Unlocking Single IRB Review with IREx: Keys to Efficiency for Lead Study Teams

IREx IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

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Disclosures

Funding for the IREx platform is support by the National Center for Advancing Translational Sciences (NCATS):

- ***Clinical and Translational Science Award (UL1TR002243)***

Vanderbilt Institute for Clinical and Translational Research

VICTR

- ***Trial Innovation Network – Trial Innovation Center (U24TR004437)***

TRIAL INNOVATION NETWORK

ECSTATIC

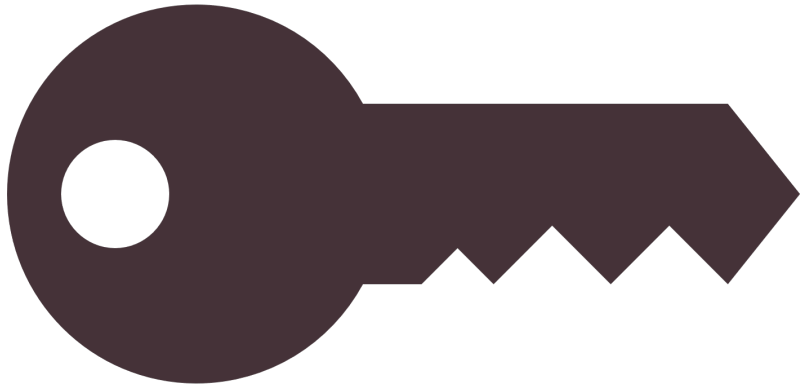
Engaging Cooperative Sites in Trial Acceleration, Trust, Innovation, and Capability

Goals

- To orient lead study teams to the basics of the single IRB review process
- To highlight critical milestones in the single IRB process
- To describe how the IREx platform helps lead study teams manage the single IRB process for relying sites

Keys to Efficient Single IRB Review

- **Understand** the basics: Single IRB 101
- **Designate** a lead study team point of contact
- **Manage** communication & documentation
- **Request** to use IREx!
- **Access** IREx Resources



Understand the basics: *Single IRB 101*

Key Terminology

sIRB = **Single IRB** (aka **Reviewing IRB**) is the "**IRB of record**" to which authority for IRB review and oversight has been ceded by another institution.

HRPP / HRPO / HRPA = **H**uman **R**esearch **P**rotection **P**rogram | **O**ffice | **A**dministrator

The organization's department, office, or person responsible for ensuring the organization complies with all applicable human subjects regulations and policies.

Relying Sites = the institutions relying on the sIRB (aka Participating Site, Study Site, Local Site)

Federal Wide Assurance # (FWA) = a unique identifier assigned by the Office for Human Research Protections (OHRPP)

Key Infrastructure

SMART IRB

Master Common Reciprocal Institutional Review Board Authorization Agreement

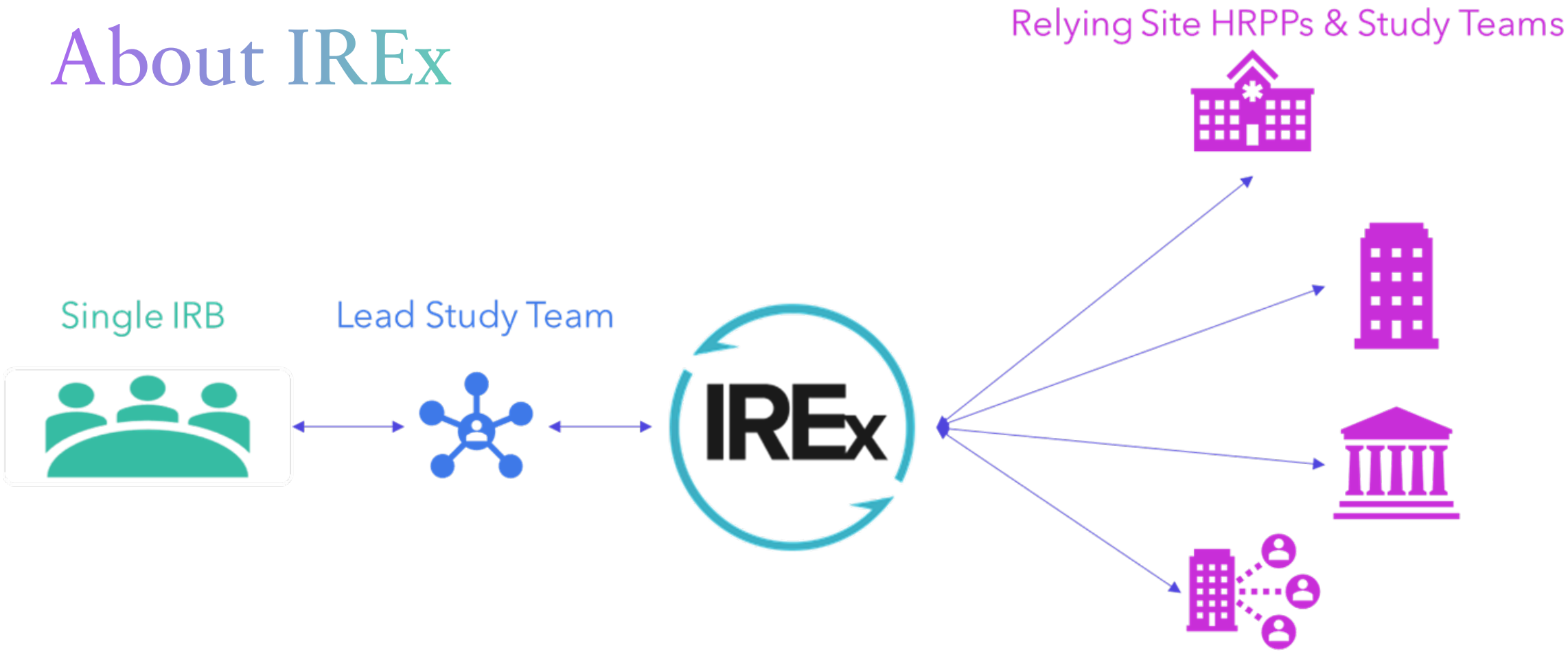
A **reliance agreement** used to outline the responsibilities of the sIRB vs. relying sites

IREx IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

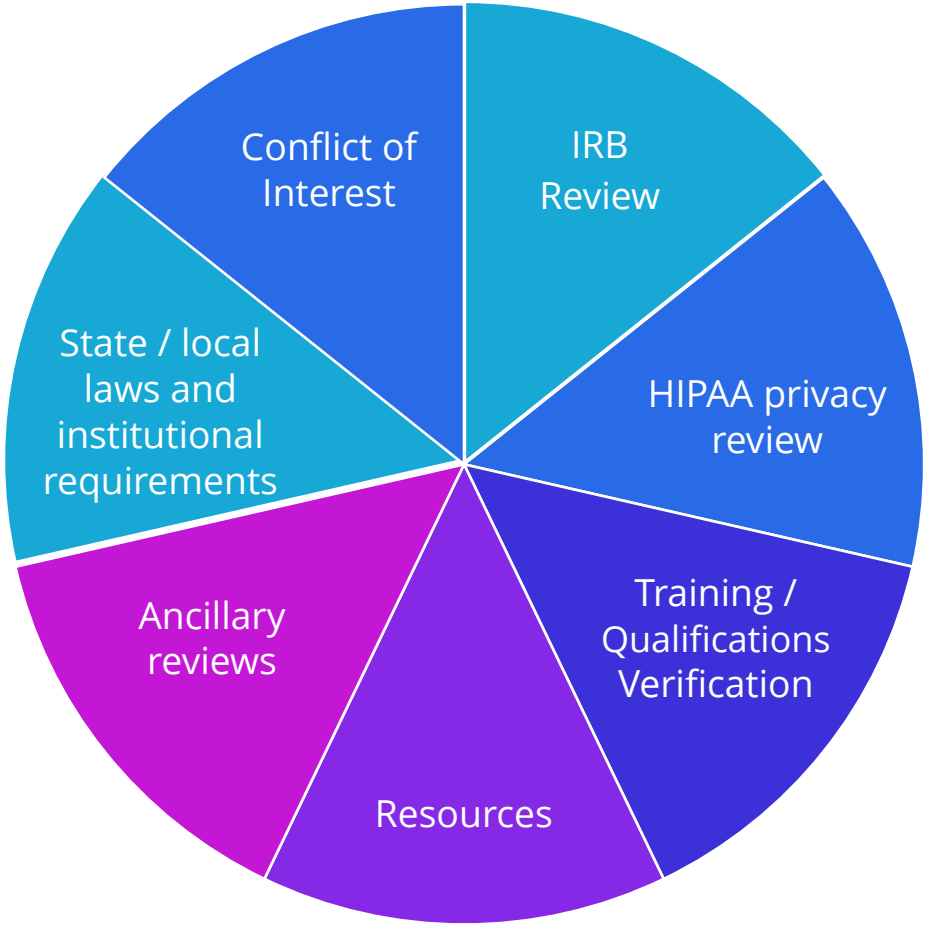
An **online tool** to manage the sIRB requirements and streamline communications for any multisite study (2+ sites)

About IREx



A freely available an **online tool** used to **help relying sites complete the single IRB documentation** and **allow the lead study team to manage the process for each site**. It also serves as **the hub that the lead study uses to disseminate all study approvals**.

