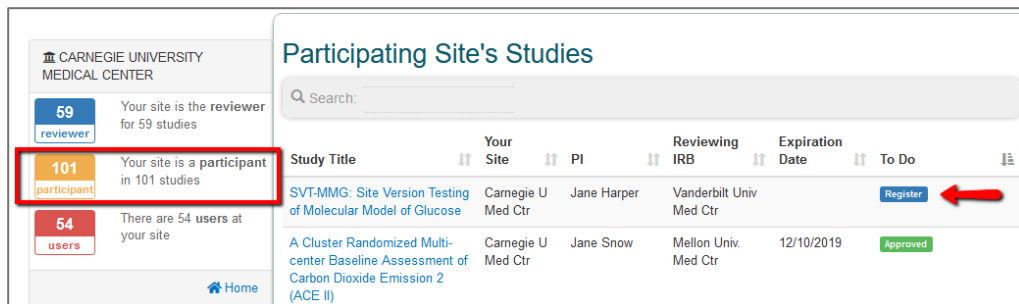


USING IREx AS A PARTICIPATING SITE HRPP

INDICATING RELIANCE AND PROVIDING LOCAL CONSIDERATIONS IN IREx

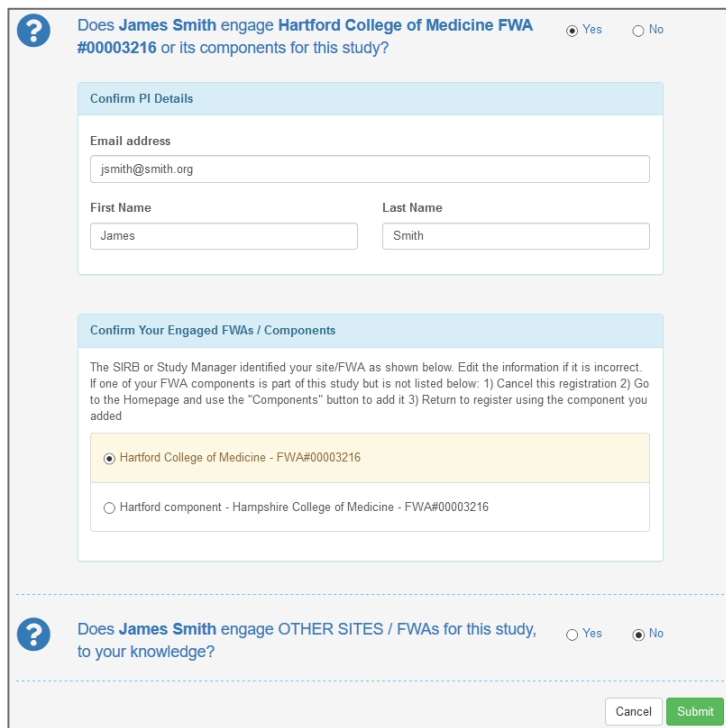
Each HRPP has a process for providing reliance documentation to a Single IRB (sIRB). Often, this process does not begin until the HRPP receives a local submission from the local study team. Follow the steps below when you are ready:

- ❑ **Register for the study:** Login to IREx and find the study on your Participating Site Dashboard. Click **Register** to go to the registration page.



Study Title	Your Site	PI	Reviewing IRB	Expiration Date	To Do
SVT-MMG: Site Version Testing of Molecular Model of Glucose	Carnegie U Med Ctr	Jane Harper	Vanderbilt Univ Med Ctr		Register
A Cluster Randomized Multi-center Baseline Assessment of Carbon Dioxide Emission 2 (ACE II)	Carnegie U Med Ctr	Jane Snow	Mellon Univ. Med Ctr	12/10/2019	Approved

If the PI 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 other FWAs. If not, answer **No** and click **Submit** to register and access the study page. This is not an indication of reliance.



Does James Smith engage Hartford College of Medicine FWA #00003216 or its components for this study? Yes No

Confirm PI Details

Email address:

First Name: Last Name:

Confirm Your Engaged FWAs / Components

The SIRB or Study Manager identified your site/FWA as shown below. Edit the information if it is incorrect. If one of your FWA components is part of this study but is not listed below: 1) Cancel this registration 2) Go to the Homepage and use the "Components" button to add it 3) Return to register using the component you added

