IRBx

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

QUARTERLY CALL AGENDA

- Welcome
- Announcements
- Recent System Updates
- Feedback Needed

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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

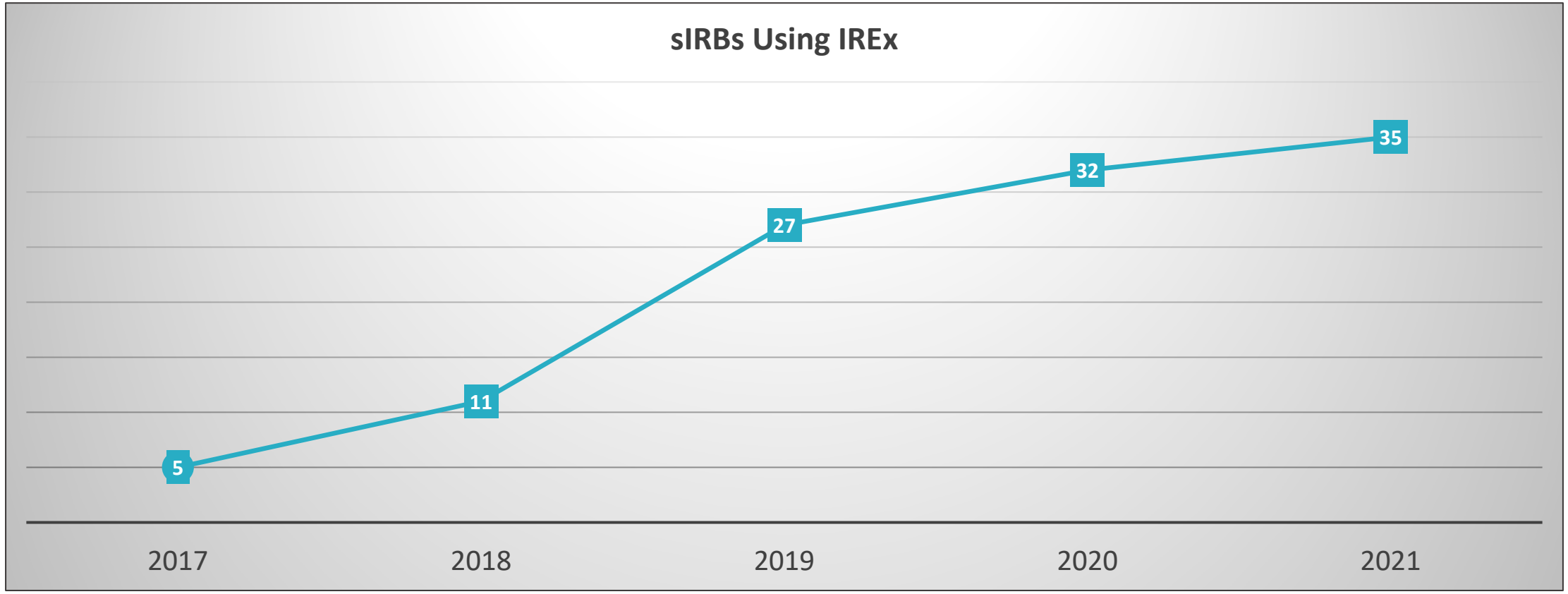
Operational Challenge	IREx Solution	Advantages	Utilization
Documenting reliance & flexible elements of reliance agreement	Study-specific Reliance Plan (SSRP) / SMART IRB Implementation Checklist	• Electronic documentation & automated emails • Easily customizable for individual sites • Centralized historical reference	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	• Electronic documentation • Collaborative HRPP & PI documentation • Central repository (instead of email) • Facilitative communications	• 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	• Minimize work for the sIRB • Automate site tracking / progress • Automate sIRB approval communications • IREx Admin Support & Training for lead study teams	• >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	• Identify averages / standards • Identify common bottlenecks • Report to policy makers	• Steadily increasing use by new sIRBs each year • Data highlight improvements & ongoing challenges

