

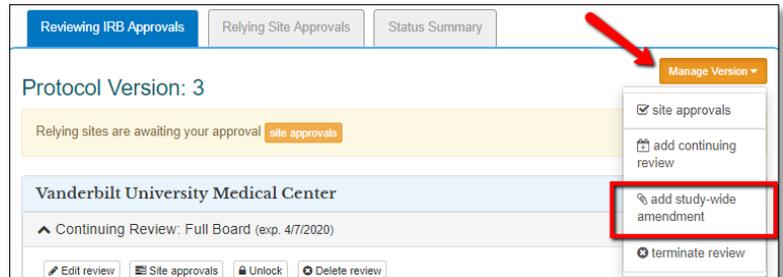
## Uploading Amendments in IREx – Reviewing IRB Quick Guide

In IREx, the **study-wide amendment** is used to upload changes to the protocol or other study materials that apply to **ALL** sites on the study. A **site-specific amendment** (see page 3) is used to upload an approved *change* (not the initial approval) for one site.

### Uploading Study-wide Amendment Approvals for the Overall Study (Reviewing IRBs Only)

A Reviewing IRB Liaison must upload the approval for the Lead Site or Overall Study, before approvals can be uploaded for relying sites.

- 1) On the *Reviewing IRB Approvals* Tab, click **Manage Version** and select **add study-wide amendment**.
- 2) In the dialog, indicate whether the amendment **changes the current version of the protocol**.
  - a. If the protocol version changed, select “Yes” and enter the **new protocol version name or number** (Note: this should match what is listed on the protocol) and upload the **new protocol**.
  - b. If the amendment *does not change the protocol version*, select “No”, and IREx will add a revision number to the current protocol version to keep track of changes.
- 3) Enter a **summary of changes**. We recommend including the **amendment # at the beginning of the change summary** as a reference for sites.
- 4) Indicate which **documents have changed** and/or should be removed.
  - a. IREx will not bring these documents into the new version, but they will remain in an archived version.
  - b. You will have an opportunity to upload any new documents.
- 5) Click “**Save**”.



Add Study-Wide Amendment

Users Viewing Studies 20190709

Does this amendment change Protocol [1.0]?  Yes  No ←

New protocol version: 08/21/2019

Upload new protocol:  PROTOCOL\_...2019.docx  This file is a draft version.

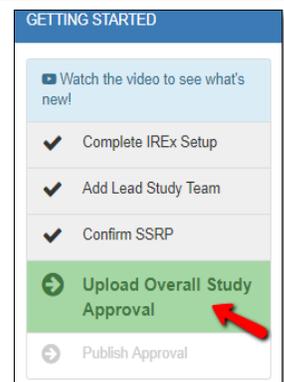
Summary of changes: Amendment 15 -- Added blood draw for participants at screening #3; modified consents as appropriate. (101 / 3999 characters)

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

The amendment has been created, now it's time to upload information about the approval.

- 6) On the study page, click the “**Upload Overall Study Approval**” step on the GETTING STARTED checklist.
- 7) In the Edit Review window, change the **Status** to “Approved” and ensure the correct **Review Type** is selected.
- 8) Next, enter the Key Review dates.
- 9) Finally, upload the new **determination letter**, an **amendment application** and any **new or updated documents** for the **LEAD** site *only* here.
- 10) Click **Publish Approval** to complete the study-wide amendment for the Lead Site.

