

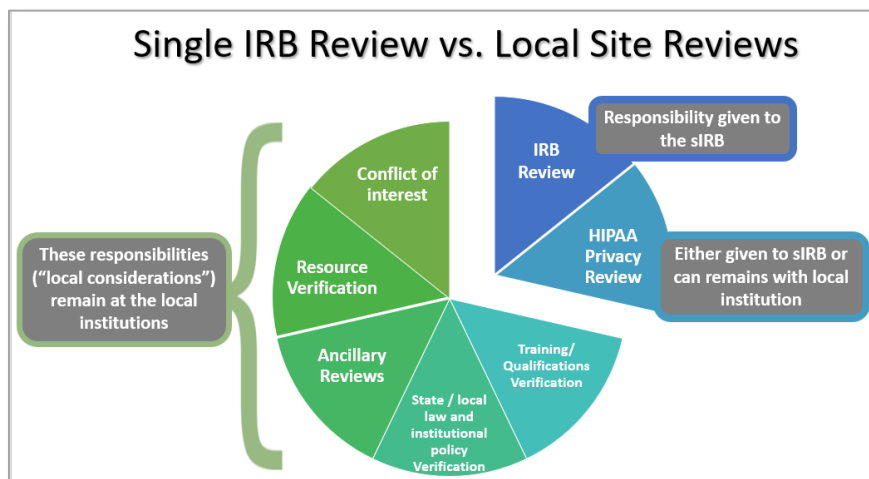
HOW PARTICIPATING SITE STUDY TEAMS USE A SINGLE IRB AND IREx

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.



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

- sIRB agreement completion
- Study-specific reliance decisions

ADVANCED RELIANCE DOCUMENTATION

- Study-specific local considerations from sites
- sIRB approval documents for sites

sIRB COORDINATION

- 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

After you receive 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 outlining your next steps in IREx (e.g., add team members, 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.

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

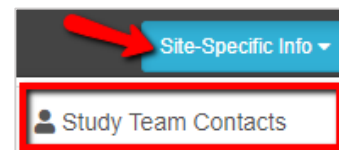
WHEN DO I GET ACCESS TO IREx FOR A STUDY?

Before you get access to IREx, you will need to communicate with your local HRPP regarding your steps to rely on another IRB. Once the HRPP receives your local submission, 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, investigators and coordinators can 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.

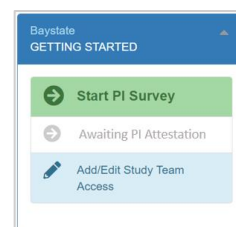
Tip: Remember to remove study contacts and add new contacts as they change. You may need to report personnel changes to your local HRPP and the sIRB depending on their policies.



HOW DO I COMPLETE THE PI SURVEY IN IREX?

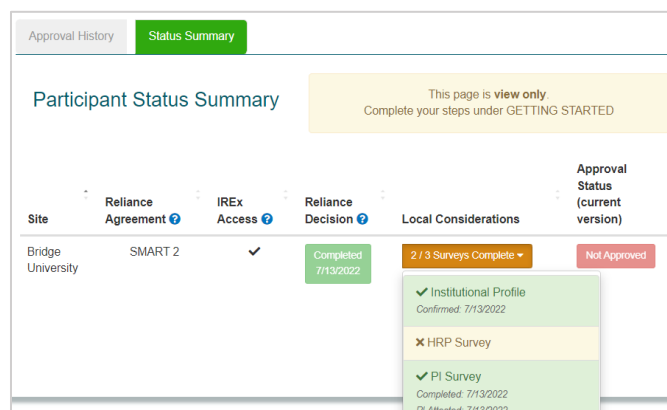
If the sIRB is using IREx to collect local considerations from your site, a PI Survey is required. If it involves written consent, the Study Team uploads the local consent forms with their site-specific language inserted to the PI Survey, **after** it has been verified by their local HRPP. Coordinators and site investigators can complete the PI Survey via their GETTING STARTED checklists; however only an investigator can attest to and finalize the PI Survey. **Note:** If two or more FWAs are engaged for a single study (Combo Site), a PI Survey is needed for each FWA. Coordinators and investigators have the option to copy and edit the responses from the first survey completed to the subsequent PI Surveys.

Tip: Coordinators 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. Coordinators 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.



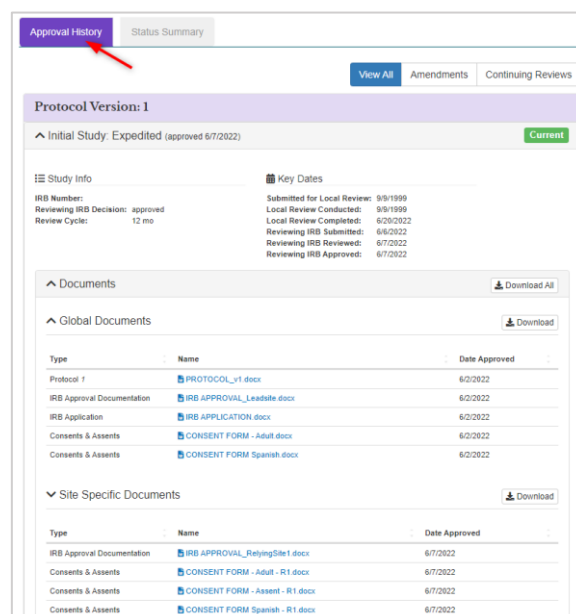
HOW DO I TRACK MY SITE'S STATUS TOWARDS sIRB APPROVAL IN IREX?

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 **Approval History** 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.

