Updated August 23, 2019

IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Using IREx as the Study Manager

IREx was developed by Vanderbilt to support IRBs, Human Research Protection Programs (HRPPs), Lead Study Team (LSTs) and Coordinating Centers (CCs), and study teams implementing single IRB (sIRB) review. IREx can be used to capture all sIRB documentation (e.g., cede decisions and local considerations) and facilitate communications between the sIRB and participating site (PSite) study teams and HRPPs.

The IREx Study Manager

ROLE: the person(s) from the Lead Study Team or Coordinating Center who is responsible for managing PSite access to IREx and overseeing PSite readiness for single IRB (sIRB) review.

STUDY MANAGER TASKS IN IREX:

- ✓ Manage participating sites' access to the study
- ✓ Notify Participating Site HRPPs of the study
- ✓ Track participating site readiness for sIRB review
- ✓ Export sites' local considerations from IREx and submit them to the sIRB
- ✓ Centrally manage participating site approval documents and notifications to participating sites

IREX STUDY MANAGER CHECKLIST

For more detailed information, check out the Study Manager User Manual on the IREx Resources page:

Step 1

SUBMIT THE LEAD SITE TO THE SIRB

- ❑ Discuss the submission process with the sIRB (What is needed for the lead site? How are Participating Sites ('PSites') added?)
- ❑ Ask the sIRB what should be communicated to sites; IREx provides **Template Reliance Instructions** on the Reviewing IRB resources page here that can be tailored to your study.

Step 2

THE STUDY IS CREATED IN IREX [COMPLETED BY THE SIRB]

You will receive access to IREx via an email notification.

Step 3

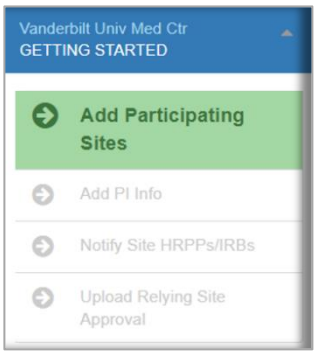
WORK WITH SITES WHO HAVE NOT COMPLETED ALL REQUIRED AGREEMENTS (IF APPLICABLE)

If any of your PSites have not executed all of the required agreements, the sIRB may (1) reach out to the PSite HRPP about any missing agreements before you have approval for the study or (2) ask you to instruct the investigator at the site to contact their local HRPP about the missing agreements. PSites who have completed all agreements do not typically have any action items until the lead site has been approved.

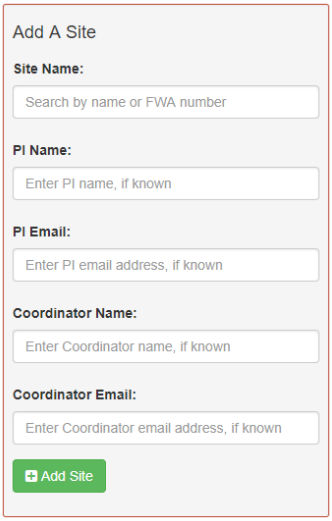
Step 4

ADD SITES TO THE STUDY IN IREX

Use the "**GETTING STARTED**" checklist to help you track your actions in IREx. **The first step is to add PSites in IREx so you can track their agreement status.**



- ❑ Only sites listed on the study can access it.
- ❑ Add sites using their name (avoid abbreviations) or Federalwide Assurance # (FWA). *Note: You can also add sites that do not appear in the search.*
- ❑ A PI name and email address are required before the site can be notified of the study; however, you can list the site name without the PI information and retun later to enter it.
- ❑ You can also include a site coordinator name and email (recommended, but not required).



Step 5a

EMAIL RELIANCE INSTRUCTIONS AND APPROVED STUDY MATERIALS TO STUDY TEAMS (OUTSIDE OF IREX)* Please "cc" the sIRB Point of Contact on these emails

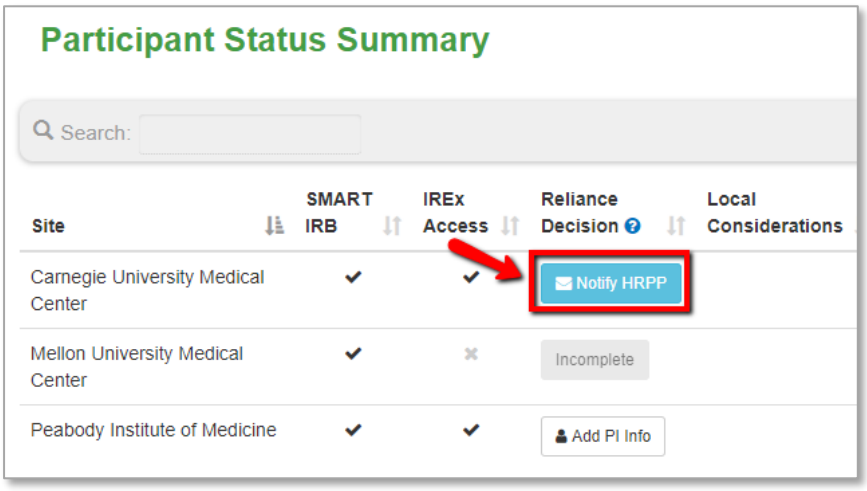
- ❑ PSite Study Teams need the study materials in order to submit to their local HRPP, which is typically required before the HRPP will access IREx, document reliance, and provide IREx access to their local study team.
- ❑ This communication should include the following types of information: approved protocol and ICF templates; sIRB determination letter for the lead site; reliance instructions; contracts; and other regulatory documents.
- ❑ If desired, you can share the link to this 4-minute video tutorial with site study teams.

