SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

This project has been funded in whole or in part with Federal funds from the National Center for Advancing Translational Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N950C00008.

FYI

Questions for the presenter or SMART IRB Team are welcome! Please post these under ‘Q/A’

Questions for fellow attendees should be posted under ‘Chat’

A link to today’s recording will be emailed to attendees. A recording will be posted on the SMART IRB website

Your feedback is valued! Please complete the survey at the end of the SMART Talk! The survey will be emailed as well.

What Is SMART IRB?

SMART IRB is…

A federally funded project to support institutions and researchers in the implementation of single IRB

SMART IRB provides…

An IRB reliance agreement

An Online Reliance System to initiate and track reliance

Zero Cost Education, Guidance, and Resources

SMART IRB is NOT…

An IRB

An electronic system for Reviewing IRBs to receive studies for review

Reach out to a SMART IRB Ambassador

Aaron Kirby
Harvard Catalyst

Polly Goodman
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Jeremy Lavigne
Harvard Catalyst

Ada Sue Selwitz
University of Kentucky

Carissa Minder
Washington University in St. Louis

Kathy Lawry
AAHRPP

Nichelle Cobb
AAHRPP

Stacey Goretzka

Lubabah Helwani
University of Southern California

Find your SMART IRB Ambassador: www.smartirb.org

Upcoming Events

Single IRB Boot Camp:
A How-to Guide with SMART IRB

February 12-13, 2025
12:00pm-3:00pm ET

Stay Tuned For Registration!

SMART IRB Version 3.0 Overview of Changes, Public Comment Periods

Proposed V3.0: A Significant Change to the SMART IRB Agreement

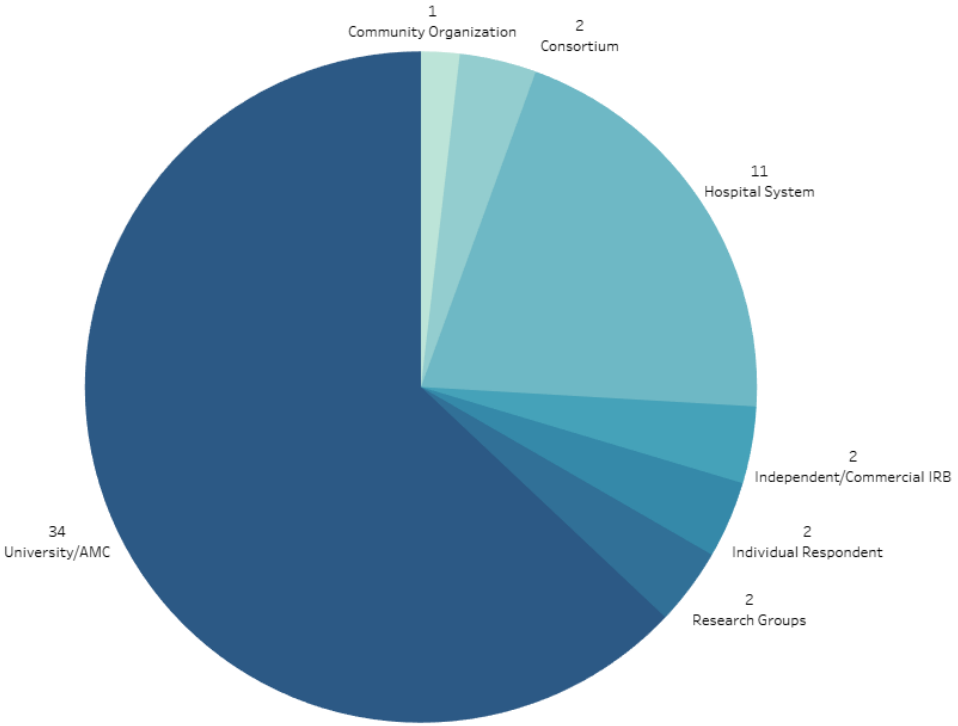
Major drivers for V3.0:

- Address feedback from current and potential Participating Institutions
- Fully reflect changes to IRB review requirements in the 2018 Common Rule; and
- Enable additional federal agencies to participate in the agreement

