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 3UL1TR002541-04S2.

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

August: No SMART Talk

September: Using AAHRPP's I-9 Standard to Guide Reliance Arrangements

FYIs

Please provide feedback by completing the survey. A link will be posted in chat and emailed.

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 or Q&A function to submit them

SMART IRB Updates

Harmonization Steering Committee Recommendations

- Post-Approval Auditing for Studies Subject to Single IRB Review
- Single IRB Continuing Review Process
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel
- Reportable Events
- Institutional Profile
- Protocol-specific Document
- Fees and Costing Models under NIH sIRB Policy
- Institution v. IRB Responsibilities Guidance
- Under review –
  - Ancillary Review
  - Conflict of Interest

For more information, see: https://smartirb.org/harmonization/

Single IRB Resources:

What, When, Why, & How to Use Them

Carissa Minder
Washington University in St. Louis
Midwest SMART IRB Ambassador

Lubabah Helwani
University of California, Los Angeles
West Coast SMART IRB Ambassador

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S2.

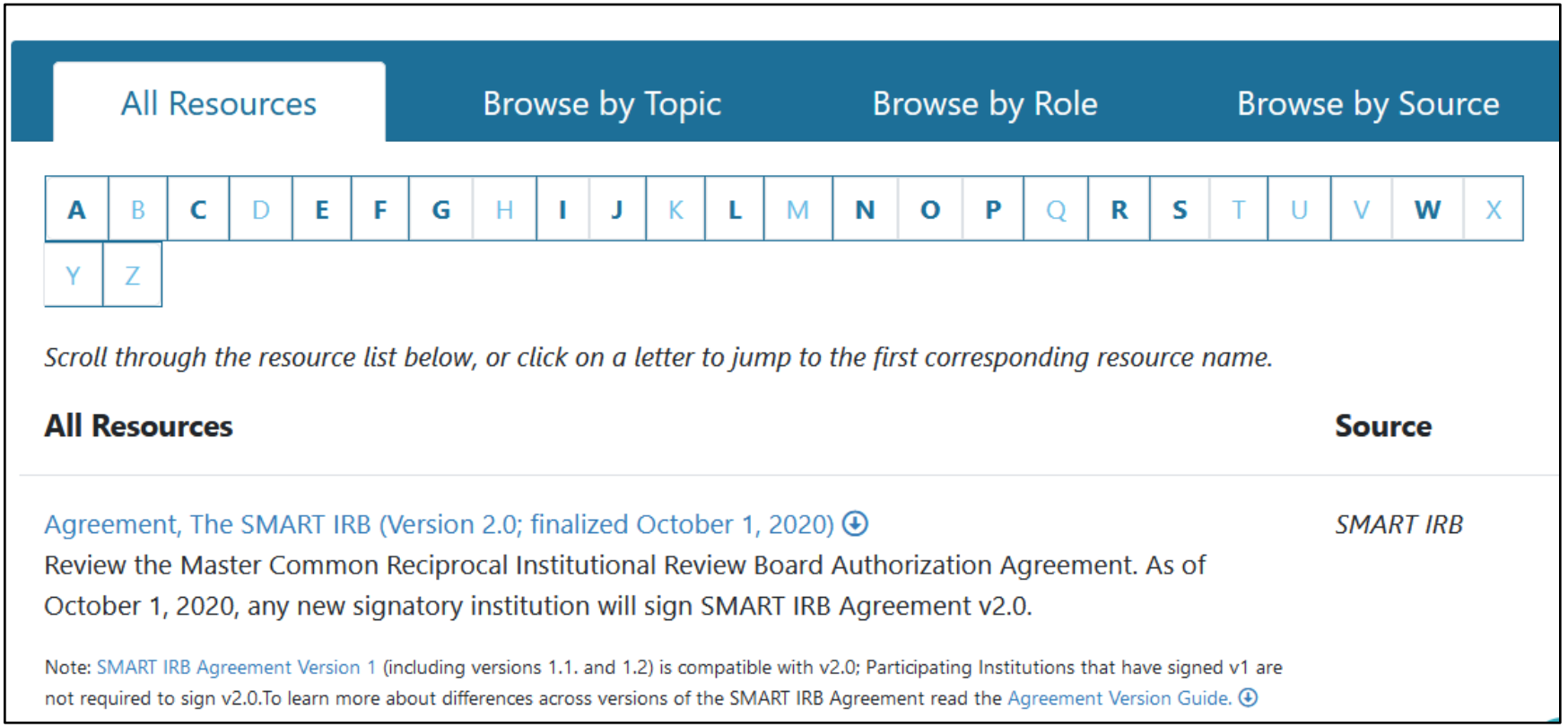
Our Speakers & SMART IRB Ambassadors

Lubabah Helwani
UCLA

Carissa Minder
Washington University in St Louis

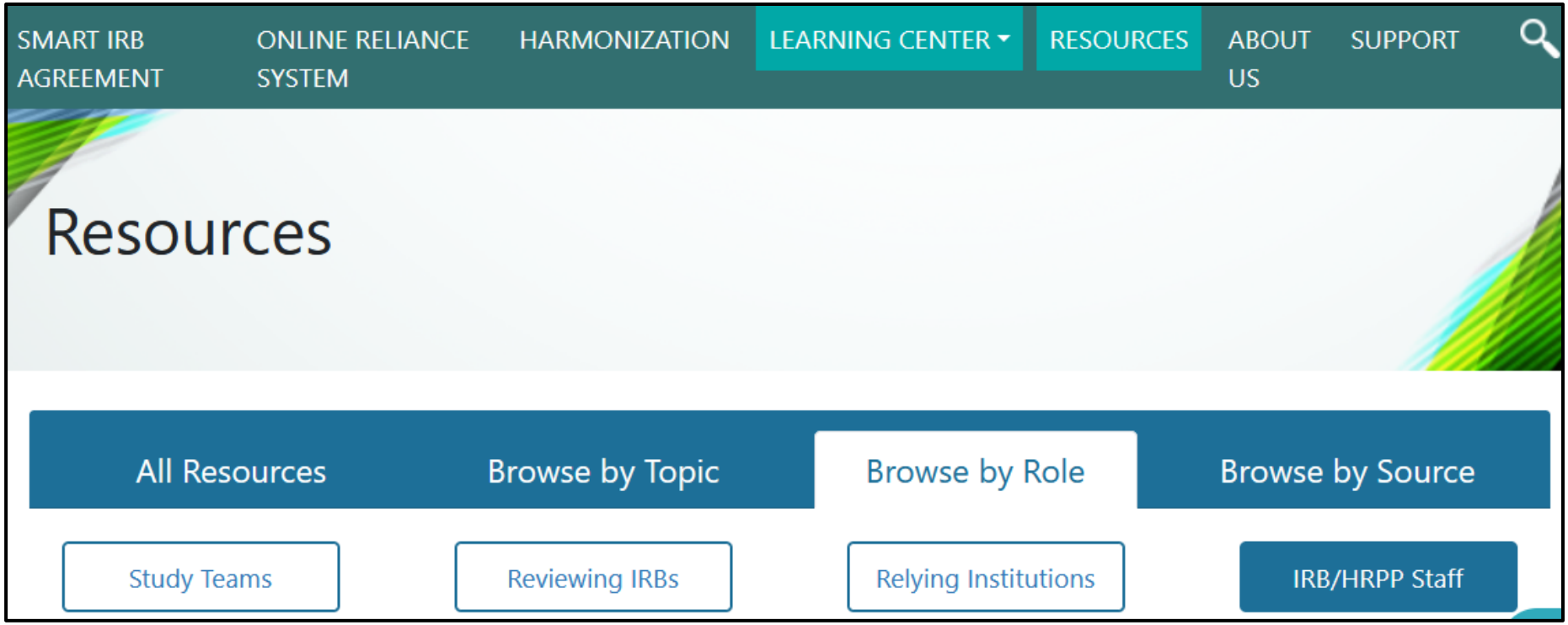
Poll Question #1

Do you know about SMART IRB resources?



Poll Question #2

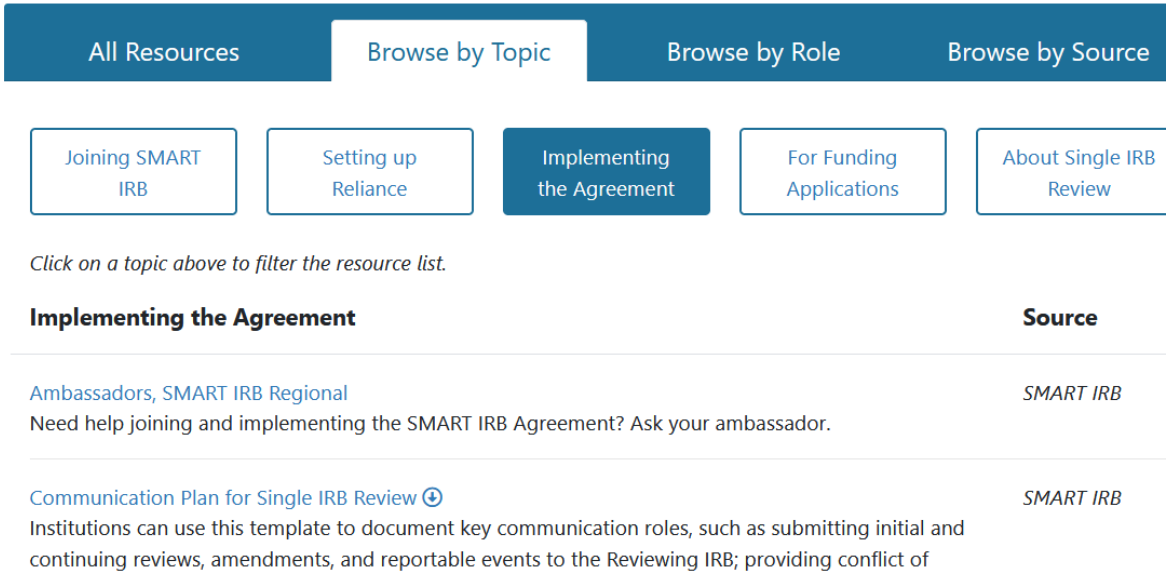
How many resources does your institution use from SMART IRB?



