



# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR HRPPS

April 17, 2020

- User Training
- Study Support

*Natalie Dilts*



- System Development
- Data analysis

*Asri Mumpuni*



- Project Manager

*Emily Serdoz*



- Site Onboarding
- Study Support

*Bridget Swindell*

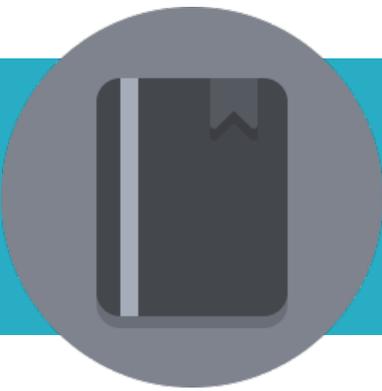


- User Support
- Study Support

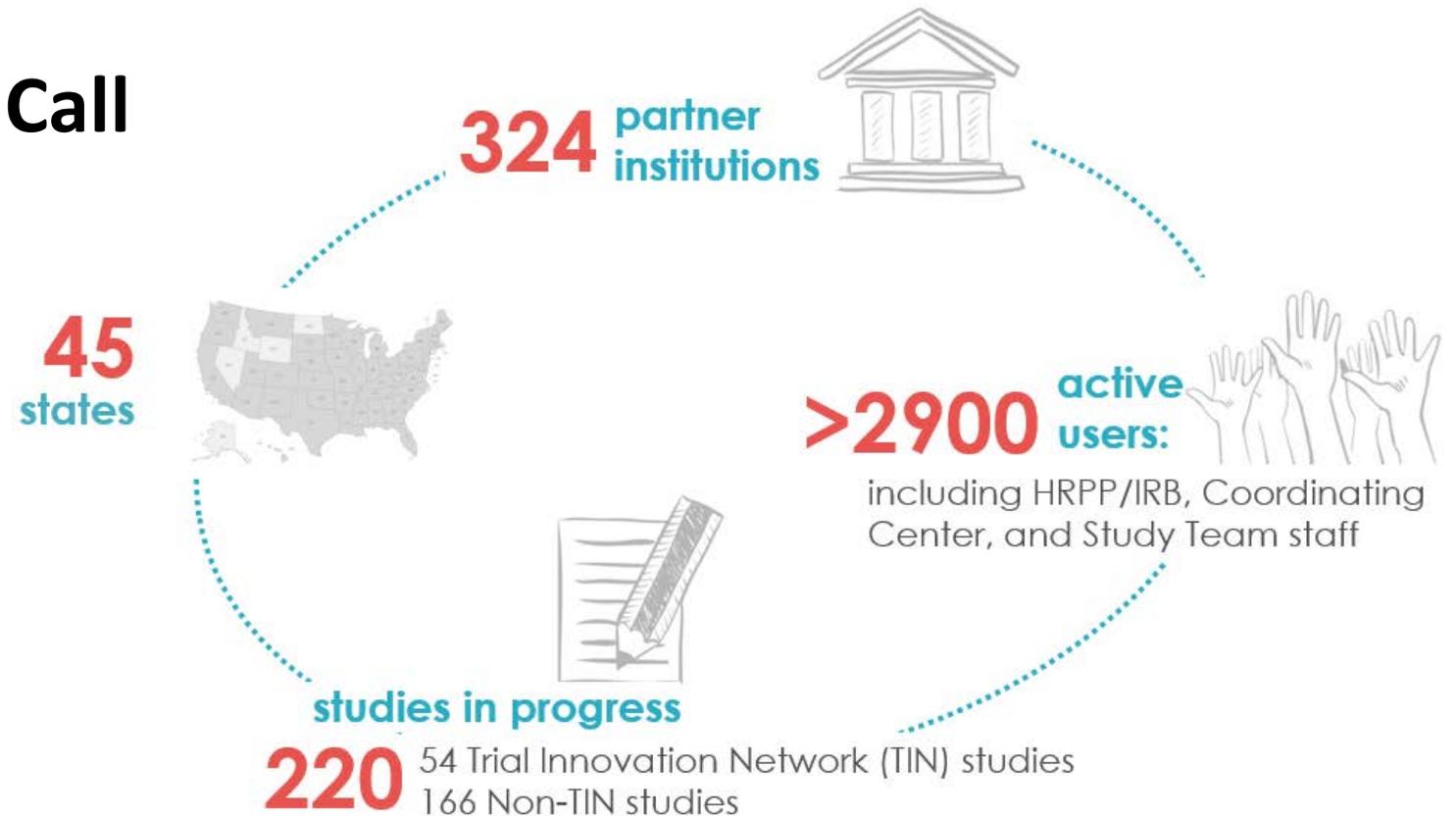
*Linda Tan*



# QUARTERLY CALL AGENDA



- Welcome
- Reminders from the Last Call
- New System Features
- Next Call



# Reminders from the Last Call

# REMINDERS FROM THE LAST CALL



## **IREx API available for Single IRBs to integrate with their local electronic system**

1. **Push** a new study & lead site approval from your e-IRB system → to IREx
2. **Pull** site-specific documentation into your e-IRB system ← from IREx
3. **Push** site approvals from your e-IRB system → to IREx

