

Using the IRB Reliance Exchange (IREx) as the Reviewing IRB

The IRB Reliance Exchange (“IREx”) was developed by Vanderbilt to support IRBs, Human Research Protection Programs (HRPPs), coordinating centers, and study teams implementing single IRB (sIRB) review for a multisite study. The IREx portal is used to support the reliance process and IREx of information for the *life of a study*—from initial IRB approval to study close.

Reviewing IRBs Use IREx To:

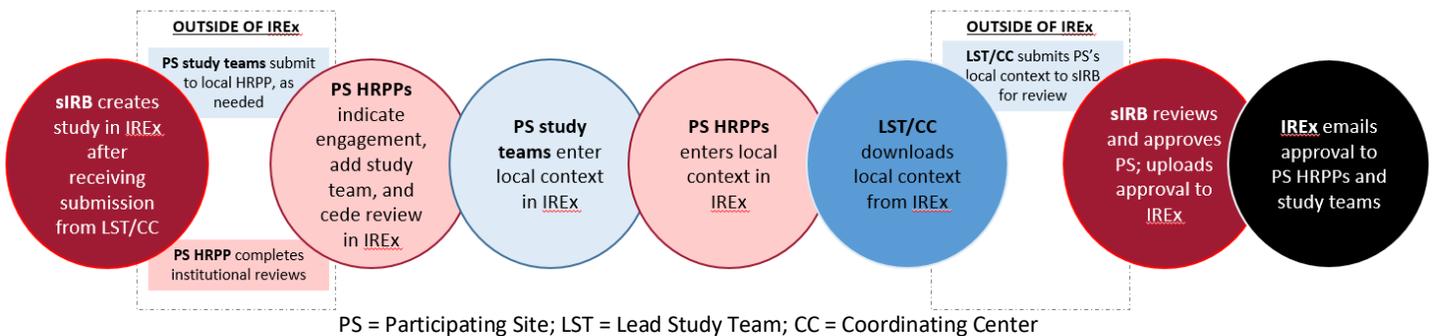
- ✓ Document and track reliance arrangements
- ✓ Track participating site progress towards initial IRB approval
- ✓ Streamline and centralize the capture of participating sites’ local considerations/context
- ✓ Centrally manage participating site approval documents
- ✓ Facilitate communications to participating sites
- ✓ Automate notifications to participating sites

PRIOR TO CREATING A STUDY IN IREx

Prior to Creating a Study in IREx, we recommend completing the following steps:

- IRB agrees to serve as sIRB for study
- sIRB completes their Institutional Profile in IREx
- sIRB prepares instructions for Participating Sites (PS) and educates the Lead Study Team (LST)/Coordinating Center (CC) on their sIRB process (visit the [IREx resources](#) page for sample communications)
- LST/CC disseminates reliance instructions along with the study materials (e.g., protocol, template ICF) to PS study teams
- LST/CC submits study for review to the sIRB's local submission system

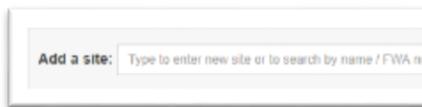
PROCESS OVERVIEW: HOW SIRBS USE IREx TO SUPPORT SIRB REVIEW



SIRB CREATES STUDY IN IREx

From IREx dashboard, click [Create a Study](#)

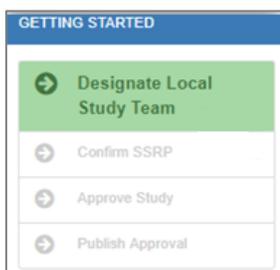
- Enter basic study information like the title, study summary, national clinical trials (NCT) #
- Upload the key study documents, even if draft, such as the **protocol** and **consent form(s)**
- *NEW*** Indicate how the study should be setup, like whether the sIRB is a participating site and **if the sIRB will collect local context from participating sites via IREx**
- Upload a file listing participating sites and their local PIs and enter the names of the participating sites. Participating Site HRPPs can use the contact list to identify their local PI. Sites that are part of another institution’s FWA (component sites) are also listed.
- Enter the participating site names (without abbreviations). The site should appear as you start typing the name. *Note: If a site does not appear, you can type the name and click the green plus symbol to contact information if known. This will prompt IREx Administrator to add the site.*



TIPS:

- ✓ **Required** fields are marked
- ✓ Mark **draft** documents so they can be replaced later
- ✓ Enter the Participating Sites to limit the institutions that can rely on the sIRB. If no sites are listed, any site in IREx can request to rely on the sIRB. Before adding sites, ensure you have the correct site name by referencing the [OHRP FWA website](#) or contacting the site’s HRPP/IRB. IRB contact info is available on the dashboard.

After saving this basic information, a **Getting Started Checklist** and **Status Summary** page are created.



Use the **Getting Started Checklist** to complete the initial study setup:

- Designate the local Study Team** (if applicable) and **Coordinating Center Staff** by entering their name(s) and email addresses. PIs and coordinators can add other study staff to IREx, if needed. *Note: The other information shown on this pop-up can be entered when the study is approved (e.g., IRB #, status, key dates, and final documents).*
- Confirm the SSRP** (study-specific reliance plan). The SSRP is automatically generated from your Institutional Profile, Section 4, and outlines how things like HIPAA, auditing, and external reporting will be handled for a specific study. Participating Sites must accept this plan before they can rely.