Resources & Guidance

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

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

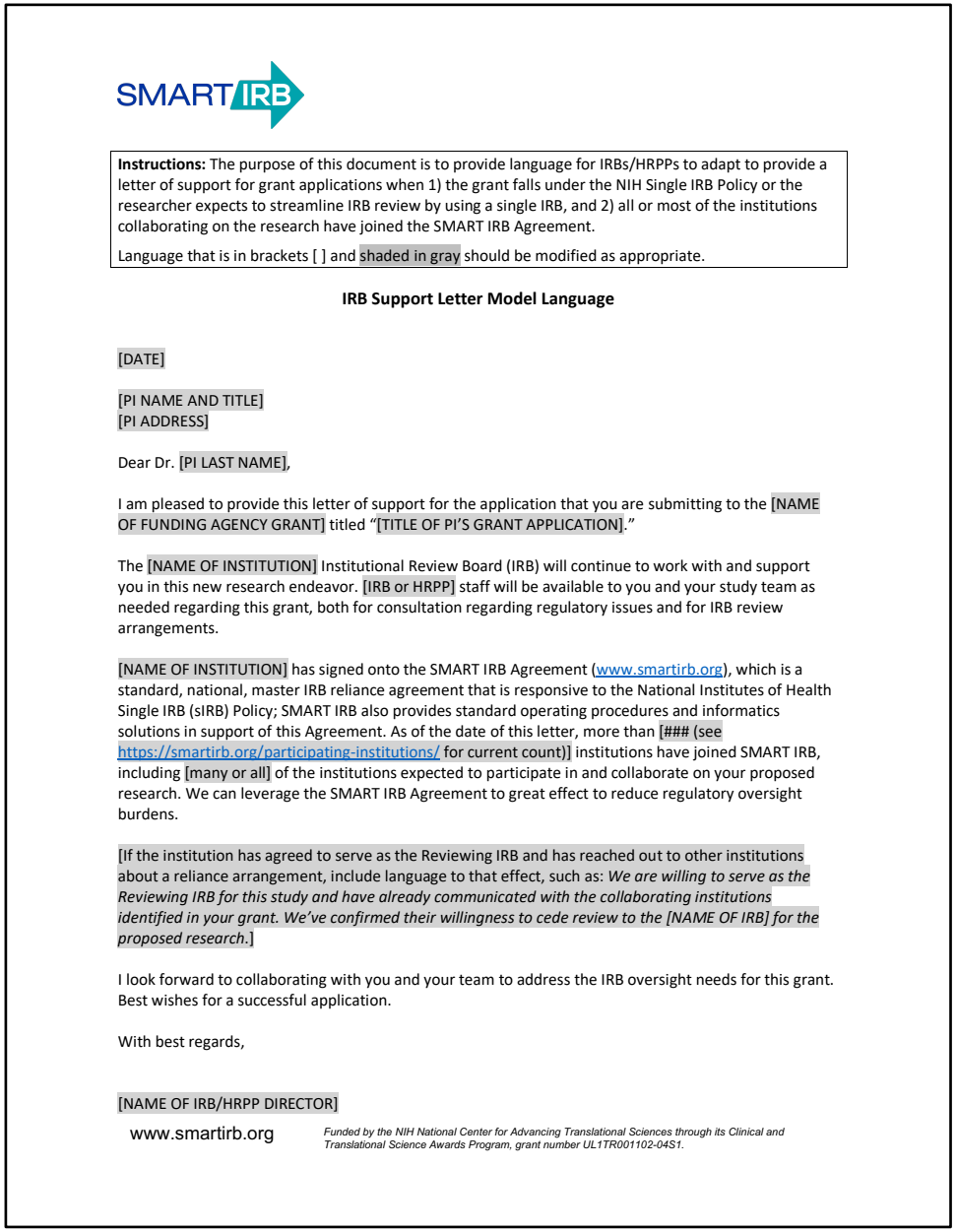


smartirb.org/resources

Before Submission

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.

IRB Letter of Support for Grants

Or make your own!

Washington University in St. Louis

Human Research Protection Office
FWA00002284

Barnes Jewish Hospital
St. Louis Children's Hospital
Washington University

[DATE]

[PI]

Re: [Grant Title]

Dear [NAME]:

We are happy to provide this letter in support of the grant application entitled [Grant].

We understand that a single IRB will be used for oversight of this study. We understand that federal funders, including the National Institutes of Health, require the use of a single IRB of record in the review of all non-exempt human subjects research protocols carried out at more than one site in order to streamline the protocol approval process for multicenter research studies.

We understand that as a condition of our participation our institution will be required to rely on the named single IRB for review of this project.

We agree that a single IRB model offers significant advantages in these large, multi-center trials. We look forward to working with you on this important research and wish you success in your funding application.

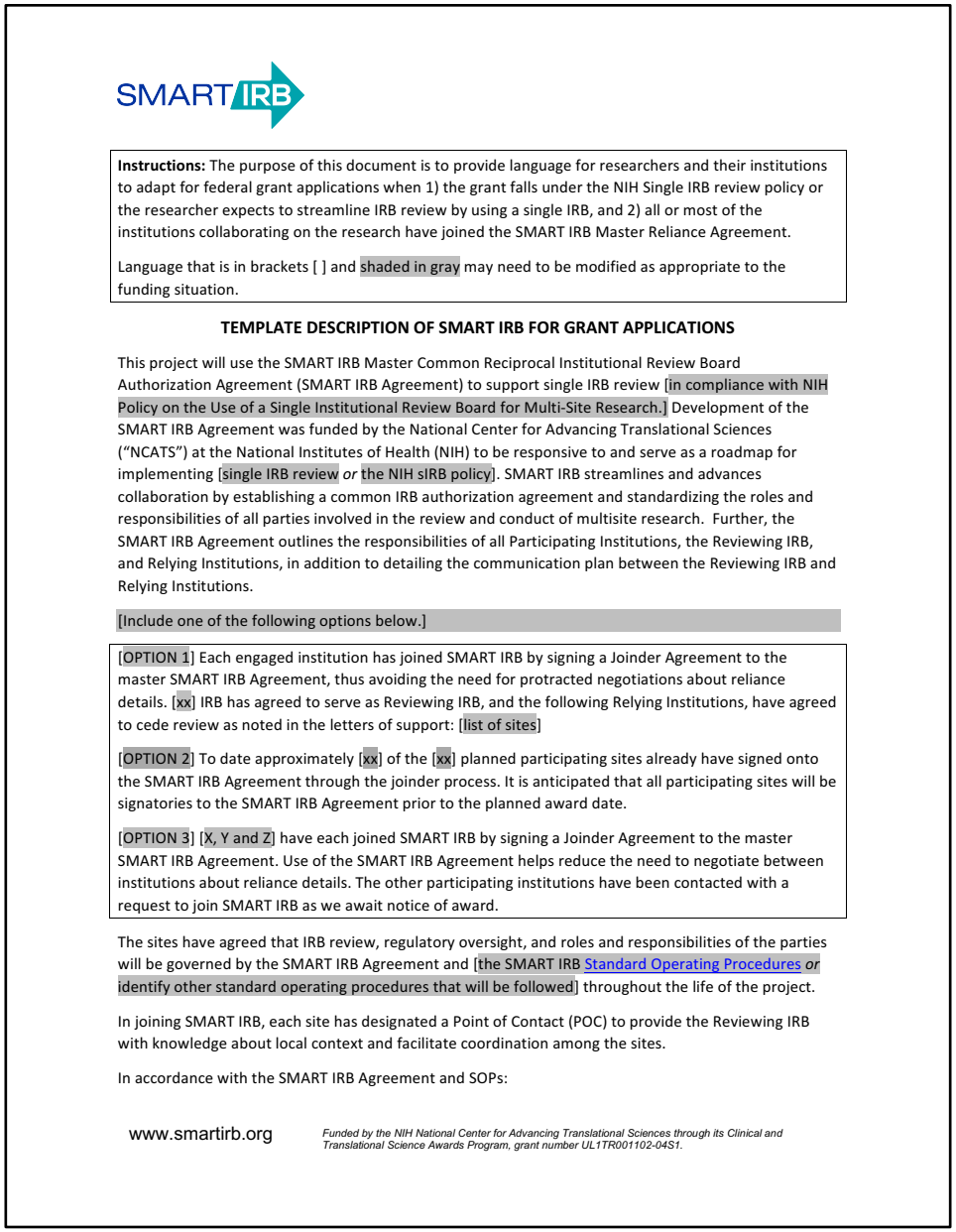
Sincerely,

Amanda Cashen, MD
IRB Executive Chair
Washington University in St. Louis Office

Jeanne Velders, JD, CIP
Executive Director
Human Research Protection

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.

