

## WHAT RELIANCE AGREEMENTS DOES IREx SUPPORT?

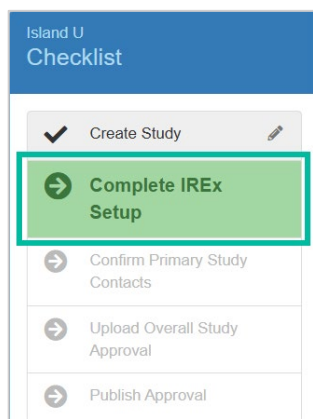
IREx can be used to support the use of any reliance agreement on a study. While we encourage use of the SMART IRB Agreement, IREx can also be used with other reliance agreements (e.g., IAAs, MOUs), for sites that are unable to join SMART IRB. IREx can also be used to track whether sites have executed an indemnification agreement.

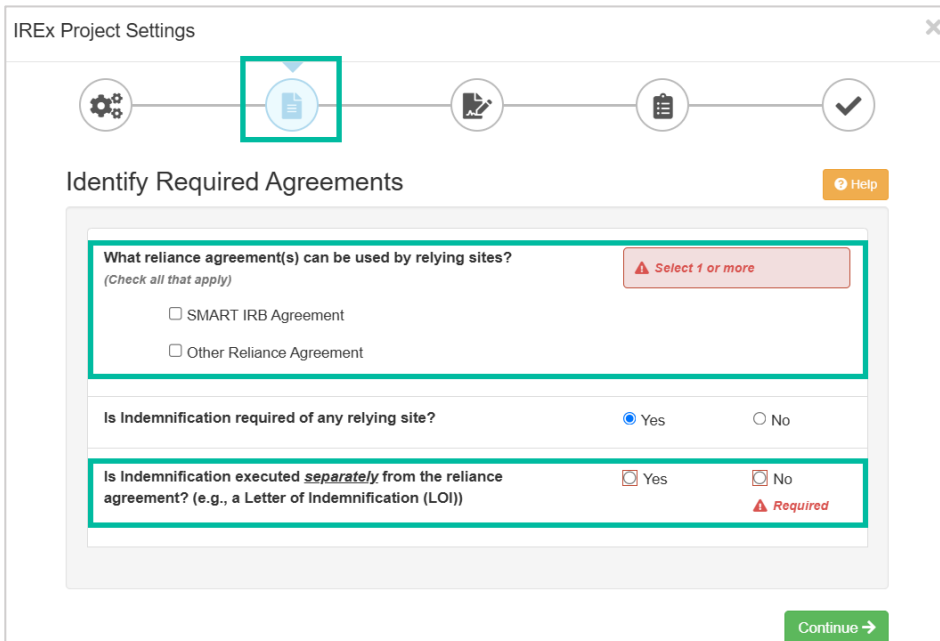
<div style="font-size: 48px; color: #009688; border-radius: 50%; width: 60px; height: 60px; margin: 0 auto; display: flex; align-items: center; justify-content: center;">1</div> <p><b>SMART IRB Agreement</b>  <b>Version 3.0</b> (studies created on/after March 17, 2025)  <b>Versions 1 and 2</b> (reliance established prior to March 17, 2025)</p>	<div style="font-size: 48px; color: #4caf50; border-radius: 50%; width: 60px; height: 60px; margin: 0 auto; display: flex; align-items: center; justify-content: center;">2</div> <p><b>Other Reliance Agreement</b>          (e.g., IAAs, MOUs) for sites who are unable to sign on to SMART IRB</p>	<div style="font-size: 48px; color: #4caf50; border-radius: 50%; width: 60px; height: 60px; margin: 0 auto; display: flex; align-items: center; justify-content: center;">3</div> <p><b>Indemnification Agreements or Letters of Indemnification (LOI), if required <u>in addition to</u> the reliance agreement</b></p>
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*Note: Reliance and Indemnification Agreements can be study specific or broad (applying to multiple studies).*

## CAN A REVIEWING IRB OFFER MULTIPLE AGREEMENTS ON A SINGLE STUDY?

Yes! The Reviewing IRB can offer the SMART IRB Agreement, another reliance agreement, and indemnification on the same study. This information is captured in the **Complete IREx Setup** step of the Reviewing IRB's Checklist.



