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.

Before we begin

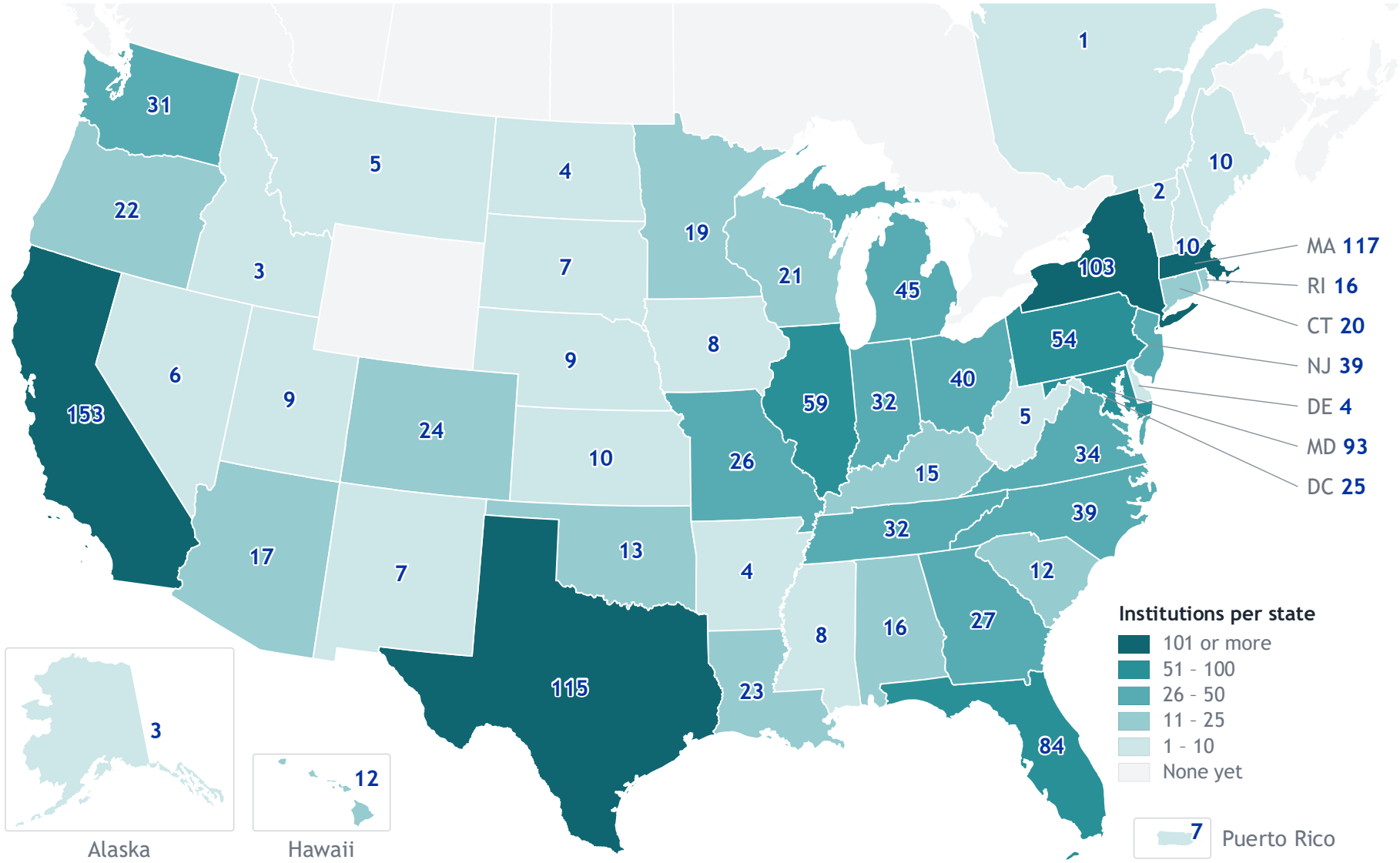
Questions are welcome! Please post these under ‘Q/A’

Discussion with 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.

Celebrating 1500 SMART IRB Participating Institutions!



SMART IRB: Your Roadmap to Single IRB Review

Agreement

Providing a common, comprehensive framework reliance agreement with 1,500 signatories across North America



Reliance System

Your home to request, document, and track reliance requests with fellow SMART IRB Participating Institutions



Harmonization

Strategically align your institution's policies and procedures with industry best practices



Resources & Education

Explore an ever-growing portfolio of customizable resources for your institution's reliance program



Support

Need assistance? Check out our Support Center, Ambassadors, and Helpdesk



Meet Your SMART IRB Ambassadors!



Aaron Kirby
Harvard Catalyst



Polly Goodman
Harvard Catalyst



Jeremy Lavigne
Harvard Catalyst



Nichelle Cobb
AAHRPP



Ada Sue Selwitz
University of Kentucky



Kathy Lawry
AAHRPP



Stacey Goretzka
Independent Consultant



Carissa Minder
WashU in St. Louis

SMART IRB

Find your SMART IRB Ambassador today

smartirb.org/ambassadors

Reliance Patch: Comprehensive Editing is Now Live!

- Site Details editable until reliance determination reached
- Relying Institution Site Admins and Research Personnel can directly edit site details
- Documents can be updated for life of study
- Site Investigators can be updated for life of study

Stay Tuned: Next patch coming soon!

Inquiring Minds Want to Know: Insights from the SMART IRB Survey

Moderator:
Nichelle Cobb, SMART IRB Ambassador At Large + Senior Advisor

Panelists:
Polly Goodman, SMART IRB Senior Associate Director, Regulatory Affairs Operations + Ambassador Northeast/New England + Middle Atlantic
Jeremy Lavigne, SMART IRB Senior Officer + Ambassador West, Mountain, and Pacific

SMARTIRB.org

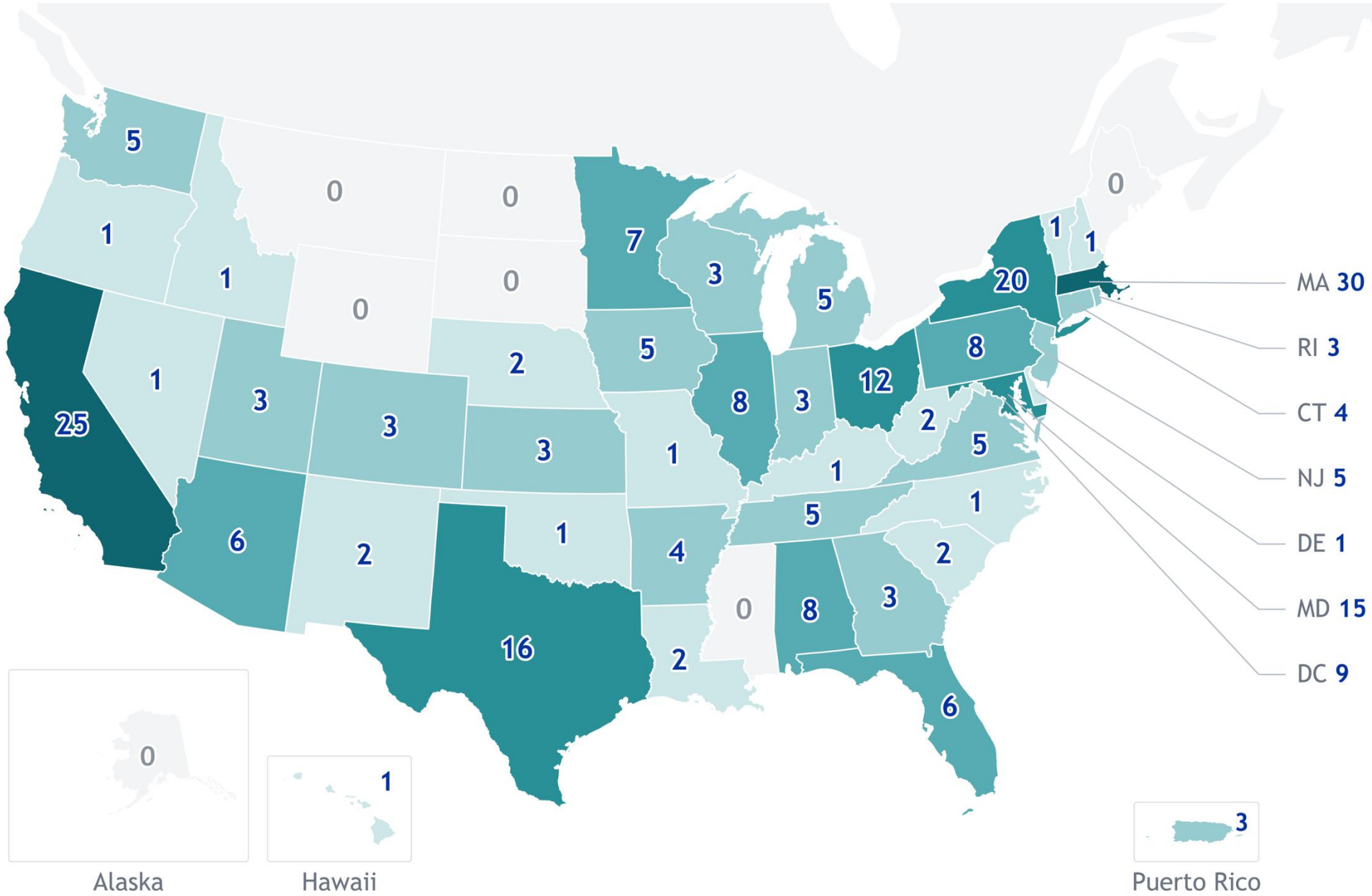
Acknowledgments and Thank You!

- **To the SMART IRB community and greater sIRB community:** thank YOU (all 258 of you!) for taking the time to thoughtfully and candidly share how SMART IRB is working for you, as well as how single IRB arrangements are really going at your institutions. Everything you will see today comes from you.

- **To the AAHRPP Metrics Working Group:** thank YOU for contributing the questions about institutional IRB operations that became the survey's optional module. Responses to these questions have provided a unique and valuable window into single IRB operations at organizations across the country.

Your contributions shape the work we do and how we plan for the future—
THANK YOU!

SMART IRB Survey 2026
Geographic Representation



258

survey responses

- **43** states with at least one response
- **203** unique institutions
- **9** in the District of Columbia
- **3** in Puerto Rico

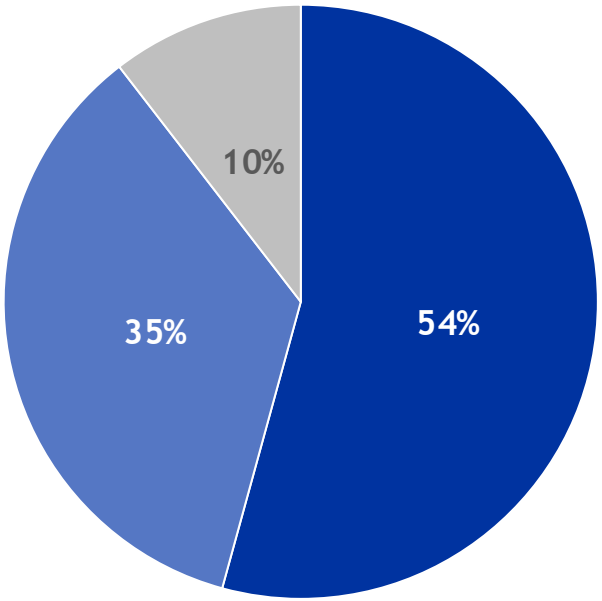
Responses per state

- 21 or more
- 11 – 20
- 6 – 10
- 3 – 5
- 1 – 2
- None

Fielded March 26 – April 30, 2026

Who Responded: Roles and Research Scope

Role (258 responses)



140 IRB/HRPP staff

91 study team members

27 other roles

Other roles included: AVP, Research Compliance; Regulatory Coordinator; Director, HRPP. "IRB/HRPP path" = IRB/HRPP staff plus these roles.

Study team members include investigators, coordinators and research nurses.

How to read these numbers: percentages are of those who answered each question (not of all 258); n is on every chart; check-all questions total more than 100%.

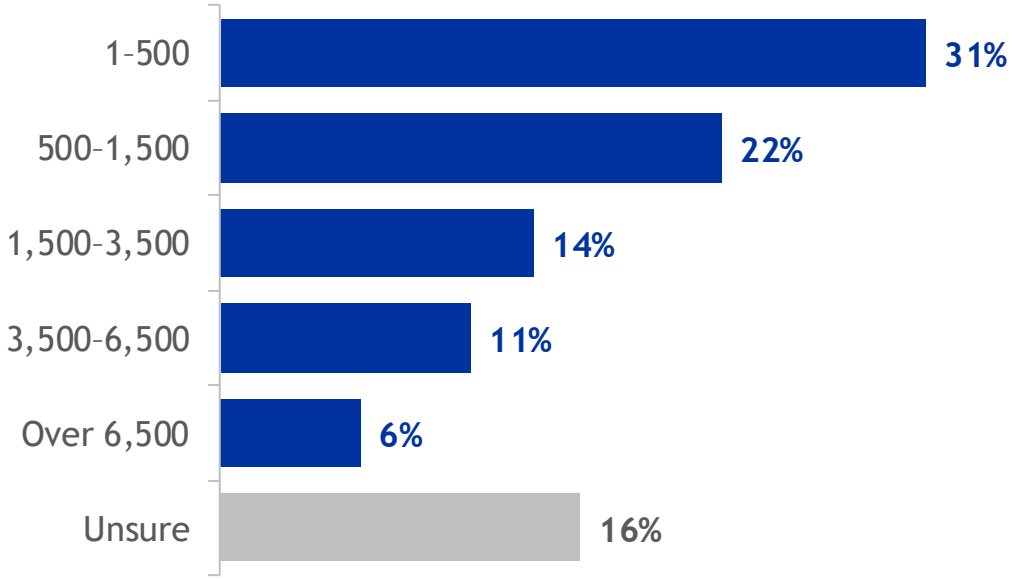
Research scope (IRB/HRPP path, n=145)

