HRPP Policy 910 Collaborating and Unaffiliated Investigators Assisting in the Conduct of Research

Scope

This policy addresses the inclusion of investigators or study personnel unaffiliated with Yale University in the design or conduct of research. The policy specifies when such collaborators must have their institution’s Institutional Review Board (IRB) approve their participation in Yale research, or when Yale will agree to serve as the IRB of record for the participation of the unaffiliated investigator. This policy also addresses the type of IRB review required when Yale faculty or personnel collaborate on non-Yale research.

Policy Statement

Persons unaffiliated with Yale University who serve as co-investigators or study personnel in the conduct of human research under the direction and supervision of a Principal Investigator representing Yale University may not take part in the conduct of research until approval from the collaborator’s IRB has been submitted to a Yale IRB. Collaborators involved in research who are not affiliated with an institution having an IRB may request permission of Yale to obtain approval from one of the Yale IRBs. Such unaffiliated collaborators may not take part in the conduct of research until permission has been granted by the University’s Institutional Signatory Official or his/her assigned designee. In certain circumstances, a Yale IRB may conduct the requisite review and approve the inclusion of the collaborator on behalf of the collaborator’s institution and its designated IRB(s) (See 920 PR 2 Authorization Agreements with Other IRBs).

Yale faculty or other persons who participate in the conduct of research that is conducted under the auspices of a Principal Investigator from another institution are required to have the protocol reviewed and approved by the appropriate Yale IRB. In some instances, Yale may designate a duly authorized IRB, external to Yale, to conduct the requisite review and approval on behalf of Yale and its representatives. (See 920 PR 2 Authorization Agreements with Other IRBs).

Reason for the Policy

Yale University recognizes that there are occasions when its research mission may be best served by including agents or representatives of institutions unaffiliated with Yale University in the conduct of specific protocols. Such collaborators may be considered by Yale to be engaged in the conduct of Yale human research. To uphold the terms of its FWA and Yale’s commitment to the protection of volunteers participating in its research, Yale must ensure that these collaborators are qualified through education, experience and professional training to perform their role in the research. Yale must further ensure that the collaborators adopt Yale’s commitment to the protection of its research subjects and promise to adhere to all relevant University, Human Research Protection Program (HRPP) and IRB policies and procedures.

Institutions that routinely perform non-exempt human subject research that is conducted or supported by the U.S. Department of Health and Human Services (DHHS) are required to provide a written assurance to DHHS. (45 CFR §46.103(a)). This assurance serves as a written attestation whereby the institution commits to complying with the requirements set forth in the regulations for the protection of human subjects at 45 CFR Part §46, which, among other rules, requires the approval of research by an IRB. The assurance is referred to as a Federal wide Assurance (FWA) and is filed by research institutions throughout the world with the Office for Human Research Protections (OHRP).

Yale further recognizes that its faculty may collaborate with colleagues from other institutions so as to ensure scientific integrity and gain valuable knowledge from research conducted elsewhere. In these instances, the responsibility to uphold federal requirements and the protection of research participants is shared by the assured institution conducting the research and by Yale, as represented by its research faculty.
Definitions

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

Collaborating Investigator
An individual from an institution with an IRB who is working on a Yale human research study.

Unaffiliated Investigator
An individual who is not an employee or agent of Yale or of an institution with an IRB and who is collaborating with a Yale principal investigator in performing research activities. Unaffiliated investigators may be (1) an "unaffiliated Institutional Investigator" who performs as an employee or agent of a non-assured institution that does not routinely conduct federally funded human research or (2) an "unaffiliated Independent Investigator" who is not an agent or employee of any institution. Examples of unaffiliated investigator tasks include an investigator consenting subjects at a non-Yale site, or analyzing data that is identifiable to a subject in a Yale study.

Unaffiliated Investigator Request
A formal written request, through which, when approved, an institution such as Yale agrees to serve as IRB of record for an unaffiliated individual investigator who agrees to abide by Yale’s policies and procedures relating to the conduct of human research.

Engagement in Research
An individual is considered engaged in human research when he/she, for the purposes of the non-exempt human subjects research project, obtains: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. An institution is considered engaged when its employees or agents conduct the above activities, or when the institution receives a direct federal award to conduct human subjects research, even when all activities involving human subjects are carried out by a subcontractor.

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.

Policy Sections

910.1 Collaborating Investigators from Assured Institutions
Yale research that is performed with co-investigators or other study personnel representing an institution other than Yale which holds a Federal wide Assurance requires approval from the collaborator’s local IRB. A copy of the collaborator’s IRB approval must be submitted to the appropriate Yale IRB and retained by the Yale Principal Investigator.

(Example: Yale researcher serving as the Principal Investigator of a research project which includes collaborating with colleagues from the UCONN Health Center. Approval is required from the UCONN IRB when the activities performed by the colleagues include those cited above).

To determine whether a collaborating site is represented by a local IRB, see http://ohrp.nih.gov/search/.

910.2 Collaborators from Non-assured Institutions and Independent Collaborators
Yale may agree to serve as IRB of record for investigators from institutions or organizations that are not required to file an assurance with the OHRP because they are not routinely engaged in the conduct of federally funded...
research, or to those investigators acting independent of an organization, by entering into an Unaffiliated Investigator Agreement.

Permission for Yale to serve as IRB of record to cover such collaborators will be granted after successfully demonstrating:

- The unaffiliated investigator is qualified through education, experience and professional training to perform the role in the research, and
- The unaffiliated investigator agrees to adopt Yale’s commitment to the protection of research participants and adhere to University, HRPP and IRB policies and procedures related to the conduct of human research, and
- When applicable, the unaffiliated investigator has the permission of his/her institution to take part in the research as documented by a letter of institutional support.

For information on how to request an Unaffiliated Investigator Agreement see http://yale.edu/hrpp/affiliates/index.html.

For additional information regarding the conditions when an external investigator may collaborate with a Yale principal investigator in the conduct of research via a Unaffiliated Investigator Agreement see: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.htm

In certain circumstances, the Yale IRBs have agreed to serve as IRB for a non-Yale agency or organization. For a partial list of institutions that have designated the Yale IRBs to review and approve research on their behalf see: http://yale.edu/hrpp/affiliates/index.html.

910.3 Yale Faculty Serving as Collaborators
Yale faculty or other persons who participate in the conduct of research that is conducted under the auspices of a Principal Investigator from another institution are required to have the protocol reviewed and approved by the appropriate Yale IRB. In some instances, Yale may designate a duly authorized IRB external to Yale to conduct the requisite review and approval on behalf of Yale and its representatives. (See 920 PR 2 Authorization Agreements with Other IRBs)

Related Information

Unaffiliated 910 PR.1 Unaffiliated Investigator Requests

910 GD. 1 Unaffiliated Investigator Instructions

910 FR 1: Unaffiliated Investigator Summary Sheet

910 FR 2: Unaffiliated Investigator Agreement

Contacts

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<tr>
<th>Subject</th>
<th>Contact</th>
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<tbody>
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<td>203.785.4688 <a href="mailto:hrpp@yale.edu">hrpp@yale.edu</a></td>
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Roles and Responsibilities

Human Investigation Committee (HIC)
The HIC I, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical human subjects research conducted at the Yale University.
Human Subjects Committee (HSC)
The HSC serves as the Institutional Review Board for social, behavioral and educational research involving human subjects at Yale University.

Institutional Signatory Official
The Associate Vice President for Research Administration serves as Institutional Signatory Official for Yale University. As such, the Institutional Signatory Official is responsible for ensuring that Yale fulfills the obligations and responsibilities promised in the terms of its Assurance.

Revision History