

**Request for Permission to Designate  
Yale University's Institutional Review Board(s) (IRB)  
As IRB of Record For Research Involving Human Subjects**

**Submission Instructions**

1. This application must be completed by the Institution seeking to designate one or more of Yale University's IRBs to review and oversee research conducted at that Institution by a Principal Investigator (PI,) who must be a full-time Yale University faculty member.
2. This application must be submitted with all supporting documentation to the IRB most likely to review the Institution's research (will be the same IRB identified in section 2.7).
3. This application and additional information for filing the application is available in electronic form on the [Yale Research Affiliate] website at [www.info.med.yale.edu/hic](http://www.info.med.yale.edu/hic)
4. Questions about this application may be directed to any of the Yale IRBs:
  - a. Yale University's School of Medicine IRB (Human Investigation Committee)
    - o <http://www.info.med.yale.edu/hic>.
    - o 203-785-4688
  - b. Yale University Faculty of Arts and Science IRB (Human Research Committee)
    - o <http://www.yale.edu/hsc>
    - o 203-436-3650
  - c. Yale University School of Nursing IRB is available by contacting the Office of Research Affairs (203-737-2420).

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**Section 1: Institutional Information**

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- 1.1 Name of Institution:  
Address:  
Telephone:  
Fax:  
Website: *(If available)*  
Institutional type: *(Select one)*  
For-profit  Not-for-profit  Government  Other  \_\_\_\_\_

State in which Institution is incorporated \_\_\_\_\_

1.2 Institutional description (*Please complete all of the following items.*)

Primary Purpose or Mission:

Number of Employees:

Number of Years in Business:

Nature of Business Activity/Work or Treatment:

1.3 Person to contact regarding this application:

Name:

Degree(s):

Title:

Phone:

Fax:

E-mail address:

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**Section 2: Description of Institutional Research**

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2.1 Please provide the following information for all of the Institution's research studies conducted during the previous five (5) years :

- Study Title:
- Principal Investigator:
- Date:
- Nature:
- Funding Source:

2.2 Is this application to provide IRB review for (check one) \_\_\_\_\_ a single research study or \_\_\_\_\_ multiple research studies?

2.3 Why is the Institution seeking Yale IRB review of its research?

2.4.1 Please provide the following for each individual study that the Institution intends to submit to a Yale IRB(if known):

- By study title, identify or describe:
  - Nature (include hypothesis) and scope of the study
  - Funding source or anticipated funding source
  - Prime recipient of the funding
  - Contractual relationships (grant sub-recipient status, subcontractor, or other) that exists or will exist (include third party entities and individuals as may be applicable)
  - Locations where research interventions or procedures will be conducted
  - Estimated duration of the study
  - Individual who initiated or intends to initiate the study (ies)

- Who is or will be primarily responsible for the design of the study (ies)
- Subject population involved
- Attach any proposed protocols and consent forms, if available.

Additionally, please provide:

- Estimated number of studies that the Institution intends to conduct in collaboration with Yale University.
- Approximate monthly or quarterly estimates of new protocols that the Institution expects to be submitted to the Yale IRB.

2.5 Please identify the type of research in which the Institution is engaged, or expects to become engaged in research (you may refer to the OHRP website at <http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fileasurt.htm> or contact a Yale IRB representative if you have questions about what constitutes research). Please check all that apply:

Institutional employees or agents are intervening or interacting directly with research subjects or prospective research subjects for research purposes.

Institutional employees or agents are obtaining or assessing individually identifiable information or biomaterials about or from subjects or prospective subjects for research purposes.

The Institution is the prime recipient of a DHHS award to conduct research. *(Check here even if none of the research will be conducted at the Institution or by any of its agents)*

Not known at this time.

Other: Please describe.

2.5 Using the chart below, indicate the name(s) and responsibilities of full time Yale faculty or staff and your Institution's employees and/or agents who will participate in research activities. Identify who will serve as the Yale University principal investigator with an asterisk. Identify Institutional employees by highlighting them in **bold**.

Please provide supplementary descriptions, as appropriate, if the table does not address all significant activity that will be conducted. (If using the chart to note the involvement of personnel for multiple studies, separate each research team and list separately under Protocol 1, Protocol 2, etc.)

Investigator and Key Study Personnel Roles and Responsibilities for Human Subject Research Studies

Name of Investigator or Research Team Member	Initiated Study Design	Collaborated in Study Design	Refers subjects to research team member	Obtains subject consent	Intervenes or interacts directly with subjects in conducting research probably need to add obtains individually identifiable information
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2.7 Identify the IRB most likely to review the Institution’s research (this is the IRB to which this application must be submitted).

