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

Open and free to anyone with interest

Upcoming sessions

- June: Practical Issues and Pragmatic Solutions for the IRB Reliance Process
- July: Single IRB and the Review of Research Involving Children
- Future: NIH's Approach to the Implementation of the NIH Single IRB policy

Key SMART IRB Resources at SMARTIRB.ORG

- Master Reliance Agreement
- Implementation Checklist for use of the SMART IRB Agreement
- Online Reliance System (Helps investigators and institutions request, track, and document reliance arrangements for each study)
- SMART IRB SOP Manual
- Communication Plan for Single IRB Review
- Reviewing IRB Instructions for Relying Institution Point(s) of Contact
- Reviewing IRB Instructions for Relying Site Study Teams
- 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
- Local Considerations: Institutional Profile
- Local Considerations: Protocol-specific Document

Join us for the next
SMART Talk
June 17, 2020
2:00-3:30 pm EDT

Practical Issues and
Pragmatic Solutions for the
IRB Reliance Process

Questions?
Contact
help@smartirb.org

Register at smartirb.org

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

SMART IRB

Roadmap to Single IRB Review

Training & Education Resources for Investigators and their Study Teams

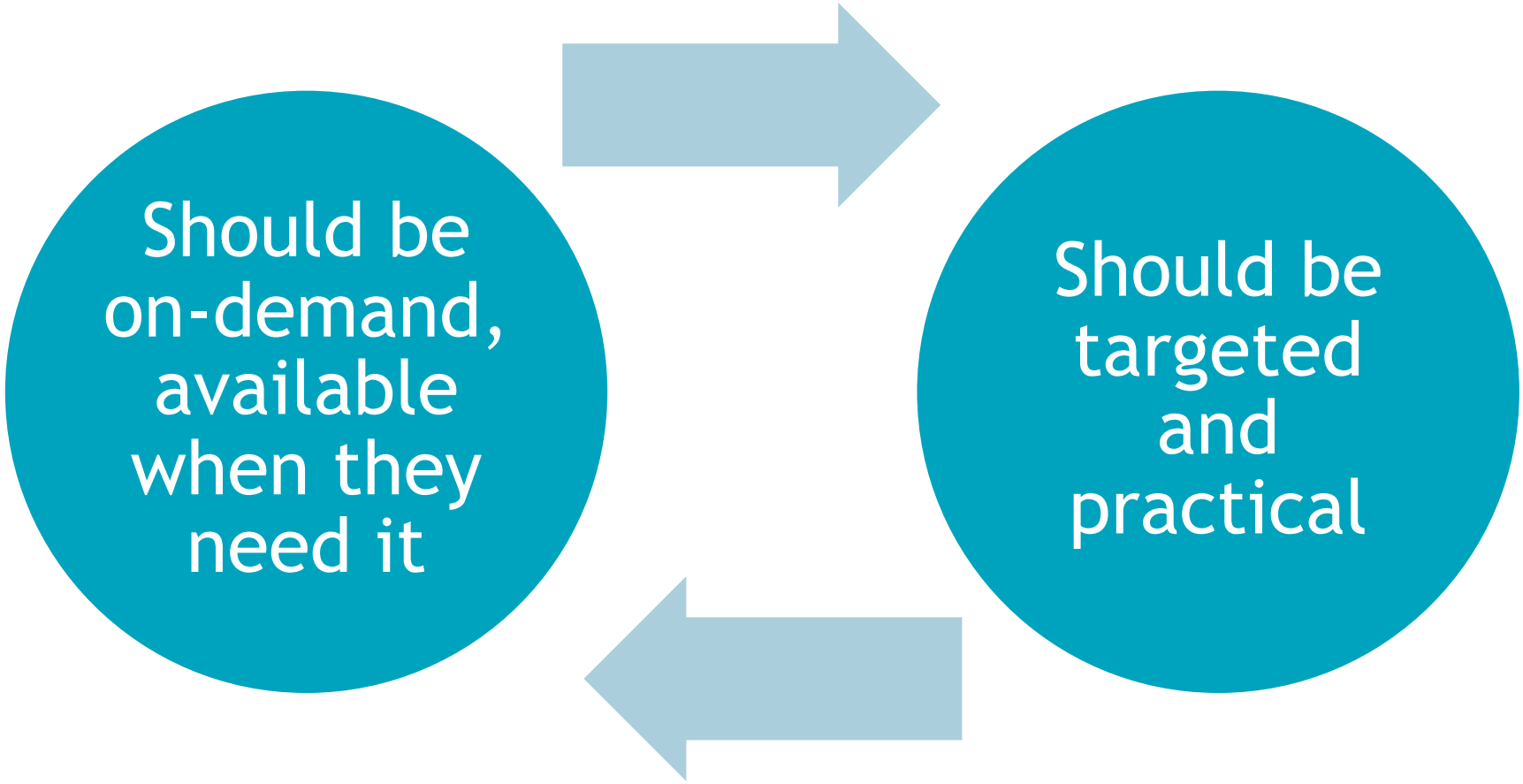
Nichelle Cobb
University of Wisconsin-Madison &
SMART IRB Director of Operations

