Updated 3/30/2020

IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

MANAGING RELIANCE DOCUMENTATION FOR MULTIPLE FWAs AND/OR PIs

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.

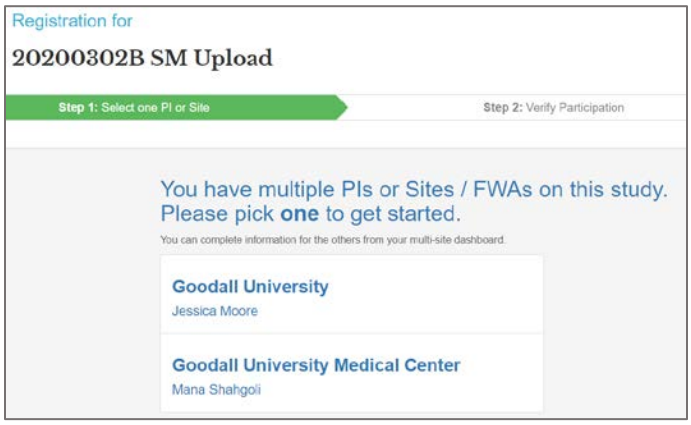
HOW DO I KNOW I HAVE MULTIPLE SITES OR INVESTIGATORS PARTICIPATING ON THE SAME STUDY?

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.

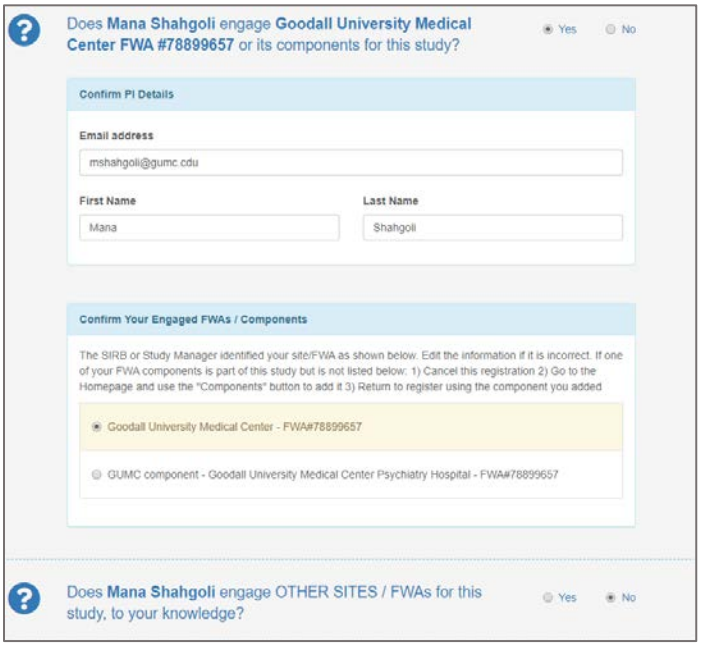
REGISTERING FOR A STUDY AS A MULTI-SITE LIAISON

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



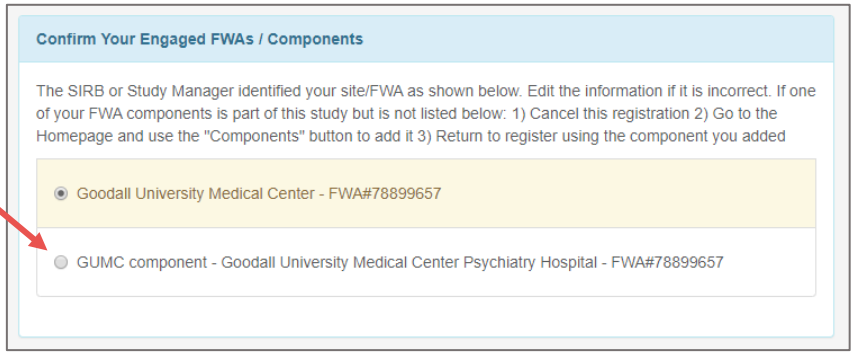
☐ First, **select the site or PI you want to register**. You can register additional FWAs or investigators once you access the study page dashboard. Registering gives you access to the study; it is not the cede decision.

