



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

July 19, 2019

- 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*



QUARTERLY CALL AGENDA – HRPPs



- Welcome
- IREx Utilization – A Look at IREx Metrics
- Reminders from the Last Call
- Recent System Updates
- SNEAK PEAK: User Interface Updates Coming Soon

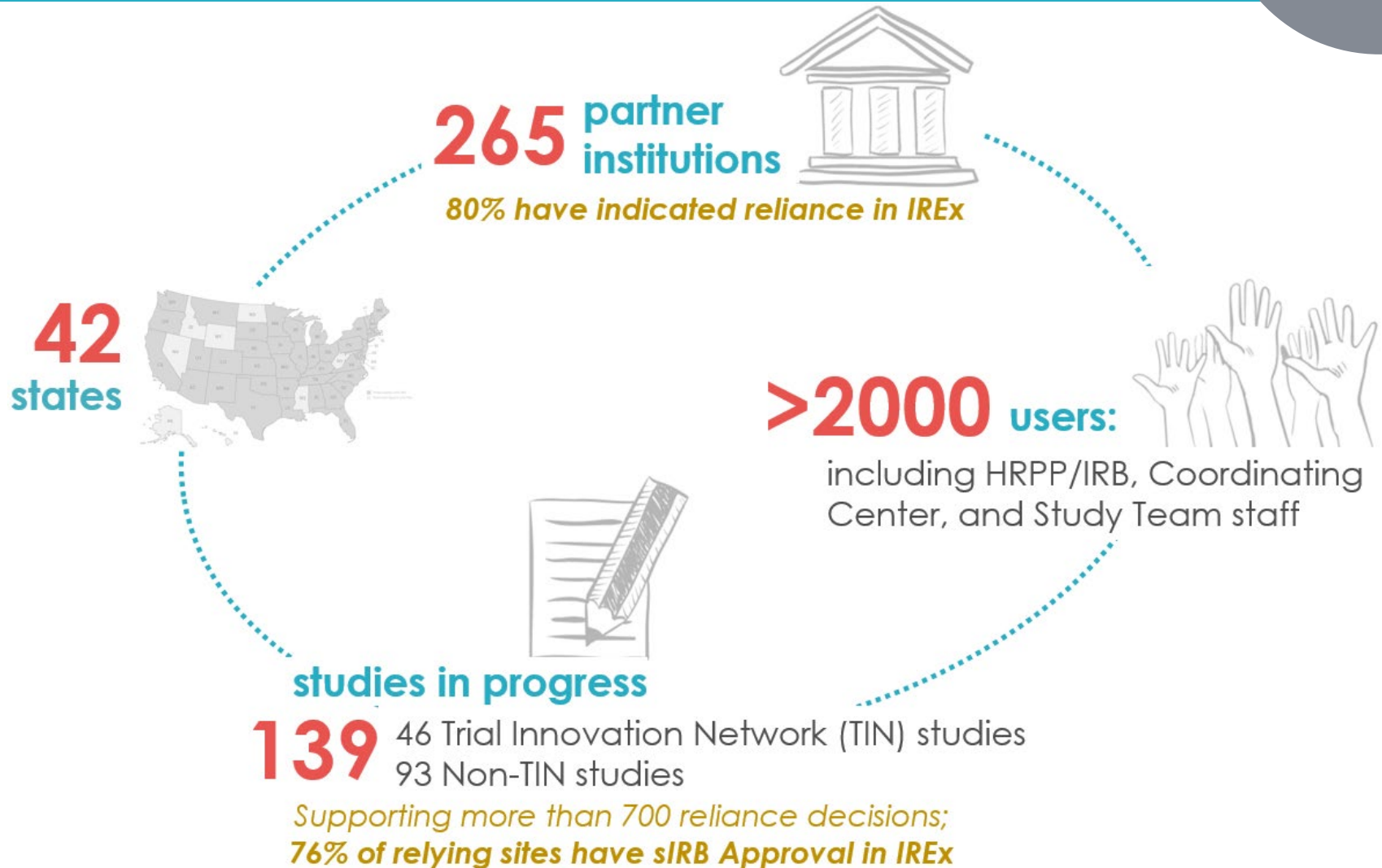
IREx Utilization – A Look at IREx Metrics

