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

- May: No SMART Talk
- June: Being a Single IRB for a Study with Many Sites
- July: A Conversation with the VA and DOD about Single IRB
- August: Everything You Wanted to Know about Single IRB but Were Afraid to Ask
- September: A Conversation with the FDA about Single IRB

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
Resource Reminders

A Selection of Previous SMART Talks and Webinars

- A Conversation with NIH and OHRP about Single IRB
- Process for Review of PI and Non-PI Personnel for Multi-Site Studies
- Recommendations for Harmonization of Post-Approval Auditing of Studies Subject to sIRB Review
- Relying Institution Roles, Responsibilities, and Opportunities
- Reviewing IRBs: Working with Relying Institutions and Study Teams
- Single IRB & Continuing Review
- Single IRB for Social, Behavioral, and Education Research
- Single IRB from the Perspective of Research Teams
- Single IRB Resources: What, When, Why, & How to Use Them
- Tackling Informed Consent under the Single IRB Model

Available at
https://smartirb.org/resources/

Harmonization Steering Committee Recommendations
https://smartirb.org/harmonization/

- Ancillary Review
- Conflict of Interest
- 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

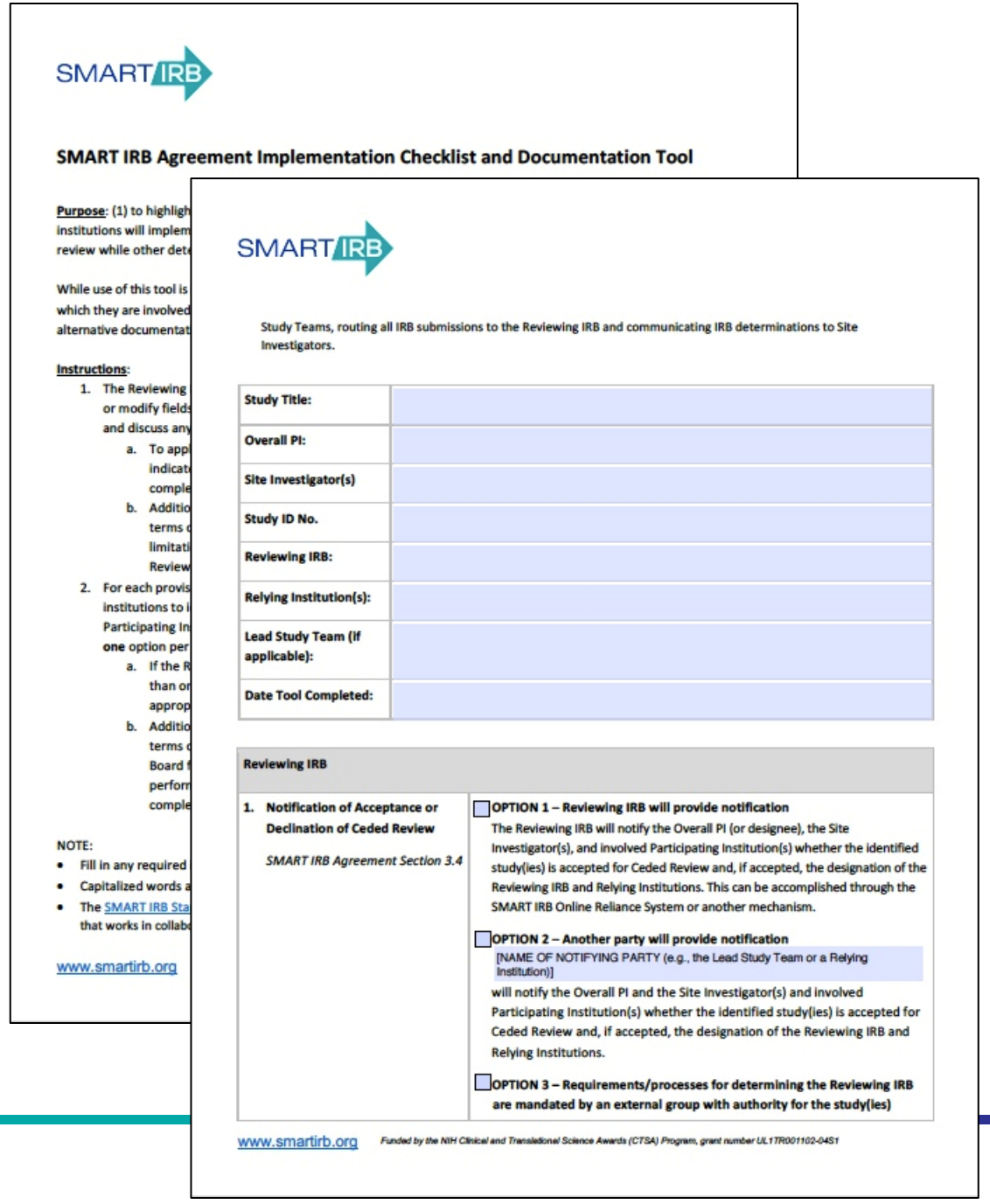
In progress:
Local considerations recommendations

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 [pdf]]

[Download the Implementation Checklist as a customizable Word document]



SMART IRB

SMART IRB Agreement Implementation Checklist and Documentation Tool

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

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

Instructions:

1. The Reviewing
or modify fields
and discuss any
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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

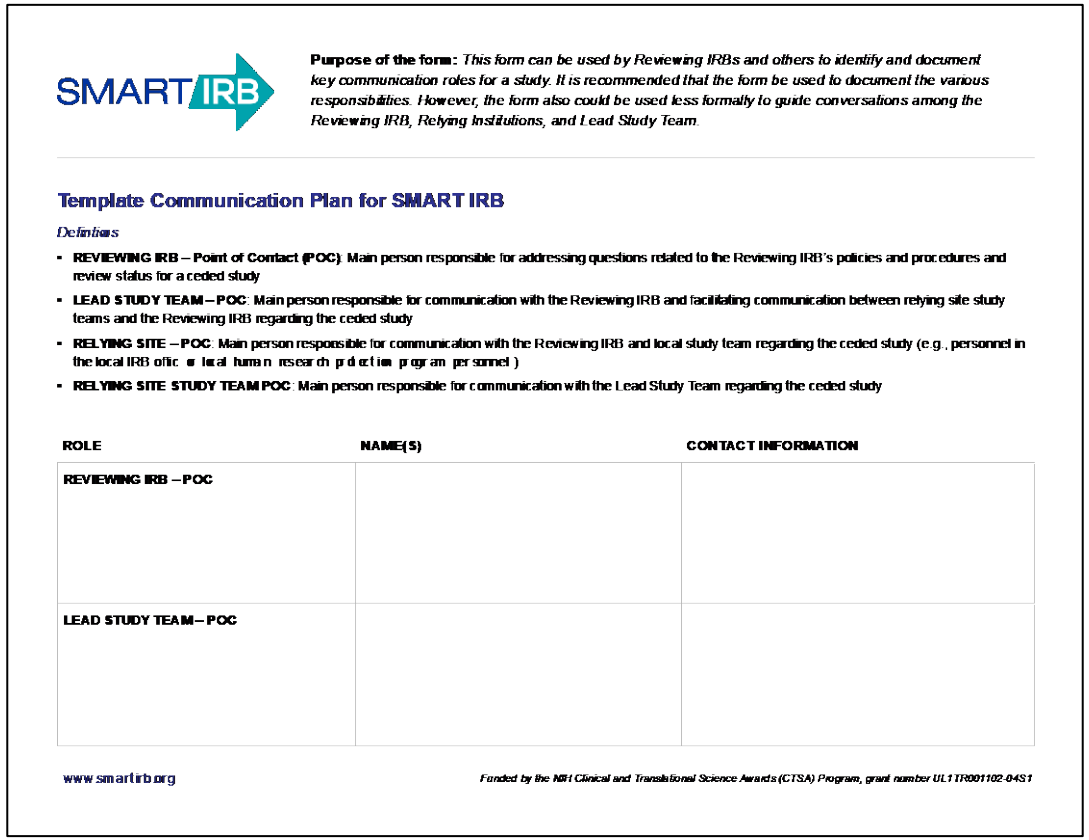
Funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR001102-04S1

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.

Download the Communication Plan [pdf]

Download the Communication Plan as customizable Word document.



