



# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR STUDY MANAGERS

July 19, 2019

- 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 – HRPPs



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

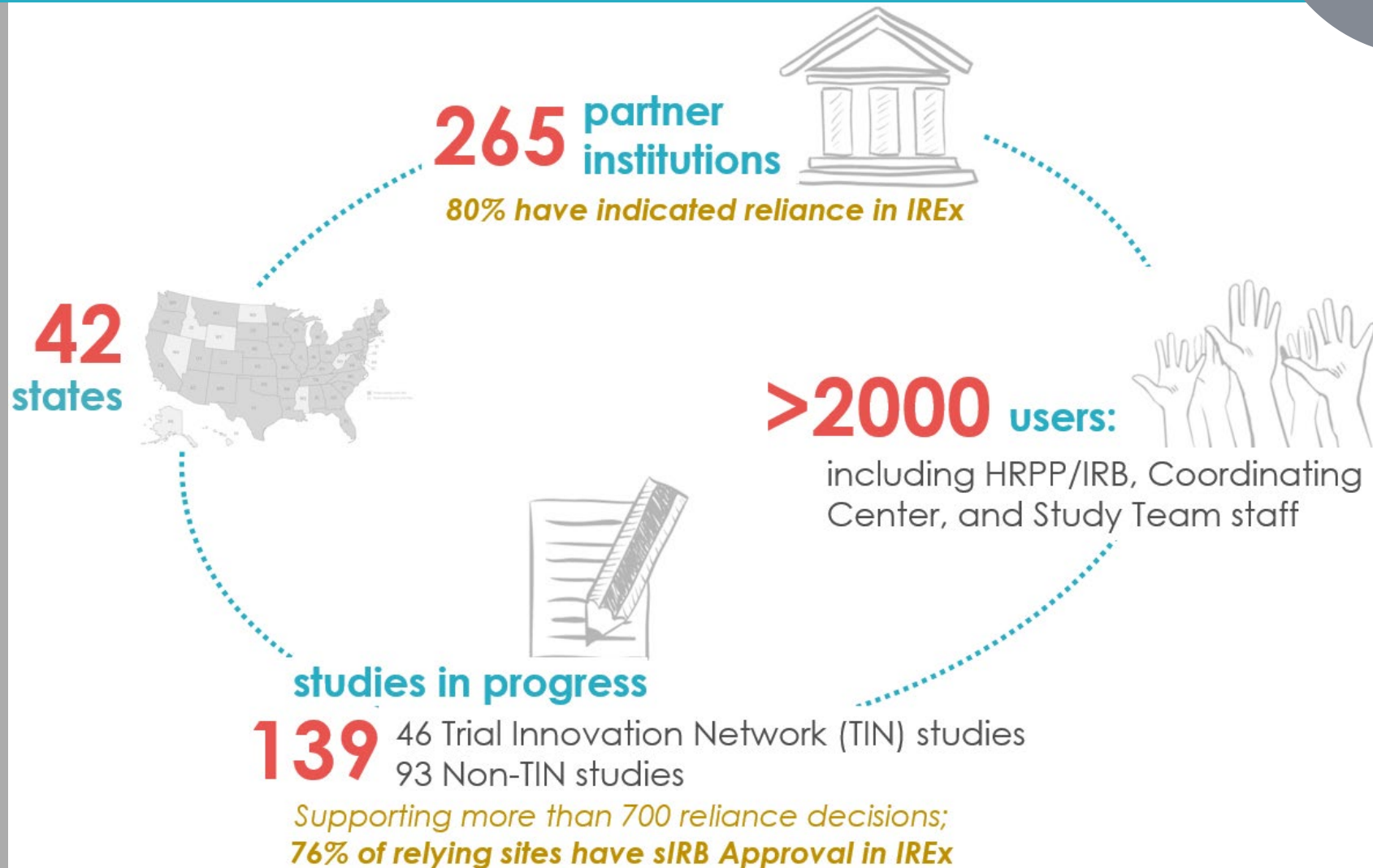
# IREx Utilization – A Look at IREx Metrics

