

## HOW TO UPLOAD CONTINUING REVIEW APPROVALS IN IREx

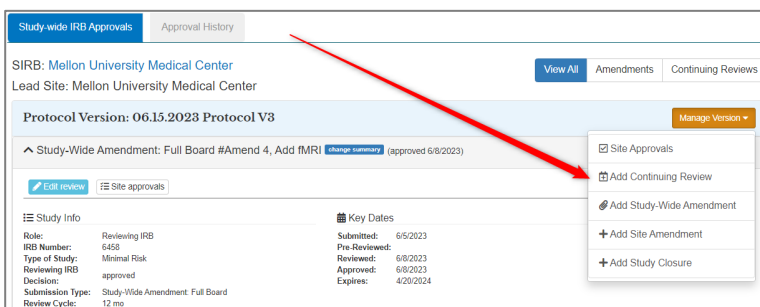
IREx is used to document and communicate the sIRB Continuing Review approval for participating sites. IREx does not capture the information the Reviewing IRB needs to conduct the Continuing Review, so this information must be gathered and submitted to the sIRB outside of IREx. Once approved, upload the Continuing Review approvals in IREx by following these three steps:



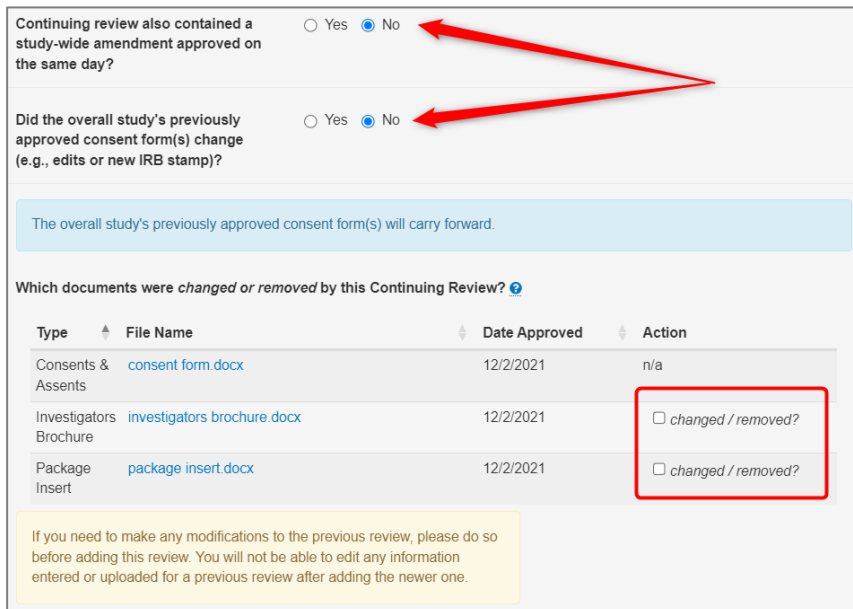
*Note: Steps B and C are separate because the newly stamped consents must be uploaded for each site. However, IREx auto-fills the relevant review dates and determination letter for sites, based on those entered for the Lead Site/Overall Study.*

### STEP A: ADD THE CONTINUING REVIEW IN IREx

The Reviewing IRB Liaison or IREx Study Manager (if permitted by the Reviewing IRB) must first add the Continuing Review for the study and upload the Continuing Review approval for the Lead Site / Overall study. Then, Continuing Review approvals can be uploaded for relying sites (see [Step C](#)).



- On the Study-wide IRB Approvals tab, click on the orange **Manage Version** button and select **Add Continuing Review**.
- In the Add Continuing Review dialog, indicate whether the **Continuing review also contained a study-wide amendment approved on the same day** – Yes/No. If **Yes**, provide the required information about whether the protocol was changed and a change summary. Additionally, indicate if **the overall study's previously approve consent form(s) changed** – Yes/No. If the consent form(s) did not change, the previously approved consent form(s) will carry forward. If they *did* change, you will upload the new approved consent form(s) in the next step.



Continuing review also contained a study-wide amendment approved on the same day? ☐ Yes ☒ No

Did the overall study's previously approved consent form(s) change (e.g., edits or new IRB stamp)? ☐ Yes ☒ No

The overall study's previously approved consent form(s) will carry forward.

Which documents were *changed* or *removed* by this Continuing Review? [?](#)

Type	File Name	Date Approved	Action
Consents & Assents	<a href="#">consent form.docx</a>	12/2/2021	n/a
Investigators Brochure	<a href="#">investigators brochure.docx</a>	12/2/2021	<input type="checkbox"/> changed / removed?
Package Insert	<a href="#">package insert.docx</a>	12/2/2021	<input type="checkbox"/> changed / removed?

If you need to make any modifications to the previous review, please do so before adding this review. You will not be able to edit any information entered or uploaded for a previous review after adding the newer one.

3. Select the documents that were changed or removed by this Continuing Review. These documents will remain in archived versions. Delete any study documents that are no longer part of the currently approved set of documents.