IREX UTILIZATION

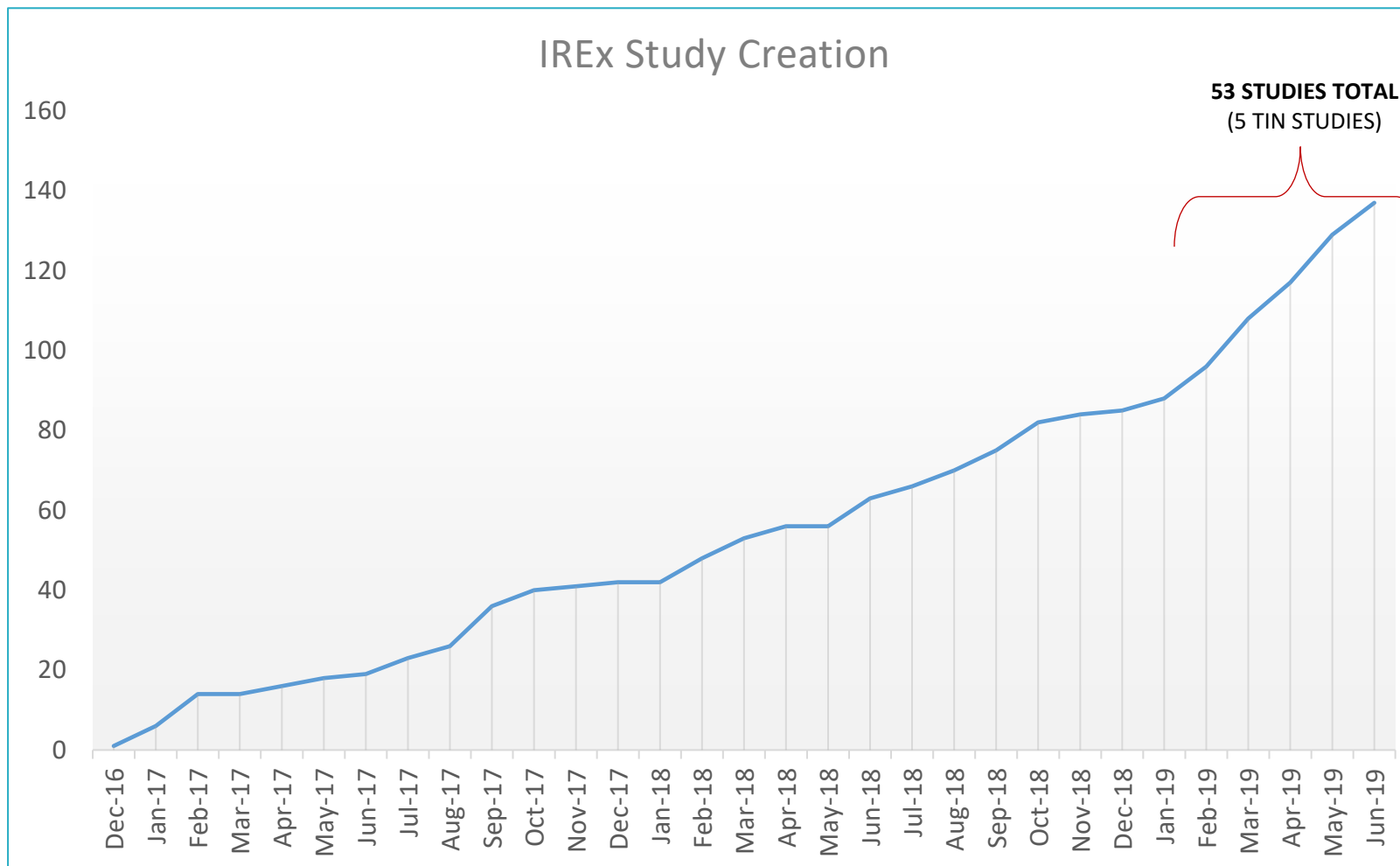


STATISTICS

- **120%** increase in studies created from Jan-June 2018 with same time in 2019
- **22** sIRBs in IREx
- **14** median days from CIRB submission to CIRB approval (*not including local review time*)
- **8** average sites per study (*Range: 2-96 sites*)



IREX UTILIZATION



Reminders from the Last Call

IN CASE YOU MISSED IT...



