

Administrative Supplements for CTSA Awardees: Development of Resources to Facilitate Single IRB Review for Multi-Site Research

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Acknowledgements

- Award includes subcontracts with:
 - Cincinnati Children's Hospital Medical Center
 - Vanderbilt University Medical Center
 - Kaiser Permanente Washington Health Research Institute
- IRB Reliance Exchange (IREx) is funded in part by the NCATS Trial Innovation Network.
- Special thank you to these significant contributors (**IT Developers, IREx IT**):
 - Vanderbilt: Jenni Beadles, **Ross Davis**, **Bryce Embry**, Kevin Gustavson, Dena Johnson, **Joshua Milford**, Julie Ozier
 - Cincinnati Children's: Jeanie Bailey, Jeremy Corsmo, and **Steven Marks**

Aim 1

- **Goals**

- Better understand how stakeholders are preparing for the new sIRB policy
- Identify how the new sIRB policy will impact genomic studies
- Identify tools, resources and technical requirements for support of sIRB's for multi-site genomic studies

- **Methods:** Qualitative Interviews

- **Respondents:** 13 participants at 8 institutions, including investigators, IRB administrators (directors), IRB chairs, and compliance officers.

- **Results:** Analysis complete and paper forthcoming



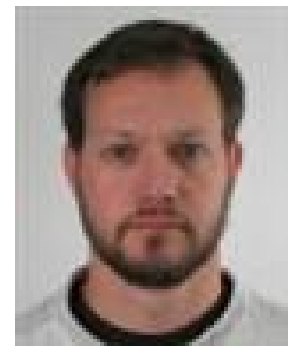
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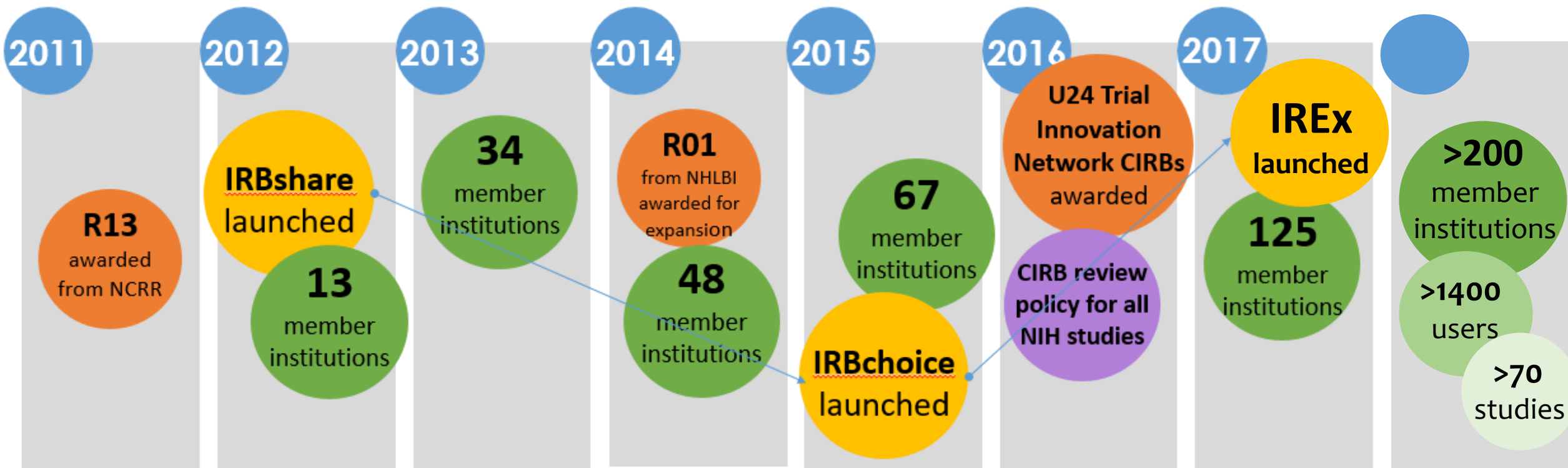
Aaron Scrol

**Kaiser Permanente Washington Health
Research Institute Supplement**

Aim 2

Build and pilot the use of web services/application programming interface (API) to enable interoperability between an established single IRB portal (IREx) and two electronic IRB systems

Brief History of IREx: An Evolving IT Platform



IRBshare and IRBchoice platforms consisted of a (1) master reliance agreement + (2) IT platform
IREx is an IT platform that can be used with any reliance agreement (e.g., SMART IRB)



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

What is IREx?

A **freely available** web-based portal that supports **single IRB (sIRB) documentation** and **communication** for multi-center clinical trials.

Centralize the capture of sIRB documentation



sIRB agreement completion
(*SMART IRB and IREx*)



Site PI attestations and any site differences in the conduct of the study



Reliance/cede decisions



sIRB approval documents for each site



Study-specific local considerations from site HRPPs/IRBs

- Standardize reliance process across sIRBs
- Harmonize sIRB data collection (local considerations)
- Complement and integrate with local eIRB systems
- Systematize capture of sIRB approval metrics

sIRB Supplement Exploratory Questions

What we know about sIRB review...



