IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

# IREx Quarterly Call

- Training
- Special projects

***Natalie Dilts***

- Manager, Application Development

***Bryce Embry***

- 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***

# 04.21.2023 QUARTERLY CALL AGENDA

- Welcome & Announcements
- Brief updates
- PREVIEW: New System Features

# 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

July 21st, 2023

October 20th, 2023

January 19, 2024

# IREx Satisfaction Survey Efforts

- April – June 2023
- sIRB Liaisons
- Relying HRPP Liaisons
- Study Managers
- $20 e gift card for responding

# IREx Study Manager Focus Group

- **June 2023**
- Feedback on IREx
- Feedback on new materials
- Feedback on outreach efforts
- Up to $150 for participating


# Features Coming Soon!

# IREx Division of Labor: 2018*

* IREx began capturing local considerations

| | Single IRB | Lead Study Team |
|---|---|---|
| Create study | X | |
| Complete IREx Setup | X | |
| Confirm Study-specific Reliance Plan (SSRP) | X | |
| Upload overall study approval | X | |
| Indicate executed IAAs and/or indemnification | NA | NA |
| Add PSites | | 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** | **7** | **4** |

# IREx Division of Labor: 2022

| | Single IRB | Lead Study Team |
|---|---|---|
| Create study | X | |
| Complete IREx Setup | X | |
| Confirm Study-specific Reliance Plan (SSRP) | X | |
| Upload overall study approval | | X |
| Indicate executed IAAs and/or indemnification | X | |
| Add PSites | | 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 | |
| Upload overall study approval | | X |
| Indicate executed IAAs and/or indemnification | X | |
| Add PSites | | 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 |

