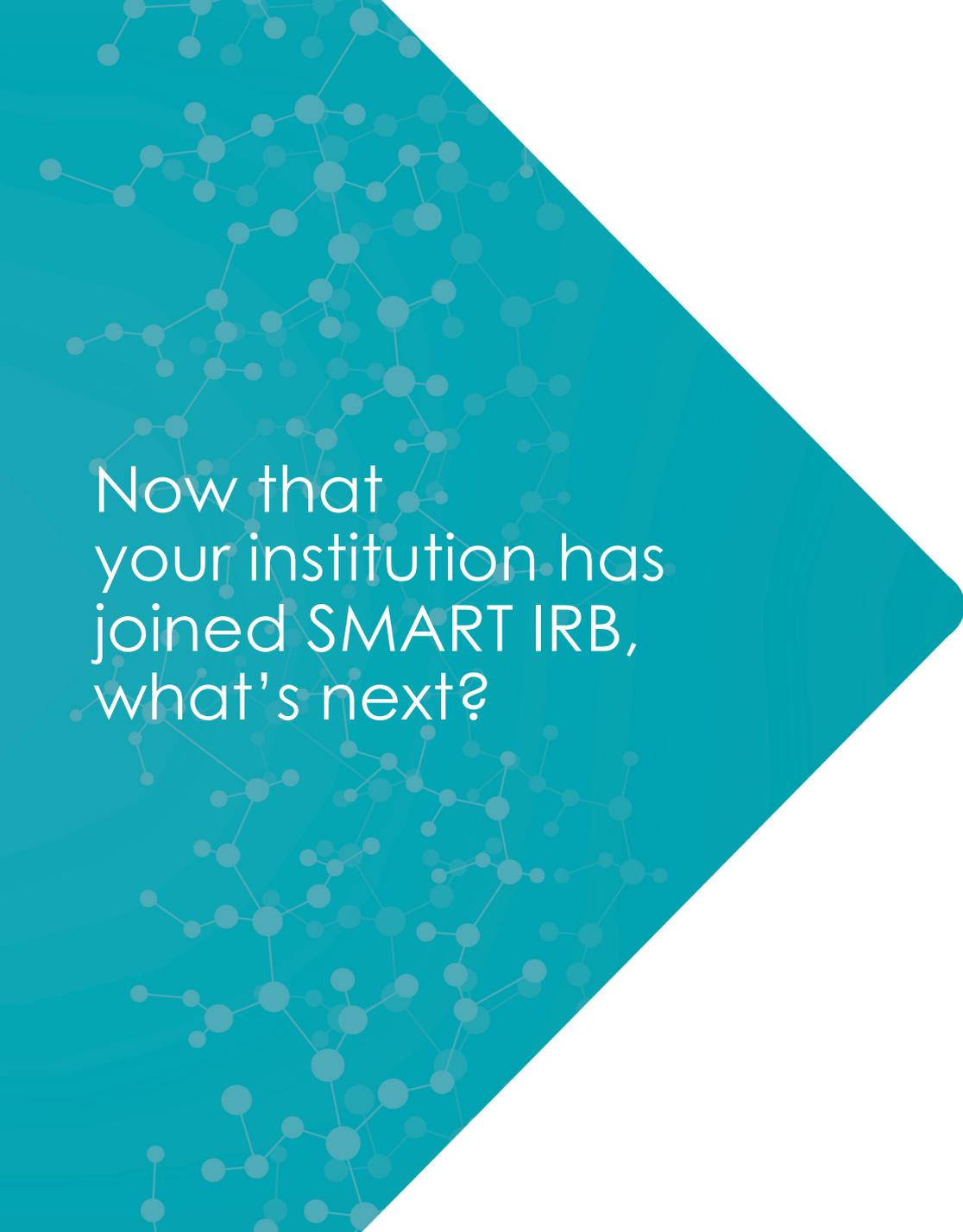




Your Roadmap to Single IRB Review

Getting Started with SMART IRB & the Online Reliance System

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Now that
your institution has
joined SMART IRB,
what's next?

