



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
Serdos*



- Site Onboarding
- Study Support

*Bridget
Swindell*



- User Support
- Study Support

*Linda
Tan*

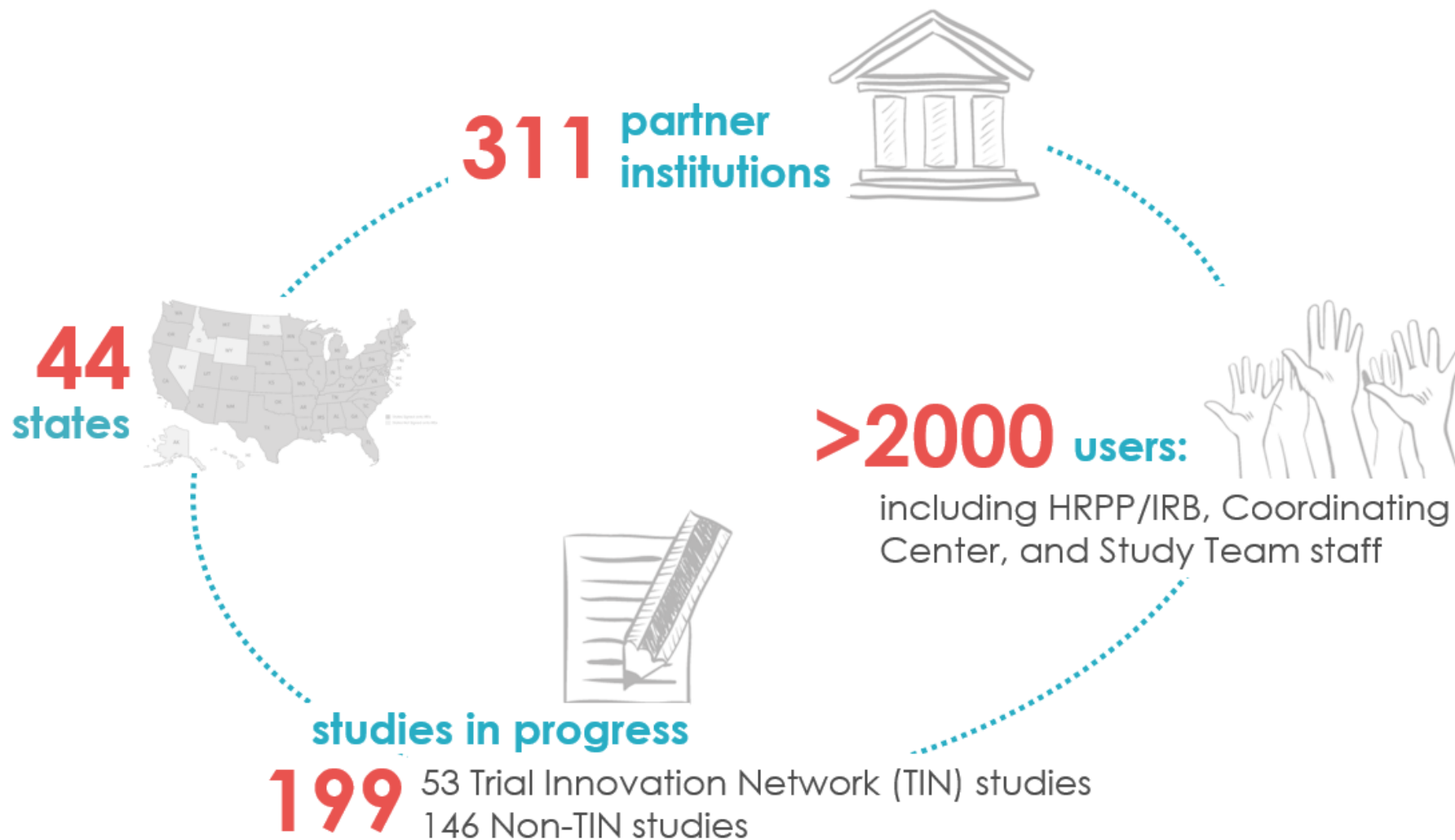


HRPPs QUARTERLY CALL AGENDA

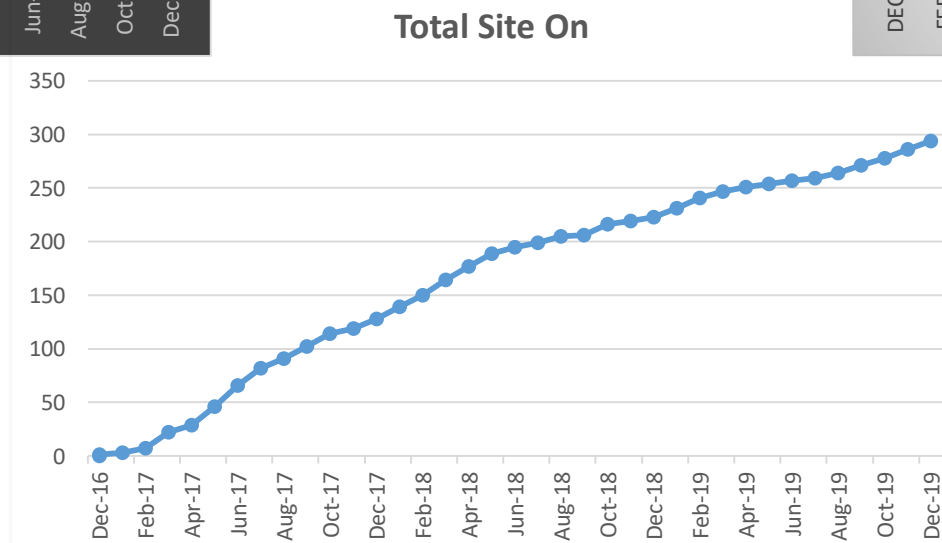
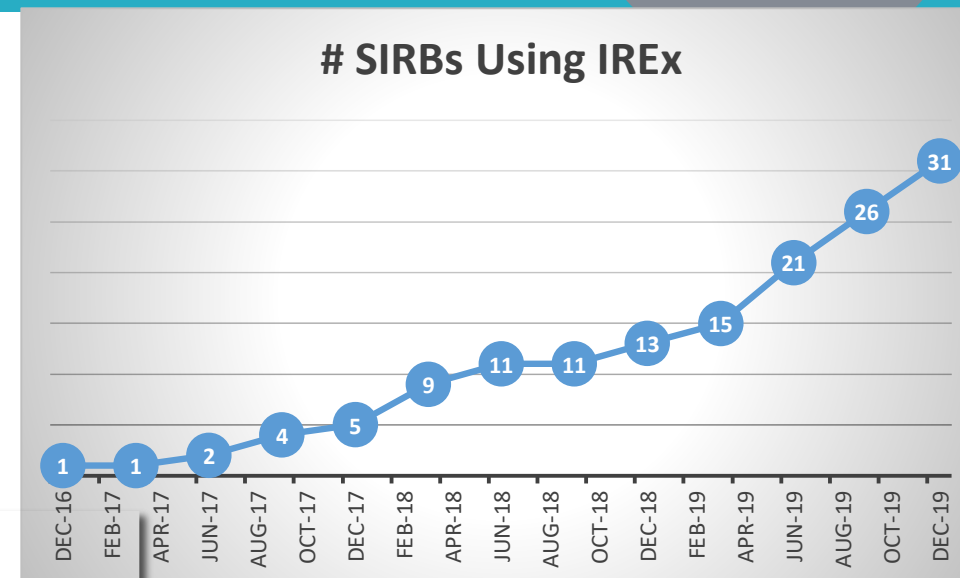
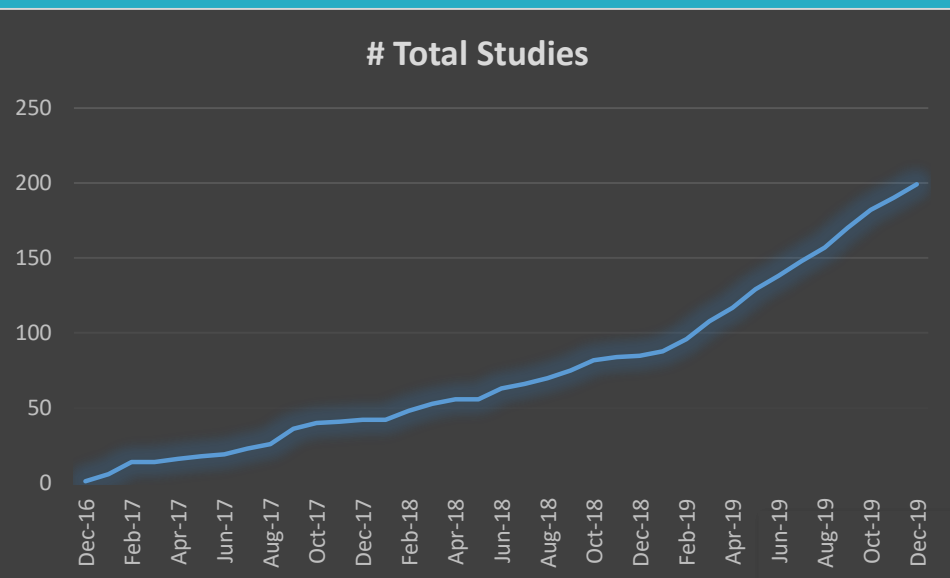


