

WHAT RELIANCE AGREEMENTS DOES IREx SUPPORT?

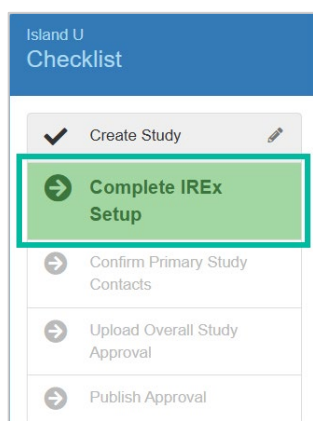
IREx can be used to support the use of any reliance agreement on a study. While we encourage use of the SMART IRB Agreement, IREx can also be used with other reliance agreements (e.g., IAAs, MOUs), for sites that are unable to join SMART IRB. IREx can also be used to track whether sites have executed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

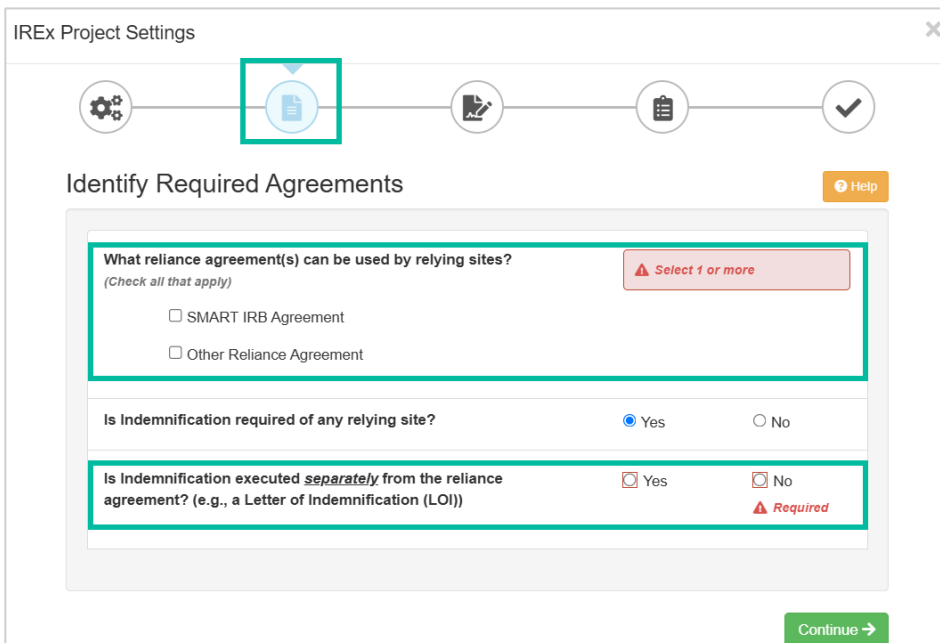
<div style="font-size: 48px; color: #0070c0; border-radius: 50%; width: 60px; height: 60px; margin: 0 auto; display: flex; align-items: center; justify-content: center;">1</div> <p>SMART IRB Agreement Version 3.0 (studies created on/after March 17, 2025) Versions 1 and 2 (reliance established prior to March 17, 2025)</p>	<div style="font-size: 48px; color: #0070c0; border-radius: 50%; width: 60px; height: 60px; margin: 0 auto; display: flex; align-items: center; justify-content: center;">2</div> <p>Other Reliance Agreement (e.g., IAAs, MOUs) for sites who are unable to sign on to SMART IRB</p>	<div style="font-size: 48px; color: #0070c0; border-radius: 50%; width: 60px; height: 60px; margin: 0 auto; display: flex; align-items: center; justify-content: center;">3</div> <p>Indemnification Agreements or Letters of Indemnification (LOI), if required <u>in addition to</u> the reliance agreement</p>
---	---	--

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.



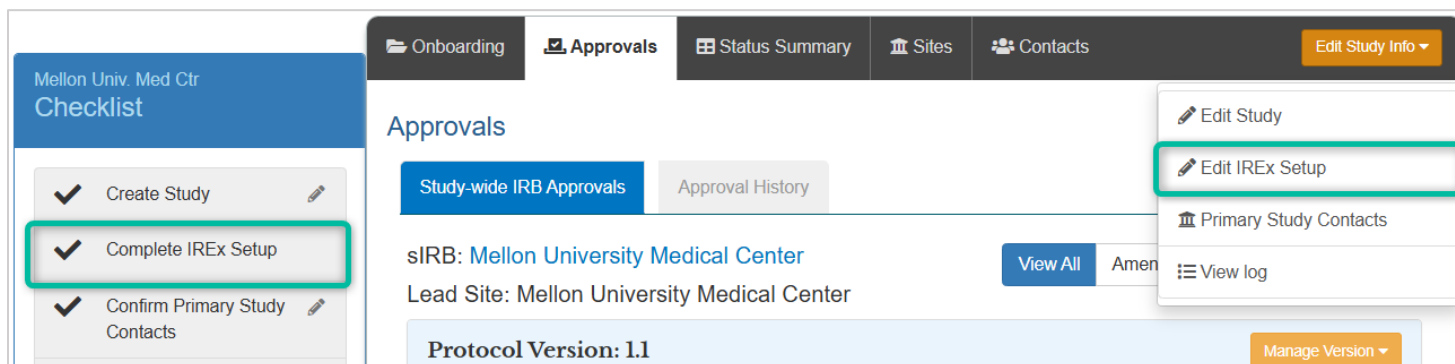


If multiple reliance agreements are offered on a study:

- **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?