SMART IRB

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

Template Communication Plan for SMART IRB

Definitions

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

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

www.smartirb.org

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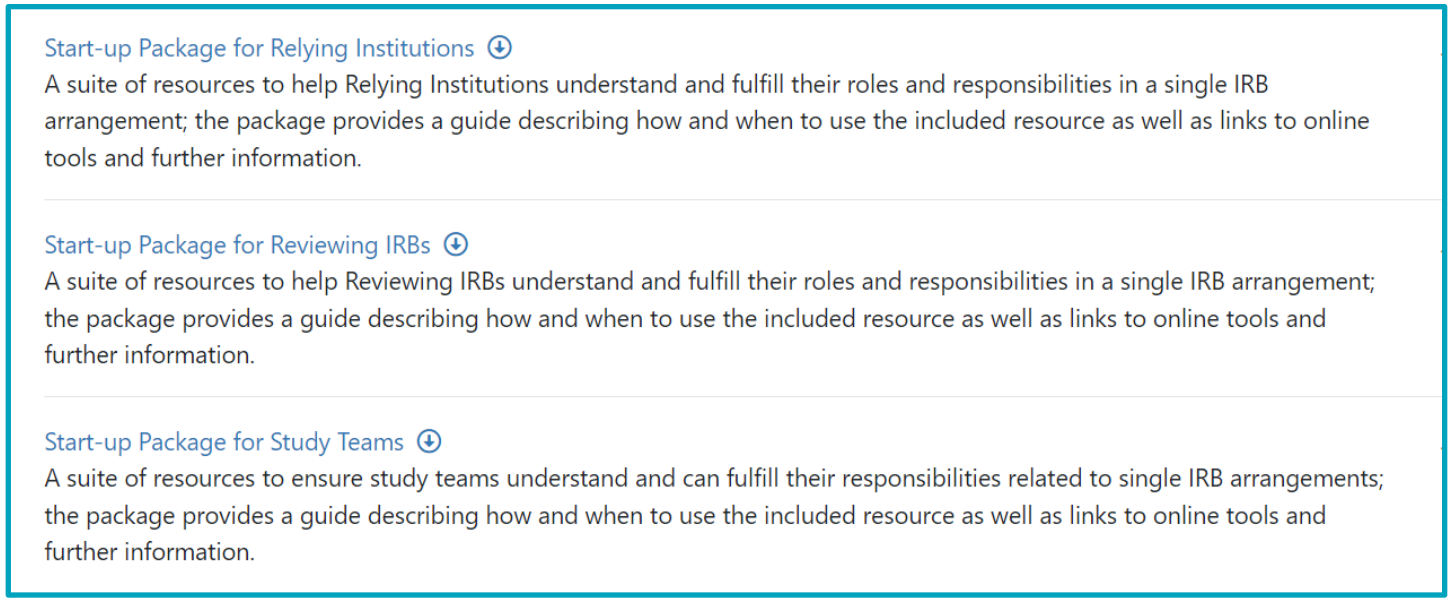
Start Up Packages at smartirb.org/resources/

These packages contain a suite of resources based on role: Study Teams, Reviewing IRBs, and Relying Institutions. Also found in the SMART IRB Learning Center.

Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.



SMART IRB Bootcamp 2022

Day 1:
https://player.vimeo.com/video/677275439

- Reliance Requests
- Using the SMART IRB Agreement
- What HRPPs need in place for single IRB review
- Online Reliance System Demonstration

Day 2:
https://player.vimeo.com/video/677279755

- Communication
- Training Study Teams
- Harmonization Guidance
- SMART IRB Resources

SMART IRB 2022: Where We've Been and Where We're Heading

Polly Goodman, Associate Director of Regulatory Affairs Operations, SMART IRB

Barbara Bierer, Director of Regulatory Policy, SMART IRB

Moderator: Nichelle Cobb

SMART IRB 2022: Where We've Been and Where We're Heading

SMART Talk - April 20, 2022

Polly Goodman, CIP
Associate Director of Regulatory Affairs Operations, SMART IRB

Barbara Bierer, MD
Director of Regulatory Policy, SMART IRB

Overview

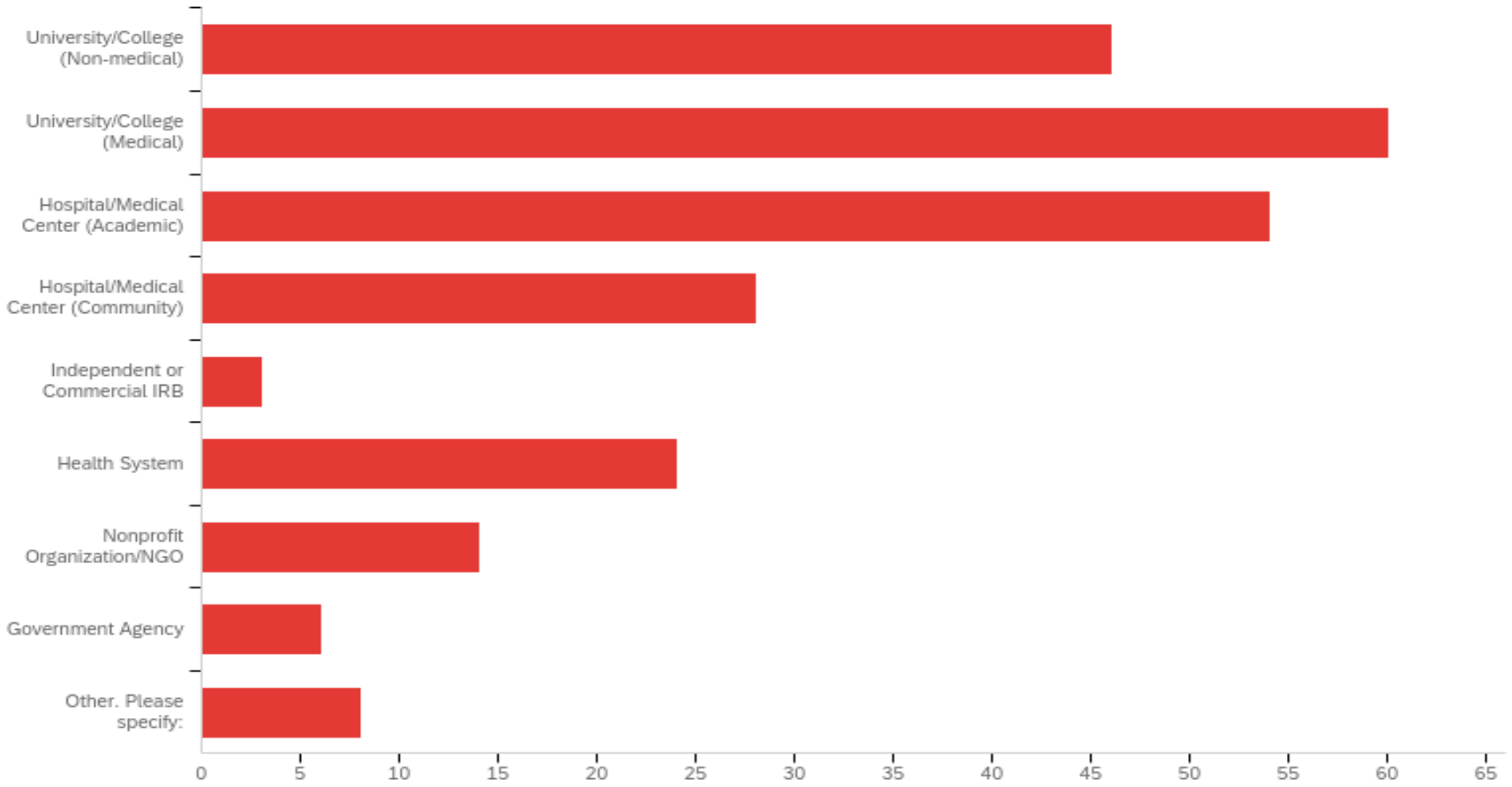
- Survey
  - Open 45 days (9/23/21- 11/7/21)
  - 109 Completed
  - 232 Initiated
  - Targeted SMART IRB Email Listserv

2021 Survey Content

- Demographics
- Implementation and usage of the SMART IRB Agreement
- Potential modifications to the SMART IRB Agreement
- SMART IRB Harmonization
- Use of SMART IRB Resources

Demographics

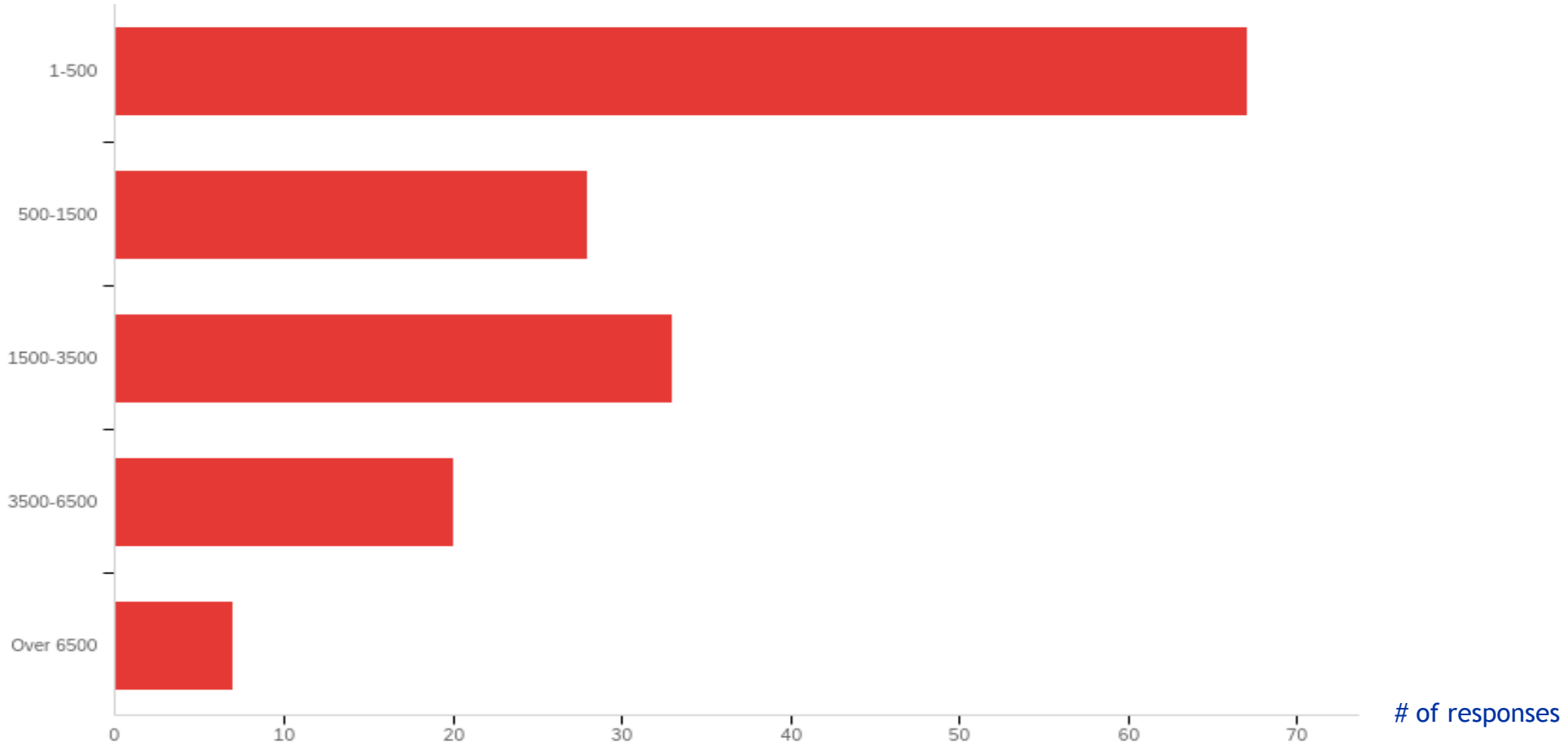
Which of the following best describes your institution?



