



• 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





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
Upload overall study approval		X
Track PSites progress		
Export PSite documentation		
Upload PSite Approval		
Upload Continuing Reviews		
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

IREx Project Settings

Confirm Site Instructions for Executing Required Agreements

An optional IREx notification can be sent to sites requesting they execute any incomplete agreements for the study. This email is triggered from the Status Summary tab.

The following document(s) will be attached to the email for sites missing the agreement(s):

Who can use IREx to send instructions for executing the required agreements?
 Lead study team and/or sIRB sIRB only

Preview the site instructions below. Do you want to include additional instructions as an attachment?
 Use default IREx instructions only Attach additional instructions

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]

SHOW MORE

Continue →

IREx Project Settings

Confirm Site Instructions for completing the Single IRB Process

Please confirm the instructions sites should receive when they are granted access to the study in IREx. This email is triggered from the Status Summary tab.

The following documents are included as an attachment, if applicable:

- Zip file of current sIRB approval documents

Would you like to send sites the default IREx instructions for completing the sIRB process or attach custom instructions?
 Use default IREx instructions Attach custom instructions

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]

SHOW MORE

Continue →

Sites Page – Adding Sites

Approvals | Status Summary | **Sites** | Contacts

Sites

[Return to participating sites list](#)

Add a participating site

Site

-- Select site --

- Goodall component - Good College of Education - FWA#303207059
- Goodall University Medical Center - FWA#78899657**
- GUMC component - Goodall Children's Hospital - FWA#78899657
- GUMC component - Goodall Psychiatry Hospital - FWA#78899657
- Grady Memorial - FWA#43412341
- Green Medical Center - FWA#123456777
- Hampshire University - FWA#

Approvals | Status Summary | **Sites** | Contacts

Sites

[Return to participating sites list](#)

Add a participating site

Site

Goodall University Medical Center - FWA#78899657

List study team contacts that will need access to IREx. Go to Status Summary to grant study access.

This Study Team engages additional sites

Personnel

Role	Email	First name	Last name
PI	<input type="text"/>	<input type="text"/>	<input type="text"/>
Coordinator	<input type="text"/>	<input type="text"/>	<input type="text"/>

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

The screenshot displays the 'Sites' page in the IREx Study Manager & sIRBs interface. The page has a navigation bar with tabs for 'Approvals', 'Status Summary', 'Sites', and 'Contacts'. The 'Sites' tab is active. Below the navigation bar, there is a table of sites with columns for 'Institution', 'Granted Access', 'PI (required)', and 'Coordinator'. The table lists five sites: Anderson Medical Center, Bridge University, Carnegie University, Peabody Institute of Medicine, and University of the Bay. Each site row includes a 'Granted Access' status (green checkmark for granted, red X for not granted), a 'PI (required)' field with a list of PIs, and a 'Coordinator' field with a list of coordinators. Action buttons for 'Contacts' and 'Email' are present for each site. A '+ Add Site' button is located in the top right corner. A tooltip message reads: 'To remove an approved site create a Site Closure'. Numbered callouts (1-5) highlight specific features: 1. '+ Add Site' button; 2. 'Contacts' button; 3. 'Granted Access' column; 4. Multiple PIs and coordinators for Bridge University; 5. 'Email' button.

Institution	Granted Access	PI (required)	Coordinator	Actions
Anderson Medical Center #54687921	✗	Anderson PI	+ Add Coordinator	Contacts, Email, [trash]
Bridge University #0120103	✓	PI Bridge PI Pete Bridge	Coordinator Bridge U Coord Bridge U New Coord Bridge Coord 2 Bridge	Contacts, Email, [trash]
Carnegie University #3232282999	✗	Carnegie PI	+ Add Coordinator	Contacts, Email, [trash]
Peabody Institute of Medicine #897645665	✓	Peabody PI	Peabody Coordinator Cory Coordinator	Contacts, Email, [trash]
University of the Bay #00012553	✗	Lead PI	UBay Coordinator Bay Uni Coordinator	Contacts, Email, [trash]

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

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.

IREx Study Manager & sIRBs

The screenshot shows the 'Status Summary' page in the IREx Study Manager. The table lists sites and their agreement status. A dropdown menu is open for the 'University of the Bay' site, showing options for 'Request Agreement(s)', 'IREx Access', 'Started 8/13/2023', and 'Notify & Grant Access'. A yellow circle with the number 1 highlights the 'Request Agreement(s)' option.

