AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

2020 Metrics for AAHRPP-Accredited Human Research Protection Programs

August 2020

About the Metrics

AAHRPP is pleased to present the 2020 metrics for Human Research Protection Program (HRPP) performance. AAHRPP provides these data to help research organizations, researchers, sponsors, government agencies, and participants identify and support high-performing practices for HRPPs.

These metrics are collected from Annual Reports, as well as Step 1 and Step 2 applications, submitted by accredited organizations.

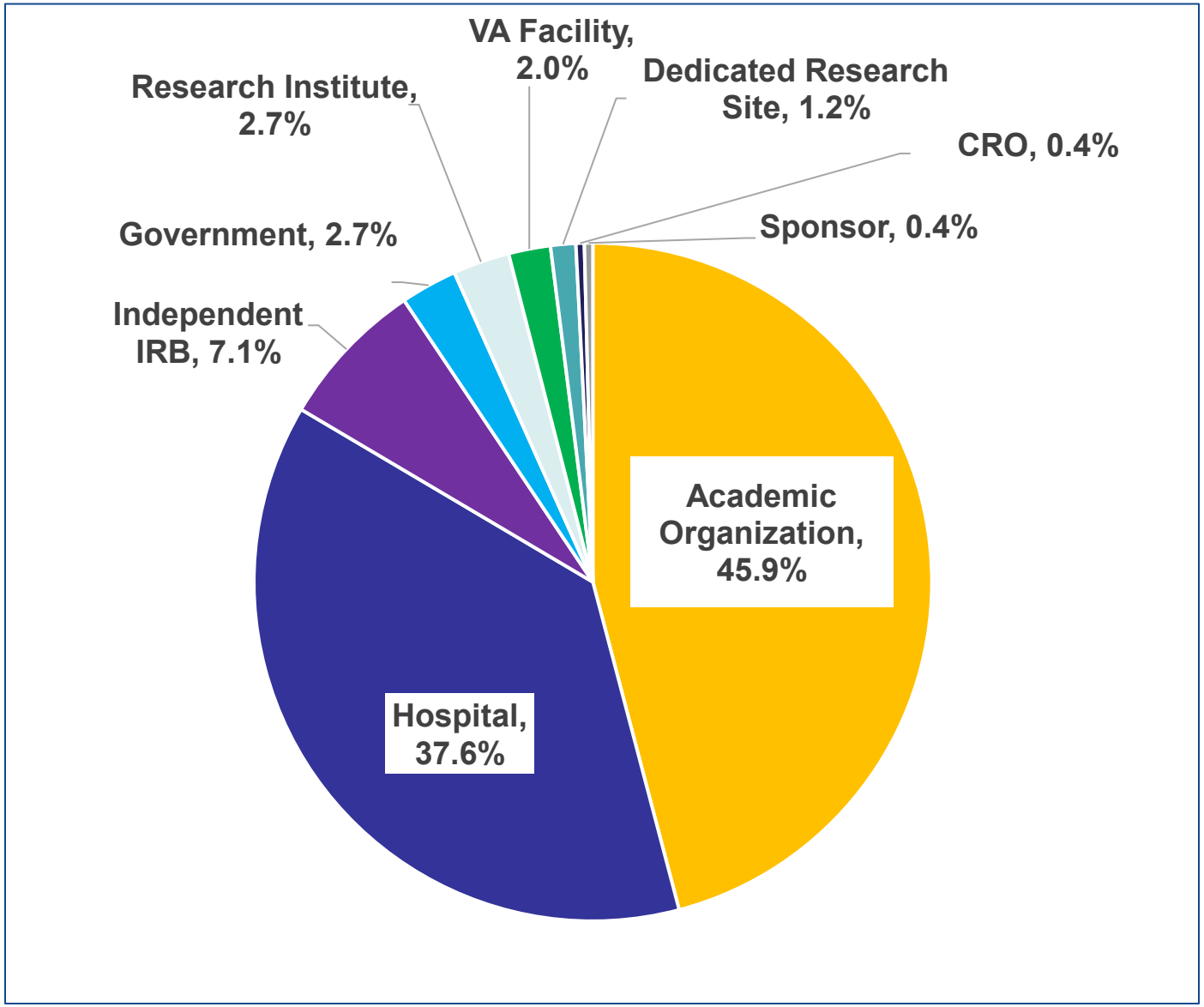
All the quantitative data were derived from the most recent reports by AAHRPP organizations.

Data were selected based on what most accurately reflected AAHRPP organizations in 2020.

Table of Contents

General Description of Organizations	• Slide 4: Accredited Organizations By Type • Slide 5: Where Accredited Organizations are Based	**Research Review: Number of Studies**	• Slide 16: Active Studies Overseen: All Organizations • Slide 17: Active Studies Overseen (by Quartile) • Slide 18: Active Studies: Internal vs. External IRB/EC • Slide 19: Active Studies Per IRB/EC • Slide 20: IRB/EC Review Times: All Review Types • Slide 21: IRB/EC Review Times: Expedited Review • Slide 22: IRB/EC Review Times: Convened Board Review • Slide 23: Review Times: Exemptions
General Description of Research	• Slide 6: Where Research Occurs • Slide 7: Research Type • Slide 8: Biomedical/Clinical Research by Type • Slide 9: Vulnerable Populations		
Research Funding and Regulations	• Slide 10: Funding Type • Slide 11: Funding Distribution • Slide 12: Regulations & Guidelines	**Resources and Budget**	• Slide 24: IRB/EC Technology • Slide 25: IRB/EC Staffing and Budget
Use of IRBs/ECs	• Slide 13: Internal IRBs/ECs • Slide 14: Relying on External IRBs/ECs • Slide 15: Compensating IRB/EC Members	**Audits, Reportable Events, and Conflicts of interest**	• Slide 26: Audits of Researchers • Slide 27: Audits of IRBs/ECs • Slide 28: Unresolved Complaints, Noncompliance, & Unanticipated Problems • Slide 29: Conflicts of Interest

