












IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR STUDY MANAGERS

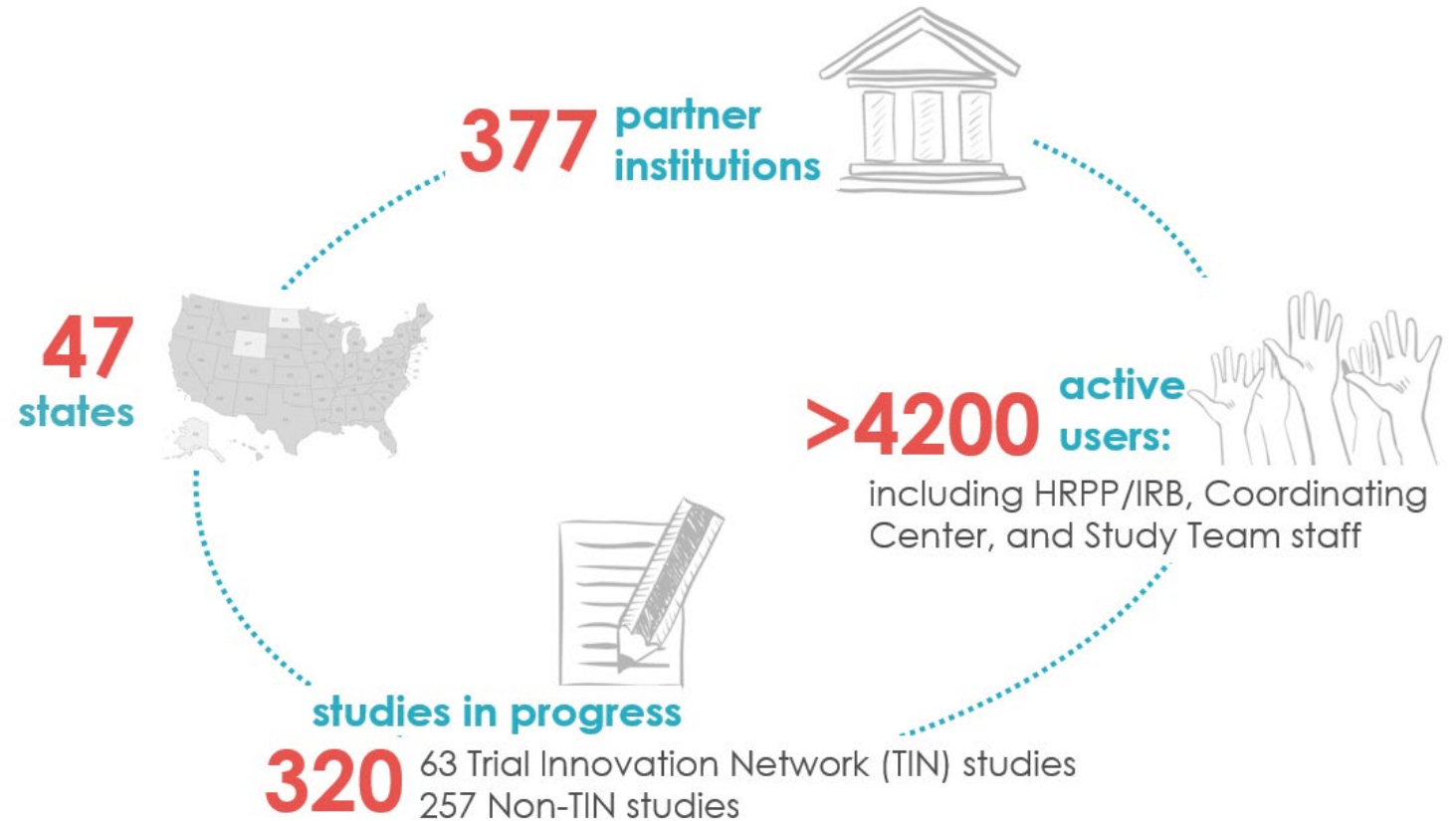
April 16, 2021

<ul style="list-style-type: none">• User Materials & Support	<ul style="list-style-type: none">• User Training• Study Support	<ul style="list-style-type: none">• Lead Application Developer	<ul style="list-style-type: none">• System Development	<ul style="list-style-type: none">• Project Director
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<ul style="list-style-type: none">• Application Developer	<ul style="list-style-type: none">• Site & User Onboarding• Study Support	<ul style="list-style-type: none">• Website & System Development• Study & User Support	<ul style="list-style-type: none">• Application Developer	
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QUARTERLY CALL AGENDA

