10.21.2022 QUARTERLY CALL AGENDA

➢ Welcome & Announcements

➢ Recent System Updates

➢ Q & A with IREx & SMART IRB

About the IREx Quarterly Calls

hear • new • features

- You're busy.
- IREx is busy.
- Call in once a quarter to hear what's new!

learn • new • trends

- Who's using IREx?
- How are folks leveraging IREx on their sIRB studies?

share • your • voice

- Give your opinion
- Ask your questions
- Express your needs

Upcoming Calls

STARTING TODAY: Quarterly calls will combine HRPPs and lead study teams

January 20th, 2022

April 21st, 2023

July 21st, 2023

Zoom: https://zoom.us/meeting/register/tJwud-irrzoiHtKcmf1BEmwhqm7YvXg0rhYq

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!
    - sIRB Liaison: Annie Risenmay, Utah
    - Participating Site HRPP Liaison: Beth Poplaski, Emory
   - Study Manager: Heather Johnson, Vanderbilt

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Checklist	• Electronic documentation & automated emails • Easily customizable for individual sites • Centralized historical reference	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

Takeaway: 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

IREx Utilization – Quarterly Update
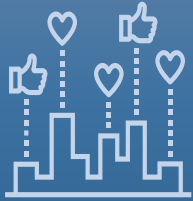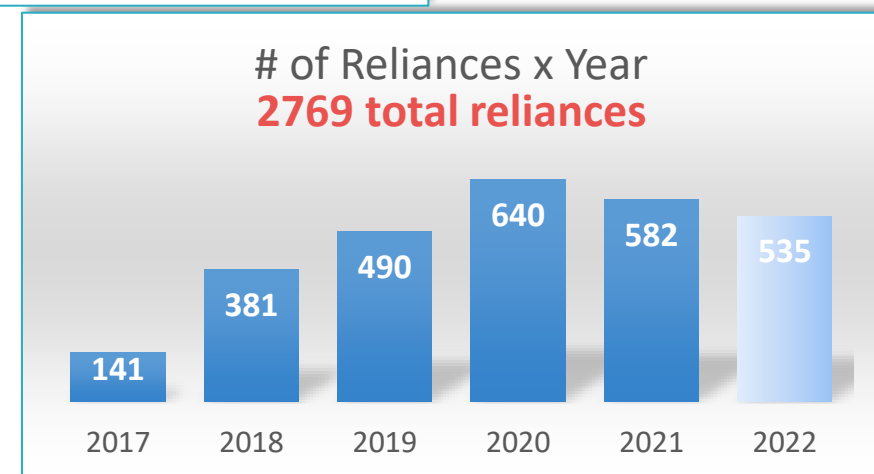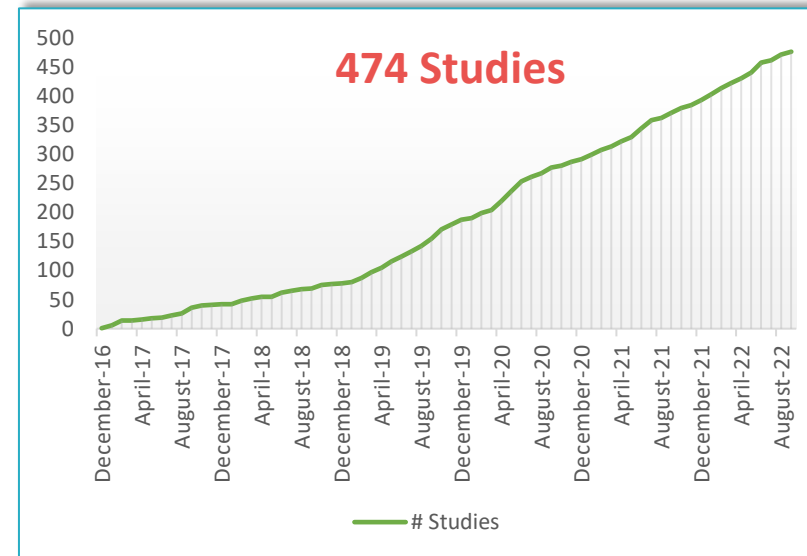
89% of IREx Institutional Profiles are complete (n=398!)

