

Version: July 11, 2006

DEPARTMENT:

Yale University Human Investigation Committee

POLICY NUMBER:

SECTION:

Policy Regarding Who May Serve as Principal Investigator on a Research Protocol Involving Human Subjects

REVIEW RESPONSIBILITY:

HIC Leadership and YSM Dean's Office

Original Creation Date:

July 11, 2006

Yale University HIC Policy Regarding Who May Serve as Principal Investigator on a Research Protocol Involving Human Subjects

I. Purpose: Yale University has an obligation to those participating as research subjects to ensure that research scientists are qualified to conduct the research ethically and in accordance with federal regulations and guidance and University policy. This policy addresses who may serve as a Principal Investigator (PI) on a research protocol submitted to the HIC for review. The policy also outlines who may require special approval to serve as PI.

II. Definitions:

Principal Investigator (PI): The individual designated to direct a research project. The Principal Investigator is responsible and accountable to the project's sponsor and to Yale University for the proper conduct of the research, and must have the technical competence and substantive scientific and administrative capabilities necessary to carry out the project.

Yale University Faculty Handbook: A compendium of Yale University policies and practices as they apply to faculties of the University. The handbook forms part of the essential employment understandings between members of the faculty and the University. (See www.yale.edu/provost/handbook)

Special Approval: An approval given to an individual who does not meet criteria as set forth in the Faculty Handbook to serve as Principal Investigator on a specified protocol

Student/Trainee Principal Investigator: A student, Post-doctoral appointee, fellow or other trainee who is performing research appropriate to his/her level of knowledge, training and skill under the oversight of a designated faculty sponsor.

III. Background:

The Yale University Faculty Handbook specifies who may serve as Principal Investigator (PI) on a research protocol. The Handbook states, *"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 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.)"*

In some instances, the University may permit an individual who does not meet the Faculty Handbook criteria to serve as Principal Investigator. Special approval is required for exemption from the Faculty Handbook policy, in order to ensure that the PI requesting special approval has the requisite education, skills and experience to conduct human subjects research.

IV. Policy:

Any individual who wishes to serve as Principal Investigator on a research study involving human subjects and whose faculty status does not meet the standard set forth in the Yale University Faculty Handbook must obtain permission, through the procedure outlined below, from the Yale School of Medicine Dean's Office or designee in order to submit a protocol to the HIC. A Request must be submitted for each protocol for which the individual wishes to act as Principal Investigator. This approval can only be given by the Dean's Office or designee, and requires the support of the Department Chair. Approval is protocol-specific; a separate request must be made for each protocol for which the individual wishes to serve as Principal Investigator.

Students, residents, fellows, post-doctoral appointees, and other trainees who wish to serve as Principal Investigator on research studies involving human subjects must have a Yale faculty member accept sponsorship of the protocol, and sign off on the HIC application. The faculty sponsor must meet the criteria to serve as PI set forth in the Faculty Handbook.

Associate Research Scientists may also use the faculty sponsor method when requesting permission to serve as PI, or may opt to obtain approval from the Yale Dean's Office or designee as outlined below.

All other individuals must use the process as outlined below.

V. Procedure:

A. The proposed PI must complete Section I of the HIC "Request for Permission to Serve as Principal Investigator on a Research Protocol Involving Human Subjects" (Request): (<http://info.med.yale.edu/hic/forms/index.html>), with signature and date.

B. The Department Chair must complete Sections II and III of the Request with signature and date.

C. A copy of the completed Request, a copy of the proposed PI's curriculum vitae or biosketch and the protocol are submitted to the HIC.

D. The HIC notifies the Dean's Office that the request has been received. The Dean or an appointed designee reviews the materials submitted to the HIC. If the Dean's Office approves the Request, the protocol will be reviewed by the HIC. The HIC will not review a protocol until this approval has been obtained. HIC staff will notify the investigator if the Request is not approved.