Key Human Subjects Reviews



For **single site** studies,
ONE organization coordinates
all of these reviews.

Key Human Subjects Reviews

Relying Site's review responsibilities when using an sIRB ("local considerations")

sIRB's review responsibilities

Key Timepoints

Pre-award

Post-award

Prior to lead site/protocol approval

After lead site/protocol approval

Identify and budget for study sIRB

Finalize Protocol

Submit lead site/protocol to sIRB

Onboard sites to sIRB infrastructure

SMART IRB IREx

sIRB approval of Lead Site/Protocol

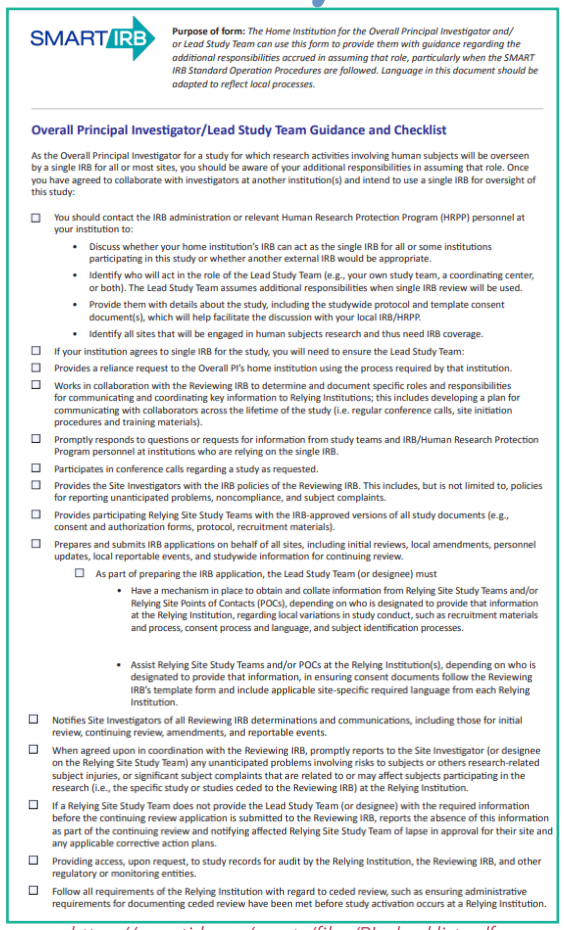
Relying site local submission, HRPP review, & documentation

Relying site sIRB submission, review, & approval

Key to Efficiency: *Designate a lead study team point of contact*

AKA IREx Study Manager

sIRB Review Requires Coordination by the Lead Study Team



SMART IRB

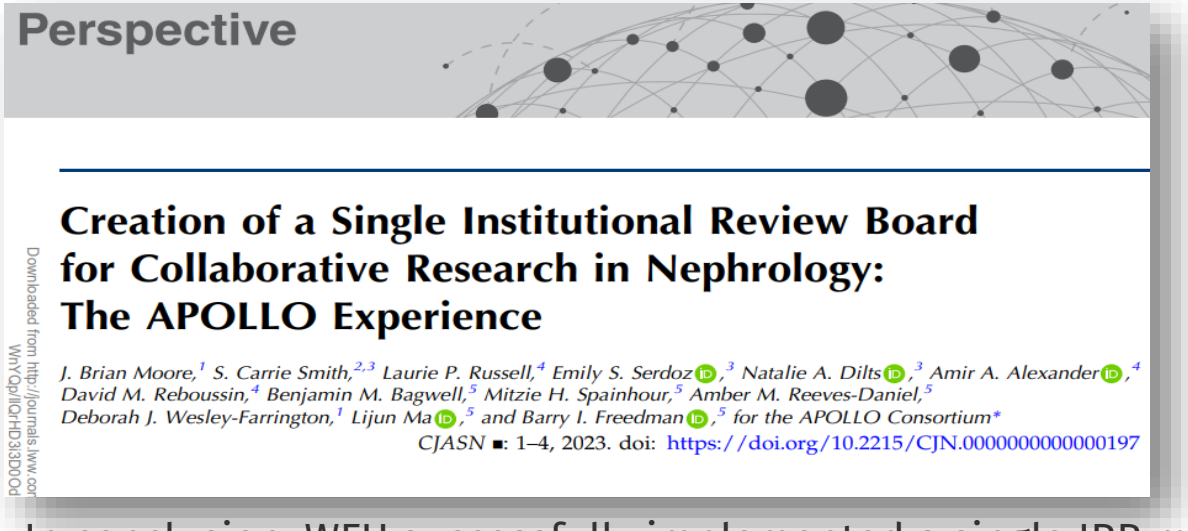
Purpose of form: *The Home Institution for the Overall Principal Investigator and/or Lead Study Team can use this form to provide them with guidance regarding the additional responsibilities accrued in assuming that role, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes.*

Overall Principal Investigator/Lead Study Team Guidance and Checklist

As the Overall Principal Investigator for a study for which research activities involving human subjects will be overseen by a single IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role. Once you have agreed to collaborate with investigators at another institution(s) and intend to use a single IRB for oversight of this study:

- ☐ You should contact the IRB administration or relevant Human Research Protection Program (HRPP) personnel at your institution to:
  - Discuss whether your home institution's IRB can act as the single IRB for all or some institutions participating in this study or whether another external IRB would be appropriate.
  - Identify who will act in the role of the Lead Study Team (e.g., your own study team, a coordinating center, or both). The Lead Study Team assumes additional responsibilities when single IRB review will be used.
  - Provide them with details about the study, including the studywide protocol and template consent document(s), which will help facilitate the discussion with your local IRB/HRPP.
  - Identify all sites that will be engaged in human subjects research and thus need IRB coverage.
- ☐ If your institution agrees to single IRB for the study, you will need to ensure the Lead Study Team:
- ☐ Provides a reliance request to the Overall PI's home institution using the process required by that institution.
- ☐ Works in collaboration with the Reviewing IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).
- ☐ Promptly responds to questions or requests for information from study teams and IRB/Human Research Protection Program personnel at institutions who are relying on the single IRB.
- ☐ Participates in conference calls regarding a study as requested.
- ☐ Provides the Site Investigators with the IRB policies of the Reviewing IRB. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.
- ☐ Provides participating Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
- ☐ Prepares and submits IRB applications on behalf of all sites, including initial reviews, local amendments, personnel updates, local reportable events, and studywide information for continuing review.
  - ☐ As part of preparing the IRB application, the Lead Study Team (or designee) must
    - Have a mechanism in place to obtain and collate information from Relying Site Study Teams and/or Relying Site Points of Contacts (POCs), depending on who is designated to provide that information at the Relying Institution, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
    - Assist Relying Site Study Teams and/or POCs at the Relying Institution(s), depending on who is designated to provide that information, in ensuring consent documents follow the Reviewing IRB's template form and include applicable site-specific required language from each Relying Institution.
- ☐ Notifies Site Investigators of all Reviewing IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events.
- ☐ When agreed upon in coordination with the Reviewing IRB, promptly reports to the Site Investigator (or designee on the Relying Site Study Team) any unanticipated problems involving risks to subjects or others research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research (i.e., the specific study or studies ceded to the Reviewing IRB) at the Relying Institution.
- ☐ If a Relying Site Study Team does not provide the Lead Study Team (or designee) with the required information before the continuing review application is submitted to the Reviewing IRB, reports the absence of this information as part of the continuing review and notifying affected Relying Site Study Team of lapse in approval for their site and any applicable corrective action plans.
- ☐ Providing access, upon request, to study records for audit by the Relying Institution, the Reviewing IRB, and other regulatory or monitoring entities.
- ☐ Follow all requirements of the Relying Institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.

https://smartirb.org/assets/files/PI_checklist.pdf



Perspective

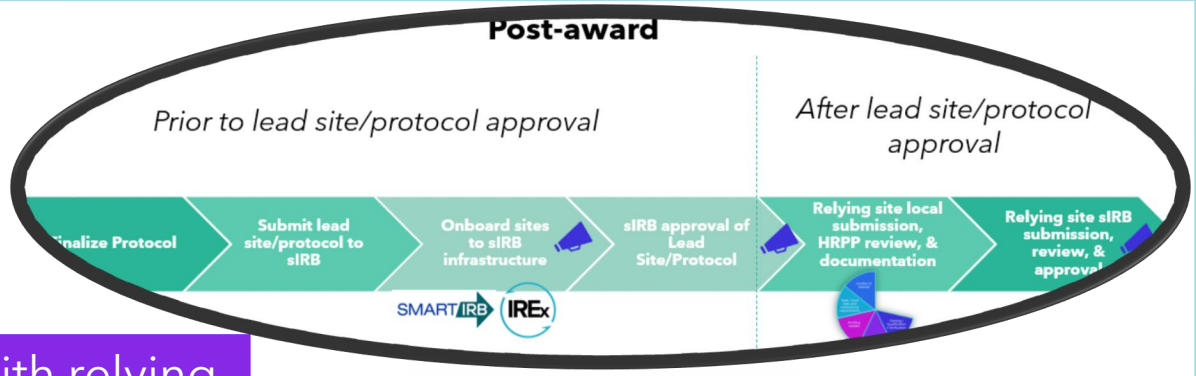
Creation of a Single Institutional Review Board for Collaborative Research in Nephrology: The APOLLO Experience

