IREx

IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

IREx Quarterly Call

• Training • Special projects	• Manager, Application Development	• Study Support • User Training	• Materials Development • Study support	• Site onboarding • Study Support
Natalie Dilts 	***Bryce Embry*** 	***David Crenshaw*** 	***Kaysi Quarles*** 	***Tiffany Chen*** 
• Platform direction • Evaluation	• Study Support • User Training	• System Development	• Application Developer	• Application Developer
Emily Serdoz 	***Bridget Swindell*** 	***Linda Tan*** 	***Jason Tan*** 	***Evan Wimberly*** 

07.21.2023 QUARTERLY CALL AGENDA

- Welcome & Announcements
- New Feature Demo
- What's Next

About the IREx Quarterly Calls

hear • new • features

- You're busy.
- IREx is busy.
- Call in once a quarter to hear what's new!

learn • new • trends

- Who's using IREx?
- How are folks leveraging IREx on their sIRB studies?

share • your • voice

- Give your opinion
- Ask your questions
- Express your needs

Upcoming Quarterly Calls

- October 20, 2023
- January 19, 2024
- April 19, 2024

New Features Released July 18th

IREx Division of Labor

	Single IRB	Lead Study Team
Create study	X	
Complete IREx Setup	X	
Confirm Study-specific Reliance Plan (SSRP)	X	
Indicate executed IAAs and/or indemnification	X	
Add PSites		X
Upload overall study approval		X
Track PSites progress		X
Export PSite documentation		X
Upload PSite Approval		X
Upload Continuing Reviews		X
Upload Study-wide Amendments		X
Upload Site Modifications		X
Total Tasks	4	8

Some Early Communications Occur Outside of IREx

	Single IRB	Lead Study Team
Create study	X	
Complete IREx Setup	X	
Confirm Study-specific Reliance Plan (SSRP)	X	
Indicate executed IAAs and/or indemnification	X	
Add PSites		X
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Upload Study-wide Amendments		X
Upload Site Modifications		X
Total Tasks	4	8

Outside of IREx

1. Request sites complete required agreements

Outside of IREx

1. Disseminate overall approval to sites
2. Include instructions for relying on the single IRB

New & Improved Features

Single IRBs can include Site Instructions in IREx.

Lead Study Teams (LSTs)/ IREx Study Managers (IREx SMs) can use IREx to request agreements & disseminate the initial overall approval documents to sites.

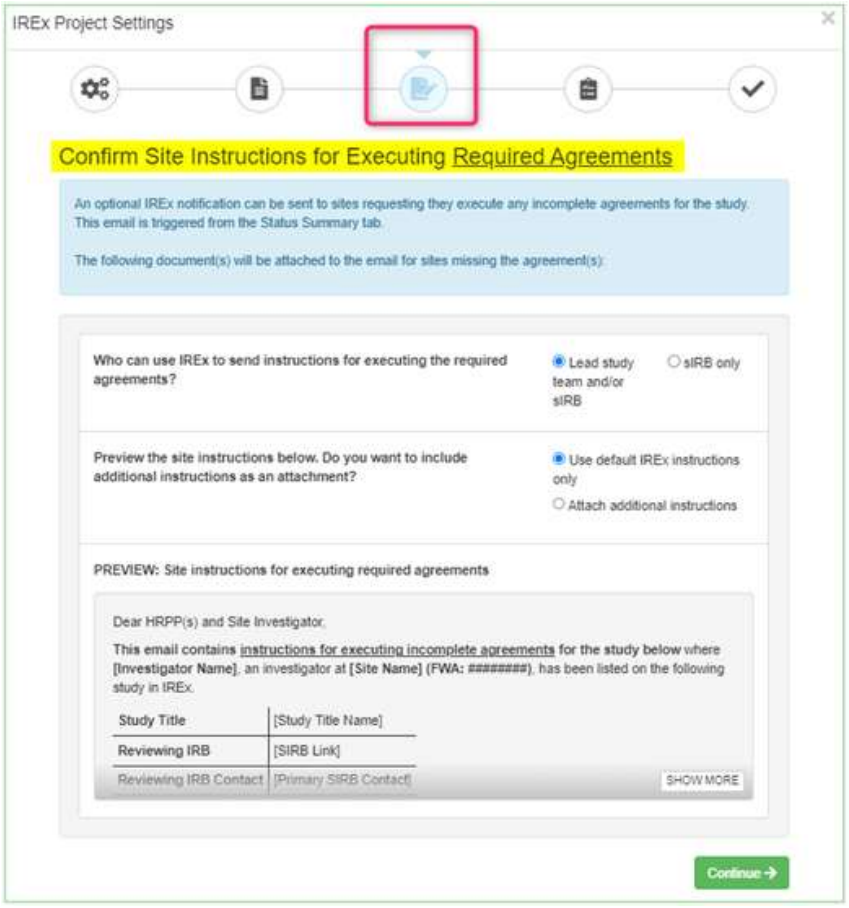
LSTs/IREx SMs can list multiple study team contacts before notifying sites of a study.

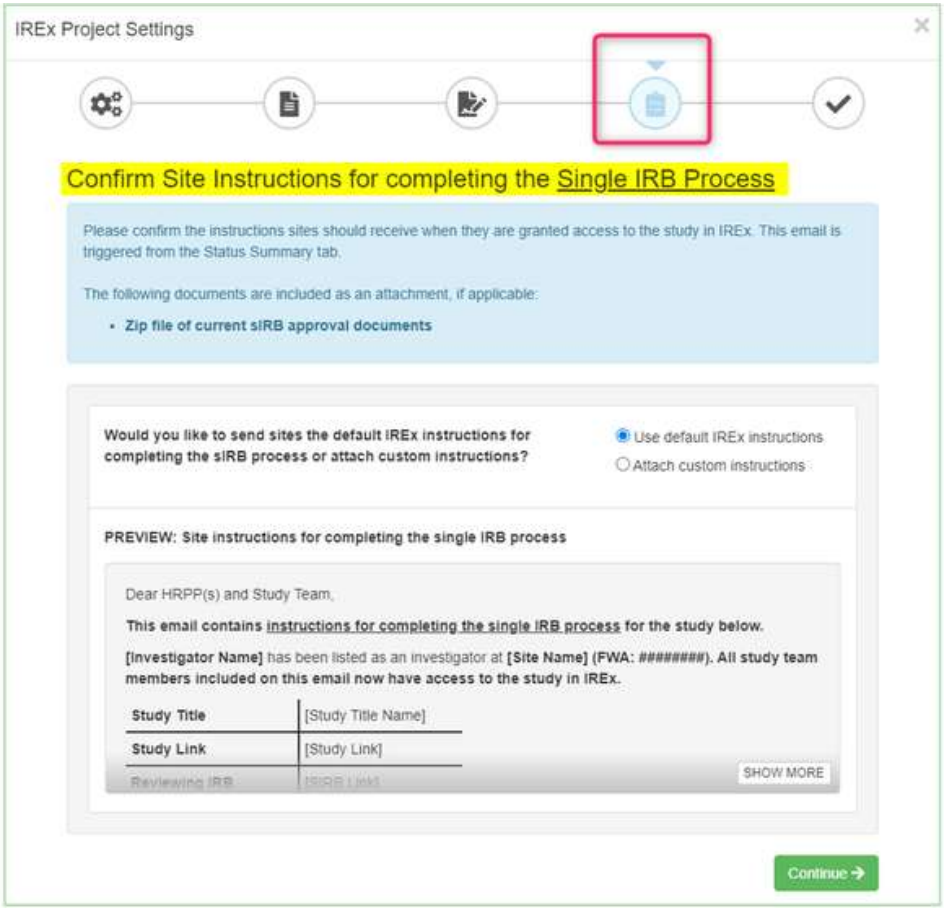
Relying Study Teams get immediate access to IREx when their site is notified of a study.

All users will notice the IREx study page has a new look!

