IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

STEPS FOR USING IREx AS THE REVIEWING/ SINGLE IRB

IREx can be used to capture all single IRB (sIRB) documentation (e.g., cede decisions, local considerations, sIRB approvals) and coordinate communications between the sIRB and site study teams and HRPPs. See how to get started below.

PRIOR TO CREATING A STUDY IN IREX

- ❑ COMPLETE or update your institution's IREx Institutional Profile (see quick guide).
- ❑ EDUCATE the lead study team or coordinating center staff ("IREx Study Manager") on your sIRB processes, like:
  - Required sIRB-related agreements
  - Process for managing consent forms (e.g., whether a template is being used)
  - Process for capturing local considerations from sites (e.g., via IREx surveys)
  - Process for submitting sites for review (e.g., as an amendment, as a site add)
- ❑ PREPARE reliance instructions for participating sites (see IREx Reliance Instructions Template).
  Tip: We recommend the Study Manager disseminate the instructions to site study teams after the lead site is approved. Learn more about the Study Manager here.

STEP 1: CREATE THE STUDY IN IREX

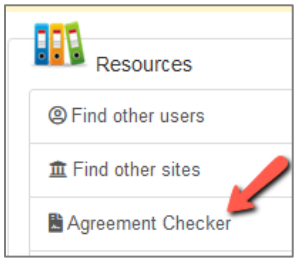
Studies are typically created after you receive the submission from the lead site. You do not have to wait for the overall study to be approved before creating the study in IREx.

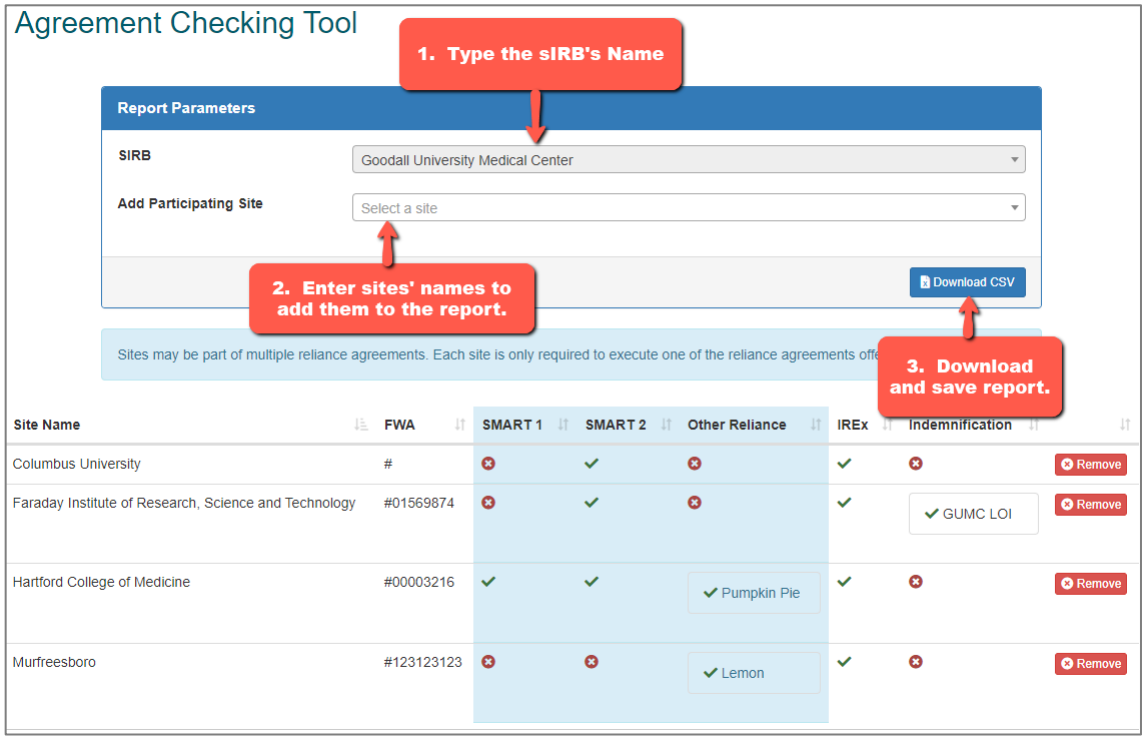
- ❑ Login to IREx and click **Create a Study** on the main homepage.
- ❑ Enter basic study information like the title, study summary, NCT #, sponsor and click **Continue**.
- ❑ Enter the protocol date/ version and upload key study documents (e.g., protocol). Tip: Document(s) uploaded here can be changed later when uploading the initial study approval.