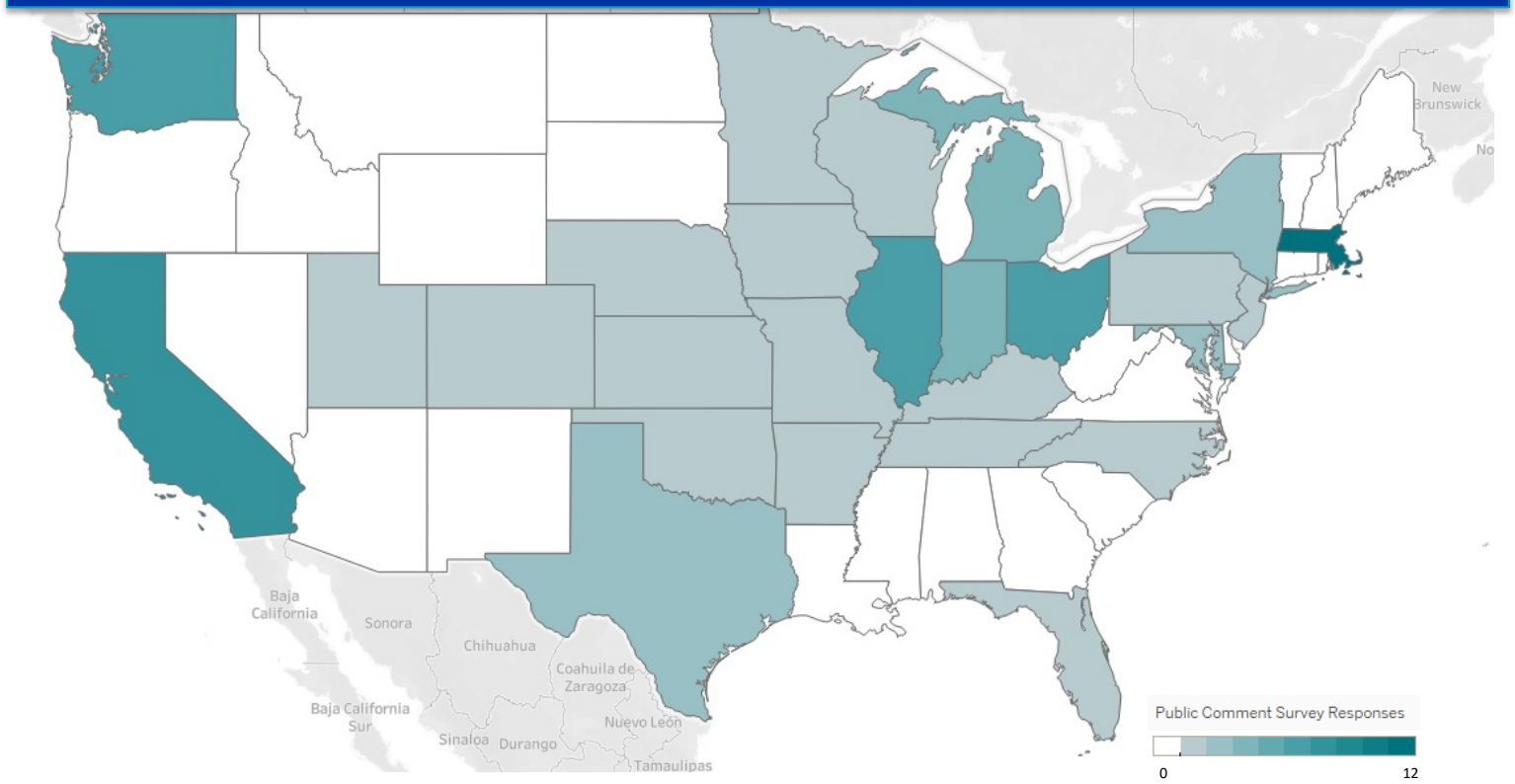
V3.0 Public Comments Round 1: 11/15/23-02/15/24

250 Comments received from 54 institutions across the United States

Public Comments by Organization Type



Public Comments by Geographic Area



‘Deal-Breakers’ and How We Addressed Them

4 Key dealbreakers arose from the 1st round of Public Comments

- Grandfathering
- Indemnification
- Governing Law and Venue (requesting silence)
- Local Considerations (Federal Policy/Processes)

