

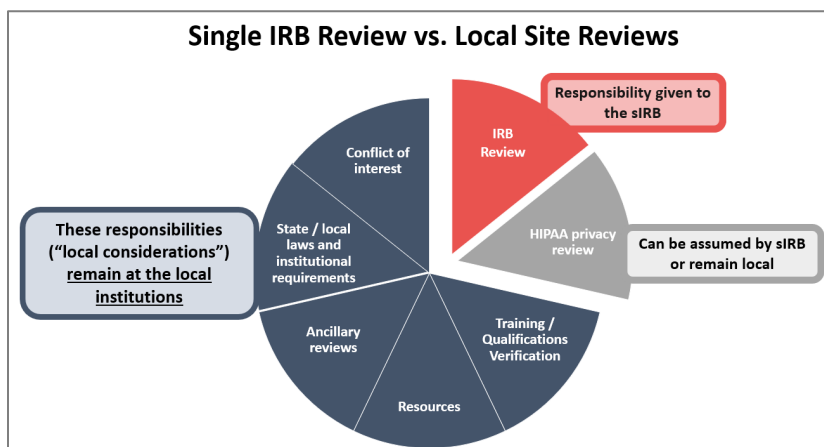
HOW RELYING SITE STUDY TEAMS USE A SINGLE IRB AND IREx

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 blue sections in 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



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 complete any required surveys in IREx.

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 you are 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.

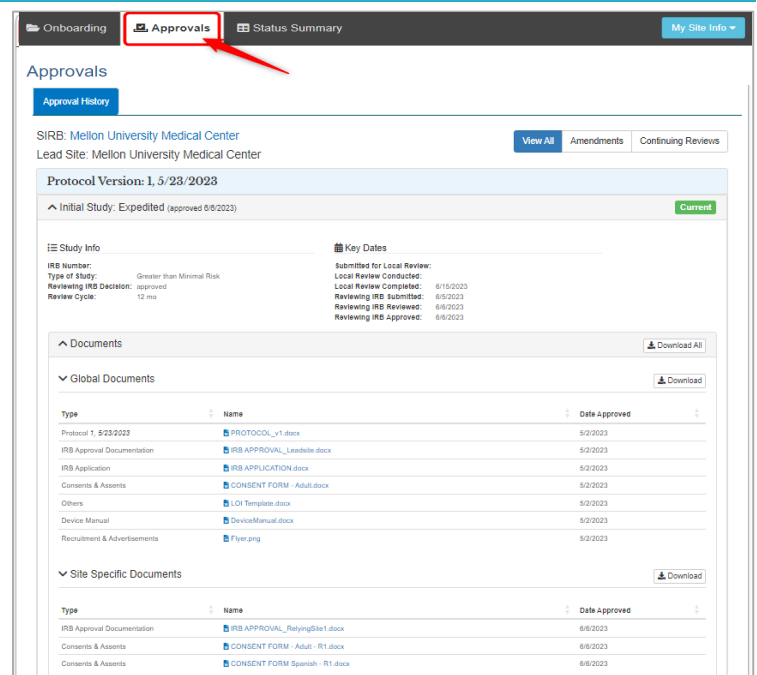
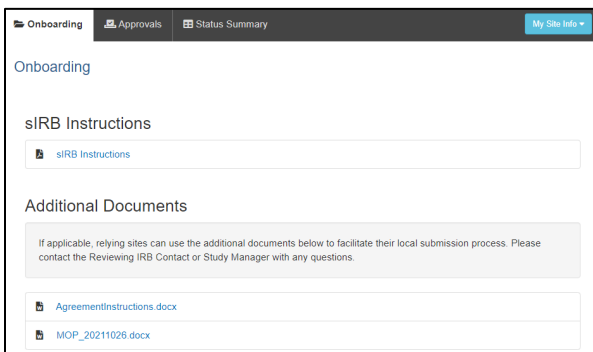
WHEN DO I GET ACCESS TO IREx FOR A STUDY?

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. 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.

HOW DO I DOWNLOAD MY IRB APPROVAL/ONBOARDING 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.

If you need to access the email containing the single IRB instructions, you can find it at any time under the **Onboarding** tab (shown below). Here, you can also find any documents (i.e., Reviewing IRB SOPs, Reviewing IRB Communication Plans, Part 2 Consent Forms) the sIRB or Study Manager has uploaded to assist you in the onboarding process.



IREx Tip: sIRBs and Study Managers upload documents to the **Onboarding** tab as needed. If you don't see any documents there, none have been uploaded.