1. Requires documentation of ***new information*** from each site...
2. Requires ***exchanging of information*** from one institution to another.

What we want to explore about sIRB review...

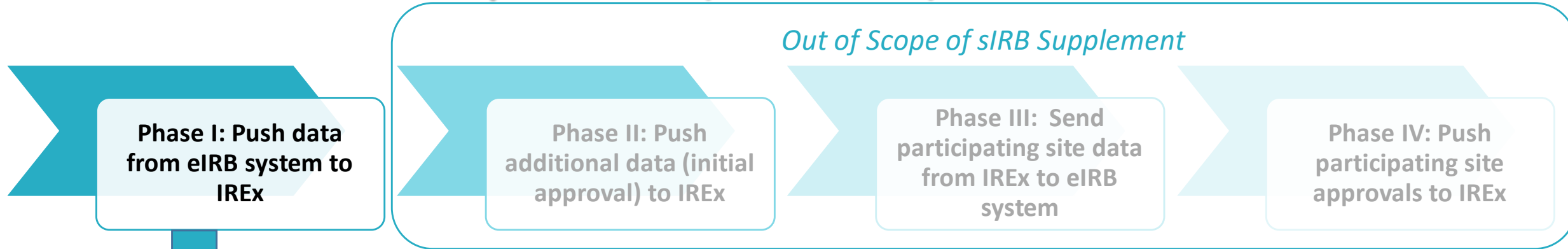


1. Is it necessary and/or possible to expect ***each Reviewing IRB system*** to accommodate this exchange of new information? Is this ***sustainable for investigators?***
2. Can ***interoperability*** with a centralized sIRB portal (IREx) ***help standardize the process and/or be a more cost-effective solution?***

sIRB Supplement Goals

1. Build/pilot web services/API to enable interoperability IREx and two IRB systems:
 - One home-grown system – DISCOVER-E at Vanderbilt
 - One common commercial system – Click at CCHMC
2. Reduce duplicative data entry and streamline use of IREx by Reviewing IRBs
3. Explore replicability of API patch developed for CCHMC at other IRBs using Click

API Pilot Development (Phase I)



Data points to create a study in IREx:

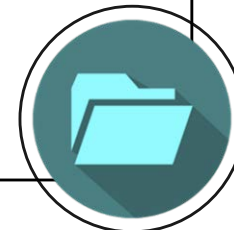
- Title
- IRB #
- Protocol version #
- Date submitted
- Date pre-review completed
- PI F/L Name and email

Information



- Draft protocol or executive summary

Files



Establishing IREx API Integration: Two Experiences

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- **30 hours over 6 weeks**
- Developers have total control over local IRB system and points of integration
- Development work largely applicable to only VUMC eIRB system integration



- **~ 100 hours over 1 month**
- Development required significant research and trial and error (~80 hours) before actually building the patch (~20 hours)
- Patch anticipated to be easily adapted (<5 hours) by other Click users (*test underway*)

IREx API Pilot Results: Successful!

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Main KSP Funding Application Document Uploads

Submission Summary

Notes for Reviewers

Save Save and Continue Delete

IREx

Send to IREx

VANDERBILT
Vanderbilt University Institutional Review Board
1313 21st Ave S, Suite 504
Nashville, TN 37232-4315
(615) 322-2918

Cincinnati Children's
changing the outcome together

ePAS Compliance Development Environment

Back Save Exit

Select External System:

IREx

Back Save Exit

Configure Attributes for IREx

IREx URI for your environment:
https://demo.irbchoice.org/s/api/create/project

API Token:
c514d7b17ef7c480208239d6abebed26b3f6ded8623d3ec6475ee3aef5843987

IRB Number:
id

Principal Investigator:
customAttributes__attribute0

Title:
name

Date Submitted:
customAttributes__attribute206

Date Pre-reviewed:
customAttributes__attribute207

Date Reviewed:
customAttributes__attribute200 x

Protocol File:
customAttributes__StudyDocuments.customAttributes__Protocol

Back Save Exit

Lessons Learned



- Interoperability requires technical expertise at the local institution



- API can automate some tasks for the sIRB, but sIRB portals (IREx) require some manual interaction from the sIRB



- Leverage the coordinating center or lead study team as much as possible for the 'manual' IREx processes



- Optimal interoperability occurs when eIRB system is built on a parent-child data model

Current Status and Next Steps

- Currently piloting replication of Click API package (from CCHMC) with NYU's e-IRB system
- Phase I of API release for broad use after final piloting
- Phase II of API in final development and near ready for piloting
- Phase III of API in initial planning stages (defining scope and variables) with the TIN CIRBs



Contact Us

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