- Welcome
- IREx Utilization Update
- Reminders from the Last Call
- New System Features
- Upcoming Development Releases
- Bonus Discussion!
- Next Call

IREX UTILIZATION



IREX UTILIZATION



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 & PIs) can view their site's status on the Status Summary

The screenshot shows the IREx interface for a study titled "Antitumoral Properties of Pig Liver Esterase (APPLE)". The page is divided into two main sections: a left sidebar with a "GETTING STARTED" checklist and a main content area titled "Participant Status Summary".

GETTING STARTED Checklist:

- ✓ Register
- ✓ Add Study Team
- ✓ Complete Agreements
- ✓ Confirm Institutional Profile
- ➔ Indicate Reliance
- ✓ Complete HRP Survey
- ✓ Validate PI Survey
- ⌚ Awaiting Reviewing IRB Approval
- 👁 View Status Summary

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 University Medical Center	✓	✓	Started 10/15/2019	3/3 Surveys Complete	Not Approved

VERSIONS:

- 20191015
 - Reviewing IRB: Peabody Inst Med (Pending)
 - Relying Sites: none listed
 - Registered/in Progress: Carnegie U Med Ctr

REMINDERS FROM THE LAST CALL



From: admin@irbexchange.org <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](#)

[Manage Version](#)

Protocol Version: 1

SIRB: Carnegie University Medical Center

Lead Site: Peabody Institute of Medicine

REMINDERS FROM THE LAST CALL



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

Distinguishing study-wide and site-specific approval documents.

New System Features!

HEADS UP: 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

Manage Version

Protocol Version: 2019-08-01

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
IRB Number: 201908091
Status: approved
Submission Type: Initial Study: Expedited
Review Cycle: 12 mo

Submitted: 8/9/2019
Pre-Reviewed: 8/12/2019
Reviewed: 8/14/2019
Approved: 8/14/2019
Expires: 8/13/2020

Documents

Type	Name	Size
Consent Forms	waived	-
Determination Letter	DETERMINATION LETTER_initial Review.docx	12 KB
IRB Application	IRB APPLICATION.docx	12 KB
Protocol [2019-08-01]	PROTOCOL_09.29.2017.docx	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.

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 A 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.

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 →

- **Relying HRPPs** confirm the contacts are correct, remove and /or add new contacts.

STUDY TEAM CONTACTS LOCKED AFTER SITE REGISTERS



participating sites

IREx is not used to disseminate the initial protocol and consent templates to the participating 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

Site Name:

Search by name or FWA number

Add Site

Participating Sites

Show All Personnel

☒ **Hartford College of Medicine #00003216**

PI: afdaf - fdafadf@facfaad.com

Coordinator: -

☒ **Harvard Univ component - The Square**

PI: fadfa - fdaf@fadad.com

Coordinator: -

☒ **Jefferson University**

PI: afdad - adfa@erfaefda.com

Coordinator: -

☒ **Mellon University Medical Center #00001111**

PI: fadf@ - fdaf@fad.acom

Coordinator: +

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

Cancel

Save

- After a site registers, contacts can longer be edited by the Study Manager.
- Sites become responsible for the contacts and access at their site.