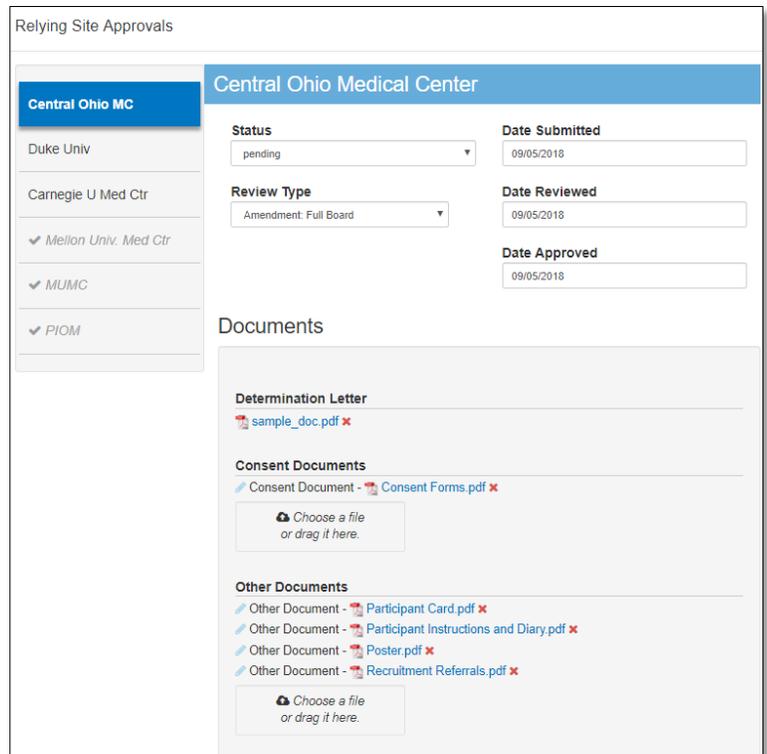
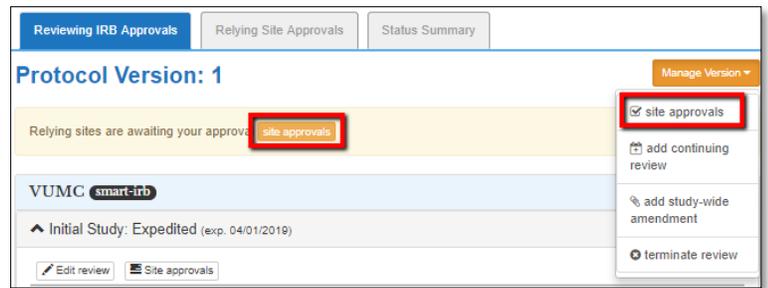
**NOTE:** Relying sites are not notified until their documents are uploaded (see next page).



## Uploading Study-wide Amendment Approvals for Relying Sites (*Recommended Study Manager Task*)

After the overall study approval has been uploaded, a Reviewing IRB Liaison or the IREx Study Manager (recommended) can add approvals for relying sites.

- 1) Click on **site approvals** button on the Reviewing IRB Approvals tab or the **Manage Version** menu.
- 2) In the dialog on the left-hand side, select on the **name of the site** for which you are uploading approval.
- 3) Change the **Status** to "Approved" and ensure the correct **Review Type** (Expedited or Full Board) is selected.
- 4) Check that the **Dates of Submission, Review and Approval** are accurate. These are auto filled based on what was entered for the overall study approval.
  - o **Uploading documents:** Be sure to add new or revised site materials and delete any materials that were changed or are no longer applicable. The **Determination Letter** from the overall study approval is carried over for all sites that had approval on the previous protocol version.
  - o **Consent Documents** that were approved under the previous version are carried forward. Click the red **x** to remove and upload the revised version.
  - o **Other Documents** that were approved under the previous version are also carried forward. Click the red **x** to remove and upload the revised version.
- 5) You can upload approvals for more than one PSite before pressing Save. Select another site name and complete steps 3-5 before saving.



After adding a site's approval and pressing **Save**, IREx will notify (1) the sIRB Liaisons, (2) PSite Liaison(s), (3) the IREx Study Manager and (4) the PSite study contacts that are listed in IREx of the new approval.

Dear Liaisons and Study Contacts,

Peabody University Medical Campus has shared IRB approval for your institution, Townsend College of Medicine, in IREx for the study below:

**Study Title:** Traditional Treatment vs. Aggressive Therapy for Cognitive Disorders  
**Type of Review / Approval:** Study-wide Amendment: Expedited  
**Version:** 08.21.2019  
**Change Summary:** Amendment 15 – Modified the telephone screening script to work for all sites  
**Expiration Date:** 1/16/2020  
**Study Link:** <https://www.irbexchange.org/study/index/?proj=112>

**Principal Investigators & Study Contacts:**

Your approval documents are available in [IREx](#). If you have any questions about your approval or future submissions, please contact the Coordinating Center (CC)/Lead Study Team (LST) or Reviewing IRB. If needed, contact information for the CC/LST is provided in a blue button just under the study title in IREx.

