IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

IREx Quarterly Call

- Training
- Special projects

Natalie Dilts

- Manager, Application Development

Joshua Milford

- Study Support
- User Training

David Crenshaw

- Materials Development
- Study support

Kaysi Quarles

- Site onboarding
- Study Support

Tiffany Chen

- Platform direction
- Evaluation

Emily Serdoz

- Study Support
- User Training

Bridget Swindell

- System Development

Linda Tan

- Application Developer

Jason Tan

- Application Developer

Evan Wimberly

- Materials Development

Katelyn Benhoff

4.19.2023 QUARTERLY CALL AGENDA

- Welcome & Announcements
- Recent Feature Releases
- Vote on IREx's Next Enhancement
- **Panel Discussion:**
  Best (& Worst) Practices Around Local Considerations

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

Next Quarterly Calls

July 19, 2024

October 18, 2024

January 17, 2025
(new Zoom information will be sent)

Announcements

Best Wishes to Bridget!

Retires April 30th, 2024 after 45 years at Vanderbilt University Medical Center

New / Revised IREx Materials

FOR STUDY MANAGERS

- ***NEW*** Updating Local Considerations Throughout the Life of the Study(for study teams)
- How to Upload Continuing Review Approvals in IREx
- How to Upload Site Amendment Approvals in IREx
- How to Upload a Study-Wide Amendment in IREx
- How to Add an Additional Study Manager
- IREx Study Manager Step-by-Step Guide
- IREx Study Manager Overview

FOR REVIEWING/SINGLE IRBS

- Using IREx as the Reviewing/Single IRB

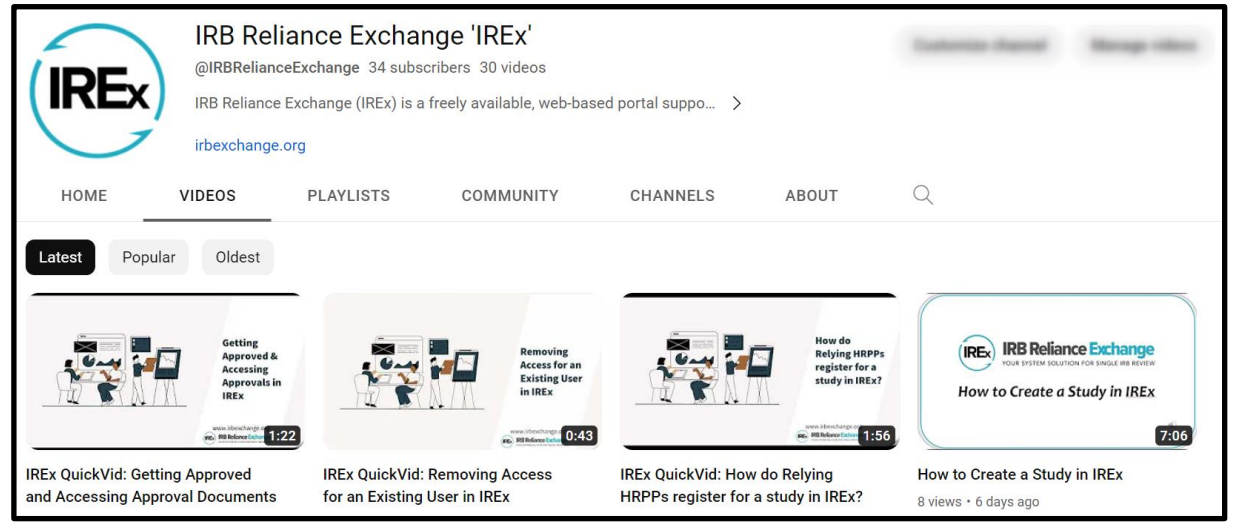
Updated Videos Available via IREx YouTube Channel

FOR STUDY MANAGERS

- How to Upload a Study-Wide Amendment in IREx
- How to Upload Continuing Review Approvals in IREx

FOR REVIEWING/SINGLE IRBs

- How to Create a Study in IREx



What's New?

Features Released Since January 2024

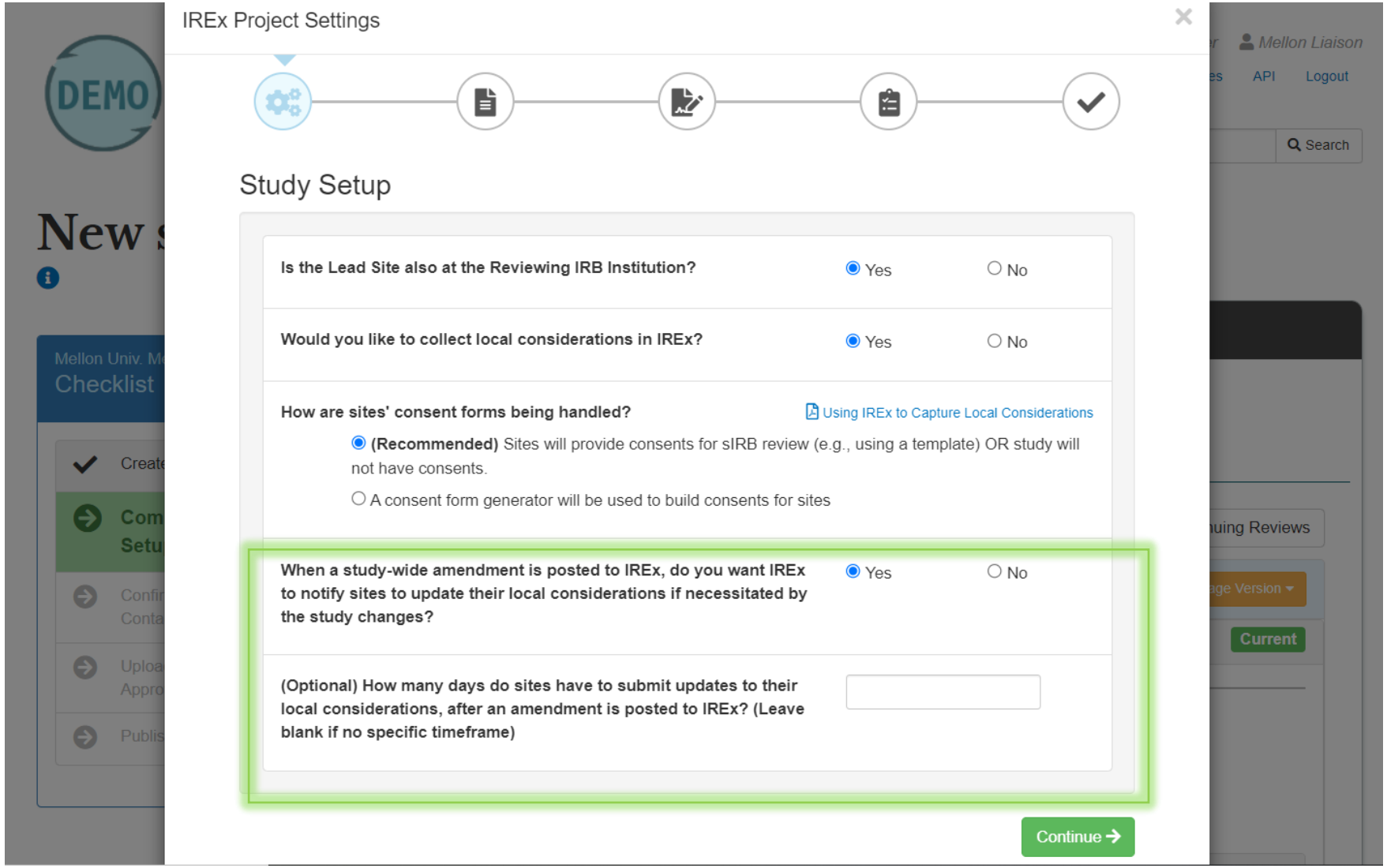
Select System Enhancements / Bug Fixes

Enhanced: Modified Primary Study Team Contacts dialog to allow Reviewing IRB to add a Study Manager first and be able to indicate if also PI.
Enhanced: Study Managers will now see the ‘Edit Study Info’ menu before initial approval is published.
Fixed: New study team contacts are included on the study access notification when a site is re-contacted.
Fixed: No longer display “Amendment #” field when uploading initial approval and continuing reviews
Fixed: Relying site notification of updated approval displays table of changes.
Fixed: Prevent Reviewing IRBs and/or Study Managers from Requesting Agreements if IREx Setup is incomplete
Fixed: Study closure notifications no longer sent to participating sites removed from a study.
Fixed: Study Managers can now ‘select a site’ from the dropdown on the Add A Contact box to add other Study Managers.

