04.18.2025 QUARTERLY CALL AGENDA

- Welcome & Announcements
- New IREx Features
- Institutional Profile Updates & Reminder
- Upcoming Features

Welcome –
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

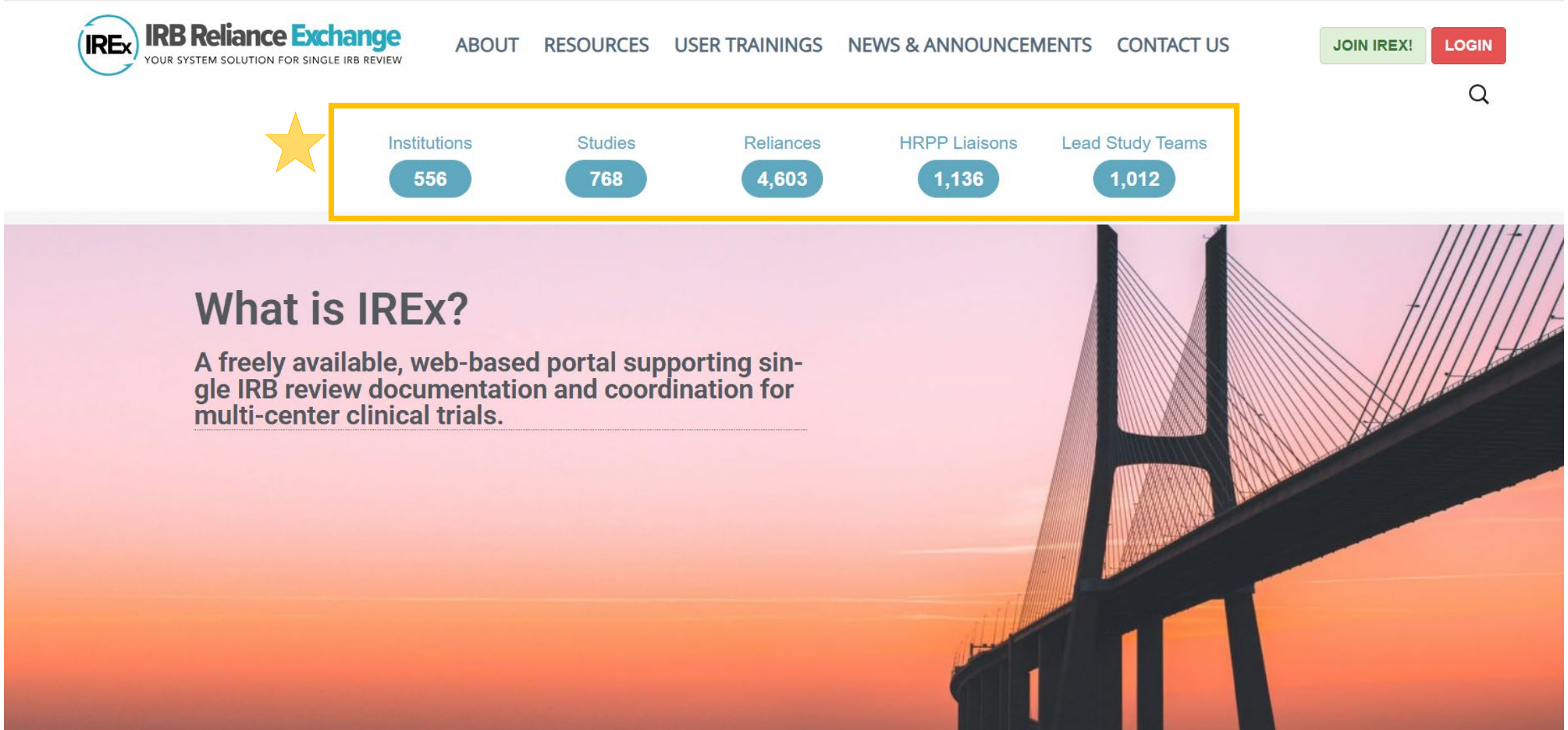
2025 Quarterly Calls

July 18, 2025

October 17, 2025

Announcements

New Metrics on IREx Website



New IREx Features

Importing Site Contacts

Importing Site Contacts

WHO

- **Reviewing IRBs** and **Lead Study Team Members**

WHAT

- **Import Site Contacts in bulk**
- Recommended for studies with large # of sites

WHEN

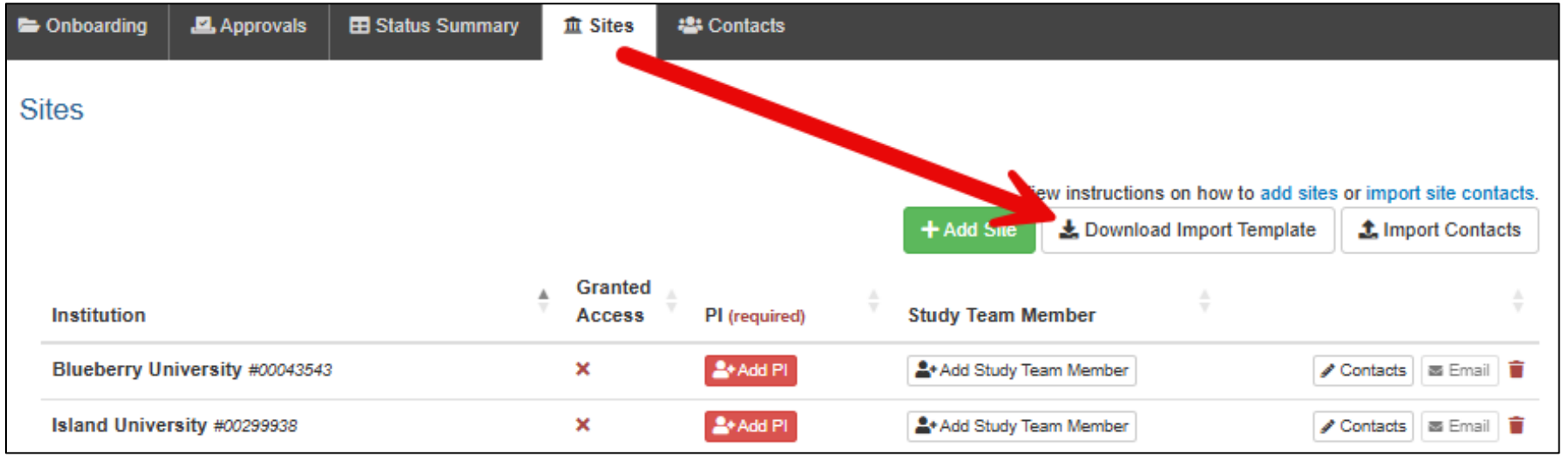
- **After sites have been added** to the study in IREx

WHERE

- **Sites** page

Add Sites & Download Template

After adding sites to the study, on the Sites page click the **Download Import Template**.



The template will have a row for each site listed on the study.

	A	B	C	D	E	F
1	FWA #	Site Name	Role (PI, Study Team Member)	First Name	Last Name	Email Address
2	43543	Blueberry University				
3	299938	Island University				
4						

Note: Sites with access will **not** appear on the template.

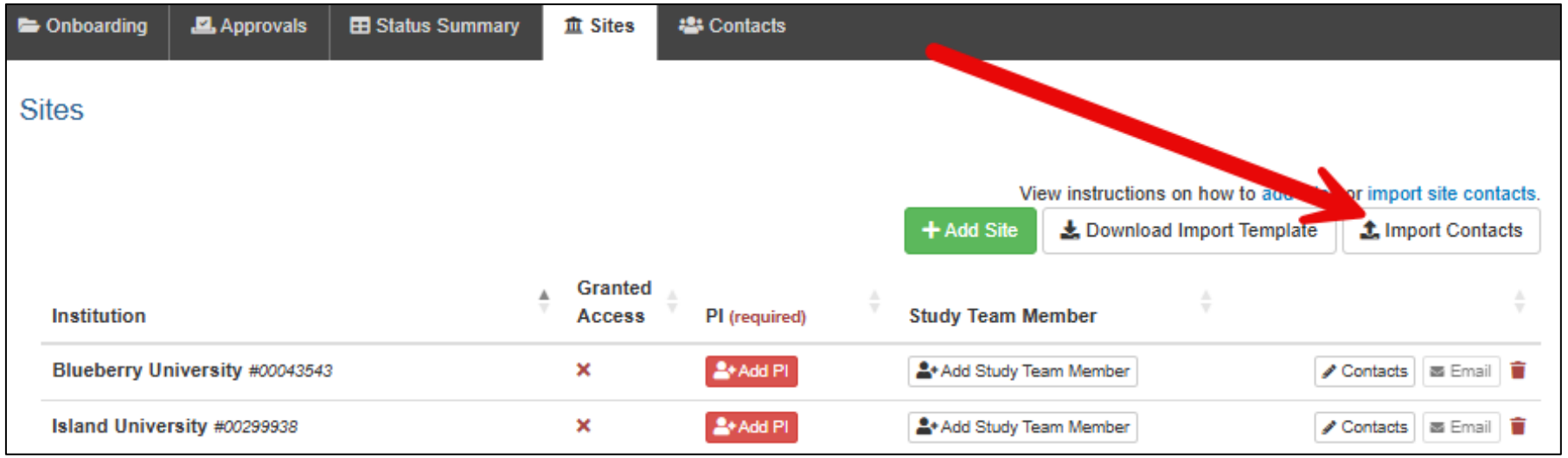
Add Contacts and Import CSV

Fill in information, one row per contact.

