IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

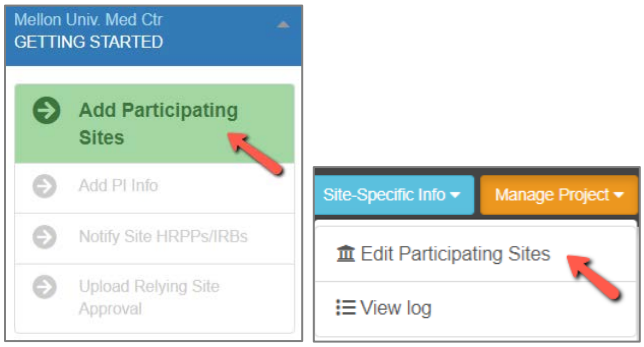
# HOW TO ADD PARTICIPATING SITES TO A STUDY

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.

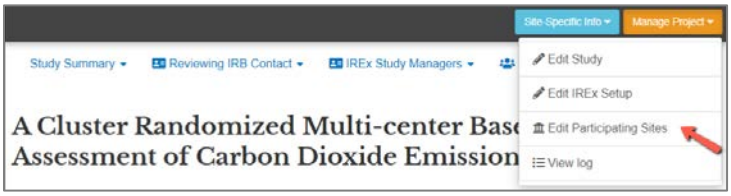
## WHERE DO I ADD OR REMOVE A SITE FROM A STUDY?

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:



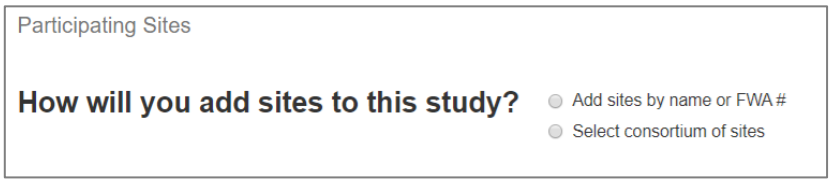

**Reviewing IRBs** use the Manage Project menu:

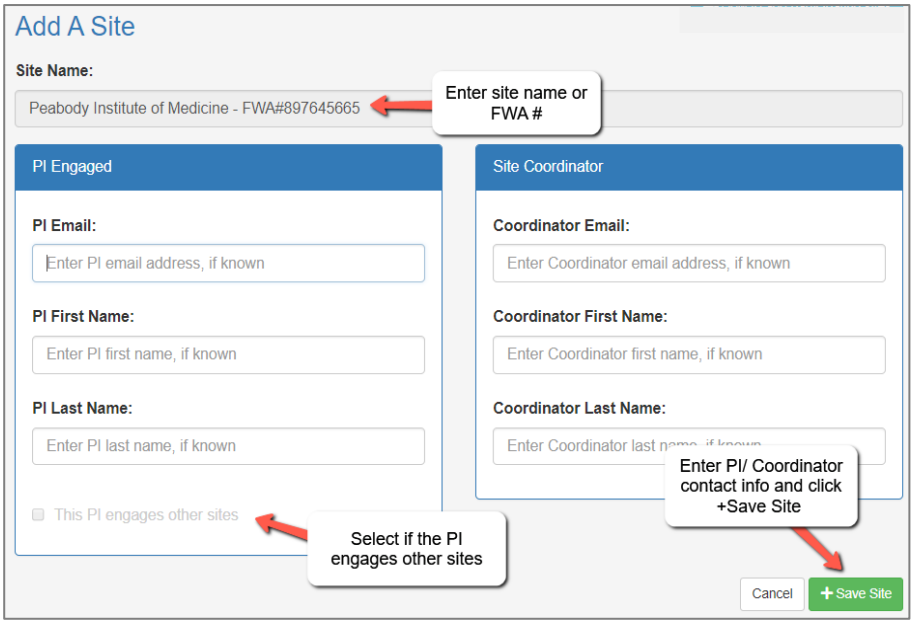



## HOW DO I ADD A NEW SITE(S)?

First, verify you have the correct site 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. After the site is verified, follow the steps below.

1. Access the Participating Sites dialog (see step above). A pop-up will ask, "How will you add sites to this study?", Select **Add sites by name or FWA #** (recommended) or **Select consortium of site**, if applicable.



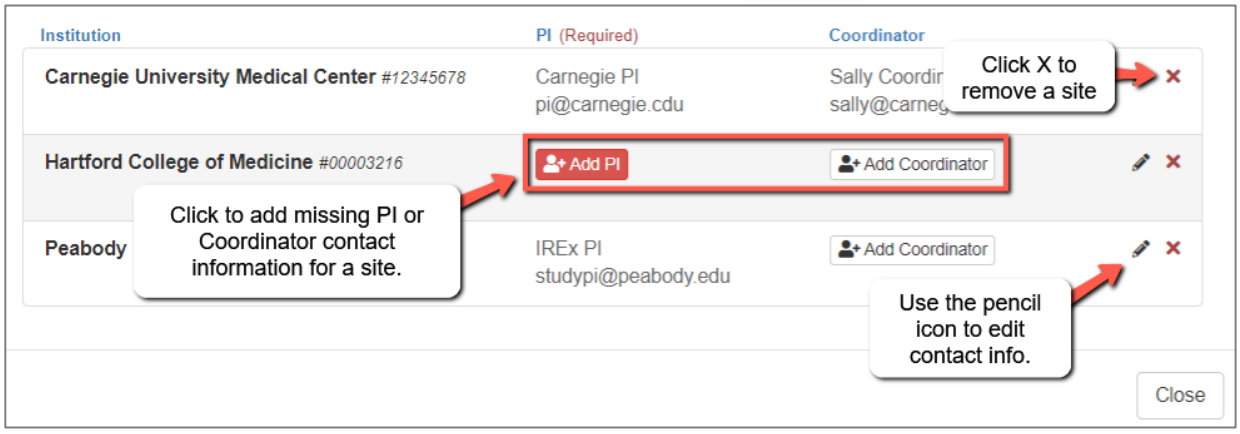

2. Search by the site's FWA or full name (avoid abbreviations, e.g., "VU"). As you type, the sites that match the name/FWA you have entered will appear. **Select the site from the drop-down menu.** You can also add sites that do not appear in the search, which means they are not yet members of IREx. Tip: The FWA-holding site appears first, followed by any components, if provided by the HRPP.

3. Enter the PI (required) and Site Coordinator contact information.

4. If the PI/study team engages another site, select **This PI engages other sites** and add the other site.

5. 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.

6. Your site(s) will be listed below. You can add missing contact information, use the **pencil icon** to make edits, or click **X** to remove sites. Tip: When a site 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.
7. After making changes, click **Close** to exit.




## WHAT HAPPENS AFTER SITES ARE LISTED ON THE STUDY?

Sites do not yet have access to the study. Access is not granted until the Lead Site or Overall Study Approval is posted to IREx by the Reviewing IRB because most Relying HRPPs will not begin their local reviews and documentation until they have a local submission, including the approved protocol and consent template.

Once the study is approved, the Study Manager from the coordinating center or lead study team should disseminate the approved protocol and template consents, along with other study materials, such as contracts and regulatory documents, 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. 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, you can grant the site access to the study using the **Notify HRPP** button on the Status Summary tab. 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.