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

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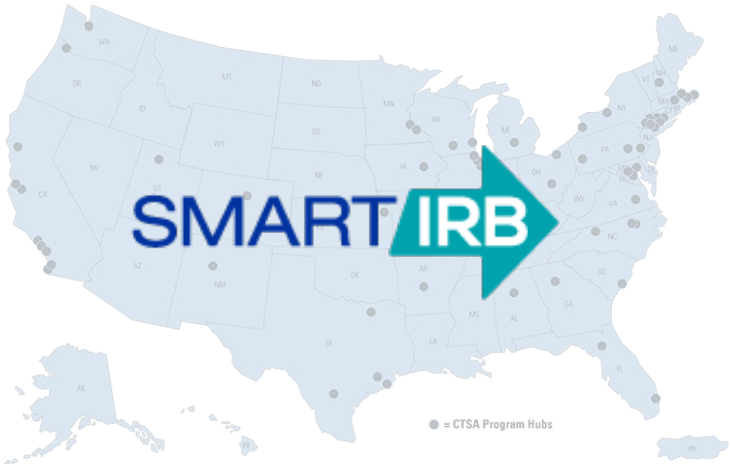
Implementation for SMART IRB

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.

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

Informatics

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

Single IRB Authorization 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 "Participating Institutions"

SMART IRB

472 Participating Institutions
including all CTSA hubs

Join SMART IRB

SMART IRB AGREEMENT | ONLINE RELIANCE SYSTEM | HARMONIZATION | RESOURCES | ABOUT US | SUPPORT

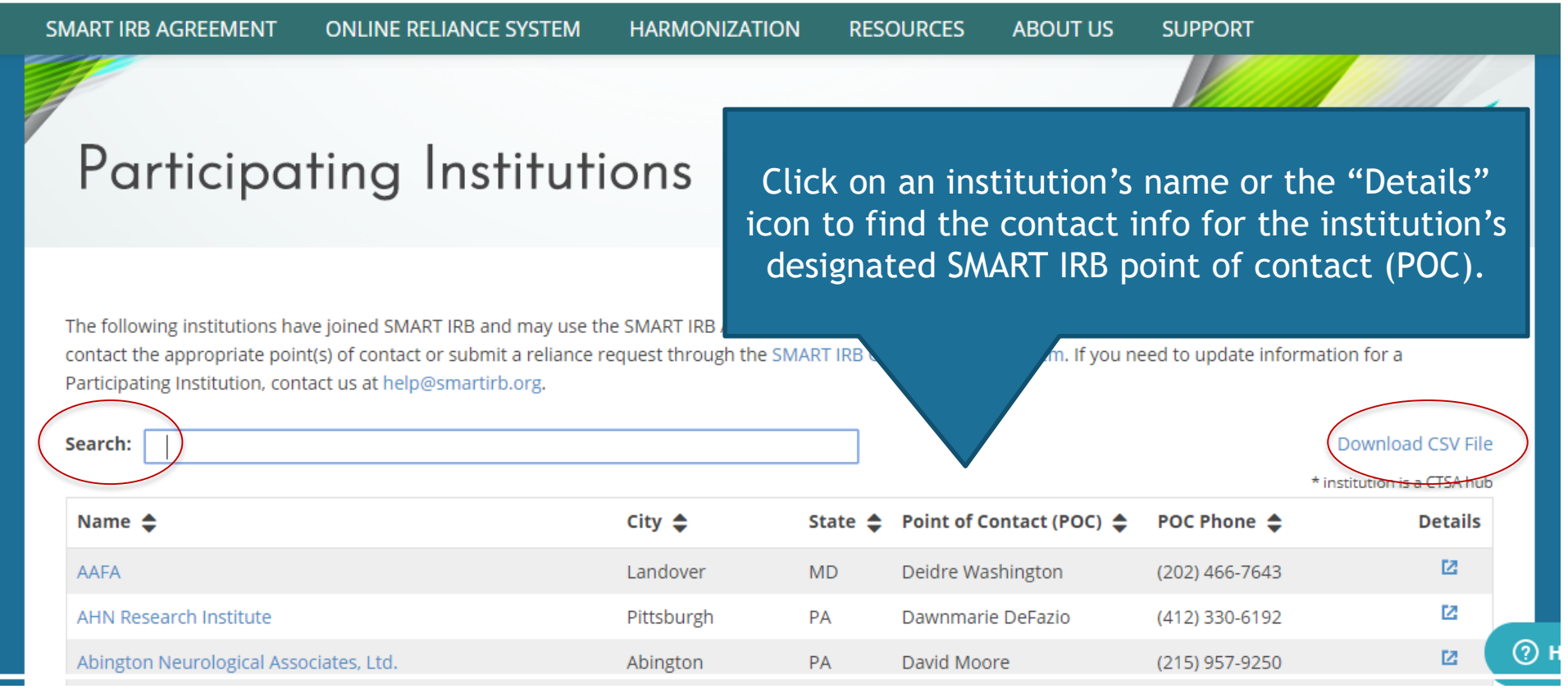
Supporting single IRB review
Advancing collaborative research

SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018). Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across

Online Reliance System

Request, track, and document reliance arrangements

List of Institutions & POCs

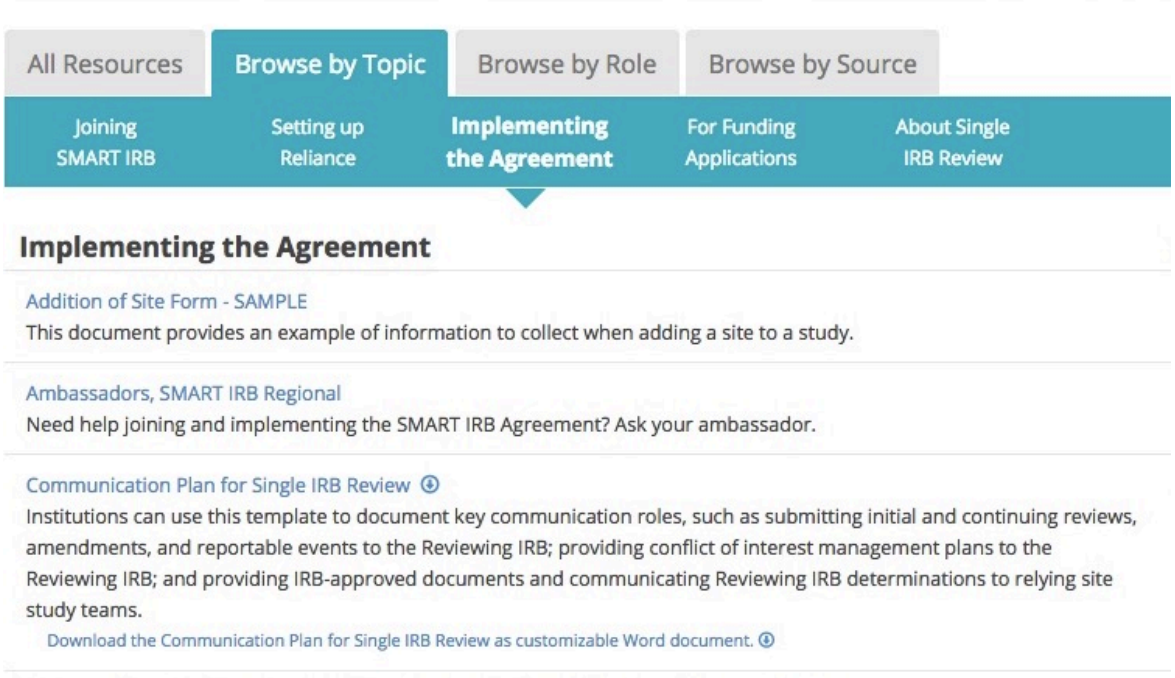


Searching the Participating Institution List

- 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.org/resources

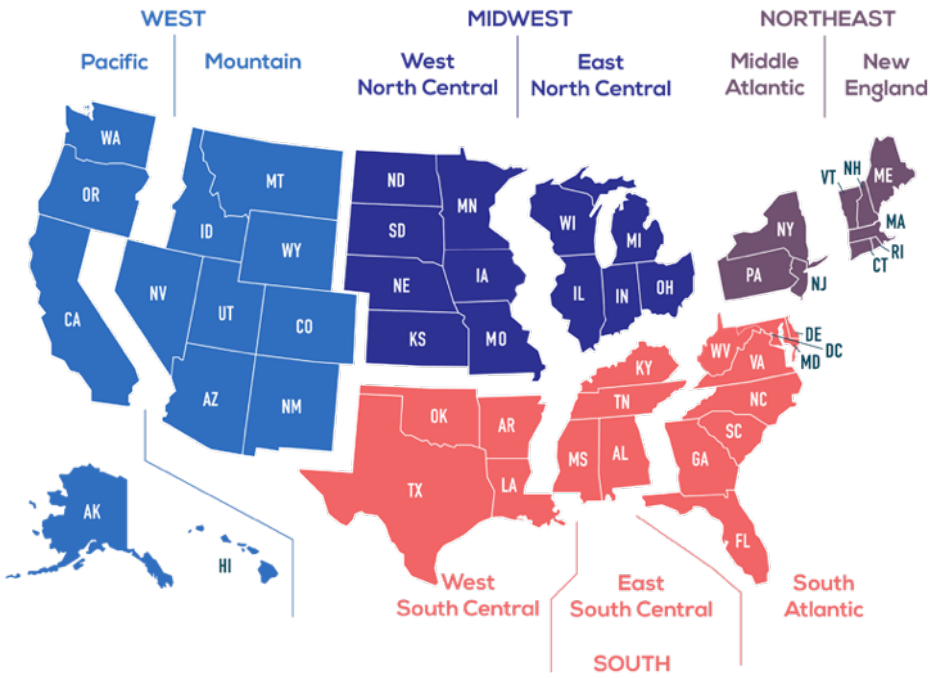
Joining SMART IRB

Resources for joining

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.