Single IRBs Confirm New Site Instructions

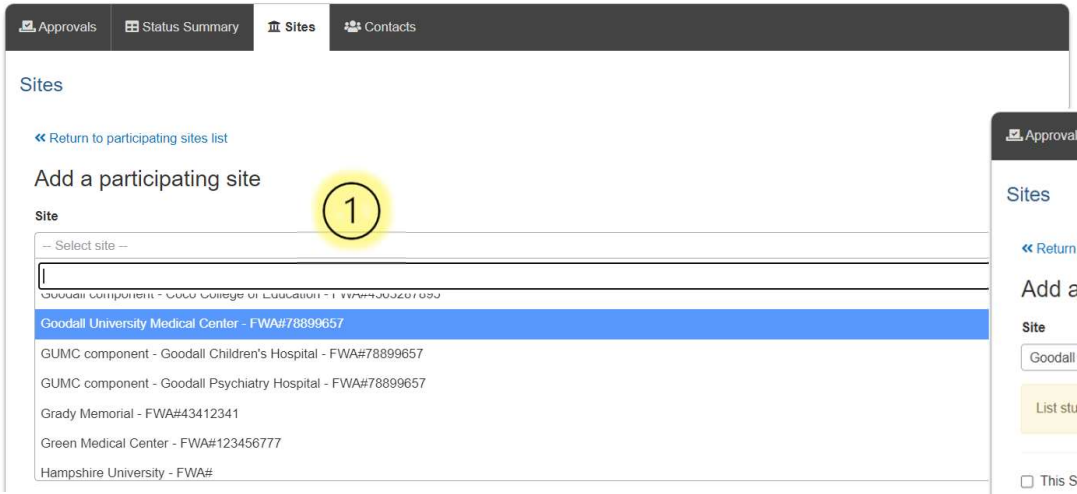
sIRBs

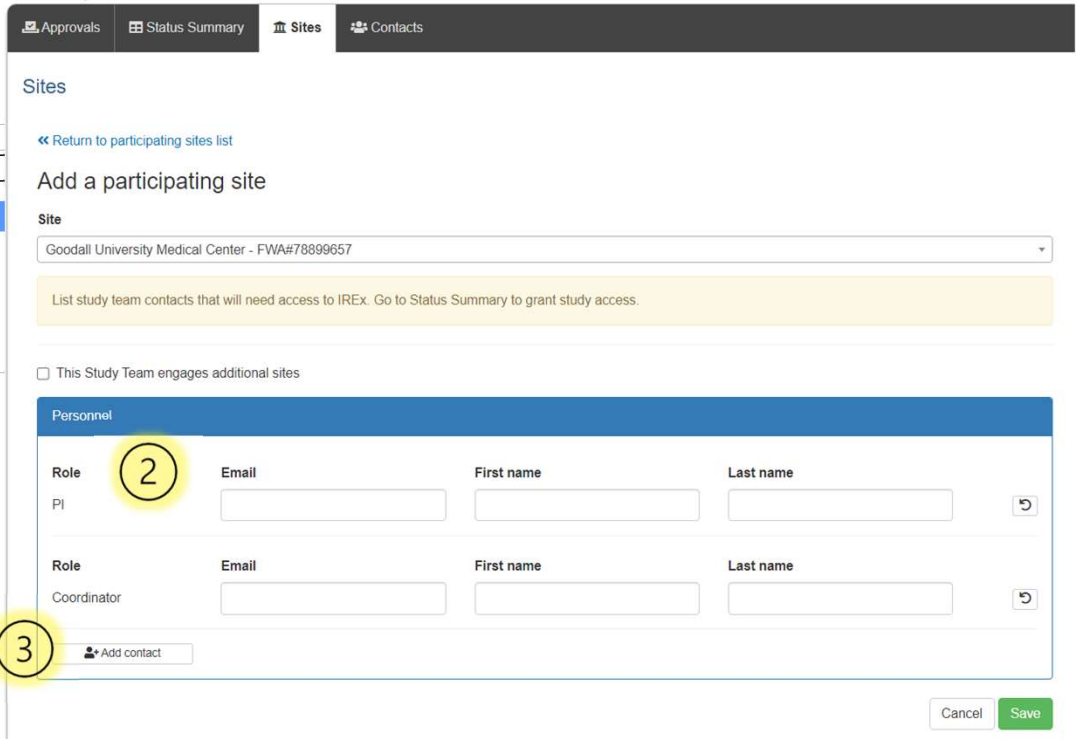




Sites Page – Adding Sites

IREx Study Manager

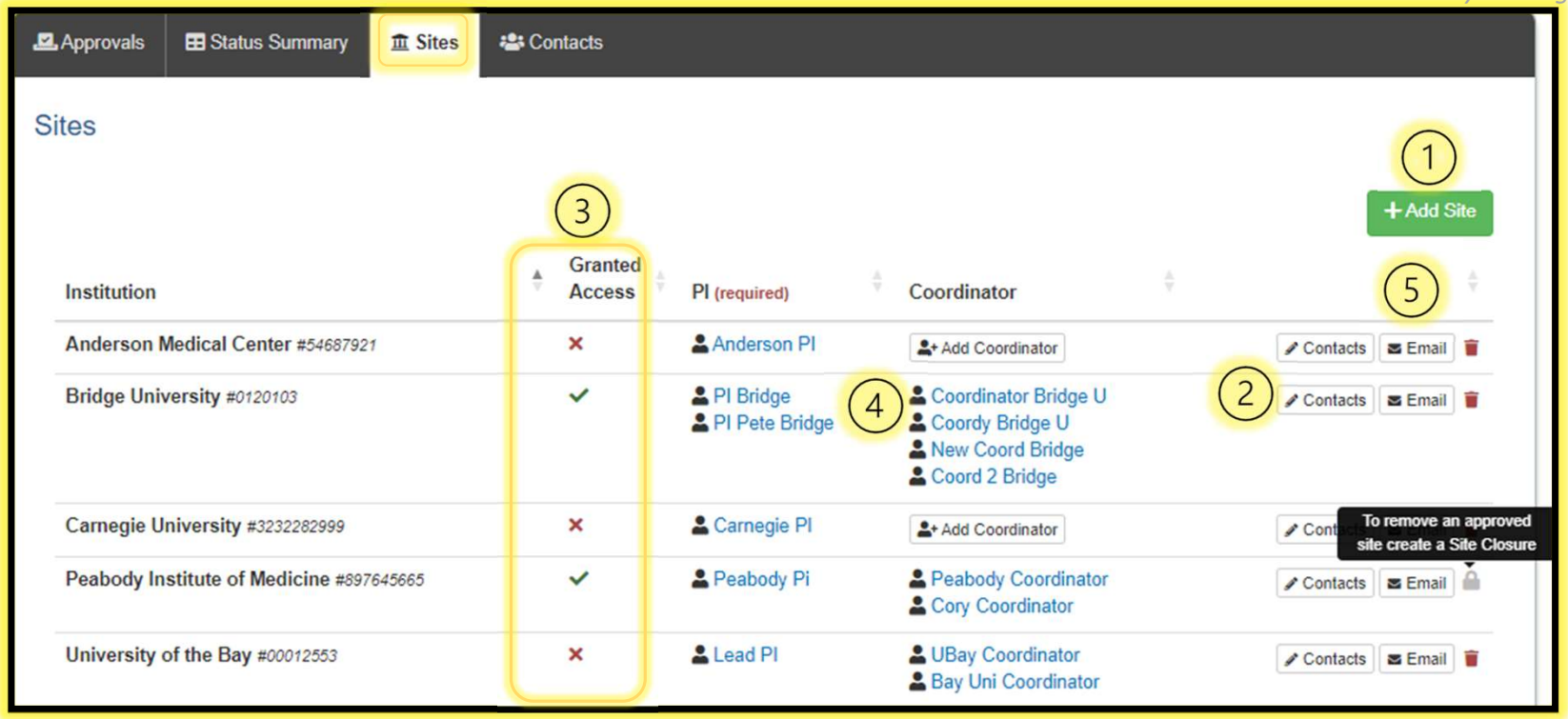




1. **Enter site name and select from dropdown**
2. **Enter PI and Coordinator information**
3. **Add additional contacts**

Sites Page Enhancements

IREx Study Manager & sIRBs

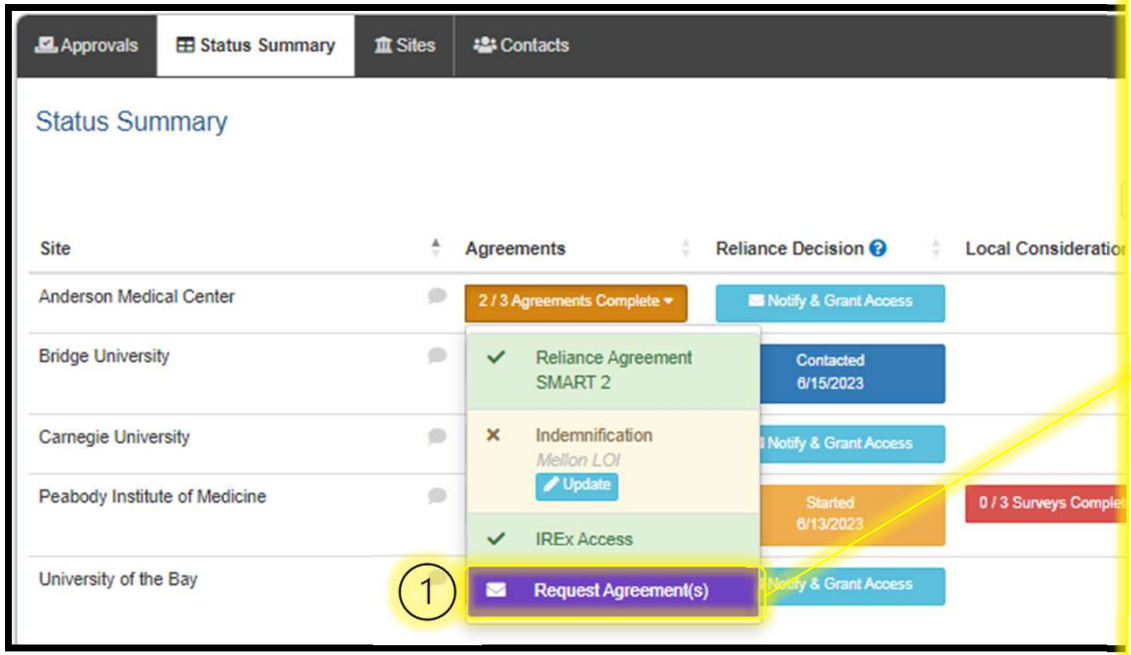


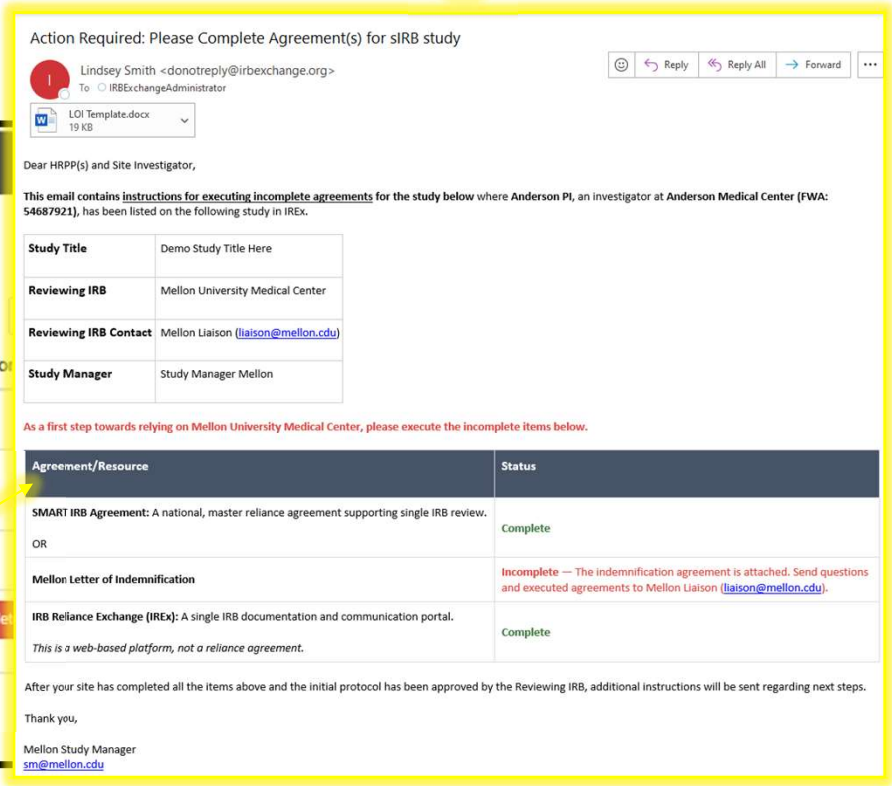
1. **Add new sites**
2. **Edit contacts for an existing site**
3. **View whether sites have been granted access to the study**
4. **View multiple PIs and/or coordinators for each site**
5. **Email all site contacts with the click of a button**