**Learn More:** <https://www.irbexchange.org/p/irex-integration-api/>

**Get Connected:** Contact [admin@IRBExchange.org](mailto:admin@IRBExchange.org) to schedule a call with your IT folks & the IREx Developers

# REMINDERS FROM THE LAST CALL



## The Reviewing IRB can edit an existing approval

### An Evidenced Based Approach to Alleviating Single IRB Headaches

Study-wide IRB Approvals | Site-specific IRB Approvals | Status Summary

Protocol Version: 2019-08-01 Manage Version

**SIRB: Carnegie University Medical Center**  
Lead Site: Peabody Institute of Medicine

Initial Study: Expedited (exp. 8/13/2020) Current

Edit review | Site approvals

**Study Info** | **Key Dates**

Role:	Reviewing IRB	Submitted:	8/9/2019
IRB Number:	201908091	Pre-Reviewed:	8/12/2019
Status:	approved	Reviewed:	8/14/2019
Submission Type:	Initial Study: Expedited	Approved:	8/14/2019
Review Cycle:	12 mo	Expires:	8/13/2020

**Documents**

Type	Name	Size
Consent Forms	waived	-
Determination Letter	<a href="#">DETERMINATION LETTER_Initial Review.docx</a>	12 KB
IRB Application	<a href="#">IRB APPLICATION.docx</a>	12 KB
Protocol [2019-08-01]	<a href="#">PROTOCOL_09_29_2017.docx</a>	12 KB

Showing 1 of 4 of 4 entries  
Download all

### Study Managers are notified of updates

EBA 2 SIRB -- IREx: Reviewing IRB updated Lead Site approval

Serdoz, Emily Sheffer  
To: Serdoz, Emily Sheffer

Reply Reply All Forward More

Wed 1/15/2020 1:55 PM

Carnegie University Medical Center updated the Study-wide IRB Approval in IREx for the study below:

TITLE: An Evidence-Based Approach to Alleviating Single IRB Headaches (EBA 2 SIRB)

TYPE OF REVIEW: Initial Study: Expedited

STUDY LINK: [Click here to view the study](#)

UPDATED: Changes are noted below.

Field	Previous	Updated
Date Submitted	01/01/2020	12/03/2019
Date Pre Reviewed	01/02/2020	12/10/2019
Date Reviewed	01/03/2020	12/23/2019
Expiration Date	01/05/2021	12/02/2021
New Document		Recruitment.docx

**Important:** These changes were not communicated to Relying Sites. If you are a Relying Site, please contact the IRB to update your approval in IREx to notify them of the updated approval.

*Thank you,  
The IREx Team*

### Relying Sites are notified if their approval is updated

EBA 2 SIRB -- IREx: Updated Approval For Your Site

Serdoz, Emily Sheffer  
To: Serdoz, Emily Sheffer

Reply Reply All Forward More

Wed 1/15/2020 1:57 PM

Dear Liaisons and Study Contacts,

Carnegie University Medical Center updated the approval for your institution, Mellon University Medical Center, in IREx for the study below:

**Study Title:** An Evidence-Based Approach to Alleviating Single IRB Headaches (EBA 2 SIRB)

**Study Link:** <https://staging.irbexchange.org/study/index/?proj=132975>

**Updated:** Changes are noted below.

Field	Previous	Updated
Added Document		Flyer.png
Added Document		CONSENT FORM Spanish.docx

Your updated approval documents are available in IREx. If you have any questions about your approval or future submissions, please contact the IREx Study Manager or Reviewing IRB. If needed, contact information for the Study Manager is provided on your study page, just above the study title.

*Thank you for using IREx,  
The IREx Team*

# REMINDERS FROM THE LAST CALL



## New question on Institutional Profile

### WHERE:

Section 3: LOCAL INSTITUTIONAL REQUIREMENTS FOR INVESTIGATORS WHEN RELYING ON ANOTHER IRB.

### WHAT:

“After your HRPP has provided local reviews to the SIRB, does your IRB or HRPP require a submission of your site’s SIRB approved documents before your site is activated/enrollment can begin?”

### WHY:

To help coordinating centers / lead study teams know when a site is fully activated to begin enrollment.