Copy and paste the FWA and site name for additional contacts.

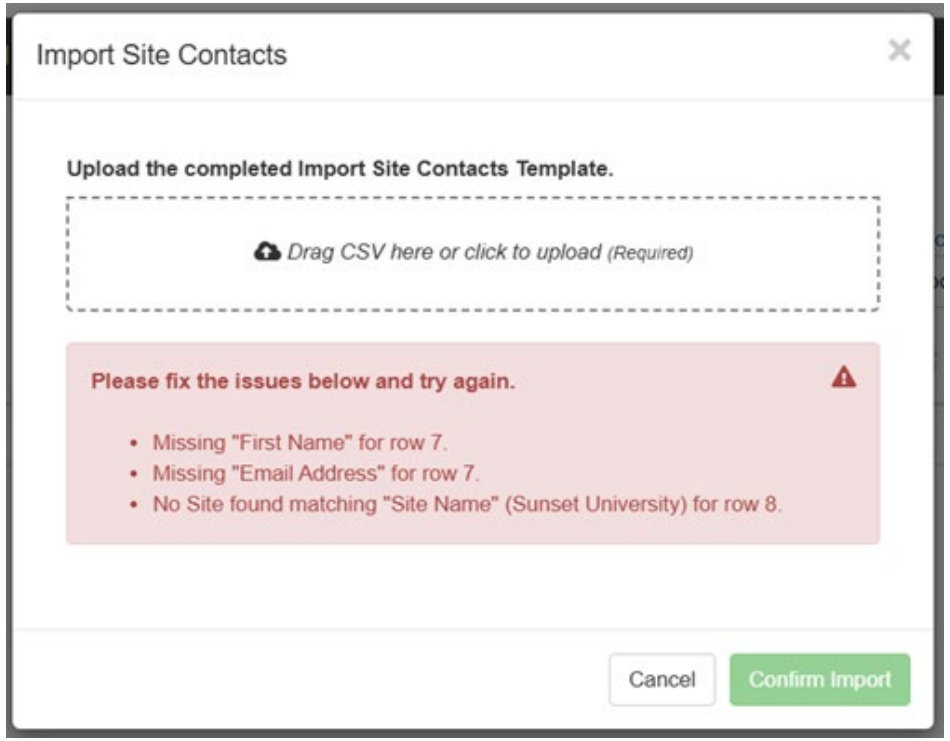
	A	B	C	D	E	F
1	FWA #	Site Name	Role (PI, Study Team Member)	First Name	Last Name	Email Address
2	43543	Blueberry University	PI	Marge	Nevea	mnev@blue.cdu
3	43543	Blueberry University	Study Team Member	Horace	Grist	hgri@blue.cdu
4	43543	Blueberry University	Study Team Member	Sasha	Lenck	slen@blue.cdu
5	299938	Island University	PI	Freda	Birch	fbir@isle.cdu
6	299938	Island University	Study Team Member	Uma	Peddrick	uped@isle.cdu
7						

Once site contacts are added, save the completed template. Return to the **Sites** tab and click **Import Contacts**.

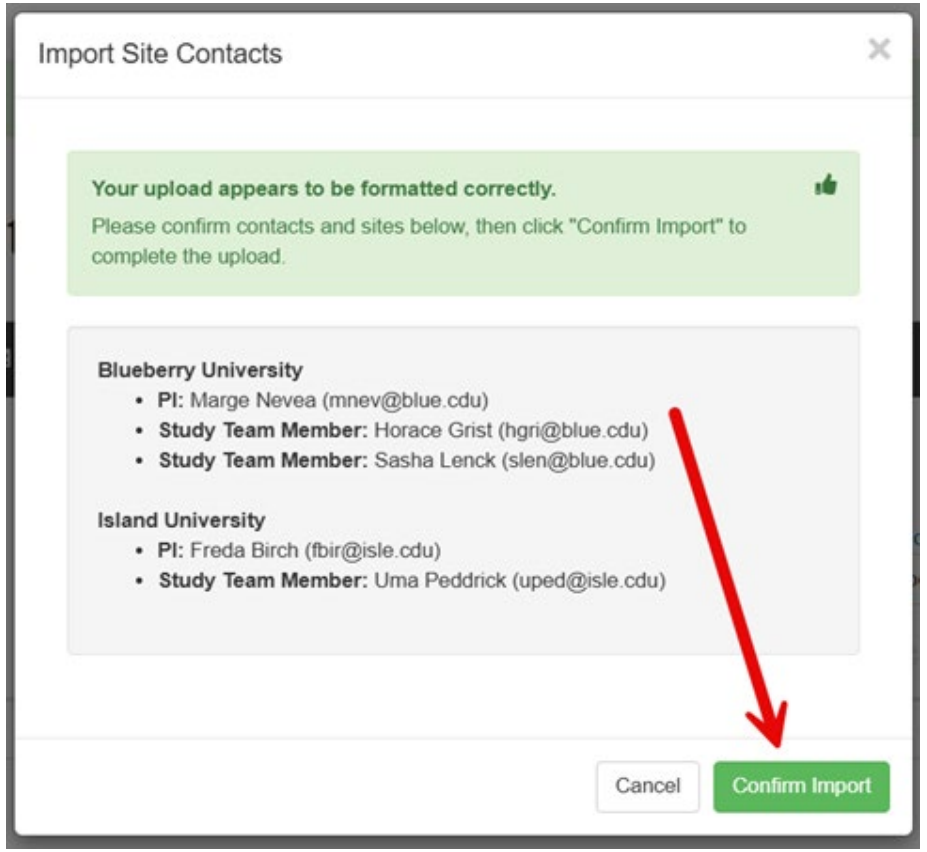


Fix Errors / Confirm Import

- If there is an error, correct the errors noted and upload the template again.

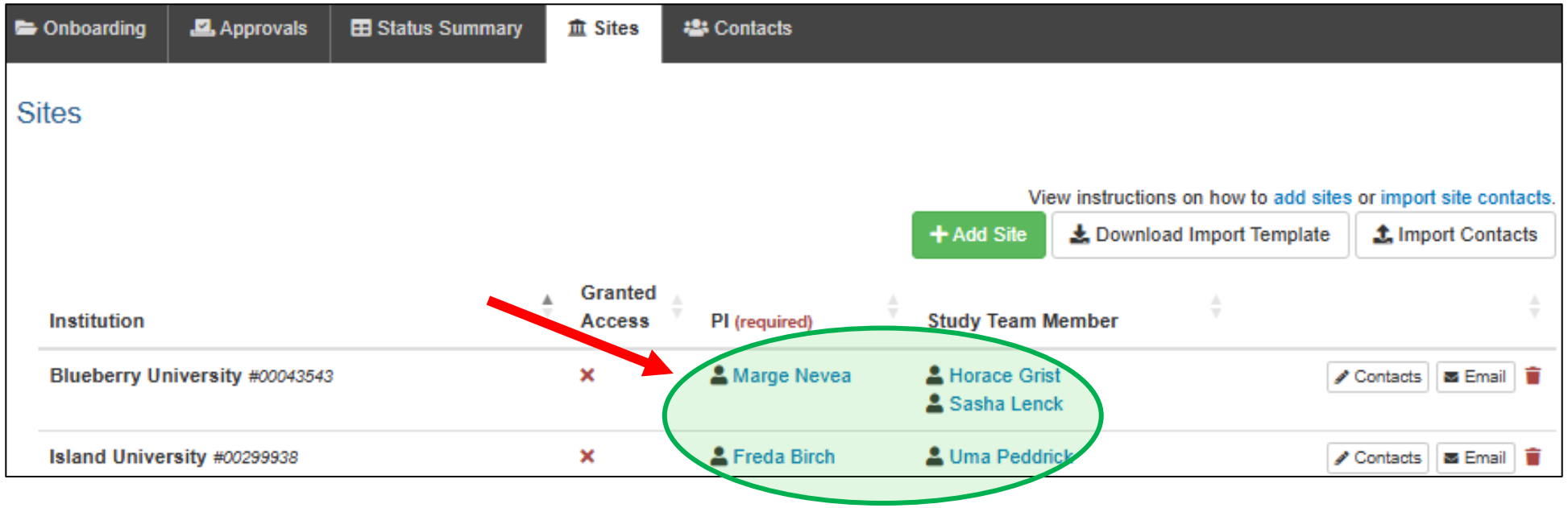


- If your upload is formatted correctly, and all the contact information is correct, click **Confirm Import**.



Contacts Added

Congrats! Site contacts successfully imported & added to study.



