 IREx **IRB Reliance Exchange**
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

HOW RELYING SITE STUDY TEAMS USE A SINGLE IRB AND IREx

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 HRPP reviews to the sIRB (see pie chart).

The sIRB uses IREx to capture reliance and local documentation from your site.

Single IRB Review vs. Local Site Reviews
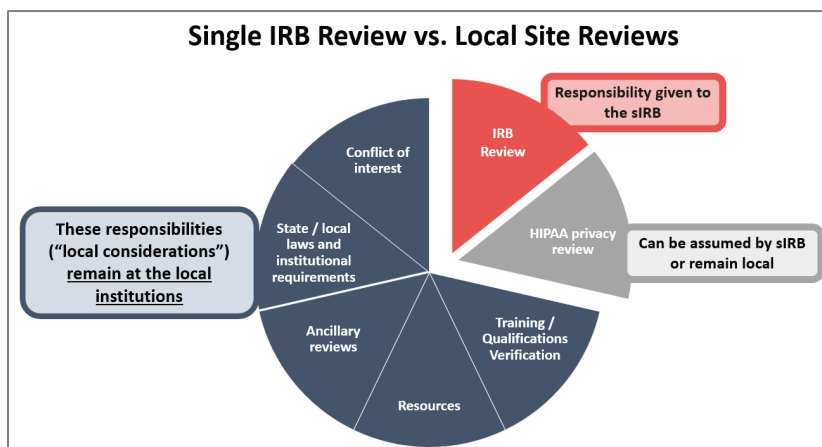
ABOUT IRB RELIANCE EXCHANGE (IREx)

IREx is a freely available web-based portal supporting single IRB documentation and coordination. Vanderbilt developed IREx to support IRBs, HRPPs, Lead Study Team and Coordinating Centers, and study teams implementing single IRB review.

BASIC RELIANCE DOCUMENTATION	ADVANCED RELIANCE DOCUMENTATION	sIRB COORDINATION
• sIRB agreement completion • Study-specific reliance decisions	• Study-specific local considerations from sites • sIRB approval documents for sites	• Communicating with sites • Tracking site readiness for sIRB review • Facilitating site submissions to the sIRB • Disseminating site approvals

TYPICAL STEPS FOR INITIATING SINGLE IRB REVIEW AND USING IREx

STEP 1: Submit approved study materials to your local HRPP/ IRB.
Log into your IREx account and download the approved materials. Then 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 register for the study in IREx and you will be able to complete your local considerations (e.g., complete the PI Survey) in IREx, if applicable. You will receive an email notification when are you able to complete the PI Survey.

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

IREx Tip: Your institution may require sIRB-approved documents be submitted for your HRPP/ IRB's final sign off.

WHEN DO I GET ACCESS TO IREX FOR A STUDY?

PIs and Study Team Members receive IREx access to a study when the Reviewing IRB/sIRB or Lead Study Team/Study Manager grants your site access. PIs and Study Team Members can also get access from anyone at your site who already has study access. If it's your first time using IREx, you will receive an email with a temporary password to log in and able to download the approved materials, if available. 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/REMOVE OTHER STUDY TEAM MEMBERS IN IREX?

Yes! On the study page, click the **My Site Info** button and select **Study Team Contacts.** If available, you can also access this dialog from the **Add/Edit Study Team Access** step on your Getting Started Checklist.

1. Use the **Add a Contact** box to select the type of contact (*PI* or *Study Team Member*) and enter the user's *email address, first name,* and *last name,* click **+Add Contact.**
2. Click **Save** and the user will automatically receive a temporary password to login and another email about study access.
3. Click the **X** for the contact you wish to remove and **Save.** The contact will no longer be able to access the study and will not receive notifications about the study.

    IREx Tip: Remember to keep the Study Team Members up to date as staff changes.

HOW DO I COMPLETE THE PI SURVEY IN IREX?

If the sIRB is using IREx to collect local considerations from your site, a PI Survey is required. Your site HRPP must first register for the study in IREx before you can start the PI Survey.

*   Site investigators and Study Team Members can complete the PI Survey via their **Getting Started Checklist**; however only an investigator can attest to and finalize the PI Survey.
*   Study Team Members can complete and submit the survey on behalf of an investigator by clicking **Start PI Survey** on the checklist. Once submitted, the investigator will receive an email notification that the survey is ready for attestation. Study Team Members can also edit the survey any time, even after it has been attested, and the investigator will be alerted to re-attest to the changes.

    IREx Tip: If two or more FWAs are engaged for a single study (Combo Site), a PI Survey is needed for each FWA. Study Team Members and investigators have the option to copy and edit the responses from the first survey completed to the subsequent PI Surveys.

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** page. If your study is capturing local considerations, you can click the orange button to expand the view and see what surveys need to be completed. If the button is gray, all items are complete. Any actionable steps can be completed from your Getting Started Checklist.

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 **Approvals** page.

HAVE A QUESTION FOR YOUR HRPP/IRB?

Your site's HRPP Liaisons are listed on the IREx Home page after logging in.

Visit the IREx Participating Site Study Team Page for more resources or contact admin@irbexchange.org for help.