



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Quarterly Call: HRPPs

- Study & User Support
- Materials Development

Katelyn Benhoff



- Training & User Support

Natalie Dilts



- Lead Application Developer

Bryce Embry



- Study Support
- New Features

Carrie Smith



- Project Director

Emily Serdoz



- Onboarding
- Study & User Support

David Crenshaw



- Onboarding
- Study Support

Bridget Swindell



- System Development
- Study Support

Linda Tan



- Application Developer

Jason Tan



- Application Developer

Evan Wimberly



QUARTERLY CALL AGENDA

- Welcome
- Announcements
- Recent System Updates
- Feedback Needed

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Announcements



Research Teams Project

Understand how investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies.

IREx participation on SMART Talk

- Here what study teams have to say about the sIRB Process & how they've used IREx with SMART IRB!

- Intro Slides:

https://smartirb.org/assets/files/SMART_Talk_Intro_Slides_March2022_sIRBInvestigatorPerspective_FINAL-ua.pdf

- Recording:

<https://player.vimeo.com/video/689280786>

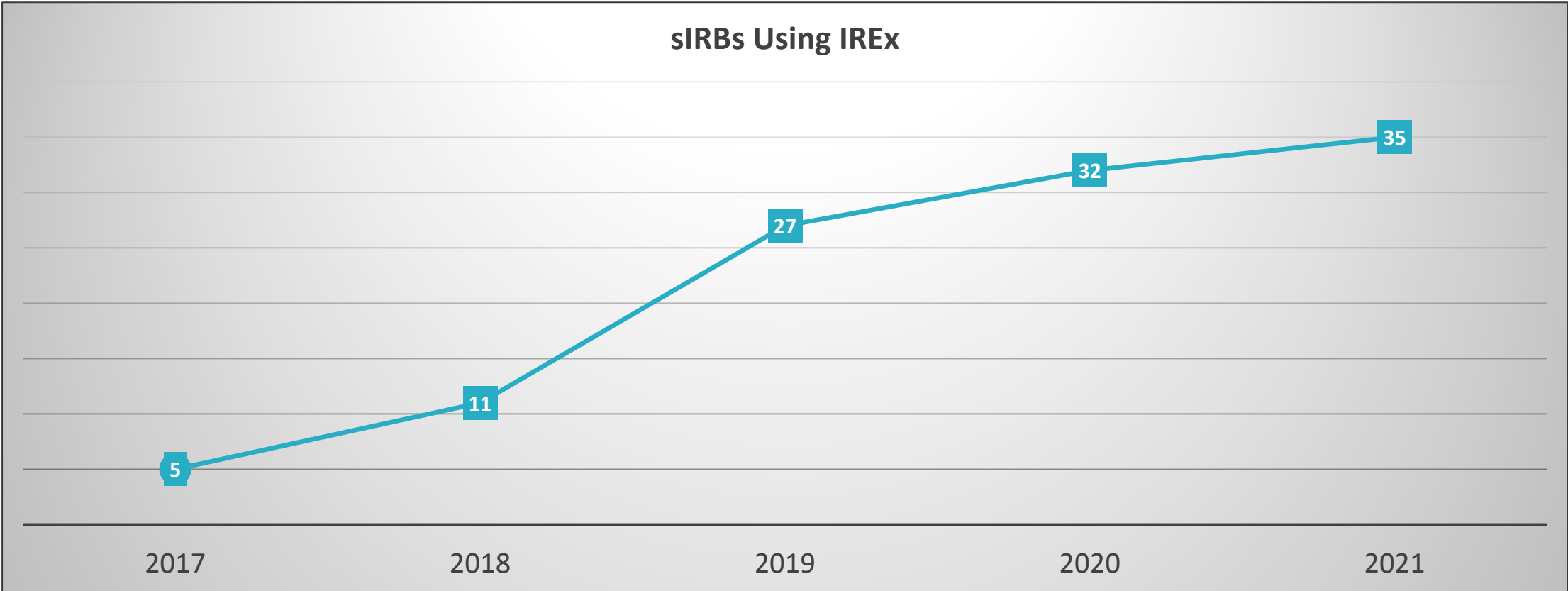
IREx PUBLICATION

HRPPs and study teams need tools to operationalize the national sIRB mandate: IREx can help!

