



• IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Quarterly Call: Study Managers

- 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



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The background of the slide features a blurred image of a workspace. On the left, a blue folder is partially visible. In the center, a calendar or planner is open, showing a grid of dates. To the right, a laptop is partially visible. The entire image is overlaid with a semi-transparent blue and orange gradient. The title 'QUARTERLY CALL AGENDA' is written in large, white, bold, sans-serif capital letters on the left side. To the right of the title, there are four small white icons: a plus sign, a dot, an open circle, and a solid circle.

QUARTERLY CALL AGENDA

- Welcome
- Announcements
- Recent System Updates
- Feedback Needed

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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>

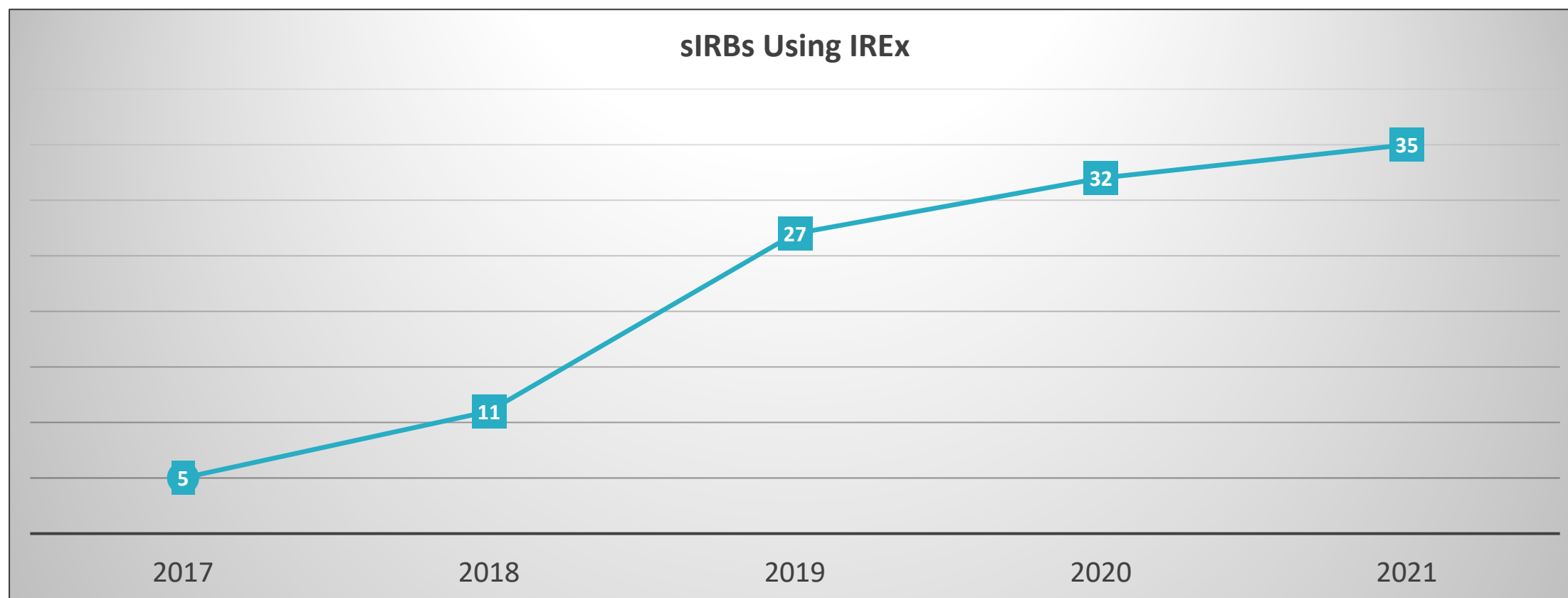
Operational Challenge	IREx Solution	Advantages	Utilization
Documenting reliance & flexible elements of reliance agreement	Study-specific Reliance Plan (SSRP) / SMART IRB Implementation Checklist	<ul style="list-style-type: none"> Electronic documentation & automated emails Easily customizable for individual sites Centralized historical reference 	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

