Your Roadmap to Single IRB Review

A Guide to SMART IRB’s Resources for IRB and HRPP Personnel

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number 3 UL1 TR002541-01S1

Nichelle Cobb, PhD
Health Sciences IRBs Office Director
University of Wisconsin-Madison & Chief Regulatory Operations Officer for Implementation for SMART IRB
In this presentation, we will cover:

- A brief overview of the SMART IRB Platform
- Eligibility and processes for joining SMART IRB
- Documenting reliance arrangements
- Getting started as a Reviewing IRB
- Educating and working with study teams
- Getting help from the SMART IRB team
The SMART IRB Platform
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.
Supporting Single IRB Review

**SMARTIRB.org**
Resources and supportive services freely available to support sIRB 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
Eligibility to Join SMART IRB

- Institution has a Federalwide Assurance (FWA)
- Institution provides oversight of all research, including exempt and not federally funded
- If the institution is or has an IRB, must have initiated or completed an evaluation of the quality assurance of its human research protection program (HRPP) within past 5 years of joining the agreement
- Institution must assign a Point of Contact (POC)
How to find out who’s joined SMART IRB

• Visit smartirb.org to find the full list of SMART IRB Participating Institutions.

• Once an institution’s joinder is activated, they are listed on the Participating Institutions page.
Click on an institution’s name or the “Details” icon to find the contact info for the institution’s designated SMART IRB point of contact (POC).

<table>
<thead>
<tr>
<th>Name</th>
<th>City</th>
<th>State</th>
<th>Point of Contact (POC)</th>
<th>POC Phone</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAFA</td>
<td>Landover</td>
<td>MD</td>
<td>Deldre Washington</td>
<td>(202) 466-7643</td>
<td></td>
</tr>
<tr>
<td>AHN Research Institute</td>
<td>Pittsburgh</td>
<td>PA</td>
<td>Dawnmarie Defazio</td>
<td>(412) 330-6192</td>
<td></td>
</tr>
<tr>
<td>Abington Neurological Associates, Ltd.</td>
<td>Abington</td>
<td>PA</td>
<td>David Moore</td>
<td>(215) 957-9250</td>
<td></td>
</tr>
</tbody>
</table>
Searching the Participating Institution List

• Use this list to identify current Participating Institutions and their points of contact (POCs).

• The list can be searched or sorted by:
  – Name
  – City
  – POC name
  – State

• A CSV file can be downloaded (note: the list on the website will be the most current and accurate).
Resources & Guidance

- **A growing library** of collaboratively-developed resources support IRBs, institutions, and investigators.

- We’ve also collected resources to help you meet NIH requirements as well as sample tools, training, and guidance generously shared by colleagues across the nation.

![SmartIRB Resources & Guidance](smartirb.org/resources)

**Implementing the Agreement**

- **Addition of Site Form - SAMPLE**
  This document provides an example of information to collect when adding a site to a study.

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

- **Communication Plan for Single IRB Review**
  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.

Joining SMART IRB
If you want to use the SMART IRB agreement and a collaborating institution has not yet signed on, SMART IRB has resources to help you work with that institution to join SMART IRB.
Reach out to 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.

Find and contact your ambassador smartirb.org/ambassadors
Guidance about how to join via the SMART IRB Joinder Platform

1. Review the Agreement
2. Request an Invitation
3. Create Your Joinder Agreement
4. Sign and Submit
5. Wait for Activation

Review the Agreement
Review the agreement with institution officials and counsel, as appropriate.

- Download the SMART IRB Agreement.
- Download the Joinder Agreement Checklist.
- Review Offline.

Do not sign the sample Joinder Agreement. You will use the SMART IRB Joinder platform to generate your institution-specific Joinder Agreement.

The process starts at smartirb.org/join.
A copy of the SMART IRB Agreement is posted on the SMART IRB website.

Before starting the joinder process, review the terms of the Agreement with institution representatives and counsel (as appropriate) to be sure all understand the terms of joining.

smartirb.org/resources
SMART IRB FAQs

Frequently asked questions covering eligibility, how to join, agreement provisions, and other important topics.

Download the FAQs

Search SMART IRB’s Support Center
Joinder Checklist

An overview of the information required to generate the institution's Joinder Agreement.

