



# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR STUDY MANAGERS

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

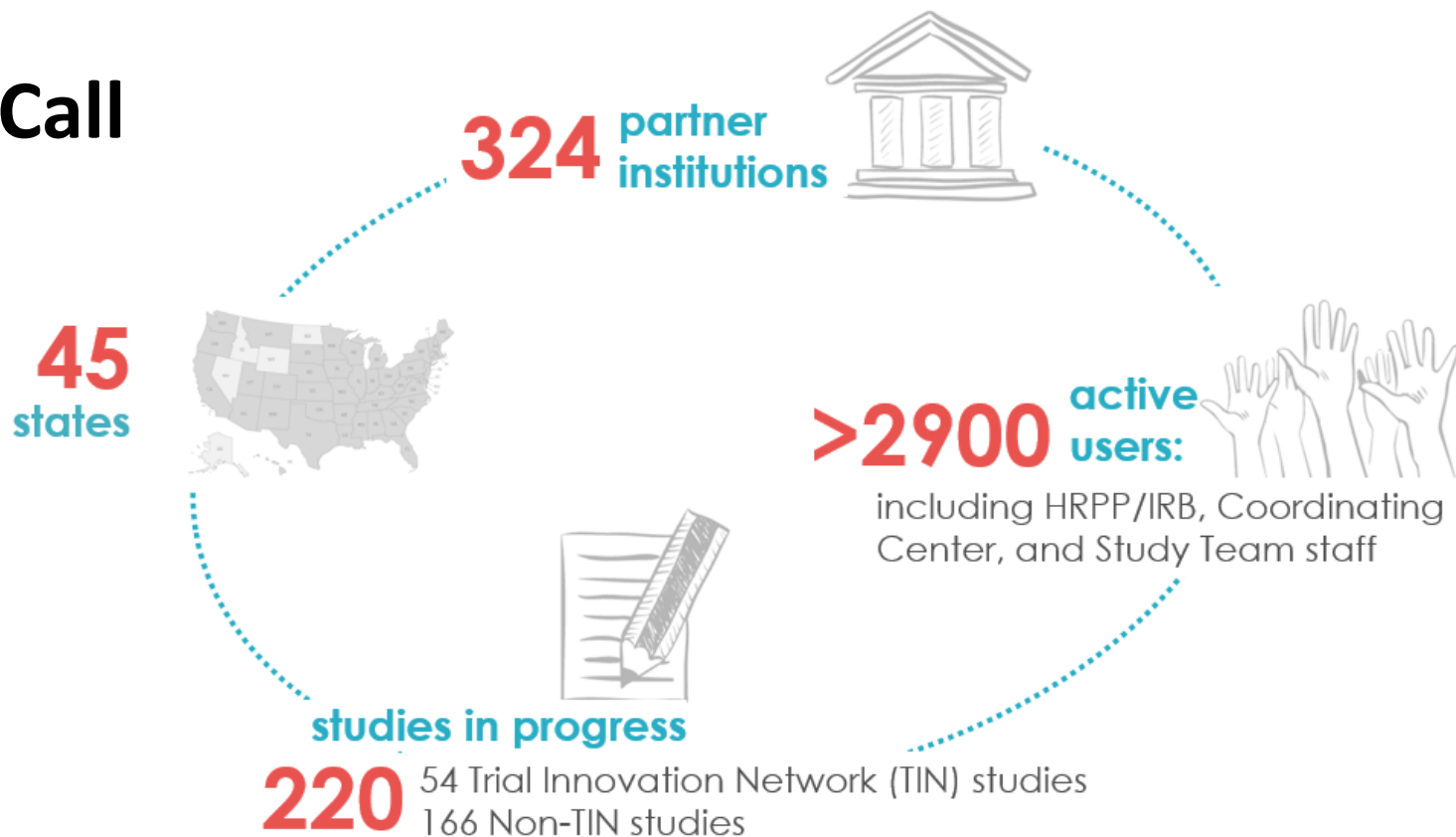
*Linda Tan*



# QUARTERLY CALL AGENDA



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



# Reminders from the Last Call

# REMINDERS FROM THE LAST CALL



## 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:	201900091	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 to 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 your 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.

