

## HOW TO UPLOAD STUDY-WIDE AMENDMENT APPROVALS IN IREx

IREx is 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 does not capture the information the Reviewing IRB needs to approve the amendment, so this information must be gathered and submitted to the sIRB outside of IREx. Once approved, upload the Study-wide Amendment approvals in IREx by following these three steps. (IREx is also used for Site Amendments, which reflect changes for a *single site* that is already approved [see [quick guide](#)]).

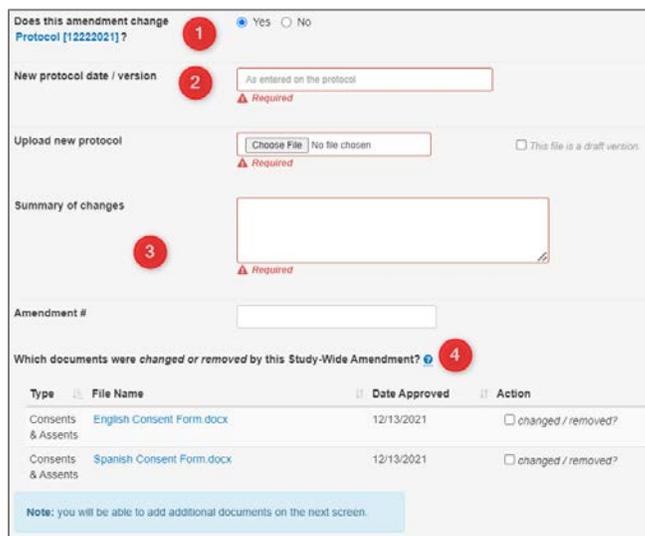


*Note: Steps B and C are separate to ensure study-wide and site-specific documents are captured in the correct place. However, IREx auto-fills the review dates for sites, based on those for the Lead Site/Overall Study.*

### STEP A: ADD AMENDMENT IN IREX

The Reviewing IRB Liaison or IREx Study Manager (if permitted by the Reviewing IRB) must add 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 the orange **Manage Version** button 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**.
- Enter a **Summary of changes** and **Amendment #** and/or brief description.
- 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 add the Study-wide Amendment. This will populate your remaining steps in your GETTING STARTED checklist where you can finish uploading the approval for the overall study.



Type	File Name	Date Approved	Action
Consents & Assents	English Consent Form.docx	12/13/2021	<input type="checkbox"/> changed / removed?
Consents & Assents	Spanish Consent Form.docx	12/13/2021	<input type="checkbox"/> changed / removed?

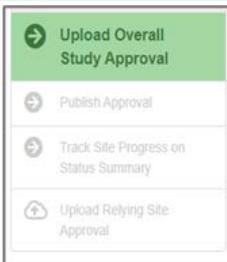
Note: you will be able to add additional documents on the next screen.



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

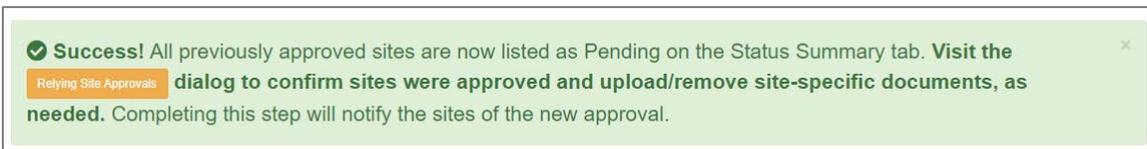
## STEP B: UPLOAD SIRB APPROVAL FOR THE LEAD SITE/OVERALL STUDY

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. **Is Site Enrolling?** will default to the most recent enrollment status for the site. If the site is not, nor plans to enroll, you will not be required to upload a Consent & Assent document.
  - e. Click Continue.



3. Enter the Key Dates when the Amendment was **Submitted, Pre-Review was Completed, Reviewed, and Approved** and **Continue**.
4. Upload the new **IRB Approval Documentation, Amendment Application**, and any other new or updated documents for the lead site only and click **Continue**. Required documents will be marked in red.
5. Review the study information and click **Save**. If required fields are missing, the section of the dialog needing attention will be highlighted.
6. To make the documents visible to relying sites, click **Publish Approval** on the GETTING STARTED checklist.
7. After the Lead Site/Overall approval is published, a banner will appear at the top of the study page confirming you have added the Amendment correctly and the final step is to upload Relying Site approvals.

Type	Document	Date Approved	
Protocol [12222021]	Protocol V1.docx	12/13/2021	
Consents & Assents	English Consent Form.docx	12/13/2021	✖ Delete
Consents & Assents	Spanish Consent Form.docx	12/13/2021	✖ Delete

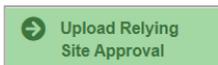


**Tip:** Relying sites cannot view and are not notified of the new Study-wide Approval. Sites are notified of approval when their site-specific approval documents are uploaded in the next section in Step C.

## STEP C: UPLOAD APPROVAL FOR RELYING SITES

**AFTER** the Study-wide Amendment has been uploaded for the Lead Site or Overall Study, site approvals can be added.

1. Click on the **site approvals** button on the Study-wide IRB Approvals tab (see **1** in the screenshot). Study Managers can also click the **Uploading Relying Site Approvals** step on their 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 in the Relying Site Approvals dialog, but only sites approved on the previous version will have a review type of Amendment: Full/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, nor plans to enroll, you will not be required to upload a Consent & Assent document.
  - o The dates from the 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 any new/revised site-specific documents and ensure the correct versions of all approved documents are listed. If consents or other documents changed, delete them, and upload new versions.
6. Click **Save**. IREx will notify the (1) Reviewing IRB Liaisons, (2) site Liaison(s), (3) the IREx Study Manager(s), and (4) site’s study contacts of the new approval. The documents will appear on the Approval History tab for the site.

**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 it blank*. You can return later to complete the approval.

The screenshot shows the 'Relying Site Approvals' dialog for 'Anderson Med Ctr'. The site name is selected (2). The status is set to 'approved' (3). A note indicates that saving this approval will trigger an email to the site's HRPP and study teams, and that the status should be changed to 'pending' if not ready to notify. The 'Is Site Enrolling?' field is set to 'Yes'. Dates for 'Date Submitted' (01/04/2022), 'Date Pre-Reviewed', 'Date Reviewed' (01/28/2022), and 'Date Approved' (02/04/2022) are shown. A callout (4) states that these dates are 'Automatically carried over from lead site/overall approval'. Under 'Site Specific Documents', there is a section for 'Consents & Assents' with a file named 'English Consent Form.docx' (Date Approved: 12/16/2021) and a 'Choose a file or drag it here.' button (5). A callout (5) says 'Upload any newly stamped consents'. At the bottom right, there are 'Cancel' and 'Save' buttons (6).