SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-01S1.

What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when participants register

Open and free to anyone with interest

Upcoming sessions

- July: Single IRB and the Review of Research Involving Children
- Updates on SMART IRB Harmonization Efforts – QA/QI, Continuing Review
- Future: NIH's Approach to the Implementation of the NIH Single IRB policy

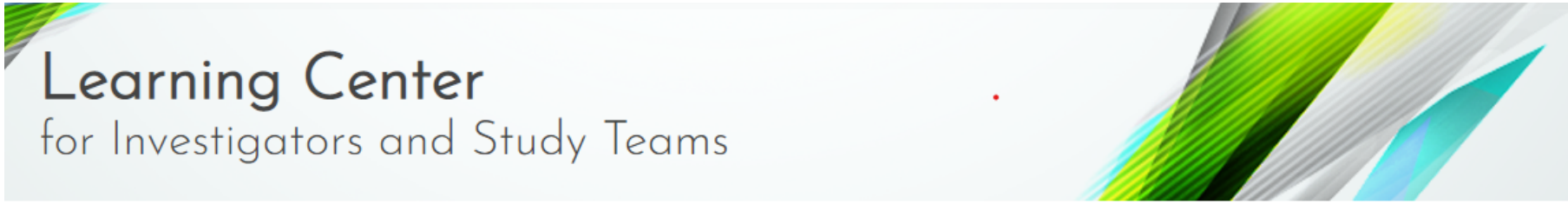
FYIs

A recording of this talk will be posted on the SMART IRB website

A link to the talk will be sent to those who registered for the talk when it is posted

If you have any questions for the panelists, please use the chat function to submit them

New SMART IRB Resource



The videos and companion resources below are designed to help investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies. Questions about local processes and policies are best addressed by your institution's SMART IRB Point of Contact.

- Introduction to Single IRB Review and SMART IRB
- Overview of the NIH Single IRB Policy
- Selecting a Single IRB
- Developing a Single IRB Plan
- Potential Effects of NIH Single IRB Policy on Research Costs
- Study Team Roles Related to Single IRB
- Using the SMART IRB Online Reliance System

On-demand, short videos and key resources aid in planning and implementation of single IRB arrangements.

https://smartirb.org/study-teams/

Coming Soon: Downloadable Start Up Packages

Start-up Package for Study Teams

These resources will help you understand your roles and responsibilities related to single IRB review, including when you are part of a Lead Study Team. See also the **Start-up Package for NIH Grant Preparation.**

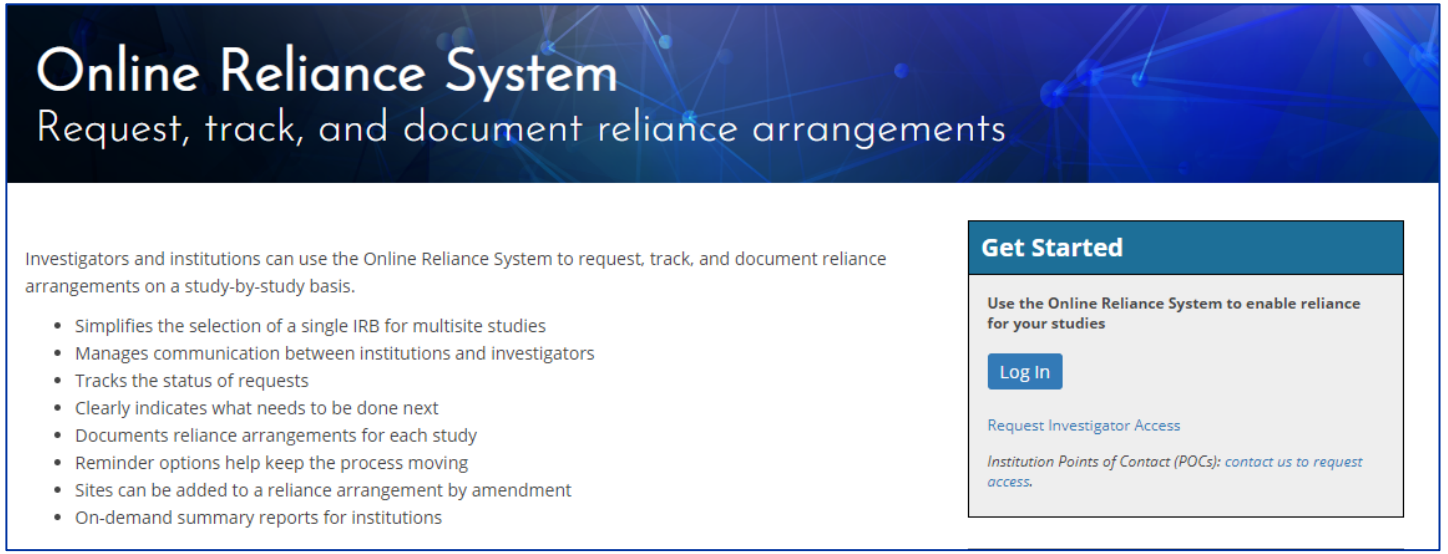
When to use? When you are . . .	What?	Why?
Identifying a Reviewing IRB and requesting a reliance arrangement	FAQs for Research Teams - Relying on an External IRB	Helpful hints for when your institution relies on an external IRB.
Understanding study team responsibilities related to Single IRB	Overall PI (and Lead Study Team) Checklist	Helps an Overall PI (and Lead Study Team, where applicable) understand and fulfill their responsibilities under single IRB review.
	Relying Site Investigator Checklist	Helps site investigators and study teams understand and fulfill their responsibilities when a study has been ceded to an external institution.
	Communication Plan for Single IRB Review	Helps IRBs, relying institutions, and study teams identify and assign key communication responsibilities for studies using a Single IRB.
Requesting and tracking single IRB arrangements	SMART IRB Online Reliance System	Allows study teams to work with their home institutions to propose a Single IRB arrangement.
Collecting and providing information for IRB review	Relying Site Study Team Survey	The Overall PI/Lead Study Team may use this tool to obtain key information from relying site study teams and determine whether particular regulatory or institutional requirements should be communicated to the Reviewing IRB.
	Informed Consent Documents: Inserting Local Context Language	Provides guidance to IRBs, relying institutions, and study teams regarding the different roles that may be involved in inserting local context language in informed consent documents.

