



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



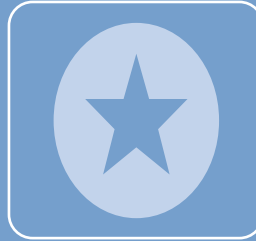
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○

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)



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-

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](#)

RESOURCES

We have resources for each role within IREx. Click the link to access each resource page:

- [Reviewing IRB Resources](#)
- [Participating Site HRPP Resources](#)
- [Study Manager Resources](#)
- [Study Team Resources](#)

Updated Videos Available via [IREx YouTube Channel](#)

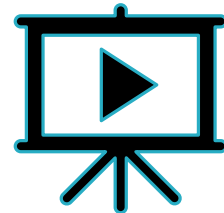


FOR STUDY MANAGERS

- [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](#)



IRB Reliance Exchange 'IREx'
@IRBRelianceExchange 34 subscribers 30 videos
IRB Reliance Exchange (IREx) is a freely available, web-based portal support... >
irbexchange.org

HOME VIDEOS PLAYLISTS COMMUNITY CHANNELS ABOUT

Latest Popular Oldest

Getting Approved & Accessing Approvals in IREx 1:22

Removing Access for an Existing User in IREx 0:43

How do Relying HRPPs register for a study in IREx? 1:56

How to Create a Study in IREx 7:06
8 views · 6 days ago



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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

IREx Project Settings

Study Setup

Is the Lead Site also at the Reviewing IRB Institution? Yes No

Would you like to collect local considerations in IREx? Yes No

How are sites' consent forms being handled? [Using IREx to Capture Local Considerations](#)

(Recommended) Sites will provide consents for sIRB review (e.g., using a template) OR study will not have consents.

A consent form generator will be used to build consents for sites

When a study-wide amendment is posted to IREx, do you want IREx to notify sites to update their local considerations if necessitated by the study changes? Yes No

(Optional) How many days do sites have to submit updates to their local considerations, after an amendment is posted to IREx? (Leave blank if no specific timeframe)

Continue →

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

Add Study-Wide Amendment

Snowday_Jan 16 2024

Does this amendment change **Protoc** of [1, 1/16/2024]? Yes No

Summary of changes

Amendment Content

- Addition of a new subject population, especially children, pregnant women, prisoners, individuals with impaired decision-making capacity, LGBTQIA, other potentially vulnerable subject populations
- Addition of non-English speakers
- Significant change in recruitment method
- Addition of genetic testing
- Addition of testing for an infectious disease
- Addition of pregnancy testing or collection of information about pregnancy status
- Providing research results to participants
- Addition of or change in contraception used in the study
- Change in study drug or device storage or distribution
- Addition of a new drug or device that could affect billing
- Change in informed consent language that is commonly affected by institutional policy, such as compensation for injury language and study costs
- Addition of a new consent process
- None of the above

[TEST] no snow - ATTN: Approved changes may require local review

admin@irbexchange.org
To Tan, Linda

Reply Reply All Forward

Fri 2/9/2024 2:33 PM

Test Email

The real email would have gone to: To: liaison@mellon.cdu; sm@mellon.xx; clara.sasaki@baystate.cdu; be@thornview.com; multisite.liaison@thornview.com; liaison@baystate.org; liaison@multisite.xx; liaison@baystate.xx; pi@baystate.xx; coordinator@baystate.xx | BCC: admin@irbexchange.org

Dear Liaisons and Study Contacts,

Mellon University Medical Center has shared IRB approval for your institution, Baystate Health, Inc, in IREx for the study below:

Study Title:	No more snow_jan 23 2024
Type of Review / Approval:	Study-Wide Amendment: Full Board
Amendment #	7
Change Summary	new consent
Amendment Content	<p>**ATTENTION** This amendment changed the following elements of the study:</p> <ul style="list-style-type: none">Significant change in recruitment method <p>If you have new or updated local considerations the Reviewing IRB should consider, the Relying HRPP & Investigator should log into IREx by 2/19/24 and update your HRP Survey and/or PI Survey. The consent form is updated on the PI Survey. View quick guide on how to edit surveys here.</p>
Expiration Date:	1/2/2025
Study Link:	https://test.irbexchange.org/feature-branch/public/project/7925909

Principal Investigators & Study Contacts:

NEW We've made accessing your approval documents more user friendly - use this [Quick Guide](#) to see the changes.