- Catch IREx improvements as they are released
 - Check out the [IREx Feature Release Log](#)
 - Read our monthly [IREx Newsletter](#)
- New to IREx or need a refresher? Join a training!
 - [Reviewing IRB trainings](#) – setting up your study in IREx
 - [Relying HRPP trainings](#) – using IREx to document reliance/ local considerations
 - [Lead Study Teams/Coordination Centers](#) – using IREx to support your sIRB study
 - Can't make the monthly trainings? [Request a demo](#) for your team
- IREx Functionality Updates...

TRACK LETTERS OF INDEMNIFICATION



Site Agreements: University of the Bay

Your Institution's LOI

External LOIs

Your LOI

Name

Template

Browse...

No file selected.

Save

Reviewing IRB Approvals

Relying Site Approvals

Status Summary

Manage LOI

Export Data

Participant Status Summary

Search: med

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Baystate component - Western Mass Med Ctr	✓	✓	✓	Contacted 02/07/2019		
Carnegie University Medical Center	✗	✓	✓	Started 02/05/2019	0 / 3 Surveys Complete	Not Approved
Eastman Medical Center of Ohio	✗	✗	✓	Started 02/13/2019	0 / 3 Surveys Complete	Not Approved
Hartford College of Medicine	✓	✓	✓	Started 02/01/2019	3 / 3 Surveys Complete	Not Approved
Mellon University Medical Center	✗	✓	✓	Notify HRPP		
Midwest University Medical Center	✓	✓	✓	Started 02/11/2019	0 / 3 Surveys Complete	Not Approved
MUMC component - Peabody Institute of Medicine	✓	✓	✓	Add PI Info		
Peabody Institute of Medicine	✓	✓	✓	Completed 02/01/2019	1 / 3 Surveys Complete	Not Approved

EXPORT STATUS SUMMARY TAB



Reviewing IRB Approvals

Relying Site Approvals

Status Summary

Participant Status Summary

Search:

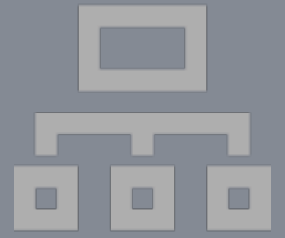
Export Data


Export Local Considerations

Export Status Summary Tab

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Carnegie University Medical Center	✓	✓	✓	Completed 12/04/2018	3 / 3 Surveys Complete	Approved
Central Ohio Medical Center	✓	✗	✓	Contacted 12/04/2018	0 / 3 Surveys Complete	Approval Not Ready
Columbus University	✗	✓	✓	Add PI Info	0 / 3 Surveys Complete	Approval Not Ready
Eastman Medical Center of Ohio	✗	✓	✓	Add PI Info	0 / 3 Surveys Complete	Approval Not Ready
Midwest University Medical Center	✓	✓	✓	Completed 12/07/2018	3 / 3 Surveys Complete	Not Approved
Peabody Institute of Medicine	✓	✓	✓	Started 12/07/2018	0 / 3 Surveys Complete	Not Approved
University of the Bay	✓	✗	✓	Notify HRPP	0 / 3 Surveys Complete	Approval Not Ready

MANAGING YOUR FWA & COMPONENTS



 Your Institution

University of the Bay

[Profile](#) [Components](#) [LOI](#)

Components

List your FWA's component sites that may rely on an IRB in IREx. Component sites do not get access to IREx; you will be able to make cede decisions and provide local context on their behalf.

As the FWA-holder of a component site, you are responsible for providing the relevant local considerations for component sites in your Institutional Profile and for specific studies, as requested by the Reviewing IRB.