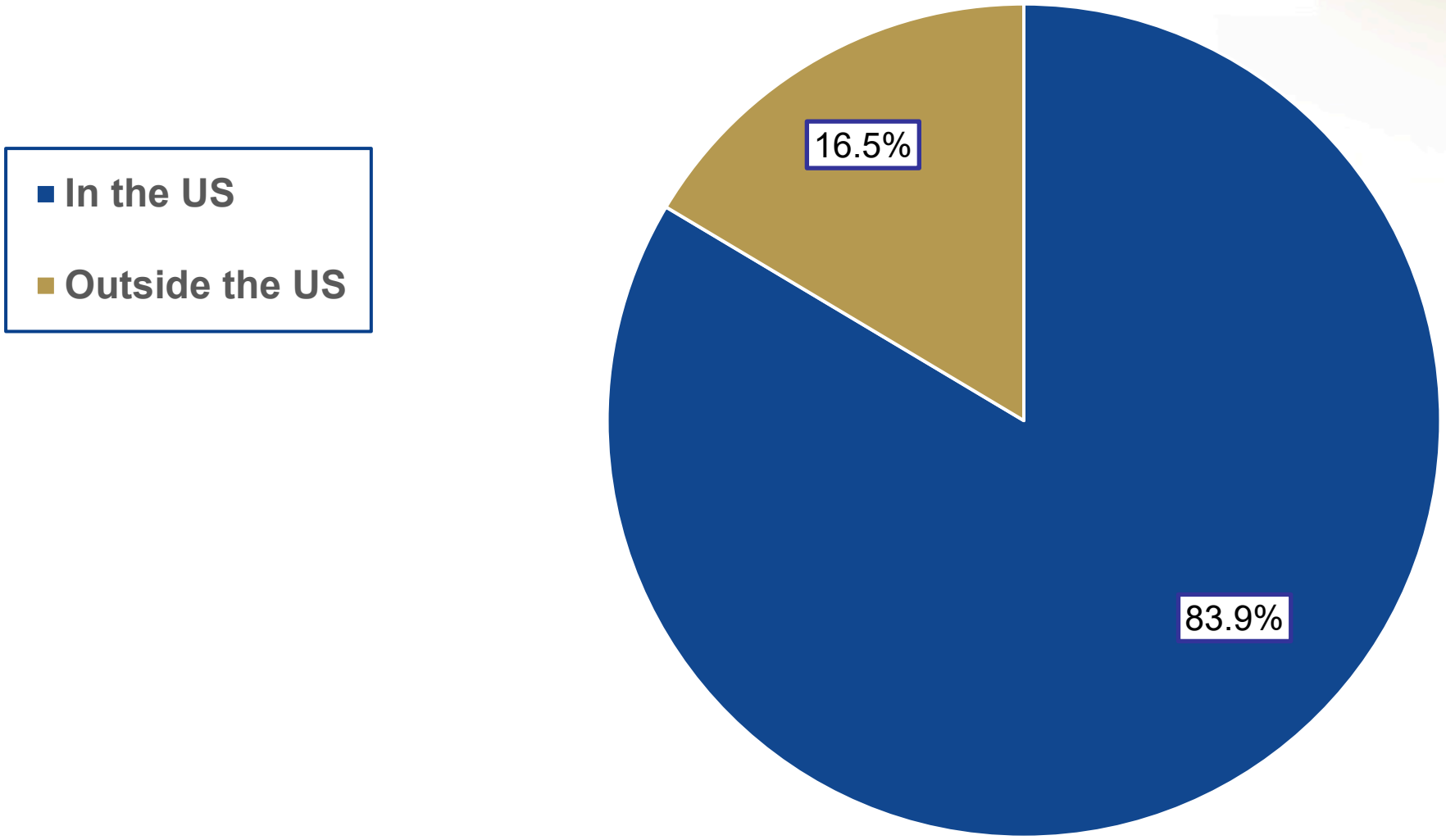
Accredited Organizations By Type



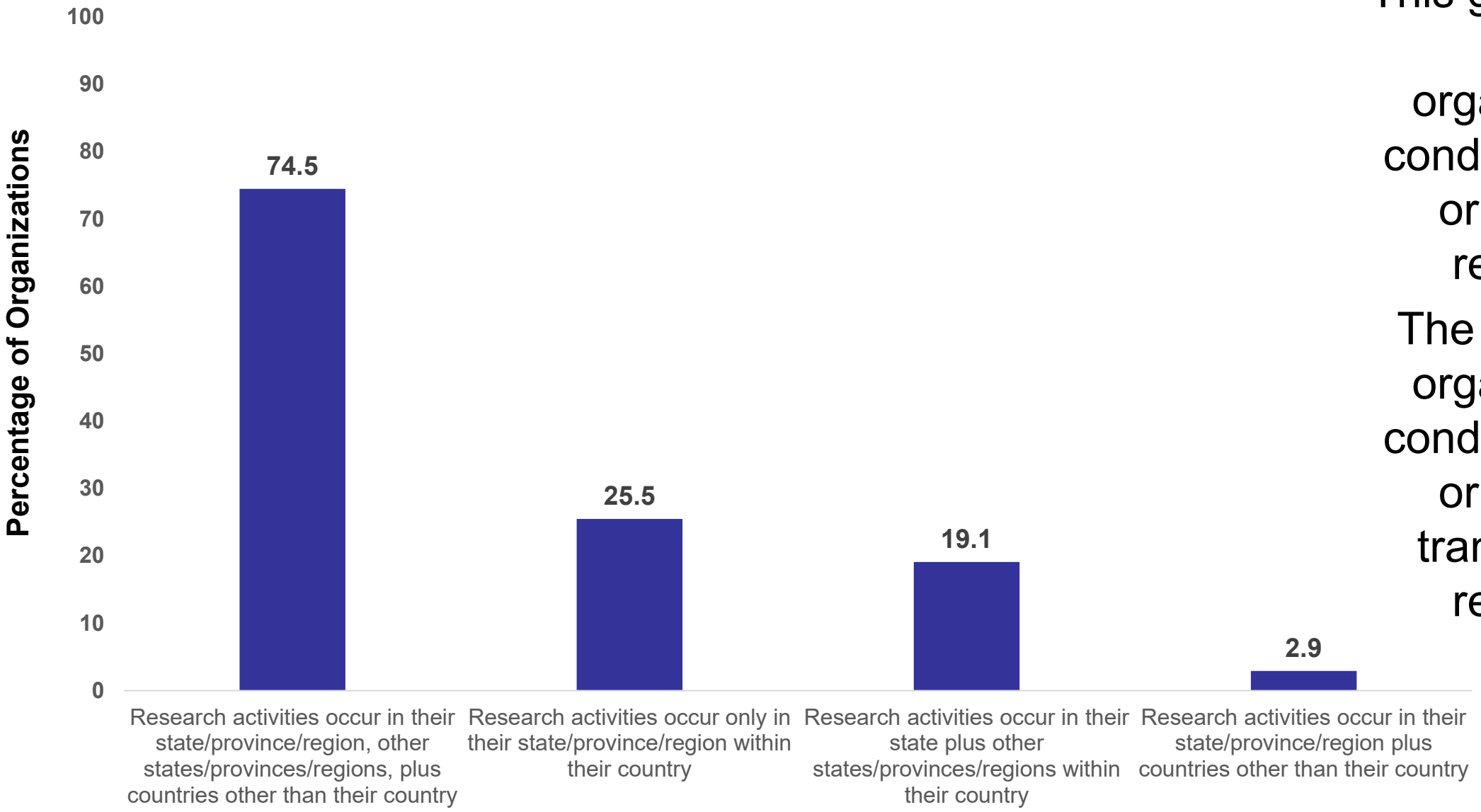
Of the 255 accredited organizations:

- 45.9% are academic organizations
- 37.6% are hospitals
- 7.1% are independent IRBs
- 2.7% are governmental organizations
- 2.7% are research institutes
- 2.0% are VA facilities
- 1.2% are dedicated research sites
- 0.4% are contract research organizations
- 0.4% are sponsors

Where Accredited Organizations are Based



Where Research Occurs



This graph shows where organizations conduct, review, or manage research.

The majority of organizations conduct, review, or manage transnational research.

Research Type

Most organizations conduct, manage, or review

biomedical/clinical research

Most organizations conduct, manage, or review

social/behavioral/education research

Biomedical/Clinical Research by Type

Drugs	93.8%
Devices	91.8%
Other Biomedical	71.7%
Planned Emergency Research	27.6%

This table shows the type of biomedical/clinical research organizations conduct, review, or manage.

Note

- 52 organizations that conduct, manage, or review biomedical research did not further specify the type
- 5 organizations did not identify whether they conducted, reviewed, or managed emergency research within the last 12 months of their most recent report

Vulnerable Populations

Children	96.4%
Adults Unable to Consent	92.5%
Employees	92.1%
Students	86.9%
Pregnant Women	89.3%
Prisoners	63.1%
Other	16.7%

This table shows the categories of vulnerable populations that participate in research conducted, reviewed, or managed by organizations.

Only 2 organizations indicated they do not conduct, review, or manage research involving any vulnerable populations.