Site	Agreements	Reliance Decision	Local Consideration
Anderson Medical Center	2 / 3 Agreements Complete	Notify & Grant Access	
Bridge University	✓ Reliance Agreement SMART 2	Contacted 8/15/2023	
Carnegie University	✗ Indemnification Mellon LOI Update	Notify & Grant Access	
Peabody Institute of Medicine		Started 8/13/2023	0 / 3 Surveys Complete
University of the Bay	✉ Request Agreement(s)	Notify & Grant Access	

The screenshot shows an email titled 'Action Required: Please Complete Agreement(s) for sIRB study'. The email is from Lindsey Smith to IRBExchangeAdministrator. It includes an attachment 'LOI Template.docx' and a table of study details. A yellow circle with the number 2 highlights the email content.

Dear HRPP(s) and Site Investigator,

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

Field	Value
Study Title	Demo Study Title Here
Reviewing IRB	Mellon University Medical Center
Reviewing IRB Contact	Mellon Liaison (liaison@mellon.cdu)
Study Manager	Study Manager Mellon

As a first step towards relying on Mellon 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
OR	
Mellon Letter of Indemnification	Incomplete — The indemnification agreement is attached. Send questions and executed agreements to Mellon Liaison (liaison@mellon.cdu).
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal.	Complete
<i>This is a web-based platform, not a reliance agreement.</i>	

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,
Mellon Study Manager
sm@mellon.cdu

New Feature: Notify & Grant Access to Study Teams

IREx Study Manager & sIRBs

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Anderson Medical Center	2 / 3 Agreements Complete	Notify & Grant Access		
Bridge University	3 / 3 Agreements Complete	Contacted 6/15/2023		
Carnegie University	3 / 3 Agreements Complete	Notify & Grant Access		
Peabody Institute of Medicine	3 / 3 Agreements Complete	Started 6/13/2023	0 / 3 Surveys Complete	Not Approved
University of the Bay	2 / 3 Agreements Complete	Notify & Grant Access		

Notify & Grant Site Access

Notification Preview — Carnegie University will receive the email below

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	Demo IREx Study Title
Study Link	https://test.irex.com
Reviewing IRB	Mellon University
Reviewing IRB Contact	Mellon Liaison (j.liaison@mellon.edu)
Study Manager	Study Manager

Next Steps:

The overall/lead site approval is available. The file is attached, please contact the study submission and initiate the reliance process.

1. LOCAL HRPP facilitates agreement. The study requires the following items:
 - Agreement/Resource
 - SMART IRB Agreement: A national agreement supporting single IRB review.
 - Mellon Letter of Indemnification.
 - IRB Reliance Exchange (IREx): A documentation and communication platform.*This is a web-based platform, not a PDF.*
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,
Mellon Liaison
liaison@mellon.edu

Cancel Send now

(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

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.

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.	Complete
<i>This is a web-based platform, not a reliance agreement.</i>	

2. STUDY TEAM prepares local consent form and submits to local HRPP for review.

- If applicable for the study, review the approved informed consent template(s) in IREx and insert your site-specific information.
- 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:

- Register** to confirm your site's engagement on this study. *This is not an indication of reliance.*
- Confirm the Institutional Profile**
- 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.
- 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.
- 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

Notify & Grant Site Access

⚠ WAIT! We recommend granting site access after the Overall/Lead Site approval is uploaded.

Why wait?

- Sites can be granted access now, but they will not see any documents.
- The Overall/Lead Site approval documents are only visible after they are approved and published in IREx.

Notification Preview — Albert Einstein College of Medicine will receive the email below

Dear HRPP(s) and Study Team,

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

Naya McKinney has been listed as an investigator at **Albert Einstein College of Medicine (FWA: 00005001)**. All study team members included on this email now have access to the study in IREx.

Study Title	General bug with sm in irex setup
Study Link	https://test.irbexchange.org/feature-branch/public/s/project/6295470
Reviewing IRB	Central Ohio Medical Center

SHOW MORE

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.

Notify & Grant Site Access

⚠ Notice: There's a **Study-Wide Amendment: Full Board** approval that has been started, but not yet published.

- To send the previously approved documents related to **Protocol Version: 3** approved on **9/1/2022**, press 'Send now'.
- To send the documents from the approval *in progress*, close this dialog and return after that has been uploaded and published.

Notification Preview — Test Site 3 will receive the email below

Dear HRPP(s) and Study Team,

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

Jill Jones has been listed as an investigator at **Test Site 3 (FWA: 00001234)**. All study team members included on this email now have access to the study in IREx.