82% of IREx sites have indicated reliance on 1+ studies

89% of ceded sites have sIRB approval in IREx

- **38 sIRBs using IREx ([view here](#))**

474 Studies

— # Studies

# of Reliances x Year
2769 total reliances

2017	2018	2019	2020	2021	2022
141	381	490	640	582	535

Recent System Updates

Since January 2022

Automatically share approvals for Relying Sites (October 2022)

- Relying site approvals no longer have to be manually confirmed when there are not site-specific changes
  - At continuing review (e.g., ICFs aren't re-stamped or sites aren't enrolling)
  - For study-wide amendments that don't alter sites' documents
- New "Site Updates" tab to inform whether sites' can be automatically notified of approval:

Study managers can now upload initial approval for the overall study/lead site (September 2022)

- **The sIRB now only needs to do the following IREx:**
  - Create the study
  - Complete the IREx Setup (agreements required, study & sIRB contacts)
  - Confirm the study-specific reliance plan (SSRP)
- **The lead study team/study manager can:**
  - Upload initial approval for the lead site
  - Add & notify participating sites (PSites)
  - Export local considerations
  - Upload approvals for PSites
  - Upload other study approvals (continuing review, amendments)
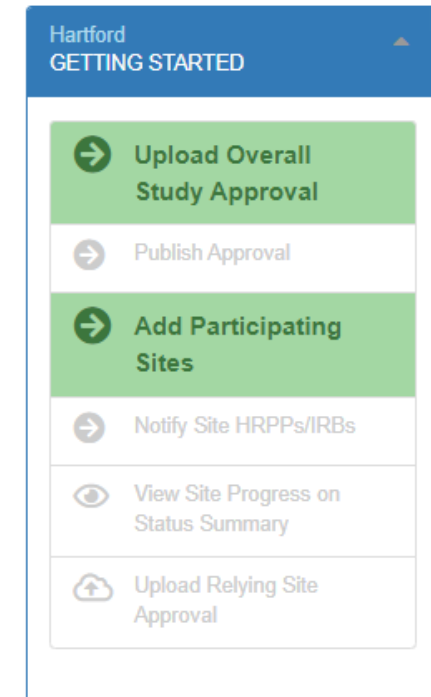
Simplified Local Considerations Workflow
(July 2022)

- **PSite Coordinators** have a Getting Started Checklist in IREx

- **PSite Coordinators** can complete the PI Survey

- **PSite Investigators** are only required to attest to the PI Survey

- **PSite** HRPPs no longer upload the locally-verified ICF to the HRP Survey

- **PSite** HRPPs are no longer required to validate the PI Survey

Complete IREx API for sIRBs

> POST: Study shell to IREx (title, sIRB, sponsor, etc)

> POST: Study initial approval for the lead site (risk categories, review dates, documents, etc.)

> GET: Relying site reliance information and local considerations

> POST: Relying site initial approval (review dates, documents, etc)

> POST: Additional study and site approvals (continuing review, amendments)

> POST: Site and study closures

GOALS
1. Minimize sIRB setup in IREx
2. Streamline ingesting of PSite local reviews
3. Streamline posting of approvals for the life of the study

- Bi-directional API between sIRB's electronic system and IREx

- System agnostic – can connect with any e-IRB system

- General information: https://www.irbexchange.org/p/irex-integration-api/

- Technical information *(IREx login required)*: https://www.irbexchange.org/s/doc/api

Relying site approval documents are all listed on a single tab

Study Managers can add access for new site coordinators and site PIs

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

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:

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

📅 Key Dates

Reviewing IRB Submitted:
Reviewing IRB Reviewed:
Reviewing IRB Approved:

Discussion with IREx & SMART IRB

Topics

- How are we unique?
- How are similar?
- How are complementary?
- How do I find help?
- Your Q&A?

What is SMART IRB?

SMART IRB is...