University of the Bay School of Engineering

Sch of Engineering



University of the Bay School of Nursing and Family Health

Sch Nursing & Fam Health



This site is listed as a participant in the following projects

- Blood pressure outcomes in neonatal intensive care unit (NICU) graduates with idiopathic hypertension: Demonstration Study
- A Cluster Randomized Multi-center Baseline Assessment of Carbon Dioxide Emission (ACE)
- Measuring Levels of Baseline Radiation Exposure in Urgent Care Visits (RADIATE II)

University of the Bay University Hospital Systems

Univ Hospital Systems



Add a component:

Name

Short Name



Cancel

Save

Recent System Updates

UPDATED FAQs ON IREX WEBSITE

[About](#)[Resources](#)[FAQs](#)[Newsletters](#)[Feature Release Log](#)[Contact](#)

FAQs

Frequently Asked Questions

[Access](#)[Creating a Study](#)[Eligibility](#)[Functionality](#)[IREx Study Manager](#)[Local Considerations](#)[Permissions](#)[Training and Resources](#)[User Roles](#)

SITE-SPECIFIC COMMENTS/NOTES



GOAL: To provide dedicated area for SIRB and/or Study Manager to log history of outreach to sites (e.g., a journal)

HOW IT WORKS:

- SIRB liaison can make comments
- SM can make comments
- Automatically logs date and time and user
- SIRB and SM can see each others comments
- Does NOT generate notifications

The screenshot displays the 'Participant Status Summary' interface. At the top, there are tabs for 'Reviewing IRB Approvals', 'Relying Site Approvals', and 'Status Summary'. Below these is a search bar and a table of sites. A red arrow points from the 'Mellon University Medical Center' row in the table to a detailed view of its comments.

Site	SMART IRB	LOI	IREX Access	Reliance Decision	Loc
Boston Medical Center	✓	✗	✓	Started 6/13/2019	3
Carnegie University Medical Center	✓	✓	✓	Completed 6/6/2018	3
Columbus University	✓	✗	✓	Contacted 2/25/2019	
Hartford College of Medicine	✓	✓	✓	Started 2/19/2019	0
Mellon University Medical Center	✗	✓	✓	Completed 6/6/2018	3
Peabody Institute of Medicine	✓	✓	✓	Started 2/19/2019	3

Mellon University Medical Center

Comments [Edit]

Jerry Shaw (Study Manager) 6/17/2019 12:43pm
Site PI changed. Sent revised reliance instructions to study coordinator and new PI.

Laura Sanders (HRPP) 6/17/2019 12:45pm
Discussed local SOPs by phone and adjusted Study Specific Reliance Plan (SSRP) accordingly. IREx automatically notified HRPP of updated SSRP for their acceptance.

Type comment here...

[Post]

TRACKING UPDATES TO LOCAL CONSIDERATIONS



GOAL: To indicate when surveys were last updated

HOW IT WORKS:

1. Site HRPP is asked to provide clarification on survey
2. Site HRPP logs in and updates information
3. sIRB and Study Manager are notified that information was updated
4. Status Summary (and export) note where surveys were updated

Reviewing IRB Approvals

Relying Site Approvals

Status Summary

Export Data

Participant Status Summary

Search:

Site	SMART IRB	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Columbus University	✓	✓	Started 6/23/2019	3 / 3 Surveys Complete	Not Approved
Hartford College of Medicine	✓	✓	Completed 6/24/2019	<div> <div> Institutional Profile Confirmed: 6/23/2019 </div> <div> HRP Survey Completed: 6/23/2019 Updated: 6/24/2019 </div> <div> PI Survey Completed: 6/23/2019 </div> <div> Email study personnel </div> </div>	Not Approved
Mellon University Medical Center	✓	✓	Started 6/23/2019		Not Approved

If a survey is updated, the date updated is listed.

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If a survey is updated, the date updated is listed.

SIRB CAN INDICATE “NO FURTHER REVIEW” FOR QUALIFYING STUDIES



VERSIONS

1

Reviewing IRB

Carnegie College Approved

Relying Sites

Peabody Research Institute Approved

Registered/In Progress

none listed

Continuing Review: Expedited (Approved) Current

Edit review Site approvals Unlock Delete review

Study Info

Role: Reviewing IRB
IRB Number: 180762
Status: approved
Submission Type: Continuing Review: Expedited
Review Cycle: No Further Review Required

Key Dates

Submitted: 6/10/2019
Pre-Reviewed: 6/17/2019
Reviewed: 6/21/2019
Approved: 6/21/2019

No expiration dates listed in IREx

SIRB CAN INDICATE “NO FURTHER REVIEW” FOR QUALIFYING STUDIES



Updated approval notification language

Dear Liaisons and Study Contacts,

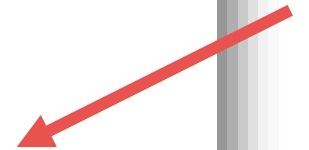
Baystate Health, Inc has shared IRB approval for your institution, Vanderbilt University Medical Center, in IREx for the study below:

Study Title: No CR required 20190719

Type of Review / Approval: Initial Study: Expedited

Expiration Date: No further IRB review required. Please refer to the sIRB determination letter and your local HRPP for any ongoing reporting requirements.