Notes for Adding Site Contacts

- The uploaded template MUST be a .csv file.
- The Role must be either ‘PI’ or ‘Study Team Member’.
- The downloaded template DOES NOT display existing contacts for a site; it is only **used to import NEW** contacts.
- The downloaded template cannot be used to add sites not already listed on the study.
- For detailed instructions: Import Site Contacts Quick Guide

Supporting SMART IRB V3

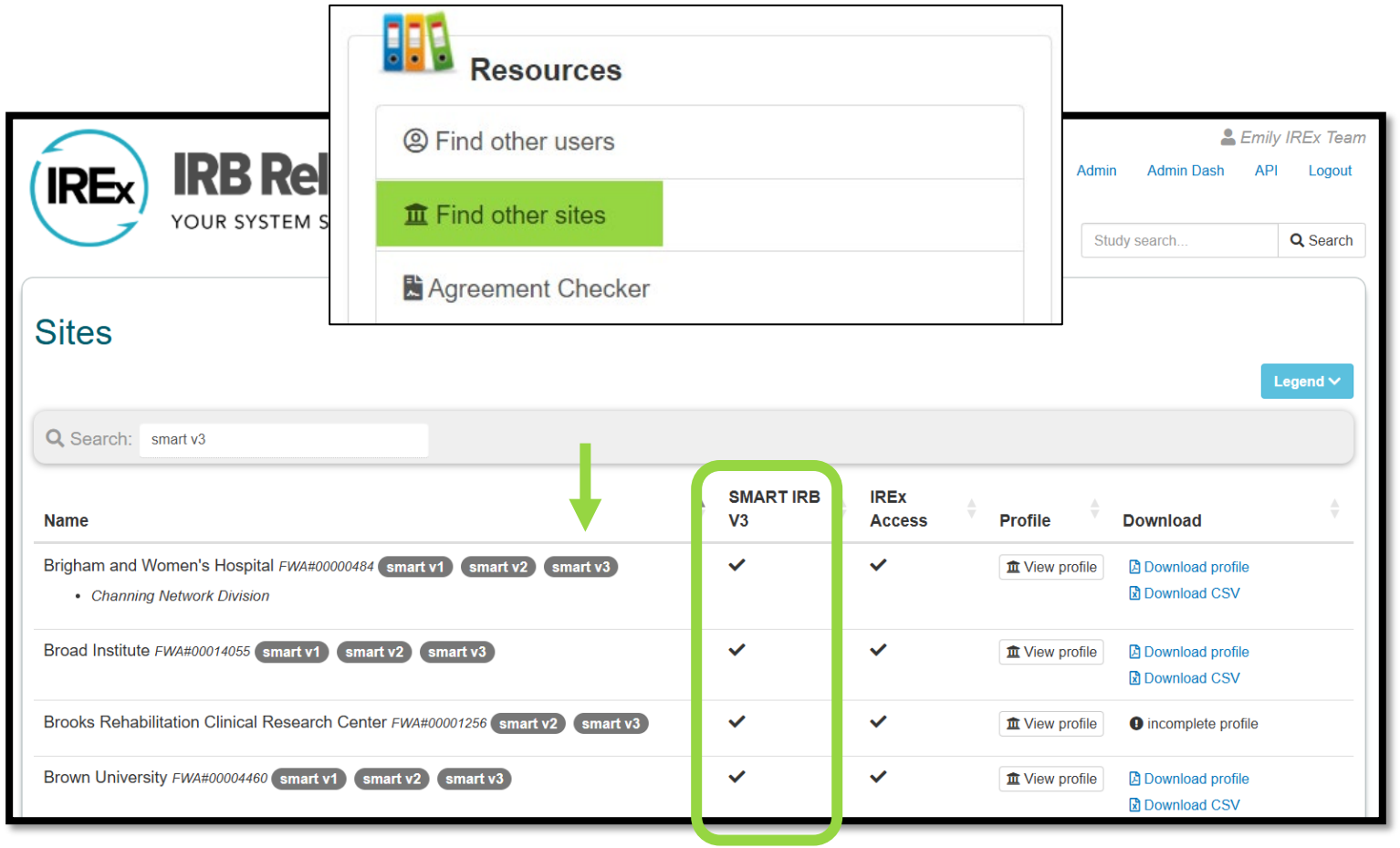
SMART IRB V3 in IREx

Only IREx Admins can indicate a site has joined SMART IRB V3

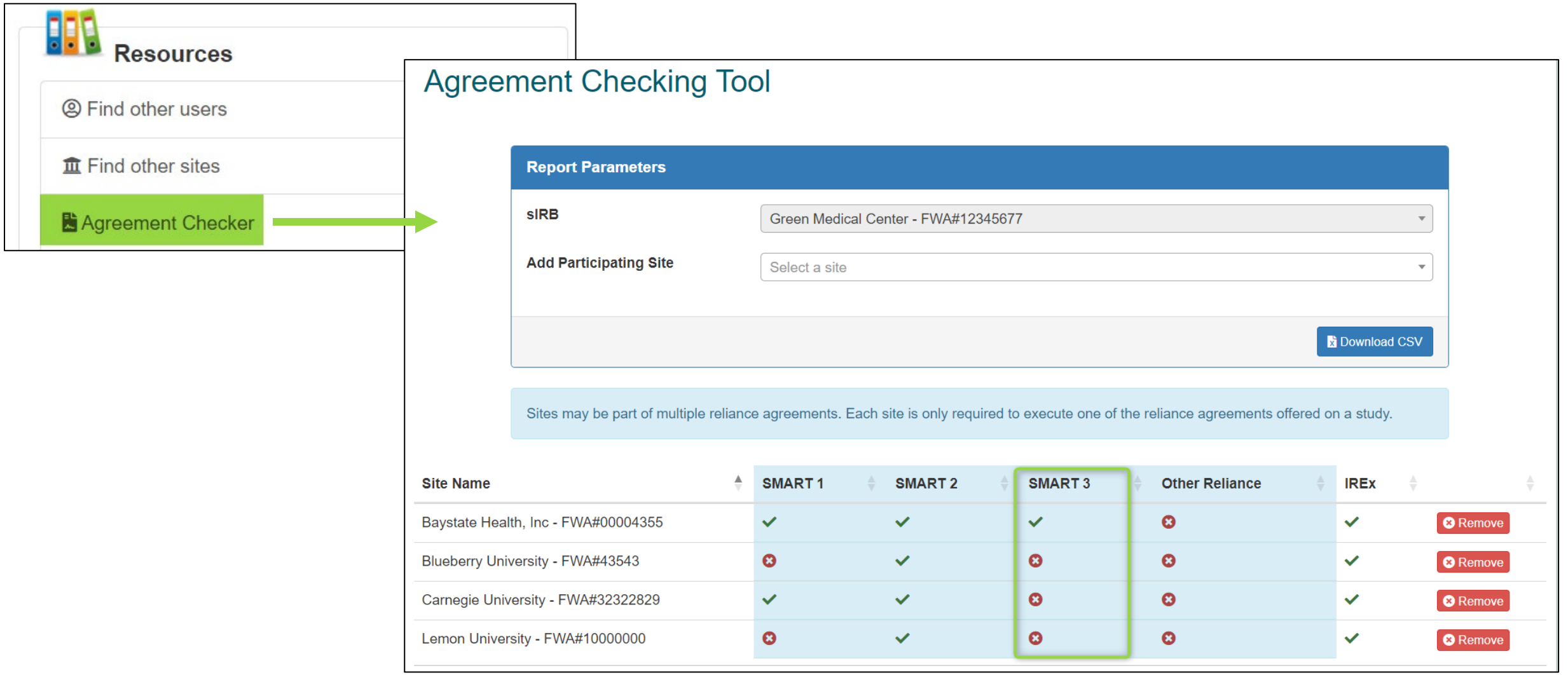
IREx performs daily check to confirm new SMART V3 signees

Email admin@IRBExchange.org if your site's status is not up to date

To view sites that have signed SMART V3:



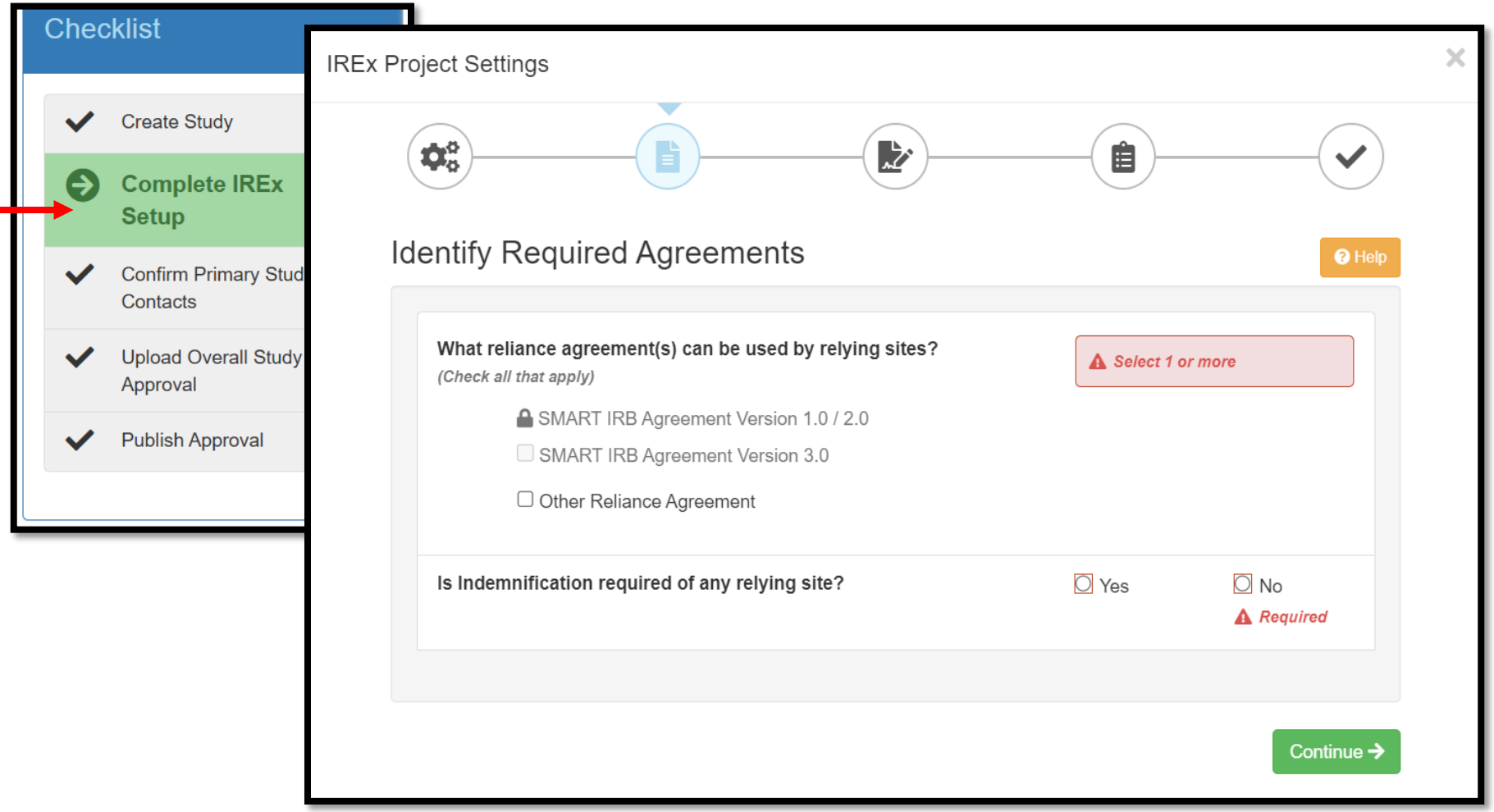
Use the Agreement Checker



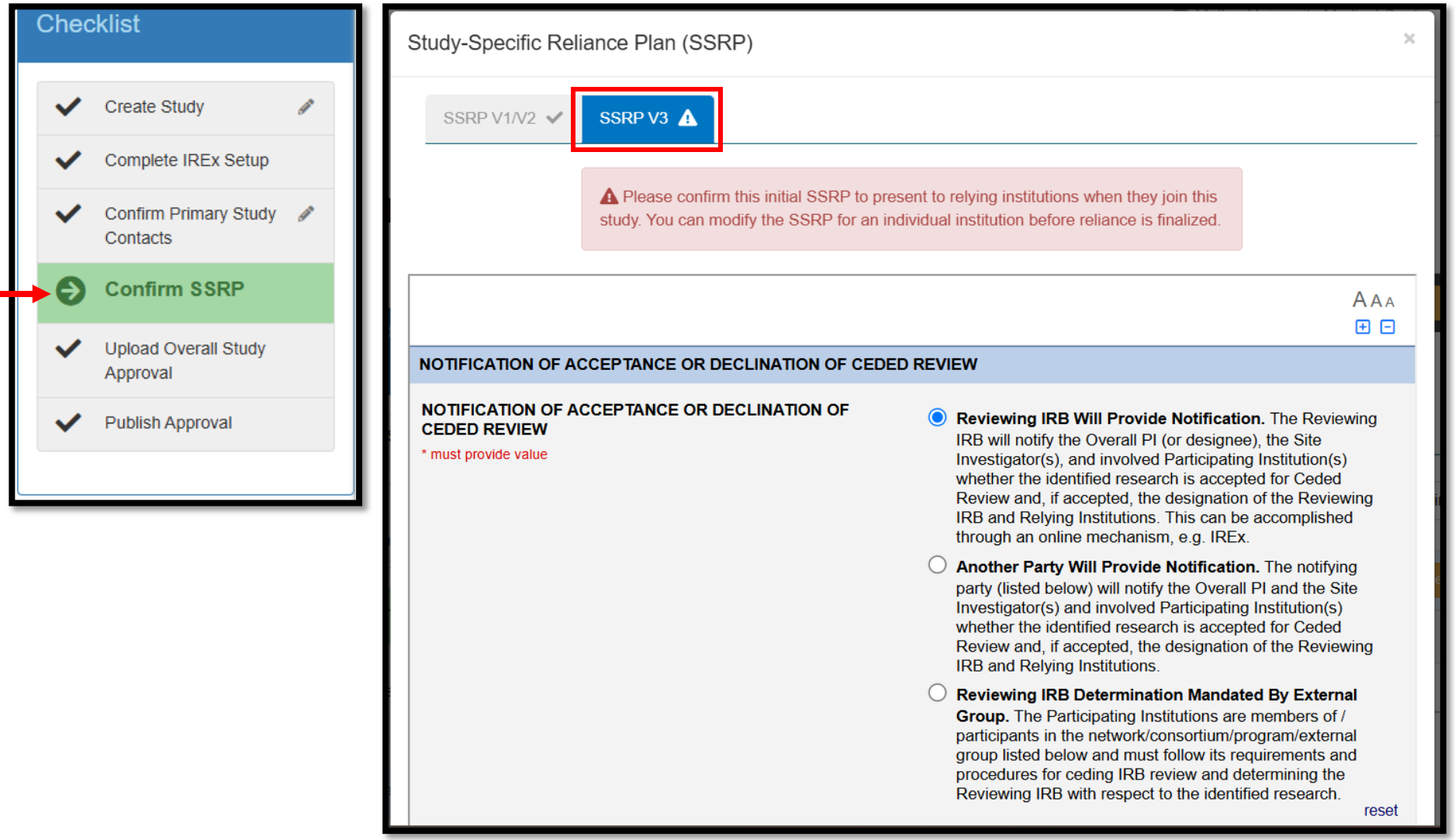
SIRB selects agreement(s) in IREx Setup

Only SMART IRB V3 can be used for reliance.

SMART IRB v3 is greyed out if the sIRB has not joined V3.