40% of respondents indicate their institution is a CTSA recipient or affiliate

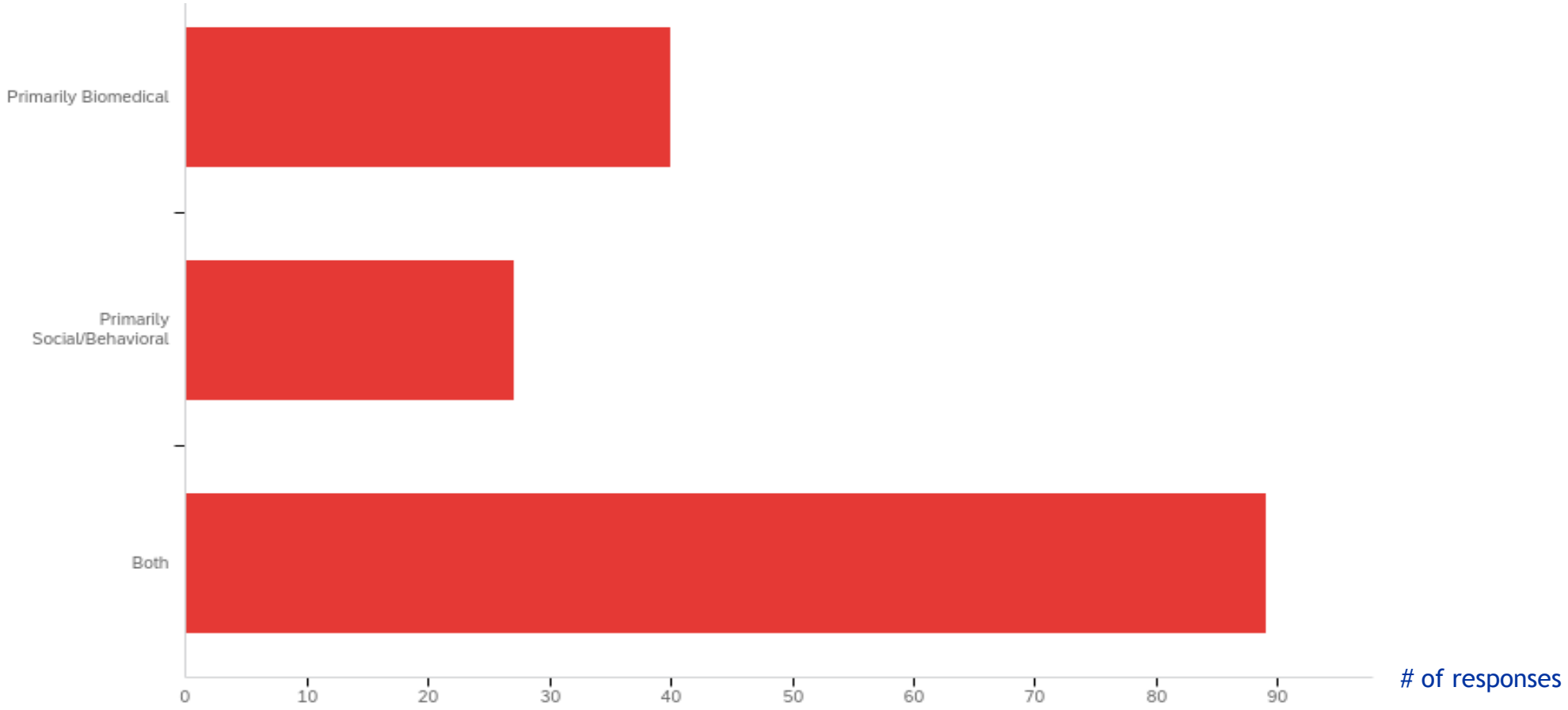
- Majority of responses came from academic institutions; these organizations are strongly engaged in SMART IRB via the CTSA consortium.

Which range best quantifies the approximate number of non-exempt, human subject research studies currently occurring at or reviewed by your institution/organization?



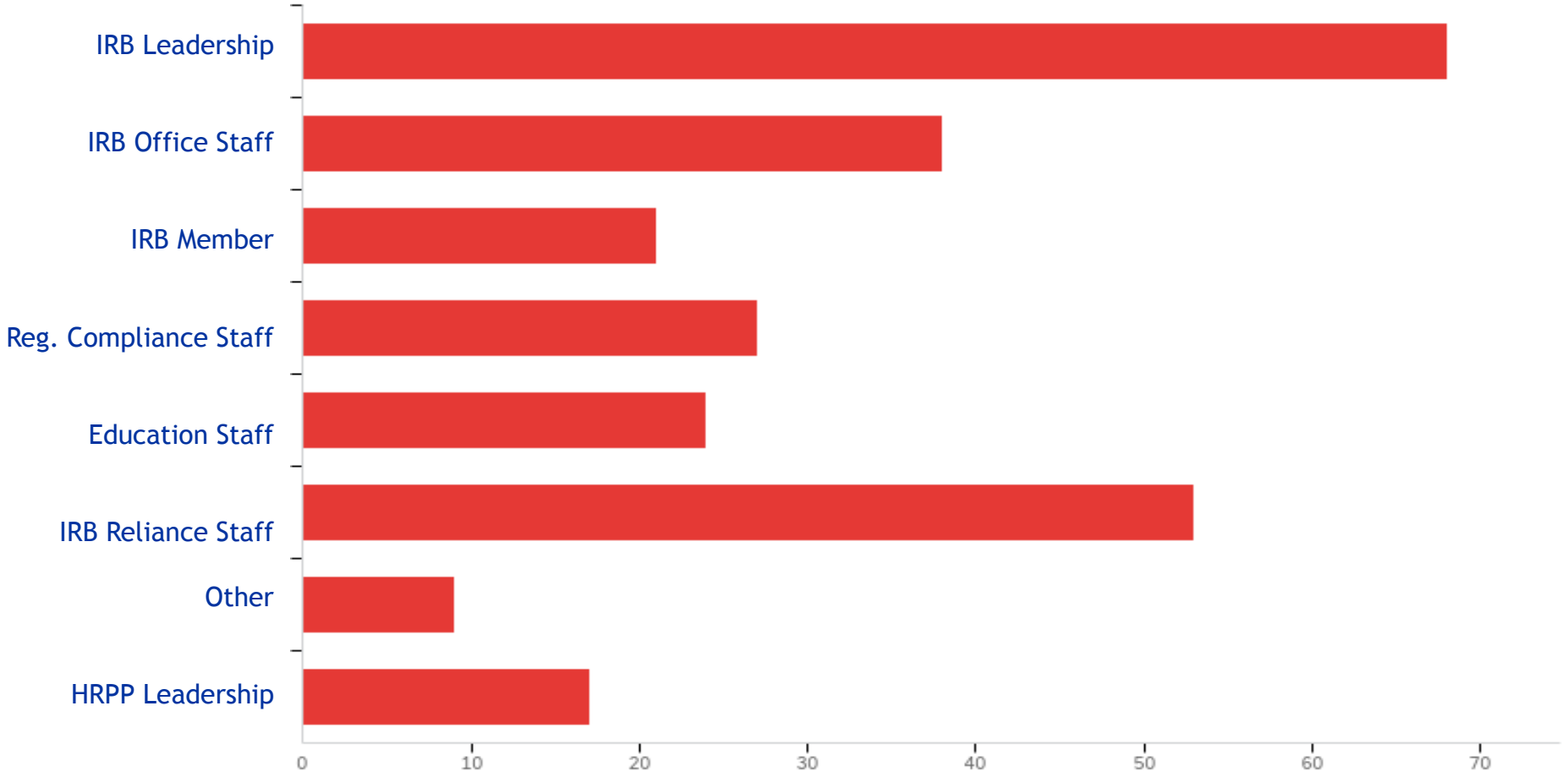
- Most institutions have less than 500 studies occurring at their site per year.

What type of research does your institution conduct and/or review?



- Majority of institutions are doing both Biomedical & Social/Behavioral research.

