



# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR HRPPS

January 18, 2019

- User Training
- Study Support

*Natalie Dilts*



- System Development
- Data analysis

*Adoma Manful*



- Project Manager

*Emily Serdoz*



- Site Onboarding
- Study Support

*Bridget Swindell*



- User Support
- Study Support

*Linda Tan*



# QUARTERLY CALL AGENDA – HRPPs



- Welcome & Reminders
- Tracking Component Sites
- Tracking Letters of Indemnification (LOIs)
- Capturing Local Considerations
- Updated Resources

# Reminders from the Last Call

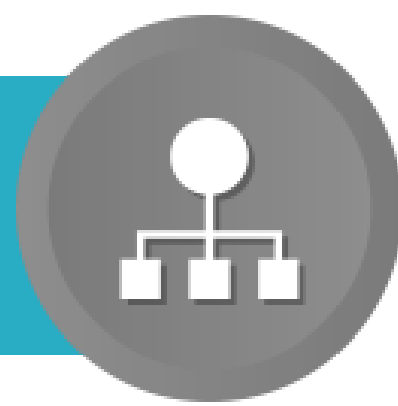
# IN CASE YOU MISSED IT...



- **IREx no longer requires institutional portal agreement** – HRPP/IRB managers or directors can request access via website:  
<https://redcap.vanderbilt.edu/surveys/?s=W98HMCHAPT>
- **Established “IREx Study Manager”** role for CCCs and Lead Study Team Coordinators to help with single IRB coordination
- **Improved “IREx Study at your site” email:** (1) local study PI is always noted and (2) highlight importance of local study team and local HRPP connecting around sIRB studies

# Tracking Component Sites

# USING IREX TO TRACK COMPONENTS



- **FWA sites can list their components in IREx**
  - + Delineate where research is happening
  - + Allows for multiple, separate study teams to be engaged on the same study

## Formatting on Studies and in Emails:

*FWA Short Name – Component Site Name*

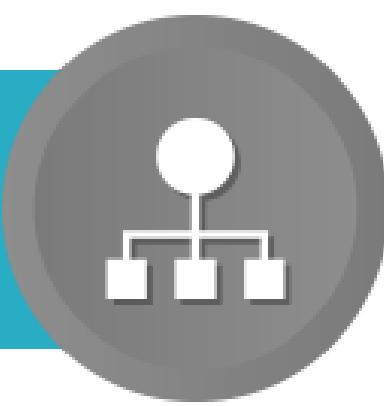
*FWA Component*


*FWA*

Site	SMART IRB	IREx Access	Reliance Decision	Approval Status (current version)
Johns Hopkins Univ SOM component - All Children's Health System, Inc. (component site)	✓	✓	Completed 09/25/2017	Approved
Johns Hopkins University School of Medicine	✓	✓	Completed 11/1/2017	Approved

- **Component sites DO NOT have liaisons or Institutional Profiles** – the FWA site's liaisons perform all actions in IREx for their components sites (e.g., ceding review, providing local considerations)

# USING IREX TO TRACK COMPONENTS




 Find a Study

by Name:


by Sponsor:







find

 Your Institution


Carnegie University Medical Center

Profile
Components

 Resources

-  Find other users
-  Find other sites
-  Add HRPP Staff / M
-  Request Help
-  Join A Training
-  Resources

site details ✕



## 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.*

Site Name	Short Name (20 characters)
Carnegie Children's Hospital	Carnegie Children's <span style="float: right; color: red; font-size: 0.8em;">✕</span>
<b>Add a component:</b>	
Carnegie Health Science Center	Carnegie HSC <span style="float: right; border: 2px dashed red; padding: 2px 5px; color: green; font-size: 1.2em;">+</span>

Cancel
Save

# Tracking Letters of Indemnification (LOIs)



# TRACKING LETTERS OF INDEMNIFICATION (LOIs)



- **Some institutions require an LOI given that SMART IRB is silent on indemnification**
- **IREx will allow for tracking of institutional-level LOIs**
  - Cannot have different LOIs for different studies
- **Internal and External LOI tracking**
  - Sites who have signed your LOI
  - External LOIs you signed

COMING SOON TO IREX!

# TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Add the LOI your Institution Requires when serving as the Reviewing IRB

Find a Study

by Name:

by Sponsor:

Your Institution  
Carnegie University Medical Center

Your Liaisons

Carnegie HRPP 555-123-4567
Liaison Multisite
Laura Sanders 555-555-4321

Resources

- 
- 
- 
- 
- 
- 

Site Agreements: Carnegie University Medical Center

Your Institution's LOI External LOIs

Your LOI

Name

Template  
 No file selected.

COMING SOON TO IREX!

# TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Your Institution's LOI External LOIs

The Carnegie Letter of Indemnification  
(Addendum to the SMART IRB Master Agreement) v. 06/13/2018

LOI Template Edit LOI

**Add A Site**

Faraday Institute of Research, Scien... ▼

**Date Sent**

10/08/2018

**Date Executed**

mm/dd/yyyy

**Agreement**

Choose File LOI Templa... Copy.docx

**Notes**

08/10/2018 -- Sent LOI to Study Team

Save Site

**LOI Sites**

Carnegie University Medical Center	▼
Central Ohio Medical Center	▼
Eastman Medical Center of Ohio	✓ ▼
Peabody Institute of Medicine	✓ ▼
University of the Bay	✓ ▼

## Tracking Your Institution's LOIs

- Site name
- "Date Sent" LOI to site
- "Date Executed" LOI with site
- Upload copy of agreement
- Add notes about correspondence

→ Sites who have signed LOI

COMING SOON TO IREX!

# TRACKING LETTERS OF INDEMNIFICATION (LOIs)



The Carnegie Letter of Indemnification  
(Addendum to the SMART IRB Master Agreement) v. 06/13/2018

[LOI Template](#) [Edit LOI](#)

**Add A Site**

Select a site

**Date Sent**

mm/dd/yyyy

**Date Executed**

mm/dd/yyyy

**Agreement**

[Choose File](#) No file chosen

**Notes**

[Save Site](#)

**LOI Sites**

Eastman Medical Center of Ohio	✓	▼
Peabody Institute of Medicine	✓	▲
<b>Date Sent</b>	8/15/2018	
<b>Date Executed</b>	10/10/2018	
<b>Document</b>	<a href="#">LOI Template.docx</a>	
<b>Comments</b>	Aug 15 - Sent LOI to PI	
	Aug 31 - Sent reminder to complete LOI to PI	
	Sept 12 - LOI routed to Peabody Legal Office for Review	
	Sept 25 - Call with Peabody Legal to review LOI. Changes requested cannot be accommodated	
	Sept 30 - Peabody Legal has agreed to sign LOI after internal discussion	
	Oct 5 - Received signed LOI from study coordinator	
	<a href="#">Remove</a>	<a href="#">Edit</a>
University of the Bay	✓	▼

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# TRACKING LETTERS OF INDEMNIFICATION (LOIs)




Track the LOIs you have executed with other institutions

Your Institution's LOI

External LOIs

## External LOIs

These are other institutions' LOIs which you have executed.

Site	↓	Date Executed	↑	Agreement	↑
Central Ohio Medical Center		01/01/2019		Not Uploaded	
Vanderbilt University Medical Center		12/14/2018		 LOI Template - Copy.docx	

Showing 1 to 2 of 2 entries

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# TRACKING LETTERS OF INDEMNIFICATION (LOIs)



The Reviewing IRB indicates whether the LOI is required for a study

IREx Project Settings

Study Setup

Is the Reviewing IRB a participating research site in the study?	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Do you require an LOI for this study?	<input checked="" type="radio"/> Yes	<input 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? <a href="#">Using IREx to Capture Local Considerations</a>	<input checked="" type="radio"/> <b>(Recommended)</b> Sites will provide consents for sIRB review (e.g., using a template)	
	<input type="radio"/> A consent form generator will be used to build consents for sites	

Continue →

COMING SOON TO IREX!