[Serdoz, E., Edwards, T., Pulley, J., Beadles, J., Ozier, J., Harris, P., . . . Rice, T. \(2022\). The IRB Reliance Exchange \(IREx\): A national web-based platform for operationalizing single IRB review. *Journal of Clinical and Translational Science*, 6\(1\), E39. doi:10.1017/cts.2022.376](#)

Operational Challenge	IREx Solution	Advantages	Utilization
Documenting reliance & flexible elements of reliance agreement	Study-specific Reliance Plan (SSRP) / SMART IRB Implementation Checklist	<ul style="list-style-type: none"> • Electronic documentation & automated emails • Easily customizable for individual sites • Centralized historical reference 	>2300 reliances
Standardizing “local considerations” questions & processes	Capture static information via the Institutional Profile and study-specific information from the HRPP & PI in the HRP & PI Surveys	<ul style="list-style-type: none"> • Electronic documentation • Collaborative HRPP & PI documentation • Central repository (instead of email) • Facilitative communications 	<ul style="list-style-type: none"> • 291 of 378 IREx studies (79%) capture local considerations • 362 (87%) completed IPs
Supporting sIRB coordination	Empower and equip lead study teams to support sites thru sIRB review and communicate sIRB approvals with sites	<ul style="list-style-type: none"> • Minimize work for the sIRB • Automate site tracking / progress • Automate sIRB approval communications • IREx Admin Support & Training for lead study teams 	<ul style="list-style-type: none"> • >400 lead study team members • Relying site time to approval is improving each year
Capturing sIRB metrics systematically	Capture all timepoints in the sIRB review & approval process	<ul style="list-style-type: none"> • Identify averages / standards • Identify common bottlenecks • Report to policy makers 	<ul style="list-style-type: none"> • Steadily increasing use by new sIRBs each year • Data highlight improvements & ongoing challenges

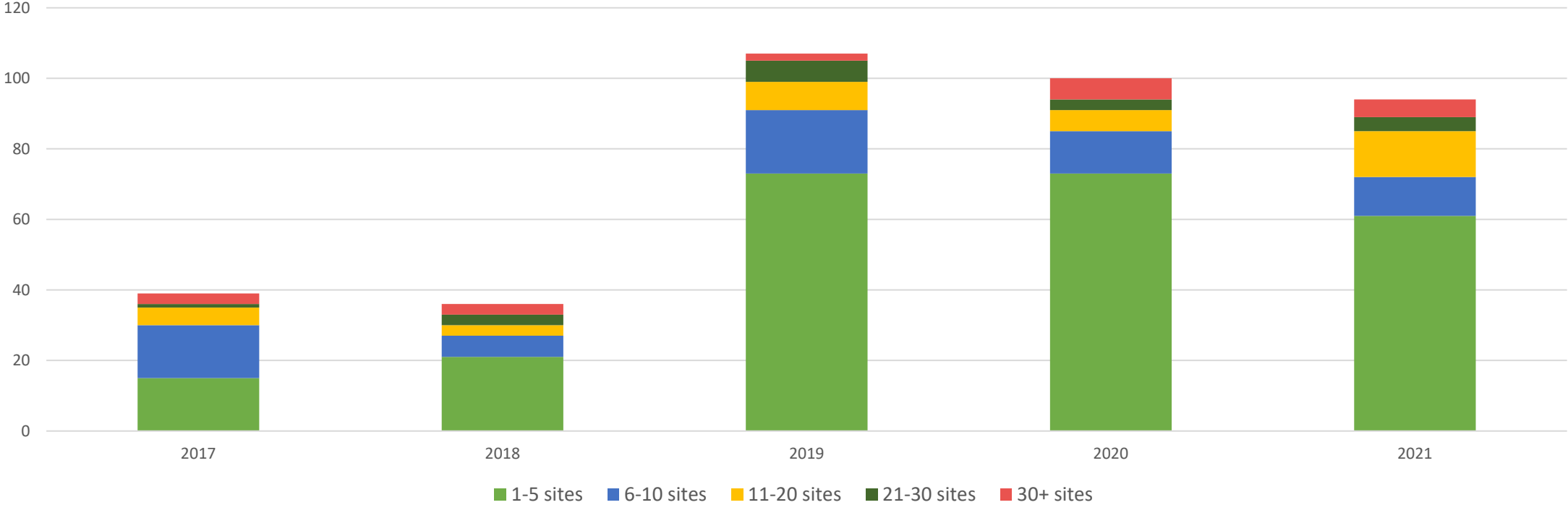
New sIRBs Creating Studies in IREx Each Year