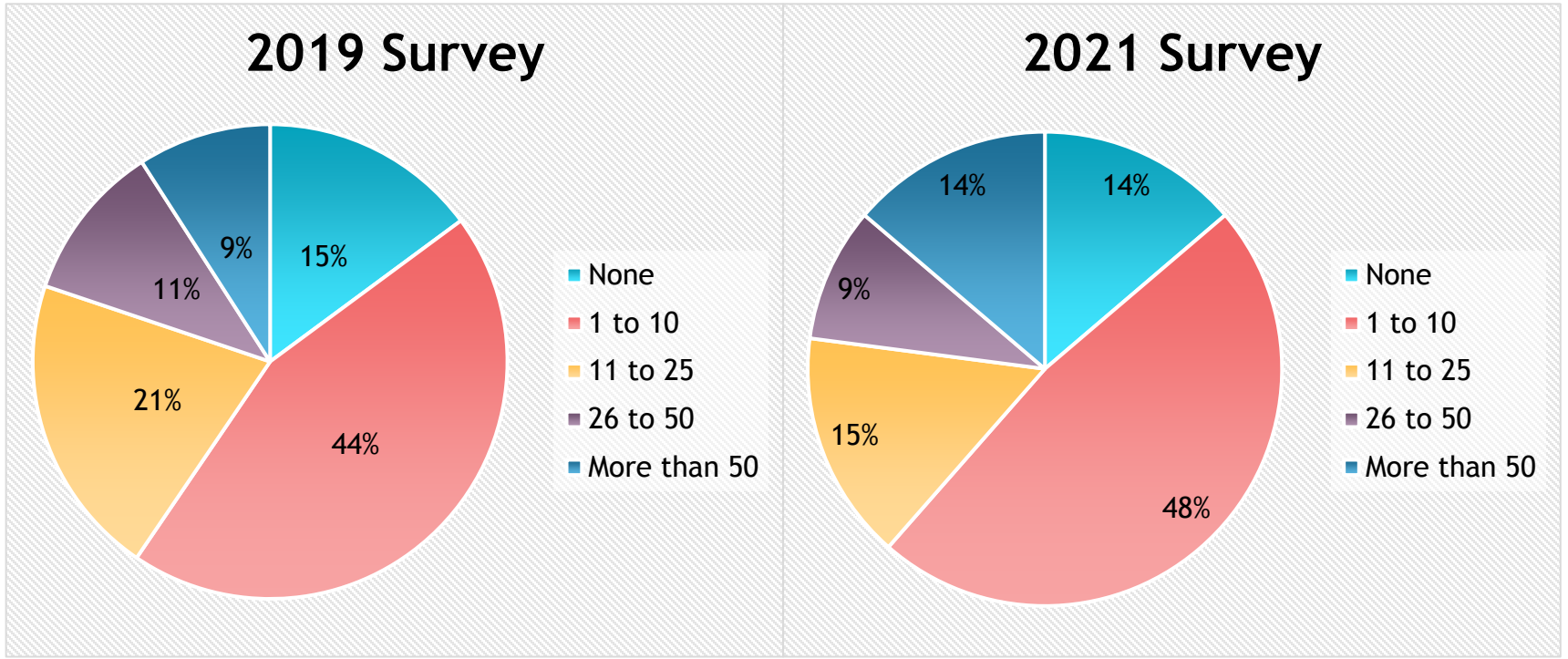
What is your institutional role(s)? (Check all that apply)



# of responses
(multiple responses permitted)

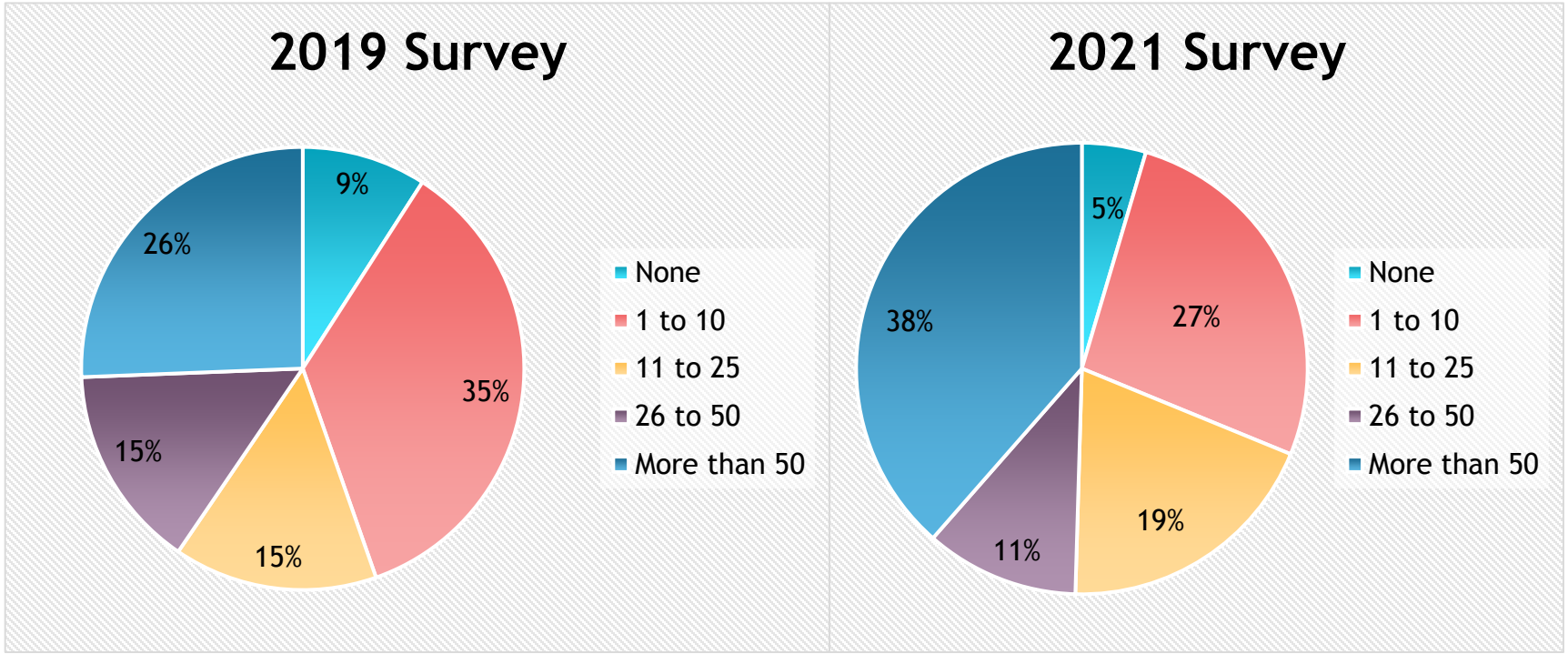
- Majority of responses received from IRB leadership and reliance staff.

Approximately how many times in the past 12 months has your institution served as the Reviewing IRB for a multisite research protocol?



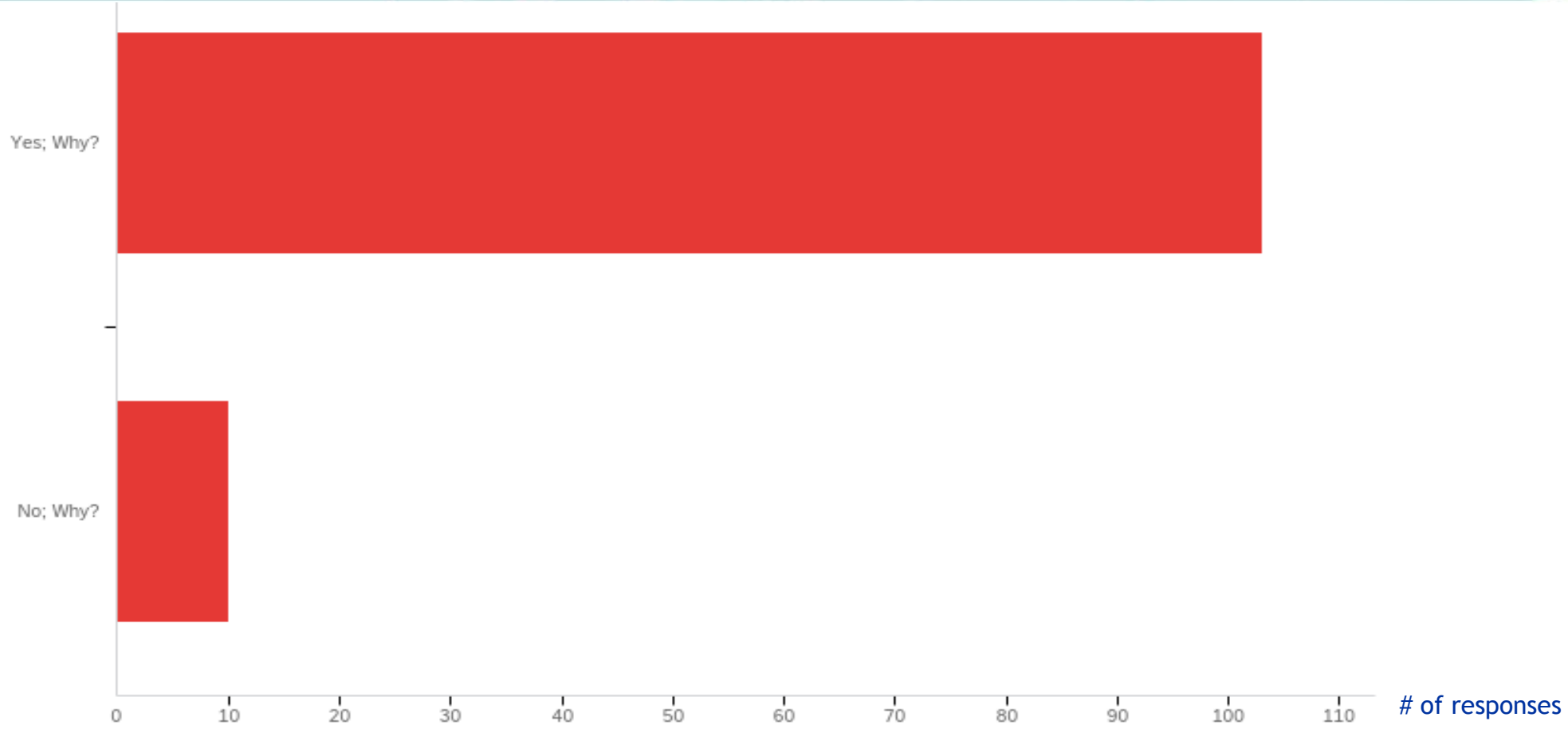
- There is little change in the frequency of institutions serving as the Reviewing IRB.