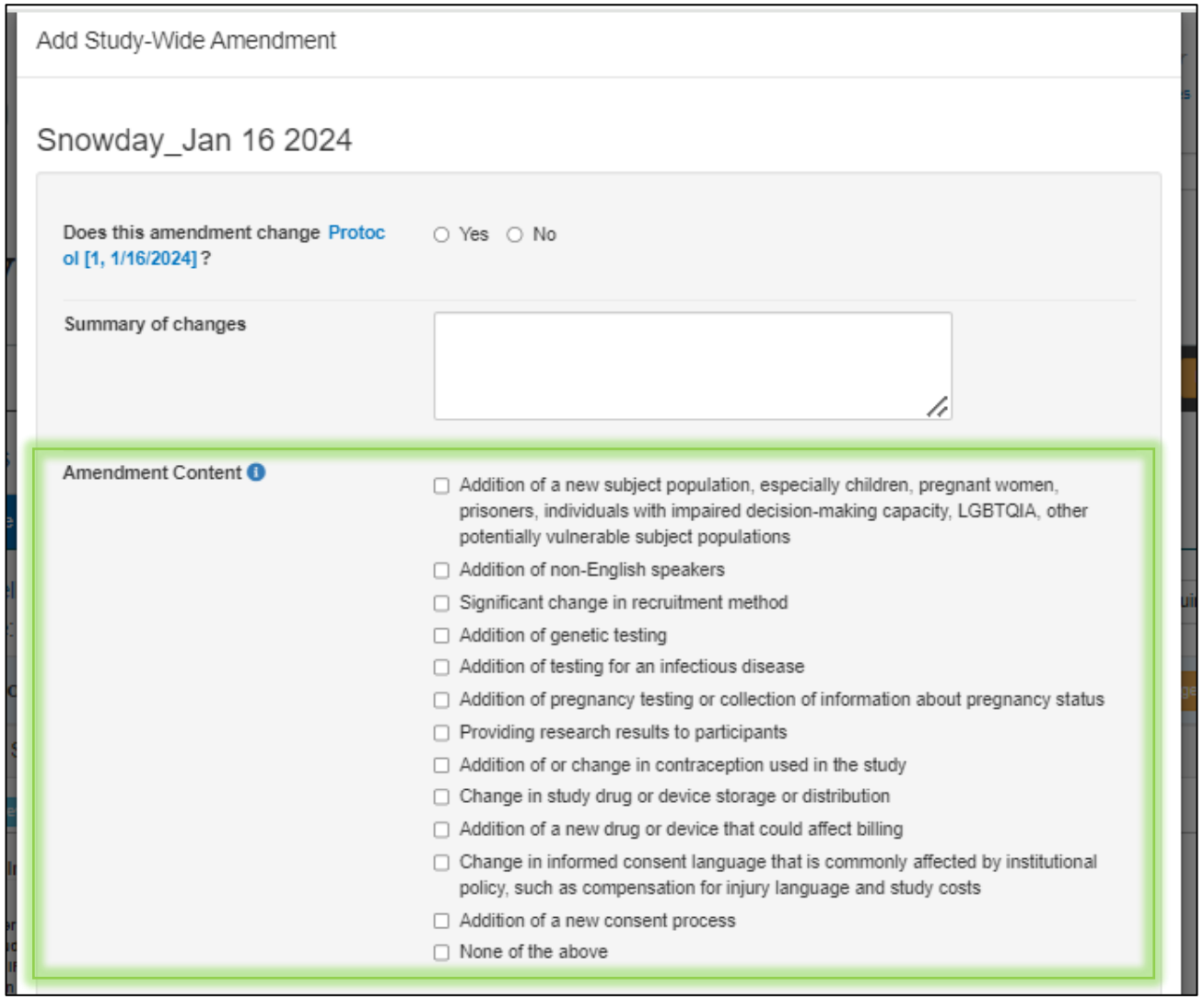
New / Updated Features

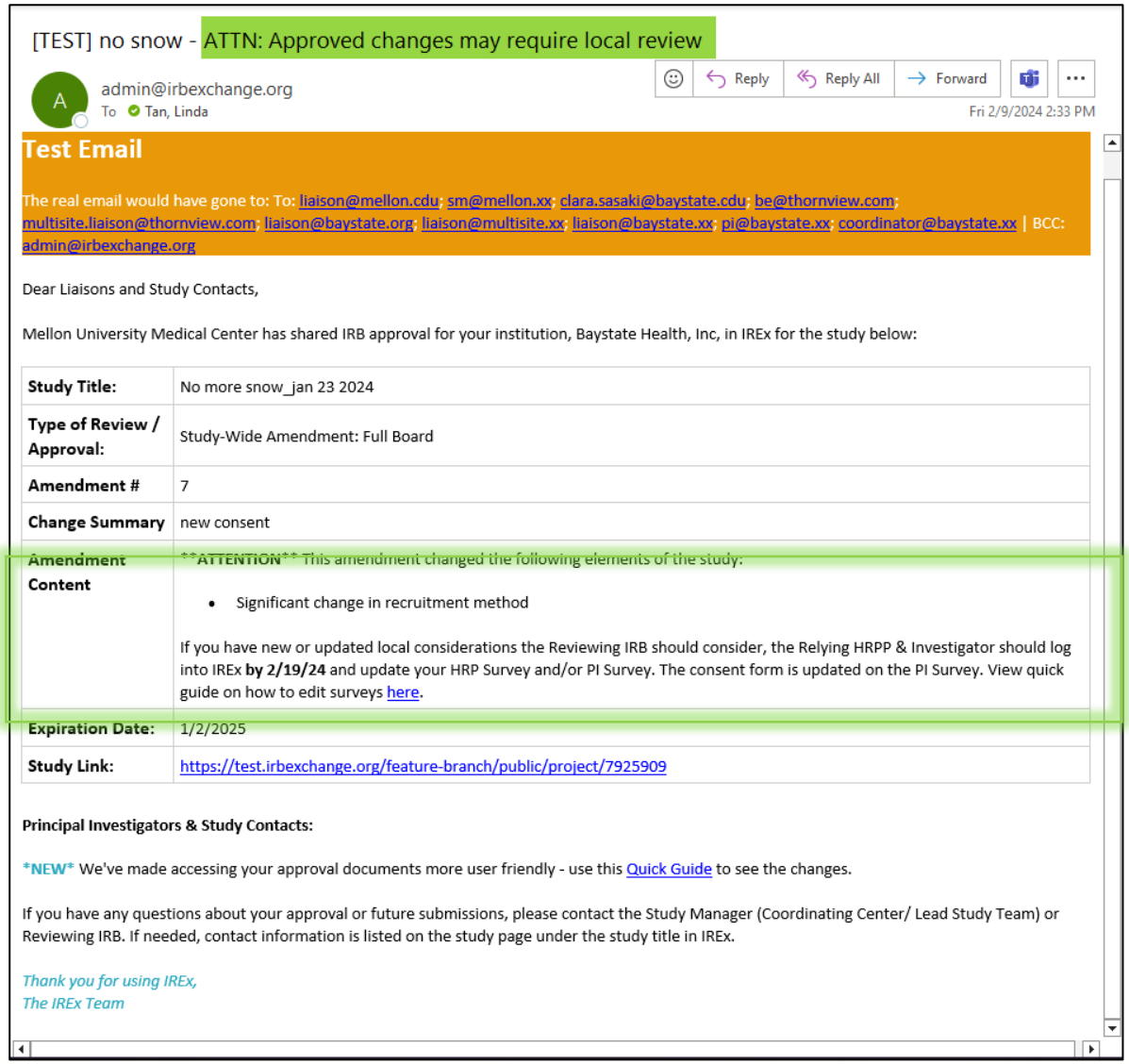
New Feature: Reviewing IRBs can capture Local Considerations Changes in IREx
New: Amendment Content can now be indicated when uploading a study-wide amendment
Updated: Modified amendment approval email notification
Updated: Relying sites can edit the HRP and PI Survey after receiving Initial Approval
Updated: HRP and PI Survey PDFs will now include Last Modified Date
Updated: Relabeled Getting Started Checklist to Checklist
Updated: Modified Uploading Approval dialog
Updated: Modified column on Participating Site’s Studies Dashboard
Updated: “Not Approved” status hidden on the Status Summary tab until site completes all steps

New Feature: Reviewing IRBs can capture Local Considerations changes for life of study in IREx

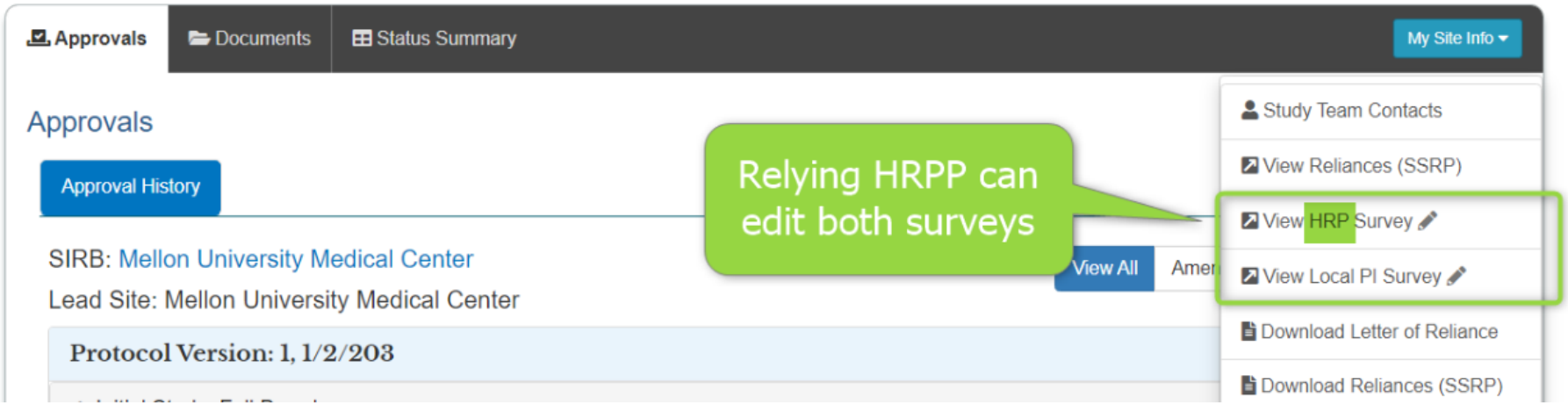


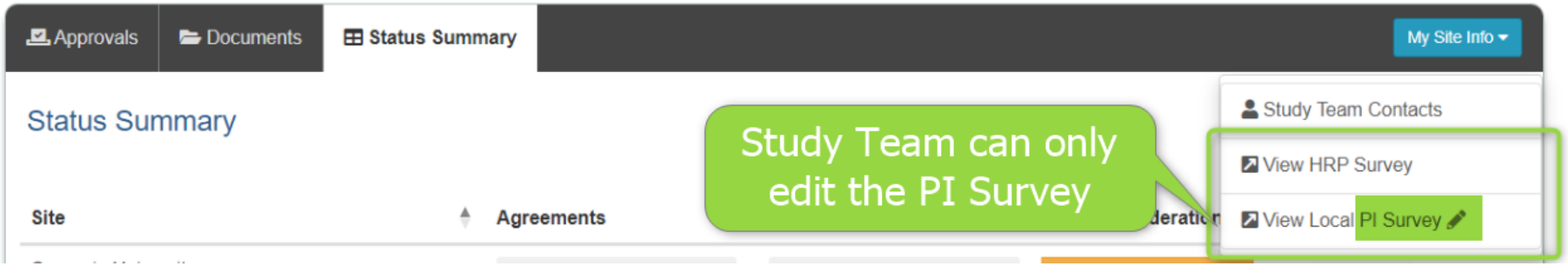
New Feature: Indicate Amendment Content when uploading a Study-Wide Amendment



