IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR COORDINATING CENTERS/LEAD STUDY TEAMS

October 19, 2018

• User Training • Study Support	• System Development • Data analysis	• Project Manager	• Site Onboarding • Study Support	• User Support • Study Support
Natalie Dilts 	***Adoma Manful*** 	***Emily Serdoz*** 	***Bridget Swindell*** 	***Linda Tan*** 

QUARTERLY CALL AGENDA

- Welcome & Reminders
- Participating Personnel List
- Adding Participating Sites to IREx
- The IREx Study Manager Role: A Refresher
- Updated Resources

Reminders from the Last Call

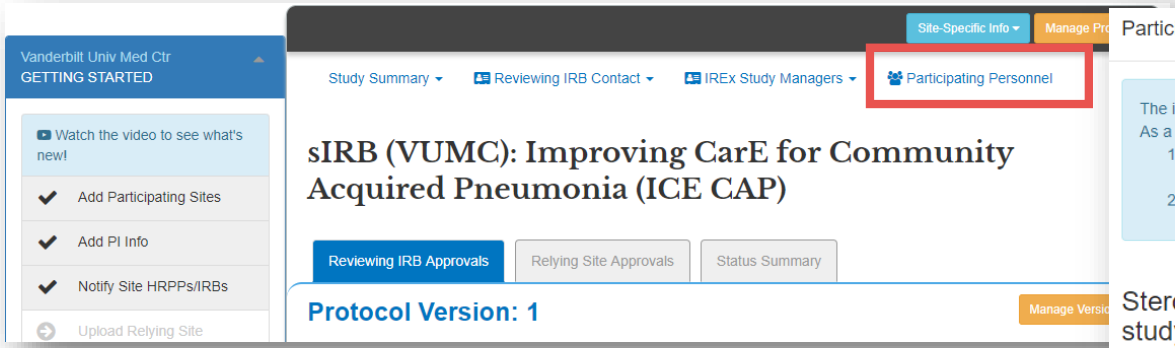
IN CASE YOU MISSED IT…

- **IREx no longer requires institutional portal agreement** – HRPP/IRB managers or directors can request access via website: https://redcap.vanderbilt.edu/surveys/?s=W98HMCHAPT
- **Established "IREx Study Manager" role** for CCCs and Lead Study Team Coordinators to help with single IRB coordination

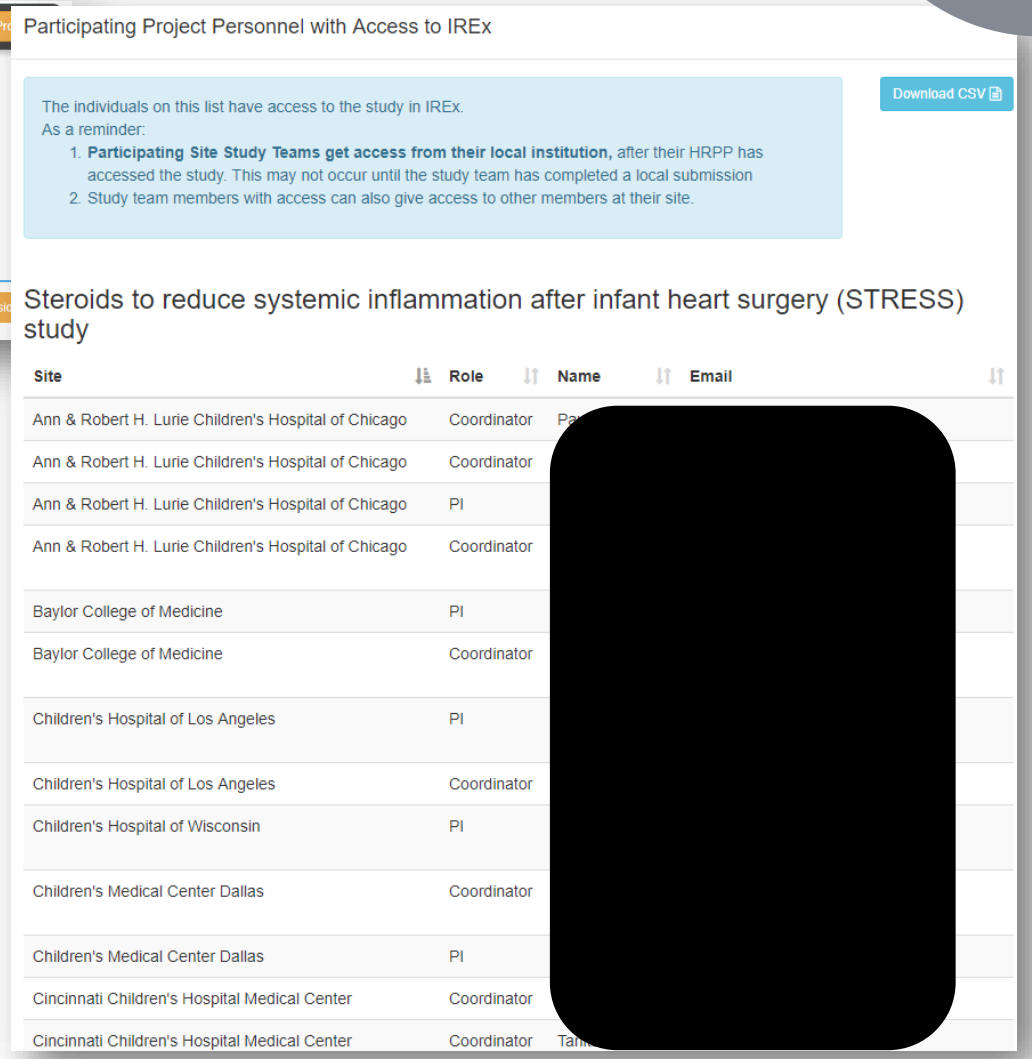
Participating Personnel List

AVAILABLE IN IREX NOW!