**Start using the
Agreement right
away for IRB reliance
arrangements.**

**The SMART IRB
Agreement is
responsive to the NIH
Single IRB Policy and
proposed revisions to
the Common Rule.**

Using SMART IRB to streamline IRB review for multi-site research



As an IRB or INSTITUTION

Use the SMART IRB Agreement to facilitate single IRB review



As a PRINCIPAL INVESTIGATOR

Work with your institution's SMART IRB Points of Contacts (POCs) to determine an appropriate reliance arrangement and discuss your responsibilities related to single IRB review

The Reviewing IRB

takes on all IRB oversight responsibilities

Relying Institutions

provide Reviewing IRB with local context regarding state law, study team member training / qualifications, and any applicable conflicts of interest

Access SMART IRB Resources at smartirb.org

Expertise and Guidance



Connect with an ambassador or request a peer consultation

Support for Single IRB Review



Access a growing library of FAQs, SOPs, templates, checklists, and guidance

Online Reliance System



Request, track, and document reliance arrangements on a study-by-study basis

SMART IRB Online Reliance System

Provides a single point of entry to standardize reliance processes

Serves as communication portal to eliminate tracking requests via email or other methods

Guides investigators and institutions through the workflow, making clear when action is required

The system works for institutions:

- 1 With and without significant reliance experience
- 2 Familiar or unfamiliar with one another
- 3 With limited or substantial infrastructure to support single IRB review

This system allows all SMART IRB Participating Institutions to work together to establish reliance decisions

Flexibility for Institutions



Institution Information

Institution Contact Info

1) Customize the displayed contact information for your institution, in case someone needs to reach you about a request



cc: email (optional)

2) Add a cc email to be included on all system notifications (e.g. an office or group email)



Reliance POC

The Reliance POC reviews requests for reliance involving their institution and determines whether their organization will be the Reviewing IRB or Relying Institution, as applicable. For requests where the Principal Investigator is from their institution, the Reliance POC will first determine whether the request is eligible for reliance.

The Reliance POC is solely responsible for:

- Determining whether to grant access to the Online Reliance System for prospective users from their institution (investigators or study coordinators) who wish to submit requests
- Defining institution contact info
- Identifying Reliance POC backups (if any)
- Identifying a cc: email (if needed)



Reliance POC Backup(s) (optional)

3) Add one or more backup(s); can perform same actions in the system as the POC, with regard to processing requests

Various configurations are available to meet your needs – contact help@smartirb.org to learn more

Centralized Tracking of Reliance Requests/Arrangements

On-demand reporting for POCs

Requests for Reliance

Filtered listview allows you to see all your requests and easily sort those requiring your action

Action Required		Under Review		Reliance Reached		All Requests ?		Filter by:	
ID	PI Name	PI Institution	Research Title	Reviewing IRB	Request Status	Latest Amendment Status	Last Updated		
11	Davis, Betsy	Adams University	Advances in Knee Bracing Technology for Prevention of Knee Injuries	Adams University (Proposed)	Reviewing IRB Identified		Jan 15, 2018 4:24 PM UTC		
14	Halters, Sarah	Adams University	Effects of co-parenting on neonatal care	Pending	Submitted		Jan 15, 2018 4:19 PM UTC		
13	Halters, Sarah	Adams University	Effects of co-parenting on neonatal care	None	Withdrawn		Jan 15, 2018 4:16 PM UTC		
2	Halters, Sarah	Adams University	The Effects of Group Education on Patients and Their Next of Kin	None	No Reliance		Jan 15, 2018 3:16 PM UTC		
1	Travers, Morgan	Adams University	Primary Prevention of Cardiovascular Disease, with Emphasis on Pharmacological Interventions	Adams University	Reliance Reached	In Progress	Jan 15, 2018 3:16 PM UTC		

Central access to arrangement details for each study

Each request “package” provides:

- Overall details of study/arrangement
- Clear picture of request status
- Contact info for key personnel
- Comments from Reviewing IRB
- Request history

