



# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR HRPPS

January 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*

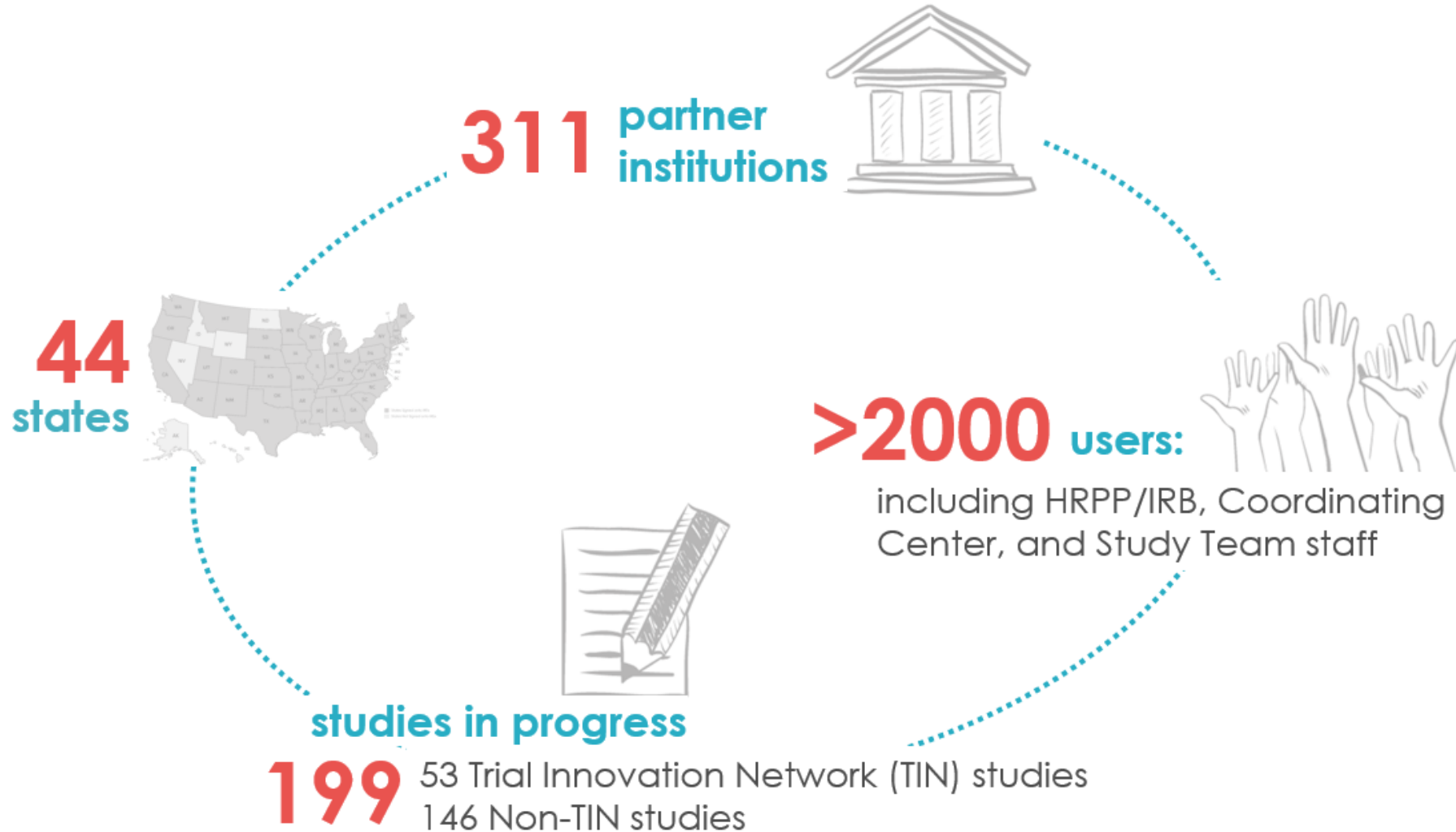


# HRPPs QUARTERLY CALL AGENDA



- Welcome
- IREx Utilization Update
- Reminders from the Last Call
- New System Features
- Upcoming Development Releases
- Next Call