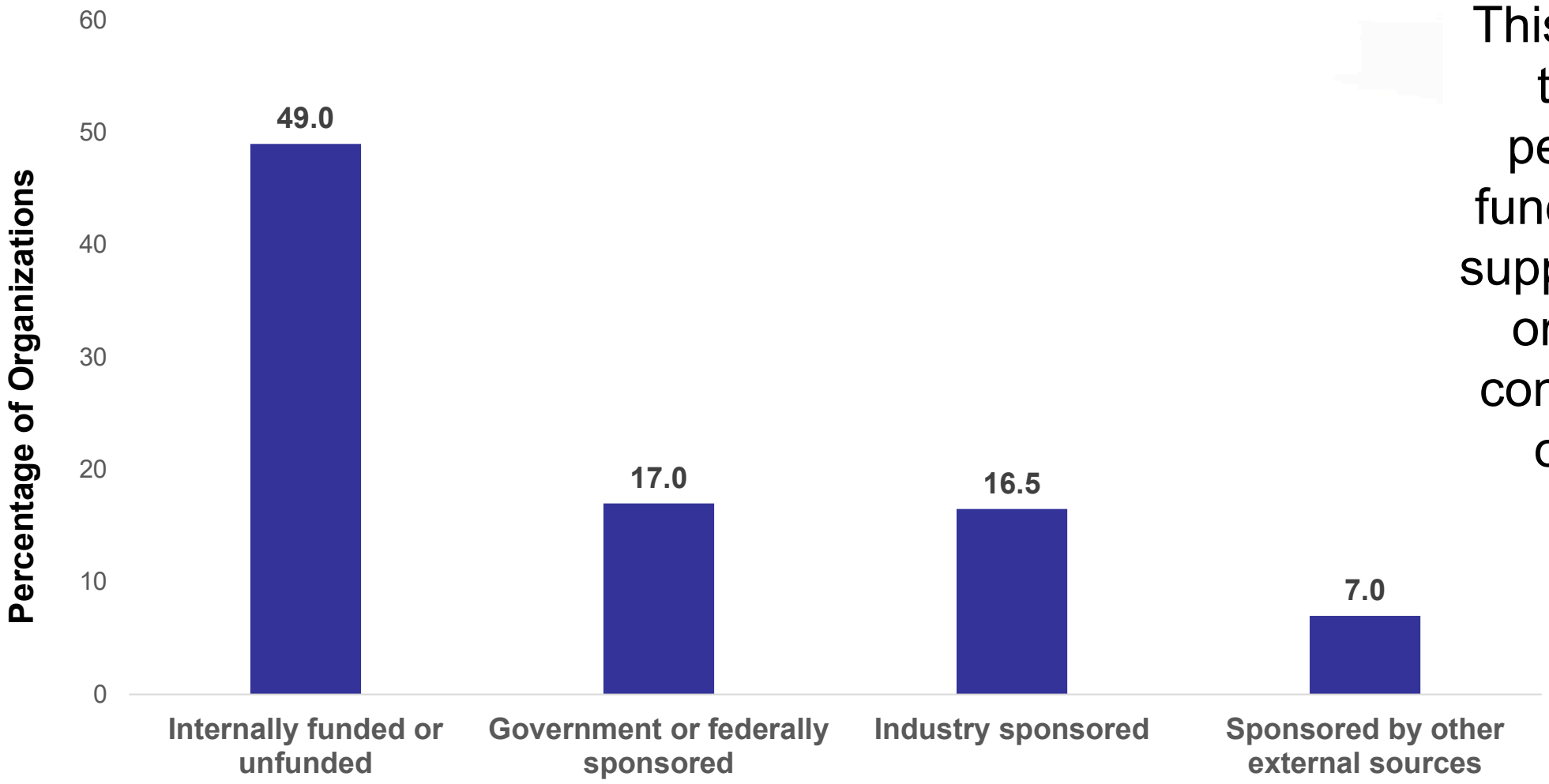
Organizations identified a range of “other” vulnerable populations, such as veterans, non-English speakers, indigenous people, and socially disadvantaged.

Funding Type

Government or federally sponsored	95.6%
Industry sponsored	95.6%
Internally funded or unfunded	90.8%
Sponsored by other external sources	88.8%

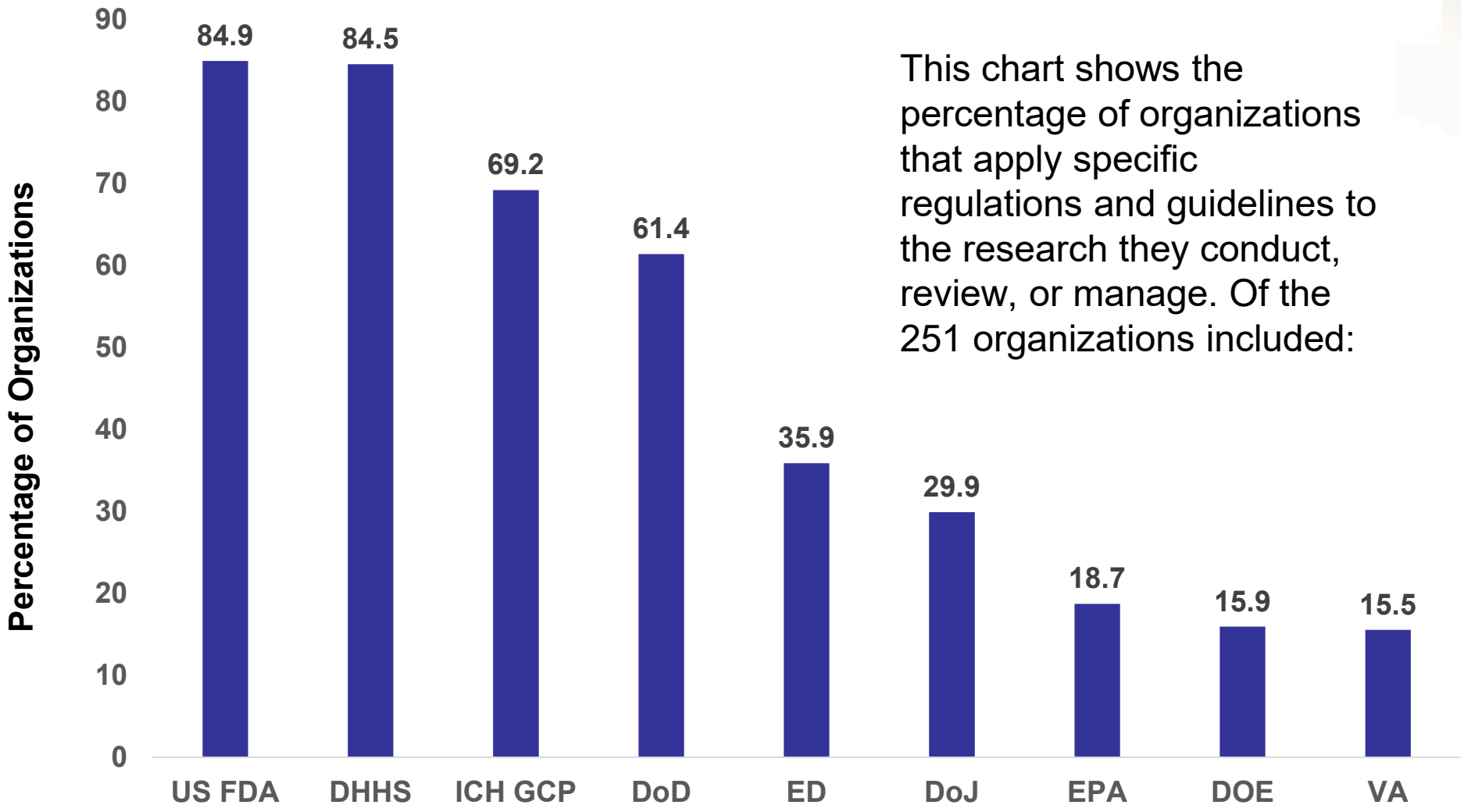
This table shows the percentage of organizations that conduct, review, or manage research by funding type that supports the research.