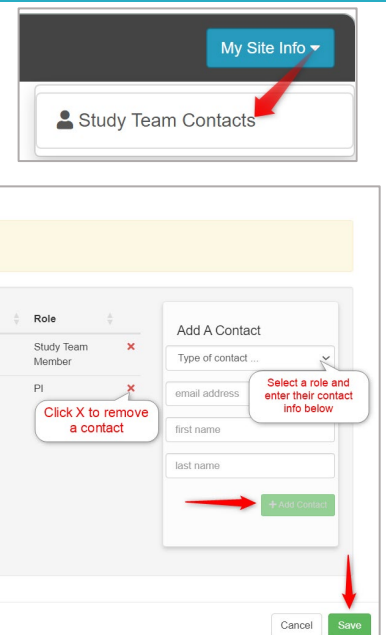
CAN I ADD/REMOVE OTHER STUDY TEAM MEMBERS IN IREx?

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 Tips:

- Remember to keep the Study Team Members up to date as staff changes.
- IREx only allows one email to be associated with one site per study. Ensure the correct staff email address, with the correct site, is added to the study to prevent access issues.



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.
- **Note:** If your site is enrolling patients, you will also need to upload any and all locally approved Informed Consent Forms in the PI Survey. Contact the Study Manager to determine the preferred formatting (i.e., clean [no tracked changes] copy of a Word document).

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.

Baystate
GETTING STARTED

Complete/Attest to PI Survey

Add / Edit Study Team Access

(PI checklist)

Baystate
GETTING STARTED

Start PI Survey for Baystate

Awaiting PI Attestation for Baystate

Add / Edit Study Team Access

Awaiting Reviewing IRB Approval

(Study Team Member checklist)

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 Checklist. As the study team, you are only responsible for completing the PI Survey.

Onboarding Approvals Status Summary My Site Info

Status Summary

Search:

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Carnegie University Medical Center	2 / 2 Agreements Complete	Completed 6/30/2022	2 / 3 Surveys Complete	Not Approved

Local Considerations dropdown:

- ✓ Institutional Profile Confirmed: 6/30/2022
- ✗ HRP Survey
- ✓ PI Survey Completed: 6/30/2022 Updated: 7/14/2022 PI Attested: 7/14/2022
- ✉ Email study personnel

EXCEPTION FROM INFORMED CONSENT (EFIC) PROCESS

Checklist

- ✓ Complete/Attest to PI Survey
- ➔ Awaiting Community Consultation Plan (CCP) Acceptance
- ⏸ Upload/Attest to CCP Summary of Results
- ✎ Add / Edit Study Team Access
- ⏸ Awaiting Reviewing IRB Approval

EFIC studies have a slightly different IREx workflow. PIs or Study Team Members should upload their Community Consultation Plan (CCP) in the PI Survey for the sIRB to review. After completing the PI Survey, study teams will see **Awaiting Community Consultation Plan (CCP) Acceptance** in their Checklist. There is no action to take in IREx at this time.

Once the CCP has been reviewed and accepted by the sIRB, the study team will receive an IREx notification, and the Checklist will change to **Community Consultation Plan (CCP) Accepted**, and the next highlighted step will be **Upload/Attest to CCP Summary of Results**. At this point, the study team may implement their CCP as laid out in the accepted plan.

Once the CCP has been fully implemented and results have been gathered, the study team will return to IREx to upload their CCP Summary of Results for sIRB review.

Checklist

- ✓ Complete/Attest to PI Survey
- ✓ Community Consultation Plan Accepted (CCP)
- ➔ Upload/Attest to CCP Summary of Results
- ✎ Add / Edit Study Team Access
- ⏸ Awaiting Reviewing IRB Approval


Checklist

- ✓ Complete/Attest to PI Survey
- ✓ Community Consultation Plan Accepted (CCP)
- ✓ Upload/Attest to CCP Summary of Results
- Add / Edit Study Team Access
- Awaiting Reviewing IRB Approval

Once the Summary of Results has been uploaded and attested to by the PI, all IREx steps for the Relying Site Study Team are complete, and they are **Awaiting Reviewing IRB Approval**. As with a non-EFIC study, the Study Manager will upload the Relying Site’s sIRB approval to IREx, and the study will receive an IREx notification via email. From this point forward, the study proceeds as a non-EFIC study would.

HAVE A QUESTION FOR YOUR HRPP/IRB?

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

 Your Liaisons

Jane Austen	555-202-3581
Anna Bates	555-258-7965
John Smith	555-202-0819

Visit the [IREx Relying Site Study Team Page](#) for more resources or contact admin@irbexchange.org for help.