
Yale University Human Research Protection Program

910 PR.1 Collaborating Investigator Requests

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Overview

This procedure describes the process for requests to serve as Collaborating Investigator on a Yale research protocol, allowing a non-affiliated individual to come under the purview of Yale IRBs in the performance of Yale research.

Request Requirements

Requests to serve as a Collaborating Investigator are generated by the Yale Principal Investigator (PI).

When a PI chooses to include a Collaborating Investigator, he or she is responsible for providing the proposed investigator with the *Collaborating Investigator Instructions* and the *Request to Serve as a Collaborating Investigator*, found on the IRB web site. The PI must provide information in support of the Request, describing the proposed role of the Collaborating Investigator, the reason the Collaborating Investigator is needed for the research, and the oversight that will be provided by the PI for the Collaborating Investigator's work on the protocol.

The Collaborating Investigator must complete the Request and submit it to the IRB with the following required documents: verification of human subjects training; verification of HIPAA for Researchers training, if applicable; a current curriculum vitae, biosketch or resumé; and a copy of current licensure, if applicable.

If the Collaborating Investigator is an agent of an institution and will be participating in research during the conduct of his or employment or using that institution's facilities or clients, a letter of institutional support must be included, signed by the institution's chief executive officer or by an institutional official of comparable status.

Collaborating Investigator Commitments

In accordance with OHRP *Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement* (January 31, 2005), the Collaborating Investigator must agree to the following:

1. To review and abide by a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent: see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); (b) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46, and all Subparts (c) the U.S. Food and Drug Administration (FDA) regulations for the protection of human subjects at 21 CFR part 50; (d) the Yale University Federalwide Assurance (FWA) and the specific terms of the Yale University FWA; (e) the relevant Yale University policies and procedures for the protection of human subjects, and (f) *HIPAA at Yale, Researcher's Guide to HIPAA* (if applicable);
2. To accept the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Request.
3. To comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research

- conducted under this Request, including, but not limited to, HIPAA's Privacy and Security Rules and the requirements governing the use and disclosure of Protected Health Information in research.
4. To abide by all determinations of the Yale University Institutional Review Board (IRB) designated under the above-referenced FWA and to accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
 5. To complete human research protection training and other applicable educational training required by Yale University and/or the IRB prior to initiating research covered under this Request.
 6. To report promptly to the Principal Investigator of this research and the IRB any proposed changes in the research conducted under this Request. To not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
 7. To report immediately to the Principal Investigator of this research and the IRB any unanticipated problems involving risks to subjects or others in research covered under this Request.
 8. If the Collaborating Investigator is involved in enrolling subjects, the Collaborating Investigator will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA referenced above) and as consistent with the IRB approved protocol.
 9. To acknowledge and agree to cooperate in assisting the IRB in carrying out its responsibility for initial and continuing review, record keeping, reporting, auditing, monitoring and certification for the research referenced above.
 10. To provide all information requested by the IRB in a timely fashion.
 11. To not enroll subjects in research or otherwise initiate research activity under this Request prior to IRB review and approval of the proposed research and approval of this Request by Yale University.
 12. To acknowledge that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.
 13. To deliver emergency medical care without IRB review and approval only to the extent permitted under applicable federal regulations and state law.

Staff Evaluation

When all documents are received, the IRB staff reviews the Request for completion, verifies the approval status of the related protocol, and prepares a staff evaluation for review by the IRB Chair/Director.

The evaluation includes a description of the study including level of risk; the Collaborating Investigator's role in the study and the PI's proposed oversight of the Collaborating Investigator; information regarding the education, training and professional experience of the Collaborating Investigator; verification of requisite training; and verification of institutional support, if required.

The evaluation and approved Request are kept on file in the IRB office.

Approval/Reporting to the Institutional Signatory Official

Approval of Collaborating Investigators has been delegated to IRB Chairs and Director. The Manager notifies the PI and the Collaborating Investigator of the decision to approve/not approve the request. The Manager maintains a log of Requests, including the Collaborating Investigator's name, protocol name and number, PI, cognizant IRB, study sponsor and any comments, if appropriate. The log is forwarded to the Offices of General Counsel and Office of Research Administration for review quarterly, if new Collaborating Investigators have been approved during the previous quarter.