Approximately how many times in the past 12 months has your institution served as a Relying Institution for a multisite research protocol?



- Frequency with which Institutions rely on an external IRB has increased.

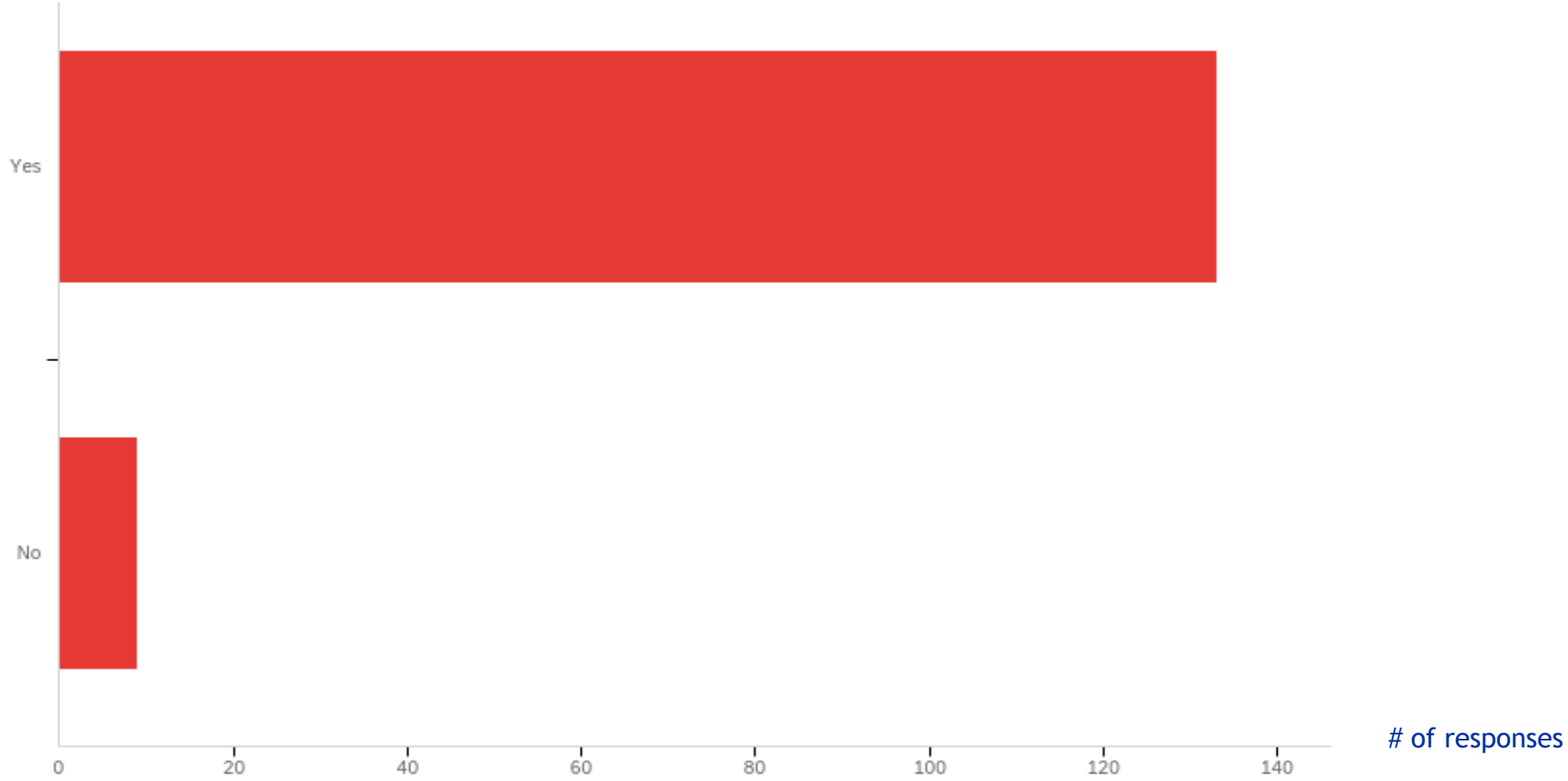
Would you recommend the SMART IRB Agreement to other institutions/organizations?



- Majority of institutions would recommend the SMART IRB Agreement.

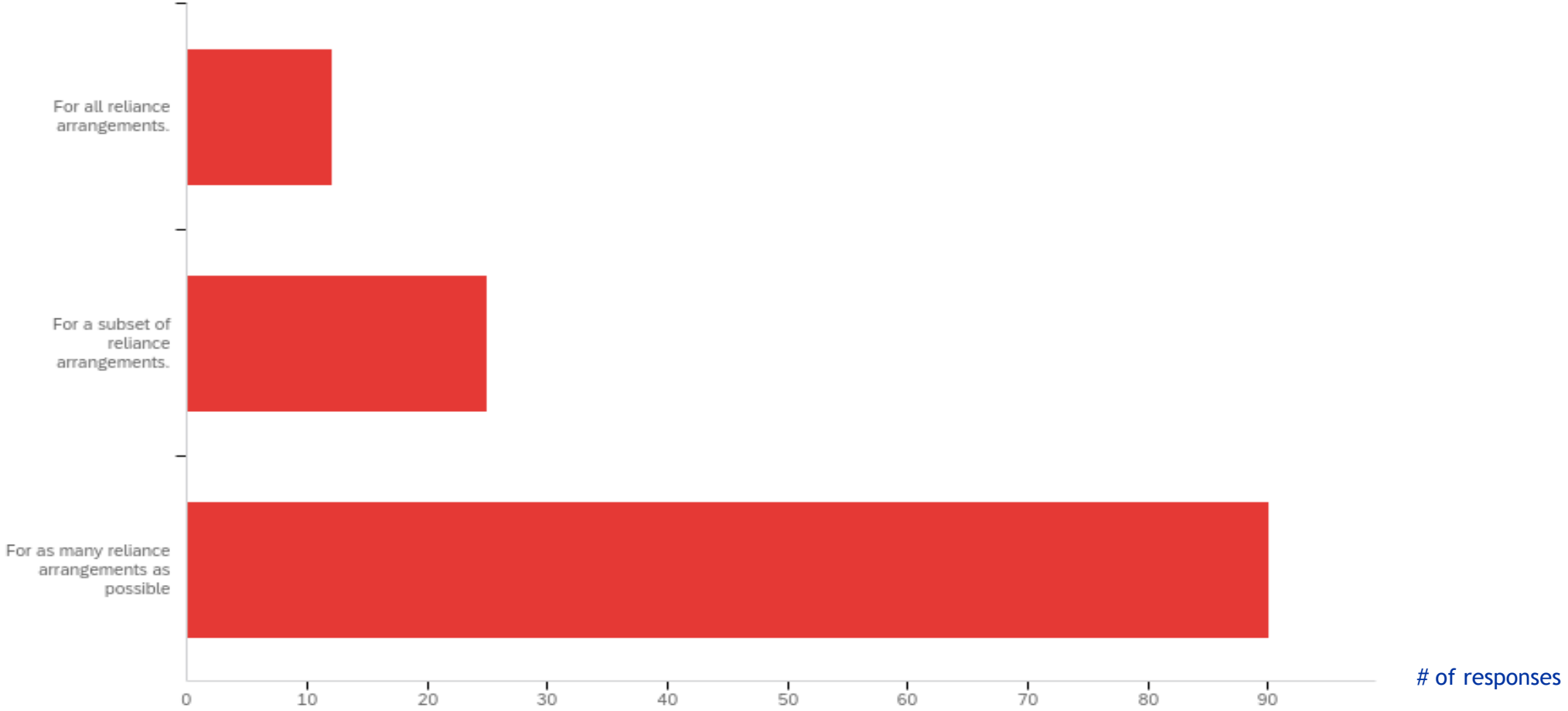
Implementation and Usage of the Agreement

Has your institution joined SMART IRB?