Transition from Versions 1.0/2.0 to Version 3.0 (Grandfathering)

Type of Request	SMART IRB Agreement Version(s)
New Reliance Requests	SMART IRB Agreement V3.0
Newly Joining Institutions	SMART IRB Agreement V3.0
Current Reliance Requests	SMART IRB Agreement V1.0 or V2.0
New Site added to an Existing Reliance Request	SMART IRB Agreement V3.0*

***SMART IRB Agreement V3.0 Required for Reviewing IRB & Newly added Relying Institution only.**

Transition to the New Optional SMART IRB Indemnification Addendum

Type of Indemnification Agreement	Scope
Existing Indemnification Agreements	SMART IRB Indemnification Addendum will not supercede any separate indemnification Agreements
SMART IRB Indemnification Addendum	Applies to any requests entered into by two (or more) institutions who are signatories to the SMART IRB indemnification addendum unless a more limited scope is agreed to by the institutions
Other Indemnification Addendums	Will continue to be permitted

V3.0 Public Comments Round 2: 11/13-12/13/24

THANK YOU to all who provided feedback!

- 20 unique comments received from 12 institutions across the United States

V3.0 Public Comments (2nd Round)

- Indemnification Addendum
- Insurance
- Other Considerations
- Audits and Investigations
- Reports and Communications with Federal Funding Agencies

Indemnification Addendum

- Request to clarify that electing to join or not join Indemnification has no impact on eligibility to participate in Agreement
  - Will add language to Section 4.1 of V3.0 stating this explicitly
- Requests to exempt all Public Institutions from providing indemnification/reimbursement or further modify Public Institutions' responsibilities
  - Will maintain reference to Public Institutions (other than federal agencies) providing reimbursement to the extent not limited by applicable law/regulation/constitution
- Requests for Indemnification Addendum to be silent on governing law/venue
  - Will retain governing law/venue provision in Indemnification Addendum

Insurance

- Request not to exempt Public Institutions from insurance requirement in Section 4.9
  - Will maintain exemption for all Public Institutions from requirement to have insurance coverage or self-funded liability coverage

Other Considerations

- Request to tighten language in Section 6.6 stating when a Relying Institution must identify and communicate “Other Considerations” (*federal* laws, regulations, and agency requirements *other than human subjects requirements*)
  - Will change language from when Other Considerations “may not be apparent from the Research protocol” to when Other Considerations “are not readily apparent from the IRB submission for the Research”

Audits and Investigations

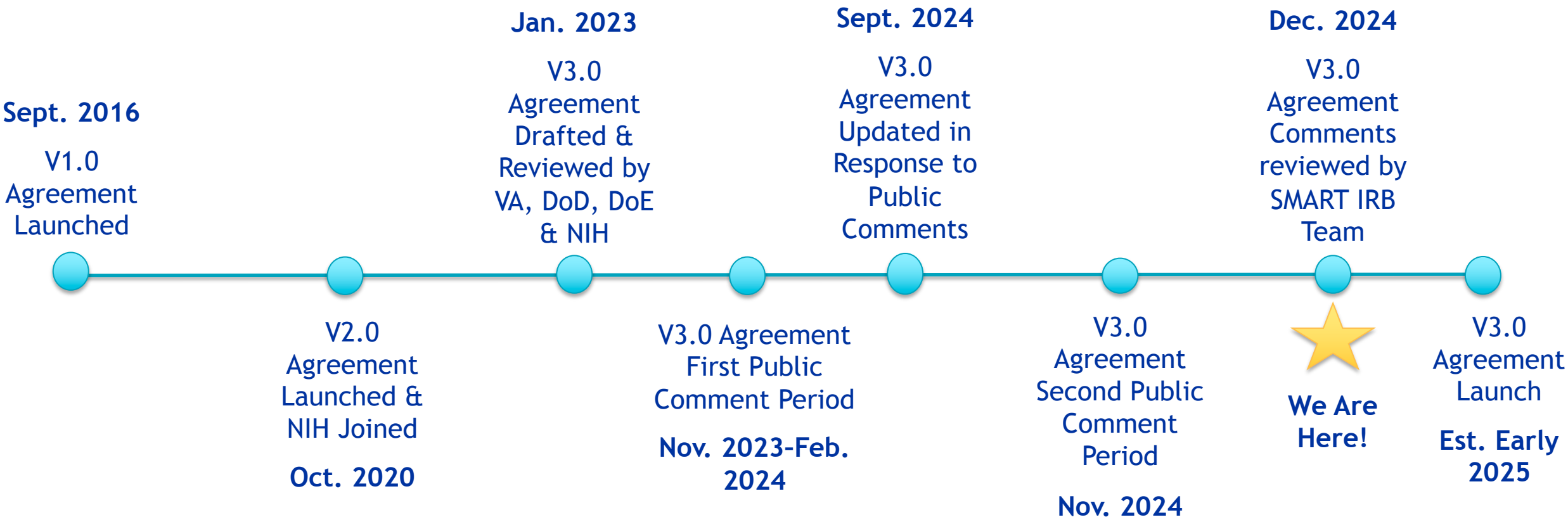
- Request to limit number and times when Reviewing IRB can require or conduct audits and/or to require Reviewing IRB to pay audit costs
  - Will leave audit provisions (Sections 5.12 and 6.15) as written
- Request to remove requirement for Participating Institutions to notify one another of for-cause compliance investigations by federal agencies
  - Will leave notification provision (Section 4.6.1) as written