Study Link: <https://staging.irbexchange.org/study/index/?proj=93596>



**SNEAK PEAK: User Interface
Updates Coming Soon**

DISTINGUISHING THE REVIEWING IRB & LEAD SITE



CURRENT ISSUE:

IREx assumes the sIRB is also the Lead Site, causing confusion about where to find documents.

SOLUTION PART 1:

1. Rewording question in IREx setup to ask whether Reviewing IRB is also the Lead Site
2. If not, the Lead Site can be identified

The screenshot shows the 'IREx Project Settings' window. A progress bar at the top has four steps: a gear icon (selected), a person icon, a person icon with a checkmark, and a checkmark icon. A yellow star is placed above the first question, and a red arrow points from the text 'Identify Lead Site' to the question. The question is 'Is the Lead Site also at the Reviewing IRB Institution?' with radio buttons for 'Yes' and 'No'. Below it is a text input field with a green 'Add Site' button. The next question is 'Is the Reviewing IRB a participating research site in the study?' with radio buttons for 'Yes' and 'No'. The third question is 'Would you like to collect local considerations in IREx?' with radio buttons for 'Yes' and 'No'. The fourth question is 'How are sites' consent forms being handled?' with a radio button for '(Recommended) Sites will provide consents for sIRB review (e.g., using a template) OR study will not have consents.' and a radio button for 'A consent form generator will be used to build consents for sites'. The fifth question is 'Do you require a Letter of Indemnification (LOI) for this study?' with radio buttons for 'Yes' and 'No'. A green 'Continue' button is at the bottom right.

IREx Project Settings

Is the Lead Site also at the Reviewing IRB Institution?

Yes No

Identify Lead Site

Is the Reviewing IRB a participating research site in the study?

Yes No

Would you like to collect local considerations in IREx?

Yes No

How are sites' consent forms being handled?

Using IREx to Capture Local Considerations

(Recommended) Sites will provide consents for sIRB review (e.g., using a template) OR study will not have consents.

A consent form generator will be used to build consents for sites

Do you require a Letter of Indemnification (LOI) for this study?

Yes No

Continue →

DISTINGUISHING THE REVIEWING IRB & LEAD SITE



SOLUTION PART 2

- Renaming the Reviewing IRB Approvals tab
- Labeling the SIRB
- Including the name of the Lead Site, which may be different from the SIRB

Site-Specific IRB

Study Summary ▾ Reviewing IRB Contact ▾ IREx Study Managers ▾ Participating Personnel

The Influence of Time-to-Diagnosis on Time-To-Treatment for STEMI Patients

Study-wide IRB Approvals Relying Site Approvals Status Summary

Protocol Version: 09/13/2017 Manage Version ▾

SIRB: Duke University Health Systems, Inc. Vanderbilt Univ Med Ctr is Lead Site

Continuing Review: Expedited (exp. 4/24/2020) Current

Edit review Site approvals Unlock Delete review

Study Info		Key Dates	
Role:	Reviewing IRB	Submitted:	4/16/2019
IRB Number:	161044	Pre-Reviewed:	4/25/2019
Status:	approved	Reviewed:	4/25/2019
Submission Type:	Continuing Review: Expedited	Approved:	4/25/2019
Review Cycle:	12 mo	Expires:	4/24/2020

Documents

DISTINGUISHING THE REVIEWING IRB & LEAD SITE



SOLUTION PART 3

- Renaming the Relying Site Approvals tab

★

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

Protocol Version: 09-Apr-2019

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

Brigham and Women's Hospital	
▼ Initial Study: Full Board	Current
Icahn School of Medicine at Mount Sinai	
▼ Initial Study: Full Board	Current
MetroHealth System site amendment	
▼ Initial Study: Expedited (exp. 3/26/2020)	Current

ADD PARTICIPATING SITE DIALOGUE (SIRB & STUDY MANAGER)



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

1 sites need attention

Show All Personnel

- ☒ Duke University Health Systems, Inc. #00009025
- ☒ Oregon H&S Univ component - Oregon Health & Science University Hospitals, Clinics, and Health Centers
- ☒ University of Colorado, Denver #00005070
- ☒ University of Iowa #00003007
PI: Barney Levy - Missing Email
Coordinator: +
- ☒ University of Wisconsin - Madison #00005399

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. ?