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](#)

New sIRBs Creating Studies in IREx Each Year



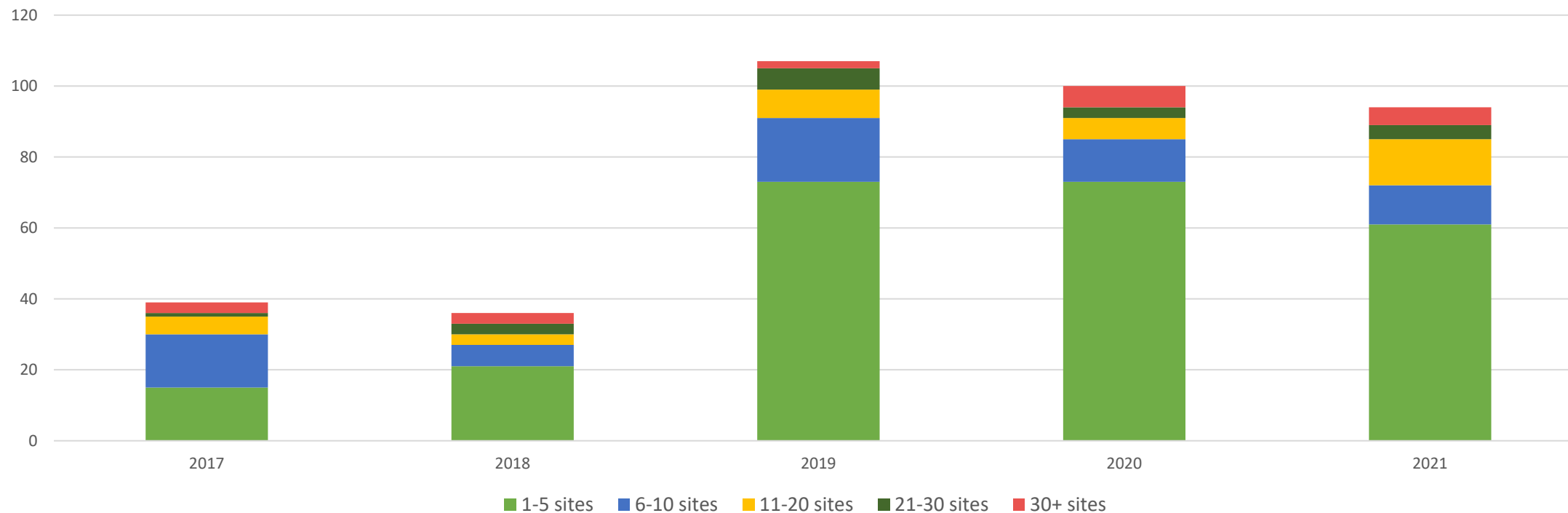
IREx Used for Small & Large Studies