4. Click **Save** to add the Continuing Review. This will add steps to your GETTING STARTED checklist where you finish uploading the approval for the overall study.

**Tip:** On the Status Summary tab, **sites' approval status will change to "Approval Pending"** until their Continuing Review approval is uploaded in Step C.

## STEP B: UPLOAD SIRB APPROVAL FOR THE LEAD SITE/OVERALL STUDY

1. Click the **Upload Overall Study Approval** step on the GETTING STARTED checklist to upload the Lead Site/Overall approval.
2. In the dialog under Study Information:
  - a. Set the Status to **Approved**.
  - b. Confirm **Type of Study** risk level.
  - c. Ensure the correct **Review Type** (*Expedited or Full Board*) is selected.
  - d. Enter the **Review Cycle**.
  - e. **Will Lead Site enroll participants?** will default to the most recent enrollment status for the lead site. If the lead site is not enrolling, nor plans to, you will not be required to upload a Consent & Assent.
  - f. Click **Continue**.

☒ Complete IREx Setup
 ☒ Confirm Primary Study Contacts
 ☒ Confirm SSRP
 

☒ **Upload Overall Study Approval**

☐ Publish Approval

### Study Information

Amendment #

**Status** ☒ Approved ☐ Pending

IRB #

**Type of Study** ☐ Greater than minimal risk ☒ Minimal risk

**Review Type**

**Review Cycle**

**Will Lead Site enroll participants?** ☒ Yes ☐ No

**Continue**

3. Enter the Key Review dates when the Continuing Review was **Submitted**, **Pre-Review was Completed**, **Reviewed**, and **Approved** and click **Continue**.
4. Upload the new **IRB Approval Documentation**, the **Continuing Review Application**, the newly stamped **Consent & Assents** and any other new or updated documents for the lead site only. Required documents will be marked in red. **Delete** any documents that are no longer part of the currently approved documents.
5. Complete any **Site Updates**, including whether any sites are still enrolling. If any sites are still enrolling, you will also answer if any site-specific documents were updated in this review. Click **Continue**
6. Review the study information and click **Save**. If required fields are missing, the section of the dialog needing attention will be highlighted.
7. To make the documents visible to relying sites, click **Publish Approval** on the GETTING STARTED checklist.
8. After the Lead Site/Overall approval is published, a banner will appear at the top of the study page confirming you have added the Continuing Review correctly.

### Upload Documents

Drag file into document type or click a document type to upload.

☒ **IRB Approval Documentation**

☐ Continuing Review Application

☐ Consents & Assents   
 ☐ **waived**

☐ Grant Application

☐ Meeting Notes
 ☐ Investigators Brochure
 ☐ Device Manual
 ☐ Package Insert

☐ Measures
 ☐ Recruitment & Advertisements
 ☐ Additional IRB Approved Documents
 ☐ Others

### Uploaded Documents

Type	Document	Date Approved	
Protocol [11.18.21, Protocol V1]	<a href="#">Protocol V1.docx</a>	12/2/2021	
Investigators Brochure	<a href="#">investigators brochure.docx</a>	12/2/2021	<input checked="" type="checkbox"/> Delete
Package Insert	<a href="#">package insert.docx</a>	12/2/2021	<input checked="" type="checkbox"/> Delete

Review

### Site Updates

Are any sites still enrolling? ☒ Yes ☐ No

Did ANY site-specific documents get updated (e.g., new stamps on consent forms)? ☒ Yes ☐ No

You can upload new documents for relying site(s) from the site approvals dialog after saving this overall approval.


**Continue**

☒ **Success!** If any relying sites had site specific changes, visit the [Relying Site Approvals](#) dialog to confirm sites were approved, upload/remove site-specific documents, and notify the sites of the new approval.

If no site-specific documents were updated in this review, you're done! Relying sites will be notified of their approval immediately upon Publishing Approval. If site-specific documents WERE updated in this review, continue on to Step C. In Step C, you will upload site-specific approval documents and relying sites will then be notified of the new Continuing Review approval.