94% social / behavioral / education

90% biomedical

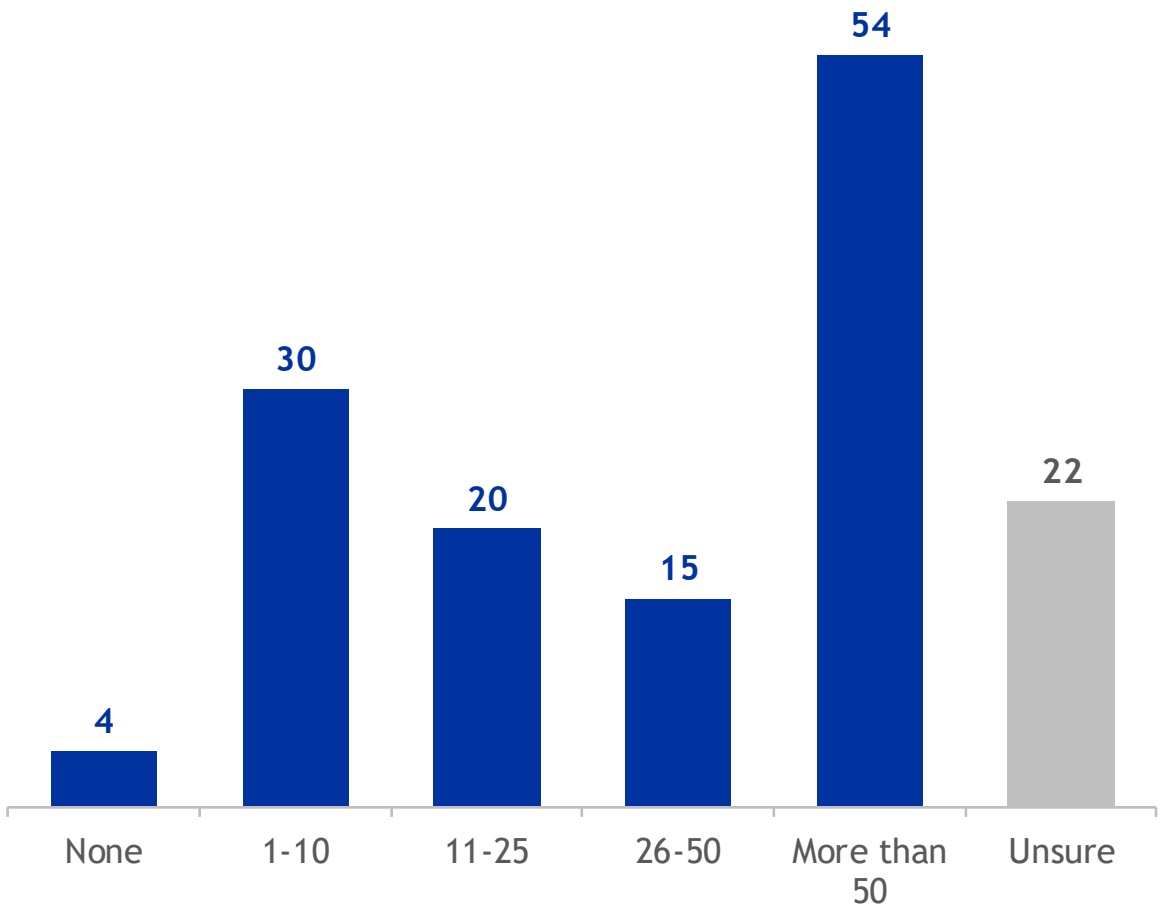
9% other

Non-exempt studies conducted or reviewed (% of respondents)

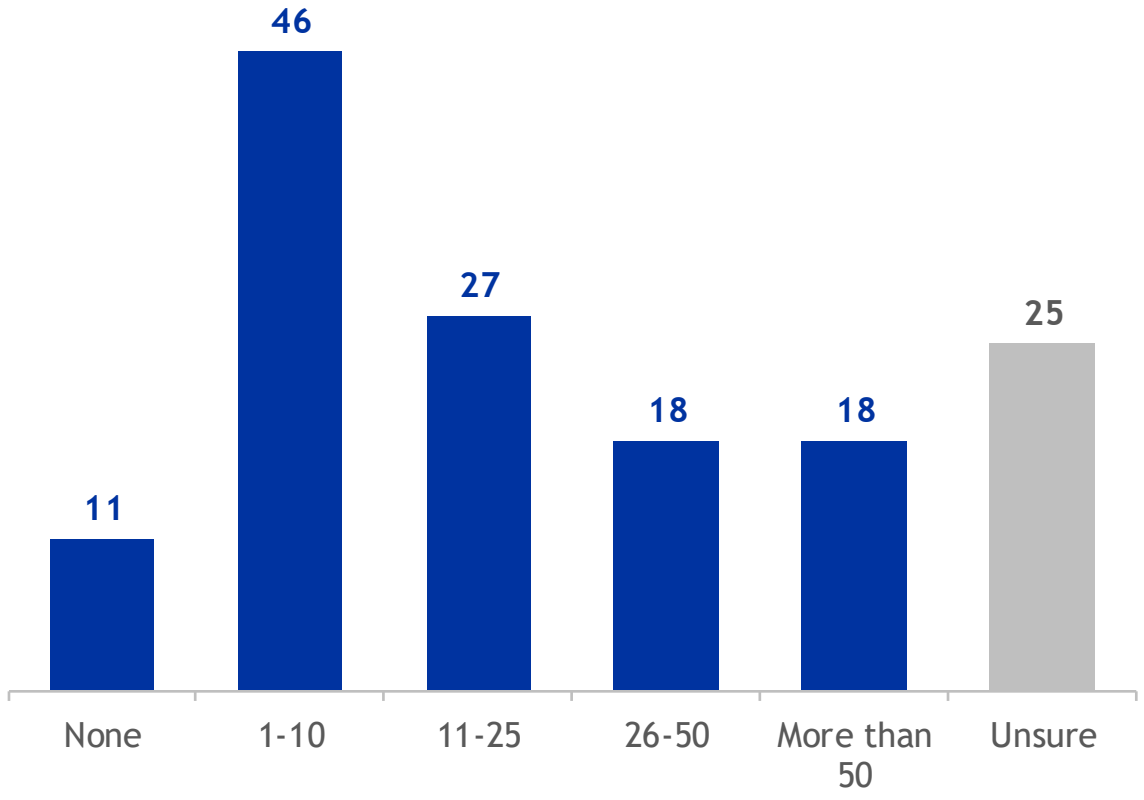


Reliance Activity in the Past 12 Months

Times ceded review to an external IRB (n=145)



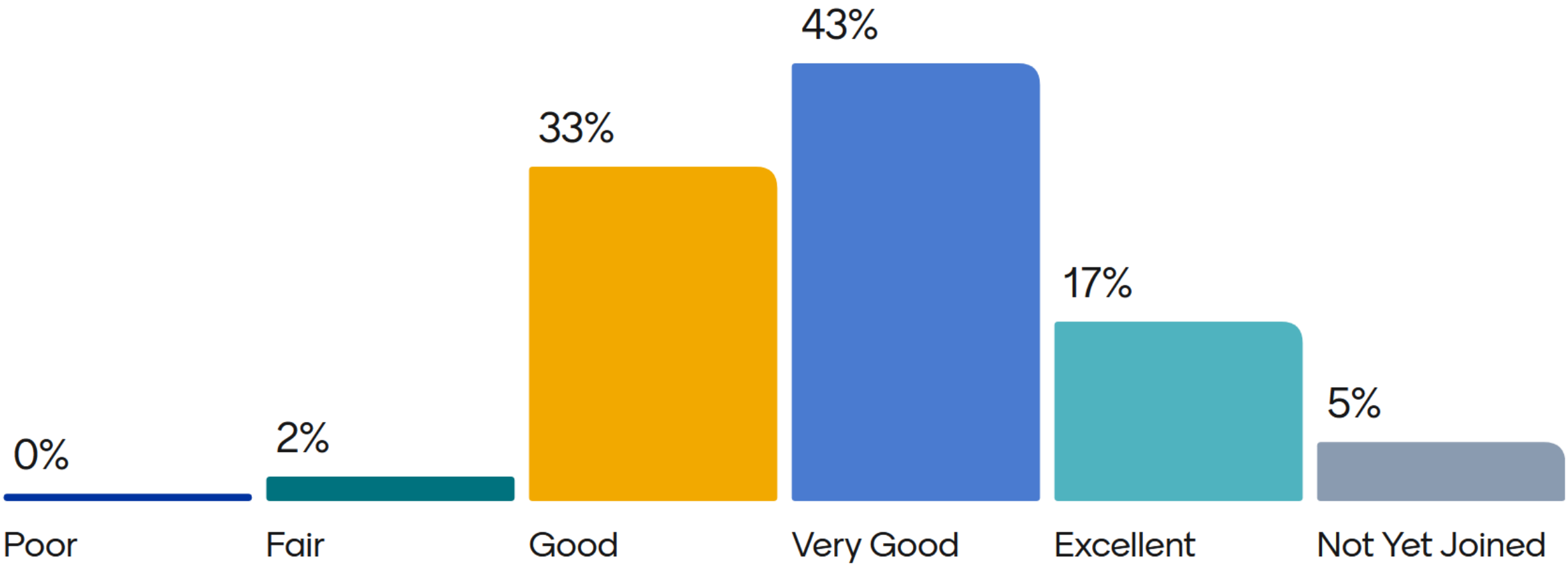
Times served as the Reviewing IRB (n=145)



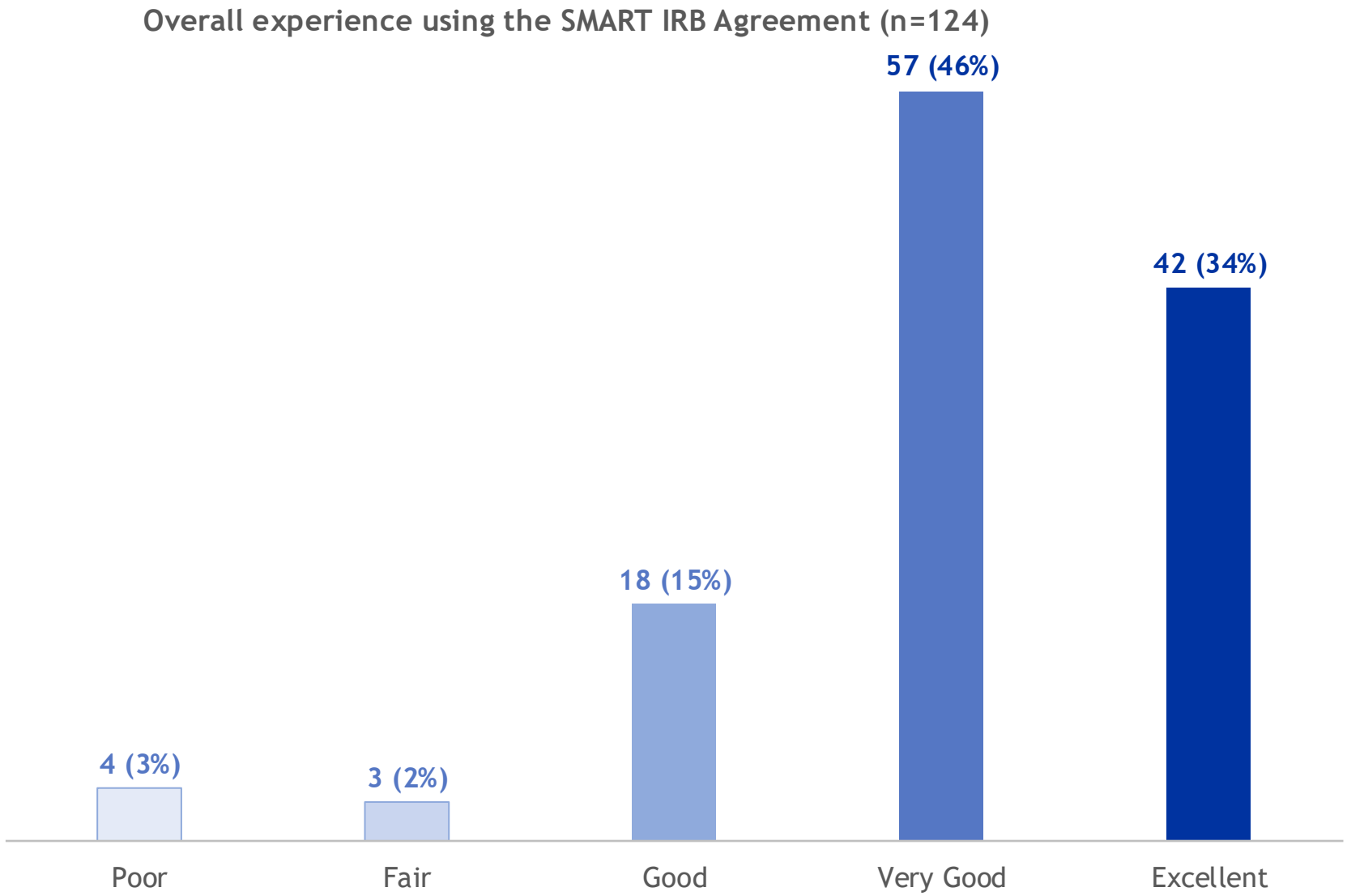
The SMART IRB Agreement



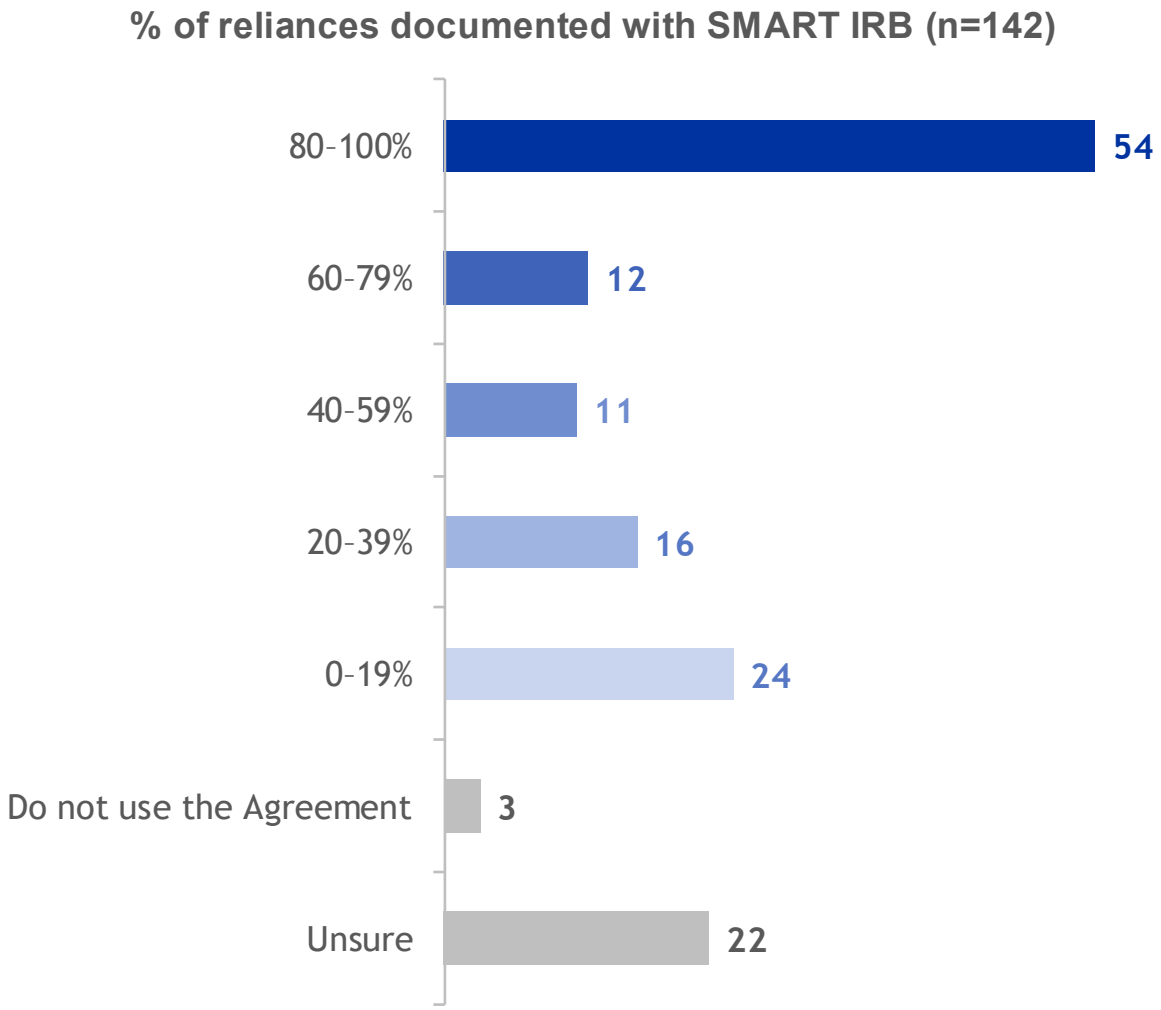
What is your overall experience using the SMART IRB Agreement?