Reports and Communications with Federal Funding Agencies

- Request to further clarify that any (non)compliance reports required to federal *funding* agencies (e.g., program officers) are the responsibility of the Relying Institution
  - Will add further clarifying language to Section 5.13 and corresponding definition of “Report”
- Request to further clarify that communications by federal funding agencies will typically be with Relying Institutions and not Reviewing IRBs
  - Will add further clarifying language to Section 5.14

V3.0 Launch: Next Steps, Resources and Discussion

The Road To V3.0: Where We've Been, Where We're Going



Most Frequently Asked Questions on V3.0 Implementation

- Is V3.0 compatible with consortium agreements (e.g. HIPAA, ICFs, etc)
- Does V3.0 include flexible options for reliance arrangements?
- Does the process for initiating reliance arrangements change under V3.0?
- How do I document which site is taking on HIPAA responsibilities?
- Can my institution (Reviewing IRB) require relying sites to transition to V3.0?

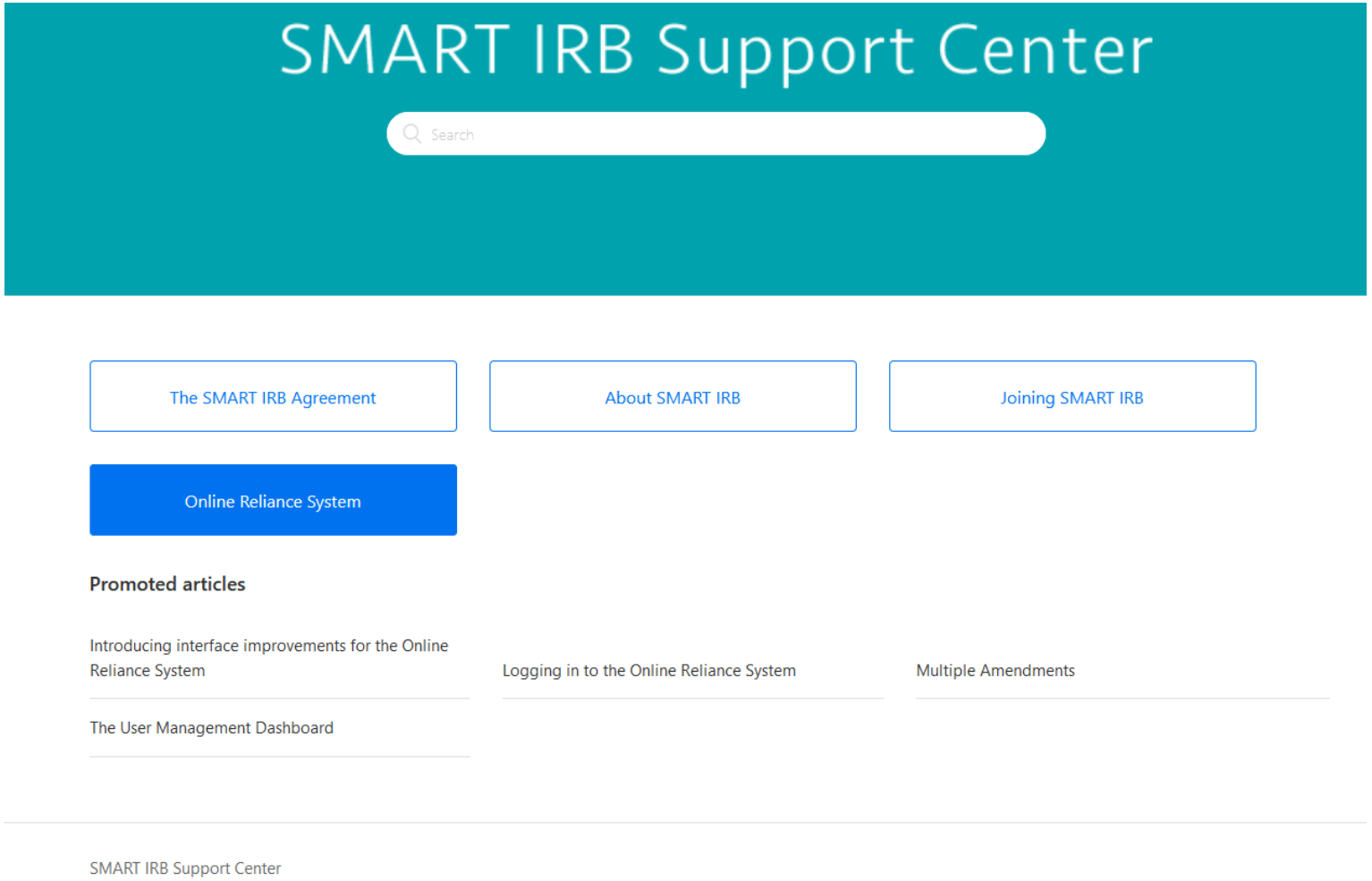
Most Frequently Asked Questions on V3.0 Implementation

- What resources will SMART IRB make available to help institutions with V3.0?
- How much support from SMART IRB can I expect when V3.0 launches?
- Does my institution need to use the new Reliance System when V3.0 launches?
- Others? Let us know using the Q/A function!

SMART IRB Resources Review/Updates Project: 2023-Ongoing

THANK YOU to **SMART IRB Ambassadors** for your tremendous efforts!

