IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

HOW TO UPLOAD THE INITIAL APPROVALS IN IREx

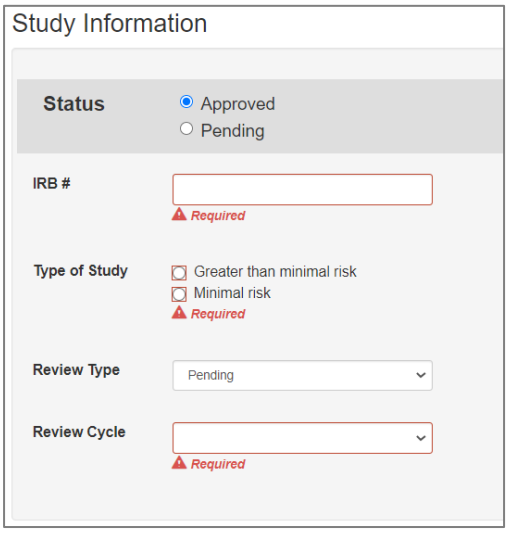
Reviewing IRBs use IREx to capture and communicate study and site approvals for the life of the study, including initial review, continuing review, site amendments and study-wide modifications or changes.

UPLOADING THE INITIAL OVERALL STUDY APPROVAL (Reviewing IRB Task)

For initial approvals, a Reviewing IRB Liaison must upload the approval for the Lead Site or Overall Study before approvals for participating sites can be uploaded by the Reviewing IRB or IREx Study Manager (see page 2).

1) On the study page, click the **Upload Overall Study Approval** on the GETTING STARTED checklist to document your initial study approval.

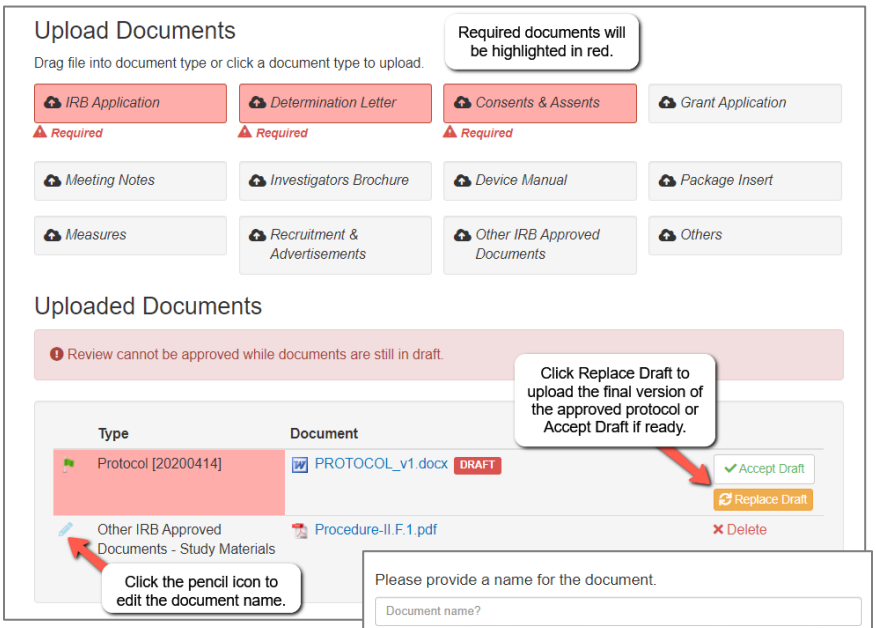
2) In the Review dialog, change the Status to **Approved** and enter the required fields, which will be highlighted red:
   a. **IRB #:** Your local IRB record, submission or tracking number
   b. **Type of Study**: Greater than minimal risk or Minimal risk
   c. **Review Type**: Full Board or Expedited Review (if Minimal risk)
   d. **Review Cycle:** 3, 6, 9, 12, >12 months or No Further IRB Review Required (if Minimal Risk & qualifies)



3) Enter the Key Review Dates when the overall study was:
   a. **Submitted** for review,
   b. **Pre-Review was Completed**,
   c. **Reviewed** by the IRB committee or subcommittee, and
   d. **Approved**.

Tip: The expiration date is pre-populated based on the approval date, but it can be edited.

4) Upload the approved study documents for the lead site or overall study only. Required documents will be marked in red:
   - **Protocol** (required)**:** Accept the draft version or replace it if changes were made
   - **IRB Application** (required)
   - **Determination Letter** (required)
   - **Consents & Assents:** Upload stamped consents for the lead site only (Note: consents are required for reater than minimal risk studies, but can be waived, if appropriate for a minimal risk study)
   - You can also upload the following if applicable for all sites: **Grant Application, Meeting Notes, Investigators Brochure, Device Manual, Package Insert, Measures, Recruitment & Adverstisements, and Other IRB Approved Documents.**



Tip: You can drag and drop multiple files of the same type (e.g., consent forms) at once or upload them individually.