IREx PUBLICATION

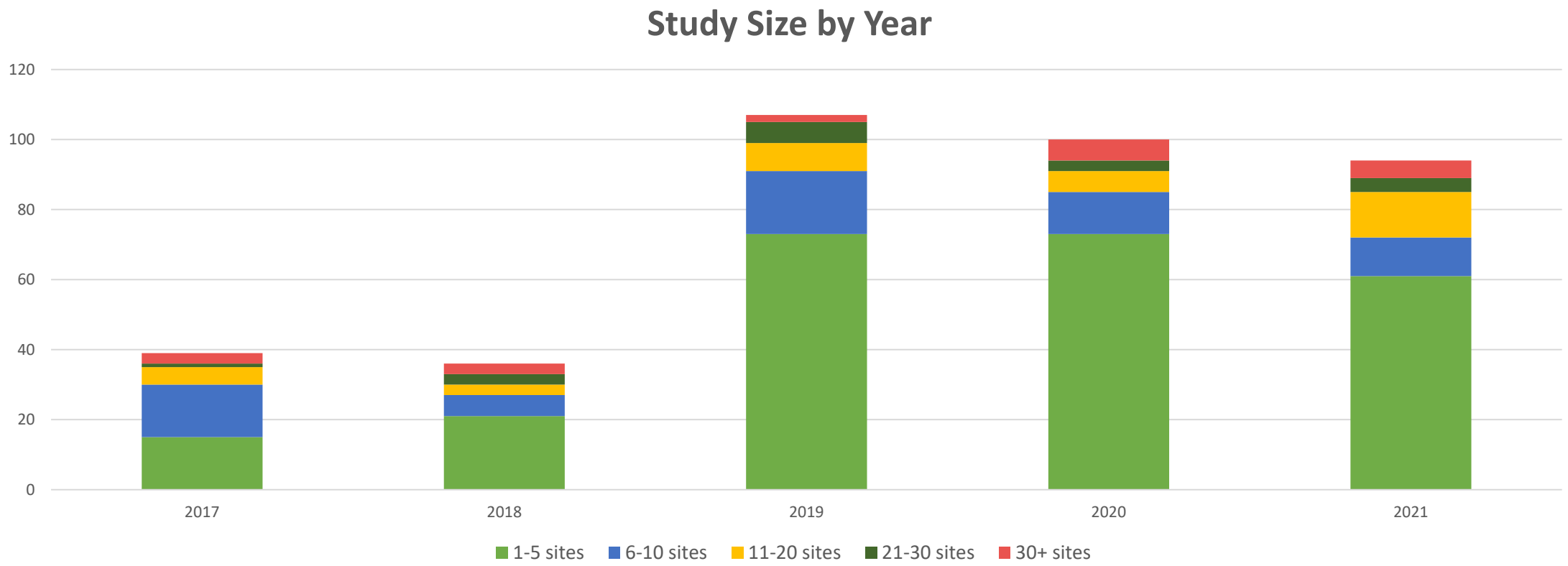
HRPPs and study teams need tools to operationalize the national sIRB mandate: IREx can help!

