a protocol involving prisoners as participants 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 participants.

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 46.102(j).

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 46.104(d) do **not** apply to research involving prisoners except for research aimed at involving a broader participant population that only incidentally includes prisoners. For more information, refer to [2018 Requirements \(2018 Common Rule\) | HHS.govparticipant](#).

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

When the study population includes prisoners, the study must undergo review by the HSPH IRB. Prior to submitting an application to the HSPH IRB, Investigators must submit a Cede application in Insight to the Mass General Brigham IRB. A study specific reliance agreement between the HSPH IRB and the MGB IRB must be established. When changes to an ongoing Mass General Brigham IRB-approved protocol include extending the study population to include prisoners, investigators must follow the same process. For questions, contact the Single IRB team at mgbsingleirb@partners.org.

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

When a participant becomes a prisoner while participating in a research study approved by the Mass General Brigham IRB, all research interactions and interventions with the participant and/or collection of identifiable private information about the participant 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 Chair or designee agrees that it is in the best interests of the participant to remain in the research study while incarcerated. In such cases, the participant may continue in the research until the requirements of the federal regulations are satisfied.

When a participant becomes a prisoner, the investigator must notify the Mass General Brigham IRB immediately of the situation by submitting an Other Event submission in Insight. The notification should include whether the participant's participation will end as a result of their incarceration or whether permission is being requested for the participant to continue in the research because it is in their best interests.

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

- the prospect of direct benefit to the individual participant
- the importance of the intervention or procedure to the individual participant'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 obtain approval from the HSPH IRB to include the prisoner as a participant in the research. Investigators must also submit a Cede application in Insight to the Mass General Brigham IRB. Once the study is approved at HSPH, the HSPH IRB will become the IRB of record for the study. The Mass General Brigham IRB approved study must be closed once HSPH IRB approval is in place. The Cede application will remain open with the Mass General Brigham IRB.