# SITE SPECIFIC SSRPS AVAILABLE FOR REVIEWING IRB TO DOWNLOAD



## Status Summary Tab

Study-wide IRB Approvals

Site-specific IRB Approvals

Status Summary

Export Data

## Participant Status Summary

Search:

Export Local Considerations

Export Status Summary Tab

LocalConsiderationsExport > Mellon Univ Med Ctr

Name

[Redcap Institutional Profile Survey Responses]site\_profile\_survey\_response

[Redcap LC HRPP Survey Responses]HRPP\_survey\_response

[Redcap LC PI Survey Responses]PI\_survey\_response

[Redcap Reliance Survey Responses]Study Specific Reliance Plan - Mellon

Site	SMART IRB	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Baystate Health, Inc	✓	✓	Started 1/14/2020	0 / 3 Sur	
Hartford College of Medicine	✓	✓	Contacted 1/14/2020		
Mellon University Medical Center	✓	✓	Completed 1/14/2020	3 / 3 Sur	

### Study-Specific Reliance Plan (SSRP)

Reviewing IRB

Jefferson University

✓ created SSRP

contact liaisons

Relying Sites

Mellon University Medical Center

✓ accepted SSRP on 01/14/2020

contact liaisons

Documents

Letter of Reliance

SSRP Response

**New System Features!**

# NEW REGISTRATION PROCESS FOR ALL RELYING HRPPS



## *What is registration?*

- Registration confirms your FWA is engaged.
- Registration gives your site access to the study to provide reliance documentation.
- Registration is ***NOT*** an indication of reliance.

**PROBLEM:** HRPPs are currently unable to change the information for their PI or FWA on registration.

## CURRENT REGISTRATION PAGE

Participate in Study

A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM)

Registration Please select one of your sites to register. You will be able to register the remaining sites on another page.

Hartford College of Medicine

Protocol The current version of the protocol is 1. [download protocol](#)

**i** If you have a different version of the protocol, contact your local investigator after registering.

Participate Cancel

# NEW QUESTIONS ON STUDY REGISTRATION



*Starting Tuesday, April 21<sup>st</sup>:*



Confirm the FWA & PI are correct



Clarify the FWA for the PI



Change the FWA engaged by the PI



Change the PI engaged for your FWA

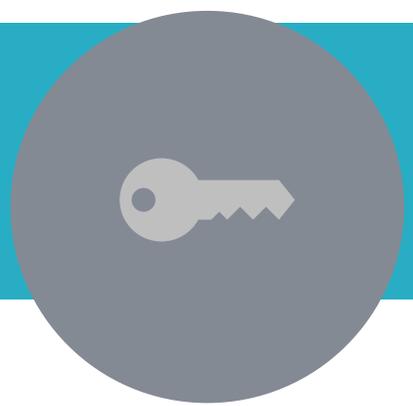


Indicate your FWA is not engaged for the study



Add an FWA for the PI

# REGISTRATION – Confirm the FWA & PI are correct



## Scenario #1

Registration for

### IREx Quarterly Features Call Demo



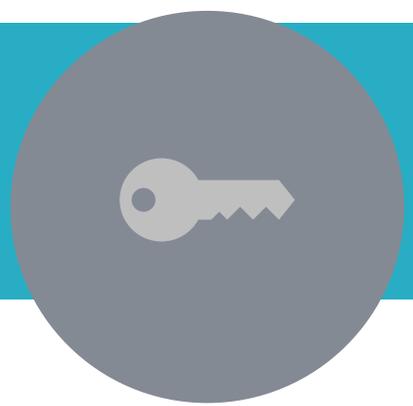
Does **Riaan Browne** engage **Carnegie University Medical Center FWA #12345678** or its components for this study?

Yes

No

 **Required**

# REGISTRATION – Clarify the FWA for the PI



## Scenario #1

**?** Does **Riaan Browne** engage **Carnegie University Medical Center FWA #12345678** or its components for this study?  Yes  No

**Confirm PI Details**

**Email address**

**First Name**  **Last Name**

**Confirm Your Engaged FWAs / Components**

The SIRB or Study Manager identified your site/FWA as shown below. Edit the information if it is incorrect. If one of your FWA components is part of this study but is not listed below: 1) Cancel this registration 2) Go to the Homepage and use the "Components" button to add it 3) Return to register using the component you added

- Carnegie University Medical Center - FWA#12345678
- Carnegie U Med Ctr component - Carnegie Children's Hospital - FWA#12345678

**?** Does **Riaan Browne** engage **OTHER SITES / FWAs** for this study, to your knowledge?  Yes  No **Required**



If no, **Submit** and your site is registered & PI given access

# REGISTRATION – Change the FWA for the PI



## Scenario #2

**?** Does **Riaan Browne** engage **Carnegie University Medical Center FWA #12345678** or its components for this study?  Yes  No

**?** Does **Riaan Browne** engage **OTHER SITES / FWAs** for this study, to your knowledge?  Yes  No

**Confirm PI Details**

**Email address**  
riann@carnegie.cdu

**First Name** **Last Name**  
Riaan Browne

**Other Sites / FWAs Engaged By This PI**

List any other sites / FWAs that may be engaged by this study team for this study. IREx will notify the HRPP Liaison(s) to confirm engagement.