A federally funded project to support institutions and researchers in the implementation of single IRB
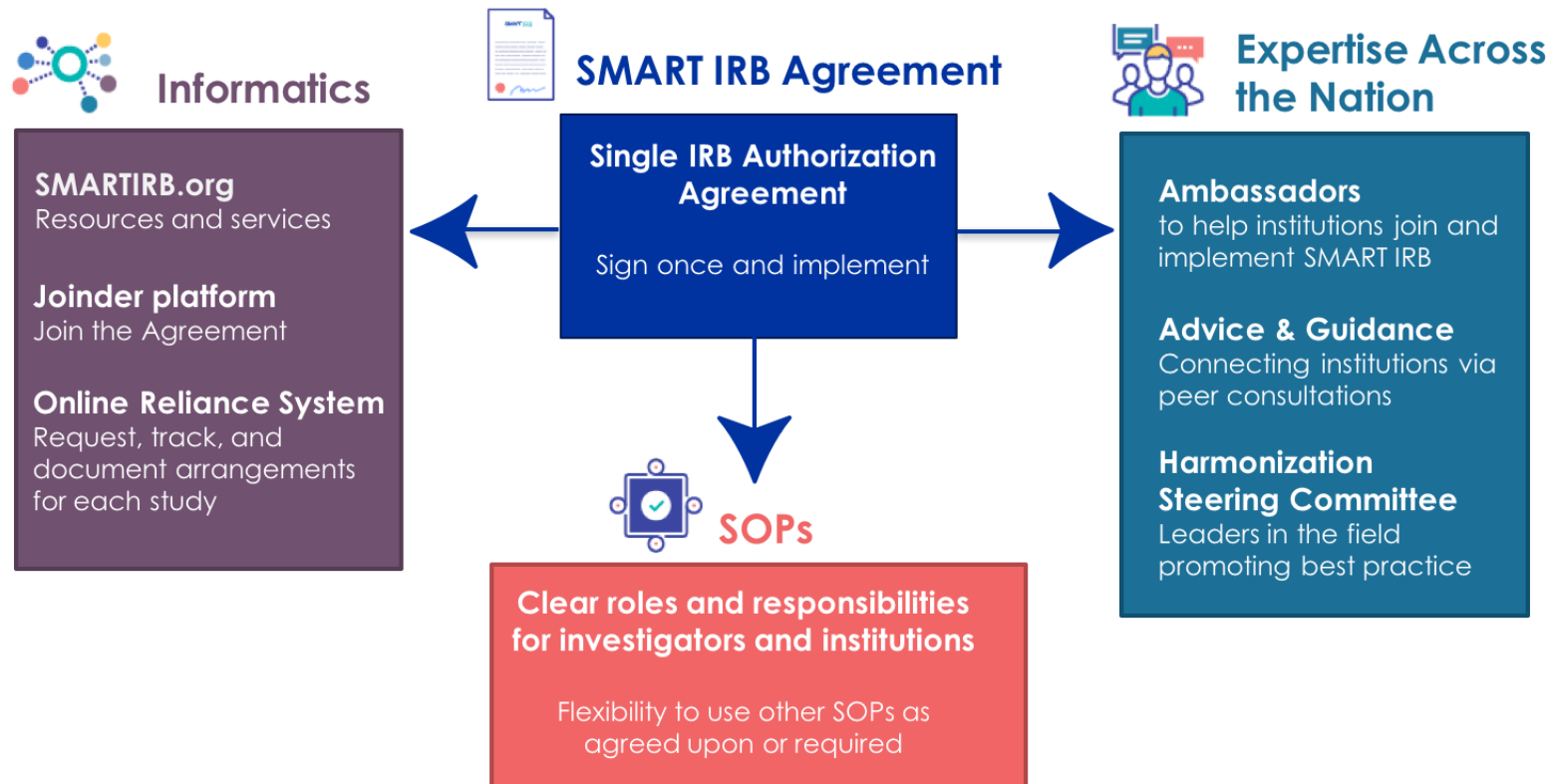
SMART IRB provides...

A master IRB reliance agreement

An Online Reliance System to initiate and track reliance

Other resources free to institutions and researchers

SMART IRB is NOT...

An IRB

An electronic system for Reviewing IRBs to receive studies for review

IREx: A platform supporting sIRB Documentation & Communication

Basic Reliance Documentation

1. sIRB agreement completion
2. Study-specific reliance decisions

Advanced Reliance Documentation

1. Study-specific local considerations from sites
2. sIRB approval documents for sites

sIRB Site Coordination

1. Communicating to sites
2. Tracking site readiness for sIRB review
3. Facilitating site submissions to the sIRB
4. Disseminating site approvals

SMART IRB & IREx:
Complementary Resources

SMART IRB Implementation Checklist	**IREx** Study-specific Reliance Plan (SSRP)
SMART IRB Letter of Acknowledgement Template	**IREx** Notification of Reliance
SMART IRB Agreement Section 6.4: Local considerations Informed Consent Documents – Inserting Local Context Language	Documenting local considerations (and consent forms) in **IREx**
SMART IRB Agreement, Section 5.9 Notification of IRB Decisions, etc	**IREx** Notification of Approval: Initial, CR, Amendments
SMART IRB Continuing Review Content & Process Recommendations	**IREx** participating site notification of continuing review approval

Question & Answer

Who is my SMART IRB Ambassador?

Regional Ambassadors

Northeast/New England + Middle Atlantic

Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont

Polly Goodman, CIP
Harvard Catalyst
polly_goodman@hms.harvard.edu

Aaron Kirby
Harvard Catalyst
aaron_kirby@hms.harvard.edu

Midwest

Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin

Carissa Minder
Washington University in St. Louis
carissa.minder@wustl.edu

South/South Atlantic

Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia, Washington DC

Stacey Goretzka
Medical University of South Carolina
goretzka@musc.edu

South + Puerto Rico

Alabama, Kentucky, Mississippi, Tennessee, Puerto Rico

Ada Sue Selwitz
University of Kentucky
ada.selwitz@uky.edu

Ambassadors at Large

Nichelle Cobb
Association for the Accreditation of Human Research Protection Programs (AAHRPP)
ncobb@aahrpp.org
Focus: Questions about using SMART IRB resources and training investigators for single IRB review.