Grant Application Language

- Highlight your strengths
- Start of Education Process for the Study Team

The WU Human Research Protection Program has been AAHRRP accredited since 2004 and oversees over 7000 open studies and processes over 15,000 applications per year. The WU IRB is supported by the Human Research Protection Office (HRPO) at Washington University (WU) and has established policies and standard operating procedures that support the role of a reviewing IRB. The WU IRB is a highly experienced and flexible committee composed of 150-180 members and alternates who represent a wide range of scientific expertise and non-scientific representation. WU-IRB's members receive robust initial training (8-12 hours didactic and interactive workshops, mock IRB experience, CITI training, and pairing with a senior IRB mentor) and continuing education ("youtube" video programming at each IRB meeting developed by IRB Executive Chair and education team).

The WU IRB has six scheduled meeting each week and the ability to add additional meetings as needed to accommodate high volume time periods. On average, a study application that is ready for review is approved within 13 calendar days. Applications to add sites to an approved protocol are typically approved as an expedited modification and completed within one-two days.

WU is involved in many large sIRB consortia, including the SMART IRB initiative, and has been an early adaptor of the idea of centralized IRB as an early user of the NCI CIRB and participant of disease-specific models such as NeuroNEXT and StrokeNET. The WU IRB currently serves as the sIRB for multi-center trials including trials with over 20 sites and has dedicated sIRB staff. The sIRB team works with each site to facilitate establishing reliance agreements and conducting IRB reviews in a timely manner. The sIRB team maintains strong communication with sites throughout the conduct of the study. The WU electronic "myIRB" data management and application system provides an sIRB module that provides participating sites the ability to efficiently submit applications and reports directly to the IRB, provides consent and approval documentation specific to sites, and manages local context and approval processes.

Fees and Costing

- Multiple Models
- Real World Examples
- Guidance from the Harmonization Steering Committee

Example #2: Calculate Hourly Rates to Apply to sIRB Activities
Vanderbilt University

Charges for Primary Activities:

1. Calculate an average rate per activity (initial review full board, initial review expedited, major amendment, minor amendment, continuing review full board, continuing review expedited).
2. Create time studies to calculate effort for each activity (e.g., pre-review and review time for initial review, continuing review, amendments, etc.).
3. Calculate an hourly rate based on time spent and salary of the individual performing the activity.
4. Apply the hourly rate to each activity.
5. Charge each activity based on hourly rate (e.g., initial review takes XX amount of time = set rate for activity).
6. The above steps set your fee schedule.

Charges for Secondary Activities

These can follow the same pathway as above, however the activity and time spent will be greatly reduced, allowing a per-site fee for each individual activity. It is important to save the data to support your charges for federal cost accounting purposes. Figure 6 below demonstrates two examples of calculating sIRB costs for Secondary Activities using this model.

FIGURE 6: CALCULATING PERCENT EFFORT

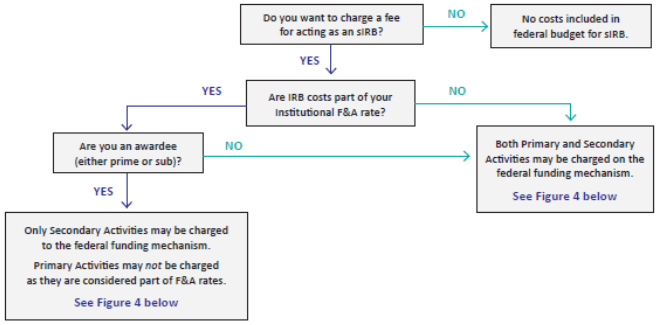
Time Study "A" Assumptions:
The project includes an average of 10-15 sites
The sIRB institution is not the Prime Awardee
The sIRB institution is the IRB of Record
No pre-existing reliance agreements

sIRB RELIANCE AGREEMENT SET UP	STAFF TIME/HOURS
Drafting of reliance	2
Negotiating reliance	16
Signatures	1
TOTAL	19
LOCAL CONTEXT	
Gathering local context from sites	8
Consent form development based on local context	10
Approval letter development	2
Consent form stamping	10
TOTAL	30
POST MEETING	
Notification to all sites of approval	4
TOTAL	4
REVIEW AND REPORTING (EXTERNAL SITES)	
Review of reportable events	1
Review of noncompliance	1
Review of complaints	6
Reporting to federal agencies	2
TOTAL	10

Time Study "B" Assumptions:
The project includes an average of 10-15 sites
The sIRB institution is not the Prime Awardee
The sIRB institution is the IRB of Record
Existing reliance agreement

sIRB RELIANCE AGREEMENT SET UP	STAFF TIME/HOURS
Drafting of reliance	0
Negotiating reliance	0
Signatures	0
TOTAL	0
LOCAL CONTEXT	
Gathering local context from sites	8
Consent form development based on local context	10
Approval letter development	2
Consent form stamping	10
TOTAL	30
POST MEETING	
Notification to all sites of approval	4
TOTAL	4
REVIEW AND REPORTING (EXTERNAL SITES)	
Review of reportable events	1
Review of noncompliance	1
Review of complaints	6
Reporting to federal agencies	2
TOTAL	10

FIGURE 3: FLOWCHART TO DETERMINE ALLOWABLE COSTS UNDER FEDERAL REQUIREMENTS



Allowable Costs At-a-Glance

Figure 4 outlines sample activities for which you may charge, based on your organization's indirect- or direct-cost model. Your organization may decide to charge for some or all of these activities, or bundle activities together for ease of accounting. These activities are not exhaustive.

FIGURE 4: SAMPLE OF ALLOWABLE COSTS UNDER INDIRECT AND DIRECT COST MODELS

Primary Activities

	Is this an allowable cost?	
SERVICE OR TRANSACTION	INDIRECT COST MODEL	DIRECT COST MODEL
Initial Review of Protocol	✗	✓
Review of Local Investigator	✗	✓
Overall Protocol Modifications	✗	✓
Annual/Continuing Review	✗	✓
Approval of Study-wide Translated ICFs	✗	✓
Reportable events* (at Reviewing IRB's local site)	✗	✓
Overall Study Closeout	✗	✓

**Consider removing any disincentive to report by not charging.*

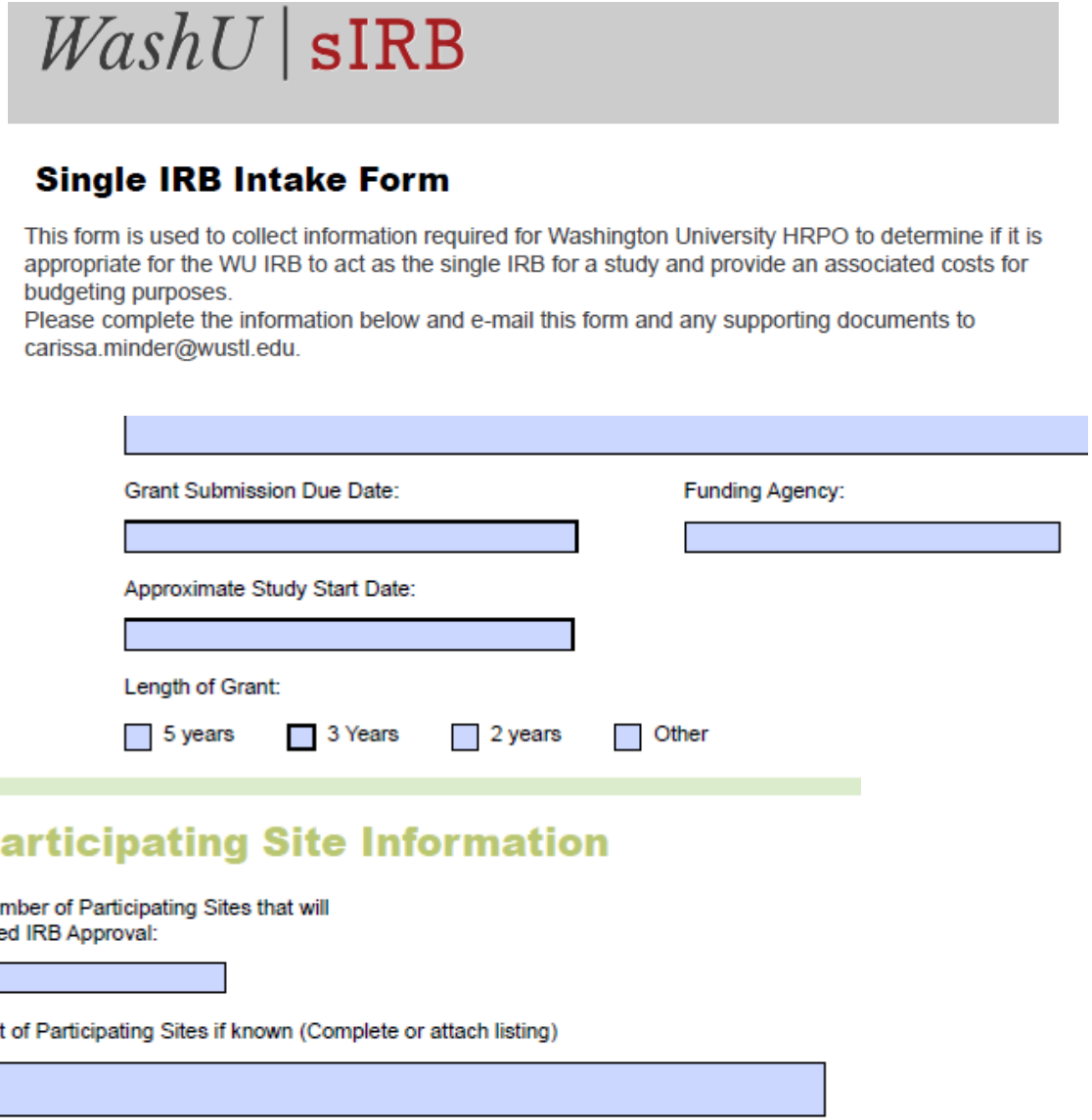
Secondary Activities

	Is this an allowable cost?	
SERVICE OR TRANSACTION	INDIRECT COST MODEL	DIRECT COST MODEL
Addition of sites 2-xx *Excludes local site*	✓	✓
Annual/Continuing Review of sites 2-xx *Excludes local site*	✓	✓
Reportable events* at sites 2-xx	✓	✓
Site-specific Modifications	✓	✓
Change of Relying Principal Investigator	✓	✓
Approval of Site-specific Recruitment Documents	✓	✓
Audit *As requested*	✓	✓
Site Closeout	✓	✓
New IRB Reliance Agreement	✓	✓

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-0151.