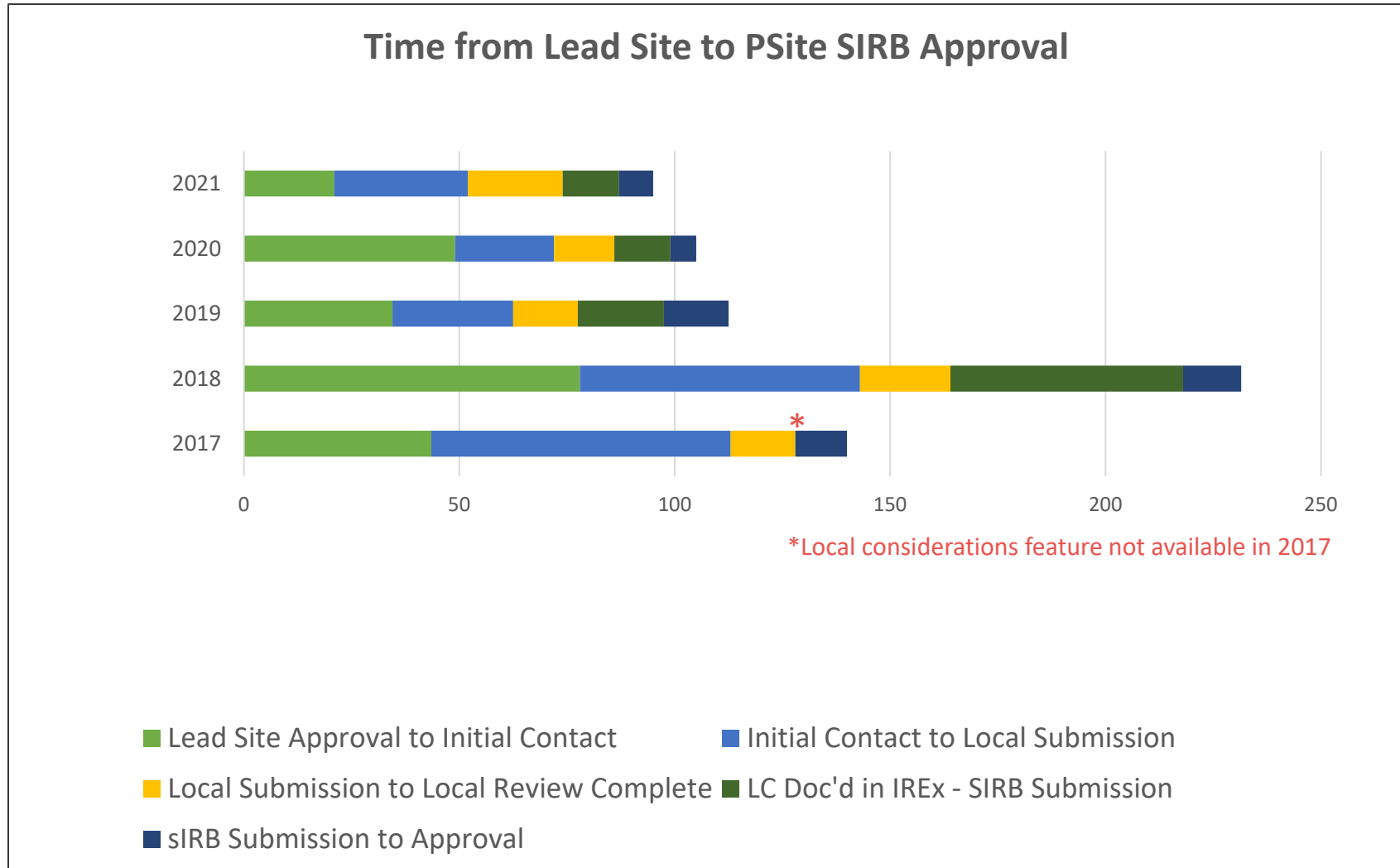
IREx Used for Small & Large Studies



Study Size by Year



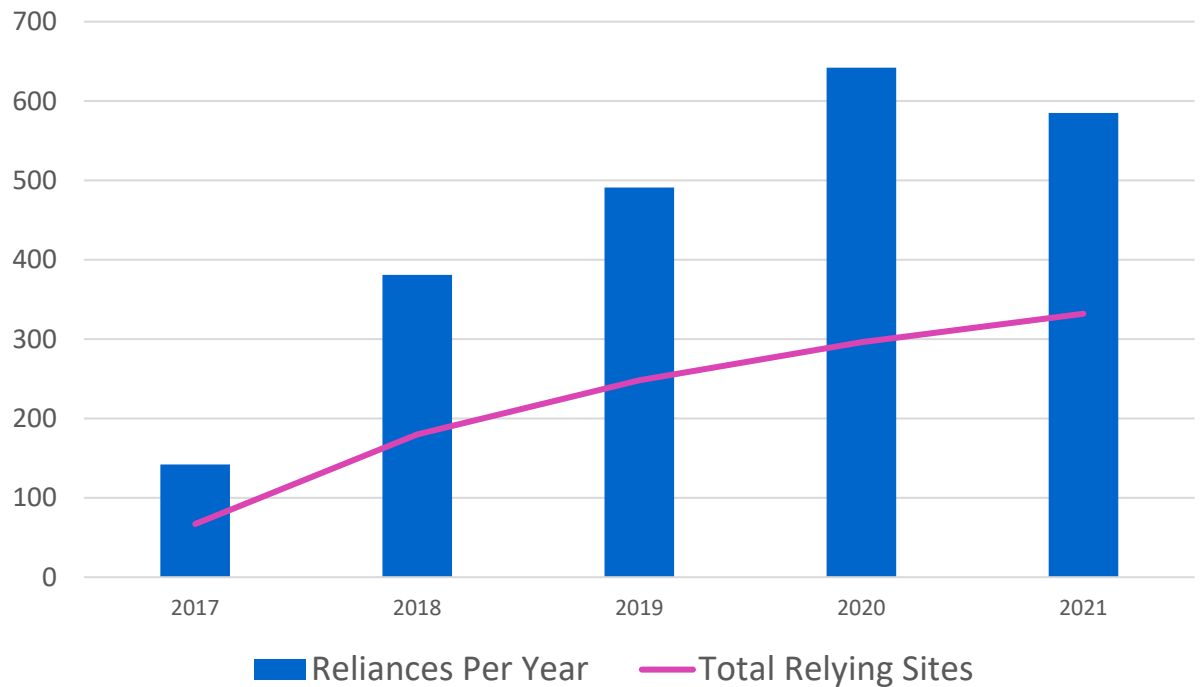