# TRACKING LETTERS OF INDEMNIFICATION (LOIs)



Reviewing IRB Approvals | Relying Site Approvals | **Status Summary**

### Participant Status Summary

Export Survey Data

Search:

Site	SMART IRB	IREx Access	LOI	Reliance Decision	Local Considerations	Approval Status (current version)
Univ of the Bay component - University of the Bay School of Medicine	✓	✓	✓	Completed 11/12/2018	2 / 3 Surveys Complete	Not Approved
University of the Bay	✓	✓	✓	Completed 10/26/2018	2 / 3 Surveys Complete	Not Approved
Univ of the Bay component - University of the Bay University Hospital Systems	✓	✓	✓	Started 10/26/2018	0 / 3 Surveys Complete	Approval Not Ready
Vanderbilt University Medical Center	✓	✓	✓	Started 10/29/2018	0 / 3 Surveys Complete	Approval Not Ready
Carnegie University Medical Center	✗	✓	✓	Contacted 10/26/2018		Approval Not Ready
Central Ohio Medical Center	✓	✓	✗	Add PI Info		Approval Not Ready

# Capturing Local Considerations



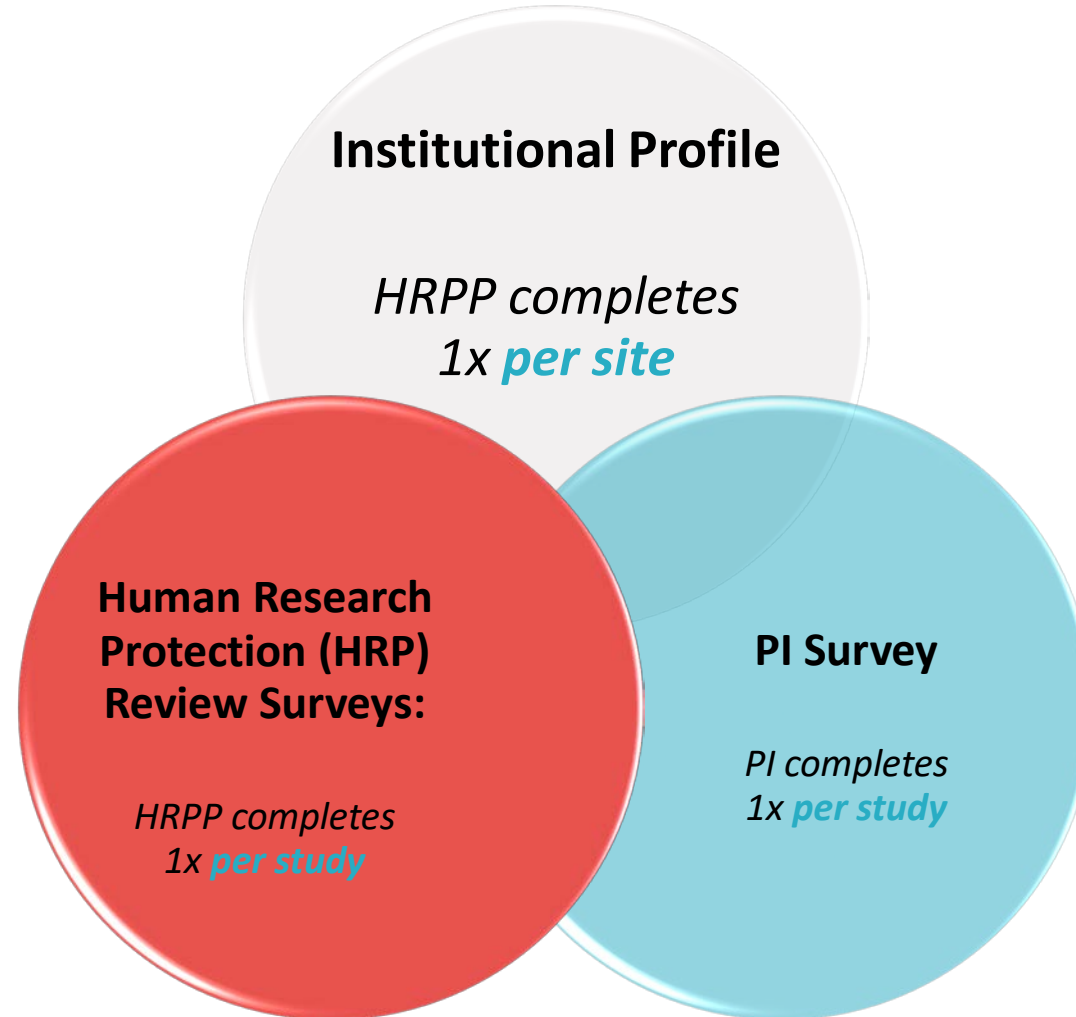
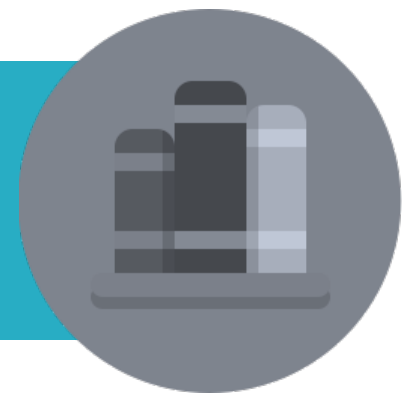
# USING IREX TO CAPTURE LOCAL CONSIDERATIONS



