IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

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 is also used for Site Amendments, which reflect changes for a *single site* that is already approved [see quick guide]).

STEP A
Add the Amendment in IREx

→

STEP B
Upload sIRB approval and indicate whether sites had changes

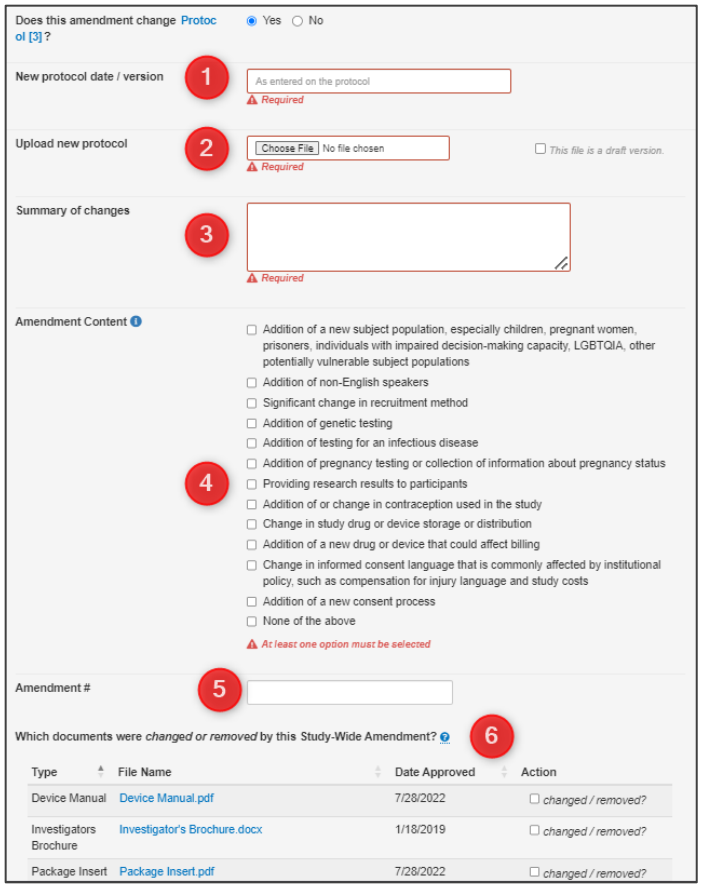
→

STEP C (if needed)
Upload approval of site-specific changes, if any

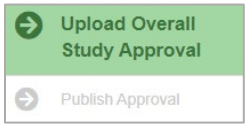
STEP A: ADD AMENDMENT IN IREX

The Reviewing IRB Liaison or Study Manager can add the Study-wide Amendment following the steps below:

1. On the Study-wide IRB Approvals tab, click the orange **Manage Version** button and select **Add Study-Wide Amendment**.
2. In the Add Study-wide Amendment dialog, indicate whether the amendment changes the current version of the protocol.
   a. If **Yes**, enter the **New protocol date/version** and **Upload the new protocol** version.
   b. If the amendment does not change the protocol version, select **No**.
3. Enter a **Summary of changes and/or brief description**.
4. If the Reviewing IRB chose to collect Local Considerations for the life of the study in the IREx study setup, a list of Amendment Content will appear. Check off any that may apply to the new amendment. This will trigger a notification to sites to review and update their Local Considerations. (If 'None of the above' is checked, the notification to review Local Considerations will not be sent.)
5. Enter the amendment number.



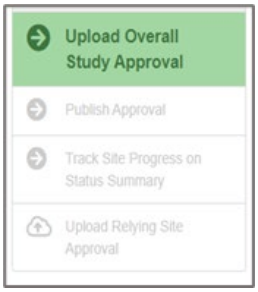
6. Select the documents that were changed or removed by this Amendment. These documents will remain in archived versions, but you should remove any that are no longer part of the currently approved set of documents. If the consent forms were changed, select "changed / removed?" so the old versions are not carried forward. You will have an opportunity to upload new documents in the steps ahead.
7. 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.



Tip: On the Status Summary tab, **sites that previously had approval will have an approval status of** "Approval Pending" until their approval is finalized in the steps below.

