

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

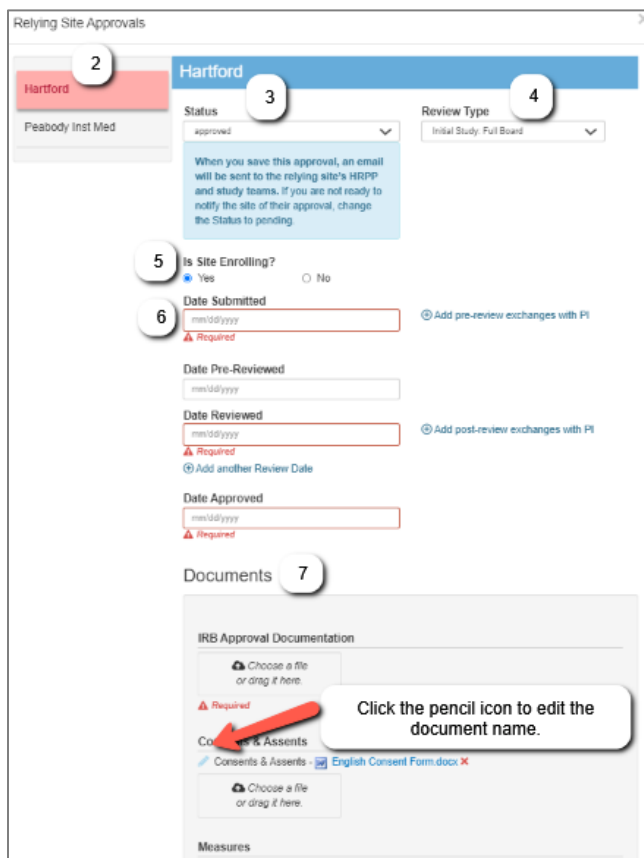
Although sites may be added to a study as an “amendment” in the Reviewing IRB’s electronic system, in IREx, you do not need to create a new study-wide or site amendment to add an Initial Approval for a new site. **AFTER** the Reviewing IRB Liaison has uploaded the initial approval for the Lead Site or 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 (Study Manager Task)

- 1) Click on the **site approvals** button on the Study-wide IRB Approvals tab or select **site approvals** from the Manage Version menu.



- 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 Site-specific IRB Approvals 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’).

