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# Yale University Human Research Protection Program

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## HRPP Policy 910 Collaborating Investigators Assisting in the Conduct of Research

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Responsible Office	Office of Research Administration	Effective Date: 3/15/09
Responsible Official	HRPP Director	Last Revision: 10/07/09

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### 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 extend the coverage of its Federalwide Assurance with the Office of Human Research Protections to cover the IRB review and participation of the collaborator. This policy also addresses the type of IRB review required when Yale faculty or personnel collaborate on non-Yale research.

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### Policy Statement

Persons unaffiliated with Yale University who serve as collaborating 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 federally funded research until approval from the collaborator's IRB has been submitted to a Yale IRB. Collaborators involved in federally funded research who are not affiliated with an assured institution may request permission of Yale to extend the coverage of its Federalwide Assurance and obtain approval from one of the Yale IRBs. Such collaborators may not take part in the conduct of research until permission to extend Yale's Federalwide Assurance to cover the participation of a collaborator has been granted by the University's Institutional Signatory Official or his/her assigned designee. Persons unaffiliated with Yale University who wish to be engaged in Yale research that is privately funded will be required to request Collaborating Investigator status.

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).

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.

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### Reason for the Policy

Institutions that routinely perform non-exempt human subject research that is conducted or supported by the U.S. Department of Health and Human Services (HHS) are required to provide a written assurance to HHS. 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

Federalwide Assurance (FWA) and is filed by research institutions throughout the world with the Office for Human Research Protections (OHRP).

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 and IRB policies and procedures.

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.

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## **Definitions**

### **Assured Institution**

An institution with an FWA currently approved by OHRP.

### **Collaborating Investigator**

An individual who is not an employee or agent of Yale and who is collaborating with a Yale principal investigator in performing research activities. Collaborating investigators may be (1) an investigator from another assured institution, (2) a "Collaborating Institutional Investigator" who performs as an employee or agent of a non-assured institution that does not routinely conduct human research or (3) a "Collaborating Independent Investigator" who is not an agent or employee of any institution. Examples of collaborating investigators include an investigator consenting subjects at a non-Yale site, or analyzing data that is identifiable to a subject in a Yale study.

### **Collaborating Investigator Request**

A formal written request, through which, when approved, an assured institution such as Yale extends the applicability of its FWA to cover a collaborating individual investigator and the collaborator 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 research project, obtain: (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 subject research, even when all activities involving human subjects are carried out by a subcontractor.

### **Federalwide 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.

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## Policy Sections

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### 910.1 Collaborators from Assured Institutions

Yale research that is performed with investigators representing an institution or organization other than Yale which holds a Federalwide 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.cit.nih.gov/search/asearch.asp#ASUR>

In certain circumstances, the Yale IRBs may conduct the requisite review and approve the inclusion of the collaborator on behalf of the collaborator's institution and its designated IRB(s). For the list of institutions that have designated the Yale IRBs to review and approve research on their behalf see: [http://yale.edu/hrpp/resources/docs/Yale\\_Research\\_Affiliate.doc](http://yale.edu/hrpp/resources/docs/Yale_Research_Affiliate.doc) .

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### 910.2 Collaborators from Non-assured Institutions and Independent Collaborators involved in Federally Funded Research

Yale may extend the application of its own Assurance to include 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 exercising a Collaborating Investigator Agreement.

Permission to extend Yale's Assurance to cover such collaborators will be granted after successfully demonstrating:

- The collaborator is qualified through education, experience and professional training to perform the role in the research, and
- The collaborator agrees to adopt Yale's commitment to the protection of research participants and adhere to University, Human Research Protection and IRB policies and procedures related to the conduct of human research, and
- When applicable, the collaborator 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 coverage through Yale's Assurance via a Collaborating Investigator Agreement see <http://yale.edu/hrpp/affiliates/collaborating-investigator.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 Collaborating Investigator Agreement see:

<http://www.hhs.gov/ohrp/humansubjects/assurance/guidanceonalternativetofwa.htm>

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### **910.3 Collaborators from Non-assured Institutions and Independent Collaborators Involved in Privately Funded Research**

Institutions that do not have an FWA and independent collaborators who wish to be engaged in Yale research that is privately funded are not required to obtain an FWA. Collaborating investigators on these projects will be required to request Collaborating Investigator status.

Permission to serve as a Collaborating Investigator on privately funded research will be granted after successfully demonstrating:

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

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### **910.4 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.

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## **Related Information**

910 FR 2: Collaborating Investigator Agreement

910 FR 1: Collaborating Investigator Summary Sheet

### **External Organizations Using Yale IRBs**

<http://info.med.yale.edu/hrpp/index.html>

### **Un-assured Institutions Wishing to Designate Yale as their IRB of Record**

<http://info.med.yale.edu/hrpp/ra.html>

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**Contacts**

Subject	Contact	Phone/Email
Delegating IRB Authority for Biomedical Research	Community and Education Outreach Manager	203.785.4688 hrpp@yale.edu
Delegating IRB Authority for Social and Behavioral Research	Human Subjects Committee	436-3650 human.subjects@yale.edu
Collaborating Investigators, Biomedical Research	Community and Education Outreach Manager	203.785.4688 hrpp@yale.edu
Collaborating Investigators, Social and Behavioral Research	Human Subjects Committee	436-3650 human.subjects@yale.edu

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**Roles and Responsibilities**

**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.

**Human Investigation Committees**

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**

The HSC is responsible for the review and oversight of social, behavioral and educational research involving human subjects.

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**Revision History : 8/17/06, 2/13/08, 10-07-09**