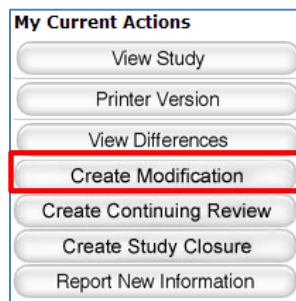


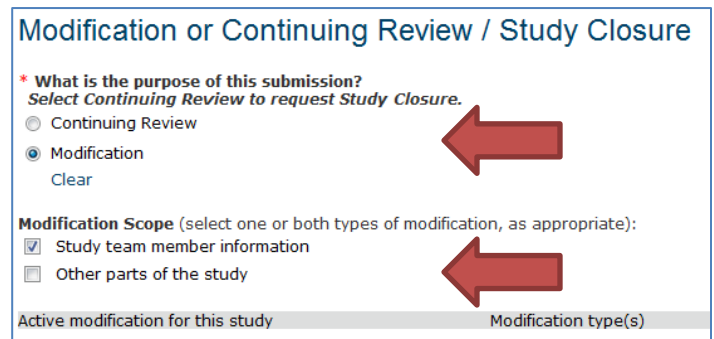
Change Study Staff

Changing Study Staff listed on the SmartForm requires a modification that must be reviewed and approved by the IRB before (1) the new study team members may work on the study and (2) the new study team member(s) can access the study in ESTR. To change study team members:

1. Log in to irb.harvard.edu
2. Click on the name of the approved study you want to change from a tab on your personal page
3. In the study workspace, click the “Create Modification” button



4. On the first page of the SmartForm:
 - Select “Modification”
 - Select “Study Team Member Information”
 - **Please Note:**
 - Under Modification Scope, one or both check boxes may be selected if they are visible.
 - The system will allow one of each type of modification to be in review at one time. A personnel change and a modification to other parts of the study may be open at a time.



Modification or Continuing Review / Study Closure

* What is the purpose of this submission?
Select Continuing Review to request Study Closure.

Continuing Review

Modification

[Clear](#)

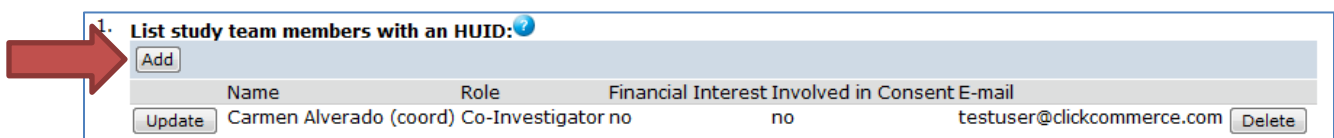
Modification Scope (select one or both types of modification, as appropriate):

Study team member information

Other parts of the study

Active modification for this study: _____ Modification type(s): _____

5. Select “Continue” to save and page through the pages of the SmartForm required to complete this submission. Fill in all the appropriate spaces.
6. When you get to the Study Team Members page of the SmartForm Study, add/remove study team members as appropriate.
 - Complete Item 1 on the Study Team Members Page: Click ‘Add’ to include each study team member that meet the criteria listed on the SmartForm. These team members will have access to the study workspace once the submission is approved.



1. List study team members with an HUID:

[Add](#)

Name	Role	Financial Interest Involved in Consent	E-mail
Update Carmen Alverado (coord)	Co-Investigator	no	testuser@clickcommerce.com Delete



- Begin typing his/her name in the space provided and select the correct name from the options (use search functionality by including “%” symbol and a part of the name, or use the “select” button to search for a name). If the person is not listed, s/he will need to obtain an HUID.

Add Study Team Member

*Study team members listed here must have an HUID.
For instructions to obtain an HUID for individuals who must be listed here, please visit your IRB website.*

1. * **Study team member:** ?

rebecca sim% Select...

Last	First	Middle Name	Email	Organization
Simms (pi)	Rebecca		testuser@clickcommerce.com	Gastroenterology

Co-Investigator
 Study Coordinator
 Project Manager
 Other Study Team Member
Clear

3. * **Is the team member involved in the consent process?**

Yes No Clear

4. * **Does the team member have a financial interest related to this research?** ?

Yes No Clear

- Complete Item 2 on the Study Team Members Page: ONLY if staff meet the criteria listed on the SmartForm and do not have or do not want to obtain an HUID, attach a Study Personnel Form listing only those individuals.

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.

Add

Document	Category	Date Modified

- When all the information has been added, select “continue” and you will be directed back to the submission workspace.
- The PI or Faculty Sponsor (if there is one) must complete the “**submit**” activity to send the submission on for IRB review (only the PI or Faculty Sponsor will see the option to complete this activity).

Important! In order to send Modification for review, the study PI will need to click the “**Submit**” activity button.