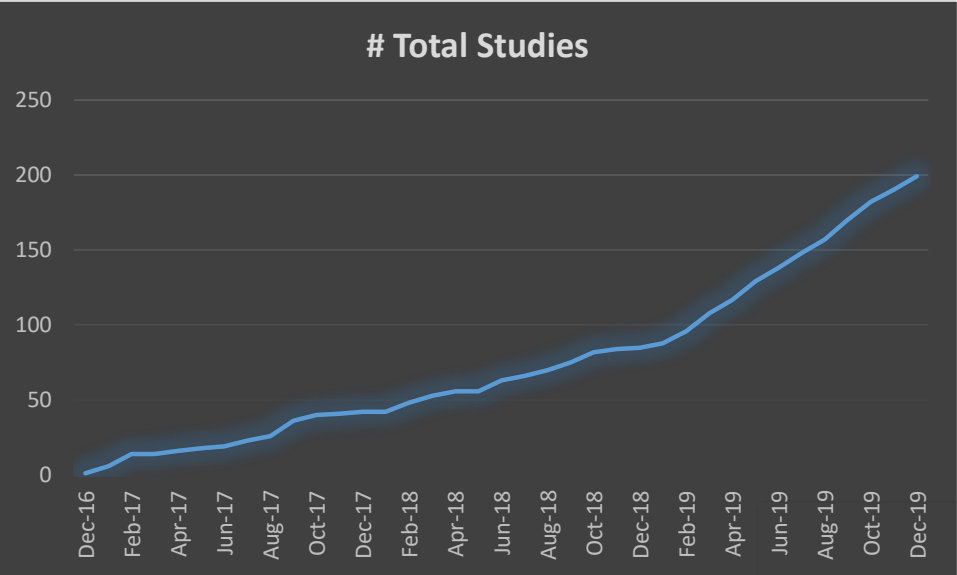
# IREX UTILIZATION



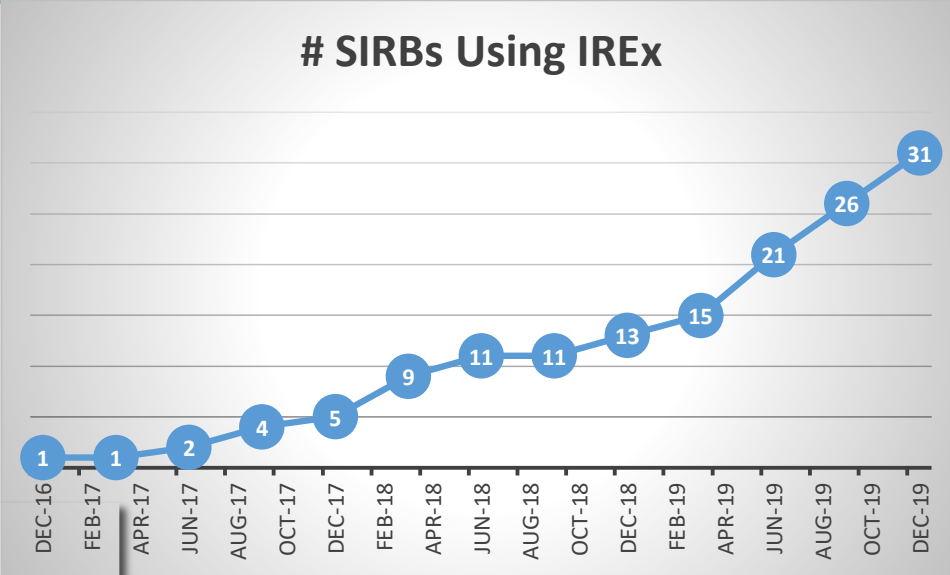
# IREX UTILIZATION



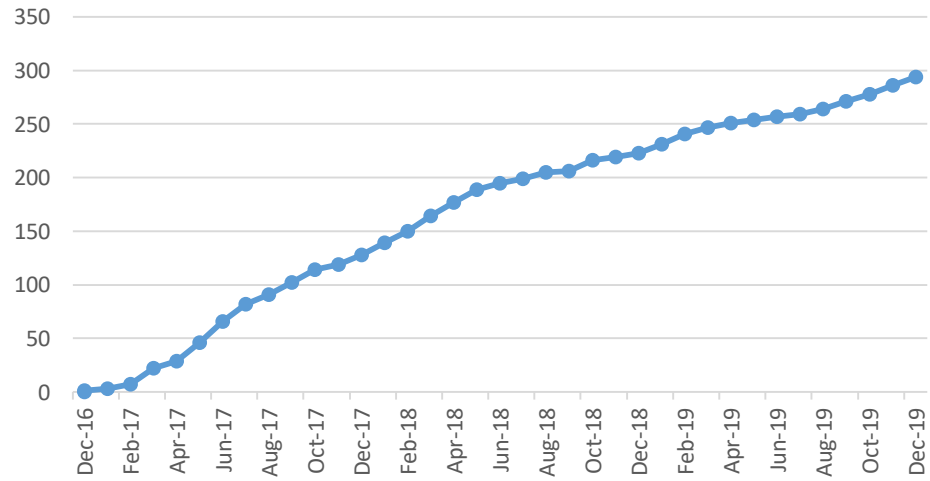
# Total Studies



# SIRBs Using IREx



Total Site Sign-On



# Reminders from the Last Call

# REMINDERS FROM THE LAST CALL



Dear Liaisons and Study Contacts,

Vanderbilt University Medical Center has shared IRB approval for your institution, Carnegie University Medical Center, in IREx for the study below:

**Study Title:** A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM-FIRST)  
**Type of Review / Approval:** Amendment: Full Board  
**Version** 10.11.2019  
**Change Summary** Amendment 2 - Includes clarification to use of divided dose and reduced dose of the study medication due to intolerance and a correction to the schedule of events table.  
**Expiration Date:** 1/9/2020  
**Study Link:** <https://staging.irbexchange.org/study/index/?proj=70199>

#### Principal Investigators & Study Contacts:

Your approval documents are available in [IREx](#). If you have any questions about your approval or future submissions, please contact the Coordinating Center (CC)/Lead Study Team (LST) or Reviewing IRB. If needed, contact information for the CC/LST is provided in a blue button just under the study title in IREx.

*Thank you for using IREx,  
The IREx Team*

**The version # and change summary you enter for amendments are included on notifications**

**Relying Sites (HRPPs & study teams) can view their site's status on the Status Summary**

The screenshot shows the IREx interface for the study 'Antitumoral Properties of Pig Liver Esterase (APPLE)'. The 'GETTING STARTED' progress bar is partially filled. The 'Participant Status Summary' section shows a table of site status:

Site	SMART IRB	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Carnegie University Medical Center	✓	✓	Started 10/15/2019	3 / 3 Surveys Complete	Not Approved

Below the table, there is a 'VERSIONS' section showing the current version 20191015 and a list of relying sites, including Peabody Inst Med (Pending) and Carnegie U Med Ctr.

# REMINDERS FROM THE LAST CALL



From: [admin@irbexchange.org](mailto:admin@irbexchange.org) <[admin@irbexchange.org](mailto:admin@irbexchange.org)>  
Sent:  
To:  
Subject: IREx: Site Updated Local Considerations Responses

Dear Coordinating Center / Lead Study Team,

Hartford College of Medicine has modified their responses to the HRP Survey on the following study:

Influenza-associated pneumonia hospitalizations in Jupiter

Survey response changes are noted below:

Survey Field	Previous Response	Updated Response
Please review the protocol and template consent, as provided to you by your local study team, and identify any institutional requirements (e.g., recruitment, data security, remuneration) that apply to this study and any steps that must be taken to adhere to these requirements.	None	Protocol and template consent have been updated with additional radiation safety information.
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.	None	This site now requires annual radiation safety review completed by the participating site's safety board.

information has already been submitted to the Reviewing IRB for review, please be sure to communicate these changes to the Reviewing IRB for this site.

