IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

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:

STEP A
Add the Continuing Review in IREx

→

STEP B
Upload sIRB approval for the lead site / overall study

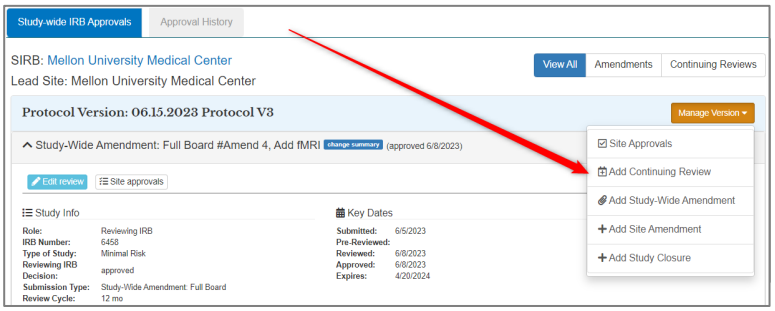
→

STEP C
Upload approval for relying sites*
(*if site-specific documents are newly approved)

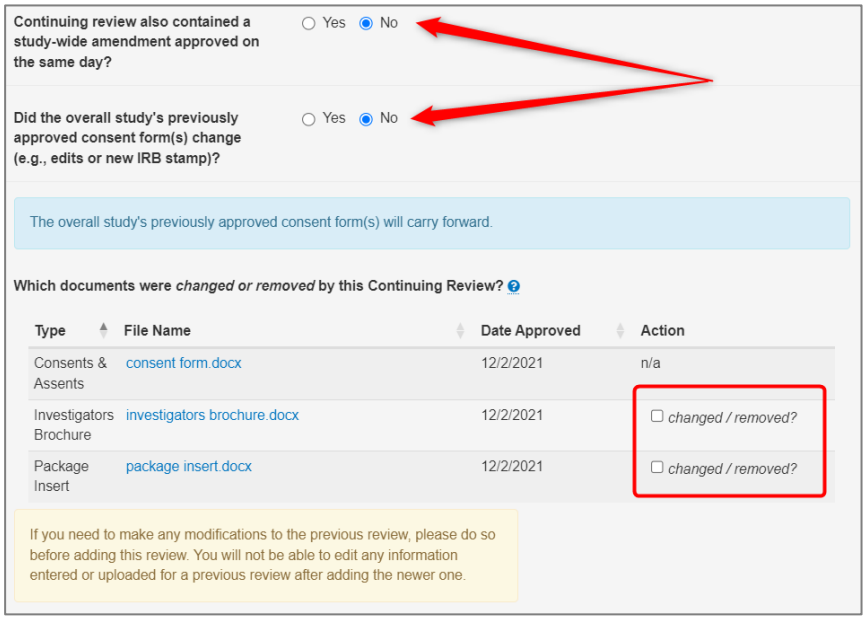
Note: Steps B and C are separate because the newly stamped consents must be uploaded for each site. However, IREx auto-fills the relevant review dates and determination letter for sites, based on those entered for the Lead Site/Overall Study.

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).



1. On the Study-wide IRB Approvals tab, click on the orange **Manage Version** button and select **Add Continuing Review**.
2. 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.



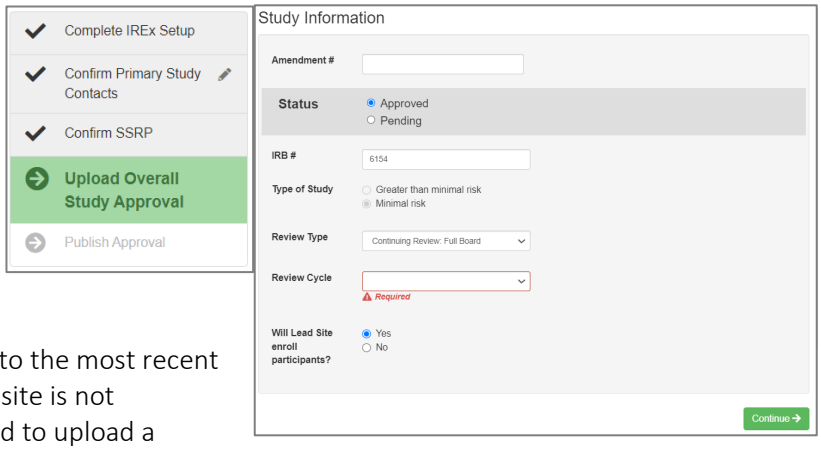
3. Select the documents that were changed or removed by this Continuing Review. These documents will remain in archived versions. Delete any study documents that are no longer part of the currently approved set of documents.

