



SmartIRB Process

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Northwestern | RESEARCH

Learning Objectives

At the end of this session you will be able to have an understanding of the SmartIRB Reliance process through the following:

- Overview of SMARTIRB
- Online Reliance System
- Northwestern SMARTIRB Process
- Key Tips

What is a Reliance Agreement?

Reliance agreements are arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human subjects research.

A Reliance Agreement can be in many different forms, but some of the main agreements are:

- Institutional Authorization Agreements (IAA)
- Memorandum of Understanding (MOU)
- Master Reliance Agreement (MRA)

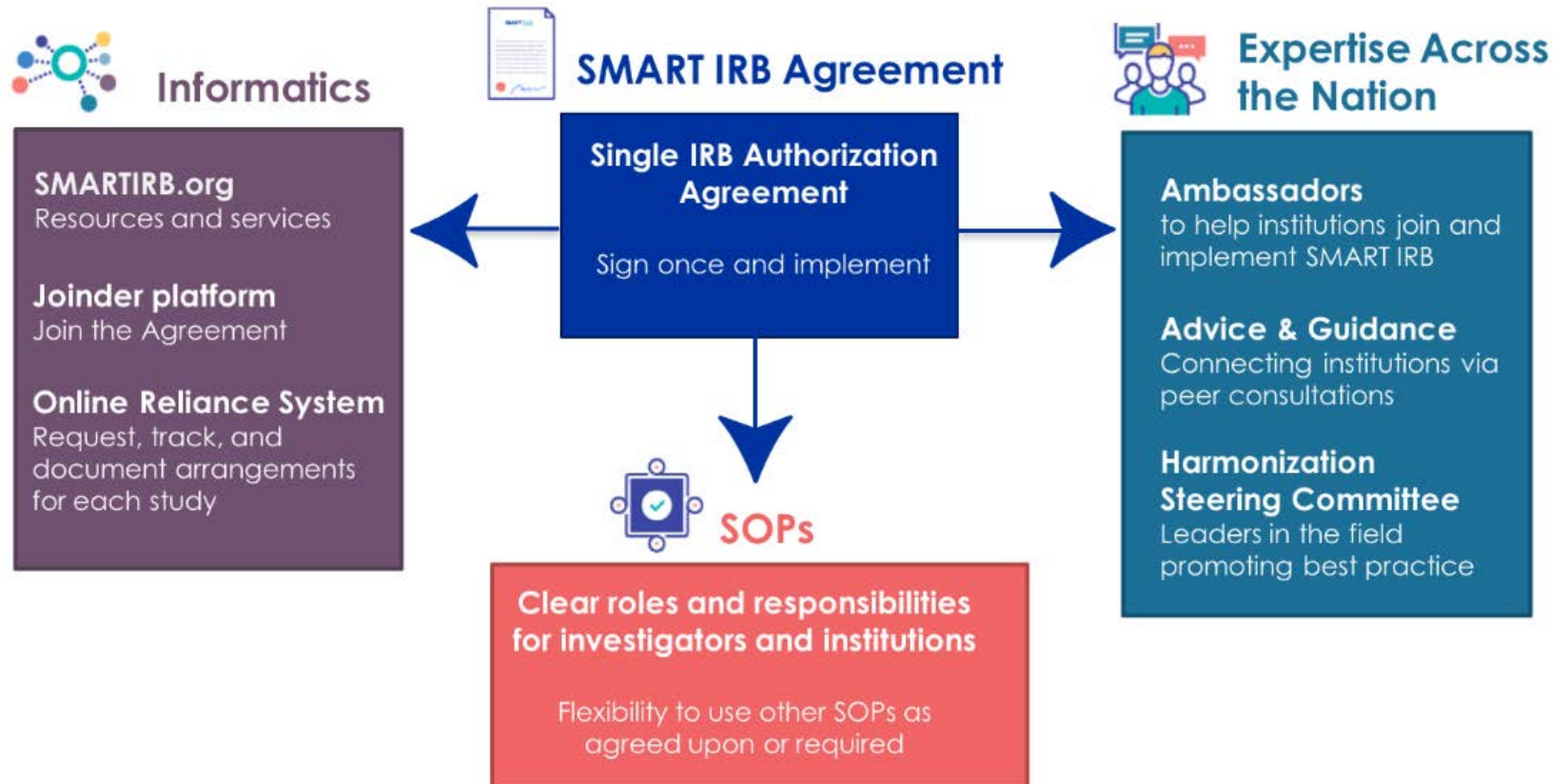


SMARTIRB

SMART IRB (Streamlined, Multisite, Accelerated Resources for Trials Institutional Review Board) was developed under an NIH grant and is responsive to the NIH Single IRB Policy.