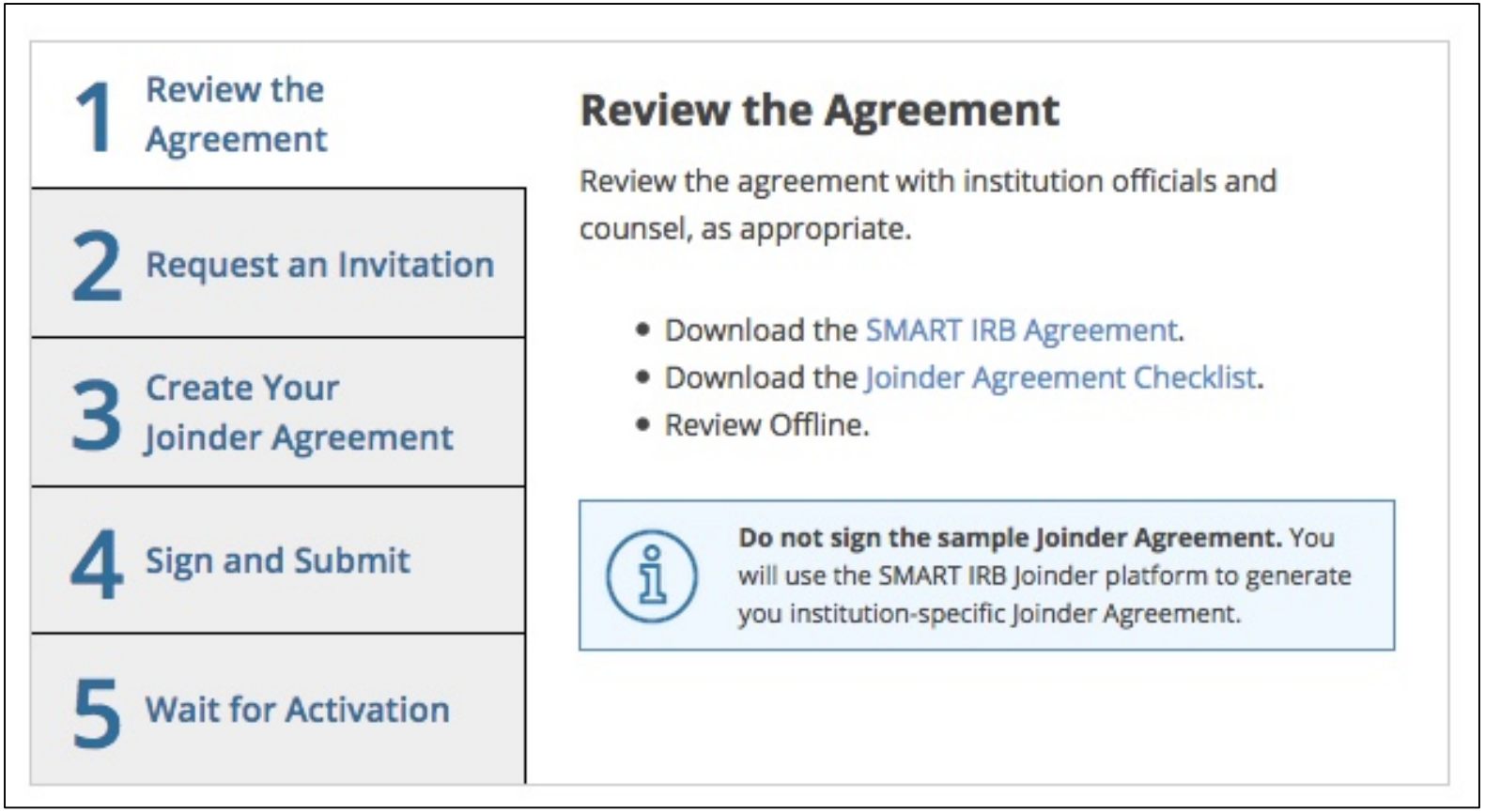
Reach out to Ambassadors

- 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

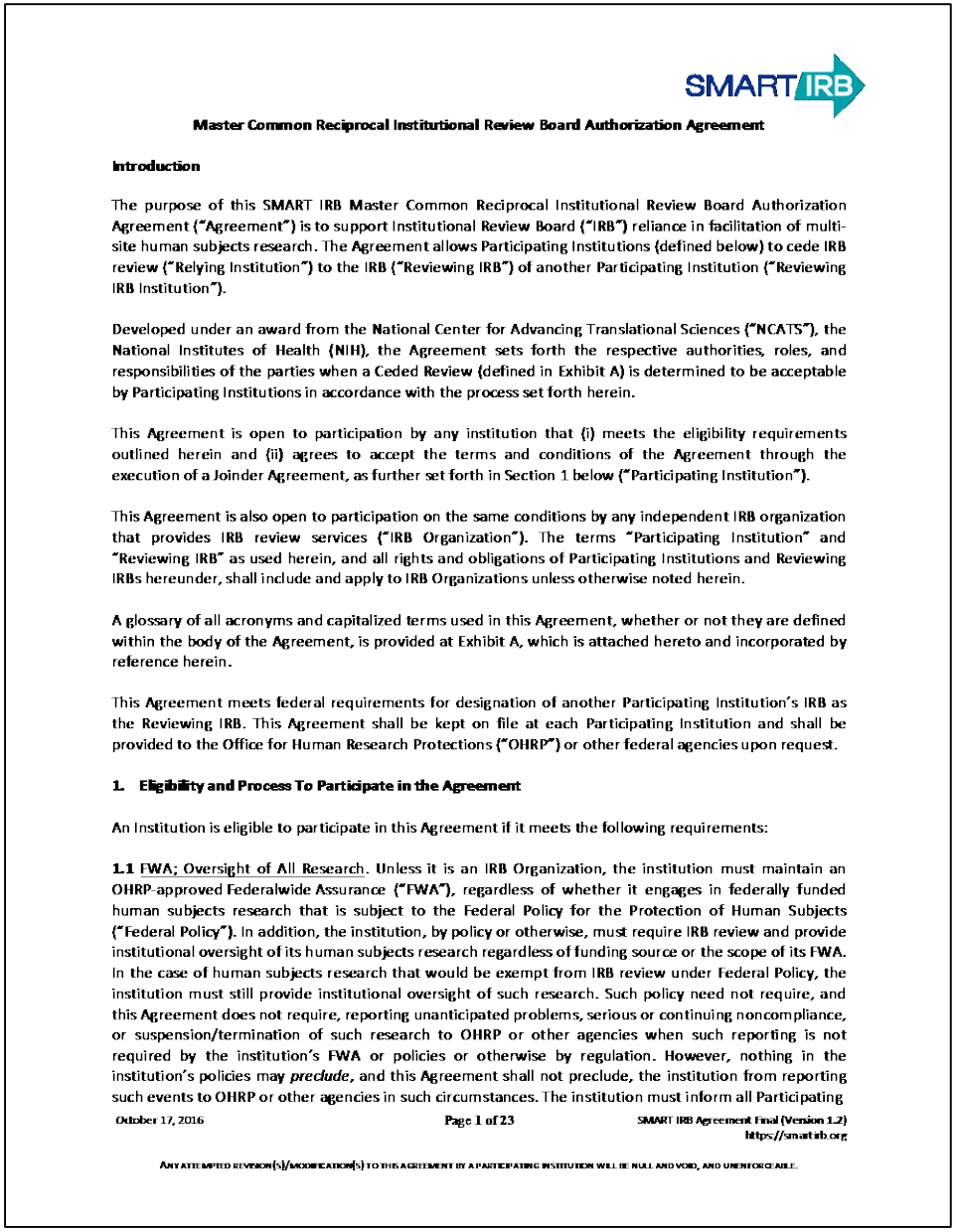
Guidance about how to join via the SMART IRB Joinder Platform



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

Master Common Reciprocal Institutional Review Board Authorization Agreement

Introduction

The purpose of this SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement ("Agreement") is to support Institutional Review Board ("IRB") reliance in facilitation of multi-site human subjects research. The Agreement allows Participating Institutions (defined below) to cede IRB review ("Relying Institution") to the IRB ("Reviewing IRB") of another Participating Institution ("Reviewing IRB Institution").

Developed under an award from the National Center for Advancing Translational Sciences ("NCATS"), the National Institutes of Health (NIH), the Agreement sets forth the respective authorities, roles, and responsibilities of the parties when a Ceded Review (defined in Exhibit A) is determined to be acceptable by Participating Institutions in accordance with the process set forth herein.

This Agreement is open to participation by any institution that (i) meets the eligibility requirements outlined herein and (ii) agrees to accept the terms and conditions of the Agreement through the execution of a Joinder Agreement, as further set forth in Section 1 below ("Participating Institution").

This Agreement is also open to participation on the same conditions by any independent IRB organization that provides IRB review services ("IRB Organization"). The terms "Participating Institution" and "Reviewing IRB" as used herein, and all rights and obligations of Participating Institutions and Reviewing IRBs hereunder, shall include and apply to IRB Organizations unless otherwise noted herein.

A glossary of all acronyms and capitalized terms used in this Agreement, whether or not they are defined within the body of the Agreement, is provided at Exhibit A, which is attached hereto and incorporated by reference herein.

This Agreement meets federal requirements for designation of another Participating Institution's IRB as the Reviewing IRB. This Agreement shall be kept on file at each Participating Institution and shall be provided to the Office for Human Research Protections ("OHRP") or other federal agencies upon request.

1. Eligibility and Process To Participate in the Agreement

An Institution is eligible to participate in this Agreement if it meets the following requirements:

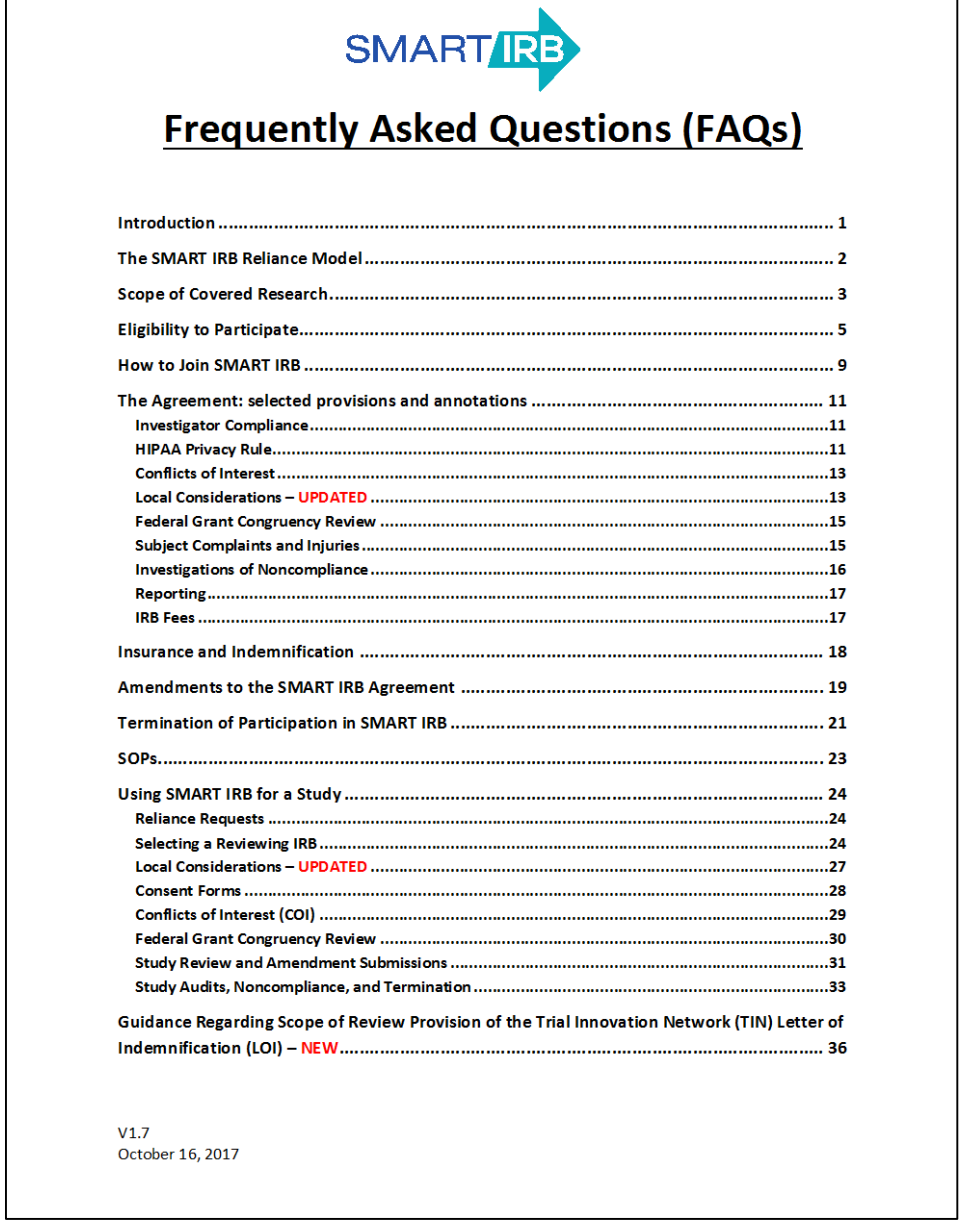
1.1 FWA; Oversight of All Research. Unless it is an IRB Organization, the institution must maintain an OHRP-approved Federalwide Assurance ("FWA"), regardless of whether it engages in federally funded human subjects research that is subject to the Federal Policy for the Protection of Human Subjects ("Federal Policy"). In addition, the institution, by policy or otherwise, must require IRB review and provide institutional oversight of its human subjects research regardless of funding source or the scope of its FWA. In the case of human subjects research that would be exempt from IRB review under Federal Policy, the institution must still provide institutional oversight of such research. Such policy need not require, and this Agreement does not require, reporting unanticipated problems, serious or continuing noncompliance, or suspension/termination of such research to OHRP or other agencies when such reporting is not required by the institution's FWA or policies or otherwise by regulation. However, nothing in the institution's policies may *preclude*, and this Agreement shall not preclude, the institution from reporting such events to OHRP or other agencies in such circumstances. The institution must inform all Participating

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



SMART IRB

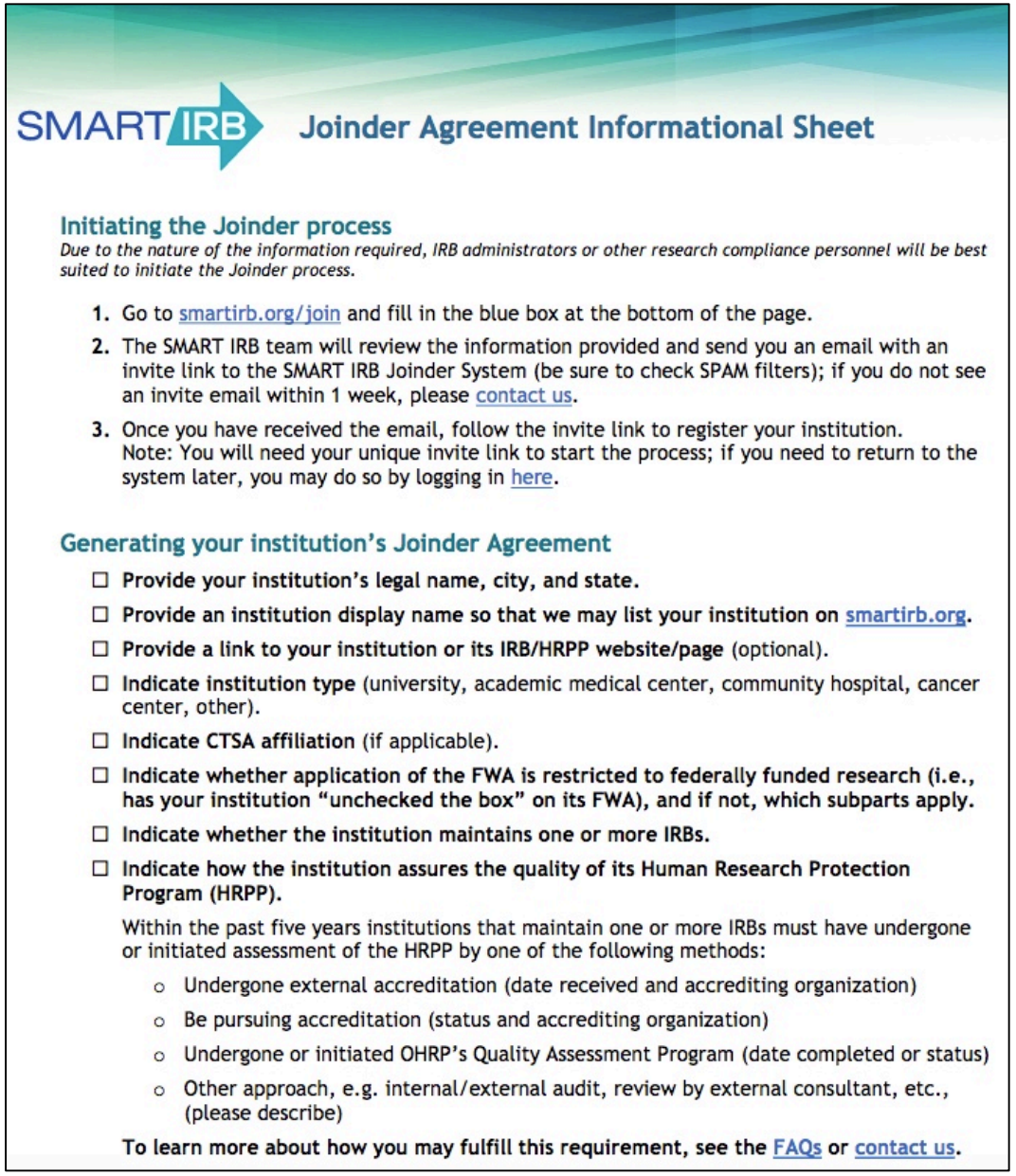
Frequently Asked Questions (FAQs)