Kathy Lawry
SMART IRB Ambassador
Senior Consultant, AAHRPP

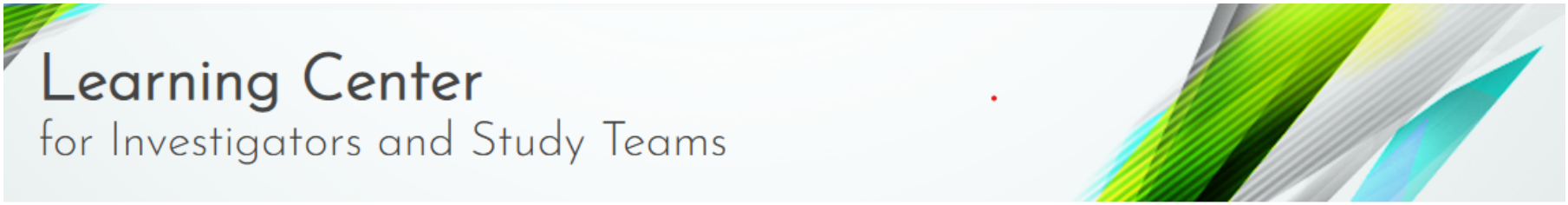
What We Will Cover

- Overview of training topics and SMART IRB training resources
- Strategies for study team training and education
- Additional information for Overall Principal Investigators (PIs) and Lead Study Teams

Approach to Study Team Training



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/

Introduction to Single IRB Review and SMART IRB

- What single IRB is with a brief history of policies & regulations
- Roles related to single IRB
- Why reliance agreements are needed/required
- What SMART IRB is and is not
- Using the SMART IRB agreement

Overview of the NIH Single IRB Policy

- Describes the NIH policy, when the policy does and does not apply
- Policy effective dates
- Differences between NIH policy and the Common Rule

Selecting a Single IRB

- Discusses who selects the single IRB when a specific IRB is not required
- Shows a tool to identify institutions who have joined SMART IRB and how to find the institution's SMART IRB Point of Contact

Developing a Single IRB Plan

- Describes the NIH single IRB plan requirement
- Discusses the need to determine which sites need a reliance agreement (i.e., are engaged in human subjects research)
- Explains the exceptions to the NIH policy that might need to be addressed in the single IRB plan
- Addresses how to leverage the SMART IRB Agreement for grants

Potential Effects of NIH Single IRB Policy on Research Costs

- Explains the potential need for study teams to address IRB fees for NIH-funded research, variation in what IRBs charge and how fees are assessed (i.e., direct vs. indirect costs)
- Discusses staffing needs due to new roles for managing communication between sites and with the IRB as well as new resource requirements (e.g., systems to store and share documents related to IRB review)
- Describes how SMART IRB can help

Study Team Roles Related to Single IRB

- Explains key study team roles and responsibilities that are a result of change in communication model between study teams and IRBs
  - Overall PI and Lead Study Team
  - Site Investigators and Relying Site Study Teams
- Describes the need for communication points of contact and who they are and a SMART IRB resource for documenting communication roles (Communication Plan)
- Identifies where Study Teams can find other SMART IRB resources, such as FAQs for relying on an external IRB, investigator checklists

Customizing the Training

Go To IRB/HRPP Administrators Learning Center Page

Download and Edit

Training for Investigators and Study Teams

Use this suite of training videos and resources as is, or customize to reflect local processes and policies.