*Thank you for using IREx,  
The IREx Team*

## Uploading Site-specific Amendments (Recommended Study Manager Task)

To upload a change for a site that already has initial approval in IREx (e.g., a PI change), Reviewing IRB Liaisons or Study Managers (recommended) can upload a site-specific amendment by following these steps:

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



Reviewing IRB Approvals | **Relying Site Approvals** | Status Summary

Protocol Version: 2, Rev. 1

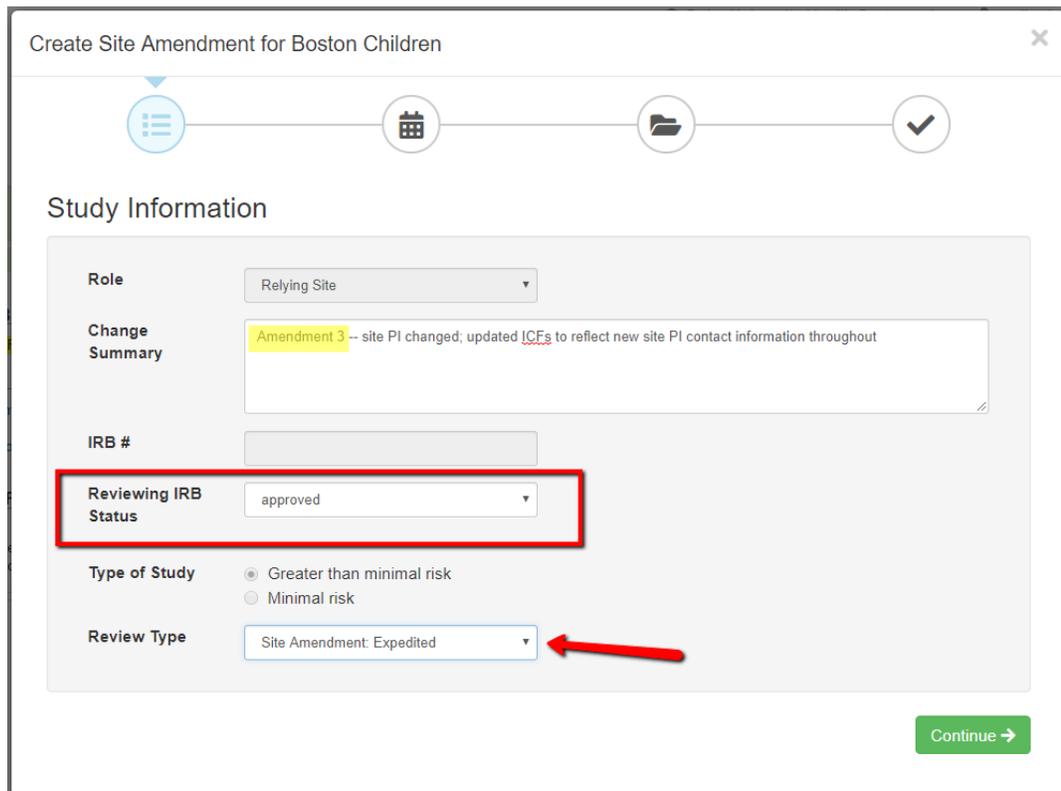
Relying sites are awaiting your approval [site approvals](#)

**Peabody Institute of Medicine** [site amendment](#)

Continuing Review: Full Board (exp. 2/11/2020) **Current**

Amendment: Expedited (exp. 6/30/2019) **Archived**

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



Create Site Amendment for Boston Children

Study Information

Role: Relying Site

Change Summary: Amendment 3 -- site PI changed; updated ICFs to reflect new site PI contact information throughout

IRB #:

Reviewing IRB Status: approved

Type of Study:  Greater than minimal risk  Minimal risk

Review Type: Site Amendment: Expedited

Continue →

- 3) Press continue and enter the required dates where indicated.
- 4) Press continue and add new approval documents and remove any that were changed or are no longer applicable for this site.
- 5) Press **Save**, and a notification will be sent to the site, just as described for study-wide amendments, immediately above.