IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

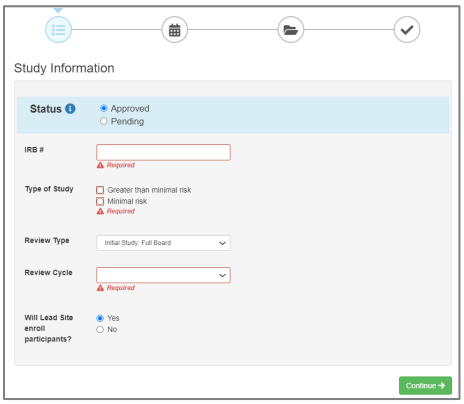
HOW TO UPLOAD THE LEAD SITE/OVERALL STUDY INITIAL APPROVAL IN IREx

Reviewing IRBs and Lead Study Teams/Coordinating Centers (IREx Study Managers) use IREx to capture and communicate approvals for the life of the study, including initial review, continuing review, site-specific, and study-wide changes.

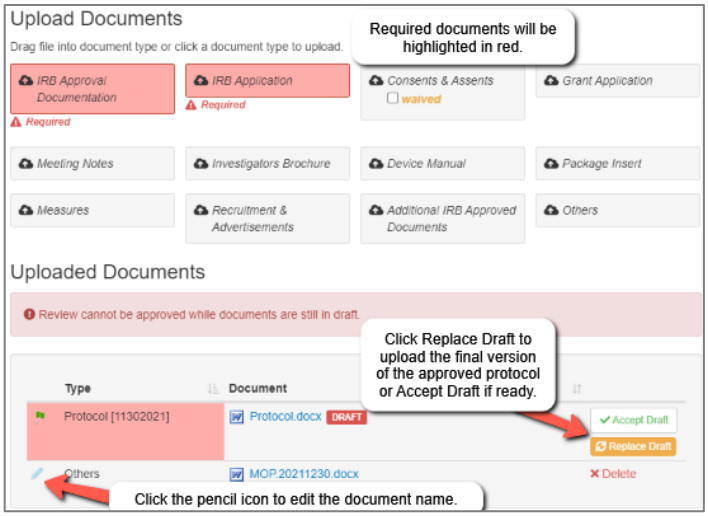
UPLOADING THE INITIAL OVERALL STUDY APPROVAL

After the Reviewing IRB has created the study, they or the IREx Study Manager (recommended) can upload the approval for the Lead Site or Overall Study. This must be posted before approvals for relying sites can be uploaded (see this Quick Guide).

1) From the Getting Started Checklist, click **Upload Overall Study Approval**.
2) In the 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)
   e. **Will Lead Site enroll participants?**: This will default to Yes; change to No if the Lead Site is not enrolling participants



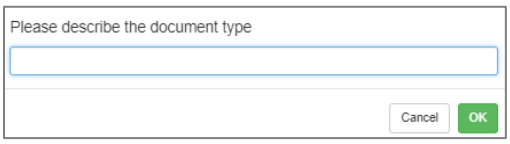
3) Enter the Key Review Dates: **Submitted** for review, **Pre-Review** was Completed, **Reviewed** by the IRB committee or subcommittee, **Approved,** and when the study **Expires.**
4) Upload the approved study documents for the lead site or overall study only. Required documents will be marked in red:
   - **Protocol** (required)**:**
     - The version shown is what the sIRB uploaded when they created the study.
     - Press **Replace Draft** if it has been updated. You can edit the version # or name & upload a new version from here.
     - Press **Accept Draft** if the protocol is what was approved.
   - **IRB Approval Documentation** (required)
   - **IRB Application** (required)



   - **Consents & Assents:** Upload final approved consents for the lead site only (Note: consents are required for Greater than minimal risk studies, but can be waived, if appropriate for a Minimal risk study)
     i. **Note:** Exception from Informed Consent (EFIC) studies do not require **Consents & Assents** to be uploaded with the initial lead site approval.
   - You can also upload the following if applicable for all sites: **Consultation Plan Template** (only available for EFIC studies), **Grant Application, Meeting Notes, Investigators Brochure, Device Manual, Package Insert, Measures, Recruitment & Adverstisements, Additional IRB Approved Documents,** and **Others.**

Tips:

- Drag and drop multiple files of the same type (e.g., consent forms) at once or upload them individually.
- After uploading documents, documents with a pencil icon (see screenshot above) can be renamed to include better descriptions. Study teams can sort the documents by *type* to find a specific document more quickly.



5) Review the study information and click **Save**. If required fields are missing, those sections will be highlighted.
6) When you are ready to publish the approval, click **Publish Approval** to make the documents visible to relying sites; however, sites are **not** notified when the overall study approval is published.