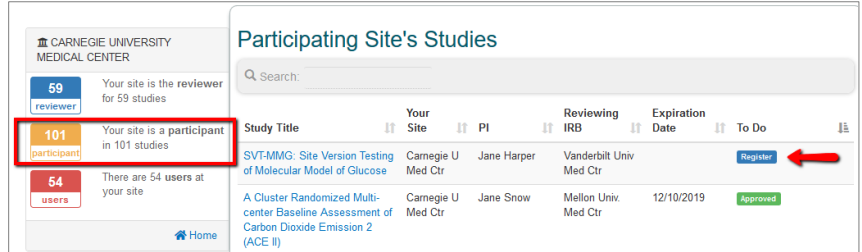


USING IREX AS A RELYING SITE HRPP

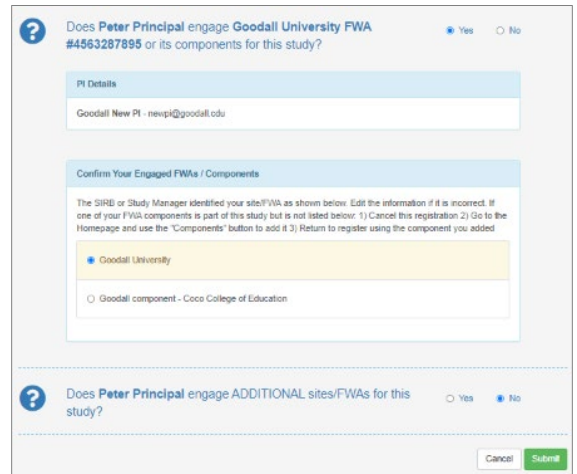
HOW AND WHEN DO I COMPLETE REGISTRATION FOR A STUDY?

Each HRPP has their own process for providing reliance documentation to the Single IRB (sIRB). Often, this process does not begin until the HRPP receives a local submission from the local study team. After receiving an email about IREx study access, follow the steps below when you are ready:

- ❑ **Register for the study:** Log in to IREx and find the study on your Participating Site Dashboard. Click **Register** to confirm your PI and FWA information.

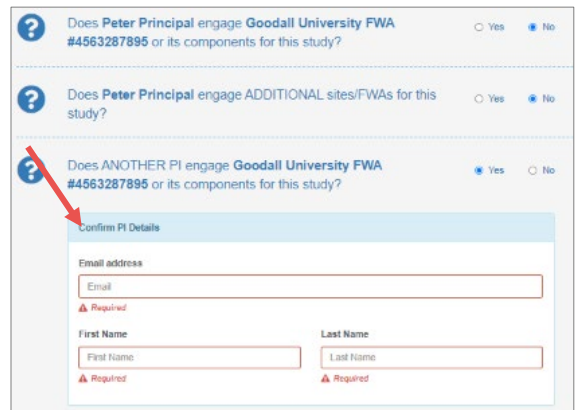


If the PI listed engages the FWA listed, select **Yes** and confirm the PI details and the FWA / component are correct.

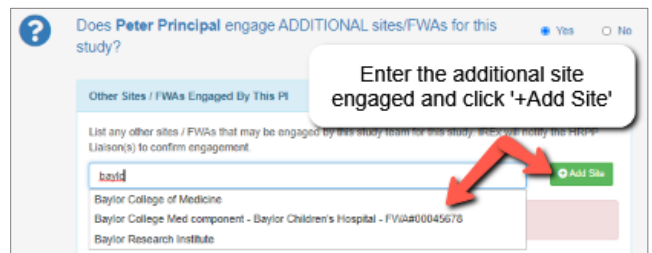


The second question asks whether the PI engages additional FWAs. If not, answer **No** and click **Submit** to register and access the study page. This is not an indication of reliance.

- ❑ If the investigator or site are not listed correctly, the registration page allows you to **MAKE EDITS**:
Change your PI – If your FWA is engaged, but the PI is wrong, answer **No** to the first two questions and **Yes** to the question that asks, “Does ANOTHER PI engage [YOUR INSTITUTION/FWA] or its components for this study?”. **Enter the correct PI and verify your FWA information is correct.**



Add additional engaged FWAs -- If your PI engages an additional FWA, answer **Yes** to the question, “Does [PI NAME] engage ADDITIONAL sites/ FWAs for this study?”. Then, enter the additional FWA and click **+Add Site**. If you do not oversee the additional FWA, the appropriate liaison will be notified to confirm engagement. You will also **identify the Primary HRPP** for the group of FWAs engaged (**Combo Sites**).