Visit the Investigator and Study Team Learning Center to view available materials; send investigators here for self-guided learning

Download presentations (no audio) to use for local training sessions or customize to reflect local processes.

To download the presentations with embedded audio, please use the links below:

- Developing a Single IRB Plan
- Overview of the NIH Single IRB Policy for Researchers
- Potential Effects of Single IRB on Research Costs
- Selecting a Single IRB
- Single IRB review and SMART IRB
- Study Team Roles Related to Single IRB

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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.

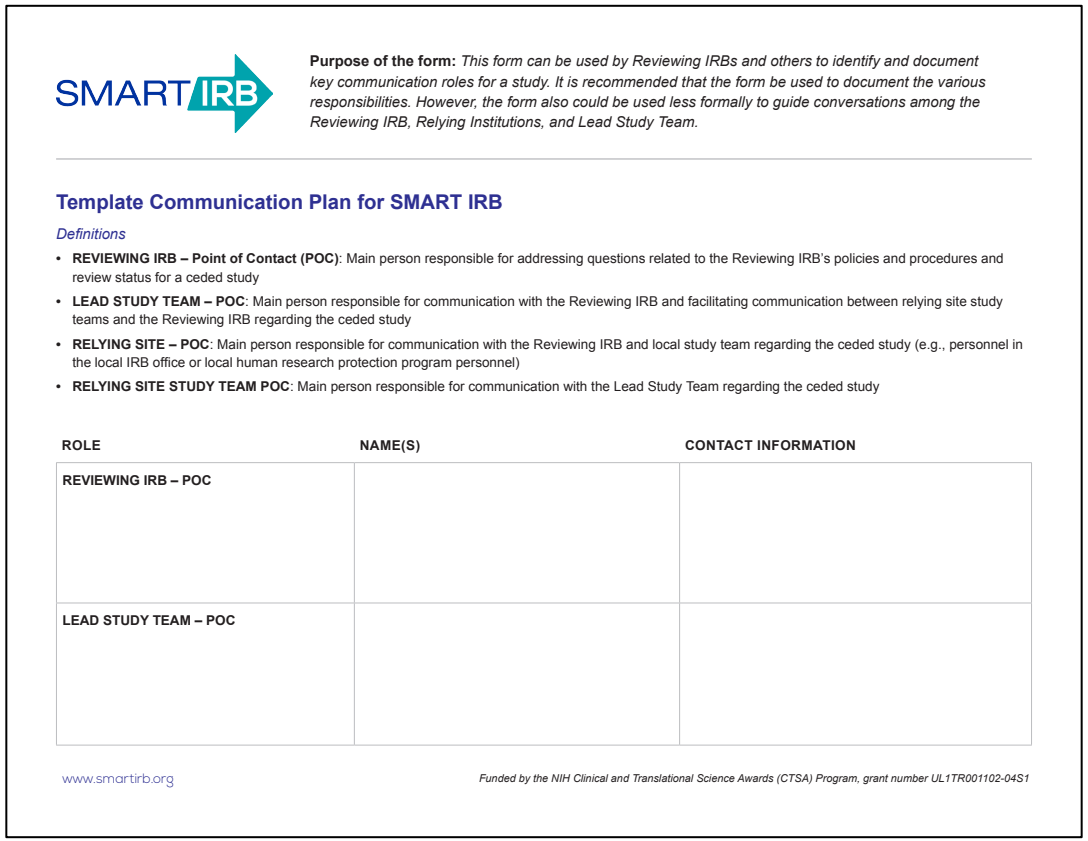
Learn more by watching the videos in the SMART IRB Learning Center

Addressing the Changes in Roles & Responsibilities and the need for a new Communication Model

- SMART IRB developed resources to recognize and facilitate this change
  - Communication plan for single IRB review
  - Checklists for Lead Investigators and study teams
  - Checklists and FAQs for Investigators Relying on an External IRB
  - Survey of the Relying Site team and the Informed Consent Document Inserting Local Context Language

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.



