

Follow-on Submissions - Changing Study Team Members

To request changes to the currently approved study team in ESTR:

- Select 'Create Modification' in the main study workspace.
- Select 'modification' to 'study team members'.
 - You will be prompted to provide information about the study.
 - Then the Study Team Members page of the SmartForm will open for edits.
- Select 'continue' to save and page through the SmartForm

REMEMBER

- ✓ Save the changes on the SmartForm
- ✓ Contact the PI to 'submit' the modification request when edits are completed

Save | Exit | H

Study Team Members

List all Harvard study team members on this page that have either:

- 1) Contact with human subjects; or
- 2) Access to data that is identifiable (including data that is indirectly identifiable using a coding system or key)

- Do not list the PI or Faculty Sponsor on this page.
- Each of the individuals named as study team members must complete human subjects training (refer to your IRB website to learn about training requirements).
- Include non-Harvard collaborators who meet these criteria only in the absence of their local IRB review.

1. ADD PEOPLE WITH AN HUID

1. Select 'add' to add a person.
2. Complete the pop-up form.
3. Select 'OK'

Note:
Only individuals with an HUID will be available in the search box.

1. List study team members with an HUID:

Name	Role	Financial Interest	Involved in Consent	E-mail
There are no items to display				

2. List study team members without an HUID (by attaching the Non-Harvard Study Personnel Form and/or attach other relevant documents) Use Add to upload a new document, Update to upload a revised version of a listed document, and Delete to remove a document.

Document	Category	Date Modified
There are no items to display		

Suggested attachments:

- Financial Interest Disclosure Form
- Non-Harvard Study Personnel Form
- Training Information
- Individual Investigator Agreement (IIA) For non-Harvard Investigators who are not covered under a local IRB. For more information about the form, please see your IRB website.

2. ATTACH OTHER REQUIRED ITEMS

1. Attach a personnel roster listing only team members without an HUID
2. Attach updated human Subjects training (if needed)
3. Attach positive disclosure forms.

