

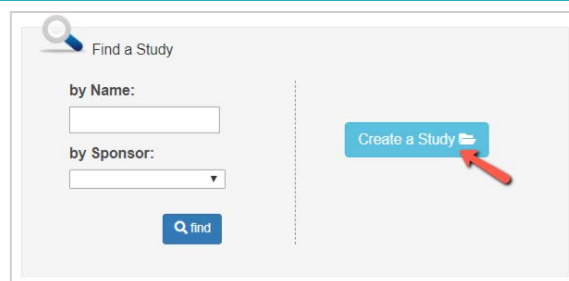
IREx can be used to capture all single IRB (sIRB) documentation (e.g., cede decisions, local considerations, sIRB approvals, as well as coordinate communications between the sIRB and participating site study teams and HRPPs.

## PRIOR TO CREATING A STUDY IN IREx

- COMPLETE** or update the IREx Institutional Profile (see [quick guide](#))
- EDUCATE** the lead study team or coordinating center staff ("IREx Study Manager") on your sIRB process such as:
  - Agreements required
  - Consent form process (e.g., whether a template is being used)
  - How sites are submitted for review (e.g., as an amendment)
- PREPARE** reliance instructions for participating sites. **Tip:** We recommend the Study Manager disseminates the instructions to site study teams after the lead site is approved. See [IREx Reliance Instructions Template](#).

## CREATING A STUDY IN IREx

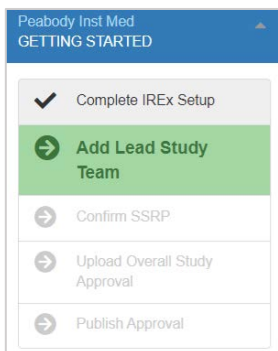
- Login to IREx and click **Create a Study** on the main homepage.  
**Tip:** Studies can be created before you have overall study approval.
- Enter basic study information like the *title*, *study summary*, *NCT #*, and *sponsor*.
- Upload key study documents, such as the *protocol* and *consent form(s)*. **Tip:** Document(s) uploaded here are marked as draft and can be changed later when uploading the initial study approval.



After saving the information, you are taken to the study page and will see a GETTING STARTED checklist that lists your remaining steps to complete the study setup.

## COMPLETE THE IREx SETUP FOR A STUDY

- Click **Complete IREx Setup** on the GETTING STARTED checklist.
- Identify the lead site, indicate if you are using IREx to capture local considerations, and if a Letter of Indemnification (LOI) is required for the study.
- Identify the IREx Study Manager (e.g., lead study team or coordinator center staff responsible for communicating with sites). See page 2 on the role of the Study Manager.
- Identify the Reviewing IRB Primary Liaison for the study and others who need to receive study notifications. All Liaisons can still access and perform all functions for the study.



### ADD LEAD STUDY TEAM CONTACTS (IF THE SIRB IS ALSO THE LEAD SITE)

If the lead site is also at the Reviewing IRB institution, the checklist will include a step to provide the name and email address for the PI (**required**) and study coordinator. If the lead site is at another site, that HRPP will add the study team contacts for their site.

### CONFIRM THE STUDY-SPECIFIC RELIANCE PLAN (SSRP)

The SSRP is automatically generated from your Institutional Profile (section 4) and outlines how the flexible elements of reliance will be handled. The Reviewing IRB can edit the SSRP for the study (all sites) or for individual sites, as requested after the site registers for the study. Site HRPPs

indicate reliance by accepting the SSRP. **Tip:** Sites cannot access the study until the SSRP is confirmed and the sites are notified on the Status Summary tab. We recommend notifying sites of the study after the approval is uploaded to IREx.

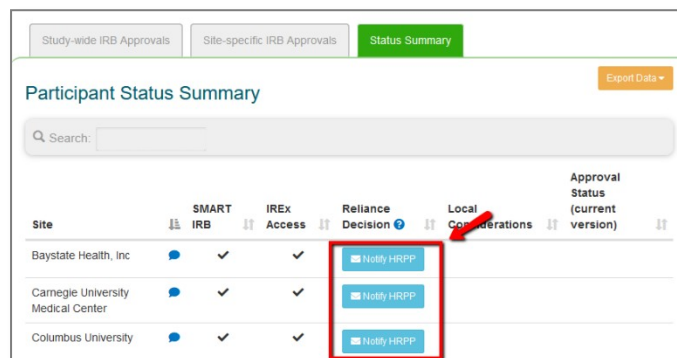
## UPLOAD OVERALL STUDY APPROVAL

- Select **Upload Overall Study Approval** on the GETTING STARTED checklist.
- Change the study status to **Approved** and enter the required review information (dates, level of review)
- Upload the required documents and accept any draft documents or replace them if they were changed. **Tip:** Remember to update the protocol version number if it has change.
- Publish Approval.