New Feature: *Request Agreements from Sites*

IREx Study Manager & sIRBs

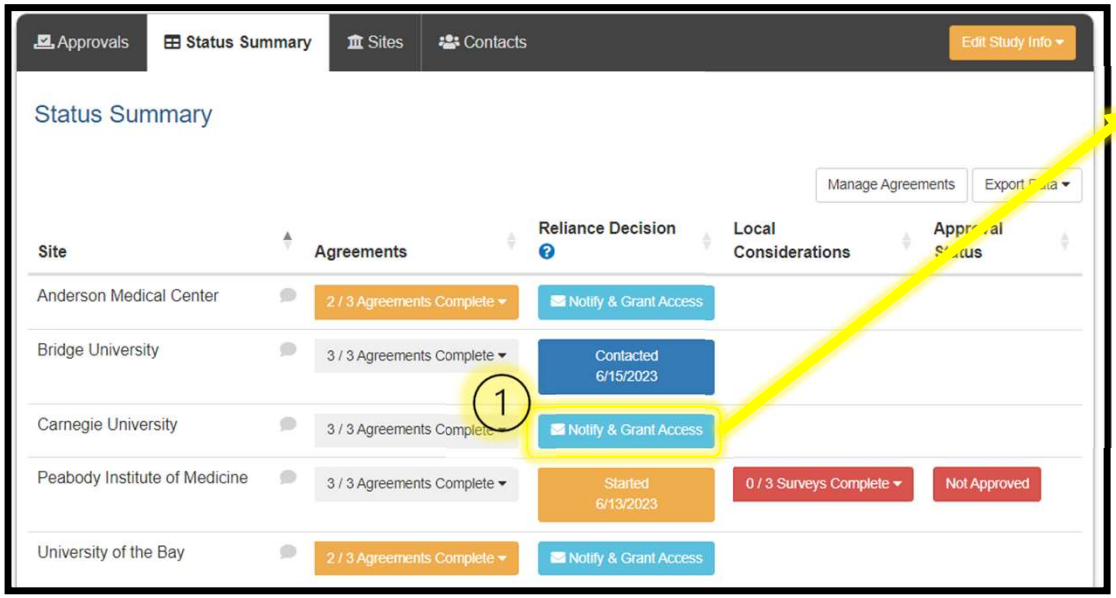
1. sIRBs or Study Managers can **Request Agreements** from any site(s) missing the required agreements.
2. Instructions include links to complete agreements (SMART IRB) or an attachment of the sIRB's required agreement template.

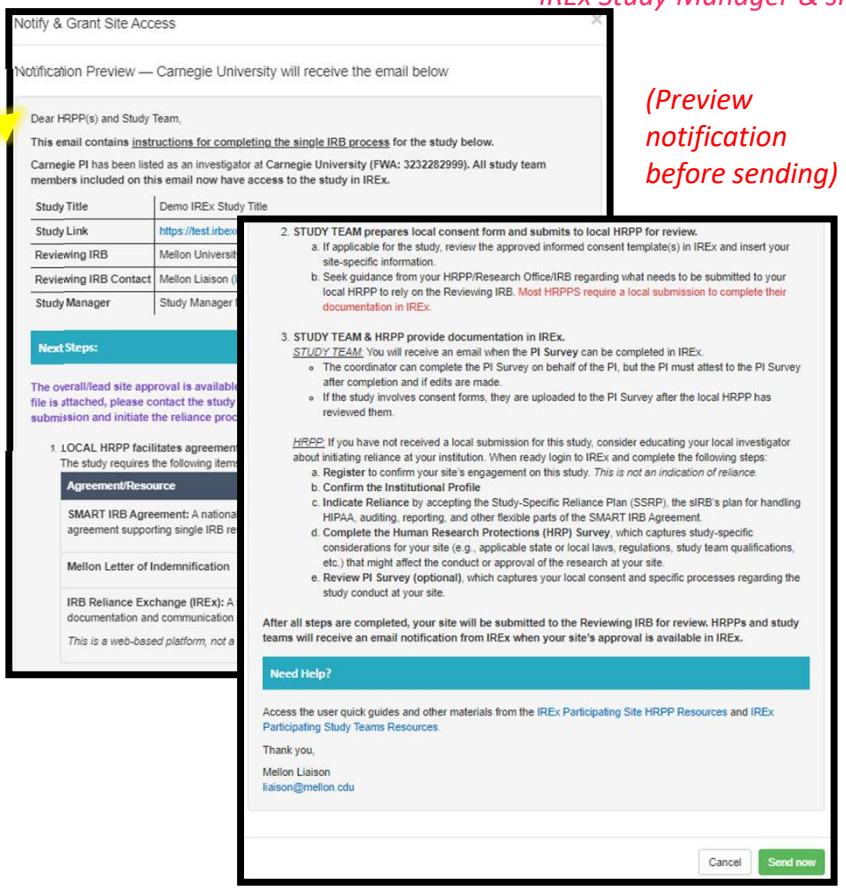




New Feature: *Notify & Grant Access to Study Teams*

IRExStudy Manager & sIRBs



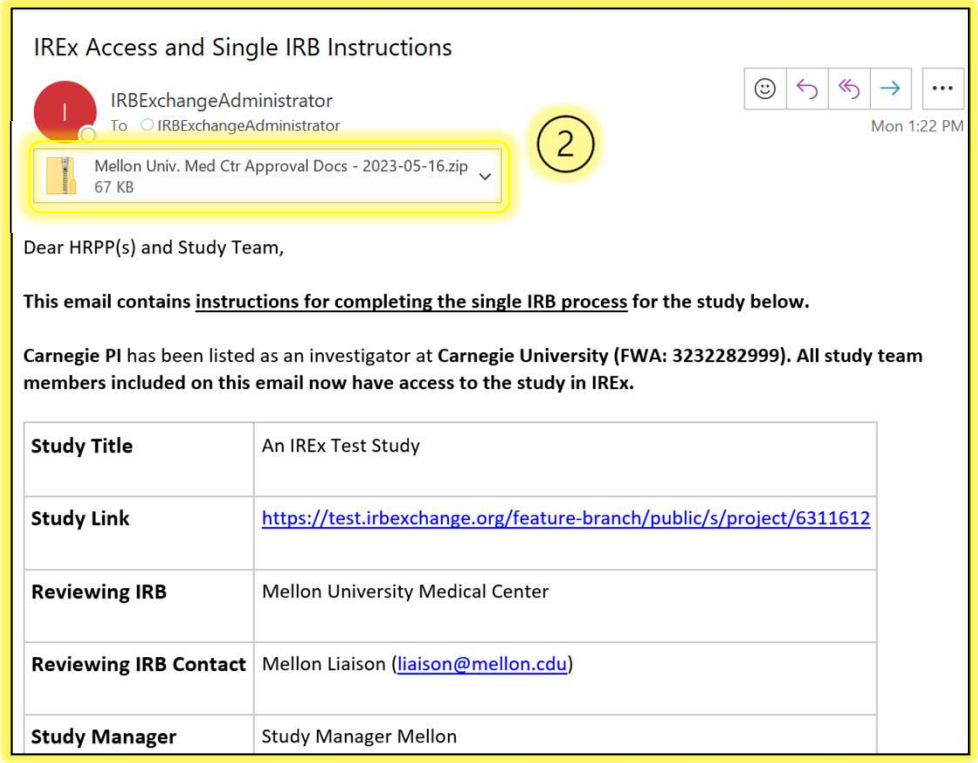


(Preview notification before sending)

1. **Notify & Grant Access** grants the study team immediate access to the study & approved study materials to prepare for local submission.

Sample Notification Email

2. A zip file of the lead site's initial approval are attached to the email.
3. The email includes instructions for completing the single IRB process.



IREx Access and Single IRB Instructions

IRBExchangeAdministrator
To IRBExchangeAdministrator
Mon 1:22 PM

2

Mellon Univ. Med Ctr Approval Docs - 2023-05-16.zip
67 KB

Dear HRPP(s) and Study Team,

This email contains instructions for completing the single IRB process for the study below.

Carnegie PI has been listed as an investigator at **Carnegie University (FWA: 3232282999). All study team members included on this email now have access to the study in IREx.**

Study Title	An IREx Test Study
Study Link	https://test.irbexchange.org/feature-branch/public/s/project/6311612
Reviewing IRB	Mellon University Medical Center
Reviewing IRB Contact	Mellon Liaison (liaison@mellon.cdu)
Study Manager	Study Manager Mellon

Next Steps:

The overall/lead site approval is available in IREx and the approval documents are attached as a zip file. If no file is attached, please contact the study manager listed above. Use these documents to prepare your local submission and initiate the reliance process at your site.

3

1. **LOCAL HRPP facilitates agreement execution:**
   The study requires the following items to be completed, which can be facilitated by the local HRPP, as needed:

Agreement/Resource	Status
SMART IRB Agreement: A national, master reliance agreement supporting single IRB review.	Complete
Mellon Letter of Indemnification	Complete
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. *This is a web-based platform, not a reliance agreement.*	Complete

2. **STUDY TEAM prepares local consent form and submits to local HRPP for review.**
   a. If applicable for the study, review the approved informed consent template(s) in IREx and insert your site-specific information.
   b. Seek guidance from your HRPP/Research Office/IRB regarding what needs to be submitted to your local HRPP to rely on the Reviewing IRB. Most HRPPS require a local submission to complete their documentation in IREx.

3. **STUDY TEAM & HRPP provide documentation in IREx.**
   STUDY TEAM: You will receive an email when the **PI Survey** can be completed in IREx.
   - The coordinator can complete the PI Survey on behalf of the PI, but the PI must attest to the PI Survey after completion and if edits are made.
   - If the study involves consent forms, they are uploaded to the PI Survey after the local HRPP has reviewed them.

   HRPP: If you have not received a local submission for this study, consider educating your local investigator about initiating reliance at your institution. When ready login to IREx and complete the following steps:

   c. **Register** to confirm your site's engagement on this study. *This is not an indication of reliance.*
   d. **Confirm the Institutional Profile**
   e. **Indicate Reliance** by accepting the Study-Specific Reliance Plan (SSRP), the sIRB's plan for handling HIPAA, auditing, reporting, and other flexible parts of the SMART IRB Agreement.
   f. **Complete the Human Research Protections (HRP) Survey**, which captures study-specific considerations for your site (e.g., applicable state or local laws, regulations, study team qualifications, etc.) that might affect the conduct or approval of the research at your site.
   g. **Review PI Survey (optional)**, which captures your local consent and specific processes regarding the study conduct at your site.

After all steps are completed, your site will be submitted to the Reviewing IRB for review. HRPPs and study teams will receive an email notification from IREx when your site's approval is available in IREx.

