

HOW TO UPLOAD AMENDMENT APPROVALS IN IREx – STUDY MANAGERS

IRB Reliance Exchange (“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. A **site-specific amendment** (see page 3) is used to upload an approved *change for an already approved site*, not the initial approval.

UPLOADING STUDY-WIDE AMENDMENT APPROVALS FOR THE OVERALL STUDY

As of March 2020, the Reviewing IRB or ****NEW** Study Manager (SM)** can upload the approval for a study-wide amendment for the lead site or overall study, which must be uploaded before site approvals can be uploaded.

- A. On the Study-wide IRB Approvals tab, click **Manage Version** and select **add study-wide amendment**.
- B. In the dialog, indicate whether the amendment changes the current version of the protocol.
 - a. If so, enter the *new protocol date/version* and upload the new version.
 - b. 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.
- C. Enter a *summary of changes*. **Tip:** We recommend including the amendment # at the beginning of the change summary as a reference for sites.
- D. Indicate which documents changed and/or should be removed because of this amendment. Documents that are changed will remain in an archived version. If the consent forms were changed, be sure to indicate that so old versions are not carried forward. You will have an opportunity to upload new documents in the steps ahead.
- E. Click **Save**.

The amendment has been created. You can now upload the approval for the lead site/overall study.

- 1) From the Getting Started Checklist, click **Upload Overall Study Approval**.
- 2) In the Review dialog, change the Status to **approved**, select the appropriate *Review Type*, and click **Continue** to move forward.

- 3) Upload the newly approved documents, like the *determination letter, continuing review application, consent documents* (if they changed), and any other new or updated documents for the lead site/overall study. Required documents will be marked in red.
- 4) Review your study information and click **Save**.
- 5) Click **Publish Approval** on the Getting Started Checklist to make the documents visible to sites. **Tip:** Sites are not notified of the new overall, approval. They are notified when their site-specific approval documents are uploaded in the next step.

UPLOADING STUDY-WIDE AMENDMENT APPROVALS FOR SITES

AFTER the amendment has been uploaded for the lead site/overall study, site approvals can be added.

- 1) Click on **site approvals** button on the Study-wide IRB Approvals tab or select it from the **Manage Version** menu.
- 2) In the Relying Site Approvals dialog, select the **name of the site** for which you are uploading approval.

Tip: 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.

- 3) Change the Status to **approved** and select the correct *Review Type*. **Tip:** 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.
- 4) Upload any new/revise documents and ensure the correct versions of all other approved documents are listed for the site.
- 5) 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.

Tip: You can upload approvals for more than one participating site at a time. Select another site name and complete steps 2-5 before saving.

UPLOADING SITE-SPECIFIC AMENDMENTS FOR SITES

Follow the steps below to upload a site-specific amendment, which is a change for a site that already has initial approval in IREx (e.g., a PI change).

- 1) From the Site-specific Approvals tab, click **site amendment** beside the site's name.

The screenshot shows the 'Site-specific IRB Approvals' tab selected. Below the tabs, the protocol version is '20200302, version 4'. Two sites are listed: Carnegie University Medical Center and Peabody Institute of Medicine. Each site has a 'site amendment' button next to its name, with a red arrow pointing to it. Below each site name, there is a dropdown menu for 'Amendment: Expedited (exp. 11/5/2020)' and a 'Current' status button.

- 2) In the dialog,
 - a. Enter a *Change Summary*;
 - b. Change the Reviewing IRB Status to **approved**; and
 - c. Select the appropriate *Review Type*.

The screenshot shows the 'Create Site Amendment for Carnegie University Medical Center' dialog box. The 'Study Information' section contains the following fields:

- Role:** Relying Site
- Change Summary:** Amendment 3 -- site PI changed; updated ICFs to reflect new site PI contact information throughou... (with a red arrow pointing to the text area)
- IRB #:** (empty field)
- Reviewing IRB Status:** approved (with a red arrow pointing to the dropdown menu)
- Type of Study:**
 - Greater than minimal risk
 - Minimal risk
- Review Type:** Site Amendment: Expedited (with a red arrow pointing to the dropdown menu)

 A 'Continue' button with a right-pointing arrow is located at the bottom right of the dialog.

- 3) Click **Continue** to enter the *dates of submission, review and approval*.
- 4) Click **Continue** to upload any updated documents and remove any documents that are no longer current.
- 5) 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.