Note: Study teams may **engage/contact (but not submit to) their local HRPP about the reliance process before the lead site has study approval.*

Step 5b

NOTIFY SITES OF STUDY IN IREX (AFTER APPROVAL FOR THE LEAD SITE)

You should only notify PSite HRPPs of a study in IREx after (1) the lead site approval has been uploaded to IREx and (2) the reliance instructions and study materials have been sent to study teams.

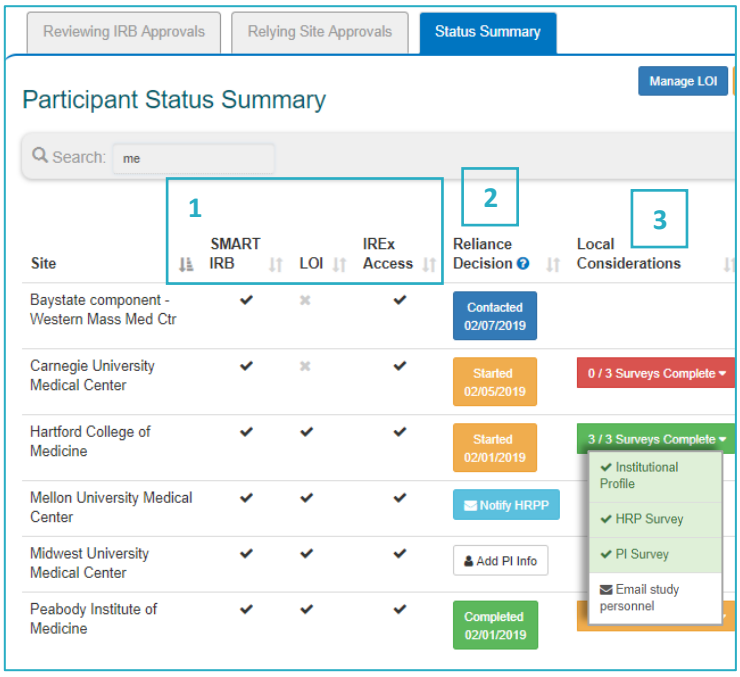


- ❑ This email lets the site's HRPP know the study is in IREx and prompts them to connect with and educate their local study team on the reliance process for their site.
- ❑ The Site PI and coordinator (if provided) are copied on the email.
- ❑ You are copied on the email.
- ❑ You can notify sites at different times, depending on when the site is being onboarded to the study.
- ❑ Only sites with IREx access can be notified (sites with a checkmark under "IREx Access"). For sites not in IREx, an HRPP/IRB director or manager can create their institutional access here.

Step 6

TRACK SITE READINESS FOR SIRB REVIEW USING THE STATUS SUMMARY TAB

Refer to the numbers in the screenshot:



1. **Is the site signed onto the required agreements and platforms?** (Check = yes)
   a. SMART IRB agreement
   b. LOI (column shown if applicable)
   c. IREx Access: If not, their HRPP/IRB Director can create access here.
2. **Has the site's HRPP made a reliance decision?**
   a. Incomplete = HRPP does not have IREx access / cannot be contacted.
   b. Notify HRPP = Site has not been contacted about study yet
   c. Contacted = date IREx notification sent
   d. Started = date HRPP first accessed study
   e. Completed = date HRPP indicated reliance
3. **Are local considerations complete?** These can be completed concurrently:
   a. **Institutional Profile**: Completed by the HRPP, this includes institutional-level information about the site.
   b. **HRP Survey:** Completed by the HRPP, this includes applicable local requirements for this study at the site.
   c. **PI Survey:** Completed by the PI, this includes information about conduct of the study at the site. *Note: this survey requires sign off by the HRPP to be marked "complete".*

Step 7

SITE TRACKING AND FOLLOW UP REGARDING OUTSTANDING ACTION ITEMS

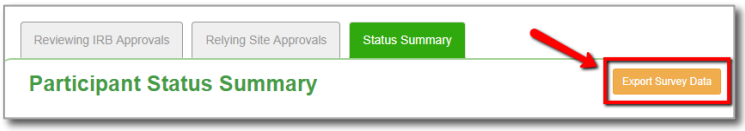
Use the Status Summary tab to guide your follow up with Sites:

- ❑ **If any of the required agreements are incomplete**, remind the PSite study team to contact their local HRPP, who can facilitate the execution of the agreements.
- ❑ **If a site's HRPP has not made a reliance decision or completed the local considerations**, ensure the study team has submitted to their local HRPP. If so, ask the study team to follow up with their HRPP Liaison (found here) regarding any additional information that is needed.
- ❑ **If the PI has not completed the PI survey**, send a reminder to the PI using the "Email Study Personnel" link in IREx. (Only the PI can complete this survey).
- ❑ **If sites add or drop from your study,** edit the list of PSites using the "Manage Project" button. (Note: ensure newly added sites have reliance instructions and a proper introduction to using a single IRB.)