STEP B: UPLOAD SIRB APPROVAL

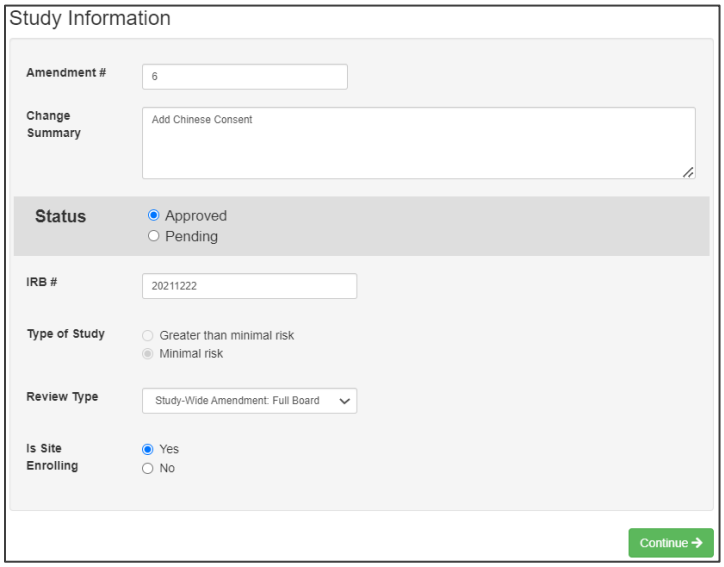
Click the **Upload Overall Study Approval** step on the GETTING STARTED checklist to begin uploading the approval. The Review dialog box shows five icons at the top representing these tabs: Study Information, Key Dates, Upload Documents, Site Updates, Review and Submit.



NOTE: The Site Updates Icon/tab will only appear if there are sites with previous approval.

1. Under **Study Information**, edit the Amendment # and Change Summary as needed, and then set the Status to **Approved;** ensure the correct **Review Type** (***Expedited or Full Board***) is selected; confirm the lead site's enrollment status (if not enrolling, consent forms will not be required), and click **Continue**.

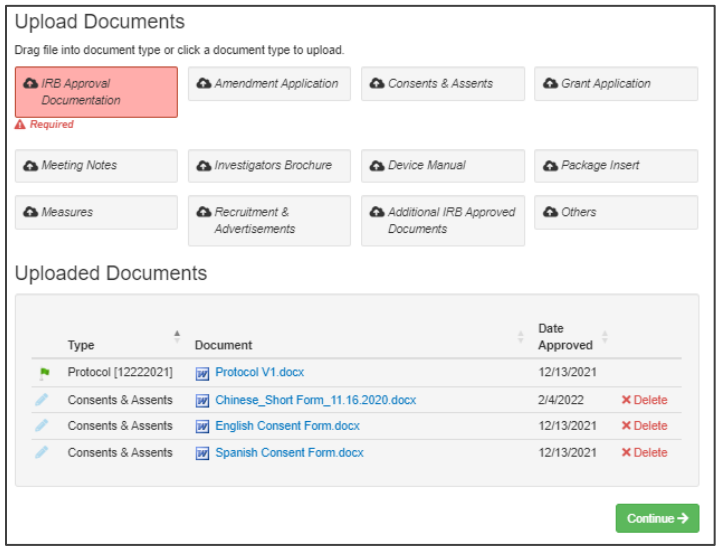
   NOTE: If the Reviewing IRB chose to collect Local Considerations for the life of the study, the Amendment Content list will also be available and editable in the **Study Information** tab.