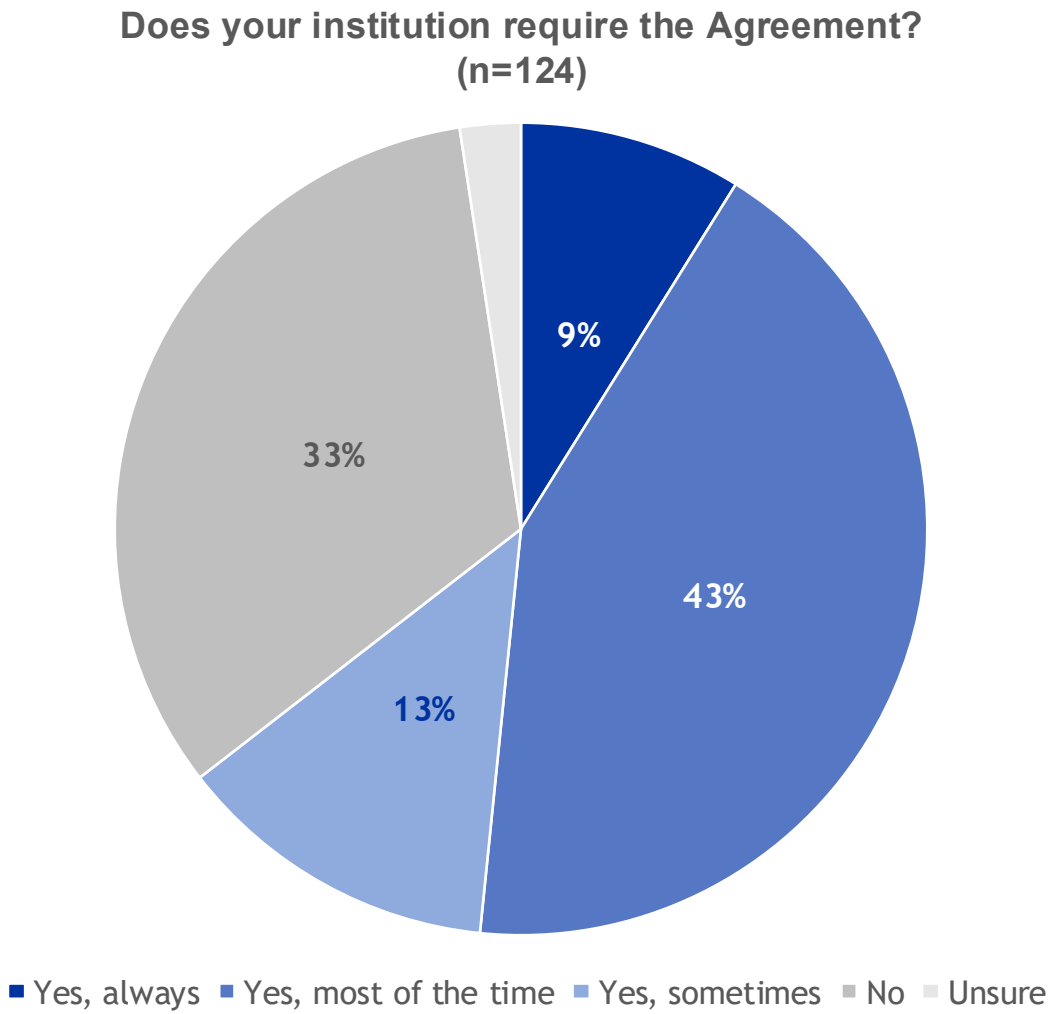


80% Rate the Agreement Very Good or Excellent

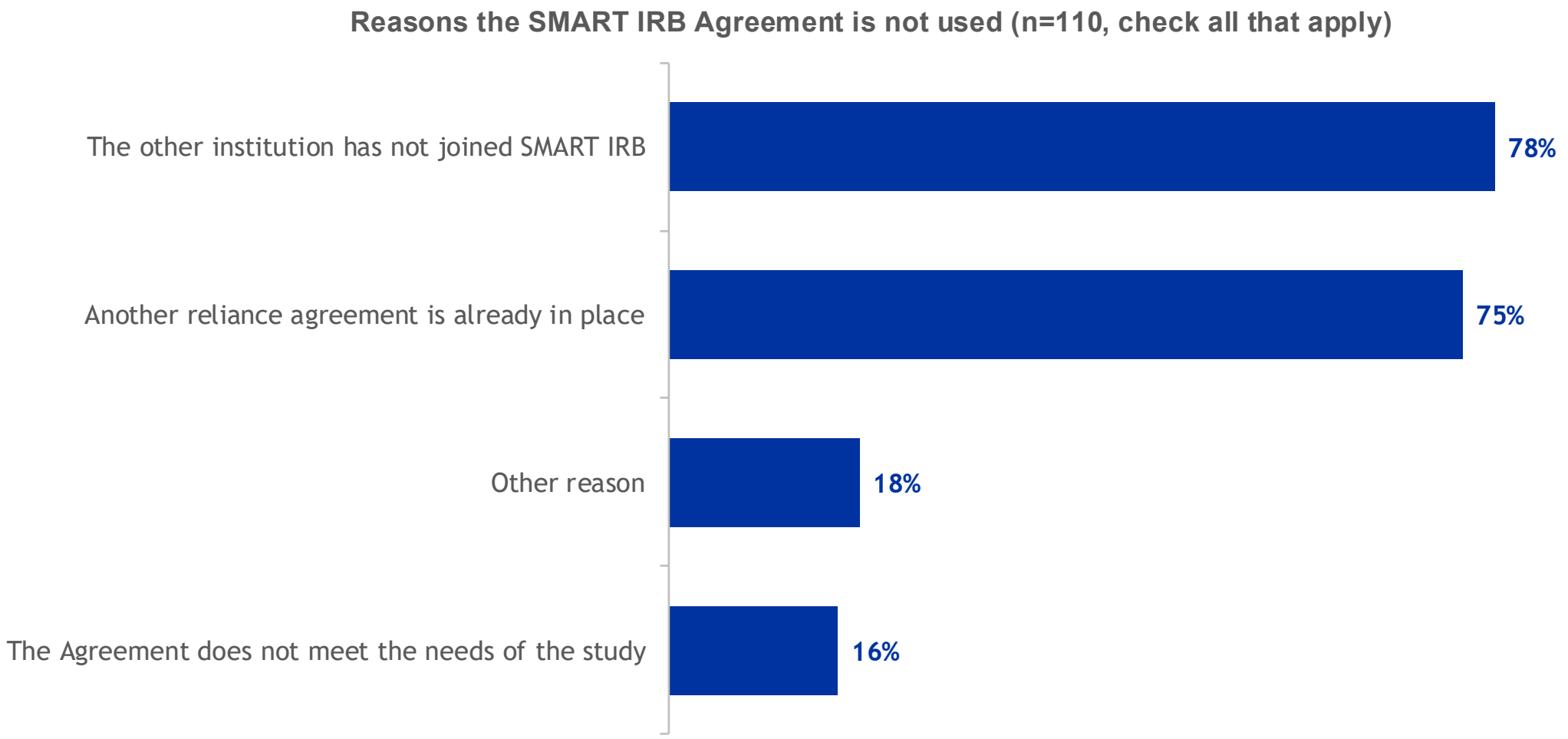


The Agreement: How Widely It Is Used

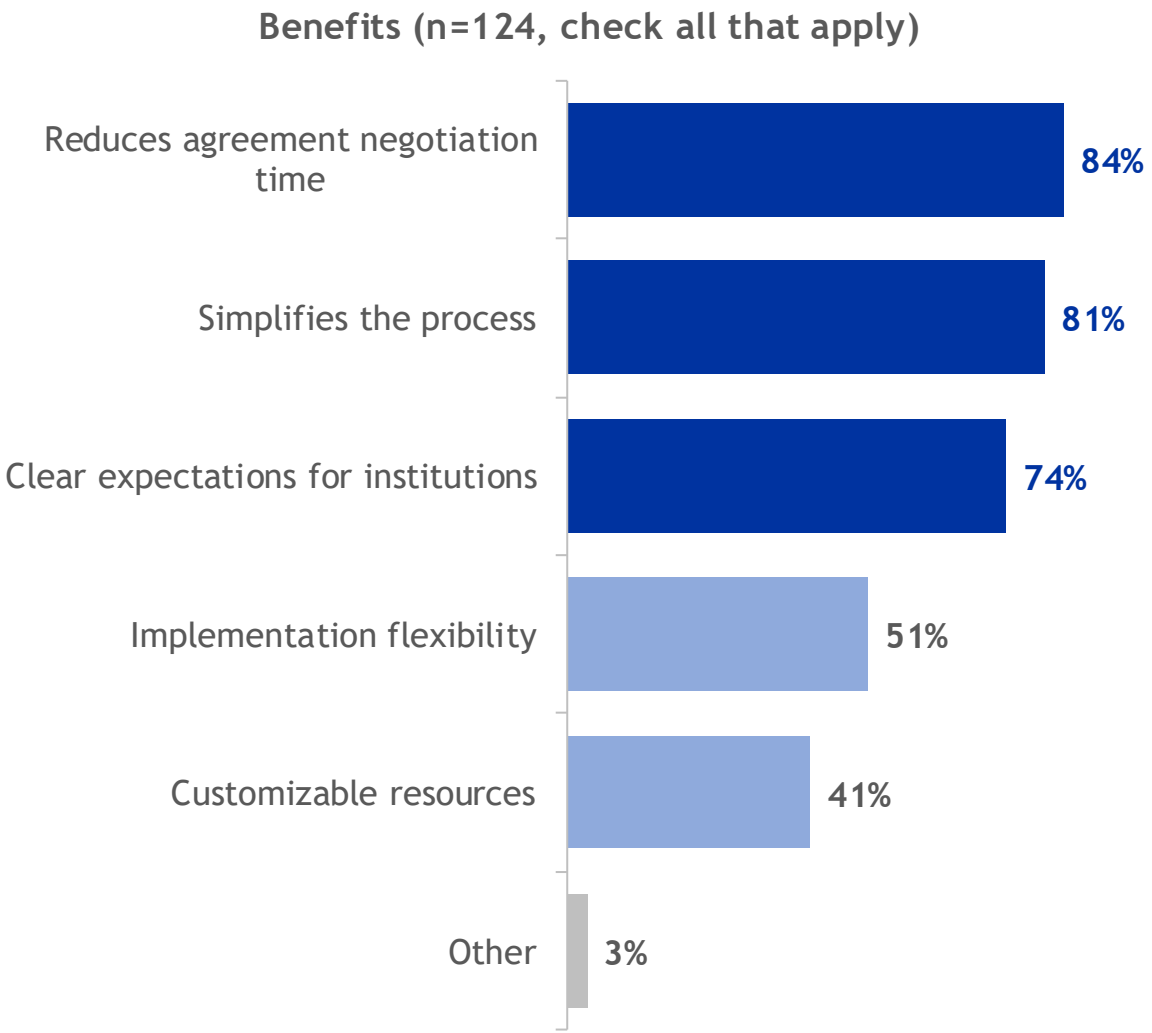


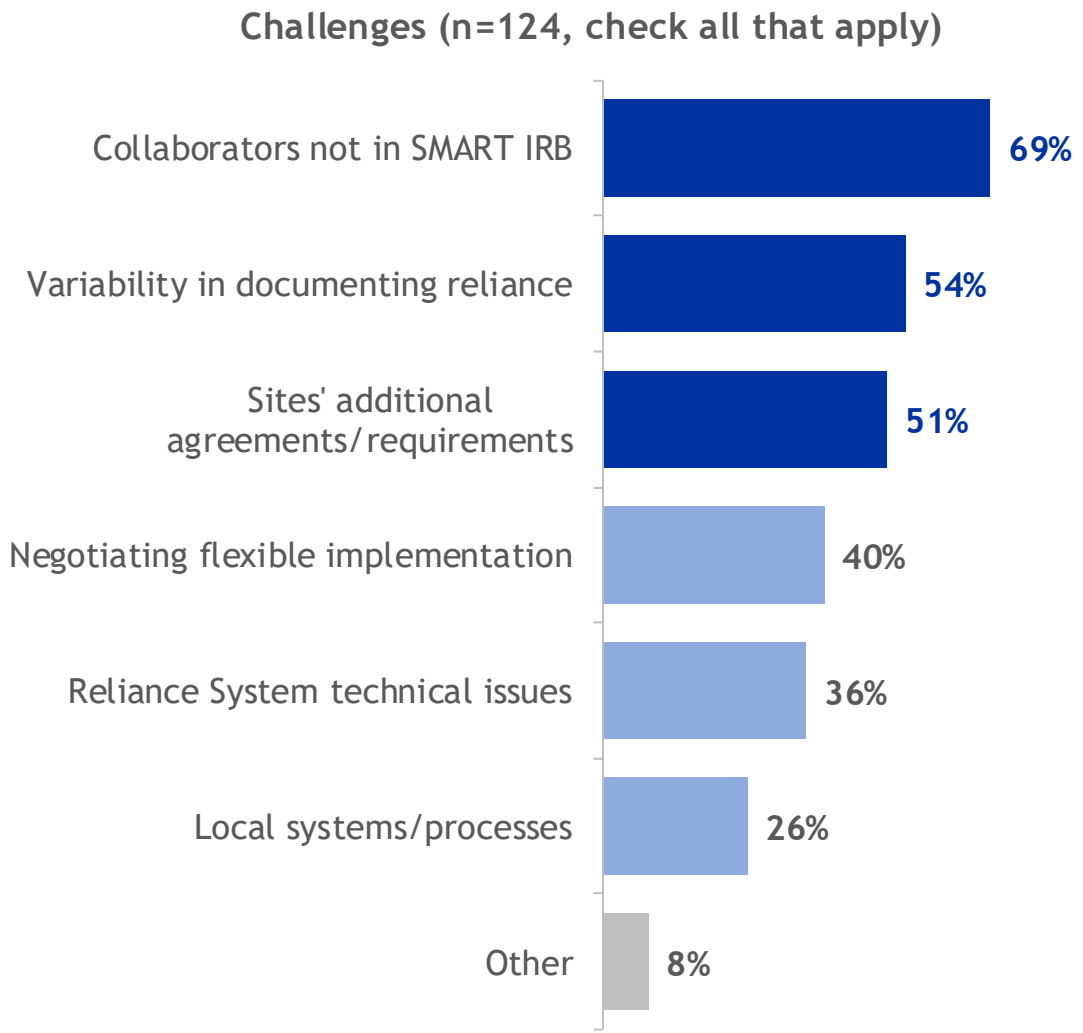


When Institutions Don't Use the Agreement



The Agreement: Benefits and Challenges





In Your Words: The SMART IRB Agreement

44 respondents explained their rating. A range of views:

Much faster than it used to be

"I remember how it could take months to get an agreement executed after going through legal review at both institutions. That pretty much never happens now."

- IRB/HRPP staff

Standard terms settle debates

"The standardization allows for little argument about pointless exclusions and falsely held beliefs regarding liability."

- IRB/HRPP staff

Still slow for some

"It's tedious, I've had numerous technical difficulties, it takes 2-4 times as long to get an agreement done, and doesn't work well with our general process."