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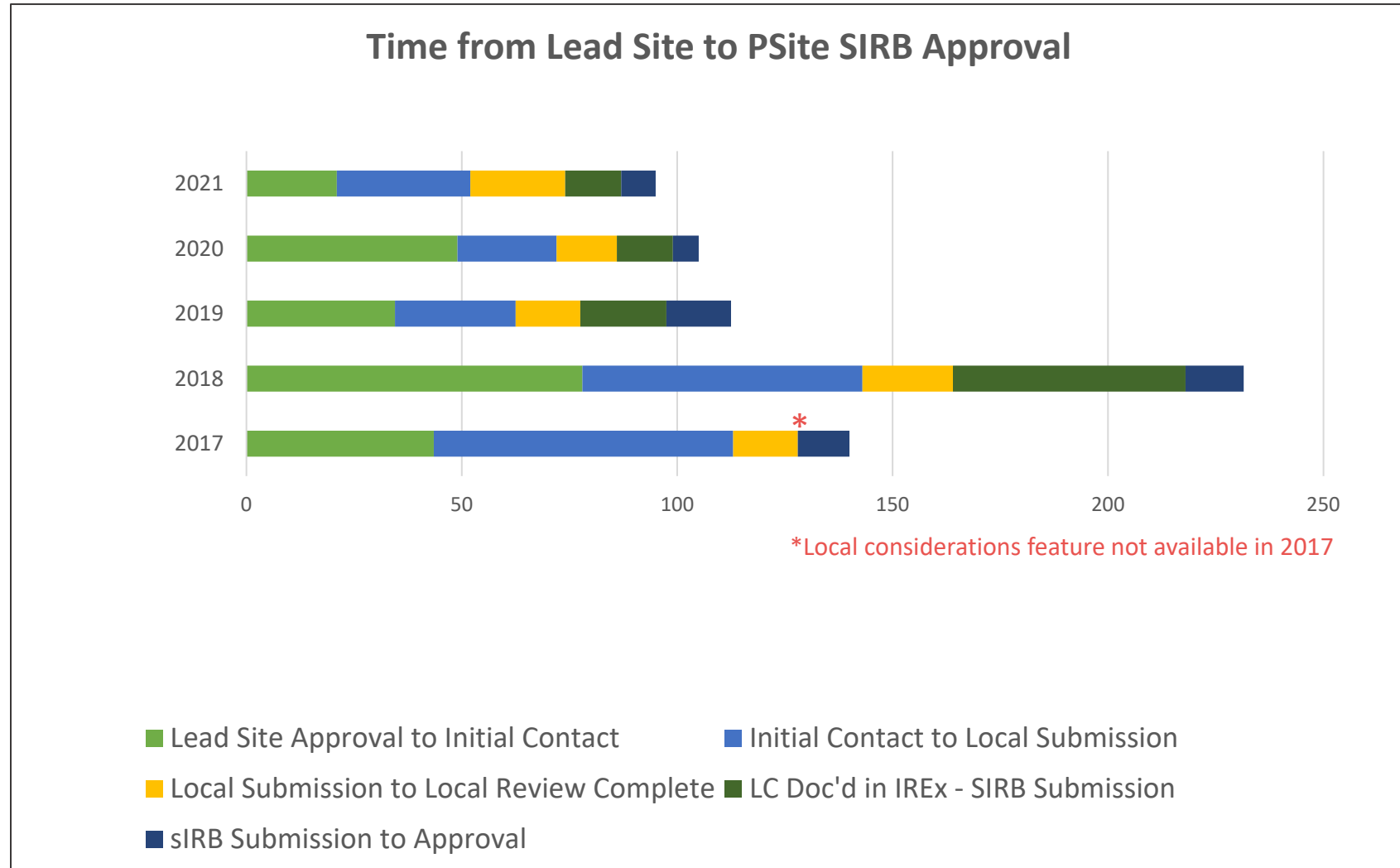
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Study Size by Year