\_\_\_\_\_ Yale University Faculty of Arts and Science IRB (Human Research Committee)

\_\_\_\_\_ Yale University School of Medicine IRB, (Human Investigation Committee I and Human Investigation Committee II)

\_\_\_\_\_ Yale University School of Nursing (Human Subjects Research Review Committee)

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**Section 3: Institutional Human Subject Protection Oversight**

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3.1 Name and contact information of the person listed as the Signatory Official on the Institution’s FWA application.

- Name:
- Degree(s):
- Title:
- Phone:
- Fax:
- E-mail address:

3.2 Name and contact information of the person listed as the Human Protections Administrator on the Institution's proposed FWA application.

Name:  
Degree(s):  
Title:  
Phone:  
Fax:  
E-mail address:

3.3 Have the Institutional Signatory Official and Human Subjects Administrator reviewed the following regulatory and guidance documents?

FWA: Yes  No

FWA Terms and Conditions: Yes  No

Applicable Yale IRB Investigator's Book of Guidance: Yes  No

Yale University IRB Operational Manual: Yes  No

HIPAA at Yale, Researcher's Guide to HIPAA (only if your Institution is considered a covered entity): Yes  No  N/A

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**Section 4: HIPAA Privacy Rule Information**

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4.1 Is the Institution considered a covered entity under the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)? (*A covered entity is defined as a health plan, or health care clearinghouse, or a healthcare provider who transmits health information via electronic transactions.*)

Yes  No

*If the Institution is not a covered entity, please skip to Section 5*

4.2 Name and contact information for the Institution's Privacy Officer:

Name:  
Degree(s):  
Title:  
Phone:  
Fax:  
E-mail address:

4.3 Does your Institution have a Privacy Board?

Yes  No

4.3.1. Will the Institution's Privacy Board review Research Authorization Forms?

Yes  No

4.3.2 Will the Institution's Privacy Board review Requests for Waiver of Authorization?

Yes  No

4.3.3 If the answer is "No" to either or both of the questions above, is the Institution interested in having the Yale IRB(s) serve as the Institution's Privacy Board for research specified in this request form?

Yes  No

(For questions about the HIPAA Privacy Rule or the functions of a Privacy Board or Officer, you may refer to the [Yale HIPAA website] at <http://www.info.med.yale.edu/hic/hipaa/guide/index.html> or contact a Yale IRB representative

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**Section 5: Training and Certifications**

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5.1 All persons engaged in research with human subjects must complete human subjects protection training. Describe the human subject protection training that the Institution's employees/agents will or are already required to undertake. Please attach a copy of any training curriculum/materials already in use.

*If the Institution is not a covered entity, please check N/A for 5.2, and proceed to question 5.3.*

5.2 Does the Institution have provisions for educating and training its employees on the HIPAA Privacy Rule as it relates to research?  
Yes  No  N/A  If yes, please provide a copy of the training curriculum.

5.3 Please provide certificates of completion for the Institutional Signatory Official and the Human Subjects Administrator for the following training. This form is not considered complete until these documents are received.

- Human subjects protection training
- HIPAA Privacy Rule as it pertains to research, if applicable
- OHRP FWA training (modules # 1, 2, and 3)

5.4 Is the Institution interested in obtaining assistance from Yale University in any human subject protection training?

- Yes
- No
- Other requests:

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## **6. Institutional Human Subject Protection Policies**

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Please attach a complete copy of all policies related to the Institution's human subject protection program and the conduct of human subject research at the Institution.

All entities that rely on a Yale IRB as the IRB of record must have and adhere to appropriate policies for the protection of human research subjects. Yale University will not permit an Institution to rely on one of its IRBs unless appropriate policies are in place at the Institution. **These policies must be submitted with this application and will be reviewed by Yale before this application is approved and the Institution's FWA is finalized.**

At a minimum, such policies must include statements regarding the following:

- a. Scope and Authority of the Human Subject Protection Program
- b. Investigator/Staff Training and Education
- c. Compliance with Yale IRB Policies
- d. Reporting of Adverse Events
- e. Reporting Noncompliance
- f. Investigator Access to Policies
- g. Document Retention
- h. Investigator Conflict of Interest
- i. Research Oversight and Auditing

A policy template is available to assist applicants in developing all necessary policies. The template can be found on the [Yale Research Affiliate] website at .... Individual Institutions should adopt a policy statement that meets these standards and may adopt additional policies or procedures tailored to that Institution. The template may be adopted in full or modified by applicant Institutions as appropriate.

**Signature Page**

Principal Investigator (Acknowledgement of this application)

\_\_\_\_\_  
Print Name and Title

\_\_\_\_\_  
Date

Institutional Signatory Official

\_\_\_\_\_  
Print Name and Title

\_\_\_\_\_  
Date