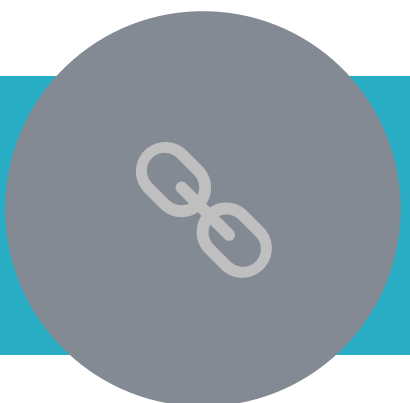



- **Welcome!**
- **Looking Back -**
Reminders from 2020
- **Looking Bright in 2021 -**
New System Features
- **Looking Forward –**
What's on Deck for IREx!
- **Next Call**

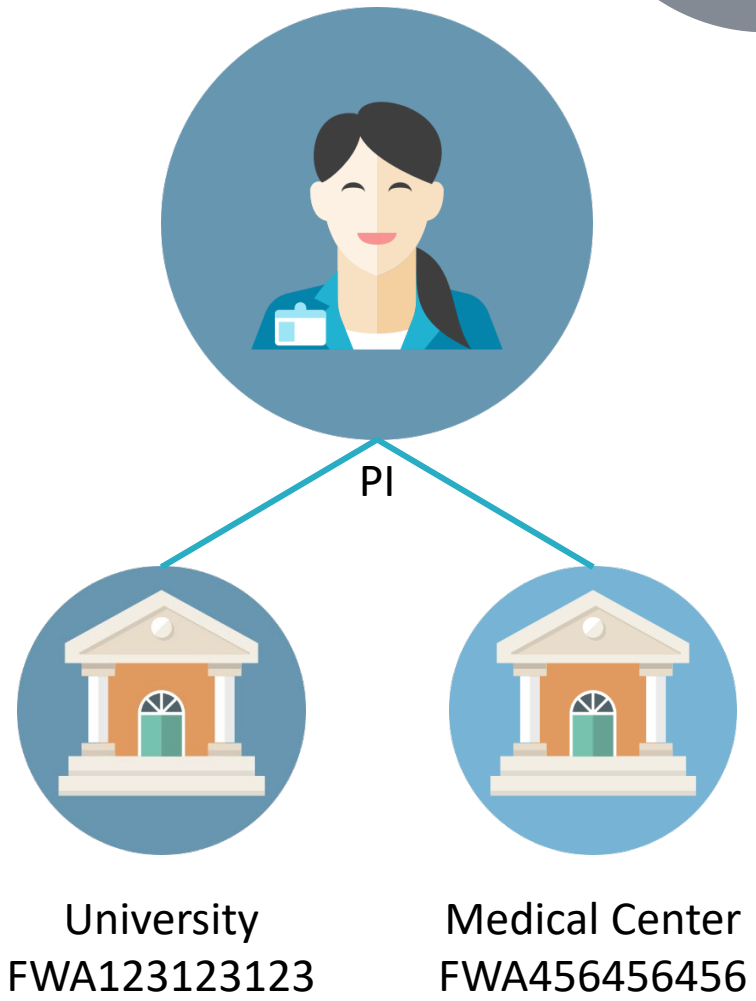
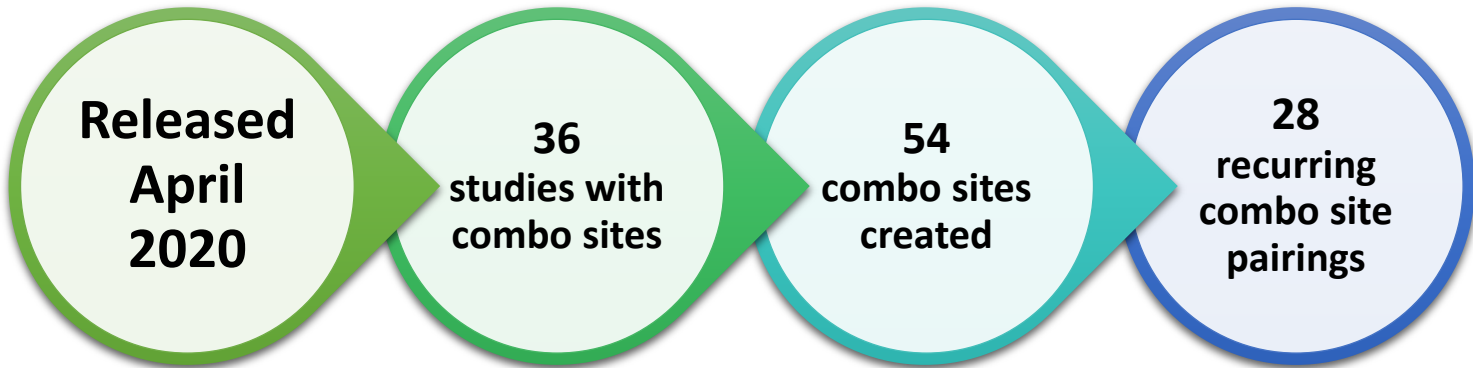