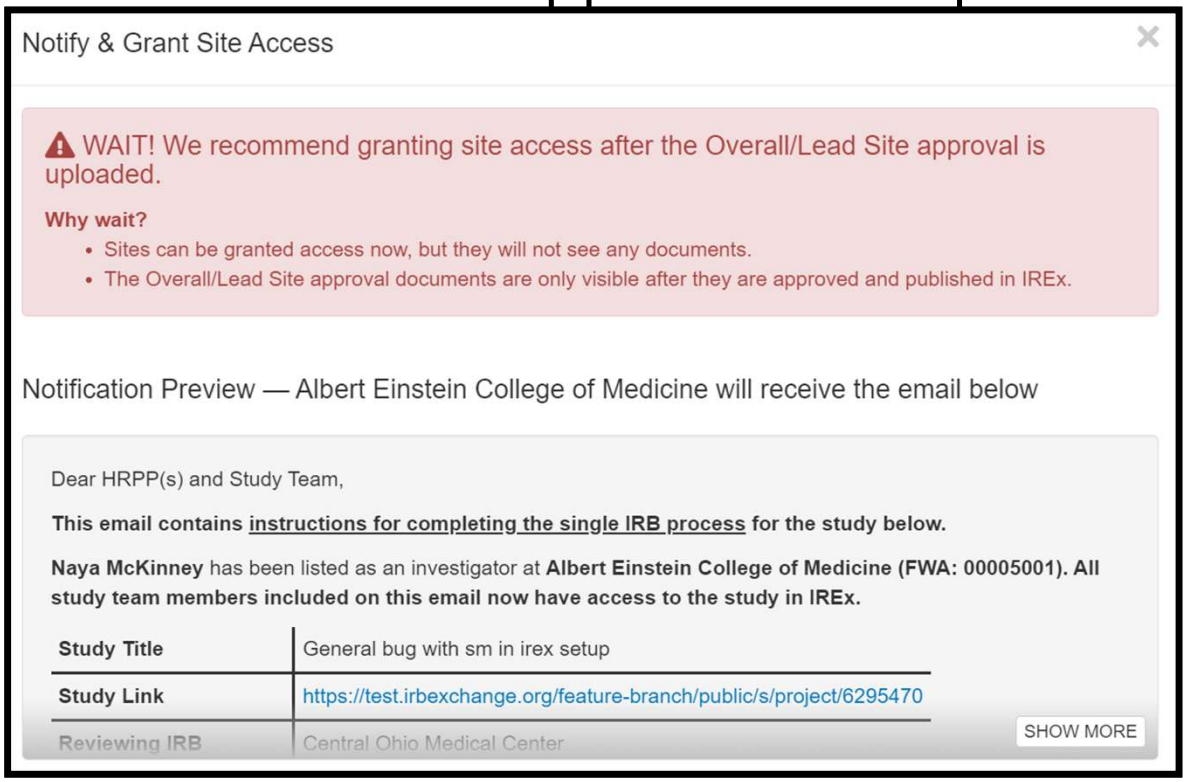
Need Help?

Access the user quick guides and other materials from the IREx Participating Site HRPP Resources and IREx Participating Study Teams Resources.

Thank you,

What documents are sent when sites are notified?

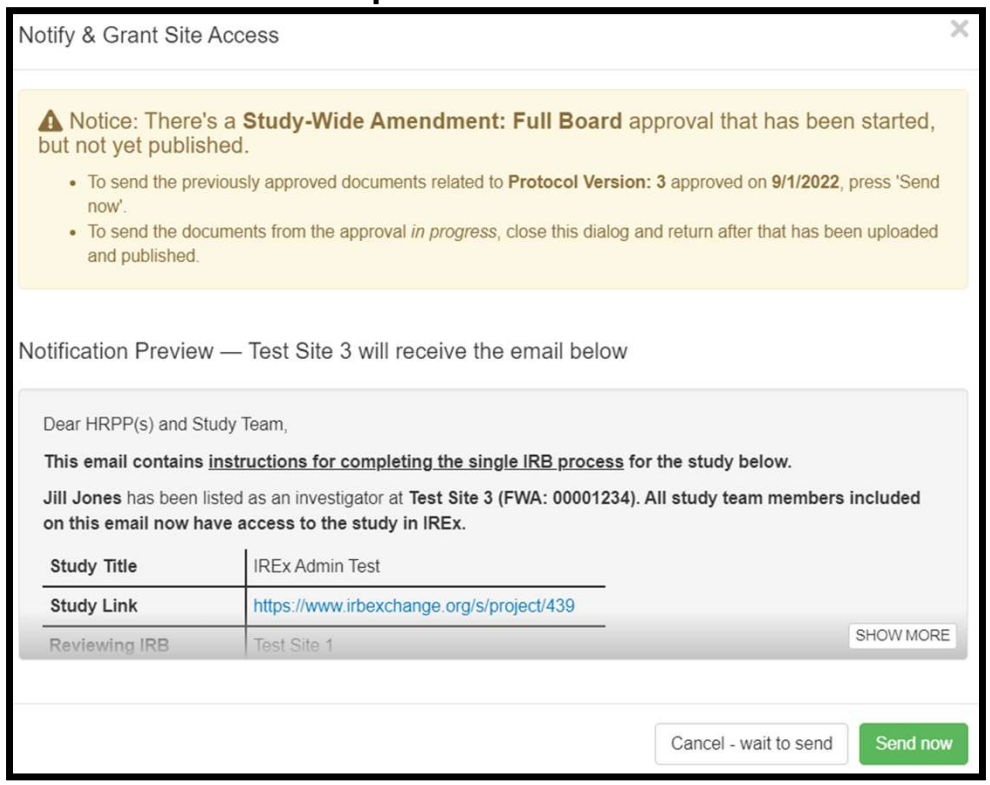
None if the lead site approval is not published



Note: Be sure to include the consent template to the lead site's approval, if one is used.

What documents are sent when sites are notified?

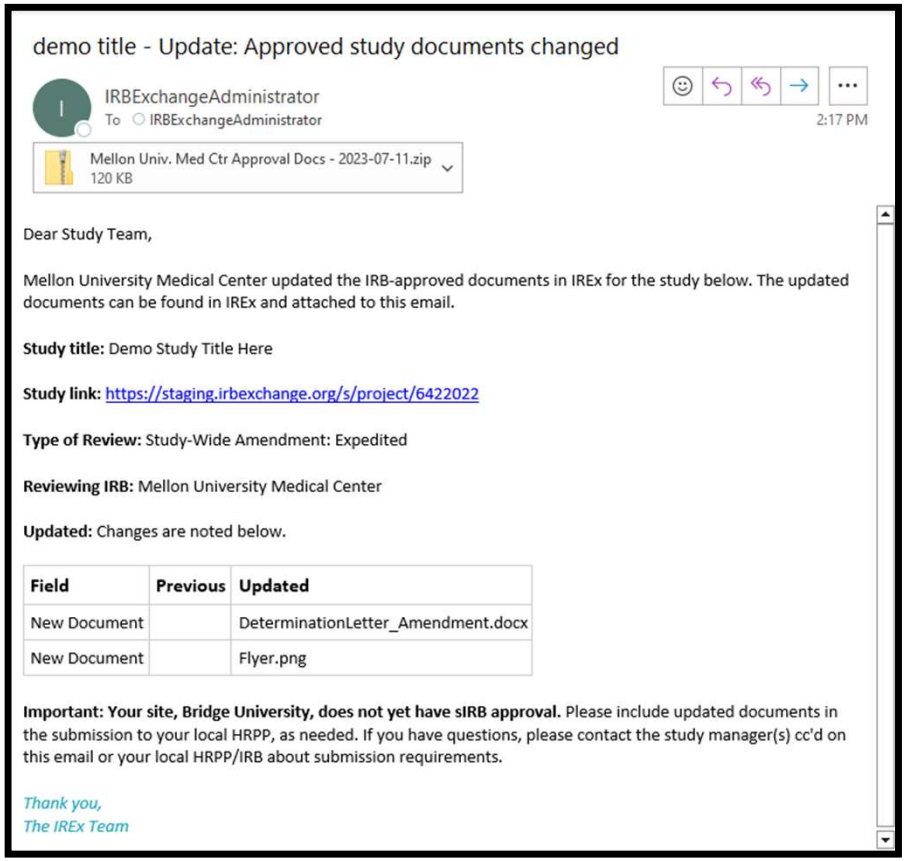
The last published version.



Note: Be sure to include the consent template to the lead site's approval, if one is used.

What documents are sent when sites are notified?

If sites were notified and a new approval is published, they get notified of the new documents.



demo title - Update: Approved study documents changed

IRBExchangeAdministrator
To IRBExchangeAdministrator
2:17 PM

Mellon Univ. Med Ctr Approval Docs - 2023-07-11.zip
120 KB

Dear Study Team,

Mellon University Medical Center updated the IRB-approved documents in IREx for the study below. The updated documents can be found in IREx and attached to this email.

Study title: Demo Study Title Here

Study link: https://staging.irbexchange.org/s/project/6422022

Type of Review: Study-Wide Amendment: Expedited

Reviewing IRB: Mellon University Medical Center

Updated: Changes are noted below.

Field	Previous	Updated
New Document		DeterminationLetter_Amendment.docx
New Document		Flyer.png

Important: Your site, Bridge University, does not yet have sIRB approval. Please include updated documents in the submission to your local HRPP, as needed. If you have questions, please contact the study manager(s) cc'd on this email or your local HRPP/IRB about submission requirements.

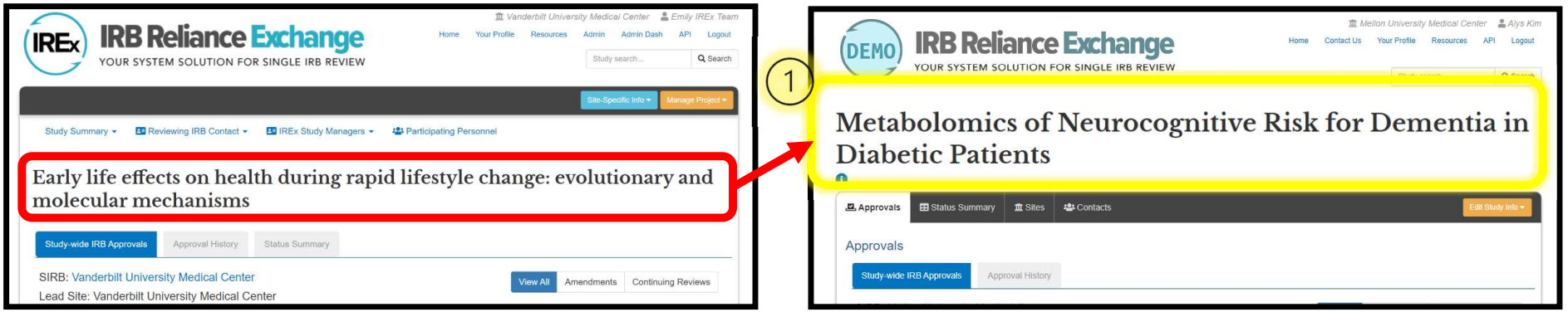
Thank you,
The IREx Team

Note: Be sure to include the consent template to the lead site's approval, if one is used.