ADD/EDIT STUDY TEAM IN PI CHECKLIST



DEMO

IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

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)

Peabody Institute of Medicine

laura@peabody.cdu

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

Study search ...

Study Summary

IREx Study Managers

Site-Specific Info

20200110 LC 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:

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

UPDATED RESOURCE MATERIALS

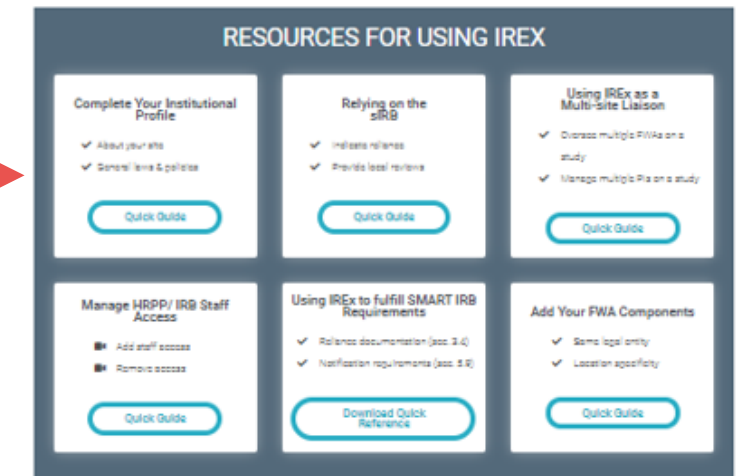
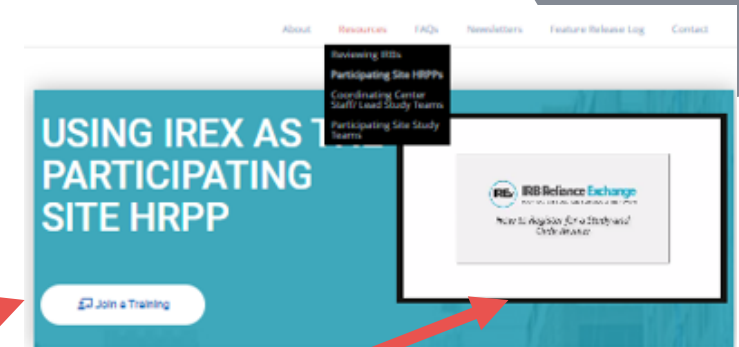


- Revamped website resources pages

- <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 – ADD PARTICIPATING SITES DIALOG UPDATES

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

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

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

COMING SOON:

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

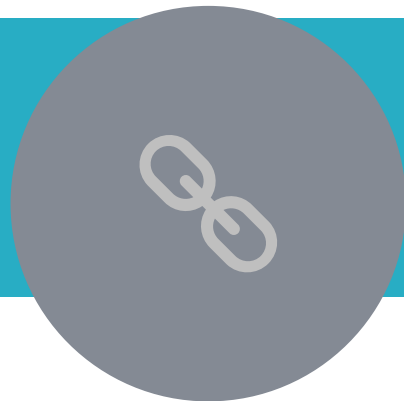
Site Coordinator

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

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 george@wash.cdu	Martha Wash martha@wash.cdu
Hartford College of Medicine #00003216	Site has registered & can now manage contacts	
Peabody Institute of Medicine 897645665		



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

Combo site
"Primary" is bold
& listed first

Single 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	
Hartford College of Medicine #00003216	george@wash.cdu	martha@wash.cdu	
Peabody Institute of Medicine 897645665	Site has registered & can now manage contacts		

Checkbox to indicate
"combo site"

Edit / delete

Optional information missing

Site has registered;
contacts are managed
by the site

BONUS DISCUSSION!

STUDY MANAGER FOCUS GROUP



MORE FEATURES FOR COORDINATING CENTERS & LEAD STUDY TEAMS

- **Ability to disseminate the overall study approval to sites** (Protocol, ICF templates, reliance instructions)
- **Ability to track other study documents (e.g., SOPs, MOPs) and documentation** (Key Study Personnel Training)
- **Ability to capture regulatory information from sites post-initial approval** (continuing review information)



We hear you and we want you to join our focus group to inform new system features and priorities!

Next Call

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