PARTICIPATING PERSONNEL LIST



- **Participating Personnel** lists who has access to your study.
- **Participating Personnel are added by their local institution**



Adding Participating Sites to IREx

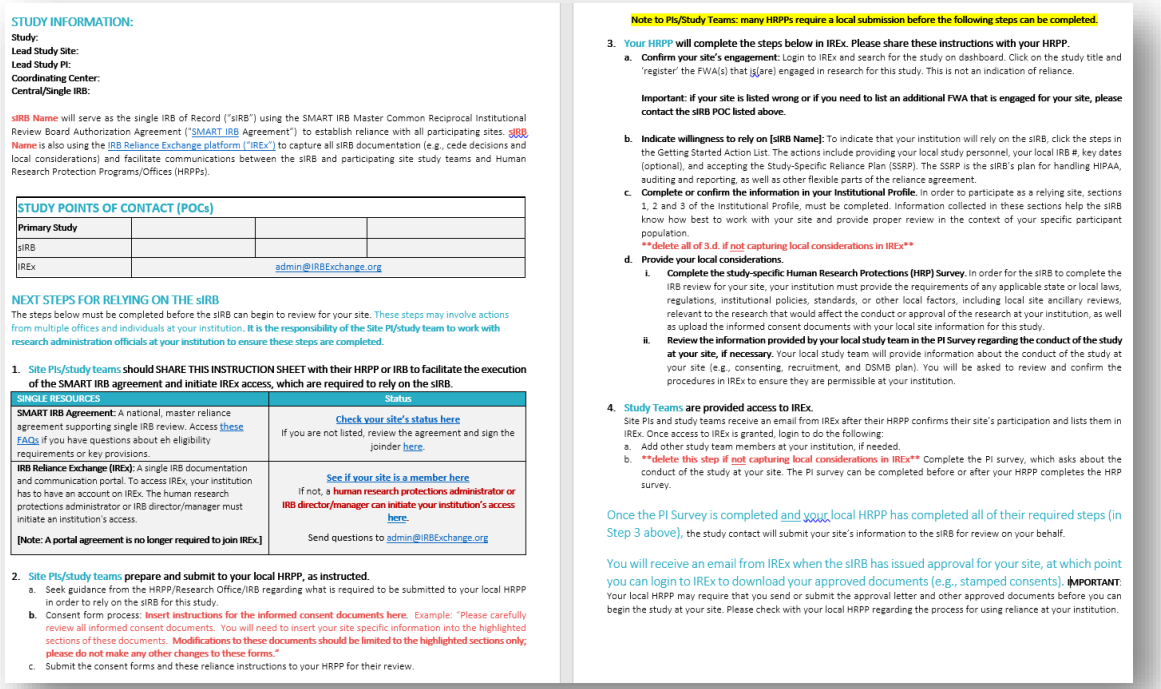
Participating Sites = PSites

AVAILABLE IN IREX NOW!

INITIAL PSITE COMMUNICATION – OUTSIDE OF IREX

BEFORE A SITE IS ADDED AND HAS ACCESS TO IREx…

- PSites need to receive an initial communication that the study will use a single IRB.
- Disseminate all materials to the PSite PIs outside of IREx – including:
  - Approved protocol and ICF templates;
  - Reliance instructions;
  - Contracts; and
  - Other regulatory documents
- Sites uses these materials to engage / submit to their local HRPP, who then documents reliance-related information in IREx.



STUDY INFORMATION:
Study:
Lead Study Site:
Lead Study PI:
Coordinating Center:
Central/Single IRB:

sIRB Name will serve as the single IRB of Record ("sIRB") using the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement ("SMART IRB Agreement") to establish reliance with all participating sites. sIRB Name is also using the IRB Reliance Exchange platform ("IREx") to capture all sIRB documentation (e.g., cede decisions and local considerations) and facilitate communications between the sIRB and participating site study teams and Human Research Protection Programs/Offices (HRPPs).

STUDY POINTS OF CONTACT (POCs)			
Primary Study			
sIRB			
IREx	admin@IRBExchange.org		

NEXT STEPS FOR RELYING ON THE sIRB

The steps below must be completed before the sIRB can begin to review for your site. These steps may involve actions from multiple offices and individuals at your institution. **It is the responsibility of the Site PI/study team to work with research administration officials at your institution to ensure these steps are completed.**

1. **Site PIs/study teams should SHARE THIS INSTRUCTION SHEET with their HRPP or IRB to facilitate the execution of the SMART IRB agreement and initiate IREx access, which are required to rely on the sIRB.**

SINGLE RESOURCES	Status
SMART IRB Agreement: A national, master reliance agreement supporting single IRB review. Access these FAQs if you have questions about eh eligibility requirements or key provisions.	Check your site's status here If you are not listed, review the agreement and sign the joinder here.
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. To access IREx, your institution has to have an account on IREx. The human research protections administrator or IRB director/manager must initiate an institution's access. **[Note: A portal agreement is no longer required to join IREx.]**	See if your site is a member here If not, a **human research protections administrator or IRB director/manager can initiate your institution's access here.** Send questions to admin@IRBExchange.org

2. **Site PIs/study teams prepare and submit to your local HRPP, as instructed.**
   a. Seek guidance from the HRPP/Research Office/IRB regarding what is required to be submitted to your local HRPP in order to rely on the sIRB for this study.
   b. Consent form process: **Insert instructions for the informed consent documents here.** Example: "Please carefully review all informed consent documents. You will need to insert your site specific information into the highlighted sections of these documents. **Modifications to these documents should be limited to the highlighted sections only; please do not make any other changes to these forms."**
   c. Submit the consent forms and these reliance instructions to your HRPP for their review.

Note to PIs/Study Teams: many HRPPs require a local submission before the following steps can be completed.

3. **Your HRPP will complete the steps below in IREx. Please share these instructions with your HRPP.**
   a. **Confirm your site's engagement:** Login to IREx and search for the study on dashboard. Click on the study title and 'register' the FWA(s) that is(are) engaged in research for this study. This is not an indication of reliance.

