

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 <u>ALL</u> 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 <u>does not</u> 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 <u>changed and/or</u> <u>should be removed</u> 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 Documents that are changed will remain in an archived version.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

100000	Study-wide IRB Approvals	Site-specific IRB Approvals	Status Summary		
t.	Protocol Version:	Manage Version -			
dment	SIRB [.] Mellon Un				
				review	
on and	Lead Site: Mellon Univ	Lead Site: Mellon University Medical Center			
	▲ Continuing Review: E	amendment			
Does this amo Protocol [3] ?	endment change	⊙ Yes () No			
New protocol date / version		As entered on the protocol			
Upload new protocol		Browse No file selected.	-	This file is a draft version.	
Summary of c	hanges				
		A Required			
		0 / 3999 characters			
Which docum	ents were changed or rem	oved by this Study-Wide Am	endment? 😧		
Consent Forms - Consent Document: C Consent Forms - Consent Document: C		ONSENT FORM Spanish.docx		□ changed / removed?	
		ONSENT FORM.docx		□ changed / removed?	

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.

no	w upload			
Mellon SETTI	Univ. Med Ctr 🛛 🔺 IG STARTED	Study Information	tion	
Wate new!	th the video to see what's	Role	Reviewing IRB	
~	Add Participating Sites	Summary	3 additional clinic visits were added and study measures were revised.	
~	Add Pl Info			
~	Notify Site HRPPs/IRBs	Status	approved	
Ð	Upload Overall	IRB #	fgsfgsq	
Ð	Publish Approval	Type of Study	 Greater than minimal risk Minimal risk 	
0	Upload Relying Site Approval	Review Type	Amendment Expedited	
				Continue 🗲

- 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

- 1) Click on site approvals button on the Stu Approvals tab or select it from the Manage Ve
- 2) In the Relying Site Approvals dialog, select the site for which you are uploading approva

Tip: The dates and determination lette

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.

- Change the Status to **approved** and 3) 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 have a review type of Amendment: Full/Expedited.
- 4) Upload anv new/revised documents and ensure the correct versions of all other approved documents are listed for the site.
- Click Save. 5)

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.

ed for the lead site/o	overall study, site a	approvals can b	e added.	
e Study-wide IRB	Study-wide IRB Approvals	Site-specific IRB Approvals	Status Summary	
elect the name of	Protocol Version: 202	200302, version		Manage Version 🔻
proval.	4			☑ site approvals
letter from the	Relying sites are awaiting your	approva site approvals		add continuing review
Relying Site Approvals				>
Comparise III Mad City	Carnegie Unive	ersity Medical C	Center	
Carnegie U Med Ctr	Status		Date Submitte	d
Peabody Inst Med	approved	Y	03/04/2020	
	Review Type		Date Reviewed	1
	Site Amendment: Exped	iited 🔻	03/04/2020	
			Date Approved	I
			03/04/2020	
	Documents		Autom	atically carried
			over	from lead site/
			overa	ll approval
	Determination Lett	er		-
	DETERMINATION	LETTER_SiteAmendmen	t_Carnegie.docx ×	
	Consent Documen	ts		
	Consent Document	- CONSENT FORM -	Carnegie.docx ×	
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	or drag it here	-		Automatically
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	Other Documents	RECOL DI dans		CONSENTS or
	Other Document -	Flver ppg X		OTHER documents
	Other Document -	HIPAATEMPLATE.doc	××	changed, delete
	Other Document -	Questionnaire.docx ×		and upload new
	/ Other Document -	Recruitment.docx ×		versions.
	Choose a for or drag it here	ile		and a shake to
				Cancel
				Gander



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.

Study-wide IRB Approvals	Site-specific IRB Approvals	Status Summary	
Protocol Version: 20200302, version 4			
Carnegie University Medical Center Site amendment			
Amendment: Expedited (exp. 11/5/2020)			
Peabody Institute of Medicine Site amendment			
✓ Amendment: Expedited (exp. 11/5/2020) Current Current			

- 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 Amendme	nt for Carnegie University Medical Center
Study Information	on
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
⊖ Greater than min ⊚ Minimal risk Review Type	Type of Study imal risk Site Amendment: Expedited
	Continue →

- 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.