Download the Joinder Checklist

SMART/IRB Joinder Agreement Informational Sheet

Initiating the Joinder process
Due to the nature of the information required, IRB administrators or other research compliance personnel will be best suited to initiate the Joinder process.

1. Go to smartirb.org/join and fill in the blue box at the bottom of the page.
2. The SMART IRB team will review the information provided and send you an email with an invite link to the SMART IRB Joinder System (be sure to check SPAM filters); if you do not see an invite email within 1 week, please contact us.
3. Once you have received the email, follow the invite link to register your institution. Note: You will need your unique invite link to start the process; if you need to return to the system later, you may do so by logging in here.

Generating your institution’s Joinder Agreement

- Provide your institution’s legal name, city, and state.
- Provide an institution display name so that we may list your institution on smartirb.org.
- Provide a link to your institution or its IRB/HRPP website/page (optional).
- Indicate institution type (university, academic medical center, community hospital, cancer center, other).
- Indicate CTSA affiliation (if applicable).
- Indicate whether application of the FWA is restricted to federally funded research (i.e., has your institution “unchecked the box” on its FWA), and if not, which subparts apply.
- Indicate whether the institution maintains one or more IRBs.
- Indicate how the institution assures the quality of its Human Research Protection Program (HRPP).

Within the past five years institutions that maintain one or more IRBs must have undergone or initiated assessment of the HRPP by one of the following methods:

- Undergone external accreditation (date received and accrediting organization)
- Be pursuing accreditation (status and accrediting organization)
- Undergone or Initiated OHRP’s Quality Assessment Program (date completed or status)
- Other approach, e.g. internal/external audit, review by external consultant, etc., (please describe)

To learn more about how you may fulfill this requirement, see the FAQs or contact us.
A decision tree to help an affiliate of another institution determine how to join SMART IRB. **Download Guidance for Affiliates**

**How may an institution/site that is affiliated with another institution join SMART IRB?**

- **Does the affiliate hold an FWA in its own name?**
  - Yes: The affiliate must register with SMART IRB and execute its own Joinder Agreement. Start the Joinder process.
  - No: Is the affiliate listed as a “component” on the FWA held by the institution with which it is affiliated?
    - Yes: Is the affiliate a separate legal corporation from the institution with which it is affiliated?
      - Yes: The affiliate must register with SMART IRB and execute its own Joinder Agreement. Contact us to get started
      - No: Is the institution with which the affiliate is affiliated already a SMART IRB Participating Institution?
        - Yes: No additional action required. The affiliate is covered by the SMART IRB registration and Joinder Agreement of the institution with which it is affiliated.
        - No: The affiliate must obtain an FWA in order to join SMART IRB. Learn more about obtaining an FWA.

Each institution that has an FWA or that is a separate legal entity needs to join the SMART IRB Agreement to be covered by a reliance arrangement.
Setting Up and Documenting Reliance Arrangements
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
Nature of the SMART IRB Agreement

<table>
<thead>
<tr>
<th>The Agreement is a “master” agreement which means:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No additional IRB authorization agreements required to enable reliance among institutions that have joined SMART IRB</td>
</tr>
<tr>
<td>Reliance arrangements, however, need to be documented for each study</td>
</tr>
</tbody>
</table>
Documenting Reliance

- The Online Reliance System provides a central web-based portal for documenting reliance arrangements on a study-by-study basis.

- SMART IRB offers the Online Reliance System to anyone who joins SMART IRB, at no cost.

- If you do not use Online Reliance System to document the reliance arrangements for a study, SMART IRB provides a template acknowledgement letter that can be adapted for use.
Request, Track, and Document Arrangements

SMART IRB Online Reliance System

Launched in May 2017

Single point of entry standardizes reliance processes

Communication portal eliminates tracking via email or other methods

Guided workflow makes 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

Allows SMART IRB Participating Institutions to work together to establish reliance arrangements on a study-by-study basis

Get started at smartirb.org/reliance.
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.
Take a look inside the system at smartirb.org/reliance

Preview a Sample Reliance Request Form.
System-generated Determination Letter

- Sent to Overall PI, Site Investigators, and designated contacts for all engaged sites; stored in the system.
- Documents the Reviewing IRB and Relying Institution(s).
- Describes responsibilities of the Overall PI and Site Investigators.
Template Letter of Acknowledgement

If not using the SMART IRB Online Reliance System to coordinate and document study-specific reliance arrangements, institutions may use this template to document theReviewing IRB and Relying Institutions for a specific study.