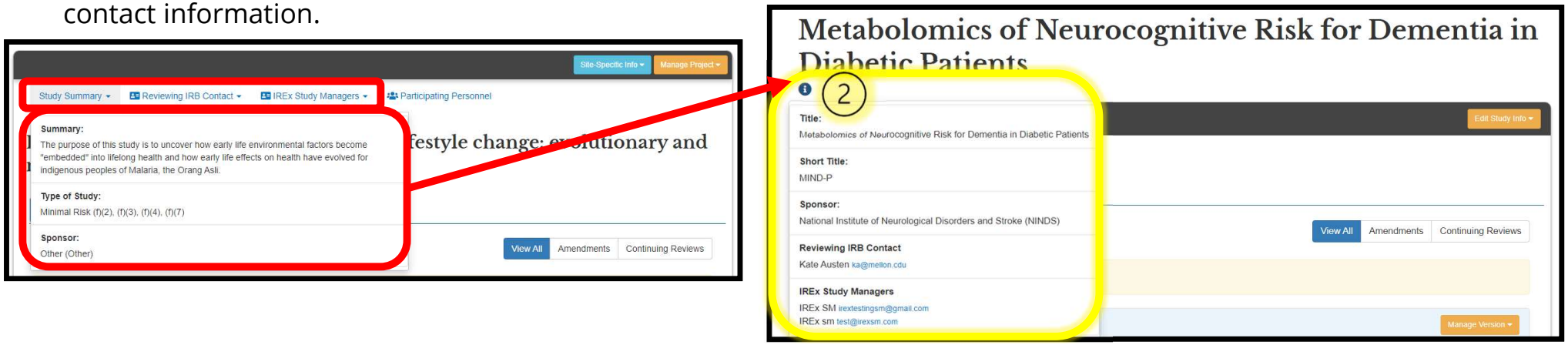
IREx Study Page Redesign

New Study Page Redesign

1. **Study title** is now at the top of the study page.



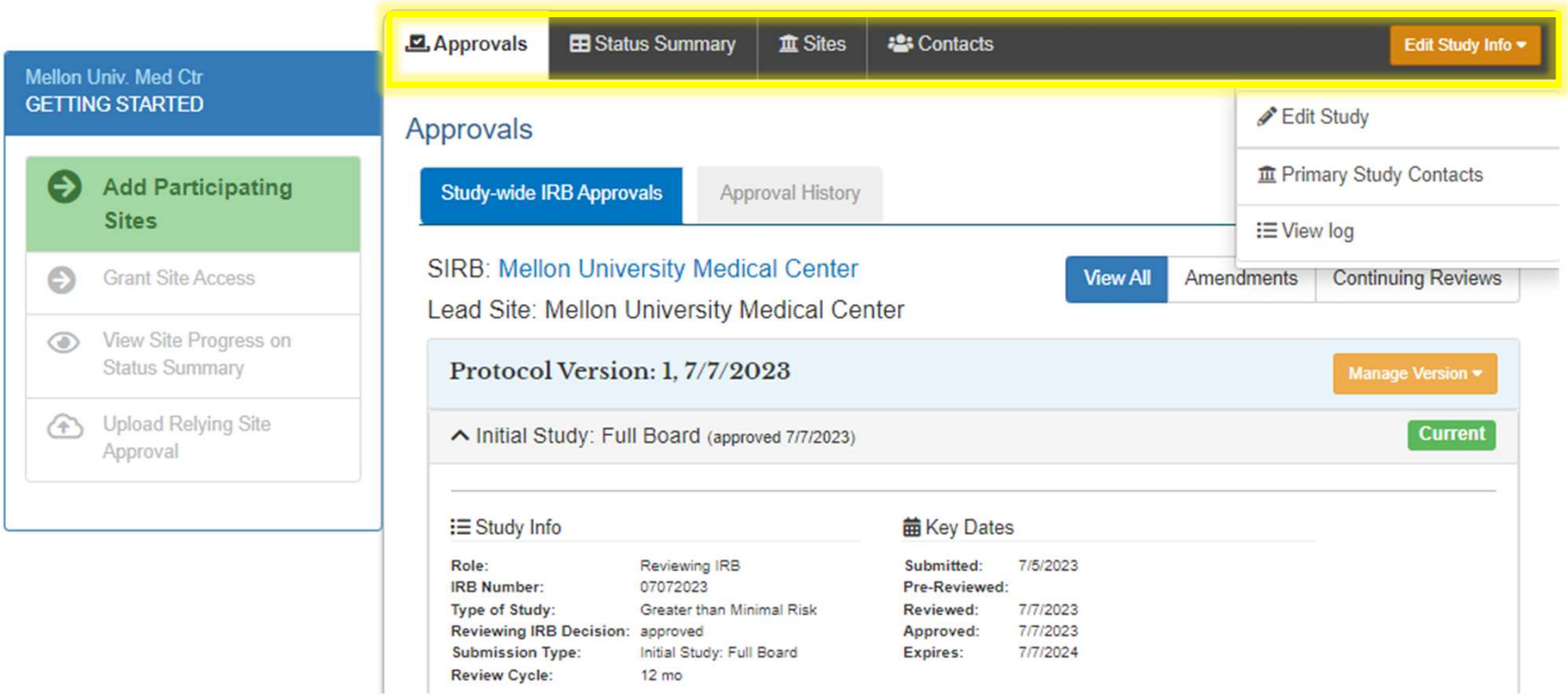
2. Use the **Info Icon** to view the Study Summary (sponsor, NCT#) and the Reviewing IRB & IREx Study Manager contact information.



New Study Page Navigation Bar

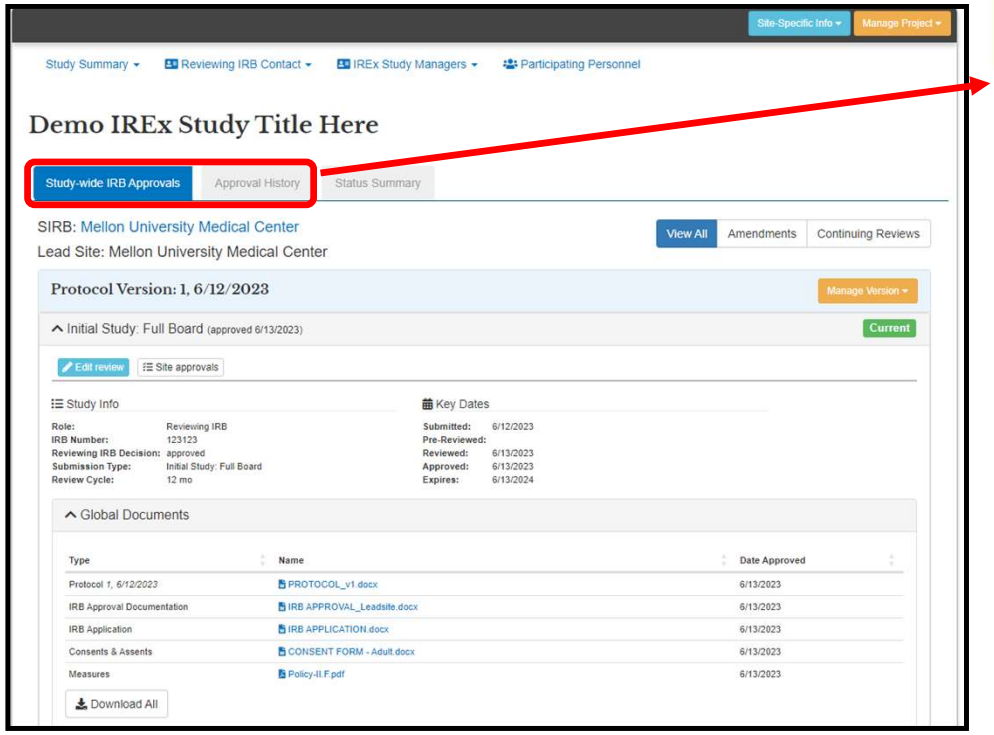
IREx Study Manager

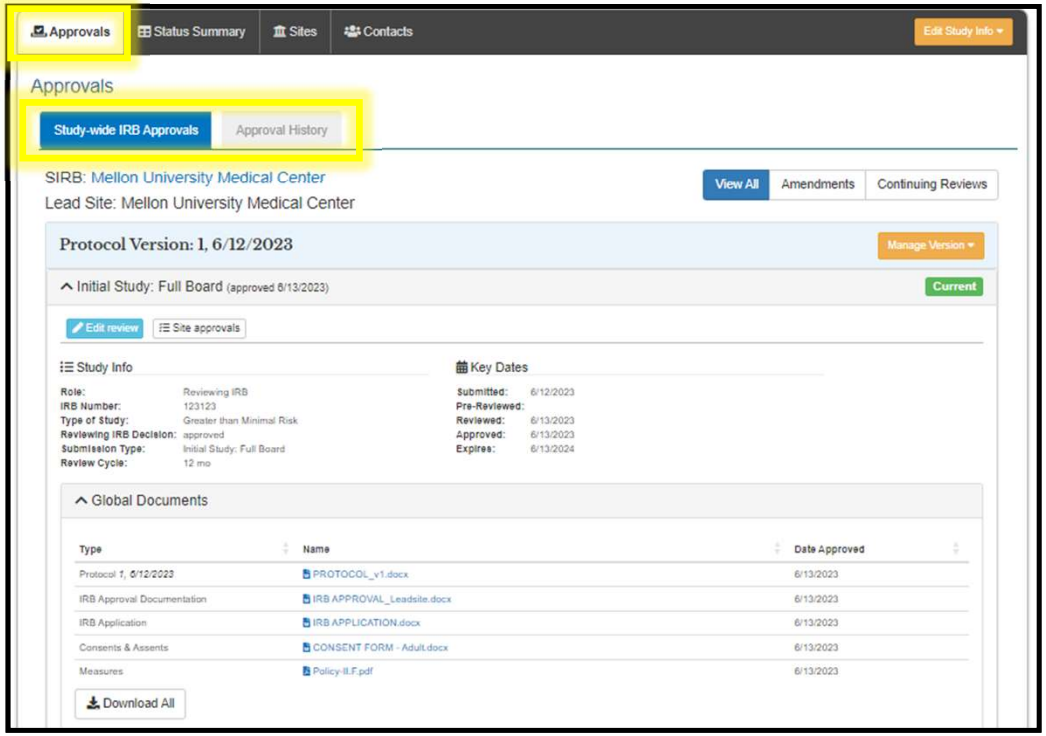
The IREx Study Page has a new look – use the navigation bar at the top to quickly view approvals, the status summary, add sites, view contacts with access to IREx .