After saving the information, you will see a GETTING STARTED checklist listing your remaining steps to setup the study.

Tip: You can use the Agreement Checker within IREx to check on the status of required agreements for participating sites:

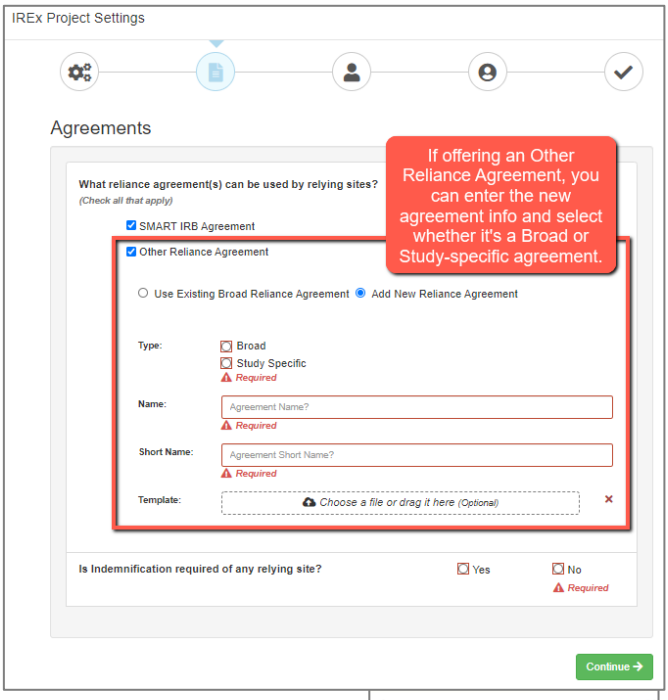
- ❑ From the IREx Homepage **Resources**, click Agreement Checker and follow steps 1, 2, and 3 in the below screenshot.





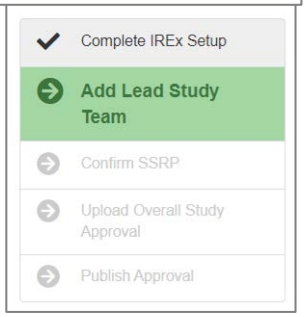
STEP 2: COMPLETE THE IREX SETUP

- ❑ Click **Complete IREx Setup** on the GETTING STARTED checklist.
- ❑ Identify the lead site and indicate if you are using IREx to capture local considerations.
- ❑ Indicate the agreement(s) required to support reliance for the study.
  - Reliance Agreement(s): The Reviewing IRB can offer SMART IRB and/or Other Reliance Agreements ("ORA"), such as IAAs or MOUs. Sites that have signed onto SMART IRB default to that agreement when it is offered. In the IREx Setup, indicate the agreements offered; site sign on is tracked on the Status Summary (see Step 7). Learn more.
  - Indemnification Agreements: Given that SMART IRB is silent on indemnification, Reviewing IRBs can require a separate Indemnification Agreement before sites can rely on a study. Indemnification Agreements can be study-specific or broad, applying to any study.
- ❑ Identify the IREx Study Manager (e.g., lead study team or coordinating center staff supporting the study [learn more]).
- ❑ Identify a Reviewing IRB Primary Liaison for the study and others who need to receive study notifications. All Reviewing IRB Liaisons can access the study and perform all functions.



STEP 3: ADD LEAD STUDY TEAM CONTACTS (IF SIRB IS THE LEAD SITE)

If the lead site is also at the Reviewing IRB institution, the checklist will include a step to provide the name and email address for the PI (required) and study coordinator. If the lead site is at another institution, that HRPP will add the study team contacts for their site when they register for the study.