- IRB/HRPP staff

Partners can be reluctant

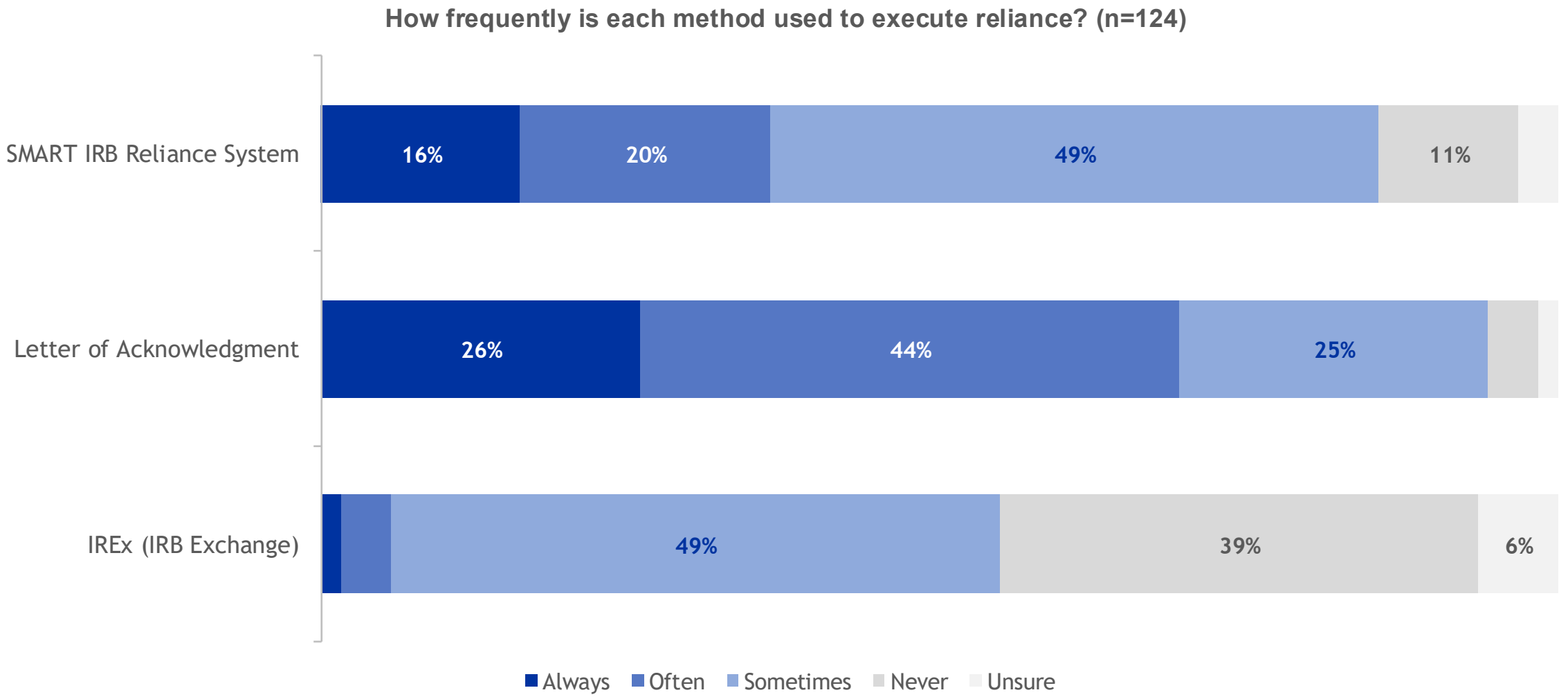
"While it helps in establishing a baseline for agreement, other institutions so far have been reluctant to partner with us using it, despite being members."

- IRB/HRPP staff

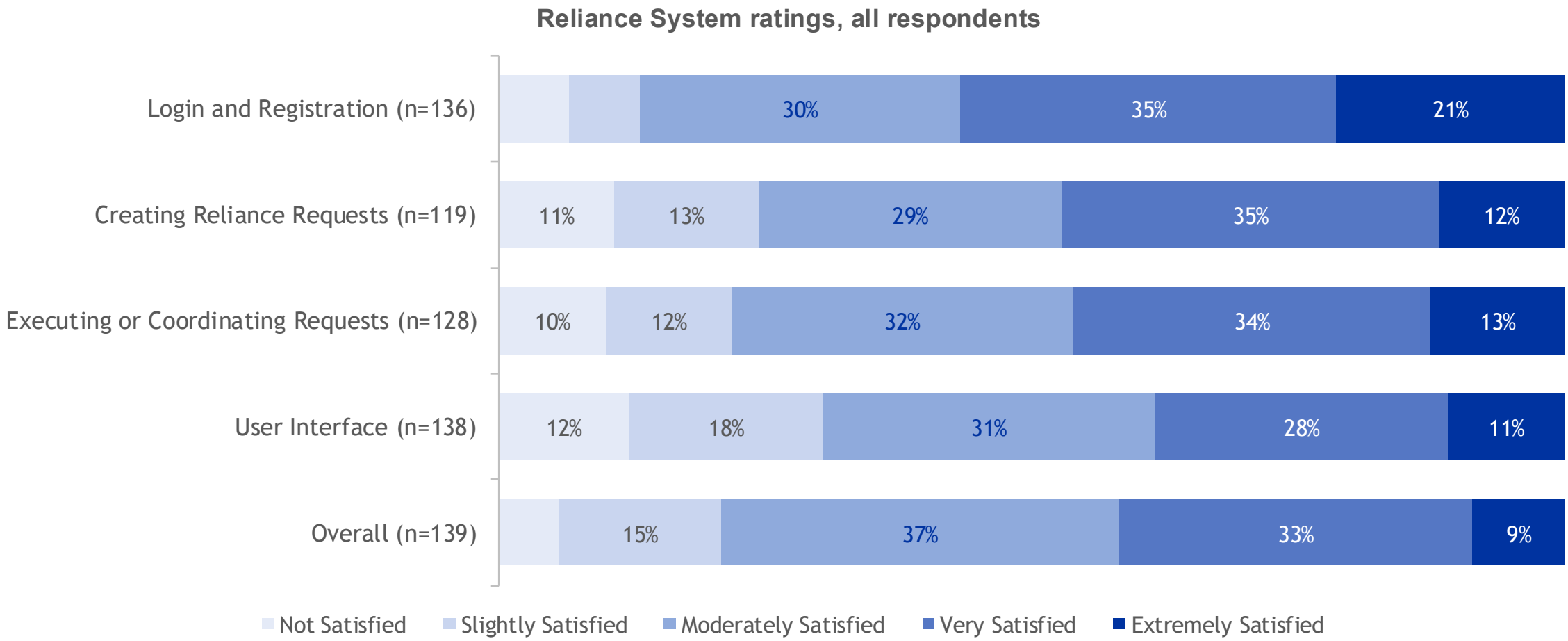
Reliance System



Executing Reliance: Method Frequency

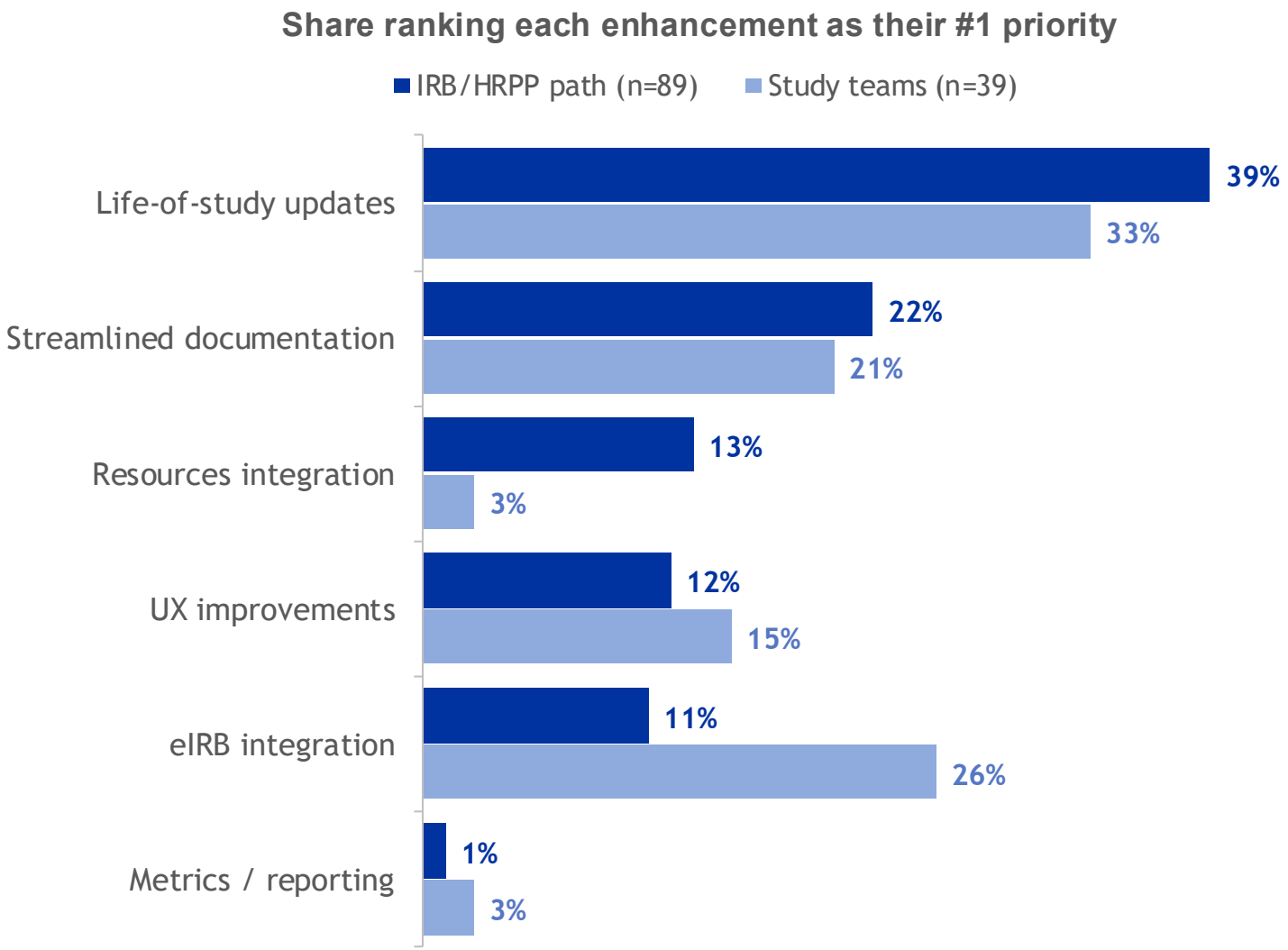


Reliance System: Satisfaction by Function



Login and registration rates highest (57% Very or Extremely Satisfied); the user interface rates lowest (38%). Overall ratings cluster at 'Moderately Satisfied', leaving room to improve. 'Executing or Coordinating' combines IRB/HRPP-path ratings of executing and study-team ratings of coordinating requests.

Reliance System: What to Improve First



39% · 33%

rank life-of-study updates (PI change, site closure, study completion) #1: IRB/HRPP path and study teams

