



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

Request for Approval of Amendment to Add or Remove Co-Investigator(s) and Study Personnel

Instructions: This form should be used only to submit to the HIC requests to *add or remove* co-investigators or other study personnel* from active protocols. Investigators must submit updated study documents that currently need to reflect the addition/removal of co-investigators or study personnel (e.g., consent form, HIPAA RAF, or advertisement, *if personnel are individually named*). If no changes to these documents are necessary at this time, then the updated HIC application and any other study documents incorporating requested changes should be submitted as usual to the HIC at time of reapproval.

* *A separate form is available and must be used for a change in principal investigator.*

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

Title of Research Project: _____

Name of Principal Investigator: _____

PI Signature: _____

PI Campus Address: _____

Email: _____

Phone Number: _____

Correspondent Name: _____

E-mail: _____

Please complete a new line for each addition or removal of study personnel (to extend the grid, press TAB from the last cell in the last row of the grid, and a new row will automatically be created):

- **Name** – Enter the full name **and** degree of the person to be added to or removed from the study.
- **Add or Remove** – Enter ‘Add’ or ‘Remove’ as appropriate for each person being added or removed from the protocol.
- **Status of Personnel** – Please identify the study status of the added or removed personnel.
- **HSPT Training** – Has this person completed required Human Subjects Protection Training? If not completed through Yale University, please submit copies of any certificate of completion.
- **HIPAA Training** – Has this person completed the required HIPAA Training? If not completed through Yale University, please submit copies of any certificate of completion.
- **Conflict of Interest** – Does this person have any conflict of interest related to this specific protocol, including either monetary or non-financial conflicts? The Yale HIC policy is located at http://info.med.yale.edu/hic/policy/IRB_COI_policy.pdf. If yes, attach protocol related COI form.
- **Yale Affiliation** – Please identify whether this person is a faculty member, an employee, trainee or student of Yale University. If Yale-affiliated, please identify their position with Yale. If non-Yale-affiliated, please identify the organization with which they are affiliated, the type of organization it is, whether that organization has an FWA (to determine if an organization has a valid FWA, please refer to the following website: <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>), and whether that organization is engaged in research on this protocol. Also, please state the nature of the person’s association with Yale University, if any.

Name	Add or Remove	Co-Investigator, Study Personnel, or Correspondent?	HSPT & HIPAA Training? Y/N	Protocol Related COI? Y/N	Yale Affiliation	Signature

For HIC Use Only

_____ Amendment Approved date

_____ Human Investigation Committee