      Important: if your site is listed wrong or if you need to list an additional FWA that is engaged for your site, please contact the sIRB POC listed above.

   b. **Indicate willingness to rely on [sIRB Name]:** To indicate that your institution will rely on the sIRB, click the steps in the Getting Started Action List. The actions include providing your local study personnel, your local IRB #, key dates (optional), and accepting the Study-Specific Reliance Plan (SSRP). The SSRP is the sIRB's plan for handling HIPAA, auditing and reporting, as well as other flexible parts of the reliance agreement.
   c. **Complete or confirm the information in your Institutional Profile.** In order to participate as a relying site, sections 1, 2 and 3 of the Institutional Profile, must be completed. Information collected in these sections help the sIRB know how best to work with your site and provide proper review in the context of your specific participant population.
      ****delete all of 3.d. if not capturing local considerations in IREx****
   d. **Provide your local considerations.**
      i. **Complete the study-specific Human Research Protections (HRP) Survey.** In order for the sIRB to complete the IRB review for your site, your institution must provide the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the research that would affect the conduct or approval of the research at your institution, as well as upload the informed consent documents with your local site information for this study.
      ii. **Review the information provided by your local study team in the PI Survey regarding the conduct of the study at your site, if necessary.** Your local study team will provide information about the conduct of the study at your site (e.g., consenting, recruitment, and DSMB plan). You will be asked to review and confirm the procedures in IREx to ensure they are permissible at your institution.

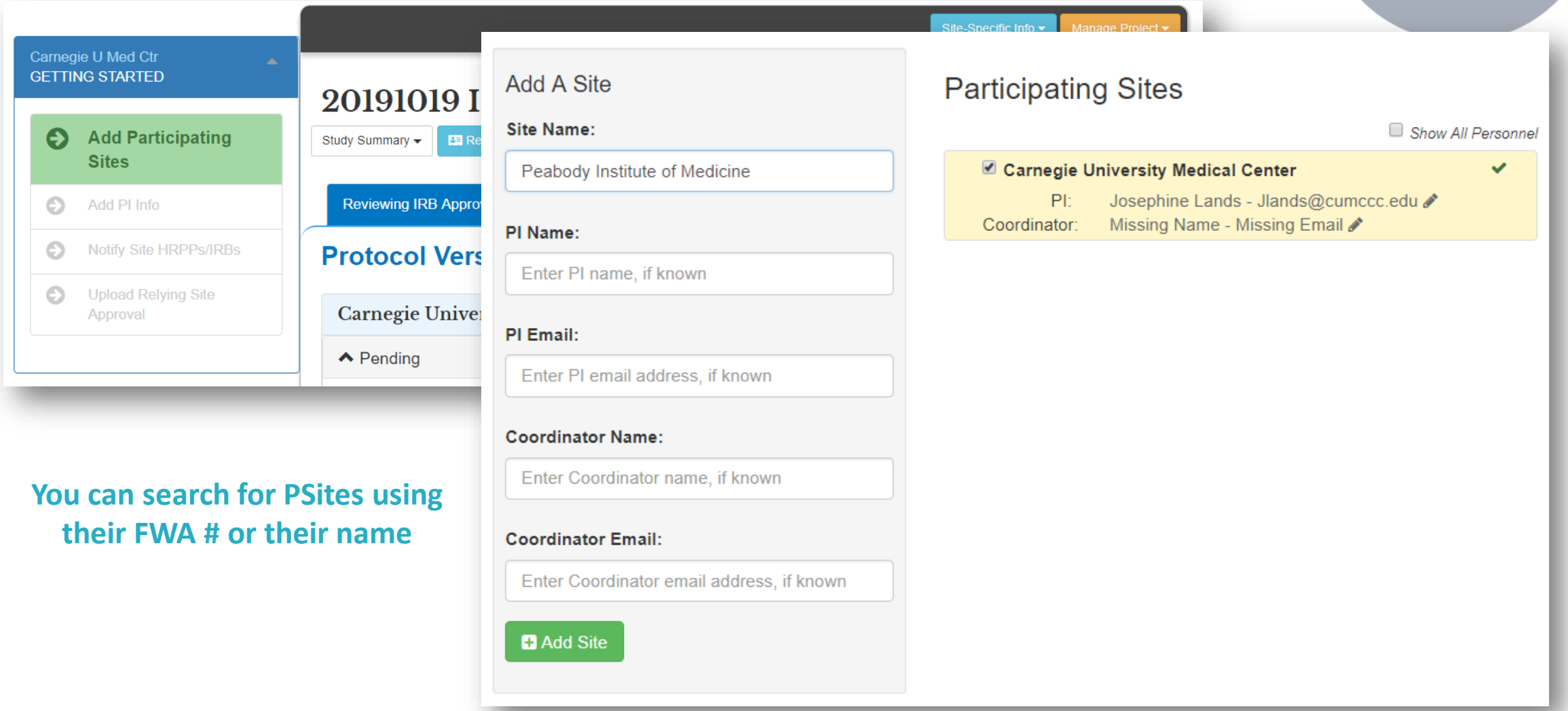
4. **Study Teams are provided access to IREx.**
   Site PIs and study teams receive an email from IREx after their HRPP confirms their site's participation and lists them in IREx. Once access to IREx is granted, login to do the following:
   a. Add other study team members at your institution, if needed.
   b. ****delete this step if not capturing local considerations in IREx**** Complete the PI survey, which asks about the conduct of the study at your site. The PI survey can be completed before or after your HRPP completes the HRP survey.

Once the PI Survey is completed and your local HRPP has completed all of their required steps (in Step 3 above), the study contact will submit your site's information to the sIRB for review on your behalf.

You will receive an email from IREx when the sIRB has issued approval for your site, at which point you can login to IREx to download your approved documents (e.g., stamped consents). **IMPORTANT**: Your local HRPP may require that you send or submit the approval letter and other approved documents before you can begin the study at your site. Please check with your local HRPP regarding the process for using reliance at your institution.

AVAILABLE IN IREX NOW!

ADDING PARTICIPATING SITES TO IREX



You can search for PSites using their FWA # or their name

AVAILABLE IN IREX NOW!

ADDING PARTICIPATING SITES TO IREX

Participant Status Summary

Search:

Site	SMART IRB	IREx Access	Reliance Decision	Local Considerations
Carnegie University Medical Center	✔	✔	Notify HRPP	
Mellon University Medical Center	✔	✖	Incomplete	
Peabody Institute of Medicine	✔	✔	Notify HRPP	

Purpose: To connect the PSite HRPP and study team around the reliance process for their site.

