The IRB Reliance Exchange ("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. IREx can be used to capture all sIRB documentation (e.g., cede decisions, local considerations, and sIRB approvals), as well as coordinate communications between the sIRB and participating site ("sites") study teams and HRPPs.

PRIOR TO CREATING A STUDY IN IREX

- Complete / update the IREx Institutional Profile
- Educate the "IREx Study Manager" (i.e., lead study team coordinator or coordinating center staff) on the sIRB process
  - Agreements required
  - Consent form process (e.g., whether a template is being used)
  - How sites are submitted for review (e.g., as an amendment)
- Prepare instructions for participating sites (PSs), which we recommend be disseminated by the study manager to site study teams after the lead site is approved. Here is the IREx template for reliance instructions.

CREATING A STUDY IN IREX FROM THE HOMEPAGE

- Enter basic study information like the title, study summary, NCT #
- Upload key study documents, such as the protocol and consent form(s)

After saving this basic information, you are taken to the study page and will see a Getting Started Checklist that lists your remaining steps, described in detail below.

COMPLETE THE IREX SETUP FOR A STUDY

- Identify the Lead Site if it is different from the Reviewing IRB institution
- Answer a few basic questions, like whether you are using IREx to capture local considerations
- List the IREx Study Manager [Tip: This is the lead study team or coordinator center staff responsible for communicating with sites. The Study Manager can add or remove sites access to the study; export local considerations for submission to the Reviewing IRB; and upload site approvals.]
- Identify the Reviewing IRB Primary Liaison and others who need to receive study notifications. All Liaisons can still access and perform all functions for the study.

ADD LEAD STUDY TEAM CONTACTS (IF THE SIRB IS ALSO THE LEAD SITE)

If the sIRB is also a the lead site, provide the name and email address for the PI (required) and Study Coordinator. PIs and coordinators can add other study staff to IREx. If the lead site is another site, that HRPP will add the study team contacts.

CONFIRM THE STUDY-SPECIFIC RELIANCE PLAN (SSRP)

The SSRP is automatically generated from your Institutional Profile (section 4) and outlines how the flexible elements of reliance will be handled. The Reviewing IRB can edit the SSRP for the study (all sites) or for individual sites, as requested after the site registers for the study. Site HRPPs indicate reliance by accepting the SSRP. [Tip: Sites cannot access the study until the SSRP is confirmed and the sites are notified on the Status Summary (see section below)].

SIRB REVIEW AND OVERALL STUDY APPROVAL

Studies can be created before you have overall study approval. However, we recommend not notifying sites of the study until approval is received and uploaded to IREx. To upload an approval for the overall study, select Upload Overall Study Approval in the Getting Started checklist, and do the following:

- Change the study status to “Approved” and enter the required review information (dates, level of review)
- Upload the required documents and accept any draft documents or replace them if they were changed.
- Publish Approval
THE ROLE OF THE IREX STUDY MANAGER

To help assuage the sIRB burden, IREx recommends delegating the tasks below to the IREx Study Manager. The Reviewing IRB can also do these tasks, if needed, as described below:

- **Add Sites**: Add sites by selecting “Manage Project’ and ‘Edit Participating Sites’'. The PI name and PI email are required to notify the site.

- **Notify Site HRPPs of the Study**: From the Status Summary, click ‘Notify HRPP’ button to send the IREx study notification.

- **Track Site Progress Towards sIRB Approval**: Use the Status Summary to track sites’ progress on agreements, reliance decisions, local considerations and approval.

- **Export Local Considerations**: The IREx Study Manager is notified to export site’s local considerations as they are completed by the site. Click “Export Survey Data”.

**WHEN TO ADD SITES IN IREX**

Sites are *added* to a study and *notified* of the study in separate steps so you can control when sites get access to the study. Sites can be *added* to a study at any time, even *before the initial approval has been uploaded*. Adding sites to the study early allows you to see whether they have completed the required agreements, like SMART IRB, and whether they have access to IREx. If any reliance-related agreements are missing for a site, the site can begin executing those while the lead site is being approved.

**WHEN TO NOTIFY SITES ABOUT THE STUDY IN IREX**

We recommend notifying sites of the study **AFTER** (1) the lead site is approved and uploaded to IREx and (2) the approved study materials and reliance instructions are distributed by the study manager to the sites (e.g., protocol, consent templates, contracts, regulatory documents, etc.). These materials are distributed outside of IREx.

Notifying a site about a study in IREx is the Reviewing IRB’s way of letting the site know that they are a site on a single IRB study. Because relying HRPPs often require a local submission before indicating reliance or completing local considerations, many HRPPs will not login immediately. Instead, the IREx notification connects the HRPP and their local study team so that the HRPP can educate the local study team on the process of using reliance at their site, which likely begins with a local submission.

**UPLOAD PARTICIPATING SITE APPROVALS (RECOMMENDED STUDY MANAGER TASKS)**

The IREx Study Manager can upload site approvals, as can the Reviewing IRB, using the **site approvals** button on the Reviewing IRB or Site-specific IRB Approvals tab (see screenshot). [IREx notifies site HRPP liaison(s) and study teams of approval. They can download approved materials on the Site-specific IRB Approvals tab.]

**ACCESSING AND EDITING INFORMATION**

1. Use **Site-Specific Info** to edit study contacts.
2. Use **Manage Project** to edit sites or study setup.
3. Use **Manage Version** to upload study-wide amendments or continuing reviews. (Site amendments are added on the Site-specific IRB Approvals tab.)