Funding Distribution



This chart shows the median percentage of funding type that supports research organizations conduct, review, or manage.

Regulations & Guidelines



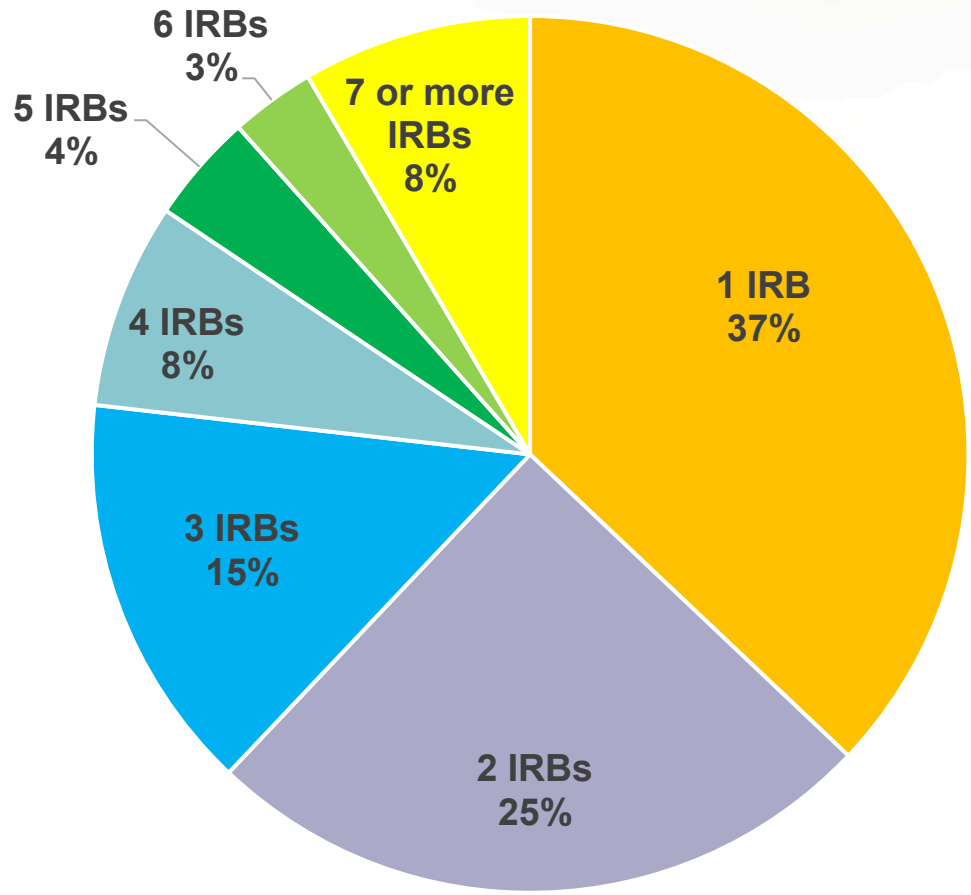
This chart shows the percentage of organizations that apply specific regulations and guidelines to the research they conduct, review, or manage. Of the 251 organizations included:

- 84.9% - US FDA
- 84.5% - US Dept of Health & Human Services
- 69.2% - ICH GCP
- 61.4% - US Dept of Defense
- 35.9% - US Dept of Education
- 29.9% - US Dept of Justice
- 18.7% - US Environmental Protection Agency
- 15.9% - US Dept of Energy
- 15.5% - Veterans Affairs

Internal IRBs/ECs*

% of organizations that have internal IRBs	95%
Median # of IRBs/ECs per organization	2

