

ABOUT THE MULTI-SITE LIAISON ROLE IN IREX

In IREx, the “Multi-site Liaison (MS Liaison)” is someone who (1) manages reliance for multiple FWAs (e.g., if your institution has multiple FWAs or oversees the HRPP functions for an affiliate institution) or (2) needs to manage reliance for multiple investigators independently conducting the same study at your institution. As a MS Liaison, *for each site/investigator engaged on a study*, you will document a cede/reliance decision and local considerations. To help ensure you complete each step for each site or investigator, IREx has created tailored dashboards for the MS Liaison.

HOW DO I KNOW I HAVE MULTIPLE SITES OR INVESTIGATORS PARTICIPATING ON THE SAME STUDY?

 **Your Study is in IREx Email:** If you have multiple sites or investigators on a study, you will receive multiple emails.

Your Participating Site Dashboard:

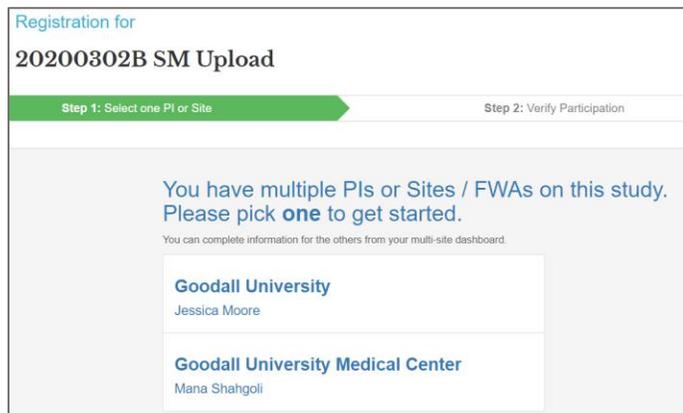
You can view studies at your site on the Participating Site Dashboard by selecting the **participant box** on the left-hand side of the IREx homepage.



Study Title	Your Site	PI	Reviewing IRB	Expiration Date	To Do
20200302B SM Upload	GUMC	Mana Shahgoli	Mellon Univ. Med Ctr		Register
20200316 User Feedback Group Test Study	Goodall		Jefferson		Register

REGISTERING FOR A STUDY AS A MULTI-SITE LIAISON

Once you have what's needed from your study team to document reliance and local considerations, register for the study:



Registration for
20200302B SM Upload

Step 1: Select one PI or Site Step 2: Verify Participation

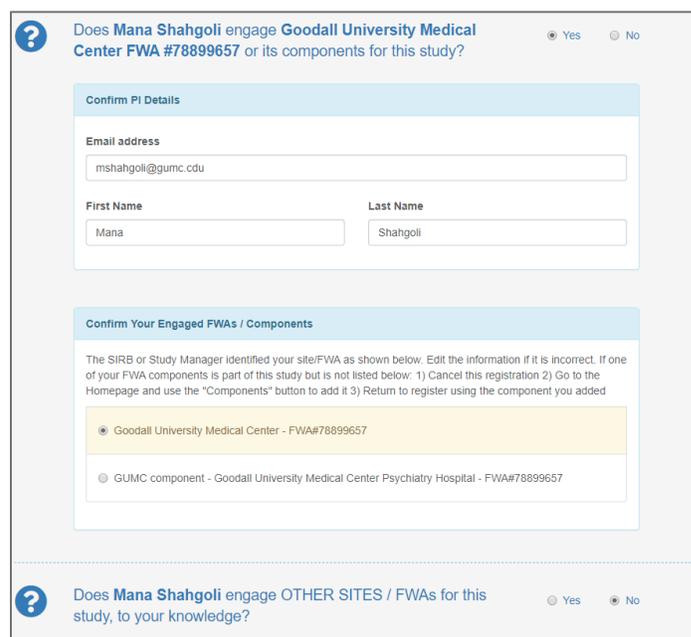
You have multiple PIs or Sites / FWAs on this study. Please pick **one** to get started.

You can complete information for the others from your multi-site dashboard.

- Goodall University**
Jessica Moore
- Goodall University Medical Center**
Mana Shahgoli

First, **select the site or PI you want to register**. You can register additional FWAs or investigators once you access the study page dashboard. Registering gives you access to the study; it is not the cede decision.

Next, **confirm whether the site (FWA) and investigator are correctly listed for your site**. These questions give you the control to ensure your site and investigator are correct.



Does **Mana Shahgoli** engage **Goodall University Medical Center FWA #78899657** or its components for this study? Yes No

Confirm PI Details

Email address
mshahgoli@gumc.edu

First Name
Mana

Last Name
Shahgoli

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

- Goodall University Medical Center - FWA#78899657
- GUMC component - Goodall University Medical Center Psychiatry Hospital - FWA#78899657

Does **Mana Shahgoli** engage **OTHER SITES / FWAs** for this study, to your knowledge? Yes No

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

- **Clarify your FWA** -- For example, perhaps it is your component that is engaged on this study.