Learn more by watching the videos in the SMART IRB Learning Center

SMART IRB
Online Reliance System

Helps investigators and institutions request, track, and document reliance arrangements for each study.

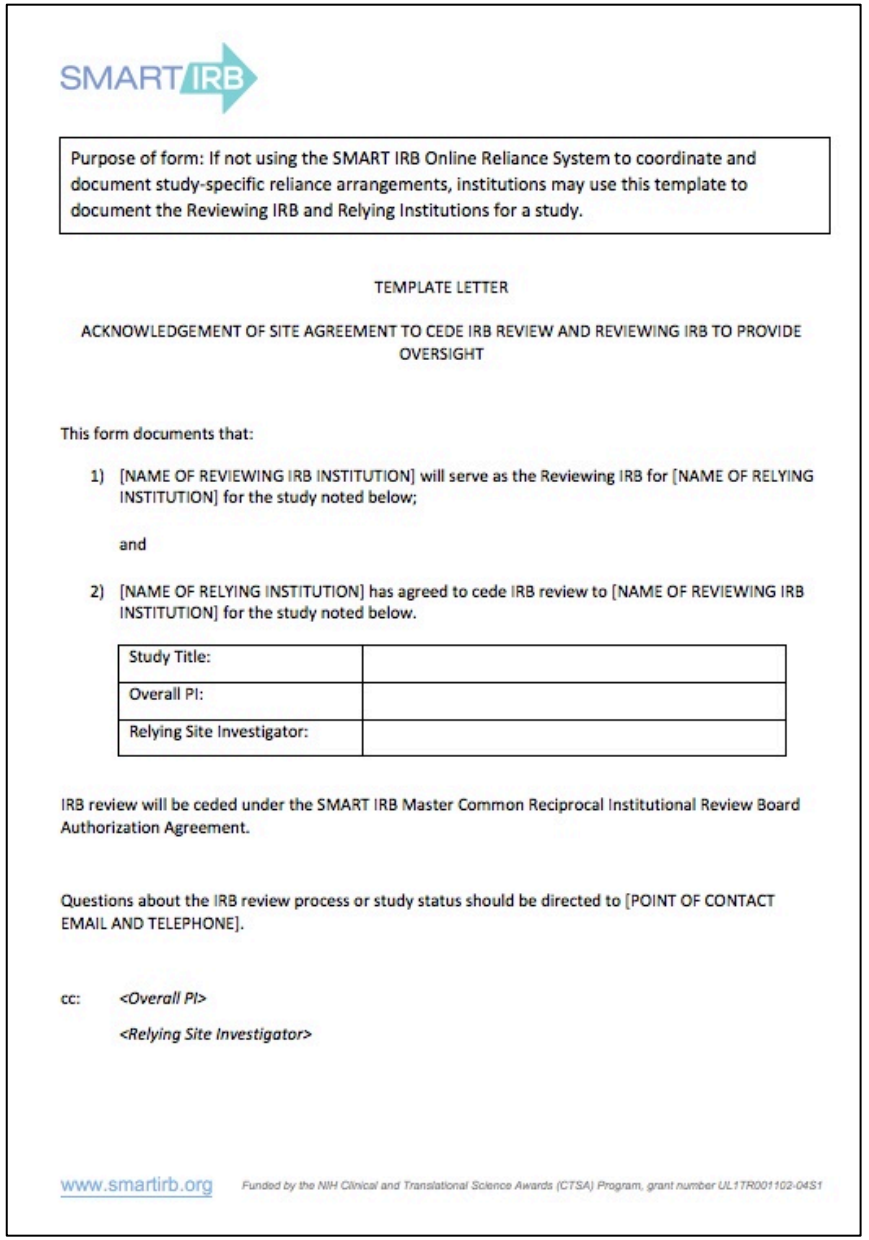
https://smartirb.org/reliance/



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.

