



# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR HRPPPS

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

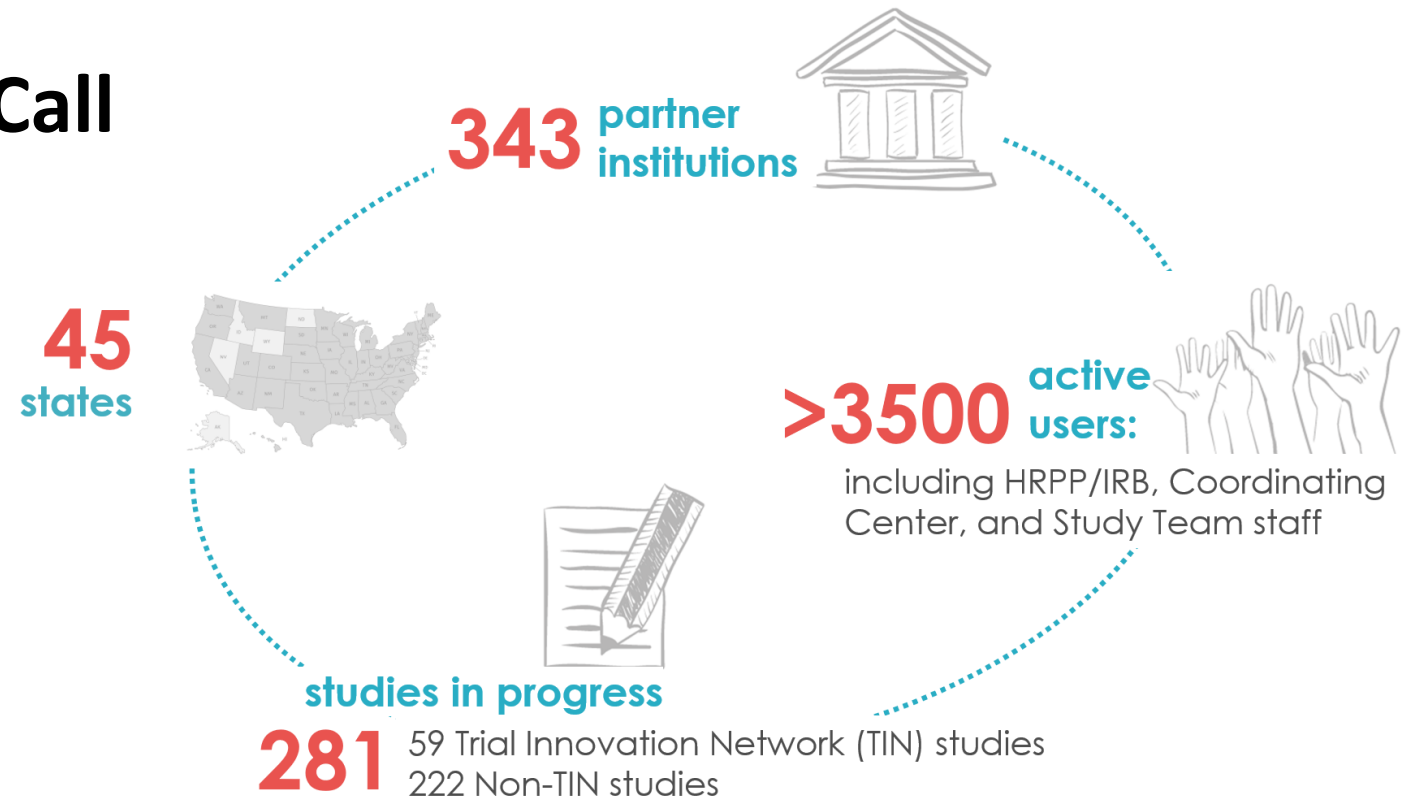
**Evan  
Wimberly**



# QUARTERLY CALL AGENDA




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



# Reminders from the Last Call

# RELYING HRPP REGISTRATION



 Does **Riaan Browne** engage **Carnegie University Medical Center FWA #12345678** 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

☒ Carnegie University Medical Center - FWA#12345678

☐ Carnegie U Med Ctr component - Carnegie Children's Hospital - FWA#12345678

 Does **Riaan Browne** engage **OTHER SITES / FWAs** for this study, to your knowledge? ☐ Yes ☒ No 

## WHAT CAN THE HRPP DO?

- Change the FWA
- Change your PI
- Add an FWA (combo site)
- Indicate institution is **not** engaged