☐ 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.

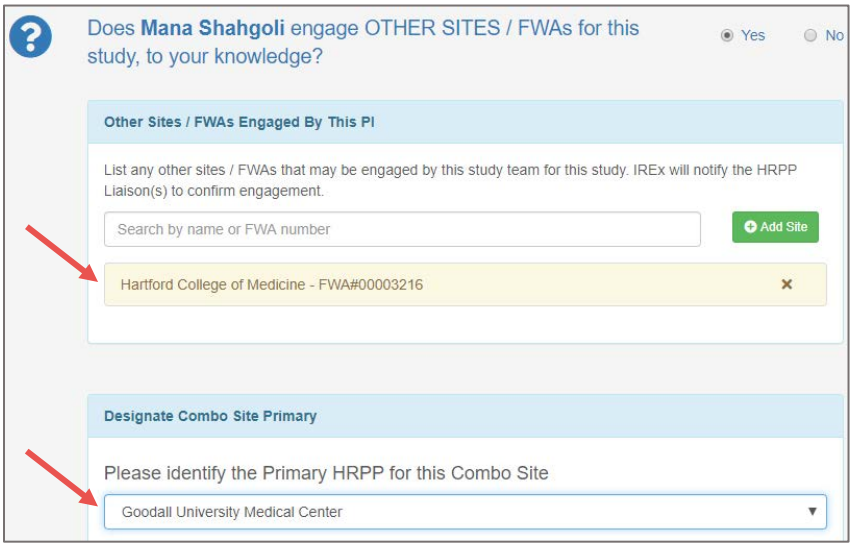


If the investigator or site are <u>not</u> listed correctly, the registration page allows you to MAKE EDITS:

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

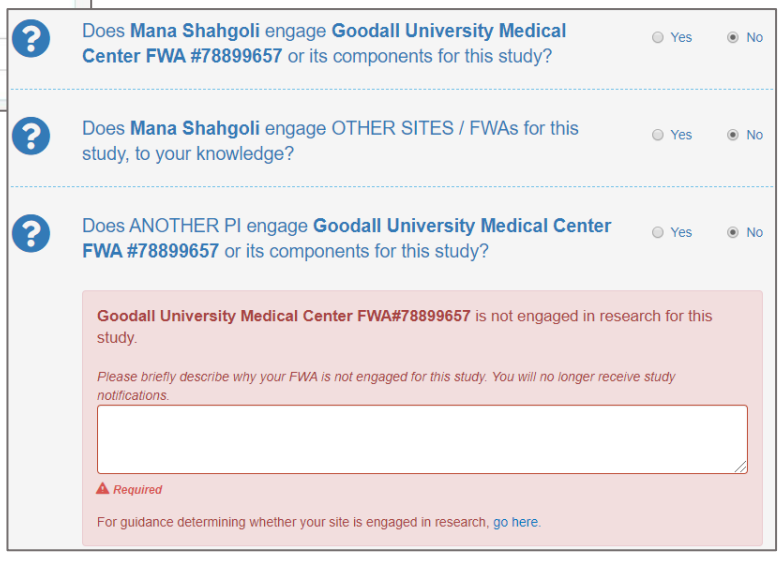


- *Add other engaged FWAs* -- If your PI and site are correct, but your PI engages an additional FWA, answer **Yes** to the question, "Does [PI NAME] engage OTHER SITES/ FWAs for this study, to your knowledge?". Then, ***list the additional FWA***. If you do not oversee the FWA, the appropriate liaison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

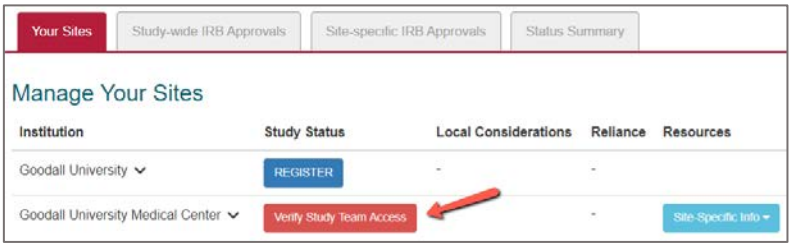
- *Indicate your site is not engaged* -- if applicable, by answering **No** to each question and providing a reason in the box provided. You will no longer receive email notifications about the study.