# REMINDERS FROM THE LAST CALL



PIs now have “Verify Study Team Contacts” on their Getting Started Checklist

GETTING STARTED

- ➔ **Verify Study Team Access**
- ➔ Complete PI Survey
- ➔ HRPP Validates PI Survey
- 👁 View Status Summary

study team contacts : Peabody Institute of Medicine

**Add A Contact**

Type of contact ...

email address

first name

last name

+ Add Contact

**Current Study Team Contacts**

Email	Name	Role	
shawn@peabody.cdu	Shawn Hamilton	Coordinator	✖
📍 laura@peabody.cdu	Laura Jones	PI	

Cancel OK

**New System Features!**

# STUDY MANAGERS CAN UPLOAD CONTINUING REVIEWS & AMENDMENTS



**\*\*Available Now – Discuss with the sIRB\*\***

## 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**

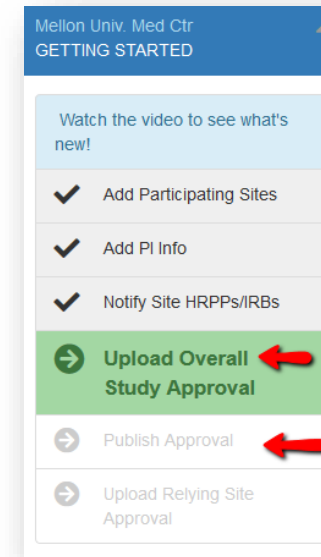
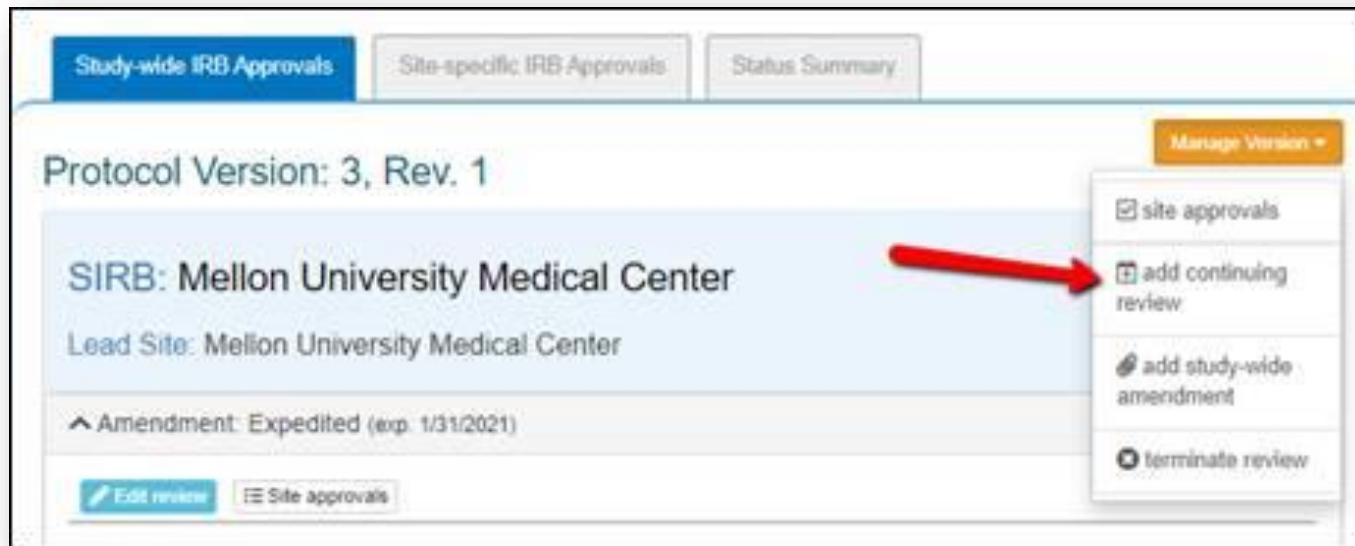


# UPLOADING CONTINUING REVIEWS & AMENDMENTS



Your queue to upload a new approval to IREx comes from the sIRB's system

## 1. Upload the approval for the overall study/lead site first



## 2. Then upload updated materials (e.g., consents) for relying sites

Relying sites are awaiting your approval [site approvals](#)

# UPLOADING SITE AMENDMENTS (E.G., PI CHANGE)



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

Protocol Version: 1

Carnegie University Medical Center	site amendment	
Initial Study: Full Board (exp. 11/30/2019)		Current