- **Does not provide PI access to IREx** *(access is granted by local HRPP)*
- **Does not provide access to study documents** *(materials are sent via email to local study team)*

Dear Liaison(s) and Study Investigator,

Mellon University Medical Center (FWA: 99999999) has been listed as a participating site in IREx for the following study:

Title	Measuring Levels of Baseline Radiation Exposure in Urgent Care Visits (RADIATE II)
Reviewing IRB	Vanderbilt University Medical Center
Local Investigator	Taylor Barbara

What do I do with this email?

Study PI

Many HRPPs require a local submission to initiate the single IRB (sIRB) process at their institution. Reach out to your Human Research Protection Program (HRPP)/IRB Liaisons on this email to find out what you need to do to initiate the sIRB process at your site.

YOU CANNOT ACCESS THE STUDY IN IREX YET.
You receive access to the study in IREx after your HRPP logs in to confirm your site is participating and lists you on the study.

HRPP Liaisons

1) If you have not received a local submission, you may want to contact your study PI (cc'd here) to let him/her know how they can initiate reliance at your institution.

2) When you are ready, login to IREx, confirm your site's engagement by registering for the study and provide access to your local PI. This is not a cede decision. **Email the contact(s) below if the wrong FWA is listed or another FWA should also be listed. You will receive a new email with the correction:**

- Edgar DeGas (edegas@duke.edu)
- Duke Study Manager (dukesm@duke.cc)
- Taylor CCC staff (vumc.test@thornview.com)

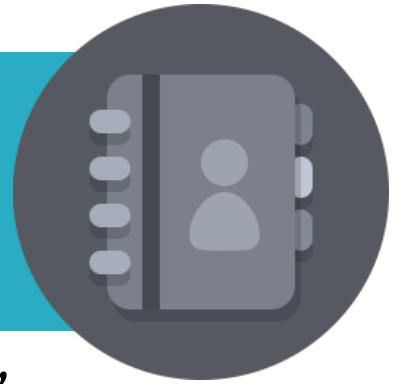
3) Use the Getting Started checklist on the IREx study page to walk you through ceding review and any other required steps.

IREx Study Manager Refresher

Study Manager = Lead Study Team or Coordinating Center

AVAILABLE IN IREX NOW!

IREX STUDY MANAGER PERMISSIONS



Formerly called "CC Staff"

IREx IRB Liaisons Permissions

- Create studies in IREx
- Confirm study-specific reliance plan (SSRP)
- Upload overall/lead site approvals
  - Initial
  - Continuing review
  - Study amendments (affecting all sites)
- Can perform all "IREx Study Manager" activities, too

IREx Study Manager Permissions

- Add other IREx Study Managers
- Add sites and list their PI
- *New* **Indicate when to send the IREx study notification to PS HRPPs *(requires SSRP be completed by sIRB)***
- Export local considerations
- Upload Relying Site approvals
  - Initial
  - Continuing review
  - Study amendments
  - Site amendments (e.g., PI change)

AVAILABLE IN IREX NOW!

IREX STUDY MANAGER NOTIFICATION

NEW →

Dear Taylor Jansen,

You have been given access, as an IREx Study Manager, to the study below in IREx. If this is your first study on this platform, a separate email was also sent with your login information.

Study Title	A Cluster Randomized Multi-Center Baseline Assessments of Carbon Dioxide Emission (ACE)
Reviewing IRB	Vanderbilt University Medical Center
Study Link	https://victrtest.irbchoice.org/embryb/irex/public/study/index/?proj=50349

Your Next Steps

Visit the resources page for detailed instructions on these steps:

1. **Designate the Participating Sites and site PIs in IREx.**
   Please login and enter the participating sites and their corresponding study PIs to help the Human Research Protection Program (HRPP)/IRB Liaisons check on the status of the study at their sites.

2. **IREx notifies the participating site HRPPs of the study.**
   After you send the study start up packet (protocol, consent templates, regulatory documents, etc) to your participating site study teams, click the "Notify HRPP" button in IREx to notify the participating site HRPPs/IRBs about the study. The HRPP/IRB will confirm their institution's engagement in research, begin the cede review process, and provide the study team with access to IREx when appropriate. Generally, a local submission is required before the HRPP/IRB will begin completing their steps in IREx.

   IMPORTANT: Participating site study teams should receive the study start-up packets BEFORE IREx notifies their HRPP/IRB about the study. Study teams need these materials to begin preparing their local IRB submission. IREx is not used to disseminate the study start up materials as study teams can not get access until their local HRPP/IRB receives a local submission.

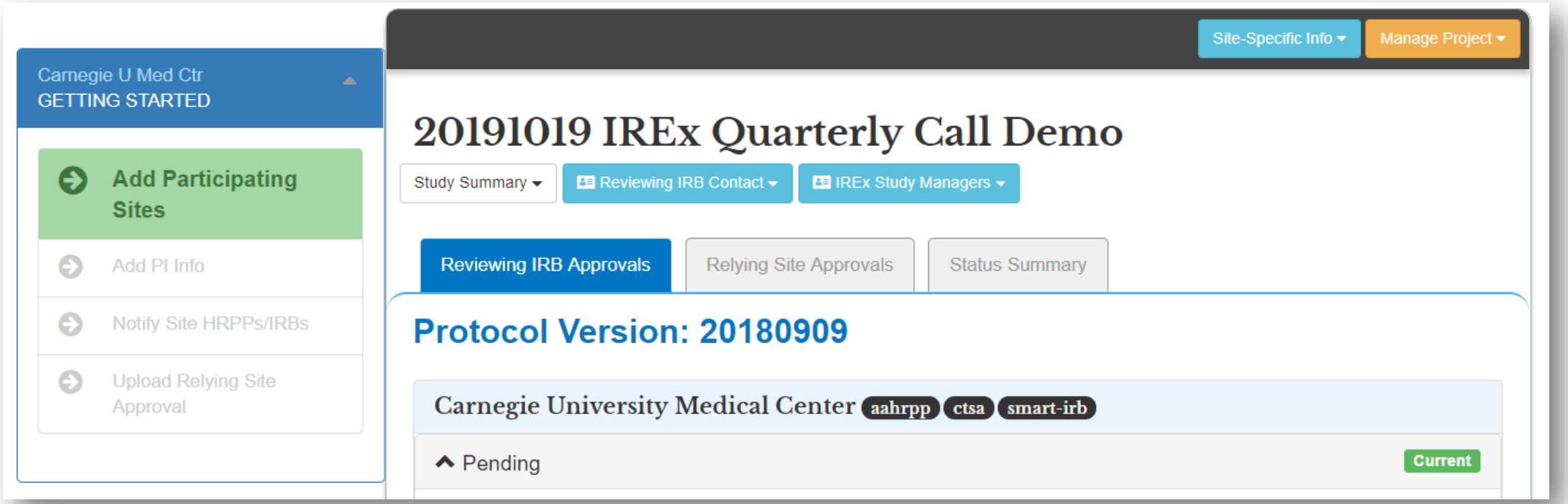
3. **Use IREx to track site progress towards reliance and initial IRB approval.**
   You will receive notifications from IREx as sites complete the required steps.