Download Template Letter of Acknowledgement
Documenting How Agreement Flexibility Will Be Implemented

The SMART IRB Agreement has several default positions, but allows for flexibility of terms in some areas, such as:

- Whether Reviewing IRB will make Privacy Board determinations
- Who reports events to federal agencies/sponsors
- Whether insurance will be required
- Whether a separate indemnification agreement will be required
- Whether the relying institution will be required to be able to conduct for cause audits
- Whether the relying institution is required to conduct COI assessments
Implementation Checklist

Highlights flexible provisions of the Agreement and allows a Reviewing IRB to document which options they will implement as part of the Ceded Review.

Download the Implementation Checklist

Download the Implementation Checklist as a customizable Word document
Getting Started as a Reviewing IRB
SMART IRB developed SOPs to support implementation of the SMART IRB Agreement and to outline study team responsibilities.

SMART IRB SOPs are not required.

If the Reviewing IRB does not use SMART IRB SOPs, it must identify which SOPs it will use.
SMART IRB SOPs

Standard operating procedures (SOPs) for establishing and implementing reliance provide clarity during the review and conduct of research using the SMART IRB Agreement.

- Provide clarity on key roles and responsibilities
- Use of SMART IRB SOPs is not mandated
- SMART IRB supports networks with existing SOPs
- Institutions communicate whether other policies or procedures apply

Download the SOP Manual

### Record Keeping and Document Retention

This section describes the process for maintaining and storing SMART IRB administrative records and the responsibilities of SMART IRB Administration, Reviewing IRBs, and Relying Institutions for the maintenance of these records, covering SMART IRB administrative records and study-specific IRB records related to reliance, but not the investigators’ research files.

SMART IRB administrators, reviewing IRBs, and relying institutions will maintain the following records in the locations specified in the table below:

<table>
<thead>
<tr>
<th>Record Type</th>
<th>Responsible Party</th>
<th>Storage Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current SMART IRB policies and procedures including: SOPs, forms, templates, etc.</td>
<td>SMART IRB Administration</td>
<td>SMARTIRB.org</td>
</tr>
<tr>
<td>Current executed SMART IRB Ballooner Agreements and similar Agreements, as well as any amendments</td>
<td>SMART IRB Administration and Participating Institutions</td>
<td>SMARTIRB.org and at Participating Institutions</td>
</tr>
<tr>
<td>Study-specific reliance requests including identification of Reviewing IRB(s) and Relying Institutions and Study Teams Information</td>
<td>Participating Institutions</td>
<td>Local storage at Participating Institutions</td>
</tr>
<tr>
<td>Minutes from IRB meetings at which research was reviewed under the SMART IRB Agreement was reviewed: portions of the minutes that are relevant to a Relying Institution available upon request</td>
<td>Reviewing IRB</td>
<td>Local storage available upon request</td>
</tr>
<tr>
<td>Records of any applicable CCR management plans provided by the Relying Institution and received by the Reviewing Institution</td>
<td>Reviewing IRB and Relying Institution</td>
<td>Local storage</td>
</tr>
<tr>
<td>Records of events reported by Relying Institution and received by the Reviewing Institutions</td>
<td>Reviewing IRB and Relying Institution</td>
<td>Local storage available on request</td>
</tr>
<tr>
<td>Study-specific review and approval notifications</td>
<td>Reviewing IRB and Relying Institution</td>
<td>Reviewing IRB and Lead Study Team; available upon request</td>
</tr>
<tr>
<td>Other general correspondence between the Relying Institution and the Reviewing IRB</td>
<td>Reviewing IRB and Relying Institution</td>
<td>Reviewing IRB and Lead Study Team; available upon request</td>
</tr>
<tr>
<td>Study-specific determinations related to deciding review (e.g., for documentation of decision to write review, any outstanding concerns or requirements that must be addressed by the Reviewing IRB, any institutional requirements related to the cyclic study that the Reviewing IRB must take into consideration)</td>
<td>Relining Institution and Reviewing Institution</td>
<td>Local storage</td>
</tr>
</tbody>
</table>
SMART IRB SOPs:
Overall PI & Lead Study Team Key Responsibilities