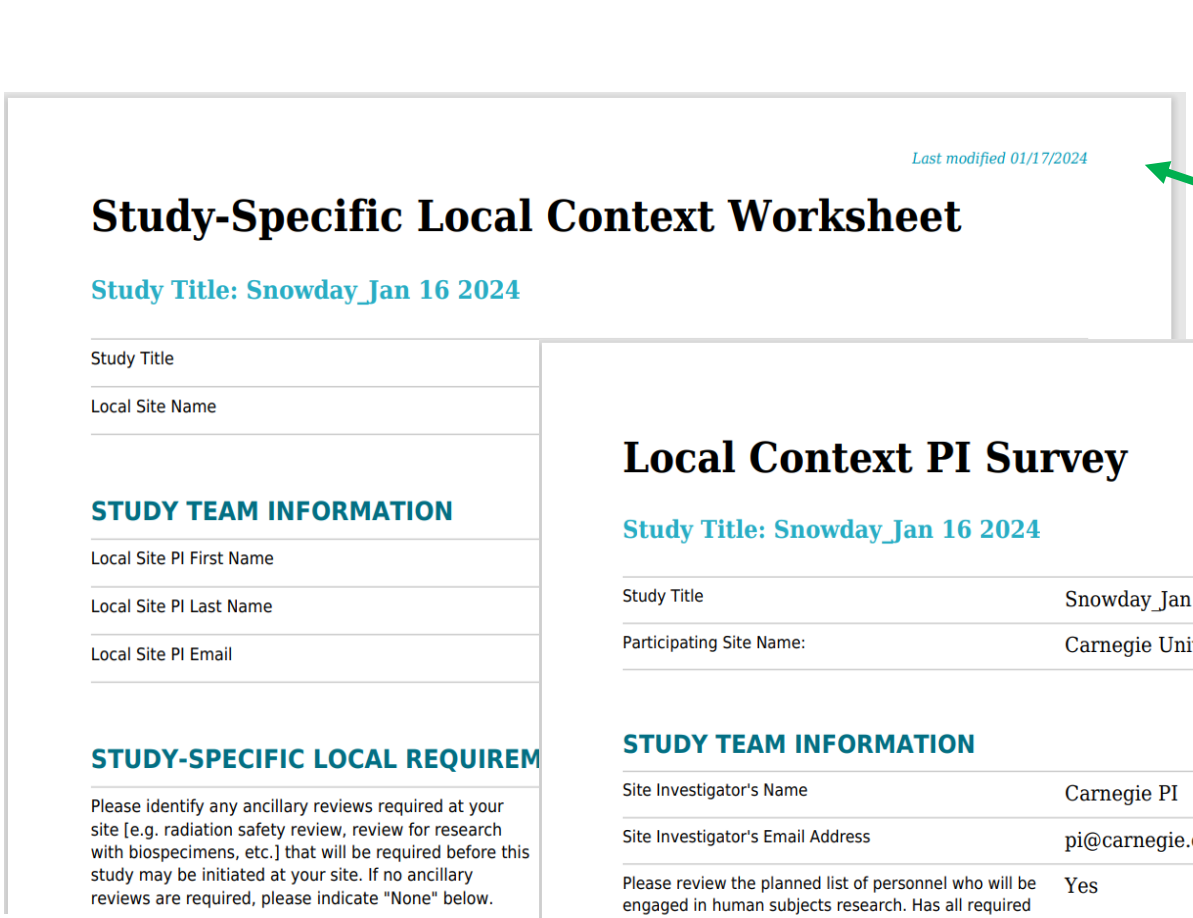


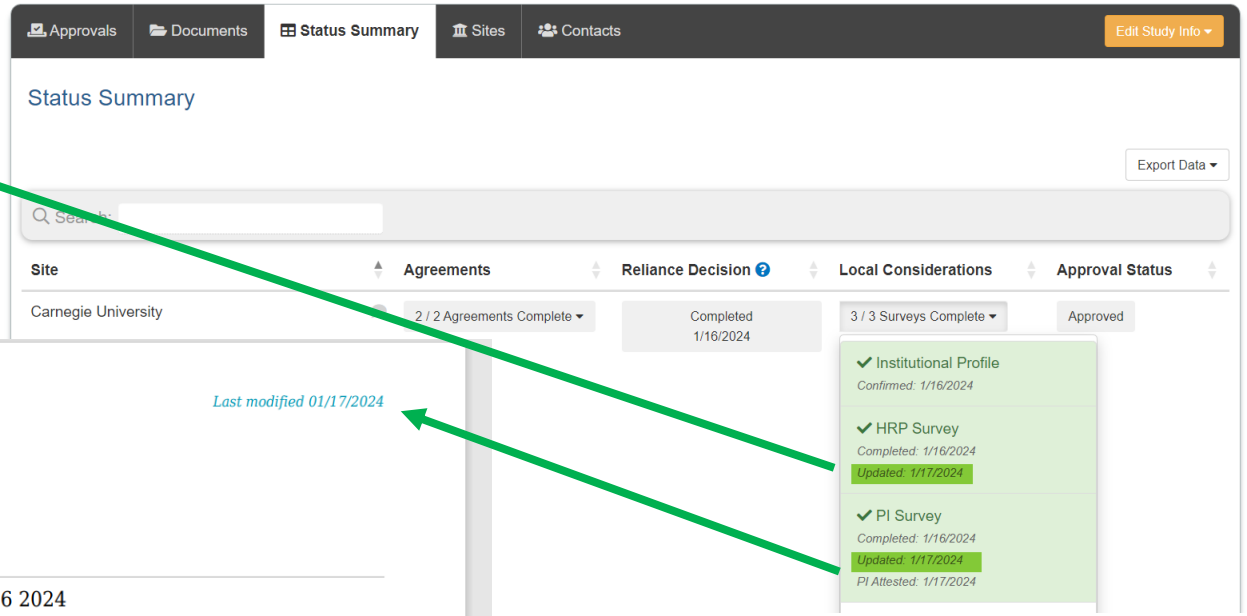
Relying Sites can edit the HRP and PI Survey after receiving Initial Approval



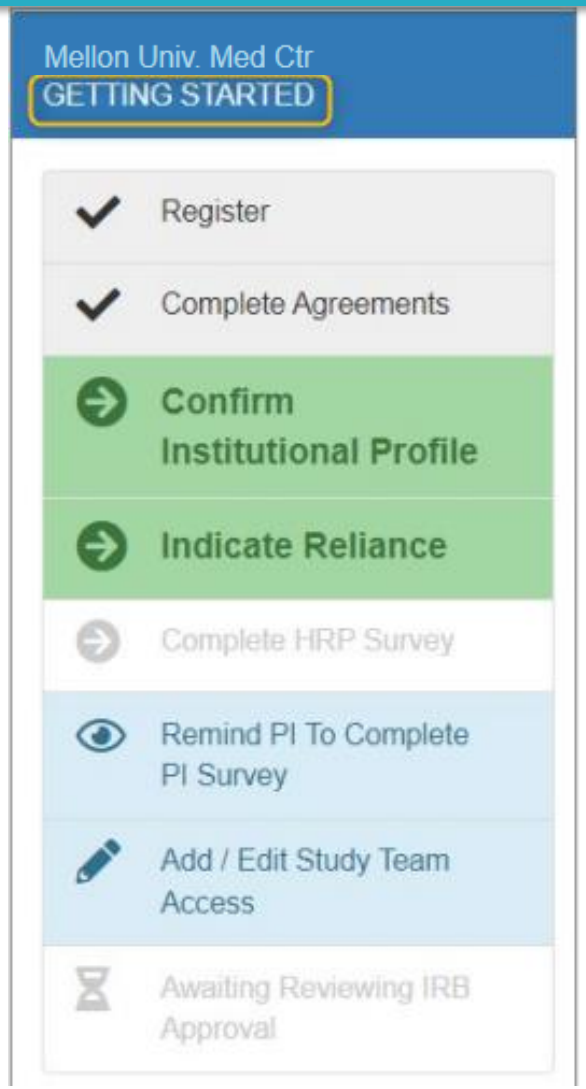


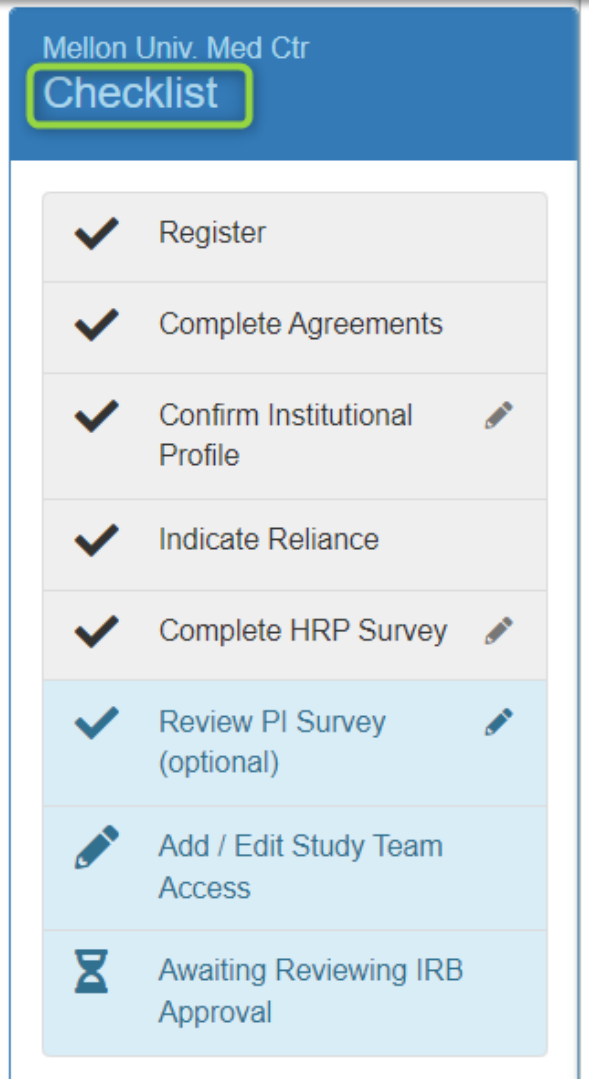
HRP and PI Survey PDFs include Last Modified Date



