Your Roadmap to Single IRB Review

Implementing the SMART IRB Agreement

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Nichelle Cobb, PhD
Director, Health Sciences IRBs Office
University of Wisconsin-Madison

Chief Regulatory Operations Officer for Implementation, SMART IRB
Advancing research together

A Roadmap to Single IRB Review

Funded by NCATS beginning in July 2016
As of July 2018, led by Harvard University and University of Wisconsin-Madison, along with a team of Ambassadors from across the U.S.

- GROW: A national IRB reliance network
- SUPPORT: Use of SMART IRB
- EDUCATE & TRAIN: Institutions & Investigators
- HARMONIZE: sIRB review processes across the nation
Supporting single IRB review

**SMARTIRB.org**
Resources and supportive services freely available to support single IRB review

**Joinder platform**
Allows institutions to join the SMART IRB Agreement

**Online Reliance System**
Provides a central system and process to request, track, and document reliance arrangements for each study

**SMART IRB Agreement**
Sign once and implement

**SOPs**
Clear roles and responsibilities for investigators and institutions
Flexibility to use other SOPs as agreed upon or required

**Expertise Across the Nation**

**Ambassadors**
Help institutions join and implement SMART IRB

**Education & Training**
Tools, templates, FAQs, checklists, guidance, peer consultations, and webinars support adoption of SMART IRB

**Harmonization Steering Committee**
Leaders in the field promote best practice

smartirb.org
Using the Agreement
## Nature of the SMART IRB Agreement

The Agreement is a “master” agreement which means:

<table>
<thead>
<tr>
<th>No additional IRB authorization agreements required to enable reliance among institutions that have joined SMART IRB</th>
<th>Reliance arrangements, however, need to be documented for each study</th>
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</table>


Initiating & Documenting Reliance with the SMART IRB Online Reliance System
The SMART IRB Online Reliance System

Request, track, and document reliance arrangements

For Investigators and Participating Institutions

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

Facilitates reliance arrangements on a study-by-study basis
Key Roles in the Reliance Process

- Overall PI
- Home Institution Point of Contact (POC)
- Reviewing IRB POC
- Relying Institution POC
Need for a Reliance Arrangement

A researcher plans on conducting a multisite research project

Single IRB review is required by a funding agency

OR

Overall PI wants to streamline the regulatory process by using a single IRB
Requesting Single IRB Review: Step 1

Overall PI (or designee)

Contact Overall PI’s Home Institution POC to discuss a reliance arrangement, including a proposed Reviewing IRB and mechanism to request single IRB review.
Requesting Single IRB Review: Step 2

Overall PI (or designee)

Submits a request for reliance via the SMART IRB Online Reliance System* and proposes a Reviewing IRB

* Or via other mechanism, as required.
Reliance Request Requirements

The Overall PI (or designee) provides:

- Draft protocol
- Consent form templates
- List of sites and study teams engaged in the research and their activities related to the study

NOTE: If the Overall PI will use the SMART IRB Standard Operating Procedures (SOPs), a Lead Study Team must be identified.
Determines if the study is eligible for single IRB review and, if so, either confirms the proposed Reviewing IRB or proposes a new Reviewing IRB
Proposed Reviewing IRB POC

If PI’s Home Institution will serve as Reviewing IRB, this will be the same as the Home Institution POC.

Proposed Reviewing IRB POC reviews materials and communicates to proposed Relying Institution POCs whether his/her institution will serve as the Reviewing IRB for the study.

Proposed Relying Institution POCs notified by Online Reliance System or via other mechanism
Requesting Single IRB Review: Step 5

Proposed Relying Institution POCs

Review materials related to the request and communicate decision whether to rely on the proposed Reviewing IRB.

If agree to rely, also communicate key local context information.

Proposed Relying Institution POCs can record determination and include local context information in the Online Reliance System.
Information Provided by Relying Institutions

If ceding review, Relying Institutions provide the Reviewing IRB POC with information about:

• State laws and/or institutional requirements that could affect the IRB’s review
• Confirmation of the training and qualifications of their study team throughout the life of the study
• Any conflicts of interest relevant to study and applicable management plans throughout the life of the study
• Locally required consent form language in 3 areas
  1. availability of treatment and compensation for research-related injury
  2. payment or reimbursement of research costs incurred by subjects
  3. local contact information
Note: If the Reviewing IRB is not using the SMART IRB SOPs, it must provide the applicable SOPs to Relying Institutions.
SMART IRB Online Reliance System Documentation: Determination Letter Information

