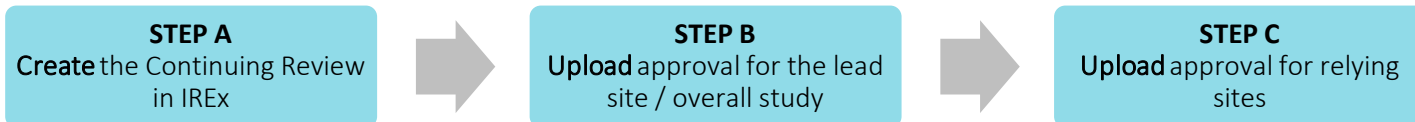


## HOW TO UPLOAD CONTINUING REVIEW APPROVALS IN IREx

IREx can be used to document and communicate the Continuing Review approval for participating sites. However, IREx does not currently capture the information the Reviewing IRB needs to conduct the Continuing Review for participating sites. This information must be captured outside of IREx. Uploading Continuing Reviews in IREx has three steps:

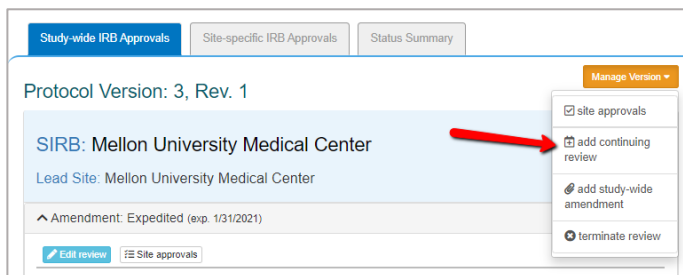
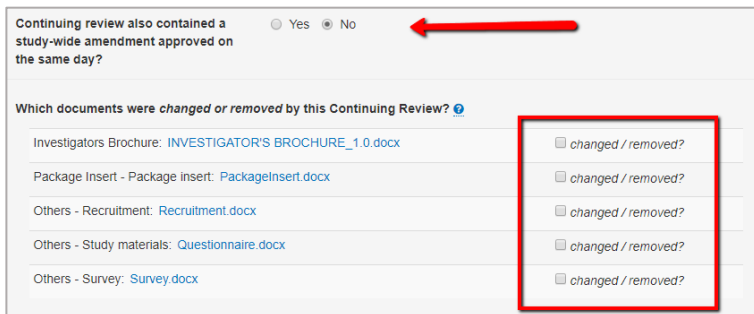


*Note: Steps B and C are separate because the newly stamped consents must be uploaded for each site. However, IREx auto-fills the relevant review dates and determination letter for sites, based on those entered for the Lead Site/Overall Study.*

### STEP A: CREATE THE CONTINUING REVIEW FOR THE STUDY

The Reviewing IRB Liaison or IREx Study Manager (if permitted by the Reviewing IRB) must first create the Continuing Review for the study and upload the Continuing Review approval for the Lead Site or 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.

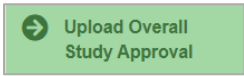



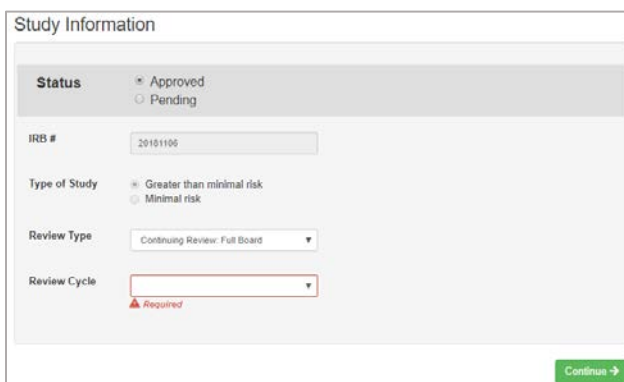
3. Select the *documents that were changed or removed* by this Continuing Review. These documents will remain in archived versions, but you should delete any that are no longer part of the currently approved set of documents.

**Tip:** Previously approved consents will be automatically removed. You can upload the newly stamped consents and other updated documents in the steps ahead.

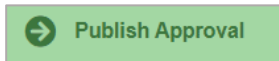
4. Click **Save** to create the Continuing Review. This will add steps to your GETTING STARTED checklist where you finish uploading the approval for the overall study. **Tip:** On the Status Summary tab, sites' approval status will change to "Not Approved" until their continuing review approval is uploaded in Step C.

