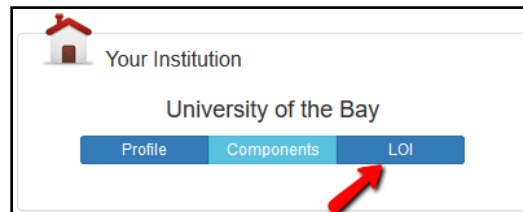


Using IREx to Track Letters of Indemnification (LOIs)

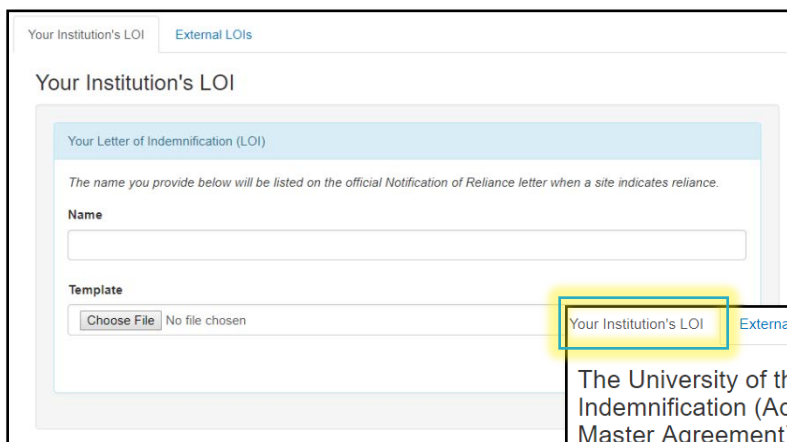
Some institutions require a Letter of Indemnification (LOI) when serving as the Reviewing IRB using the SMART IRB Agreement, which is silent on indemnification (see section 4.11). IREx allows Reviewing IRBs to track institutions with which they have an executed LOI. The LOI can be a unique agreement between the Reviewing IRB and another institution; however, only one executed LOI can be tracked per institution.

HOW DO I TRACK WHO HAS SIGNED AN LOI WITH MY INSTITUTION?

1. Click the blue **Agreements** button on the home page.
2. On the **Your Institution's LOI** tab, enter the name of your LOI and upload a template.

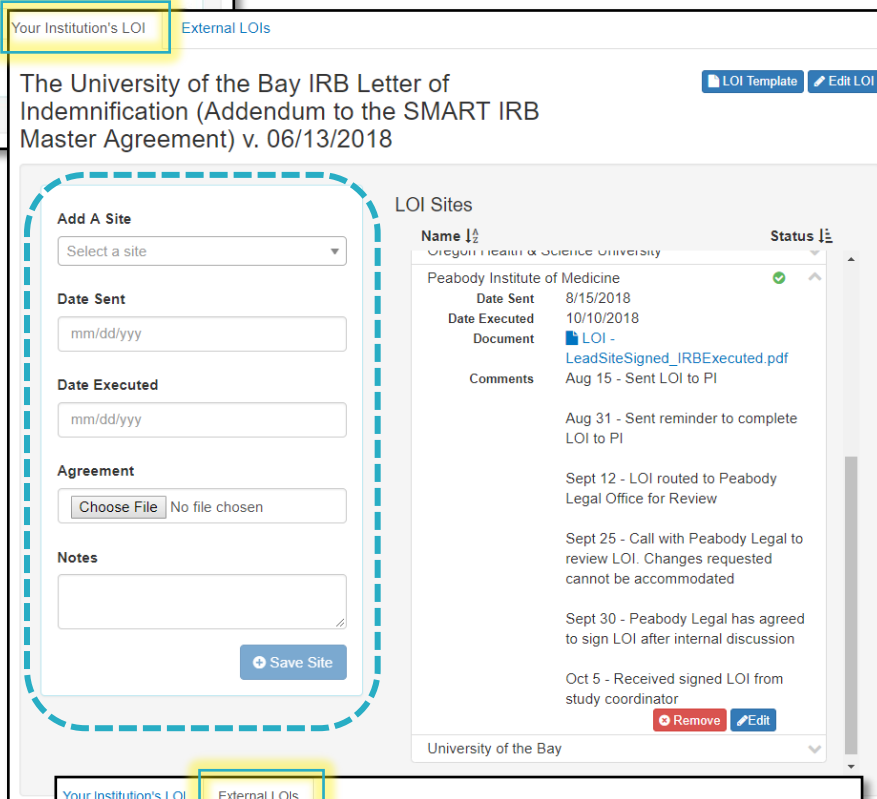


NOTE: THE NAME YOU PROVIDE WILL BE LISTED ON THE OFFICIAL NOTIFICATION OF RELIANCE LETTER WHEN A SITE INDICATES RELIANCE.



The screenshot shows the 'Your Institution's LOI' form. It has two tabs: 'Your Institution's LOI' (highlighted with a yellow box) and 'External LOIs'. The form includes a 'Name' field, a 'Template' section with a 'Choose File' button, and a note: 'The name you provide below will be listed on the official Notification of Reliance letter when a site indicates reliance.'

3. Next, use the **Add a Site** box to log the institutions that need to or have signed your LOI. Enter the following information, as it is known or completed:
 - a. **Date sent** the LOI to the site.
 - b. **Date executed** the LOI with the site. A green check mark will appear next to completed sites in the list of "LOI Sites".
 - c. **Upload the executed LOI**. This will be available for the site to download.
 - d. Enter **site-specific notes** of activity (e.g., dates of last contact; questions received, etc.).
 - e. Click **Save Site** to add the site.