If you have questions about using IREx, you can email us your questions (admin@irbexchange.org) or request additional training.

Thank you for using IREx,
The IREx Team

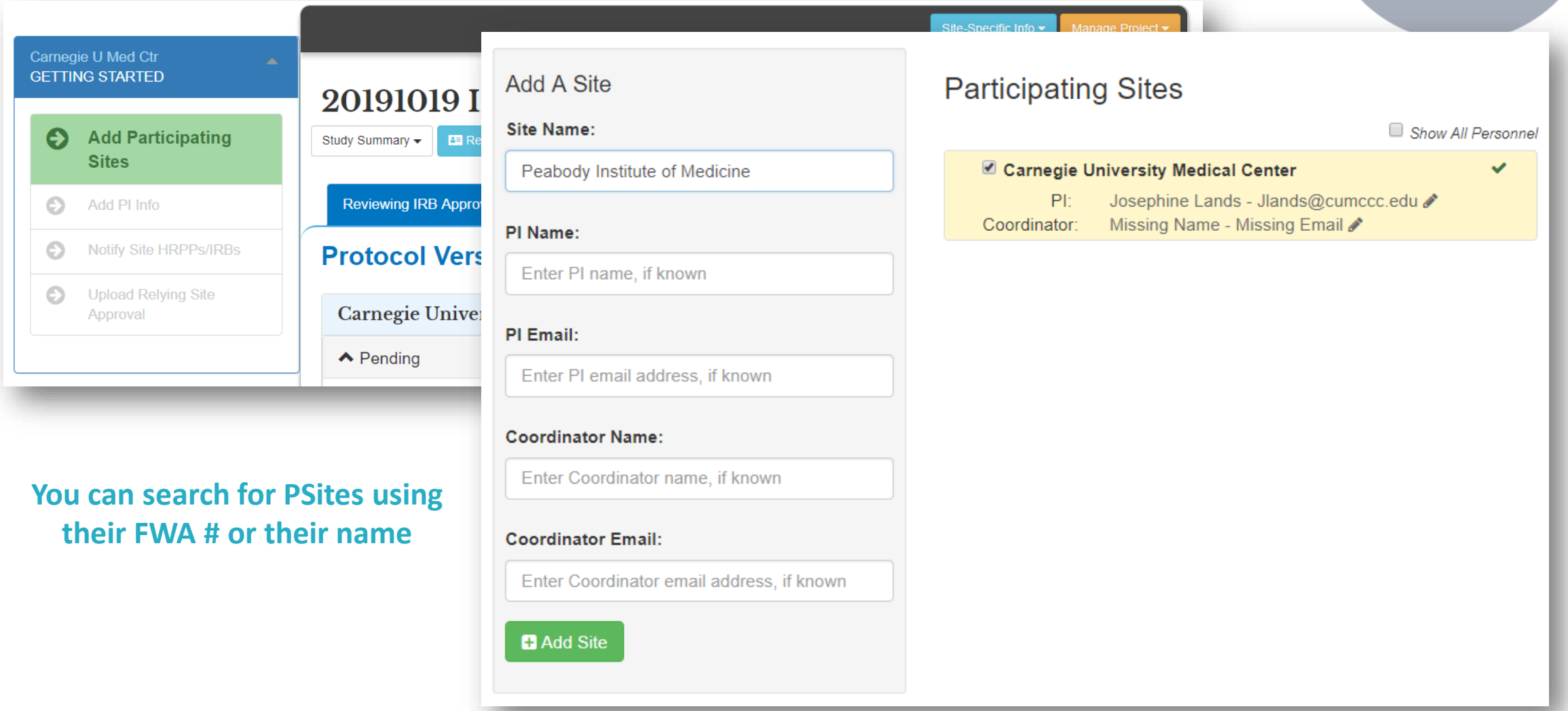
AVAILABLE IN IREX NOW!

IREx Study Manager Checklist



AVAILABLE IN IREX NOW!