Study Title	IREx Admin Test
Study Link	https://www.irbexchange.org/s/project/439
Reviewing IRB	Test Site 1

SHOW MORE

Cancel - wait to send **Send now**

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.

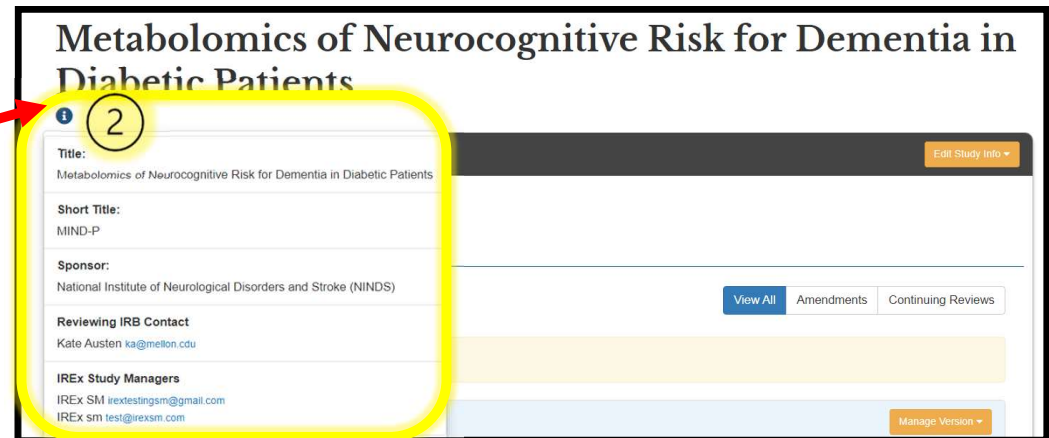
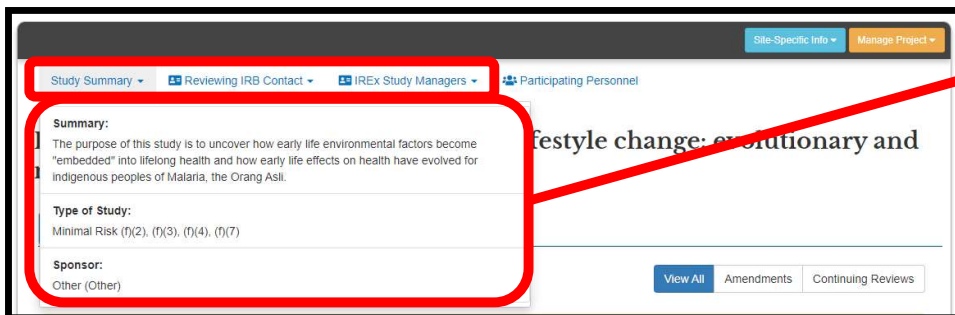
IREx Study Page Redesign

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 .

The screenshot displays the IREx Study Manager interface. On the left is a sidebar for 'Mellon Univ. Med Ctr GETTING STARTED' with options: 'Add Participating Sites', 'Grant Site Access', 'View Site Progress on Status Summary', and 'Upload Relying Site Approval'. The top navigation bar is highlighted in yellow and contains: 'Approvals', 'Status Summary', 'Sites', 'Contacts', and 'Edit Study Info'. The main content area is titled 'Approvals' and includes tabs for 'Study-wide IRB Approvals' and 'Approval History'. It shows 'SIRB: Mellon University Medical Center' and 'Lead Site: Mellon University Medical Center' with a 'View All' button and tabs for 'Amendments' and 'Continuing Reviews'. Below this is 'Protocol Version: 1, 7/7/2023' with a 'Manage Version' button. A section for 'Initial Study: Full Board (approved 7/7/2023)' is marked as 'Current'. At the bottom, there are two columns: 'Study Info' and 'Key Dates'.

