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

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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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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

- **2011**: IRBshare launched
- **2012**: R13 awarded from NCRR
- **2013**: 13 member institutions
- **2014**: 34 member institutions, R01 from NHLBI awarded for expansion
- **2015**: 48 member institutions, IRBchoice launched
- **2016**: 67 member institutions, U24 Trial Innovation Network CIRBs awarded
- **2017**: IREx launched
- **2018**: >200 member institutions, >1400 users, >70 studies

**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).
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)
- Reliance/cede decisions
- Study-specific local considerations from site HRPPs/IRBs

- Site PI attestations and any site differences in the conduct of the study
- sIRB approval documents for each site

- 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 – DISCOVR-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)

Phase I: Push data from eIRB system to IREx

Phase II: Push additional data (initial approval) to IREx

Phase III: Send participating site data from IREx to eIRB system

Phase IV: Push participating site approvals to IREx

Data points to create a study in IREx:

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

Out of Scope of sIRB Supplement

Information

Files

Draft protocol or executive summary
Establishing IREx API Integration: Two Experiences

- **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!
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

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