

HOW TO UPLOAD THE INITIAL APPROVAL FOR RELYING SITE(S) IN IREX

Although sites may be added to a study as an "amendment" in the Reviewing IRB's electronic system, in IREx, you <u>do not</u> need to create a new study-wide or site amendment to add an Initial Approval for a new site. **AFTER** the Reviewing IRB Liaison has uploaded the initial approval for the Lead Site or Overall Study, the Reviewing IRB Liaison or the IREx Study Manager (recommended) can add approvals for sites that have ceded review.

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UPLOADING THE INITIAL STUDY APPROVAL FOR RELYING SITES

- Click Upload Relying Site Approval in the IREx Checklist.
- In the Relying Site Approvals dialog, click on the **name of the site** for which you are uploading approval.
- Change the Status to **approved**. All the required fields will be highlighted in red.
- Enter the **Review Type** (Expedited or Full Board).
- Is Site Enrolling? will default to Yes. Change to No if the site will not be enrolling participants.
- Enter the date the site was **Submitted** to the sIRB, **Date Reviewed**, and **Date Approved** by the sIRB.
- Upload the IRB Approval Documentation, Consents & Assents, and any other site-specific documents, such as Measures, Recruitment & Advertisements, Additional IRB Approved Documents, or Other Documents.
- Click **Save** to complete the approval upload. Unless the 'turn OFF approval notification' box is checked, IREx will notify the people listed below of the new approval:
 - the sIRB Liaison(s)
 - the site Liaison(s)
 - the IREx Study Manager(s)
 - the site study team contacts listed in IREx

Regardless of whether an approval notification is sent, the approval documents will appear on the Approval History tab for that site.

• If available and desired, check the box to turn OFF the approval notification. By checking this box, any sIRB liaisons and Study Managers will also NOT receive the approval notification. (*This is not recommended for the initial study approval.*)

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ADDITIONAL TIPS:

- You can upload approvals for multiple sites at once by selecting another site name and completing steps 2-6 before saving.
- If you need to pause the approval upload and return later, you can change the approval status to *pending* or leave blank. This saves the information without notifying the site so you can return later to complete the approval.
- Descriptors can be added to the Consents & Assents and Package Insert document types (e.g., 'Consents & Assents – Spanish ICF'; 'Package Insert – Sucraid Oral Solution').

Please describe the do	cument type	
Consents & Assents -	Spanish ICF	
		Cancel OK

• To better organize documents for your sites, you can customize documents by relabeling the Additional IRB Approved Documents and Other Documents (e.g., 'MOP').

Carnegie U Med Ctr Checklist		
~	Add Participating Sites 🖋	
~	Request Agreements	
~	Grant Site Access	
~	View Site Progress on Status Summary	
Ŧ	Upload Relying Site Approval	