If you have any questions about your approval or future submissions, please contact the Study Manager (Coordinating Center/ Lead Study Team) or Reviewing IRB. If needed, contact information is listed on the study page under the study title in IREx.

Thank you for using IREx,
The IREx Team

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

Approvals Documents Status Summary My Site Info

Approvals

Approval History

SIRB: Mellon University Medical Center
Lead Site: Mellon University Medical Center

Protocol Version: 1, 1/2/203

View All Amer

- Study Team Contacts
- View Reliances (SSRP)
- View HRP Survey
- View Local PI Survey
- Download Letter of Reliance
- Download Reliances (SSRP)

Relying HRPP can edit both surveys

Approvals Documents Status Summary My Site Info

Status Summary

Site Agreements

- Study Team Contacts
- View HRP Survey
- View Local PI Survey

Study Team can only edit the PI Survey

HRP and PI Survey PDFs include Last Modified Date

Approvals Documents **Status Summary** Sites Contacts [Edit Study Info](#)

Status Summary

Export Data

Search

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Carnegie University	2 / 2 Agreements Complete	Completed 1/16/2024	3 / 3 Surveys Complete	Approved

- ✓ Institutional Profile
Confirmed: 1/16/2024
- ✓ HRP Survey
Completed: 1/16/2024
Updated: 1/17/2024
- ✓ PI Survey
Completed: 1/16/2024
Updated: 1/17/2024
PI Attested: 1/17/2024

Study-Specific Local Context Worksheet

Study Title: [Snowday_Jan 16 2024](#)

Study Title
Local Site Name
STUDY TEAM INFORMATION
Local Site PI First Name
Local Site PI Last Name
Local Site PI Email

STUDY-SPECIFIC LOCAL REQUIREMENTS

Please identify any ancillary reviews required at your site [e.g. radiation safety review, review for research with biospecimens, etc.] that will be required before this study may be initiated at your site. If no ancillary reviews are required, please indicate "None" below.

Local Context PI Survey

Study Title: [Snowday_Jan 16 2024](#)

Study Title	Snowday_Jan 16 2024
Participating Site Name:	Carnegie University

STUDY TEAM INFORMATION

Site Investigator's Name	Carnegie PI
Site Investigator's Email Address	pi@carnegie.edu

Please review the planned list of personnel who will be engaged in human subjects research. Has all required training for the conduct of the research at your site been completed for each individual, including human subjects protections training, GCP training, and HIPAA training, as applicable? Yes

Additional Information regarding the verification that all training requirements are met. hello i'm hrpp editing the pi survey - 1/17

Last modified 01/17/2024

Last modified 01/17/2024

Relabeled 'Getting Started Checklist' to 'Checklist'

Mellon Univ. Med Ctr
GETTING STARTED

- ✓ Register
- ✓ Complete Agreements
- ➔ **Confirm Institutional Profile**
- ➔ **Indicate Reliance**
- ➔ Complete HRP Survey
- 👁️ Remind PI To Complete PI Survey
- ✎ Add / Edit Study Team Access
- 🕒 Awaiting Reviewing IRB Approval

Mellon Univ. Med Ctr
Checklist

- ✓ Register
- ✓ Complete Agreements
- ✓ Confirm Institutional Profile ✎
- ✓ Indicate Reliance
- ✓ Complete HRP Survey ✎
- ✓ Review PI Survey (optional) ✎
- ✎ Add / Edit Study Team Access
- 🕒 Awaiting Reviewing IRB Approval

Modified Uploading Approval Dialog

Study Information

Select Approved if you are ready to share the approval and Pending to save and return later.

Status ⓘ Approved Pending **▲ Required**

IRB #

Type of Study Greater than minimal risk Minimal risk

Minimal risk category

(f)(1) (f)(5)
 (f)(2) (f)(6)
 (f)(3) (f)(7)
 (f)(4) (f)(9)

check all that apply

Review Type

Review Cycle

Will Lead Site enroll participants? Yes No

Modified column on Participating Site's Studies Dashboard

VANDERBILT UNIVERSITY
MEDICAL CENTER

163
reviewer
Your site is the **reviewer** for 163 studies

36
participant
Your site is a **participant** in 36 studies

424
users
There are 424 **users** at your site

[Dashboard](#) [Home](#)

Participating Site's Studies

All Studies ▾ Export ▾

Search:

Study Title	Your Site	PI (Local IRB #)	Reviewing IRB	Expiration Date	To Do
PREVENTABLE SPPB Ancillary	Vanderbilt Univ MC	Amanda Mixon IRB #230015 ←	Wake Forest Univ Hlth Sci	8/20/2024	Approved 8/21/2023
APOLLO	Vanderbilt Univ MC	Kelly Birdwell IRB #181986 ←	Wake Forest Univ Hlth Sci	9/20/2024	Approved 3/14/2024
Prophylactic Antibiotic Coated Nail to Prevent Infection: A Clinical Trial	Vanderbilt Univ MC	Daniel Stinner IRB #231263 ←	Wake Forest Univ Hlth Sci	10/8/2024	Approved 9/19/2023
I-SPY 2 TRIAL: Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And Molecular Analysis 2	Vanderbilt Univ MC	Laura Kennedy	Wake Forest Univ Hlth Sci	10/25/2024	Approved 3/27/2024

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

The screenshot displays a 'Status Summary' tab with a table of sites and their approval progress. A green callout box highlights the 'Not Approved' status for Anderson Medical Center, indicating that this status is only shown when all steps are completed.

Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status
Anderson Medical Center	2 / 2 Agreements Complete	Completed 2/6/2024	3 / 3 Surveys Complete	Not Approved
Baylor College of Medicine	2 / 2 Agreements Complete	Completed 2/13/2024	1 / 3 Surveys Complete	
Baystate Health, Inc	2 / 2 Agreements Complete	Completed 1/24/2024	3 / 3 Surveys Complete	Approved
Carnegie University	2 / 2 Agreements Complete	Contacted 1/24/2024		
University of the Bay	2 / 2 Agreements Complete	Started 2/9/2024	0 / 3 Surveys Complete	

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

The screenshot shows a web interface for the 'Onboarding' tab. At the top, there is a navigation bar with tabs for 'Onboarding', 'Approvals', 'Status Summary', 'Sites', and 'Contacts'. An 'Edit Study Info' button is located in the top right corner. Below the navigation bar, the page title is 'Onboarding' and the view is 'Study Manager View'. The main content area is divided into sections: 'sIRB Instructions' with a document icon and the text 'sIRB Instructions'; 'Additional Documents' with a '+ Add Document' button and a text box stating: 'If applicable, relying sites can use the additional documents below to facilitate their local submission process. Please contact the Reviewing IRB Contact or Study Manager with any questions.' Below this, there is a list of documents: 'Site-specific consent form guidance.docx', 'sIRB Communication Plan.docx', 'sIRB SOP.docx', and 'Part II Consent.docx', each with an 'Archive' button. At the bottom, there is a section for 'Archived Documents' with a dropdown arrow and an information icon, containing the document 'DeviceManual.docx' with a 'Restore' button.

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 HRRP to request changes to SSRP

Study-Specific Reliance Plan (SSRP)

Reviewing IRB
Vanderbilt University Medical Center
✓ SSRP automatically confirmed by VUMC.
[contact liaisons](#)

Relying Sites
Mellon Children's Hospital Medical Center
⚠ waiting on Mellon Childrens to accept
[contact liaisons](#)

⚠ Please review this SSRP and click **Accept SSRP** if you agree with this plan. If you need changes to this SSRP, please click **Request changes** and contact the Reviewing Site liaisons.

[Accept SSRP](#) [Request changes](#)

STANDARD OPERATING PROCEDURES ("SOPs") Using SMART IRB SOPs (recommended)

HIPAA DETERMINATIONS AND ACTIONS

HIPAA DETERMINATIONS AND ACTIONS If one or more Relying Institution(s) are HIPAA Covered n(s) will make any HIPAA determinations or perform any

Study-Specific Reliance Plan (SSRP)

Reviewing IRB
Vanderbilt University Medical Center
✓ SSRP automatically confirmed by VUMC.
[contact liaisons](#)

Relying Sites
Mellon Children's Hospital Medical Center
⚠ waiting on Mellon Childrens to accept
[contact liaisons](#)

⚠ Please review this SSRP and click **Accept SSRP** if you agree with this plan. If you need changes to this SSRP, please click **Edit SSRP** to make changes.