IREx Data: Improvements in PSite Time to Approval + Bottlenecks Persist



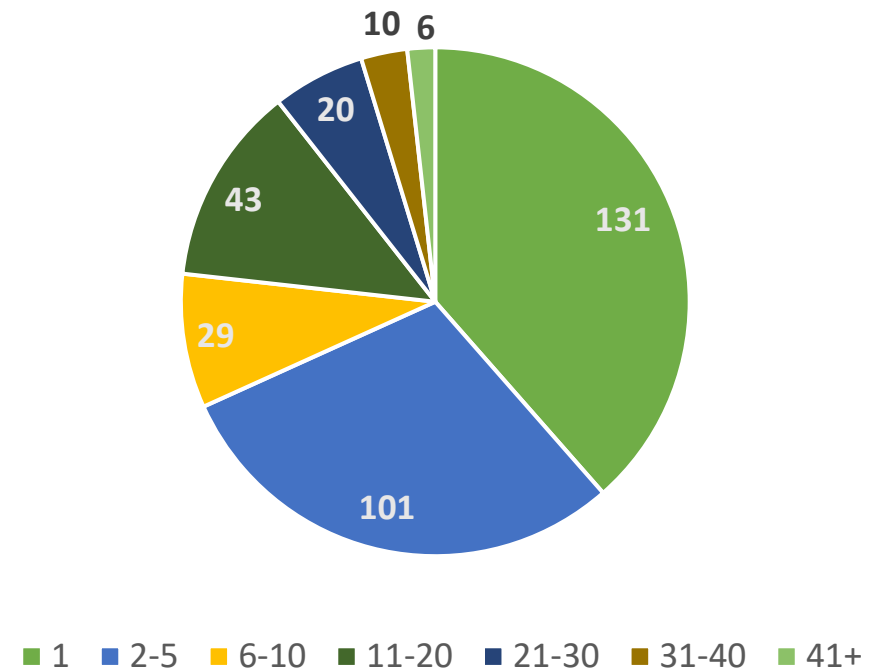
More Relying Sites Using IREx for More Studies