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.

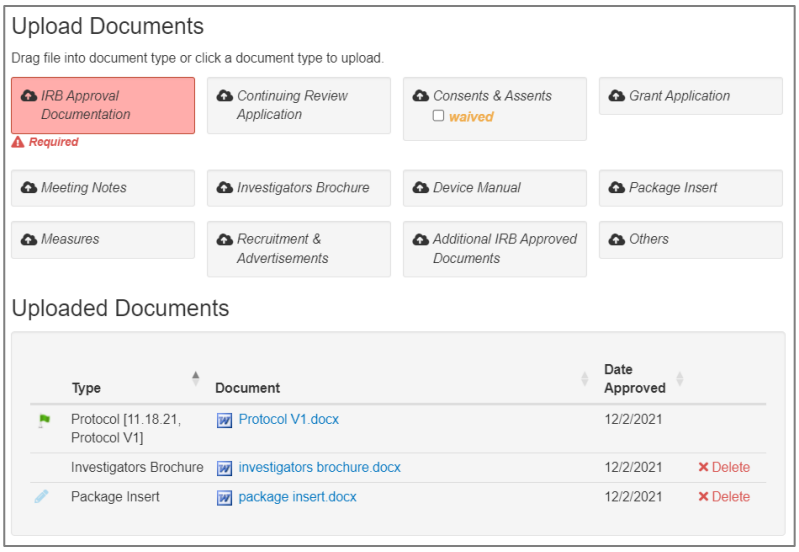
STEP B: UPLOAD SIRB APPROVAL FOR THE LEAD SITE/OVERALL STUDY

1. Click the **Upload Overall Study Approval** step on the GETTING STARTED checklist to upload the Lead Site/Overall approval.



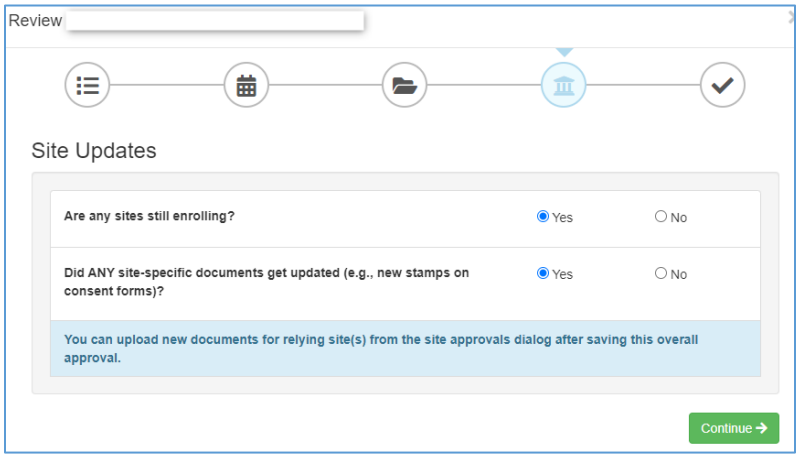
2. In the dialog under Study Information:
   a. Set the Status to **Approved.**
   b. Confirm **Type of Study** risk level.
   c. Ensure the correct **Review Type** (***Expedited or Full Board***) is selected.
   d. Enter the **Review Cycle**.
   e. **Will Lead Site enroll participants?** will default 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**.