[Accept SSRP](#) [Edit SSRP](#)

STANDARD OPERATING PROCEDURES ("SOPs") Using SMART IRB SOPs (recommended)

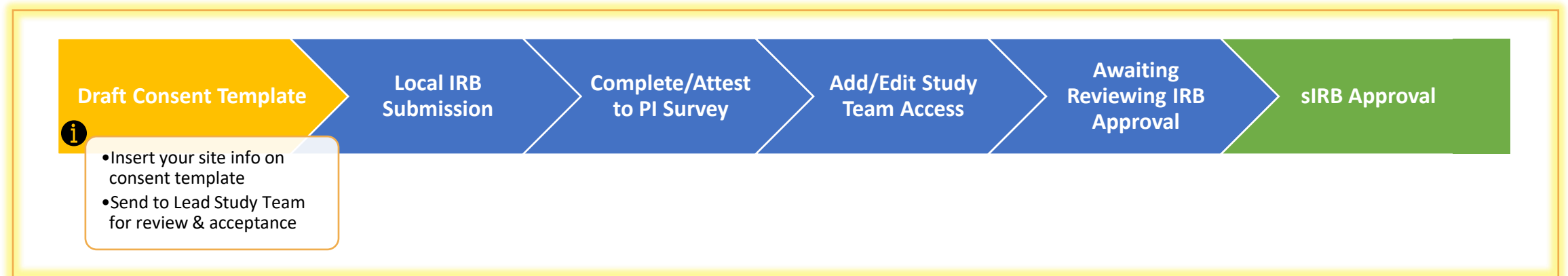
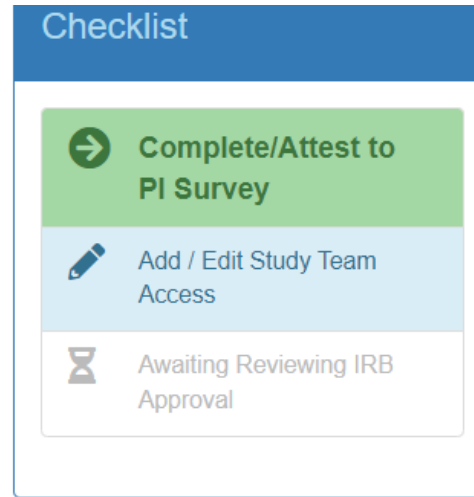
HIPAA DETERMINATIONS AND ACTIONS

HIPAA DETERMINATIONS AND ACTIONS If one or more Relying Institution(s) are HIPAA Covered Entities, Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions.



Revamp Checklist/Site Onboarding Workflow

PI Checklist





Incorporate satisfaction surveys into IREx

The screenshot displays the IREx (IRB Reliance Exchange) user interface. At the top left, there is a 'DEMO' logo and the main title 'IRB Reliance Exchange' with the tagline 'YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW'. The top right navigation bar includes 'Mellon University Medical Center', 'Study Manager Mellon', and links for 'Home', 'Contact Us', 'Your Profile', 'Resources', 'API', and 'Logout'. A search bar is located on the right side.

On the left sidebar, the user is identified as 'MELLON UNIVERSITY MEDICAL CENTER'. The sidebar contains three summary cards: '71 Managing' (You are managing 71 studies), '0 Participant' (You are participating in 0 studies), and '87 users' (There are 87 users at your site). A 'Home' button is at the bottom of the sidebar.

The main content area features a 'Study Manager Dashboard' button. A feedback survey modal is centered on the screen. The modal has a blue header and contains the IREx logo, the text 'We Value Your Feedback! Thank you for using IREx! Help us improve.', and the prompt 'Rate your experience:'. Below this are five emoji icons representing a range of satisfaction levels from sad to happy with heart eyes. A text input field with the placeholder 'Tell us what you think...' is provided, along with a green 'Send feedback' button.

At the bottom, there are sections for 'Your Institution' (Mellon University Medical Center) with 'Profile' and 'Components' buttons, and 'Resources' with options to 'Find other users' and 'Find other sites'.