NOTE: IREx will automatically email the HRPP/IRB liaisons of sites that have signed IREx Portal Access Form when you confirm the SSRP. This is an FYI notification. Many HRPPs require a local submission before indicating reliance and submitting their local context. Participating sites that have not signed IREx Portal Access Form will not be notified because they do not have access to the system.

Use the **Status Summary** page to track and monitor each site's (1) progress completing the required agreements; (2) cede/reliance decisions; (3) the completion of local context (if being captured in IREx); and (4) each site's approval status.

Note: the Lead Study Team and Coordinating Center also have access to this page after you give them access (see previous step).

Has the site's HRPP made a reliance decision? Before you can review for a site, the Participating Site's HRPP has to indicate they are willing to cede review.

Incomplete = the HRPP has not been contacted by IREx about the study (either because the Reviewing IRB has not completed the SSRP for the study yet or because the site has not signed onto IREx).

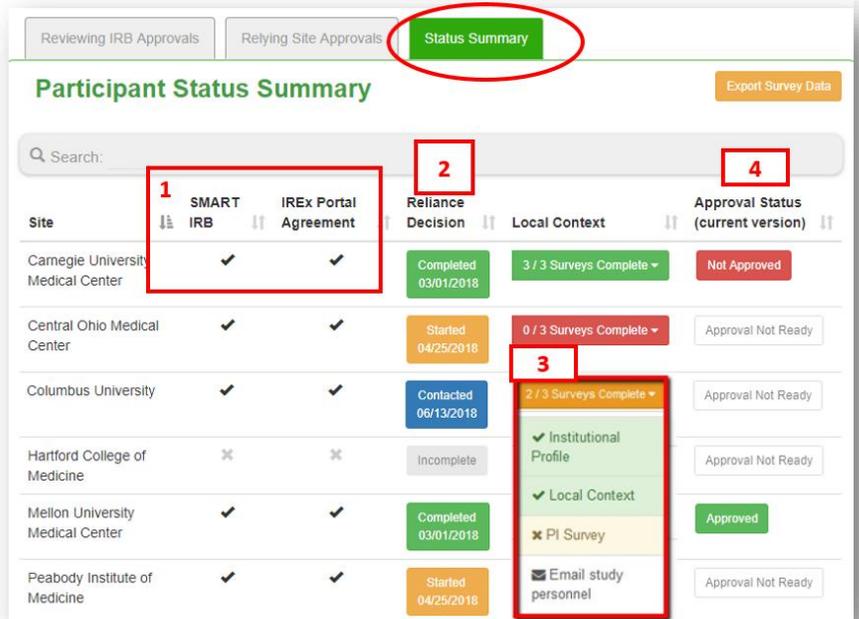
Contacted = date IREx notified the HRPP about the study.

Started = date the HRPP first accessed the study in IREx and started the reliance process.

Complete = date the HRPP ceded review.

***NEW*: EXPORTING LOCAL CONTEXT**

IREx can capture and track the completion of local context information from participating sites. The Lead Study Team (LST) and/or Coordinating Center (CC) are notified when any site completes their local context. The LST/CC can then export the information to be submitted to the sIRB's submission system for review. HRPP staff can also view and export the information, if needed.



SIRB REVIEW AND APPROVAL

The first approval uploaded to IREx is the Lead Site Approval. From the Getting Started Checklist:

- Click **Approve Study** and change the "Status" to Approved. This will highlight all of the required fields.
- Upload the required documents and accept any draft documents, or replace them if they were changed.
- Share the study documents to publish the approval, making it visible to participating sites.

Once the study is approved for a participating site, click on **site approvals** to enter the following:

- o Change the status to "Approved" and indicate the appropriate review type (i.e., Full board or expedited review)
- o Enter key dates for review and approval
- o Upload the site-specific approval documents

Note: IREx will automatically notify the Participating Site HRPP liaison(s) and study personnel of the approval. The approval documents will be available for download on the Relying Site Approvals tab for each site.

AFTER INITIAL IRB REVIEW AND APPROVAL

1. Use the **Site-Specific Info** button to edit your local study team contacts or the coordinating center.
2. Use the **Manage Project** button to do the following:
 - Upload all study-wide modifications or amendments
 - Upload continuing reviews
 - Update the list of participating sites
3. Use the **Manage Version** button to upload study-wide amendments or continuing reviews.

To upload a **site-specific amendment**, go to the Relying Site Approvals tab and click **Site Amendment** next to the name of the participating site to:

- Enter a summary of changes and indicate if documents were changed or removed.
- Under the current amendment, use **Edit review** to upload the approval for the site. The site will be notified of the approval.

Note: if you are the Reviewing IRB and Lead Site, you do not need to upload local amendments for your local site, as those are communicated to your local study team via your local IRB system.