*J. Brian Moore,[1] S. Carrie Smith,[2,3] Laurie P. Russell,[4] Emily S. Serdoz,[3] Natalie A. Dilts,[3] Amir A. Alexander,[4] David M. Reboussin,[4] Benjamin M. Bagwell,[5] Mitzie H. Spainhour,[5] Amber M. Reeves-Daniel,[5] Deborah J. Wesley-Farrington,[1] Lijun Ma,[5] and Barry I. Freedman,[5] for the APOLLO Consortium**

CJASN ■: 1–4, 2023. doi: https://doi.org/10.2215/CJN.0000000000000197

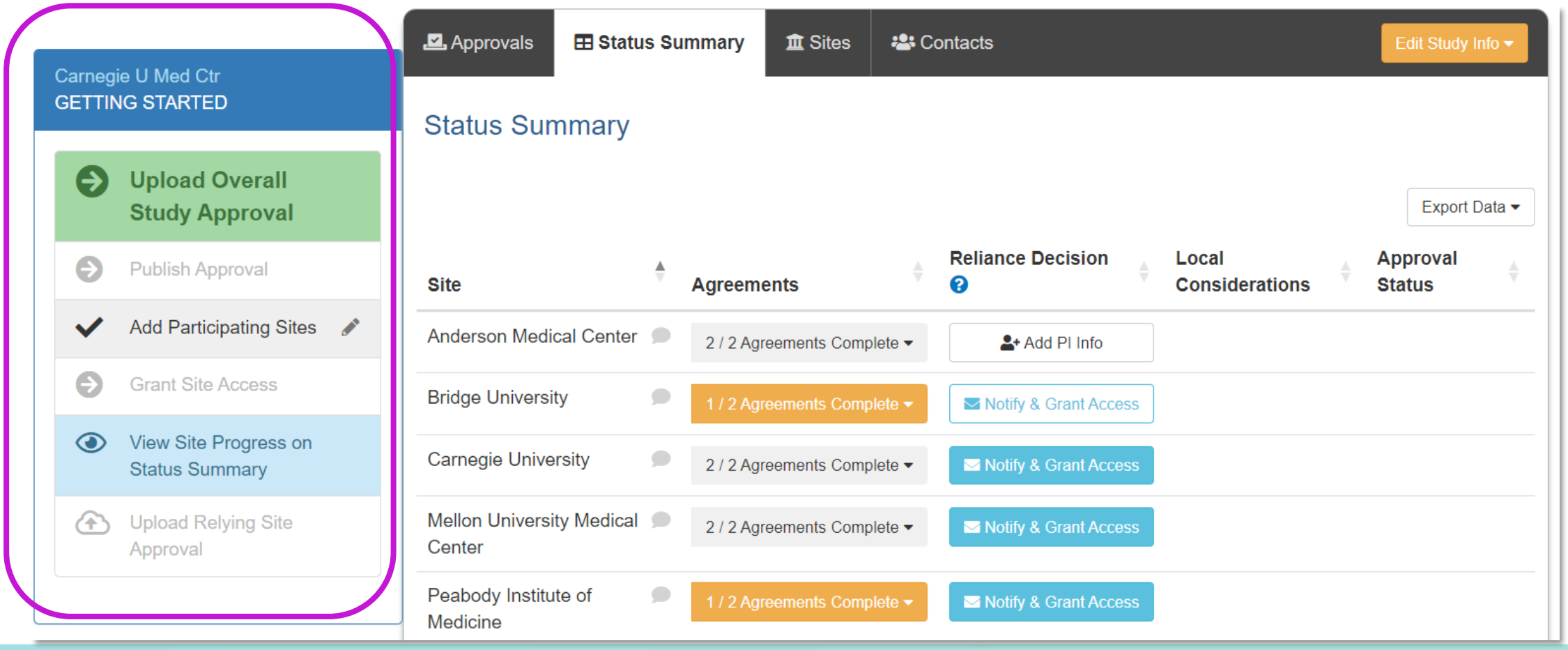
In conclusion, WFU successfully implemented a single IRB model for APOLLO, consistent and compliant with its determinations, and maintained reasonable timelines for approval. **Communication and collaboration between multiple groups was pivotal. We recommend identifying an IREx Study Manager with sufficient effort dedicated to the study.** Without the coordination, support, and resources available from researchers, staff, and collaborators, these processes would have been more burdensome, onerous, and time-consuming.

Key Responsibilities of the Lead Study Team

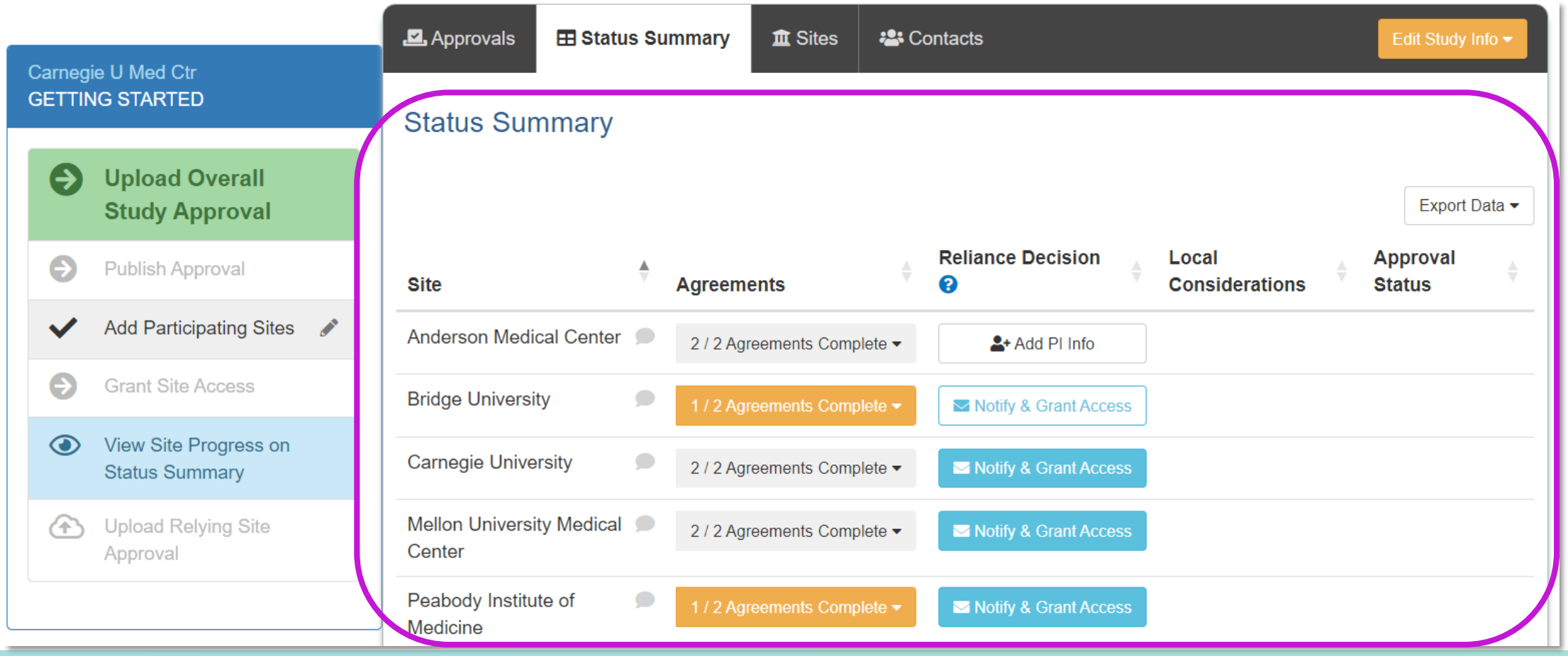


- Communicate process & requirements with relying sites
- Disseminate lead site approval documents to relying sites
- Track relying site documentation
- Submit relying site documentation to the sIRB
- Share approvals with relying sites