New Navigation Bar: *Approvals Page*

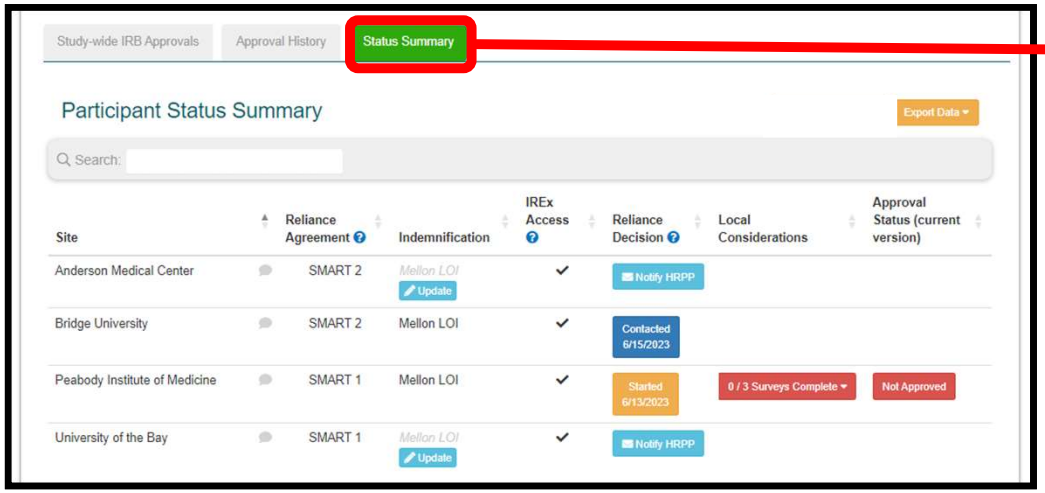
IREx Study Manager & sIRBs

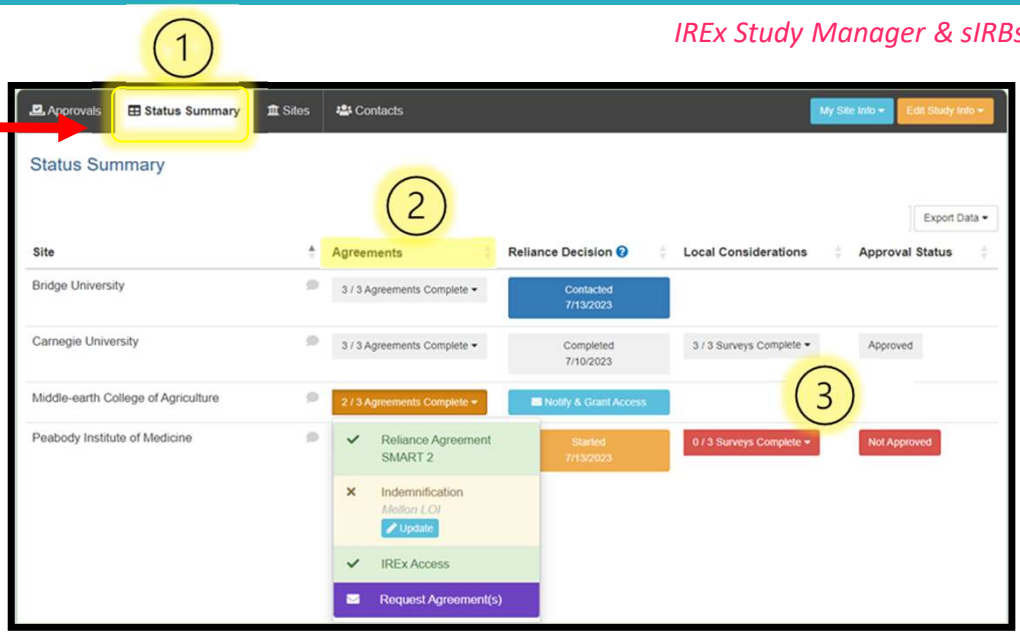




New Navigation Bar: *Status Summary Page*

IREx Study Manager & sIRBs

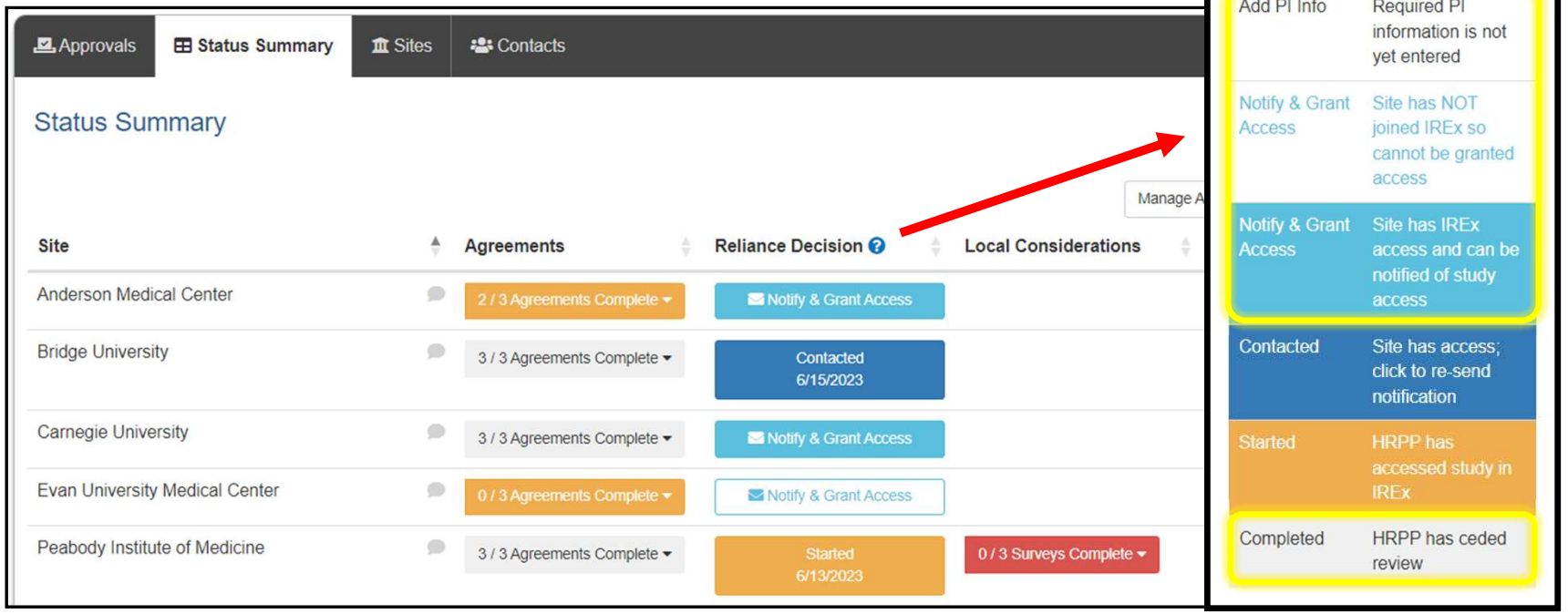




1. **Status Summary** is a separate page on the study navigation bar.
2. **Agreements** combines the Reliance Agreement, Indemnification, and IREx Access into a single column.
3. **Color** is used to draw attention to **steps** that are **incomplete** or **need action**. Completed steps are greyed out.

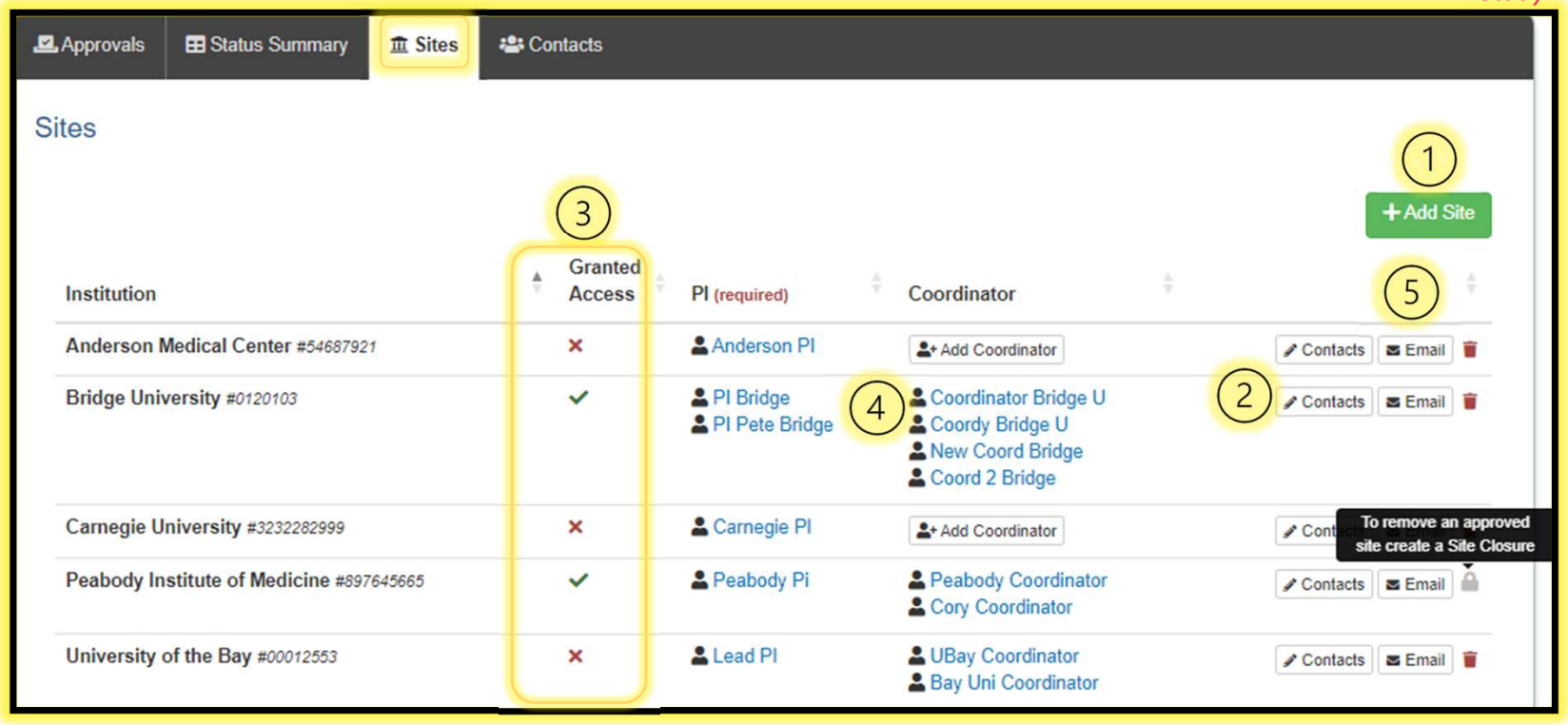
Status Summary Legend Update

The **Reliance Decision Legend** has been updated. The **Completed** status is now grey colored, indicating no further actions are required.