PI Create Study/Request sIRB use IREx



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Participating Institutions **531**

Studies **650**

[Join IREx!](#)



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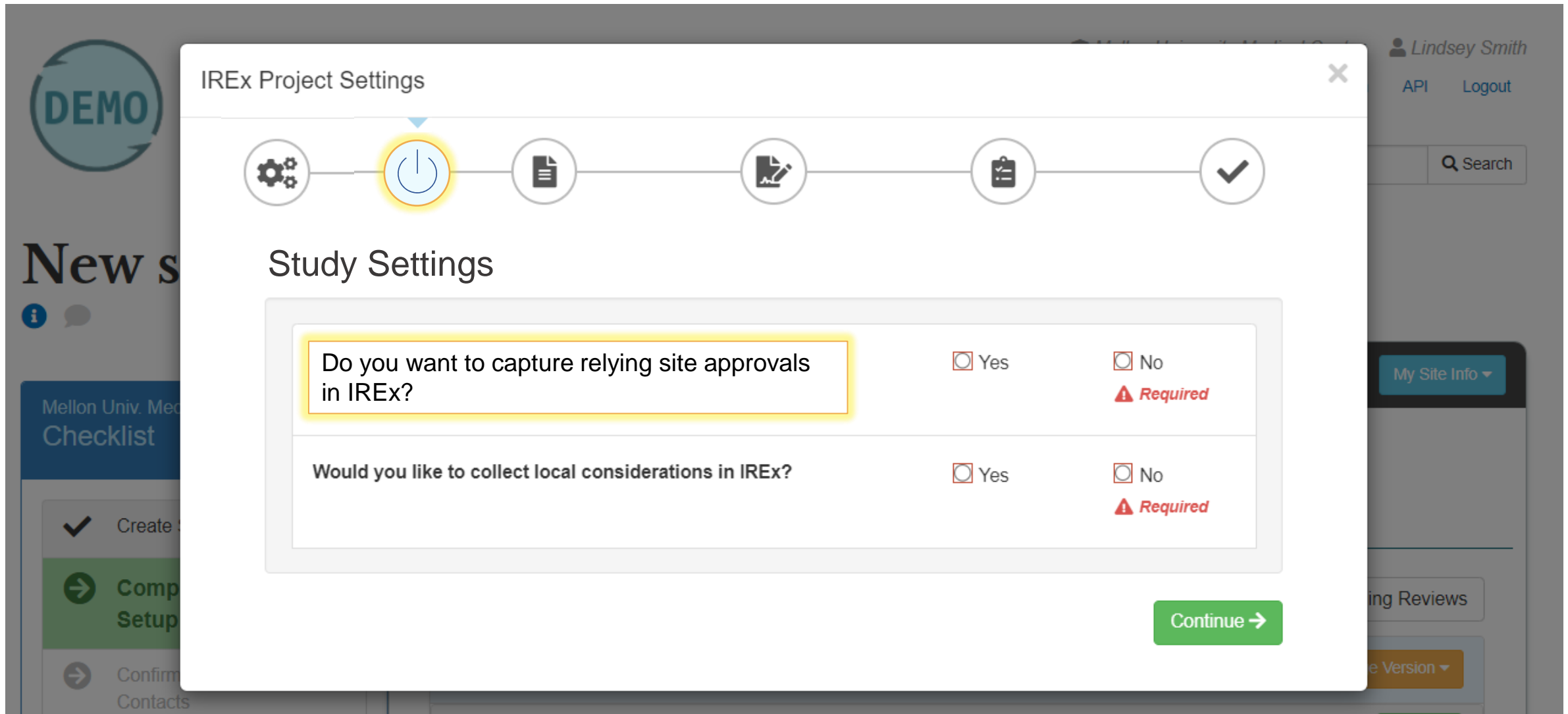
Request sIRB use IREx

Create study

What is IREx?

A freely available, web-based portal supporting single IRB review documentation and coordination for multi-center clinical trials.

Reviewing IRBs turn On/Off approvals



IREx Project Settings

Study Settings

Do you want to capture relying site approvals in IREx?

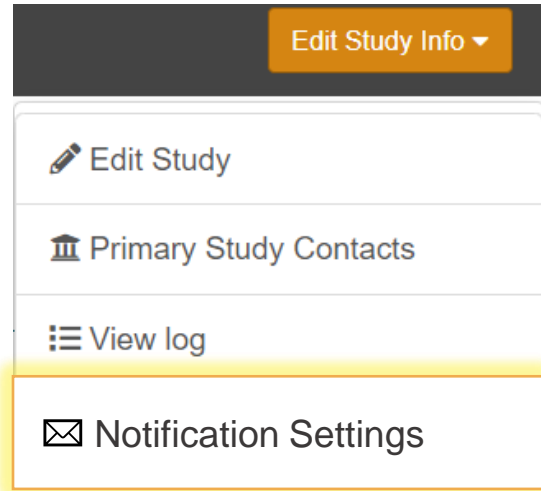
Yes No **Required**

Would you like to collect local considerations in IREx?