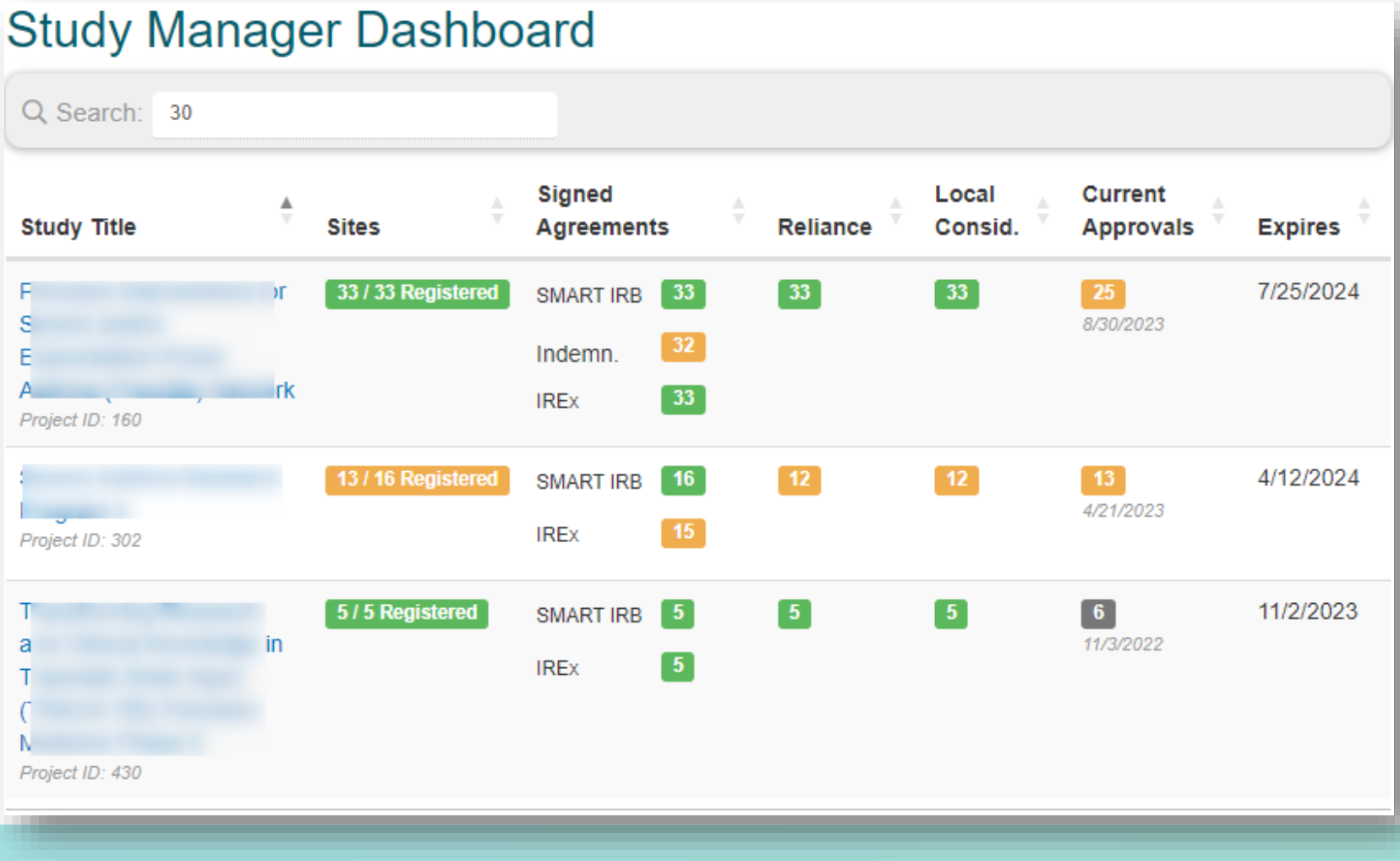
IREx Can Help: *Lead Study Team Checklist*



IREx Can Help: *Status Summary*

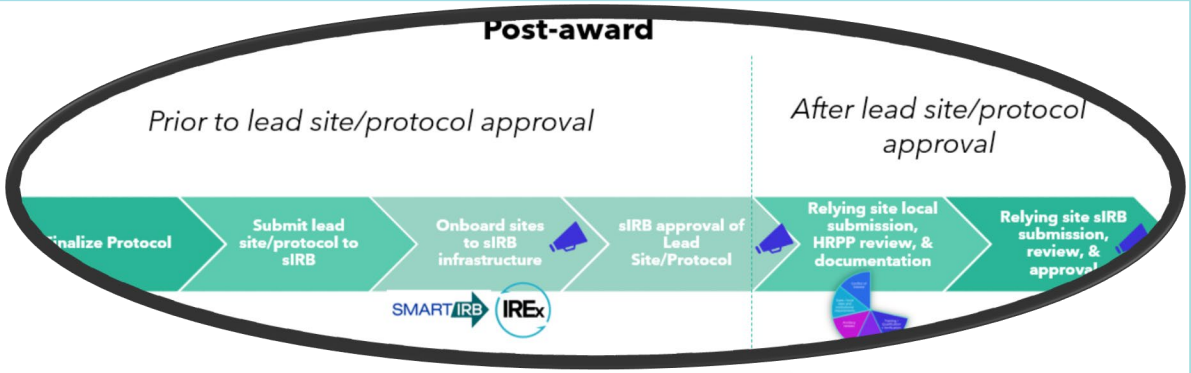


IREx Can Help: *Dashboard for All Studies*



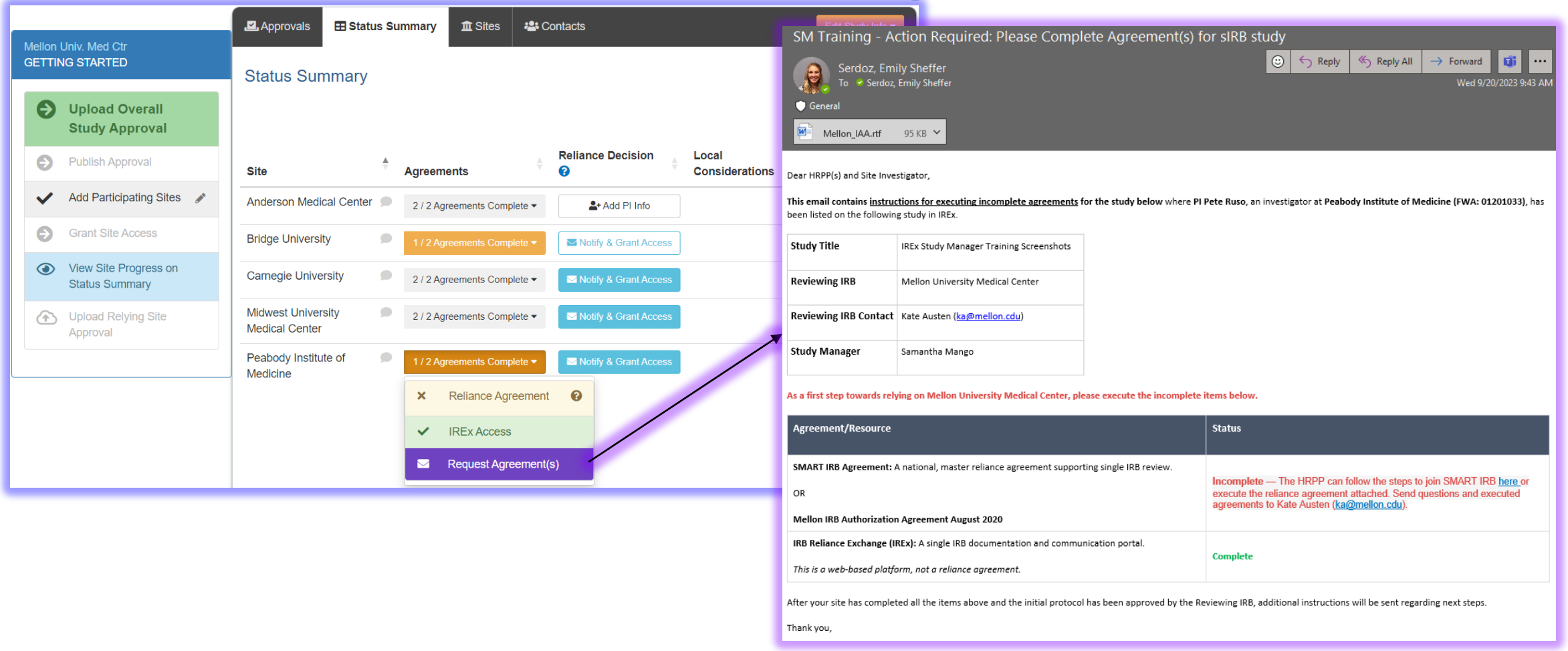
Key to Efficiency: *Communications & Documentation*