# IREX UTILIZATION

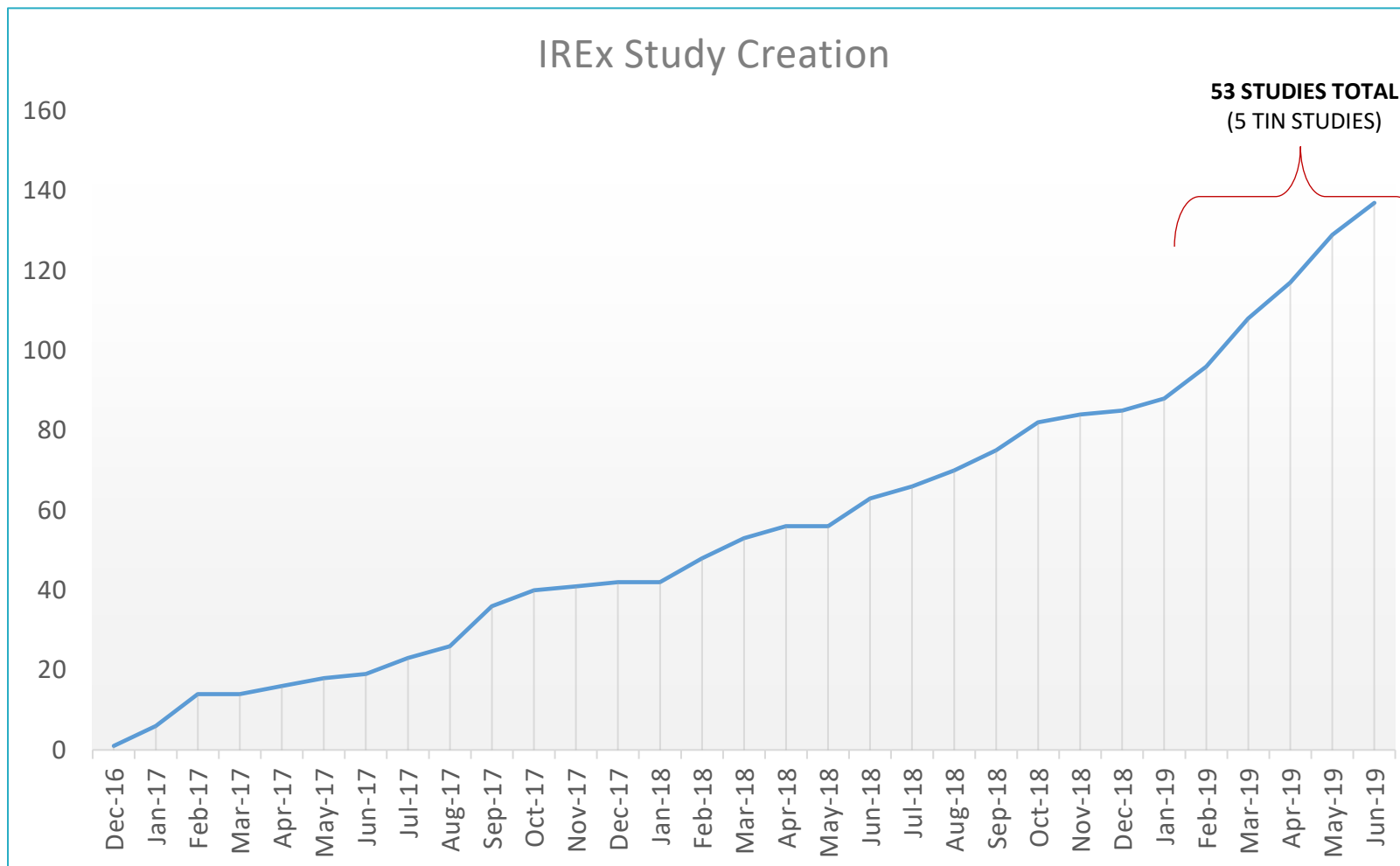


## STATISTICS

- **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...

