Overview

This procedure describes the process for requests to serve as an Unaffiliated Investigator on a Yale human subjects research protocol, allowing a non-affiliated individual to come under the purview of Yale designated Institutional Review Boards (IRBs) in the performance of Yale research.

Request Requirements

Requests to serve as an Unaffiliated Investigator are generated by the Yale Principal Investigator (PI) and submitted via IRES IRB.

When a PI chooses to include an Unaffiliated Investigator, he or she is responsible for providing the proposed investigator with the Unaffiliated Investigator Instructions (910 GD.1) and the Request to Serve as an Unaffiliated Investigator (910 FR1), found on the Yale Human Research Protection Program (HRPP) website and IRES IRB Library. The PI must complete the first section of the Request, providing information to the HRPP in support of the Request, describing the proposed role of the Unaffiliated Investigator, the reason the Unaffiliated Investigator is needed for the research, and the oversight that will be provided by the PI for the Unaffiliated Investigator’s work on the protocol.

The Unaffiliated Investigator must complete the second part of the Request. The PI must submit it to the HRPP via IRES IRB with the following required documents: verification of human subjects training; Good Clinical Practice training if applicable; 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 Unaffiliated 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.

Unaffiliated Investigator Commitments

In accordance with OHRP Guidance on Extension of an FWA to Cover Unaffiliated Individual Investigators and Introduction of the Individual Investigator Agreement (January 31, 2005), the Unaffiliated 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 Federal wide 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 Federal wide 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 Unaffiliated Investigator is involved in enrolling subjects, the Unaffiliated 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.

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**Staff Evaluation and Approval**

When all documents are received, the HRPP staff reviews the Request for completion, verifies the approval status of the related protocol, and makes a recommendation regarding approval for review by the Institutional Official or the designee (the HRPP Director).

The approved Request is kept on file in IRES IRB system.

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**History**

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<th>Date</th>
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<tr>
<td>3/7/2013</td>
<td>Initial effective</td>
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<tr>
<td>3/8/2021</td>
<td>Revision to clarify that the requests are submitted to the HRPP via IRES IRB and that GCP training may be required when necessary. Reference to Education and Community Outreach Manager have been removed.</td>
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