- Carnegie University - FWA#3232282999
- Carnegie University Medical Center - FWA#12345678
- Carnegie U Med Ctr component - Carnegie Children's Hospital - FWA#12345678
- Midwest Univ Med Ctr component - Carnegie University Medical Center - FWA#00951753



# REGISTRATION – Change the PI engaged for your FWA



## Scenario #3

**?** Does **Riaan Browne** engage **Carnegie University Medical Center FWA #12345678** or its components for this study?  Yes  No

**?** Does **Riaan Browne** engage OTHER SITES / FWAs for this study, to your knowledge?  Yes  No

**?** Does ANOTHER PI engage **Carnegie University Medical Center FWA #12345678** or its components for this study?  Yes  No

**Confirm PI Details**

**Email address**

Email

**▲ Required**

**First Name**  **Last Name**

**▲ Required** **▲ Required**

**Confirm Your Engaged FWAs / Components**

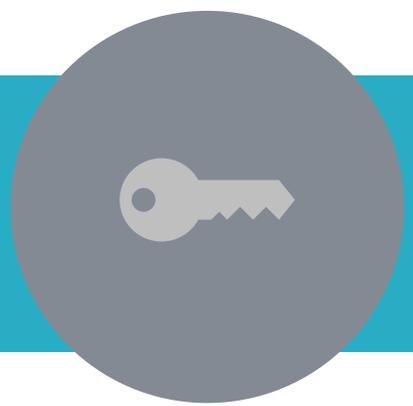
The SIRB or Study Manager identified your site/FWA as shown below. Edit the information if it is incorrect. If one of your FWA components is part of this study but is not listed below: 1) Cancel this registration 2) Go to the Homepage and use the "Components" button to add it 3) Return to register using the component you added

Carnegie University Medical Center - FWA#12345678

Carnegie U Med Ctr component - Carnegie Children's Hospital - FWA#12345678

# REGISTRATION –

## Indicate your FWA is not engaged for the study



### Scenario #4

**?** Does **Riaan Browne** engage **Carnegie University Medical Center FWA #12345678** or its components for this study?  Yes  No

---

**?** Does **Riaan Browne** engage OTHER SITES / FWAs for this study, to your knowledge?  Yes  No

---

**?** Does ANOTHER PI engage **Carnegie University Medical Center FWA #12345678** or its components for this study?  Yes  No

**Carnegie University Medical Center FWA#12345678** is not engaged in research for this study.

Please briefly describe why your FWA is not engaged for this study. You will no longer receive study notifications.

**▲ Required**

For guidance determining whether your site is engaged in research, [go here](#).

# REGISTRATION: Add an FWA for the PI



## Scenario #5

**?** Does **Riaan Browne** engage **Carnegie University Medical Center FWA #12345678** or its components for this study?  Yes  No

**Confirm PI Details**

**Email address**

**First Name**  **Last Name**

**Confirm Your Engaged FWAs / Components**

The SIRB or Study Manager identified your site/FWA as shown below. Edit the information if it is incorrect. If one of your FWA components is part of this study but is not listed below: 1) Cancel this registration 2) Go to the Homepage and use the "Components" button to add it 3) Return to register using the component you added

- Carnegie University Medical Center - FWA#12345678
- Carnegie U Med Ctr component - Carnegie Children's Hospital - FWA#12345678

**?** Does **Riaan Browne** engage **OTHER SITES / FWAs** for this study, to your knowledge?  Yes  No

**Other Sites / FWAs Engaged By This PI**

List any other sites / FWAs that may be engaged by this study team for this study. IREx will notify the HRPP Liaison(s) to confirm engagement.

- Carnegie University - FWA#3232282999

**Designate Combo Site Primary**

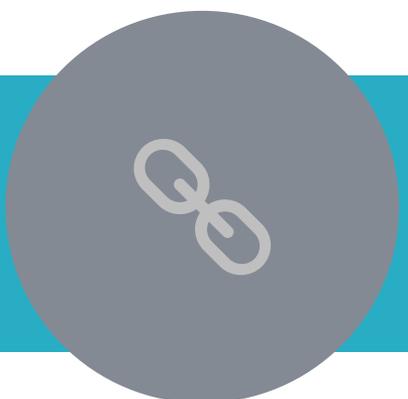
Please identify the Primary HRPP for this Combo Site

**About Combo Sites**  
Combo Sites are created when investigators engage multiple sites/FWAs.

Each HRPP must complete their Institutional Profile and indicate reliance. If local considerations are captured in IREx, the Primary HRPP must complete the HRP Survey and validate the PI Survey. Non-primary HRPPs can defer to the Primary HRPP's answers to the HRP survey or respond separately. Additionally, non-primary HRPPs can view, but not change, the PI Survey responses.