Central Ohio Medical Center	site amendment	
Initial Study: Full Board (exp. 11/30/2019)		Current

Create Site Amendment for Carnegie University Medical Center

Study Information

Role: Relying Site

Change Summary:

**Required**

IRB #:

Reviewing IRB Status: approved

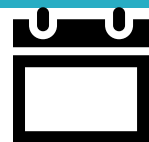
Type of Study

Greater than minimal risk  
 Minimal risk

Review Type: Site Amendment: Full Board

Continue →

# NEW DIALOG FOR ADDING PARTICIPATING SITES



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

## Goals:

- To improve the user interface
- To allow for the capture of combo sites

### 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

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

<input checked="" type="checkbox"/> <b>Baystate Health, Inc #00004355</b>	PI: Baystate PI - pi@baystate.cdu	Coordinator: <input type="button" value="edit"/>	<input type="button" value="up"/>
<input checked="" type="checkbox"/> <b>Boston Medical Center #00000214</b>	PI: Baystate PI - pi@baystate.cdu	Coordinator: <input type="button" value="+"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> <b>Case Western Reserve University #00000161</b>	PI: Only PI - onlypi@eastman.cdu	Coordinator: <input type="button" value="+"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> <b>Clinical Eye Research of Boston</b>	PI: Blue Harvy - blue@harvard.cdu	Coordinator: <input type="button" value="+"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> <b>Eastman Medical Center of Ohio #45648974865</b>	PI: Only PI - onlypi@eastman.cdu	Coordinator: <input type="button" value="edit"/>	<input type="button" value="up"/>

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

# NEW DIALOG FOR ADDING PARTICIPATING SITES



## Participating Sites

### How will you add sites to this study?

- Add sites by name or FWA #
- Select consortium of sites

#### Provide Site Names and PI Contact Information

This information is used to notify the site HRPP and PI that the study is in IREx so they can begin documenting reliance. IREx is not used to disseminate the initial protocol and consent templates to site PIs. The **lead study team / coordinating center** should provide these materials to the site PIs, along with other study materials, contracts and regulatory documents outside of IREx. [?](#)

## Add A Site

[How to add participating sites](#)

Site Name:

Cancel

+ Save Site

Close

# NEW DIALOG FOR ADDING PARTICIPATING SITES



## Add A Site

How to add participating sites

Site Name:

Carnegie University Medical Center - FWA#12345678

### PI Engaged

PI Email:

pi@carnegie|

studypi@carnegie.cdu  
studypi@carnegie.edu  
pi@carnegie.edu  
irexpi@carnegie.edu  
pi@carnegie.cdu

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

## WHAT'S NEW?

- How to video in dialog
- PIs with IREx access auto populate as you type
- Indicate PIs engage additional FWAs
  - **Creating a Combo Site** 

# NEW DIALOG FOR ADDING PARTICIPATING SITES



Participating Sites

[How to add participating sites](#)

## Add A Site

**Site Name:**

[Cancel](#) [+ Save Site](#)

Institution	PI (Required)	Coordinator	
<a href="#">Carnegie University Medical Center #12345678</a> <a href="#">Carnegie University 3232282999</a>	Site has registered & can now manage contacts		
<b>Hartford component - Hampshire College of Medicine #00003216</b>	Haris Gomez haris@hartford.cdu	<a href="#">+ Add Coordinator</a>	
<b>Mellon University Medical Center #00001111</b>	<a href="#">+ Add PI</a>	<a href="#">+ Add Coordinator</a>	
<b>Midwest University Medical Center #00951753</b>	Rudra Hansen rudra@midwest.cdu	Keyam Weaver keyan@midwest.cdu	

# NEW DIALOG FOR ADDING PARTICIPATING SITES



Participating Sites

[How to add participating sites](#)

## Add A Site

Site Name:

Search by name or FWA number

Institution	PI (Required)	Coordinator	
Carnegie University Medical Center #12345678 Carnegie University 3232282999	Site has registered & can now manage contacts		
Hartford component - Hampshire College of Medicine #00003216	Haris Gomez haris@hartford.cdu	Add Coordinator	
Mellon University Medical Center #00001234	Add PI	Add Coordinator	
Midwest University Medical Center #00951753	Rudra Hansen rudra@midwest.cdu	Keyam Weaver keyam@midwest.cdu	