**PRIOR TO OVERALL APPROVAL**

1. Request sites complete required agreements

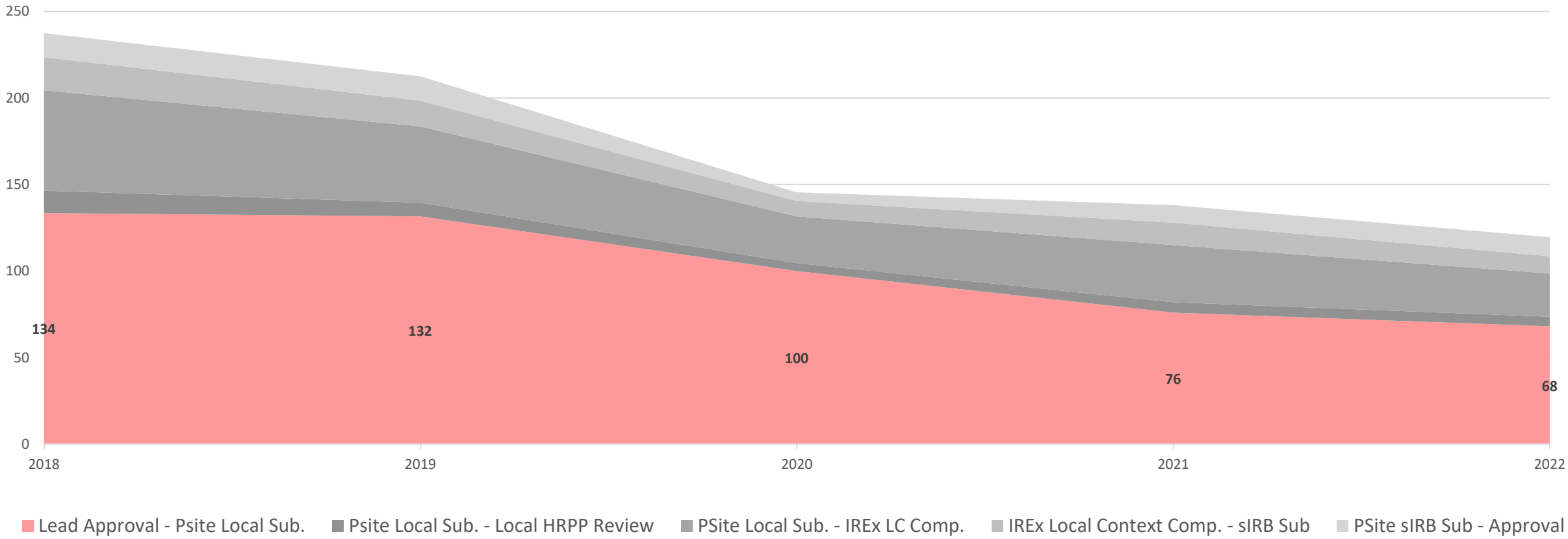
**AFTER OVERALL APPROVAL**

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

# These early communications are critical!

## Time to PSite Approval by the sIRB –

*Time from Lead Site Approval to PSite Submission*



# Upcoming IREx Enhancements

Prior to overall study approval

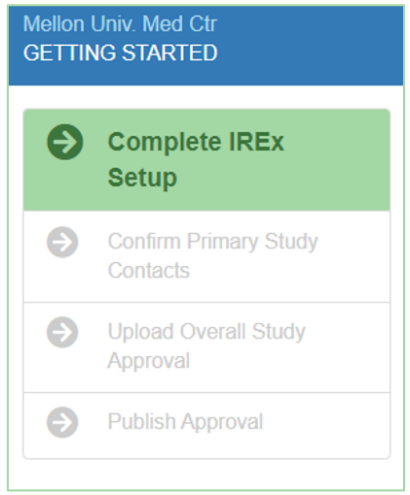
Request required agreements from IREx

After overall study approval

Provide single IRB / reliance instructions to sites from IREx

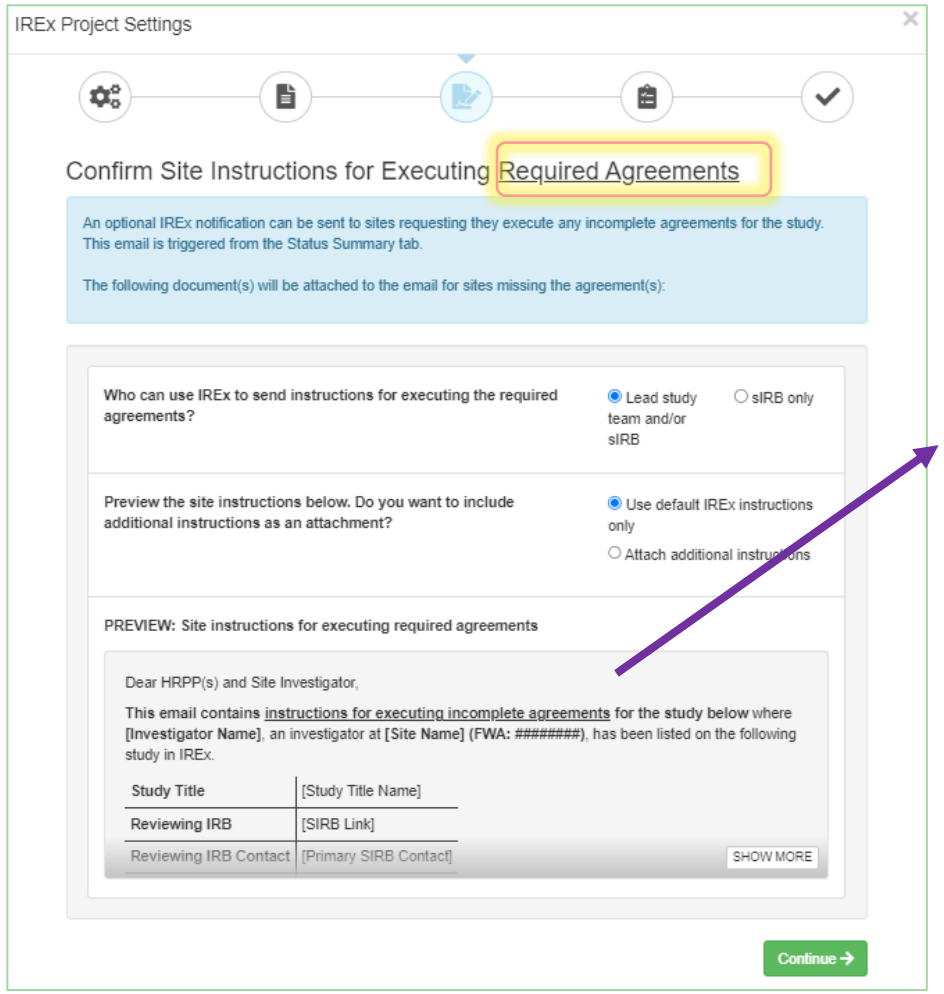
Grant Study Teams access to the overall approval in IREx *without requiring HRPP to register*

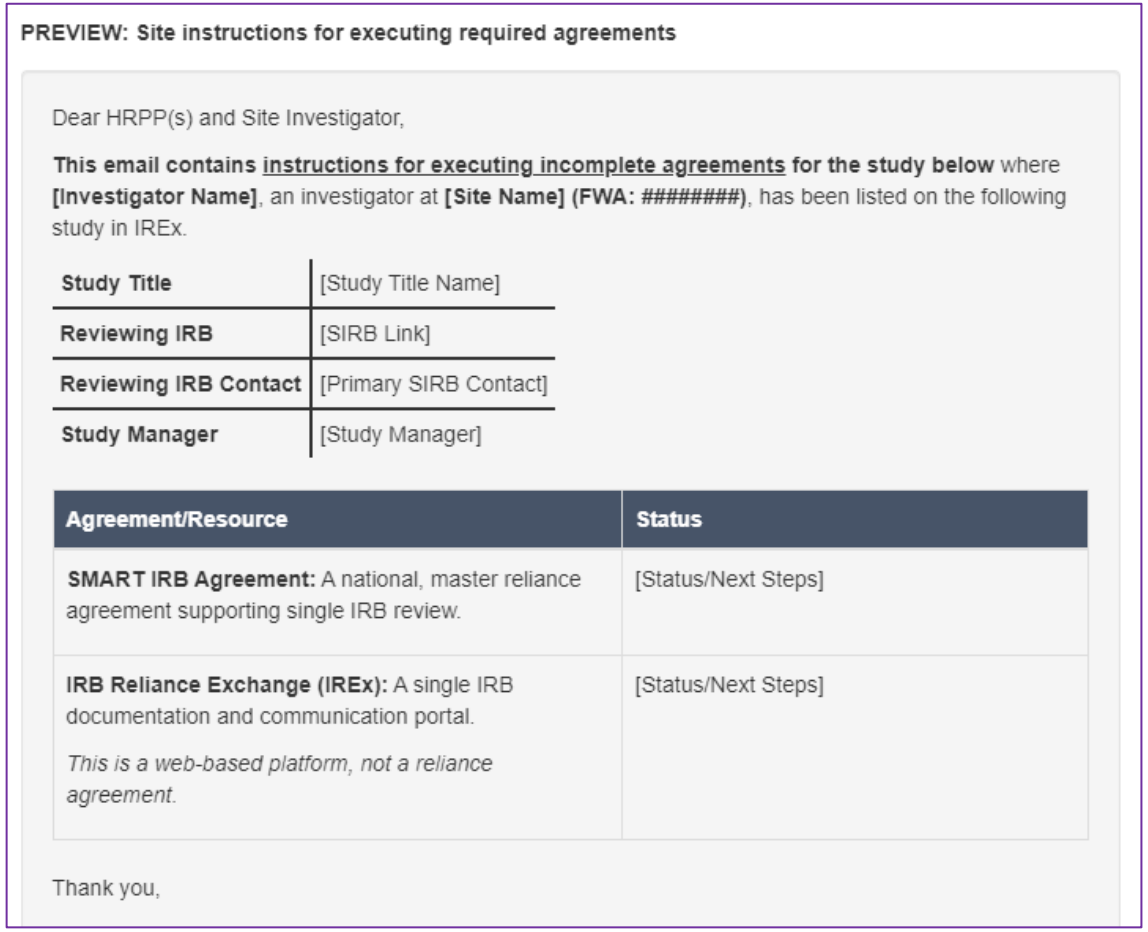
# NEW for Single IRBs:
# Include Instruction Templates for PSites




**sIRB Options:**

1. Use the default IREx instructions
2. Upload your own instructions
3. Control whether the Study Manager can request agreements