Key Communications

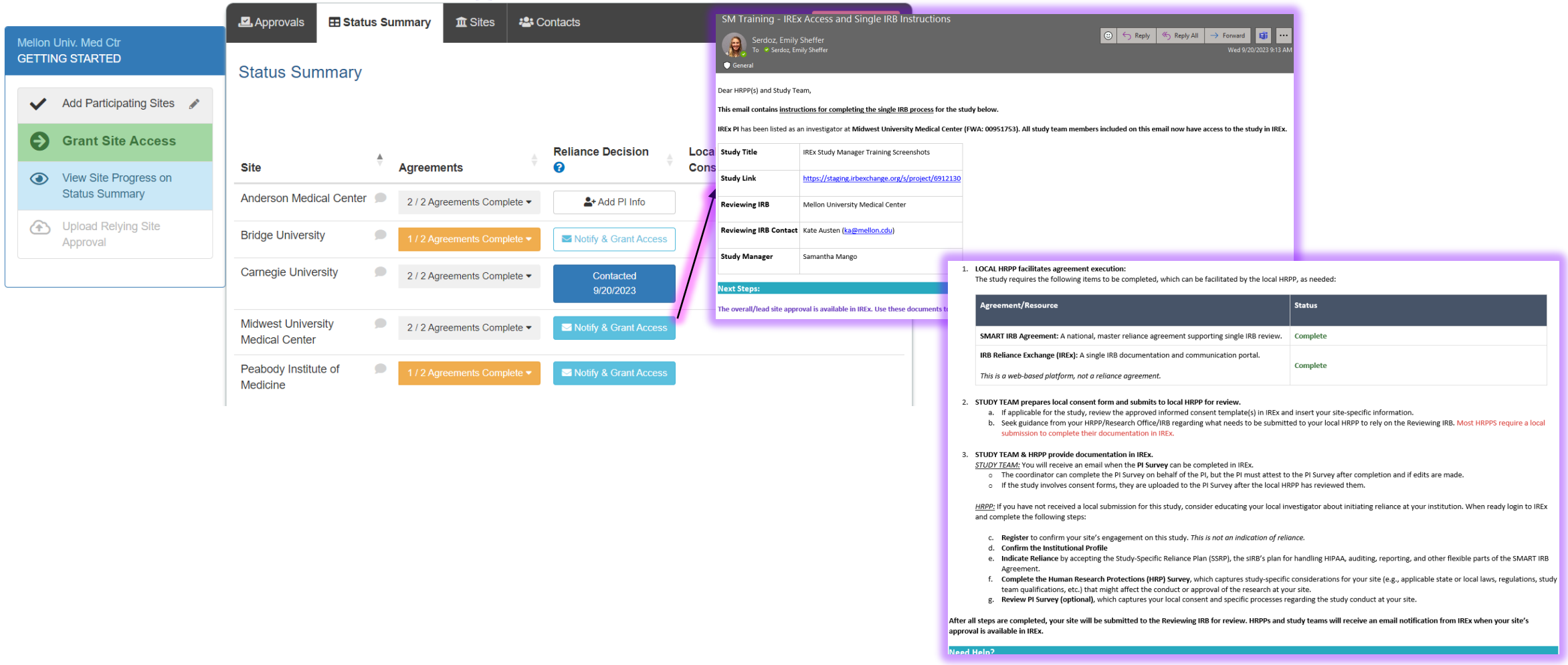


- Request required agreements be completed
- Distribute sIRB instructions & documents after lead site approval
- Disseminate sIRB approval of sites

IREx Can Help: *Request Agreements*



IREx Can Help: *Communicate sIRB Instructions*



IREx Can Help: *Disseminate Site Approvals*

Dear Liaisons and Study Contacts,

Mellon University Medical Center has shared IRB approval for your institution, Carnegie University, in IREx for the study below:

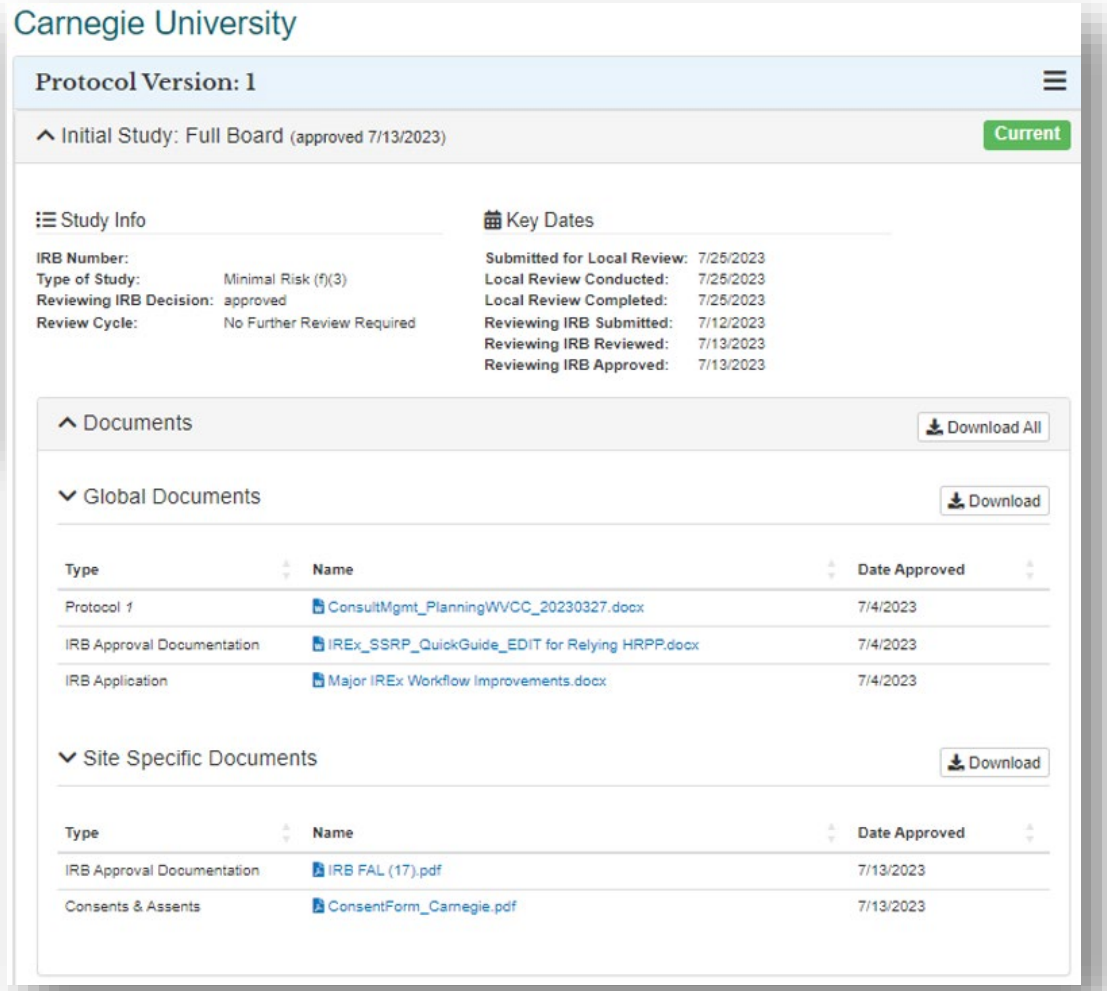
Study Title:	Metabolomics of Neurocognitive Risk for Dementia in Diabetes
Type of Review / Approval:	Initial Study: Expedited
Expiration Date:	11/18/2022
Study Link:	https://staging.irbexchange.org/s/project/007

Principal Investigators & Study Contacts:

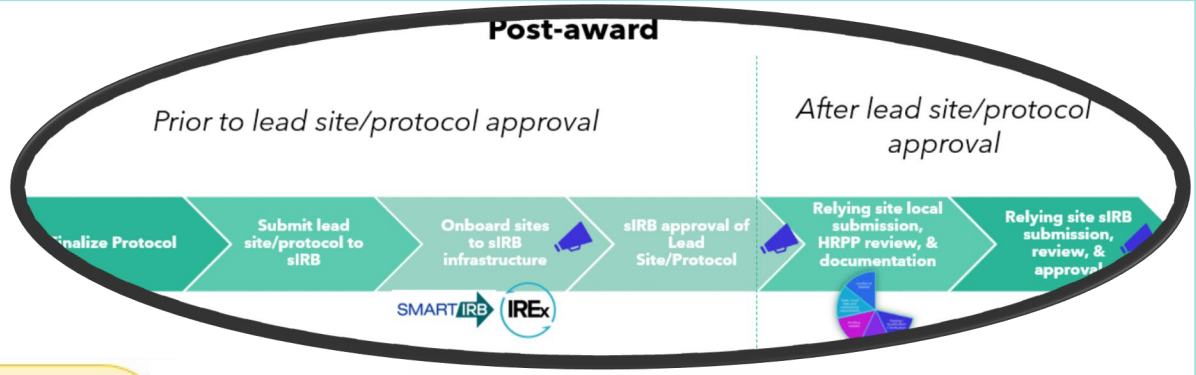
NEW We've made accessing your approval documents more user friendly - use this Quick Guide to see the changes.