Hartford College of Medicine - FWA#00003216

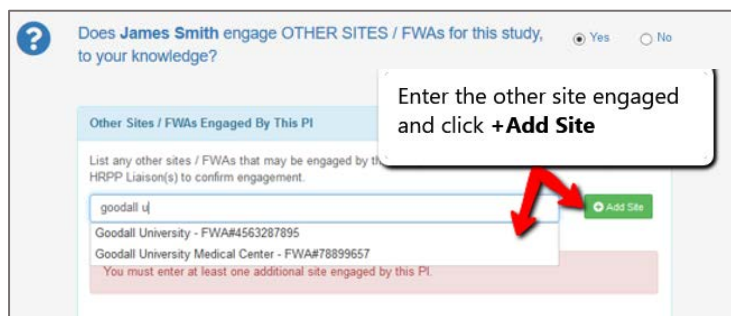
Hartford component - Hampshire College of Medicine - FWA#00003216

Does James Smith engage OTHER SITES / FWAs for this study, to your knowledge? Yes No

[Cancel](#) [Submit](#)

If the investigator or site are not listed correctly, the registration page allows you to **MAKE EDITS**:

- **Add other engaged FWAs** -- If your PI and site are correct, but your PI engages an additional FWA, answer **Yes** to the question, "Does [PI NAME] engage OTHER SITES/ FWAs for this study, to your knowledge?". Then, **list the additional FWA**. If you do not oversee the 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*)**.



Does James Smith engage OTHER SITES / FWAs for this study, to your knowledge? Yes No

Other Sites / FWAs Engaged By This PI

List any other sites / FWAs that may be engaged by the HRPP Liaison(s) to confirm engagement.

[+Add Site](#)

Goodall University - FWA#4563287895

Goodall University Medical Center - FWA#78899657

You must enter at least one additional site engaged by this PI.

Does James Smith engage Hartford College of Medicine FWA #00003216 or its components for this study? Yes No

Does James Smith engage OTHER SITES / FWAs for this study, to your knowledge? Yes No

Does ANOTHER PI engage Hartford College of Medicine FWA #00003216 or its components for this study? Yes No

Confirm PI Details

Email address

 ▲ Required

First Name Last Name
 ▲ Required ▲ Required

- **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.
- **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**.

Hartford College of Medicine FWA#00003216 is not engaged in research for this study.

Please briefly describe why your FWA is not engaged for this study. You will no longer receive study notifications.

▲ Required

For guidance determining whether your site is engaged in research, go here.

After registering, if engaged, your PI will be given study access. Find your next steps in the GETTING STARTED Checklist:

Carnegie U Med Ctr
GETTING STARTED

- ✓ Register
- ➔ **Verify Study Team Access**
- ✓ Complete Agreements
- ➔ Confirm Institutional Profile
- ➔ Indicate Reliance
- ➔ Complete HRP Survey
- ➔ Remind PI To Complete PI Survey
- ➔ Awaiting Reviewing IRB Approval
- 👁 View Status Summary

- ❑ **Verify Study Team Access:** Click to verify who has access to the study at your site. Additional study team contacts can be added by you or the PI. You can enter additional information, such as your local IRB submission # and dates of review, but this is not required. After saving, new contacts will receive an email with their login information.
 - ❑ **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 plan in the 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, as well as the consent form for this study. If the study has consents, they should be submitted to your HRPP by your local study team, verified by your HRPP, and then uploaded by the HRPP into the HRP Survey.
- *Combo Sites*:** The non-primary HRPP has the option to complete the HRP Survey from scratch or select the option to copy and edit the Primary HRPP’s survey response.

❑ **The PI Survey:** If the sIRB is using IREx to capture local considerations, your PI will complete a PI survey asking about the conduct of the study at your site. Please verify the PI’s responses align with institutional policies.

➔ Remind PI To Complete PI Survey

➔ Validate PI Survey

- **Remind PI to Complete the PI Survey:** If your PI has not completed the survey when you get to this step, you can send a reminder email from IREx. When the survey is completed, you will receive an email notification to login and verify the responses.
- **Validate PI Survey:** Once your PI has completed the survey, you can view and edit the PI’s responses, as needed. The PI will be notified of any changes. ***Combo Sites*:** Combo Sites have one PI Survey. The non-primary HRPP can view, but not edit or validate, the survey.

AFTER YOU HAVE COMPLETED YOUR STEPS

The GETTING STARTED Checklist includes a pencil icon to indicate what information can be edited (e.g., the HRP Survey).

After the study is approved, use the **Site-specific Info** menu to make edits.

GETTING STARTED

- ✓ Register
- ✓ Verify Study Team Access
- ✓ Complete Agreements
- ✓ Confirm Institutional Profile
- ✓ Indicate Reliance
- ✓ Complete HRP Survey
- ✓ Validate PI Survey
- ➔ Awaiting Reviewing IRB Approval
- 👁 View Status Summary

Site-Specific Info

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