



USING IREx TO TRACK INDEMNIFICATION

Some institutions require indemnification when serving as the Reviewing IRB. Indemnification could be part of a reliance agreement used on a study, or it could be a separate document. IREx allows Reviewing IRBs to track institutions with whom they have executed indemnification agreements.

REVIEWING IRBS: HOW DO I INDICATE INDEMNIFICATION IS REQUIRED ON A STUDY?

1. The Reviewing IRB indicates whether an agreement will be used on the second page of the IREx Study Setup (**Identify Required Agreements**), answer Yes for the question, “**Is Indemnification required of any relying site?**”. If indemnification is a separate agreement from the reliance agreement, answer yes to the follow up question, too: “**Is Indemnification executed separately from the reliance agreement?**”
2. Indicate whether the study will use an Existing or a New Indemnification Agreement.
 - A. If using a New Agreement, indicate the agreement **Type** (whether the agreement is broad [applying to any study] or study specific); the agreement **Name** and **Short Name**; and upload a **Template** of the agreement.
3. Additionally, be sure the Study-Specific Reliance Plan (SSRP) also reflects that indemnification is required for the study. This is the last question on the SSRP.

REVIEWING IRBS: HOW DO I TRACK WHO HAS EXECUTED INDEMNIFICATION ON A SPECIFIC STUDY?

1. Go to the study page in IREx.
2. From the Status Summary tab, click the **Agreements Complete** button for a site to view if that site has executed indemnification.
3. To add an executed Indemnification Agreement, click **(1) Update** for the appropriate site; or click **(2) Manage Agreements**.

4. Input the **Date Sent**, **Date Executed**, and any **Notes**. Upload a **Signed Copy** of the agreement, if desired.
5. If applicable, the Reviewing IRB can indicate:
 - (1) if a relying site is restricting a broad agreement to this one specific study.
 - (2) that a specific site has an exception from indemnification for the study.

Study Indemnification

Use this tab to indicate what sites have signed or plan to sign your institution's indemnification agreement offered on this study.

Carnegie University Medical Center Letter of Indemnification

Site: **Albert Einstein College of Medicine** Signed Copy: [Choose File](#) No file chosen

Date Sent: Date Executed: Notes:

1 This site is restricting the broad indemnification agreement to this study only.

2 Allow reliance on this study without indemnification

[Cancel](#) [Save](#)

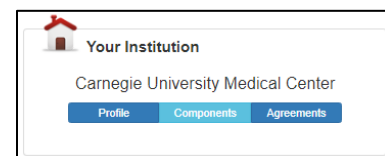
Q Search:

Site	Agreement	Date Sent	Date Executed	Signed Copy	Notes
Albert Einstein College of Medicine	CUMC LOI				
Child & Family Resources, Inc.	CUMC LOI				
Faraday Institute of Research, Science and Technology	CUMC LOI				

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REVIEWING IRBS: CAN I VIEW A LIST OF ALL INDEMNIFICATION AGREEMENTS WITH RELYING INSTITUTIONS?

1. Click the blue **Agreements** button on the home page.
2. Click the **Your Indemnification** tab.
3. For each **Site**, IREx displays the **Agreement Name**; whether the agreement **Type** is Broad or Study-Specific; any **Related Studies** on which the agreement is used; the date the agreement was **Sent** to the relying site, if entered; the date the agreement was **Executed**; the **Document** itself; and any **Notes**.
4. As needed, click the pencil to edit the information for any site.
5. Download the indemnification agreement for any site by clicking the file in the **Document** column.



Your Reliance Agreements **Your Indemnification** External Agreements

Your Indemnification Agreements

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

Carnegie University Medical Center Letter of Indemnification

[Download CSV](#)

Q Search:

Site	Agreement Name	Type	Related Studies	Sent	Executed	Document	Notes
Goodall University Medical Center	CUMC LOI	BROAD INDEMNIFICATION	Related Studies	3/15/2021	4/5/2021	Signed Agreement	
Hartford College of Medicine	CUMC LOI	BROAD INDEMNIFICATION	Related Studies		6/1/2022	Signed Agreement	

RELYING INSTITUTIONS: HOW DO I KNOW WHEN INDEMNIFICATION IS REQUIRED FOR A STUDY?

1. If indemnification is required on a study, this will be clearly outlined in the **IREx Access and Single IRB Instructions** email Relying HRPP Liaisons and Relying Site Study Teams receive. See the **Agreement/Resource** table, which will include more information on how to execute the indemnification agreement. The template agreement will be attached to the email.

Next Steps:

The overall/lead site approval is available in IREx on the Approvals tab of the study page. Use the Onboarding tab to view any additional documents shared by the sIRB and/or lead study team. Use these documents to prepare your local submission and initiate the reliance process at your site.

1. **LOCAL HRPP facilitates agreement execution:**
The study requires the following items to be completed, which can be facilitated by the local HRPP, as needed:

Agreement/Resource	Status
SMART IRB Agreement: A national, master reliance agreement supporting single IRB review.	Completed
Carnegie University Medical Center Letter of Indemnification	Incomplete — The indemnification agreement is attached. Send questions and executed agreements to Liaison Carnegie (liaison@carnegie.org).
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. <small>This is a web-based platform, not a reliance agreement.</small>	Completed

2. Additionally, after registering for the study, click **Complete Agreements** from the IREx Checklist to view information about Indemnification.
3. Relying sites cannot indicate reliance until the required agreements are executed/completed.

Einstein Checklist

- ✓ Register
- ➔ Complete Agreements
- ➔ Confirm Institutional Profile
- ➔ Indicate Reliance
- ➔ Complete HRP Survey
- 👁️ Remind PI To Complete PI Survey
- 🔧 Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

Required Agreements

Reliance Agreements

- Your site has signed the SMART IRB Agreement ✓

Indemnification

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

RELYING INSTITUTIONS: HOW DO I TRACK WHICH REVIEWING IRBS REQUIRE AN INDEMNIFICATION AGREEMENT?

1. From the **Agreements** button on the home page, click the **External Agreements** tab. Sort by type to bring all Indemnification agreements to the top of the list.
2. View the **Agreement Name** and any **Related Studies** (studies on which the agreement is in place).
3. The date the agreement was **Sent** by the Reviewing IRB, the date the agreement was indicated as **Executed** by the Reviewing IRB, and the **Document** itself will be available for upload, if that information was logged by the Reviewing IRB.

Your Reliance Agreements Your Indemnification External Agreements							
External Agreements							
This is a VIEW ONLY list of other institutions' agreements that your institution needs to sign or has executed.							
The sIRB of the study must indicate all agreements have been executed.							
Q Search: <input type="text"/>							
sIRB	Type	Agreement Name	Related Studies	Sent	Executed	Document	
Albert Einstein College of Medicine	Indemnification	Albert Einstein Letter of Indemnification	Related Studies ▾		10/7/2021	Signed Copy.docx	
Carnegie University	Indemnification	Carnegie University LOI	Related Studies ▾		8/8/2023	Signed Copy.docx	