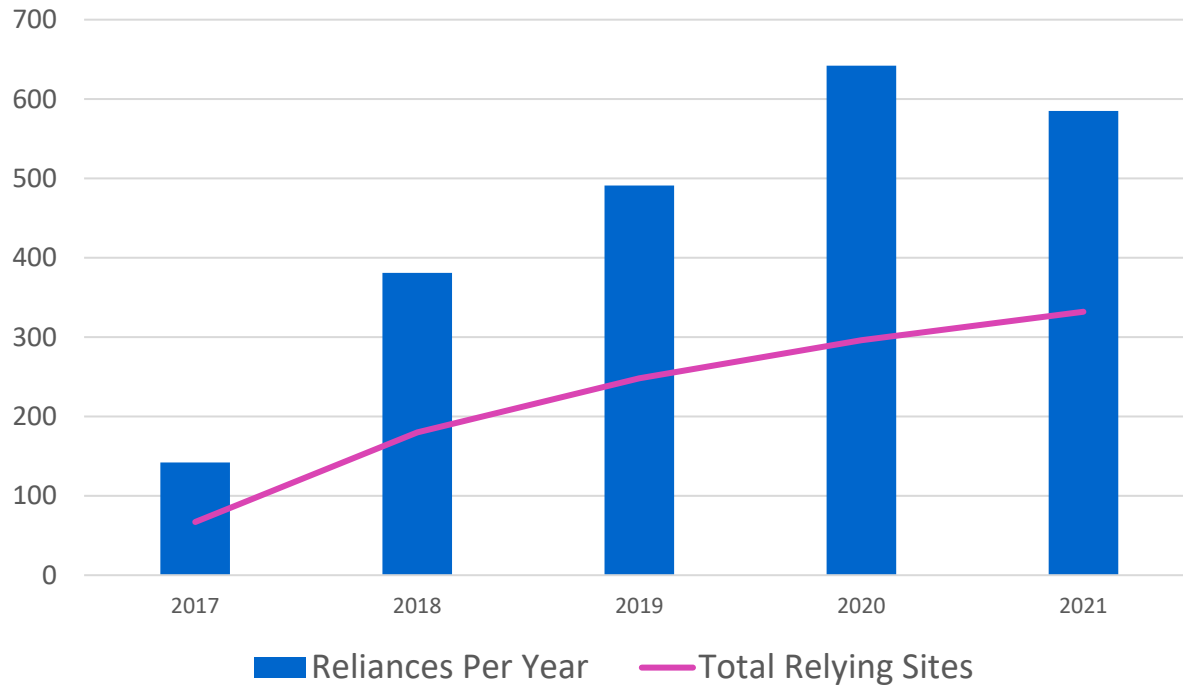
IREx Data Show Improvements in PSite Time to Approval + Bottlenecks Persist



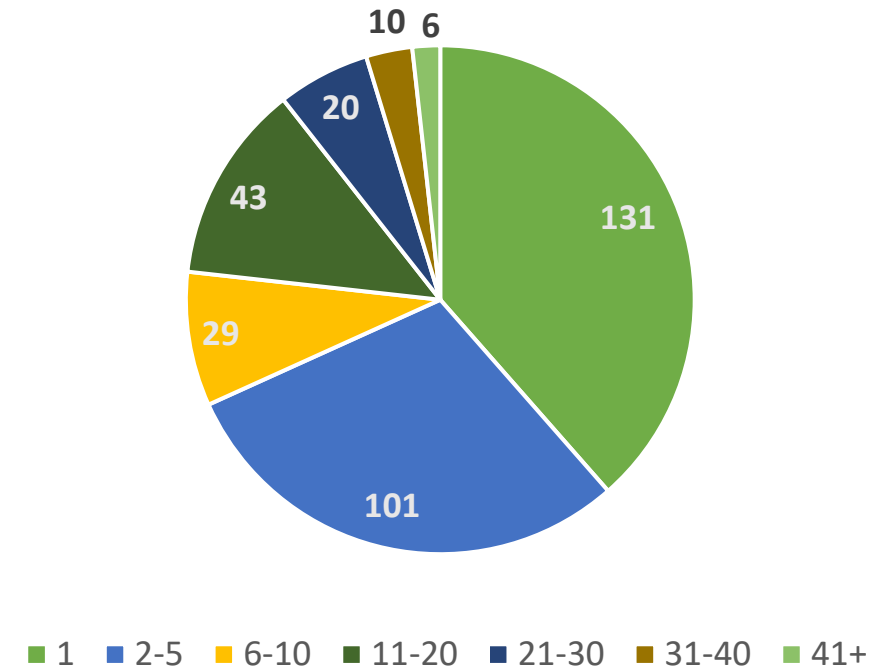
More Relying Sites Using IREx for More Studies



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



Do Site-specific Docs need to be
available above Global Docs?

