
Yale University Institutional Review Boards Procedure

Procedure 320 PR.2 Institution Certification of Prisoner Findings to OHRP

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Overview

For any Department of Health and Human Services (DHHS) -conducted or -supported research involving prisoners that Yale IRBs are responsible for overseeing, either because it is conducted by Yale researchers or by Research Affiliates for which the Yale IRB is the IRB of record, Yale, through delegating its authority to the IRB, must certify to the Secretary through the Office of Human Research Protection (OHRP) that the IRB reviewed the research and made seven findings as required by the regulations. The certification materials must be forwarded to OHRP. OHRP then will determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so which one. Following its review of the certification, OHRP will send Yale a letter authorizing the involvement of prisoners in the proposed research, if OHRP determines that the research involves one of the permissible categories.

If research is not DHHS-conducted or -supported, then per OHRP requirements, Yale should not submit any certification materials to OHRP.

Prisoner Findings Certification Letter

A certification letter sent to OHRP by Yale must indicate that the IRB reviewed the research under Subpart C and made the seven findings as required by the regulations (45 CFT 46.305(a)).

OHRP requires Yale, as the responsible institution, to submit a copy of the research proposal so OHRP can determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2). The term “research proposal” includes:

- the Yale IRB-approved protocol; any relevant DHHS grant application or proposal(s) or excerpts from the proposal including the Notice of Grant Award and background and methods sections, and the name of the Agency program officer who administers the grant;
- any IRB application forms required by the Yale IRB; and
- any other information requested or required by the Yale IRB that is considered during its initial review.

The following information must also be included in a prisoner research certification letter sent by Yale:

- Yale’s OHRP Federalwide Assurance (FWA) number;
 - the IRB registration number for the Yale IRB that conducted the review and issued approval; and
 - the date(s) of the IRB meeting(s) in which the protocol was considered, including a brief chronology that encompasses:
 - the date of initial IRB review; and
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- the date of Subpart C review, if not done at the time of initial IRB review.

The Signatory Official of a Research Affiliate that has identified Yale IRBs as their IRB of record must co-sign the certification letter along with the IRB Chair to indicate their endorsement of the Yale IRB's prisoner findings and approval of the research.

Research Studies Involving Review by More than one IRB

All Yale investigators, and their non-Yale collaborators on the protocol who intend to engage in the conduct of prisoner research, must have IRB approval of the study prior to initiating the research involving prisoners. When Yale investigators collaborate with non-Yale investigators or institutions on multi-center research, each institution engaged in the research study involving prisoners must certify to OHRP in accordance with the requirements of DHHS regulations, unless (a) an institution formally relied upon the review of the Yale IRB as their IRB of record; and (b) the Yale IRB certified to OHRP on behalf of both institutions. Such reliance must be formalized by an IRB Authorization Agreement (IAA), and the institution that relies on Yale for its certification must list Yale on its FWA.

Of special note: Not all IRBs responsible for reviewing the multicenter research protocol and certifying their findings to OHRP must have a prisoner representative on board to review the protocol, provided that one of the IRBs reviewing the protocol is duly constituted with a prisoner representative. In this case, the certification letter and materials sent by the institution that made prisoner findings without a prisoner representative must indicate if the prisoner representative's review was conducted by another IRB.

All approval documentation from external IRBs should be included in the certification packet submitted to OHRP.

When Yale Relies on Another IRB

Yale University has a limited number of agreements in place with other IRBs which authorize their review of Yale's engagement in research (for example, Western IRB). If another IRB is relied upon by Yale to review Yale research involving prisoners, Yale University, through the Yale IRB, will still certify to OHRP the prisoner findings made by the other IRB on Yale's behalf. The Yale IRB will require the following documentation from the reviewing IRB:

- the IRB meeting minutes reflecting review of the research and the applicable prisoner regulations; the IRB-approved protocol; any relevant DHHS grant application or proposal, and the name of the Agency program officer who administers the grant;
- any IRB application forms required by the IRB;
- any other information requested or required by the IRB that was considered during its initial review;
- The IRB's OHRP Federalwide Assurance (FWA) number;
- the IRB registration number for the IRB that conducted the review and issued approval; and
- the date(s) of the IRB meeting(s) in which the protocol was considered, including a brief chronology that encompasses:
 - the date of initial IRB review; and
 - the date of Subpart C review, if not done at the time of initial IRB review.

References

Julia Gorey, J.D., Division of Policy and Assurances, Office for Human Research Protections (OHRP), e-mail communications clarifying certification requirements.