5) Review the study information and click **Save**. If required fields are missing, the section will be highlighted.

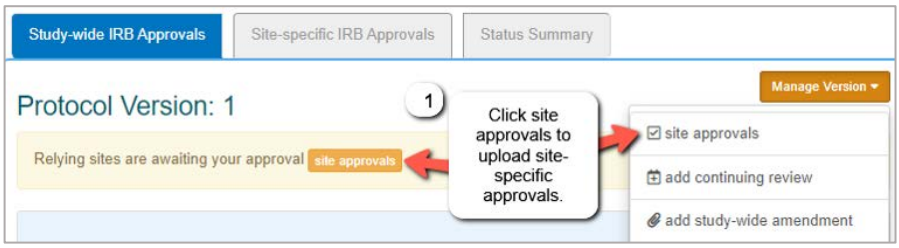
6) When you are ready to publish your approval, click **Publish Approval** to make the documents visible to participating sites. Sites that have been alerted of the study in IREx will be notified of the Lead Site or Overall Study approval.

UPLOADING THE INITIAL STUDY APPROVAL FOR RELYING SITES (Study Manager Task)

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.

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.

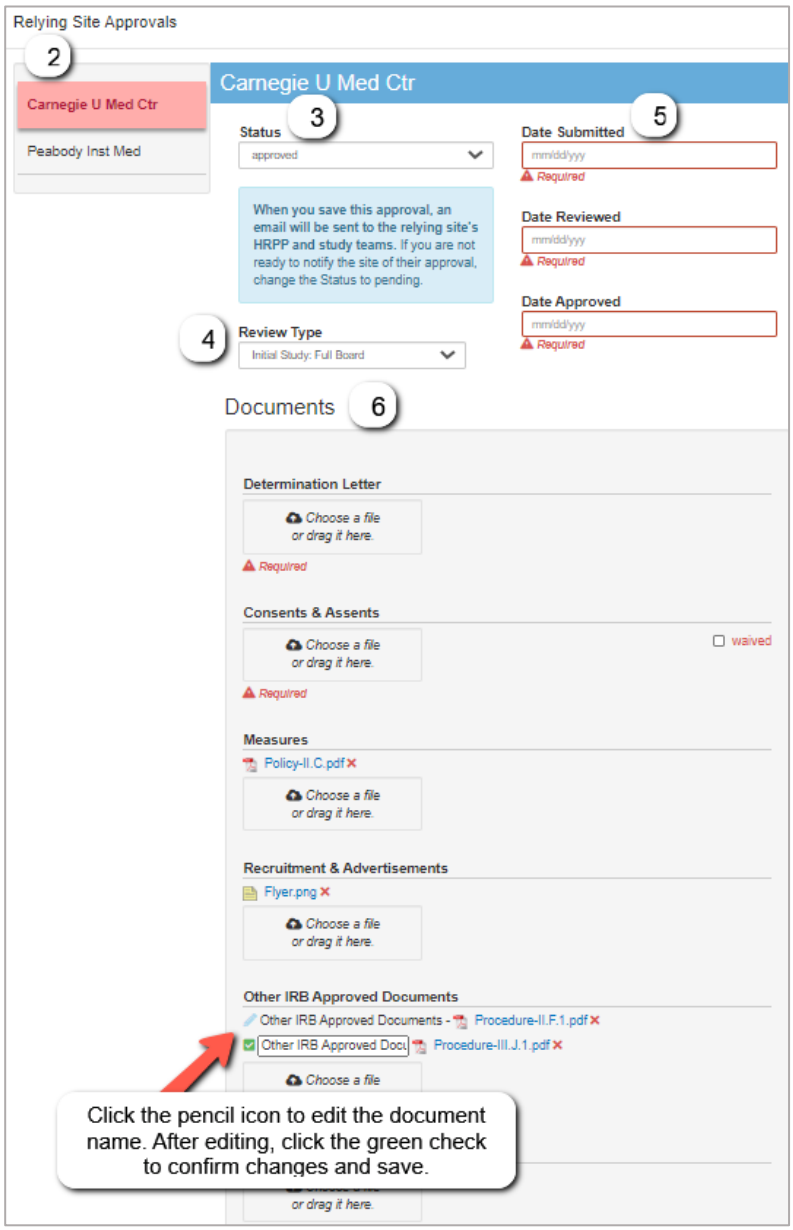
4) Enter the **Review Type** (Expedited or Full Board).

5) Enter the date the site was **Submitted** to the sIRB, **Date Reviewed,** and **Date Approved** by the sIRB.

6) Upload the **Determination Letter, Consent & Assents,** and any other site-specific documents, such as **Measures, Recruitment & Advertisements, or Other IRB Approved Documents.**

7) 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.