Developing a Grant Budget

- Have a method for determining costs
- Have a mechanism for PIs to request budget
- Have a template prepared
- Educate, educate, educate



WashU | sIRB

Single IRB Intake Form

This form is used to collect information required for Washington University HRPO to determine if it is appropriate for the WU IRB to act as the single IRB for a study and provide an associated costs for budgeting purposes.
Please complete the information below and e-mail this form and any supporting documents to carissa.minder@wustl.edu.

Grant Submission Due Date:

Funding Agency:

Approximate Study Start Date:

Length of Grant:

☐ 5 years ☐ 3 Years ☐ 2 years ☐ Other

Participating Site Information

Number of Participating Sites that will need IRB Approval:

List of Participating Sites if known (Complete or attach listing)

NIH Grant Prep Package: smartirb.org/study-teams/

Start-up Package for NIH Grant Preparation

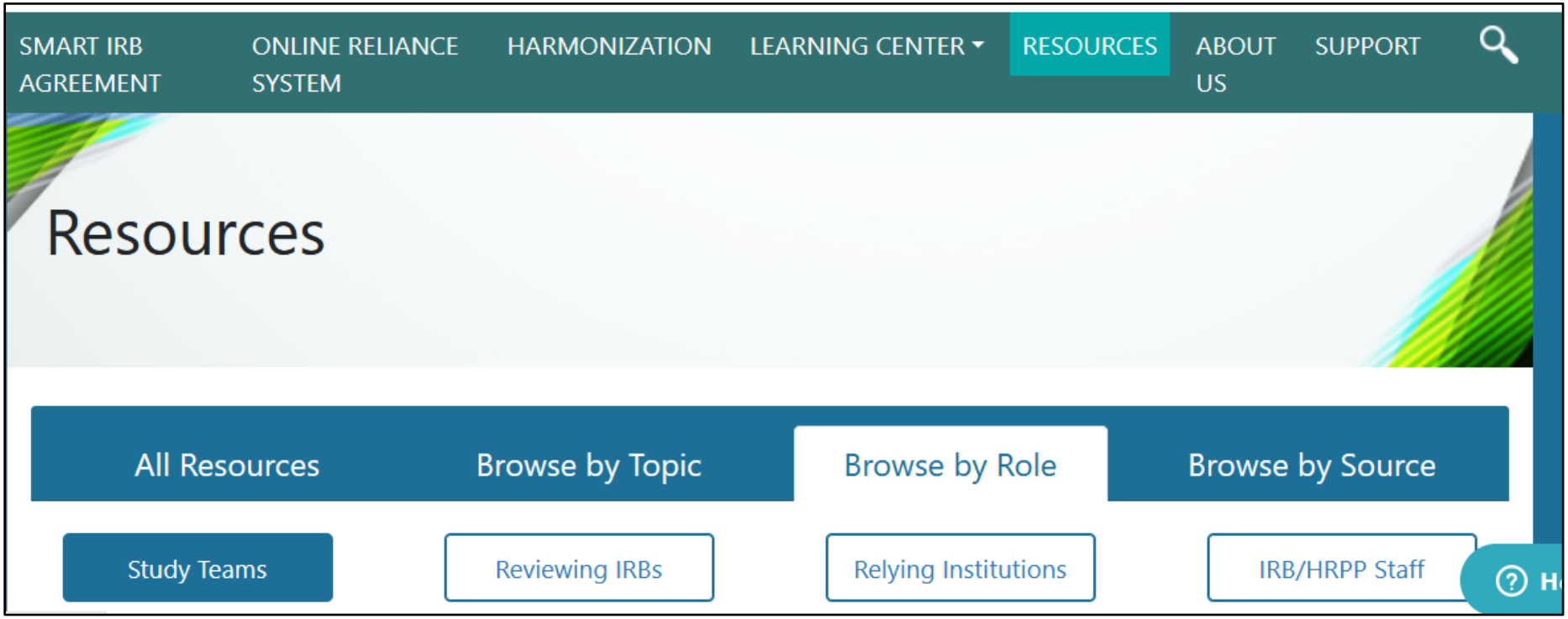
For study teams and other personnel involved in the grant preparation process.

WHEN TO USE? WHEN YOU ARE…	WHAT?	WHY?
GETTING STARTED WITH THE SINGLE IRB REQUIREMENT FOR NIH GRANTS	Grant Submission and Review Guidance	Understand how the NIH Single IRB Policy changes the processes for funding applications.
PUTTING TOGETHER A STUDY BUDGET	Fees and Costing Models under NIH sIRB Policy	Although geared towards IRBs, this document may also help institutions anticipate fees for Single IRB review and address them in funding application budgets.
CREATING A SINGLE IRB PLAN FOR A GRANT APPLICATION	Grant Applications, Template Description of SMART IRB	Researchers and institutions may adapt this language for federal grant applications to describe their use of SMART IRB.
	SMART IRB Participating Institutions List	Identify which institutions have joined the SMART IRB Agreement.
	IRB Support Letter Model Language	IRBs/HRPPs may adopt this language to provide a letter of support for grant applications.

Educating and Working with Study Teams

Poll Question #3

How do you train your research community about sIRB?



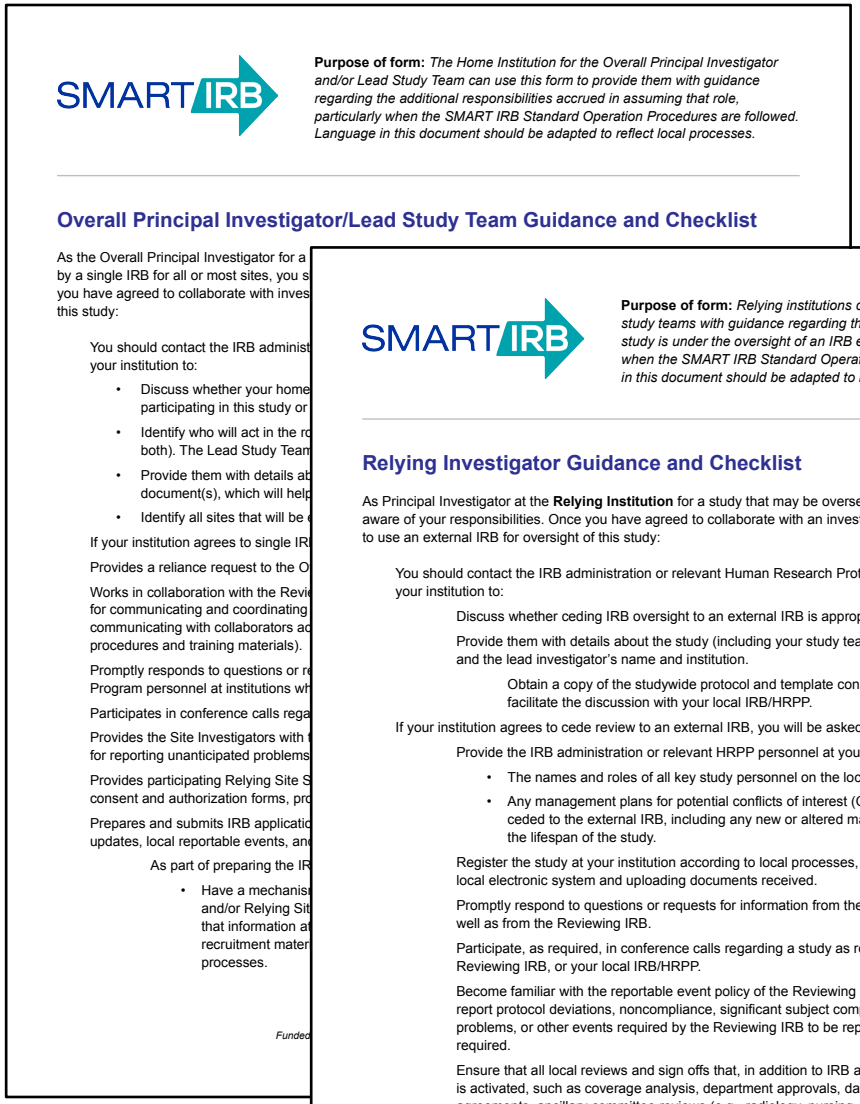
Investigator Checklists

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 rc
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
for reporting unanticipated problems