# 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



# NEW STUDY MANAGER DASHBOARD




 Find a Study

by Name:

by Sponsor:

 find

 Study Manager Dashboard

*Note: Each counter will turn green when **all** the participating sites listed on the study have completed the step.*

## Study Manager Dashboard

Study Title	Sites	Registered?	Completed Agreements?	Indicated Reliance?	Completed Local Context?	Approved?
		Signed Agreements	Reliance	Local Context	Current Version Approved	
Master Randomized Multi-center Baseline Assessment of Carbon Dioxide Emission (ACE)	1 / 4 Registered	SMART IRB	4	1	1	1
		LOI	1			
		IREx	4			
Evidence for the Association between Reduced Sleep and Noise Pollution (EARN)	Add Participating Sites					
Assessing the Influenza-A Checklist for Health Outcome Optimization (ACHOO)	21 / 21 Registered	SMART IRB	1	21	21	20
		IREx	2			
A Randomized, Double- Blind, Placebo-Controlled Trial to Assess the Primary Outcomes of Tramadol to treat acute post-surgical pain (PRIMARY)	6 / 14 Registered	SMART IRB	9	3	n/a	2
		LOI	10			
		IREx	13			

# 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 SMs 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 the tabs 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	0
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
<div> <div>If a survey is updated, the date updated is listed.</div> <div> <div> <div>✓ Institutional Profile</div> <div>Confirmed: 6/23/2019</div> </div> <div> <div>✓ HRP Survey</div> <div>Completed: 6/23/2019</div> <div>Updated: 6/24/2019</div> </div> <div> <div>✓ PI Survey</div> <div>Completed: 6/23/2019</div> </div> <div> <div>Email study personnel</div> </div> </div> </div>					
Hartford College of Medicine	✓	✓	Completed 6/24/2019		Not Approved
Mellon University Medical Center	✓	✓	Started 6/23/2019		Not Approved

© COPYRIGHT 2019. VANDERBILT UNIVERSITY MEDICAL CENTER.

**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, and a checkmark icon. A yellow star and a red arrow point to the first question: 'Is the Lead Site also at the Reviewing IRB Institution?'. Below this, another yellow star points to the text 'Identify Lead Site' next to a search input field. The form contains several other questions with radio button options.

Question	Options
Is the Lead Site also at the Reviewing IRB Institution?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Is the Reviewing IRB a participating research site in the study?	<input type="radio"/> Yes <input checked="" type="radio"/> No
Would you like to collect local considerations in IREx?	<input checked="" type="radio"/> Yes <input type="radio"/> No
How are sites' consent forms being handled?	<input checked="" type="radio"/> (Recommended) Sites will provide consents for sIRB review (e.g., using a template) OR study will not have consents. <input type="radio"/> A consent form generator will be used to build consents for sites
Do you require a Letter of Indemnification (LOI) for this study?	<input type="radio"/> Yes <input checked="" type="radio"/> No

Buttons: 'Add Site' (green), 'Continue →' (green)

# 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

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

Role:	Reviewing IRB
IRB Number:	161044
Status:	approved
Submission Type:	Continuing Review: Expedited
Review Cycle:	12 mo

#### Key Dates

Submitted:	4/16/2019
Pre-Reviewed:	4/25/2019
Reviewed:	4/25/2019
Approved:	4/25/2019
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

**Participating Sites**

1 sites need attention ☐ Show All Personnel

<input checked="" type="checkbox"/> Duke University Health Systems, Inc. #00009025	
<input checked="" type="checkbox"/> Oregon H&S Univ component - Oregon Health & Science University Hospitals, Clinics, and Health Centers	
<input checked="" type="checkbox"/> University of Colorado, Denver #00005070	
<input checked="" type="checkbox"/> University of Iowa #00003007	
PI: Barney Levy - Missing Email	
Coordinator: +	
<input checked="" type="checkbox"/> 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		<input type="button" value="+ Add Coordinator"/>	
John Hopkins component - All Childrens Hospital	fad dfa@dfa.com		<input type="button" value="+ Add Coordinator"/>	
Mellon University Medical Center #00001111	fadf dfad@dfad.cdd		<input type="button" value="+ Add Coordinator"/>	
Vanderbilt University Medical Center #00005756	to dfda@dfad.com		<input type="button" value="+ Add Coordinator"/>	

