
Yale University Human Research Protection Program

HRPP Policy 920 Research Partnerships with Individuals and Institutions External to Yale

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Scope

This policy describes the circumstances under which the University may allow its Institutional Review Boards (IRBs) to serve as the IRB of record for individuals and/or institutions external to Yale. The policy also describes when the University may request a non-Yale IRB to serve as IRB of record for research involving agents of the University.

Policy Statement

Whenever the University will engage institutions or individuals not otherwise affiliated with the University in human research, appropriate written agreements with the collaborating institution or investigator will be obtained to ensure that all University human research is conducted in accordance with IRB approval and oversight requirements. Under such agreements, the University may choose to provide IRB oversight to the project or to rely on the oversight of another federally registered IRB.

Reason for the Policy

The University recognizes that investigators frequently collaborate with researchers from outside of the University when designing and/or conducting human research and that such collaboration is vital to maintaining the University's robust research program. Research may extend beyond the boundaries of a single institution to encompass other academic entities, community organizations and agencies, local medical practices, and/or non-affiliated individuals whose expertise is needed for the effective conduct of a study. In order to ensure the ethical conduct of research involving human participants, Yale requires that all individuals engaged in research be under the purview of a federally registered IRB.

Definitions

Assured Institution

An institution with a Federalwide Assurance (FWA) that is approved by the Office for Human Research Protections (OHRP).

Collaborating Investigator

An individual who is not otherwise an employee or agent of an assured institution and who is conducting collaborative research activities with a Yale investigator. Collaborating investigators may be either (1) "Collaborating Institutional Investigators" who are acting as an employee or agent of a

non-assured institution that does not routinely conduct human subjects research or (2) “Collaborating Independent Investigators” who are not acting as an agent or employee of any institution.

Collaborating Investigator Request

A formal written request for Yale to extend the applicability of its FWA and/or IRB oversight to cover a collaborating investigator and the collaborating investigator agrees to abide by the terms of Yale’s FWA and 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.

IRB Authorization Agreement (IAA)

A formal, written, binding agreement in which Yale University agrees to serve as the IRB for another institution or vice versa. The IAA sets out terms and conditions for the institutions.

Institutional Support Letter

A letter signed by an executive director, chief executive officer, board president or other individual with authority to commit the institution’s resources, acknowledging the proposed research activity, and granting permission for the engagement of their employee and facilities (if applicable) in that activity.

Research Affiliate

An institution with whom Yale U has entered into an IRB Authorization Agreement (IAA), allowing the institution to designate Yale IRB(s) as IRB(s) of record on the institution’s FWA or vice versa.

Policy Sections

920.1 Institutions Without an IRB Engaged in Federally Funded Research

When institutions engaged in federally funded research do not have an IRB, or are not affiliated with an IRB, it may be in the interest of both Yale and the institution to establish a research partnership whereby Yale will provide IRB oversight for research involving agents and/or representatives of the research Affiliate. In such cases, the institution would file a Federalwide Assurance with OHRP designating Yale as the institution’s IRB of record and would enter into an IRB Authorization Agreement with Yale. This affiliation may be for a single protocol, several protocols, or for all research conducted by the affiliate institution. Generally the IAA requires that a full time Yale faculty member serve as Principal Investigator of the IRB protocol.

Research Affiliate status for single or groups of projects with a Yale Principal Investigator is appropriate when the collaborative arrangements are limited to those studies and the affiliate institution meets the standards described in Procedure 920.1

Research Affiliate status covering all human research conducted at or by the affiliate institution is appropriate when the proposed Affiliate has a long-standing, integrated research relationship with the University which is expected to continue indefinitely.

920.2 Institutions Without an IRB Engaged in Non-Federally Funded Research

When institutions without a federally registered IRB or FWA are engaged in non-federally funded University human research, Yale may obtain collaborating investigator agreements with all employees or agents of the institution who will be investigators or study personnel for the research. (See 920.4 below).