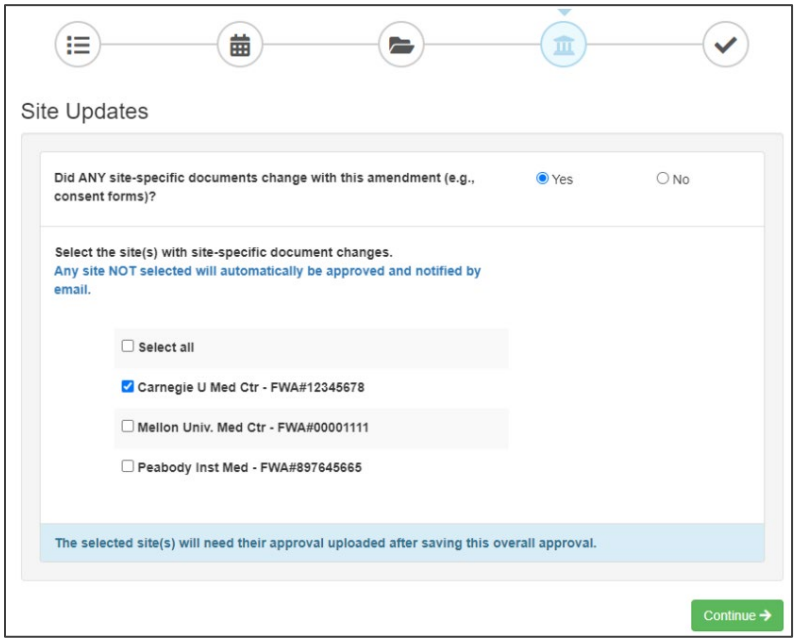
2. Enter the **Key Dates** when the Amendment was **Submitted, Pre-Review was Completed, Reviewed,** and **Approved** and click **Continue**.

3. **Upload Documents** including the new **IRB Approval Documentation** and any other new or updated documents for the <u>lead site only</u> and click **Continue**. Required documents will be marked in red. be required), and click **Continue**.

   NOTE: Lead Site Documents are considered to be Global Documents, or documents that all Relying Sites will use for the study.

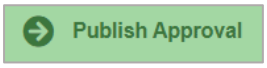


4. Complete the **Site Updates** questions to indicate whether there were any site-specific changes with the amendment (for sites that previously had approval on the study).
   a. If there were **NO** changes to site-specific documents:
      i. Sites that previously had approval will automatically be approved and notified of the approval.
      ii. All previously approved documents for the site will carry forward.
      iii. Skip Step C below. Sites will be notified of the new approval.
   b. If **YES**, some or all sites had changes to site-specific documents, select the sites that had changes from the list.
      i. The approval for the selected sites is uploaded after saving this overall approval.
      ii. Any site(s)not selected will automatically be approved and notified by email.

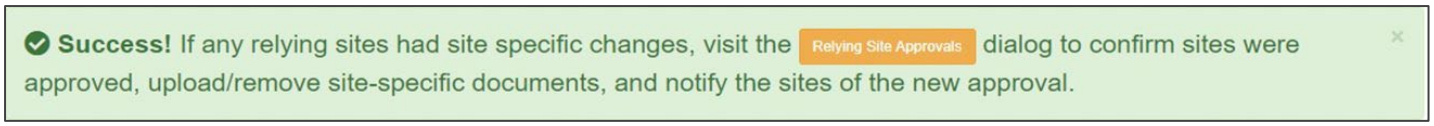


5. **Review** the study information and click **Save**. If required fields are missing, the section of the dialog needing attention will be highlighted in dark pink.

6. To make the documents visible to relying sites, click **Publish Approval** on the GETTING STARTED checklist.



7. After the Overall Amendment approval is published, a banner will appear at the top of the study page confirming you have added the Amendment correctly. If any sites had site-specific changes, proceed to Step C to upload those in the Relying Site Approvals dialog. These sites will not be notified of their approval until this step is completed.



NOTE: Additional information for studies requesting local considerations updates throughout the life of the study