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

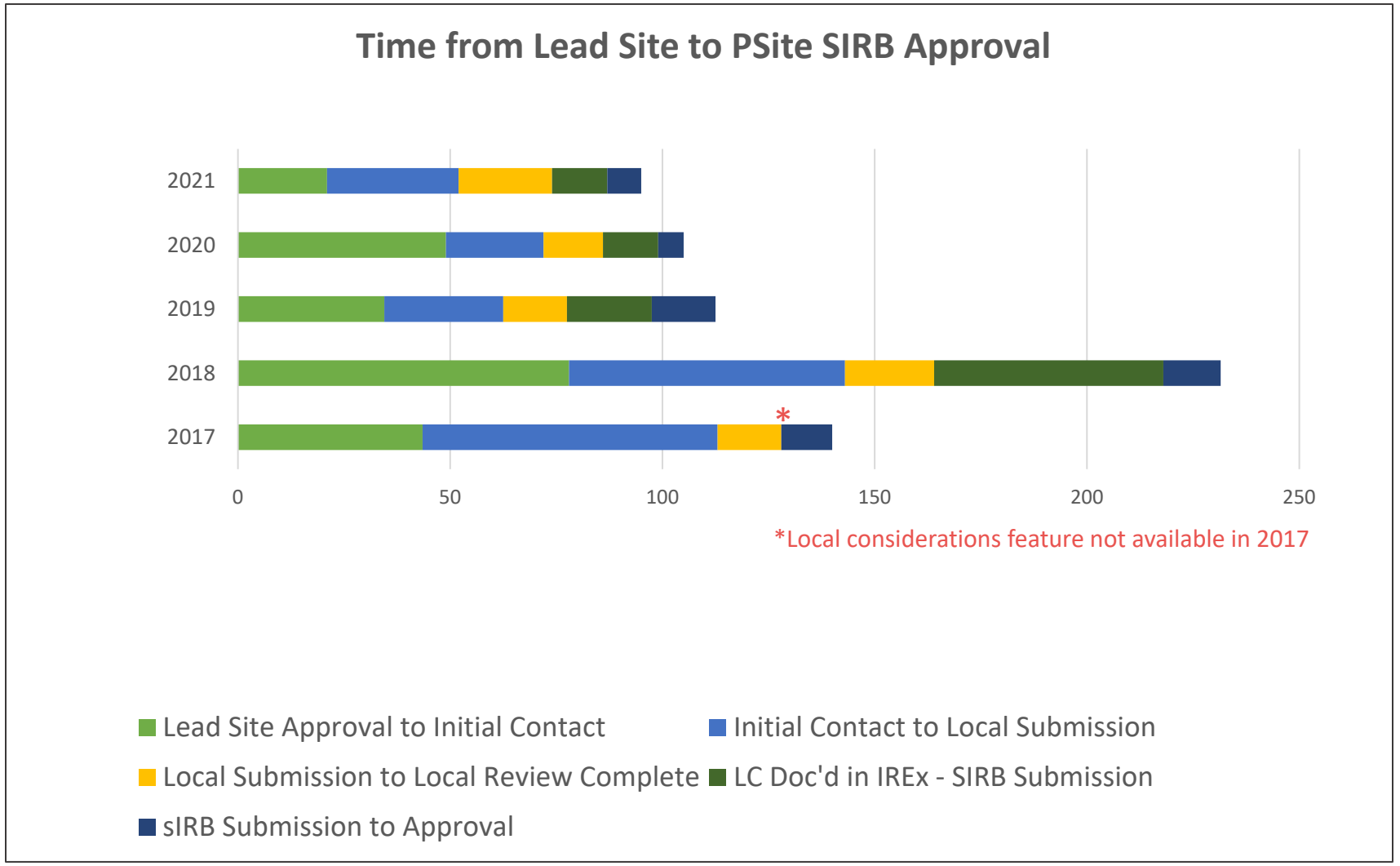
New sIRBs Creating Studies in IREx Each Year