Step 8

EXPORT LOCAL CONSIDERATIONS (IF APPLICABLE)

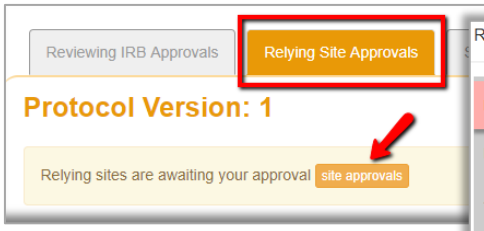
You will receive an email from IREx when the local considerations for a PSite are complete. Next, login to IREx to:

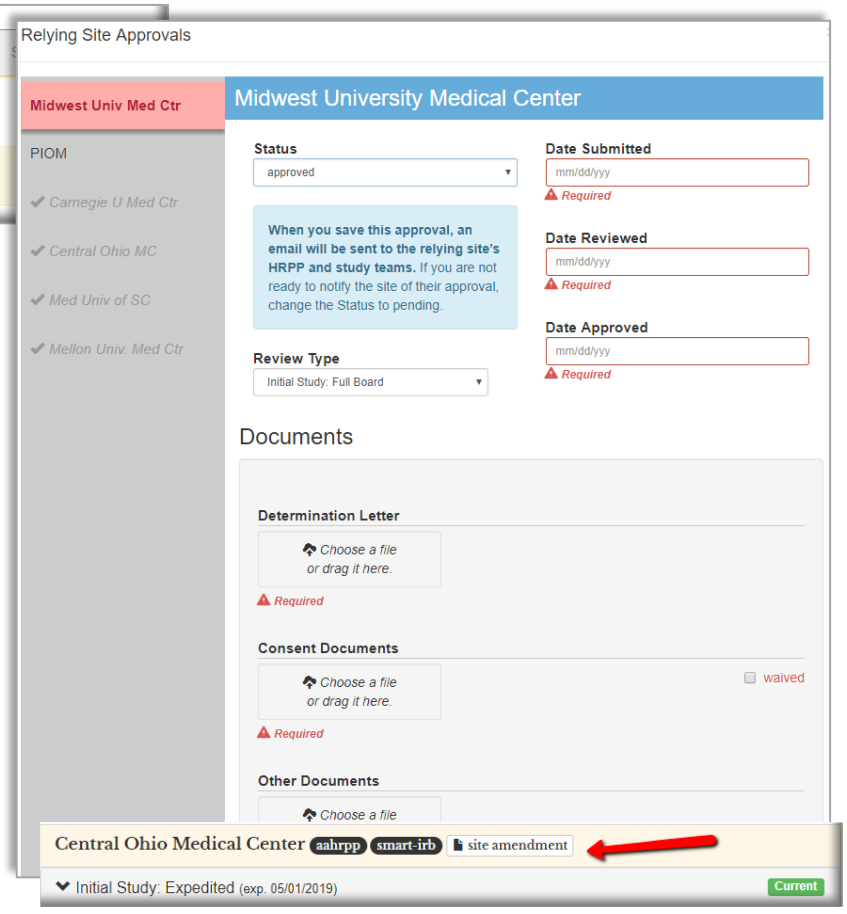


- ❑ Pre-screen the surveys for completion.
- ❑ Ensure consent forms are uploaded to the HRP Survey, if applicable, and that they are complete(e.g., is any information missing; does the language provided read properly)
- ❑ If changes or clarifications are needed, the HRPP liaison at the site can make the changes to the PI survey and HRP survey. Reach out to the local study team who can work with their HRPP to make changes, as needed.
- ❑ Go to the Status Summary tab and select "Export Survey Data". Select the site who is complete and save their files. (Note: The export contains a folder for each site who has *started* local considerations, even if they are not complete. You can view what has been completed from the Status Summary tab)
- ❑ Submit the site's files to the sIRB for review.

Step 9

UPLOAD SIRB APPROVALS FOR PARTICIPATING SITES (as issued by the sIRB)





To upload **Initial Site Approval, Continuing Review** and **Study-wide Amendments,** use the **Site Approvals** button at the top of the Reviewing IRB or Relying Site Approvals tab:

- ❑ Change the **Status** to approved;
- ❑ Indicate the **Review Type** (full board or expedited review);
- ❑ Enter the requested **dates**; and
- ❑ Upload a site's IRB **approved documents** (determination letter, consents, "Other" site specific documents).

Upload site-specific changes (e.g., PI change) on the Relying Site Approvals tab using the "**Site Amendment**" button next to the site name.

The PSite HRPP and Study Team are notified by email when new approvals are uploaded, and you are cc'd.