**This is new!**

**Let us know if you experience problems  
(screenshots are so helpful!)  
Your feedback is welcome!**

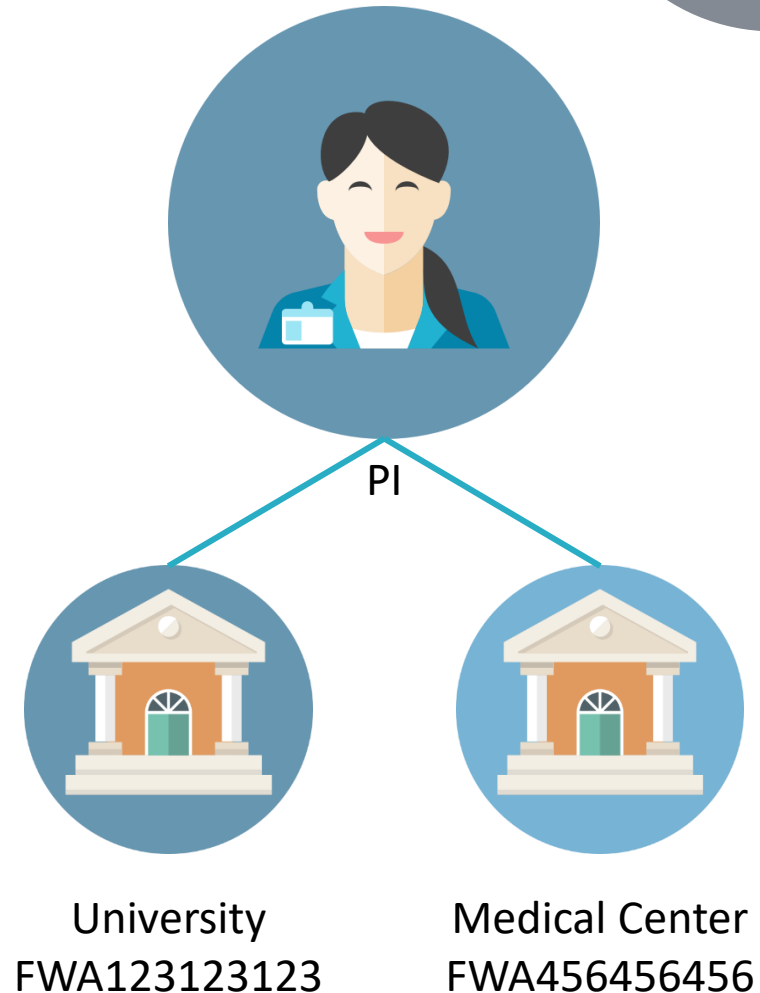
# IREX FACILITATES COMBO SITES!



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

## BENEFITS:

1. Capture reliance from all engaged FWAs
2. Streamline local considerations for HRPPs – one FWA can defer HRP answers to HRP Survey to another FWA
3. One (1) PI Survey



# UPDATED PARTICIPATING SITES DIALOG



## 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  
Boston Medical Center 00000214

Baystate PI  
pi@baystate.cdu

+ Add Coordinator

Eastman Medical Center of Ohio  
#45648974865  
Case Western Reserve University  
00000161

Only PI  
onlypi@eastman.cdu

+ Add Coordinator

George Washington University #00002344

George Wash  
george@wash.cdu

Martha Wash  
martha@wash.cdu

Hartford College of Medicine #00003216  
Peabody Institute of Medicine 897645665

Site has registered & can  
now manage contacts

+ Add Coordinator

# 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

The screenshot displays the SMART IRB web application interface. At the top, there is a 'Find a Study' section with input fields for 'by Name:' and 'by Sponsor:', a 'find' button, and a 'Create a Study' button. Below this, the 'Your Institution' section shows 'Carnegie University' with tabs for 'Profile', 'Components', and 'LOI'. The 'Your Liaisons' section lists 'Carnegie U Liaison' and 'Lindsey Smith'. On the right, the 'Resources' menu is visible, with the 'Agreement Checker' option highlighted by a red box and a red arrow. Other resources listed include 'Find other users', 'Find other sites', 'Add HRPP Staff / Members', 'Request Help', 'Join A Training', and 'Resources'.

# AGREEMENT CHECKER



## Agreement Checking Tool

**Report Parameters**

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

Add Participating Site:  Start typing or select a site from the drop down to add to the list.

