



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR STUDY MANAGERS

October 16, 2020

- Training
- Study Support

Natalie Dilts



- Lead Application Developer

Bryce Embry



- System Development

Asri Mumpuni



- Project Director

Emily Serdoz



- User Support
- Study Support

Samuel Stradley



- Onboarding
- Study Support

Bridget Swindell



- User Materials
- Study Support

Linda Tan



- Application Developer

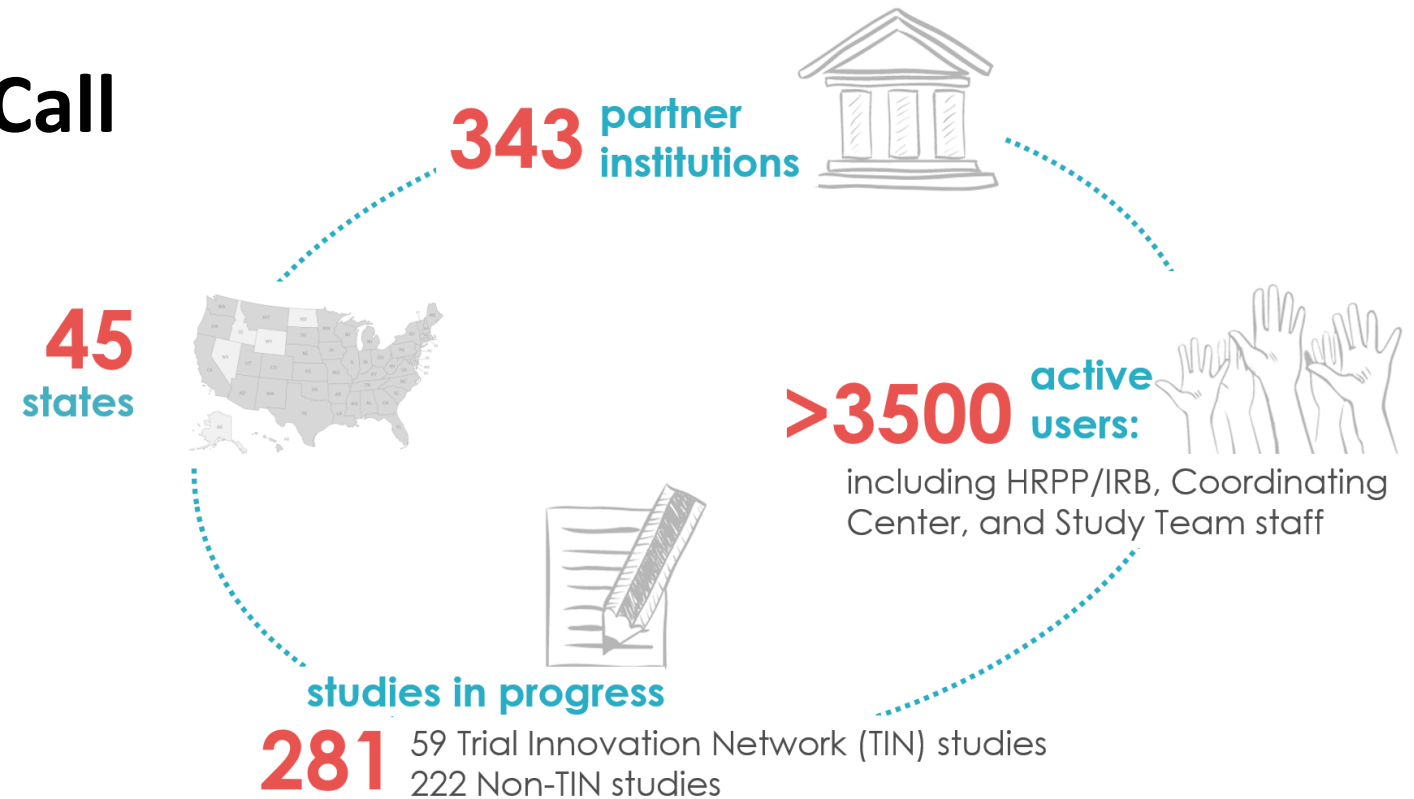
Evan Wimberly



QUARTERLY CALL AGENDA




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

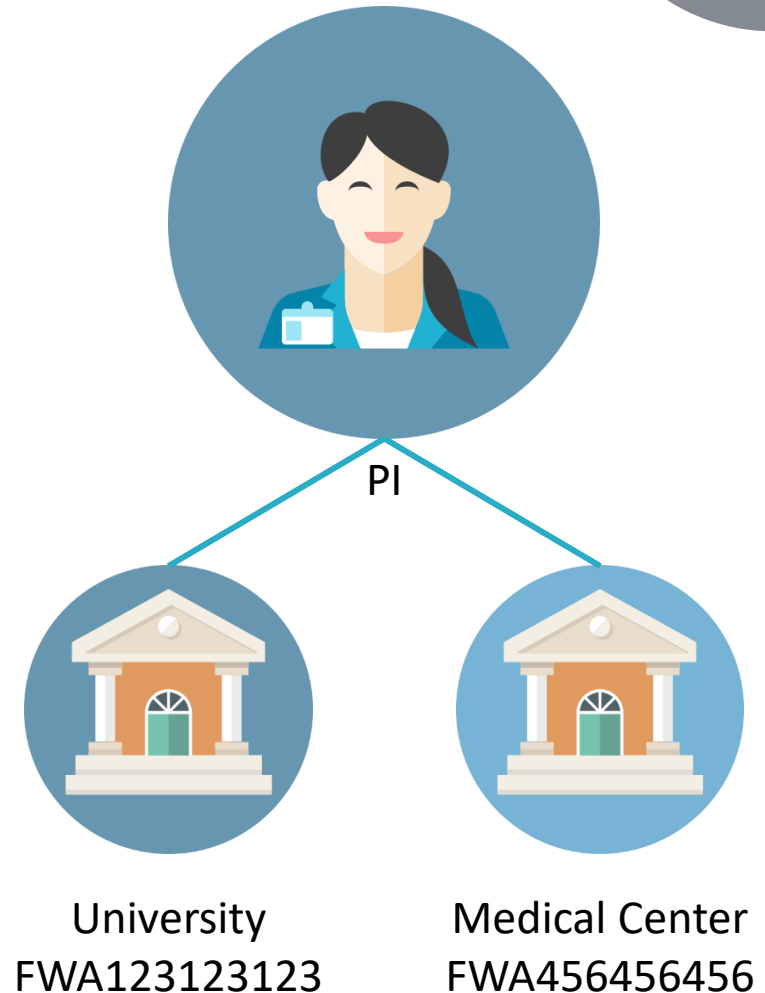


Reminders from the Last Call

IREX FACILITATES COMBO SITES!



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



UPDATED PARTICIPATING SITES DIALOG



As the **Study Manager**, you can indicate a site is a combo site.

But you don't have to!

The Relying Site knows best and can add other FWAs, as needed.

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

Institution	PI (Required)	Coordinator	
Baystate Health, Inc #00004355	Baystate PI	Add Coordinator	✎ ✕
Boston Medical Center 00000214	pi@baystate.edu		
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	✎ ✕
	george@wash.cdu	martha@wash.cdu	
Hartford College of Medicine #00003216	Site has registered & can		✕
Peabody Institute of Medicine 897645665	now manage contacts		

STUDY MANAGERS CAN UPLOAD CONTINUING REVIEWS & AMENDMENTS



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*
- Upload site-specific amendments
- Upload continuing reviews
- Upload study-wide amendments

NEW

*API available to connect to your sIRB e-IRB system

New System Features!

AGREEMENT CHECKER



- Before a study is created, check whether potential sites have signed onto SMART IRB and an LOI, if required by the sIRB

Find a Study

by Name:

by Sponsor:

find

Create a Study

Your Institution

Carnegie University

Profile Components LOI

Your Liaisons

Carnegie U Liaison

Lindsey Smith

Resources

Find other users

Find other sites

Agreement Checker

Add HRPP Staff / Members

Request Help

Join A Training

Resources

AGREEMENT CHECKER



Agreement Checking Tool

Report Parameters

SIRB: Mellon University Medical Center

Add Participating Site: Select a site

[Download CSV](#)

Select a SIRB (for report to know whether to pull in LOI status)

Start typing or select a site from the drop down to add to the list.