- **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 Site”)**.

- **Change your PI** -- If your FWA is engaged, but the PI is wrong, you can indicate that in the question that asks, “Does ANOTHER PI engage [YOUR INSTITUTION/FWA] or its components for this study?”. **Enter the correct PI information** and make sure your FWA is listed correctly.

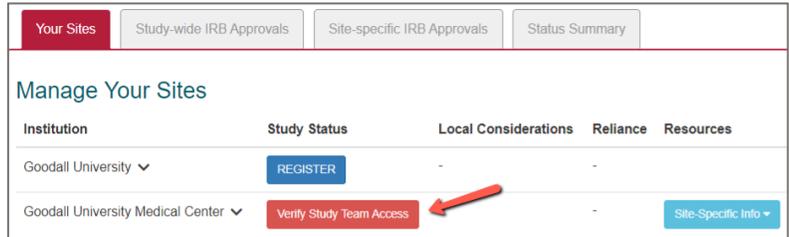
After registering your engaged FWA, your local PI will **automatically be given access to the study**.

- **Indicate your site is not engaged** -- If applicable, by answering **No** to each question and **providing a reason why your FWA is not engaged** in the box provided. You will no longer receive email notifications about the study.

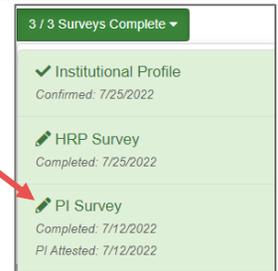
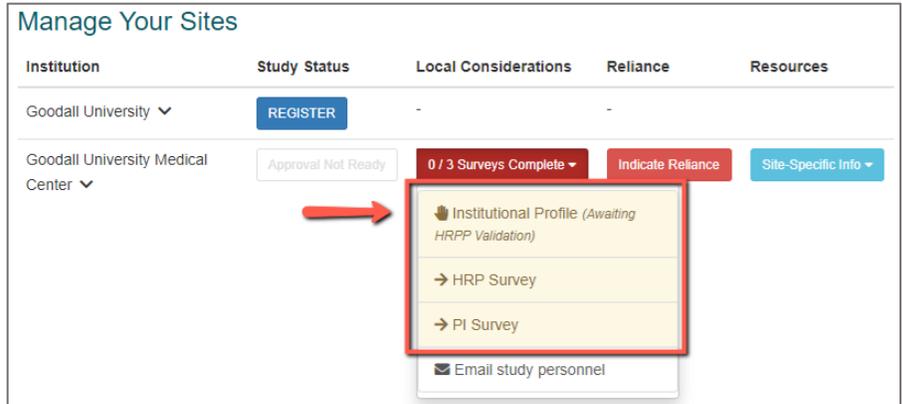
HOW DO MULTI-SITE LIAISONS DOCUMENT RELIANCE AND LOCAL CONSIDERATIONS IN IREX?

After registering for the study, **Your Sites** Dashboard will be visible. All sites thought to be engaged will be listed.

- ❑ Register other FWAs, when ready.
- ❑ Document Local Considerations – Complete the Three Parts Using the Dropdown:

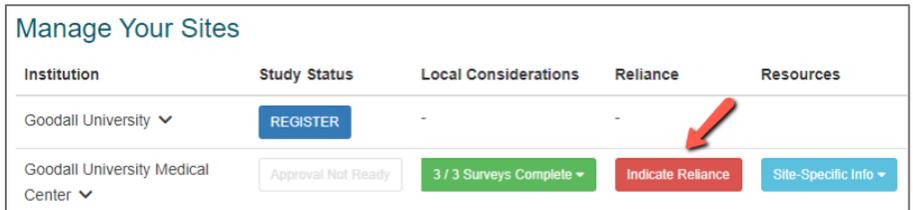


- **Confirm the Institutional Profile (IP)** -- The IP captures general information about your organization, over-arching state laws or institutional policies affecting research, and how your site operationalizes reliance. If you have already completed the IP, you can edit or confirm the information provided.
- **Complete the 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 conduct or approval of the research at your institution.
- **Review PI Survey (optional)** -- Once your local PI has completed the PI survey, click the **PI Survey** in the dropdown to review and edit the survey, if needed. The PI will be notified of any changes and must re-attest. If the study has consent forms, the study team should submit them to the HRPP for local review before they upload the consents to the PI Survey.



- ❑ Complete Agreements and Indicate Reliance:

- **“Complete Agreements”** will appear under the Reliance column if your site has not completed the required agreements to rely on the sIRB. You will not be able to indicate reliance until you complete the required agreements.
- **Indicate Reliance** -- To indicate that your institution will rely on the sIRB, 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).



USE THE SITE-SPECIFIC INFO MENU TO ACCESS INFORMATION

Access and edit your local study team contacts or download the Letter of Reliance and SSRP for the study from the **Site-specific Info** button.