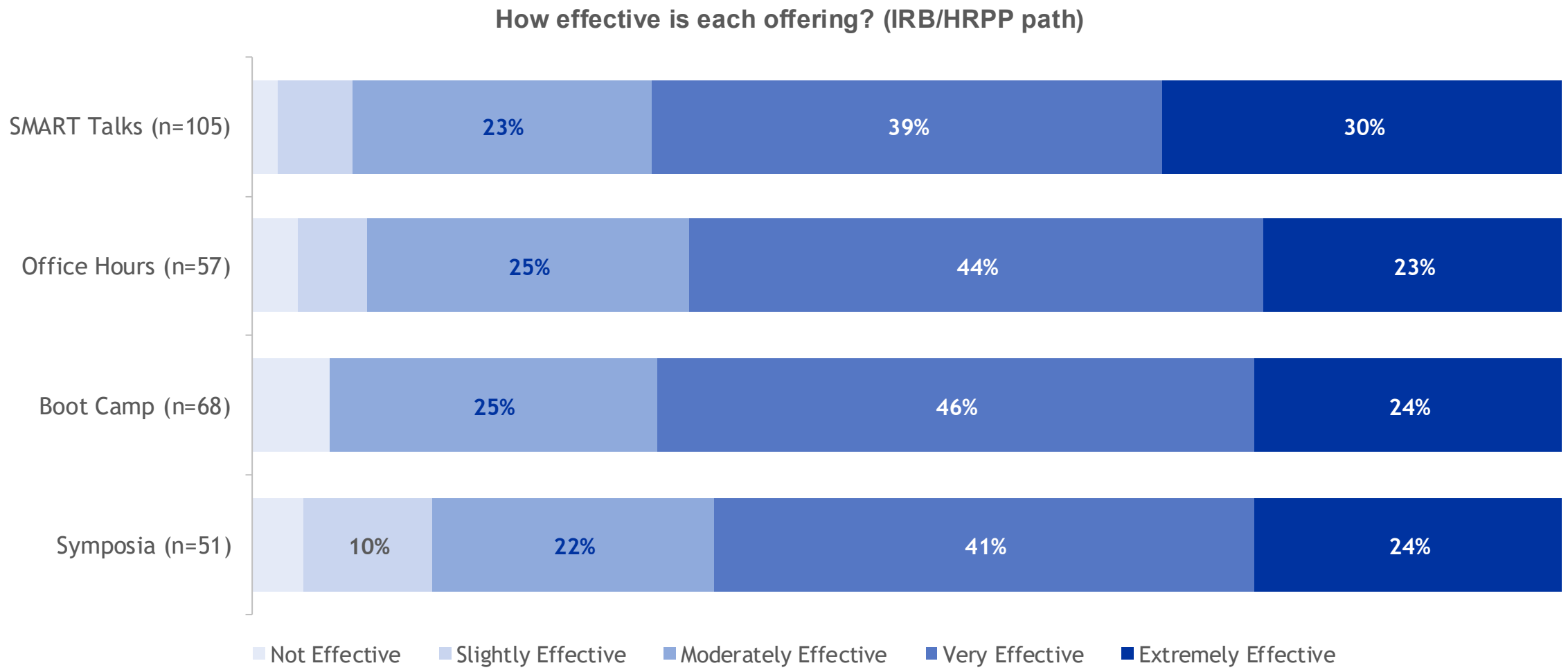
26% vs 11%

rank eIRB integration #1: study teams vs IRB/HRPP path, the biggest difference

Resources and Education

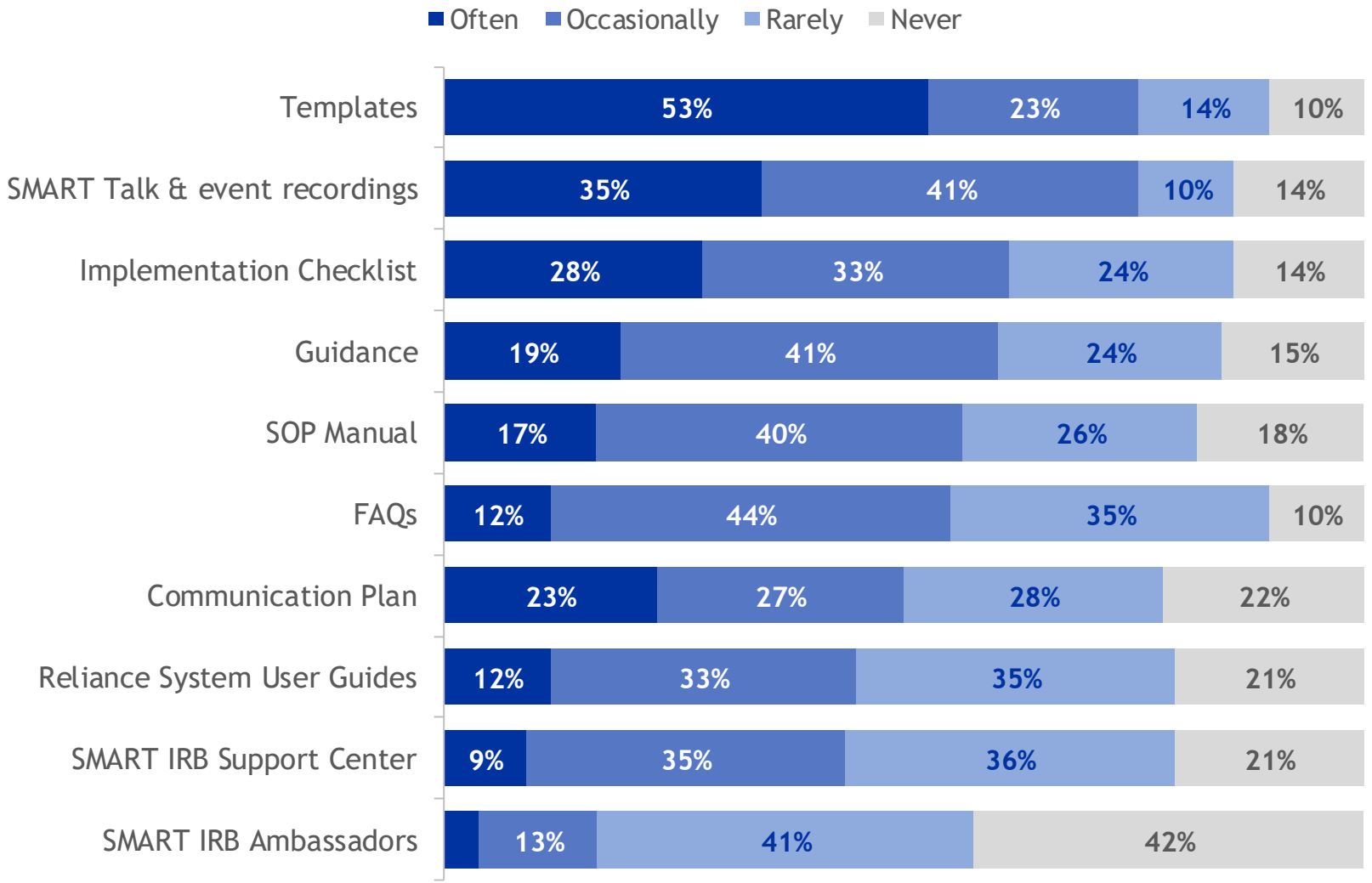


Educational Initiatives: Overall Ratings



About two-thirds rate SMART Talks, Office Hours, Boot Camp and Symposia Very or Extremely Effective (65-70%).

Templates and SMART Talks Lead Resource Use



IRB/HRPP path, n = 78

62%

use the Implementation Checklist at least occasionally

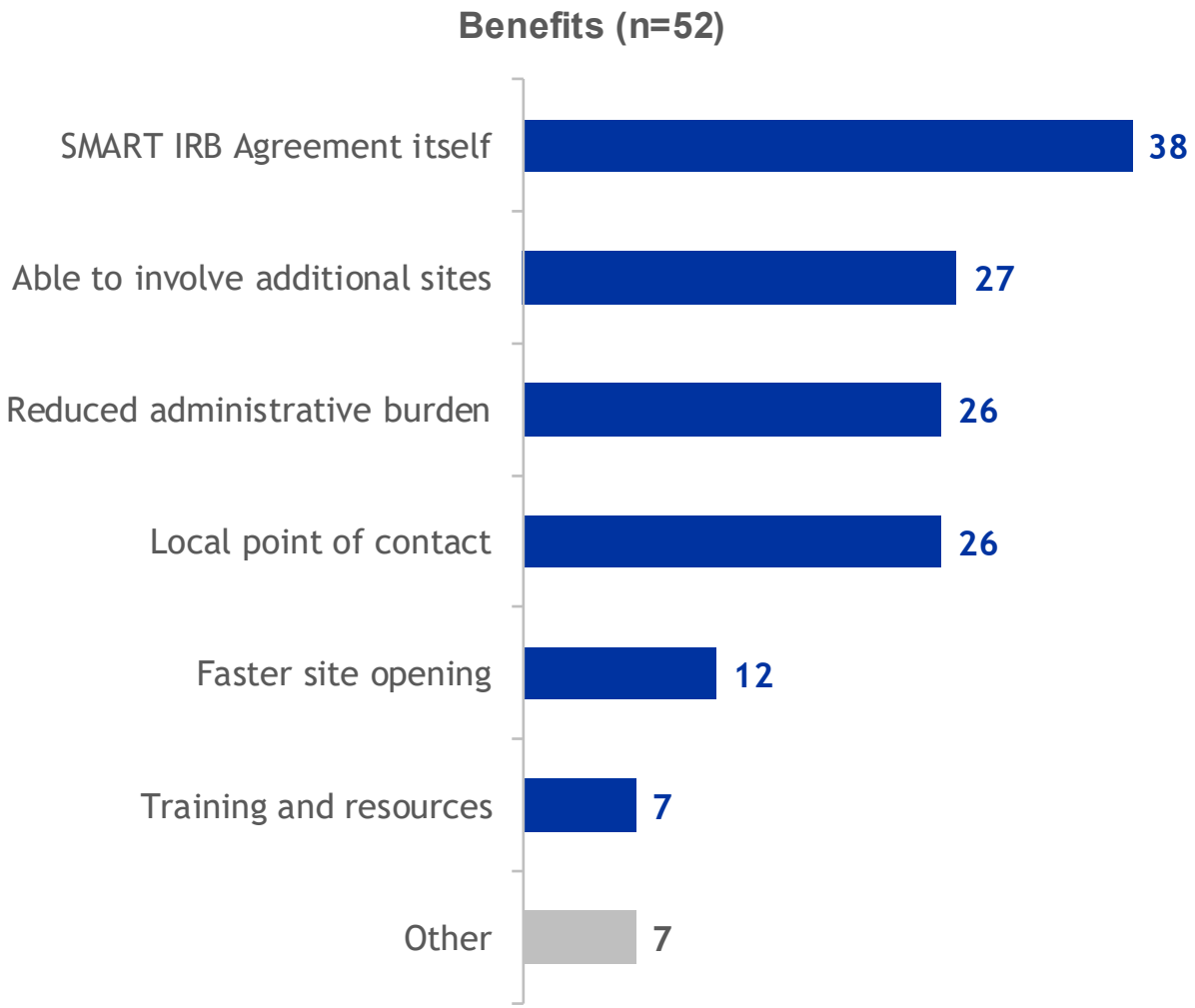
53%

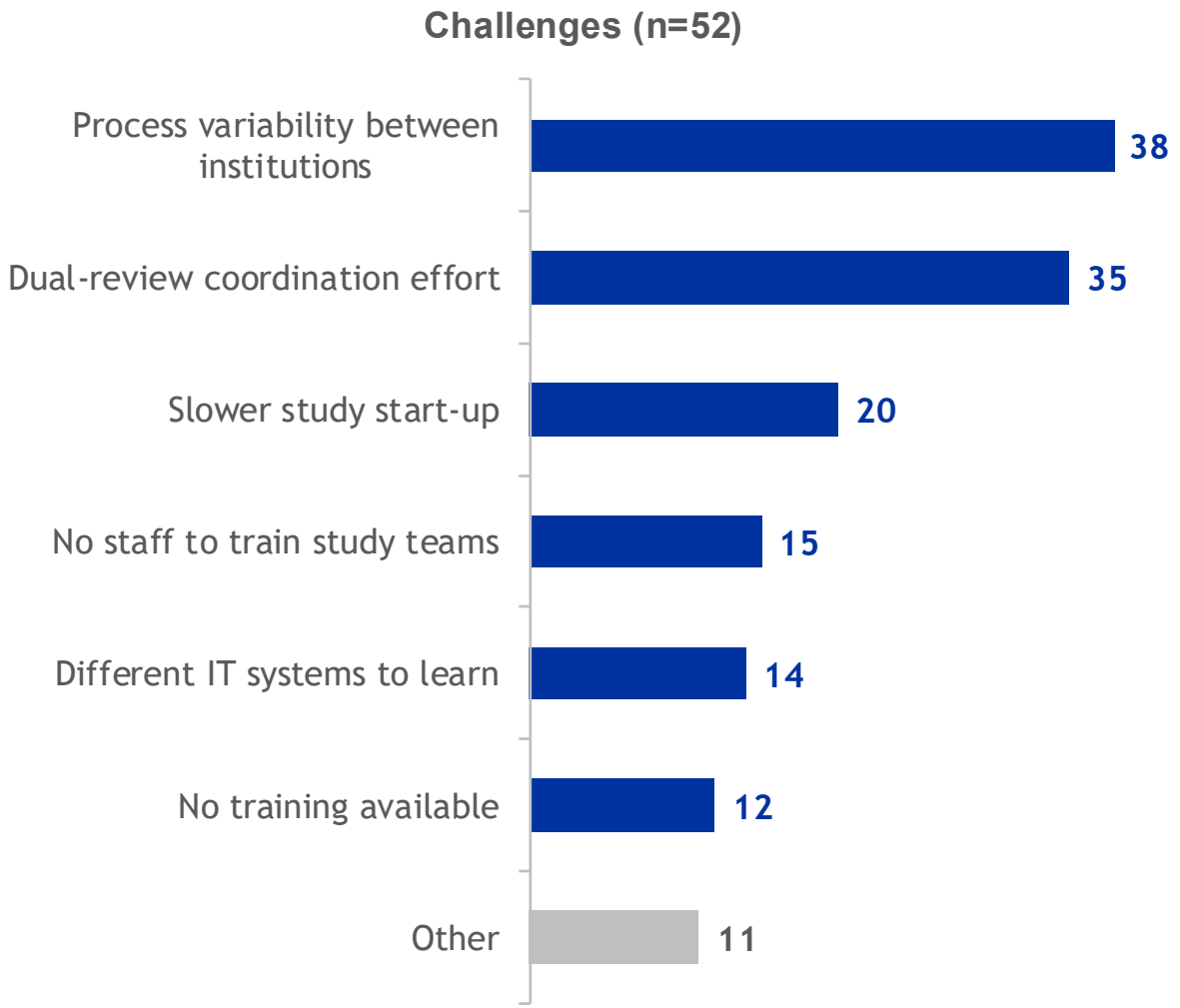
use Templates often, the most of any resource

60%

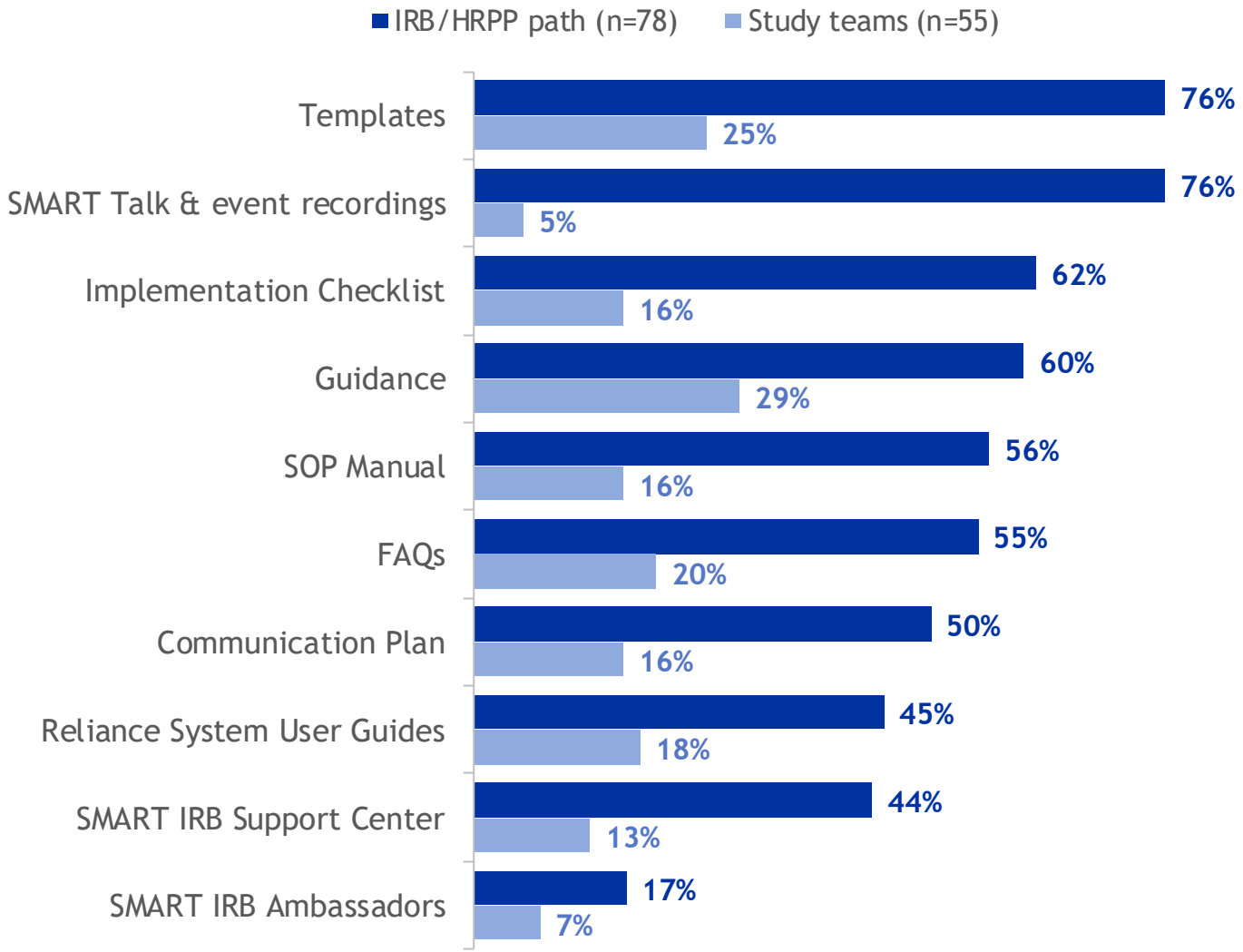
use Guidance at least occasionally (includes Institution vs. IRB responsibilities)