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		

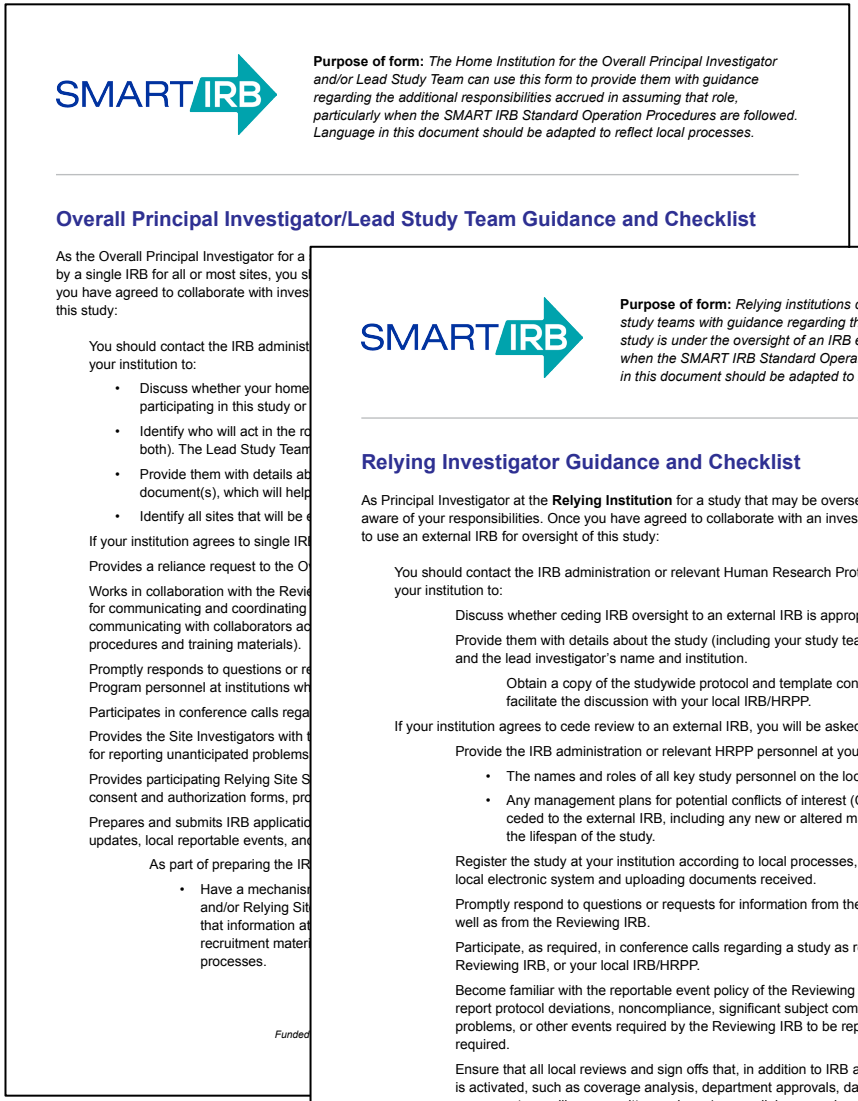
www.smartirb.org

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

Investigator Checklists

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

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.



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 ro
both). The Lead Study Tean
- Provide them with details ab
document(s), which will help
- 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 Revie
for communicating and coordinating
communicating with collaborators ac
procedures and training materials).

Promptly responds to questions or re
Program personnel at institutions wh

Participates in conference calls rega

Provides the Site Investigators with t
for reporting unanticipated problems

Provides participating Relying Site S
consent and authorization forms, pro

Prepares and submits IRB applicatio
updates, local reportable events, and

As part of preparing the IR

- Have a mechanis
and/or Relying Sit
that information at
recruitment mater
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.