https://smartirb.org/assets/files/Template_Letter_of_Acknowledgement.docx



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>*

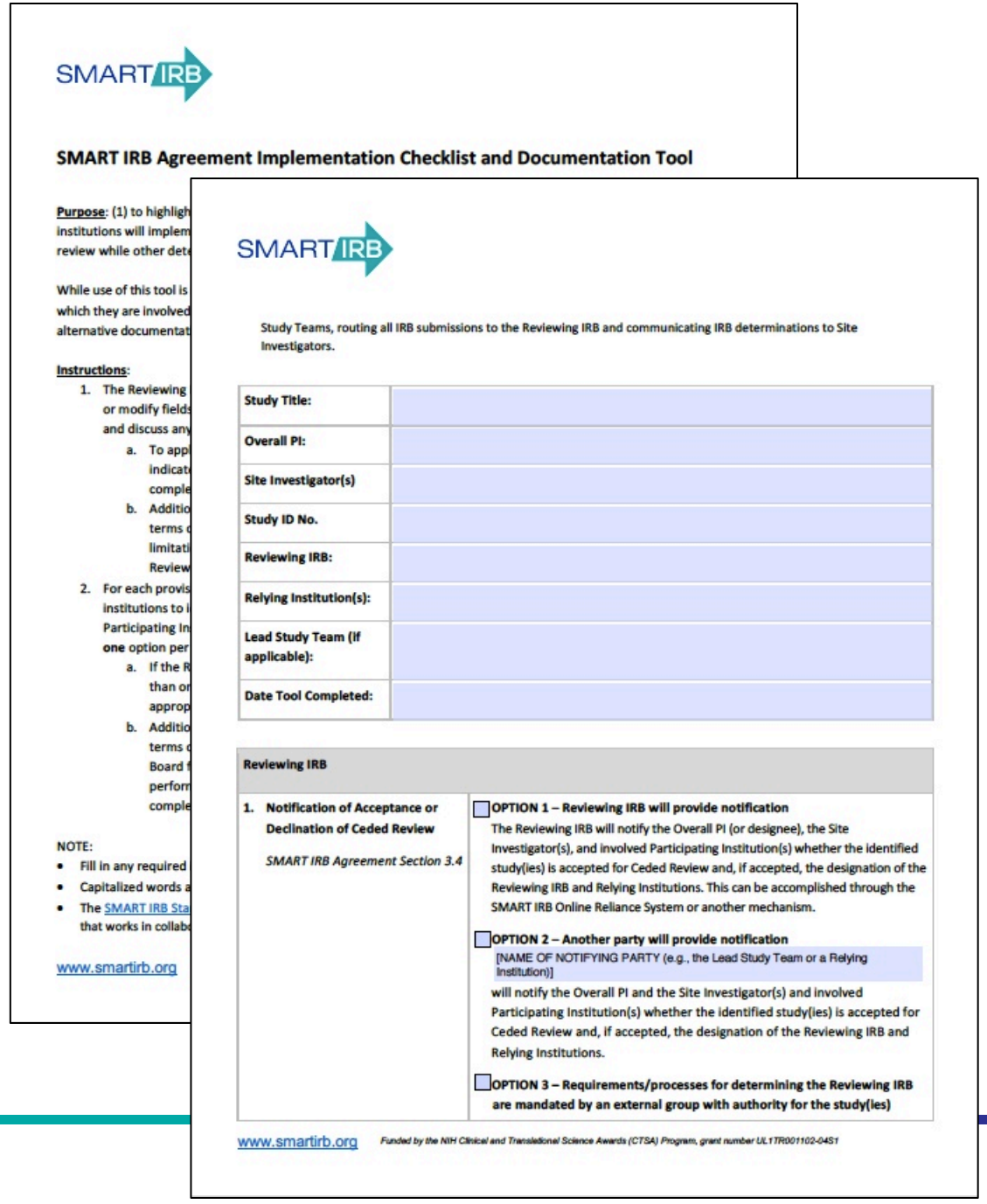
<Relying Site Investigator>

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

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.

https://smartirb.org/assets/files/SMART_IRB_Agreement_Implementation_Checklist_FORM.pdf



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
   perfor
   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)**