Close

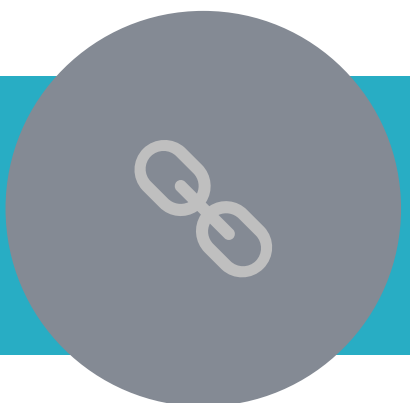
**Combo Site identifier** (points to link icon in Institution column)


**Cannot edit personnel after site has registered; they manage access going forward** (points to 'Site has registered & can now manage contacts')

**Edit & Delete options** (points to edit and close icons in Coordinator column)

**PI still required to notify** (points to 'Add PI' button in PI column)

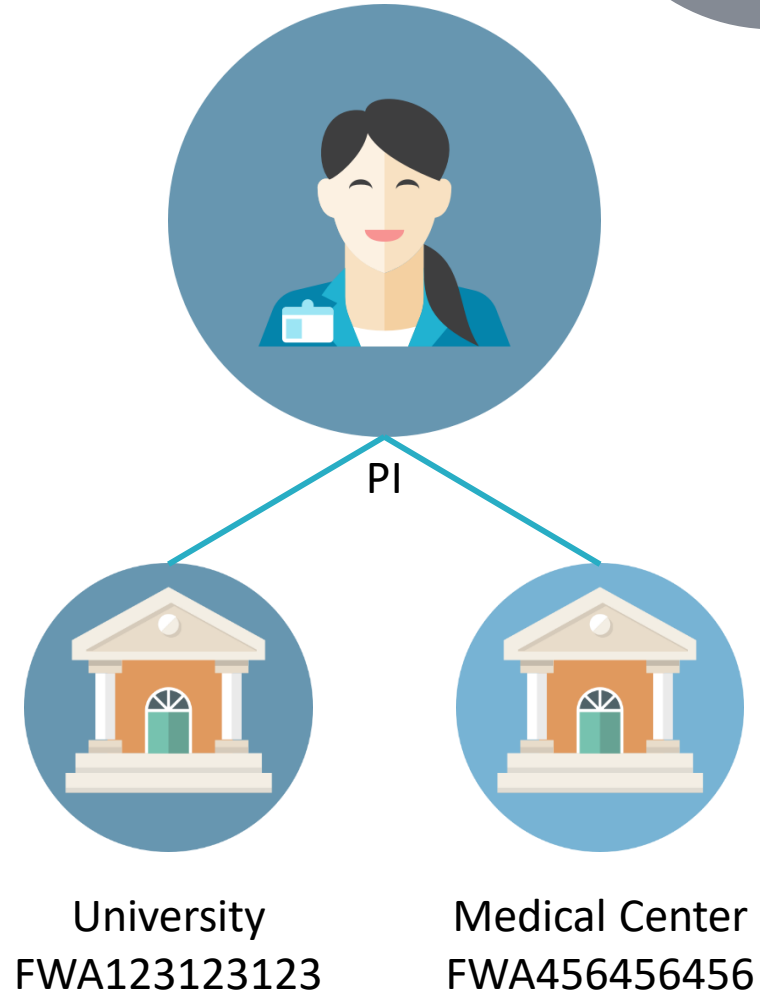
# WHAT IS A COMBO SITE?



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

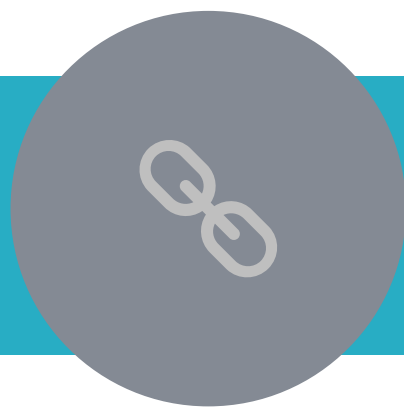
## CHALLENGES:

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





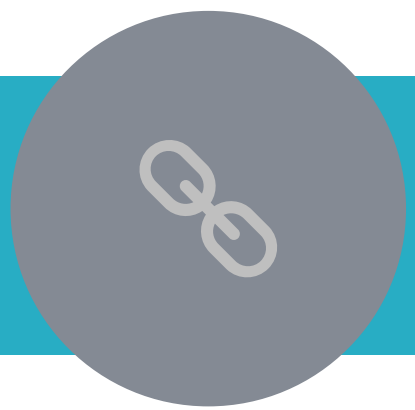
# RELIANCE DOCUMENTATION FOR COMBO SITES



- 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	

# COMBO SITES ON THE STATUS SUMMARY



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

Participant Status Summary Export Data ▾

Search:

Site	SMART IRB	IREx Access	Reliance Decision ?	Approval Status (current version)
<a href="#">Carnegie U Med Ctr   Carnegie Univ</a> Carnegie University	✓	✓	<a href="#">Notify HRPP</a>	
<a href="#">Carnegie U Med Ctr   Carnegie Univ</a> Carnegie University Medical Center	✓	✓	<a href="#">Notify HRPP</a>	
Hartford component - Hampshire College of Medicine	✓	✓	<a href="#">Notify HRPP</a>	
Mellon University Medical Center	✓	✓	<a href="#">Add PI Info</a>	
Midwest University Medical Center	✓	✓	<a href="#">Notify HRPP</a>	

- Listed alphabetically based on the Combo Site Primary
- Grouped together, but include a row for each Combo Site
- Press Notify HRPP for each site in Combo Site

# NEW REGISTRATION QUESTIONS ALLOW HRPP TO MAKE CHANGES



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

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**



Does **Riaan Browne** engage **OTHER SITES / FWAs** for this study, to your knowledge?

Yes

No

**Required**

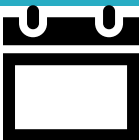


Does **ANOTHER PI** engage **Carnegie University Medical Center FWA #12345678** or its components for this study?

Yes

No

# NEW SITE REGISTERED FOR STUDY



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

## The site confirmed their PI & FWA – No Changes!

Dear Study Manager and Reviewing IRB Liaison,  
An HRPP Liaison completed registration for the study as shown below:

<b>Study Title</b>	Study Manager Upload Continuing Reviews 20200304
<b>Site</b>	Hartford component - Hampshire College of Medicine (#00003216)
<b>PI</b>	Haris Gomez ( <a href="mailto:haris@hartford.cdu">haris@hartford.cdu</a> )
<b>PI Access</b>	Haris Gomez now has access to the study.

If you have questions about this site's registration, please contact [Alys Kim](#).

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

# NEW SITE REGISTERED FOR STUDY



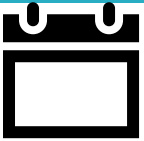
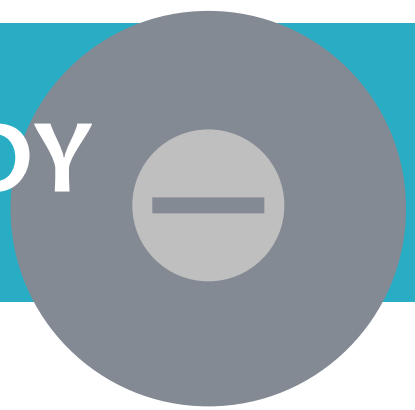
**Starting Tuesday, April 21<sup>st</sup>:**

**The site added an additional FWA, creating a combo!**

<b>Study Title</b>	Study Manager Upload Continuing Reviews 20200304
<b>Site</b>	Midwest University Medical Center (#00951753)
<b>PI</b>	Rudra Hansen ( <a href="mailto:rudra@midwest.cdu">rudra@midwest.cdu</a> )
<b>The Liaison updated the site/PI information as shown below</b>	
<b>Additional FWA Engaged.</b>	<p>The HRPP Liaison indicated an additional FWA may be engaged for this PI: Central Ohio Medical Center (#123456).</p> <p>The HRPP Liaison(s) at Central Ohio Medical Center (#123456) has been notified to confirm whether their FWA is engaged in research for this study.</p>
<b>Confirmed Site</b>	Midwest University Medical Center (#00951753)
<b>Confirmed PI</b>	Rudra Hansen
<b>This PI looks to be part of a "Combo Site"</b>	<p>This PI may be part of a combo site, which means multiple FWAs are engaged for this PI/study team. Each FWA will have to complete the required agreements, indicate reliance, and complete an HRP Survey; however, only one PI survey will be required.</p> <p>The status of each FWA is below:</p> <ul style="list-style-type: none"><li>• Midwest University Medical Center (#00951753) is the primary HRPP for this combo site and has completed registration.</li><li>• Central Ohio Medical Center (#123456) is the secondary HRPP for this combo site and has not completed registration.</li></ul>
<b>PI Access</b>	Rudra Hansen now has access to the study.