- **SMART IRB Agreement | 6. Responsibilities of the Relying Institution(s)**  
*Section 6.4 “Local Considerations”...[Each Relying Institution will...] Communicate to the Reviewing IRB the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews, **relevant to the Research** (“Local Considerations”) that would affect the conduct or approval of the Research at the Relying Institution. Such communication may be made through the Reviewing IRB’s designee, as determined by the Participating Institutions **in connection with the specific Research**.*
- **Reviewing IRBs can use IREx to centralize this documentation for their studies**
  - Standardizes the *questions* asked of Relying Sites
  - Standardizes the *process* of providing local considerations
  - Ensure *local HRPP involvement* in the reliance process
  - Facilitate *site-specific tracking* and documentation on a study-by-study basis

AVAILABLE IN IREX NOW!

# USING IREX TO CAPTURE LOCAL CONSIDERATIONS



AVAILABLE IN IREX NOW!

# USING IREX TO CAPTURE LOCAL CONSIDERATIONS



The Reviewing IRB or Lead Study Team/Coordinating Center can track Local Considerations in IREx

Once complete for a site, surveys are exported and submitted to sIRB system for review.

Want more info? Sign up for a training:  
<https://attendee.gototraining.com/rt/485841592003962113>

Reviewing IRB Approvals | Relying Site Approvals | **Status Summary**

### Participant Status Summary

Export Survey Data

Search: \_\_\_\_\_

Site	SMART IRB	IREx Portal Agreement	Reliance Decision	Local Context	Approval Status (current version)
Carnegie University Medical Center	✓	✓	Completed 03/01/2018	3 / 3 Surveys Complete	3 / 3 Surveys Complete
Central Ohio Medical Center	✓	✓	Started 04/25/2018	0 / 3 Surveys Complete	Approval Not Ready
Columbus University	✓	✓	Contacted 06/13/2018	0 / 3 Surveys Complete	Approval Not Ready
Hartford College of Medicine	✗	✗	Incomplete	0 / 3 Surveys Complete	Approval Not Ready
Mellon University Medical Center	✓	✓	Completed 03/01/2018	3 / 3 Surveys Complete	Approved
Peabody Institute of Medicine	✓	✓	Started 04/25/2018	1 / 3 Surveys Complete	Approval Not Ready

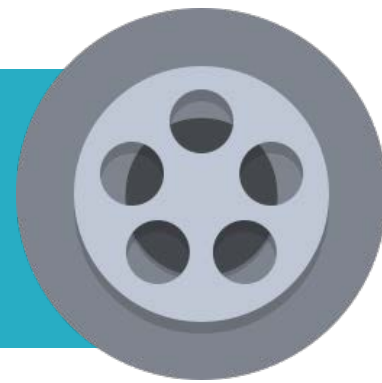
**Approval Status (current version) dropdown menu:**

- ✓ Institutional Profile
- ✓ Local Context
- ✓ PI Survey
- ✗ Email study personnel