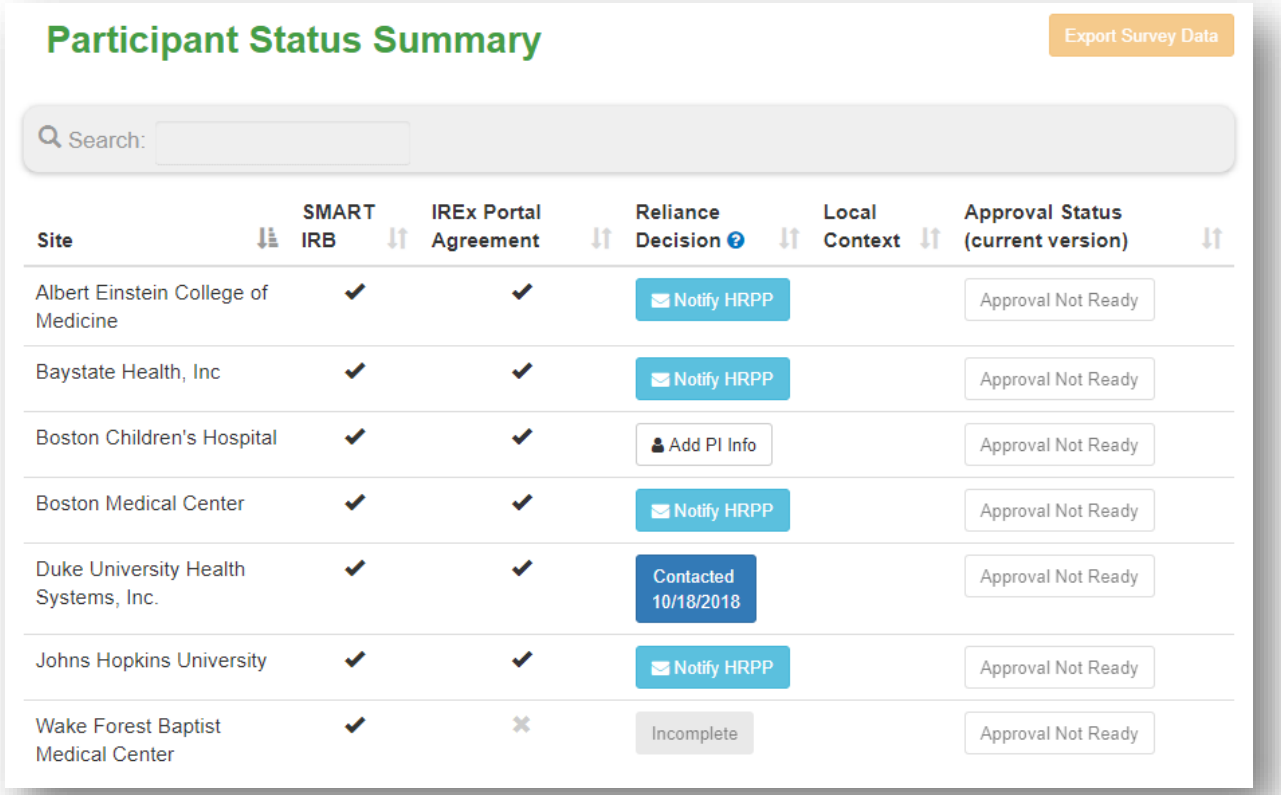
ADDING PARTICIPATING SITES TO IREX



You can search for PSites using their FWA # or their name

AVAILABLE IN IREX NOW!

NOTIFYING SITE HRPPS OF STUDIES IN IREX



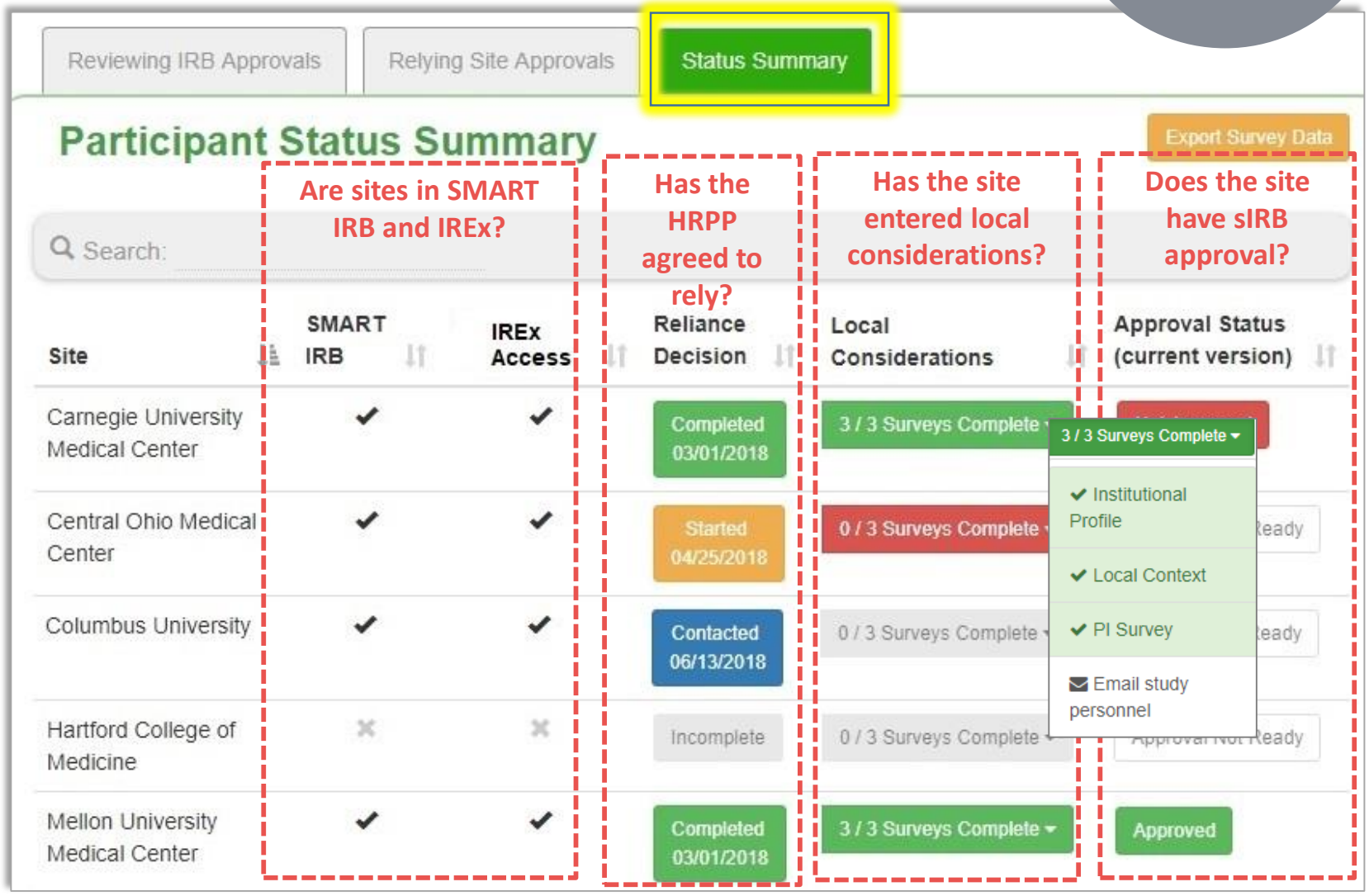
After the sIRB has confirmed the SSRP for the study…

- **IREx SM** manually notifies site HRPP of the study.
  - Sites can no longer be contacted without listing their local PI
  - Local PI is copied on notification email

AVAILABLE IN IREX NOW!