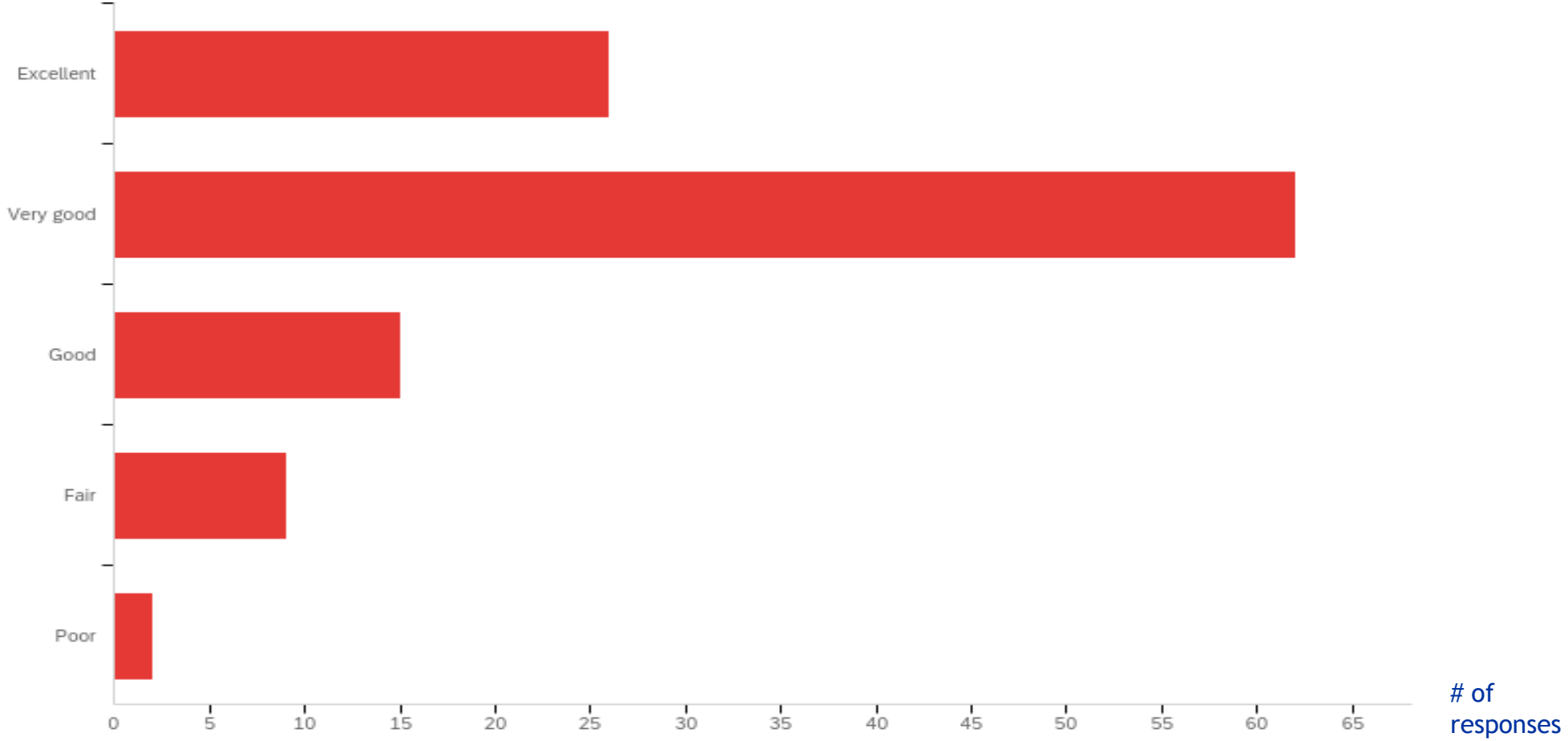
- Majority of respondents are with institutions that have joined SMART IRB.

Which of the following describes your institution's use of the SMART IRB Agreement for reliance arrangements?



- Users report using the SMART IRB Agreement for as many reliance arrangements as possible.

Rate your overall experience using the SMART IRB Agreement for reliance arrangements.



- Majority of respondents indicate a positive experience when using the SMART IRB Agreement.

Overall Experience Using SMART IRB – Positive – Write-in responses received (n=71)

- Ease of documenting the arrangement (x33)
- Simplifies the reliance process (x15)
- Standardizes the reliance process (x9)
- Streamlines the reliance process (x4)
- Provides clear documentation (x3)
- Makes the reliance process more efficient (x5)
- Better then traditional reliance agreements
- Fosters collaboration between institutions
- Fulfills AAHRPP requirements

Overall Experience – Room for Improvement (Write-in responses)

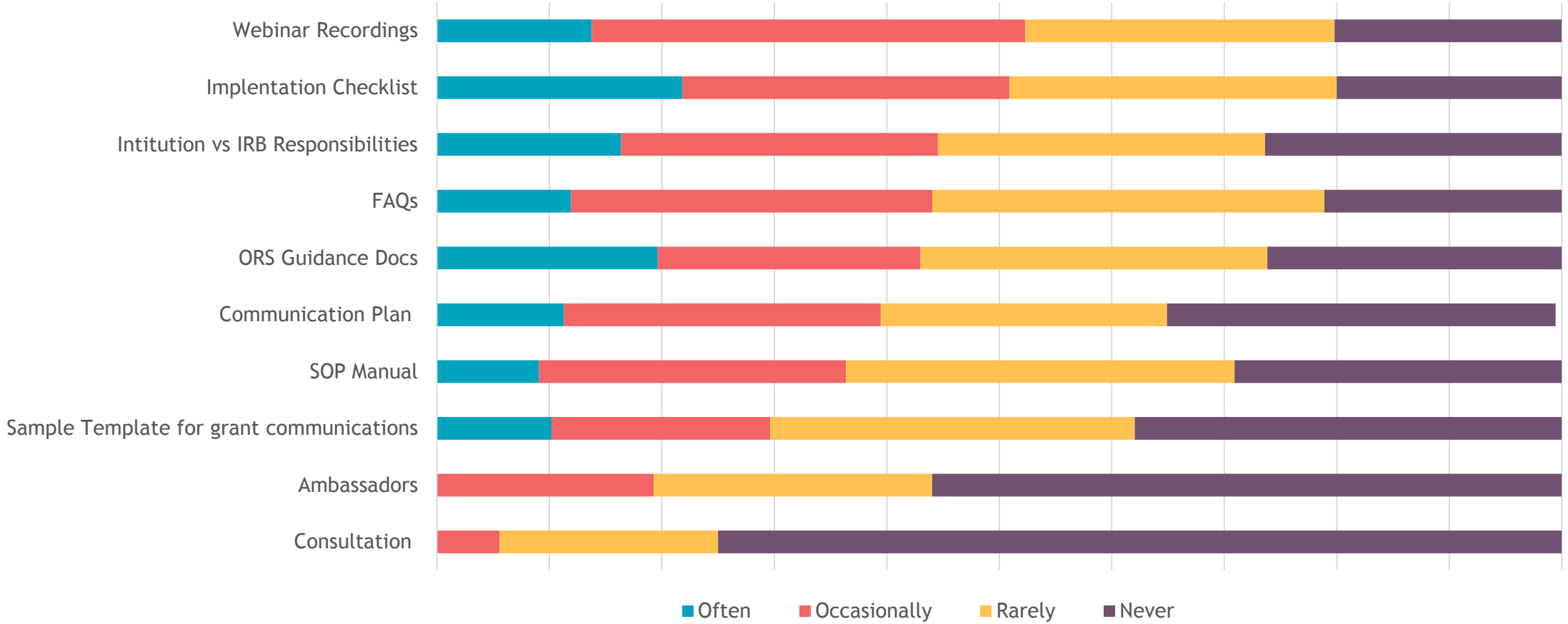
- Documenting flexible terms
- Would like to be able to use for Exempt research
- Would love to see the VA and DoD sign on
- Institutions only use SMART IRB for certain types of studies
- Not all sites use the ORS
- Some institutions requiring the IO or some other official to sign the SMART IRB letter of acknowledgment or a local context survey, or flexible terms form, which creates delays
- Institutions require significant dual review

Challenges Encountered – Systems

- New systems to figure out
- No way make changes to reliance arrangements in ORS
- Would like an option for institutions to initiate the reliance agreements in the ORS rather than study staff
- Different logins needed for ORS & Joinder
- Would like to be able to document flexible terms in the ORS or to make them a default

Use of SMART IRB Resources

Please indicate how frequently you use the following resources.



- Webinar recordings & the implementation checklist ranked highest in frequency of use.

Potential Modifications to the SMART IRB Agreement

Please describe any issues you have encountered with the SMART IRB Agreement, with sufficient detail to ensure our understanding of those concerns.