**PREVIEW: Site instructions for executing required agreements**

Dear HRPP(s) and Site Investigator,

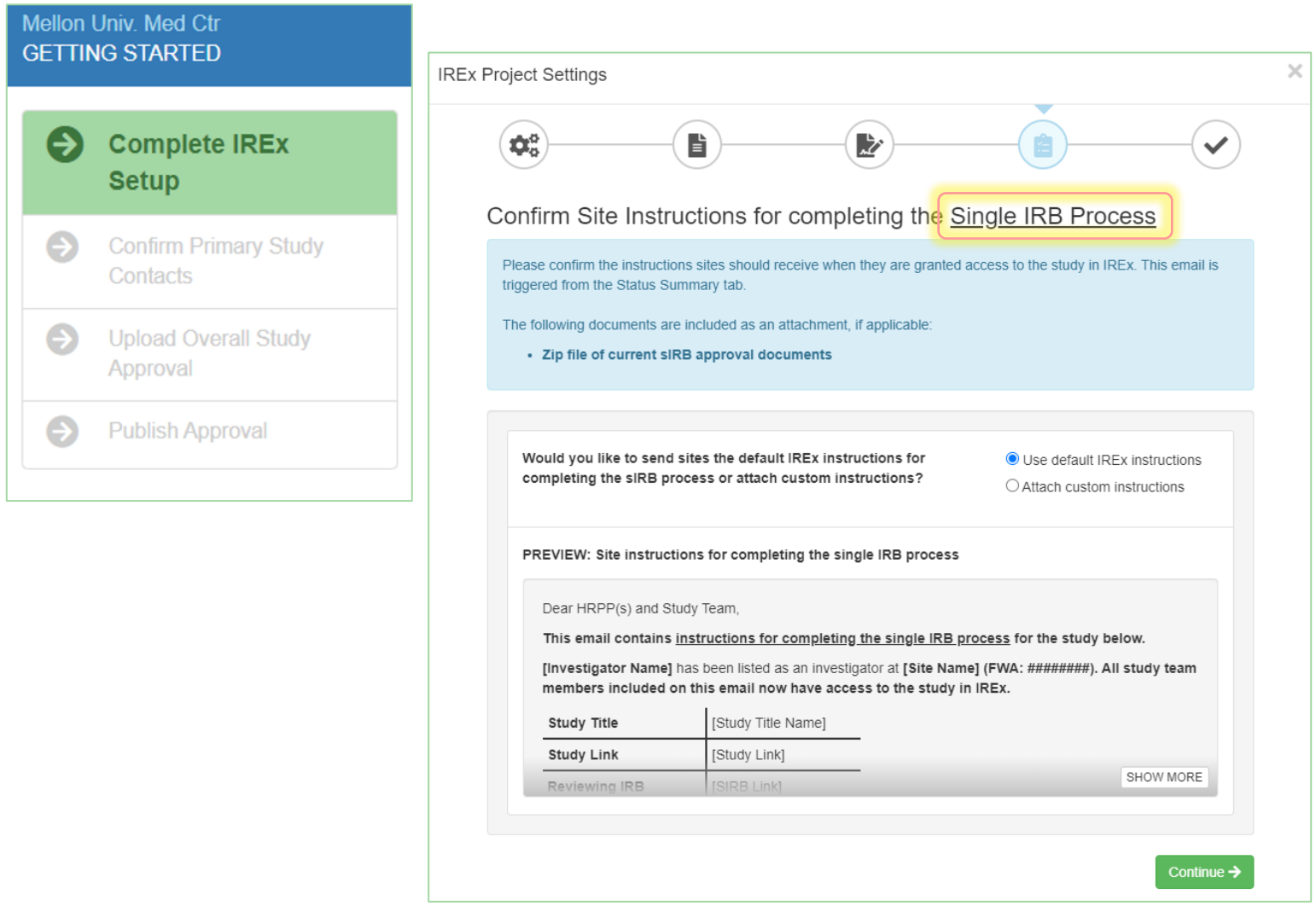
**This email contains instructions for executing incomplete agreements for the study below** where **[Investigator Name]**, an investigator at **[Site Name] (FWA: ########)**, has been listed on the following study in IREx.

| | |
|---|---|
| **Study Title** | [Study Title Name] |
| **Reviewing IRB** | [SIRB Link] |
| **Reviewing IRB Contact** | [Primary SIRB Contact] |
| **Study Manager** | [Study Manager] |

| Agreement/Resource | Status |
|---|---|
| **SMART IRB Agreement:** A national, master reliance agreement supporting single IRB review. | [Status/Next Steps] |
| **IRB Reliance Exchange (IREx):** A single IRB documentation and communication portal. *This is a web-based platform, not a reliance agreement.* | [Status/Next Steps] |

Thank you,

# NEW for Single IRBs:
# Include Instruction Templates for PSites




**sIRB Options:**

1. Use the default IREx instructions
2. Upload your own instructions

# NEW for Single IRBs:
# Include Instruction Templates for PSites

**PREVIEW: Site instructions for completing the single IRB process**

Dear HRPP(s) and Study Team,

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

**[Investigator Name]** has been listed as an investigator at **[Site Name] (FWA: ########). All study team members included on this email now have access to the study in IREx.**

| | |
|---|---|
| **Study Title** | [Study Title Name] |
| **Study Link** | [Study Link] |
| **Reviewing IRB** | [SIRB Link] |
| **Reviewing IRB Contact** | [Primary SIRB Contact] |
| **Study Manager** | [Study Manager] |

**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.**

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. | [Status/Next Steps] |
| **ACTS LOI** | [Status/Next Steps] |
| **IRB Reliance Exchange (IREx):** A single IRB documentation and communication portal.<br>*This is a web-based platform, not a reliance agreement.* | [Status/Next Steps] |

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:
   a. **Register** to confirm your site's engagement on this study. *This is not an indication of reliance.*
   b. **Confirm the Institutional Profile**
   c. **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.
   d. **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.
   e. **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?**