Looking Back – *Reminders from 2020*

Combo Sites



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



Combo Sites



Lessons Learned:

1. Reliance on an external IRB creates challenging workflows for AMC IRBs and local hospitals/research centers with long standing relationships between.
2. Who should create the combo?
 1. sIRB/Study Manager during study setup
 2. Participating sites when they register (**recommended**)

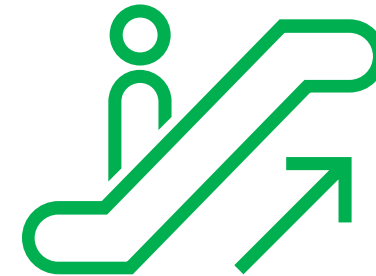
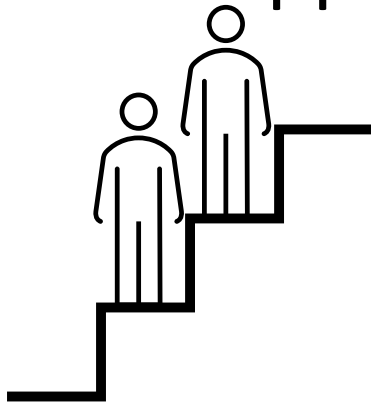
FWA123123123

Medical Center
FWA456456456

Study Managers can Upload Continuing Reviews / Amendments



Originally: sIRB had to upload **overall approval for continuing review and study-wide amendments.** Then, Study Managers could upload site-specific approvals.



To save the sIRB time, **Study Managers can now upload the overall and site-specific approvals for continuing reviews and study-wide amendments.**

Agreement Checker



- **Use case:** Identify whether sIRB has agreements in place with potential study sites
- **Available to all users**
- **Data can be exported**

Agreement Checking Tool

Report Parameters

SIRB: Mammoth University

Add Participating Site: Select a site

[Download CSV](#)

Site Name	FWA	SMART 1	SMART 2	Other Reliance	IREx	Indemnification	
Faraday Institute of Research, Science and Technology	01569874	✘	✔	✘	✔	Mammoth LOI	✘ Remove
Relying Site 3 (NS)	31341424234	✘	✘	Mammoth IAA	✔	✘	✘ Remove
University of Arkansas for Medical Sciences	00001119	✔	✘	✘	✔	✘	✘ Remove
Vanderbilt University Medical Center	00005756	✔	✔	✘	✔	✘	✘ Remove

Looking Bright in 2021 – *New System Features*

MORE AGREEMENT OPTIONS



1

SMART IRB
Versions 1 & 2

2

Other Reliance
Agreements
(IAAs, MOUs)

3

Indemnification
Agreements
(Broad & Study
Specific)

- 1. SIRBs can offer SMART IRB + an IAA on the same study.**
(Sites in SMART IRB will default to that agreement.)
- 2. SIRBs can add an IAA to an existing IREx study.**
- 3. Reliance and indemnification agreements can be study-specific or broad in scope.**

Agreement Resources



The screenshot shows a dashboard for Vanderbilt University Medical Center. On the left, there are three summary cards: '92 reviewer' (Your site is the reviewer for 92 studies), '19 participant' (Your site is a participant in 19 studies), and '238 users' (There are 238 users at your site). Below these are navigation links for 'Dashboard' and 'Home'. The main content area features a green banner with the text 'New February 2021' and 'IREx can be used with ANY reliance or indemnification agreement.' To the right of this text are two buttons: 'Read more' and 'Watch a video'. A red arrow points to the 'Watch a video' button. Below the banner is a 'Find a Study' section with a search bar, a dropdown menu for 'by Name', a dropdown menu for 'by Sponsor', and a 'find' button. To the right of the search section are two buttons: 'Create a Study' and 'Admin Dashboard'.