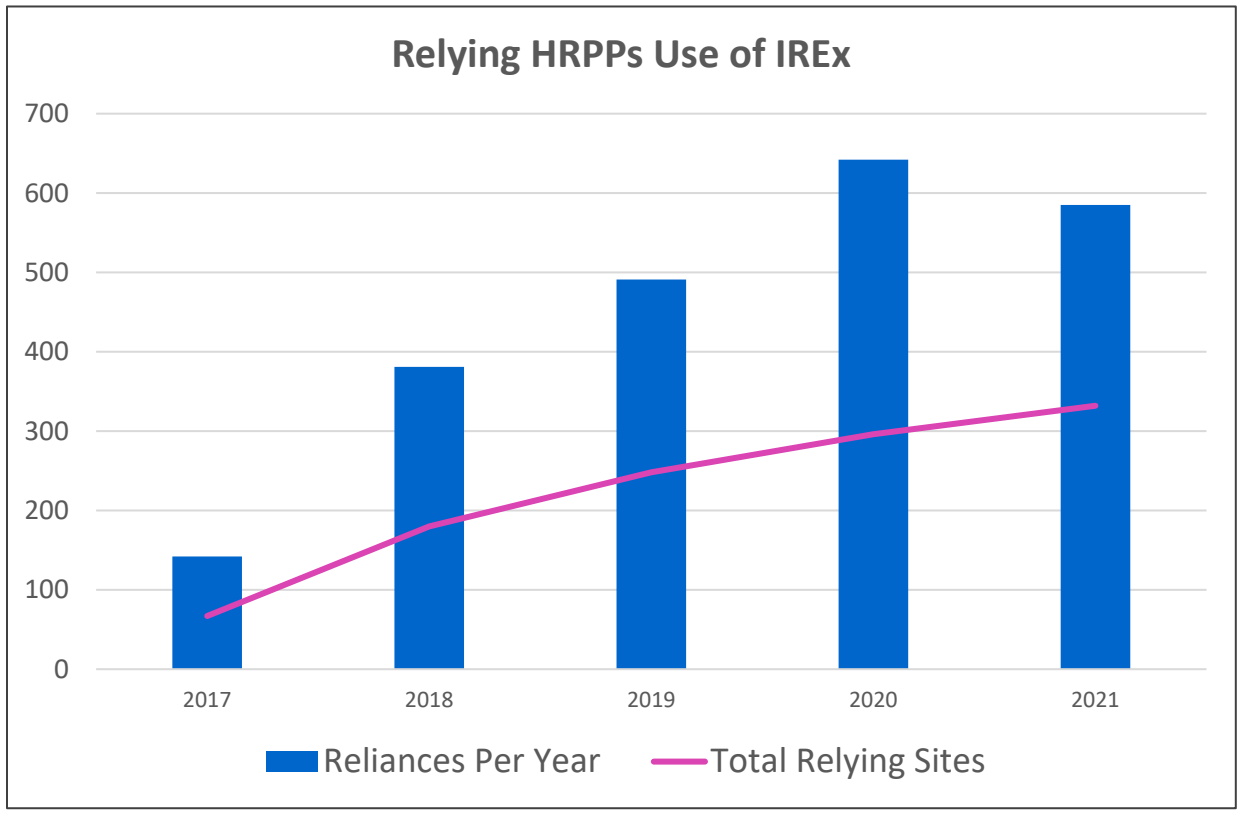
IREx Used for Small & Large Studies

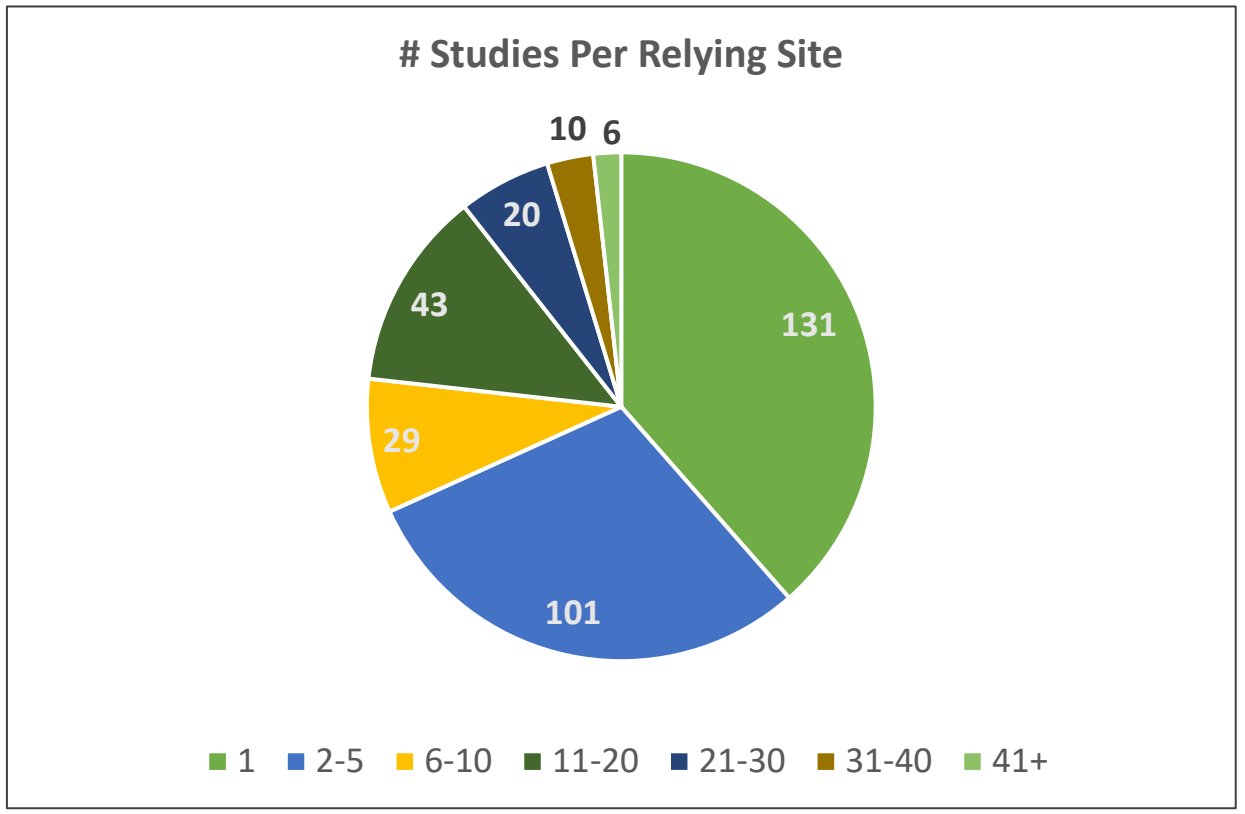


IREx Data Show Improvements in PSite Time to Approval + Bottlenecks Persist