SMARTIRB cont.



SMARTIRB Overall Process

1

Contact your SMART IRB Point of Contact (POC)

Overall Principal Investigators, connect with your institution's POC(s) to determine an appropriate arrangement and discuss your responsibilities.

For more information, see:

[SMART IRB FAQs](#)

[SMART IRB SOP Manual](#)

2

Submit a reliance request

Use SMART IRB's [Online Reliance System](#) to request, track, and document reliance arrangements for your study (or other process as indicated by your POC). First-time users, [request access here](#).

For more information, see:

[Online Reliance System Walkthrough](#)

[SMART IRB Support Center](#)

[Sample Reliance Request Form](#)

3

Check out our Resources for study teams

SMART IRB tools and resources will help you to understand and fulfill your responsibilities and regulatory obligations when using the SMART IRB Agreement and serving as a Lead or Relying Site Study Team.

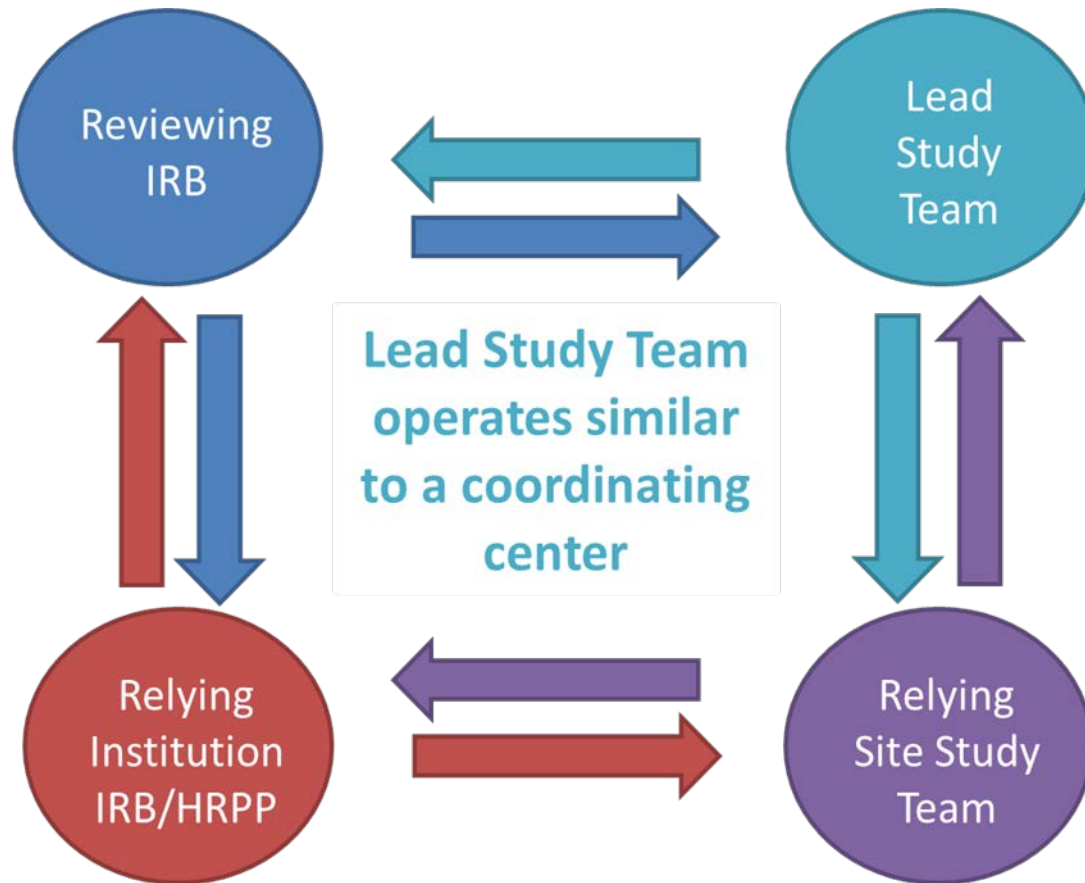
For more information, see:

[Overall PI \(and Lead Study Team\) Checklist](#)

[Relying Institution PI Checklist](#)

[FAQs for Research Teams - Relying on an External IRB](#)

SMARTIRB Communication Model



Online Reliance System

Online Reliance System

Request, track, and document reliance arrangements

Investigators and institutions can use the Online Reliance System to request, track, and document reliance arrangements on a study-by-study basis.