Study Teams: Single IRB Benefits and Challenges





Resource Utilization: IRB/HRPP + Study Teams



55%

of study team respondents use none of the resources even occasionally

76% vs 5%

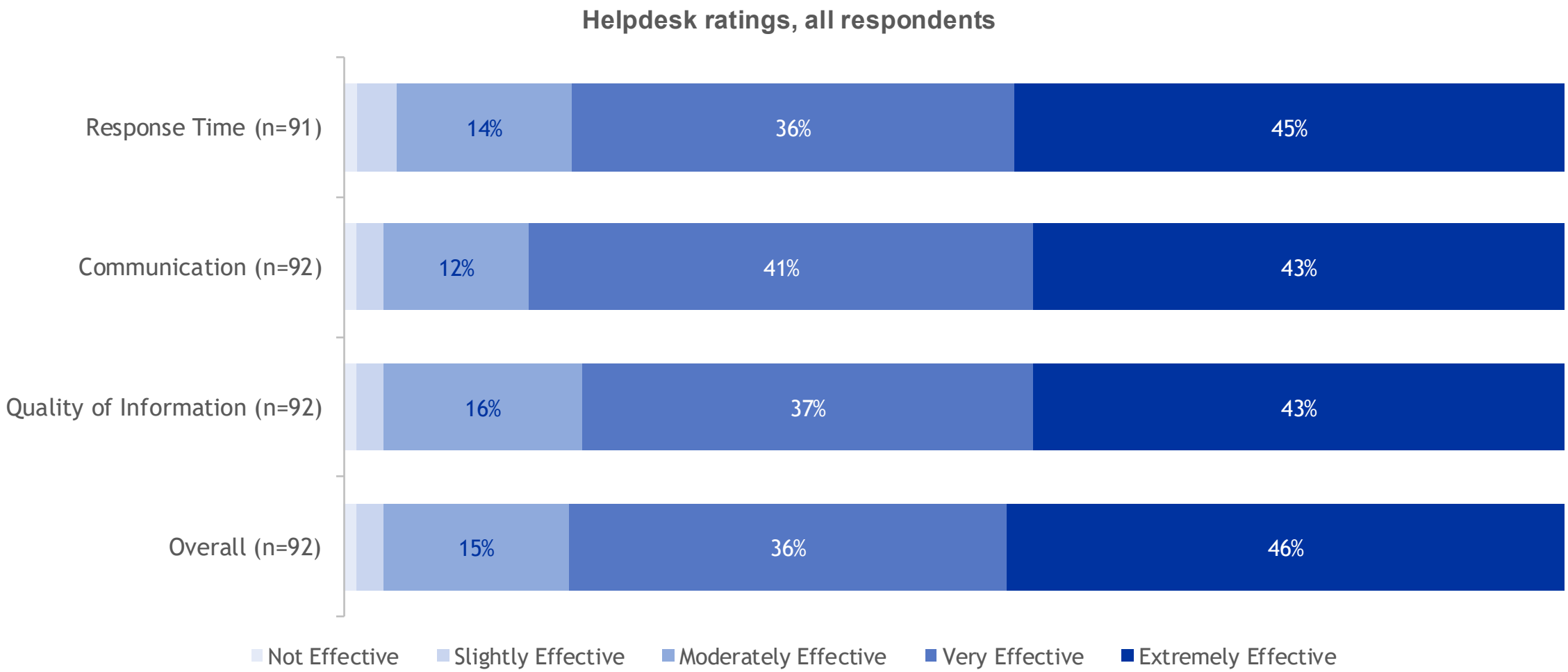
SMART Talk use: IRB/HRPP vs. study teams, the widest gap

44% of IRB/HRPP-path respondents want SMART IRB to build study team resources

"More general education templates that can then be adapted for the individual institution."

- IRB/HRPP staff

Helpdesk Effectiveness: All Four Dimensions

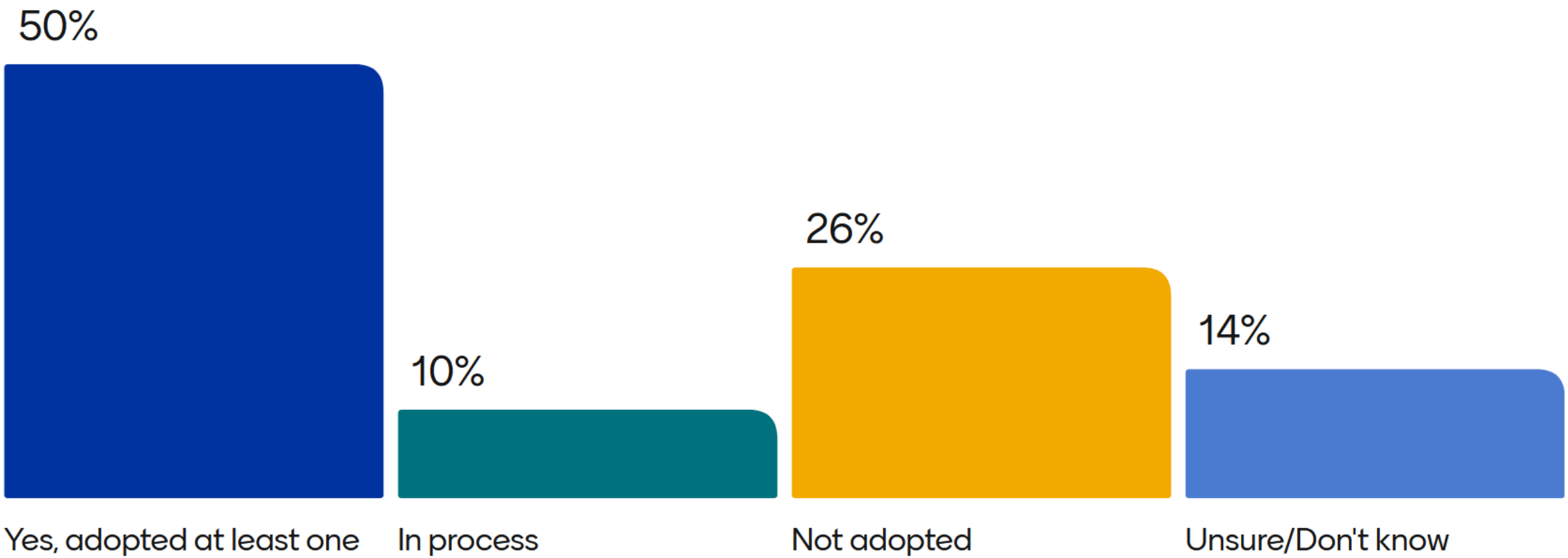


Across all four dimensions, 80-85% of respondents rate the Helpdesk Very or Extremely Effective, and no more than 5% rate it below Moderately.

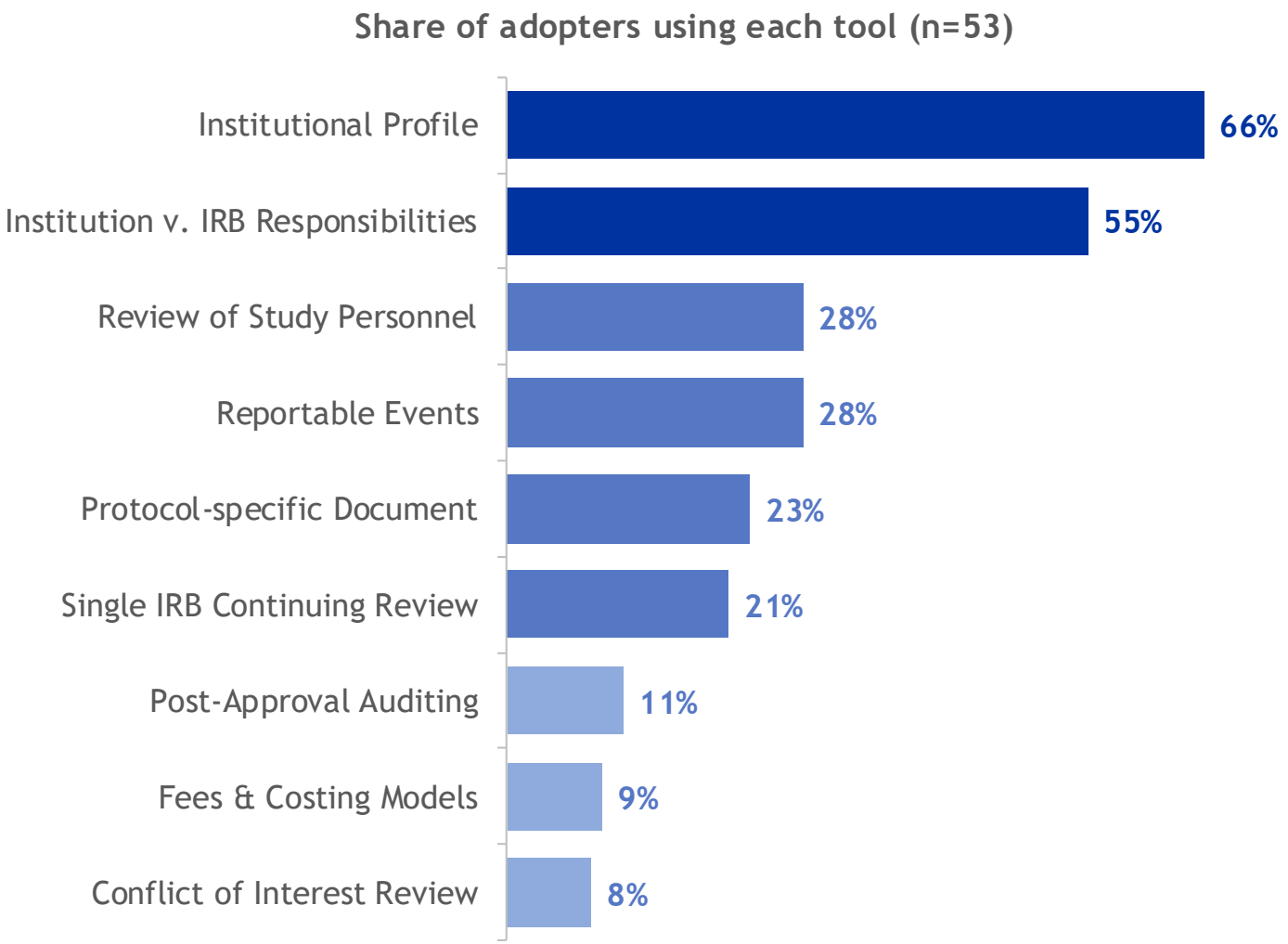
Harmonization



Has your institution adopted any SMART IRB Harmonization guidance or tools?



Half Have Adopted; Most Use One or Two Tools



Adoption status (n=101)

53 adopted ≥1 tool (52%)

7 in process only (7%)

41 not adopted (41%)

2 median tools per adopter

58% use one or two tools

Tools needing finance, compliance or COI reach about 1 in 10 adopters.

Using Isn't the Same as Adopting

23 of 30

non-adopters still use SMART IRB Guidance or Templates at least occasionally

Using is not the same as "adopting"

"Do we use these references all the time. Yes - but I'm not sure I would call that adopting these."

- IRB/HRPP staff

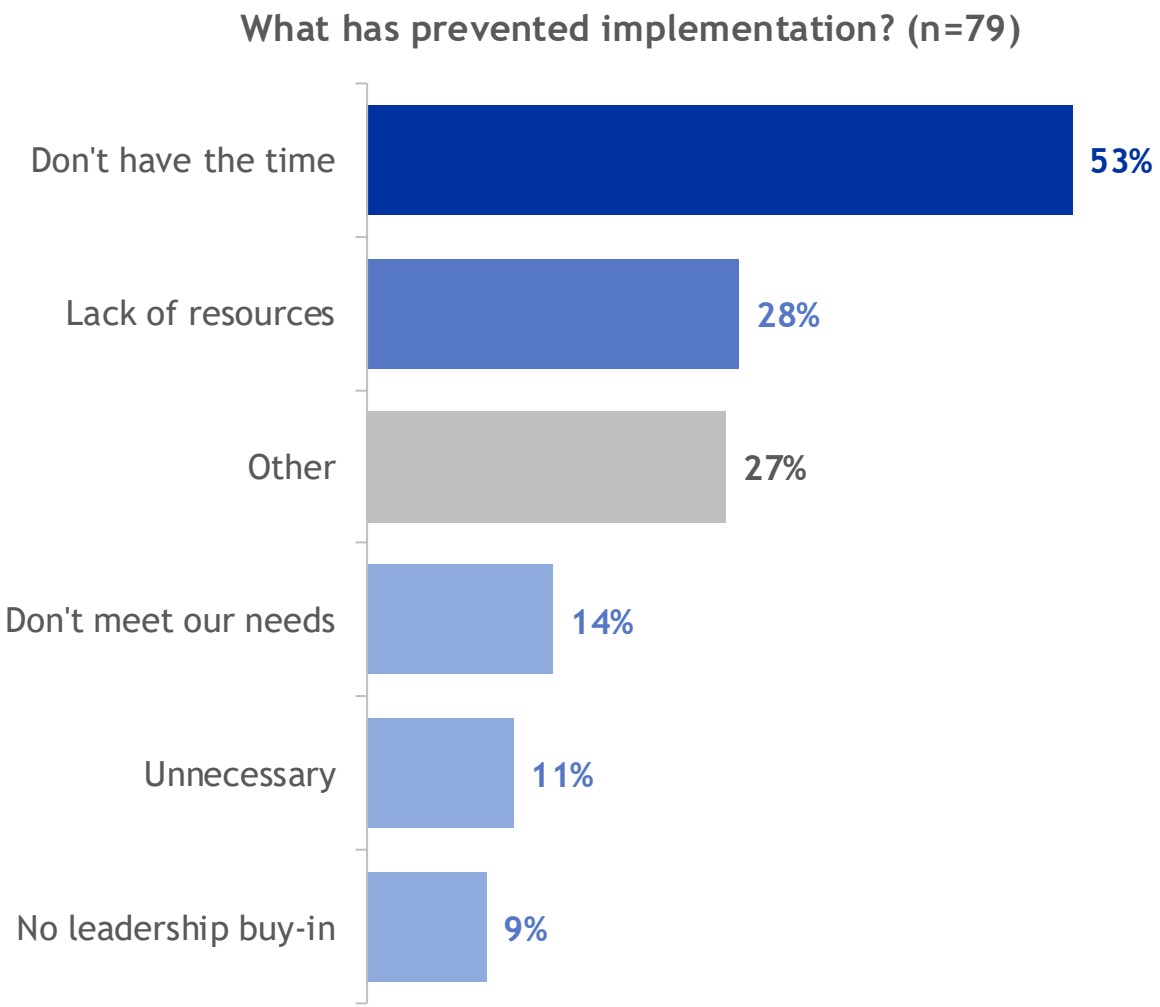
Unsure whether they align

"Our institution has processes in place, but we are unsure if they align with what is in the guidance material, and as a result, we did not check any of the boxes."

- IRB/HRPP staff

What it suggests: self-reported adoption likely understates real use, because many offices draw on the tools without formally "adopting" them.