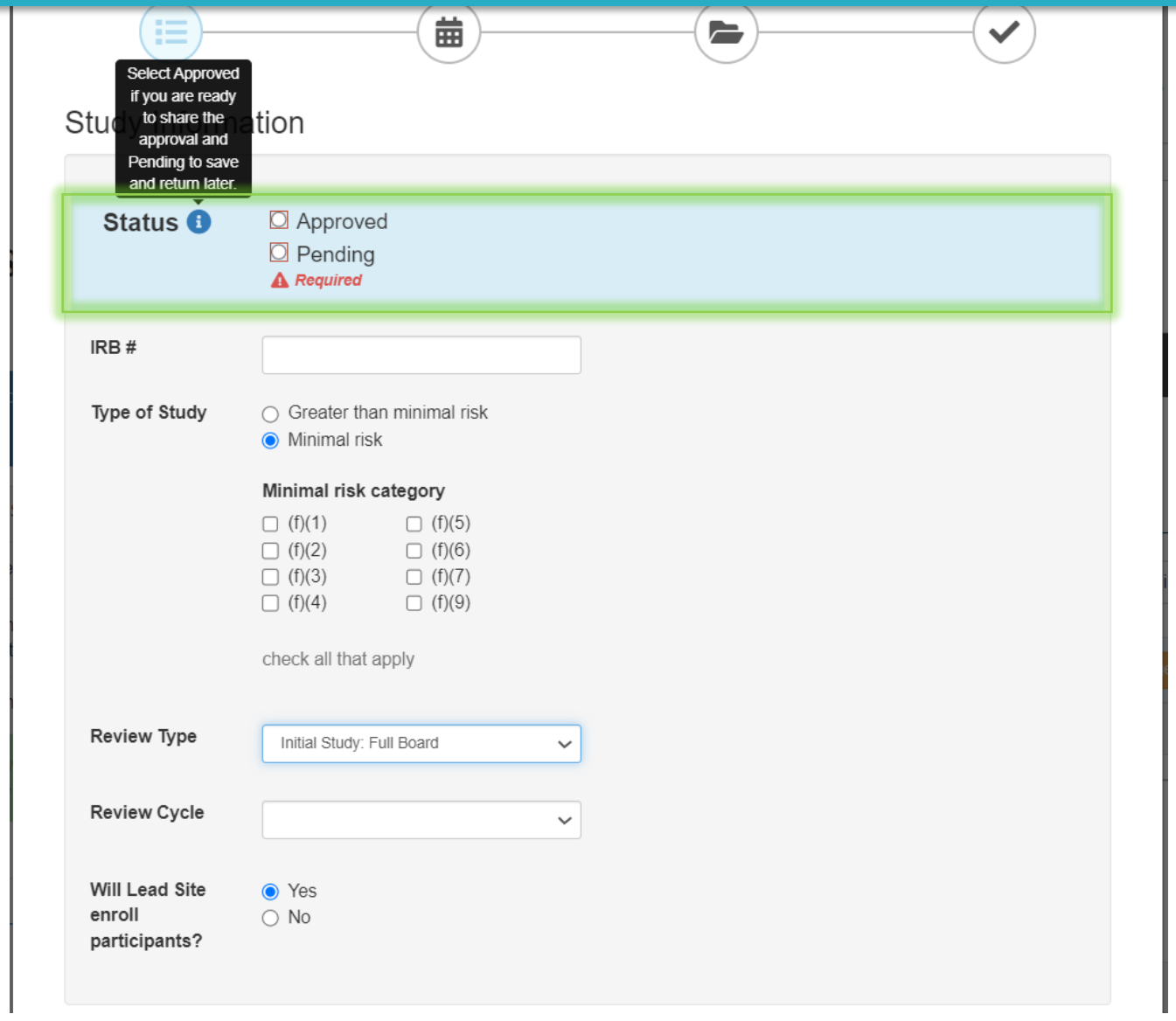


Relabeled ‘Getting Started Checklist’ to ‘Checklist’

