



Your Roadmap to Single IRB Review
Getting Started with SMART IRB &
the Online Reliance System



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



- 1) Connect with an ambassador in your region who is knowledgeable in the practicalities of IRB reliance, or
- 2) Request guidance through our consultation service

Support for Single IRB Review



Access our growing collection of resources, including SMART IRB's FAQs and SOPs, as well as a Single IRB Review Start-up

Online Reliance System (beta)



Use our open-source, web-based system to track, facilitate, 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 (New!)



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

SMART IRB Online Reliance System

Add a site to an existing 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

- Amendments can be added to any request that has resulted in a reliance arrangement.
- Only the submitter of the original request can submit an amendment.
- One site can be added per amendment; only 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