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

DEMO

VUMC GETTING STARTED

- ✓ Add P
- ✓ Add P
- ✓ Notify
- ➔ Track Prog Status
- ✓ Upload Appro

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.cdu
Stanford University	PI	Laurie Stanford PI	laurie@stanford.cdu
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](#)

[+ Add Site Amendment](#)
[+ Add Site Closure](#)
[+ Add Site Coordinator Access](#)

Study Info

IRB Number:
Status:
Review Cycle:

Key Dates

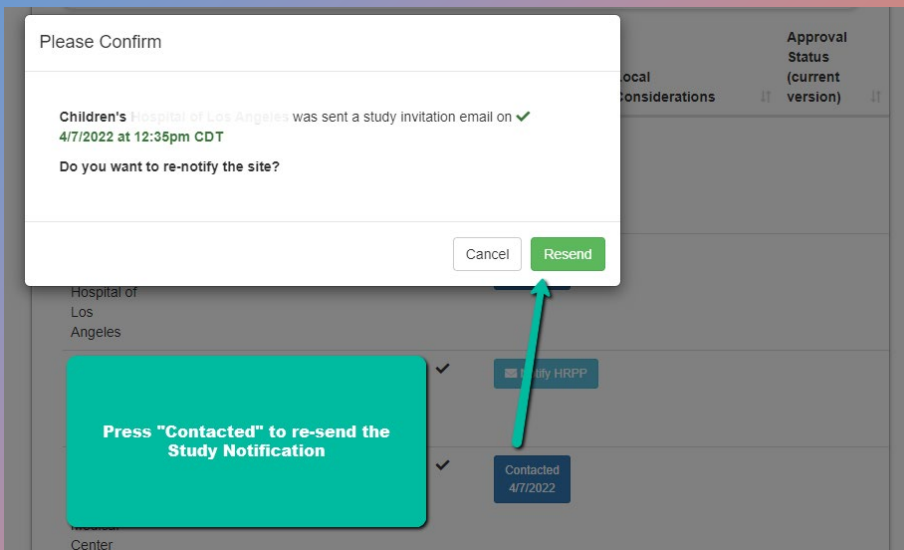
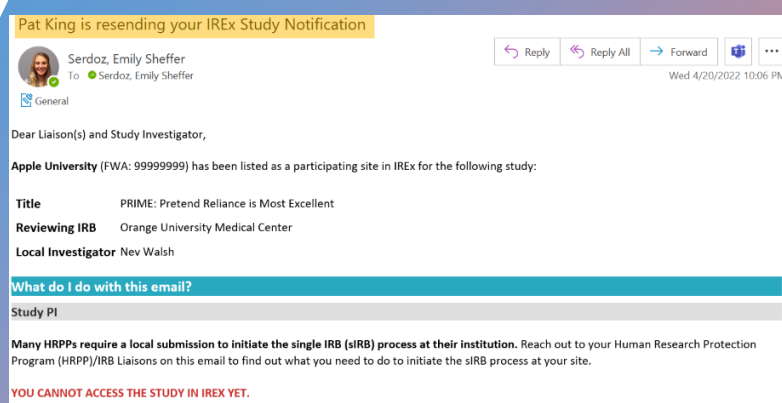
Reviewing IRB Submitted:
Reviewed:
Reviewing IRB Approved:

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

Study Managers can Re-send Study Notifications

Useful when...

- Relying HRPPs request the notification be re-sent
- Relying Sites have a change in PI
- Significant time has past since the notification went out
- Sites were notified prior to lead site approval or too early, and approval has now been granted.



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 - • Feedback & Future 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)

- PROPOSED IREX CHANGES

- 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.