 This creates a "Combo Site"

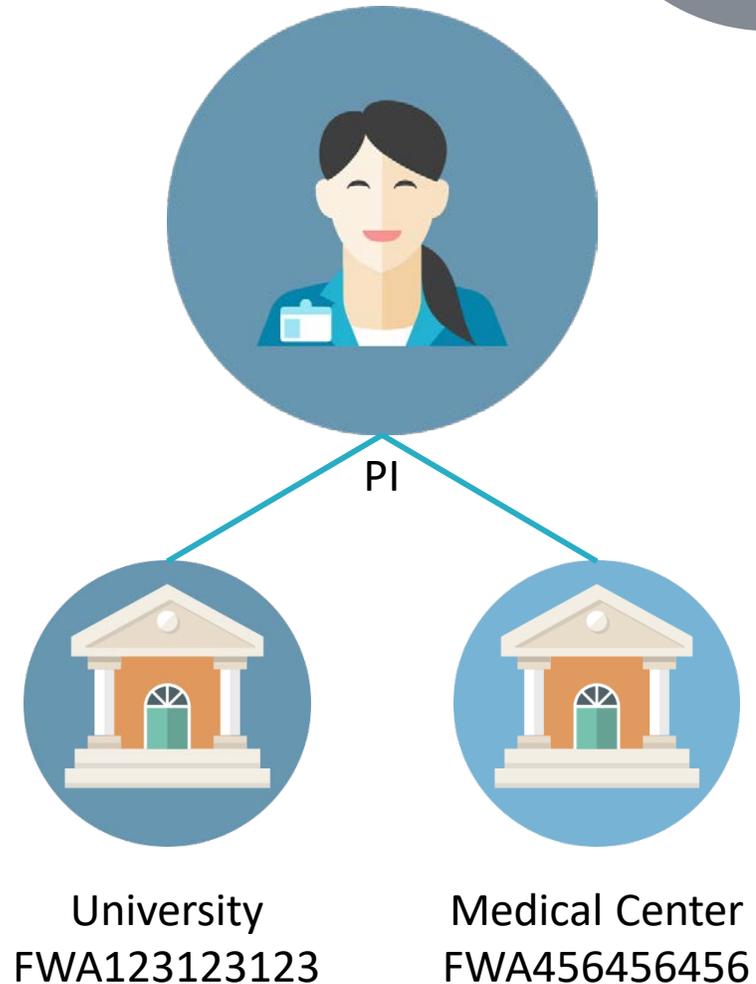
# What is a Combo Site?



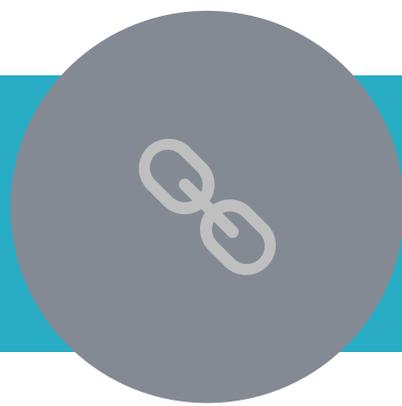
A **Combo Site**  occurs when **one investigator or study team** engages **multiple FWAs** for a study

## CHALLENGES:

1. sIRB needs reliance documentation (cede decision + local considerations) from all engaged FWAs/sites
2. Sites could not be identified as Combos in IREx



# Reliance Documentation for Combo Sites



- Combo Sites have similar reliance documentation as non-combo sites.
- Combo Sites have a self-identified “Primary” who assumes responsibility for the PI Survey & serves as the primary POC.

Documentation	Primary HRPP	Non-Primary HRPP(S)
Reliance Decision	X	X
Institutional Profile	X	X
HRP Survey	X	<i>Option to defer to Primary HRPP's responses</i>
PI Survey	<b>One PI survey</b> <i>Validated by Primary HRPP, viewable by Non-Primary HRPP(s)</i>	
Approval Documents from sIRB	One set of approval documents	

# REGISTRATION: Add an FWA for the PI



**?** Does **Riaan Browne** engage **Carnegie University Medical Center FWA #12345678** or its components for this study?  Yes  No

**Confirm PI Details**

**Email address**

**First Name**  **Last Name**

**Confirm Your Engaged FWAs / Components**

The SIRB or Study Manager identified your site/FWA as shown below. Edit the information if it is incorrect. If one of your FWA components is part of this study but is not listed below: 1) Cancel this registration 2) Go to the Homepage and use the "Components" button to add it 3) Return to register using the component you added

- Carnegie University Medical Center - FWA#12345678
- Carnegie U Med Ctr component - Carnegie Children's Hospital - FWA#12345678

**?** Does **Riaan Browne** engage **OTHER SITES / FWAs** for this study, to your knowledge?  Yes  No

**Other Sites / FWAs Engaged By This PI**

List any other sites / FWAs that may be engaged by this study team for this study. IREX will notify the HRPP Liaison(s) to confirm engagement.

- Carnegie University - FWA#3232282999

**Designate Combo Site Primary**

Please identify the Primary HRPP for this Combo Site

**About Combo Sites**  
Combo Sites are created when investigators engage multiple sites/FWAs.

Each HRPP must complete their Institutional Profile and indicate reliance. If local considerations are captured in IREX, the Primary HRPP must complete the HRP Survey and validate the PI Survey. Non-primary HRPPs can defer to the Primary HRPP's answers to the HRP survey or respond separately. Additionally, non-primary HRPPs can view, but not change, the PI Survey responses.