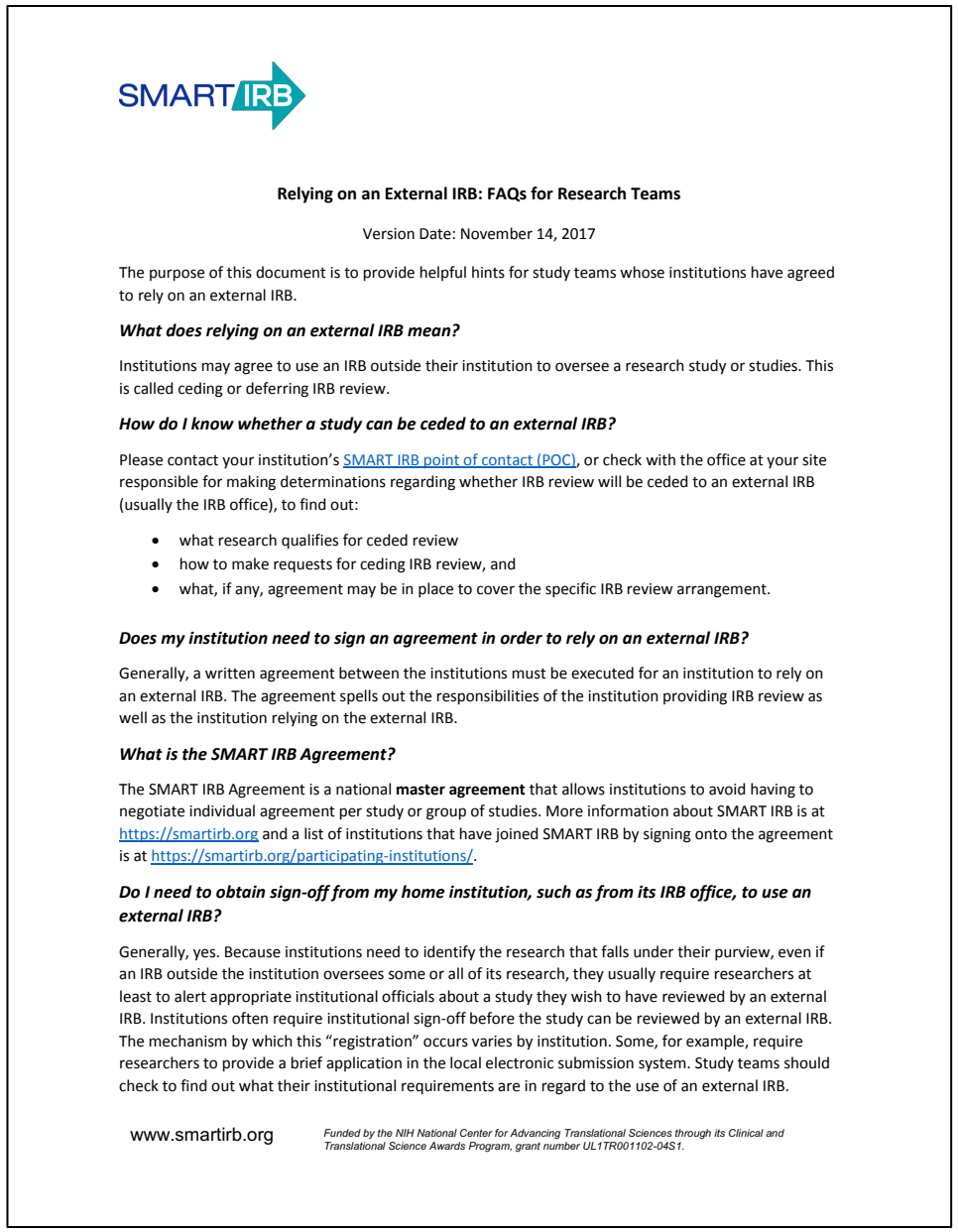
For externally funded studies, provide your sponsored programs office with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

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?