New Navigation Bar: *Sites Page*

IREx Study Manager & sIRBs

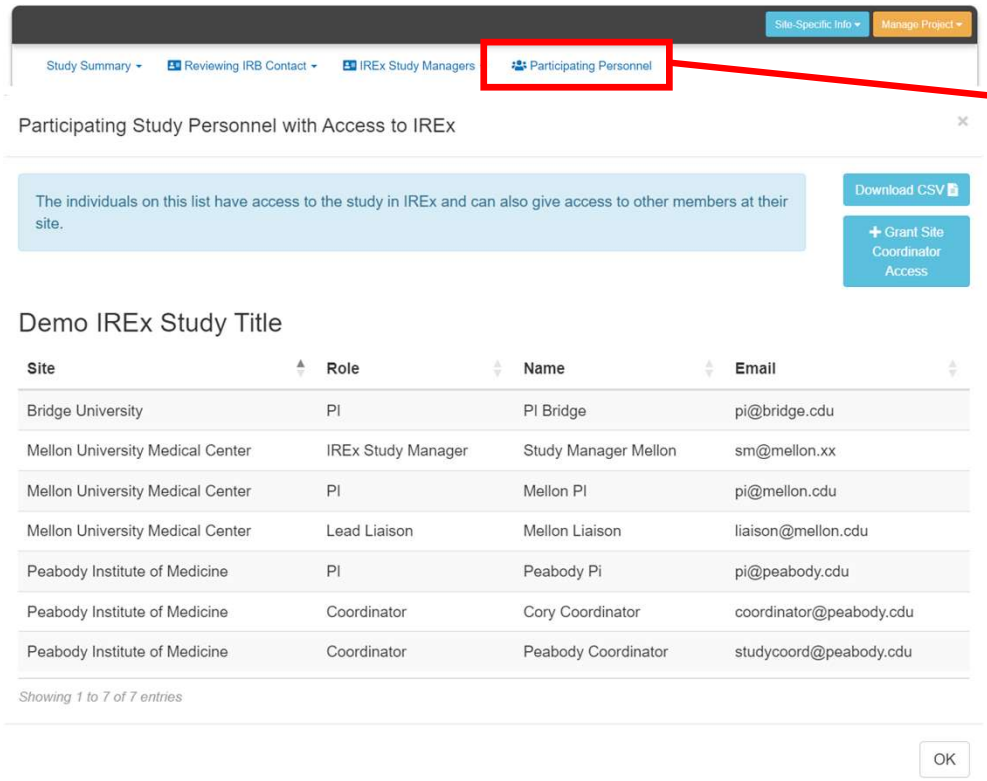


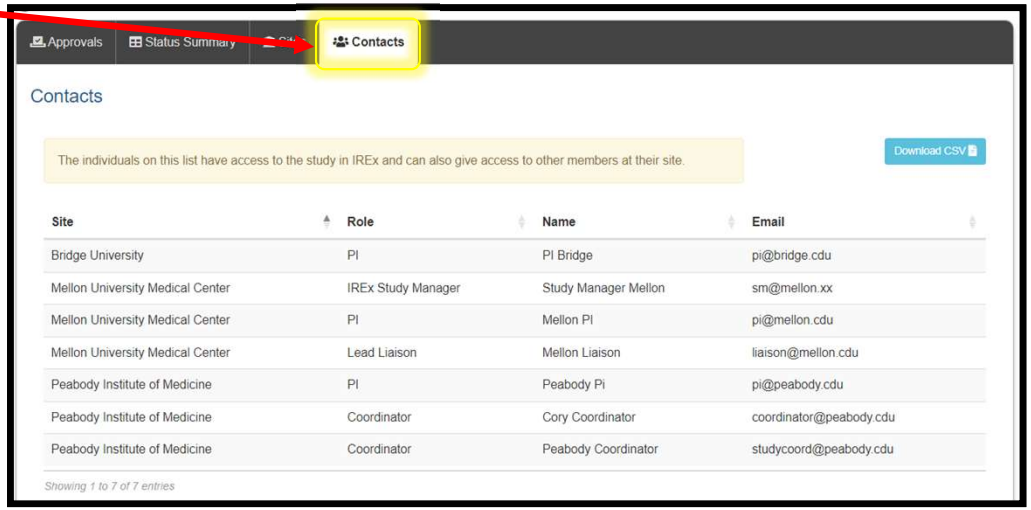
1. Add new sites
2. Edit contacts for an existing site
3. View whether sites have been granted access to the study
4. View multiple PIs and/or coordinators for each site
5. Email all site contacts with the click of a button

New Navigation Bar: *Contacts Page*

IREx Study Manager & sIRBs

View all study personnel with study access on the new **Contacts** page.

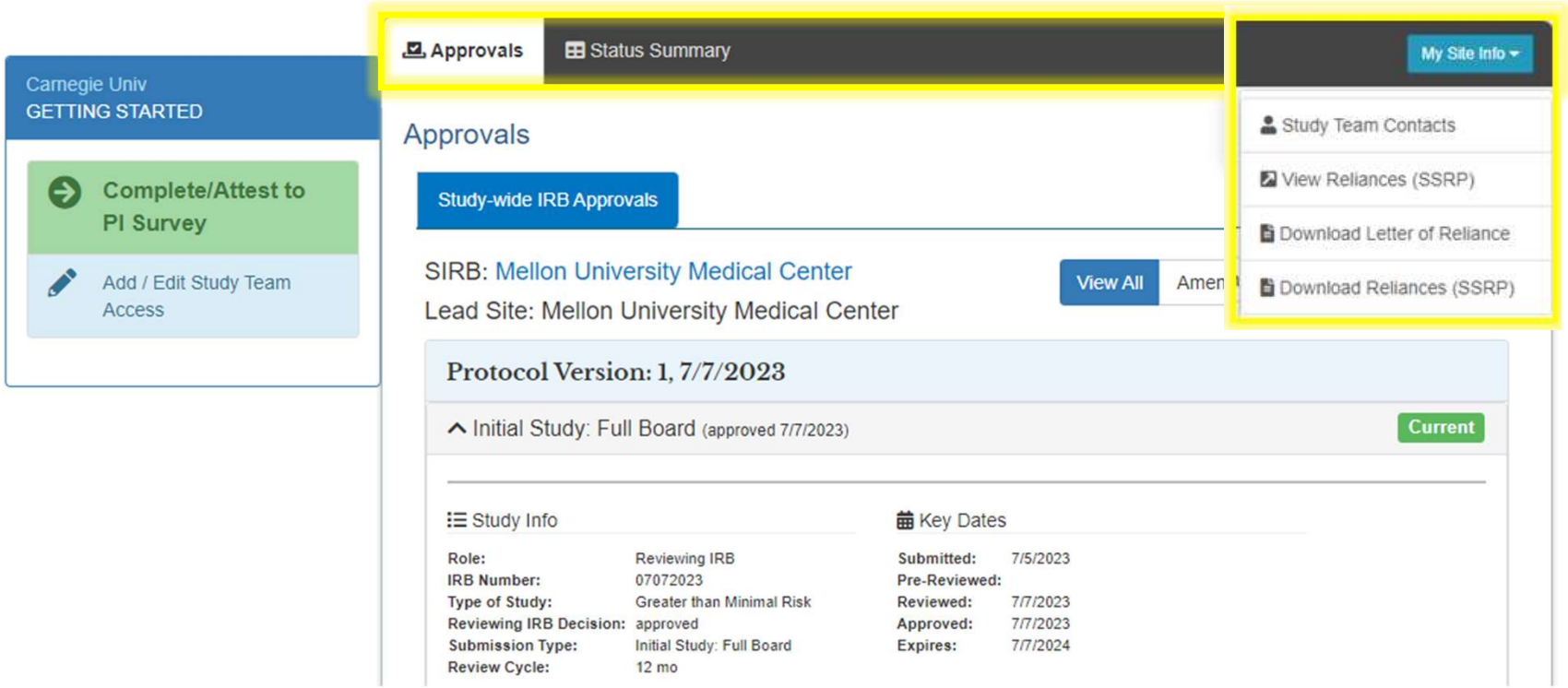




Study Team Navigation Bar

Relying Site Study Team – PI View

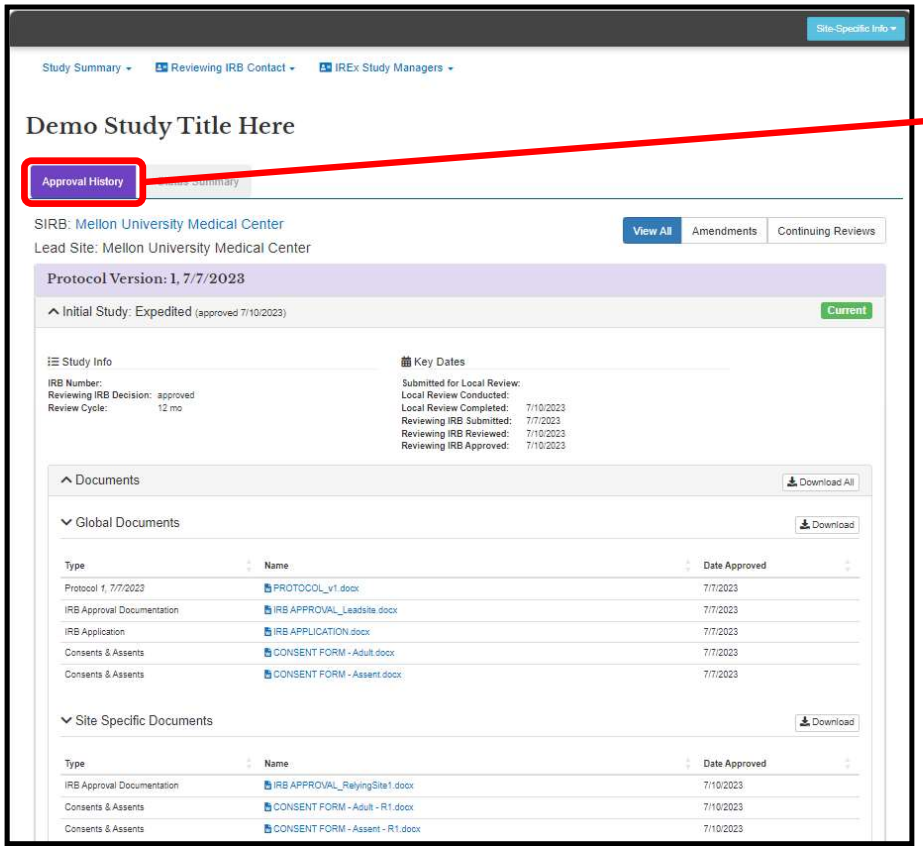
Relying Sites only have the **Approvals**, **Status Summary** pages, and a **My Site Info** menu.