V1.7
October 16, 2017

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

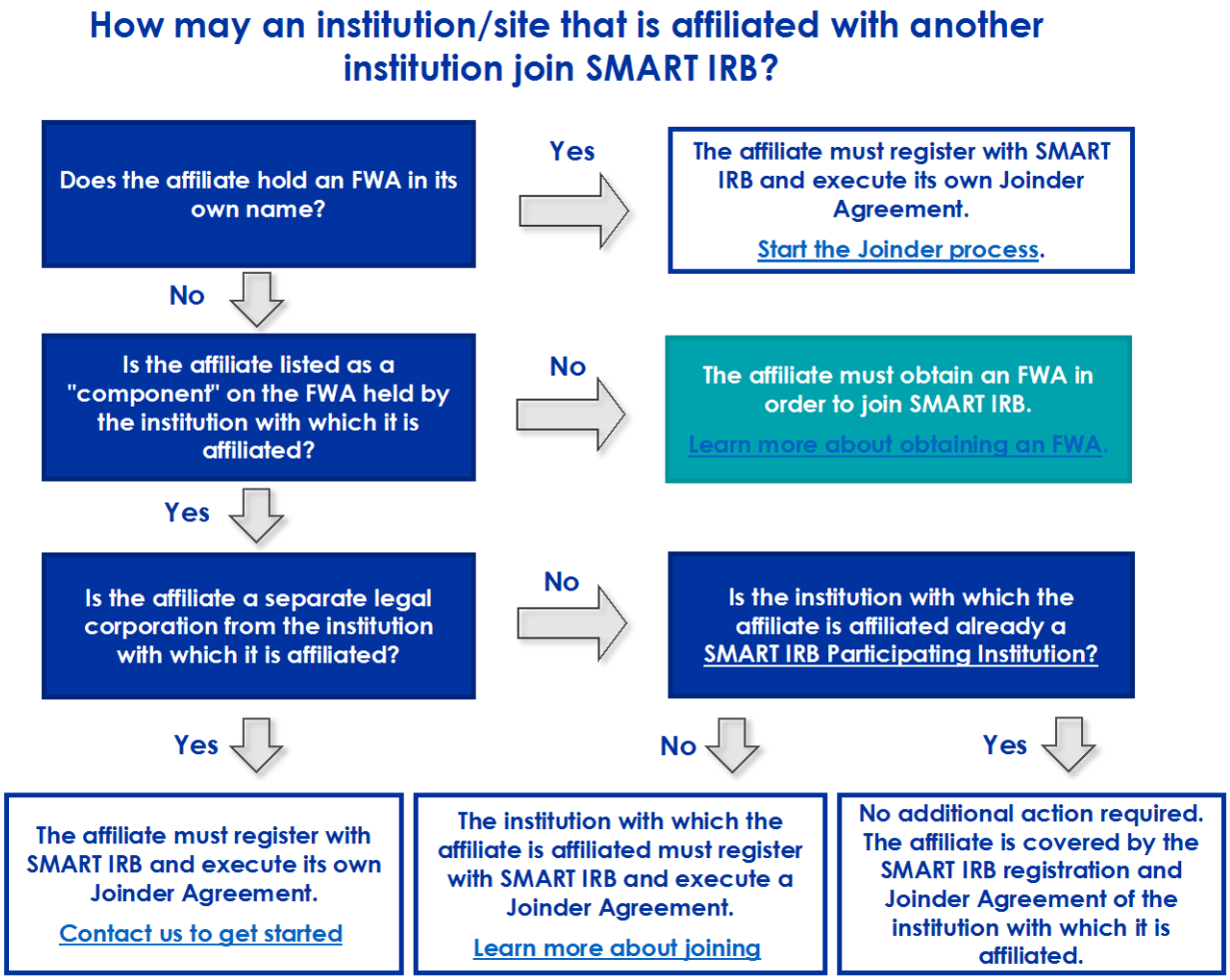
- ☐ **Provide your institution's legal name, city, and state.**
- ☐ **Provide an institution display name so that we may list your institution on smartirb.org.**
- ☐ **Provide a link to your institution or its IRB/HRPP website/page** (optional).
- ☐ **Indicate institution type** (university, academic 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



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

The Agreement is a “master” agreement which means:	
No additional IRB authorization agreements required to enable reliance among institutions that have joined SMART IRB	Reliance arrangements, however, need to be documented for each study

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

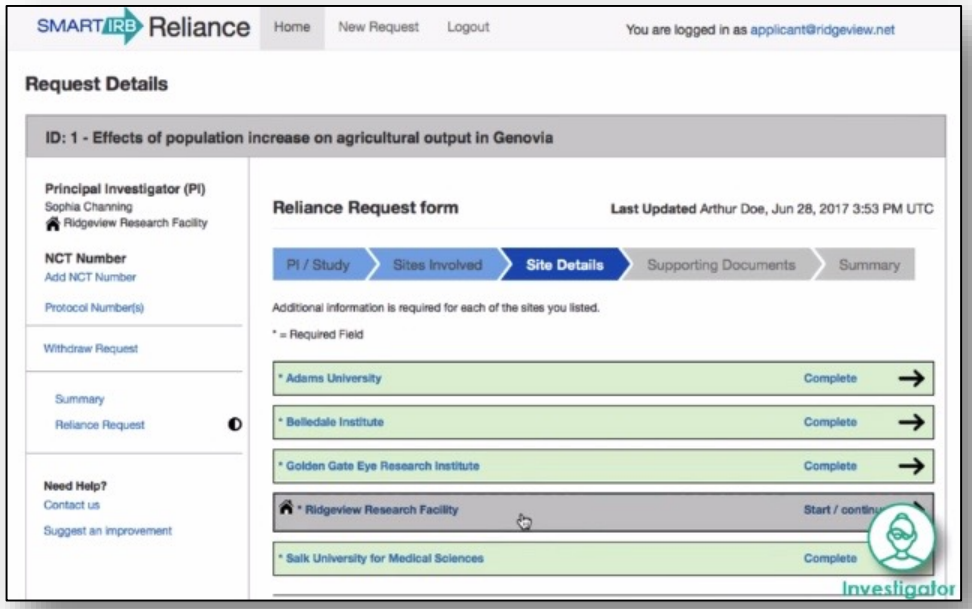
Provides a centralized place to record and track reliance arrangements on a study-by-study basis

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

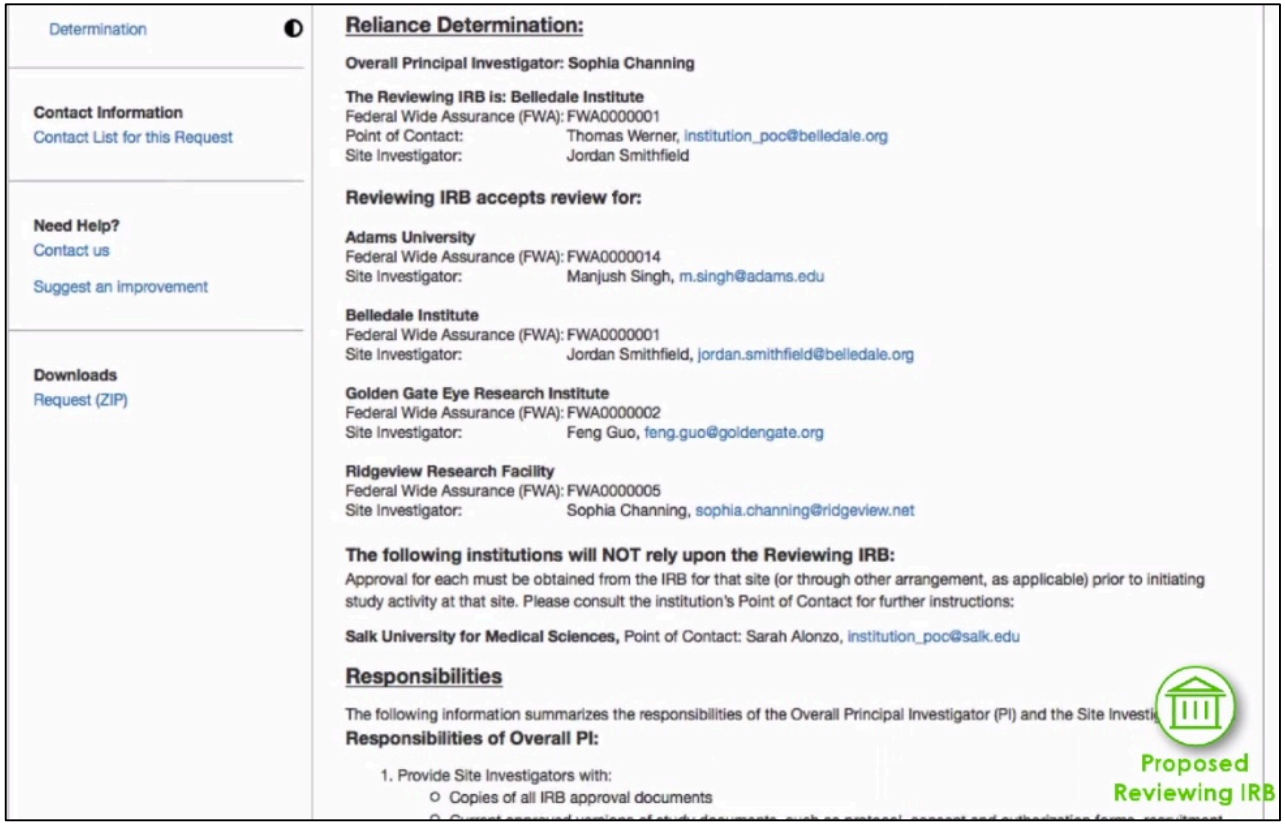
Provides a central, transparent platform to communicate local context issues

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



Preview a Sample Reliance Request Form.

System-generated Determination Letter



Determination

Contact Information
Contact List for this Request

Need Help?
Contact us
Suggest an improvement

Downloads
Request (ZIP)

Reliance Determination:

Overall Principal Investigator: Sophia Channing

The Reviewing IRB is: Belledale Institute
Federal Wide Assurance (FWA): FWA0000001
Point of Contact: Thomas Werner, institution_poc@belledale.org
Site Investigator: Jordan Smithfield

Reviewing IRB accepts review for:

Adams University
Federal Wide Assurance (FWA): FWA0000014
Site Investigator: Manjush Singh, m.singh@adams.edu

Belledale Institute
Federal Wide Assurance (FWA): FWA0000001
Site Investigator: Jordan Smithfield, jordan.smithfield@belledale.org

Golden Gate Eye Research Institute
Federal Wide Assurance (FWA): FWA0000002
Site Investigator: Feng Guo, feng.guo@goldengate.org

Ridgeview Research Facility
Federal Wide Assurance (FWA): FWA0000005
Site Investigator: Sophia Channing, sophia.channing@ridgeview.net

The following institutions will NOT rely upon the Reviewing IRB:
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:

Salk University for Medical Sciences, Point of Contact: Sarah Alonzo, institution_poc@salk.edu

Responsibilities

The following information summarizes the responsibilities of the Overall Principal Investigator (PI) and the Site Investi

Responsibilities of Overall PI:

