

## **Yale University Human Investigation Committee Review of Research Proposals from Individuals Who Require Special Approval to Serve as a Principal Investigator**

The Yale University Faculty Handbook names the specific members of the Yale Community who are eligible, by virtue of their faculty appointment, to serve as a principal investigator (PI) on a research proposal. Only these named faculty are eligible to serve as PI on research protocols involving human subjects and to submit such protocols to the Human Investigation Committee (HIC) for review. All other members of the Yale community who wish to serve as PI require special approval. Approval is protocol-specific, and must be obtained for each protocol submitted to the HIC.

The Handbook states that *“In order to ensure that research is conducted by those who have the requisite training and skill, as well as the appropriate relationship to Yale, the University will normally sponsor proposals only when the principal investigator or project director is employed full-time by the University and holds an appointment as assistant professor, associate professor, professor, research scientist/scholar, or senior research scientist/scholar. Exceptions require the approval of the Provost, or where appropriate, the dean of the relevant professional school. (In some cases, the Provost or dean may delegate approval to the department chair.)”*

Yale community members who require special approval to serve as PI include all part time appointees, faculty members who have left the university and wish to continue the conduct of research at Yale, voluntary faculty who wish to conduct research either at Yale or consistent with their duties at Yale, and all other members of the Yale community, including associate research scientists, lecturers, instructors, and staff members.

**The Request form does not apply to students, postdoctoral appointees, fellows and other trainees. They may serve as a PI provided that the protocol design and conduct is appropriate for the trainee’s level of knowledge, training and skill and that they perform the research under the oversight of a designated faculty sponsor. The HIC Protocol Application Form, “Application to Involve Human Subjects in Research”, includes instructions on serving as PI on a project with a faculty sponsor.**

Associate Research Scientists may either conduct research under the oversight of a faculty sponsor, as described above, or may request special approval to serve as PI.

To obtain special approval to serve as a PI, a copy of the **Request for Permission to Serve as a Principal Investigator on a Research Protocol Involving Human Subjects** and the candidate’s curriculum vitae or biosketch must be submitted with the research protocol to the applicant’s Department Chair for review and signature. Following approval of the Department Chair, the materials should be forwarded for approval to the HIC with the protocol. The HIC will arrange to have the form reviewed by the Dean’s designee; the HIC will not review a protocol until this approval has been obtained.

For questions regarding this procedure contact Jean Larson, 785-5183.



**Yale University School of Medicine  
Human Investigation Committee**

**Request for Permission to Serve as Principal Investigator on a Research Protocol  
Involving Human Subjects**

*A Yale School of Medicine researcher who wishes to serve as a Principal Investigator (PI) on a research protocol involving human subjects but who does not meet the eligibility criteria to serve as a PI as set forth in the Yale University Faculty Handbook ([www.yale.edu/provost/handbook/yfhtoc.html](http://www.yale.edu/provost/handbook/yfhtoc.html)) is required to obtain permission from the Department Chair and the Dean's Office designée.*

**Title of Research Protocol:** \_\_\_\_\_  
**HIC #:** \_\_\_\_\_  
**Proposed PI:** \_\_\_\_\_  
**Email Address:** \_\_\_\_\_  
**Yale Affiliation/Title/Position:** \_\_\_\_\_  
 \_\_\_\_\_  
**Full time:** \_\_\_ **Part time** \_\_\_ **Voluntary** \_\_\_ **Former Faculty Wishing to Retain Research at Yale** \_\_\_  
**Department:** \_\_\_\_\_  
 \_\_\_\_\_

***I. Applicant Attestation***

I have completed Human Subjects Protection training and other applicable education training required by Yale University prior to initiating research covered under this protocol.

I understand and accept the responsibility to conduct this research protocol in accordance with applicable federal, state and local laws and regulations and University policies related to human subjects research.

I acknowledge and agree to cooperate with and assist the HIC and other University oversight committees charged with the protection of human subjects.

I will report immediately to the HIC any unanticipated problems involving risks to subjects or others in research covered by this request.

I will abide by all determinations of the Yale University Human Investigation Committee (HIC) and will accept the final authority and decisions of the HIC, including but not limited to, any directive to suspend or terminate the conduct of the designated research protocol.

\_\_\_\_\_  
Signature of applicant

\_\_\_\_\_  
Date

## ***II. Protocol Information***

1. Briefly describe the research plan, including study purpose and interventions with human subjects.
2. Briefly describe past experience involving research with human subjects (Include number of years conducting research and type of research performed.)
3. Will the research protocol be conducted as any part of the applicant's employment responsibilities at another institution? (e.g., does the potential PI have a paid appointment at another institution which is also engaged or participating in the research project? See [www.hhs.gov/ohrp/humansubjects/assurance/engage.htm](http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm)) Yes \_\_\_ No \_\_\_ N/A \_\_\_  
Describe:
4. For part time faculty or voluntary faculty: Will the research protocol be conducted as any part of the applicant's Yale responsibilities? (e.g., is the protocol purpose consistent with Yale's expectations of the applicant's role?) Yes \_\_\_ No \_\_\_ Describe:
5. If the proposal is from a part time faculty member, have appropriate arrangements been made to oversee the project when the PI is not present at Yale? Yes \_\_\_ No \_\_\_ N/A \_\_\_

Name of responsible Yale full time faculty member:

\_\_\_\_\_

Print name

6. If the proposal is from a voluntary faculty member, have appropriate arrangements been made to ensure that the project will be managed by a full-time Yale faculty member in accord with Yale policies ?

Yes \_\_\_ No \_\_\_ N/A \_\_\_

Name of person responsible for oversight:

\_\_\_\_\_  
Print name

**NOTE: If the proposal is from a former faculty member Yale Grants and Contracts must be notified of the change.**

***III. Attestation of Qualification***

1. The applicant has the training, skills, and knowledge necessary to serve as PI on this project, ensuring that the proposed research will be conducted according to ethical principals and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects. Yes \_\_\_ No \_\_\_
2. The applicant understands and assumes full responsibility for the conduct of this research, including but not limited to, the protection of subjects and ensuring sufficient resources are available to conduct this research initiative. Yes \_\_\_ No \_\_\_
3. This Request for Permission to Serve as PI on a Research Protocol Involving Human Subjects and submission of the protocol has the approval and support of the chair. Yes \_\_\_ No \_\_\_

\_\_\_\_\_  
Name of Chair (Print)

\_\_\_\_\_  
Signature of Chair

\_\_\_\_\_  
Date

\_\_\_\_\_  
Dean's Office Reviewer (Print Name)

\_\_\_\_\_  
Approved for the Dean's Office (Signature)

\_\_\_\_\_  
Date