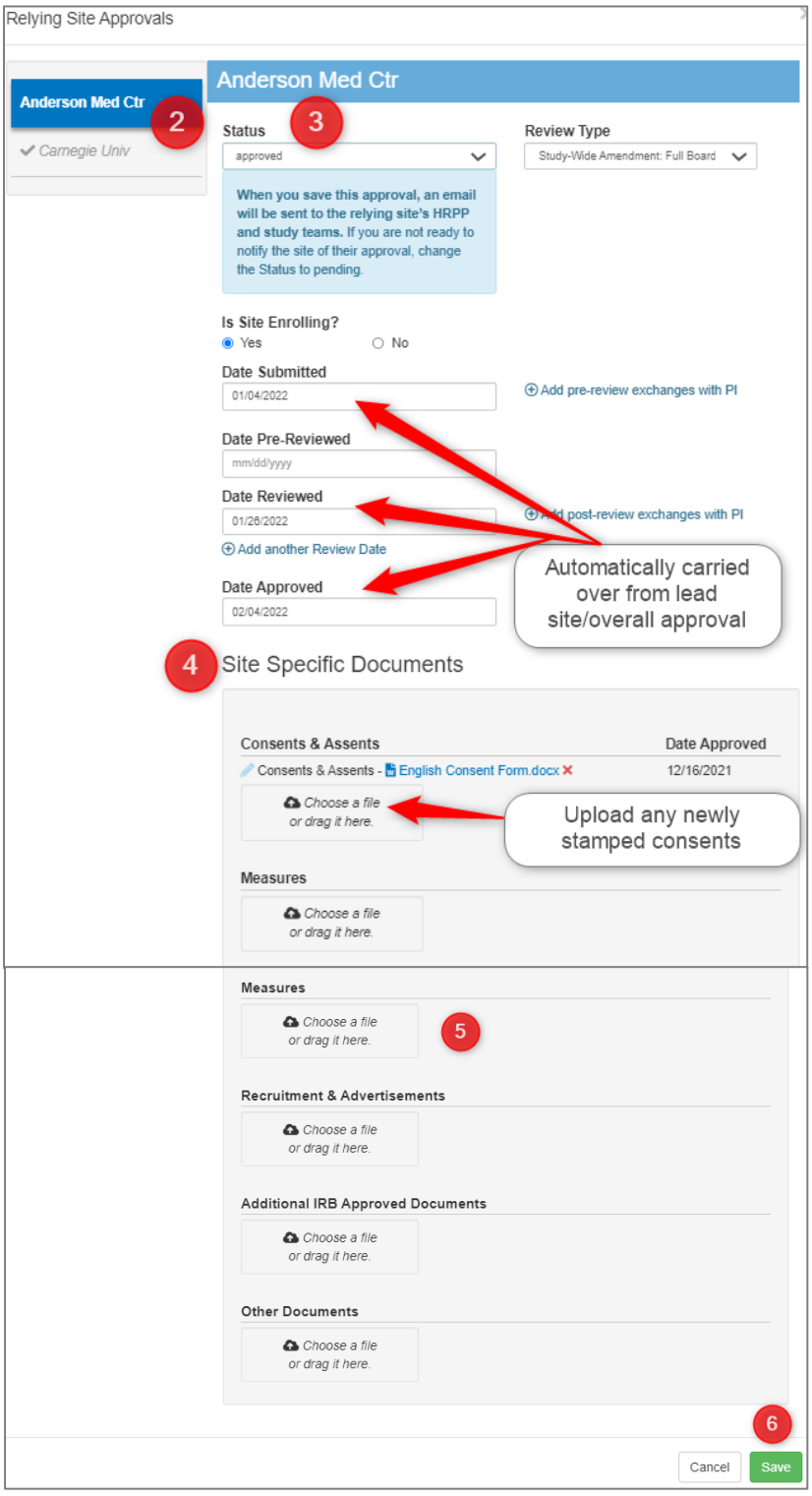
- If a relying site updates their local considerations as the result of a Study-wide amendment (or at any other time), the Reviewing IRB Liaisons and Study Managers will receive an IREx notification alerting you to this change.
- Upon receiving this email, log into IREx to review the updated local considerations. If the sIRB should be notified of this change, export the local considerations as you did when you exported them for site onboarding, and submit them to your sIRB via their eIRB system.
- If the sIRB publishes a site amendment as a result of these changes, disseminate this information by uploading a Site Amendment in IREx.

STEP C: UPLOAD APPROVAL FOR RELYING SITES WITH SITE-SPECIFIC CHANGES

AFTER the Study-wide Amendment has been uploaded for the Overall Study, approvals for sites with site-specific document changes can be added.

1. Click **Uploading 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 in the Relying Site Approvals dialog, but only sites approved on the previous version will have a have a Review Type listed of Amendment: Full/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, nor plans to enroll, you will not be required to upload a Consent & Assent document.
   - 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.