1. Provide Site Investigators with:
   - Copies of all IRB approval documents

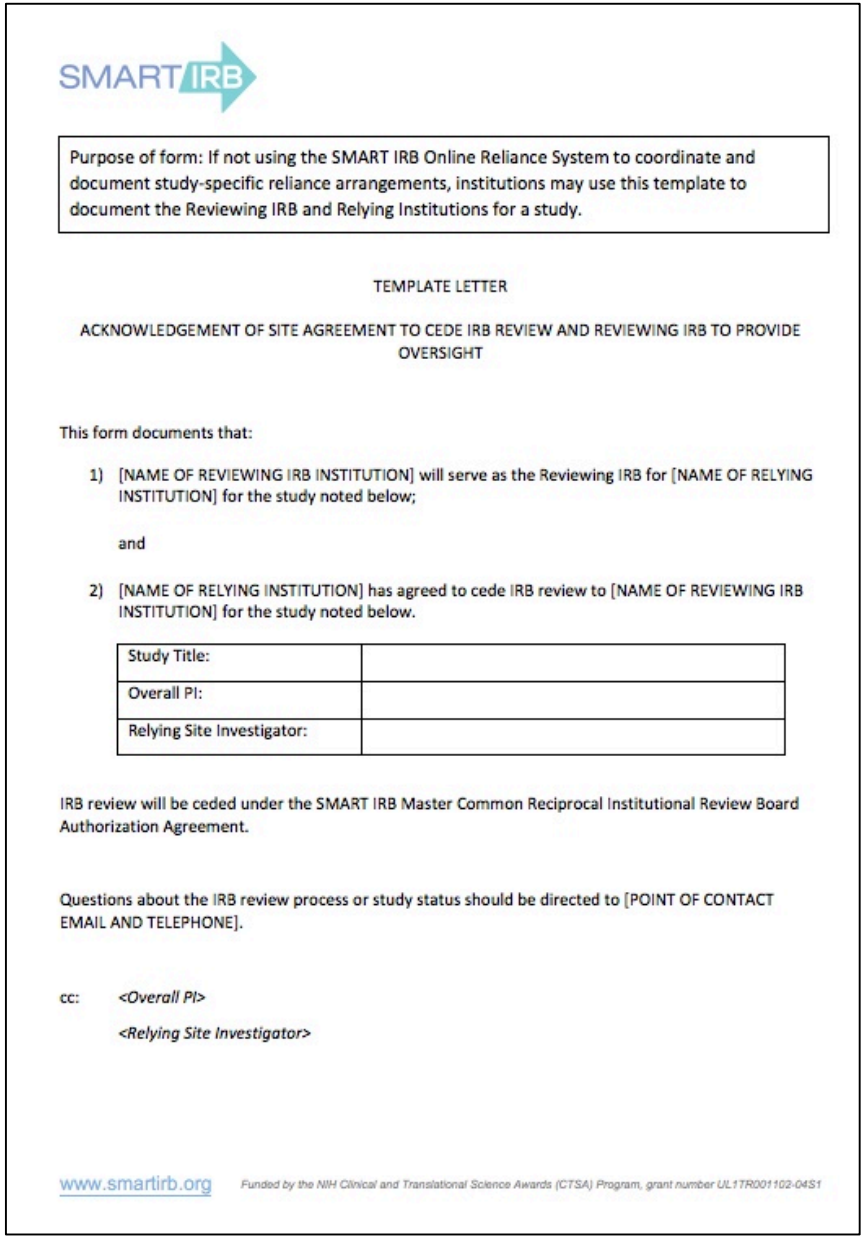
Proposed Reviewing IRB

- 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 the Reviewing IRB and Relying Institutions for a specific study.

[Download Template Letter of Acknowledgement]



SMART IRB

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

TEMPLATE LETTER

ACKNOWLEDGEMENT OF SITE AGREEMENT TO CEDE IRB REVIEW AND REVIEWING IRB TO PROVIDE OVERSIGHT

This form documents that:

1) [NAME OF REVIEWING IRB INSTITUTION] will serve as the Reviewing IRB for [NAME OF RELYING INSTITUTION] for the study noted below;

and

2) [NAME OF RELYING INSTITUTION] has agreed to cede IRB review to [NAME OF REVIEWING IRB INSTITUTION] for the study noted below.

Study Title:	
Overall PI:	
Relying Site Investigator:	

IRB review will be ceded under the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement.

Questions about the IRB review process or study status should be directed to [POINT OF CONTACT EMAIL AND TELEPHONE].

cc: *<Overall PI>*

<Relying Site Investigator>

www.smartirb.org

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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:

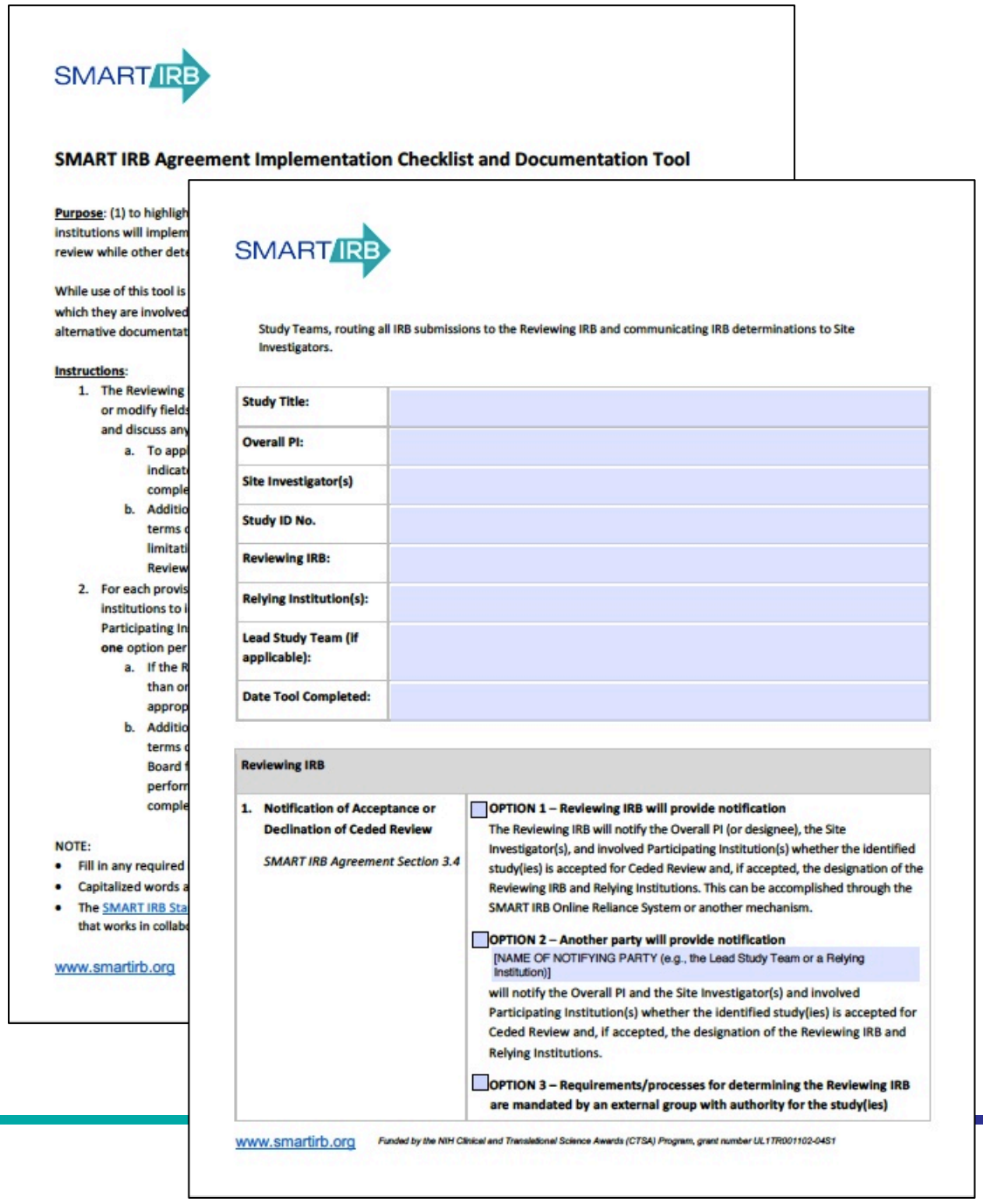
- Whether Reviewing IRB will make Privacy Board determinations
- Who reports events to federal agencies/sponsors
- Whether insurance will be required
- Whether a separate indemnification agreement will be required
- Whether the relying institution will be required to be able to conduct for cause audits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



SMART IRB

SMART IRB Agreement Implementation Checklist and Documentation Tool

Purpose: (1) to highligh
institutions will implem
review while other dete

While use of this tool is
which they are involved
alternative documentat

Instructions:

1. The Reviewing
or modify fields
and discuss any
   a. To appl
indicat
comple
   b. Additio
terms
limitati
Review
2. For each provis
institutions to i
Participating In
one option per
   a. If the R
than or
approp
   b. Additio
terms
Board
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comple

NOTE:

- Fill in any required
- Capitalized words a
- The SMART IRB Sta
that works in collab

www.smartirb.org

SMART IRB

Study Teams, routing all IRB submissions to the Reviewing IRB and communicating IRB determinations to Site Investigators.

Study Title:	
Overall PI:	
Site Investigator(s)	
Study ID No.	
Reviewing IRB:	
Relying Institution(s):	
Lead Study Team (if applicable):	
Date Tool Completed:	

Reviewing IRB	
1. Notification of Acceptance or Declination of Ceded Review *SMART IRB Agreement Section 3.4*	☐ **OPTION 1 – Reviewing IRB will provide notification** The Reviewing IRB will notify the Overall PI (or designee), the Site Investigator(s), and involved Participating Institution(s) whether the identified study(ies) is accepted for Ceded Review and, if accepted, the designation of the Reviewing IRB and Relying Institutions. This can be accomplished through the SMART IRB Online Reliance System or another mechanism. ☐ **OPTION 2 – Another party will provide notification** [NAME OF NOTIFYING PARTY (e.g., the Lead Study Team or a Relying Institution)] will notify the Overall PI and the Site Investigator(s) and involved Participating Institution(s) whether the identified study(ies) is accepted for Ceded Review and, if accepted, the designation of the Reviewing IRB and Relying Institutions. ☐ **OPTION 3 – Requirements/processes for determining the Reviewing IRB are mandated by an external group with authority for the study(ies)**

www.smartirb.org

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

Getting Started as a Reviewing IRB

Identify the Standard Operating Procedures that Will Apply

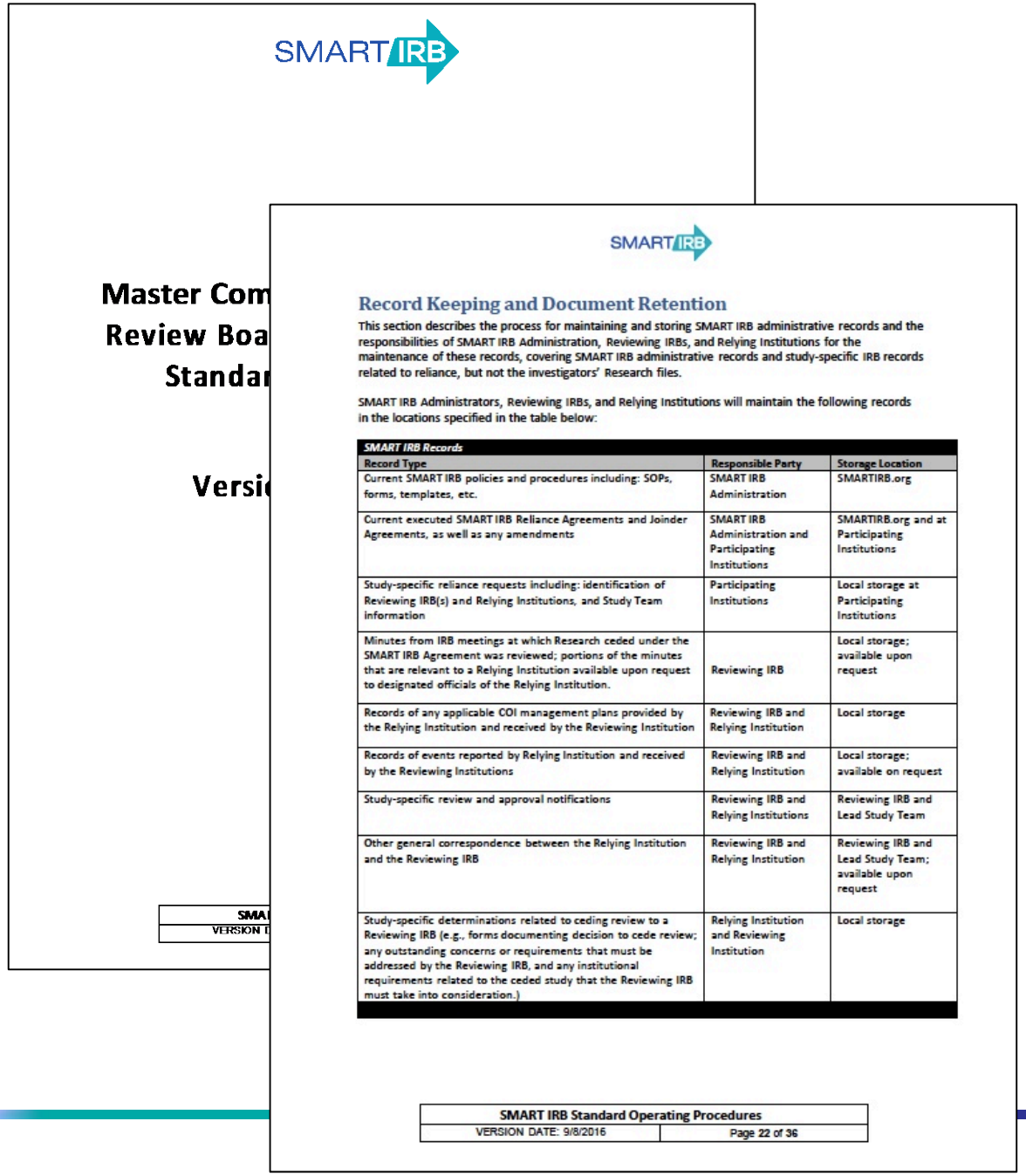
- SMART IRB developed SOPs to support implementation of the SMART IRB Agreement and to outline study team responsibilities.
- SMART IRB SOPs are not required.
- If the Reviewing IRB does not use SMART IRB SOPs, it must identify which SOPs it will use.