Kathy Lawry
klawry@aahrpp.org
Focus: Trial Innovation Network sites, healthcare systems, and research team education.

Ada Sue Selwitz
ada.selwitz@uky.edu
Focus: Community-based groups, physician practices, and smaller organizations.

Southwest + Mountain

Arizona, Arkansas, Colorado, Idaho, Louisiana, Montana, Nevada, New Mexico, Oklahoma, Texas, Utah, Wyoming

John Baumann
Indiana University
baumannj@iu.edu

West and Pacific

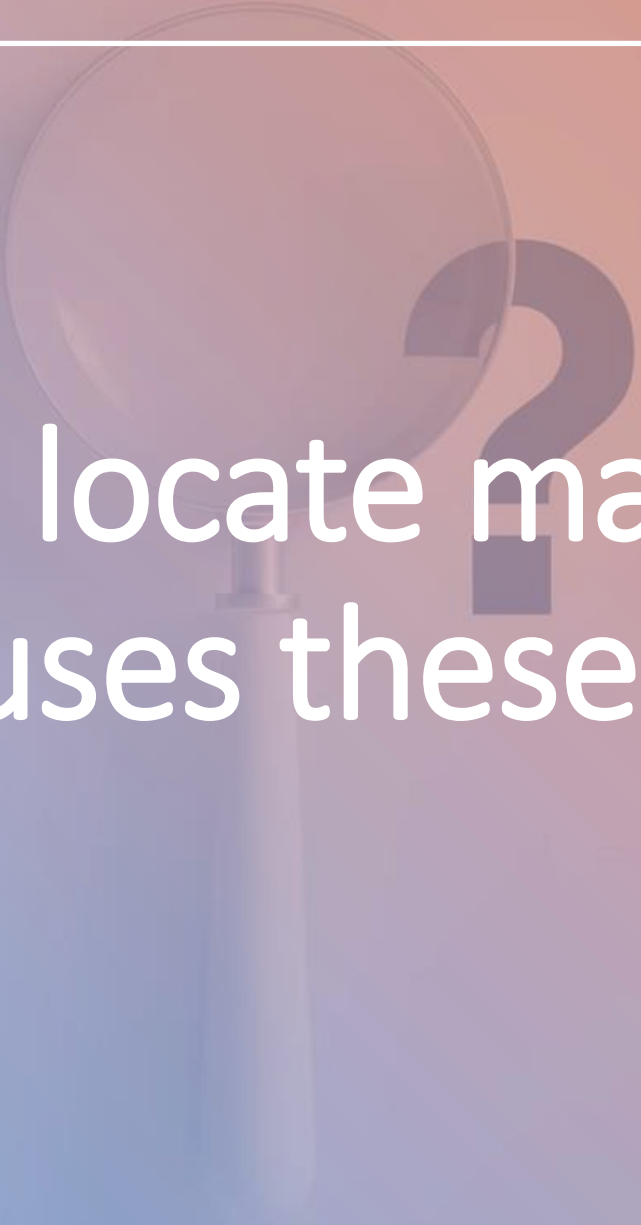Alaska, California, Hawaii, Oregon, Washington

Lubabah Helwani
University of California, Los Angeles
Lubabah.helwani@research.ucla.edu

What questions can SMART IRB Ambassadors help with?

- How to join SMART IRB?
- How can we handle a disagreement between the Reviewing IRB and Relying Institution?
- How can I use SMART IRB to document reliance for a network or group of studies?

+. Where can I locate materials to help me uses these resources?

SMART IRB Resources

SMART Talk – Monthly virtual forums
- Best practices
- Emerging issues
- Ask the experts

Learning Center
for Investigators and Study Teams

The videos and companion resources below are designed to help investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies. Questions about local processes and policies are best addressed by your institution's SMART IRB *Point of Contact*.

- Start-Up Packages
- Introduction to Single IRB Review and SMART IRB
- Overview of the NIH Single IRB Policy
- Selecting a Single IRB
- Developing a Single IRB Plan
- Potential Effects of NIH Single IRB Policy on Research Costs
- Study Team Roles Related to Single IRB
- Using the SMART IRB Online Reliance System

SMART IRB Start-Up Packages

These packages contain a suite of resources to help you prepare NIH grant applications that require single IRB review and to ensure you understand and can fulfill your responsibilities related to single IRB arrangements. Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

Download Study Team Package   Download NIH Grant Preparation Package

Resources Website

All Resources	Browse by Topic	Browse by Role	Browse by Source

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Scroll through the resource list below, or click on a letter to jump to the first corresponding resource name.