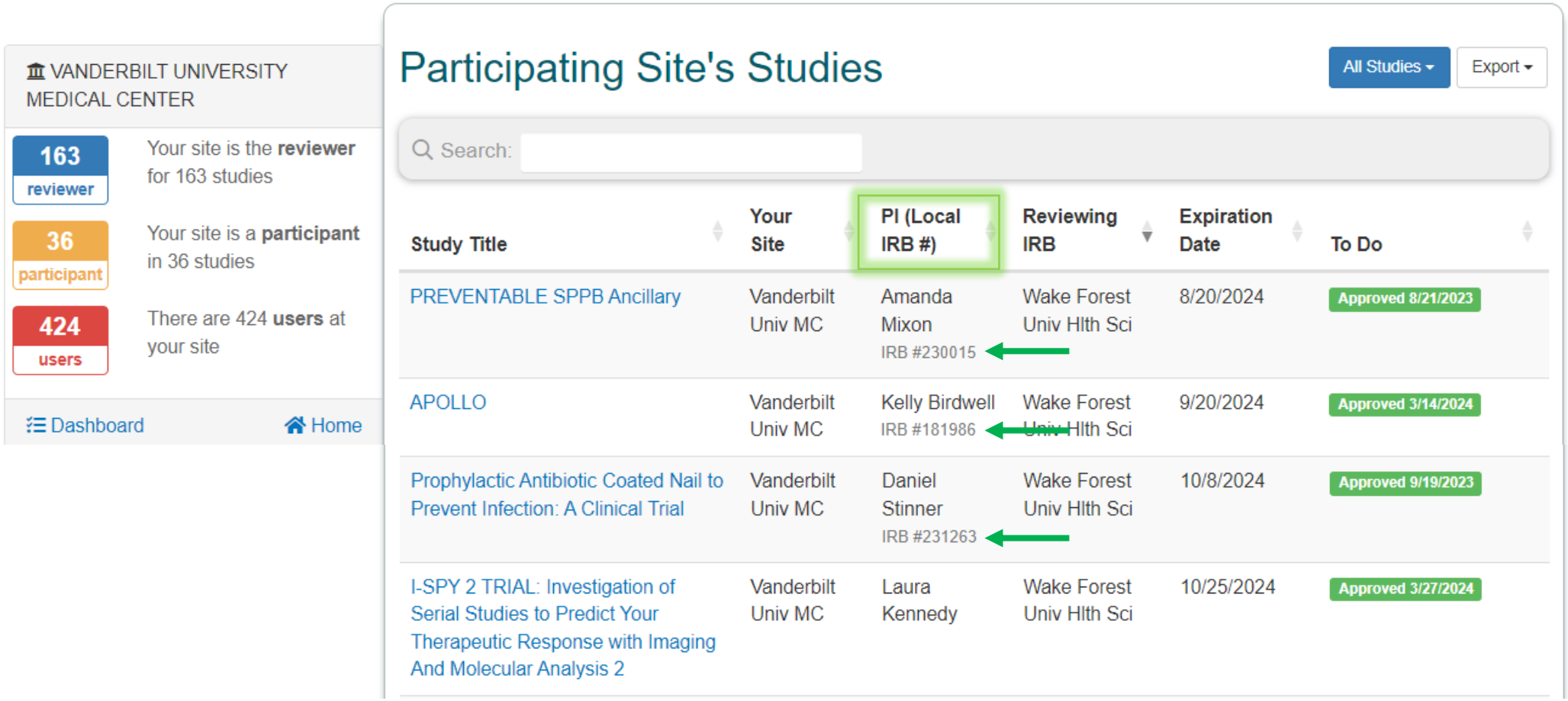




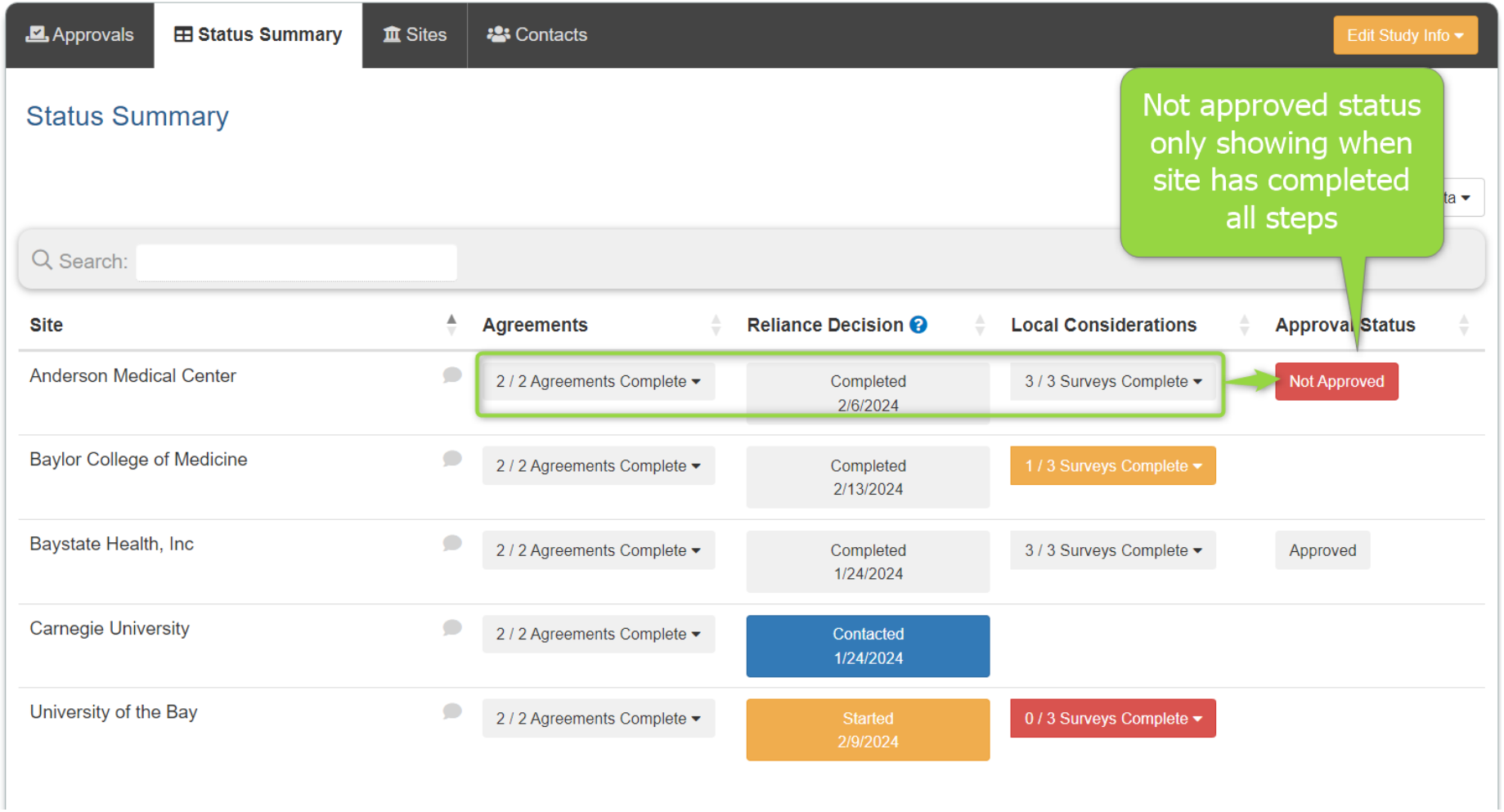
Modified Uploading Approval Dialog



Modified column on Participating Site's Studies Dashboard

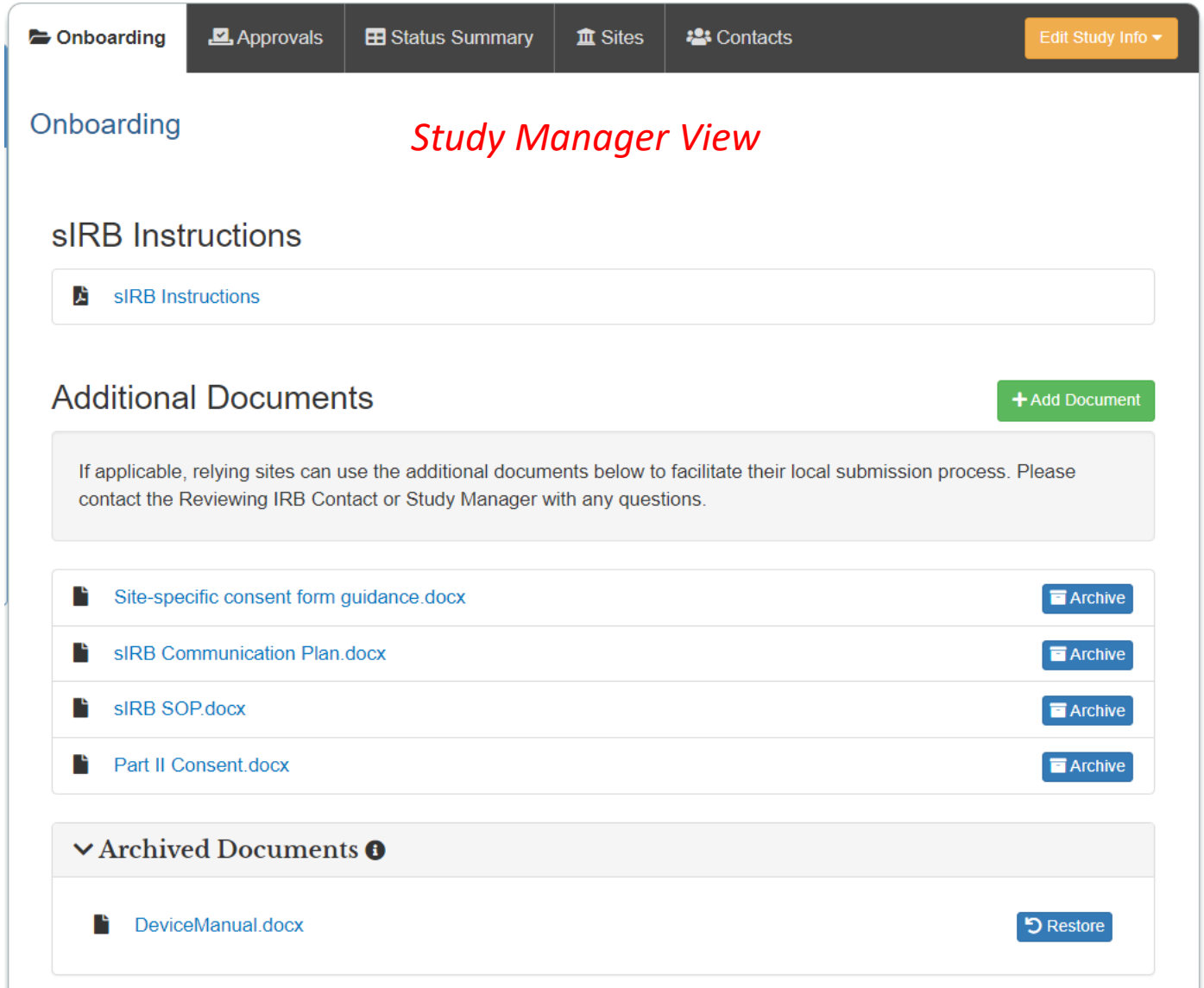


“Not Approved” Status hidden on the Status Summary tab until site completes all steps



Coming Soon: Onboarding Tab

- Repurposed Documents tab
- Default page view for sites not yet approved
- Includes copy of the sIRB Instructions
- sIRB & SM can add documents for site onboarding
- sIRB & SM can archive documents that no longer apply to the study



Panel Discussion: Best (& Worst) Practices Around Local Considerations

Janelle Maddox-Regis, JHU

Anna Martin. UW-Madison

Jessica Phillips, UCSF

Lisa Rigtrup, Univ. of Utah

Background: SMART IRB's Recommendations for the Harmonization of Local Considerations

Executive Summary

The Working Group identified several challenges and inconsistencies related to local considerations (aka local context) and recommended harmonization in three key areas to improve the process for providing, collecting, and reviewing local considerations:

1. Definition of local considerations (aka local context).
2. The type and detail of information collected to address local considerations.
3. Assessing local considerations throughout the life of a study.

The following resources were developed in support of these recommendations:

- Institutional Profile
- Study-Specific Document
- Local Considerations Information Guidance Table
- Local Considerations Throughout the Life of a Study
- Considerations for Investigators Writing Multi-Site Protocols
- Single IRB Review Case Study: Addressing Variation in Institutional Assent Policies
- Template Checklists for Reviewing IRBs and Relying Institutions to Identify When to Address Local Considerations after Initial Approval of a Study

- IREx plans to harmonize with SMART IRB by adding questions to our IP, HRP Survey, and PI Surveys
- IREx will not harmonize on some points:
  - Keeping some questions that were cut in the IREx IP, HRP Survey, and / or PI Surveys
  - Keeping HRP & PI Surveys separate
- IREx will the IP available in a CSV format on the public website (and after logging in)

Institutional Profile Changes

New to SMART – Add to IREx

1. sIRB willingness to serve as privacy board
2. Requirements to apply common rule to all studies
3. Requirements to apply subparts B, C, or D to all studies
4. Affiliated sites, university, clinics, hospitals
5. Local considerations (i.e., customs, beliefs, values, or practices of a distinct subject population(s))

Removed/not in SMART – Keep in IREx

- AAHRPP accreditation status
- Issued FDA warning letter in past 12 mos
- Board specialties
- Outstanding FDA Form 483s
- Method of HRPP/IRB quality assessment in past 5 years
- To what state laws is institution subject
- ICD mandatory reporting language
- eConsent platforms
- Logo requirements
- Require waiver for review of med records to identify eligible subjects
- Require HIPAA authorization separate from ICD

HRP / PI Survey Changes

New to SMART – Add to IREx

- Confirm drug/device storage/management in alignment with protocol & local policies
- Site differs from study plan around minors (e.g., age of majority, assent process, pregnancy testing in minors, wards of state emancipated minors, who can assess the capacity of consent, etc.)
- Site differs from study plan for impaired decision making and LARs (e.g., who can obtain informed consent, who served as an acceptable LAR, identifying capacity to consent, etc.)
- Site differs from study plan for vulnerable subjects (e.g., categories of research in which prisoners may participate, who can conduct studies on students, who can conduct studies on employees, etc.)
- Is there anything additional related to state law, local law, or institutional policy that impacts this particular study?
- Does study fall under HIPAA privacy
- Does your site have a limited role (data analysis)