More Relying Sites Using IREx for More Studies



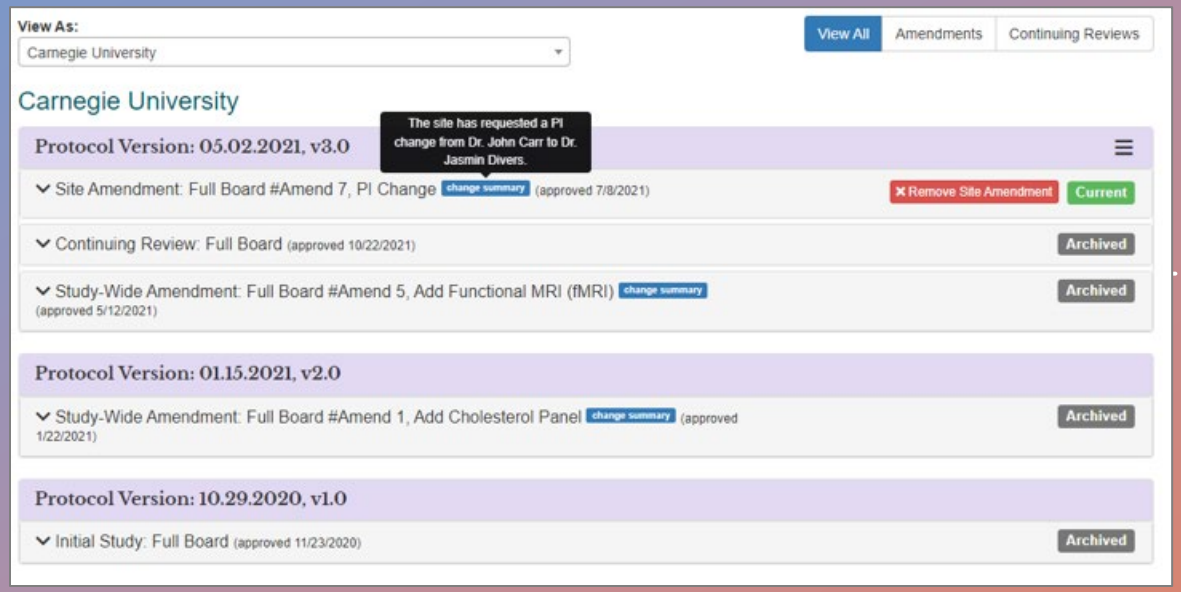


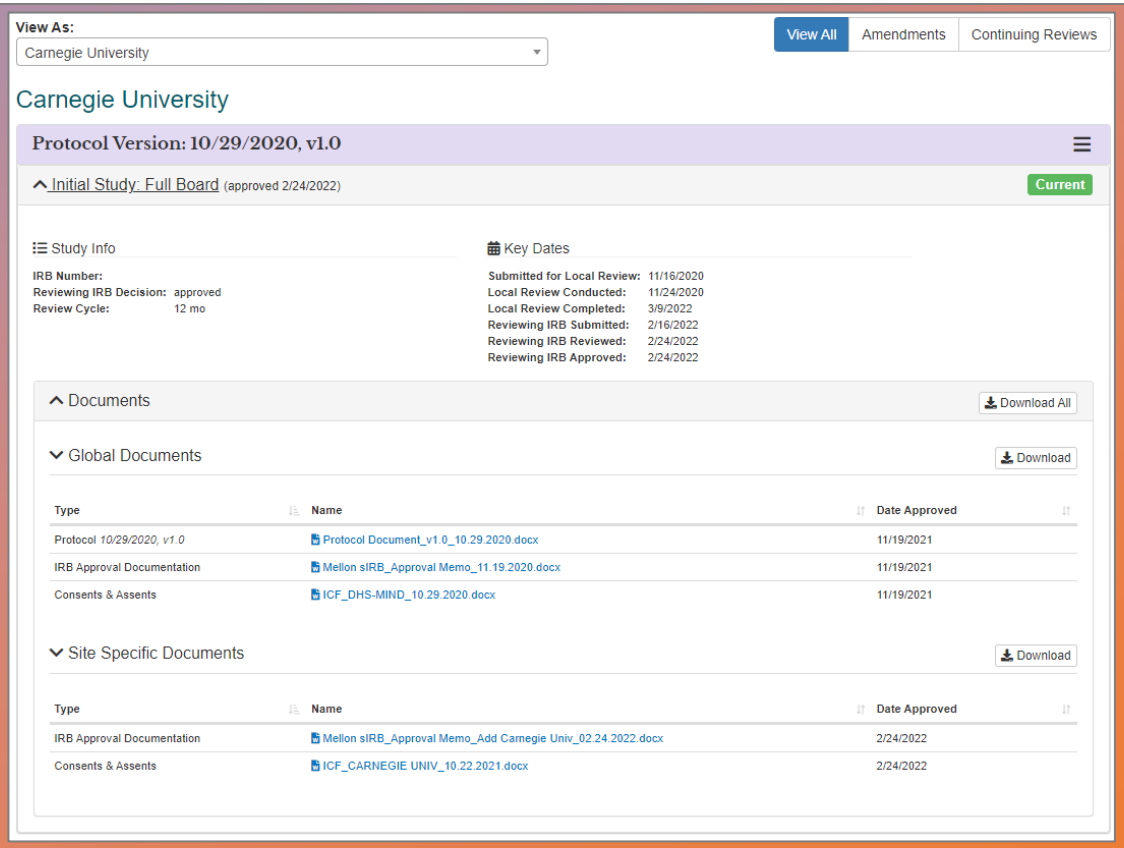
Recent System Updates

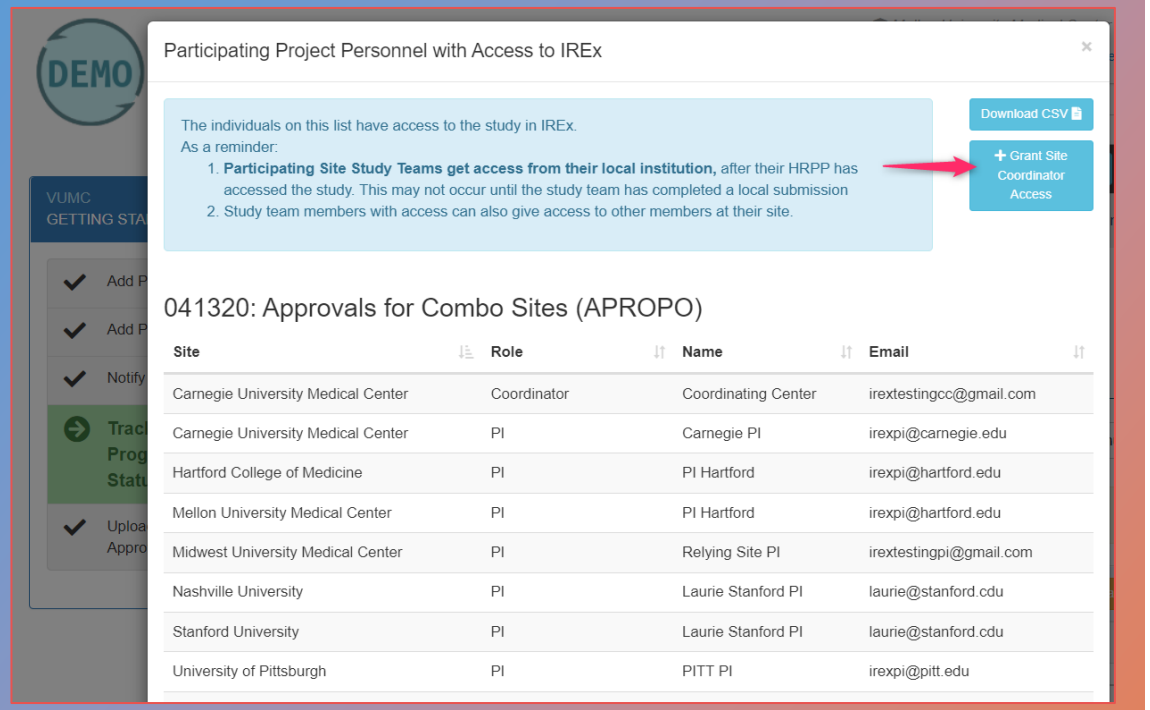