All Resources   **Source**

Agreement, The SMART IRB (Version 2.0; finalized October 1, 2020)   *SMART IRB*
Review the Master Common Reciprocal Institutional Review Board Authorization Agreement. As of October 1, 2020, any new signatory institution will sign SMART IRB Agreement v2.0.

Note: SMART IRB Agreement Version 1 (including versions 1.1. and 1.2) is compatible with v2.0; Participating Institutions that have signed v1 are not required to sign v2.0.To learn more about differences across versions of the SMART IRB Agreement read the Agreement Version Guide.

Ambassadors, SMART IRB Regional   *SMART IRB*
Need help joining and implementing the SMART IRB Agreement? Ask your ambassador.

Communication Plan for Single IRB Review   *SMART IRB*
Institutions can use this template to document key communication roles, such as submitting initial and continuing reviews, amendments, and reportable events to the Reviewing IRB; providing conflict of interest management plans to the Reviewing IRB; and providing IRB-approved documents and communicating Reviewing IRB determinations to relying site study teams.
Download the Communication Plan for Single IRB Review as customizable Word document.

Communications Between Institutions and Outside IRBs – Considerations Document
This document outlines legal and ethical responsibilities in the oversight of clinical trials, providing

Help Desk

- Help button on bottom right of every page
- You can also contact us directly at Help@SMARTIRB.org

Help

How can we help?

Top suggestions

1. Create an account as the Point of Contact (POC) for an institution
2. Introduction to the Online Reliance System
3. Information needed to submit a request for reliance

zendesk   Contact us

Monthly Newsletter

SMART IRB: The Essentials
The "Fall, Leaves, Fall" Edition.

All things being equinox.
Balancing apples with single IRB review.
Who's on first? Who's doing what? Reporting to federal agencies? Ensuring personnel training? Identifying COI? We've got it all mapped out in our Institution v. IRB Responsibilities guide for reviewing IRBs and relying institutions (thanks to the Harmonization Steering Committee for navigating the corn maze!).

Take a hint.
Helpful tips for study teams, at your service.
Looking to get investigators and study staff up to speed on what it really means to rely on an external IRB? Send them our FAQs for Research Teams. Or, use our template to customize the FAQs to reflect your institution's extra special particularities. But wait, there's more to fall for at smartirb.org/resources - one-stop shopping for tools, templates, and checklists to help with single IRB review at prices you can't beat.

Immediate gratification.
Data at your finger tips.
When your institution uses SMART IRB's Online Reliance System to document reliance arrangements, you can pull on-demand reports with information about all reliance requests involving your institution. Just log in and click on the "Reports" tab. Note: this feature is only available to an institution's Reliance POC and POC Backups. On-demand pumpkin lattes downloaded separately.

Class picture perfect.
(Awkwardly) smile if you're one of our Participating Institutions. Take a look at our big, beautiful, and ever-expanding reliance network! Be a pal and let us know if we have any apple crisp between our teeth.

Fall fashion trend.
Voted Vogue's #1 accessory for '18.
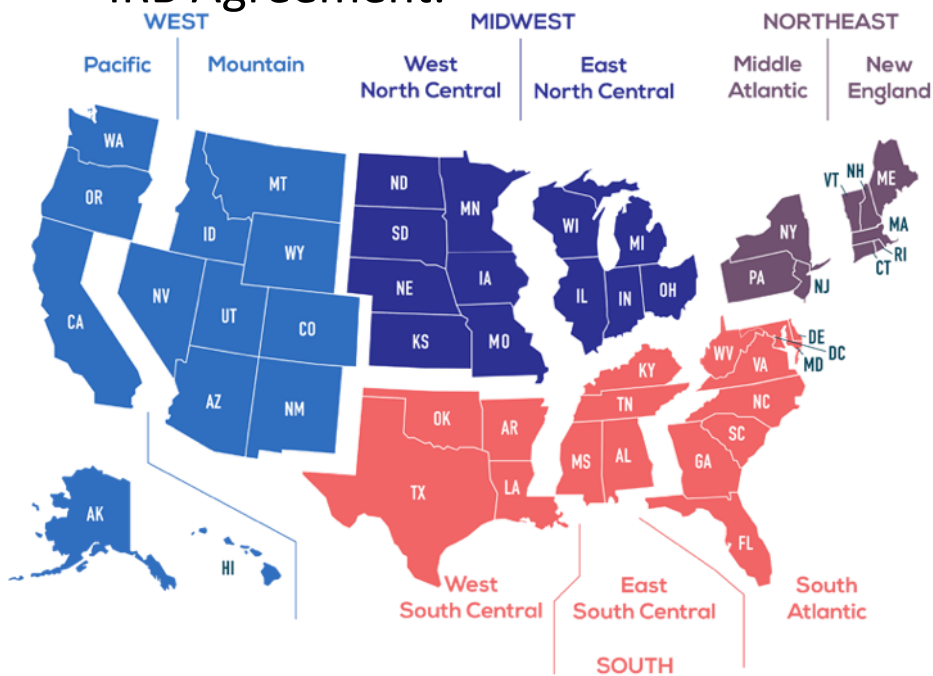Once you've joined, sport a SMART IRB badge on your website.