**Overall Principal Investigator**

- Assumes leadership and has ultimate responsibility for conduct of the research study
  (generally, the initiating principal investigator or funding principal investigator, as applicable).
- Designates a Lead Study Team*, can be a coordinating center

**Lead Study Team**

- Submits materials to the Reviewing IRB for all sites, including study-wide and site-specific changes of protocol, continuing reviews, and reportable events (e.g., unanticipated problems, noncompliance, and new information).
- Provide draft study materials to all site study teams, including proposed consent form template
- Provide IRB-approved materials/determinations to all site study teams

*The Lead Study Team is often (but not always) the study team at the Reviewing IRB’s institution. In collaboration with the Reviewing IRB, the Lead Study Team ensures study coordination, communication, and the routing of IRB submissions.
SMART IRB SOPs: Site PIs & Relying Site Study Teams

- **Site Investigator** = the investigator (Site PI) responsible for conduct of the Research at his/her institution.
- **Relying Site Study Team** = a study team whose institution ceded IRB Review to the Reviewing IRB, includes Site investigator and any local site personnel designated to carry out the applicable communication, coordination, and administrative procedures described within the Agreement and SOPs.*

- **Follow the policies and procedures of the Reviewing IRB** (e.g., for reportable events, personnel changes)
- **Provide Lead Study Team information about study progress for continuing review and local events** (e.g., unanticipated problems, noncompliance) so that it can be reported to the Reviewing IRB
- **Use the Reviewing IRB’s consent form template** (excepting limited local language that can be added/changed)
- **Obtain authorization from their SMART IRB POCs in the case of personnel changes, COI updates, and/or changes that may be affected by State law or institutional requirements**

*If the Lead Study Team is from an institution other than the Reviewing IRB Institution, the roles and responsibilities of the “Relying Site Study Team” also apply to the study team at the Reviewing IRB’s institution.*
SMART IRB SOPs: Communication Model

- Reviewing IRB
- Lead Study Team
- Relying Institution IRB/HRPP
- Relying Site Study Team
Communication plan for single IRB review

Document key communication roles, e.g., submitting initial and continuing reviews, amendments, and reportable events; providing conflict of interest management plans; and providing IRB-approved documents and communicating Reviewing IRB determinations.

Download the Communication Plan

Download the Communication Plan as customizable Word document.
Local Context Survey

Local Context Survey: Reviewing IRB POCs may use this to obtain local context from Relying Institutions.

Download the Local Context Survey as a customizable Word document
Relying Site Study Team Survey

Relying Site Study Team Survey: The Overall PI/Lead Study Team may use this to obtain information from a relying site study team regarding whether regulatory or institutional requirements should be communicated to the Reviewing IRB.

Download the Relying Site Study Team Survey as a customizable Word document
Handling Consent Forms and Local Considerations

SMART IRB Guidance: Inserting “Local Context” Language in Informed Consent Documents

Illustrates roles the Reviewing IRB, Overall PI, Relying Site Study Team, and Relying Institution POC may play in providing information and language for local consent forms.
Educating and Working with Study Teams
Investigator Checklists

Overall PI (and Lead Study Team) Checklist: Helps Overall PIs (and Lead Study Teams) understand and fulfill their responsibilities.

Download the Overall PI (and Lead Study Team) Checklist as customizable Word document

Relying Institution PI Checklist: Helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external IRB.

Download the Relying Institution PI Checklist as customizable Word document
FAQs for Research Teams

FAQs for Research Teams - Relying on an External IRB:

Provides helpful hints for study teams whose institutions have agreed to rely on an external IRB.

Also available in a customizable Word Template: Institutions may use this template to create institution-specific guidance for study teams whose research study is ceded to an external IRB.

Relying on an External IRB: FAQs for Research Teams

Version Date: November 14, 2017

The purpose of this document is to provide helpful hints for study teams whose institutions have agreed to rely on an external IRB.

What does relying on an external IRB mean?

Institutions may agree to use an IRB outside their institution to oversee a research study or studies. This is called ceding or deferring IRB review.

How do I know whether a study can be ceded to an external IRB?

