

Yale University IRBs
Collaborating Investigator Instructions
Version February 14, 2008

These instructions provide the materials needed to submit a Request to Serve as a Collaborating 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 collaborating investigator, or have approval from their own IRB. Note: If an institution routinely engages in research, the Collaborating Institutional Investigator Request does not apply. The institution should file for an FWA. (See [http://info.med.yale.edu/hic/irb/.](http://info.med.yale.edu/hic/irb/))

Overview and 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. Collaborators 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 institutional IRB unless provisions have been made for a Yale IRB to review the research.

The University acknowledges, however, that some of these 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 Collaborating Investigators by the University's Signatory Official or his or her designee prior to engaging in any Yale research project involving human subjects.

In accordance with Yale IRB policy and federal guidance, approval to participate as a Collaborating Investigator is required when an investigator or research team member is not affiliated with Yale University, is not covered under the FWA of another institution, and will assist in the conduct of Yale research under the direction and supervision of a Yale University Principal Investigator. Potential collaborating investigators may not engage in the conduct of Yale research until a Collaborating Investigator Request has been approved and signed by the University's Signatory Official or his or her designee, and the investigator. See: Yale University IRB Policy Regarding Collaborating Investigators Assisting in the Conduct of Research at Yale <http://info.med.yale.edu/hic/policy/index.html>.

Definitions:

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.

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.

Assured Institution: An institution with an FWA currently approved by 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 an investigator or member of an assured institution. 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, through which, when approved, Yale extends the applicability of its FWA 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 subjects research.

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.

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.

Required Materials:

The following materials are required for preparing a request for approval of a collaborating investigator to take part in a Yale research project. The materials must be used only by collaborating investigators who are not affiliated with any institution that regularly conducts research.

The request is available online at <http://info.med.yale.edu/hic/forms/index.html>, “Request for Permission to Serve as a Collaborating 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 provided to the Principal Investigator for the research study file.

These instructions include the following:

1. A checklist of materials requiring completion by the collaborating investigator.
2. A list of the documents and their internet locations that collaborating investigators must attest to having reviewed before submitting their request for approval.
3. A sample institutional support letter.
4. A sample statement from the Principal Investigator, describing the proposed Collaborating Investigator role in the research protocol.
5. Information describing how to access the human subjects protection and HIPAA training courses that must be completed by the collaborating investigator prior to submitting the request.

Questions concerning this process should be directed to Jean Larson, Education and Community Outreach Manager at the HIC, 203-785-5183.

1. Collaborating Investigator Checklist

For each Collaborating Investigator:

___ *Request to Serve as a Yale University Collaborating Investigator (Choose the appropriate type.)*

___ Individual 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)

___ Letter of Institutional Support (for Collaborating Institutional Investigators)

___ Statement from the Principal Investigator, describing the proposed Collaborating Investigator role in the research protocol.

___ Copy of Collaborating Investigator curriculum vitae

___ Copy of Collaborating Investigator current license, if applicable

___ Copy of verification of human subjects protection training

___ Copy of verification of HIPAA training, if applicable.

2. Accessing Required Review Materials

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

A. The Belmont Report

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

B. U.S. Dept of Health and Human Subjects (HHS) Regulations for the protection of human subjects at 45 CFR, part 46 and all subparts

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

C. The U.S. Food and Drug Administration (FDA) regulations for the protection of human subjects at 21 CFR part 50

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>

D. The Yale University Federalwide Assurance (FWA)

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

E. The specific terms of the Yale University FWA

<http://www.info.med.yale.edu/hic/assurances/index.html>

F. Relevant Yale University institutional and IRB policies and procedures for the protection of human subjects

<http://www.info.med.yale.edu/hic/policy/index.html>

<http://www.yale.edu/hsc/Investigator/guidebook.htm>

<http://www.info.med.yale.edu/hic/guidelines/index.html>

<http://www.info.med.yale.edu/hic/policy/index.html>

G. HIPAA at Yale, Researchers Guide to HIPAA

<http://www.info.med.yale.edu/hic/hipaa/index.html>

3. Sample letter of support/Collaborating 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 collaborating 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

4. Required Training

Collaborating Investigators taking part in Yale research projects are required to complete the human subjects training requirements as defined at:

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

HIPAA compliance for researchers is available at:

<http://info.med.yale.edu/hic/hipaa/guide/index.html>. Collaborating 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.

5. Sample Statement from Principal Investigator

Protocol Title:

Brief Summary of the Research Plan:

Proposed role for the Collaborating Investigator:

Plan for the Oversight of the Collaborating Investigator Activity:

As Principal Investigator of the above-referenced protocol, I request that _____ be approved to serve as Collaborating Investigator for this study. I will direct and supervise all of the collaborative research activities to be performed by the Collaborating Investigator.

Principal Investigator Name (please print)

Signature

Date:

6. Collaborating Investigator Request

The Request is available at <http://info.med.yale.edu/hic/forms/index.html>. The Collaborating 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 Collaborating 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 Collaborating Institutional Investigator