IREx Tip: Remember, you are *relying* on the sIRB; they are not *engaged* in the study. The sIRB should NOT be listed here.

Indicate your site is not engaged – To indicate your institution and faculty/staff are not engaged for the study, answer **No** to each question, and **provide a reason in the box provided**.

WHEN DOES MY INVESTIGATOR GET ACCESS TO THE STUDY IN IREx?

Your PI will be given study access to IREx once the sIRB or Lead Study Team notifies your site that the study is in IREx. They will then be able to log into IREx to retrieve the approved overall study documents for their local site submission.

HOW AND WHEN DO I PROVIDE STUDY-SPECIFIC DOCUMENTATION?

Bridgeton U
GETTING STARTED

- ✓ Register
- ✓ Complete Agreements
- ➔ Confirm Institutional Profile
- ➔ Indicate Reliance
- ➔ Complete HRP Survey
- 👁️ Remind PI To Complete PI Survey
- ✎ Add / Edit Study Team Access
- 🕒 Awaiting Reviewing IRB Approval

After registering, your next steps are listed in the GETTING STARTED checklist on the left of the study page:

Complete Agreements: Click to view the required agreements.

Confirm the Institutional Profile (IP): The IP captures general information about your institution, over-arching state laws or institutional policies affecting research, and the reliance process at your site. If you have completed the IP, you can edit or confirm it.

Indicate Reliance: Before indicating reliance, agreements must be complete and your institution and the sIRB must agree on how to implement the flexible elements of the reliance agreement (e.g., handling HIPAA, auditing, and external reporting). Indicate reliance by accepting the sIRB's Study-specific Reliance Plan (SSRP).

Complete HRP Survey (if indicated): The HRP Survey asks about requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the specific study or trial that would affect the research at your institution.

Review PI Survey (optional): If the sIRB is using IREx to capture

local considerations, a PI Survey is required, which asks about the conduct of the study at your site. You can send a reminder email from IREx to the investigator to complete the survey.

✓ Review PI Survey (optional) ✎

Once the survey is done, you can review and edit it, if needed.

If the study has consent forms, the study team should submit them to the HRPP for local review before uploading the consents to the PI Survey.

Add/ Edit Study Team Access (optional): You can edit and give access to additional study team members who will need to access approval documents for your site.

Local PI Survey

HRPPs can edit the PI Survey as needed → Edit Survey

Study Title	A study with a PI Survey
Participating Site Name:	Bridge University
STUDY TEAM INFORMATION	
Site Investigator's Name	Nola PI
Site Investigator's Email Address	pi@bridgeton.cdu
Please review the planned list of personnel who will be engaged in human subjects research. Has all required training for the conduct of the research at your site been completed for each individual, including human subjects protections training, GCP training, and HIPAA training, as applicable?	Yes

CAN I VIEW AND MAKE CHANGES TO THE INFORMATION DOCUMENTED IN IREx?

Yes, the GETTING STARTED checklist includes pencil icons next to information that can be edited (e.g., the HRP Survey). After receiving sIRB approval, you will not be able to make changes. Use the **Site-specific Info** menu to view study documentation.

Goodall
GETTING STARTED

- ✓ Register
- ✓ Complete Agreements
- ✓ Confirm Institutional Profile ✎
- ✓ Indicate Reliance
- ✓ Complete HRP Survey ✎
- ✓ Review PI Survey (optional) ✎
- ✎ Add / Edit Study Team Access
- 🕒 Awaiting Reviewing IRB Approval

My Site Info

- 👤 Study Team Contacts
- 📄 View Reliances (SSRP)
- 📄 View Local Context Survey
- 📄 View Local PI Survey
- 📄 Download Letter of Reliance
- 📄 Download Reliances (SSRP)

After all steps are completed (including the PI Survey), your site will be submitted to the Reviewing IRB for review. HRPPs and study teams will receive an email notification from IREx when your site's approval is available in IREx.