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]



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SMART IRB

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:

SMART IRB Records		
Record Type	**Responsible Party**	**Storage Location**
Current SMART IRB policies and procedures including: SOPs, forms, templates, etc.	SMART IRB Administration	SMARTIRB.org
Current executed SMART IRB Reliance Agreements and Joinder Agreements, as well as any amendments	SMART IRB Administration and Participating Institutions	SMARTIRB.org and at Participating Institutions
Study-specific reliance requests including: identification of Reviewing IRB(s) and Relying Institutions, and Study Team information	Participating Institutions	Local storage at Participating Institutions
Minutes from IRB meetings at which Research ceded under the SMART IRB Agreement was reviewed; portions of the minutes that are relevant to a Relying Institution available upon request to designated officials of the Relying Institution.	Reviewing IRB	Local storage; available upon request
Records of any applicable COI management plans provided by the Relying Institution and received by the Reviewing Institution	Reviewing IRB and Relying Institution	Local storage
Records of events reported by Relying Institution and received by the Reviewing Institutions	Reviewing IRB and Relying Institution	Local storage; available on request
Study-specific review and approval notifications	Reviewing IRB and Relying Institutions	Reviewing IRB and Lead Study Team
Other general correspondence between the Relying Institution and the Reviewing IRB	Reviewing IRB and Relying Institution	Reviewing IRB and Lead Study Team; available upon request
Study-specific determinations related to ceding review to a Reviewing IRB (e.g., forms documenting decision to cede review; any outstanding concerns or requirements that must be addressed by the Reviewing IRB, and any institutional requirements related to the ceded study that the Reviewing IRB must take into consideration.)	Relying Institution and Reviewing Institution	Local storage

SMART IRB Standard Operating Procedures
VERSION DATE: 9/8/2016 | Page 22 of 36

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

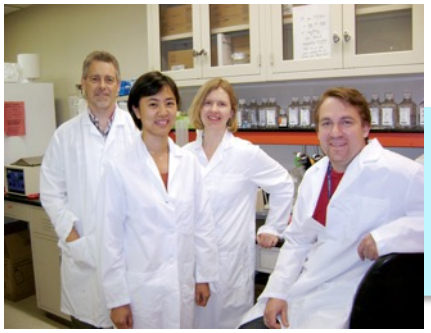
Lead Study Team

- **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)

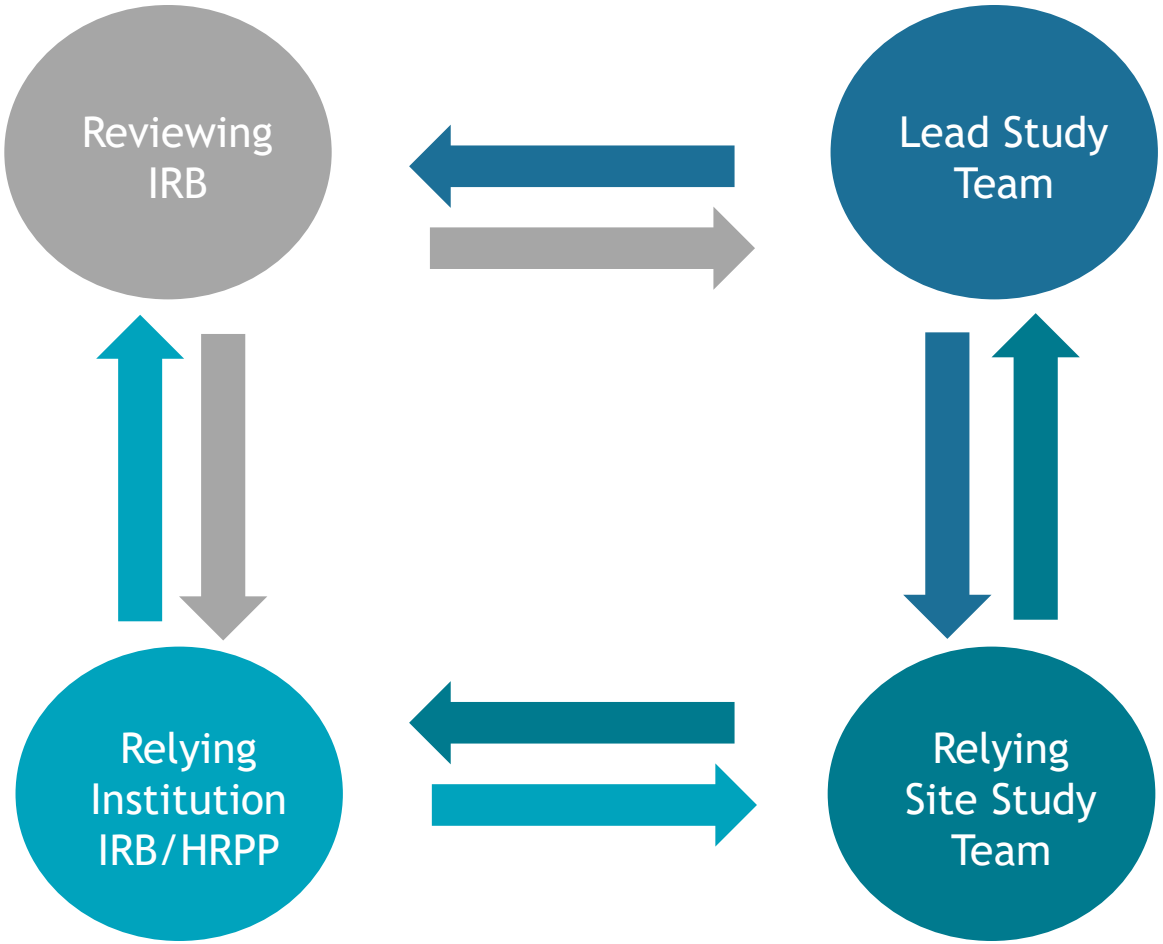
Provide Lead Study Team information about study progress for continuing review and local events (e.g., unanticipated problems, noncompliance) so that it can be reported to the Reviewing IRB

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

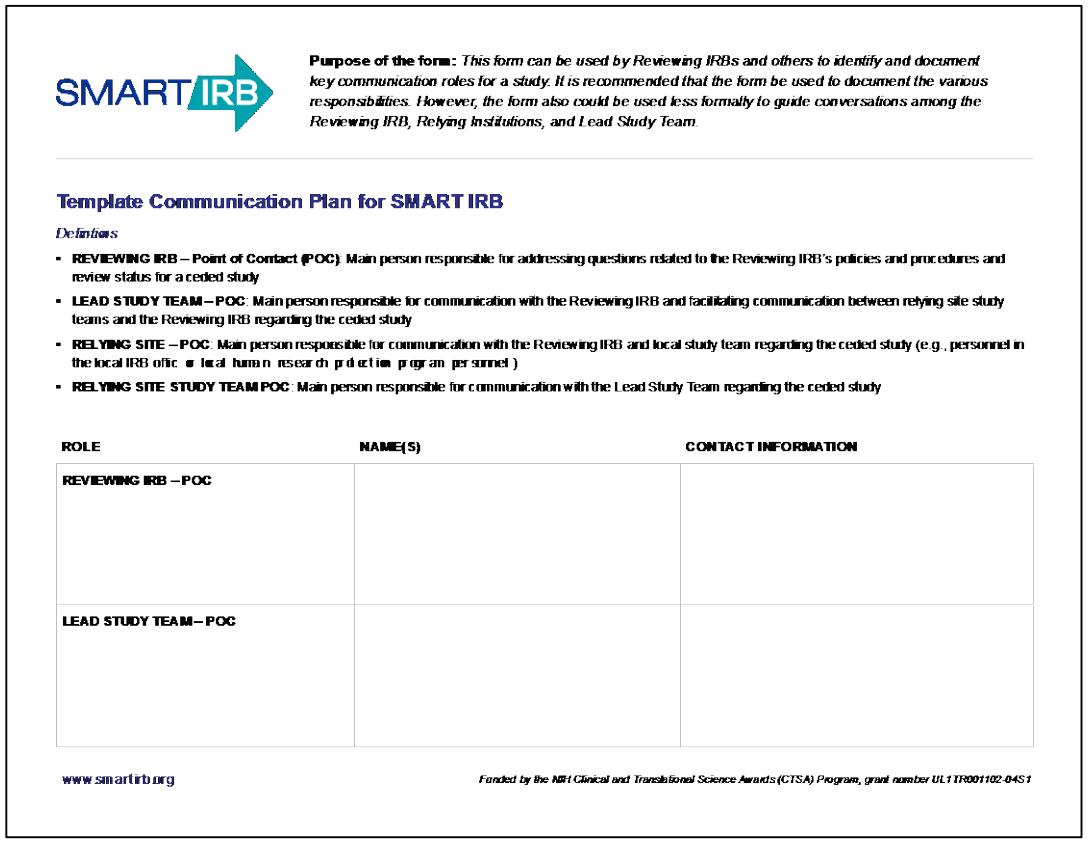


Communication plan for single IRB review

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.



SMART IRB

Purpose of the form: *This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team.*

Template Communication Plan for SMART IRB

Definitions

- **REVIEWING IRB – Point of Contact (POC)**: Main person responsible for addressing questions related to the Reviewing IRB's policies and procedures and review status for a ceded study
- **LEAD STUDY TEAM – POC**: Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
- **RELYING SITE – POC**: Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
- **RELYING SITE STUDY TEAM POC**: Main person responsible for communication with the Lead Study Team regarding the ceded study

ROLE	NAME(S)	CONTACT INFORMATION
REVIEWING IRB – POC		
LEAD STUDY TEAM – POC		

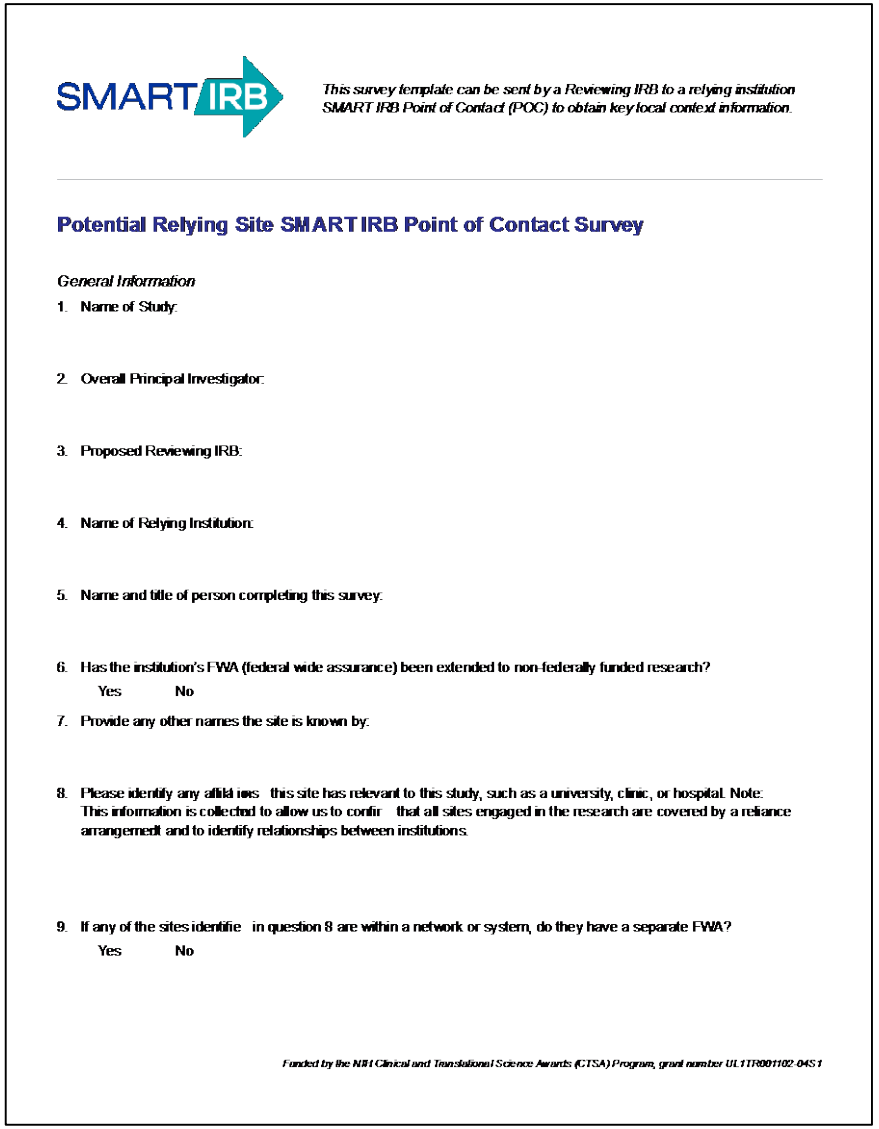
www.smartirb.org

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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



SMART IRB

This survey template can be sent by a Reviewing IRB to a relying institution SMART IRB Point of Contact (POC) to obtain key local context information.