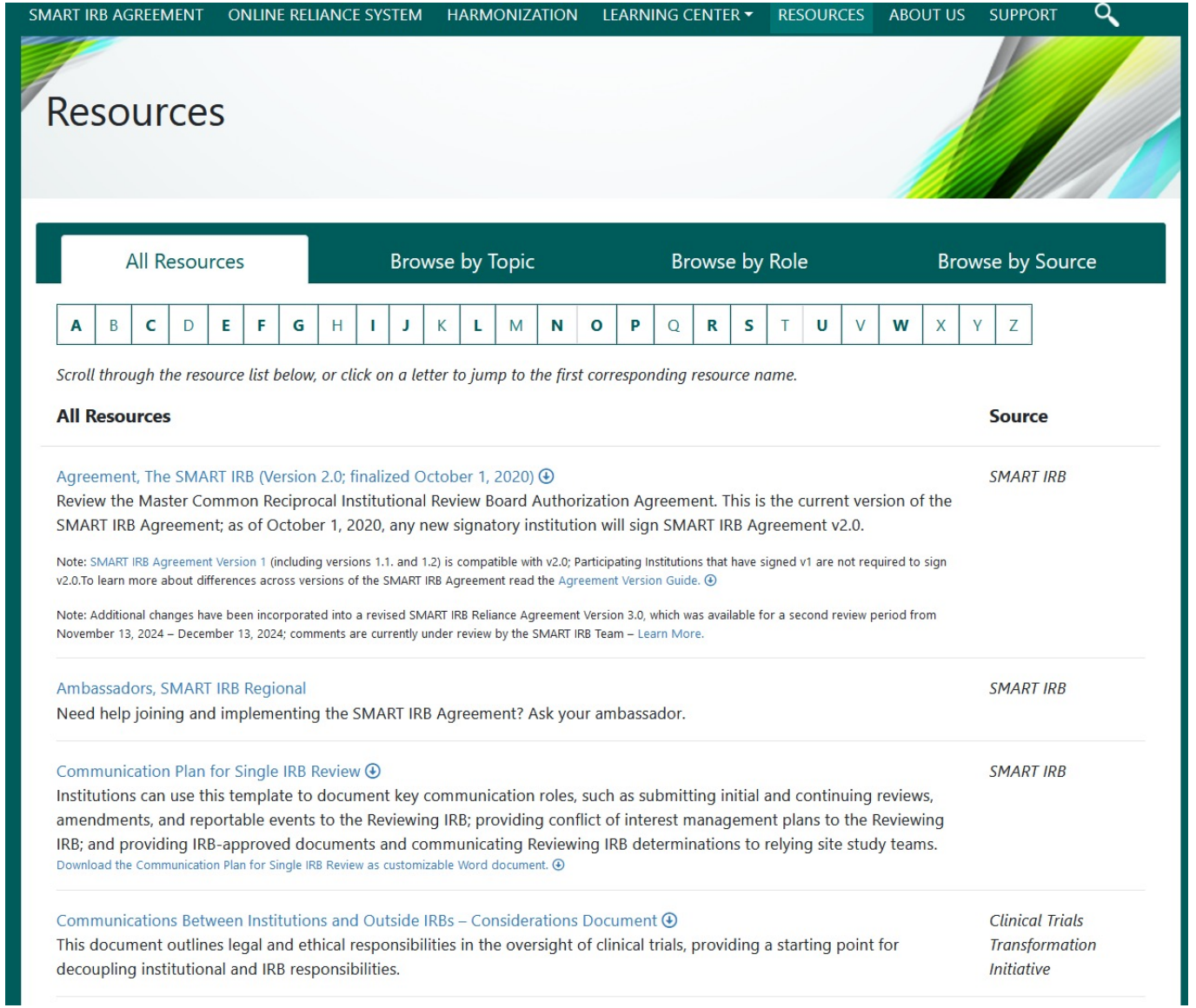
- Support Center (https://smartirb.org/support/)
  - 70 of 155 articles updated (45%)
  - Also accessible via the Help Widget