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.**

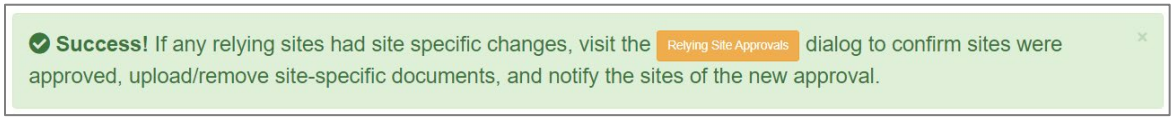
5. Complete any **Site Updates**, including whether any sites are still enrolling. If any sites are still enrolling, you will also answer if any site-specific documents were updated in this review. Click **Continue**



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.

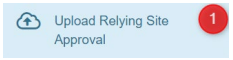


If no site-specific documents were updated in this review, you're done! Relying sites will be notified of their approval immediately upon Publishing Approval. If site-specific documents WERE updated in this review, continue on to Step C. In Step C, you will upload site-specific approval documents and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

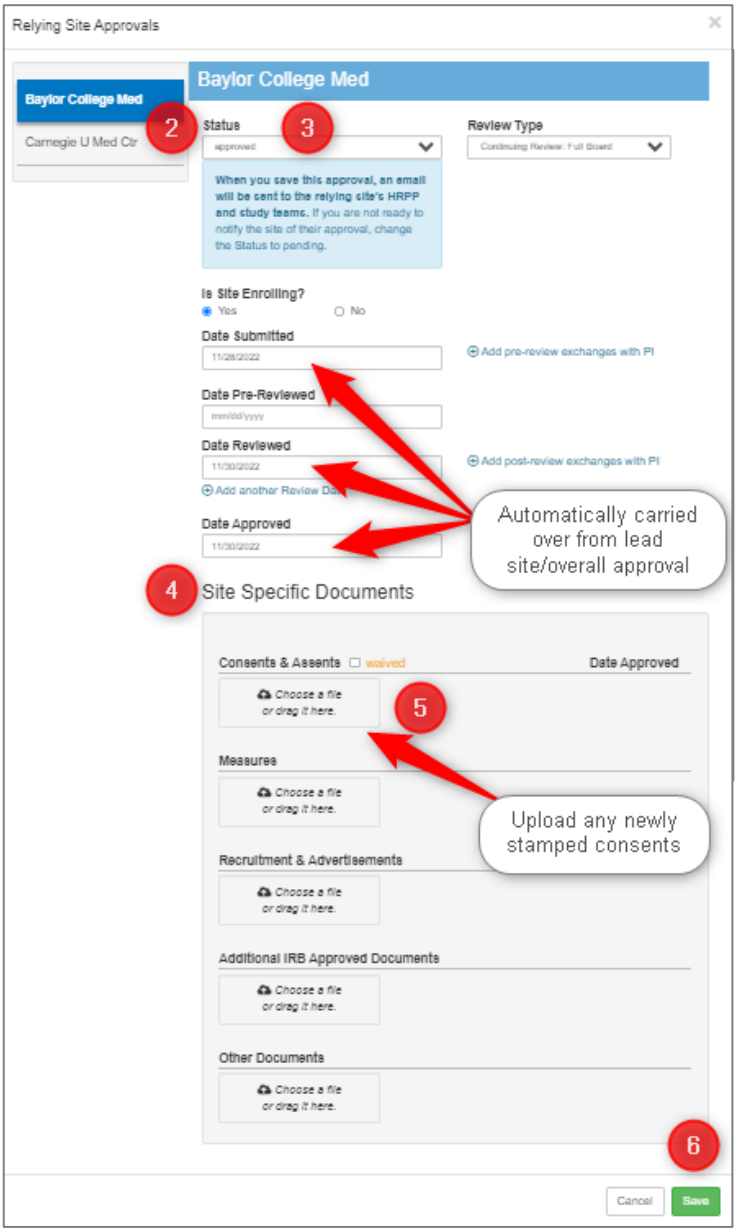
1. Click **Upload Relying Site Approval** step on the GETTING STARTED checklist.



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
   - Ensure the correct **Review Type** is selected.
   - **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.
   - 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.