IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

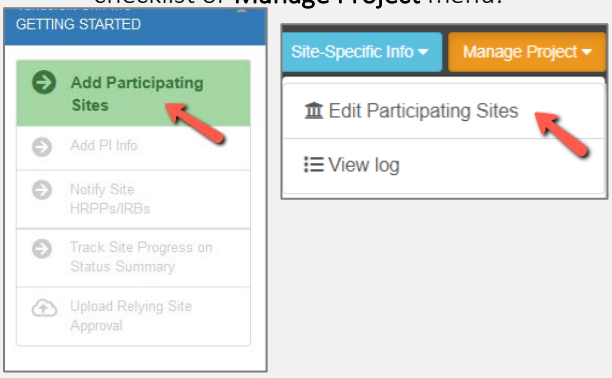
HOW TO ADD PARTICIPATING SITES TO A STUDY

The IREx Study Managers and Reviewing IRB Liaisons are responsible for ensuring participating sites have access to, and are notified about, studies in IREx. This may also include removing sites that are no longer participating in a study.

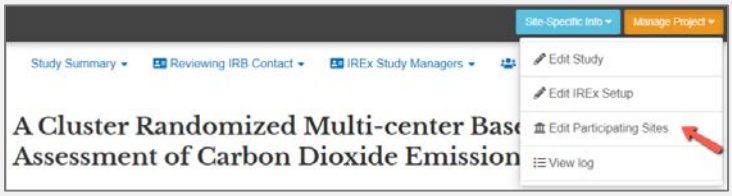
WHERE DO I ADD OR REMOVE A SITE FROM A STUDY?

Depending on your role, use the screenshots below to identify how to make changes to sites listed on your study.

Study Managers use their **GETTING STARTED** checklist or **Manage Project** menu:

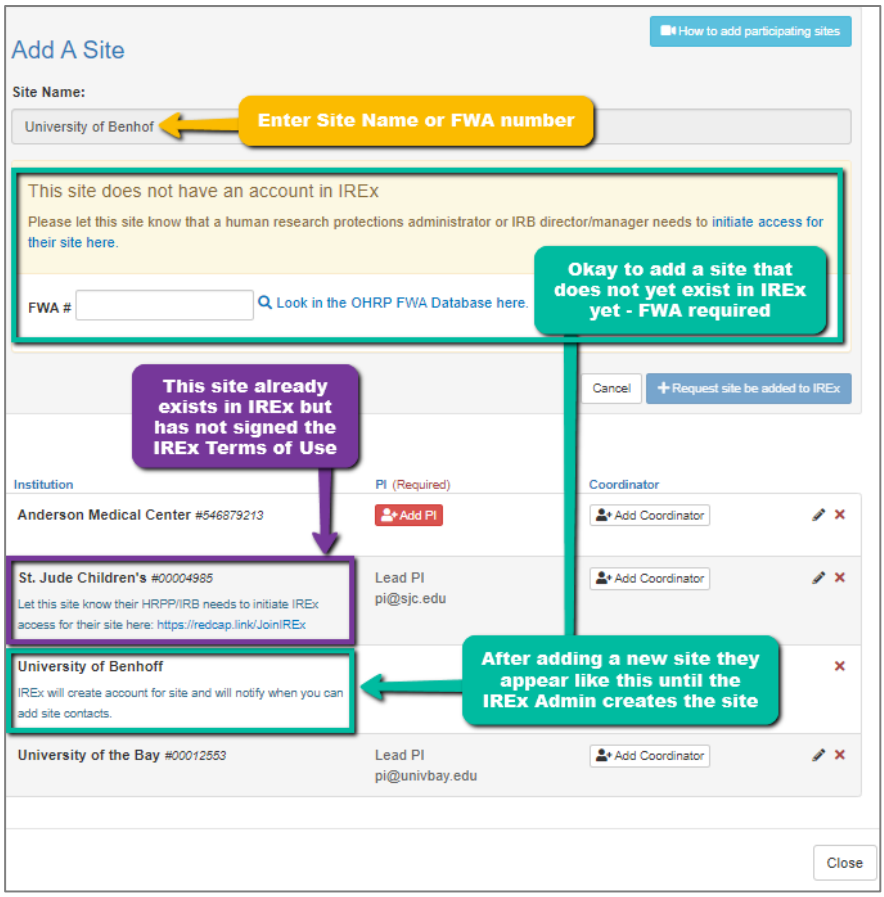


Reviewing IRBs use the **Manage Project** menu:



HOW DO I ADD A NEW SITE(S)?