Rolling admissions.
The time has never been better to join SMART IRB. Lend your affiliates a helping hand by sharing this guidance...and forward them the signature element of our press kit, the SMART IRB newsletter.

Study hall.

SMART IRB Resources: Ambassadors

- SMART IRB Ambassadors can help you with getting the institution signed on.

- Ambassadors are HRPP professionals knowledgeable in the processes and practicalities of IRB reliance who are available to assist institutions in joining and implementing the SMART IRB Agreement.

Regional Ambassadors

Northeast/New England + Middle Atlantic

Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont

Polly Goodman, CIP
Harvard Catalyst
polly_goodman@hms.harvard.edu

Aaron Kirby
Harvard Catalyst
aaron_kirby@hms.harvard.edu

Midwest

Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin

Carissa Minder
Washington University in St. Louis
carissa.minder@wustl.edu

South/South Atlantic

Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia, Washington DC

Stacey Goretzka
Medical University of South Carolina
goretzka@musc.edu

South + Puerto Rico

Alabama, Kentucky, Mississippi, Tennessee, Puerto Rico

Ada Sue Selwitz
University of Kentucky
ada.selwitz@uky.edu

Ambassadors at Large

Nichelle Cobb
Association for the Accreditation of Human Research Protection Programs (AAHRPP)
ncobb@aahrpp.org
Focus: Questions about using SMART IRB resources and training investigators for single IRB review.

Kathy Lawry
klawry@aahrpp.org
Focus: Trial Innovation Network sites, healthcare systems, and research team education.

Ada Sue Selwitz
ada.selwitz@uky.edu
Focus: Community-based groups, physician practices, and smaller organizations.

Southwest + Mountain

Arizona, Arkansas, Colorado, Idaho, Louisiana, Montana, Nevada, New Mexico, Oklahoma, Texas, Utah, Wyoming

John Baumann
Indiana University
baumannj@iu.edu

West and Pacific

Alaska, California, Hawaii, Oregon, Washington

Lubabah Helwani
University of California, Los Angeles
Lubabah.helwani@research.ucla.edu

IREx Resources

IREx Administrators
admin@IRBExchange.org

Quick Videos on using IREx - YouTube

IREx Resources for sIRBs, PSite HRPPs, Lead Study Teams, and PSite Study Teams

IREx Quarterly Calls

IREx Announcements & Newsletters (past issues)

How do I get sites to sign the SMART IRB Agreement?

- Have sites review the Join Page and Join checklist. Sites can meet with a SMART IRB ambassador to discuss the sign on process and answer any questions.

- IREx recommends sending the link to the SMART IRB Joinder page to sites while a) once a grant receives a score/indication of funding or b) the lead site is getting approved.

Why are not all SMART IRB member institutions members of IREx?

- The SMART IRB Agreement is the basis for reliance and is used broadly for document reliance, even if a study isn't using a web-based platform to document reliance or sIRB coordination.

- Sites typically join IREx because they are on a study where the sIRB is using IREx. Unlike the reliance agreement, sites can join via a clickable Terms of Use (no major agreement to execute).

Are the SMART IRB Institutional Profile & IREx Institutional Profile the same?

- No, but they are VERY similar, and both contain the basic, static information an sIRB might need to know about an institution with whom they're in a reliance relationship.

- They do not differ in substantive ways other than one being electronic and another PDF.

- IREx requires the Institutional Profile be completed to indicate reliance (per the guidance of the TIN SIRBs)

- IREx plans to align their Institutional Profile with the next iteration of the SMART IRB Institutional Profile (and local considerations documents) once released, under the guidance of the IREx User Feedback Group

What are my options for documenting reliance on an sIRB?