Study Info		Key Dates	
Role:	Reviewing IRB	Submitted:	7/5/2023
IRB Number:	07072023	Pre-Reviewed:	
Type of Study:	Greater than Minimal Risk	Reviewed:	7/7/2023
Reviewing IRB Decision:	approved	Approved:	7/7/2023
Submission Type:	Initial Study: Full Board	Expires:	7/7/2024
Review Cycle:	12 mo		

New Navigation Bar: Approvals Page

IREx Study Manager & sIRBs

This screenshot shows the top navigation bar of the IREx Study Manager. The main navigation items are 'Study Summary', 'Reviewing IRB Contact', 'IREx Study Managers', and 'Participating Personnel'. A red box highlights the 'Study-wide IRB Approvals' and 'Approval History' tabs. A red arrow points from this box to the right-hand screenshot. Below the navigation bar, the study title 'Demo IREx Study Title Here' is displayed. The 'Study-wide IRB Approvals' tab is selected, showing the study name 'SIRB: Mellon University Medical Center' and 'Lead Site: Mellon University Medical Center'. The 'Protocol Version: 1, 6/12/2023' is also visible, along with a 'Current' status indicator for the 'Initial Study: Full Board'.

Type	Name	Date Approved
Protocol 1, 6/12/2023	PROTOCOL_v1.docx	6/13/2023
IRB Approval Documentation	IRB APPROVAL_Leadsite.docx	6/13/2023
IRB Application	IRB APPLICATION.docx	6/13/2023
Consents & Assents	CONSENT FORM - Adult.docx	6/13/2023
Measures	Policy-II.F.pdf	6/13/2023

This screenshot shows the detailed 'Approvals' page. The navigation bar includes 'Approvals', 'Status Summary', 'Sites', and 'Contacts'. The 'Approvals' tab is selected, and the 'Study-wide IRB Approvals' sub-tab is highlighted. The page displays the study name 'SIRB: Mellon University Medical Center' and 'Lead Site: Mellon University Medical Center'. The 'Protocol Version: 1, 6/12/2023' is shown, along with a 'Current' status indicator for the 'Initial Study: Full Board'.

Study Info

Role:	Reviewing IRB	Submitted:	6/12/2023
IRB Number:	123123	Pre-Reviewed:	6/13/2023
Type of Study:	Greater than Minimal Risk	Reviewed:	6/13/2023
Reviewing IRB Decision:	approved	Approved:	6/13/2023
Submission Type:	Initial Study: Full Board	Expires:	6/13/2024
Review Cycle:	12 mo		

Global Documents

Type	Name	Date Approved
Protocol 1, 6/12/2023	PROTOCOL_v1.docx	6/13/2023
IRB Approval Documentation	IRB APPROVAL_Leadsite.docx	6/13/2023
IRB Application	IRB APPLICATION.docx	6/13/2023
Consents & Assents	CONSENT FORM - Adult.docx	6/13/2023
Measures	Policy-II.F.pdf	6/13/2023

New Navigation Bar: Status Summary Page

IREx Study Manager & sIRBs

Participant Status Summary

Site	Reliance Agreement	Indemnification	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Anderson Medical Center	SMART 2	Mellon LOI Update	✓	Notify HRPP		
Bridge University	SMART 2	Mellon LOI	✓	Contacted 6/15/2023		
Peabody Institute of Medicine	SMART 1	Mellon LOI	✓	Started 6/13/2023	0 / 3 Surveys Complete	Not Approved
University of the Bay	SMART 1	Mellon LOI Update	✓	Notify HRPP		

Status Summary

Site	Agreements	Reliance Decision	Local Considerations	Approval Status
Bridge University	3 / 3 Agreements Complete	Contacted 7/13/2023		
Carnegie University	3 / 3 Agreements Complete	Completed 7/10/2023	3 / 3 Surveys Complete	Approved
Middle-earth College of Agriculture	2 / 3 Agreements Complete	Notify & Grant Access		
Peabody Institute of Medicine	Reliance Agreement SMART 2 Indemnification Mellon LOI IREx Access	Started 7/13/2023	0 / 3 Surveys Complete	Not Approved

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.

Site	Agreements	Reliance Decision ?	Local Considerations
Anderson Medical Center	2 / 3 Agreements Complete	Notify & Grant Access	
Bridge University	3 / 3 Agreements Complete	Contacted 6/15/2023	
Carnegie University	3 / 3 Agreements Complete	Notify & Grant Access	
Evan University Medical Center	0 / 3 Agreements Complete	Notify & Grant Access	
Peabody Institute of Medicine	3 / 3 Agreements Complete	Started 6/13/2023	0 / 3 Surveys Complete

Reliance Decision Legend	
Awaiting Confirmation	Reviewing IRB must accept SSRP
Add PI Info	Required PI information is not yet entered
Notify & Grant Access	Site has NOT joined IREx so cannot be granted access
Notify & Grant Access	Site has IREx access and can be notified of study access
Contacted	Site has access; click to re-send notification
Started	HRPP has accessed study in IREx
Completed	HRPP has ceded review

