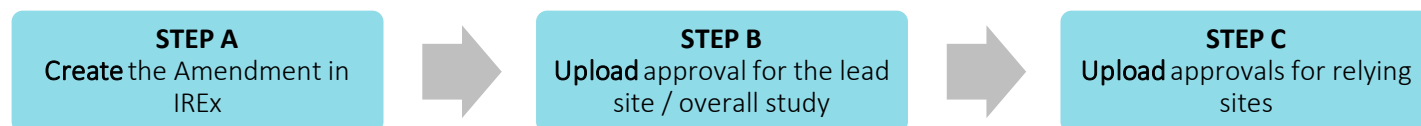


HOW TO UPLOAD STUDY-WIDE AMENDMENT APPROVALS IN IREx

IREx can be used to document and communicate the approval of amendments to participating sites. **Study-wide Amendments** include changes to the protocol or other study materials that apply to ALL sites. IREx is also used for Site Amendments, which reflect changes for a *single site* that is already approved (see [quick guide](#)).



Note: Steps B and C are separate to ensure study-wide and site-specific documents are captured in the correct place. However, IREx auto-fills the review dates and determination letter for sites, based on those for the Lead Site/Overall Study.

STEP A: CREATE THE STUDY-WIDE AMENDMENT FOR THE OVERALL STUDY

The Reviewing IRB Liaison or IREx Study Manager (if permitted by the Reviewing IRB) must create the Study-wide Amendment and upload approval for the Lead Site or Overall Study before relying site approvals can be uploaded ([Step C](#)).

- On the Study-wide IRB Approvals tab, click **Manage Version** and select **add study-wide amendment**.
- In the Add Study-wide Amendment dialog, indicate whether the amendment changes the current version of the protocol.
 - If **Yes**, enter the **New protocol date/version** and **Upload the new protocol** version.
 - If the amendment does not change the protocol version, select **No**. IREx will add a revision number (e.g., Rev. 1) to the current version to indicate changes were made, but the protocol version stayed the same.
- Enter a **Summary of changes**. **Tip:** We recommend including the amendment # at the beginning of the change summary as a reference for sites.

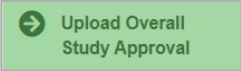
Type	File Name	Action
Consents & Assents - Consents & Assents	CONSENT FORM - Adult.docx	<input type="checkbox"/> changed / removed?
Consents & Assents - Consents & Assents	CONSENT FORM - Assent.docx	<input type="checkbox"/> changed / removed?
Measures	Procedure-II.F.1.pdf	<input type="checkbox"/> changed / removed?

Note: you will be able to add additional documents on the next screen.

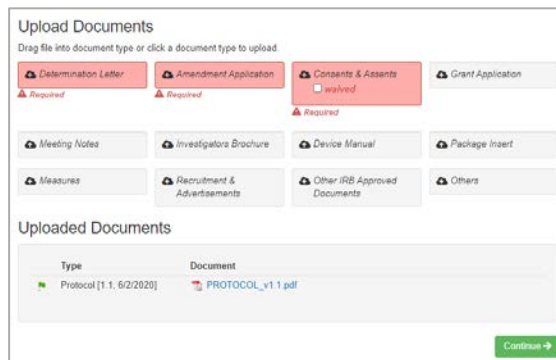
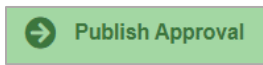
- Select the documents that were changed or removed by this Amendment. These documents will remain in archived versions, but you should delete any that are no longer part of the currently approved set of documents. If the consent forms were changed, select “changed / remove” so the old versions are not carried forward. You will have an opportunity to upload new documents in the steps ahead.
- Click **Save** to create the Study-wide Amendment. This will add steps to your GETTING STARTED checklist where you can finish uploading the approval for the overall study.

Tip: On the Status Summary tab, **sites' approval status will change to “Not Approved”** until their Study-wide Amendment approval is uploaded in Step C.

STEP B: UPLOAD STUDY-WIDE AMENDMENT APPROVAL FOR THE OVERALL STUDY

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

- Upload the new **Determination Letter, Amendment Application**, and any other new or updated documents for the lead site only and click **Continue**.
- 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.

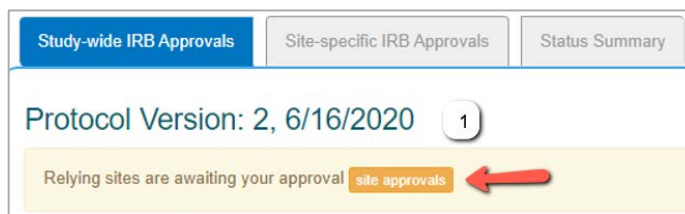
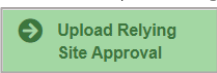


Tip: Relying sites are not notified of the new Study-wide Approval – sites are notified of approval when their site-specific approval documents are uploaded in the next section in Step C.

STEP C: UPLOAD APPROVALS FOR RELYING SITES

AFTER the Study-wide Amendment has been uploaded for the Lead Site or Overall Study, site 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.

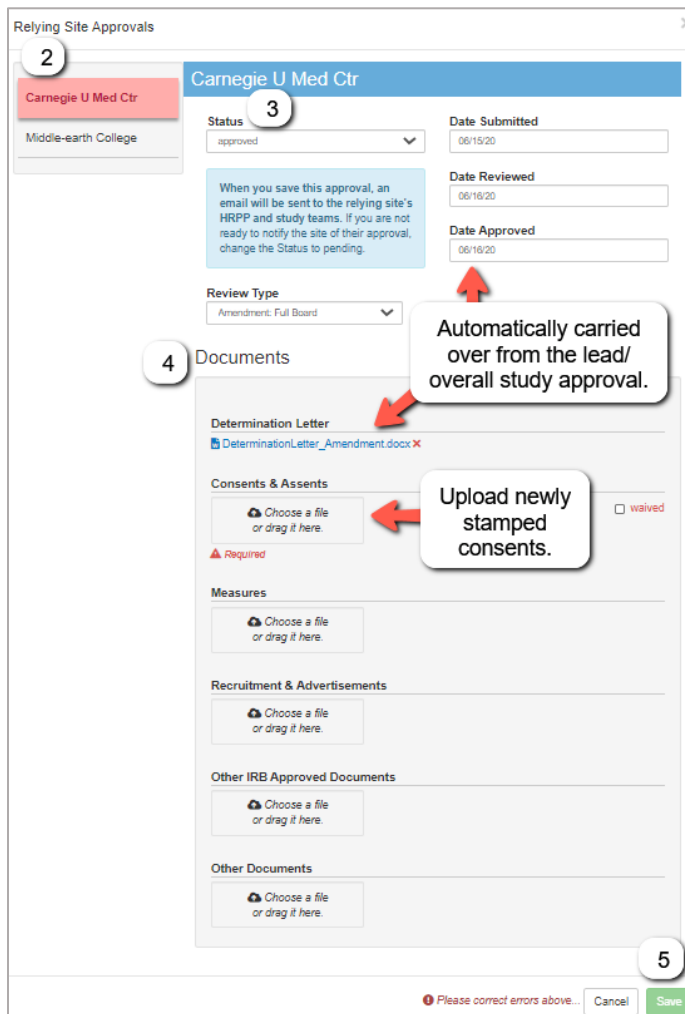


All sites who have ceded review appear in the Relying Site Approvals dialog, but only sites approved on the previous version will have a review type of Amendment: Full/Expedited.

- 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 any new/revised documents and ensure the correct versions of all other approved documents are listed for the site. If consents or other documents changed, delete, and upload new versions.
- 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.