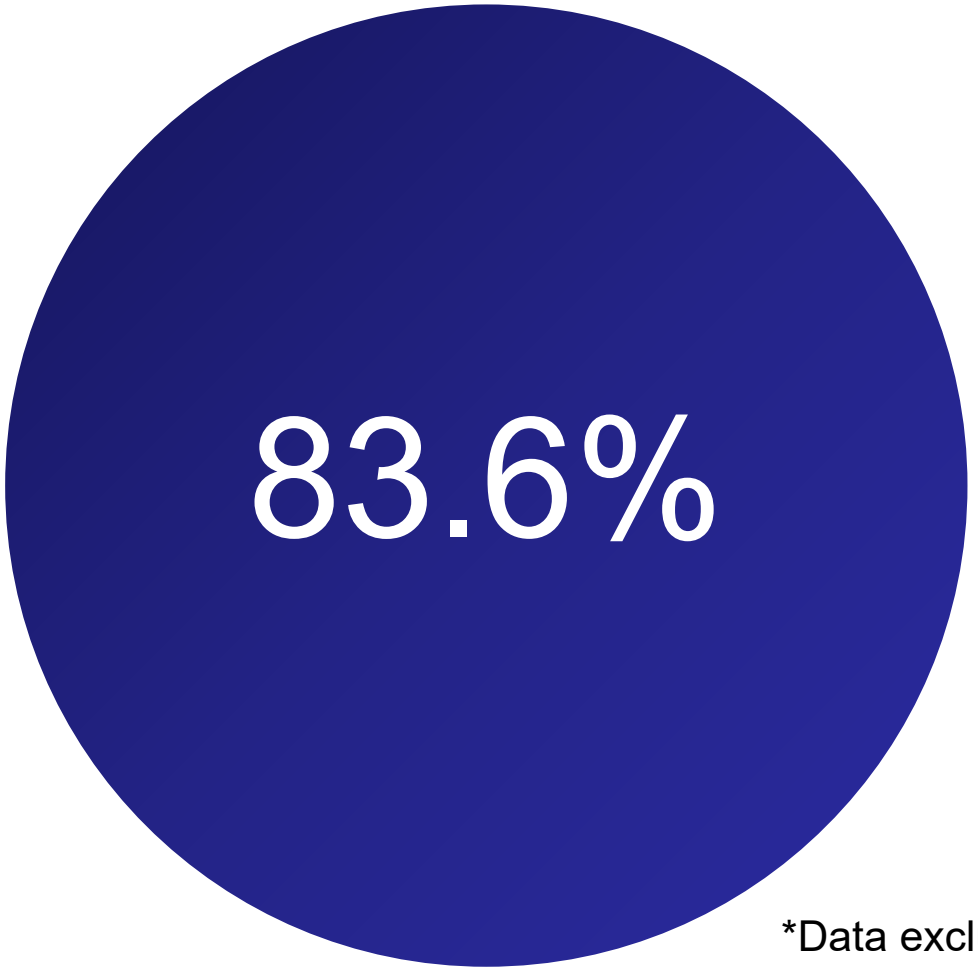
Number of internal IRBs/ECs organizations support