- SMART IRB Online Reliance System (ORS)

- IRB Reliance Exchange (IREx)

- Email – using the SMART IRB Letter of Acknowledgement Template

NOTE: No system is required by regulation.

How do I know when to use the ORS vs IREx?

1. **The single IRB should communicate which system is being used for the study.**

2. **SMART IRB ORS** may work well if **another mechanism is in place to capture and share study related approvals and documents.**

3. **IREx** may work well when the sIRB & lead study team **need to a mechanism to capture and track site completion of local considerations** and **capture and notify sites of sIRB approvals.**
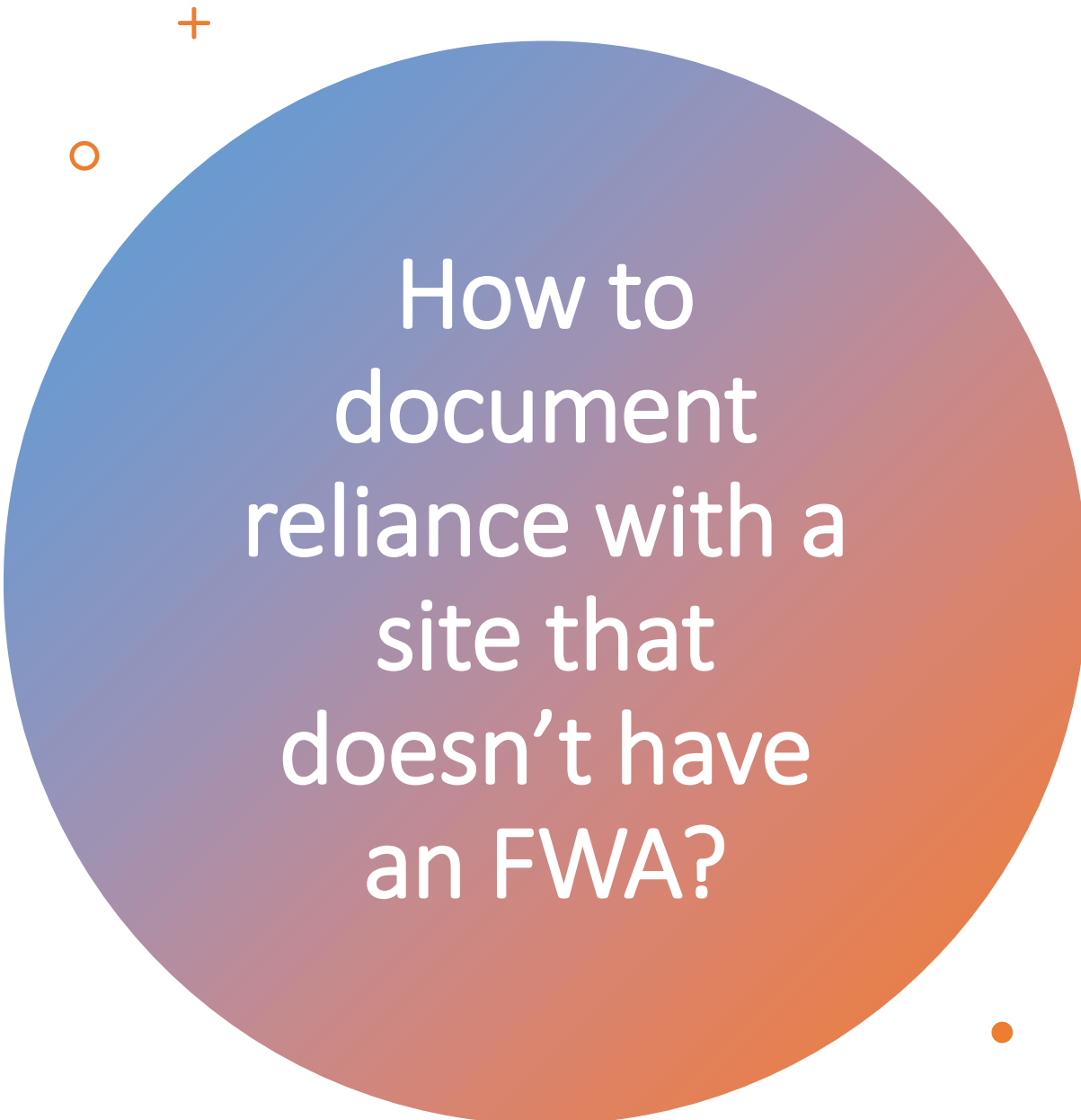
It's NOT RECOMMEND to use BOTH systems for the SAME study to avoid confusion from sites and extra work by the sIRB.
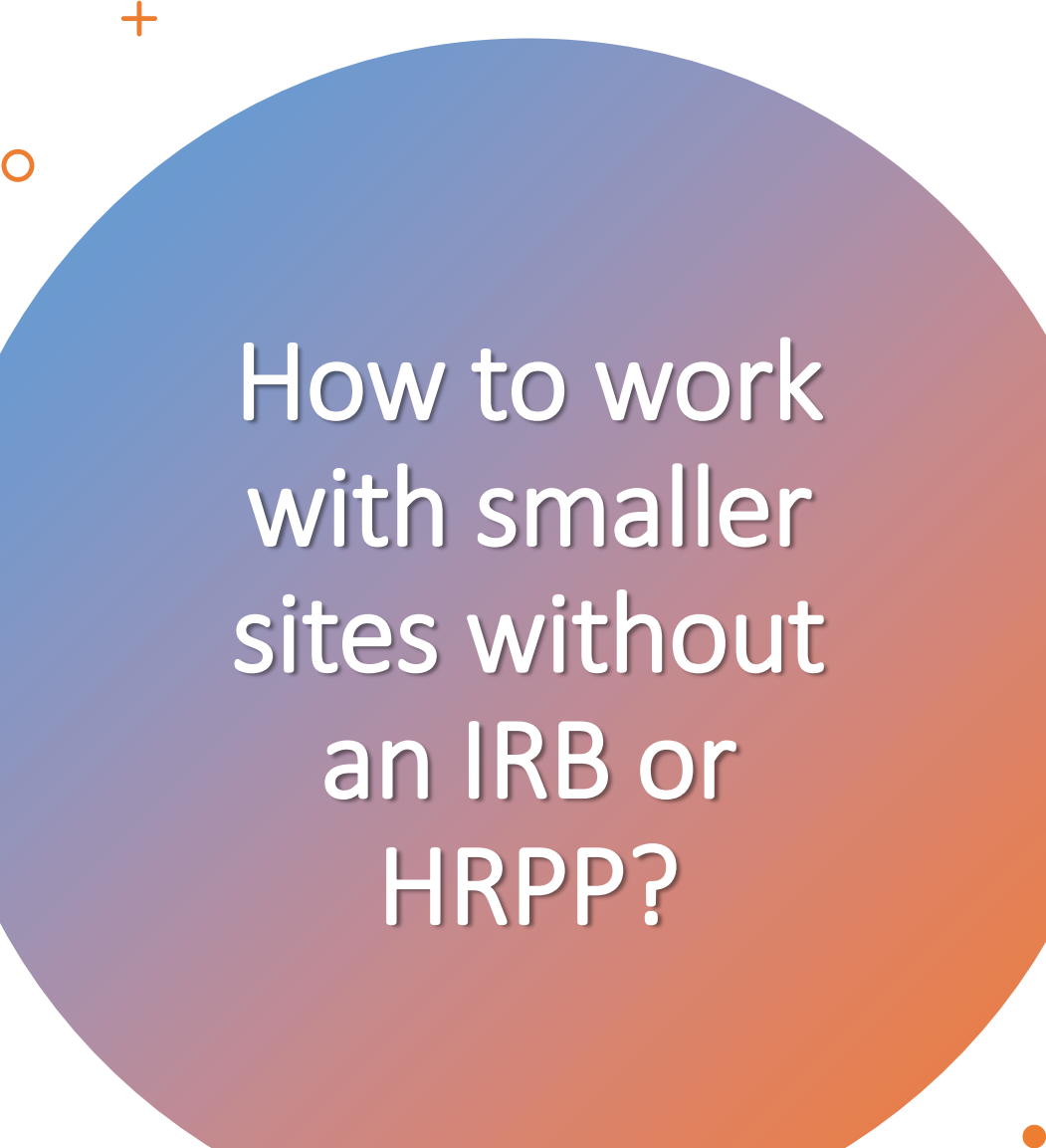
How to document reliance with a site that is not a member of SMART IRB?

1. Ask the site to join SMART IRB – always ask. It's in their best interest ☺

2. Use IREx to track one-off / study-specific reliance agreements with sites that cannot join SMART

3. Document reliance via email

How to document reliance with a site that doesn't have an FWA?

1. For most reliance arrangements the site needs to get an FWA. ☺

2. Individual Investigator Agreement can be used in limited instances.

3. Next the site needs to join SMART IRB (or a one-off agreement if they are prohibited from joining SMART)

4. Documenting reliance: ORS, IREx, Email

How to work with smaller sites without an IRB or HRPP?

- Use the SMART IRB Investigator Learning Center and resources to help train study teams.

- IREx team typically connects site with sIRB for consultation and hand-holding to ensure sIRB has relationship & the information they need