HOW TO ADD/REMOVE 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.

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HOW DO I ADD/REMOVE NEW SITES?

1. **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. **Click** the **Sites** tab in the top navigation bar. Study Manager can also click **"Add Participating Sites"** from their Getting Started Checklist.
3. **Indicate** whether you will **Add sites by name or FWA #** (recommended) or **Select consortium of sites**, if applicable.
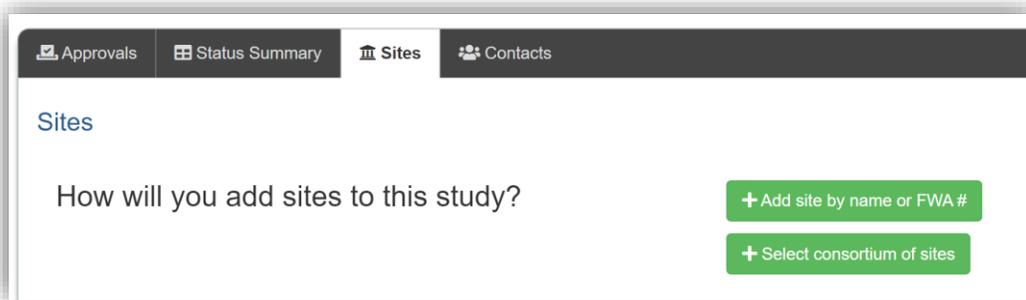
4. **Search** by the site's FWA or full name (avoid abbreviations, e.g., "VU"). As you type, the sites that match the name/FWA you have entered will appear. **Select** the site from the drop-down menu. If adding by the FWA, only enter the numeric characters.
   - The FWA-holding site appears first, followed 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.

5. **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.

6. If the PI/study team engages another site, check the box "This Study Team engages additional sites" and select the other site from the drop down.

7. **Click** the +**Add Contact** button to add additional study team members.

8. Click **Save** to list the site on your **Sites** page.

9. **Click** the **trash can icon** to remove any sites that will *not* be participating in the study.

10. **Click** the **+Add Site** button to add additional sites.

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. 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 sIRB approval,** sIRB Liaisons or Study Managers can simply delete the site by following the steps above. 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 were approved by the sIRB**, sIRB Liaisons or Study Managers can use the **Add Site Closure** button on the Approval History tab. (See Site Closure Quick Guide **here**.) 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.
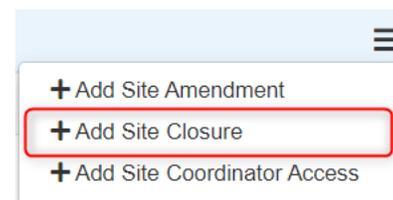
HOW DO I ADD/REMOVE A CONSORTIUM OF SITES?

1. From your **Sites** page, click **Select consortium of sites**. Select the consortium from the drop down to save them to your sites page.

   - If you do not see your desired consortium, contact the IREx Support Team by completing this survey. Our team will let you know when the consortium can be added to the study.

2. **Click** the **trash can icon** to remove any consortium sites that will *not* be participating in the study.
3. **Add** each sites' PI (required) and coordinator information.
4. **Click** the **+Add Site** button to add additional sites.

WHAT HAPPENS AFTER SITES ARE LISTED ON THE STUDY?

Sites do not have access to the study yet. Use your **Status Summary** page, to check which sites have agreements that still need to be completed. See your Study Manager or Reviewing IRB quick guide on how to request these agreements. We recommend granting sites' access after the Lead Site or Overall Study Approval is posted to IREx. Sites must first join IREx before you can grant them access to the study.