Note: the completed surveys are now viewable on the Status Summary tab in IREx; however, **please allow up to ten minutes for the Export feature to be available for download.**

[Click here to view the study.](#)

Thank you for using IREx,  
The IREx Team

## Edits made to the HRP and PI Surveys are tracked and sent via email.

## Distinguish the Single IRB from the Lead Site, when needed

Site-Specific Info Manage Project

Study Summary Reviewing IRB Contact IREx Study Managers Participating Personnel

### A Randomized, Placebo-Controlled Trial of Long-Acting Insulin for Treatment of Type 2 Diabetes Mellitus (TANDEM-T2DM)

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

Protocol Version: 1 Manage Version

SIRB: Carnegie University Medical Center

Lead Site: Peabody Institute of Medicine

# REMINDERS FROM THE LAST CALL



**Distinguishing study-wide and site-specific approval documents.**

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

- 1. Push** a study to IREx
- 2. Pull** site-specific documentation into your e-IRB system
- 3. Push** site approvals to IREx





**New System Features!**

# REVIEWING IRB CAN EDIT APPROVALS ANYTIME



## 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 to 4 of 4 entries  
Download all

- **Reviewing IRB Liaisons can edit / update an existing approval at any time.**
- This is **NOT** for amendments or new approvals. Only *additions & corrections* to existing approvals (e.g., if a document was left out of the approval or a date was incorrect)
- NOTE: The protocol is locked to changes. Email [admin@IRBExchange.org](mailto:admin@IRBExchange.org) to update the protocol document or version #.

# STUDY MANAGER NOTIFIED OF LEAD SITE'S UPDATED APPROVAL



- If the Lead Site's materials are changed, the Study Manager (SM) is notified.
- If Participating Sites have changes, the SM can update their approvals & they will be notified.

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

Reply Reply All Forward 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 any site-specific information or approved documents were changed, update relying sites' IRB approvals in IREx to notify them of the updated approval.

*Thank you,  
The IREx Team*

# IF PARTICIPATING SITE'S APPROVAL IS UPDATED, THEY ARE NOTIFIED



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

← Reply   ← Reply All   → Forward   ⋮

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*

# NEW QUESTION ON THE 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

# STUDY TEAM CONTACTS AUTO-POPULATE



Review - Roosevelt College

Primary Study Team Contacts

Add A Contact

Type of contact ...

email address

first name

last name

+ Add Contact

Current Study Team Contacts

Email	Name	Role
goodie@fada.com	Oldie	PI

This team member was entered by the Reviewing IRB or Study Manager and will not have access to the study until you confirm their participation by saving this dialog.

Continue →

- **Study Managers** list site personnel for each site they add to the study.
- **Relying HRPPs** confirm the contacts are correct, remove and /or add new contacts.

Study Personnel

Primary Investigators  
Bill Kraus

Coordinators  
Leslie Willis

Key Dates

Date Submitted: Not entered

Date Reviewed: Not entered

Date Approved: Not entered

Cancel Save

Be sure to “continue”  
through the dialog to save  
the information.

# ADD/EDIT STUDY TEAM IN PI CHECKLIST



## IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Peabody Institute of Medicine | laura@peabody.edu

[Home](#) [Contact Us](#) [Your Profile](#) [Resources](#) [Logout](#)

Study search ...