VANDERBILT UNIVERSITY
MEDICAL CENTER

92
reviewer
Your site is the reviewer for 92 studies

19
participant
Your site is a participant in 19 studies

238
users
There are 238 users at your site

Dashboard Home

New February 2021
IREx can be used with ANY reliance or indemnification agreement. [Read more](#) or [Watch a video](#)

Find a Study

by Name:

by Sponsor:

find

Create a Study

Admin Dashboard

sIRBs List Agreement Options in IREx Setup



IREx Project Settings

Agreements Help

What reliance agreement(s) can be used by relying sites?
(Check all that apply)

SMART IRB Agreement
 Other Reliance Agreement

Use Existing Broad Reliance Agreement Add New Reliance Agreement

Type: Broad Study Specific
Required

Name:
Required

Short Name:
Required

Template: **X**

Is Indemnification required of any relying site? Yes No

Is Indemnification executed separately from the reliance agreement? (e.g., a Letter of Indemnification (LOI)) Yes No

Name (ShortName)	Template Name
Faraday_Indemnification_Broad	Faraday_INDEM_12122019

Be sure the Study-Specific Reliance Plan (SSRP) also reflects that indemnification is required for this study. This is the last question on the SSRP.

Do sites using "Custom Reliance Agreement" also complete a separate indemnification agreement? Yes No

Note: Answer NO if indemnification is included in "Custom Reliance Agreement"

sIRBs

Track Agreement Completion



Participant Status Summary Manage Agreements Export Data ▾

Search:

Site	Reliance Agreement ?	Indemnification	IREx Access ?	Reliance Decision ?	Local Considerations	Approval Status (current version)
Relying Site 1 S1	SMART 1	SIRB MC - Indem.	✓	<input type="button" value="Add PI Info"/>		
Relying Site 3 (NS)	IAA v20200821	N/A	✓	<input type="button" value="Add PI Info"/>		
Relying Site 6 NS	<input type="button" value="x"/> <input type="button" value="+ Agreement"/>	<input type="button" value="pencil"/> SIRB MC - Indem. <input type="button" value="Update"/>	✓	<input type="button" value="Add PI Info"/>		

1. Study Managers **cannot** enter completed agreements
2. Relying Site HRPPs do not upload executed agreements

Relying HRPP Agreement Requirements



The screenshot displays the IRB Reliance System interface. On the left, a sidebar contains a 'DEMO' logo and a navigation menu with the following items: 'Mellon Univ. Med Ctr GETTING STARTED', 'Using IREx as the Participating Site HRPP', 'Introducing Combo Sites', 'Register', 'Verify Study Team Access', 'Complete Agreements', and 'Confirm Institutional Profile'. The main content area shows two overlapping 'Required Agreements' pop-up windows.

Required Agreements (Left Window):

- Reliance Agreements** (Green background, checkmark):
 - Your site has signed the **SMART IRB Agreement**.
- Indemnification** (Red background, X mark):
 - Your institution must sign University of Houston's "**Terms of Indemnification for use with SMART IRB - University of Houston**" before you can indicate reliance.
 - Please send your executed indemnification and/or questions to [Liaison Houston \(liaison@houston.cdu\)](mailto:liaison@houston.cdu), unless otherwise indicated.
 - Your indemnification status will be updated by the sIRB once received.

Required Agreements (Right Window):

- Reliance Agreements** (Red background, X mark):
 - Your institution must sign the **SMART IRB Agreement** before you can indicate reliance.
 - Please contact [Vanderbilt Liaison \(liaison@vanderbilt.edu\)](mailto:liaison@vanderbilt.edu) if you have any questions about the reliance agreement requirements.
 - Your status will be updated for you when your site joins SMART IRB.
- Indemnification** (Green background, checkmark):
 - Your site has signed the **VUMC LOI**.

