MANAGING RELIANCE DOCUMENTATION FOR MULTIPLE FWAs AND/OR PIs

The IRB Reliance Exchange (“IREx”) is a freely available web-based portal supporting single IRB documentation and coordination. IREx was developed by Vanderbilt to support IRBs, Human Research Protection Programs (HRPPs), Lead Study Team (LSTs) and Coordinating Centers (CCs), and study teams implementing single IRB (sIRB) review.

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, including 1) confirming your Institutional Profile, 2) completing the Human Research Protections (HRP) Survey, and 3) verifying the PI Survey. 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 MULTIPLE SITES OR INVESTIGATORS PARTICIPATING ON THE SAME STUDY?

a) Your Study is in IREx Email: Anytime your site has an investigator engaged in a study, you will receive a “Your Study Is In IREx” email from IREx. The email will include your investigator and the site(s) and components thought to be engaged. If you have multiple sites or investigators, you will receive two separate emails.

b) Your Participating Site Studies Dashboard: You can also view your sites that are participating on the Participating Site’s Dashboard by selecting the yellow number on the left-hand side of the IREx Homepage. Here you can see (a) “Your Site(s)” participating in the study, (b) the Reviewing IRB for the study, and (c) what “To Do” next.

ACCESSING (REGISTERING FOR) THE STUDY AS A MULTISITE LIAISON

When you have the information needed from your study team to document reliance and local considerations, you can:

- Register for the study:
  Select the site you want to register from the dropdown. You can register additional FWAs or investigators on the study page. Registering gives you access to the study; it is not the cede decision.

- (Automatic) Provide Access to the Local Investigator: The investigator conducting the study will be granted access after registration is completed, if your site is engaged.
HOW DO MULTISITE LIAISONS DOCUMENT RELIANCE AND LOCAL CONSIDERATIONS IN IREX?

After registering for the study, you will see the Your Sites Dashboard on the study. You should see all sites and components that are engaged for the study. Steps can be completed concurrently for each site/component.

- **Add/edit your Study Team Contacts:** Add additional study team contacts, if needed. Note: PIs and coordinators can add other study team members, as needed. All users added receive an email from IREx after their contact information is saved.

- **Document Local Considerations – Three Parts:**
  - **Confirm (or complete) the Institutional Profile (IP):** The IP captures general information about your organization, overarching 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 Local Considerations (optional):** If the sIRB is using IREx to capture local considerations from participating sites, a “Local Considerations” column will appear. 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 consents, it should have been submitted to your HRPP by your local study team, verified, and then uploaded in the HRP Survey.
  - **Verify the information provided by your local study team:** After your local PI completes the PI survey, you will receive an email that you need to validate the answers provided, as will be indicated on the Your Sites Dashboard. You can edit the PI Survey, if needed.

- **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 willingness to rely on the sIRB for a site or investigator, you must accept the Study-specific Reliance Plan (SSRP), which is the sIRB’s plan for implementing the flexible elements of the reliance agreement (e.g., how to handle HIPAA, auditing and external reporting). You can request changes to the SSRP via direct communication (email/phone) with the sIRB. Once you accept the SSRP, a confirmation of reliance email will be sent to you and the sIRB.

**COMPLETE THE STEPS FOR EACH SITE / INVESTIGATOR ENGAGED.**

Once the steps are completed for a site or investigator, that site will be listed on the Site-specific IRB Approvals tab. To complete steps for another site or investigator, you can complete them on the from the Your Sites dashboard.