[Download CSV](#)

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	✗	✓	✗	<a href="#">Remove</a>
Faraday Institute of Research, Science and Technology	01569874	✓	✓	✗	<a href="#">Remove</a>
Goodall University Medical Center	78899657	✓	✓	✓	<a href="#">Remove</a>
Middle-earth College of Agriculture	456431546	✗	✓	✓	<a href="#">Remove</a>
Peabody Institute of Medicine	897645665	✓	✓	✓	<a href="#">Remove</a>

Showing 1 to 5 of 5 entries

# RESET SSRP



## About the SSRP

- Documents how the flexible elements of reliance agreement will be handled (e.g., SOPs and HIPAA determinations and actions, insurance and indemnification).
- Aligns with the SMART IRB Implementation Checklist and Documentation Tool

Site	SMART IRB	LOI	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Me Re	<b>Edit prior to acceptance</b>	✓	✓	Started 9/15/2020	1 / 3 Surveys Complete ▾	Not Approved
Our Lady of Hospital, In	<b>Edit after acceptance</b>	✓	✓	Completed 9/4/2020	3 / 3 Surveys Complete ▾	Not Approved

# RESET SSRP



## Reviewing IRB

### Study-Specific Reliance Plan (SSRP)

#### Reviewing IRB

**Faraday Institute of Research,  
Science and Technology**

✓ created SSRP

contact liaisons

#### Relying Sites

**The Square**

✓ accepted SSRP on Sep 15, 2020

contact liaisons

Reset SSRP

#### Documents

Letter of Reliance

SSRP Response

STANDARD OPERATING PROCEDURES ("SOPs")	Using other SOPs as mandated by an external group with authority for the study.
NAME OR DESCRIPTION OF MANDATORY SOPs	harvard component
WHERE CAN PARTICIPATING INSTITUTIONS ACCESS THE SOPs	I will provide a hyperlink to the SOPs
ENTER THE URL FOR ACCESS THE SOPS	square


#### HIPAA DETERMINATIONS AND ACTIONS

# RESET SSRP



## Email to Relying HRPP

[TEST] 123 -- IREx Update: Reviewing IRB revised your SSRP



admin@irbexchange.org  
To ✓ Serdoz, Emily Sheffer

↶

↷

→

⋮

3:22 PM

Dear Liaison,

**Faraday Institute of Research, Science and Technology** has edited the Study-Specific Reliance Plan (SSRP) for your site for the study below. Please login to [IREx](#) to view the revised SSRP and indicate reliance on the Reviewing IRB.

**Study Title:** Turning off Lead Site Approval Notification to Notified Sites

Field	Previous Value	Updated Value
INDEMNIFICATION	Indemnification agreements not required: Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified study(ies).	One or more Participating Institutions require an indemnification agreement: The Reviewing IRB and Relying Institution will enter a separate indemnification agreement or agreements or other contractual arrangements for allocation of liability among them with respect to the identified study(ies): The executed separate indemnification agreement(s) will be maintained on file with the Reviewing IRB.
Indemnification Terms	-	Changed for Central OH-IO

[View the Study](#)

*Thank you,*  
*IREx Administrator*

# RESET SSRP



Study-wide IRB Approvals

Site-specific IRB Approvals

Status Summary

Export Data ▾

## Participant Status Summary

Search: cen

Site		SMART IRB	IREx Access	Reliance Decision ?	Local Considerations	Approval Status (current version)
Carnegie University Medical Center		✓	✓	Reset 9/15/2020	3 / 3 Surveys Complete ▾	Not Approved
Central Ohio Medical Center		✓	✓	Updated 9/15/2020	3 / 3 Surveys Complete ▾	Approved

# RESET SSRP



## Email to Reviewing IRB and Relying HRPP

[TEST] 123 -- IREx: Relying HRPP Accepted Revised SSRP

admin@irbexchange.org  
To ✓ Serdoz, Emily Sheffer 3:59 PM

PDF Study Specific Reliance Plan - Harvard Univ-The Square.pdf 75 KB

Dear all,

This email confirms that **Harvard Univ component - The Square** has **accepted the revisions** to the Study-Specific Reliance Plan (SSRP) from **Faraday Institute of Research, Science and Technology** for the study below:

<b>Study Title</b>	Turning off Lead Site Approval Notification to Notified Sites
<b>Study Short Title</b>	123
<b>IREx Project ID</b>	199325
<b>Reviewing IRB</b>	Faraday Institute of Research, Science and Technology (FWA #01569874)
<b>Relying Institution</b>	Harvard Univ component - The Square (FWA #00004837)
<b>Study Link</b>	<a href="https://victptest.irbchoice.org/embryb/irex/public/study/index/?proj=199325">https://victptest.irbchoice.org/embryb/irex/public/study/index/?proj=199325</a>

**NOTE:** This is not a new indication of reliance. A PDF of the Notification of Reliance can be download from the [study page in IREx](#).