Provides participating Relying Site S
consent and authorization forms, pro

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

As part of preparing the IR

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

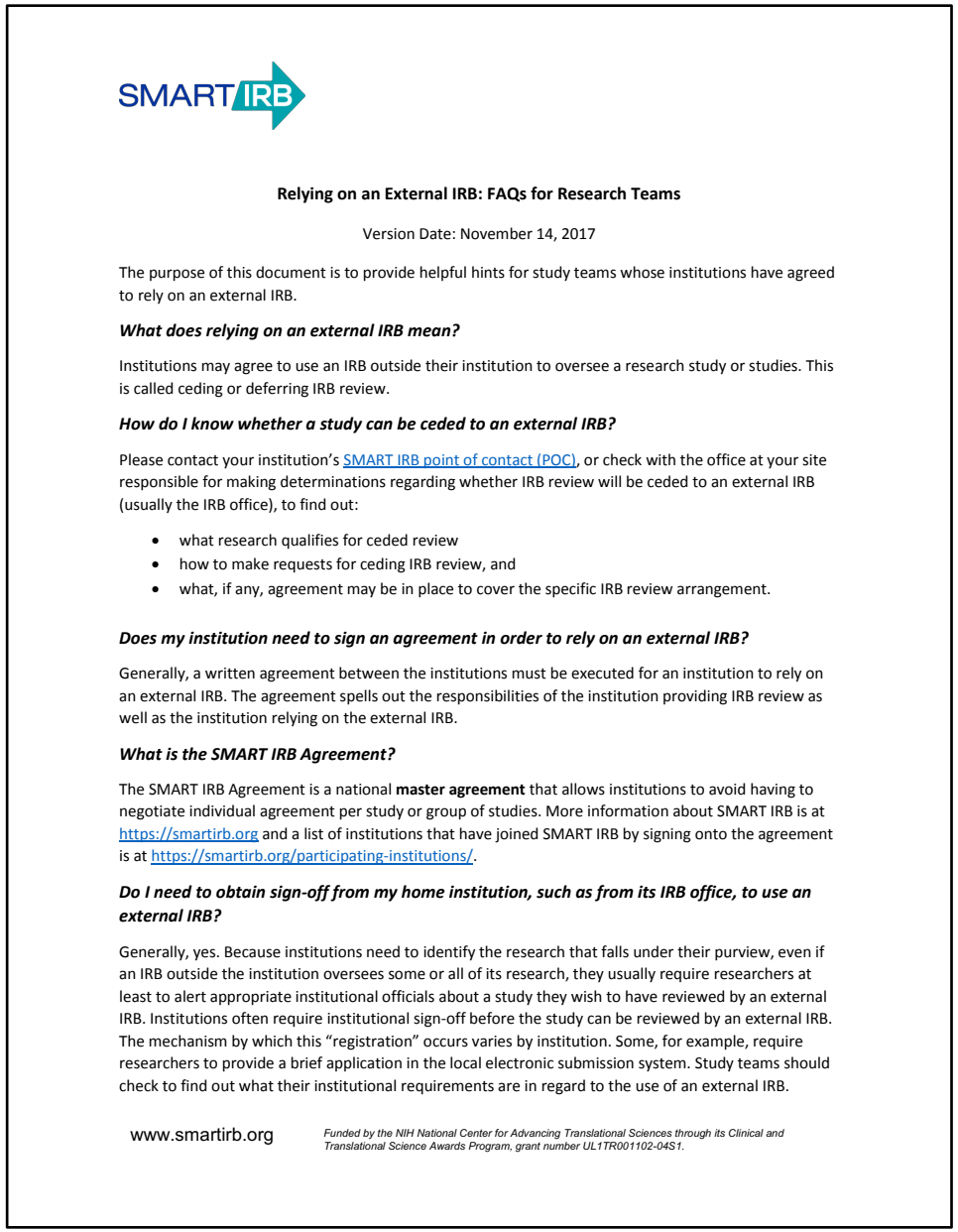
For externally funded studies, provide your sponsored programs office with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

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/.

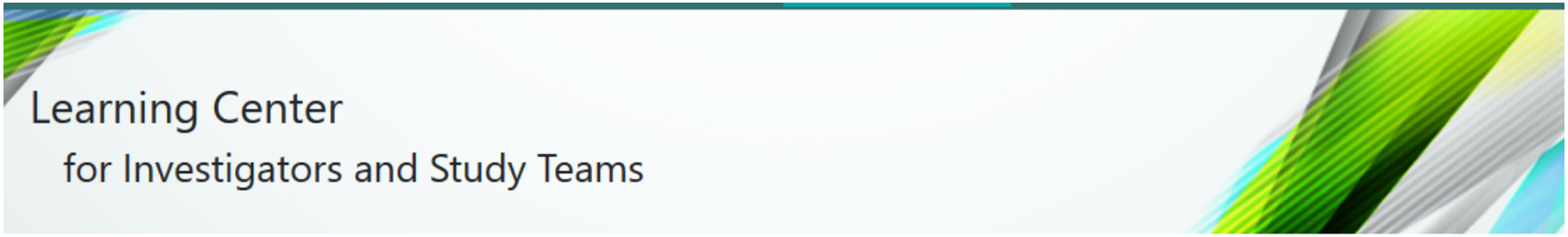
Do I need to obtain sign-off from my home institution, such as from its IRB office, to use an external IRB?

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.

Investigator Guidance at smartirb.org/study-teams/



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.

Start-Up Packages	Introduction to sIRB Review	NIH sIRB Policy	Selecting an sIRB
Developing an sIRB Plan	Effects on Research Costs	Study Team Roles	Online Reliance System

SMART IRB Start-Up Packages

These packages contain a suite of resources to help you prepare NIH grant applications that require single IRB review and to ensure you understand and can fulfill your responsibilities related to single IRB arrangements. Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

Download Study Team Package

Download NIH Grant Preparation Package

Customized Learning

https://smartirb.org/irb-admin/

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

Study Team Packet: smartirb.org/study-teams/

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.

Roadmap for Submission by Sites to get Approval

Maps for Study Teams- Reviewing IRBs

WHO IS YOUR AUDIENCE?

- Overall PI/ Study Team
  - Local or External
- Participating Site PI/ Study Teams
  - Local or External
- Relying Site HRPP Staff

Maps for Study Teams- Reviewing IRBs

WHAT INFORMATION DO THEY NEED?

- Email Templates
  - Numbers, Bullets or Charts
  - Specify Responsible Party
- Manuals
  - Screenshots and Images

Templates for Communication

Relying Site Study Teams

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

Relying Institution POC

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

Study Name: NAME

PI: NAME

Hello,

The above named PI at your institution is going to be participating in the above named study. A single IRB will be used for this study. Washington University IRB will be the Reviewing IRB.

When acting as the single IRB, WU uses the *my*IRB electronic submission system to document your institution's determination to rely and review and approval each site.

We will be using the SMART IRB agreement for this reliance.

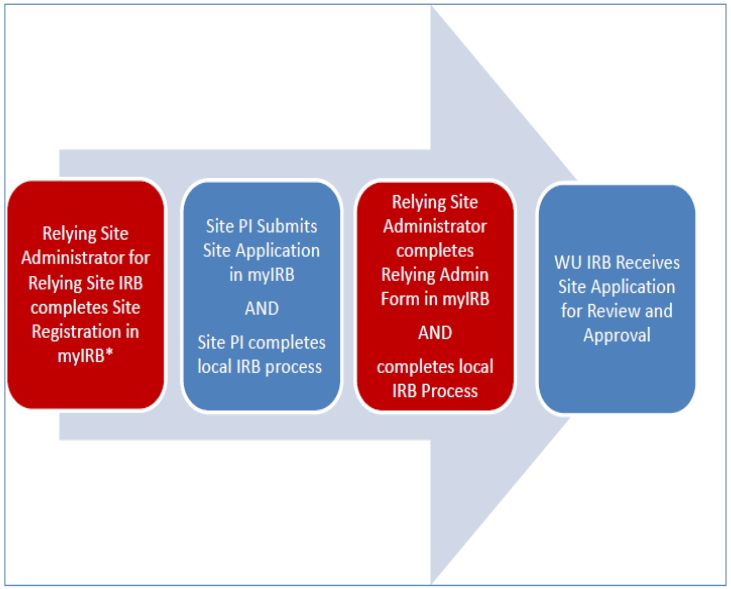
ACTIONS FOR PI/ STUDY TEAM

1. The first step for you to complete are to obtain an IDs for our system, set up delegates if desired and complete the sIRB New Site application. I have attached the user reference manual for our system. Please review this ASAP and set up your ID and any delegates you want to be able to work in myIRB on your behalf.
    a. You will need IRB ID number 202006141.
2. Determine the process that needs to be completed locally in order to obtain their agreement to defer oversight with your IRB and complete that process. Contact your IRB or research office for information if you are unsure.
    a. The approval memo, approved protocol and all approved template documents are or will be available in myIRB. PLEASE CAREFULLY READ THE ATTACH MANUAL FOR INSTRUCTIONS REGARDING THE CONSENT FORM.

ACTIONS FOR IRB

1. I have attached an Addendum to the SMART IRB agreement. You will find that this document lays out how the items left flexible in the agreement will be operationalized for this study. Unless you have a Master Addendum on file with us, we ask that you review, sign and return to me via email. Please note this addendum is NOT an agreement to defer, this is only documenting the flexible terms. You will only be asked to agree to defer after you have had the opportunity to review the study. If you need to request changes, please email me at Carissa.minder@wustl.edu.

Section 1: Washington University sIRB Review Process



* One-time process. May already be completed. WU IRB will provide specific instructions on what steps a Relying Institution Site Administer needs to complete on a study by study basis.