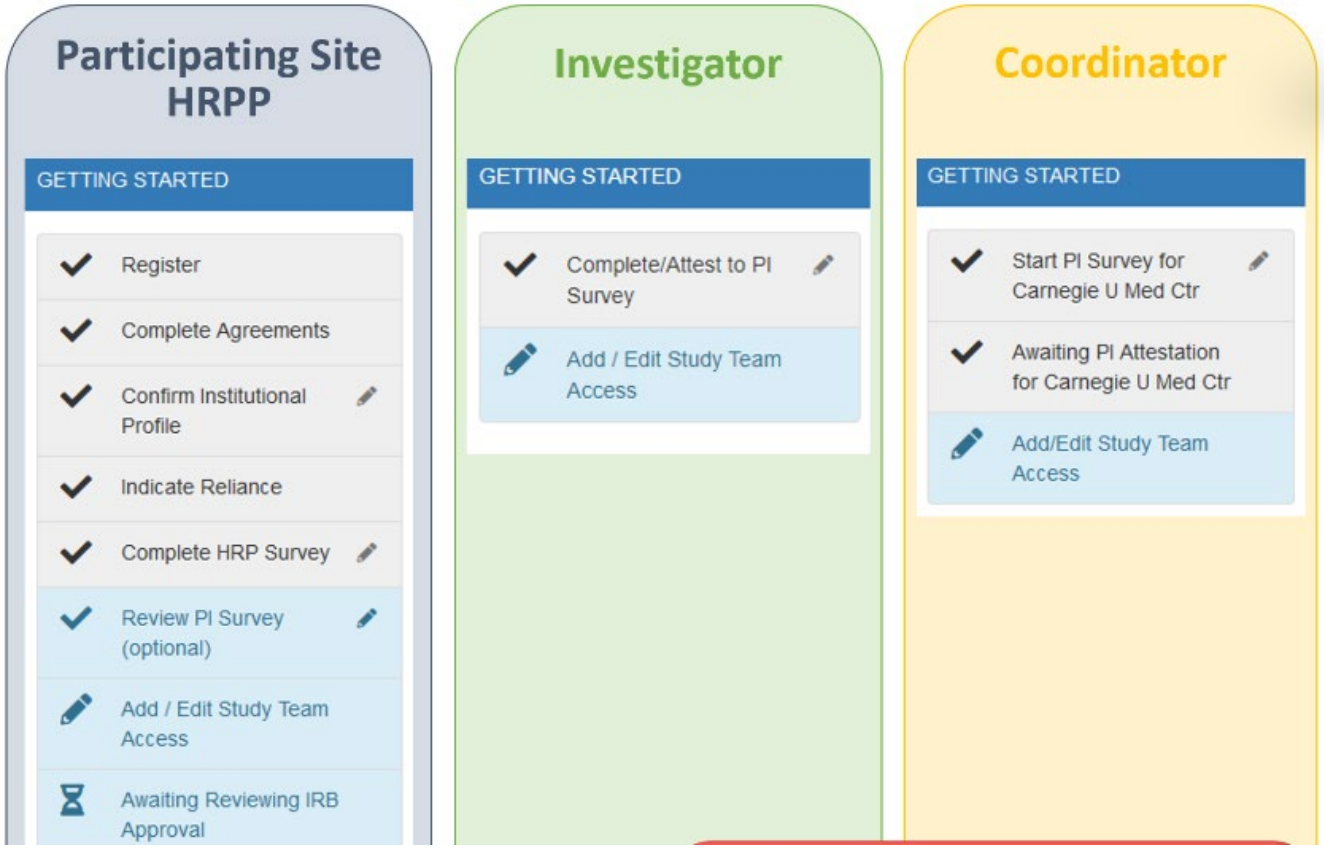
If you have any questions about your approval or future submissions, please contact the Study Manager (Coordinating Center/ Lead Study Team) or Reviewing IRB. If needed, contact information is listed on the study page above the study title in IREx.

Thank you for using IREx,
The IREx Team



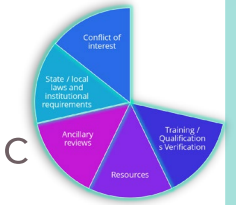
Key Documentation



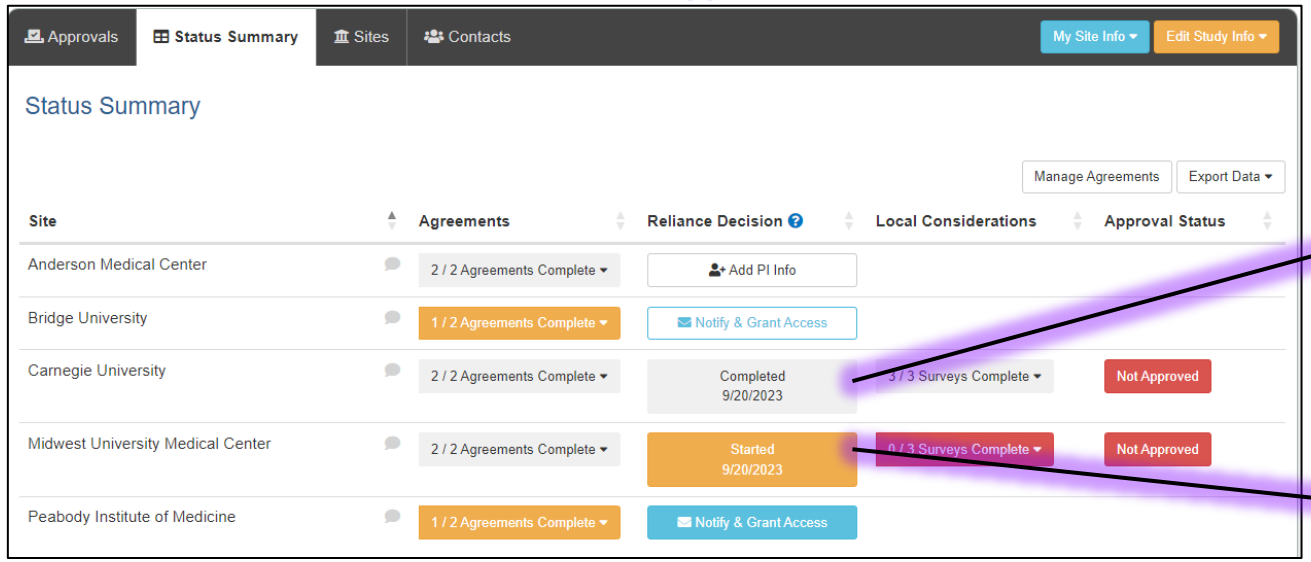


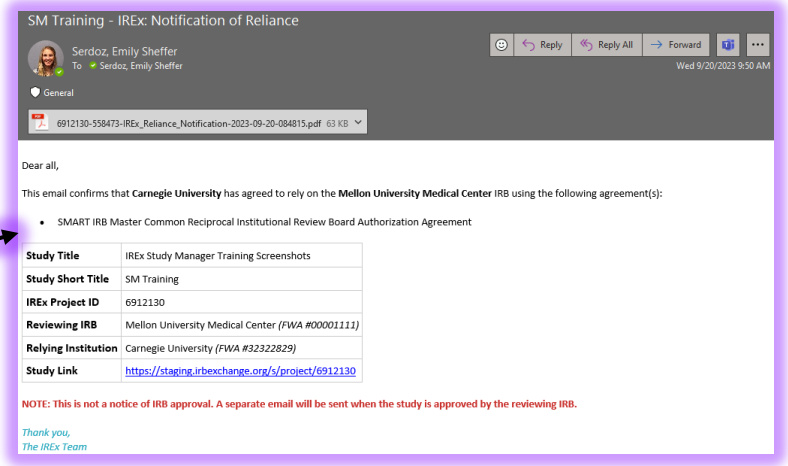
Relying Site Documentation

- **Reliance decision**
- **Institutional Profile** – relatively static organization-level information from the HRPP
- **HRP Survey** – study specific information from the HRPP
- **PI Survey** – documentation of site differences from the protocol, if any



IREx Can Help: *Automated Notifications*




SM Training - IREx: Notification of Reliance

Serdoz, Emily Sheffer
To Serdoz, Emily Sheffer

Reply | Reply All | Forward
Wed 9/20/2023 9:50 AM

General

6912130-558473-IREx_Reliance_Notification-2023-09-20-084815.pdf 63 KB

Dear all,

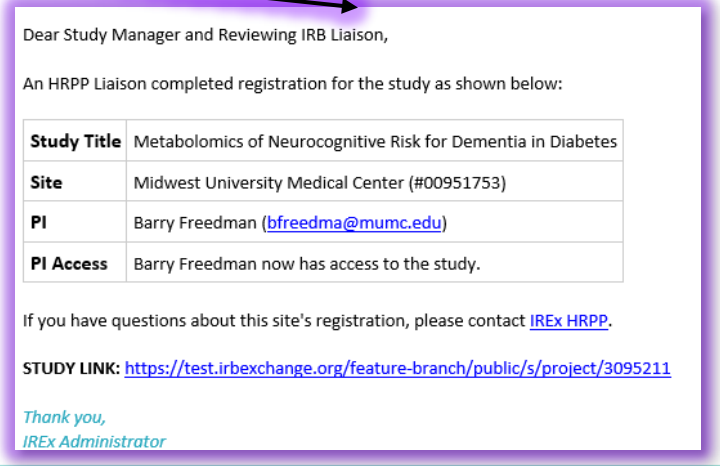
This email confirms that **Carnegie University** has agreed to rely on the **Mellon University Medical Center** IRB using the following agreement(s):

- SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement

Study Title	IREx Study Manager Training Screenshots
Study Short Title	SM Training
IREx Project ID	6912130
Reviewing IRB	Mellon University Medical Center *(FWA #00001111)*
Relying Institution	Carnegie University *(FWA #32322829)*
Study Link	https://staging.irbexchange.org/s/project/6912130

NOTE: This is not a notice of IRB approval. A separate email will be sent when the study is approved by the reviewing IRB.