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

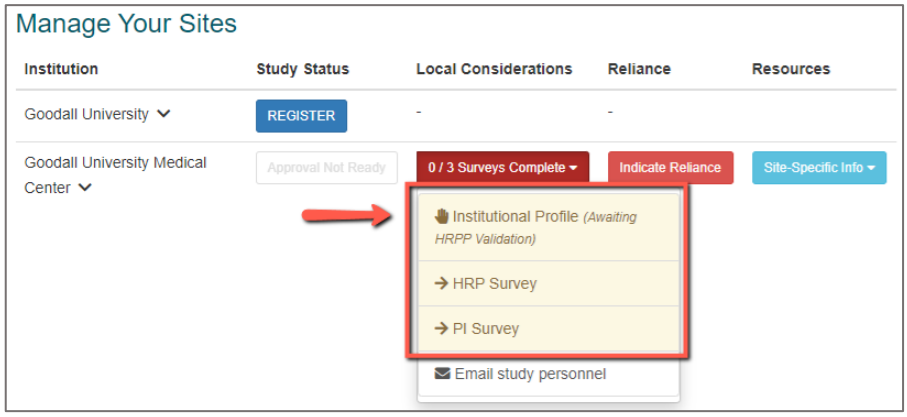
HOW DO MULTI-SITE LIAISONS DOCUMENT RELIANCE AND LOCAL CONSIDERATIONS IN IREX?

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

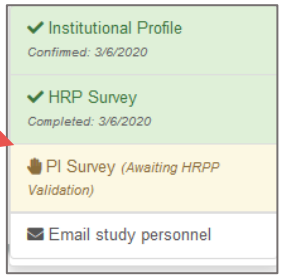


- ☐ **Register other FWAs,** when ready.
- ☐ **Verify Study Team Access:** Click to verify study team contacts. Additional study team contacts such as the study coordinator can be added by you or the PI who now has access. Enter local IRB# and local review dates (optional). After saving, all users added receive an email from IREx with their login information.

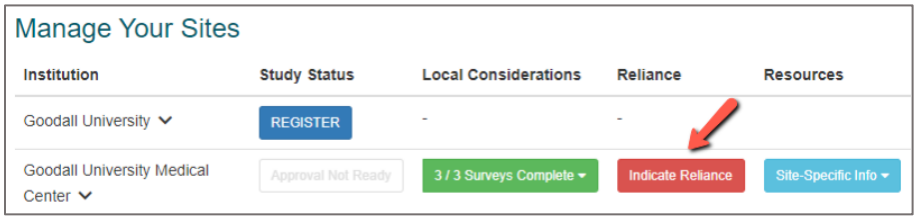
- ☐ **Document Local Considerations – Complete the Three Parts Using the Dropdown:**
  - *Validate (or complete) the Institutional Profile (IP)* -- The IP captures general information about your organization, over-arching state laws or institutional policies affecting research, and how your site operationalizes 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, as well as the consent form for this study. If the study has consent forms, the consents should have been submitted to your HRPP by your local study team, verified by your HRPP, and then uploaded by you in the HRP Survey.
  - *Validate the PI Survey* -- Once your local PI has completed the PI survey, click the **PI Survey** in the Local Considerations dropdown to validate it. You can edit the PI Survey, if needed, and the PI will be notified of any changes.



- ☐ **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, you and the sIRB must agree on how to implement the flexible elements of the reliance agreement. The sIRB's plan is outlined in the Study-specific Reliance Plan (SSRP), and it covers things such as how to handle HIPAA, auditing and external reporting.

USE THE SITE-SPECIFIC INFO MENU TO ACCESS INFORMATION AND MAKE UPDATES

Access your local study team contacts or download the letter of reliance or SSRP for the study from the **Site-specific Info** button.