Relying HRPPs Use of IREx



Studies Per Relying Site



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Recent System Updates

Since January 2022

Simplified Access to Approved Documents for Study Teams

View As: Carnegie University View All Amendments Continuing Reviews

Carnegie University

Protocol Version: 05.02.2021, v3.0 The site has requested a PI change from Dr. John Carr to Dr. Jasmin Divers.

- Site Amendment: Full Board #Amend 7, PI Change [change summary](#) (approved 7/8/2021) Remove Site Amendment Current
- Continuing Review: Full Board (approved 10/22/2021) Archived
- Study-Wide Amendment: Full Board #Amend 5, Add Functional MRI (fMRI) [change summary](#) (approved 5/12/2021) Archived

Protocol Version: 01.15.2021, v2.0

- Study-Wide Amendment: Full Board #Amend 1, Add Cholesterol Panel [change summary](#) (approved 1/22/2021) Archived

Protocol Version: 10.29.2020, v1.0

- Initial Study: Full Board (approved 11/23/2020) Archived

View As: Carnegie University View All Amendments Continuing Reviews

Carnegie University

Protocol Version: 10/29/2020, v1.0

Initial Study: Full Board (approved 2/24/2022) Current

Study Info

IRB Number:
Reviewing IRB Decision: approved
Review Cycle: 12 mo

Key Dates

Submitted for Local Review: 11/16/2020
Local Review Conducted: 11/24/2020
Local Review Completed: 3/9/2022
Reviewing IRB Submitted: 2/16/2022
Reviewing IRB Reviewed: 2/24/2022
Reviewing IRB Approved: 2/24/2022

Documents Download All

Global Documents Download

Type	Name	Date Approved
Protocol 10/29/2020, v1.0	Protocol Document_v1_0_10_29_2020.docx	11/19/2021
IRB Approval Documentation	Mellon sIRB_Approval Memo_11.19.2020.docx	11/19/2021
Consents & Assents	ICF_DHS-MIND_10_29_2020.docx	11/19/2021

Site Specific Documents Download

Type	Name	Date Approved
IRB Approval Documentation	Mellon sIRB_Approval Memo_Add Carnegie Univ_02.24.2022.docx	2/24/2022
Consents & Assents	ICF_CARNEGIE UNIV_10.22.2021.docx	2/24/2022

Participating Project Personnel with Access to IREx

The individuals on this list have access to the study in IREx.
As a reminder:

1. **Participating Site Study Teams get access from their local institution**, after their HRPP has accessed the study. This may not occur until the study team has completed a local submission
2. Study team members with access can also give access to other members at their site.

Download CSV

+ Grant Site Coordinator Access

041320: Approvals for Combo Sites (APROPO)

Site	Role	Name	Email
Carnegie University Medical Center	Coordinator	Coordinating Center	irextestingcc@gmail.com
Carnegie University Medical Center	PI	Carnegie PI	irexpi@carnegie.edu
Hartford College of Medicine	PI	PI Hartford	irexpi@hartford.edu
Mellon University Medical Center	PI	PI Hartford	irexpi@hartford.edu
Midwest University Medical Center	PI	Relying Site PI	irextestingpi@gmail.com
Nashville University	PI	Laurie Stanford PI	laurie@stanford.edu
Stanford University	PI	Laurie Stanford PI	laurie@stanford.edu
University of Pittsburgh	PI	PITT PI	irexpi@pitt.edu

Streamlined New Access for Study Team Members

- As study team members change, lead study teams/coordinating centers (IREx Study Managers) can grant their access
- Relying HRPPs no longer have to log in to IREx to add new PIs or coordinators.