# SITE DECLINED ENGAGEMENT FOR STUDY



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

**The site indicated they are NOT engaged.**

Dear Study Manager and Reviewing IRB Liaison,  
An HRPP Liaison indicated their site is not engaged for the study as shown below:

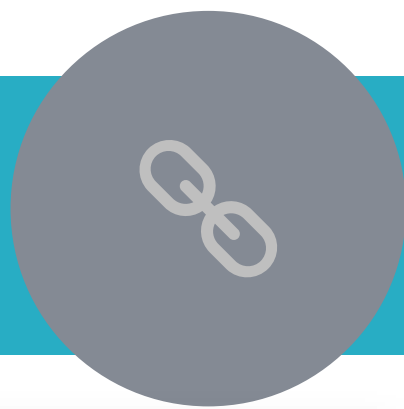
<b>Study Title</b>	Study Manager Upload Continuing Reviews 20200304
<b>Site</b>	Mellon University Medical Center (#00001111)
<b>PI</b>	PI Mellon ( <a href="mailto:pi@mellon.org">pi@mellon.org</a> )

**The Liaison updated the site/PI information as shown below**

<b>Site is not engaged</b>	Mellon University Medical Center (#00001111) provided the following reason they are not engaged:  The PI moved to another institution.  This information is captured on the Status Summary under “Non-Engaged Sites”.
----------------------------	---



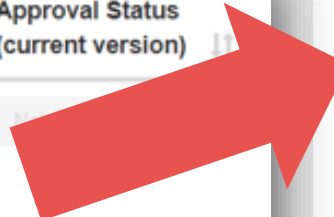
# NEW REGISTRATION PROCESS FOR RELYING HRPPS



Local considerations must be complete for ALL sites in Combo before exporting Local Considerations

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
<a href="#">Carnegie U Med Ctr   Hartford</a> Carnegie University Medical Center	✓	✗	✓	Started 4/10/2020	3 / 3 Surveys Complete	Not Approved
<a href="#">Carnegie U Med Ctr   Hartford</a> Hartford College of Medicine	✓	✗	✓	Started 4/10/2020	1 / 3 Surveys Complete	Not Approved

Site	SMART IRB	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
<a href="#">Peabody Inst Med   Hartford</a> Hartford College of Medicine	✓	✓	Completed 4/10/2020	3 / 3 Surveys Complete	Not Approved
<a href="#">Peabody Inst Med   Hartford</a> Peabody Institute of Medicine	✓	✓	Completed 4/10/2020	3 / 3 Surveys Complete	Not Approved



Name	Type	Compressed size
Peabody Inst Med -- Hartford	File folder	
HRPP_survey_responses	Microsoft Excel Comma Sepa...	
PI_survey_responses	Microsoft Excel Comma Sepa...	
Study Specific Reliance Plan	Microsoft Excel Comma Sepa...	

# UPLOAD ONE SET OF APPROVAL DOCUMENTS FOR COMBO SITES



Peabody Inst Med   Mellon Univ. Med Ctr Mellon University Medical Center				Completed 4/7/2020	3 / 3 Surveys Complete ▾	Not Approved
Peabody Inst Med   Mellon Univ. Med Ctr Peabody Institute of Medicine				Completed 4/7/2020	3 / 3 Surveys Complete ▾	Not Approved

Will inherit approval of primary combo site

Relying Site Approvals

Peabody Inst Med | Mellon Univ. Med Ctr

Peabody Inst Med | Mellon Univ. Med Ctr

✓ Midwest Univ Med Ctr

Combo Sites indicated

Status

Date Submitted

Review Type

Date Reviewed

Date Approved

Documents

Cancel Save



# 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/7231248688485046273>

- April 22 at 12 ET
- April 29 at 3 ET
- April 30 at 2 ET

# Next Call

- July 17, 2020 @ 2 PM ET/11 AM PT