1.1: Reliance Agreements

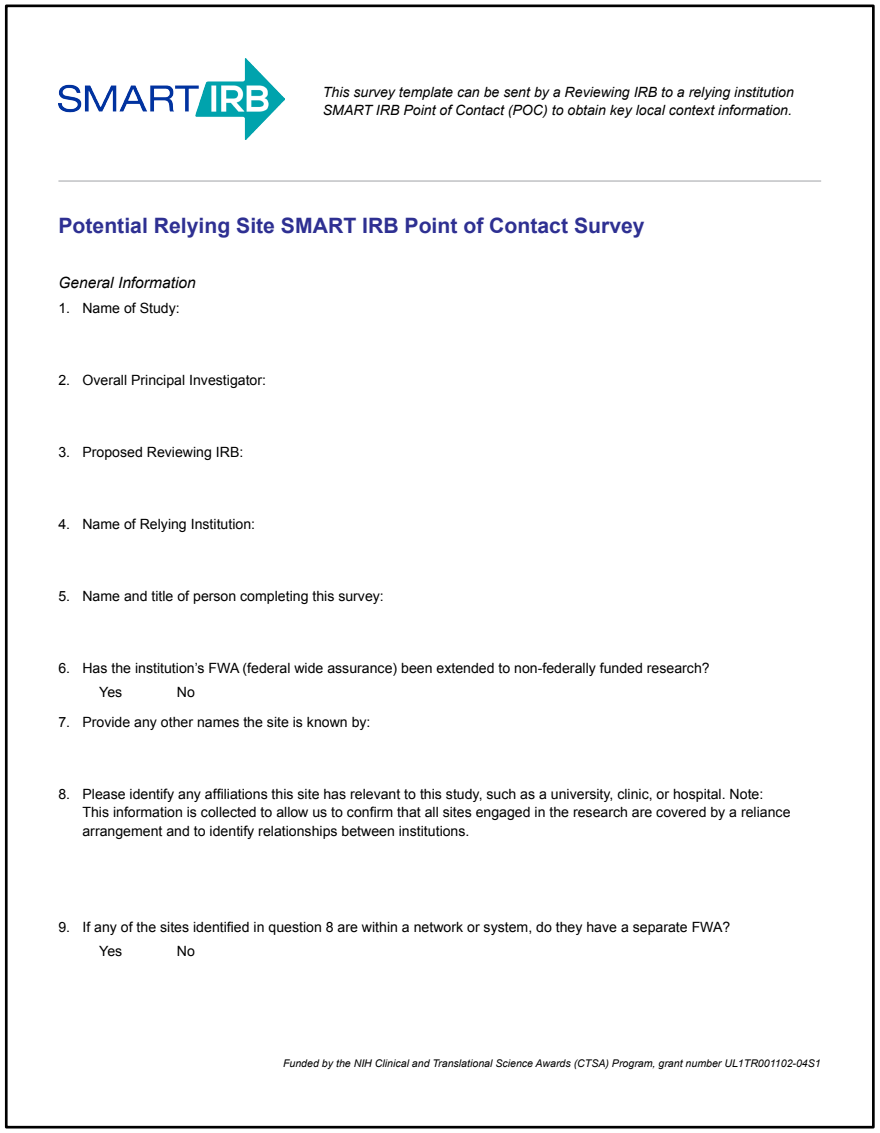
Relying Institutions will also be asked to sign a Reliance Agreement or an addendum to an existing Master Reliance agreement on a study by study basis. This will be done via email directly with the appropriate contact at the Relying Institution. This process will happen concurrently with the above process.

Site Specific Information

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

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Protocol Specific Document

Protocol-Specific Document: Reviewing IRB POCs may use this to obtain local context specific to a given protocol from Relying Institutions.


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

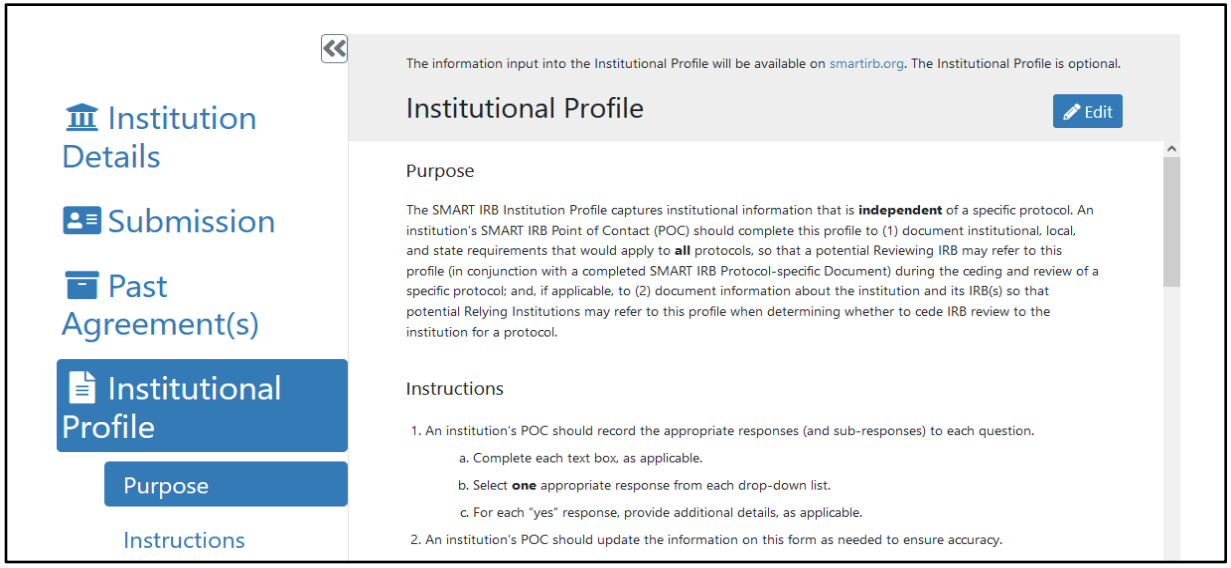
Harmonized: This document underwent a review and input process from February 2017 to July 2018 and has now been finalized.

SMART IRB Joinder - Institutional Profile

SMART IRB Joinder: Designated POCs can log in to complete their Institutional Profile

1) Documents institutional, local, and state requirements that applies to all protocols and

2) Institutions can use this profile when determining whether to cede IRB review.



Finalizing the Reliance Arrangement

Request, Track, and Document Arrangements

SMART IRB Online Reliance System Launched in May 2017

Single point of entry standardizes reliance processes

Communication portal eliminates tracking via email or other methods

Guided workflow makes clear when action is required

The system works for institutions:

1. With and without significant reliance experience
2. Familiar or unfamiliar with one another
3. With limited or substantial infrastructure to support single IRB review

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

Get started at smartirb.org/reliance.

Benefits for INVESTIGATORS

Clarity and Guidance

The system guides you through the request process, collecting the information institutions need to determine an appropriate arrangement for your study

Automatic Notifications

Email notifications ensure you are informed at key points in the decision-making process

Reliance Tracking

The system gives you a window into the decision-making process and provides a single place to track reliance arrangements for your studies

Benefits for INSTITUTIONS

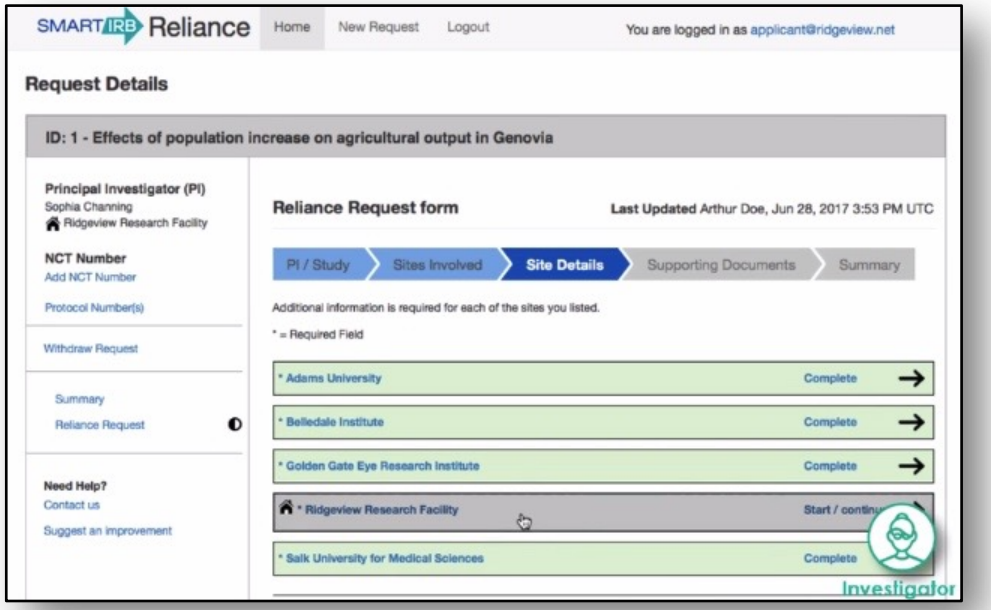
Provides a centralized place to record and track reliance arrangements on a study-by-study basis

Connects you with the appropriate POC for each site, eliminating the need to track down their information

Guides you through the decision-making process, making clear when your action is required