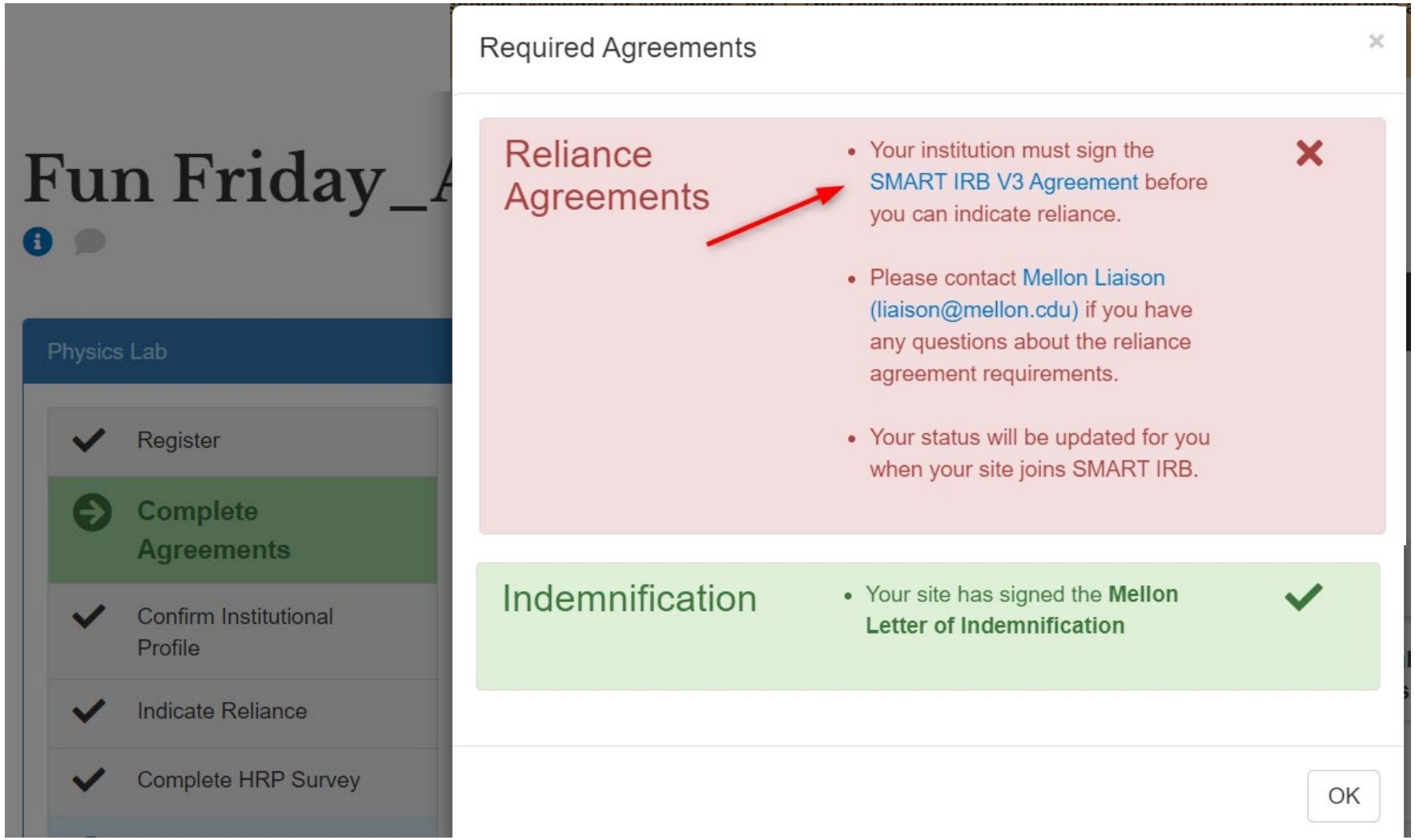


SIRB confirms the SSRP for SMART IRB V3



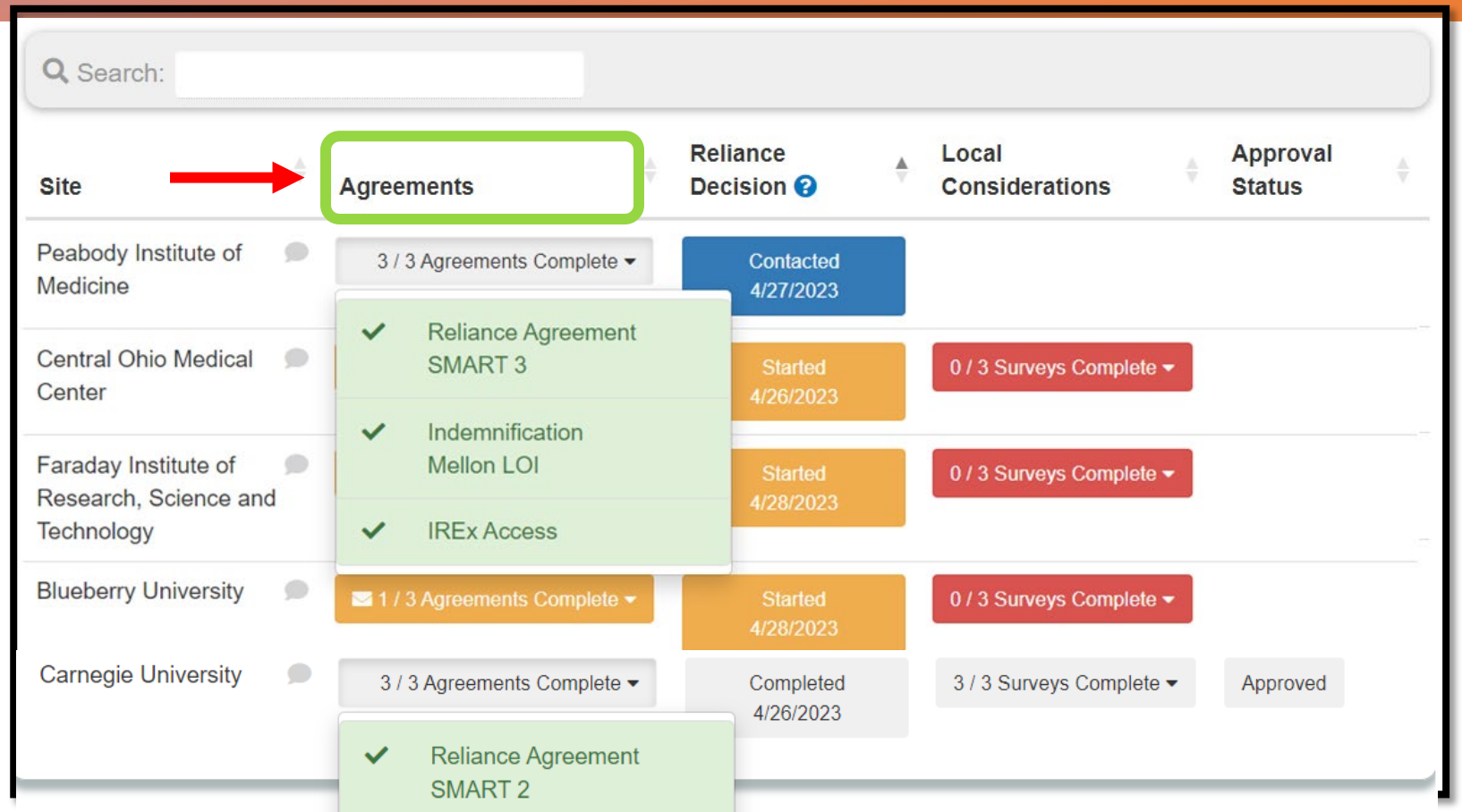
Relying Institutions Must Join SMART IRB V3 to Rely in IREx

Relying HRPPs cannot indicate reliance (on studies using V3) until they have signed SMART IRB V3



Using the Status Summary Tab

Agreements column indicates whether SMART IRB V3 has been signed.

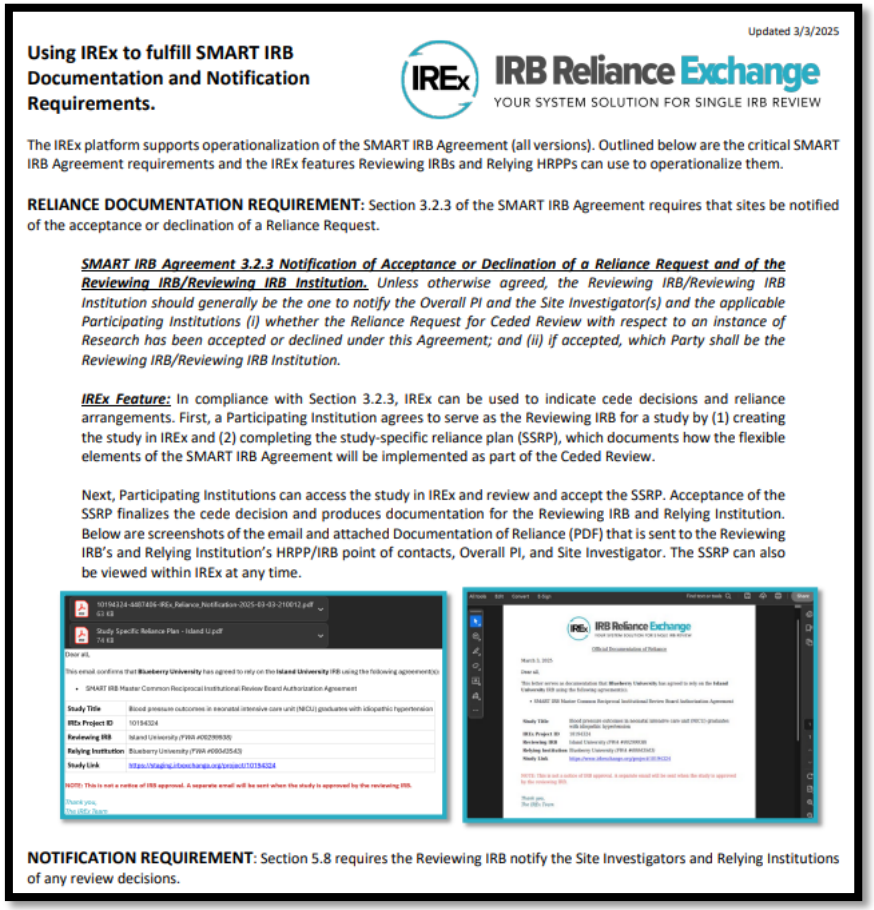


Existing Studies

- No changes required for reliances already confirmed
- If any sites have not indicated reliance:
  - The sIRB is prompted on the study to re-Complete IREx Setup and offer another agreement (SMART v3 listed)
  - If sIRB offers SMART IRB v3 they will confirm a separate SSRP
  - Relying site must join v3 to rely on the sIRB
- If new sites are added to existing studies:
  - The sIRB is prompted on the study to re-Complete IREx Setup and offer another agreement (SMART v3 listed)
  - If sIRB offers SMART IRB v3 they will confirm a separate SSRP
  - Relying site must join v3 to rely on the sIRB

Updated Materials Related to Reliance Agreements / SMART

- Agreements Overview
- SSRP Quick Guide
- Relying HRPP SSRP Quick Guide
- Using IREx to fulfill SMART IRB Documentation



Updated 3/3/2025

Using IREx to fulfill SMART IRB Documentation and Notification Requirements.

IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

The IREx platform supports operationalization of the SMART IRB Agreement (all versions). Outlined below are the critical SMART IRB Agreement requirements and the IREx features Reviewing IRBs and Relying HRPPs can use to operationalize them.