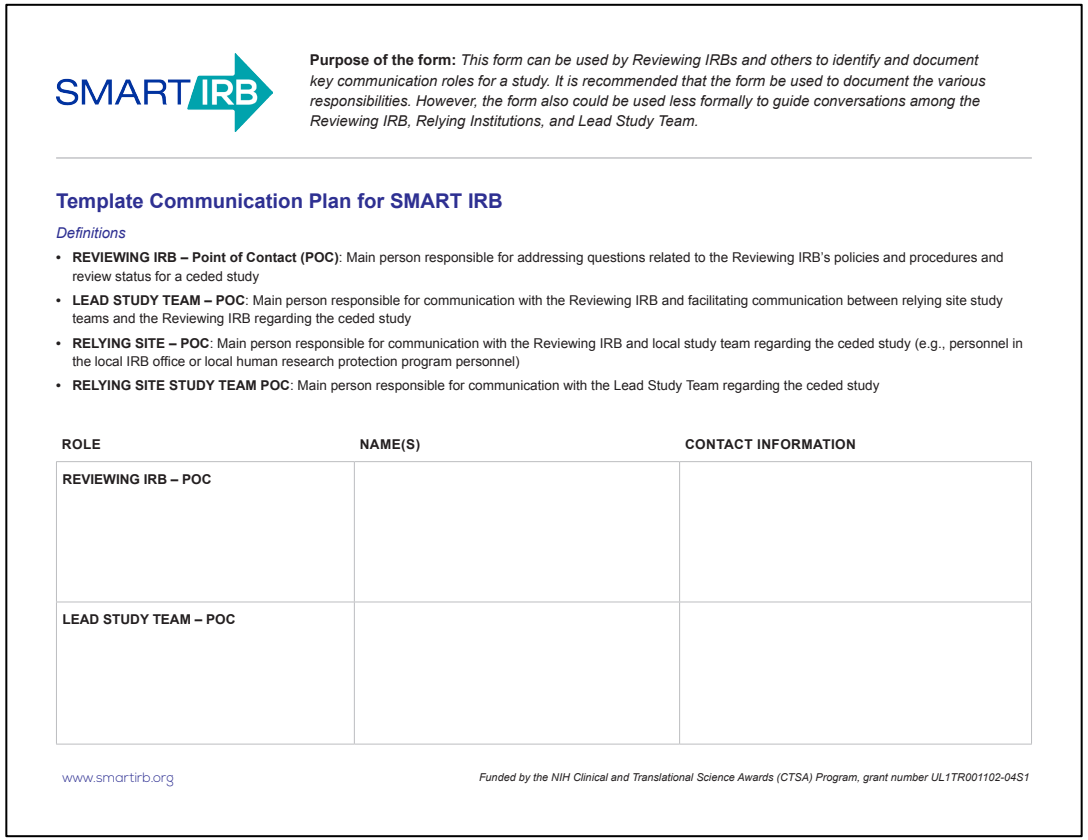
www.smartirb.org

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

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.