## THE ROLE OF THE IREX STUDY MANAGER

To help assuage the sIRB burden, IREx recommends delegating the tasks below to the IREx Study Manager (See [Study Manager Quick Guide](#)). The Reviewing IRB can also do these tasks, if needed, as described below:

- **Add Sites:** Add sites by selecting **Manage Project** then **Edit Participating Sites**. The PI name and PI email are required to notify the site.
- **Notify Site HRPPs of the Study:** From the Status Summary, click the **Notify HRPP** button to send the IREx study notification.
- **Track Site Progress Towards sIRB Approval:** Use the Status Summary to track sites' progress on agreements, reliance decisions, local considerations and approval.
- **Export Local Considerations:** The IREx Study Manger are notified to export site's local considerations as they are completed by the site. Click **Export Survey Data** and select to download local considerations.



## WHEN TO ADD SITES IN IREX

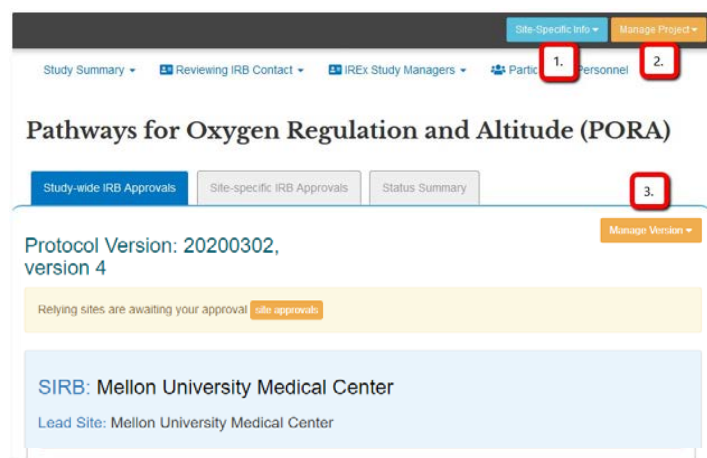
Sites are added to a study and notified of the study in separate steps so you can control when sites get access to the study. Sites can be added to a study at any time, even before the initial approval has been uploaded. Adding sites to the study early allows you to see whether they have completed the required agreements, like SMART IRB, and whether they have access to IREx. If any reliance-related agreements are missing for a site, the site can begin executing those while the lead site is being approved

## WHEN TO NOTIFY SITES ABOUT THE STUDY IN IREX

We recommend notifying sites of the study AFTER (1) the lead site is approved and uploaded to IREx and (2) the approved study materials and reliance instructions are distributed by the study manager to the sites (e.g., protocol, consent templates, contracts, regulatory documents, etc.). These materials are distributed outside of IREx.

Notifying a site about a study in IREx is the Reviewing IRB's way of letting the site know that they are a site on a single IRB study. Because relying HRPPs often require a local submission before indicating reliance or completing local considerations, many HRPPs will not login immediately. Instead, the IREx notification connects the HRPP and their local study team so that the HRPP can educate the local study team on the process of using reliance at their site, which likely begins with a local submission.

## UPLOADING PARTICIPATING SITE APPROVALS (RECOMMENDED STUDY MANAGER TASKS)



The IREx Study Manager can upload site approvals, as can the Reviewing IRB, using the yellow **site approvals** button on the Study-wide IRB or Site-specific IRB Approvals tab. **Tip:** IREx notifies site HRPP Liaison(s) and study teams of approval. They can download approved materials on the Site-specific IRB Approvals tab.

## ACCESSING AND EDITING INFORMATION

1. Use **Site-Specific Info** to edit study contacts.
2. Use **Manage Project** to edit sites or study setup.
3. Use **Manage Version** to upload study-wide amendments or continuing reviews. (Site amendments are added on the Site-specific IRB Approvals tab.)