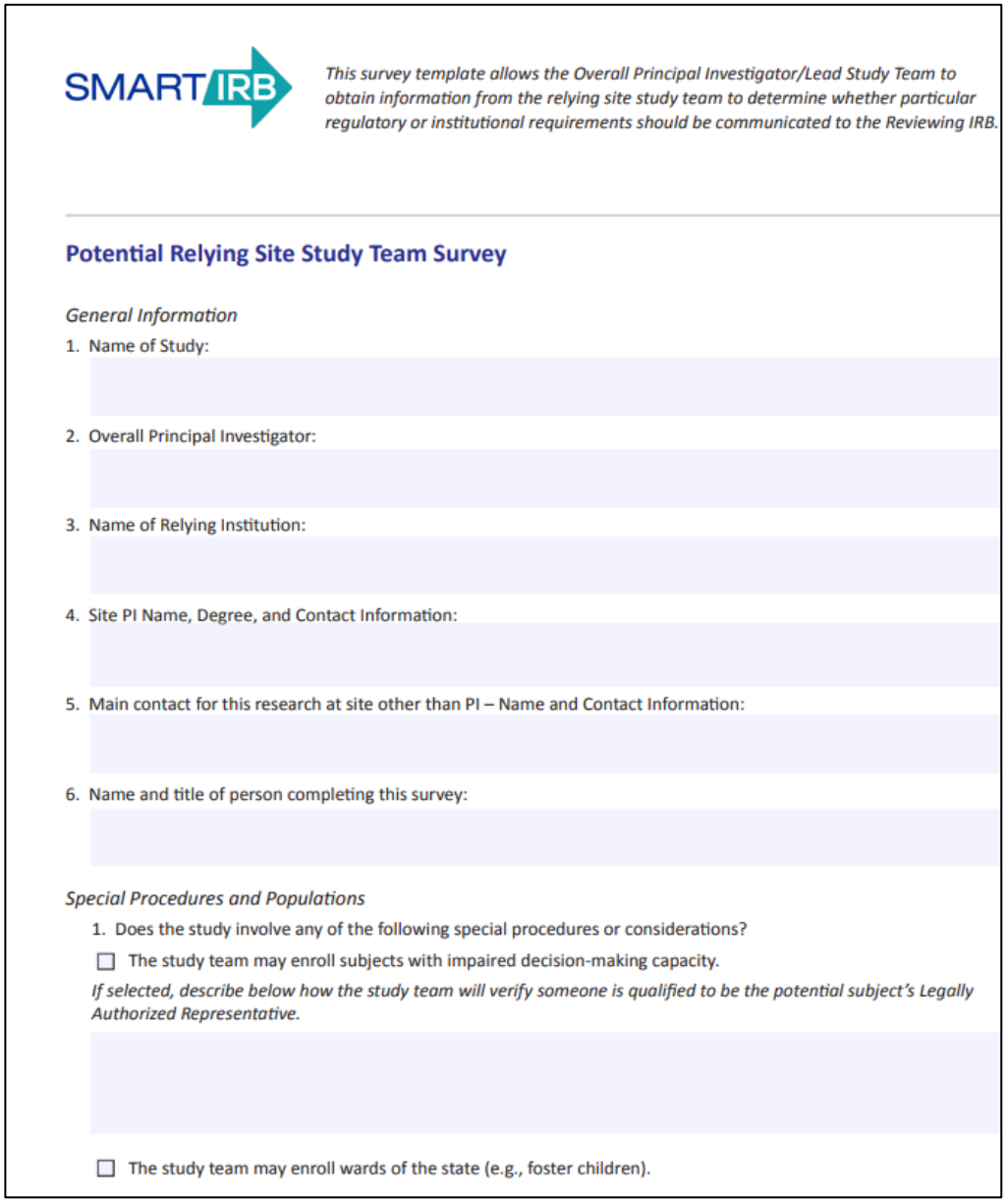
Generally, yes. Because institutions need to identify the research that falls under their purview, even if an IRB outside the institution oversees some or all of its research, they usually require researchers at least to alert appropriate institutional officials about a study they wish to have reviewed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

Information for IRB Review

Relying Study Team Survey: 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.