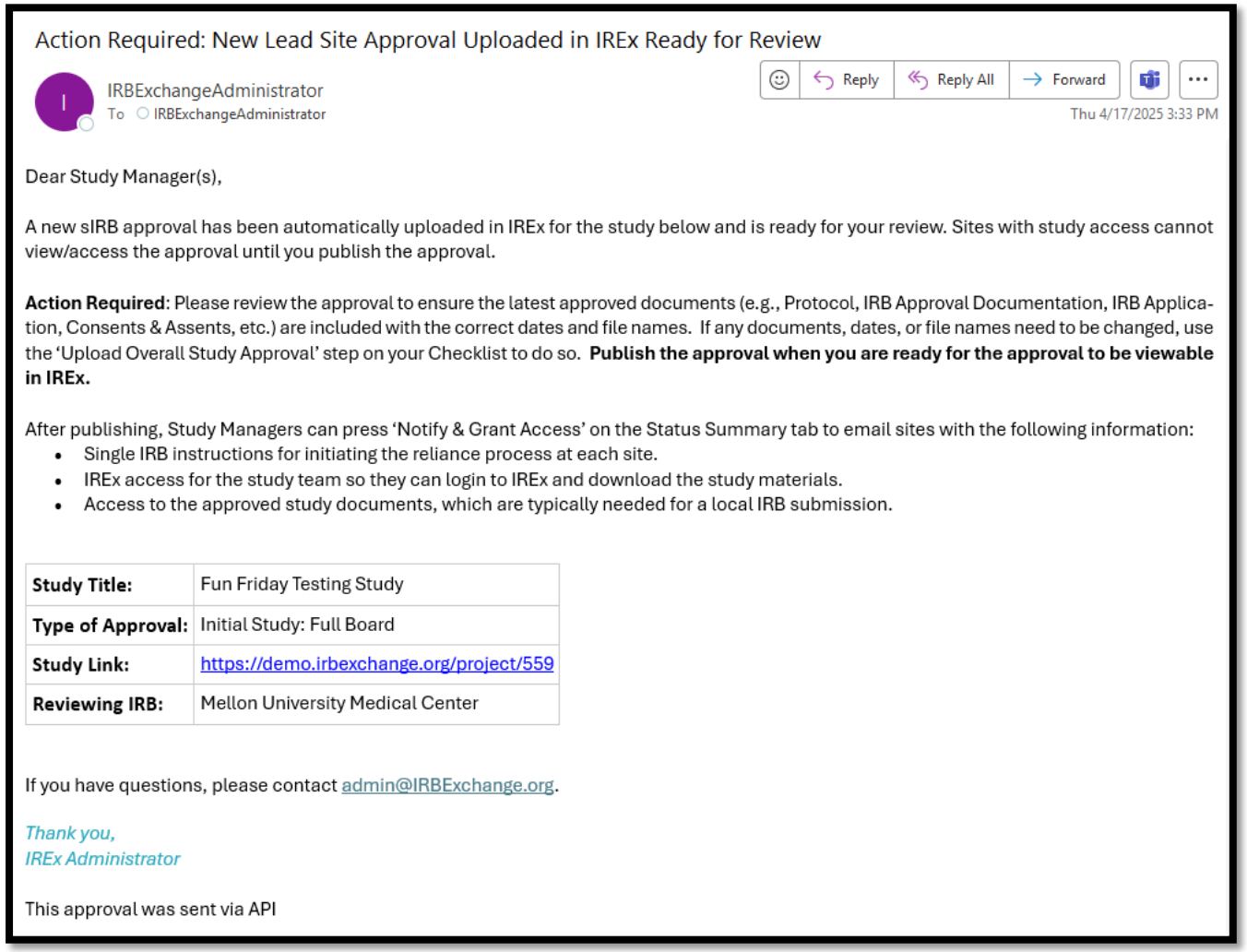
RELIANCE DOCUMENTATION REQUIREMENT: Section 3.2.3 of the SMART IRB Agreement requires that sites be notified of the acceptance or declination of a Reliance Request.

> ***SMART IRB Agreement 3.2.3 Notification of Acceptance or Declination of a Reliance Request and of the Reviewing IRB/Reviewing IRB Institution.*** *Unless otherwise agreed, the Reviewing IRB/Reviewing IRB Institution should generally be the one to notify the Overall PI and the Site Investigator(s) and the applicable Participating Institutions (i) whether the Reliance Request for Ceded Review with respect to an instance of Research has been accepted or declined under this Agreement; and (ii) if accepted, which Party shall be the Reviewing IRB/Reviewing IRB Institution.*
>
> ***IREx Feature:*** In compliance with Section 3.2.3, IREx can be used to indicate cede decisions and reliance arrangements. First, a Participating Institution agrees to serve as the Reviewing IRB for a study by (1) creating the study in IREx and (2) completing the study-specific reliance plan (SSRP), which documents how the flexible elements of the SMART IRB Agreement will be implemented as part of the Ceded Review.
>
> Next, Participating Institutions can access the study in IREx and review and accept the SSRP. Acceptance of the SSRP finalizes the cede decision and produces documentation for the Reviewing IRB and Relying Institution. Below are screenshots of the email and attached Documentation of Reliance (PDF) that is sent to the Reviewing IRB's and Relying Institution's HRPP/IRB point of contacts, Overall PI, and Site Investigator. The SSRP can also be viewed within IREx at any time.

NOTIFICATION REQUIREMENT: Section 5.8 requires the Reviewing IRB notify the Site Investigators and Relying Institutions of any review decisions.

New API Feature

- IREx API now allows for Lead Study Team/Study Manager approval document review (e.g., renaming) prior to publishing the approval
- Lead Study Team/Study Managers will receive an email to go **review the approval and publish**
- Updated API Study Manager Step-by-Step Guide



Action Required: New Lead Site Approval Uploaded in IREx Ready for Review

IRBExchangeAdministrator
To IRBExchangeAdministrator

Reply | Reply All | Forward

Thu 4/17/2025 3:33 PM

Dear Study Manager(s),

A new sIRB approval has been automatically uploaded in IREx for the study below and is ready for your review. Sites with study access cannot view/access the approval until you publish the approval.

Action Required: Please review the approval to ensure the latest approved documents (e.g., Protocol, IRB Approval Documentation, IRB Application, Consents & Assents, etc.) are included with the correct dates and file names. If any documents, dates, or file names need to be changed, use the 'Upload Overall Study Approval' step on your Checklist to do so. **Publish the approval when you are ready for the approval to be viewable in IREx.**

After publishing, Study Managers can press 'Notify & Grant Access' on the Status Summary tab to email sites with the following information:

- Single IRB instructions for initiating the reliance process at each site.
- IREx access for the study team so they can login to IREx and download the study materials.
- Access to the approved study documents, which are typically needed for a local IRB submission.

Study Title:	Fun Friday Testing Study
Type of Approval:	Initial Study: Full Board
Study Link:	https://demo.irbexchange.org/project/559
Reviewing IRB:	Mellon University Medical Center

If you have questions, please contact admin@IRBExchange.org.

Thank you,
IREx Administrator

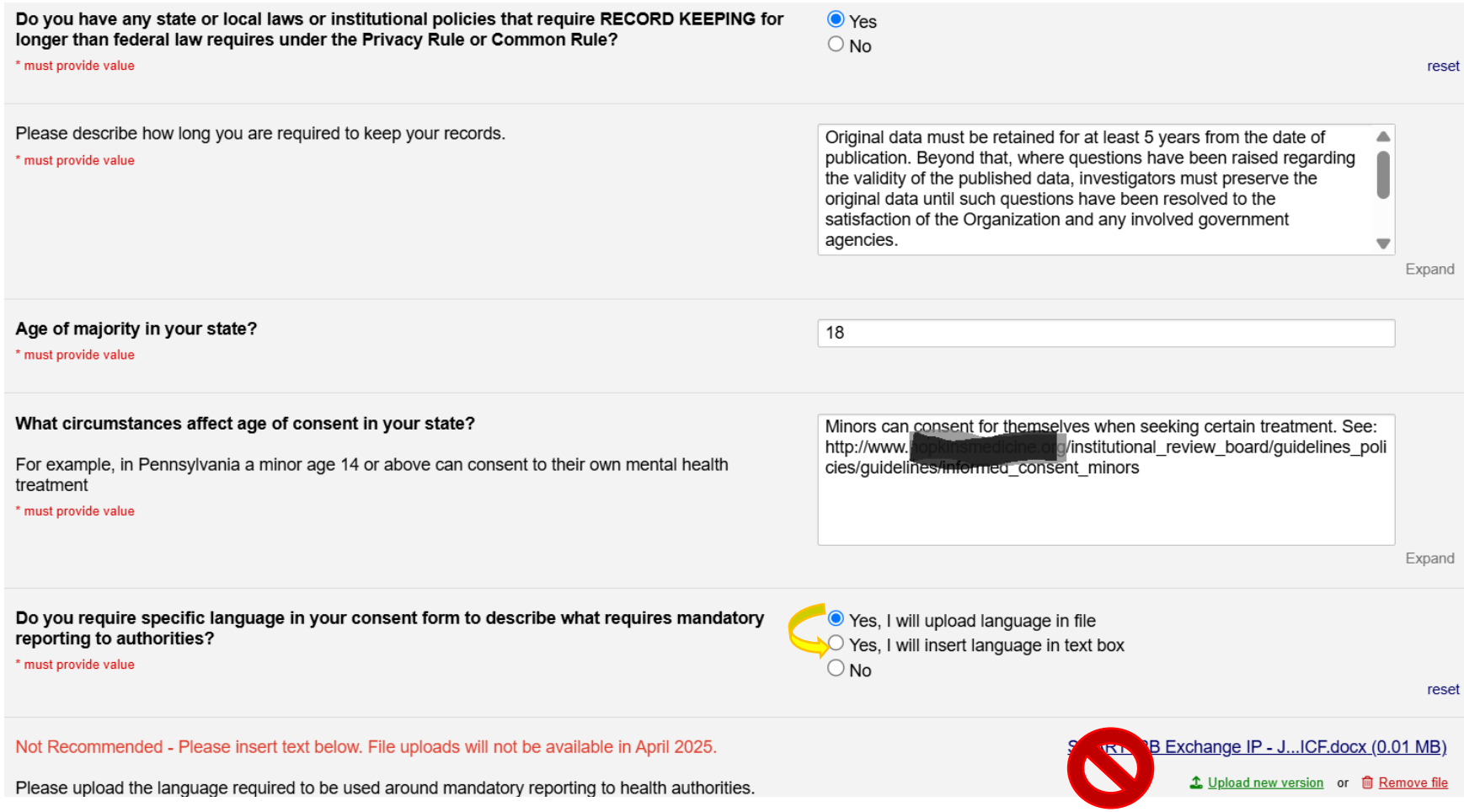
This approval was sent via API

Institutional Profile (IP) Updates & Reminder

IP Reminder

File Upload fields will be removed from Local Considerations Section .

- To minimize out of date information.
- **LIAISON ACTION NEEDED:** Transfer relevant information from File Upload field to corresponding Open Text field.



New IP Fields: Section 1

- Does your institution require you to apply the Common Rule to all studies regardless of federal funding?
- Does your institution require you to apply any subparts (B, C, D) that provide additional protections for certain populations in research to all studies regardless of federal funding?