Thank you,
The IREx Team


Dear Study Manager and Reviewing IRB Liaison,

An HRPP Liaison completed registration for the study as shown below:

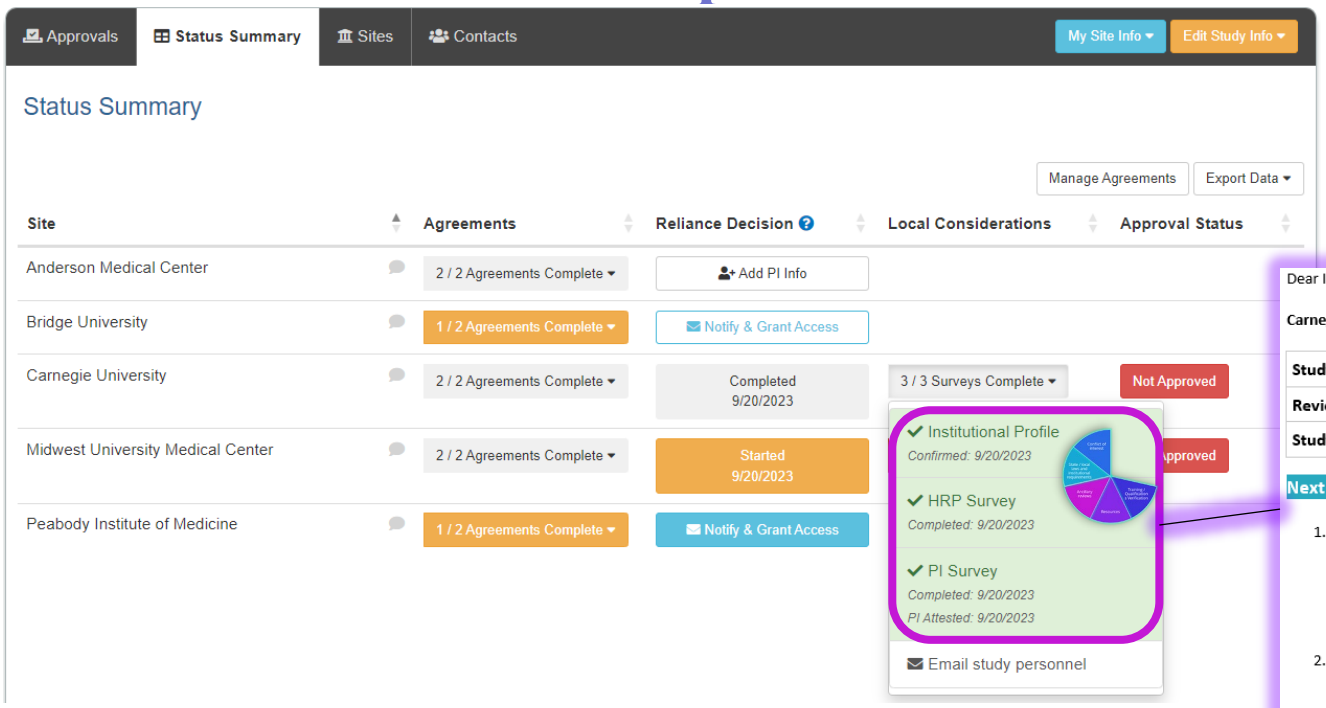
Study Title	Metabolomics of Neurocognitive Risk for Dementia in Diabetes
Site	Midwest University Medical Center (#00951753)
PI	Barry Freedman (bfreedma@mumc.edu)
PI Access	Barry Freedman now has access to the study.

If you have questions about this site's registration, please contact IREx HRPP.

STUDY LINK: https://test.irbexchange.org/feature-branch/public/s/project/3095211

Thank you,
IREx Administrator

IREx Can Help: *Automated Tracking*



Dear IREx Study Manager(s),

Carnegie University has completed the local considerations for the study below.

Study Title:	Metabolomics of Neurocognitive Risk for Dementia in Diabetes
Reviewing IRB:	Mellon University Medical Center
Study Link:	https://test.irbexchange.org/feature-branch/public/s/project/507062

Next Steps

1. **PRE-SCREEN LOCAL CONSIDERATIONS**
   - Pre-screen the HRP and PI surveys and the consent form, if applicable, for completion (e.g., is any information missing from the consent form sections; does the language provided read properly). Consent forms are uploaded to the PI survey.
   - To request changes, reach out to the local study team who can make changes to the PI Survey and work with their HRPP if changes are needed for the HRP Survey.

2. **EXPORT LOCAL CONSIDERATIONS FROM IREx**
   Allow up to ten minutes for the Export feature to be available for download. From the Status Summary tab on your study page, click the "Export Data" button and select "Export Local Considerations" to download the local considerations for this site. These files will be included in the export:
   - Notification of Reliance Letter
   - HRP Survey responses (PDF)
   - PI Survey responses (PDF)
   - Institutional Profile (PDF)
   - Site-specific consent forms, if applicable for this study.
   - Other documents that are uploaded to the HRP or PI Surveys and the Institutional Profile. The survey type will be included in the file name (e.g., [Institutional Profile]_filename)

3. **SUBMIT THE SITE TO THE SIRB FOR REVIEW**

   If you have questions about how to submit to the Reviewing IRB, contact the Reviewing IRB Liaison(s): LaDonna Liaison (lliaison@sirbmc.cdu).

Thank you,
IREx Administrator

Key to Efficiency: *Request to use IREx!*

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journal homepage: www.elsevier.com/locate/conctc

ELSEVIER

Using single IRB consultations to meet the educational needs of investigative teams

Ann R. Johnson [a,*], Mary Pautler [b], Jeri S. Burr [b], Nael Abdelsamad [b], John M. VanBuren [b], Lisa M. Rigtrup [a], J. Michael Dean [b], Erin Rothwell [c]

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[b] University of Utah School of Medicine, Department of Pediatrics, 295 Chipeta Way, Salt Lake City, UT, 84108, USA
[c] University of Utah School of Medicine, Department of Obstetrics and Gynecology, 50 North Medical Drive, Salt Lake City, UT, 84132, USA

Perspective

Creation of a Single Institutional Review Board for Collaborative Research in Nephrology: The APOLLO Experience

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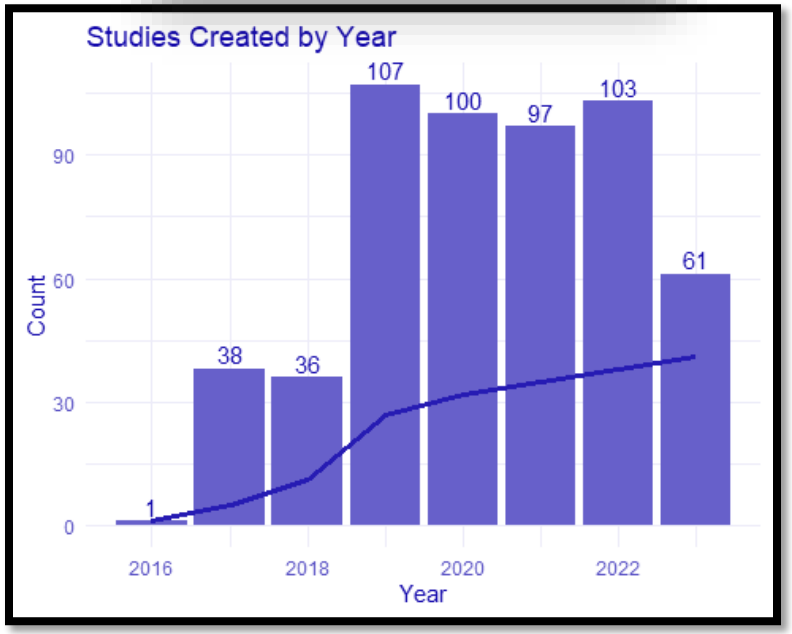
CJASN ■: 1–4, 2023. doi: https://doi.org/10.2215/CJN.0000000000000197

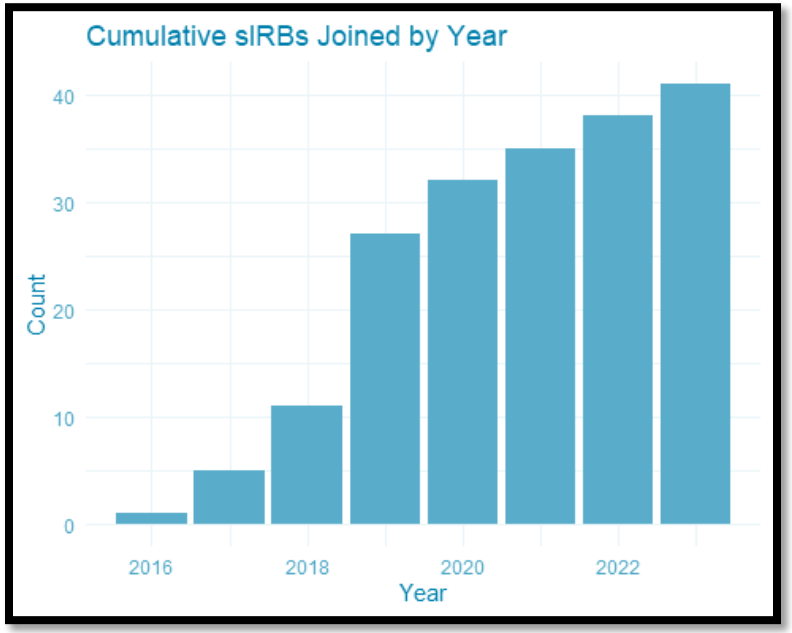
"To streamline the SIRB review process, **the use of electronic systems to coordinate the flow of information and the timing of actions is often key**… The platform TIN SIRBs use to document reliance is the **IRB Reliance Exchange system, or IREx**. This platform connects institutions' IRBs, HRPPs, and study teams; enables documentation of reliance relationships in a central location; and captures local review and institutional profiles."

In conclusion, WFU successfully implemented a single IRB model for APOLLO, consistent and compliant with its determinations, and maintained reasonable timelines for approval. **Communication and collaboration between multiple groups was pivotal. We recommend identifying an IREx Study Manager with sufficient effort dedicated to the study.** Without the coordination, support, and resources available from researchers, staff, and collaborators, these processes would have been more burdensome, onerous, and time-consuming.