Please contact your institution's SMART IRB point of contact (POC), or check with the office at your site responsible for making determinations regarding whether IRB review will be ceded to an external IRB (usually the IRB office), to find out:

- what research qualifies for ceded review
- how to make requests for ceding IRB review, and
- what, if any, agreement may be in place to cover the specific IRB review arrangement.

Does my institution need to sign an agreement in order to rely on an external IRB?

Generally, a written agreement between the institutions must be executed for an institution to rely on an external IRB. The agreement spells out the responsibilities of the institution providing IRB review as well as the Institution relying on the external IRB.

What is the SMART IRB Agreement?

The SMART IRB Agreement is a national master agreement that allows institutions to avoid having to negotiate individual agreement per study or group of studies. More information about SMART IRB is at https://smartrib.org and a list of institutions that have joined SMART IRB by signing onto the agreement is at http://smartrib.org/participating-institutions/.

Do I need to obtain sign-off from my home institution, such as from its IRB office, to use an external IRB?

Generally, yes. Because institutions need to identify the research that falls under their purview, even if an IRB outside the institution oversees some or all of its research, they usually require researchers at least to alert appropriate institutional officials about a study they wish to have reviewed by an external IRB. Institutions often require institutional sign-off before the study can be reviewed by an external IRB. The mechanism by which this “registration” occurs varies by institution. Some, for example, require researchers to provide a brief application in the local electronic submission system. Study teams should check to find out what their institutional requirements are in regard to the use of an external IRB.

www.smartrib.org

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number U11CT000025-04S1
Comparison of Grant Submission and Review Process Before & After the NIH SIRB Policy

Grant Submission and Review Guidance: Illustrates the new steps required for research teams and administrators when applying for NIH grants that require a single IRB.
IRB Letter of Support for Grants

**IRB Support Letter Model Language**: Provides language for IRBs/HRPPs to provide for grants that demonstrates support for single IRB review.

---

SMART IRB

**Instructions**: The purpose of this document is to provide language for IRBs/HRPPs to adapt to provide a letter of support for grant applications when: 1) the grant falls under the NIH Single IRB Policy or the researcher expects to streamline IRB review by using a single IRB, and 2) all or most of the institutions collaborating on the research have joined the SMART IRB Agreement.

Language that is in brackets [] and shaded in gray should be modified as appropriate.

**IRB Support Letter Model Language**

[D]ate

[PI NAME AND TITLE]

[PI ADDRESS]

Dear Dr. [PI LAST NAME],

I am pleased to provide this letter of support for the application that you are submitting to the [NAME OF FUNDING AGENCY GRANT] titled "[TITLE OF PI'S GRANT APPLICATION]."

The [NAME OF INSTITUTION] Institutional Review Board (IRB) will continue to work with and support you in this new research endeavor. [IRB or HRPP] staff will be available to you and your study team as needed regarding this grant, both for consultation regarding regulatory issues and for IRB review arrangements.

[NAME OF INSTITUTION] has signed onto the SMART IRB Agreement (www.smartirb.org), which is a standard, national, master IRB reliance agreement that is responsive to the National Institutes of Health Single IRB (sIRB) Policy. SMART IRB also provides standard operating procedures and informatics solutions in support of this Agreement. As of the date of this letter, more than [SMART IRB count] institutions have joined SMART IRB, including [many or all] of the institutions expected to participate in and collaborate on your proposed research. We can leverage the SMART IRB Agreement to great effect to reduce regulatory oversight burdens.

If the institution has agreed to serve as the Reviewing IRB and has reached out to other institutions about a reliance arrangement, include language to that effect, such as: We are willing to serve as the Reviewing IRB for this study and have already communicated with the collaborating institutions identified in your grant. We’ve confirmed their willingness to code review to the [NAME OF IRB] for the proposed research.

I look forward to collaborating with you and your team to address the IRB oversight needs for this grant. Best wishes for a successful application.

With best regards,

[NAME OF IRB/HRPP DIRECTOR]

www.smartirb.org

---

© 2019 SMART IRB. All rights reserved. www.smartirb.org

For more information, please visit www.translationalreviews.org.
Grant Application Language

Grant Applications: Template Description of SMART IRB: Provides language for researchers and their institutions to adapt for federal grant applications.