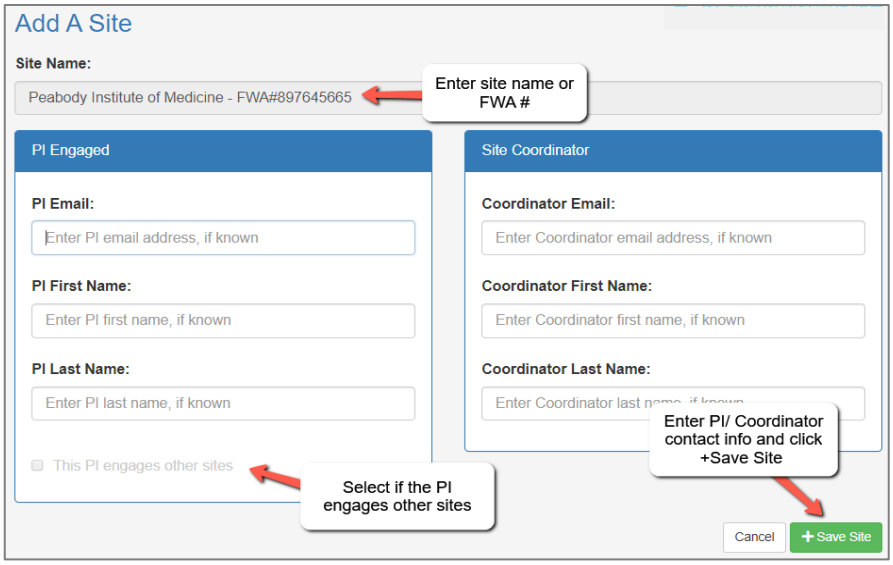
1. First, verify the site's name by referencing the OHRP FWA website, contacting the site's HRPP, or asking the local PI/study team to contact their HRPP and confirm.
2. Access the Participating Sites dialog and indicate whether you will **Add sites by name or FWA #** (recommended) or **Select consortium of sites**, if applicable (see next section).



3. Search by the site's FWA or full name (avoid abbreviations, e.g., "VU"). As you type, the sites that match the name/FWA you have entered will appear. **Select the site from the drop-down menu.**

Tip: The FWA-holding site appears first, followed by any components, if provided by the HRPP.

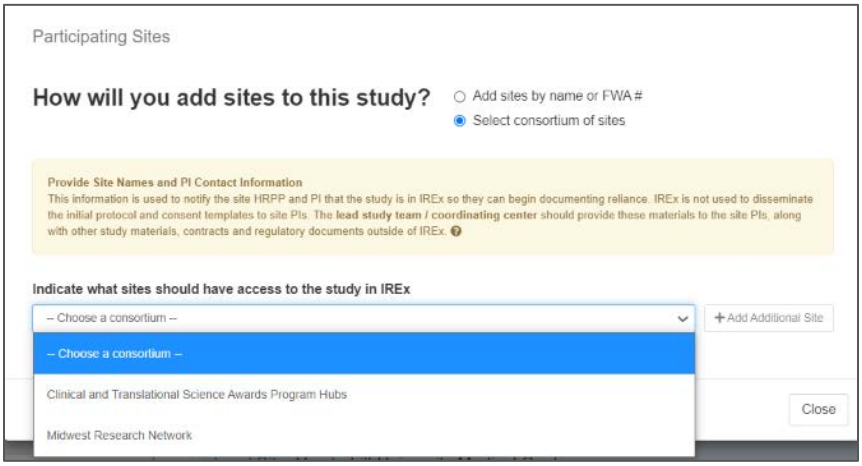
Sites that do not appear in the search can also be added by typing their name and FWA number. The IREx Admin will create the site and notify you when you can add contacts. Let the site know their HRPP/IRB needs to initiate IREx access for their site using this LINK.



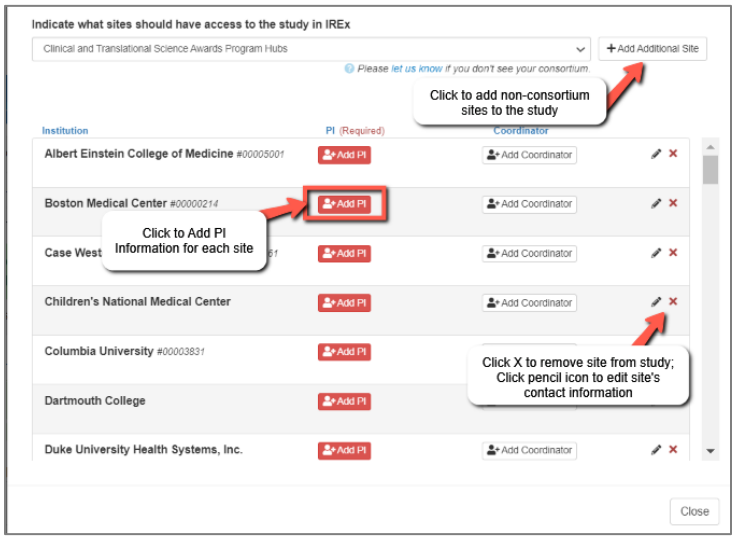
4. Enter the PI and Site Coordinator contact information, if known at the time. If not, save the site and return later to add this information.
5. If the PI/study team engages another site, select **This PI engages other sites** and add the other site.
6. Click **+ Save Site** to list the site(s).
   Tip: This does not provide the PI/ coordinator access, but ensures they are included on the email to their HRPP when the site is notified about the study. Study contacts get access after the site HRPP registers for the study.