STEP 4: CONFIRM THE STUDY-SPECIFIC RELIANCE PLAN (SSRP)

The SSRP is automatically generated from your Institutional Profile (section 4) and outlines how the flexible elements of reliance will be handled. The Reviewing IRB can edit the SSRP for the study (all sites) or individual sites (see Step 8). Site HRPPs indicate reliance by accepting the SSRP.

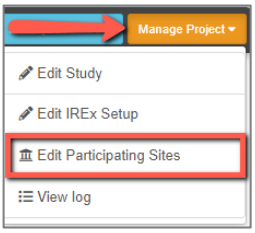
Tip: Sites using an Other Reliance Agreement indicate reliance, but do not accept an SSRP because it is specific to the SMART IRB Agreement.

STEP 5: UPLOAD INITIAL APPROVAL FOR THE OVERALL STUDY/ LEAD SITE

- ❑ Select **Upload Overall Study Approval** on the GETTING STARTED checklist.
- ❑ Change the study status to **Approved** and enter the required review information (dates, level of review).
- ❑ **Upload Documents** that were approved. The required fields will be indicated.
- ❑ Under **Uploaded Documents,** for the protocol, select **Accept Draft** if the original protocol was approved or **Replace Draft** it if it was modified during the review. Tip: If the protocol was updated, be sure to change the version or date before uploading the new protocol. Replace other draft documents uploaded when the study was created, as needed.
- ❑ Publish Approval (doing so makes approved global documents visible to the participating sites)

STEP 6: UTILIZE YOUR STUDY MANAGER TO MANAGE SITES AND APPROVALS ON THE STUDY

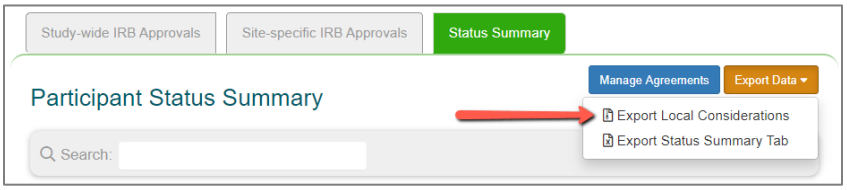
To help reduce the sIRB burden, IREx recommends delegating the tasks below to the IREx Study Manager (Quick Guide). However, the Reviewing IRB can also complete these tasks in IREx, if needed, as shown below:



- Add Participating Sites: Select **Manage Project** > **Edit Participating Sites**. Adding sites to the study allows you to see whether they have completed your required agreements and whether they have access to IREx. Sites added do not receive access to the study until they have been notified (see next step below).

- Notify Sites of the Study: After adding sites and uploading the initial approval, alert sites that the study is in IREx from the Status Summary tab using the **Notify HRPP** button. The PI name and email are required to notify site(s). Tip: The Lead Study Team or Coordinating Center should disseminate the initial approval materials (protocol, consents, etc.) by email to the sites. Participating site study teams use this to prepare their local submission, which is typically required before a site HRPP will login to IREx to indicate reliance and document local considerations.

- Export Local Considerations: When notified that a site has completed their local considerations, the information can be downloaded from the Status Summary tab using the **Export Survey Data** menu.

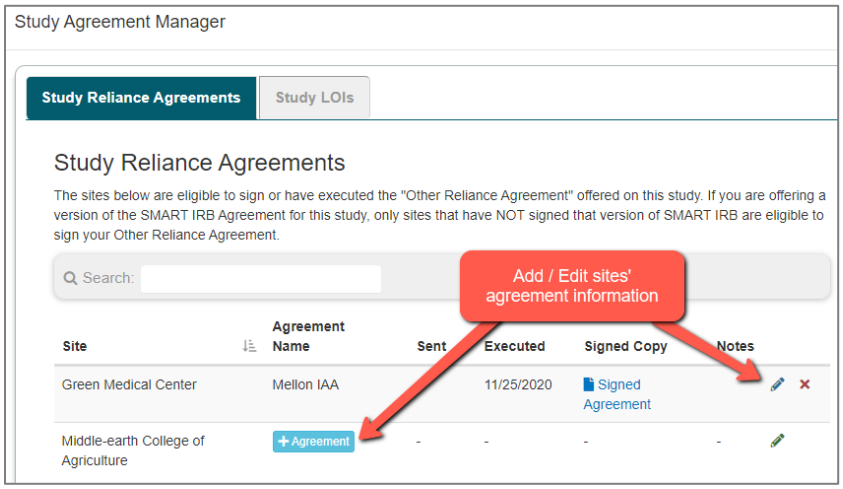


- Upload sIRB Site Approval Letter: Site approvals are uploaded using the yellow **Site Approvals** banner on the Study-wide IRB or Site-specific IRB Approvals tabs. Tip: IREx notifies the site HRPP Liaison(s) and study teams of approval.