SMART IRB Resources Review/Updates Project: 2023-Ongoing

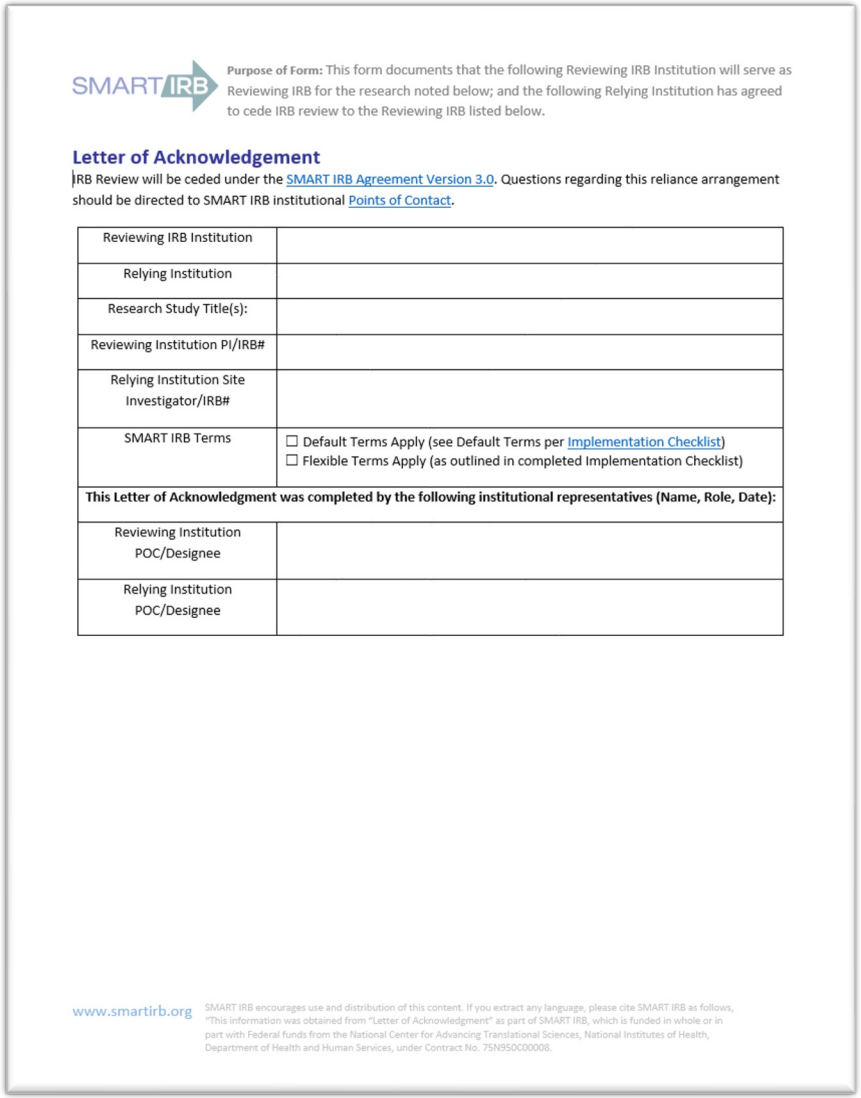
THANK YOU to **SMART IRB Ambassadors** for your tremendous efforts!

