Yale University Human Research Protection Program

HRPP Policy 920 Research Partnerships with Institutions and Other Organizations External to Yale

Responsible Office	Office of Research Administration	Effective Date	4/14/05
Responsible Official	Director, Human Research Protection Program	Last Revision	4/3/2017

Scope

This policy describes the circumstances under which Yale University may allow its Institutional Review Boards (IRBs) to serve as the IRB of record for institutions external to Yale as well as when the University may request a non-Yale IRB to serve as IRB of record for research in which the University is considered to be engaged as described in *IRB Policy 100, IRB Review of Research Protocols*.

Policy Statement

Whenever the University allows the Yale IRBs to serve as the IRB of record for institutions external to Yale or when the University approves the use of an external IRB to serve as the IRB of record for the review and oversight of research involving human subjects conducted by Yale University investigators and their staff, appropriate written agreements must be in place that outline the roles and responsibilities of the parties, including the obligation and oversight responsibilities for the review of research in order to ensure compliance with applicable laws, regulations, guidance, contractual obligations, and Yale University policy.

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, and/or local medical practices, whose expertise is needed for the effective conduct of a study. In addition, Yale recognizes that there are a number of institutions with which we have had long standing, mutually beneficial relationships whose own research programs would be facilitated by Yale serving as the IRB of record on behalf of these separate legal entities. This policy also addresses the research affiliates program which was developed in response to the IRB needs of these closely affiliated institutions.

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).

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.

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.

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 which does not have an IRB of its own and with whom Yale 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 affiliation whereby Yale will provide IRB oversight for research involving agents and/or representatives of the collaborating institution or Research Affiliate. If the number of staff who would be engaged in the research is limited, and the scope of the affiliation is for a single study, Yale may decide to approve the institutional staff as independent investigators under an independent investigator agreement in accordance with HRPP Policy 910, Independent Investigators Assisting in the Conduct of Research. If a more in depth involvement of the affiliate is envisioned, then the institution may request to become a Research Affiliate, by requesting an IRB Authorization Agreement with Yale and subsequently filing a Federal wide Assurance with OHRP designating Yale as the institution's IRB of Record.

The 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 covering all human research in which the affiliate institution is considered to be "engaged in research," irrespective of whether the study is conducted by a Yale Principal Investigator 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 independent investigator agreements with all employees or agents of the institution who will be investigators or study personnel for the research. (See *HRPP Policy 910, Collaborating and Unaffiliated Investigators Assisting in the Conduct of Research*).

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. IRB Authorization Agreements may be made for single or multiple projects and may 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 External (Commercial) IRBs

A Principal Investigator (PI) or designee may submit a study to an external IRB if prior approval is obtained from the Yale University Human Research Protection Program (HRPP) office. In addition, the Yale HRPP may submit a study to an external IRB even if a PI does not submit a request to use an external IRB. See, Procedure *920 PR.4, Use of External IRBs for Review and Oversight of Research Involving Human Subjects.* Yale University maintains agreements with external IRBs to provide review and oversite of research conducted by Yale University investigators and staff who are involved in the conduct, oversight, or management of research involving human subjects that is approved by the Yale HRPP to be sent to an external IRB.

920.5 National Cancer Institute's Central IRB (CIRB)

Investigators may request, and the HRPP may authorize, the acceptance of the CIRB approval for clinical trials submitted to the CIRB for review from cooperative oncology groups, as well as other protocols opened in the Cancer Trials Support Unit (CTSU).

The Yale HRPP 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 Yale IRB.

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 External IRBs for Review and Oversight of Research Involving Human Subjects

920.PR 5 Use of CIRB

920 FR 7 Request for an IAA

HRPP Policy 910 Independent Investigators Assisting in the Conduct of Research

Contacts

Subject	Contact	Phone
HRPP approval	Director, Human Research Protection Program	203-436-8303
Research Affiliation	IRB of Record Specialist	203-785-4688
IRB Authorization Agreements with Other IRBs	IRB of Record Specialist	203-785-4688
IAA process	IRB of Record Specialist	203-785-4688
IAA consultation to HRPP staff	Office of the General Counsel	203-432-4949
Institutional Official	Office of Research Administration	203-432-8630

Roles and Responsibilities

IRB of Record Specialist:
Responsible for research affiliation process. Determines when a request for an IAA may be sent for consideration to the Institutional Signatory Official.

Director, Human Research Protection
Responsible for research partnerships with institutions and other organizations external to Yale, including the approval of requests send studies to an external IRB.

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, the Office of General Counsel (OGC) determines appropriate contractual language for the IAA and determines when the request may be approved by Yale's Institutional Signatory Official.

Institutional Signatory Official:
Responsible for final approval and execution of IAAs and approving requests to use an external IRB for certain categories of studies.

Reference:

Office for Human Research Protections (OHRP) http://www.hhs.gov/ohrp/

Guidance on Engagement of Institutions in Human Subjects Research http://www.hhs.gov/ohrp/policy/engage08.html

Revision History:

Revised 1/3/2013, 4/3/2017