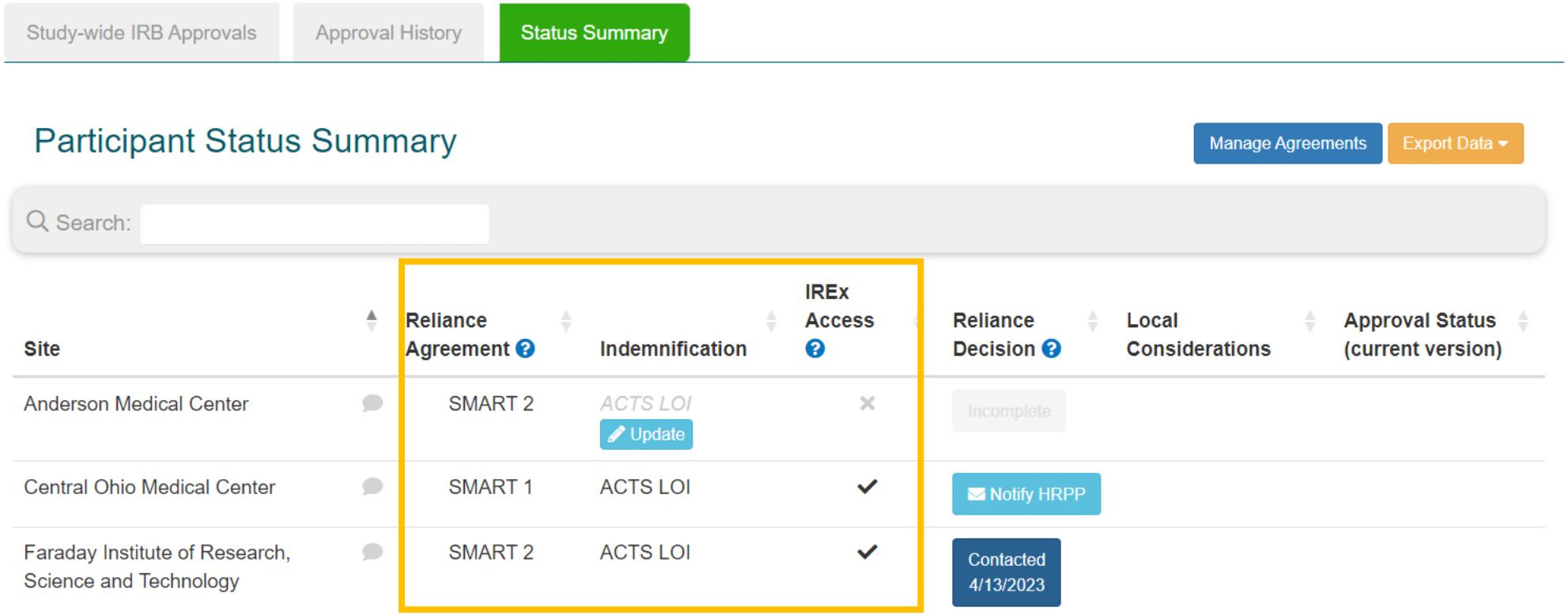
Access the user quick guides and other materials from the IREx Participating Site HRPP Resources and IREx Participating Study Teams Resources.

Thank you,

Aalanya Sanders (HRPP)

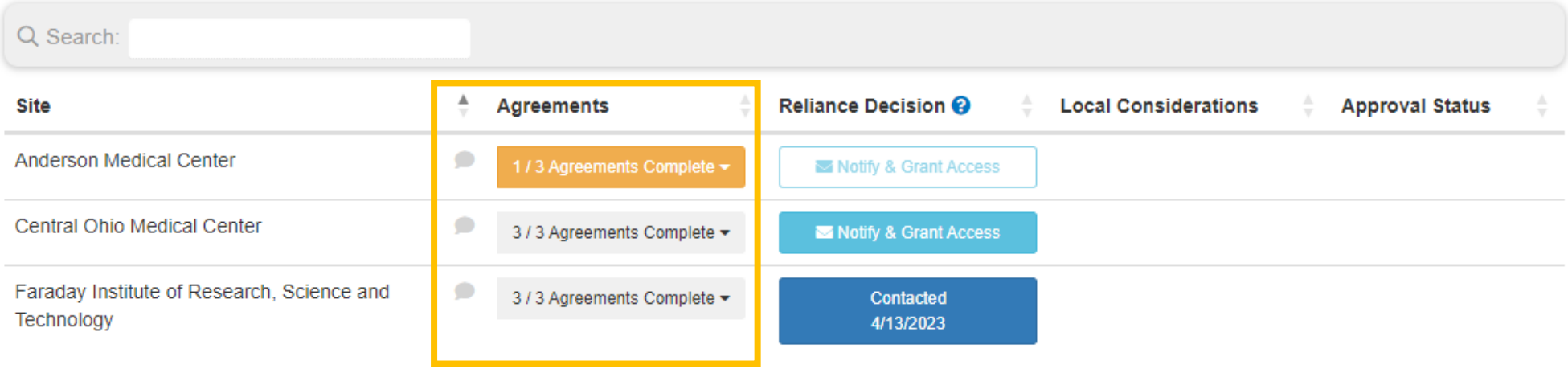
# NEW: Redesigned Status Summary

**CURRENT**



# NEW: Redesigned Status Summary

**UPDATED**



# NEW: Redesigned Status Summary

**UPDATED**

Study-wide IRB Approvals | Approval History | Status Summary

## Participant Status Summary

Search:

| Site | Agreements | Reliance Decision |
|---|---|---|
| Anderson Medical Center | 1 / 3 Agreements Complete | Notify & Grant A |
| Central Ohio Medical Center | | Notify & Grant A |
| Faraday Institute of Research, Science and Technology | | Contacted 4/13/202 |

- ✓ Reliance Agreement SMART 2
- ✗ Indemnification *ACTS LOI* Update
- ✗ IREx Access
- Request Agreement(s)

ACTS 2023 - Action Required: Please Complete Agreement(s) for sIRB study

Reply | Reply All | Forward

IndemnificationAgreement_forCUMC.docx 19 KB

**This email contains instructions for executing incomplete agreements for the study below** where **Andrea Medi**, an investigator at **Anderson Medical Center (FWA: 54687921)**, has been listed on the following study in IREx.

| | |
|---|---|
| **Study Title** | Association for Clinical and Translational Research: A panel presentation 2023 |
| **Reviewing IRB** | Carnegie University Medical Center |
| **Reviewing IRB Contact** | Bianca Fisher (bianca@fisher.cdu) |
| **Study Manager** | IREx SM |