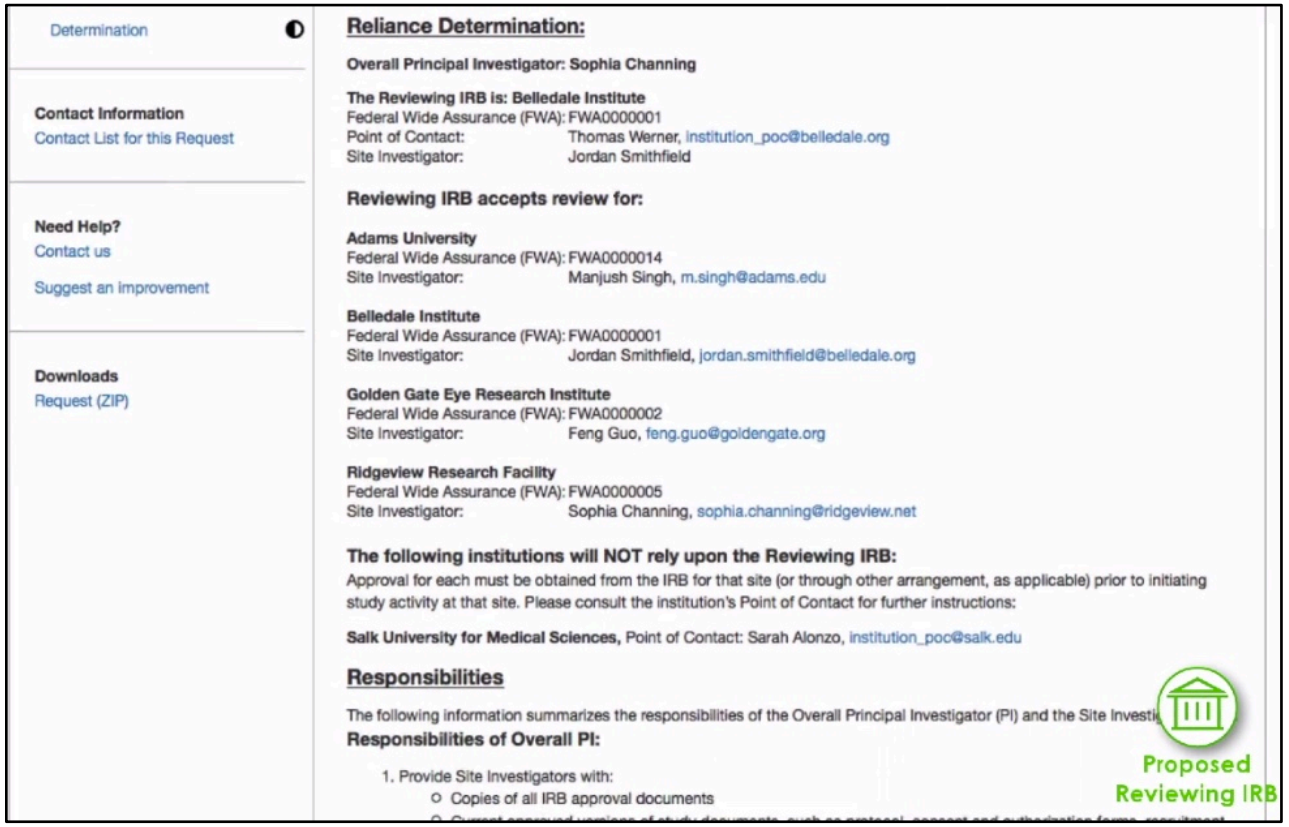
Provides a central, transparent platform to communicate local context issues

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



Preview a Sample Reliance Request Form.

System-generated Determination Letter

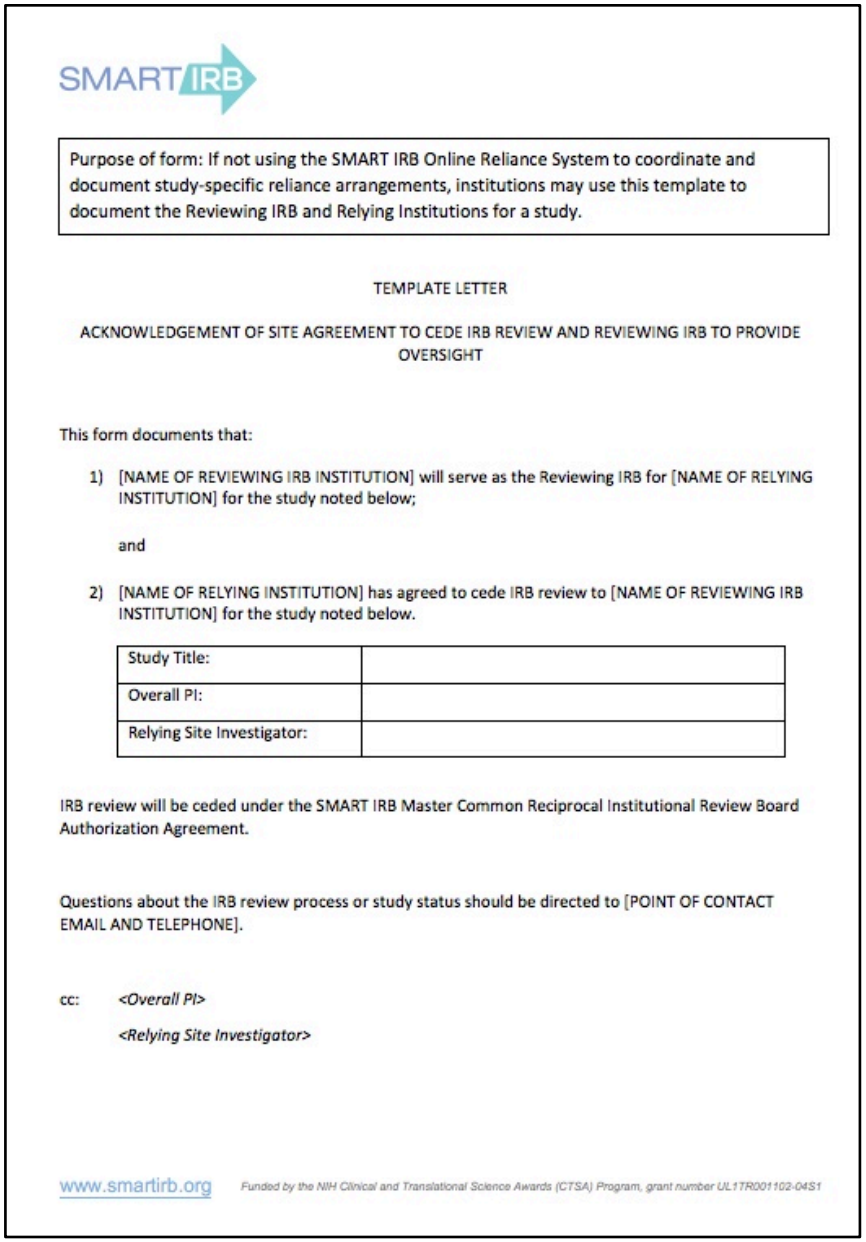


- Sent to Overall PI, Site Investigators, and designated contacts for all engaged sites; stored in the system.
- Documents the Reviewing IRB and Relying Institution(s).
- Describes responsibilities of the Overall PI and Site Investigators.

Template Letter of Acknowledgement

If not using the SMART IRB Online Reliance System to coordinate and document study-specific reliance arrangements, institutions may use this template to document 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>

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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:

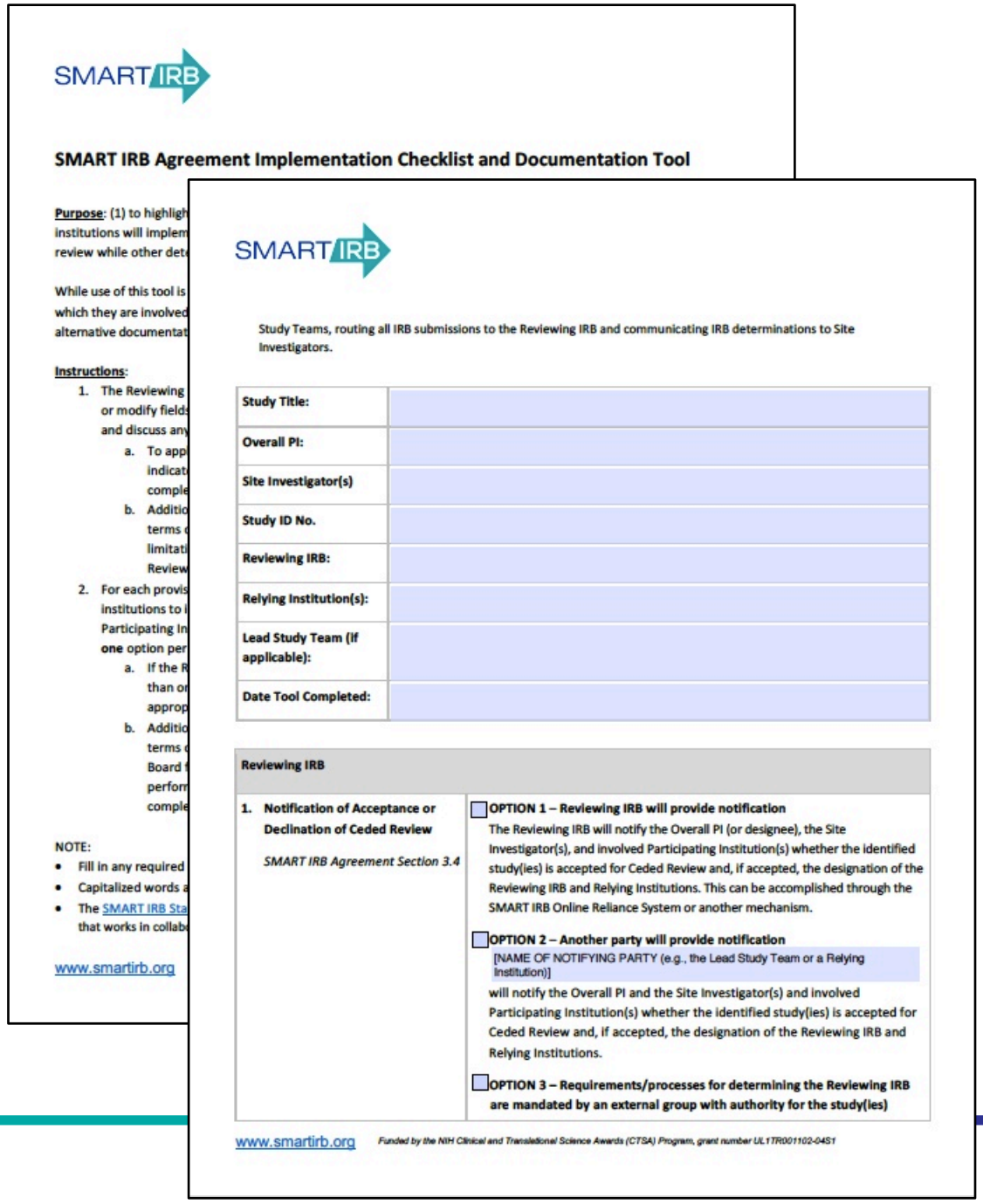
- Whether Reviewing IRB will make Privacy Board determinations
- Who reports events to federal agencies/sponsors
- Whether insurance will be required
- Whether a separate indemnification agreement will be required
- Whether the relying institution will be required to be able to conduct for cause audits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