Time Is the Main Barrier to Adoption



62%

cite time and/or resources

9%

cite leadership buy-in

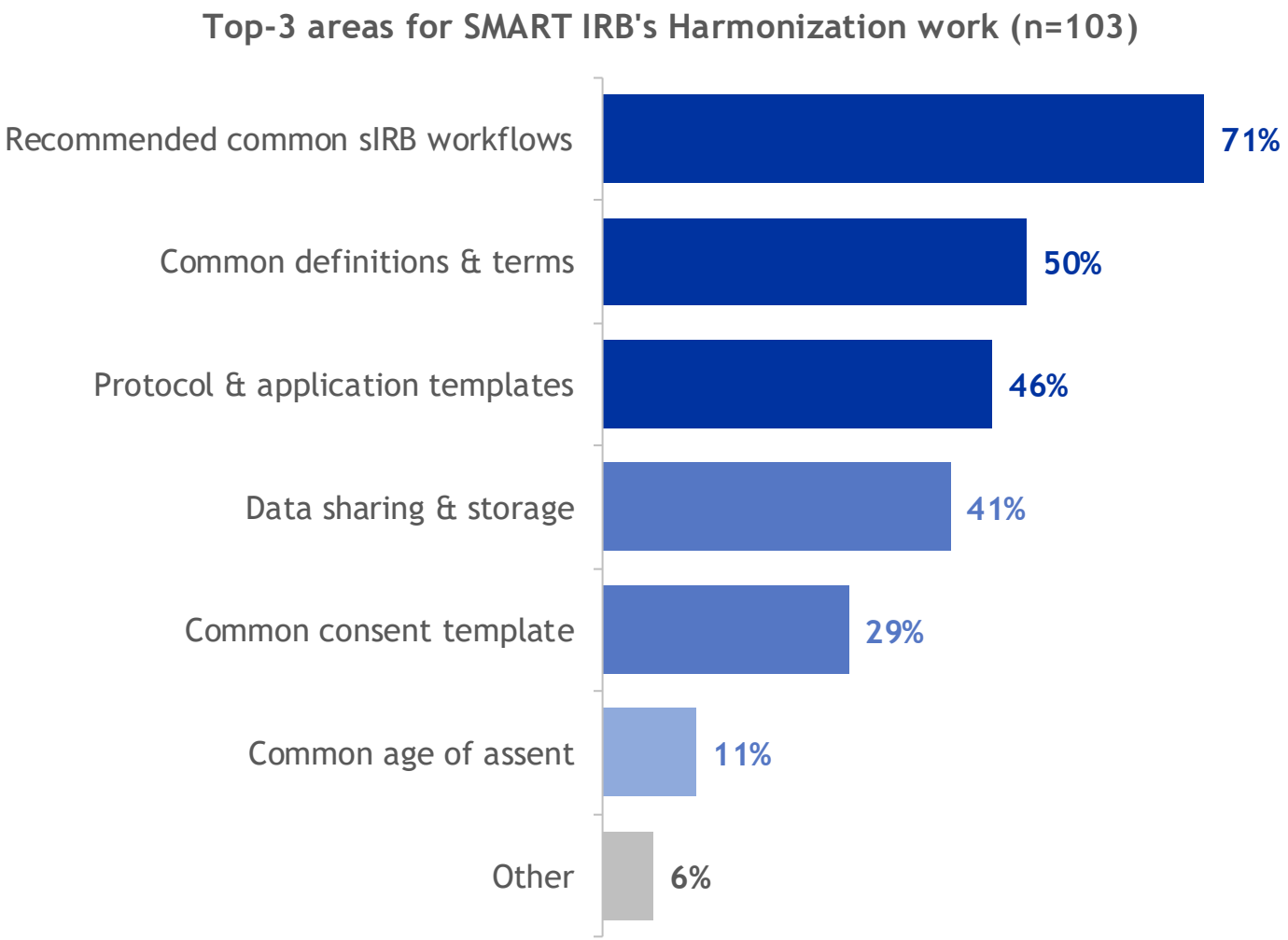
66%

adopted where the SMART IRB Agreement is required (33% where not)

54%

of adopters also cite lack of time (21 of 39)

Most Wanted: Workflows and Definitions



85% picked workflows or definitions

Workflows is the top choice for adopters and non-adopters alike.

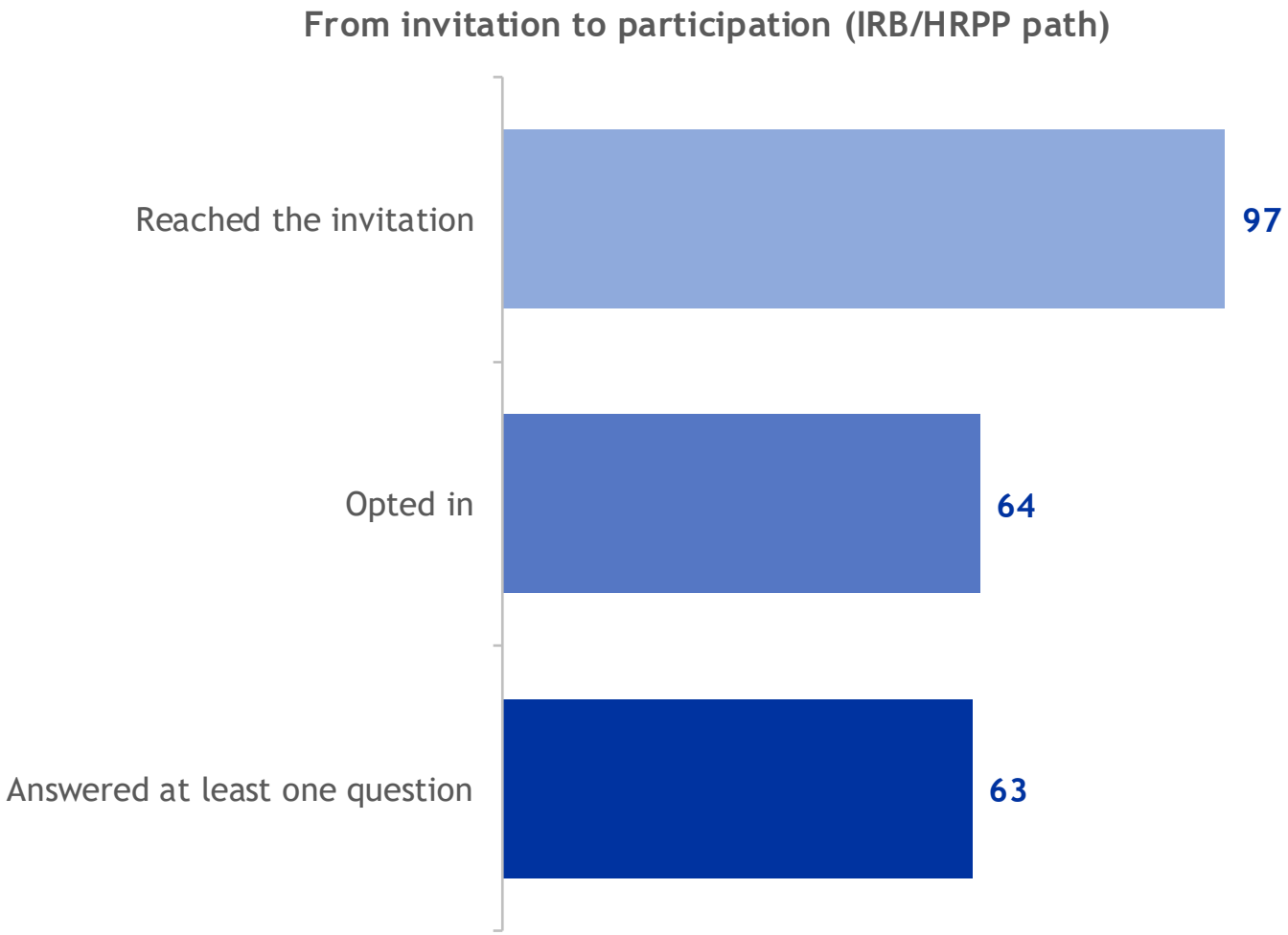
Also suggested (write-ins)

- sIRB for program, center & training grants
- Aligning sponsors, networks & funders
- Reportable-events workflow diagrams
- Hospital-university collaboration agreements
- A short investigator summary template

Optional Module: Single IRB in Practice



About the Optional Module: Who Answered



63

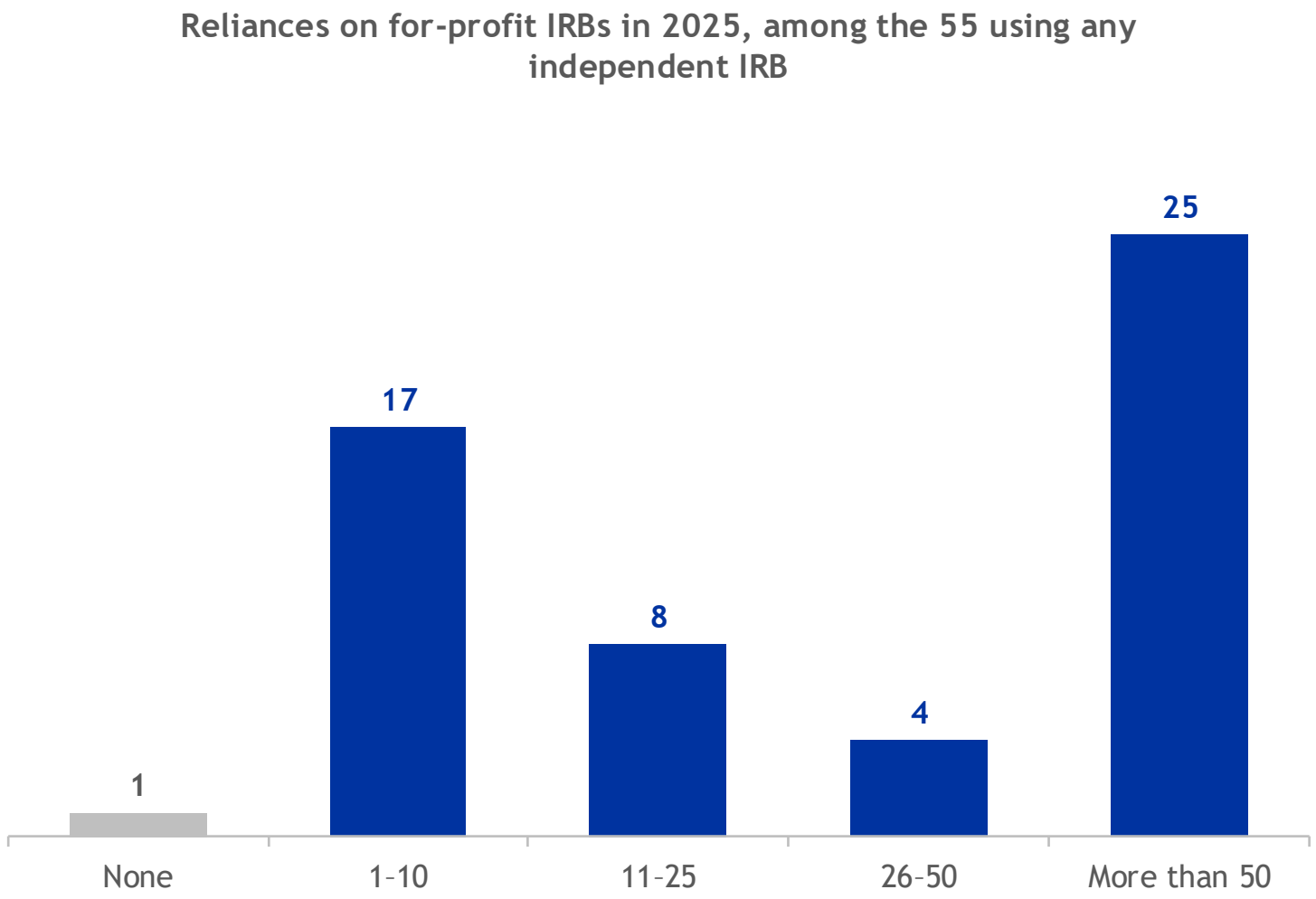
respondents took part: 56 IRB/HRPP staff (89%) and 7 in other roles (11%). 90% serve as Reviewing IRB for other institutions (57/63). Study team members were not offered this module.

53–63

answers per question (smaller for subgroups). Read the next slides as benchmarks from a self-selected group of engaged institutions, not national estimates.

Optional module offered at the end of the survey, with questions provided by the AAHRPP Metrics Working Group on how institutions operationalize single IRB review.

Relying on External IRBs: Local Steps Persist



87%

rely on at least one independent IRB, commercial or non-profit (55/63)

87%

still conduct local administrative or institutional review when relying (54/62)

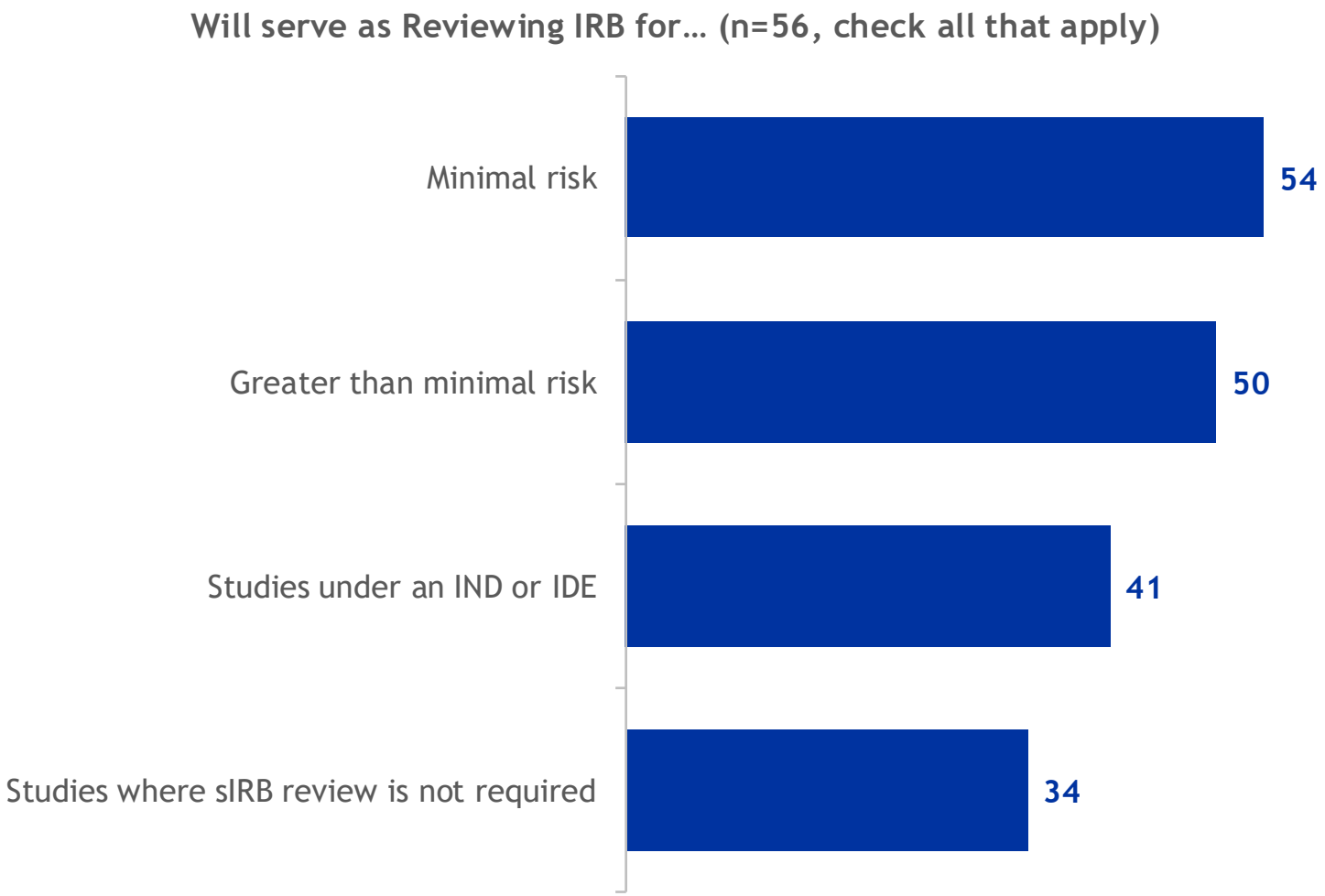
80%

do not ask whether another IRB previously disapproved the study (45/56)

74%

route reportable events to both the Reviewing IRB and their own institution (46/62)

Local Context Is Still Collected Study by Study



71%

have reliance staff perform local context review (45/63)

74%

re-collect local context for every study rather than once per site (39/53)