This creates a "Combo Site"

# REGISTRATION – Creating a Combo Site



**Starting Tuesday, April 21<sup>st</sup>:**

**?** Does **Riaan Browne** engage OTHER SITES / FWAs for this study, to your knowledge?  Yes  No

**Other Sites / FWAs Engaged By This PI**

List any other sites / FWAs that may be engaged by this study team for this study. IREx will notify the HRPP Liaison(s) to confirm engagement.

Search by name or FWA number

Carnegie University - FWA#3232282999

**Designate Combo Site Primary**

Please identify the Primary HRPP for this Combo Site

**About Combo Sites**  
Combo Sites are created when investigators engage multiple sites/FWAs.

Each HRPP must complete their Institutional Profile and indicate reliance. If local considerations are captured in IREx, the Primary HRPP must complete the HRP Survey and validate the PI Survey. Non-primary HRPPs can defer to the Primary HRPP's answers to the HRP survey or respond separately. Additionally, non-primary HRPPs can view, but not change, the PI Survey responses.

- If **you're the Liaison** for the FWA added, it is registered on the study.
- If **you're not the Liaison** for the FWA added, they are notified.



Dear Liaison(s) and Study Investigator,

Carnegie University (FWA: 3232282999) has been listed as a participating site in IREx for the following study:

**Title** IREx Quarterly Features Call Demo  
**Reviewing IRB** Mellon University Medical Center  
**Local Investigator** Riaan Browne

**What do I do with this email?**

**Study PI**

Many HRPPs require a local submission to initiate the single IRB (sIRB) process at their institution. Reach out to your Human Research Protection Program (HRPP)/IRB Liaisons on this email to find out what you need to do to initiate the sIRB process at your site.

**YOU CANNOT ACCESS THE STUDY IN IREX YET.**  
You receive access to the study in IREx after your HRPP logs in to confirm your site is participating and lists you on the study.

**HRPP Liaisons**

1) **NEW: Make sure your FWA is captured correctly in IREx!**  
[Login to IREx](#) to verify whether your site is engaged for this study and identified correctly. This may require contacting your local PI if they have not submitted the study for review. On the Study Registration Pop-up in IREx you can now:

- Correct the information if your site is engaged, but the incorrect FWA or PI is listed.
- Indicate your site is not engaged, if applicable. You will no longer receive email notifications about the study.

# REGISTRATION – Confirm you are a Combo Site



Registration for

## IREx Quarterly Features Call Demo



Does **Riaan Browne** engage **Carnegie University FWA #3232282999** or its components for this study?

Yes

No

**Required**



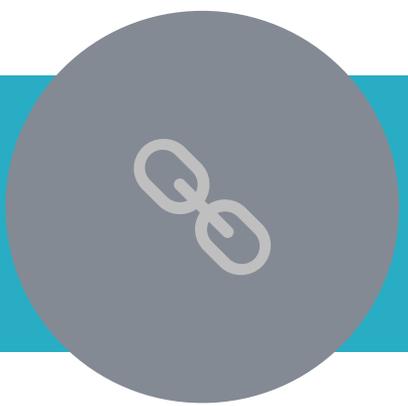
**Riaan Browne** engages the following sites in this study:

Carnegie University

Carnegie University Medical Center **Combo Primary**

**Note: If the sIRB or lead study team listed your site as a Combo Site, your registration will also look like this.**

# REGISTRATION – Confirm you are a Combo Site



**?** Does **Riaan Browne** engage **Carnegie University FWA #3232282999** or its components for this study?  Yes  No

**PI Details**

Riaan Browne - riann@carnegie.edu

**Confirm Your Engaged FWAs / Components**

The SIRB or Study Manager identified your site/FWA as shown below. Edit the information if it is incorrect. If one of your FWA components is part of this study but is not listed below: 1) Cancel this registration 2) Go to the Homepage and use the "Components" button to add it 3) Return to register using the component you added

Carnegie University - FWA#3232282999

---

**?** Does **Riaan Browne** engage **OTHER SITES / FWAs** for this study, to your knowledge?  Yes  No

---

**🔗** **Riaan Browne** engages the following sites in this study:

Carnegie University
Carnegie University Medical Center <b>Combo Primary</b>

# BUSINESS AS USUAL FOR THE PRIMARY



***Combo Site HRPPs can see the status of each site on the Status Summary Tab.***

Carnegie U Med Ctr  
GETTING STARTED

- Using IREx as the Participating Site HRPP
- Introducing Combo Sites
- Register
- Verify Study Team Access**
- Complete Agreements
- Confirm Institutional Profile
- Indicate Reliance
- Complete HRP Survey
- Remind PI To Complete PI Survey
- Awaiting Reviewing IRB Approval
- View Status Summary