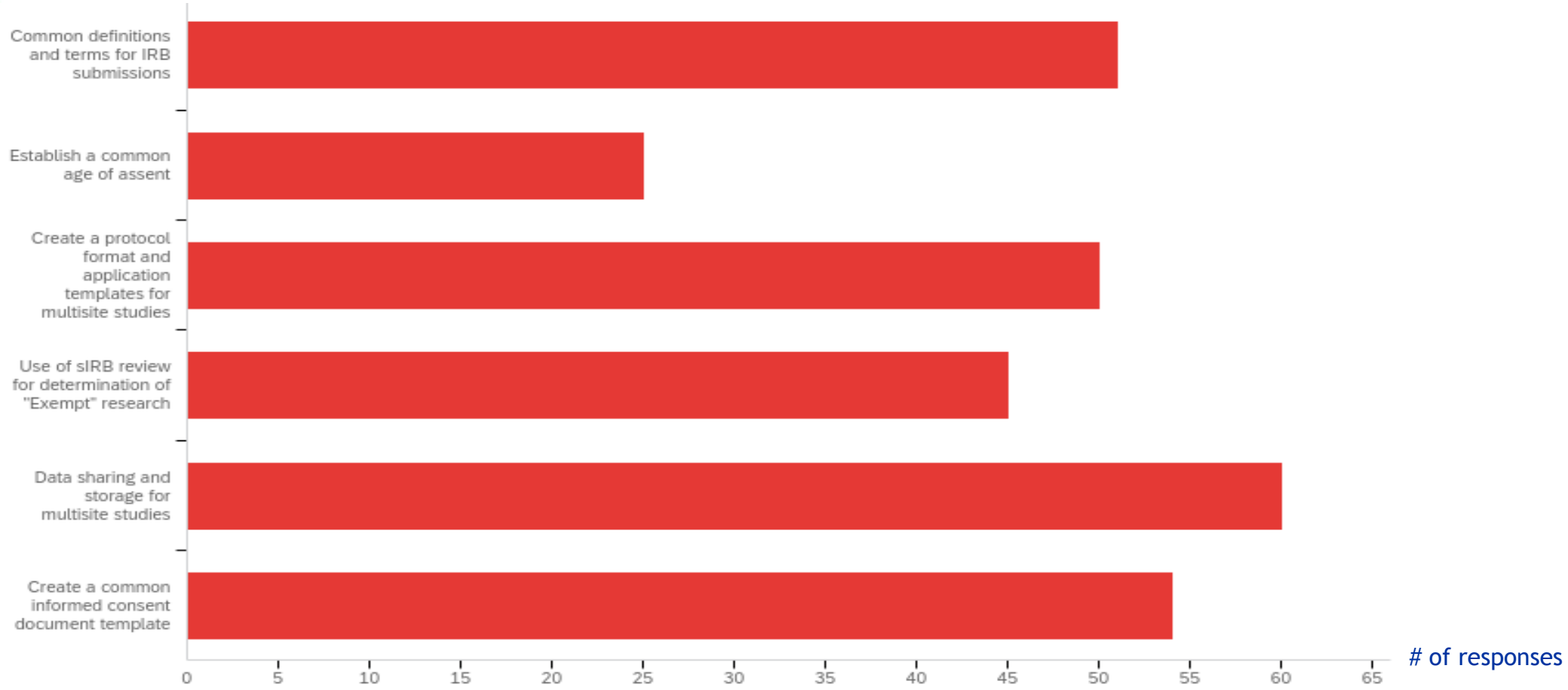
- Difficult for some institutions to meet the HRPP QA requirement for joining. Would be helpful to provide a "relying only" membership level
- Allow for DoD and/or the VA to join
- Coverage of exempt determinations
- Fees should be addressed

What are some features you'd like to see included in the revised agreement? (Please note the sliding scale below denotes the following: 0 = not interested, 50 = neutral/indifferent, 100 = very interested)

Suggested Feature	Sliding Scale Interest
Allow for Agreement to cover exemption determinations	59
Allow for Agreement to cover limited IRB review	53
Addition of an optional common Indemnification Agreement	67
Update HIPAA to provide flexibility regarding which institution will perform the privacy board review	68
Clarify or remove the HRPP quality assessment requirement	51
Permit institutions that do not maintain a federal wide assurance (FWA) to join	41
Permit organizations outside the USA to join	40

SMART IRB Harmonization

Please select the top five areas for which you would like the SMART IRB Harmonization Steering Committee to develop guidance or tools:



- Interest is strong in data sharing and storage guidance as well as common definitions, consent, protocol and application templates.

Please indicate additional areas that would be helpful to harmonize:

- Data Security
- Expectations for implementation of amendments by relying institutions
- Guidance for reliance arrangement for exemptions
- Harmonize the workflow for the relying institution
- Approval letter format
- Guidance on what to do when types of review are different
- Formalize the definition for serious and continuing non-compliance
- Guidance on receiving and tracking external IRB submissions
- Further guidance on exact roles for Relying institutions vs Reviewing IRB

Where We’re Heading

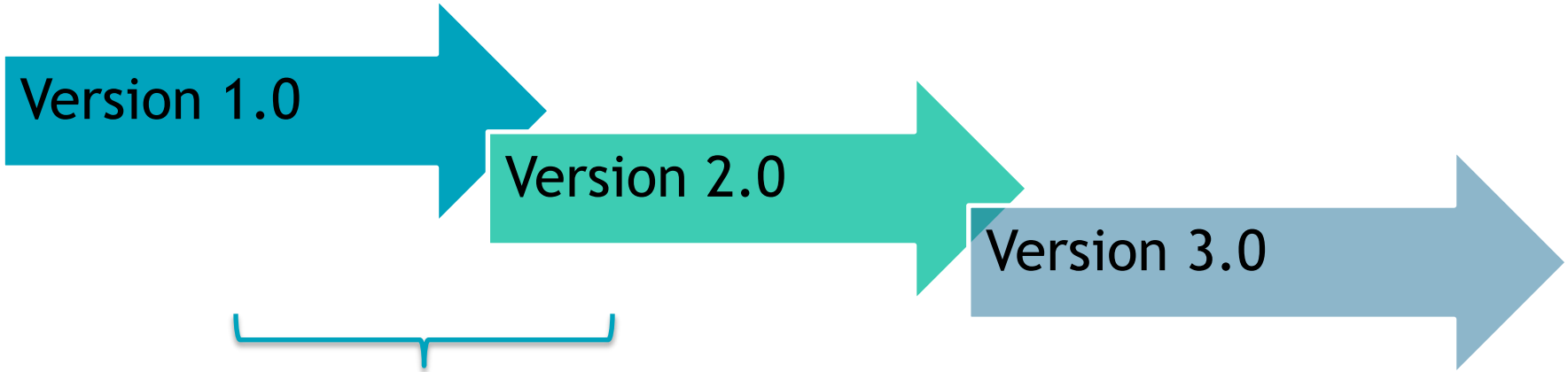
Master Reliance Agreement V3.0 (1 of 2)

- Substantive Changes in Response to feedback from:
  - Federal Agencies
  - Common Rule Changes
  - Participating Institutions
  - Survey Results

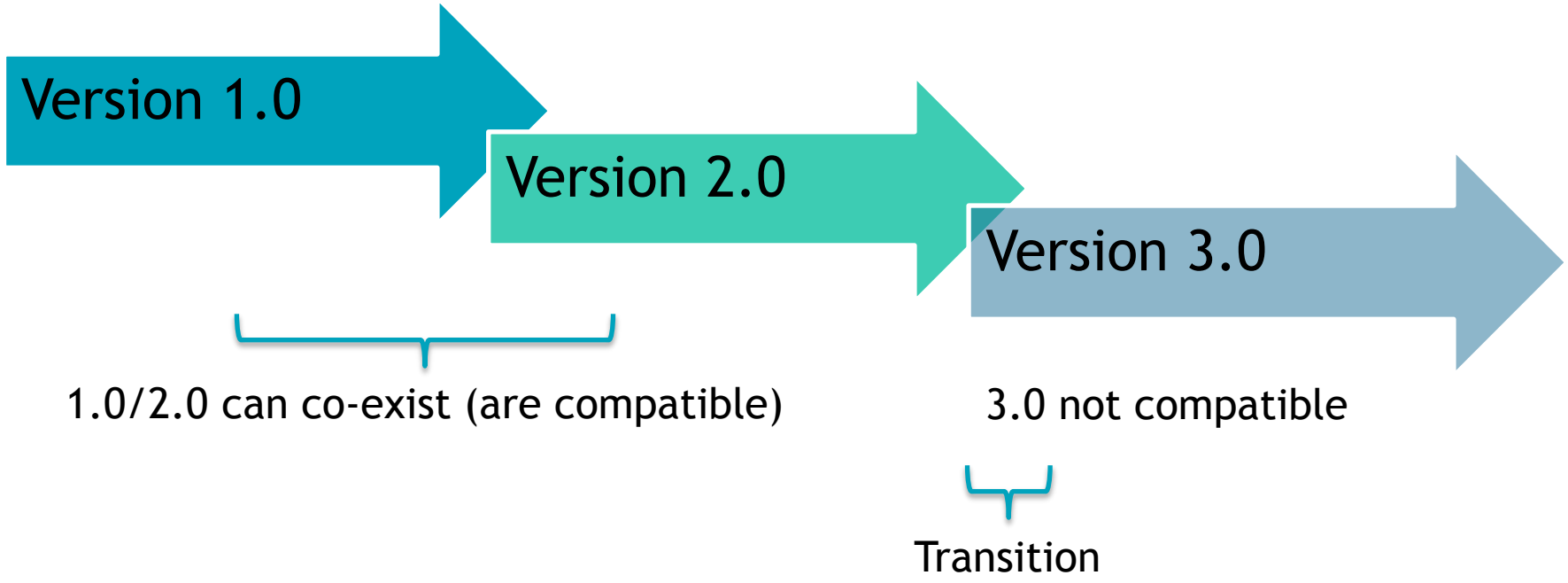
Master Reliance Agreement V3.0 (2 of 2)

- Proposed Revisions reviewed and discussed with:
  - SMART IRB Harmonization Steering Committee
  - Representatives from VA, DoD, DOE & NIH

MRA Versions To Date (Brief Recap) (1 of 2)