# IREx Resources Update

# IREX VIDEOS ON YOUTUBE

<https://www.youtube.com/channel/UCVXKpNczhIPcsQRwF7oWcwA/videos>



Video Title	Target Audience	Length	Link
How to: Register and Cede Review	Participating Site HRPPs	4 mins	<a href="https://www.youtube.com/watch?v=-yW-TS-z6So">https://www.youtube.com/watch?v=-yW-TS-z6So</a>
What is the Study Specific Reliance Plan (SSRP)?	<ul style="list-style-type: none"> <li>Participating Site HRPPs</li> <li>Reviewing IRBs</li> </ul>	1.5 mins	<a href="https://www.youtube.com/watch?v=T9FbOV6oN7U">https://www.youtube.com/watch?v=T9FbOV6oN7U</a>
How HRPP/ IRB Liaisons use the IRB Dashboards	<ul style="list-style-type: none"> <li>Participating site HRPPs</li> <li>Reviewing IRBs</li> </ul>	1.5 mins	<a href="https://www.youtube.com/watch?v=TKy0Z9_yhf4">https://www.youtube.com/watch?v=TKy0Z9_yhf4</a>
How to: Add/Remove Study Team Members from a study in IREx	<ul style="list-style-type: none"> <li>Coordinating Center Staff or Lead Study Teams</li> <li>Participating site study teams</li> </ul>	2 mins	<a href="https://www.youtube.com/watch?v=f_hKS8nqbb8">https://www.youtube.com/watch?v=f_hKS8nqbb8</a>
Using IREx as a Participating Site Study Team	Participating site study teams	4 mins	<a href="https://www.youtube.com/watch?v=iKjO47Qslws">https://www.youtube.com/watch?v=iKjO47Qslws</a>
What is IREx?	All Users	2.5 mins	<a href="https://www.youtube.com/watch?v=NV94eUBylMg">https://www.youtube.com/watch?v=NV94eUBylMg</a>
<b>**NEW**</b> How to: Manage Participating Sites in IREx	<ul style="list-style-type: none"> <li>Reviewing IRBs</li> <li>Coordinating Center Staff or Lead Study Teams</li> </ul>	4 mins	<a href="https://www.youtube.com/watch?v=1sxprbGZN5M">https://www.youtube.com/watch?v=1sxprbGZN5M</a>
<b>**NEW**</b> New Features Highlight for HRPPs/ IRBs	<ul style="list-style-type: none"> <li>Participating Site HRPPs</li> <li>Reviewing IRBs</li> </ul>	4 mins	<a href="https://www.youtube.com/watch?v=Xv6xLNAxKBA">https://www.youtube.com/watch?v=Xv6xLNAxKBA</a>
<b>**NEW**</b> New Features Highlight for Lead Study Teams and Coordinating Centers	<ul style="list-style-type: none"> <li>Coordinating Center Staff or Lead Study Teams</li> <li>Participating site study teams</li> </ul>	4.5 mins	<a href="https://www.youtube.com/watch?v=KoBAytIY5Cw">https://www.youtube.com/watch?v=KoBAytIY5Cw</a>
<b>**NEW**</b> How to: Create a Study	Reviewing IRBs	6 mins	<a href="https://www.youtube.com/watch?v=xli8YXgDIN4">https://www.youtube.com/watch?v=xli8YXgDIN4</a>
<b>**NEW**</b> How to: Add Study-wide and Site-specific Amendments	<ul style="list-style-type: none"> <li>Reviewing IRBs</li> <li>Coordinating Center Staff or Lead Study Teams</li> </ul>	9 mins	<a href="https://www.youtube.com/watch?v=vlrEUIV-BMY&amp;t=2s">https://www.youtube.com/watch?v=vlrEUIV-BMY&amp;t=2s</a>

# REQUEST A DEMO OR TRAINING



**IREx IRB Reliance Exchange**  
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

members **214** studies **81** [LOGIN](#)

[About](#) [Resources](#) [FAQs](#) [Contact](#)

## Sign-up for Training

Join our interactive training sessions to learn more about IREx, meet other users across the nation, ask questions, and watch a live demo.

*Click on the links below to select a time and sign up for training.*

- [Reviewing IRB Trainings](#)
- [Relying HRPP Trainings](#)
- [Lead/Relying Study Team Trainings](#)
- [Using IREx to Capture Local Considerations](#)

*You can also request a live IREx demo for your team [here](#).*

[WHAT IS IREX?](#) [JOIN IREX!](#) **SIGN UP FOR TRAINING**

# Next Call

- April 19, 2019 @ 1 PM ET/10 AM PT