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

## IREx Quarterly Features Call Demo

Getting Started | Study-wide IRB Approvals | Site-specific IRB Approvals | Status Summary

Protocol Version: 20200414

**Carnegie University Medical Center**

Initial Study: Full Board

Edit review | Delete review

Study Info | Key Dates

Role: Relying Site | Submitted for Local Review: | IRB Number: | Local Review Conducted: | Status: | Local Review Completed: | Review Cycle: | Expires:

Participant Status Summary

This page is view only. Complete your steps under GETTING STARTED

Site	SMART IRB	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Carnegie U Med Ctr   Carnegie Univ Carnegie University	x	✓	Started 4/15/2020	0 / 3 Surveys Complete	Not Approved
Carnegie U Med Ctr   Carnegie Univ Carnegie University Medical Center	✓	✓	Started 4/15/2020	0 / 3 Surveys Complete	Not Approved

# MULTISITE LIAISON STUDY DASHBOARD



Navigation tabs: **Your Sites** | Study-wide IRB Approvals | Site-specific IRB Approvals | Status Summary

**Manage Your Sites** Using IREx as the Participating Site HRPP

Institution	Study Status	Local Considerations	Reliance	Resources
Carnegie University	Approval Not Ready	2 / 3 Surveys Complete	View Reliance (SSRP)	Site-Specific Info
Carnegie University Medical Center	Approval Not Ready	2 / 3 Surveys Complete	View Reliance (SSRP)	Site-Specific Info

# NON-PRIMARY HRPPS & THE HRP SURVEY



 Carnegie Univ | Carnegie U Med Ctr

The sIRB needs **local considerations/reviews for Carnegie University - FWA#3232282999.**

As a non-primary HRPP for this combo site, please indicate how you would like to proceed:

Complete the survey from scratch.

Copy & edit responses from **Carnegie U Med Ctr**

**Carnegie University Medical Center - FWA#12345678**, the Primary HRPP for this combo site, has not completed their HRP Survey yet, so responses cannot be copied. You will be notified by email when their survey is completed.

Go back and complete the survey from scratch.

Ok. Wait for email notification.

# NON-PRIMARY HRPPS & THE HRP SURVEY



 Carnegie Univ | Carnegie U Med Ctr

The sIRB needs **local considerations/reviews for Carnegie University - FWA#3232282999.**

As a non-primary HRPP for this combo site, please indicate how you would like to proceed:

[Complete the survey from scratch.](#)

[Copy & edit responses from Carnegie U Med Ctr](#)

## Non-Primary HRPPs must add:

1. Local HRPP contact info
2. Consent language, if applicable
3. Signature

STUDY TEAM INFORMATION	
Local Site PI First Name <small>* must provide value</small>	<input type="text" value="Riaan"/>
Local Site PI Last Name <small>* must provide value</small>	<input type="text" value="Browne"/>
Local Site PI Email	<input type="text" value="riann@carnegie.edu"/>
Please review the planned list of personnel who will be engaged in human subjects research.	<input checked="" type="radio"/> Yes
	<input type="radio"/> No
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?	<input type="radio"/> Our institution delegates this responsibility to the PI <small>reset</small>
Please attach the list of key study personnel associated with this study at this site.	<a href="#">Upload file</a>
Additional Information regarding the verification that all training requirements are met.	<div style="border: 1px solid #ccc; padding: 5px;"><p><i>"Neque porro quisquam est, qui dolorem ipsum quia dolor sit amet, consectetur, adipisci velit, sed quia non numquam eius modi tempora incidunt ut labore et dolore magnam aliquam quaerat voluptatem."</i></p></div> <small>(optional) <a href="#">Expand</a></small>
Are all involved individuals at the institution for this protocol credentialed and/or appropriately qualified and meet the institution's standards for eligibility to conduct research?	<input type="radio"/> Yes
	<input checked="" type="radio"/> No <small>reset</small>
Please review the planned list of personnel who will be engaged in human subjects research and indicate whether COI applies:	<input checked="" type="radio"/> I have verified these personnel do not have any financial interests to disclose
	<input type="radio"/> I have verified any relevant interests have been disclosed per my institutional policy and managed, as applicable
	<input type="radio"/> Our institutional policy requires the researcher to disclose conflicts to another office/department and send the management plan to the Reviewing IRB <small>reset</small>

# COMBO SITES ON THE SITE-SPECIFIC APPROVALS TAB



## IREx Quarterly Features Call Demo

Study-wide IRB Approvals

Site-specific IRB Approvals

Status Summary

Protocol Version: 20200414

Carnegie Univ | Carnegie U Med Ctr

Initial Study: Full Board

Current

Edit review

Site approvals

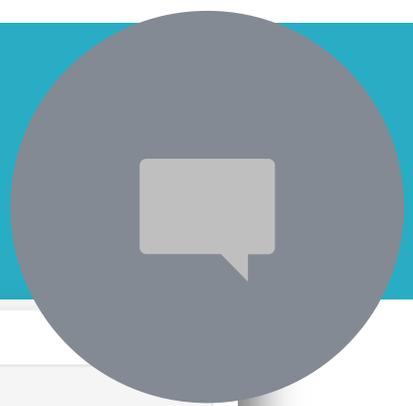
Study Info

Role: Relying Site  
IRB Number:  
Status:  
Review Cycle:

Key Dates

Submitted for Local Review:  
Local Review Conducted:  
Local Review Completed:  
Expires:

# ENHANCED PARTICIPATING SITES DIALOG



Starting Tuesday, April 21<sup>st</sup>:

## CURRENT:

### Add A Site

**Site Name:**  
University of Kentucky - FWA#00005295

**PI Name:**  
Enter PI name, if known

**PI Email:**  
Enter PI email address, if known

**Coordinator Name:**  
Enter Coordinator name, if known

**Coordinator Email:**  
Enter Coordinator email address, if known

Cancel **+ Add Site**

Note: This does not grant the site PI / Coordinator access to IREx. Study team access is granted by the local HRPP/IRB

### Participating Sites

**1 sites need attention**  Show All Personnel

- Baystate Health, Inc #00004355**  
PI: Baystate PI - pi@baystate.cdu  
Coordinator:
- Boston Medical Center #00000214** ✓  
PI: Baystate PI - pi@baystate.cdu  
Coordinator: **+**
- Case Western Reserve University #00000161** ✓  
PI: Only PI - onlypi@eastman.cdu  
Coordinator: **+**
- Clinical Eye Research of Boston** ✓  
PI: Blue Harvy - blue@harvard.cdu  
Coordinator: **+**
- Eastman Medical Center of Ohio #45648974865**  
PI: Only PI - onlypi@eastman.cdu  
Coordinator:

- Site has registered for the study and cannot be edited.

Cancel **Save**

### Participating Sites

#### Add A Site

**Site Name:**  
University of Kentucky - FWA#00005295

**PI Engaged**

**PI Email:**  
Enter PI email address, if known

**PI First Name:**  
Enter PI first name, if known

**PI Last Name:**  
Enter PI last name, if known

This PI engages other sites

**Site Coordinator**

**Coordinator Email:**  
Enter Coordinator email address, if known

**Coordinator First Name:**  
Enter Coordinator first name, if known

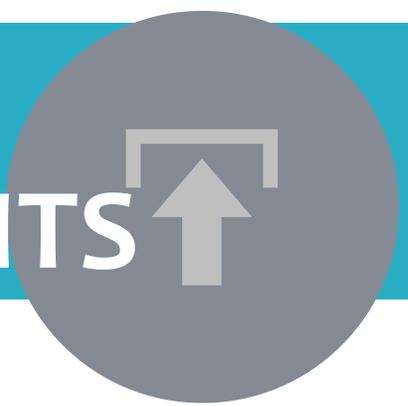
**Coordinator Last Name:**  
Enter Coordinator last name, if known

Cancel **+ Save Site**

Institution	PI (Required)	Coordinator	
Baystate Health, Inc #00004355	Baystate PI	Add Coordinator	
Boston Medical Center 00000214	pi@baystate.cdu		
Eastman Medical Center of Ohio #45648974865	Only PI	Add Coordinator	
Case Western Reserve University 00000161	onlypi@eastman.cdu		
George Washington University #00002344	George Wash	Martha Wash	
George Wash	george@wash.cdu	martha@wash.cdu	
Hartford College of Medicine #00003216			
Peabody Institute of Medicine 897645665	Site has registered & can now manage contacts		



# STUDY MANAGERS CAN UPLOAD CONTINUING REVIEWS & AMENDMENTS



**\*\*Available Now\*\***

## sIRB

- Create study\*
- Assign Study Manager
- Complete SSRP
- Upload initial approval\*

## Study Manager

- Add sites
- Track site progress completing steps
- Export local considerations\*
- Upload initial site approvals from sIRB\*
- **\*\*NEW\*\*** Upload continuing reviews
- **\*\*NEW\*\*** Upload study-wide and site-specific amendments

\*API available for interconnectivity with sIRB e-IRB system

# UPDATED RESOURCE MATERIALS



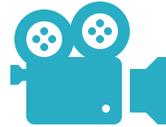
- New Videos on YouTube
  - [Combo Site Trailer](#)
  - [Participating Site HRPPs](#)
  - [Adding Participating Sites](#)
- [Combo Site Overview Handout](#)
- New Quick Guides:
  - [Reviewing IRB](#)
  - [PSite HRPPs](#)
  - [Multisite Liaisons](#)
  - [Study Manager](#)
  - [PSite Study Teams](#)

# JOIN A TRAINING TO LEARN MORE



<https://attendee.gototraining.com/rt/6676527480060440578>

- April 23 at 3 ET
- April 27 at 12 ET
- April 28 at 2 ET



# Next Call

- July 17, 2020 @ 1 PM ET/10 AM PT