Thank you,  
The IREx Team

## SIRB – View Reliance

Site SMART IRB IREx Access Reliance Decision ?

Harvard Univ component - The Square ✓ ✓ Updated 9/15/2020

Study-Specific Reliance Plan (SSRP)

Reviewing IRB  
**Faraday Institute of Research, Science and Technology** ✓ created SSRP  
contact liaisons

Relying Sites  
**The Square** ✓ accepted SSRP on Sep 15, 2020  
contact liaisons

Documents  
Letter of Reliance SSRP Response

## Relying Site HRPP – View Reliance

Study Summary Reviewing IRB Contact IREx Study Managers Site-Specific Info

Turning off Lead Site Approval Notification to Notified Sites

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

Site Review  
Study Team Contacts  
View Reliances (SSRP)  
Letter of Reliance  
Download Reliances (SSRP)

# 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



- 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 cedes 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:

[+ Save Agreement](#)

 Choose a file or drag it here (Optional)

---

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:

[+ Save LOI Agreement](#)

 Choose a file or drag it here (Optional)

# Broad or Study-specific Agreements



- Indemnification and Other Reliance Agreements can be broad – apply to multiple studies – or study specific.
- Broad agreements can be added to multiple studies

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 ceases 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:

[+ Save Agreement](#)

[Choose a file or drag it here \(Optional\)](#)

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:

[+ Save LOI Agreement](#)

[Choose a file or drag it here \(Optional\)](#)

# SIRB tracks when Relying HRPPs execute an agreement



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

Participant Status Summary

Search:

**Manage Agreements** **Export Data**

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	+ Agreement	Chopped Salad	✓	Started 10/15/2020	0 / 3 Surveys Complete	Not Approved

## Study Agreement Manager

### Study Reliance Agreements

### Study LOIs

### Study Reliance Agreements

The sites below are eligible to sign or have executed the "Other Reliance Agreement" offered on this study. If you are offering a version of the SMART IRB Agreement for this study, only sites that have NOT signed that version of SMART IRB are eligible to sign your Other Reliance Agreement.

Search:

Site	Agreement Name	Sent	Executed	Signed Copy	Notes
Middle-earth College of Agriculture	Blackberry Turnover		10/2/2020		
Norfolk Pine University	+ Agreement	-	-	-	

Previous 1 Next

*SMART IRB sites are tracked automatically*

# Relying HRPPs view the Required Agreements



**DEMO** IRB Reliance YOUR SYSTEM SCREEN

Mellon Univ. Med Ctr  
GETTING STARTED

- Using IREx as the Participating Site HRPP
- Introducing Combo Sites
- ✓ Register
- ✓ Verify Study Team Access
- ➔ Complete Agreements
- ➔ Confirm Institutional Profile

Initial Study: Full Board

Complete HRP Survey

Remind PI To Complete

Mellon University Medical Center

### Required Agreements

Your site has signed the SMART IRB Agreement ✓

**Reliance Agreements**

**LOI** Your institution must sign Goodall University Medical Center's "GUMC SIRB LOI" before you can indicate reliance. ✗

Please send your executed LOI and/or questions to [Joe Goodman \(joe@good.all\)](mailto:joe@good.all), unless otherwise indicated.

Your LOI status will be updated by the SIRB once received. You will get a notification to login and indicate reliance when your agreements are complete.

OK

### Required Agreements

Your institution must sign the SMART IRB Agreement before you can indicate reliance. ✗

**Reliance Agreements**

Please contact [Gina Boyd \(gina.boyd@gumc.cdu\)](mailto:gina.boyd@gumc.cdu) if you have any questions about the reliance agreement requirements.

Your status will be updated for you when your site joins SMART IRB. You will get a notification to log in and indicate reliance when your agreements are complete.

**LOI** Your site has signed the Turnip Greens LOI ✓

OK

# Next Call

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