SMART IRB

Instructions: The purpose of this document is to provide language for researchers and their institutions to adapt for federal grant applications when 1) the grant falls under the NIH Single IRB review policy or the researcher expects to streamline IRB review by using a single IRB, and 2) all or most of the institutions collaborating on the research have joined the SMART IRB Master Reliance Agreement. Language that is in brackets [ ] and shaded in gray may need to be modified as appropriate to the funding situation.

TEMPLATE DESCRIPTION OF SMART IRB FOR GRANT APPLICATIONS

This project will use the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement) to support single IRB review (in compliance with NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research). Development of the SMART IRB Agreement was funded by the National Center for Advancing Translational Sciences (“NCATS”) at the National Institutes of Health (NIH) to be responsible to and serve as a roadmap for implementing single IRB review (the NIH single IRB policy). SMART IRB streamlines and advances collaboration by establishing a common IRB authorization agreement and standardizing the roles and responsibilities of all parties involved in the review and conduct of multisite research. Further, the SMART IRB Agreement outlines the responsibilities of all Participating Institutions, the Reviewing IRB, and Relying Institutions, in addition to detailing the communication plan between the Reviewing IRB and Relying Institutions.

[Include one of the following options below.]

**OPTION 1** Each participant institution has joined SMART IRB by signing a Jointer Agreement to the master SMART IRB Agreement, thus avoiding the need for protracted negotiations about reliance details. [The IRB has agreed to serve as Reviewing IRB, and the following Relying Institutions, have agreed to code review as noted in the letters of support: List of sites.]

**OPTION 2** To date approximately [X] of the [Y] planned participating sites have signed onto the SMART IRB Agreement through the jointer process. It is anticipated that all participating sites will be signatories to the SMART IRB Agreement prior to the planned award date.

**OPTION 3** [X, Y, and Z] have each joined SMART IRB by signing a Jointer Agreement to the master SMART IRB Agreement. Use of the SMART IRB Agreement helps reduce the need to negotiate between institutions about reliance details. The other participating institutions have been contacted with a request to join SMART IRB as we await notice of award.

The sites have agreed that IRB review, regulatory oversight, and roles and responsibilities of the parties will be governed by the SMART IRB Agreement and [the SMART IRB Standard Operating Procedures or identify other standard operating procedures that will be followed] throughout the life of the project.

In joining SMART IRB, each site has designated a Point of Contact (POC) to provide the Reviewing IRB with knowledge about local context and facilitate coordination among the sites.

In accordance with the SMART IRB Agreement and SOPs:

www.smartrirb.org

Prepared by the NIH National Center for Advancing Translational Sciences through the Clinical and Translational Science Award Program, grant number UL1TR000114.
Investigator Guidance at smartirb.org/go

Use SMART IRB to enable single IRB review for your next study

You will need an IRB reliance arrangement if:
- You will conduct a multisite study and...
- You want to streamline the regulatory process by using a single IRB
- You will use an IRB your institution does not already use

More than 300 institutions have joined SMART IRB to simplify and speed single IRB reviews. Starting January 25, 2018, all NIH-funded studies must use a single IRB for review and oversight of the research, but regardless of funding source or study type. SMART IRB can help support your IRB reliance arrangements.

Once your institution has joined SMART IRB, you can start using the SMART IRB Agreement to enable reliance arrangements with any other SMART IRB Participating Institutions. To find out if your institution has already joined, visit the Participating Institutions page or contact your IRB or human research protections program.

Follow these 3 easy steps to get started with SMART IRB

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.org
Getting Help from the SMART IRB Team
We’re Here to Help

- **Contact an Ambassador** for help joining and implement SMART IRB.
- **Search the Support Center** for answers to frequently asked questions.
- **Subscribe to the SMART IRB Mailing List** for updates and new resource announcements.
- **Contact help@smartirb.org** - we’ll get back to you as soon as possible.

smartirb.org/support/
Expert Advice and Guidance

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.

Request a Consultation
More Learning Opportunities

Webinar series

- Getting Started with SMART IRB & the Online Reliance System
- Implementing the SMART IRB Agreement
- Responsibilities of Relying Institutions
- Serving as a Reviewing IRB

Bringing together a community of users, to aid in adoption and implementation of SMART IRB and single IRB review

Visit smartirb.org to watch a previous session and download slides.
Questions and Discussion