Removed/not in SMART – Keep in IREx

- Any special characteristics/concerns of your community of which the reviewing IRB should be aware for this specific study
- Site differs from study plan for data & safety monitoring

Panel Discussion

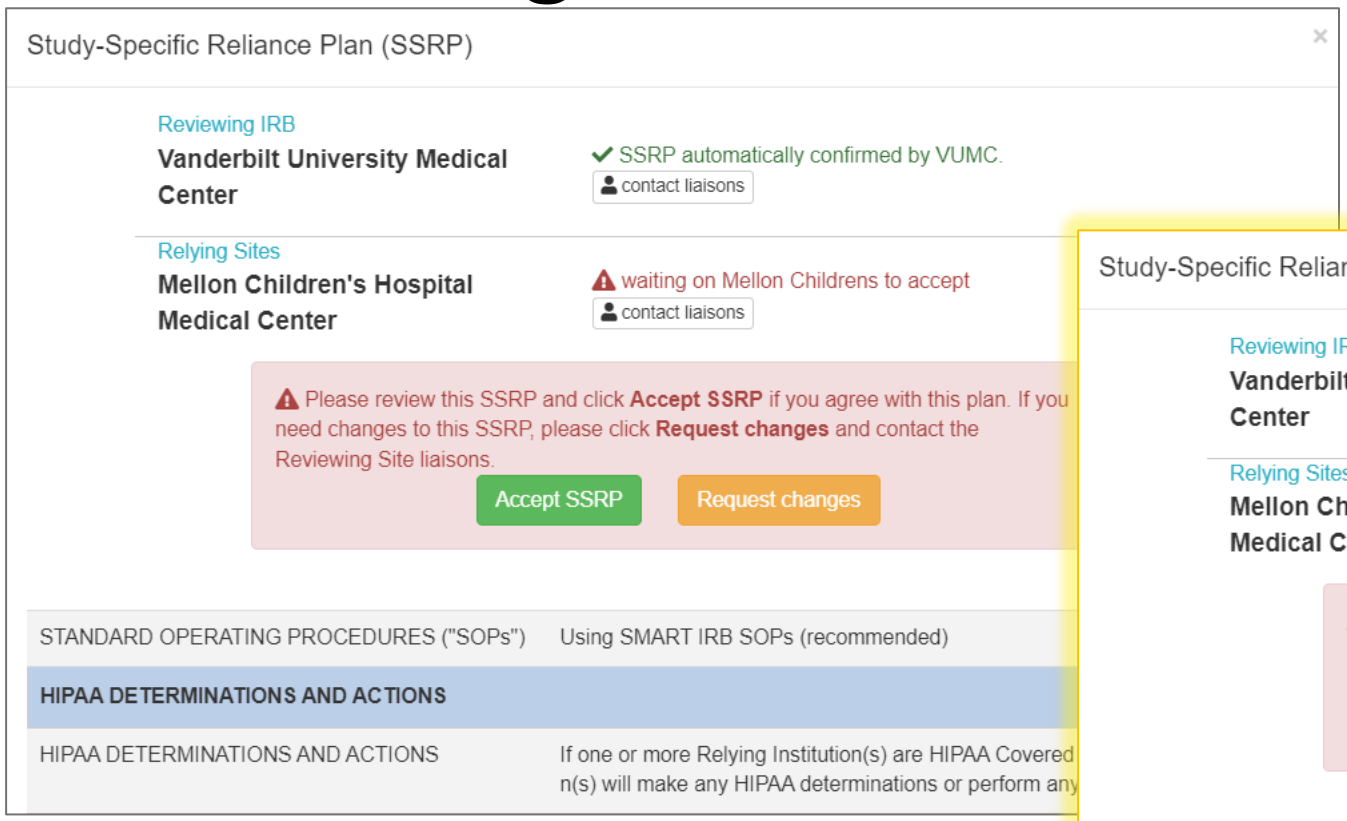
- **When you're a single IRB:**
  - How do you use the IREx IP, HRP, and PI Survey information
  - Have you noticed any relying site processes/documents that have been especially helpful in reviewing the local considerations?
  - Have you noticed any relying site processes/documents that have been especially unhelpful in reviewing the local considerations?
- **When you're a relying HRPP:**
  - How do you provide information to the single IRB?
  - Do you leverage any of the information in IREx?
  - Are there documents or information NOT in IREx that you find your institution sharing frequently with an SIRB? (e.g., consent language; document listing of all their local context items)
- **What is your process is for capturing changes to LC when there are study modifications?**
- **Questions from the audience?!**

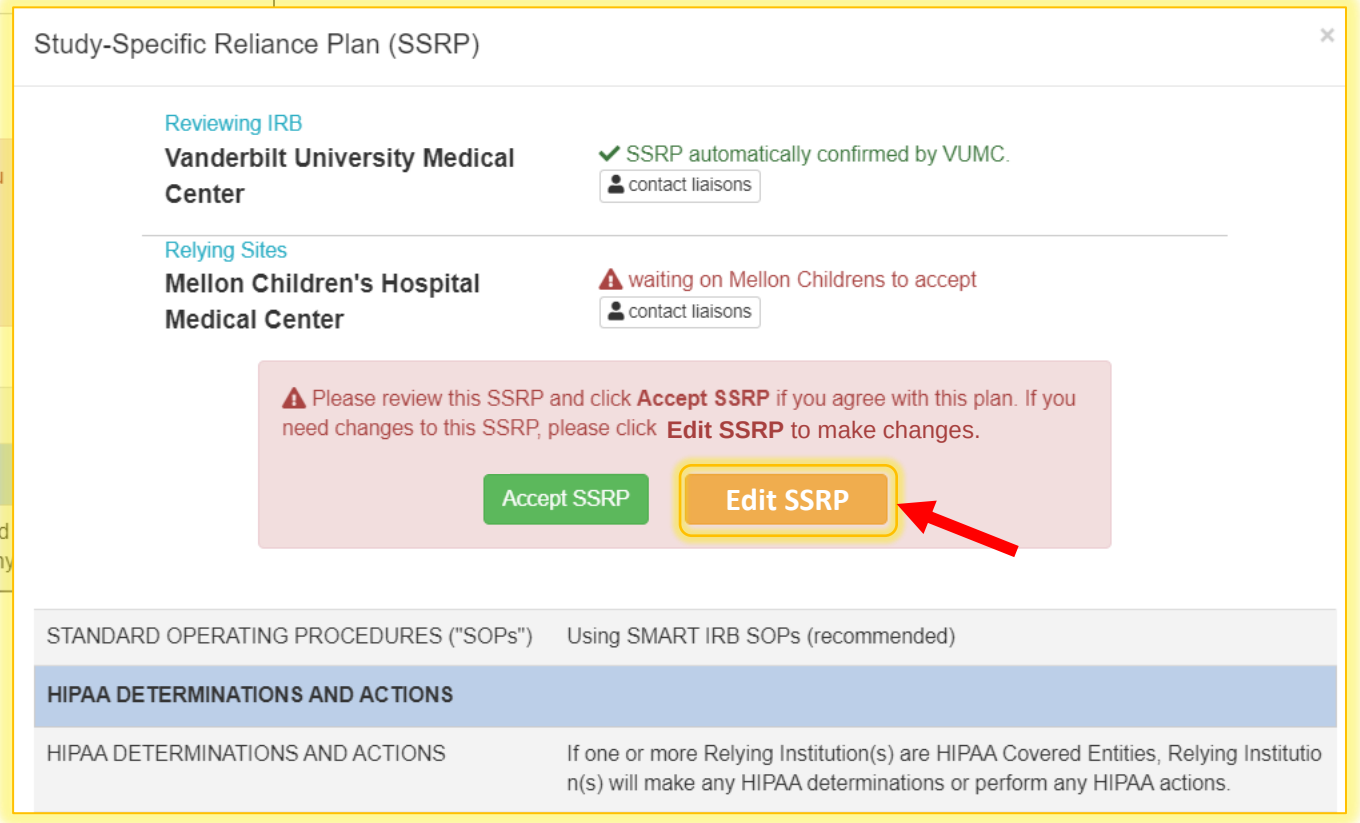
What's Next? Help us Decide!

Features In / Slated for Development

- Allow relying site HRPP to edit SSRP
- Revamp checklist/site onboarding Workflow
- Incorporate 3-item satisfaction surveys into IREx
- PI Create Study/Request sIRB use IREx
- Reviewing IRBs turn On/Off approvals
- Reviewing IRBs & SMs turn On/Off notifications
- Rearrange site approvals; show Document History

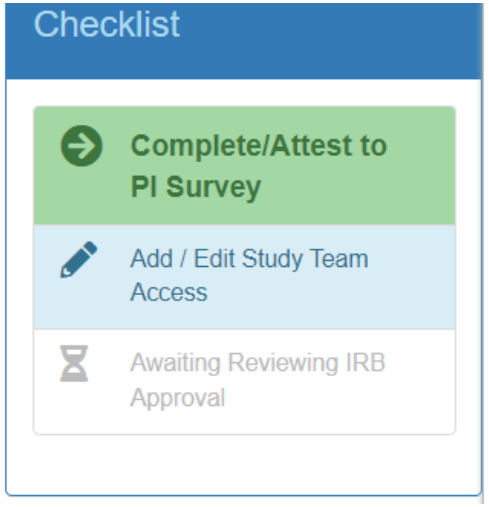
Allow relying site HRPP to request changes to SSRP