Potential Relying Site SMART IRB Point of Contact Survey

General Information

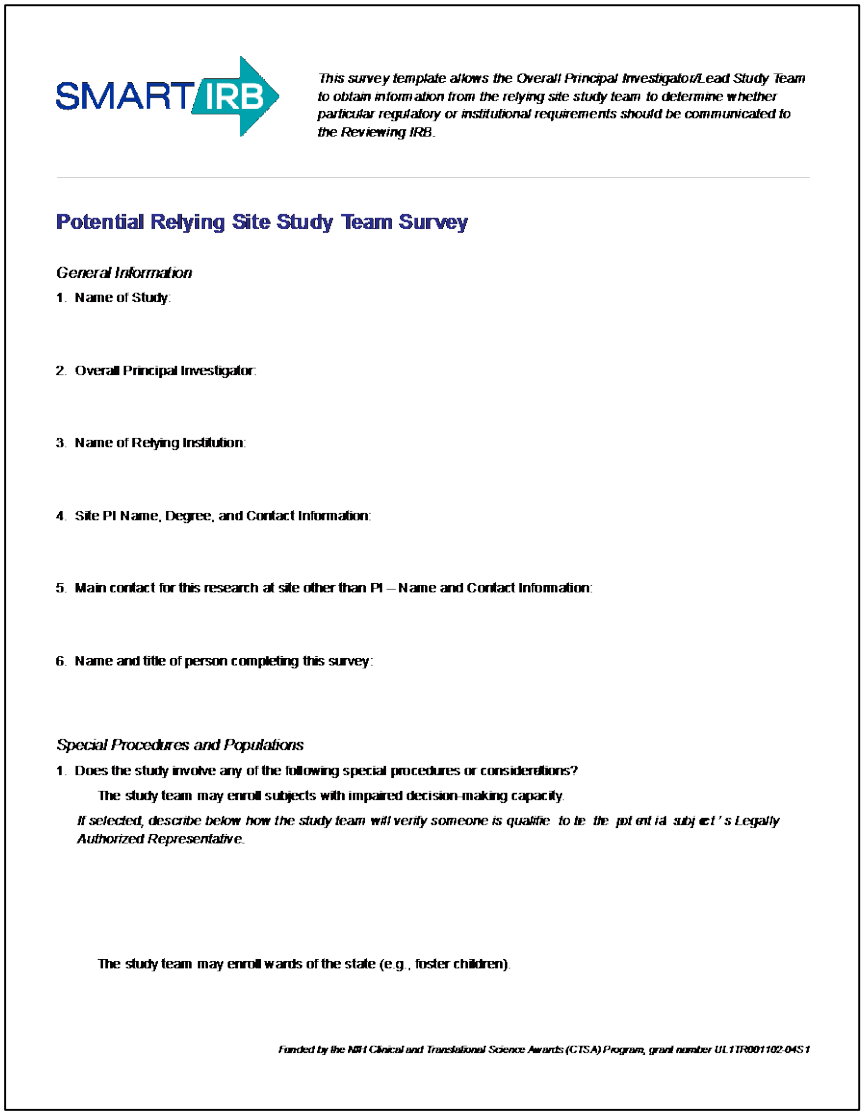
1. Name of Study:
2. Overall Principal Investigator:
3. Proposed Reviewing IRB:
4. Name of Relying Institution:
5. Name and title of person completing this survey:
6. Has the institution's FWA (federal wide assurance) been extended to non-federally funded research?
   Yes No
7. Provide any other names the site is known by:
8. Please identify any affiliations this site has relevant to this study, such as a university, clinic, or hospital. Note: This information is collected to allow us to confirm that all sites engaged in the research are covered by a reliance arrangement and to identify relationships between institutions.
9. If any of the sites identified in question 8 are within a network or system, do they have a separate FWA?
   Yes No

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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



SMART IRB

This survey template allows the Overall Principal Investigator/Lead Study Team to obtain information from the relying site study team to determine whether particular regulatory or institutional requirements should be communicated to the Reviewing IRB.

Potential Relying Site Study Team Survey

General Information

1. Name of Study:

2. Overall Principal Investigator:

3. Name of Relying Institution:

4. Site PI Name, Degree, and Contact Information:

5. Main contact for this research at site other than PI – Name and Contact Information:

6. Name and title of person completing this survey:

Special Procedures and Populations

1. Does the study involve any of the following special procedures or considerations?

The study team may enroll subjects with impaired decision-making capacity.

If selected, describe below how the study team will verify someone is qualified to be the potential subject's Legally Authorized Representative.

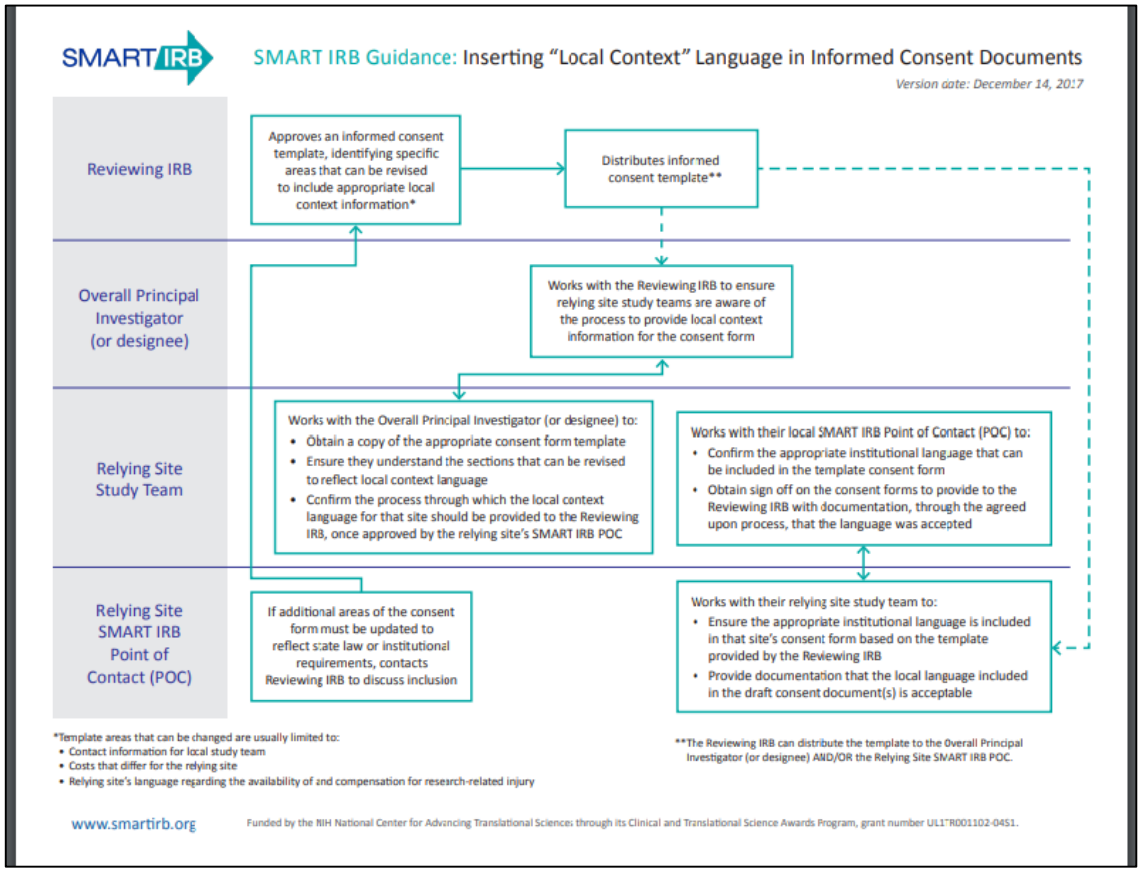
The study team may enroll wards of the state (e.g., foster children).

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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

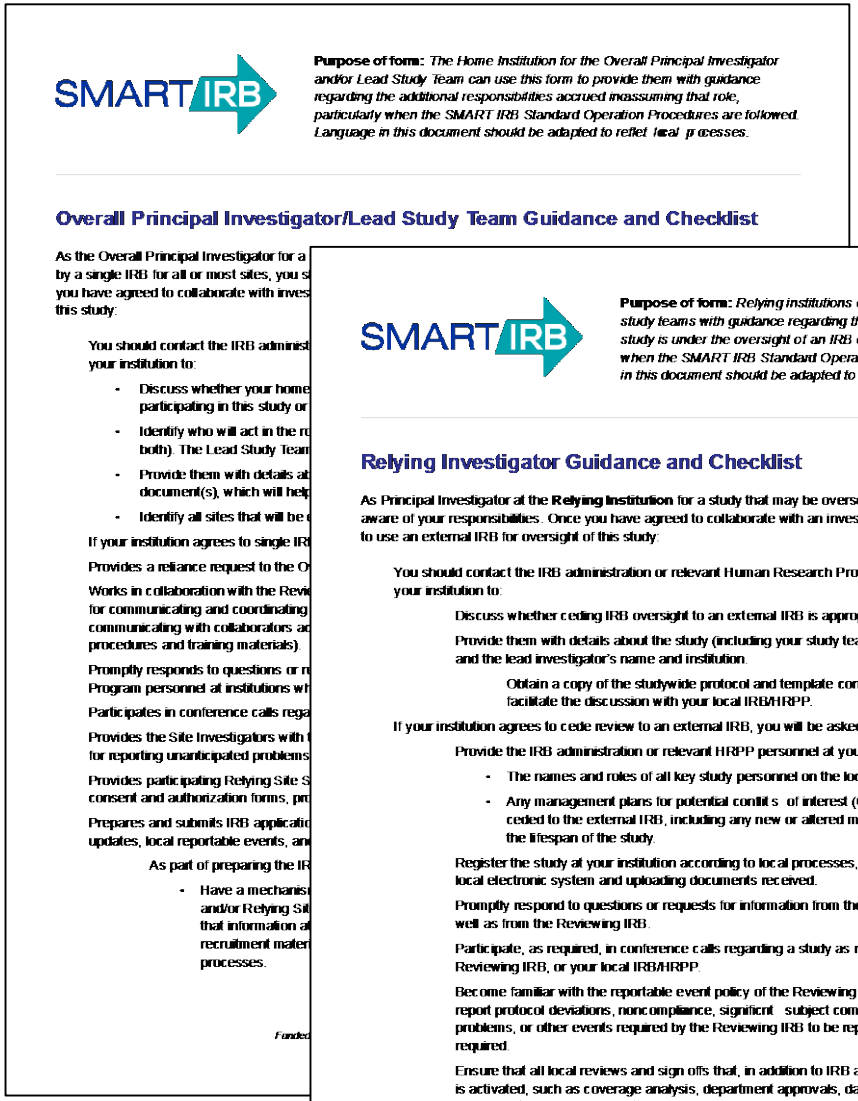
Investigator Checklists

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



SMART IRB

Purpose of form: *The Home Institution for the Overall Principal Investigator and/or Lead Study Team can use this form to provide them with guidance regarding the additional responsibilities accrued in assuming that role, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes.*

Overall Principal Investigator/Lead Study Team Guidance and Checklist

As the Overall Principal Investigator for a

by a single IRB for all or most sites, you s

you have agreed to collaborate with inves

this study:

You should contact the IRB administ

your institution to:

- Discuss whether your home
participating in this study or
- Identify who will act in the r
both). The Lead Study Tean
- Provide them with details a
document(s), which will hel
- Identify all sites that will be

If your institution agrees to single IR

Provides a reliance request to the O

Works in collaboration with the Revi

for communicating and coordinating

communicating with collaborators a

procedures and training materials).

Promptly responds to questions or r

Program personnel at institutions w

Participates in conference calls rega

Provides the Site Investigators with

for reporting unanticipated problems

Provides participating Relying Site S

consent and authorization forms, pr

Prepares and submits IRB applicati

updates, local reportable events, an

As part of preparing the IR

- Have a mechanis
and/or Relying Si
that information a
recruitment mate
processes.

Funded

SMART IRB

Purpose of form: *Relying institutions can use this form to provide their local study teams with guidance regarding the investigator's responsibilities when a study is under the oversight of an IRB external to their institution, particularly when the SMART IRB Standard Operation Procedures are followed. Language in this document should be adapted to reflect local processes.*

Relying Investigator Guidance and Checklist

As Principal Investigator at the **Relying Institution** for a study that may be overseen by an external IRB, you should be aware of your responsibilities. Once you have agreed to collaborate with an investigator at another institution and intend to use an external IRB for oversight of this study:

You should contact the IRB administration or relevant Human Research Protection Program (HRPP) personnel at your institution to:

Discuss whether ceding IRB oversight to an external IRB is appropriate.

Provide them with details about the study (including your study team's role), the proposed reviewing IRB, and the lead investigator's name and institution.

Obtain a copy of the studywide protocol and template consent documents(s), which will help facilitate the discussion with your local IRB/HRPP.