New IP Fields: Section 2

- Describe any required consent form language when pregnancy testing will be performed
- Does your site require specific signature blocks (e.g., signatures for translators for folks who can't read)
- What is your institution's prefer regarding Certificates of Confidentiality Protections in the consent form?
  - Stay silent
  - Require specific language (insert or list contact)
- Describe any required consent form language for studies involving drugs/devices that may impact billing
- Genetic Testing
  - Describe any state laws related to genetic testing
  - Insert template language required in the consent form
- Text/Email Communications
  - Does your site have an institutional policy for text and/or email communications for research purposes?
  - Does your site require specific language in your consent around text and/or email communications?
  - Please insert your template language require in the consent.

New/Revised IP Fields: Section 4

IP Section 4 Feeds the IREx Study-specific Reliance Plan (SSRP)

NEW Notification of Acceptance or Declination of Ceded Review

- Reviewing IRB Will Provide Notification.
- Another Party Will Provide Notification.
- Reviewing IRB Determination Mandated By External Group.

Revised Indemnification

- SMART IRB Version 3.0 Indemnification Required
- Indemnification agreements not required
- Separate indemnification agreement required

Revised HIPAA DETERMINATIONS AND ACTIONS

- Relying Institution or 3rd Party Will Provide Determination:
- Reviewing IRB Will Provide Determination
- Relying Institution(s) will make any HIPAA determinations or perform any HIPAA Actions as the Reviewing IRB does not as a matter of policy or otherwise, review requests for HIPAA waivers/ alterations
- Ceded Research does not fall under HIPAA Privacy Rule regulations, OR Relying Institution is NOT HIPAA Covered Entity

Revised HIPAA AUTHORIZATION LANGUAGE & CONSENT FORMS

- Relying Institution will provide Reviewing IRB with its own HIPAA language to be inserted into the informed consent documents OR provide a separate HIPAA Authorization.
- Reviewing IRB will Provide and Insert HIPAA Authorization Language into the Informed Consent Document(s)
- Reviewing IRB will Provide separate HIPAA Authorization Form
- Not Applicable – HIPAA does NOT apply, or the Relying Institution is NOT a HIPAA Covered Entity

Coming Soon to the IP

IREx Institutional Profile will soon support Line Breaks in Notes fields.

- Easier reading for sIRBs!
- Prettier PDFs

May 20th: All IPs set to 'Incomplete'

HRPP Liaisons will be required to update information:

- ❑ File upload fields will be removed – text should be added directly to IP fields.
- ❑ Answer new questions in Sections 1 & 2
- ❑ Review / Update section 4 if you plan to (or do) use IREx as the sIRB (Section 4 = Study-Specific Reliance Plan questions)

Upcoming Features

ETA – Late Summer/Early Fall 2025

Automating Elements of Local Consideration

Reliance Requirements (from SMART v3):

- 6.6 Local and Other Considerations. A Relying Institution will identify and communicate to the Reviewing IRB/Reviewing IRB Institution (i) …("Local Considerations"); and (ii) … ("Other Considerations") that would affect the conduct by or approval of the **Research**…

Challenges:

- Reporting local reviews is burdensome for the Relying HRPP
- Navigating local policies to identify pertinent information is burdensome for the sIRB

IREx Goals:

- To make it easier **for Relying HRPPs** to report their local considerations and avoid duplicating information from their Institutional Profile
- To improve the information reported to **the single IRB** and streamline the # of documents they must review for each site

Step 1: sIRB Indicates Required & Important Study Elements

Draft

Study-specific Consent and Protocol Elements

Indicate the study elements that apply to this study to help Relying HRPPs confirm the local and other considerations that should be considered when reviewing their study.

Federally Regulated Study Elements	
	Children
	Pregnant women
	Prisoners
	Other vulnerable populations (e.g., students)
	Study has a consent form
	EFIC
	Assent
	Waiver or alteration of informed consent
	HIPAA applies to this study
	Drugs/devices
	Genetic Testing

Other Elements Related to State Laws /Local Policies	
	Individuals with impaired decision making
	Non-English speaking Individuals
	Pregnancy testing or collecting pregnancy status
	Testing for an infectious disease (e.g., STI testing for children/minors)
	Mandatory reporting (e.g., diseases, abuse/neglect)
	Drug or device that could impact billing
	Drug storage or distribution
	Investigational biosafety review
	Involves radiation of any kind
	Is federally funded
	Other

A Use Case

- Study is a multisite, Phase 3 clinical trial studying investigational drug ABC.
- Participants will be aged 7-40.
- Recruitment will not be limited to English speakers.
- Procedures include
  - X-ray
  - Collection of biospecimens for genetic research
  - Biobanking for future unspecified research
  - A pregnancy test will be required for participants of childbearing age

*Study is a multisite, Phase 3 clinical trial studying **investigational drug ABC**. Participants will be **aged 7-40**. Recruitment will **not be limited to English speakers**. Procedures include an **x-ray, collection of biospecimens for genetic research, and biobanking for future unspecified research**. A **pregnancy test** will be required for participants of childbearing age.*

Study-specific Consent and Protocol Elements

Indicate the study elements that apply to this study to help Relying HRPPs confirm the local and other considerations that should be considered when reviewing their study.

Federally Regulated Study Elements	
☑	Children
☐	Pregnant women
☐	Prisoners
☐	Other vulnerable populations (e.g., students)
☑	Study has a consent form
☐	EFIC
☑	Assent
☐	Waiver or alteration of informed consent
☑	HIPAA applies to this study
☑	Drugs/devices
☑	Genetic Testing

Other Elements Related to State Laws /Local Policies	
☐	Individuals with impaired decision making
☑	Non-English speaking individuals
☑	Pregnancy testing or collecting pregnancy status
☐	Testing for an infectious disease (e.g., STI testing for children/minors)
☐	Mandatory reporting (e.g., diseases, abuse/neglect)
☑	Drug or device that could impact billing
☑	Drug storage or distribution
☐	Investigational biosafety review
☑	Involves radiation of any kind
☐	Is federally funded
☐	Other

Step 2: IREx Matches Elements to Institutional Profile Questions

Draft

Study Element	IP Question(s)
Children/Assent	Circumstances affecting age of consent | Emancipation standards | Age of majority Does your institution require a separate Assent document or an Assent signature on the main consent form for children/adolescents ?
Consent	• Additional documents/riders required with consent • Compensation-related policies, guidelines, or language • Payment for research-related injury • Policies around impaired decision making • Signature line requirements (e.g., date AND time, for translators when participants can't read, financial info sheet; physician consent)
Non-English speaking individuals	• Policies re: use of short forms for non-English speaking individuals and/or translation of consents for non-English speaking individuals • Does your site allow the use of a short form? | # of times SF can be used before needing fully translated consent? • Is Translator/Witness required to sign the Short form? | Is Translator/Witness required to sign the full English consent document?
HIPAA	Covered entity | Waiver for review of medical records to ID participants | Is authorization required to be separate/other formatting
Genetic testing	Describe any state laws related to genetic testing | Template language required in the consent form
Pregnancy testing	Describe any required consent form language when pregnancy testing will be performed.
Drug/device impacts billing	Describe any required consent form language for studies involving drugs/devices that may impact billing
Drug storage	Describe any state laws or policy that may impact drug storage or shipping
Radiation review	Are ancillary reviews required when studies involve radiation review? If so, who conducts those reviews

Step 3: Relying HRPP completes HRP Survey, confirming / updating Institutional Profile Info

Draft

Study-specific HRP Survey

AAA

STUDY OVERVIEW

Study Title	Real Time Glucose Monitoring in Vulnerable F
Local Site Name	Vanderbilt University Medical Center
Local Study PI * must provide value	Sam Smith

Please confirm the following information from your Institutional Profile

FWA: FWA00005756

Information has changed

FWA Expiration: 17-10-2024

Information has changed

Is the IRB AAHRPP accredited: Yes

Information has changed

Is your institution a covered entity?: Hybrid

Information has changed

The sIRB has identified the following characteristics of the protocol that will likely impact local considerations.

- **Federally Regulated Study Elements:** Children
- **Other Study Elements:** Pregnancy testing or collecting pregnancy status, Drug or device that could impact billing, Drug storage or distribution, Involves radiation of any kind

Please indicate if the information in red (from your Institutional Profile) has changed.