https://smartirb.org/assets/files/Communications_Plan_Form.pdf



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		

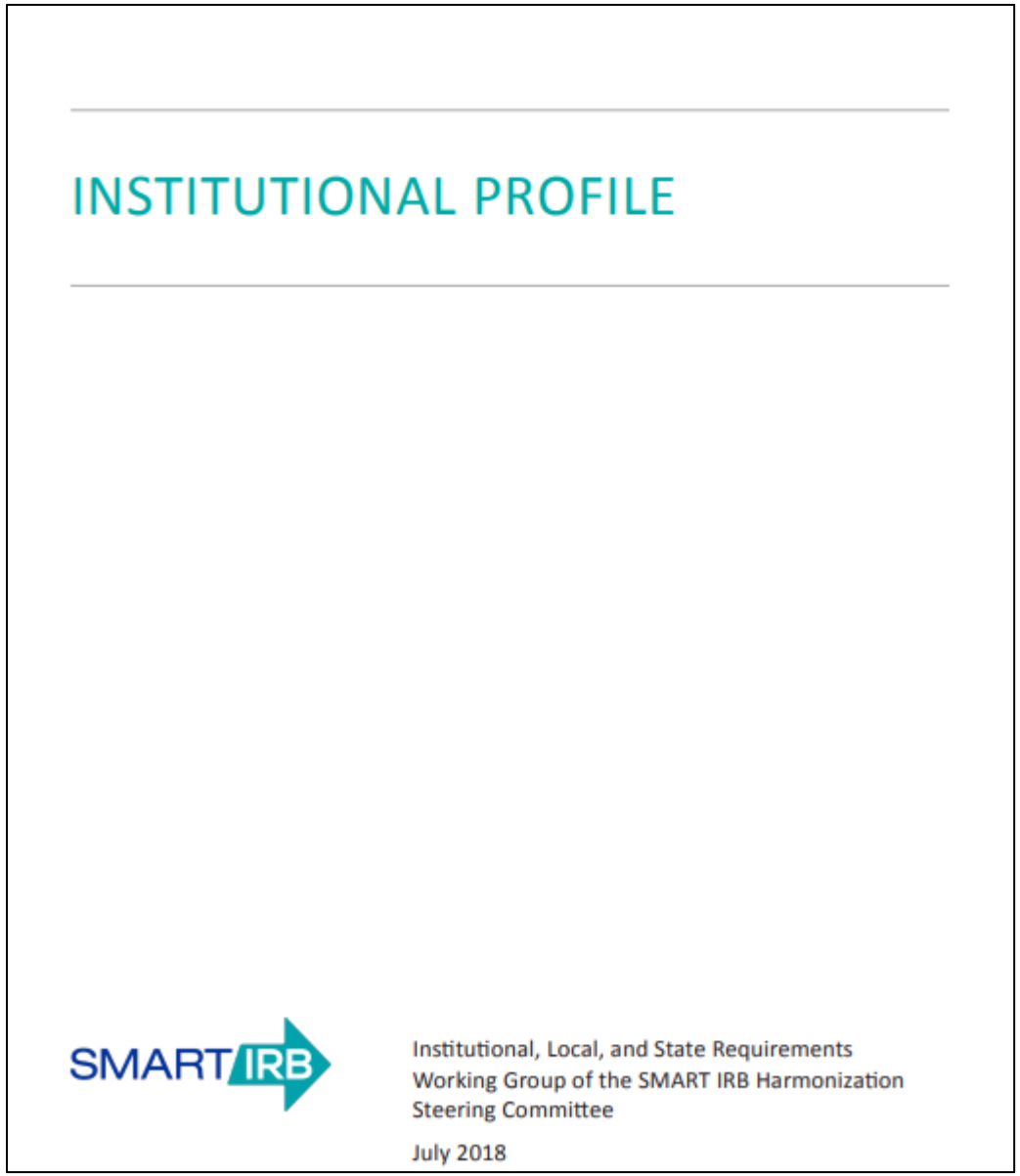
www.smartirb.org

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

Institutional Profile

Captures institutional, local, and state requirements that a Reviewing IRB may need to apply to its review and oversight of studies on behalf of another institution as well as information about an institution's IRB(s), if applicable.

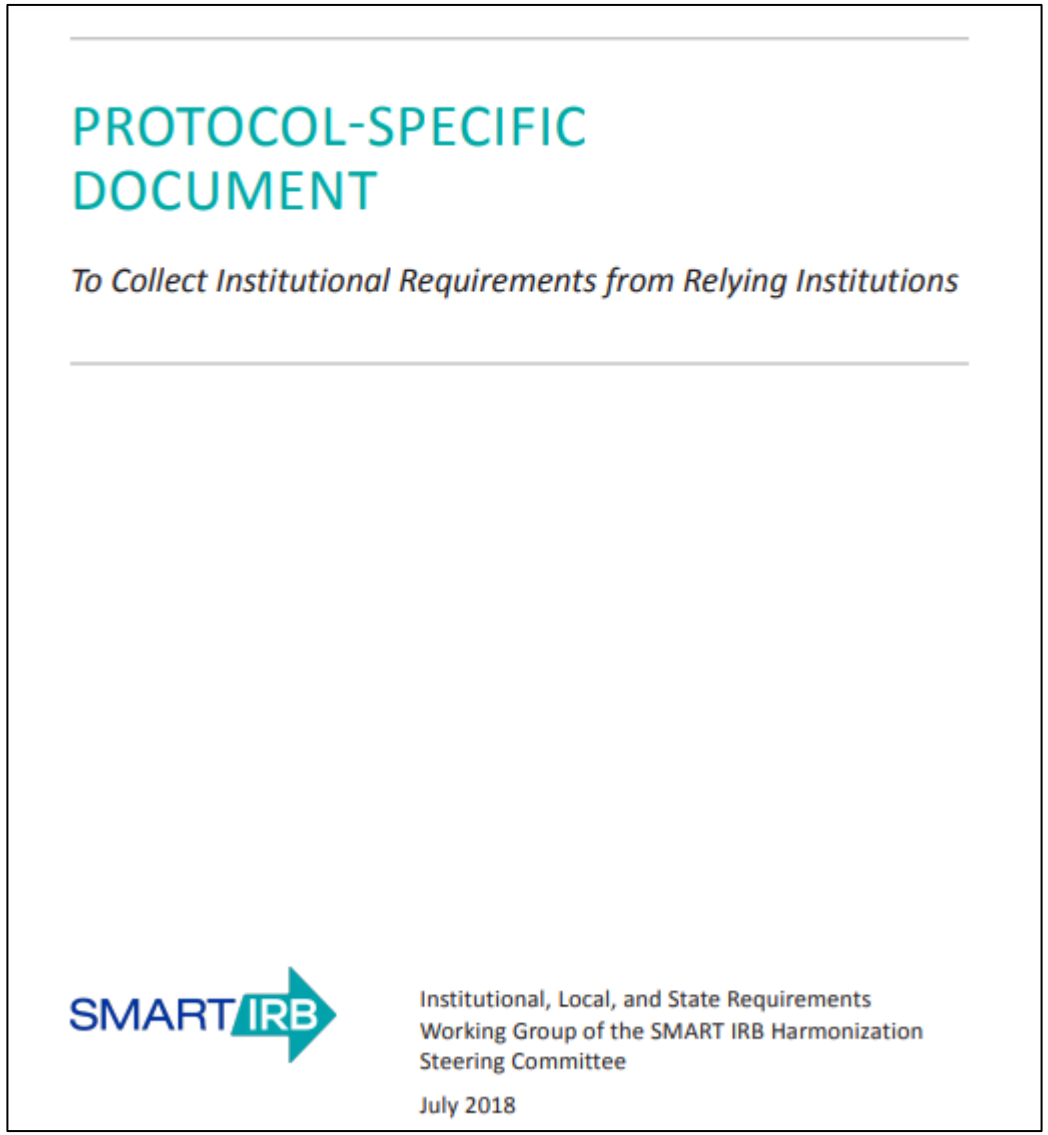
https://smartirb.org/assets/files/Institutional-Profile-20180726.pdf



