



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

Request for Approval of Amendment to Change Principal Investigator

Instructions: This form should be used only to submit to the HIC requests to *change* a **Principal Investigator (PI)** on active protocols. This form should accompany the following study documents—protocol application, consent form, and HIPAA RAF—and any other documents which must be amended to reflect the change of the Principal Investigator. An investigator may not act as the PI of a study without IRB approval.
Note: All active subjects participating in research activities must be notified promptly that the PI has changed. Notification must be documented in research records.

HIC Protocol Number: _____ **Date:** _____

Title of Research Project: _____

Current PI: _____ **New PI*:** _____

New PI Campus Address:	
Email:	Phone Number:
Correspondent Name:	E-mail:

- **HSPT Training** – Has the new Principal Investigator completed the required Human Subjects Protection Training? YES NO (If not completed through Yale University, please submit copies of any certificate of completion.)
- **HIPAA Training** – Has the new Principal Investigator completed the required HIPAA Training? YES NO (If not completed through Yale University, please submit copies of any certificate of completion.)
- **Conflict of Interest** – Does the new Principal Investigator have any conflict of interest related to this specific protocol, including either monetary or non-financial conflicts? YES NO (The Yale HIC policy is located at http://info.med.yale.edu/hic/policy/IRB_COI_policy.pdf.) If yes, attach protocol-related COI disclosure form.

**Individuals must meet the criteria set out in the Yale University Faculty Handbook (located at <http://www.yale.edu/provost/handbook/yfhtoc.html>) in order to serve as principal investigators on Yale research studies. Researchers not meeting these criteria who wish to serve as PI require special approval. Approval is protocol-specific, and must be obtained for each protocol submitted to the HIC. To obtain the form to request special approval, visit <http://info.med.yale.edu/hic/forms/index.html>.*

Current Principal Investigator Attestation:

I will no longer serve as PI on the study noted above.
 (Insert name of new PI) _____ has the appropriate knowledge and credentials to serve as PI on this study and I have provided him/her with all of the necessary information and critical documents for the study.

Signature of Current Principal Investigator

New Principal Investigator Assurance

As the Principal Investigator of this research project, I certify the following:

- I assume full responsibility for the protection of human subjects and the proper conduct of the research.
- Subject safety will be of paramount concern, and every effort will be made to protect subjects' rights and welfare.
- The research will be performed according to ethical principles and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects.
- All members of the research team will be kept apprised of research goals.
- I will obtain approval for any subsequent changes or modifications to this study prior to their initiation, as well as approval for continuing review prior to the date that approval for the study expires.
- I will report to the HIC any serious injuries and/or other unanticipated problems involving risk to participants.
- I am in compliance with the requirements set forth in the Yale University Faculty Handbook and qualify to serve as the Principal Investigator of this project or have acquired the appropriate approval from the Dean's Office or Office of the Provost, or Yale-New Haven Hospital General Counsel.
- I will identify a successor if I stop being Principal Investigator and facilitate a smooth transfer of investigator responsibilities.
- I have reviewed the study and the documents associated with the study, and accept responsibility to serve as the PI on this study.

Signature of New Principal Investigator

Acknowledged by Department Chairperson Signature

FOR HIC USE ONLY

Amendment Approval date

Human Investigation Committee (staff signature)