
Yale University Institutional Review Boards Guidance

Guidance 320 GD.1 Prisoner Research Guidance

Date: 12/30/2008

Overview

This guidance is provided for the use of the IRB and investigators as a supplement to the policy on the Participation of Prisoners in Research (IRB Policy 320), as well as to further describe the application of the policy and its procedures (see PR 1, Measures to be Taken When a Current Research Participant Becomes a Prisoner, and PR 2, Institution Certification of Prisoner Findings to OHRP).

Prospective Application of Subpart C Review

When investigators anticipate that some of the subjects in a planned research study population are likely to be prisoners or become prisoners during the course of the study (for example, subjects on parole, probation, under electronic monitoring, or in substance abuse treatment studies) the IRB may review the research prospectively for prisoner involvement in accordance with the requirements of Subpart C of 45 CFR part 46. When an IRB reviews a research proposal in which the subjects are not prisoners, but in anticipation of the likelihood that some of the subjects will become prisoners during the course of the research, some of the seven findings required by 45 CFR 46.305(a) may not be applicable. As examples, if subjects are not recruited from within a prison, the finding under 45 CFR 46.305(a)(4) would not be applicable; and, if there is no particular parole board involved yet, the finding under 45 CFR 46.305(a)(6) would not be applicable. The IRB must document these findings accordingly, and the IRB Chair must certify the research on behalf of Yale University (the Institution) to the Office of Human Research Protection (OHRP) if the research is supported by federal funds. In that case, the investigator must wait for notification from the IRB that OHRP has authorized the research study prior to initiating any interaction or intervention with, or obtaining identifiable private information about, prisoners. **Regardless of the source of funding, no research involving prisoners may commence without prior approval from the State of Connecticut Department of Corrections Research Committee and other involved entities (e.g., Department of Children and Families), if applicable.**

IRBs should use their discretion in deciding whether to apply the additional requirements of Subpart C to research in anticipation of some subjects being or becoming (re)incarcerated. In some cases, the involvement of subjects who may be prisoners or become prisoners can be anticipated by the investigator and/or the IRB in ways that make the additional protections of Subpart C meaningful. In other cases there may be insufficient information available at that time to make the seven findings required by 45 CFR 46.305(a) (for example, the investigator and the IRB may not know the specific penal institutions where subjects will be incarcerated and therefore will lack important information about the local research context), and the investigator and the IRB may have to wait until more specific information becomes available. In these instances, the investigator must submit an amendment request to the IRB to conduct the Subpart C review after research subject(s) have become incarcerated.

Expedited Review of Research Involving Prisoners

Yale IRBs may use the expedited review of research involving prisoners as permitted under the regulations. However, because of the vulnerability of prisoners, it is recommended by OHRP that all research involving prisoners be reviewed by the convened IRB. If the research is reviewed under the expedited review procedure, OHRP recommends, but does not require, that the IRB member(s) reviewing the research include a prisoner or prisoner representative. (See OHRP's website for further guidance on the use of expedited review procedures and the list of expedited review categories.)

Exemption from Review

None of the exemption categories in the HHS regulations for research involving human subjects at 45 CFR 46.101(b) apply to federally funded research involving prisoners. This type of prisoner research may not be exempt from IRB review.

Exceptions

The requirements of 45 CFR 46 Subpart C were developed in the context of biomedical and behavioral research and are not easily applied to other types of human research such as historical or other humanities research projects. In particular, the categories of biomedical and behavioral research allowable under 45 CFR 46.306 do not include interviews with prisoners on topics unrelated to their status as incarcerated individuals. The IRBs recognize both the validity and importance to certain non-biomedical and non-behavioral research of interviews with key informants who happen to be incarcerated, and the need to provide appropriate protections for prisoners as a vulnerable population. To balance these needs, the IRB may grant an exception to the requirement that research involving prisoners fall within the federally defined categories at 45 CFR 46.306 when specific criteria are met, below. All other applicable requirements of 45 CFR 46 Subpart C should still be met, as these requirements provide protections which are necessary irrespective of the nature of the research.

Investigators proposing to include prisoners in non-biomedical or non-behavioral research must explain how their project meets the following criteria for exception:

- The project must be conducted without the involvement of federal funds
- The majority of participants must not be incarcerated. The exception expects that the project will minimize the involvement of incarcerated individuals and concentrate on obtaining information from individuals who are not subject to the vulnerabilities inherent to incarceration.
- The proposed incarcerated participant must be essential to study integrity. The IRB requires justification as to why incarcerated participants are necessary and add value to the study that can't be gained from other sources.
- The interview questions must be unrelated to the proposed participant's status as a prisoner or the reasons for their incarceration. Note that studies which relate to an individual's status as a prisoner or the reason for incarceration would likely be allowable without the exception.