HOW DO I ADD A CONSORTIUM OF SITES?

1. First, complete this survey to have a consortium of sites entered in IREx. Our team will let you know when the consortium can be added to the study.
2. Follow the steps above to access the Participating Sites dialog and choose **Select consortium of sites**.
3. Select a consortium and the consortium's sites will appear in the dialog. If you do not see your desired consortium, contact the IREx Support Team.



4. Remove any consortium sites that will *not* be participating in the study.
5. Add additional sites outside the consortium that will be participating in the study.
6. Add each site's PI (required) and coordinator.
7. When complete, click **Close** to exit.

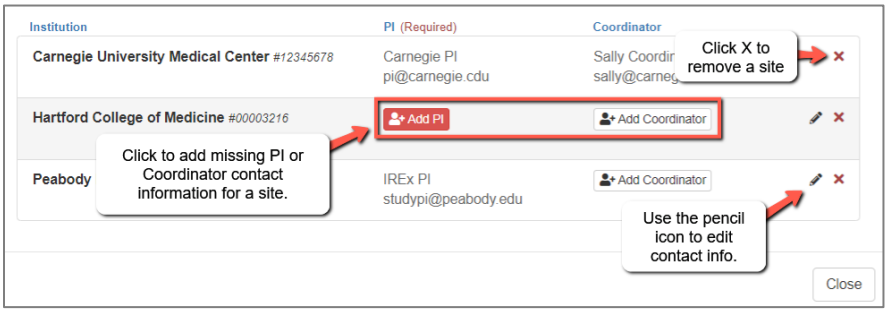


HOW DO I EDIT OR REMOVE SITES FROM THE STUDY?

Tip: When a site HRPP registers, you will no longer be able to make edits to the site's study contacts. The site will be able to manage their own contacts after registering for the study.

After sites are listed on the study,

1. Click the X to remove a site, including any of their existing documentation*.
2. Use the **pencil icon** to make edits or the + Add PI or Coordinator buttons.
3. After making changes, click **Close** to exit.



*Removing vs. Closing a Site on a Study

Sites that are no longer participating on a study can be removed. Whether sites are 'removed' or 'closed' is up to the discretion of the sIRB, but we **recommend the following, depending on the site's level of participation in the trial:**

- **For sites that began the reliance process, but did not receive IRB approval, sIRB Liaisons or Study Managers** can simply delete the site from the Participating Sites dialog by following the steps below. This removes the site's access and the record of their participation in the trial. No email notifications are sent to the site when this occurs, as no further action is required.
- **For sites that completed the reliance process and were approved by the sIRB, sIRB Liaisons or Study Managers** can use the "site closure" button beside the site's name on the Site-specific IRB Approvals tab. (See our Site Closure Quick Guide here for further instructions.) Sites will retain access to the study for 30 days, after which access is removed completely. The site's HRPP and study team will be notified of the closure.

WHAT HAPPENS AFTER SITES ARE LISTED ON THE STUDY?

Sites do not yet have access to the study. **Access should be granted after the Lead Site or Overall Study Approval is posted to IREx by the Reviewing IRB**. Once the study is approved, the Study Manager (e.g., coordinating center or lead study team) should disseminate the approved protocol and template consents, along with other study materials, to each site outside of IREx. The local study team uses these materials to submit to their local HRPP, who then logs in to document reliance in IREx and grants their study team access. It is helpful to provide reliance instructions to the study teams. You can access template reliance instructions here.

HOW DO I GRANT SITES ACCESS TO THE STUDY?

After the Lead Site Approval has been posted to IREx, use the **Notify HRPP** button on the Status Summary tab to grant the site access to the study. This sends an email alert to the site HRPP and PI that the study is in IREx. However, PIs and Coordinators will not be able to access the study until their HRPP registers for the study.

Tip: You will not be able to notify the site until you enter the PI name and email.