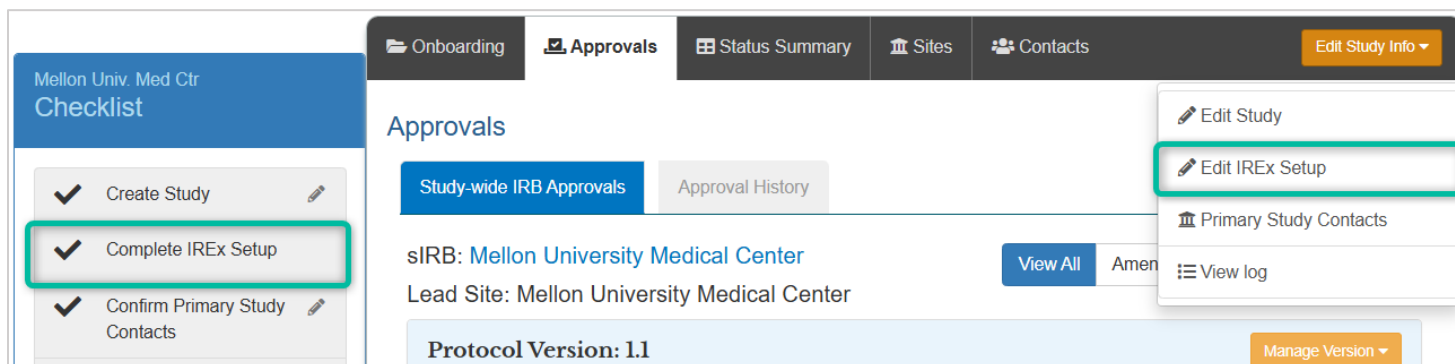


### If multiple reliance agreements are offered on a study:

- **SMART IRB is the default, if signed.** If SMART IRB and another reliance agreement are offered on the same study, sites in SMART IRB will default to that agreement for the study.
- Joining SMART IRB does not override prior studies where a Relying Institution used an institutional reliance agreement.

## CAN REVIEWING IRBS OFFER AN ADDITIONAL RELIANCE AGREEMENT ON AN EXISTING STUDY?

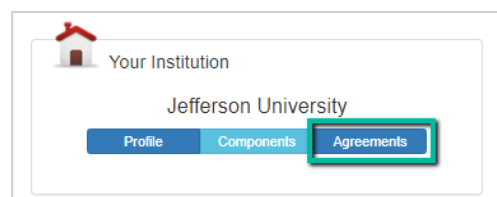
Yes, agreements can be added at any time to facilitate reliance with new sites or for sites that are unable to execute the SMART IRB Agreement. To add an agreement to existing study in IREx, access the **IREx Setup** dialog from the Checklist or the **Edit Study Info** menu.



## HOW ARE AGREEMENTS EXECUTED AND TRACKED IN IREx?



Sites' SMART IRB status is updated in IREx based on the SMART IRB website [Participating Institution list](#). For all other agreements, **the Reviewing IRB indicates which sites have executed their institutional agreements.**

Using the IREx homepage **Agreements** button, a Reviewing IRB can quickly indicate when a site on a study has executed a reliance or indemnification agreement. The date the agreement was **sent** and **executed** can be included, as well as **notes** and a **copy of the executed agreement**, if desired.



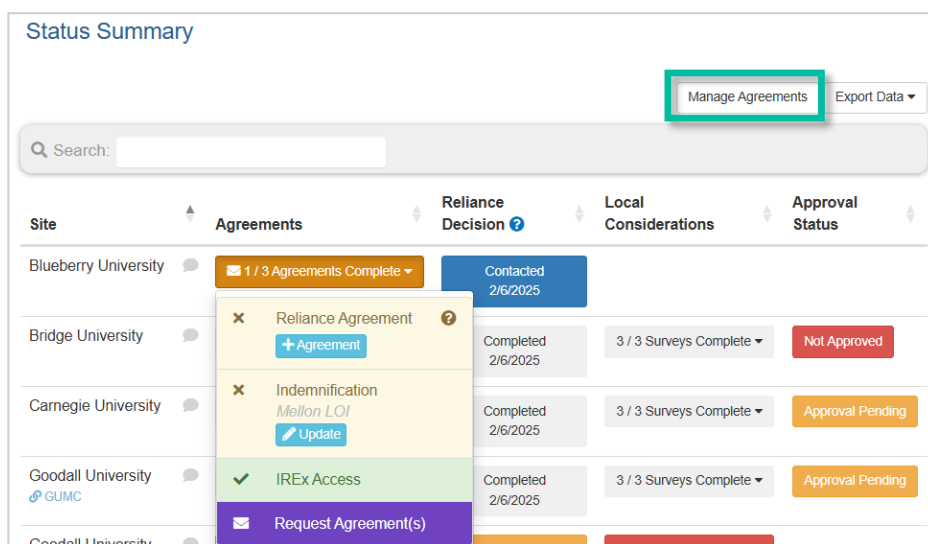
Reviewing IRBs can also view and update site's agreement statuses from a study's **Status Summary Tab**.