New Navigation Bar: Sites Page

IREx Study Manager & sIRBs

Institution	Granted Access	PI (required)	Coordinator	Contacts	Email
Anderson Medical Center #54687921	×	Anderson PI	+ Add Coordinator	Contacts	Email
Bridge University #0120103	✓	PI Bridge PI Pete Bridge	Coordinator Bridge U Coordy Bridge U New Coord Bridge Coord 2 Bridge	Contacts	Email
Carnegie University #3232282999	×	Carnegie PI	+ Add Coordinator	Cont	To remove an approved site create a Site Closure
Peabody Institute of Medicine #897645665	✓	Peabody Pi	Peabody Coordinator Cory Coordinator	Contacts	Email
University of the Bay #00012553	×	Lead PI	UBay Coordinator Bay Uni Coordinator	Contacts	Email

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.

Participating Study Personnel with Access to IREx

The individuals on this list have access to the study in IREx and can also give access to other members at their site.

Download CSV

+ Grant Site Coordinator Access

Demo IREx Study Title

Site	Role	Name	Email
Bridge University	PI	PI Bridge	pi@bridge.cdu
Mellon University Medical Center	IREx Study Manager	Study Manager Mellon	sm@mellon.xx
Mellon University Medical Center	PI	Mellon PI	pi@mellon.cdu
Mellon University Medical Center	Lead Liaison	Mellon Liaison	liaison@mellon.cdu
Peabody Institute of Medicine	PI	Peabody PI	pi@peabody.cdu
Peabody Institute of Medicine	Coordinator	Cory Coordinator	coordinator@peabody.cdu
Peabody Institute of Medicine	Coordinator	Peabody Coordinator	studycoord@peabody.cdu

Showing 1 to 7 of 7 entries

OK

Contacts

The individuals on this list have access to the study in IREx and can also give access to other members at their site.

Download CSV

Site	Role	Name	Email
Bridge University	PI	PI Bridge	pi@bridge.cdu
Mellon University Medical Center	IREx Study Manager	Study Manager Mellon	sm@mellon.xx
Mellon University Medical Center	PI	Mellon PI	pi@mellon.cdu
Mellon University Medical Center	Lead Liaison	Mellon Liaison	liaison@mellon.cdu
Peabody Institute of Medicine	PI	Peabody PI	pi@peabody.cdu
Peabody Institute of Medicine	Coordinator	Cory Coordinator	coordinator@peabody.cdu
Peabody Institute of Medicine	Coordinator	Peabody Coordinator	studycoord@peabody.cdu

Showing 1 to 7 of 7 entries

Study Team Navigation Bar

Relying Sites only have the **Approvals**, **Status Summary** pages, and a **My Site Info** menu. *Relying Site Study Team – PI View*

Approvals | **Status Summary** | **My Site Info**

GETTING STARTED

- Complete/Attest to PI Survey
- Add / Edit Study Team Access

Approvals

Study-wide IRB Approvals

SIRB: Mellon University Medical Center | View All | Amen

Lead Site: Mellon University Medical Center

Protocol Version: 1, 7/7/2023

Initial Study: Full Board (approved 7/7/2023) **Current**

Study Info		Key Dates	
Role:	Reviewing IRB	Submitted:	7/5/2023
IRB Number:	07072023	Pre-Reviewed:	
Type of Study:	Greater than Minimal Risk	Reviewed:	7/7/2023
Reviewing IRB Decision:	approved	Approved:	7/7/2023
Submission Type:	Initial Study: Full Board	Expires:	7/7/2024
Review Cycle:	12 mo		

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

Study Summary | Reviewing IRB Contact | IREx Study Managers | Site-Specific Info

Demo Study Title Here

Approval History | Submit

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

View All | Amendments | Continuing Reviews

Protocol Version: 1, 7/7/2023

Initial Study: Expedited (approved 7/10/2023) Current

Study Info

IRB Number: [redacted]
Reviewing IRB Decision: approved
Review Cycle: 12 mo

Key Dates

Submitted for Local Review: [redacted]
Local Review Conducted: 7/10/2023
Local Review Completed: 7/7/2023
Reviewing IRB Submitted: 7/7/2023
Reviewing IRB Reviewed: 7/10/2023
Reviewing IRB Approved: 7/10/2023