Revamp Checklist/Site Onboarding Workflow

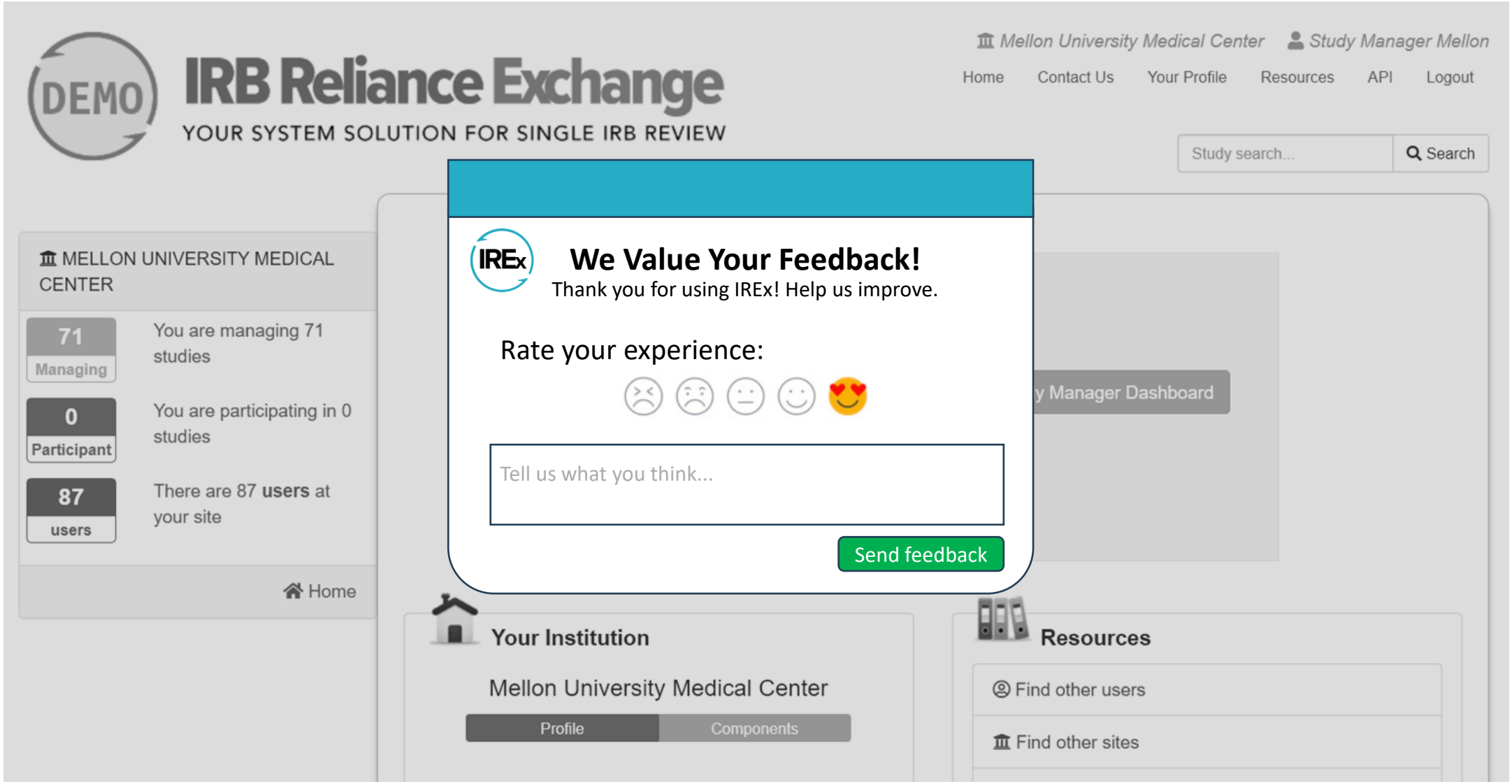
PI Checklist



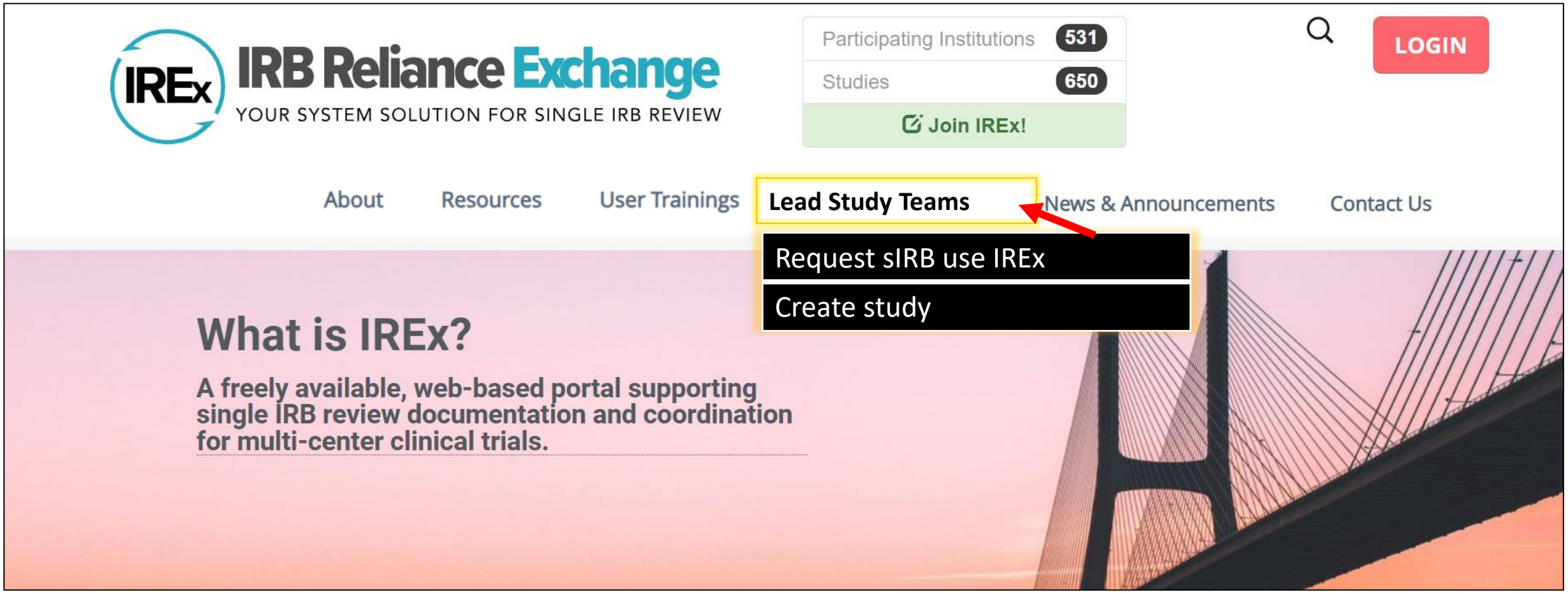
Draft Consent Template → **Local IRB Submission** → **Complete/Attest to PI Survey** → **Add/Edit Study Team Access** → **Awaiting Reviewing IRB Approval** → **sIRB Approval**

- Insert your site info on consent template
- Send to Lead Study Team for review & acceptance

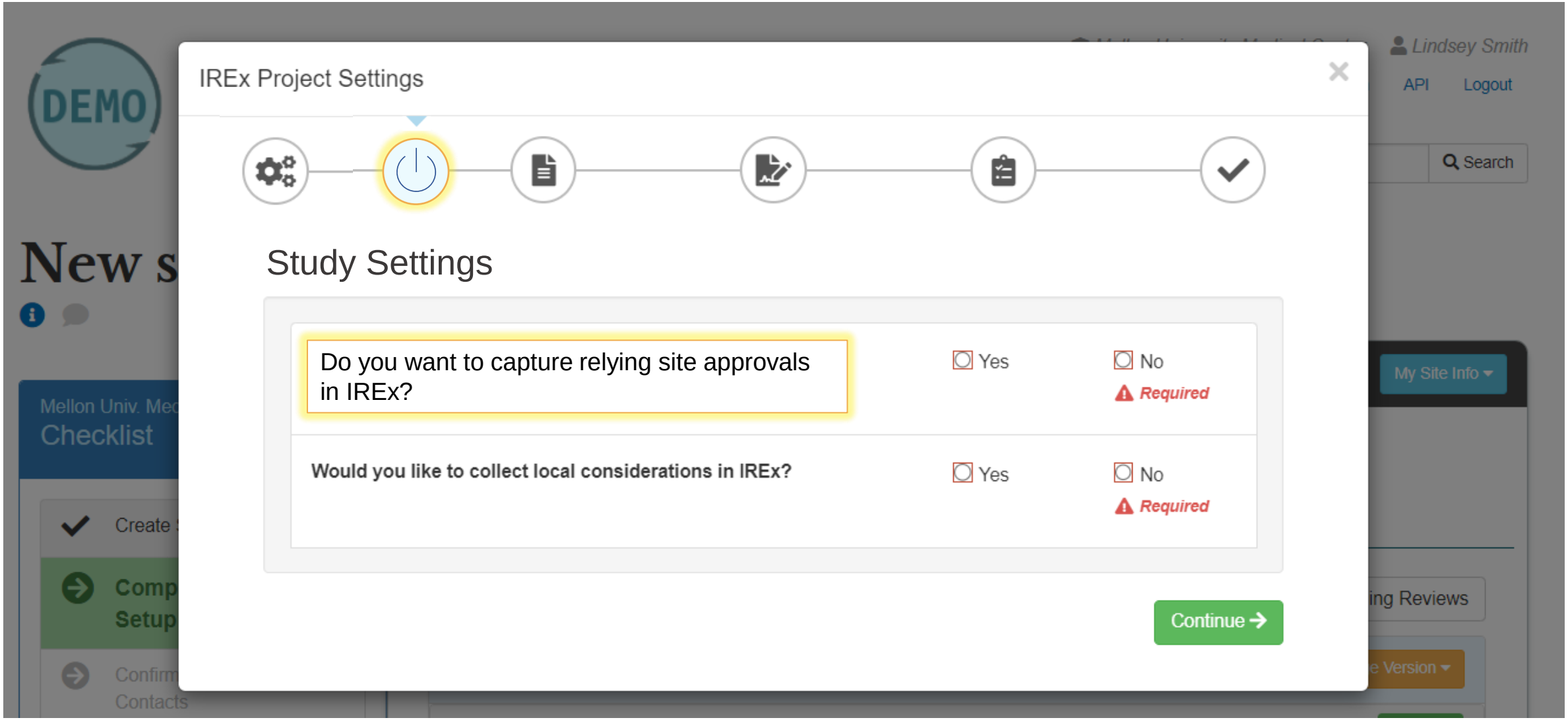
Incorporate satisfaction surveys into IREx