Local Considerations: Protocol-Specific Document

Allows a Reviewing IRB to collect variations across participating sites regarding key information about study teams (e.g., training and conflicts of interests) and variations in study conduct (e.g., ancillary reviews required; HIPAA requirements; subject population).

https://smartirb.org/assets/files/Protocol-Specific-20180726.pdf


PROTOCOL-SPECIFIC DOCUMENT

To Collect Institutional Requirements from Relying Institutions

SMART IRB

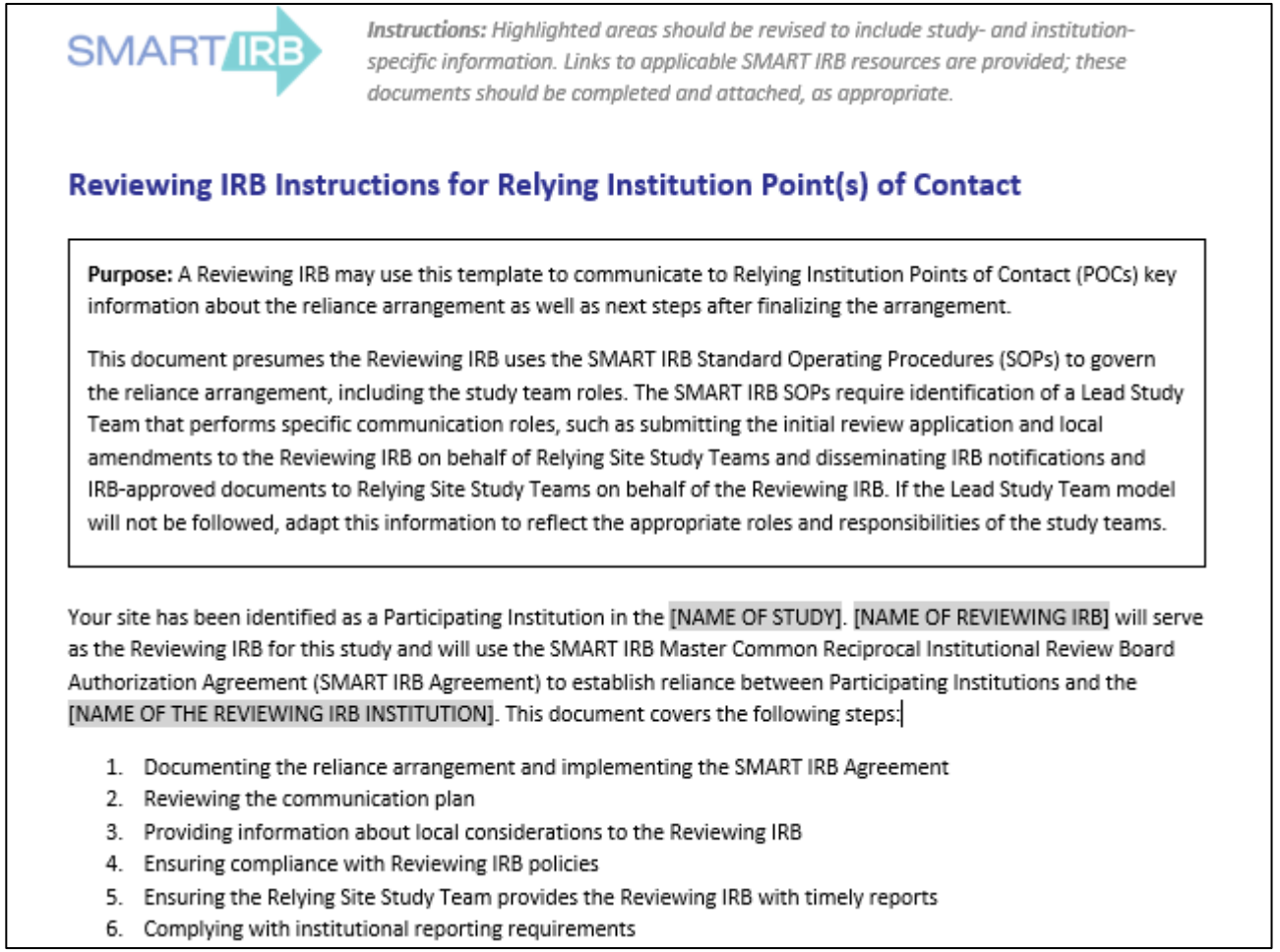
Institutional, Local, and State Requirements Working Group of the SMART IRB Harmonization Steering Committee