1. Sites with incomplete agreements will have an orange Agreements Complete dropdown on the **Agreements** column. View the reliance agreements offered by hovering over the **?** icon.
2. Agreement Status:

- a. A green check  indicates an agreement is executed/complete.
- b. A brown x  indicates incomplete agreements/the site has not executed the agreement.

- c. The **+ Agreement** button can be used to open the **Study Agreement Manager** (use the **Study Agreement Manager** to mark the agreement as executed; more information in Step 3 on the following page).

- d. The **Update** button to make edits to a site's agreement.



3. The **Study Agreement Manager** can also be opened by clicking the **Manage Agreements** button on the **Status Summary Tab**. To indicate an agreement has been executed:
- Click **+ Agreement** for the site.
  - Enter the **Date Executed** and any other information. (*The Date Executed is all that's needed to mark the Agreement as Complete.*)
  - Click **Save**.

**Tip:** The Reviewing IRB and/or Study Manager can notify sites about the agreement(s) offered on the study in the *Agreement Instructions* and *Single IRB Instructions* sent from IREx. See our template [here](#) (IREx will generate study and site details). View Step 3 and Step 6, b. in this [quick guide](#) on how to notify sites.

## CAN THE INDEMNIFICATION AGREEMENT BE REQUIRED FOR A LIMITED NUMBER OF SITES?

Yes. The Reviewing IRB can indicate in the IREx Setup if it requires a separate indemnification agreement from any site on the study. If a site(s) does not have to complete indemnification (e.g., because it is a state institution), the Reviewing IRB can indicate the site is not required to complete the indemnification agreement for that study using the **Manage Agreements** button on the **Status Summary Tab**. The site's indemnification status will then appear as 'not required' on the Status Summary Tab.

**Status Summary**

Manage Agreements Export Data

Search:

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Blueberry University	2 / 3 Agreements Complete	Completed		
Bridge University	✓ Reliance Agreement SMART 3			
Carnegie University	✗ Indemnification Mellon LOI			
Goodall University	✓ IREx Access	Completed 2/6/2025	3 / 3 Surveys Complete	Approval Pending

**Reviewing IRBs can edit a site's indemnification status by using the Update button or accessing the Manage Agreements dialog**

**Indicate the site is allowed to rely without the indemnification**

**Mellon Letter of Indemnification**

Site: Blueberry University

Signed Copy: Choose File No file chosen

Date Sent: mm/dd/yyyy

Date Executed: mm/dd/yyyy

Notes:

☐ This site is restricting the broad Reliance Agreement to this study only.

☒ Allow reliance on this study without indemnification

Cancel Save

## HOW DO RELYING SITE HRPPS KNOW WHAT AGREEMENTS ARE REQUIRED ON A STUDY?

Required Agreements

Reliance Agreements

- Your site has signed the SMART IRB V3 Agreement

Indemnification

- Your institution must sign Mellon University Medical Center's "Mellon Letter of Indemnification" before you can indicate reliance.
- Please send your executed indemnification and/or questions to [Mellon Liaison \(liaison@mellon.cdu\)](mailto:liaison@mellon.cdu), unless otherwise indicated.
- Your indemnification status will be updated by the sIRB once received.

OK

- Relying Institutions can view the agreement(s) required for a study on the **Complete Agreements** step in their Checklist.
- Relying Institutions are unable to indicate reliance until **the Reviewing IRB indicates the site's agreements are executed.**
- Relying Institutions send executed agreements (other than SMART IRB) to the Reviewing IRB to document in IREx.
- Relying Institutions are not able to indicate their site has executed an agreement in IREx.
- Relying Institutions can complete local considerations (e.g., HRP Survey and PI Survey) before agreements are executed.

## HOW DO RELYING SITE HRPPS INDICATE RELIANCE?

When using the SMART IRB Agreement on a study, reliance is indicated by accepting the Study-Specific Reliance Plan (SSRP). When *not* using the SMART IRB Agreement, the Relying Institution HRPP Liaison clicks **Indicate Reliance** on their Checklist; then clicks **Rely**. The Relying Institution should not take this step until they are ready to indicate reliance on the sIRB.