Emancipation Process:

By judicial petition, By marriage, By joining the armed forces

Information has changed

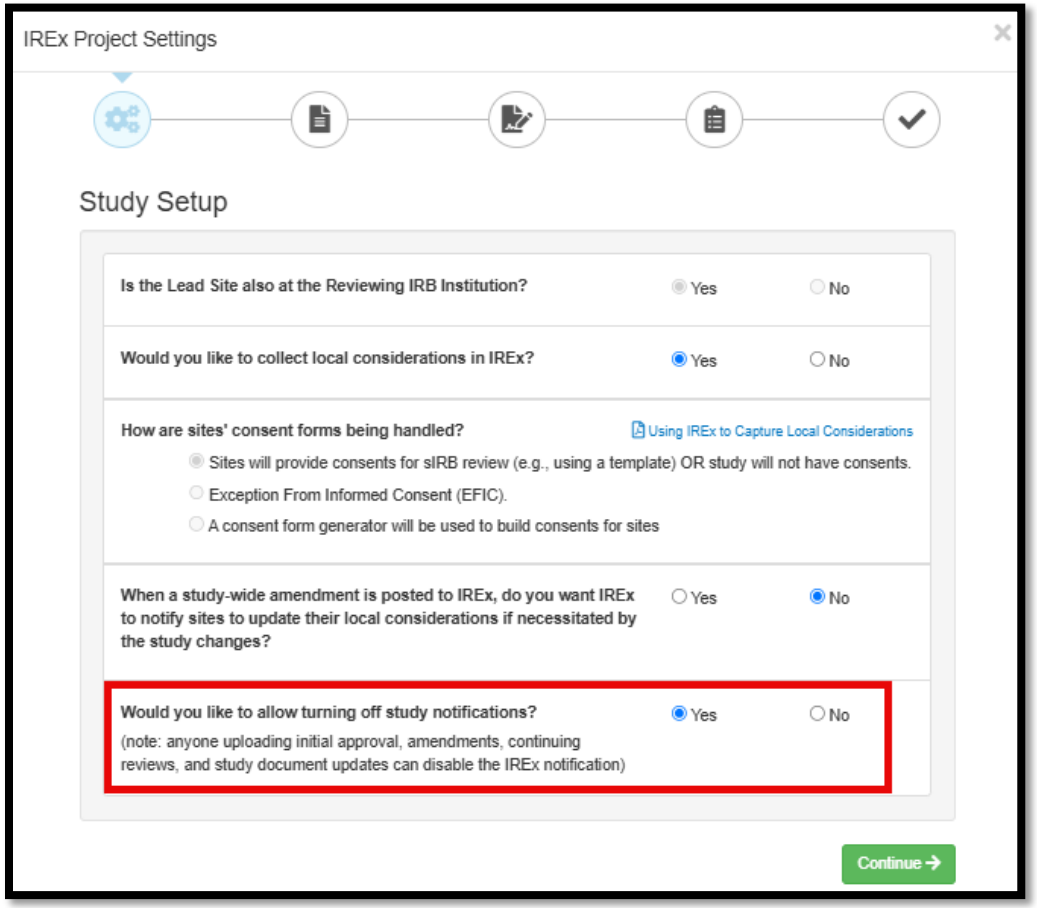
Circumstances affecting age of consent:

In certain circumstances Utah law authorizes an individual under the age of 18 to function as an adult when seeking or receiving health care. In such circumstances, parental permission is not required as part of the research consent process. When an individual under the age of 18 is authorized to consent for care or treatment because the care or treatment is connected to a sexually transmitted disease or pregnancy/childbirth, the individual may only consent for himself/herself in connection with that treatment or care and the individual may only provide full informed consent for research that is directly connected to that treatment or care. Researchers are required to conduct a full consent process in a way that is understandable to the individual under 18. The IRB may require parental permission or other methods to ensure comprehension of the study prior to enrollment.

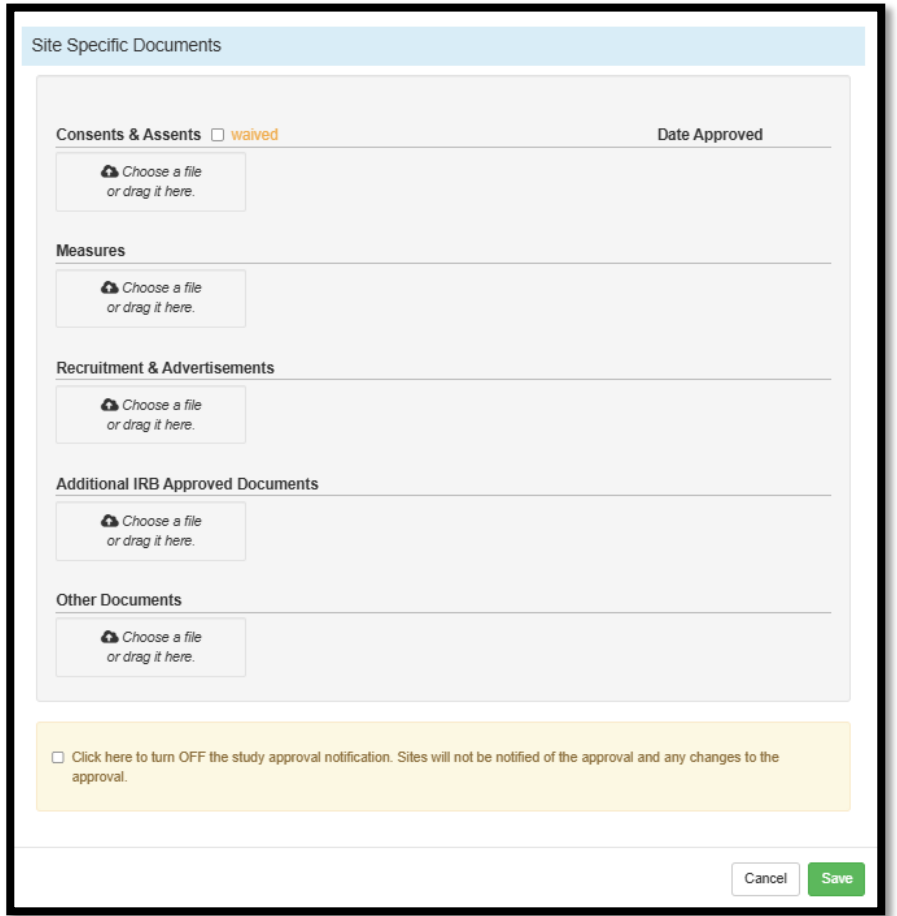
Information has changed

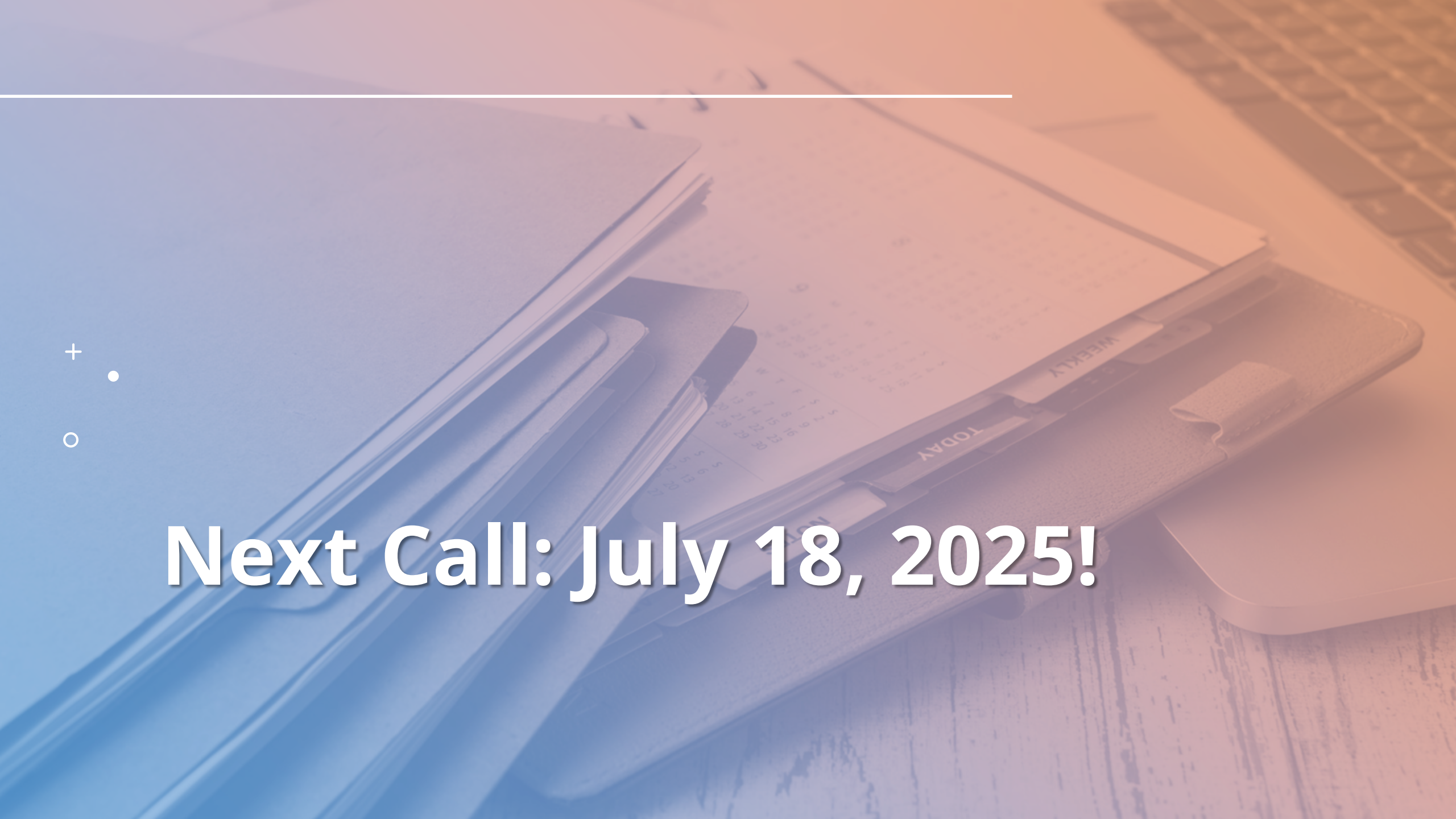
Coming Soon:
Allow Reviewing IRBs & SMs to disable approval notification emails

1. Single IRB will have option to allow Lead Study Team / CC to turn off approval notifications



2. If allowed, **Lead Study Team / CC** can check box to publish approval WITH / WITHOUT sending notifications





Next Call: July 18, 2025!