- Manage Versions: Upload study-wide amendments and continuing reviews using the Manage Versions button on the Study-wide IRB Approvals tab. Study Managers can add site amendments from the Site-specific IRB Approvals tab.

STEP 7: TRACK SITES' AGREEMENTS

The Reviewing IRB tracks and logs required institutional reliance and indemnification agreements from participating sites on the Status Summary tab using the **Manage Agreements** button – which is only accessible to Reviewing IRB Liaisons.

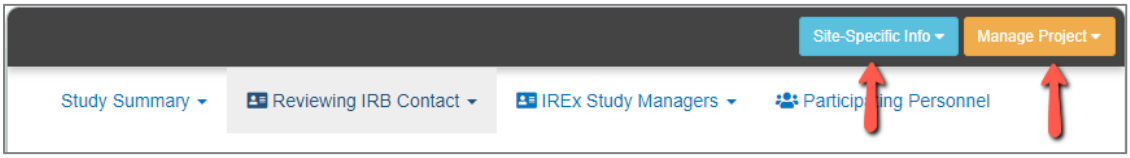


Institutions that sign the SMART IRB Agreement are tracked and updated by IREx Administrators.

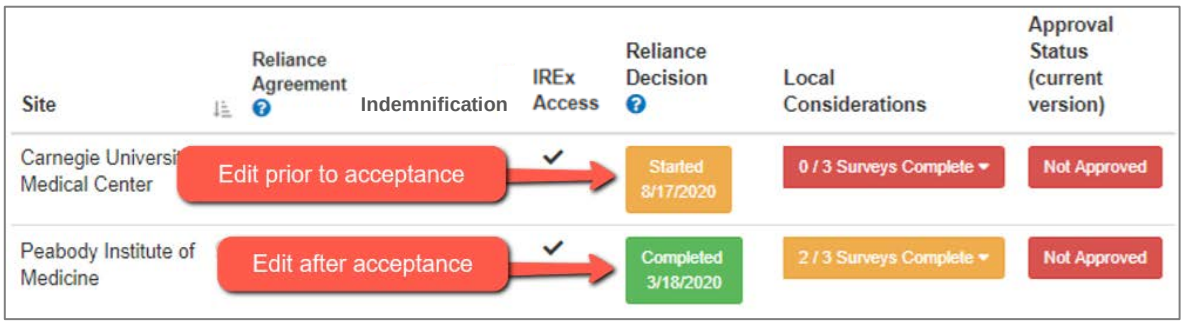
The Reviewing IRB can indicate a site will be signing an institutional reliance agreement and/or indemnification agreement before it is executed. Once executed, a copy of the executed agreement(s) can be uploaded, but only the **Date Executed** is required to indicate completion.

STEP 8: MANAGING AND EDITING INFORMATION

- ❑ Use **Site-Specific Info** to edit Lead Study Team contacts.
- ❑ Use **Manage Project** to edit sites or the IREx Setup (Step 2 above).



