Adding Study Team Members and PI Proxies on a Migrated Study in Hutch IRB

Explanation

When an existing study is migrating into Hutch IRB, only the names of the PI and Primary Contact are merged with the data. This means those are the only two individuals from the study team who can access the study in Hutch IRB (once they have completed their required System Access training).

In addition, only the PI can **submit** on the study at launch. If the PI wishes for a study team member to submit on their behalf, the PI must normally designate a PI Proxy in the system. However, at launch IRO staff may run this activity for the PI if requested, if the PI provides a signed memo designating specific study team members to submit on their behalf. (If the PI does not wish to provide a memo, the PI will have to not only submit the Modification in Step 2 below, but will also then need to run the Assign PI Proxy activity *after* the Modification is approved.)

A PI Proxy must be assigned on a study-by-study basis. Once a PI Proxy is assigned on a particular study, that person is authorized to submit on that study for the life of the study, unless later removed as a PI Proxy. The PI may designate more than one proxy.

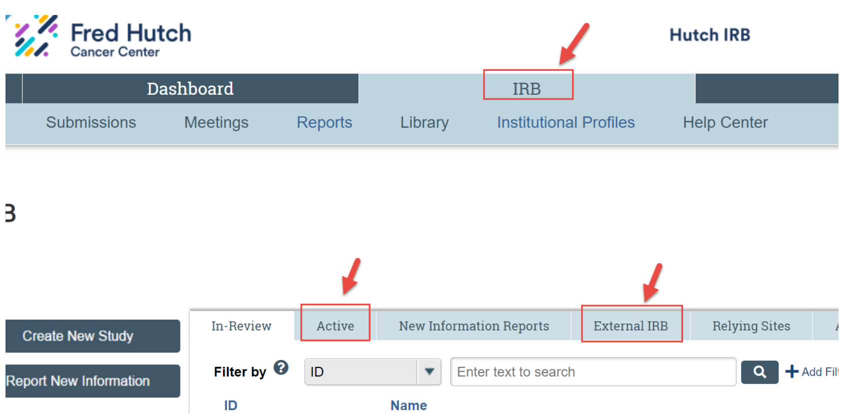
Instructions

For a migrated study, please follow the below steps to ensure study team members can access and submit on the study after launch.

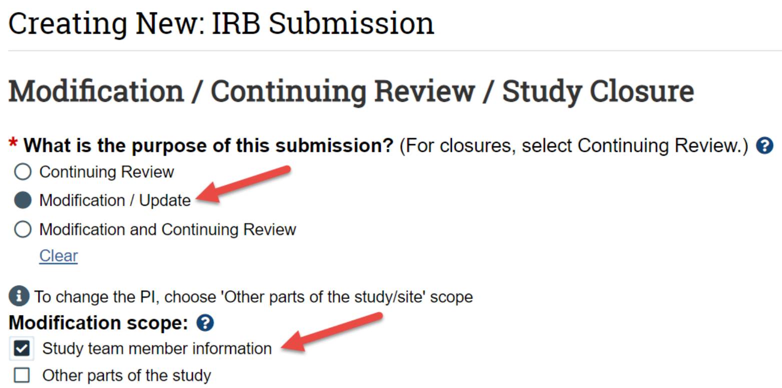
You may choose to use this document as a checklist.

☐ Step 1: The Primary Contact creates a Modification.

- ☐ In Hutch IRB, find the migrated study on either the “Active” or “External IRB” tab. Click the Name of the study to open the study workspace.



☐ Click the big blue **Create Modification/CR** button. Select “Modification / Update” and then select “Study team member information.” Click Continue.



TIP: For a quick tutorial on creating a Modification, view this Online Video.

☐ In Question 2, Summarize the Modifications, write: “Study team member updates.” (No other changes can be made at the same time.)

☐ In Question 3, you do **not** need to attach a Mod Supplement for this type of update.

For migrated studies only: If you have a memo signed by the PI that designates specific study team members to submit on the PI’s behalf, attach that here.

Click Continue.

☐ The Local Study Team Members SmartForm page appears for you to add any individuals who need to be able to view, edit, or be assigned as a PI Proxy to submit on the study. When done, click Finish.

NOTE: Only Cancer Consortium employees can obtain access to Hutch IRB, so the local study team here must work with the external pSite to make submissions.

☐ Back on the Mod workspace, copy the URL of the submission from your browser window. Email this to the PI so they can login and click the **Submit** activity.

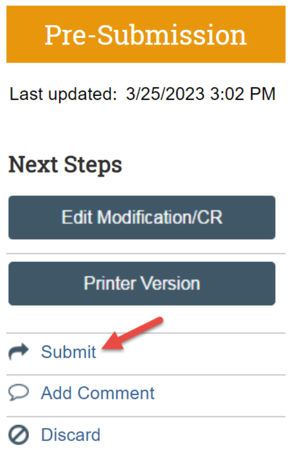
☐ Step 2: The PI submits the modification.

☐ Click the link in the email from the study team member to open the submission workspace. If you are not logged in to Hutch IRB, do so now using your Fred Hutch or UW credentials.

☐ Click the big blue **Edit Modification / CR** button to review what the study team has prepared.

☐ If acceptable, click **Exit** to return to the submission workspace.

☐ On the left-hand side, click **Submit**.



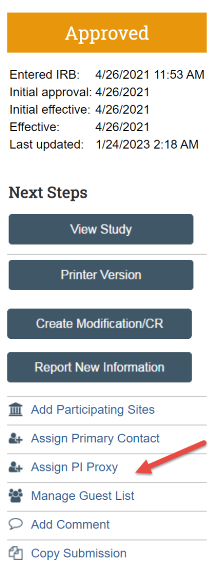
You now wait for IRO staff to approve the administrative modification and to run the PI Proxy activity on the PI's behalf (if a PI memo was provided).

☐ Step 3: The PI assigns the PI Proxy (only if no PI memo was provided).

☐ After the administrative modification to add study team members is approved by IRO, the study team provides the URL of the study to the PI.

☐ The PI clicks the link in the email from the study team member to open the study workspace. If not logged in to Hutch IRB, do so now using your Fred Hutch or UW credentials.

☐ Click the Assign PI Proxy activity.



☐ Click the three dots to Select study team members. The slide-in that appears shows all study team members who are available for selection. Select one or more individuals to designate them as PI Proxy. Click OK twice. The PI Proxies have now been added.

Questions? Contact IRO@fredhutch.org for assistance with this process.