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:
   o Select “Modification”
   o Select “Study Team Member Information”
   o **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 other parts of the study may be open at a time.

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.
   o 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.
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.

7. 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.

8. When all the information has been added, select “continue” and you will be directed back to the submission workspace.

9. 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.