Request Details

ID: 11 - Advances in Knee Bracing Technology for Prevention of Knee Injuries

Principal Investigator (PI)
Betsy Davis
[Adams University](#)

Requested Reviewing IRB
[Adams University](#)

NCT Number
[Add NCT Number](#)

Protocol Number(s)

Summary

- [Reliance Request](#) ●
- [Reliance Pre-Check](#) ●
- [Reviewing IRB](#) ●
- [Adams University](#) ●
- Involved Institutions**
- [Adams University](#)
- [Belledeale Institute](#) ●
- [Golden Gate Eye Research Institute](#) ○
- [Lansing State College](#) ○
- [Plainview Institute for Genomic Studies](#)
- [Ridgeview Research Facility](#) ○
- [Saint August Hospital](#) ○
- [Salk University for Medical Sciences](#) ○
- [Determination](#) ○

Contact Information
[Contact List for this Request](#)

Need Help?
[Contact us](#)
[Suggest an improvement](#)

Downloads
[Request \(ZIP\)](#)

Summary

Overall Status: Reviewing IRB Identified ?

No Action Required

Roles: Overall PI's Home Institution, Proposed Reviewing IRB, Requested Reviewing IRB, Site Involved

- Adams University has been identified as the Proposed Reviewing IRB
- This request will move to the next step after all Sites Involved have indicated their decision to rely / not rely.
- Contact the [POC of a specific Site](#) with any questions or concerns.

Reviewing IRB

Adams University
(Pending final determination)

Sites Involved

5 Awaiting Response Send Reminder

- [Golden Gate Eye Research Institute](#)
- [Lansing State College](#)
- [Ridgeview Research Facility](#)
- [Saint August Hospital](#)
- [Salk University for Medical Sciences](#)

1 Willing to Rely

- [Belledeale Institute](#)

0 Not Willing to Rely

1 Removed as Site Involved

- [Plainview Institute for Genomic Studies](#)

Comments from the Reviewing IRB Add a Comment

Comment	Comment posted by	Date and Time
Please use the SMART IRB SOPs for this request.	Jared Turner	Jan 17, 2018 5:12 PM UTC

Request History

Action	Action taken by	Date and Time
Plainview Institute for Genomic Studies removed from request: Incorrect site chosen. Correct site will be added through an amendment.	Claire Cooper	Jan 15, 2018 4:24 PM UTC

Adding a site to a reliance arrangement

This amendment feature is ideal for sites that join a study at a later date, or for those that were not yet ready to rely when the original arrangement was documented.

The process is simple:

- 1 An investigator or study team member completes and submits a brief site amendment form.**
- 2 The POC at the new site indicates whether they are willing to rely on the Reviewing IRB.**
- 3 The Reviewing IRB POC confirms whether they will review for the new site and issues the determination.**

About the amendment process

- Only the submitter of the original request can submit an amendment.
- One site added per amendment; one amendment may be under consideration at a time.
- Requests that are under review cannot be amended until a reliance determination is issued.

The Reliance System Is...

For Investigators (or their designees)

A centralized mechanism to request single IRB review for their studies and track the status of those requests

For Institutions

A platform to review reliance requests and determine and record appropriate reliance arrangements for each study

The Reliance System Is NOT...

A mechanism to submit an application for IRB review and approval

A document storage system

Benefits for INVESTIGATORS

Clarity and Guidance



The system guides you through the request process, collecting the information institutions need to determine an appropriate arrangement for your study

Automatic Notifications



Email notifications ensure you are informed at key points in the decision-making process

Reliance Tracking



The system gives you a window into the decision-making process and provides a single place to track reliance arrangements for your studies

Benefits for INSTITUTIONS



Provides a centralized place to record and track reliance arrangements on a study-by-study basis



Connects you with the appropriate POC for each site, eliminating the need to track down their information



Guides you through the decision-making process, making clear when your action is required



Provides a central, transparent platform to communicate local context issues

SMART IRB Online Reliance System DEMO



With the short video that follows we highlight key features of the SMART IRB Online Reliance System