If your institution agrees to cede review to an external IRB, you will be asked to:

Provide the IRB administration or relevant HRPP personnel at your institution with:

- The names and roles of all key study personnel on the local study team
- Any management plans for potential conflicts of interest (COI) relevant to the study that will be ceded to the external IRB, including any new or altered management plans put in place throughout the lifespan of the study.

Register the study at your institution according to local processes, such as creating a shell study in the local electronic system and uploading documents received.

Promptly respond to questions or requests for information from the Lead Study Team (or their designee) as well as from the Reviewing IRB.

Participate, as required, in conference calls regarding a study as requested by the Lead Study Team, Reviewing IRB, or your local IRB/HRPP.

Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required.

Ensure that all local reviews and sign offs that, in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).

Work with the Lead Study Team and the IRB/HRPP POC from your institution to incorporate locally required language into the consent template to be used by the local study team, such as institutionally required compensation for injury language, local study team contact information, and additional costs that subjects may incur that differ from those identified in the template consent form.

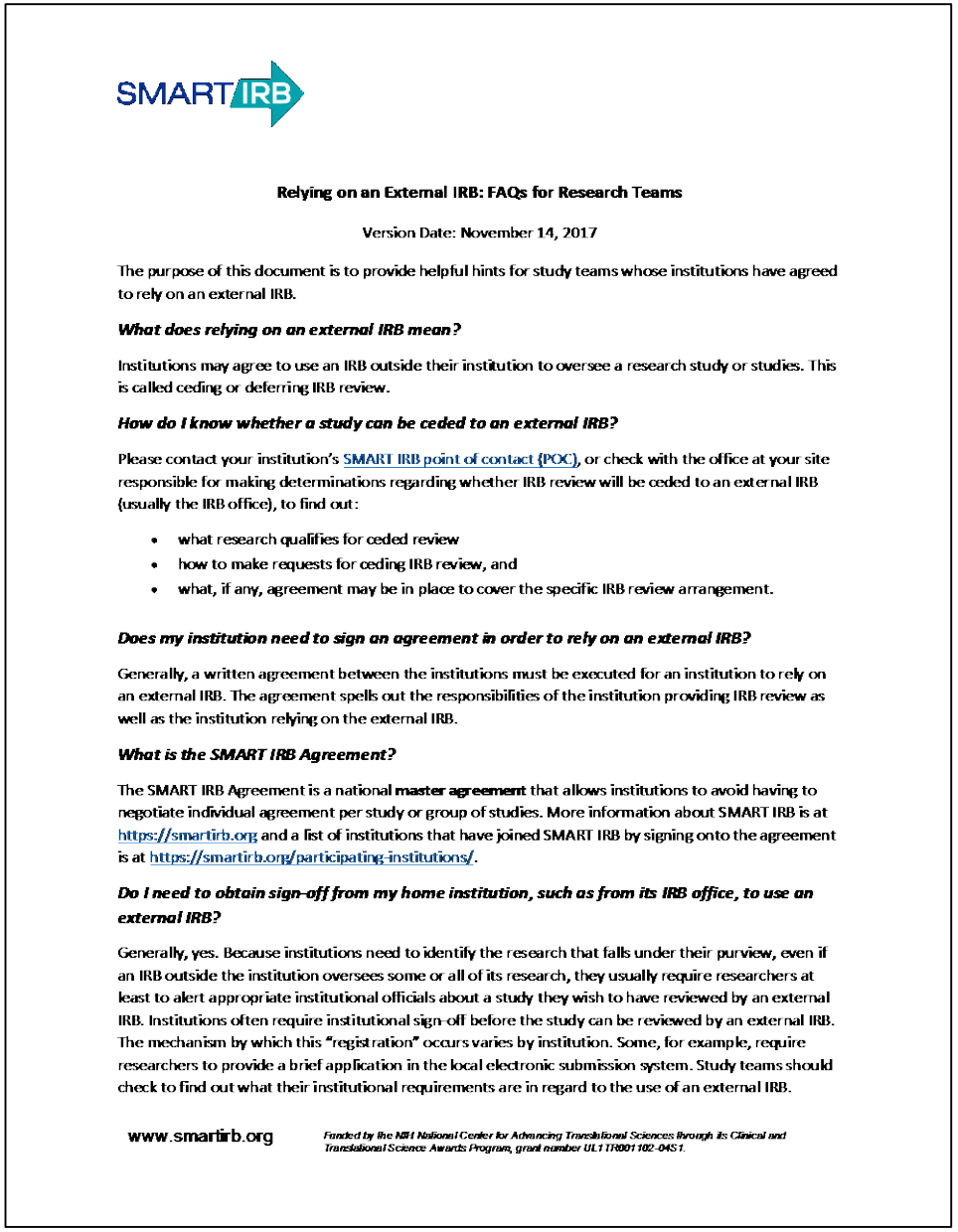
For externally funded studies, provide your sponsored programs office with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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.



SMART 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://smartirb.org and a list of institutions that have joined SMART IRB by signing onto the agreement is at https://smartirb.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?

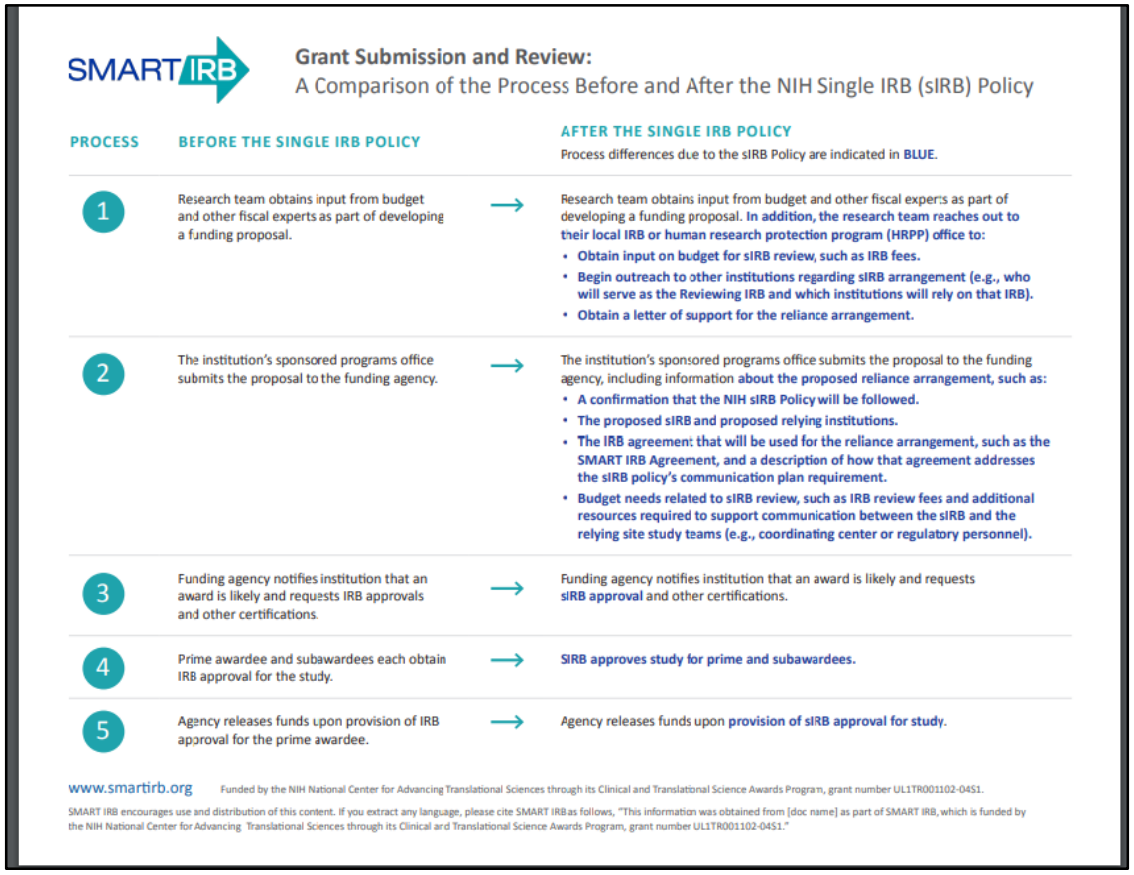
Generally, yes. Because institutions need to identify the research that falls under their purview, even if an IRB outside the institution oversees some or all of its research, they usually require researchers at least to alert appropriate institutional officials about a study they wish to have reviewed 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.smartirb.org

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

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.



SMART IRB

Grant Submission and Review:
A Comparison of the Process Before and After the NIH Single IRB (sIRB) Policy

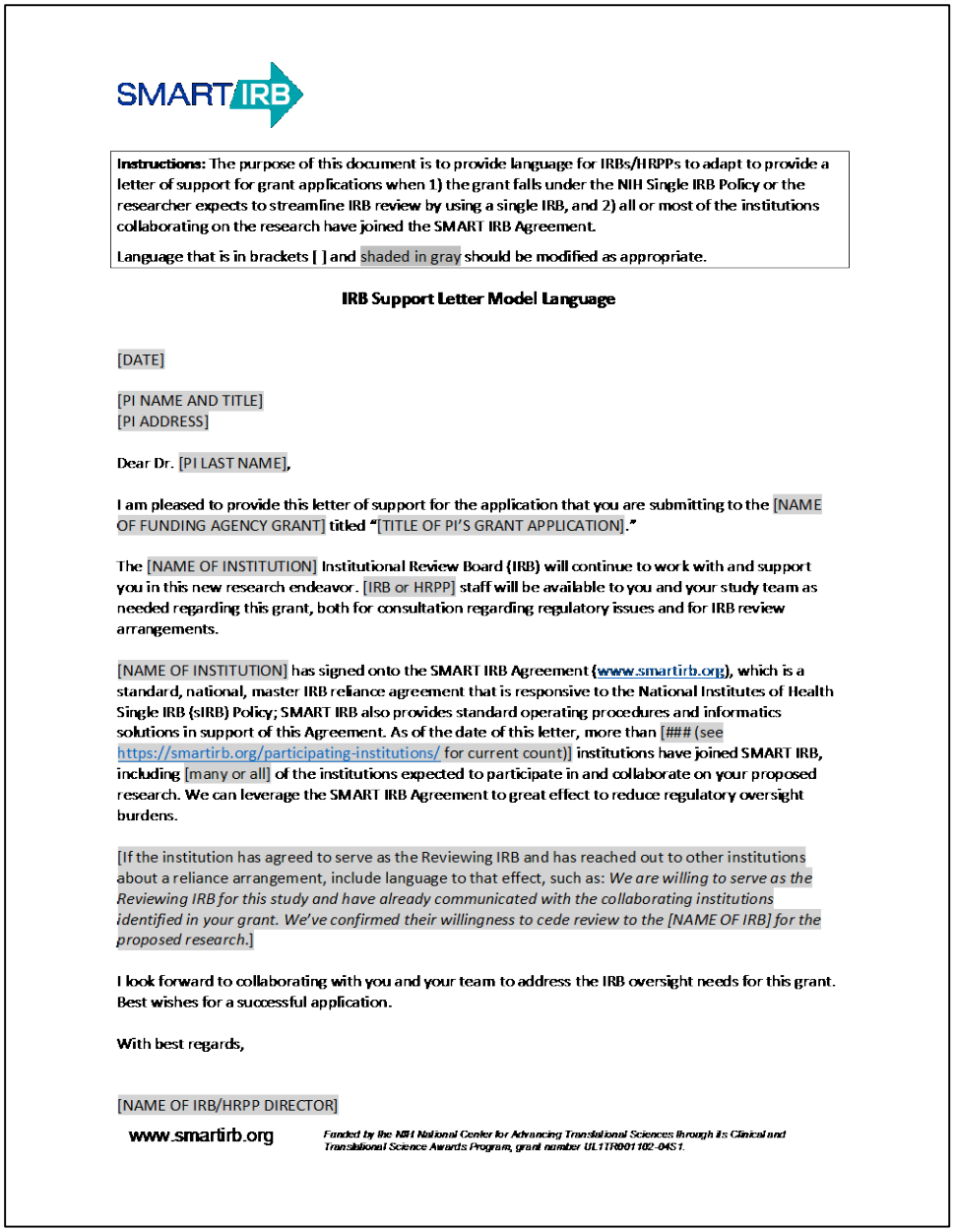
PROCESS	BEFORE THE SINGLE IRB POLICY		AFTER THE SINGLE IRB POLICY Process differences due to the sIRB Policy are indicated in **BLUE**.
1	Research team obtains input from budget and other fiscal experts as part of developing a funding proposal.	→	Research team obtains input from budget and other fiscal experts as part of developing a funding proposal. **In addition, the research team reaches out to their local IRB or human research protection program (HRPP) office to:** • **Obtain input on budget for sIRB review, such as IRB fees.** • **Begin outreach to other institutions regarding sIRB arrangement (e.g., who will serve as the Reviewing IRB and which institutions will rely on that IRB).** • **Obtain a letter of support for the reliance arrangement.**
2	The institution's sponsored programs office submits the proposal to the funding agency.	→	The institution's sponsored programs office submits the proposal to the funding agency, including information **about the proposed reliance arrangement, such as:** • **A confirmation that the NIH sIRB Policy will be followed.** • **The proposed sIRB and proposed relying institutions.** • **The IRB agreement that will be used for the reliance arrangement, such as the SMART IRB Agreement, and a description of how that agreement addresses the sIRB policy's communication plan requirement.** • **Budget needs related to sIRB review, such as IRB review fees and additional resources required to support communication between the sIRB and the relying site study teams (e.g., coordinating center or regulatory personnel).**
3	Funding agency notifies institution that an award is likely and requests IRB approvals and other certifications.	→	Funding agency notifies institution that an award is likely and requests **sIRB approval** and other certifications.
4	Prime awardee and subawardees each obtain IRB approval for the study.	→	**SIRB approves study for prime and subawardees.**
5	Agency releases funds upon provision of IRB approval for the prime awardee.	→	Agency releases funds upon **provision of sIRB approval for study.**

www.smartirb.org

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

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

[DATE]