<table>
<thead>
<tr>
<th>Reliance Determination:</th>
<th>Identifies the Reviewing IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Principal Investigator: Stacy Miller</td>
<td></td>
</tr>
<tr>
<td>The Reviewing IRB is: Belledale Institute</td>
<td></td>
</tr>
<tr>
<td>Federal Wide Assurance (FWA): FWA00000001</td>
<td></td>
</tr>
<tr>
<td>Point of Contact: Thomas Werner, <a href="mailto:institution_poc@belledale.org">institution_poc@belledale.org</a></td>
<td></td>
</tr>
<tr>
<td>Site Investigator: John Dorean</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reviewing IRB accepts review for:</th>
<th>Identifies the institutions the IRB will oversee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adams University</td>
<td></td>
</tr>
<tr>
<td>Federal Wide Assurance (FWA): FWA00000014</td>
<td></td>
</tr>
<tr>
<td>Site Investigator: Christopher Turk, <a href="mailto:example@test.com">example@test.com</a></td>
<td></td>
</tr>
<tr>
<td>Belledale Institute</td>
<td></td>
</tr>
<tr>
<td>Federal Wide Assurance (FWA): FWA00000001</td>
<td></td>
</tr>
<tr>
<td>Site Investigator: John Dorean, <a href="mailto:example@test.com">example@test.com</a></td>
<td></td>
</tr>
<tr>
<td>Golden Gate Eye Research Institute</td>
<td></td>
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<tr>
<td>Federal Wide Assurance (FWA): FWA00000002</td>
<td></td>
</tr>
<tr>
<td>Site Investigator: John Doe, <a href="mailto:jdoe@gmail.com">jdoe@gmail.com</a></td>
<td></td>
</tr>
<tr>
<td>Ridgeview Research Facility</td>
<td></td>
</tr>
<tr>
<td>Federal Wide Assurance (FWA): FWA00000005</td>
<td></td>
</tr>
<tr>
<td>Site Investigator: Stacy Miller, <a href="mailto:applicant@ridgeview.net">applicant@ridgeview.net</a></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>The following institutions will NOT rely upon the Reviewing IRB:</th>
<th>Identifies the institutions the IRB will NOT oversee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval for each must be obtained from the IRB for that site (or through other arrangement, as applicable) prior to initiating study activity at that site. Please consult the institution's Point of Contact for further instructions:</td>
<td></td>
</tr>
<tr>
<td>Salk University for Medical Sciences, Point of Contact: Sarah Alonzo, <a href="mailto:institution_poc@salk.edu">institution_poc@salk.edu</a></td>
<td></td>
</tr>
</tbody>
</table>

If institutions are not using the Online Reliance System, suggested templates and other materials are available on the Resources page at smartirb.org.
Summary of Reliance Steps
<table>
<thead>
<tr>
<th>STEP</th>
<th>ROLE</th>
<th>ACTION</th>
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<tbody>
<tr>
<td>1</td>
<td>Overall PI</td>
<td>Contacts Home Institution POC to discuss a reliance arrangement, including a proposed Reviewing IRB and mechanism to request single IRB review.</td>
</tr>
<tr>
<td>2</td>
<td>Overall PI</td>
<td>Initiates a request for reliance via the SMART IRB Online Reliance System (or alternative approach agreed upon) and proposes a Reviewing IRB.</td>
</tr>
<tr>
<td>3</td>
<td>Home Institution POC</td>
<td>Reviews and determines if study eligible for reliance and, if so, either confirms the proposed Reviewing IRB or proposes a new Reviewing IRB.</td>
</tr>
<tr>
<td>4</td>
<td>Proposed Reviewing IRB POC</td>
<td>Reviews materials and communicates to proposed Relying Institution POCs whether his/her institution will serve as the Reviewing IRB for the study.</td>
</tr>
<tr>
<td>5</td>
<td>Proposed Relying Institution POCs</td>
<td>Review materials related to the request and communicate decision whether to rely on the proposed Reviewing IRB. If agree to rely, also communicate key local context information.</td>
</tr>
</tbody>
</table>
| 6    | Proposed Reviewing IRB POC          | After receiving decisions/information from other institutions:  
1. Reviews provided local context information  
2. Confirms for which institutions the IRB will oversee the research  
3. Documents the reliance determination  
4. Communicates which SOPs the Reviewing IRB will follow |
Other Implementation Issues
Addressing the SMART Agreement Flexibility

The Reviewing IRB should explain to Relying Institutions how it will implement flexibility allowed by the Agreement

Example areas of flexibility

- Privacy Board determinations
- Use of a combined consent/authorization form vs. separate documents
- Reporting events to federal agencies/sponsors

Resource: SMART IRB Implementation Checklist at smartirb.org/resources
Communicating with the Overall PI (or designee, such as the Lead Study Team)

The Reviewing IRB POC should reach out to the Overall PI (or designee) to:

- Communicate when the IRB application should be submitted for review
- Explain how to request approval for relying institutions (e.g., by creating separate applications vs. adding each new site as an amendment)
- Develop a communication plan
Elements of a Communication Plan

Clarify and document who will:

- Provide confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research
- Communicate local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study
- Submit studywide initial application and amendments to the Reviewing IRB
- Prepare site-specific applications and site-specific amendments to the Reviewing IRB
- Distribute IRB determinations and IRB-approved study materials to relying site study teams

Template Communication Plan at smartirb.org/resources
Disseminating IRB documents & policies

A key consideration is how IRB approvals and other determinations will be distributed to study teams (e.g., by providing access to the review system or posting documents on a shared secure platform)

The Reviewing IRB also must ensure the Overall PI (or designee) and Relying Site Study Team are aware of their relevant policies, such as:

- Reportable events: what needs to be reported, when, and to whom
- Personnel changes
The SMART IRB Online Reliance System provides a mechanism to collect key local context information. If this system will not be used, the Reviewing IRB needs to identify how it will obtain this information.