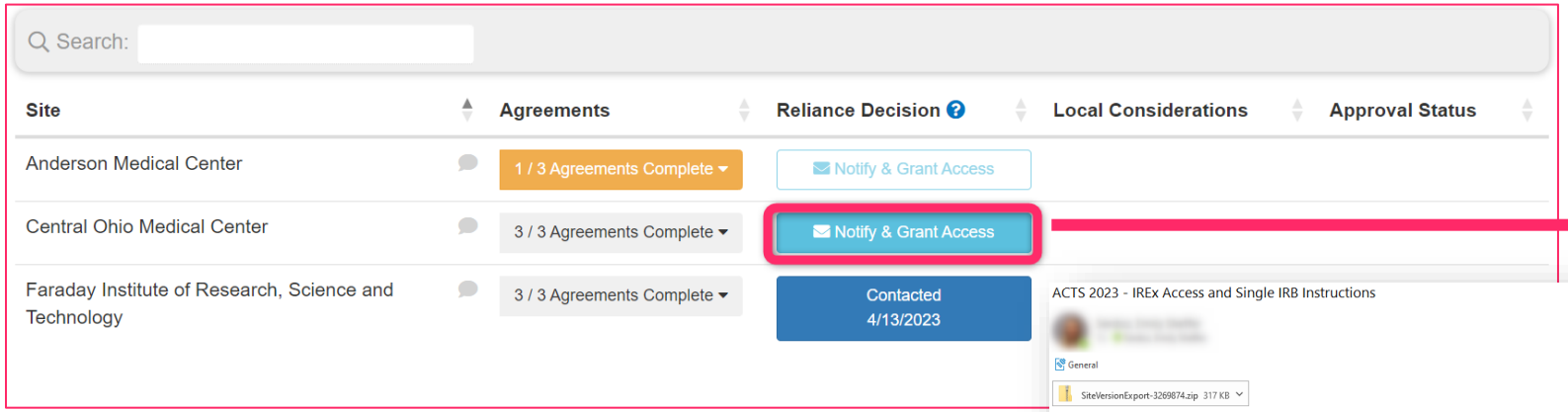
**As a first step towards relying on Carnegie University Medical Center, please execute the incomplete items below.**

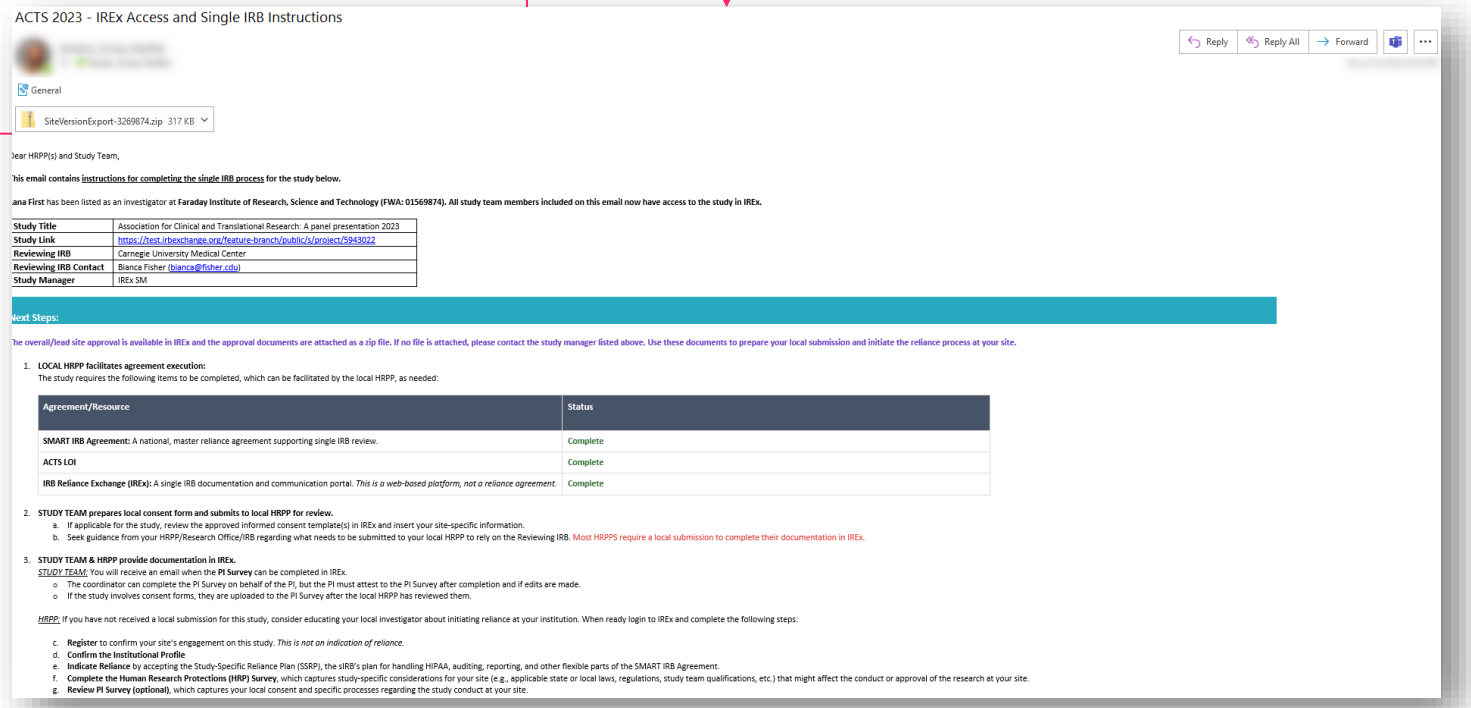
| Agreement/Resource | Status |
|---|---|
| **SMART IRB Agreement:** A national, master reliance agreement supporting single IRB review. | Complete |
| **Carnegie University Medical Center (CUMC) Indemnification Agreement** | **Incomplete** — The indemnification agreement is attached. Send questions and executed agreements to Bianca Fisher (bianca@fisher.cdu). |
| **IRB Reliance Exchange (IREx):** A single IRB documentation and communication portal. *This is a web-based platform, not a reliance agreement.* | **Incomplete** — A HRPP administrator, director, or manager can initiate access here. |

After your site has completed all the items above and the initial protocol has been approved by the Reviewing IRB, additional instructions will be sent regarding next steps.