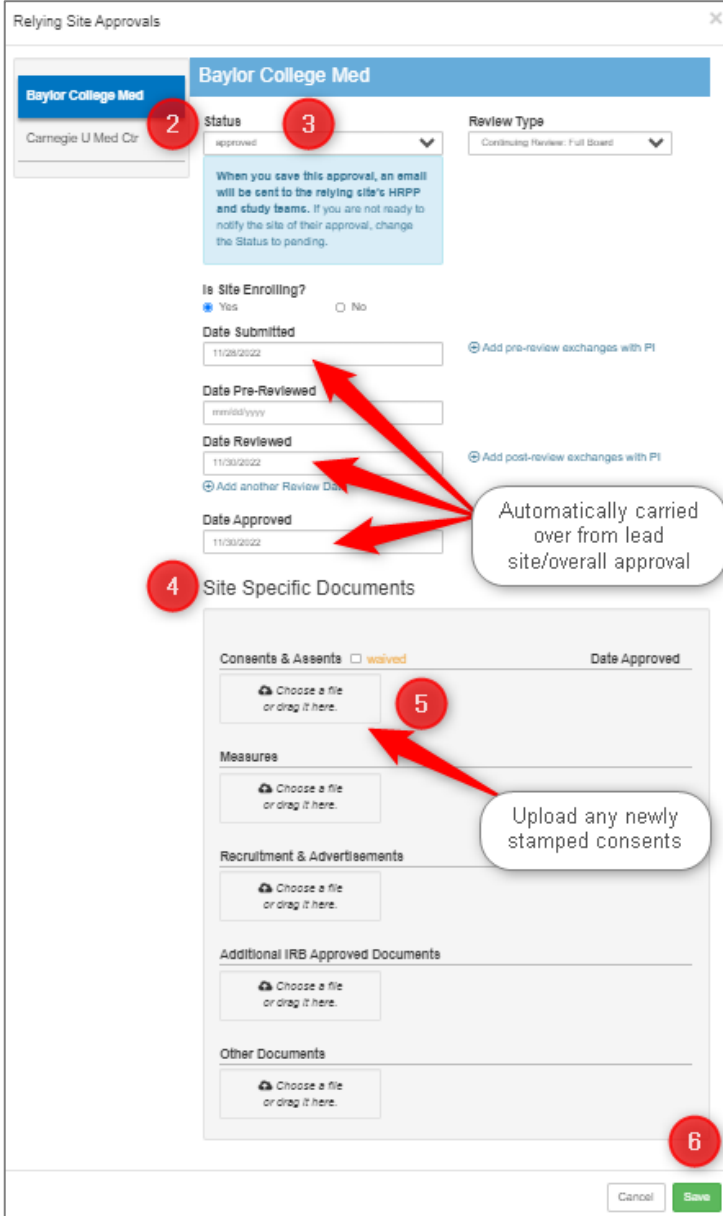
## STEP C: UPLOAD APPROVAL FOR RELYING SITES

**AFTER** the Continuing Review Approval has been uploaded for the Lead Site /Overall study, Relying sites' approvals can be added.

1. Click **Upload Relying Site Approval** step on the GETTING STARTED checklist. 
2. In the Relying Site Approvals dialog, select the **name of the site** for which you are uploading approval.  
(All sites who have ceded review appear, but only sites approved on the previous version will have a review type of Continuing Review: Full Board/Expedited.)
3. Change the Status to **approved** and
  - o Ensure the correct **Review Type** is selected.
  - o **Is Site Enrolling?** will default to the most recent enrollment status for the site. If the site is not enrolling, nor plans to, you will not be required to upload a Consent & Assent document.
  - o The dates and determination letter from the Lead Site / Overall study approval will be auto-populated for all sites that had approval on the previous version.
4. Other **Site-Specific Documents** that were approved in the previous version will also be carried forward. Please verify that these documents are still part of the approved set of documents.
5. Upload the new consent forms (or indicate a waiver was approved) and ensure the correct versions of all other approved documents are listed for the site.
6. Click **Save**. IREx will notify the (1) Reviewing IRB Liaisons, (2) site Liaison(s), (3) the IREx Study Manager(s), and (4) site study team contacts in IREx of the new approval. The documents will appear on the Site-specific IRB Approvals tab.

### ADDITIONAL TIPS:

- You can upload approvals for more than one site at a time by selecting another site name (item 2 above) and completing items 3-5 for each site before saving.
- To save information without notifying a site, change the approval status to *pending* or *leave blank*. You can return later to complete the approval.



The screenshot shows the 'Relying Site Approvals' dialog box. At the top, there's a list of sites: 'Baylor College Med' and 'Carnegie U Med Ctr'. A red circle '2' is next to 'Baylor College Med'. Below the site list, there's a 'Status' dropdown menu with 'approved' selected, and a red circle '3' next to it. To the right is a 'Review Type' dropdown menu with 'Continuing Review: Full Board' selected. A blue information box states: 'When you save this approval, an email will be sent to the relying site's HRPP and study teams. If you are not ready to notify the site of their approval, change the Status to pending.' Below this, there's a section for 'Is Site Enrolling?' with 'Yes' selected. Further down are date fields: 'Date Submitted' (11/28/2022), 'Date Pre-Reviewed' (mm/dd/yyyy), 'Date Reviewed' (11/30/2022), and 'Date Approved' (11/30/2022). Red arrows point from these date fields to a text box that says 'Automatically carried over from lead site/overall approval'. Below the dates is a section for 'Site Specific Documents' with a red circle '4'. This section includes 'Consents & Assents' (with a 'waived' checkbox), 'Measures', 'Recruitment & Advertisements', 'Additional IRB Approved Documents', and 'Other Documents'. Each of these sections has a 'Choose a file or drag it here.' button. A red circle '5' is next to the 'Consents & Assents' button, and a red arrow points to it from a text box that says 'Upload any newly stamped consents'. At the bottom right, there's a red circle '6' next to the 'Save' button. A 'Cancel' button is also present.