- Simplifies the selection of a single IRB for multisite studies
- Manages communication between institutions and investigators
- Tracks the status of requests
- Clearly indicates what needs to be done next
- Documents reliance arrangements for each study
- **NEW!** Sites can be added to a reliance arrangement by amendment

Get Started

Use the Online Reliance System to enable reliance for your studies

[Log In](#)

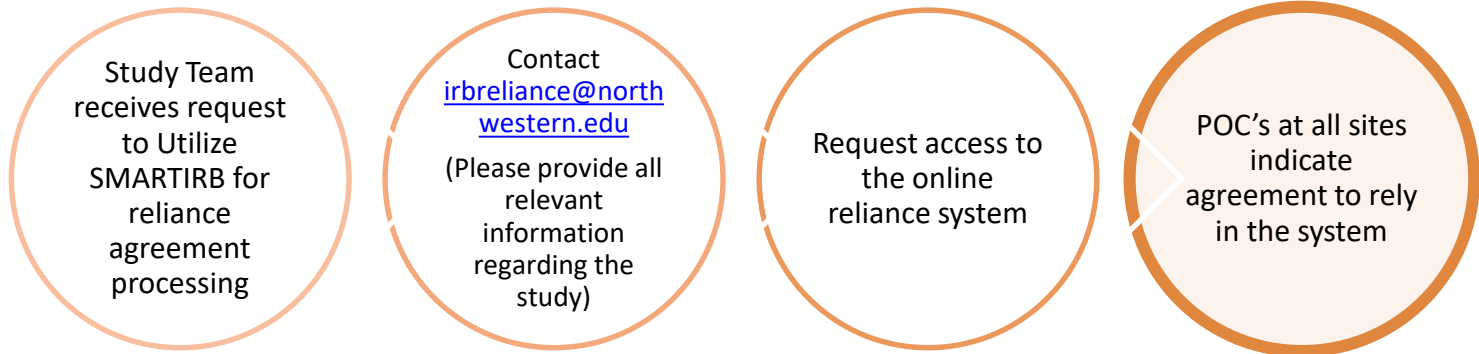
[Request Investigator Access](#)

Institution Points of Contact (POCs): contact us to request access.

Online Reliance System

- [Overview of the decision making process \[1:53\]](#)
- [Investigator submits a request \[2:44\]](#)
- [Identifying a proposed reviewing IRB \[2:30\]](#)
- [Recording Institution decisions \[1:40\]](#)
- [Issuing the determination \[3:17\]](#)

Northwestern IRB SMART IRB Process



Key Tip!

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

eIRB+ Application

Once the SMARTIRB process has been completed the eIRB+ application for the study should be finalized and submitted for review.

- External IRB (Study and Site application)
- Multi-Site Submission (pSite applications)

Key Tip!

The eIRB+ application should mention that the reliance process has been completed utilizing SMARTIRB!

Determination Letter

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Overall PI: Darren Gitelman

Overall PI Home Institution: Cedars Sinai Medical Center

Title of Research Study: Researching Outcomes for IRB Staff

Summary

- Contact irbreliance@northwestern.edu as soon as you hear SMARTIRB
- Request Access to the Online Reliance System
- eIRB+ Application should reference the use of SMARTIRB for reliance
- SMARTIRB is only for processing of the reliance agreement between institutions

When In Doubt

Set-Up a Consultation Appointment
(irbreliance@northwestern.edu)



General Contact Information

For additional information on IRB submission templates, regulatory guidance, upcoming education/training opportunities, and staff contacts, please visit our [website](#):

<https://eirbplus.northwestern.edu>

- Main number (Bio-medical): 312-503-9338
- General IRB Questions: irb@northwestern.edu
- Social and Behavioral Questions: sbsirb@northwestern.edu
- Reliance Agreements: irbreliance@northwestern.edu
- eIRB assistance/queries: eirb@northwestern.edu
- Compliance queries/issues: irbcompliance@northwestern.edu
- Training queries/issues: irbtraining@northwestern.edu
- Social and Behavioral IRB: 847-467-1723



Contact Information

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QUESTIONS?