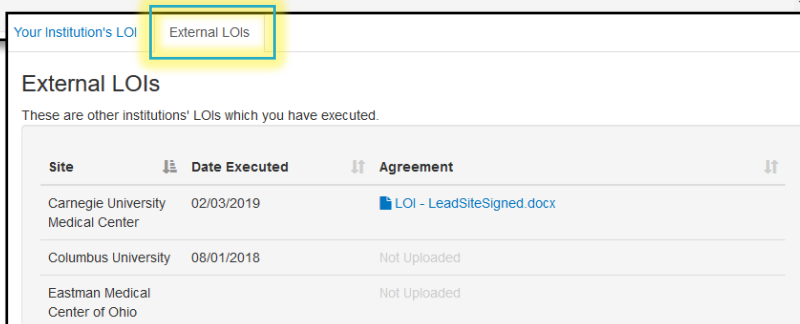


The screenshot shows the 'LOI Sites' management interface. It has two tabs: 'Your Institution's LOI' (highlighted with a yellow box) and 'External LOIs'. The main title is 'The University of the Bay IRB Letter of Indemnification (Addendum to the SMART IRB Master Agreement) v. 06/13/2018'. There are 'LOI Template' and 'Edit LOI' buttons. On the left is an 'Add A Site' form with fields for 'Select a site', 'Date Sent', 'Date Executed', 'Agreement', and 'Notes', and a 'Save Site' button. On the right is a table of 'LOI Sites'.

Name	Status
Peabody Institute of Medicine	✓
Date Sent: 8/15/2018 Date Executed: 10/10/2018 Document: LOI - LeadSiteSigned_IRBExecuted.pdf Comments: Aug 15 - Sent LOI to PI Aug 31 - Sent reminder to complete LOI to PI Sept 12 - LOI routed to Peabody Legal Office for Review Sept 25 - Call with Peabody Legal to review LOI. Changes requested cannot be accommodated Sept 30 - Peabody Legal has agreed to sign LOI after internal discussion Oct 5 - Received signed LOI from study coordinator	
University of the Bay	

HOW DO I TRACK WHICH INSTITUTIONS (REVIEWING IRBS) HAVE ASKED MY INSTITUTION TO SIGN AN LOI?

You can see what LOIs you have signed for other institutions on the External LOI tab. The **Site**, **Date Executed**, and **Agreement** will be shown if it has been logged in IREx by the Reviewing IRB.



The screenshot shows the 'External LOIs' table. It has two tabs: 'Your Institution's LOI' and 'External LOIs' (highlighted with a yellow box). The table title is 'External LOIs' and it includes a note: 'These are other institutions' LOIs which you have executed.'

Site	Date Executed	Agreement
Carnegie University Medical Center	02/03/2019	LOI - LeadSiteSigned.docx
Columbus University	08/01/2018	Not Uploaded
Eastman Medical Center of Ohio		Not Uploaded

HOW DO I ENABLE LOI TRACKING FOR A STUDY?

1. After creating a study, indicate that the study requires an LOI in the "Complete IREx Setup".

NOTE: BE SURE TO UPDATE YOUR STUDY SPECIFIC RELIANCE PLAN (SSRP) TO REFLECT THE REQUIREMENT. THIS IS THE LAST QUESTION ON THE SSRP.

Study Setup

Is the Reviewing IRB a participating research site in the study? Yes No

Would you like to collect local considerations in IREx? Yes No

How are sites' consent forms being handled?
 (Recommended) Sites will provide consents for sIRB review (e.g., using a template)
 A consent form generator will be used to build consents for sites

Do you require a Letter of Indemnification (LOI) for this study? Yes No

Be sure the Study-Specific Reliance Plan (SSRP) also reflects that indemnification is required for this study. This is the last question on the SSRP.

Reviewing IRB Approvals | Relying Site Approvals | **Status Summary**

Participant Status Summary Manage LOI Export Survey Data

Search: med

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Carnegie University Medical Center	✓	✓	✓	Completed 01/31/2019	0 / 3 Surveys Complete	Not Approved
Eastman Medical Center of Ohio	✗	✓	✓	Notify HRPP		
Midwest University Medical Center	✓	✗	✓	Add PI Info		
Peabody Institute of Medicine	✓	✓	✓	Completed 01/31/2019	1 / 3 Surveys Complete	Not Approved

The LOI column will appear on the status summary tab indicating which of the listed sites have signed your LOI.

2. To update a site's LOI status, click the grey "X" beside a site's name or use the **Manage LOI** button at the top of the status summary.

3. If institutions are added to the study that are not already an institution on your LOI tracker, they will be added.

AS A RELYING SITE, HOW DO I

KNOW WHEN AN LOI IS REQUIRED FOR A STUDY?

1. In the Getting Started Checklist, click Complete Agreement to see which agreements are needed to rely on the Reviewing IRB.
2. You will not be able to indicate reliance until you complete the required agreements.

- ✓ Register
- ✓ Add Study Team
- ➔ **Complete Agreements**
- ➔ Confirm Institutional Profile
- ➔ Indicate Reliance
- ➔ Complete HRP Survey
- ➔ Remind PI To Complete PI Survey
- ➔ Awaiting Reviewing IRB Approval

Required Agreements

SMART Your site has signed the SMART IRB agreement. ✓

LOI Your site must sign the LOI from Vanderbilt University Medical Center before you can indicate reliance. ✗

LOI Template from the Reviewing IRB
[LOI Template.docx](#)

Reviewing IRB Liaison
 Please send any questions and return the executed LOI to [Taylor Jansen](#)