TRACKING SITE PROGRESS IN IREX

Study Managers use this information to follow up with participating site study teams around outstanding actions



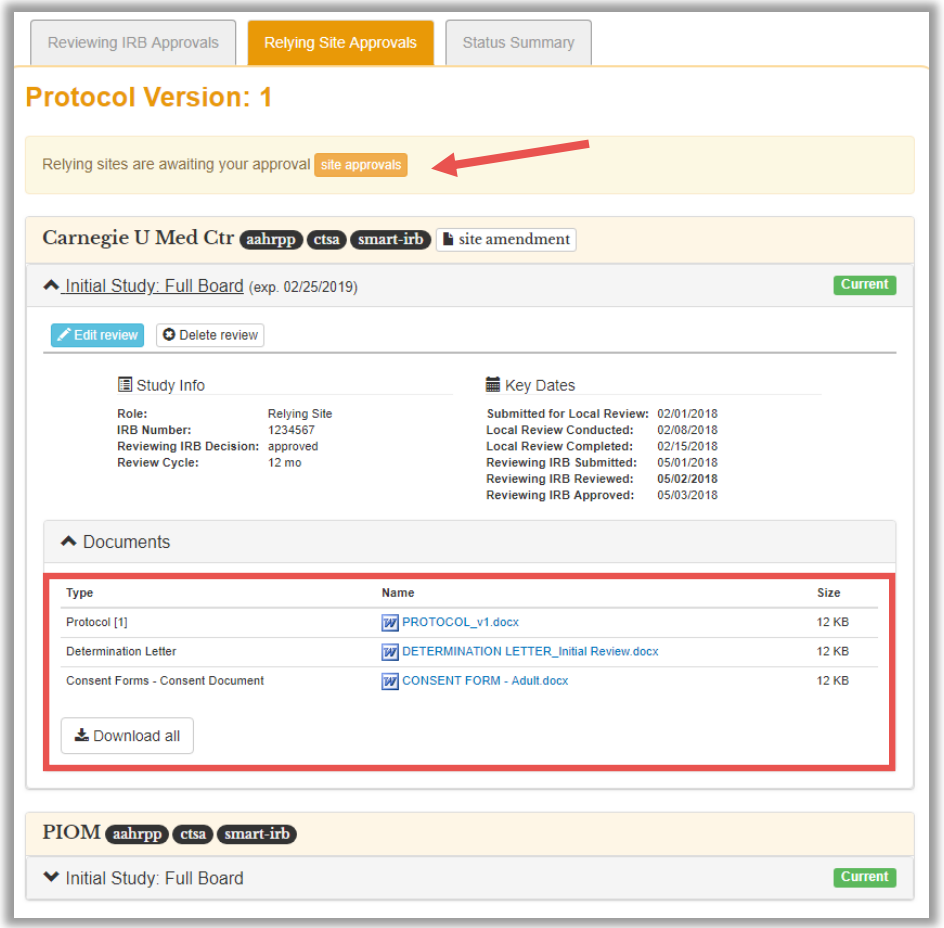
EXPORTING LOCAL CONSIDERATIONS AND SUBMIT TO SIRB FOR REVIEW

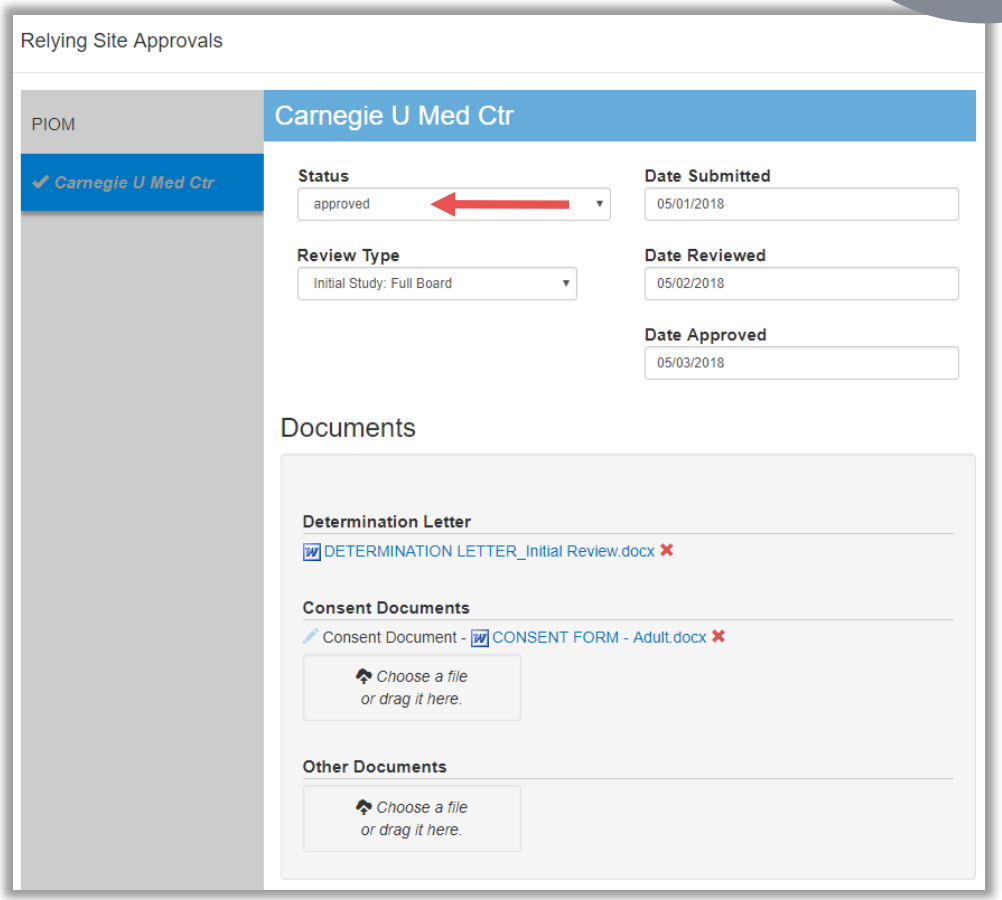
Once a site's local considerations and PI surveys are complete…