Documents Download All

Global Documents Download

Type	Name	Date Approved
Protocol 1, 7/7/2023	PROTOCOL_v1.docx	7/7/2023
IRB Approval Documentation	IRB APPROVAL_Leadsite.docx	7/7/2023
IRB Application	IRB APPLICATION.docx	7/7/2023
Consents & Assents	CONSENT FORM - Adult.docx	7/7/2023
Consents & Assents	CONSENT FORM - Assent.docx	7/7/2023

Site Specific Documents Download

Type	Name	Date Approved
IRB Approval Documentation	IRB APPROVAL_RelyingSite1.docx	7/10/2023
Consents & Assents	CONSENT FORM - Adult - R1.docx	7/10/2023
Consents & Assents	CONSENT FORM - Assent - R1.docx	7/10/2023

Approvals | Status Summary | My Site Info

Approvals

Approval History

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

View All | Amendments | Continuing Reviews

Protocol Version: 1, 7/7/2023

Initial Study: Expedited (approved 7/10/2023) Current

Study Info

IRB Number: [redacted]
Type of Study: Greater than Minimal Risk
Reviewing IRB Decision: approved
Review Cycle: 12 mo

Key Dates

Submitted for Local Review: [redacted]
Local Review Conducted: [redacted]
Local Review Completed: 7/10/2023
Reviewing IRB Submitted: 7/7/2023
Reviewing IRB Reviewed: 7/10/2023
Reviewing IRB Approved: 7/10/2023

Documents Download All

Global Documents Download

Type	Name	Date Approved
Protocol 1, 7/7/2023	PROTOCOL_v1.docx	7/7/2023
IRB Approval Documentation	IRB APPROVAL_Leadsite.docx	7/7/2023
IRB Application	IRB APPLICATION.docx	7/7/2023
Consents & Assents	CONSENT FORM - Adult.docx	7/7/2023
Consents & Assents	CONSENT FORM - Assent.docx	7/7/2023

Site Specific Documents Download

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Relying Site's Approvals Page

Relying Site HRPP & Study Teams

Study Summary | Reviewing IRB Contact | IREx Study Managers | Site-Specific Info

Demo Study Title Here

Approval History | Submit

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

View All | Amendments | Continuing Reviews

Protocol Version: 1, 7/7/2023

Initial Study: Expedited (approved 7/10/2023) **Current**

Study Info

IRB Number: [redacted]
Reviewing IRB Decision: approved
Review Cycle: 12 mo

Key Dates

Submitted for Local Review: [redacted]
Local Review Conducted: 7/10/2023
Local Review Completed: 7/7/2023
Reviewing IRB Submitted: 7/7/2023
Reviewing IRB Reviewed: 7/10/2023
Reviewing IRB Approved: 7/10/2023

Documents | Download All

Global Documents | Download

Type	Name	Date Approved
Protocol 1, 7/7/2023	PROTOCOL_v1.docx	7/7/2023
IRB Approval Documentation	IRB APPROVAL_Leadsite.docx	7/7/2023
IRB Application	IRB APPLICATION.docx	7/7/2023
Consents & Assents	CONSENT FORM - Adult.docx	7/7/2023
Consents & Assents	CONSENT FORM - Assent.docx	7/7/2023

Site Specific Documents | Download

Type	Name	Date Approved
IRB Approval Documentation	IRB APPROVAL_RelyingSite1.docx	7/10/2023
Consents & Assents	CONSENT FORM - Adult - R1.docx	7/10/2023
Consents & Assents	CONSENT FORM - Assent - R1.docx	7/10/2023

Approvals | Status Summary | My Site Info

Approvals

Approval History

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

View All | Amendments | Continuing Reviews

Protocol Version: 1, 7/7/2023

Initial Study: Expedited (approved 7/10/2023) **Current**

Study Info

IRB Number: [redacted]
Type of Study: Greater than Minimal Risk
Reviewing IRB Decision: approved
Review Cycle: 12 mo

Key Dates

Submitted for Local Review: [redacted]
Local Review Conducted: [redacted]
Local Review Completed: 7/10/2023
Reviewing IRB Submitted: 7/7/2023
Reviewing IRB Reviewed: 7/10/2023
Reviewing IRB Approved: 7/10/2023

Documents | Download All

Global Documents | Download

Type	Name	Date Approved
Protocol 1, 7/7/2023	PROTOCOL_v1.docx	7/7/2023
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Consents & Assents	CONSENT FORM - Adult - R1.docx	7/10/2023
Consents & Assents	CONSENT FORM - Assent - R1.docx	7/10/2023

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



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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?**



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Next Call: October 20, 2023