Yes No **Required**

Continue →

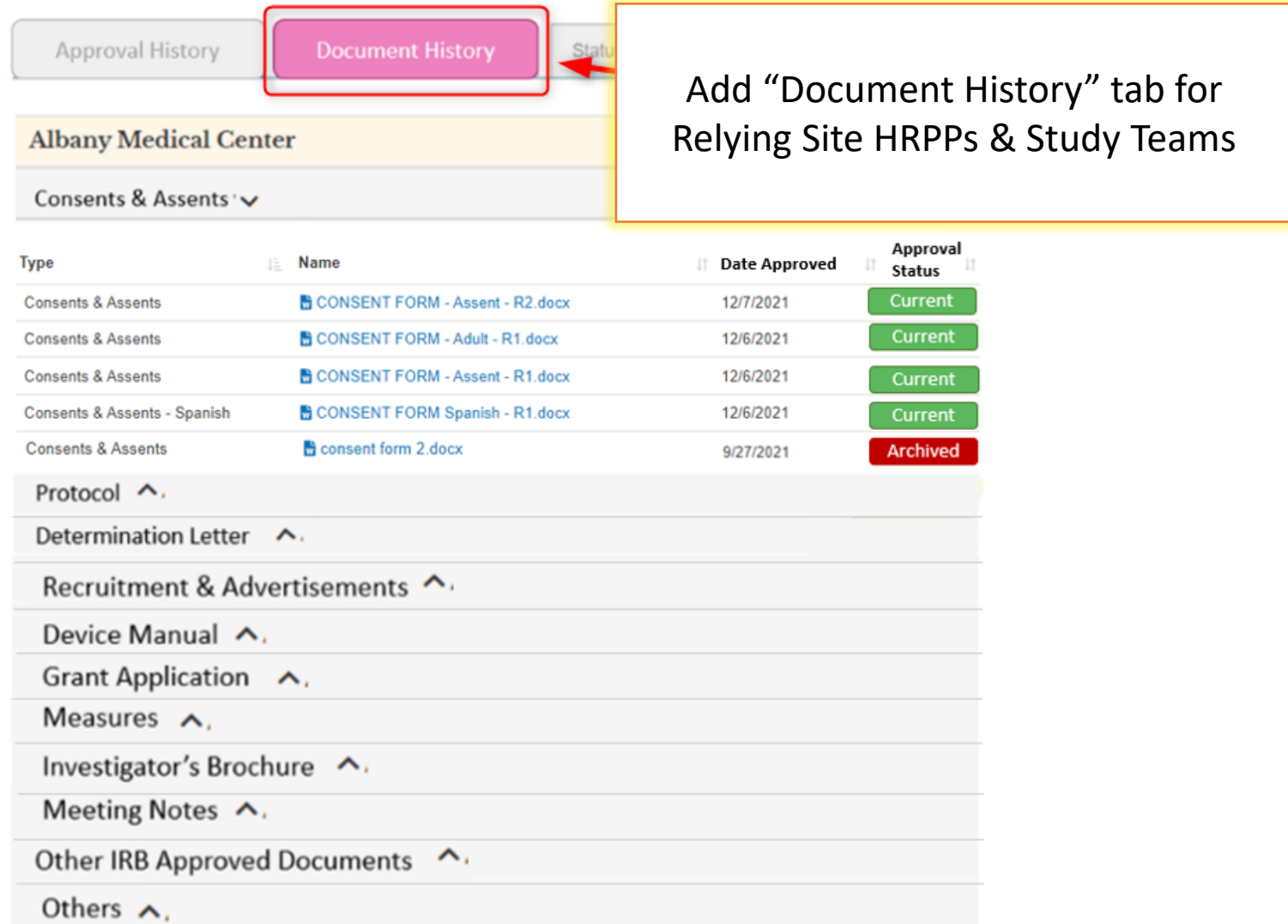
Reviewing IRBs & SMs turn On/Off notifications



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



Approval History **Document History** Status

Albany Medical Center

Consents & Assents ▾

Type	Name	Date Approved	Approval Status
Consents & Assents	 CONSENT FORM - Assent - R2.docx	12/7/2021	Current
Consents & Assents	 CONSENT FORM - Adult - R1.docx	12/6/2021	Current
Consents & Assents	 CONSENT FORM - Assent - R1.docx	12/6/2021	Current
Consents & Assents - Spanish	 CONSENT FORM Spanish - R1.docx	12/6/2021	Current
Consents & Assents	 consent form 2.docx	9/27/2021	Archived