Thank you,

# NEW for Study Managers:
# Disseminate Overall / Lead Site Approval Docs via IREx

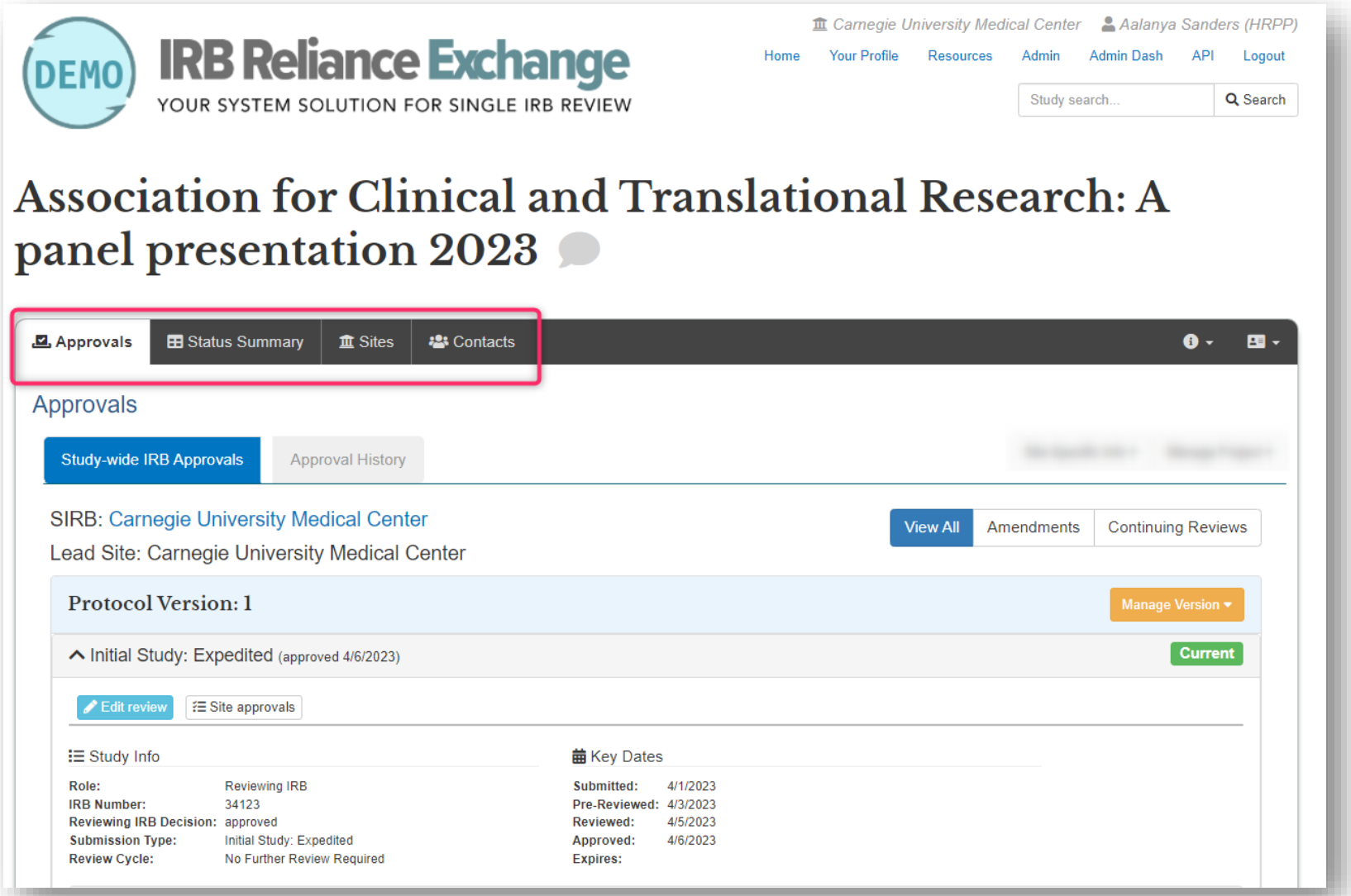



**NEW!**

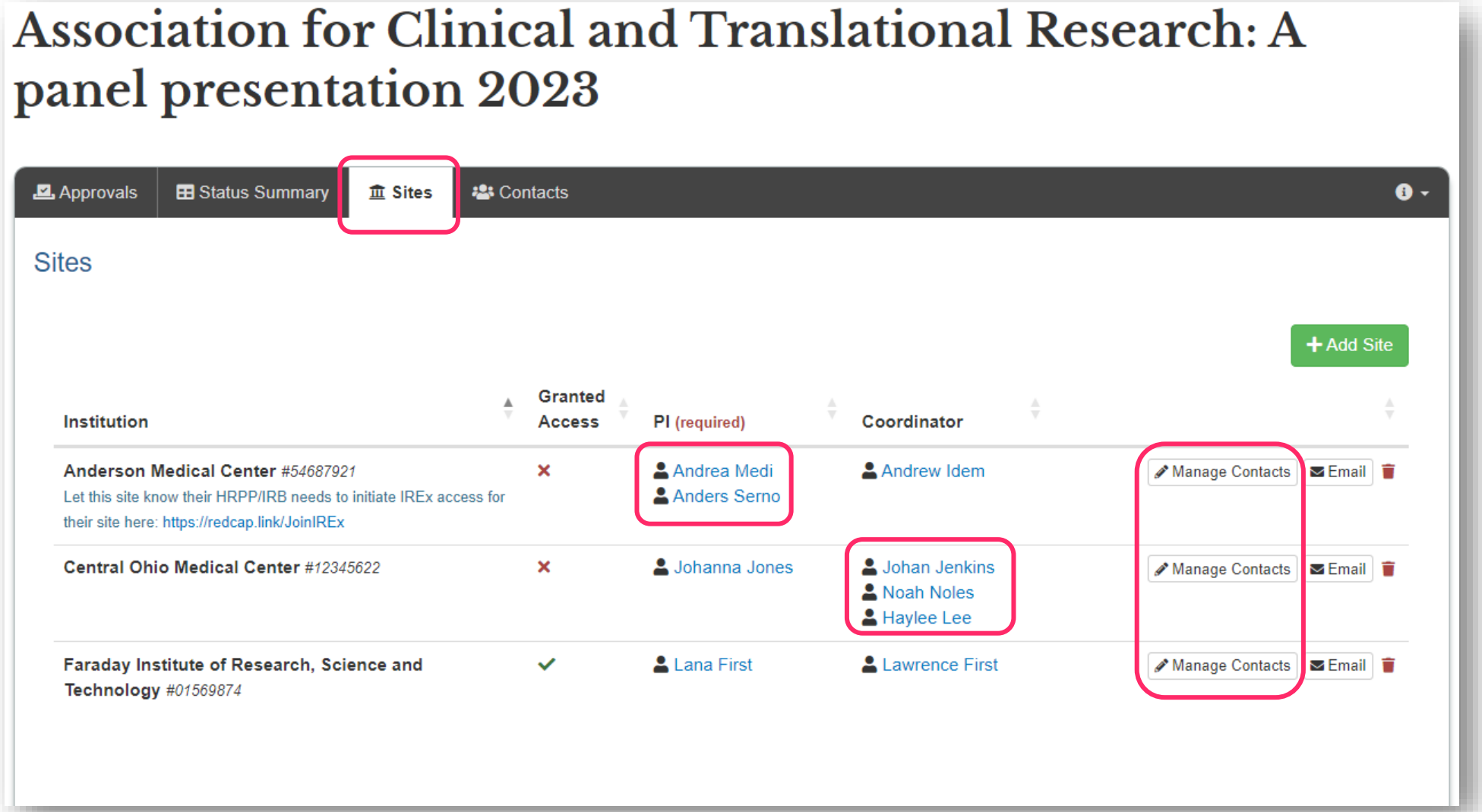
1. **Include instructions**
   instead of creating your own
2. **Include approval documents**
   instead of emailing them separately
3. **Grant immediate IREx Access to study teams**
   instead of waiting for HRPP to register