041320: Approvals for Combo Sites (APROPO)

Study-wide IRB Approvals | **Approval History** | Status Summary

View As: Hartford College of Medicine | View All | Amendments | Continuing Reviews

Hartford College of Medicine

Protocol Version: Protocol V3

Study-Wide Amendment: Full Board [change summary](#)

Study Info

IRB Number:
Status:
Review Cycle:

Key Dates

Reviewing IRB Submitted:
Reviewed:
Reviewing IRB Approved:

Change Summary: Amendment 3, 04/22/2021: This amendment includes a correction to the schedule of events table; clarification to the use of divided dose of the study medication due to intolerance; and

+ Add Site Amendment
+ Add Site Closure
+ Add Site Coordinator Access

Study Managers can Re-send Study Notifications

HRPPs can request their IREx Study notification be re-sent when they're ready to login and document reliance + local reviews

Pat King is resending your IREx Study Notification

Serdoz, Emily Sheffer
To: Serdoz, Emily Sheffer
Wed 4/20/2022 10:06 PM

General

Dear Liaison(s) and Study Investigator,

Apple University (FWA: 99999999) has been listed as a participating site in IREx for the following study:

Title PRIME: Pretend Reliance is Most Excellent
Reviewing IRB Orange University Medical Center
Local Investigator Nev Walsh

What do I do with this email?

Study PI

Many HRPPs require a local submission to initiate the single IRB (sIRB) process at their institution. Reach out to your Human Research Protection Program (HRPP)/IRB Liaisons on this email to find out what you need to do to initiate the sIRB process at your site.

YOU CANNOT ACCESS THE STUDY IN IREX YET.

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 - • Upcoming Feature Enhancements

IREx SATISFACTION SURVEYS

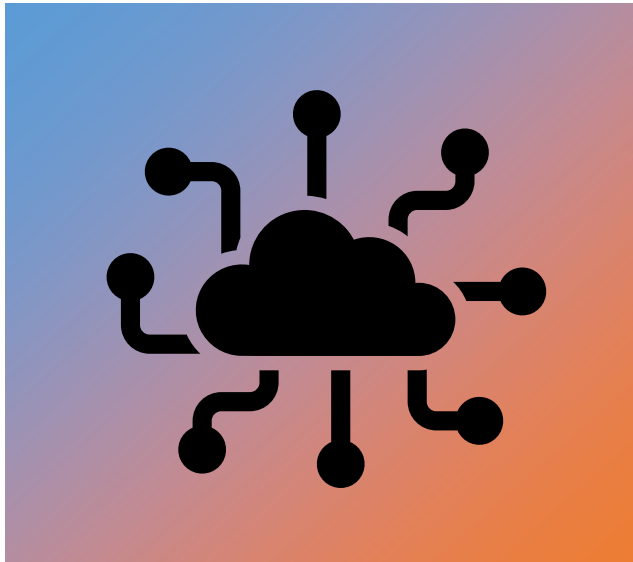
- **Respondents**
 - **sIRB Liaisons**, after uploading lead site approval
 - **Study managers**, after a few relying sites get approval
 - **PSite HRPPs**, after receiving approval from sIRB
- **Satisfaction with using IREx...**
 - on THIS study
 - in general
 - resources
- **Are there features we should improve/add**
- **Participating Site experience**
- ***NEW* Quarterly drawing for \$50 gift card!**



Streamlining Documentation of Local Considerations

- Challenges
 - PIs request Coordinator complete the PI Survey
 - HRPPs request the study team upload the ICF (instead of uploading it to the HRP Survey)
- Allow greater flexibility by
 - Allowing site coordinators to complete the PI Survey (still require PI signature)
 - Allowing the site study teams to upload the local ICF to the PI Survey (after local IRB verifies)
 - Relying HRPPs are **not required** to
 - Upload ICF to HRP Survey
 - Verify PI Survey, but they can, if preferred.
- ETA: June 2022





Other Enhancements in 2022

IREx API for sIRBs

Reduce sIRB/SM burden by capturing continuing reviews & amendments for lead and relying sites ([learn more](#))

Disseminate lead site approvals via IREx (rather than email)

Reduce SM burden of emailing lead site approval to site + streamline communications

Capture other sIRB communications (e.g., reporting acknowledgments)

Streamline documentation & communication for relying site study teams (and HRPPs)

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Next Call: July 15 , 2022