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?

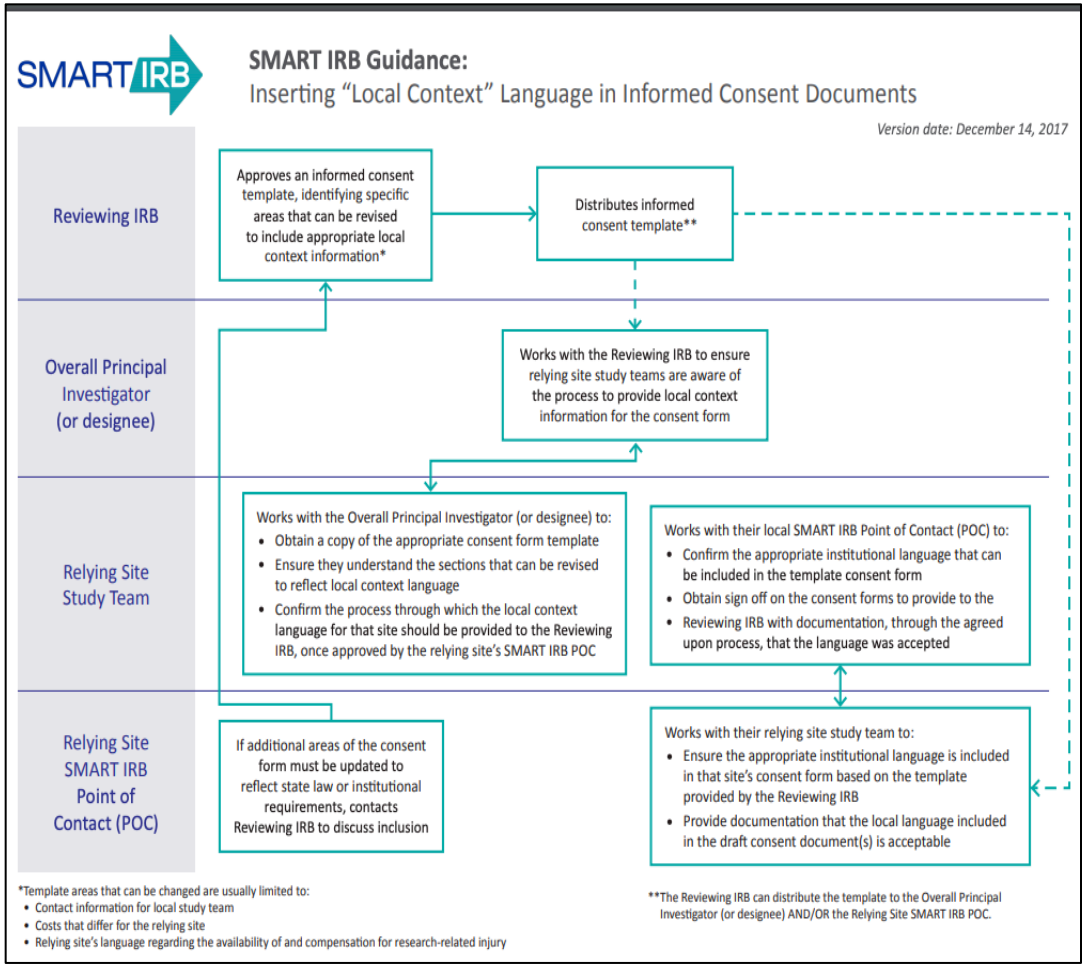
☐ The study team may enroll subjects with impaired decision-making capacity.

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).

Informed Consent Form Documents: Inserting Local Context Language

Provides guidance to IRB's, relying institutions, and study teams regarding the different roles that may be involved in inserting local context language in informed consent documents.



SMART IRB

Roadmap to Single IRB Review

Training & Education Resources for Investigators and their Study Teams

- Carey Gorden, MetroHealth
- Sarah Mumford, University of Utah
- Ada Sue Selwitz, University of Kentucky & SMART IRB Ambassador

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