55%

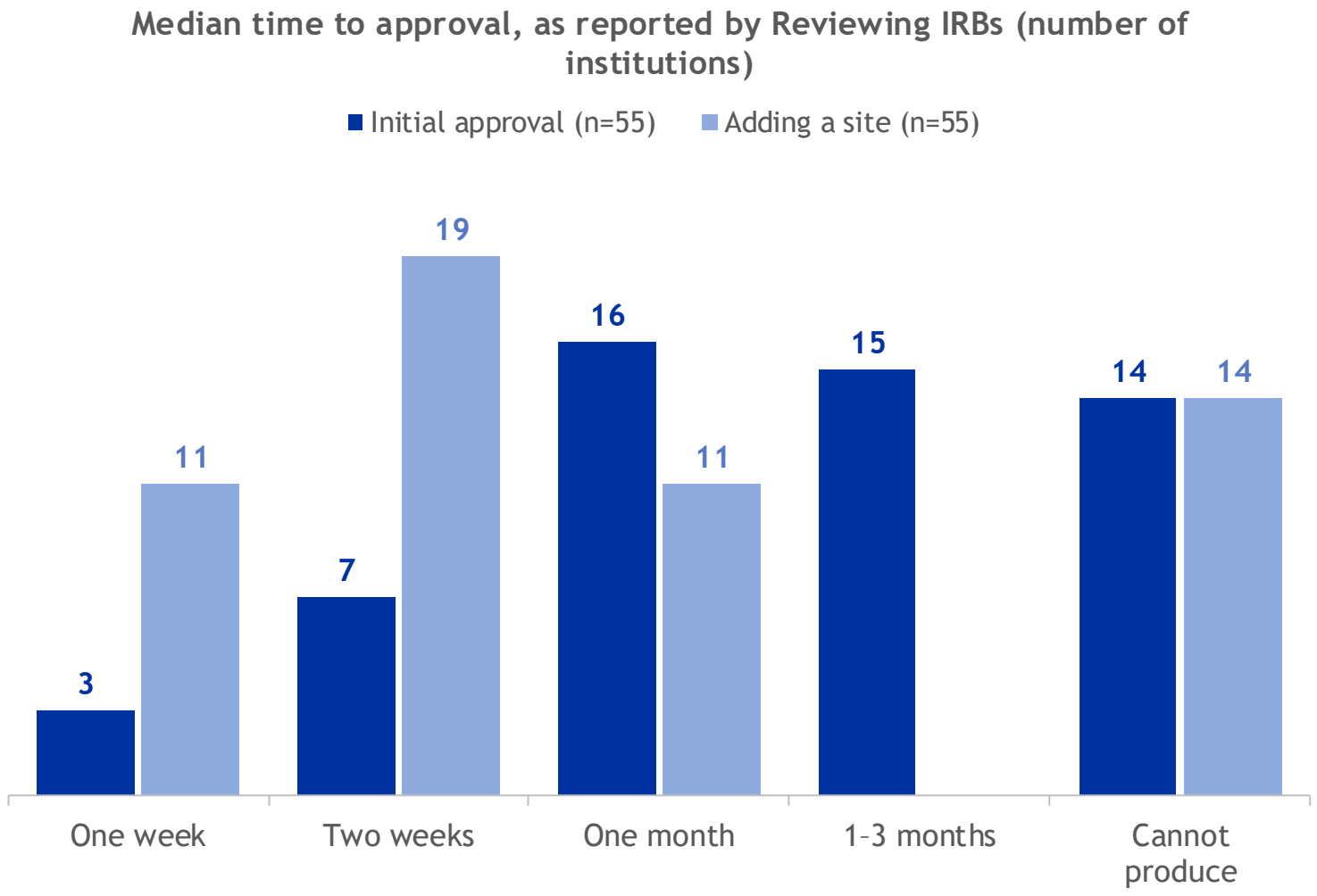
collect local context with their own standardized questionnaire (30/55)

29%

collect it with the SMART IRB Institutional Profile (16/55)

Re-collecting for every study is a concrete Harmonization opportunity.

Turnaround: A Measurement Gap at Every Size



25%

can't report their median time to initial approval (14 of 55); 11 of them can't report time to add a site either

Similar at every size

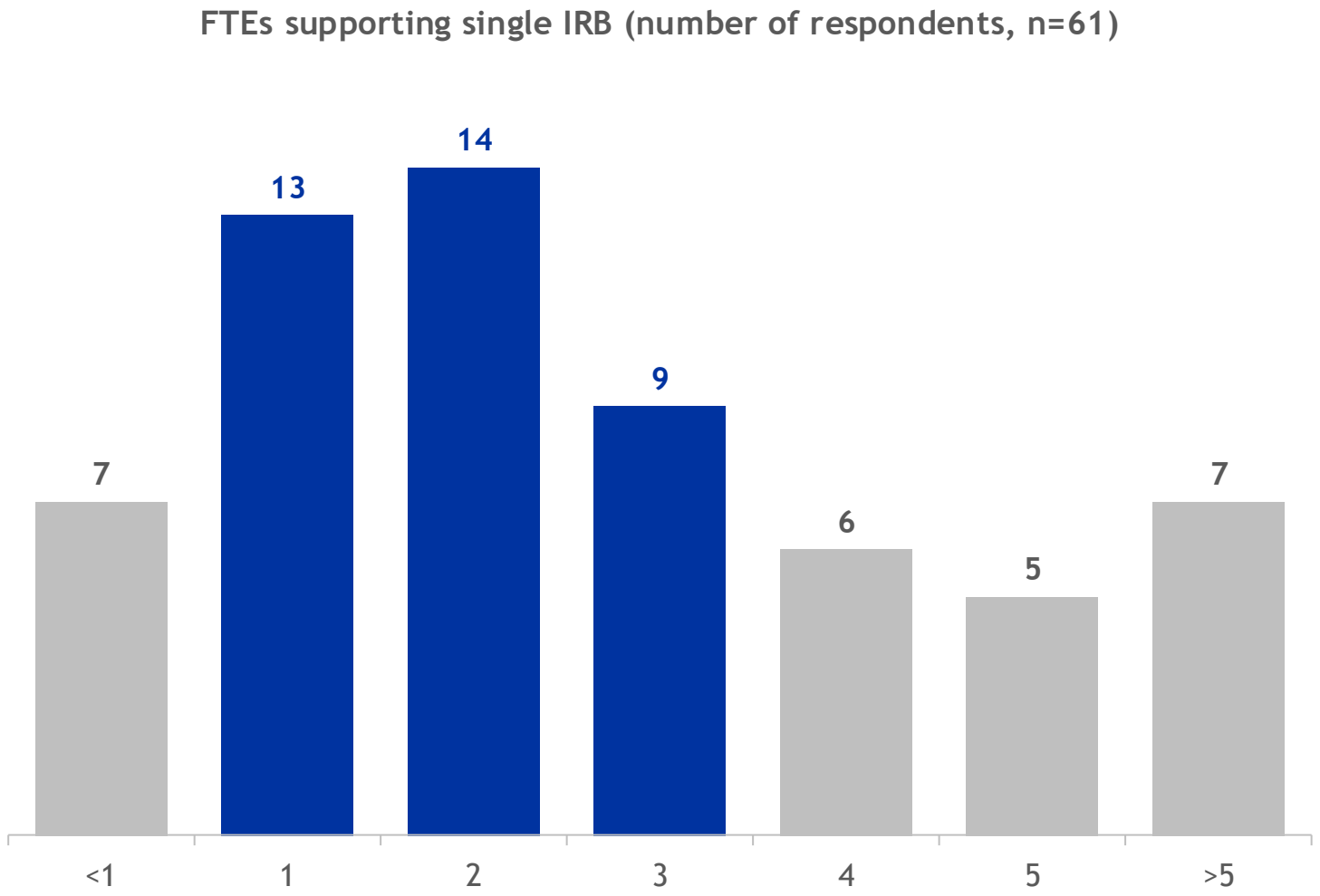
27% review 25 or fewer open studies for others (7 of 26)

25% review 26-50 open studies for others (3 of 12)

24% review more than 50 open studies for others (4 of 17)

No statistically significant difference by study volume, FTEs or staffing model either (small groups).

Single IRB Runs on Small Teams



59%

have 1 to 3 FTEs supporting single IRB (36 of 61)

69%

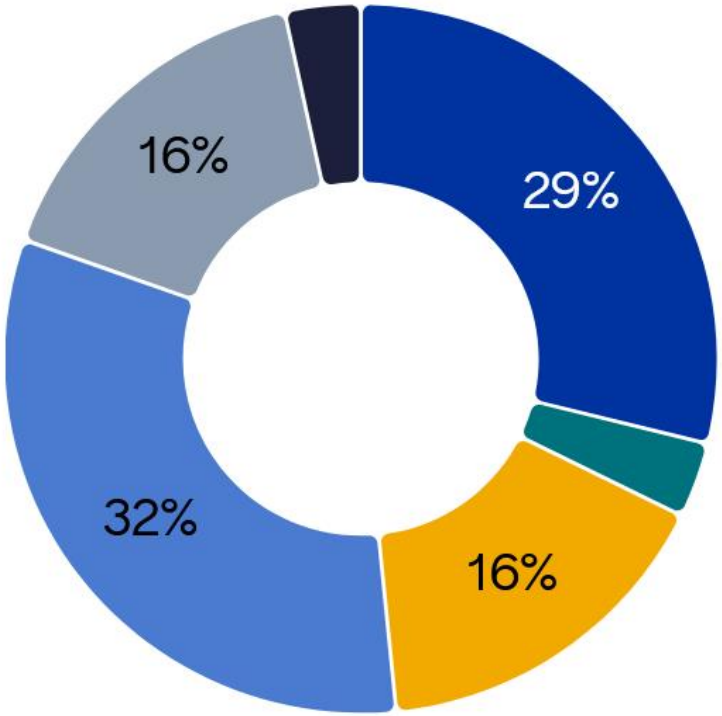
have staff dedicated to single IRB; the rest spread the work across other staff (42 of 61)

Optional module, IRB/HRPP-path respondents. FTEs include staff who do single IRB work part-time.

Future of SMART IRB



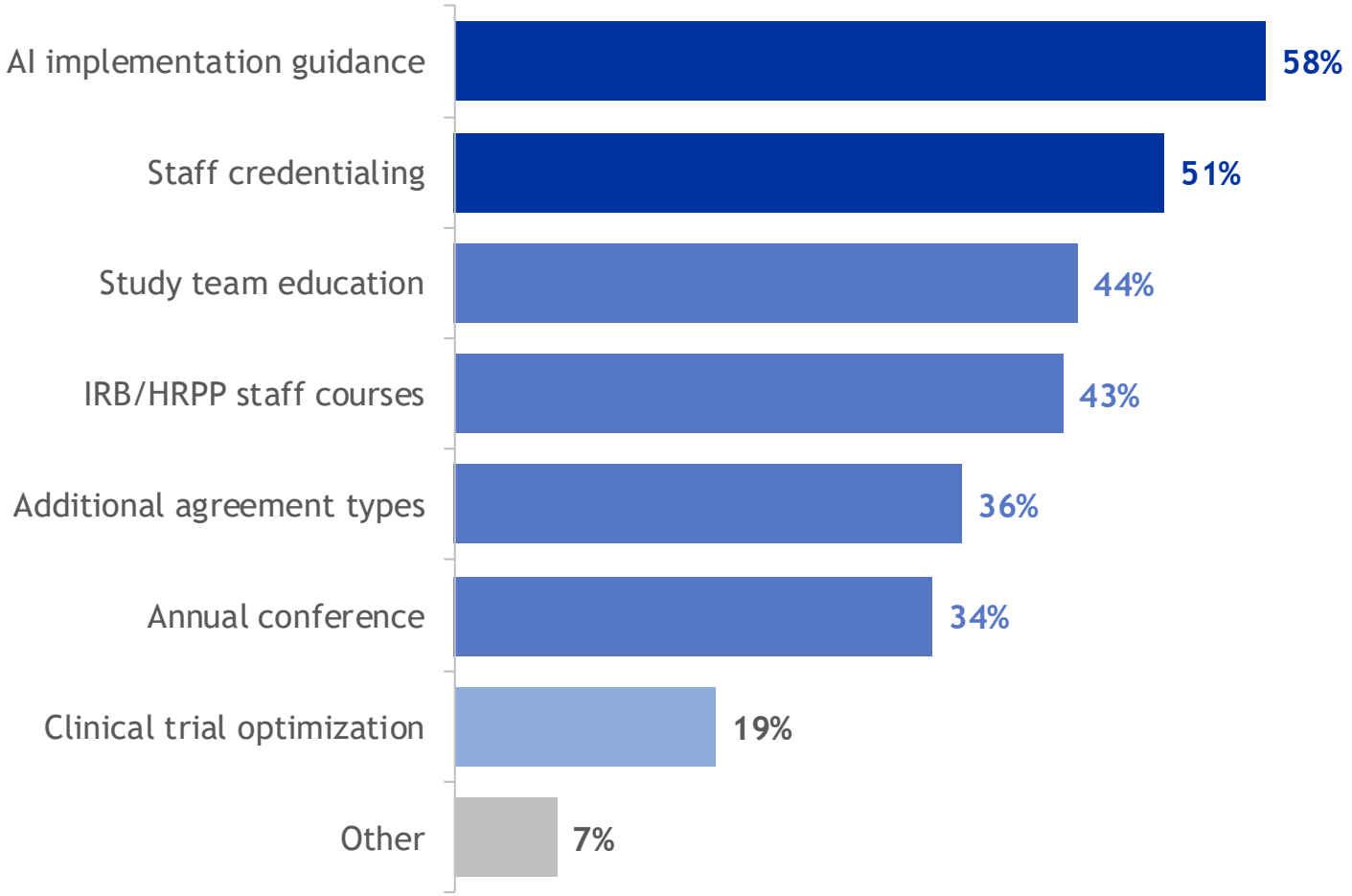
Pick your top choice for SMART IRB to focus on next



29%	AI Implementation Guidance
3%	Staff Credentialing
16%	Study Team Education
32%	IRB/HRPP Staff Courses
0%	Additional Agreement Types
16%	Annual Conference
3%	Clinical Trial Optimization

Future of SMART IRB: Priority Areas

What should SMART IRB focus on? (check all that apply; IRB/HRPP path, n=97)



58%

want guidance on AI implementation in single IRB, the top choice

44%

want study team education, echoing the resource gap for study teams

What would be the most helpful SMART IRB credentialing offering?



47% Certificates of Completion for Educational Events



13% Structured Coursework



13% Certificate(s)



27% Certification

What You Asked Us to Teach

For IRB/HRPP staff (33 comments)

Topics suggested by IRB/HRPP-path respondents

- SMART IRB 101 and plain-language agreement walkthroughs
- Local context review, fees and billing, managing sIRB studies, AI

"SMART IRB 101: registration, how to set up a reliance agreement, collecting the information needed to complete the agreement."

"A 'what to know about reliance' resource for people in HRPPs who do not manage reliance…"

For study teams (37 comments)

Topics suggested by IRB/HRPP-path respondents

- Single IRB basics, roles and responsibilities
- Navigating the Reliance System; managing studies after activation

"An annual study team sIRB certification course similar to CITI that institutions could require…"

"I would like for you all to develop … a 'sIRB Demystified' … resource for my study team members."

Also suggested: a virtual option for the annual conference, networking working groups, website improvements, and fewer supplemental agreements across institutions.

Thank You

for your support in advancing single IRB multi-site research.

Questions? Reach out to us at

Help@smartirb.org