Site Name	FWA	SMART	IREx	LOI
Anderson Medical Center	546879213	no	yes	no
Faraday Institute of Research, Science and Technology	01569874	yes	yes	no
Goodall University Medical Center	78899657	yes	yes	yes
Middle-earth College of Agriculture	456431546	no	yes	yes
Peabody Institute of Medicine	897645665	yes	yes	yes

Site Name	FWA	SMART	IREx	LOI	
Anderson Medical Center	546879213	✘	✔	✘	Remove
Faraday Institute of Research, Science and Technology	01569874	✔	✔	✘	Remove
Goodall University Medical Center	78899657	✔	✔	✔	Remove
Middle-earth College of Agriculture	456431546	✘	✔	✔	Remove
Peabody Institute of Medicine	897645665	✔	✔	✔	Remove

Showing 1 to 5 of 5 entries

COMING SOON

Anticipated end of October/beginning of November

MORE AGREEMENT OPTIONS



1

**SMART IRB Agreement
Versions 1 and 2**
(Released Oct 1, 2020)

2

**Other Reliance
Agreement** (e.g., IAAs,
MOUs) for sites who are
unable to sign on to
SMART IRB

3

**Indemnification terms
or Letters of
Indemnification (LOI)**, if
required in addition to
the reliance agreement

SIRB Sets Up Agreements



SIRB

- Ability to offer SMART IRB Agreement, an Other Reliance Agreement, **and** indemnification on the same study.
- If SMART IRB and an Other Reliance Agreement are offered on the same study, sites in SMART IRB will default to SMART IRB for the study.
- If the reliance involves the NIH Intramural Research Program, both the Reviewing IRB and Relying Institutions will be required to use SMART IRB version 2.

What reliance agreement(s) can be used by relying sites?
You can offer multiple agreements, if needed

SMART IRB Agreement ([view agreement](#))

Other Reliance Agreement

Please name the agreement, which will be referenced in the Notification of Reliance after a site ceedes review (e.g., Individual Authorization Agreement, MOU, [Institution] Reliance Agreement).

Use Existing Broad Reliance Agreement Add New Reliance Agreement

Type: Broad Study Specific

Name:

Short Name:

Do you require a Letter of Indemnification (LOI) for this study? Yes No

Use Existing Broad LOI Agreement Add New LOI Agreement

Type: Broad Study Specific

Name:

Short Name:

Study Managers can view each site's agreement status



- Status Summary tab

SMART IRB sites are tracked automatically

SIRB tracks when Relying HRPPs execute an agreement

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

Participant Status Summary

Q Search:

Site	Reliance Agreement	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Eastman Medical Center of Ohio	SMART2	Chopped Salad	✓	Contacted 10/1/2020		
Faraday Institute of Research, Science and Technology	SMART2	Chopped Salad	✓	Completed 10/15/2020	0 / 3 Surveys Complete	Not Approved
Goodall University	SMART1	Chopped Salad	✓	Started 10/1/2020	0 / 3 Surveys Complete	Not Approved
Jefferson University	SMART1	Chopped Salad	✓	Started 10/5/2020	0 / 3 Surveys Complete	Not Approved
Middle-earth College of Agriculture	Blackberry Turnover	Chopped Salad	✓	Notify HRPP		
Norfolk Pine University	×	Chopped Salad	✓	Started 10/15/2020	0 / 3 Surveys Complete	Not Approved

Study Managers are notified



- When sites have completed required agreements
- When sites rely →
- When sites join IREx

Dear all,

This email confirms that **Dunder Mifflin University** has agreed to rely on the **University of Hamilton** IRB using the following agreement(s):

- SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement
- Hamilton Master sIRB Letter of Indemnification

Study Title	Responses to Infarction in Clinical sEttings
Study Short Title	RICE
IREx Project ID	152991
Reviewing IRB	University of Hamilton (FWA #00025295)
Relying Institution	Dunder Mifflin University (FWA #00029025)
Study Link	https://staging.irbexchange.org/study/index/?proj=152991

NOTE: This is not a notice of IRB approval. A separate email will be sent when the study is approved by the reviewing IRB.

*Thank you,
The IREx Team*

Next Call

- January 15, 2021 (wahoo a new year!!!)