[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 [### (see https://smartirb.org/participating-institutions/ for current 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 cede 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,

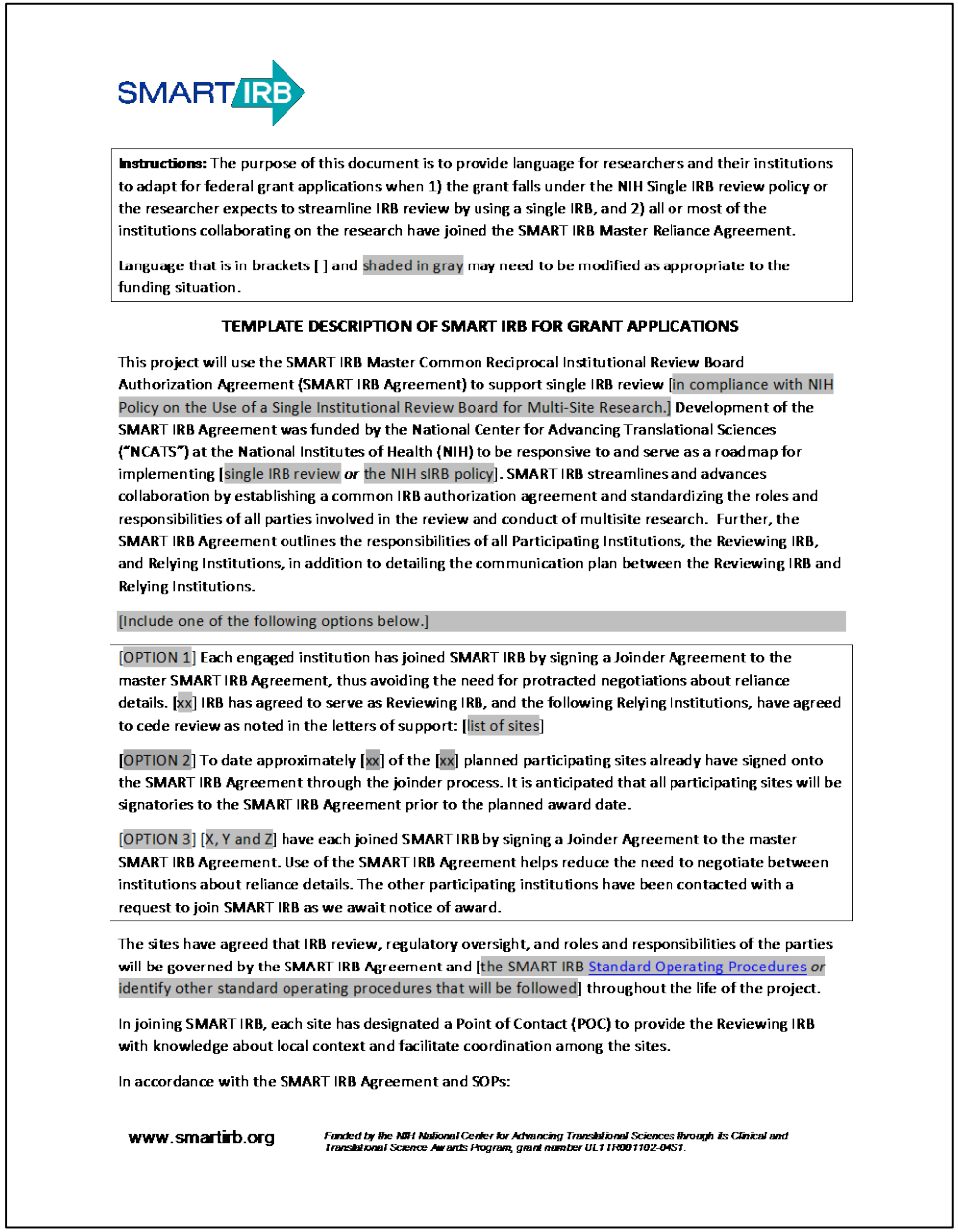
[NAME OF IRB/HRPP DIRECTOR]

www.smartirb.org

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

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 responsive to and serve as a roadmap for implementing [single IRB review *or* the NIH sIRB 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 engaged institution has joined SMART IRB by signing a Joinder Agreement to the master SMART IRB Agreement, thus avoiding the need for protracted negotiations about reliance details. [xx] IRB has agreed to serve as Reviewing IRB, and the following Relying Institutions, have agreed to cede review as noted in the letters of support: [list of sites]

[OPTION 2] To date approximately [xx] of the [xx] planned participating sites already have signed onto the SMART IRB Agreement through the joinder 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 Joinder 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.

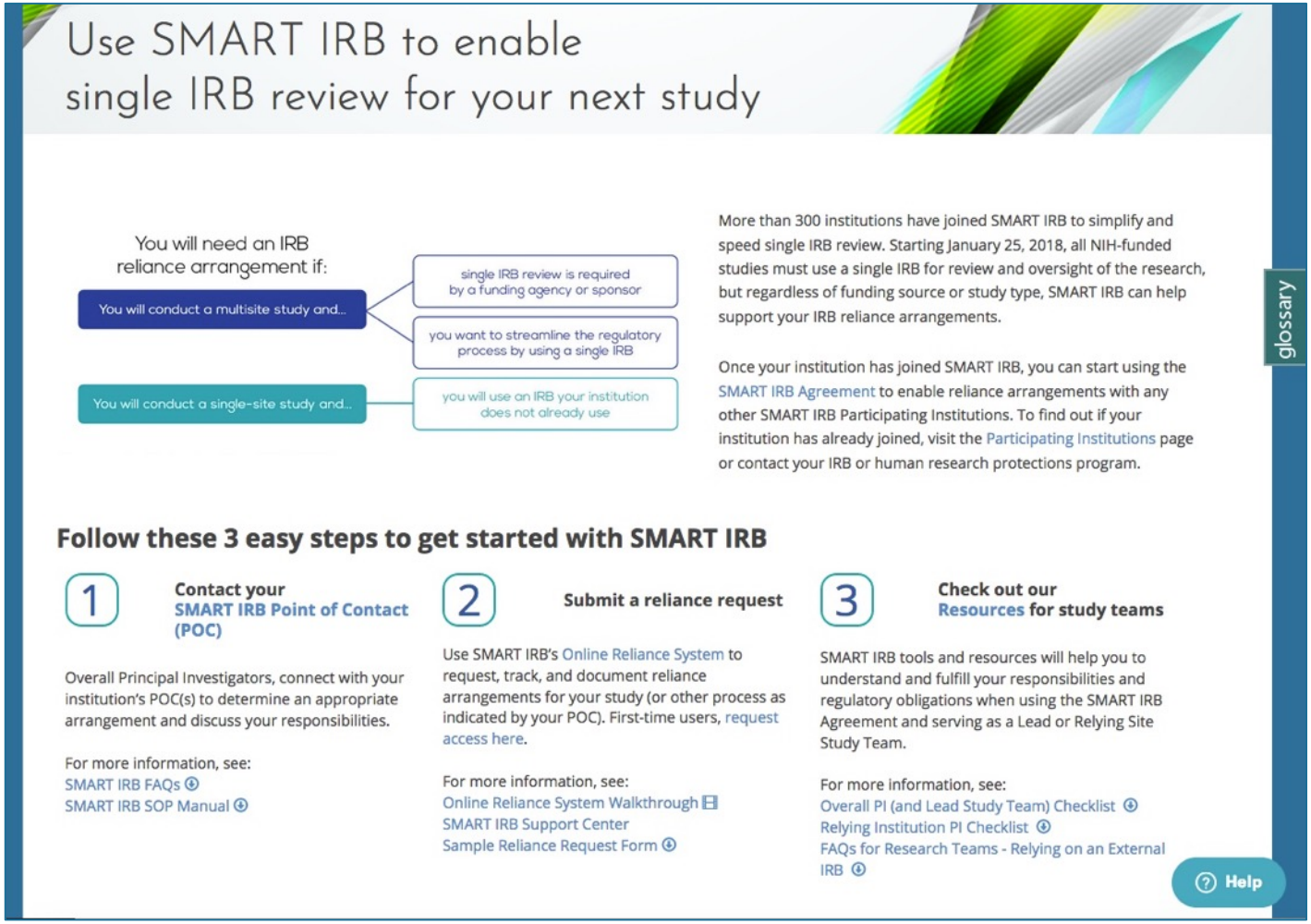
In joining SMART IRB, each site has designated a Point of Contact (POC) to provide the Reviewing IRB with knowledge about local context and facilitate coordination among the sites.

In accordance with the SMART IRB Agreement and SOPs:

www.smartirb.org

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

Investigator Guidance at smartirb.org/go



Getting Help from the SMART IRB Team

We're Here to Help

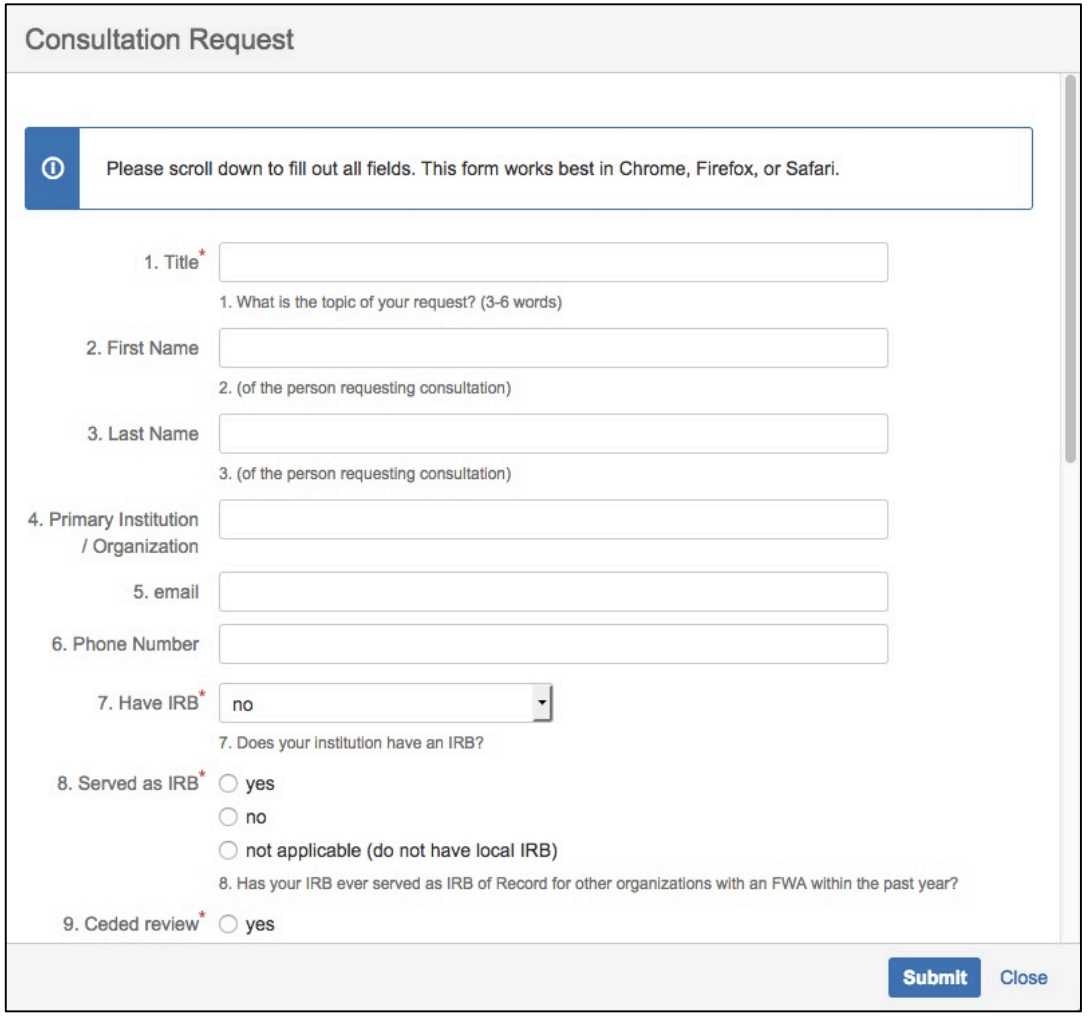
- Contact an Ambassador for help joining and implement SMART IRB.
- Search the Support Center for answers to frequently asked questions.
- Subscribe to the SMART IRB Mailing List for updates and new resource announcements.
- Contact help@smartirb.org - we'll get back to you as soon as possible.

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

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