- Resources
  - 27 of 101 resources updated (27%)
  - Key V2.0/V1.0 resources will be kept as ‘Legacy’



Resource Updates for V3.0: Letter of Acknowledgment

- AKA the “Paper Copy”, “One Pager”, “LOA”
- Primarily used when sites opt against using the Online Reliance System or when using “flexible terms”
- Multiple accepted versions of LOA to be provided to community
- New LOA incorporates much-requested items:
  - Reduction in time to completion
  - Default vs flexible terms
  - Hyperlinking to key SMART IRB Resources
  - Validation/Signature Options



SMART IRB

Purpose of Form: This form documents that the following Reviewing IRB Institution will serve as Reviewing IRB for the research noted below; and the following Relying Institution has agreed to cede IRB review to the Reviewing IRB listed below.

Letter of Acknowledgement

IRB Review will be ceded under the SMART IRB Agreement Version 3.0. Questions regarding this reliance arrangement should be directed to SMART IRB institutional Points of Contact.

Reviewing IRB Institution	
Relying Institution	
Research Study Title(s):	
Reviewing Institution PI/IRB#	
Relying Institution Site Investigator/IRB#	
SMART IRB Terms	☐ Default Terms Apply (see Default Terms per Implementation Checklist) ☐ Flexible Terms Apply (as outlined in completed Implementation Checklist)
This Letter of Acknowledgment was completed by the following institutional representatives (Name, Role, Date):	
Reviewing Institution POC/Designee	
Relying Institution POC/Designee	