# NEW: Study Navigation Bar

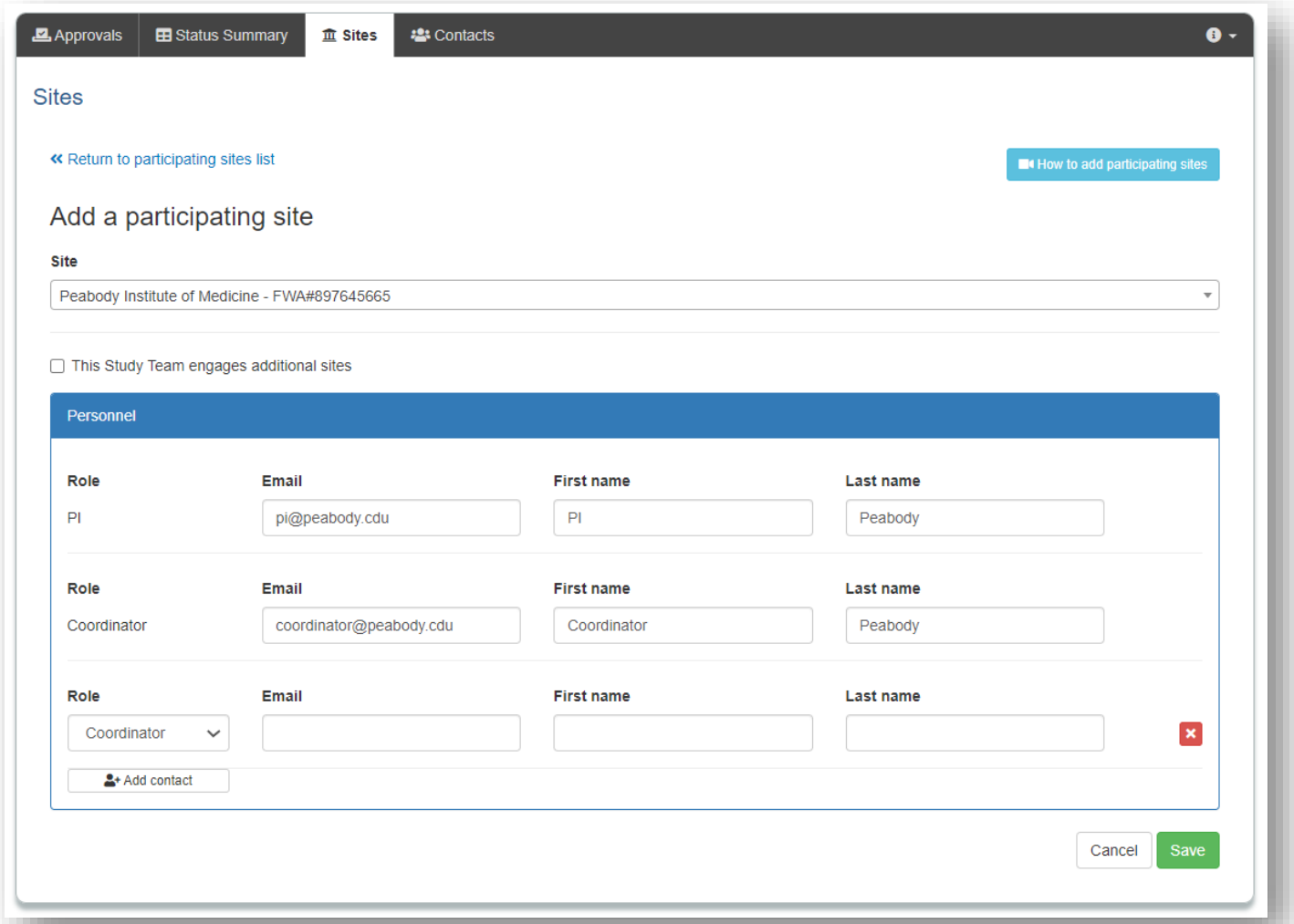


# NEW: Participating Sites Page – "Sites"

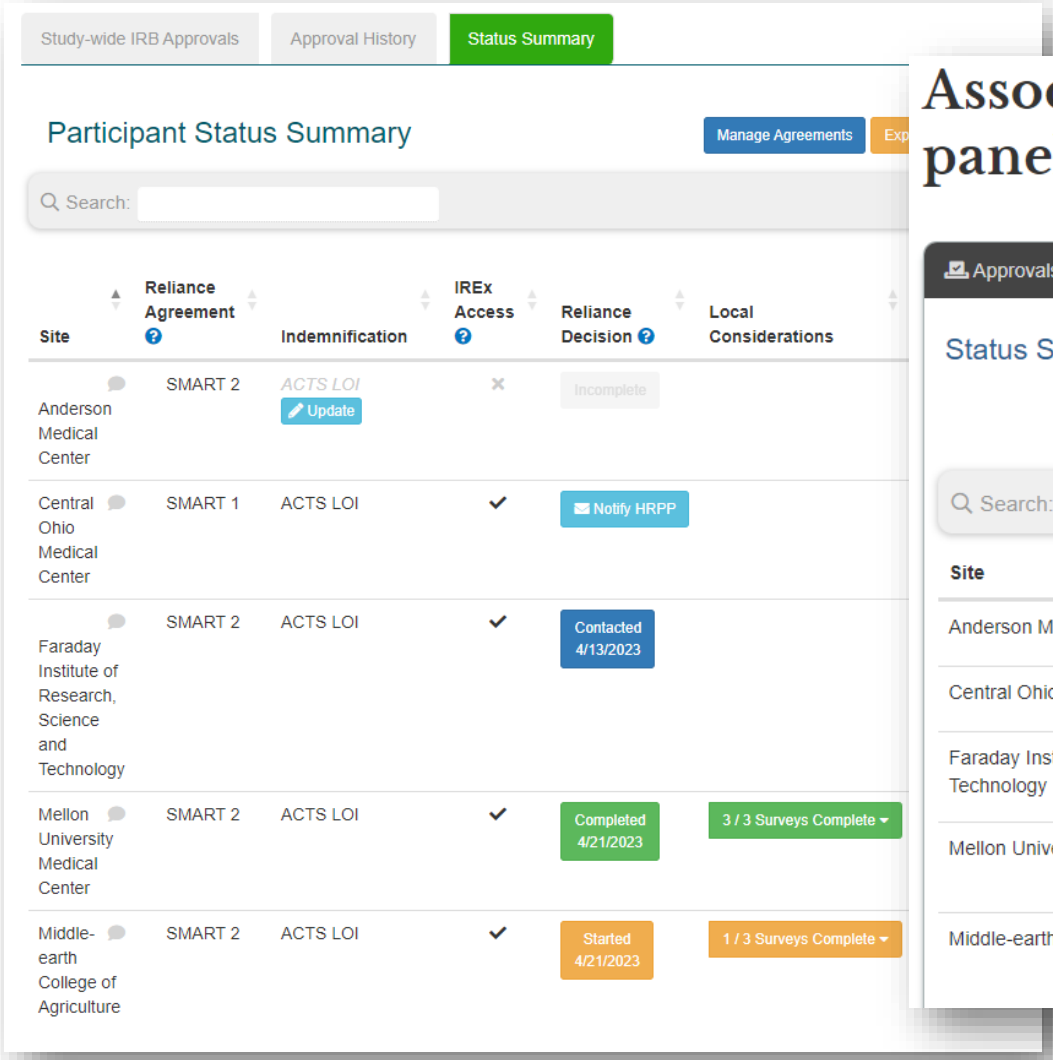
1. Include multiple PIs and/or Contacts
2. Edit contacts any time
3. Contacts never disappear from view