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

Instructions:

1. The Reviewing
or modify field
and discuss any
   a. To app
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   b. Additio
terms
limitati
Review
2. For each provis
institutions to i
Participating In
one option per
   a. If the R
than o
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NOTE:

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

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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

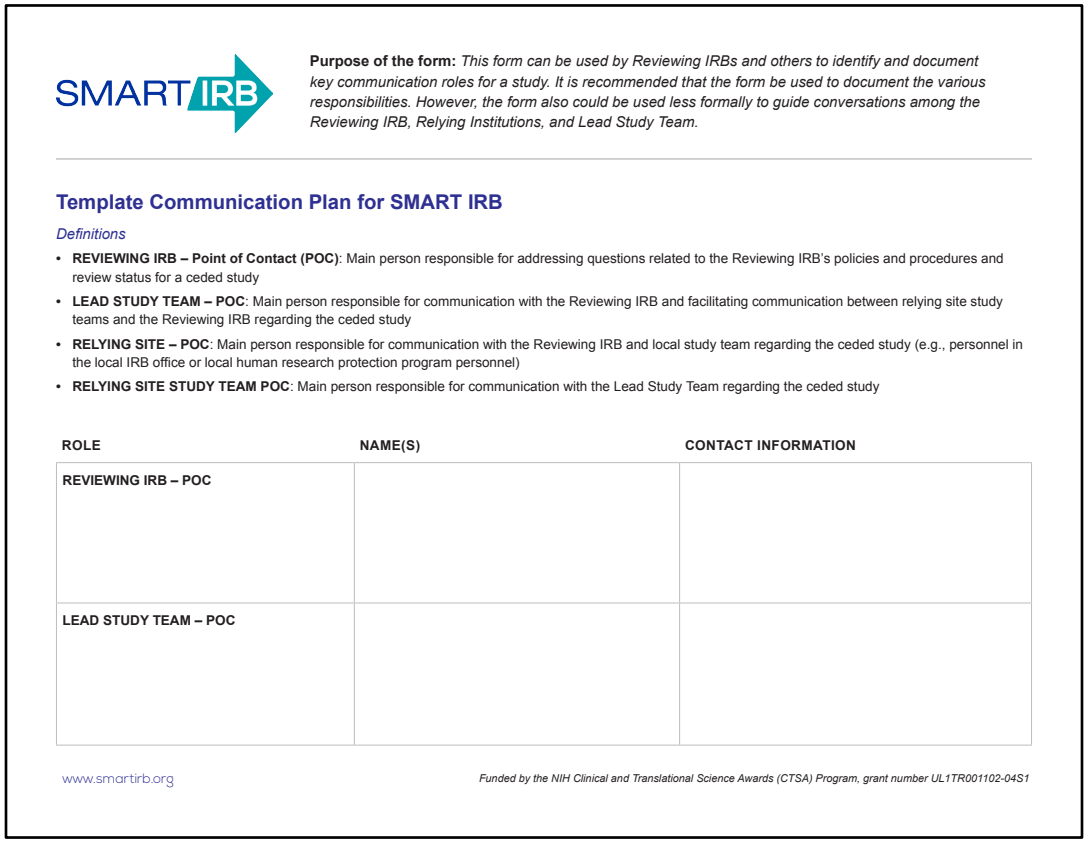
Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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.

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		

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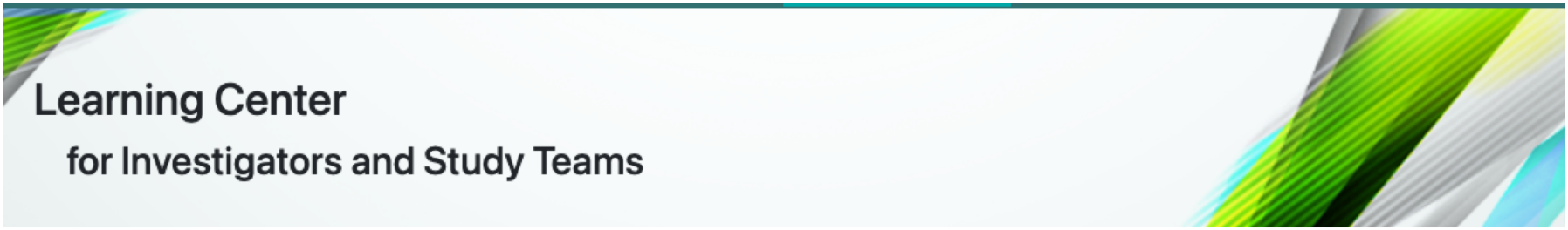
Investigator Guidance at smartirb.org/study-teams/



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.

Start-Up Packages	Introduction to sIRB Review	NIH sIRB Policy	Selecting an sIRB
Developing an sIRB Plan	Effects on Research Costs	Study Team Roles	Online Reliance System

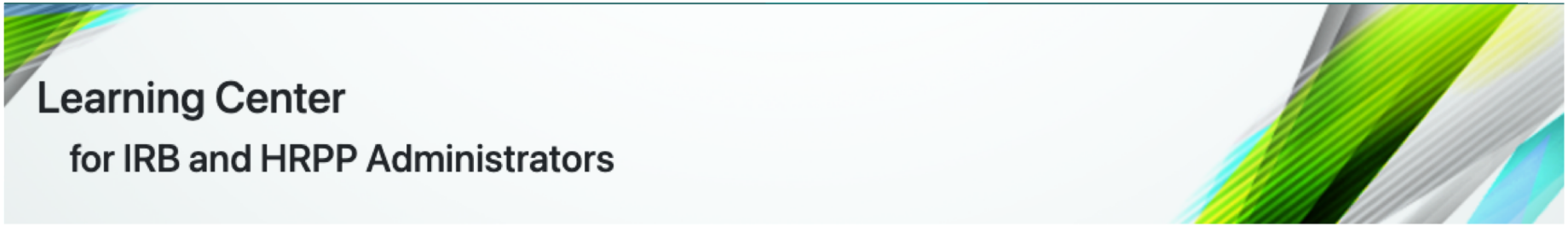
SMART IRB Start-Up Packages

These packages contain a suite of resources to help you prepare NIH grant applications that require single IRB review and to ensure you understand and can fulfill your responsibilities related to single IRB arrangements. Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

Download Study Team Package

Download NIH Grant Preparation Package

IRB/HRPP Guidance at smartirb.org/irb-admin/



The videos and companion resources below are designed to help IRB and HRPP administrators and staff successfully manage single IRB arrangements.

Start-Up Packages | Implementing the Agreement | Reviewing IRBs | Relying Institutions | Getting Started

Online Reliance System | Resources for IRB/HRPPs | SMART Talk Forum | Training Study Teams

SMART IRB Start-Up Packages

These packages contain a suite of resources to help you understand and fulfill your roles and responsibilities in a single IRB arrangement. Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.

See also: Start-up Packages for Study Teams.

Download Reviewing IRB Package

Download Relying Institution Package

Getting Help from the SMART IRB Team

We're Here to Help

- SMART IRB Ambassadors are available to help institutions join 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.

More Learning Opportunities

Watch past webinars on the basics:

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

Ongoing, mostly-monthly SMART Talks address topics related to sIRB review.

Catch-up on past sessions, and join our mailing list to be notified of upcoming offerings.

Visit the SMART IRB Resource library to watch previous sessions and download slides.

Questions and Discussion

Save the date for the next SMART Talk
September 15, 2021
2:00-3:30 pm ET

Using AAHRPP's I-9 Standard to Guide Reliance Arrangements

Questions?
Contact help@smartirb.org

Register at smartirb.org

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