### STEP B: UPLOADING CONTINUING REVIEW APPROVALS FOR THE OVERALL STUDY

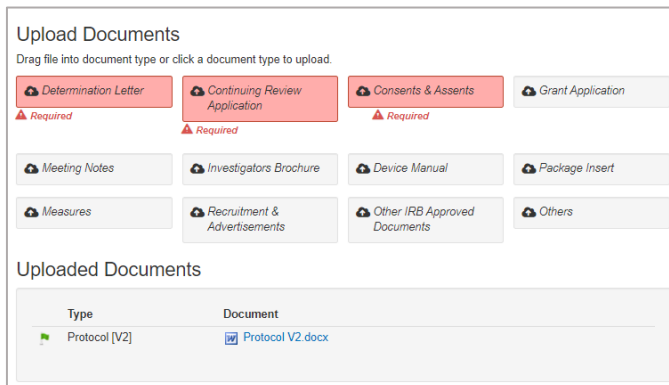
1. Click the **Upload Overall Study Approval** step on the GETTING STARTED checklist to upload the Lead Site/Overall approval.
 
2. In the dialog under Study Information:
  - a. Set the Status to **Approved**.
  - b. Ensure the correct **Review Type** (*Expedited or Full Board*) is selected.
  - c. Enter the **Review Cycle** and click **Continue**.
3. Enter the Key Review dates when the Continuing Review was **Submitted, Pre-Review was Completed, Reviewed, and Approved** and **Continue**.



- Upload the new **Determination Letter**, 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.
- Review the study information and click **Save**. If required fields are missing, the section will be highlighted.
- To make the documents visible to relying sites, click **Publish Approval** on the GETTING STARTED checklist.



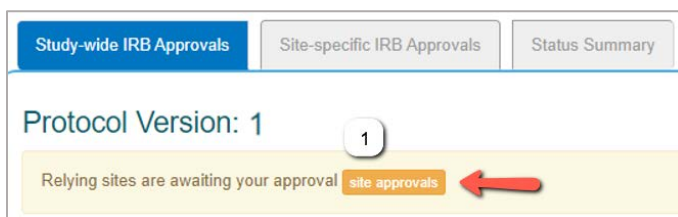
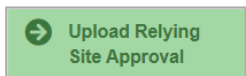
**Tip:** Relying sites are not notified of the new Continuing Review approval – they are notified of approval when their site-specific approval documents are uploaded in Step C.



### STEP C: UPLOADING CONTINUING REVIEW APPROVALS FOR RELYING SITES

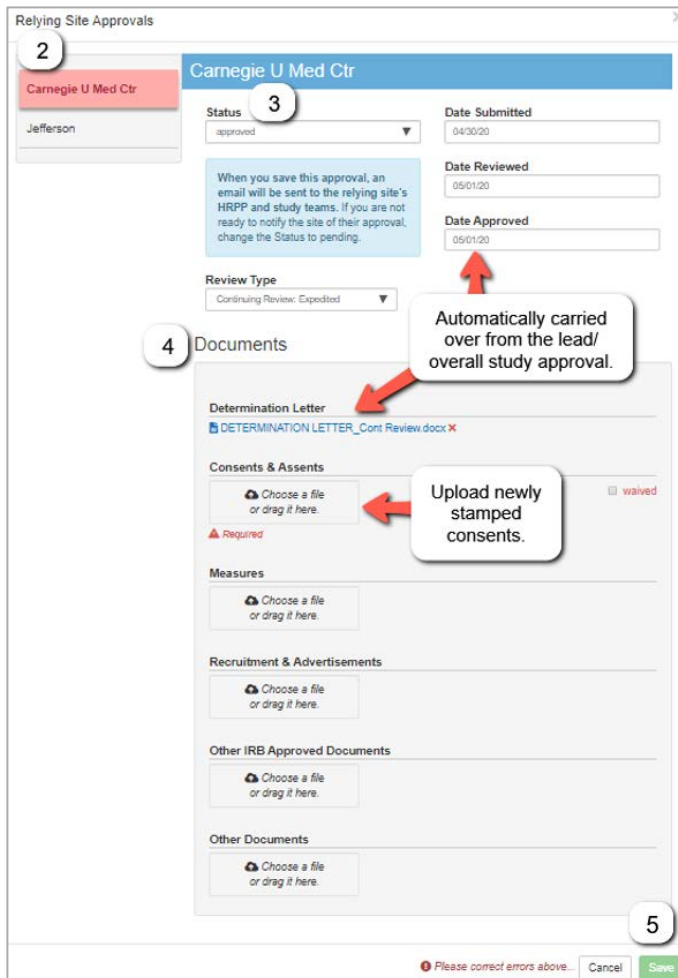
**AFTER** the Continuing Review Approval has been uploaded for the Lead Site or Overall study, sites' approvals can be added.

- Click on the **site approvals** button on the Study-wide IRB Approvals tab. Study Managers can also click the **Uploading Relying Site Approvals** step on their GETTING STARTED checklist.



- 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/Expedited.



- Change the Status to **approved** and ensure the correct **Review Type** is selected.

The dates and determination letter from the overall study approval will be auto-populated for all sites that had approval on the previous version. 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.

- 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.
- Click **Save**. IREx will notify the (1) Reviewing IRB Liaisons, (2) site Liaison(s), (3) the IREX Study Manager(s), and (4) site study 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 once by selecting another site name and complete steps 2-4 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.