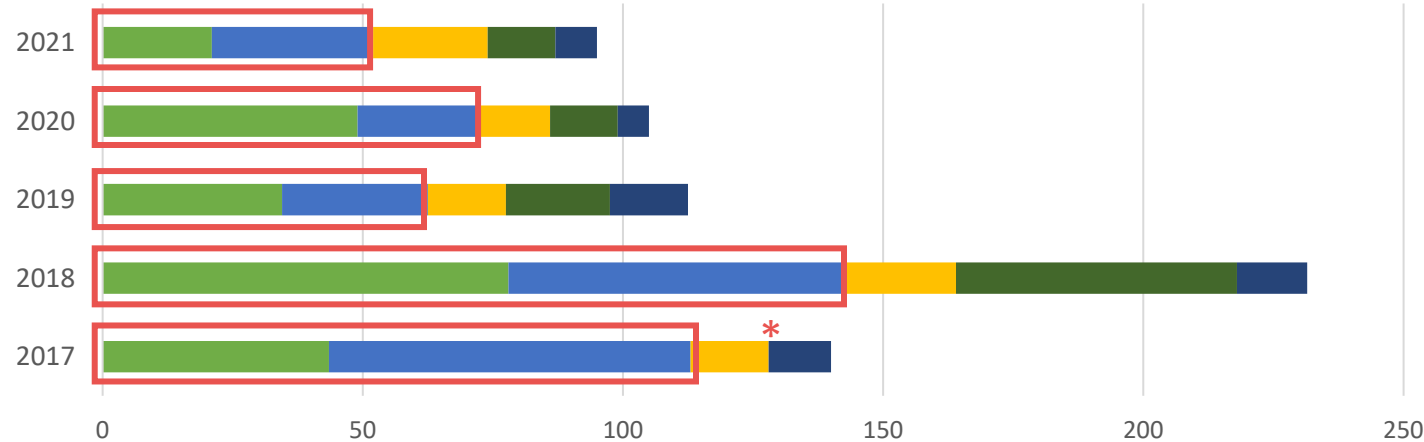
- Questions & Concerns?

ETA: June 2022

Can we reduce the time from Lead Site Approval to Local Submission?



Time from Lead Site to PSite SIRB Approval



*Local considerations feature not available in 2017

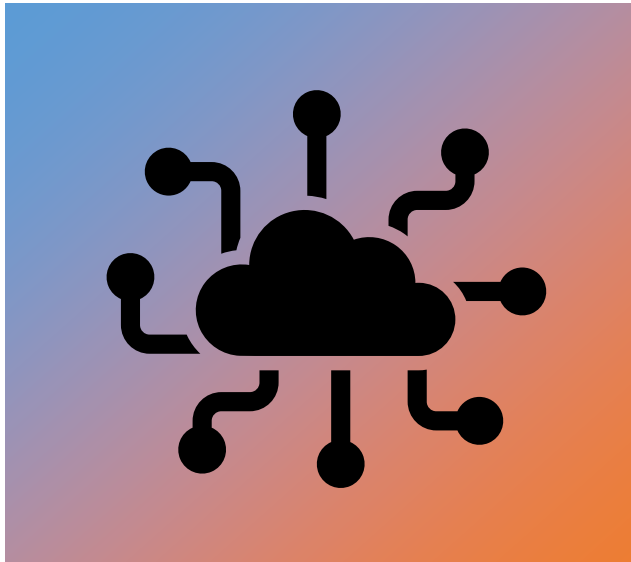
- Lead Site Approval to Initial Contact
- Initial Contact to Local Submission
- Local Submission to Local Review Complete
- LC Doc'd in IREx - SIRB Submission
- SIRB Submission to Approval

1. Allow PSite study teams to access lead site approvals via IREx

- Minimize burden of Study Manager
- Provide instructions to initiate contact/ submission to local HRPP
- PI can begin PI Survey earlier

2. No longer require HRPP to register first

- IREx can be a one-touch process for SIRBs



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