ABOUT SINGLE IRB REVIEW

Single IRB (sIRB) review requires collaboration between the sIRB and your local IRB/Human Research Protection Program (HRPP).

Human Research Protections involve several components and “IRB Review” is only one. Your institution must communicate other relevant information from its local reviews to the sIRB (see pie chart).

The sIRB can use IREx to document reliance and capture local reviews from your site.

ABOUT IRB RELIANCE EXCHANGE (IREx)

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 and Coordinating Centers, and study teams implementing single IRB review.

TYPICAL STEPS FOR INITIATING SINGLE IRB REVIEW AND USING IREx

After the Lead Study Team/Coordinating Center sends the approved study materials, follow the steps below:

**STEP 1: Submit approved study materials to your local HRPP/IRB.**
Upon receipt of the sIRB-approved materials from the lead study team/coordinating center, contact your local HRPP and prepare your local submission as directed.

**STEP 2: Your HRPP/IRB will give you access to IREx to complete any required steps.**
Once your IRB/HRPP receives your local submission, they will grant you access to IREx. You will receive an email notification from IREx outlining any steps you need to complete in IREx (e.g., add team members, complete the PI Survey).

**STEP 3: Once your site is sIRB approved, IREx will notify you and you can log in to access approved documents.**
Once your site has sIRB approval, you can access IREx to retrieve your site-specific approved study documents.

**Tip:** Your institution may require a local submission of the sIRB approved materials for your own HRPP/IRB’s final sign off.
WHEN DO I GET ACCESS TO IREX FOR A STUDY?

Before you get access to IREx, you will need to communicate with your local HRPP regarding your steps to rely another IRB. Once they have the information they need from you, your HRPP will log in to IREx and give you access to your study. If it’s your first time using IREx, you will receive an email with a temporary password to log in. **Tip:** Log in and change your password using the **Your Profile** link at the top of the screen. Click **Change Password** to set a new password.

CAN I ADD OTHER STUDY TEAM MEMBERS TO MY STUDY IN IREX?

Yes! On the study page, use the **Site-Specific Info** button and select **Study Team Contacts** to give additional study team member access to the study. Each person added will receive an email with a temporary password to log in and a separate email with a link to the study page. **Tip:** Remember to remove study contacts and add new contacts as they change. You may need to report personnel changes to your local HRPP and the sIRB depending on their policies.

HOW DO I COMPLETE THE PI SURVEY IN IREX?

The sIRB may use IREx to collect the information from your HRPP and your site PI regarding your local considerations. If so, the site PI will first click **Add/Edit Study Team** to confirm or add study team contacts not already listed. Next, click **Complete PI Survey** on the GETTING STARTED checklist when the item turns green to complete the PI Survey. If the PI does not see this option, local considerations are being captured outside of IREx. **Tip:** Only PIs have access to complete the PI Survey. Coordinators cannot view or edit the PI Survey in IREx.

HOW DO I TRACK MY SITE’S STATUS TOWARDS sIRB APPROVAL IN IREX?

Study Team members can view their site’s progress towards sIRB approval on the **Status Summary** tab.

HOW DO I DOWNLOAD MY IRB APPROVAL DOCUMENTS IN IREX?

IREx will email the study team and HRPP when your site’s approval has been uploaded to IREx. Log in to download the approval documents from the **Site-specific IRB Approvals** tab.

HAVE A QUESTION FOR YOUR HRPP/IRB?

Your site’s HRPP Liaisons are listed on the IREx website and on the IREx homepage after logging in.