Overview

These instructions provide the materials needed to submit a Request to Serve as an Unaffiliated Investigator when needed for a Yale human subjects research project. Any individual not affiliated with Yale working on a Yale research protocol is required to either be approved as a unaffiliated investigator, or have approval from their own Institutional Review Board (IRB).

Note: If an institution routinely engages in federally funded research, the Unaffiliated Institutional Investigator Request does not apply. The institution must file an FWA. (See http://www.yale.edu/hrpp/affiliates/index.html)

Purpose

Yale University recognizes that investigators frequently collaborate with researchers from outside of the University when designing and/or conducting Yale biomedical and social/behavioral research projects involving human subjects. Researchers from institutions external to Yale University who wish to take part in the conduct of a Yale research protocol are required to obtain approval of the research protocol from their own institutional IRB unless provisions have been made for a Yale IRB to review the research.

The University acknowledges, however, that some collaborators are representatives from institutions that do not routinely engage in research and thus do not have a designated IRB. Alternatively, these collaborators may not be affiliated with any institution. In either scenario, it is important that collaborators understand their obligations to protect human subjects participating in Yale research. The University requires that independent collaborators and collaborators from institutions that are not routinely engaged in research be held to the same standards as required of all University research personnel. In order to ensure that collaborators are knowledgeable about the Yale expectations of persons conducting research, Yale requires that these individuals be approved as Unaffiliated Investigators by the University’s Institutional Signatory Official or his or her designee prior to engaging in any Yale research project involving human subjects.

In accordance with Yale Human Research Protection Program (HRPP) policy and federal guidance, approval to participate as a Unaffiliated Investigator is required when an investigator or research team member is not affiliated with Yale University, is not covered under the IRB of another institution, and will assist in the conduct of Yale research under the direction and supervision of a Yale University Principal Investigator. Potential unaffiliated investigators may not engage in the conduct of Yale research until an Unaffiliated Investigator Request has been approved and signed by the University’s Institutional Signatory Official or his or her designee, and the investigator. See: Yale University HRPP Policy Regarding 910 Collaborating and Unaffiliated Investigators Assisting in the Conduct of Research at Yale http://yale.edu/hrpp/policy/index.html.

Definitions

Assured Institution
An institution with an FWA currently approved by OHRP.

Federal wide Assurance (FWA)
A formal written, binding attestation in which an institution assures to DHHS that it will comply with applicable regulations governing research with human subjects.
Institutional Support Letter
A letter signed by an executive director, chief executive officer, board president or other individual with the authority to commit an institution’s resources and grant permission for the engagement of their employee to participate in the conduct of research.

Office for Human Research Protections (OHRP)
An office within the U.S. Department of Health and Human Services (DHHS) that is responsible for implementing DHHS regulations (45 CFR Part §46) and guidance governing research involving human subjects.

Unaffiliated Investigator:
An individual who is not otherwise an employee or agent of an assured institution and who is conducting collaborative research activities with an investigator or member of an assured institution. Unaffiliated investigators may be either (1) “Unaffiliated Institutional Investigators” who are acting as an employee or agent of a non-assured institution that does not routinely conduct human research or (2) “Unaffiliated Independent Investigators” who are not acting as an agent or employee of any institution.

Unaffiliated Investigator Request:
A formal written request, through which, when approved, Yale extends the applicability of its FWA to cover a unaffiliated investigator and the unaffiliated investigator agrees to abide by the terms of Yale’s FWA and policies and procedures relating to the conduct of human research.

Yale Research:
Research in which Yale University is considered to be engaged, by virtue of one or more of the following: (1) the research is sponsored by Yale University, (2) the research is conducted, in whole or in part, by members of the University faculty, staff or students acting in their University capacity, (3) the research is conducted by an agent of another institution using any of the University’s property or facilities, (4) the University receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor.

Unaffiliated Investigator Request
The Request is available at [http://yale.edu/hrpp/forms-templates/biomedical.html](http://yale.edu/hrpp/forms-templates/biomedical.html). The Unaffiliated Investigator should indicate on the request whether he or she is seeking approval as an Individual or an Institutional Investigator. Proposed investigators who are not affiliated with any institution must complete the materials for Unaffiliated Individual Investigator. Proposed investigators who are affiliated with an institution, agency or practice that is not routinely engaged in research must complete the materials for Unaffiliated Institutional Investigator.

Required Materials
The materials listed on the Unaffiliated Investigator Checklist below are required for preparing a request for approval of an unaffiliated investigator to take part in a Yale research project. The materials must be used only by investigators who are not affiliated with any institution that regularly conducts federally funded human subjects research.

The request is available online at [http://www.yale.edu/hrpp/forms-templates/biomedical.html](http://www.yale.edu/hrpp/forms-templates/biomedical.html)

“Request for Permission to Serve as an Unaffiliated Investigator”.

Completed requests and required supporting materials should be submitted to the IRB reviewing the applicable protocol. The IRB will review the request and make a recommendation regarding approval. When a decision is made, the IRB will notify the Principal Investigator. If approved, a copy of the approved request will be filed with the IRB protocol file.

Questions concerning this process should be directed to the Education and Community Outreach Manager at hrpp@yale.edu.

Unaffiliated Investigator Checklist
For each Unaffiliated Investigator:

___ Request to Serve as a Yale University Unaffiliated Investigator (Choose the appropriate type.)
Independent Investigator (not acting as an employee or agent of any institution)

Institutional Investigator (acting as an employee or agent of an institution that will be engaged in the conduct of the research)

Note: the Request includes a section requiring a statement from the Principal Investigator, describing the proposed Unaffiliated Investigator’s role in the research protocol, the Principal Investigator’s supervision of the Unaffiliated Investigator, and the reason the Unaffiliated Investigator is needed for the research.

Copy of Unaffiliated Investigator curriculum vitae

Copy of Unaffiliated Investigator current license, if applicable

Copy of verification of human subjects protection training

Copy of verification of HIPAA training, if applicable.

Letter of Institutional Support (for Unaffiliated Institutional Investigators)

Accessing Required Review Materials

Unaffiliated Investigators are required to be familiar with the following documents. These documents can be accessed by clicking on the links listed below.


D. The Yale University Federal wide Assurance (FWA) http://ohrp.cit.nih.gov/efile/

E. The specific terms of the Yale University FWA http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html

F. Relevant Yale University institutional and IRB policies and procedures for the protection of human subjects http://www.yale.edu/hrpp/policies/index.html


Sample letter of support/Unaffiliated Institutional Investigator

Date

To Whom It May Concern:

This is to certify that ___________________________ has reviewed the protocol:

(name of Institution/agency/practice)

(title of protocol and name of PI)

and grants permission for ___________________________ to participate in the

(name of unaffiliated institutional investigator)

activities related to this research [and, if applicable: and to use the facilities and resources of this institution in the conduct of the research].
Please do not hesitate to contact us if you have any questions or comments.

Sincerely,

(Signature of CEO, Executive Director, Managing Partner, Owner)

Signature Name
Title

**Required Training**

Unaffiliated Investigators taking part in Yale research projects are required to complete the National Institutes of Health human subjects protection training available at [http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php)

HIPAA compliance for researchers is available at: [http://dev.hipaa.yale.edu/sites/default/files/files/Researchers-Guide-to-HIPAA.pdf](http://dev.hipaa.yale.edu/sites/default/files/files/Researchers-Guide-to-HIPAA.pdf)

Unaffiliated Investigators using this site for HIPAA training should complete and print the Researcher Certification page.

Documentation of training must be included in the materials submitted to the IRB.