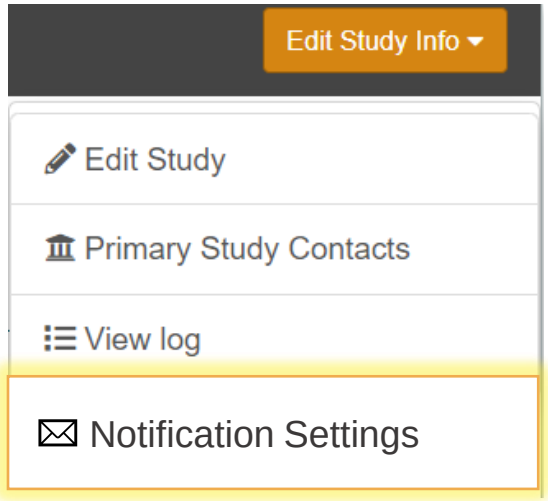
PI Create Study/Request sIRB use IREx



Reviewing IRBs turn On/Off approvals



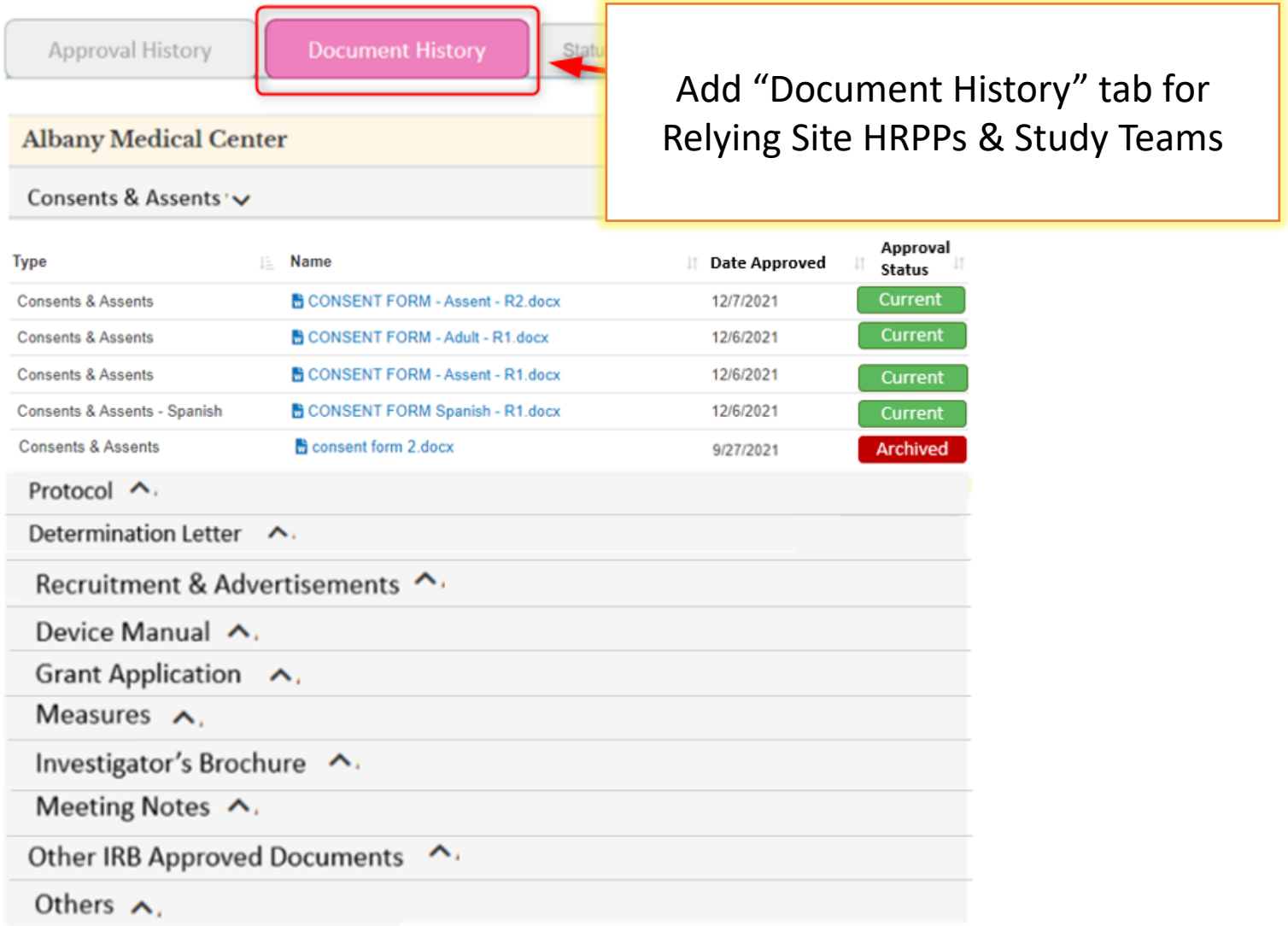
Reviewing IRBs & SMs turn On/Off notifications

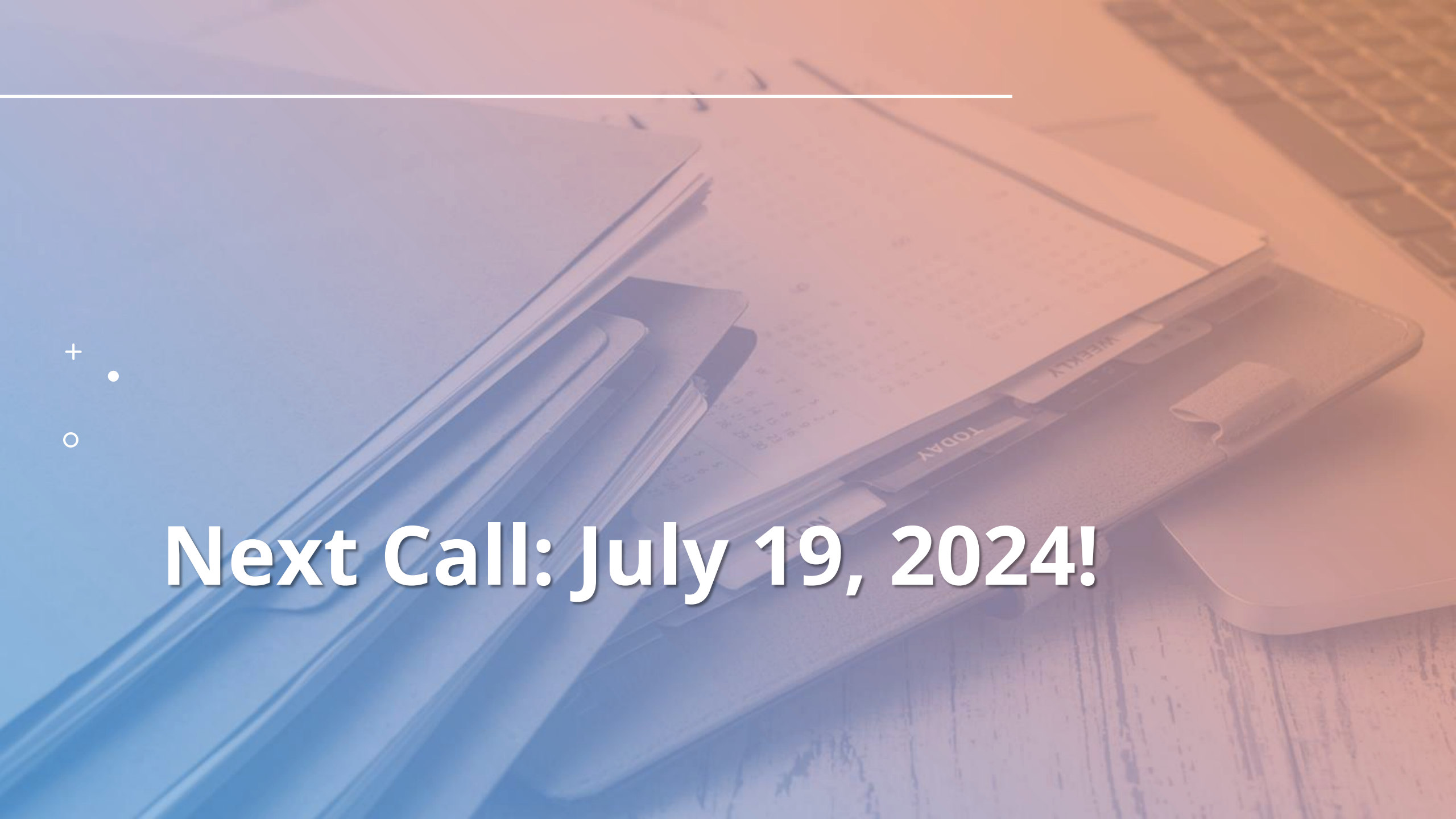


Notification Settings

Send notification to relying sites when site approval uploaded	Always Active
Send notification to relying sites when Lead Approval is uploaded	
Send notification to relying sites when Lead Approval is edited	
Receive notification when relying site approvals are uploaded	
Receive notification when site deleted from study	
Receive notification when site closure issued	

Rearrange site approvals; show Document History





Next Call: July 19, 2024!