The Overall PI (or designee) also needs a mechanism to collect information about variations in local implementation of the study, such as:

- Consent form language
- Subject identification and recruitment
- Recruitment materials

Template Local Context Surveys available at smartirb.org/resources
Educating Study Teams about their Responsibilities

Under the SMART IRB Agreement, institutions are responsible for ensuring their study teams are aware of and comply with the terms of the Agreement.

Investigators will need assistance in understanding their roles and responsibilities related to single IRB and how they differ when they are the Overall PI (or Lead Study Team) vs. a Relying Site Study Team, especially when the SMART IRB SOPs are followed.

Overall PI and Study Team Checklists are available at smartirb.org/resources
Post Reliance Processes
After Initial Review: Reviewing IRB

The Reviewing IRB is responsible for overseeing:

- Reportable events (e.g., noncompliance)
- Personnel changes
- Continuing reviews for the entire study
- Study wide & local amendments
After Initial Review: Relying Institution

Relying Institutions must have processes in place to provide information to the Reviewing IRB after their site is approved, including mechanisms for:

- Ensuring personnel added to the study after initial approval are qualified and have completed required training
- Providing the Reviewing IRB with information regarding:
  - New or updated management plans for their personnel related to the ceded study
  - Audits of ceded research
  - Information/events that could affect the ceded research (e.g., serious noncompliance finding for the research team on another study)
Scenario One

Belledale and Ridgeview have joined the SMART IRB Agreement.

Belledale is willing to serve as Reviewing IRB.

Ridgeview agrees to cede review to Belledale.

Adams also agrees to cede review to Belledale.

Belledale and Ridgeview use the SMART IRB agreement. A separate IRB authorization agreement between Belledale and Adams will be required (or Adams may join SMART IRB).
Scenario Two

Collaborate on a research project

All have joined the SMART IRB Agreement

- Belledale is willing to serve as Reviewing IRB
- Ridgeview agrees to cede review to Belledale
- Due to study population, Adams retains local IRB review

Belledale and Ridgeview can still use the SMART IRB Agreement to cover their reliance arrangement.
Collaborate on a research project

All have joined the SMART IRB Agreement

Overall PI proposes her Home Institution, Belledale, as Reviewing IRB

Ridgeview has more expertise & agrees to be Reviewing IRB at Belledale’s request

Adams University agrees to cede review to Ridgeview

SMART IRB Online Reliance System allows Home Institution (Belledale) POC to suggest a different Reviewing IRB.
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
## Implementing the Agreement

<table>
<thead>
<tr>
<th>Resource</th>
<th>Source</th>
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</thead>
<tbody>
<tr>
<td>Addition of Site Form - SAMPLE</td>
<td>University of Texas</td>
</tr>
<tr>
<td>This document provides an example of information to collect when adding a site to a study.</td>
<td></td>
</tr>
<tr>
<td>Ambassadors, SMART IRB Regional</td>
<td>SMART IRB</td>
</tr>
<tr>
<td>Need help joining and implementing the SMART IRB Agreement? Ask your ambassador.</td>
<td></td>
</tr>
<tr>
<td>Communication Plan for Single IRB Review</td>
<td>SMART IRB</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Communications Between Institutions and Outside IRBs – Considerations Document</td>
<td>Clinical Trials Transformation Initiative</td>
</tr>
<tr>
<td>This document outlines legal and ethical responsibilities in the oversight of clinical trials, providing a starting point for decoupling institutional and IRB responsibilities.</td>
<td></td>
</tr>
<tr>
<td>Consent Template Requirements (when using an external IRB) – SAMPLE</td>
<td>University of Pennsylvania</td>
</tr>
<tr>
<td>This document provides an example of step-by-step guidance to revise informed consent form templates when relying on an external IRB.</td>
<td></td>
</tr>
<tr>
<td>Consultations: Expert Advice and Guidance</td>
<td>SMART IRB</td>
</tr>
<tr>
<td>Prepare to serve as a Reviewing IRB or Relying Institution by consulting with an IRB experienced in the conduct, review, and oversight of multisite research.</td>
<td></td>
</tr>
<tr>
<td>FAQs</td>
<td>SMART IRB</td>
</tr>
<tr>
<td>Frequently asked questions covering eligibility, how to join, agreement provisions, and other important topics.</td>
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</table>
Questions and Discussion