Peabody Inst Med  
GETTING STARTED

➔ Add / Edit Study Team

➔ Complete PI Survey

➔ HRPP Validates PI Survey

👁 View Status Summary

VERSIONS

123

Reviewing IRB

Carnegie U Med Ctr (Pending)

Study Summary | IREx Study Managers

### 20200110 IC refactor

Getting Started

Study-wide IRB Approvals

Site-specific IRB Approvals

Status

Protocol Version: 123

Peabody Institute of Medicine

Initial Study: Full Board

Study Info

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

Key Dates

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

Site-Specific Info

### 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.edu	Shawn Hamilton	Coordinator <span>✖</span>
📍 laura@peabody.edu	Laura Jones	PI

Cancel

OK



# UPDATED RESOURCE MATERIALS

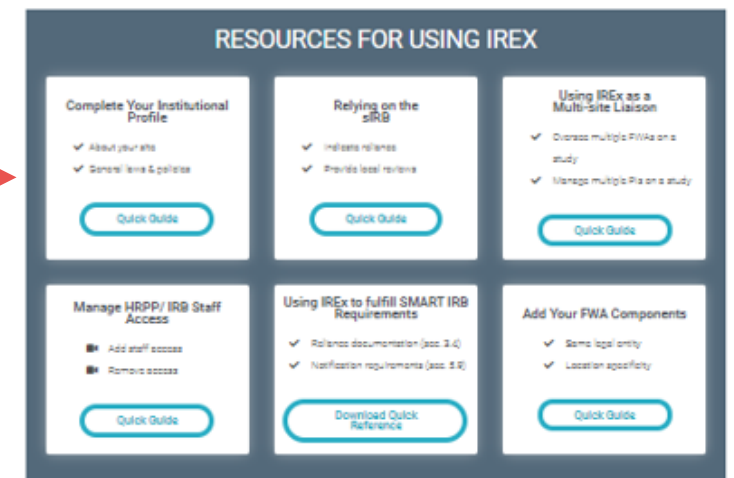
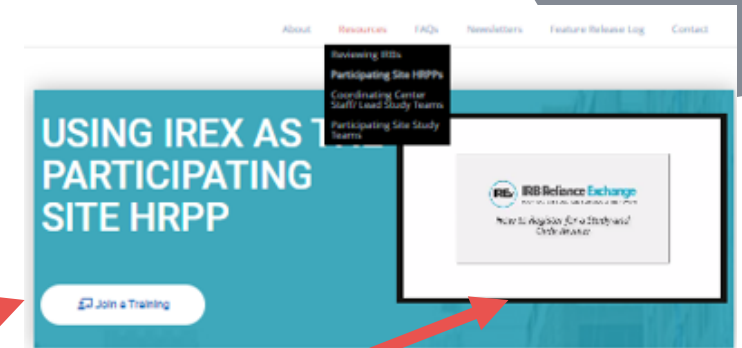


- Revamped website resources pages

- <https://www.irbexchange.org/p/reviewingirb/>
- <https://www.irbexchange.org/p/participating-site-hrpps/>
- <https://www.irbexchange.org/p/irexstudymanager/>
- <https://www.irbexchange.org/p/participating-site-study-teams/>

- Organization of each page

- Quick link to sign up for training
- Quick link to general video for specific user type
- Brief descriptions of how the user type uses IREx
- Newly organized resources for the user type



# UPDATED RESOURCE MATERIALS



- NEW VIDEOS ON YOU TUBE

- Local considerations video:

<https://www.youtube.com/watch?v=iN3mEDQ9kx8&feature=youtu.be>

- How to Add HRPP/IRB Contacts:

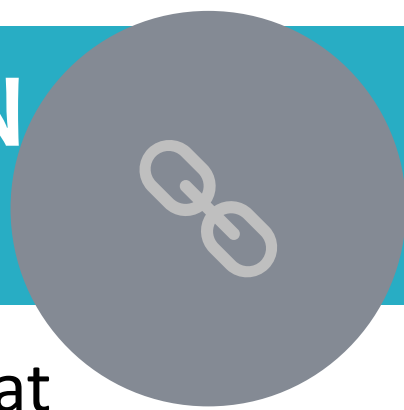
<https://www.youtube.com/watch?v=870HCtnCAWI>