# 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:**

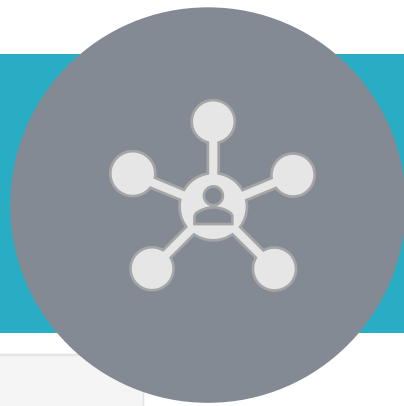
Enter Coordinator email address, if known

#### 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.

☒ Duke University Health Systems, Inc. - FWA#00009025

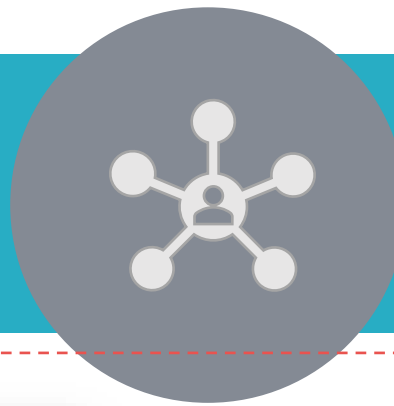
☐ Duke Univ component - Duke Children's Hospital - FWA#00009025

☐ 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)



**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

Albert Einstein College of Medicine

Boston Med Ctr component - Boston Children

Carnegie University Medical Center

SMART  
IRB

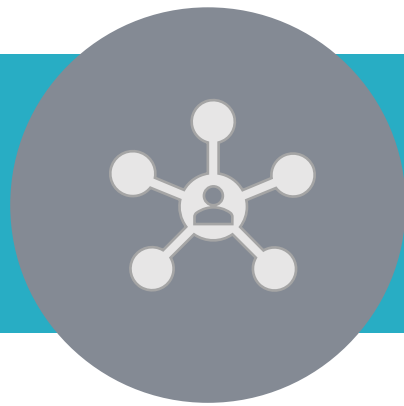
## Non-Engaged Sites

Site	Reason Site Not Engaged	Response	Response By	
Medical University of South Carolina - FWA#00001888	PI left institution	7/16/2019	Laura Sanders (HRPP)	<a href="#">Re-enlist</a>
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)	<a href="#">Re-enlist</a>

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

Showing 1 to 2 of 2 entries

# 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**

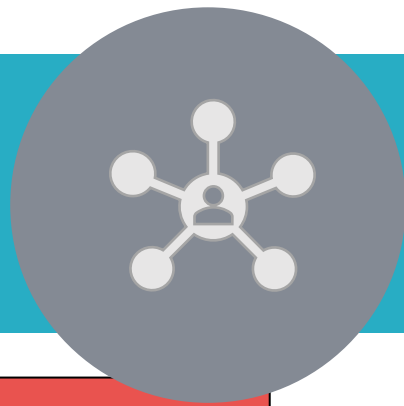
List any other FWAs that may be engaged by this study team for this study. IREx will notify the HRPP Liaison(s) to confirm engagement.

Search by name or FWA number

**Sites in this performance group**

- Wake Forest University Health Sciences - FWA#123132183

# ONE STEP CLOSER: COMBO SITES IN IREX



## *Streamline Reliance Documentation*

	<b>FWA #1 "Primary"</b>	<b>FWA #2</b>
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 @ 2 PM ET/11 AM PT