Institution

PI

Coordinator

Boston Med Ctr component - Boston Children

boston
bost@pi.com



+ Add Coordinator



John Hopkins component - All Childrens
Hospital

fad
dfa@dfa.com



+ Add Coordinator



Mellon University Medical Center #00001111

fadf
dfad@dfad.cdd



+ Add Coordinator



Vanderbilt University Medical Center
#00005756

to
dfda@dfad.com



+ Add Coordinator



+ Add Site

Cancel

Save

ADD PARTICIPATING SITE DIALOGUE (SIRB & STUDY MANAGER)



Add A Site

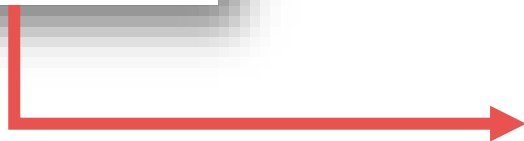
Site Name:
University of Alabama Birmingham - FWA#000

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



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:

University of Alabama Birmingham - FWA#00005960

PI Engaged

PI First Name:

Enter PI first name, if known

PI Last Name:

Enter PI last name, if known

PI Email:

Enter PI email address, if known

☒ This PI engages other sites

Site Coordinator

Coordinator First Name:

Enter Coordinator first name, if known

Coordinator Last Name:

Enter Coordinator last name, if known

Coordinator Email:

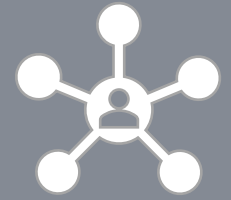
Enter Coordinator email address, if known

Sites Engaged By This PI

List any other 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

STUDY REGISTRATION DIALOGUE (RELYING SITE HRPPS)



Register for Study

Testing Performance Group UI Again

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

Duke University Health Systems, Inc.

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.

Cancel Register



Investigator will get access here and
you do not have to re-enter their
contact info

? Does **Coach K** engage **Duke University Health Systems, Inc.** FWA #00009025 or one of its components in this study? ☒ Yes ☐ No

Confirm PI Details

First Name Last Name

Coach K -- Krzyzewski

Email address

coachk@duke.mbb

Confirm Your Engaged FWAs / Components

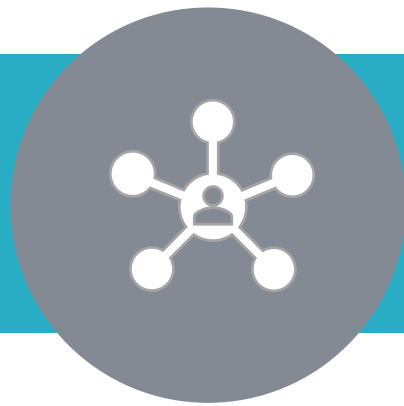
The SIRB or Study Manager identified your site as shown below. Edit the information if it is incorrect. If one of your FWA components is part of this study, but is not listed below, cancel this registration; go to the Homepage and use the "Components" button to add it; and then return to register using the component you added.

<input checked="" type="checkbox"/>	Duke University Health Systems, Inc. - FWA#00009025
<input type="checkbox"/>	Duke Univ component - Duke Children's Hospital - FWA#00009025
<input type="checkbox"/>	Duke Univ component - Mildred Duke Rehabilitation Center - FWA#00009025

? Are you aware of other sites/FWAs that **Coach K** engages in this study? ☐ Yes ☒ No

Cancel Submit

STUDY REGISTRATION DIALOGUE (RELYING SITE HRPPS)



Testing Performance Group UI Again

**Your site is engaged
+ another FWA may be, too**

? Does Coach K engage Duke University Health Systems, Inc. FWA #00009025 or one of its components in this study? ☒ Yes ☐ No

Confirm PI Details

First Name: Coach Last Name: K -- Krzyzewski

Email address: coachk@duke.mbb

Confirm Your Engaged FWAs / Components

The SIRB or Study Manager identified your site 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, cancel this registration, go to the Homepage and use the "Components" button to add it; and then return to register using the component you added.