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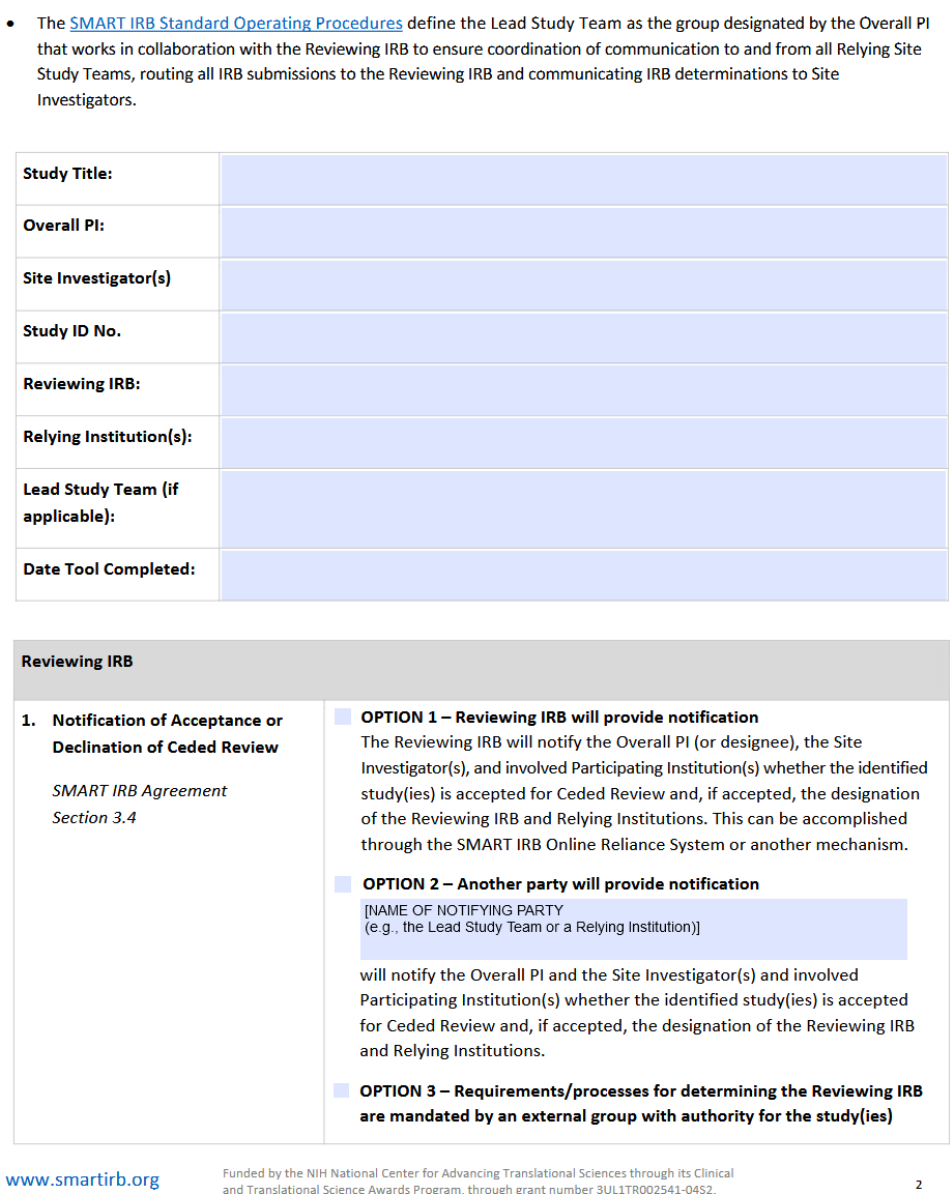
SMART IRB encourages use and distribution of this content. If you extract any language, please cite SMART IRB as follows, "This information was obtained from "Letter of Acknowledgment" as part of SMART IRB, which is funded in whole or in part with Federal funds from the National Center for Advancing Translational Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N950C00008.

Implementation Checklist for V3.0

- Traditional means of outlining key flexible options within the SMART IRB Agreement
- Document updates include:
  - Institutional validation
  - New sections of the agreement
  - ‘Default’ vs ‘Flexible’ terms
  - Reduction in whitespace



- The SMART IRB Standard Operating Procedures define the Lead Study Team as the group designated by the Overall PI that works in collaboration with the Reviewing IRB to ensure coordination of communication to and from all Relying Site 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)**

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Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-04S2.

2

Resource Updates for V3.0: SMART IRB SOPs

- SMART IRB Standard Operating Procedures updated to reflect the new V3.0 Agreement
- Updates to key sections with standalone documents as well, including:
  - PI/Lead Study Team Checklist
  - Relying Site Study Team Checklist
  - Relying Institution POC Checklist
  - And more!

Next Steps/Stay Tuned: Final Steps to Prepare for V3.0

- Finalized Agreement and resources to be posted soon on the SMART IRB website
- Share final copy of V3.0 agreement with your institutional leadership
- SMART IRB to host additional SMART Talk(s), Office Hours, etc
- In Online Reliance System
  - Finish up ongoing reliance requests
  - Update your institutional details in Joinder
  - Questions? E-mail us at Help@SMARTIRB.org

Questions and Discussion