Export the information

Submit the site to the sIRB for review

UPLOADING APPROVALS TO IREX

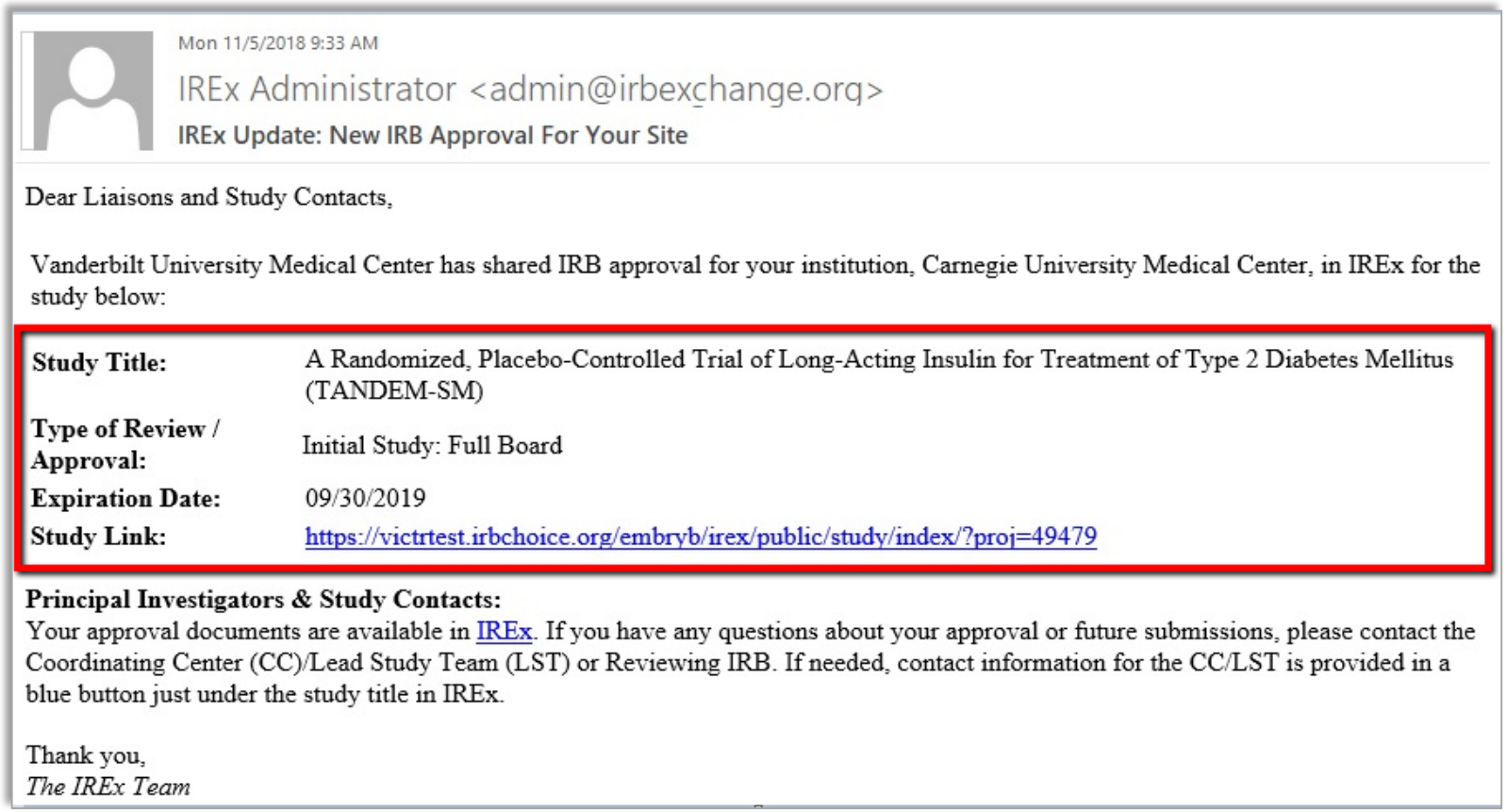




Note: The Reviewing IRB can also upload approvals.
Study Managers should discuss *who* uploads approvals for relying sites

PSITES NOTIFIED OF SIRB APPROVAL

- Notification sent to site's study team and HRPP/IRB contacts
- IREx Study Manager is copied on the email sent to the site
- Study teams login to access/download their approvals



Mon 11/5/2018 9:33 AM

IREx Administrator <admin@irbexchange.org>

IREx Update: New IRB Approval For Your Site

Dear Liaisons and Study Contacts,

Vanderbilt University Medical Center has shared IRB approval for your institution, Carnegie University Medical Center, in IREx for the study below:

Study Title:	A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM-SM)
Type of Review / Approval:	Initial Study: Full Board
Expiration Date:	09/30/2019
Study Link:	https://victrtest.irbchoice.org/embryb/irex/public/study/index/?proj=49479

Principal Investigators & Study Contacts:
Your approval documents are available in IREx. If you have any questions about your approval or future submissions, please contact the Coordinating Center (CC)/Lead Study Team (LST) or Reviewing IRB. If needed, contact information for the CC/LST is provided in a blue button just under the study title in IREx.

Thank you,
The IREx Team

IREx Resources Update

IREX VIDEOS ON YOUTUBE

https://www.youtube.com/channel/UCVXKpNczhlPcsQRwF7oWcwA/videos

Video Title	Approximate Length	Link
What is IREx?	~2 minutes	https://www.youtube.com/watch?v=NV94eUBylMg&t=11s
How to: Register and Cede Review	4 minutes	https://www.youtube.com/watch?v=-yW-TS-z6So
What is the Study Specific Reliance Plan (SSRP)?	90 seconds	https://www.youtube.com/watch?v=T9FbOV6oN7U
How HRPP / IRB Liaisons use the IRB Dashboards	90 seconds	https://www.youtube.com/watch?v=TKyoZ9_yhf4&t
How to Add/Remove Study Team Members from a study in IREx	2 minutes	https://www.youtube.com/watch?v=f_hKS8nqbb8
Using IREx as a Participating Site Study Team	4 minutes	https://www.youtube.com/watch?v=iKjO47QsIws
****NEW** New Features Highlight for Lead Study Teams and Coordinating Centers**	4.5 mins	https://www.youtube.com/watch?v=KoBAytIY5Cw
****NEW** How to: Add Study-wide and Site-specific Amendments**	9 mins	https://www.youtube.com/watch?v=vIrEUIV-BMY&t=2s

Next Call

- **April 19, 2019 @ 2 PM ET/11 PT**