Updates to SM Dashboard



Study Manager Dashboard

Q Search:

Study Title	Sites	Signed Agreements	Reliance	Local Consid.	Current Approvals	Expires
0403: Spring Has Sprung study (SHS) <i>Project ID: 152982</i>	15 / 12 Registered	SMART IRB 11 IREx 12	0	0	0	
04102020: SStudy Manager VIEW (STEW) study <i>Project ID: 154452</i>	6 / 4 Registered	SMART IRB 4 Indemnificatio 0 IREx 4	5	5	4 3/8/2021	5/4/2021
041320: Approvals for Combo Sites (APROPO) <i>Project ID: 153970</i>	6 / 6 Registered	SMART IRB 6 IREx 6	4	0	0 Upload Approval	
1024 - An Anniversary Test <i>Project ID: 50575</i>	4 / 5 Registered	SMART IRB 5 IREx 4	2	2	0 1/31/2021	12/2/2021

Updates to SM Getting Started Checklist



- ✓ Add Participating Sites
- ✓ Add PI Info
- ✓ Notify Site HRPPs/IRBs
- ➔ Track Site Progress on Status Summary**
- Upload Relying Site Approval

Effects of limiting studies to only one reliance agreement

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

Participant Status Summary Export Data

Search:

Site	Reliance Agreement	Indemnification	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Relying Site 1 S1	SMART 1	SIRB MC - Indem.	✓	Contacted 4/13/2021		
Relying Site 3 (NS)	IAA v20200821	N/A	✓	Contacted 4/13/2021		
Relying Site 6 NS	✗	SIRB MC - Indem.	✓	Started 4/13/2021	1 / 3 Surveys Complete	Not Approved

VERSIONS

1

Reviewing IRB

SIRB Med Ctr
Pending

Registered / In Progress

RS6 NS
Initial: Full

Site Dialog Now Distinguishes whether Site is in IREx



Participating Sites

[How to add participating sites](#)

Add A Site

Site Name:

Union County Methodist Hospital

This site does not have an account in IREx
Please let this site know that a human research protections administrator or IRB director/manager needs to [initiate access for their site here](#).

FWA # [Look in the OHRP FWA Database here.](#)

Add site that doesn't yet exist in IREx - FWA required

Cancel [Request site be added to IREx](#)

Institution	PI (Required)	Coordinator
Anderson Medical Center #546879213	Add PI	Add Coordinator
Duke University Health Systems, Inc. #0009025		Add Coordinator
Relying Site 3 (NS) #31341424234		Add Coordinator
St. Jude Children's #00004985		Add Coordinator
University of Benhoff		
Vanderbilt University #00024139	to dd todd@pi.ccc	

If a site has not signed the IREx Terms of Use, help text explains what should happen next



This site exists in IREx, but hasn't signed the IREx Terms of Use yet





After adding a new site to IREx, they appear like this until the IREx Admins create the site

New Continuing Review Notification




EFFORT -- Time to upload Continuing Review to IREx

 Serdoz, Emily Sheffer
To  Serdoz, Emily Sheffer

 Reply  Reply All  Forward 

Fri 3/19/2021 9:31 AM

 General

Dear Liaison and Study Manager,

The expiration date listed in IREx for the study below is: Jun 16, 2021.

If a new approval has been issued, site liaisons and study managers can upload the new approval in IREx to keep the study up to date.

Title	The Effect of Higher Protein Dosing in Critically Ill Patients: A Multicenter Registry-based Randomized Trial The EFFORT Trial
Link	https://www.irbexchange.org/study/index/?proj=51

Need Help?



Use this [Continuing Review Quick Guide](#) to walk you through the steps to upload approval.

*Thank you for using IREx,
The IREx Team*

New Notification when Sites Removed from Study



[EFFORT] IREx: Participating Sites Removed from Study

 IRBExchangeAdministrator
To  IRBExchangeAdministrator

[← Reply](#) [↶ Reply All](#) [→ Forward](#) [⋮](#)

Fri 3/19/2021 9:45 AM

Alys Kim, acting as Study Manager on this project, has removed the following sites from the study in IREx. If you feel this site was removed in error, please contact the staff who removed the site.

Study Title 20210317 Testing SM Checklist + Agreement Checker + PI/SM + Liaison is only liaison

Reviewing IRB Samma Health University

Study Link <https://test.irbexchange.org/main-branch/public/study/index/?proj=311782>