920.3 Institutions With an IRB

When a research protocol is to be conducted with another institution and that institution has an IRB that is registered with OHRP, it may be in the best interests of both institutions to enter into an IRB Authorization Agreement, naming one of the IRBs as IRB of record for the study, eliminating the need for dual protocol review. Agreements may be made for single or multiple projects and require that the Institution agreeing to rely on the other institution's IRB amend its FWA accordingly. In such agreements, Yale IRBs may serve as IRB of record, or Yale may designate another federally registered IRB as IRB of record.

920.4 Individual Investigators Unaffiliated with an IRB

When an individual is proposed to be involved in the conduct of a Yale human research study and the individual is not affiliated with an IRB, he or she may be approved as a Collaborating Investigator and must agree to adhere to IRB approval and oversight requirements as a Collaborating Investigator. The Collaborating Investigator may be either an Independent Investigator with no agency or institutional affiliation, or may be an Institutional Investigator: an agent of an institution that is not routinely engaged in research.

Special Situations**A. Western IRB**

Yale University has entered into an agreement with the Western Institutional Review Board (WIRB) to serve as an additional Institutional Review Board (IRB). WIRB works in concert with Yale IRBs and is considered a component of the current IRB system within Yale University. Protocols will be sent to WIRB when one of the following eligibility criteria is met:

- Research projects which are funded by Pfizer, Inc. under the Pfizer Bioimaging Research Collaboration and involving non-exempt human subject research which are either:
 1. A project performed exclusively at facilities owned by or operated by Yale University and for which a full time Yale faculty member serves as principal investigator, OR
 2. A project conducted by Yale investigators in collaboration with researchers from Pfizer where the research is conducted at the Pfizer Clinical Research Unit (CRU) and at facilities owned or operated by Yale University.
- Protocol applications for research projects that have approval by the Yale IRB and the Institutional Signatory Official for external IRB consideration.

B. National Cancer Institute's Central IRB (CIRB)

Investigators may request, and the IRB may authorize, the acceptance of the CIRB approval for Phase III adult clinical trials submitted to the CIRB for review from the following cooperative oncology groups: ACOSOG, CALGB, ECOG, GOG, NCCTG, NCIC, NSABP, RTOG, and SWOG, as well as any other Phase III protocols opened in the Cancer Trials Support Unit (CTSU).

The Yale IRB is responsible for determining when Yale University may authorize the CIRB approval of a research protocol to substitute for the review and approval of the protocol by the HIC.

The Yale IRB may also authorize the Pediatric CIRB to serve as its IRB of record and thus accept the Pediatric CIRB approval of all NCI-approved COG Phase 2, 3, and pilot trials.

Related Information

920.PR 1 Research Affiliate Requests

920.PR 2 IRB Authorization Agreements with other IRBs

920.PR 3 Renewal of IRB Authorization Agreements

920.PR 4 Use of WIRB

920.PR 5 Use of CIRB

HRPP Policy 910 Collaborating Investigators Assisting in the Conduct of Research

Contacts

Subject	Contact	Phone
Research Affiliation	Education and Community Outreach Manager	203-785-4688
IRB Authorization Agreements with Other IRBs	Education and Community Outreach Manager	203-785-4688
Collaborating Investigator Requests	Education and Community Outreach Manager	203-785-4688
IAA process	IRB Chair/Director	203-785-4688
IAA preliminary approval	Office of the General Counsel	203-432-4949
Institutional Signatory Official	Office of Research Administration	203-432-8630

Roles and Responsibilities

Education and Community Outreach Manager

Responsible for research affiliation process.

IRB Chair/Director

Responsible for review of staff evaluation and recommendation regarding research affiliation requests. Determines when a request for an IAA may be sent for consideration to Offices of the General Counsel and Institutional Signatory Official. Approves/disapproves requests to serve as Collaborating Investigator.

Office of the General Counsel:

Responsible for review of staff evaluation and recommendation regarding research affiliation requests when the IRB determines that the nature and/or circumstances of the request require such review. In those cases General Counsel determines appropriate contractual language for the IAA and determines when the request may be approved by the Institutional Signatory Official.

Institutional Signatory Official

Responsible for final approval and execution of IAAs.

Reference:

Office for Human Research Protections (OHRP)

Department of Health and Human Services

Guidance on Engagement of Institutions in Human Subjects Research