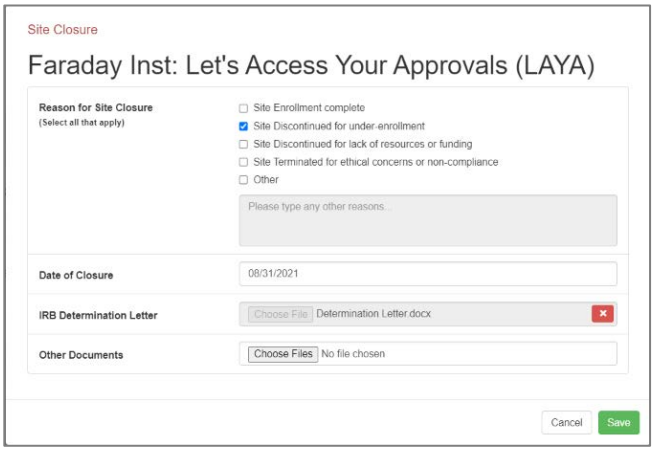
- ❑ Edit a Site's SSRP (Quick Guide):
  - Before a site has accepted the SSRP: From the Status Summary tab, click on the "Started" Reliance Decision (the site has registered for the study). After making and submitting the edits, IREx notifies the site that changes were made. SSRPs cannot be edited for sites whose status is "Contacted".
  - After a site has accepted the SSRP: Click on the "Completed" Reliance Decision for the site and use the **Reset SSRP** button to make changes. The changes made will be detailed in an email to the site, and the Reviewing IRB and Relying Site will receive an updated SSRP via email after it is accepted. The Reliance Decision Status will be listed as "Updated".



STEP 9: DOCUMENTING A SITE CLOSURE, AS APPLICABLE (sIRB or Study Manager)

IREx can be used to document and communicate site closure(s), when appropriate. Closing a site ensures that only active sites retain access to ongoing studies. Follow the steps below to close a study:

- ❑ Navigate to the **Site-specific IRB Approvals** tab on the study page, and click **Add Site Closure** for the site you need to close.
- ❑ In the **Site Closure** dialog, complete all required information and upload necessary documents.
- ❑ Click **Save**.
- ❑ Once you click **Save**, a confirmation screen will appear. Click **OK** to complete the site closure.



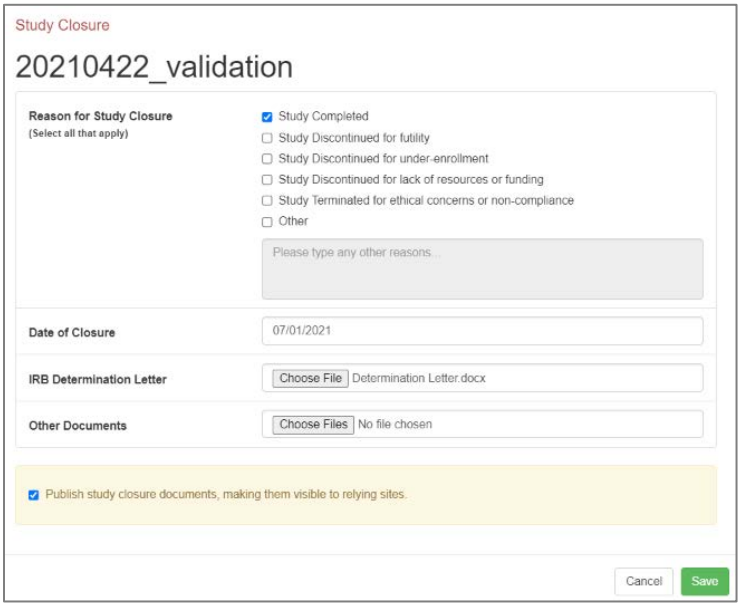
Next, a notification is sent to the closed site's liaisons and study contacts. The closed site will have 30 days to access the closure information. After 30 days, the site will no longer have access to the study in IREx.

See our Site Closure Quick Guide here for further instructions.

STEP 10: DOCUMENTING STUDY CLOSURE (sIRB or Study Manager)

IREx can be used to document and communicate study closure, when appropriate. Closing a study ensures all sites are aware that the study ended, but retains a record of the reliance and a history of sIRB site approvals. Follow the steps below to close a study:

- ❑ Navigate to the **Manage Version** box on the study page, and click **Add Study Closure.**
- ❑ In the **Study Closure** dialog, complete all required information and upload necessary documents.
- ❑ Check the box to **Publish study closure** to immediately notify sites, or press save to finalize the Study Closure at a later time.



Next, a notification is sent to each site (individually) that the study was closed. Sites retain access to the study closure, and a history of past approvals (dates) remains available. However, outside of the study closure documents, no past approval documents can be downloaded.

See our Study Closure Quick Guide here for further instructions.