Since January 2022

Simplified Access to Approved Documents for Study Teams

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

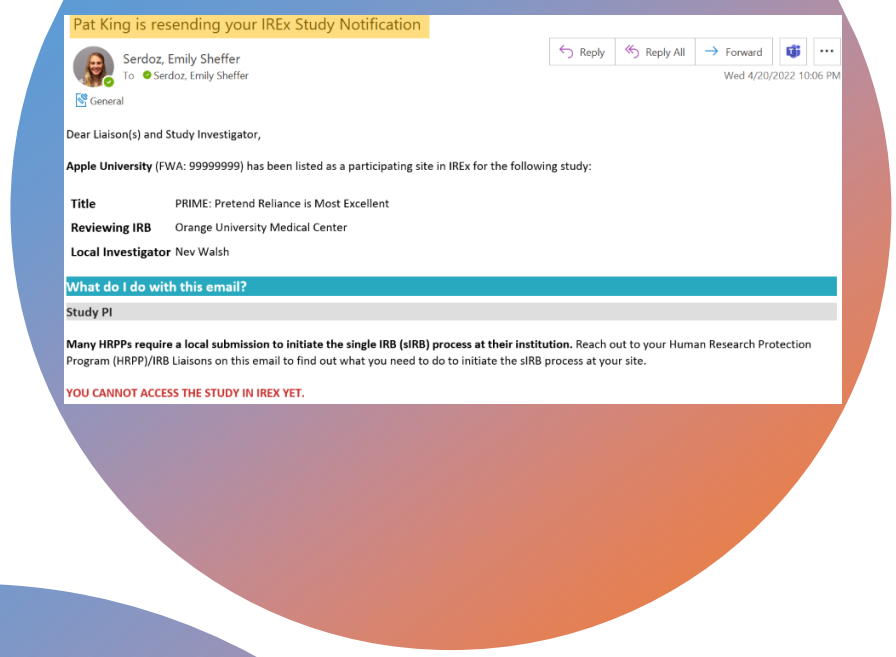


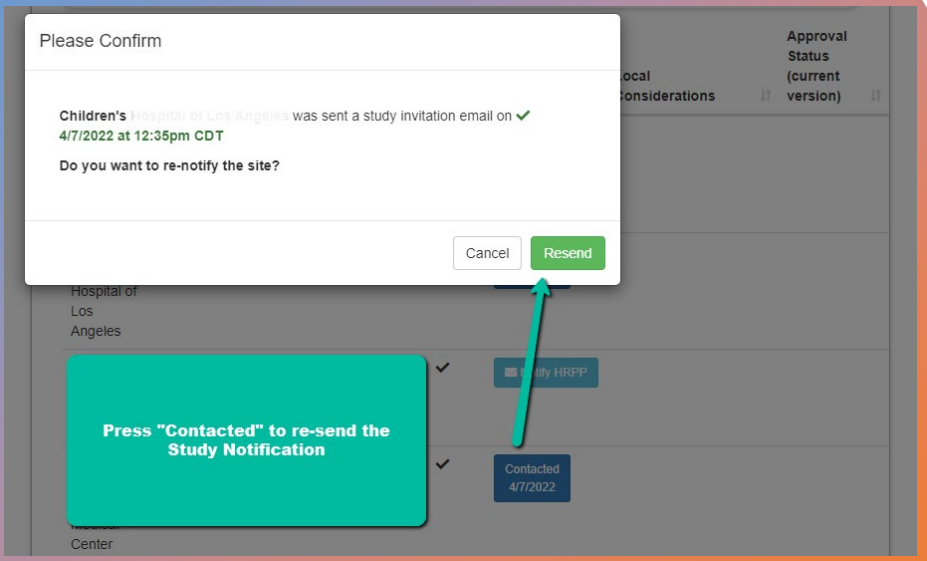




Streamlined New Access for Study Team Members

- 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.





Study Mangers 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.