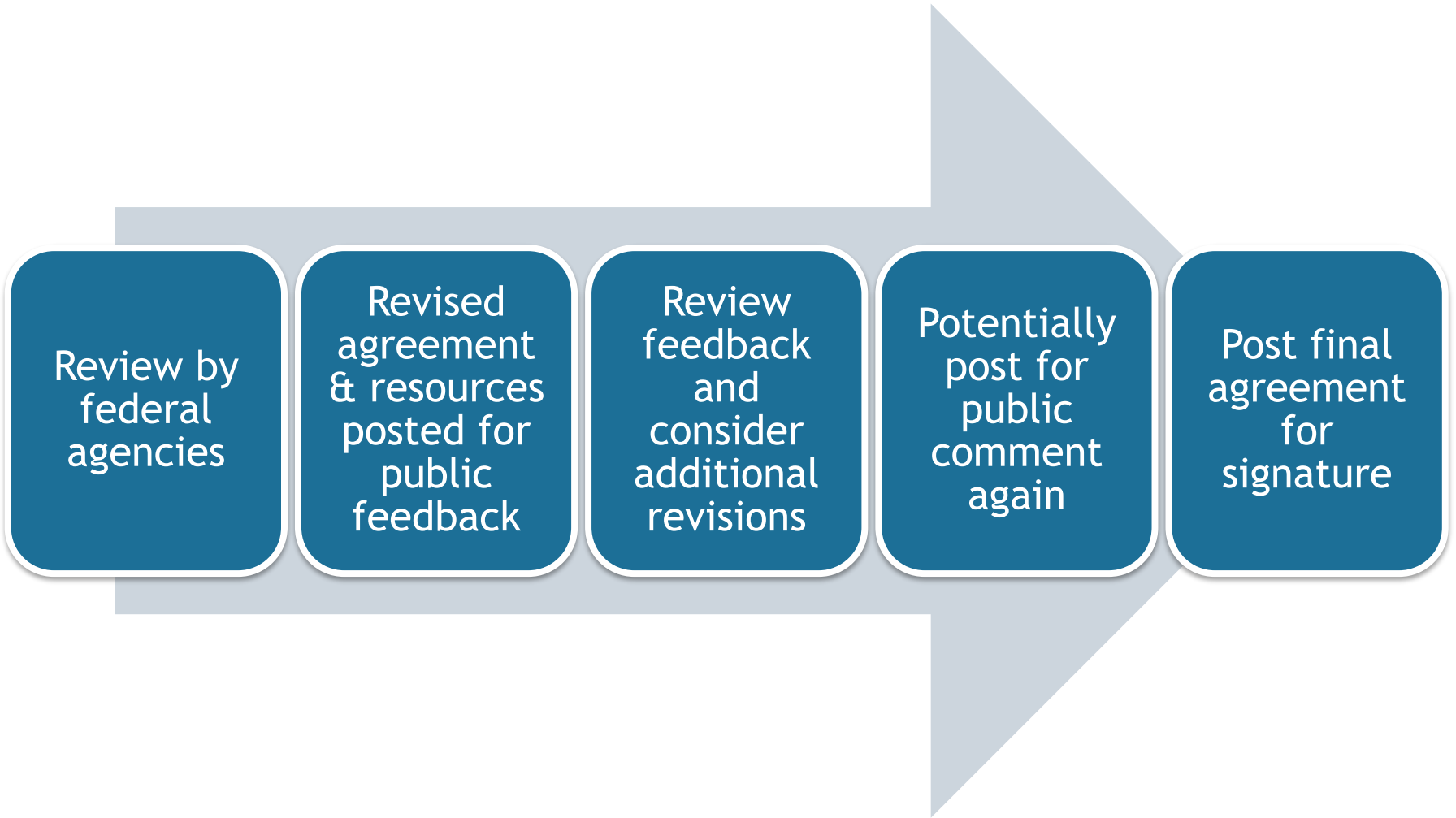
MRA Versions To Date (Brief Recap) (2 of 2)



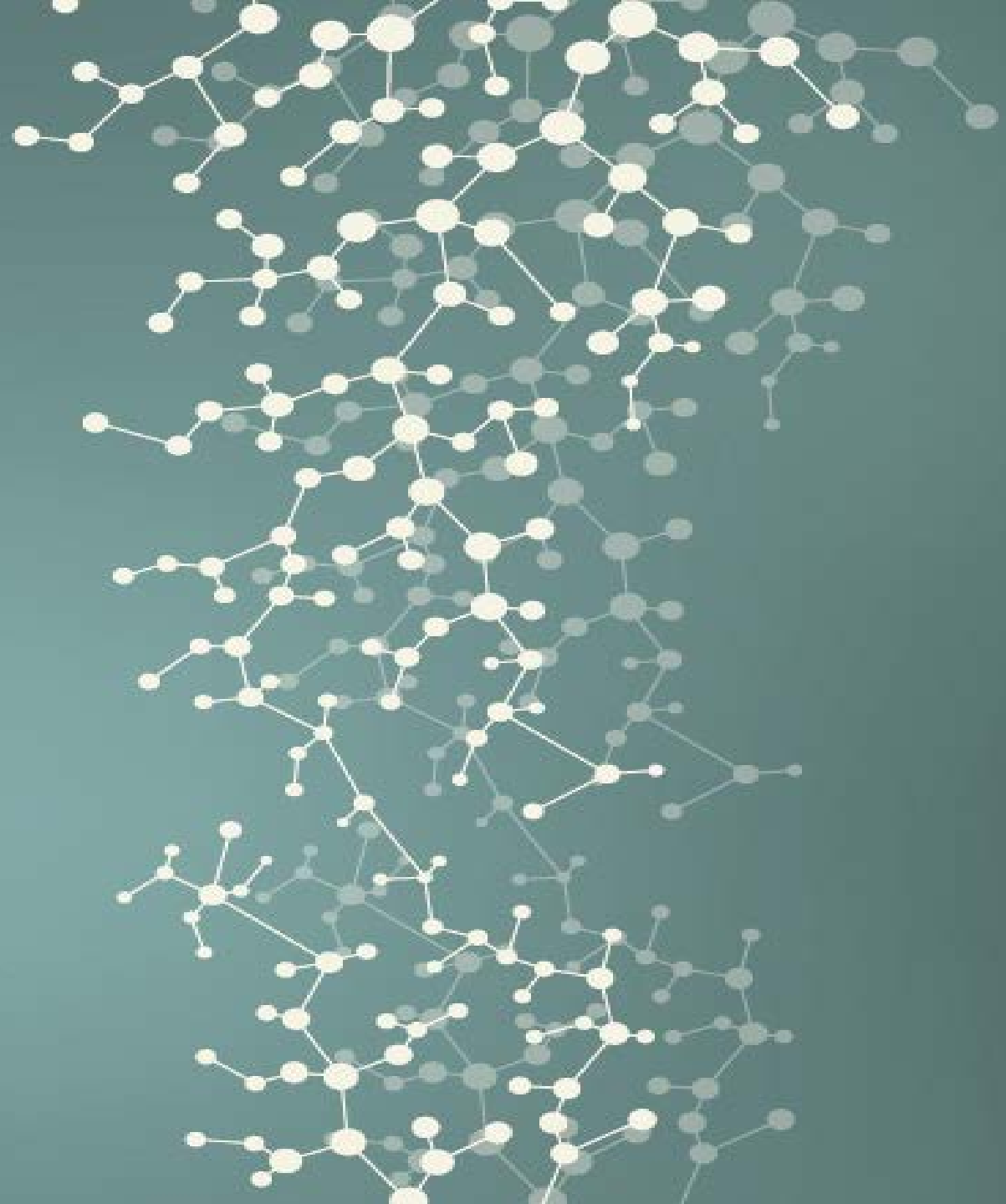
Revisions to the Master Reliance Agreement

- HIPAA
- Optional Indemnification Addendum
- Eligibility to participate in the Agreement
- Reliance for Exemption Determinations
- Local Considerations/Local Context
- Additional Agreements
- Withdrawal of Research from Ceded Review
- Determination of Applicable Policies & Procedures
- IRB recordkeeping obligations and access to minutes

Next Steps for Master Reliance Agreement



2022 Emerging Issues Workshop Post-Event Feedback Summary



Emerging Issues Workshop Overview

- 3.5 hour workshop held on 3/7/22
- 72 invited IRB/HRPP leaders
- 22 surveys received

Key Suggestions from Emerging Issues Workshop

1. Develop investigator/study team training sessions & resources
2. Cross-agency regulatory guidance on when sIRB review is required
3. Provide further clarification on Relying Institution vs. Reviewing IRB responsibilities with a specific focus on what reviews must be performed at a Relying Institution and the timing of those reviews
4. Identify strategies for institutions to adopt SMART IRB harmonization guidance
5. Provide feedback to Federal Agencies on studies where single IRB review increases efficiencies and reduces burden vs. when it does not
6. Develop resources for IRB reviewers to better understand when Relying Institution policies vs. Reviewing IRB policies apply to a study

Additional Suggestions from Emerging Issues Workshop

1. Request NIH or other federal agency to maintain a 50-state database of relevant laws related to human participant research.
2. Suggest common template, workflow, and IT infrastructure be developed to minimize redundances and inefficiencies
3. Reassess requirement for sIRB review for certain types of studies
4. Incremental IT enhancements to ORS and website requested

Harmonization Next Steps

- Evaluate current investigator/study team training resources
- Collect information on sIRB exceptions to provide feedback to OHRP & NIH
- Prioritize topics for future Harmonization working groups
- Local Context working group currently underway

Discussion & Questions

Save the date for the next
SMART Talk
June 20, 2022
2:00-3:30 pm ET

Being a Single IRB for a Study with Many Sites

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

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