

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 do not 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.

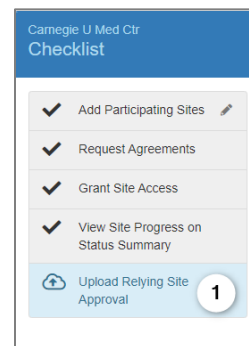
UPLOADING THE INITIAL STUDY APPROVAL FOR RELYING SITES

- 1) Click **Upload Relying Site Approval** in the IREx Checklist.
- 2) In the Relying Site Approvals dialog, click on the **name of the site** for which you are uploading approval.
- 3) Change the Status to **approved**. All the required fields will be highlighted in red.
- 4) Enter the **Review Type** (Expedited or Full Board).
- 5) **Is Site Enrolling?** will default to **Yes**. Change to **No** if the site will not be enrolling participants.
- 6) Enter the date the site was **Submitted** to the sIRB, **Date Reviewed**, and **Date Approved** by the sIRB.
- 7) 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**.
- 8) Click **Save** to complete the approval upload. 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

The documents will appear on the Approval History tab for that site.

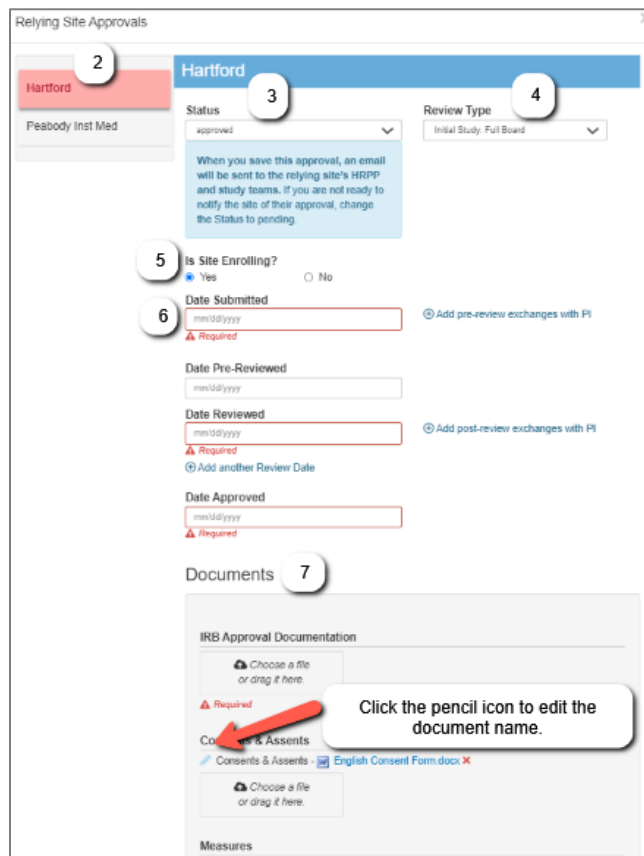
ADDITIONAL TIPS:

- 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’).
- 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
- Upload Relying Site Approval **1**



Relying Site Approvals

Hartford

Status: approved

Review Type: Initial Study - Full Board

When you save this approval, an email will be sent to the relying site's HRPP and study teams. If you are not ready to notify the site of their approval, change the Status to pending.

Is Site Enrolling?
 Yes No

Date Submitted: [mm/dd/yyyy] **Required**

Date Pre-Reviewed: [mm/dd/yyyy]

Date Reviewed: [mm/dd/yyyy] **Required**

Date Approved: [mm/dd/yyyy] **Required**

Documents **7**

IRB Approval Documentation

Choose a file or drag it here

Required

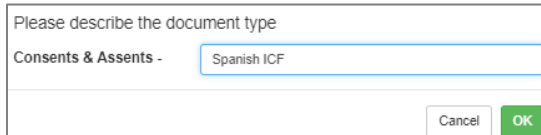
Consents & Assents

Consents & Assents - English Consent Form.docx

Choose a file or drag it here

Measures

Click the pencil icon to edit the document name.



Please describe the document type

Consents & Assents - Spanish ICF

Cancel OK