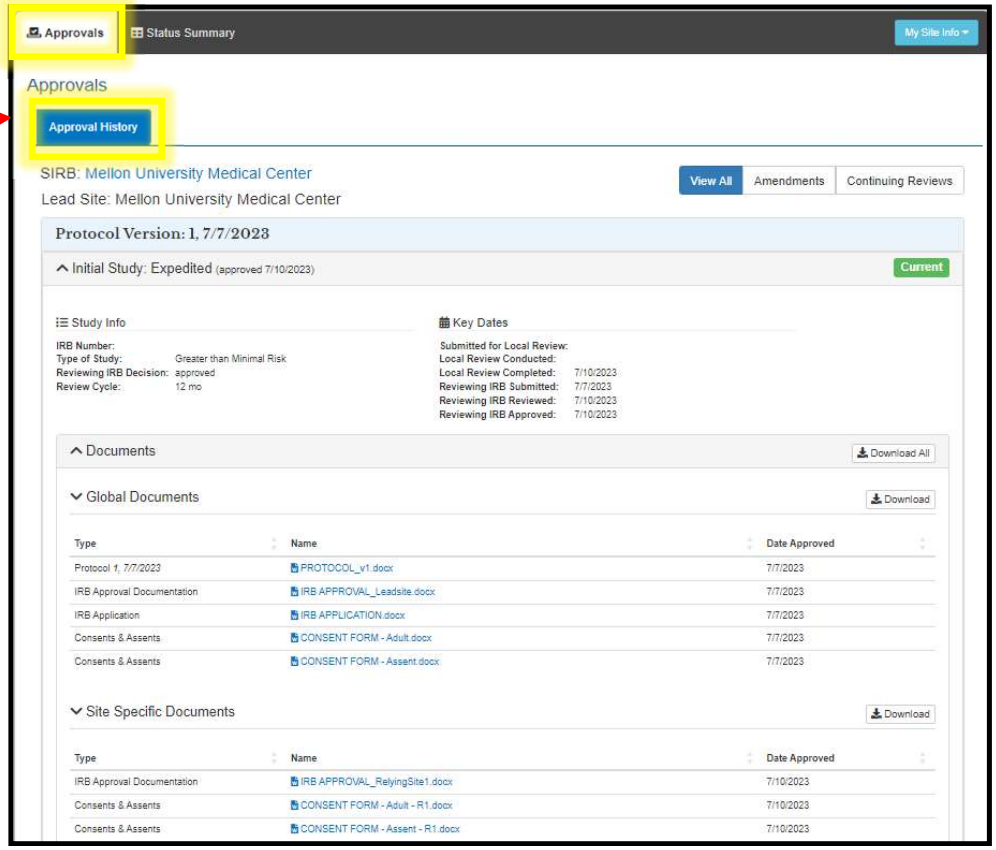


Note: Study teams get access to the PI Survey when their HRPP confirms study participation.

Relying Site's Approvals Page

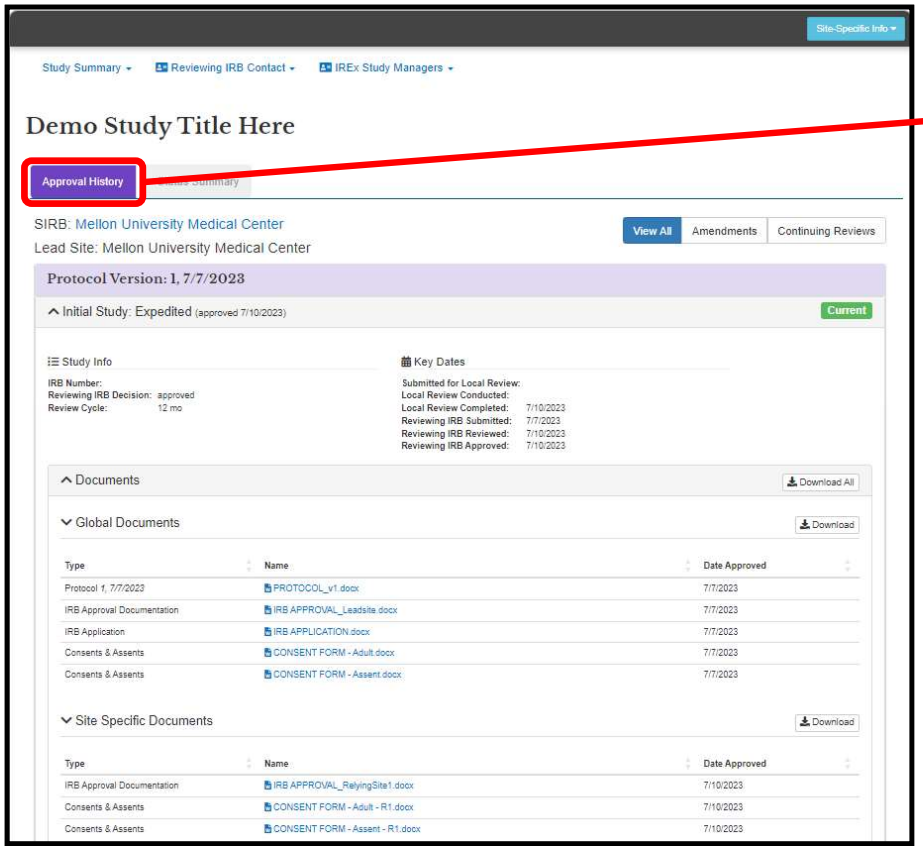
Relying Site HRPP & Study Teams

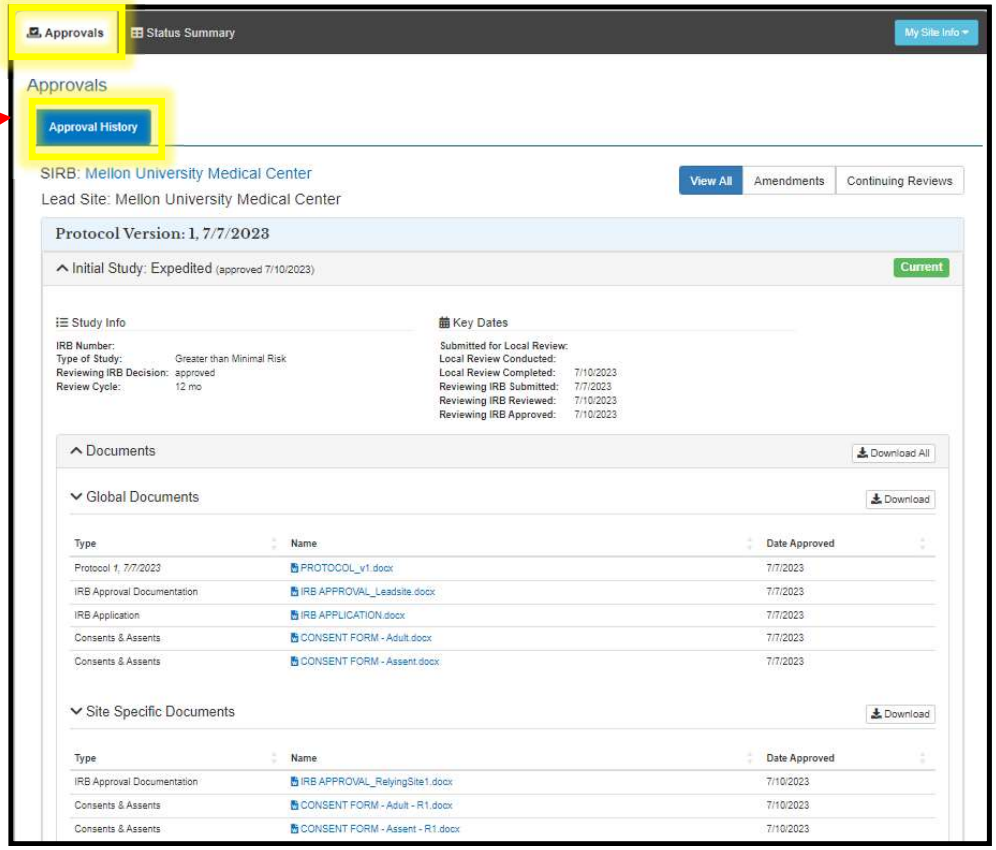




Relying Site's Approvals Page

Relying Site HRPP & Study Teams





Wait – what's this mean for existing studies?!

- **Studies created prior to 7/18 –** are automatically set to use the default IREx instructions so the SIRB doesn't have log in and edit anything.
- **Sites/study teams contacted before 7/18** – did not get single IRB instructions, zip file of approval documents, or immediate access for study teams
  - Relying study teams must wait for their HRPP to register to log in before they get access.
  - To send instructions, documents, and grant immediate approval, you can re-contact the site – just be sure it won't be confusing to the site to get something new.
- **Adding new contacts for existing sites –**
  - If the site has not registered, they will not get access to IREx until their HRPP registers.
  - If their site has registered, they get access when they are added.
- **Adding new sites to a study created before 7/18 –** study teams will get the default IREx single IRB instructions, approval documents zip, immediate access for study teams

What's Next for IREx?

What's Next?

- **Capturing other single IRB communications – not just approvals**
  - IRB letter from protocol deviation that doesn't result in any changes.
  - important study-related changes that aren't IRB approved yet (e.g., FDA issues Safety Memo)
  - communicate preliminary reports to relying sites, and later send final determination letters, action plans
- **Enhancing document history & displayed for study teams**
- **Revising local considerations to account for study-specific questions** (e.g., accounting for standard of care / routine care) **& SMART IRB recommendations** (released for comment today!)
- **Capturing information needed for Continuing Review from Relying Study Teams**
- **Supporting SMART IRB Version 3, once released**
- **Other Suggestions?**

Next Call: October 20, 2023