# NEW for Study Managers:
# Include Additional Site Contacts



# NEW Streamlined Status Summary

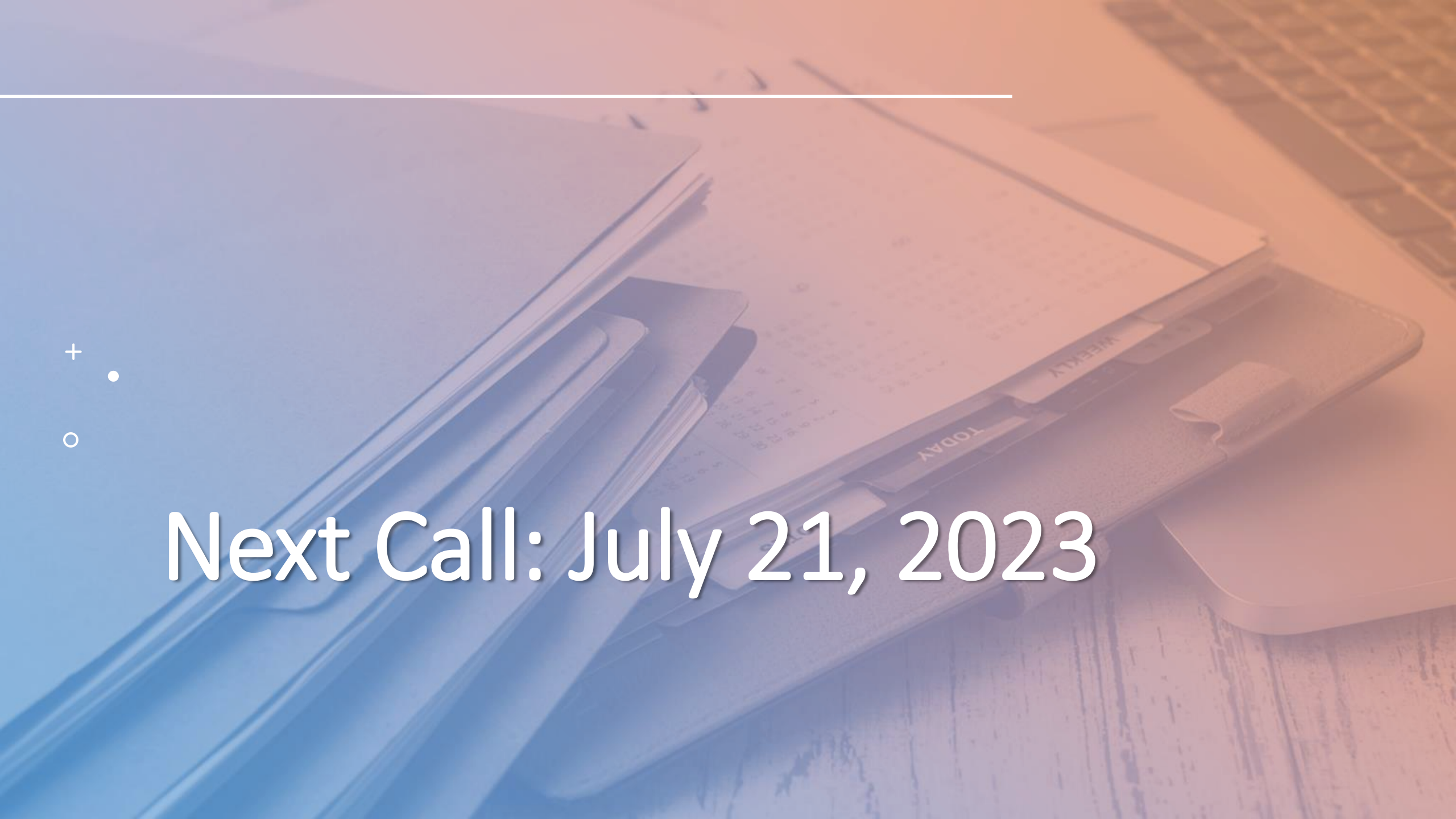



# Considerations for Single IRBs

1. **IREx is your friend**
   - It's easy
   - Steps are front-loaded
   - It empowers your lead study team
2. **Just get it over with** – *create the study in IREx after the study has been through pre-review*
   - Don't wait until the overall study / lead site is approved.
   - The Lead Study Team / Study Manager can begin requesting sites complete agreements
3. **Set your preferences –** *use IREx's default instructions or upload your own!*
   - Instructions for completing agreements
   - Instructions for completing the single IRB process

# New Feature Release

- Week of May 15th
- Newsletter announcement a few days before the release
- Tips for Study Managers of existing studies
- Updated quick guides, videos, and trainings




# Next Call: July 21, 2023