Sites Removed

Site	Registered	Ceded	Approved
St. Judith Children's Research	No	No	No

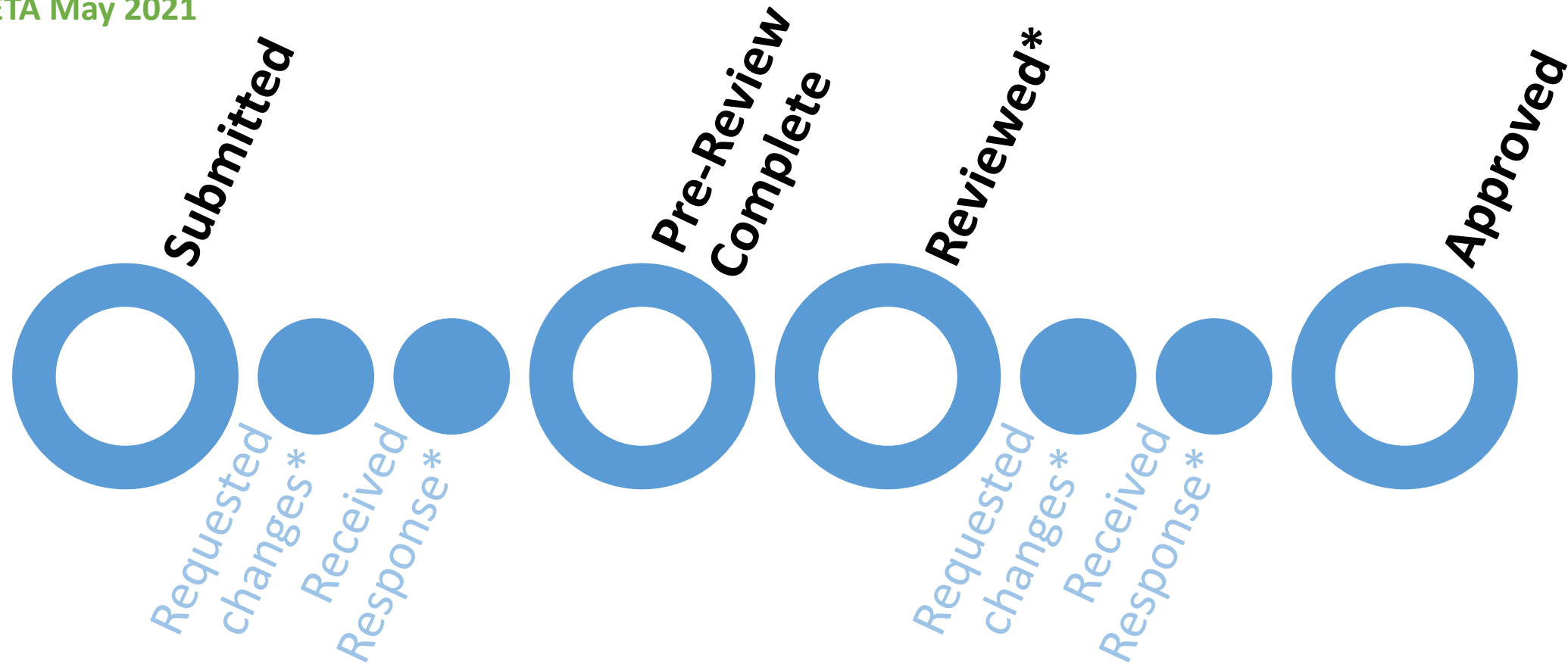
*Thank you,
IREx Administrator*

Looking Forward – *What's on Deck for IREx!*

Capture & Export Additional sIRB Metrics in IREx



ETA May 2021



* = Can have multiple iterations
Bold = Required

Additional Development Priorities for 2021



Summer 2021: Allowing sIRBs to document site and study closures



Fall 2021: Reorganize how approvals are stored and accessed by study teams



Winter 2021: API Phase V – Pushing any type of approval to IREx (not just Initial approvals for lead + Psites)

Additional Priorities: (1) Capturing PSite information at Continuing Review; (2) Improving how Study Managers upload approvals; (3) Customizing Local Considerations

New Training Offerings!

Basic Trainings moving to YouTube

- Reviewing IRB Liaison
- Relying HRPP Liaison
- Study Manager

Potential Trainings (POLL!)

- Uploading Approvals in IREx
- How to use IREx Resources
- How to work IREx into your workflow
- Responsibilities of the sIRB vs. Lead Study Team in IREx
- Managing Combo Sites (one PI at multiple locations)
- Multi-site Liaison training

Spotlight Use Cases

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○

Join the IREx User Feedback Group!

- Open to HRPP Liaisons and Study Managers
- Members provide input on upcoming features and priorities.
- Current membership includes:
 - Indiana
 - Johns Hopkins
 - Ohio State
 - Oregon
 - Pennington Biomedical
 - Utah
 - Vanderbilt
 - Wake Forest
 - WashU
- Meets the 3rd Friday each month at 1 ET.
- [Sign up here](#)

Next Call

- July 16, 2021