➔ Indicate Reliance

Reliance

Study	Manage Agreements_20250530
Relying Site	Blueberry University
Agreement	Island MOU

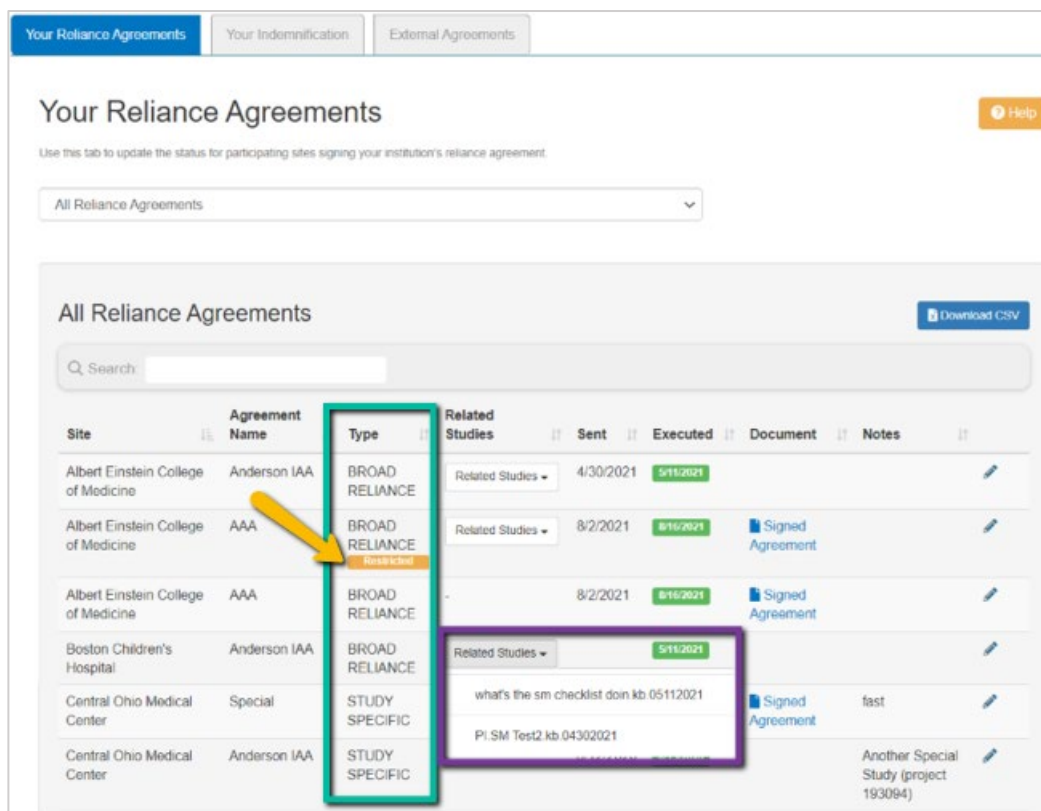
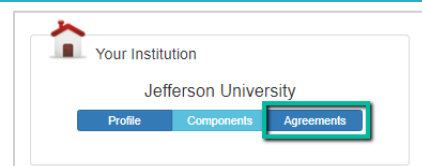
By clicking "rely", you affirm that your institution is participating in this study using the agreement listed. A confirmation email will be sent to you and the Reviewing IRB. If you are not ready to indicate reliance you may close this window.

Cancel

Rely

## CAN I SEE ALL THE SITES THAT HAVE SIGNED MY AGREEMENTS?

Yes. You can see all the sites that have signed your site's agreements on the Agreements Dashboard. Access the Agreements Dashboard by clicking **Agreements** on the IREx homepage.



If your institution has existing reliance agreements, you will land on the **Your Reliance Agreements** tab. If your institution has only used Indemnification Agreements, you will land on the **Your Indemnification** tab.

In the tab, you can view the following:

- **Agreement Type**, which will be either Broad or Study-Specific.
  - Broad agreements can be used for multiple studies between institutions.
    - Broad agreements can also be **restricted** to a single study.
  - Study-specific agreements apply only to the study on which they are used.
- For all broad agreements, the **Related Studies** column lists all the studies on which a site is using that agreement.
- Date the agreement was **Sent**
- Date **Executed**
- Signed copy of the agreement **Document**
- **Notes** entered about the agreement.
- Use the pencil icon to edit the date sent, date executed, upload a copy of the signed agreement, and any notes.
- Above the Search bar, you will see a blue '**Download CSV**' button. At any time, you can download a CSV of all the information available in the Agreements Tab.