The IRB Reliance Exchange (“IREx”) was developed by Vanderbilt to support single IRB (sIRB) documentation and communication. IREx is used by sIRBs, Human Research Protection Programs/Offices (HRPPs), coordinating centers and lead study teams, as well as relying site study teams.

**BEFORE RELYING ON AN SIRB**

Each HRPP has a process for ceding review to an sIRB. Often, the cede review process does not begin until the HRPP receives a local submission from the local study team. IREx does not require a change in this process.

**INDICATING RELIANCE AND PROVIDING LOCAL CONSIDERATIONS IN IREX**

As you are ready, follow the steps below to document reliance and provide the information required by the sIRB for your site:

- **Register for the study:** To confirm your site’s engagement in a study, login to IREx and find the study on your Participant Dashboard. Click on the study title and, after confirming the appropriate FWA is listed, click ‘Register’. This is not an indication of reliance.

  **Tip:** if the wrong FWA is listed or if you need to add an additional FWA, contact the sIRB to add the other FWAs.

You can find sIRB Liaison emails on the [IREx members page](#).

- **Add your Local Study Team Contacts:** Provide access to your local PI(s) (required) and study coordinator(s). You can add more study staff; however, the PI and coordinator can add other study team members, as needed. All users added to the study receive access to IREx via email after their contact information is saved. **Tip:** in this pop-up you can enter other information, such as your local IRB number and institutional review dates, but it is not required.

- **Complete Agreements:** Ensure that your site has signed the SMART IRB agreement and the Letter of Indemnification, if indicated and required by the Reviewing IRB. You will not be able to indicate reliance until you complete the required agreements.
 Confirm (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. You must complete all required fields to continue. If you have already completed the IP, you can edit or confirm the information provided.

 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.

 Complete HRP Survey (if shown in the checklist): If the sIRB is using IREx to capture local considerations from participating sites, “Complete HRP Survey” will appear in the Getting Started Checklist. 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. You will be asked to upload your locally verified consent documents to the survey or to enter your locally required language into the survey, depending on the consent process identified by the sIRB.

 Remind PI to Complete the PI Survey/Verify the PI Survey (if shown in the checklist): If the sIRB is using IREx to capture local context from participating sites, your site PI has to complete a PI survey asking about the conduct of the study at your site, and you have to verify their responses.

 1. If your PI has not completed the survey when you get to this step, you can send him/her a reminder email from IREx. Next, you will receive an email notification to login and verify the once acknowledgement is needed.

 2. If your PI has completed the survey, you will be asked to verify the information provided. You can edit the PI’s responses, as needed.

 Once these steps are completed, your site will appear on the Site-specific IRB Approvals tab and you have no other actions required in IREx. Tip: You can use the GETTING STARTED checklist to edit the Study Team, Institutional Profile, HRP Survey, and PI Survey until you receive sIRB approval. After the study is approved, you can edit the study team from the “Site-specific Info” menu.