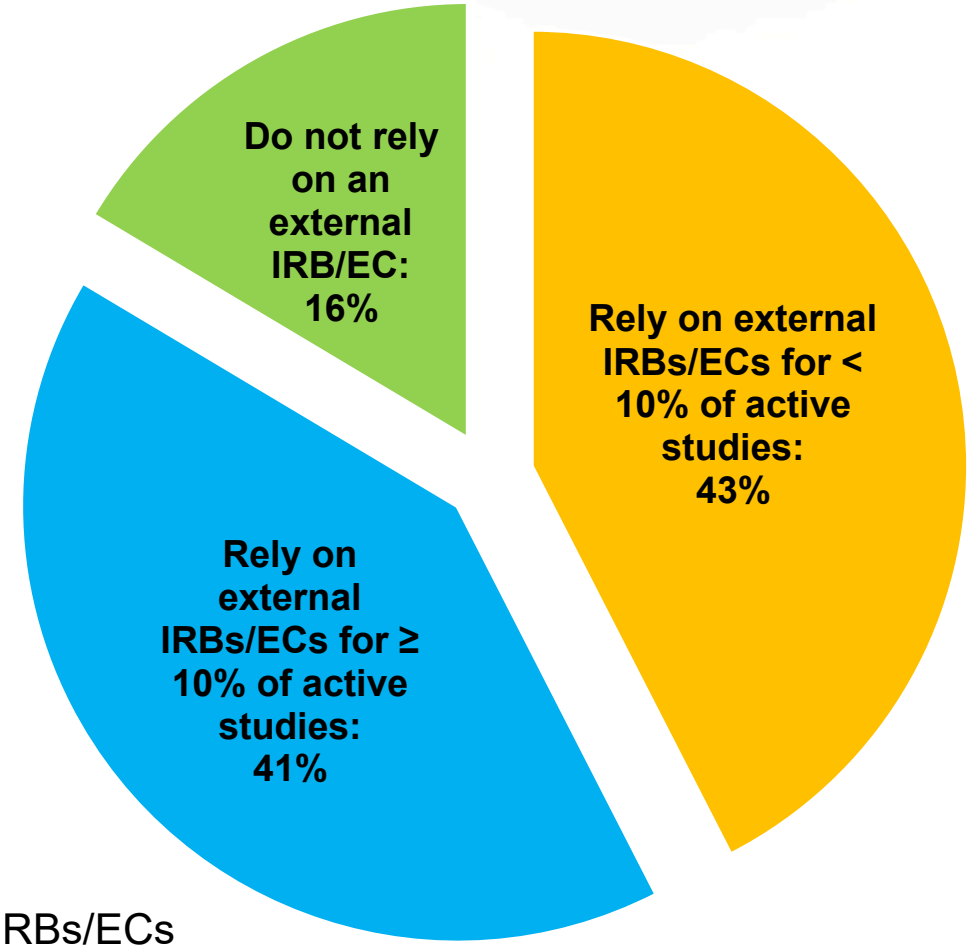
*Data exclude independent IRBs/ECs

Relying on External IRBs/ECs*

% of organizations with internal IRBs/ECs that also use external IRBs/ECs



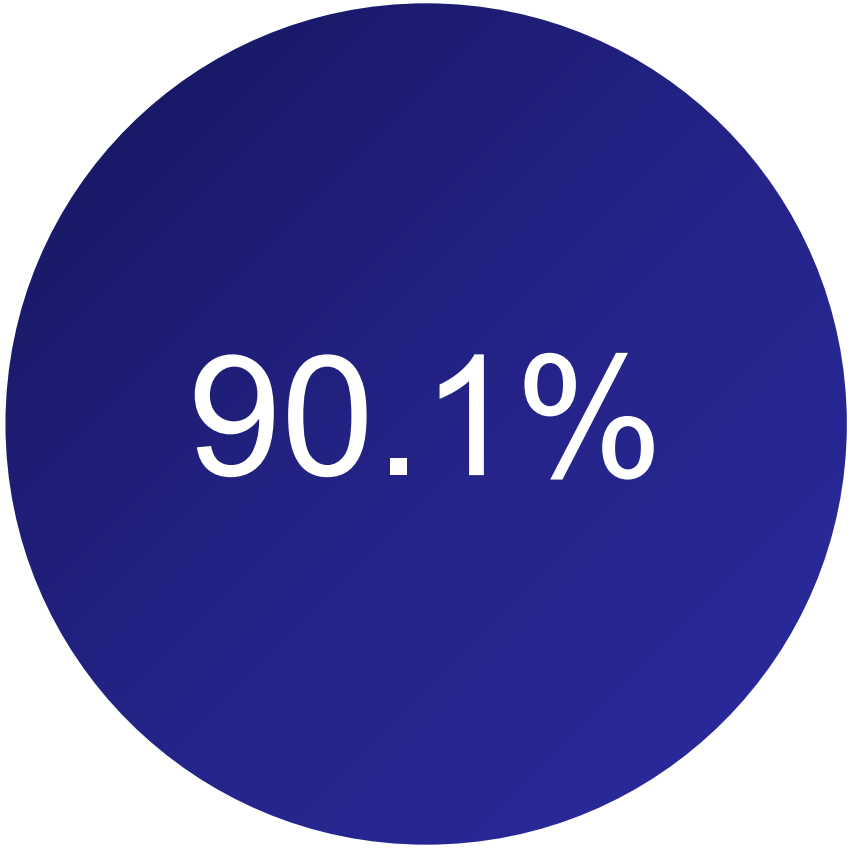
Use of external IRBs/ECs by organizations with internal IRBs/ECs