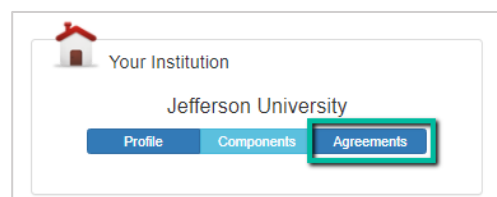
Yes, agreements can be added at any time to facilitate reliance with new sites or for sites that are unable to execute the SMART IRB Agreement. To add an agreement to existing study in IREx, access the **IREx Setup** dialog from the Checklist or the **Edit Study Info** menu.



HOW ARE AGREEMENTS EXECUTED AND TRACKED IN IREx?

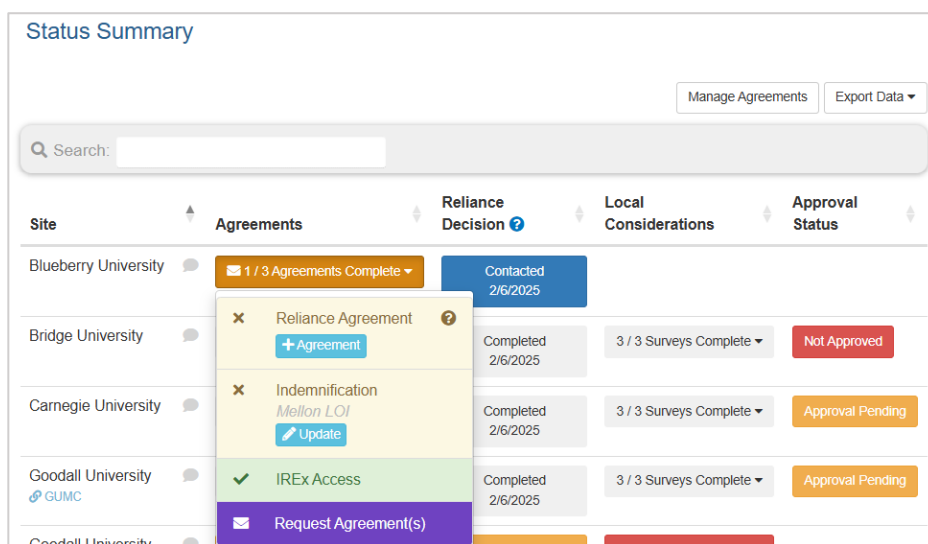
Sites' SMART IRB status is updated in IREx based on the SMART IRB website [Participating Institution list](#). For all other agreements, **the Reviewing IRB indicates which sites have executed their institutional agreements.**

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 button appears if multiple agreements are offered on a study (e.g., SMART and an IAA) and neither is executed. To indicate an institutional reliance agreement (e.g., IAA) will be used instead of SMART IRB, click the button for the site and prior to execution. Use the button to make edits to a site's agreement.



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.

The screenshot shows the **Status Summary** tab with a table of sites. The **Agreements** column shows the status for each site. A callout box points to the **Update** button in the **Indemnification** row for Carnegie University, stating: "Reviewing IRBs can edit a site's indemnification status by using the Update button or accessing the Manage Agreements dialog".

The **Mellon Letter of Indemnification** dialog box is shown on the right. It has a **Site** dropdown set to **Blueberry University**. The **Signed Copy** section has a **Choose File** button. The **Date Sent** field is set to **mm/dd/yyyy**. The **Date Executed** field is empty. The **Notes** field is empty. There is a checkbox labeled **This site is restricting**. At the bottom, there is a button labeled **Allow reliance on this study without indemnification**, and **Cancel** and **Save** buttons. A callout box points to the **Allow reliance on this study without indemnification** button, stating: "Indicate the site is allowed to rely without the indemnification".

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

The **Required Agreements** dialog box shows two sections:

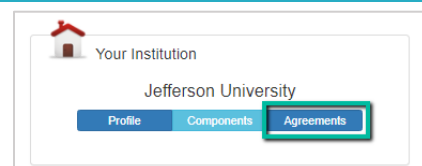
- Reliance Agreements** (green background):
 - Your site has signed the **SMART IRB V3 Agreement** ✓
- Indemnification** (red background):
 - Your institution must sign Mellon University Medical Center's **"Mellon Letter of Indemnification"** before you can indicate reliance. ✗
 - Please send your executed indemnification and/or questions to **Mellon Liaison** (liaison@mellon.cdu), unless otherwise indicated.
 - Your indemnification status will be updated by the sIRB once received.

An **OK** button is at the bottom right.

- 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.

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.



Your Reliance Agreements

Use this tab to update the status for participating sites signing your institution's reliance agreement.

All Reliance Agreements

Download CSV

Search:

Site	Agreement Name	Type	Related Studies	Sent	Executed	Document	Notes
Albert Einstein College of Medicine	Anderson IAA	BROAD RELIANCE	Related Studies	4/30/2021	5/15/2021		
Albert Einstein College of Medicine	AAA	BROAD RELIANCE	Related Studies	8/2/2021	8/16/2021	Signed Agreement	
Albert Einstein College of Medicine	AAA	BROAD RELIANCE		8/2/2021	8/16/2021	Signed Agreement	
Boston Children's Hospital	Anderson IAA	BROAD RELIANCE	Related Studies		5/15/2021		
Central Ohio Medical Center	Special	STUDY SPECIFIC	what's the sm checklist doi kb 05112021 Pl:SM Test2 kb 04302021			Signed Agreement	fast
Central Ohio Medical Center	Anderson IAA	STUDY SPECIFIC					Another Special Study (project 193094)

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.