- ☒ Duke University Health Systems, Inc. - FWA#00009025
- ☐ Duke Univ component - Duke Children's Hospital - FWA#00000025
- ☐ Duke Univ component - Mildred Duke Rehabilitation Center - FWA#00009025

? Are you aware of other sites/FWAs that Coach K engages in this study? ☒ Yes ☐ No

Other Sites Engaged By This PI

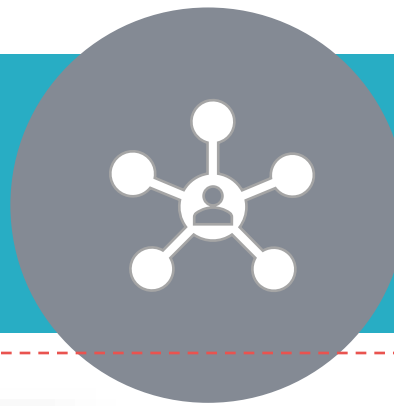
List any other FWAs that may be engaged by this study team for this study. IREx will notify the HRPP Liaison(s) to confirm engagement.

Search by name or FWA number

Sites in this performance group

- Wake Forest University Health Sciences - FWA#123132163 x

STUDY REGISTRATION DIALOGUE (RELYING SITE HRPPS)



**Your site is not engaged
+ why**

Registration for
Testing Performance Group UI Again

- ? Does **Coach K** engage **Duke University Health Systems, Inc. FWA #00009025** or one of its components in this study? ☐ Yes ☒ No
- ? Are you aware of other sites/FWAs that **Coach K** engages in this study? ☐ Yes ☒ No
- ? Is **Duke University Health Systems, Inc. FWA #00009025** or one of its components engaged by another PI? ☐ Yes ☒ No

Duke University Health Systems, Inc. FWA#00009025 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](#).

Cancel Submit

Reviewing IRB Approvals

Relying Site Approvals

Status Summary

Non-engaged Sites

Export Data

Participant Status Summary

Search:

Site	SMAR IRB
Albert Einstein College of Medicine	
Boston Med Ctr component - Boston Children	
Carnegie University Medical Center	

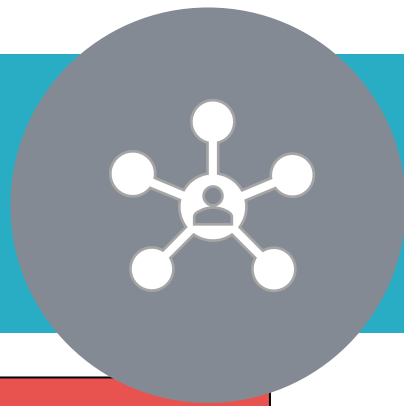
Non-Engaged Sites

Site	Reason Site Not Engaged	Response	Response By	
Medical University of South Carolina - FWA#00001888	PI left institution	7/16/2019	Laura Sanders (HRPP)	Re-enlist
University of Wisconsin - Madison - FWA#00005399	Lorem ipsum is a pseudo-Latin text used in web design, typography, layout, and printing in place of English to emphasise design elements over content. It's also called placeholder (or filler) text. It's a convenient tool for mock-ups. It helps to outline the visual elements of a document or presentation, eg typography, font, or layout. Lorem ipsum is mostly a part of a Latin text by the classical author and philosopher Cicero. Its words and letters have been changed by addition or removal, so to deliberately render its content nonsensical; it's not genuine, correct, or comprehensible Latin anymore. While lorem ipsum's still resembles classical Latin, it actually has no meaning whatsoever. As Cicero's text doesn't contain the letters K, W, or Z, alien to latin, these, and others are often inserted randomly to mimic the typographic appearance of European languages, as are digraphs not to be found in the original.	7/16/2019	Laura Sanders (HRPP)	Re-enlist

**sIRB + Study
Manager can track
non-engaged sites**

Showing 1 to 2 of 2 entries

ONE STEP CLOSER: COMBO SITES IN IREX



Streamline Reliance Documentation

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

Next Call

- October 18, 2019 @ 1 PM ET/10 AM PT