IREx Utilization

Participating Institutions	512
Studies	573





Relying HRPP Use of IREx

NAME	STUDY PARTICIPATION	INSTITUTIONAL PROFILE
Children's Hospital of Philadelphia AAHRPP	73	updated 4/4/2023
University of Michigan AAHRPP CTSA	63	updated 8/29/2023
Stanford University AAHRPP CTSA	61	updated 8/24/2023
Duke University Health Systems, Inc. AAHRPP CTSA	58	updated 8/7/2023
University of California, Los Angeles AAHRPP CTSA	58	updated 6/15/2023

Institution Name *NEW* sIRB in Q1 of 2023	# of Studies
Ann & Robert H. Lurie Children's Hospital of Chicago	4
Ball State University	1
Baylor College of Medicine	1
Baystate Health, Inc	3
Children's Hospital of Los Angeles *NEW*	1
Cincinnati Children's Hospital Medical Center	1
Dartmouth-Hitchcock Clinic	2
Duke University Health Systems, Inc.	9
Emory University	3
George Washington University	1
Indiana University	3
Intermountain Healthcare	1
Johns Hopkins University School of Medicine	22
Louisiana Department of Health	1
Louisiana State University A and M	5
Louisiana State University Health Science Center at New Orleans	31
Louisiana State University Health Science Center at Shreveport	1
MaineHealth *NEW*	1
Memorial Sloan Kettering Cancer Center	1
Nationwide Children's Hospital	9
Ochsner Clinic Foundation	5
Pennington Biomedical Research Center	49
St. Jude Children's Research Hospital	1
The Ohio State University *NEW*	1
Tulane University	41
University of Alabama Birmingham	3
University of California, San Francisco	42
University of Colorado, Denver	2
University of Maryland Baltimore	2
University of Massachusetts Medical School	1
University of Mississippi Medical Center	1
University of Pittsburgh	5
University of Rochester	6
University of Texas Southwestern Medical Center	8
University of Texas, MD Anderson Cancer Center	4
University of Utah	68
University of Wisconsin – Madison	2
Vanderbilt University Medical Center	137
Virginia Commonwealth University	2
Wake Forest University Health Sciences	27
Woman's Hospital Foundation	2

Key to Efficiency: *IREx Resources*

Our Best Resource: The IREx Team!

- Training
- Special projects

Natalie Dilts

- Manager, Application Development

Bryce Embry

- Resources & Materials

Katelyn Benhoff

- Study Support
- User Training

David Crenshaw

- Materials Development
- Study support

Kaysi Quarles

- Study Support
- Evaluation

Tiffany Chen

- Program Manager

Emily Serdoz

- Study Support
- User Training

Bridget Swindell

- System Development

Linda Tan

- Application Developer

Jason Tan

- Application Developer

Evan Wimberly

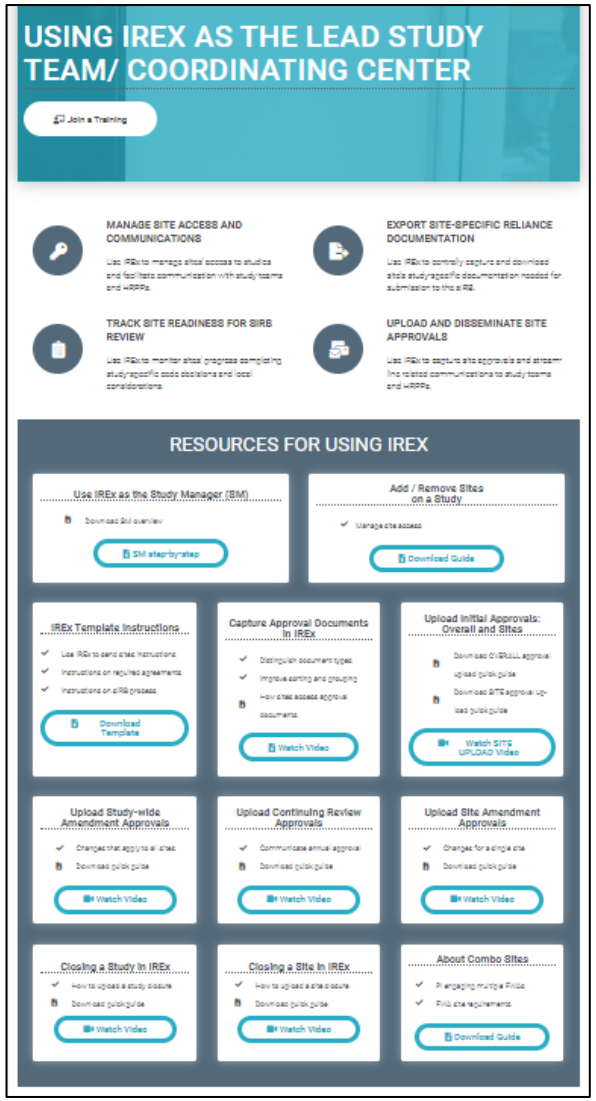
IREx Resources

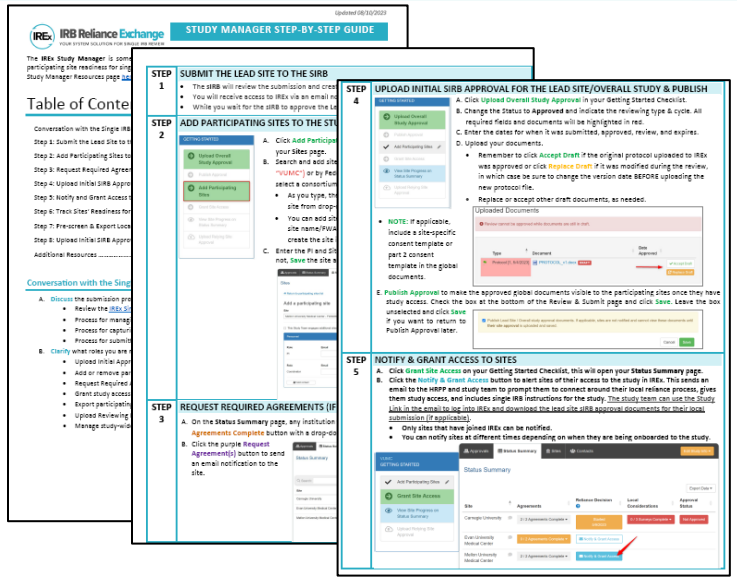
Website:
https://IRBExchange.org

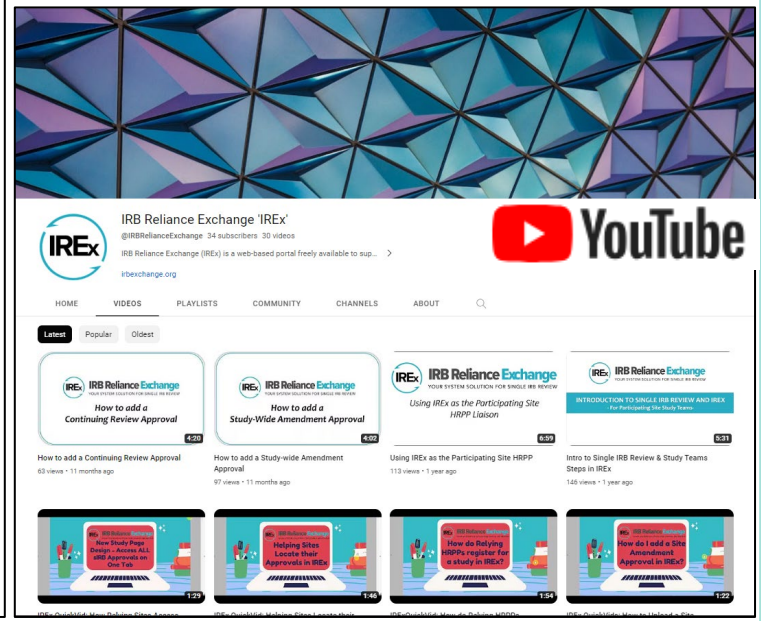
Visit the Study Manager Resources Page

Email Us:
admin@irbexchange.org

Request a Study-specific training for your team







What Our Users Say:

https://www.irbexchange.org/p/what-our-users-say/

"..thanks to IREx I was able to onboard the sites to the study in a methodical, rapid and organized process, including preparation of site-specific consent documents."

"...The IREx support team has been accessible and helpful to solve any user issue on demand."

Ariela
Study Manager, MGH

"We consider IREx to be the "helping hand" to facilitate increased collaboration among the LA CaTS institutions by building trust and executing the once uncharted territory of full reliance... **If we are the Lead (sIRB), we usually insist on using the IREx platform**. We have included this information in our local IRB reliance request form so our investigators are aware of our preference."

Michelle
HRPP Liaison, PBRC

"I think IREx is useful for study teams who have yet to create their own system of organizing the single IRB process. It's **easy for them to keep track of which sites have filled out which forms and the email notifications help to understand what activity has occurred by relying sites** in IREx. But most of all I like that **IREx has amazing customer service**. For me this is the key to long-term success of the IREx platform."

Jessica
HRPP Liaison, UCSF