July 2018

Reviewing IRB Instructions for Relying Institution Point(s) of Contact

A Reviewing IRB may use this template to communicate to Relying Institution Points of Contact (POCs) key information about the reliance arrangement as well as next steps after finalizing the arrangement.

https://smartirb.org/assets/files/Reviewing_IRB_Instructions_to_Relying_Institution_POC.docx



SMART IRB

Instructions: *Highlighted areas should be revised to include study- and institution-specific information. Links to applicable SMART IRB resources are provided; these documents should be completed and attached, as appropriate.*

Reviewing IRB Instructions for Relying Institution Point(s) of Contact

Purpose: A Reviewing IRB may use this template to communicate to Relying Institution Points of Contact (POCs) key information about the reliance arrangement as well as next steps after finalizing the arrangement.

This document presumes the Reviewing IRB uses the SMART IRB Standard Operating Procedures (SOPs) to govern the reliance arrangement, including the study team roles. The SMART IRB SOPs require identification of a Lead Study Team that performs specific communication roles, such as submitting the initial review application and local amendments to the Reviewing IRB on behalf of Relying Site Study Teams and disseminating IRB notifications and IRB-approved documents to Relying Site Study Teams on behalf of the Reviewing IRB. If the Lead Study Team model will not be followed, adapt this information to reflect the appropriate roles and responsibilities of the study teams.

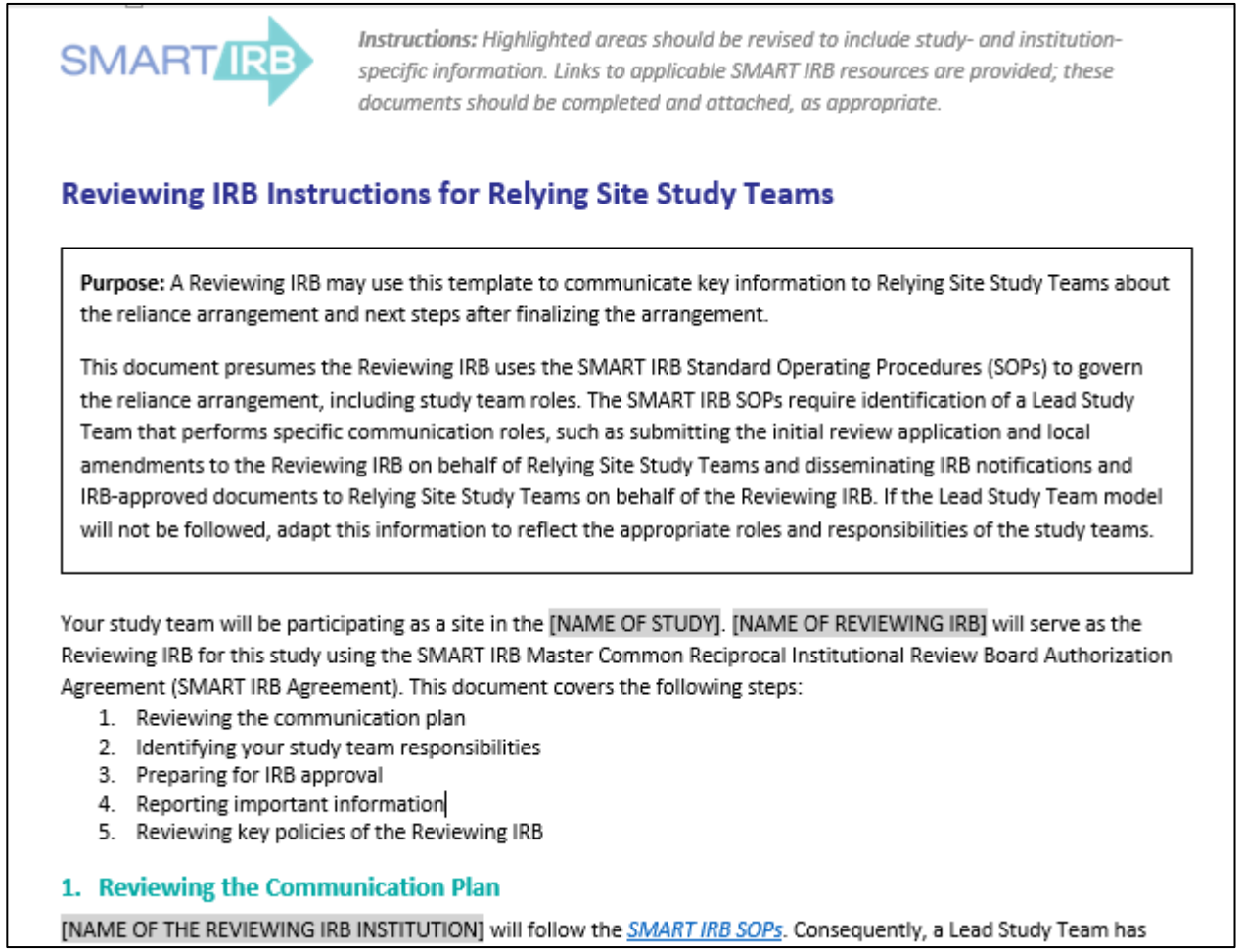
Your site has been identified as a Participating Institution in the [NAME OF STUDY]. [NAME OF REVIEWING IRB] will serve as the Reviewing IRB for this study and will use the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement) to establish reliance between Participating Institutions and the [NAME OF THE REVIEWING IRB INSTITUTION]. This document covers the following steps:

1. Documenting the reliance arrangement and implementing the SMART IRB Agreement
2. Reviewing the communication plan
3. Providing information about local considerations to the Reviewing IRB
4. Ensuring compliance with Reviewing IRB policies
5. Ensuring the Relying Site Study Team provides the Reviewing IRB with timely reports
6. Complying with institutional reporting requirements

Reviewing IRB Instructions for Relying Site Study Teams

A Reviewing IRB may use this template to communicate key information to Relying Site Study Teams about the reliance arrangement and next steps after finalizing the arrangement.

https://smartirb.org/assets/files/Reviewing_IRB_Instructions_to_Relying_Site_Study_Team.docx



SMART IRB

Instructions: *Highlighted areas should be revised to include study- and institution-specific information. Links to applicable SMART IRB resources are provided; these documents should be completed and attached, as appropriate.*

Reviewing IRB Instructions for Relying Site Study Teams

Purpose: A Reviewing IRB may use this template to communicate key information to Relying Site Study Teams about the reliance arrangement and next steps after finalizing the arrangement.

This document presumes the Reviewing IRB uses the SMART IRB Standard Operating Procedures (SOPs) to govern the reliance arrangement, including study team roles. The SMART IRB SOPs require identification of a Lead Study Team that performs specific communication roles, such as submitting the initial review application and local amendments to the Reviewing IRB on behalf of Relying Site Study Teams and disseminating IRB notifications and IRB-approved documents to Relying Site Study Teams on behalf of the Reviewing IRB. If the Lead Study Team model will not be followed, adapt this information to reflect the appropriate roles and responsibilities of the study teams.

Your study team will be participating as a site in the [NAME OF STUDY]. [NAME OF REVIEWING IRB] will serve as the Reviewing IRB for this study using the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement). This document covers the following steps:

1. Reviewing the communication plan
2. Identifying your study team responsibilities
3. Preparing for IRB approval
4. Reporting important information
5. Reviewing key policies of the Reviewing IRB

1. Reviewing the Communication Plan

[NAME OF THE REVIEWING IRB INSTITUTION] will follow the *SMART IRB SOPs*. Consequently, a Lead Study Team has

Other SMART IRB Resources at SMARTIRB.ORG

- Master Reliance Agreement
- Implementation Checklist for use of the SMART IRB Agreement
- SMART IRB SOP Manual
- FAQs for Research Teams - Relying on an External IRB
- Overall PI (and Lead Study Team) Checklist
- Relying Site Investigator Checklist
- Grant Applications: Template Description of SMART IRB

Today's Speakers:

Crystal Lijadu, Thomas Jefferson University
Tony Quinlan, University of Iowa
Kenia Viamonte, University of Miami

Join us for the next
SMART Talk
July 15, 2020
2:00-3:30 pm EDT

Single IRB and the Review of Research Involving Children

Questions?
Contact help@smartirb.org

Register at smartirb.org

Sign up for our mailing list to be notified of future offerings