- How to Remove HRPP/IRB Contacts:

<https://www.youtube.com/watch?v=LUo0uVE-bvQ>

# Upcoming Development Releases

# COMBO SITES: A BRIEF INTRODUCTION TO A FEW NEW FEATURES

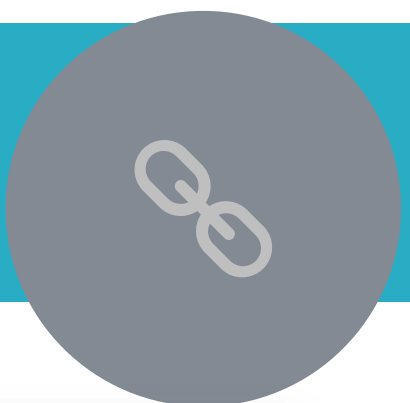


- Facilitating reliance documentation for a **single study team** that **engages multiple FWAs** for a study
  - For example, if a PI engages University of Pittsburgh Medical Center (FWA 00006735) & University of Pittsburgh (FWA 00006790).

- Reviewing IRB needs cede decision & local considerations from both FWAs before they review “the site”
- Only need 1 PI survey & 1 set of approval documents

	FWA #1 “Primary”	FWA #2
<i>Cede Decision</i>	Required	Required
<i>Institutional Profile</i>	Required	Required
<i>HRP Survey</i>	Required	Option to default to Primary HRPP
<i>PI survey</i>	One survey	
<i>Validate PI survey</i>	Required	View only
<i>Approval docs from sIRB</i>	One set of documents	

# COMBO SITES – NEW REGISTRATION PAGE



Registration for

**Study Title**



**A Super Statistical Kaplan-Meier Survival Analysis of the  
Hunger Games**

**PI & Presumed  
FWA listed in  
question**



Does **James Smith** engage **Hartford College of Medicine FWA  
#00003216** or its components for this study?

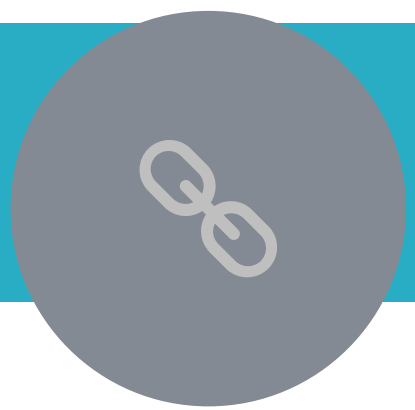
Yes

No

Cancel

Submit

# A Super Statistical Kaplan-Meier Survival Analysis of the Hunger Games



**?** Does **James Smith** engage **Hartford College of Medicine FWA #00003216** or its components for this study?  Yes  No

**Confirm PI Details**

Email address

First Name  Last Name

**Confirm Your Engaged FWAs / Components**

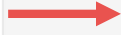
The SIRB or Study Manager identified your site/FWA as shown below. Edit the information if it is incorrect. If one of your FWA components is part of this study but is not listed below: 1) Cancel this registration 2) Go to the Homepage and use the "Components" button to add it 3) Return to register using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

Hartford College of Medicine - FWA#00003216

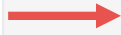
Hartford component - Hampshire College of Medicine - FWA#00003216

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

If yes, confirm the auto-filled information (or edit it)



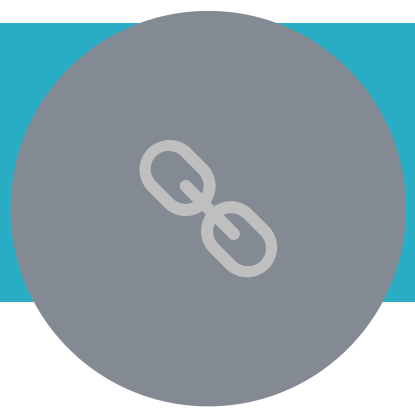
Ensure your FWA or component is appropriately identified



Indicate if you know of other FWAs engaged



# COMBO SITES – INDICATING YOUR NOT ENGAGED



Registration for

**A Super Statistical Kaplan-Meier Survival Analysis of the  
Hunger Games**

If you're not engaged  
on the study, you can  
indicate that so the  
CCC & SIRB know...