Feedback & Future Enhancements

IREx SATISFACTION SURVEYS

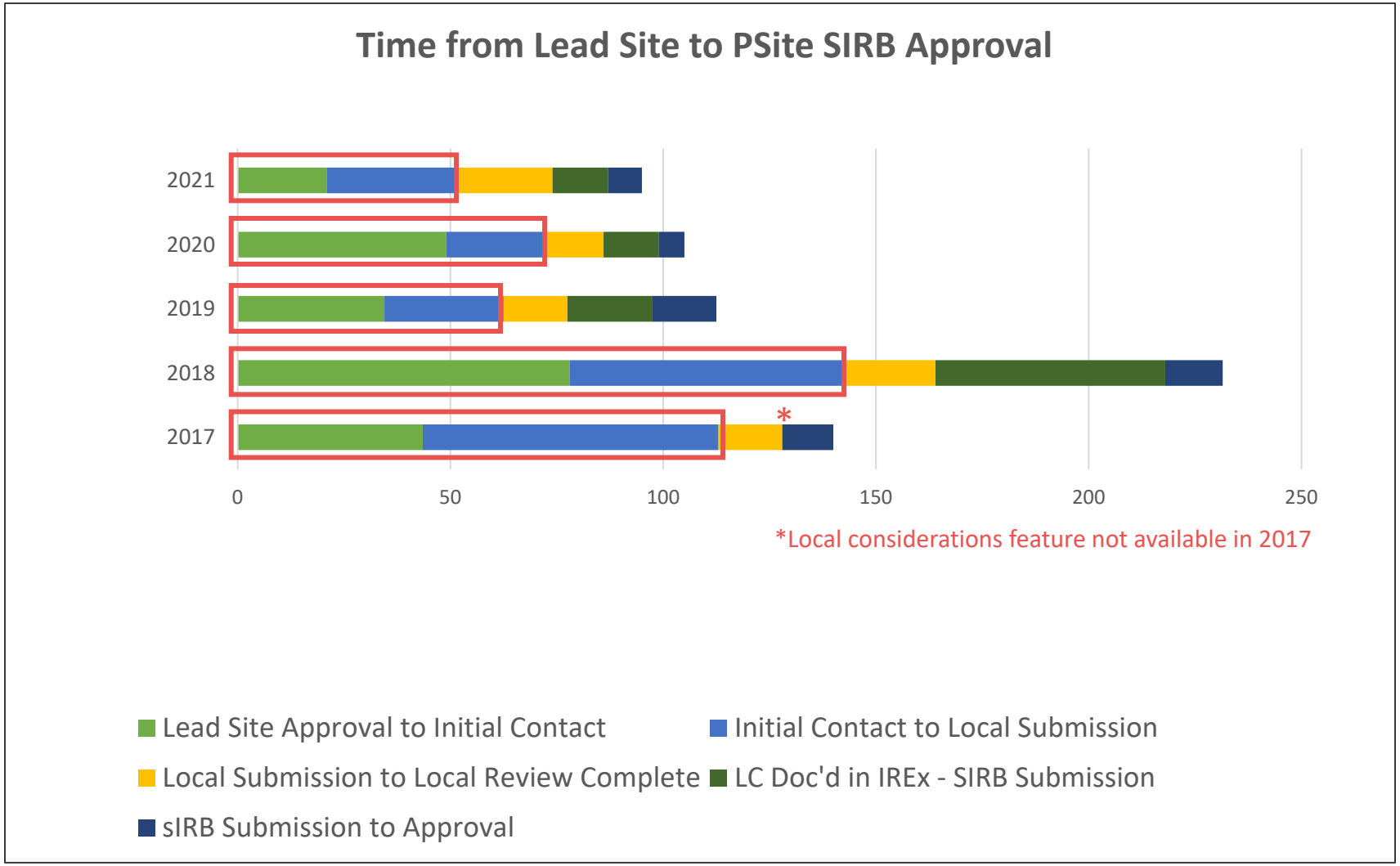
- **Respondents**
  - **sIRB Liaisons**, after uploading lead site approval
  - **Study managers**, after a few relying sites get approval
  - **PSite HRPPs**, after receiving approval from sIRB
- **Satisfaction with using IREx…**
  - on THIS study
  - in general
  - resources
- **Are there features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

Streamlining Documentation of Local Considerations

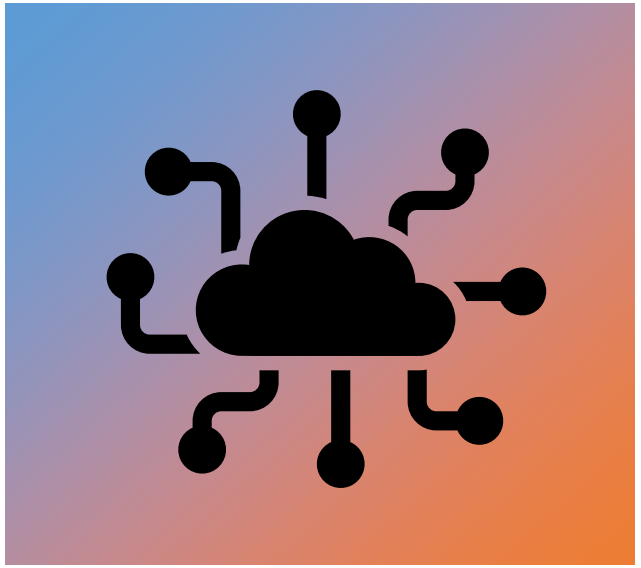
- CHALLENGES
  - PIs request Coordinator complete the PI Survey
  - HRPPs request the study team upload the ICF (instead of uploading it to the HRP Survey)
- PROPOSED IREX CHANGES
  - Allowing site coordinators to complete the PI Survey (still require PI signature)
  - Allowing the site study teams to 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?



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)

Next Call: July 15 , 2022