Protocol ^

Determination Letter ^

Recruitment & Advertisements ^

Device Manual ^

Grant Application ^

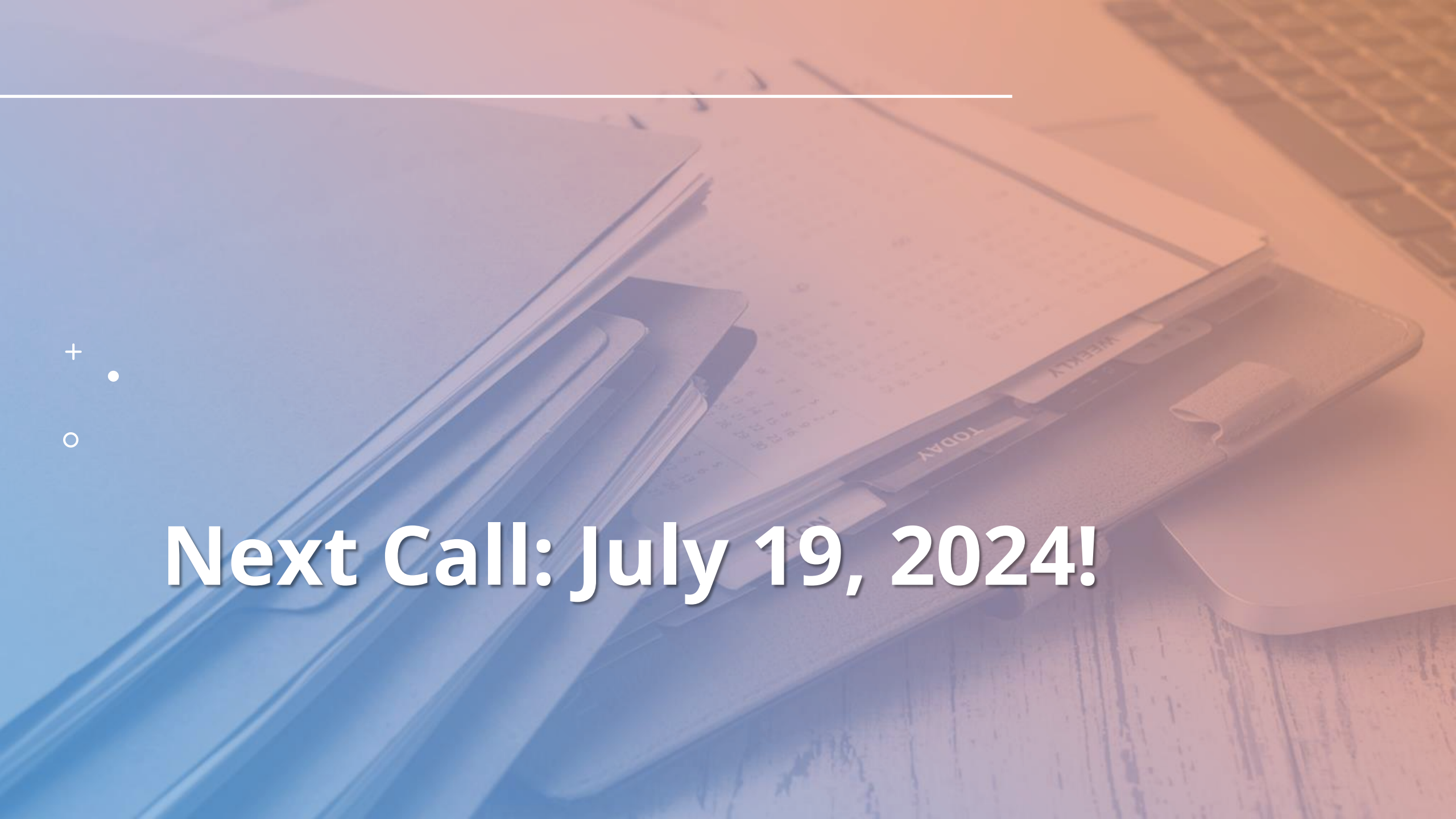
Measures ^

Investigator's Brochure ^

Meeting Notes ^

Other IRB Approved Documents ^

Others ^



Next Call: July 19, 2024!