And, you stop  
receiving emails!

**?** Does **James Smith** engage **Hartford College of Medicine FWA #00003216** or its components for this study?  Yes  No

---

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

---

**?** Does ANOTHER PI engage **Hartford College of Medicine FWA #00003216** or its components for this study?  Yes  No

**Hartford College of Medicine FWA#00003216** 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](#).

# COMBO SITES – WHEN YOU’RE PART OF A COMBO SITE



- When your site is part of a combo, potentially engaged sites are listed
- The presumed “Primary” site is indicated, but can be edited.

Registration for

## Using Descriptive Ticketing to Alleviate System Glitches and Bugs 20200102



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

Yes  No



Jeff PI engages the following sites in this study:

Carnegie University Medical Center

Jefferson University **Combo Primary**



# COMBO SITES – ADD PARTICIPATING SITES DIALOG UPDATES



COMING SOON:

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

### 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: <span style="border-bottom: 1px solid black; display: inline-block; width: 50px;"></span>
<input checked="" type="checkbox"/>	<b>Boston Medical Center #00000214</b>	PI: Baystate PI - pi@baystate.cdu	Coordinator: <span style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;">+</span>
<input checked="" type="checkbox"/>	<b>Case Western Reserve University #00000161</b>	PI: Only PI - onlypi@eastman.cdu	Coordinator: <span style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;">+</span>
<input checked="" type="checkbox"/>	<b>Clinical Eye Research of Boston</b>	PI: Blue Harvy - blue@harvard.cdu	Coordinator: <span style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;">+</span>
<input checked="" type="checkbox"/>	<b>Eastman Medical Center of Ohio #45648974865</b>	PI: Only PI - onlypi@eastman.cdu	Coordinator: <span style="border-bottom: 1px solid black; display: inline-block; width: 50px;"></span>

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

Cancel Save

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

### Participating Sites

#### Add A Site

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

**PI Engaged**

**PI Email:**

**PI First Name:**

**PI Last Name:**

This PI engages other sites

**Site Coordinator**

**Coordinator Email:**

**Coordinator First Name:**

**Coordinator Last Name:**

Cancel + Save Site

Institution	PI (Required)	Coordinator	
<input checked="" type="checkbox"/> Baystate Health, Inc #00004355	Baystate PI	pi@baystate.cdu	<span style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;">+ Add Coordinator</span> <span style="border-bottom: 1px solid black; display: inline-block; width: 20px;"></span> <span style="color: red;">✕</span>
<input checked="" type="checkbox"/> Boston Medical Center 00000214			
<input checked="" type="checkbox"/> Eastman Medical Center of Ohio #45648974865	Only PI	onlypi@eastman.cdu	<span style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;">+ Add Coordinator</span> <span style="border-bottom: 1px solid black; display: inline-block; width: 20px;"></span> <span style="color: red;">✕</span>
<input checked="" type="checkbox"/> Case Western Reserve University 00000161			
<input checked="" type="checkbox"/> George Washington University #00002344	George Wash	george@wash.cdu	Martha Wash martha@wash.cdu <span style="border-bottom: 1px solid black; display: inline-block; width: 20px;"></span> <span style="color: red;">✕</span>
<input checked="" type="checkbox"/> Hartford College of Medicine #00003216			
<input checked="" type="checkbox"/> Peabody Institute of Medicine 897645665	Site has registered & can now manage contacts		<span style="border-bottom: 1px solid black; display: inline-block; width: 20px;"></span> <span style="color: red;">✕</span>

# Next Call

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