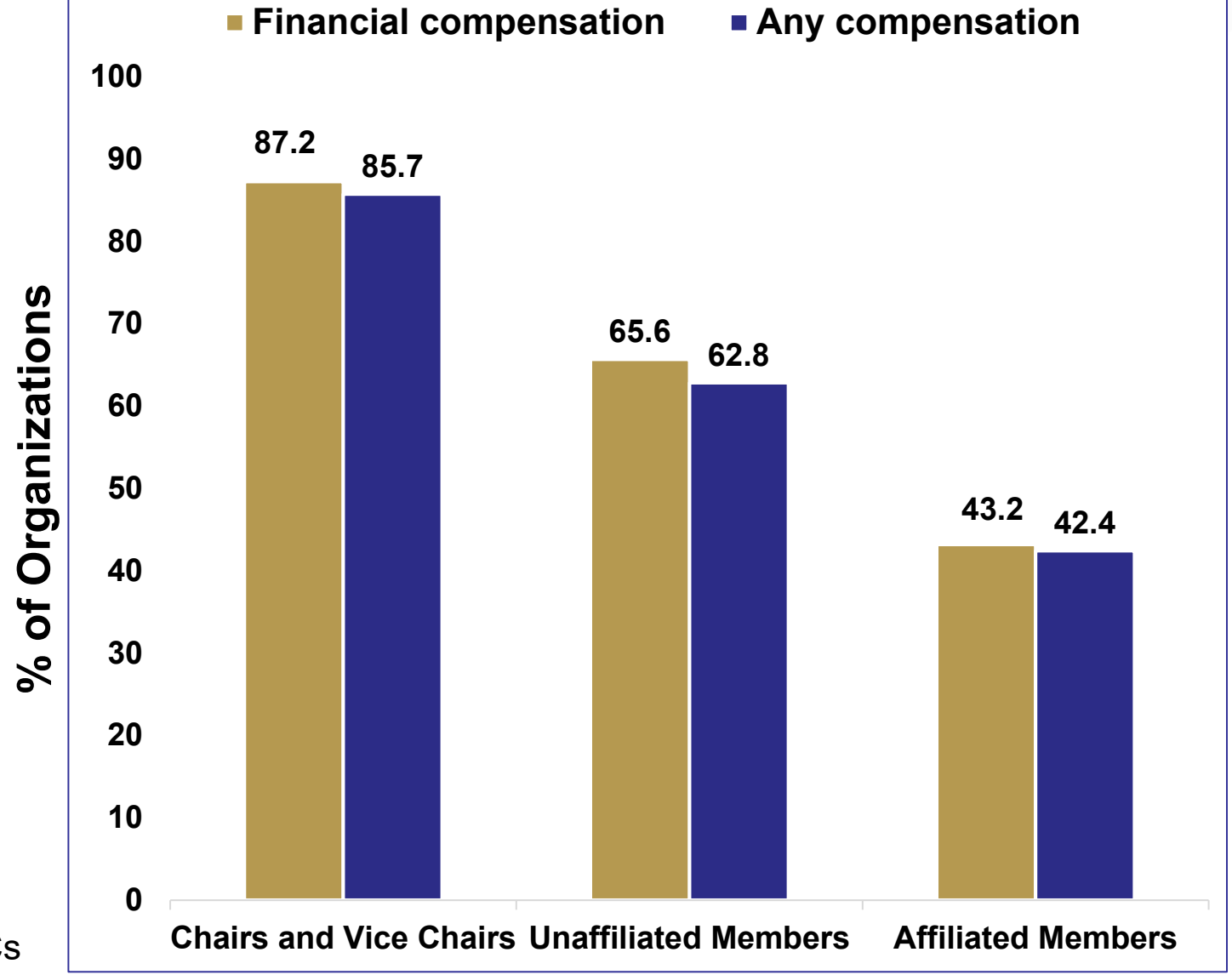
*Data exclude independent IRBs/ECs

Compensating IRB/EC Members*

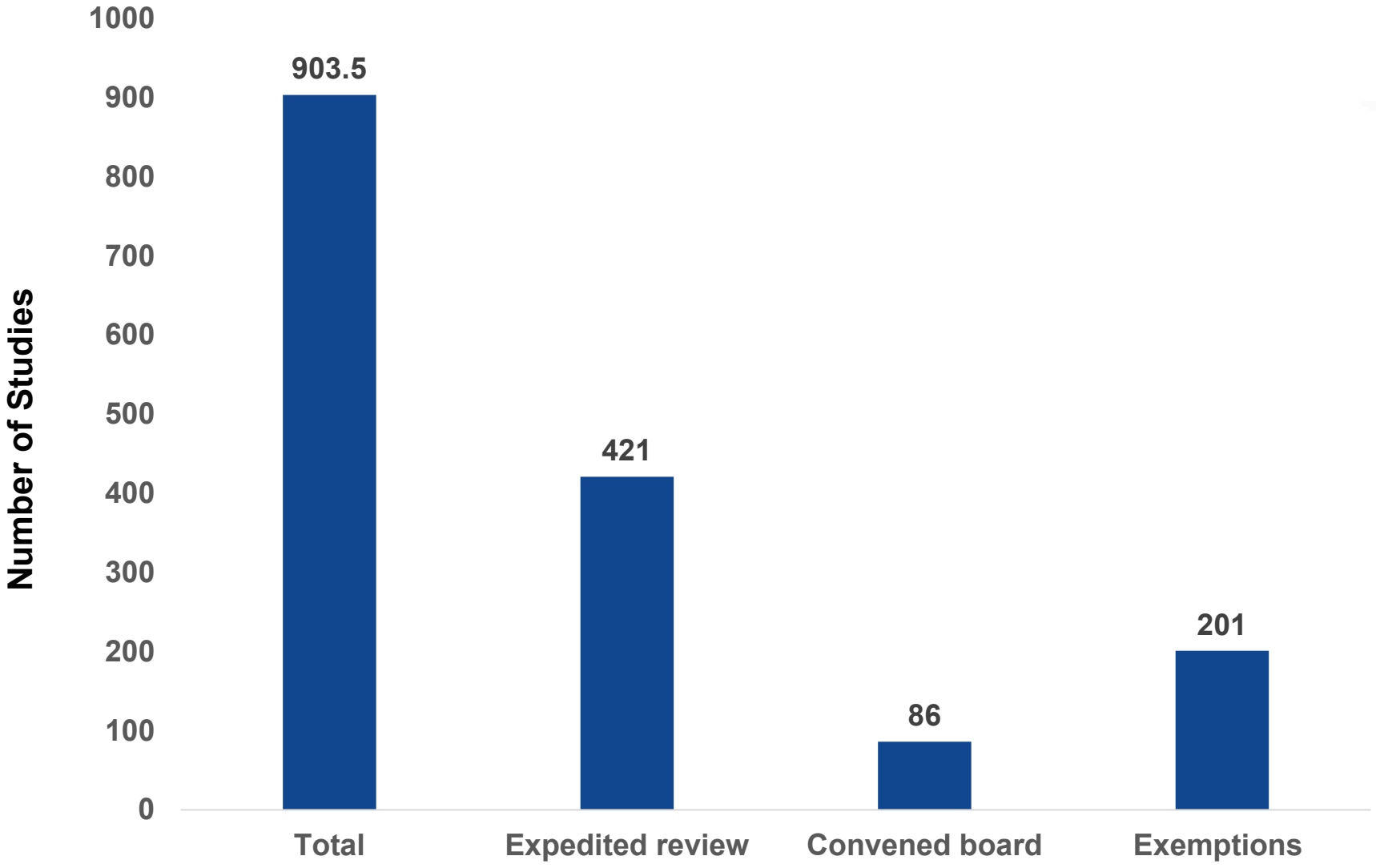
% of organizations with internal IRBs/ECs that compensate IRB/EC members



*Data exclude independent IRBs/ECs



Active Studies Overseen: All Organizations

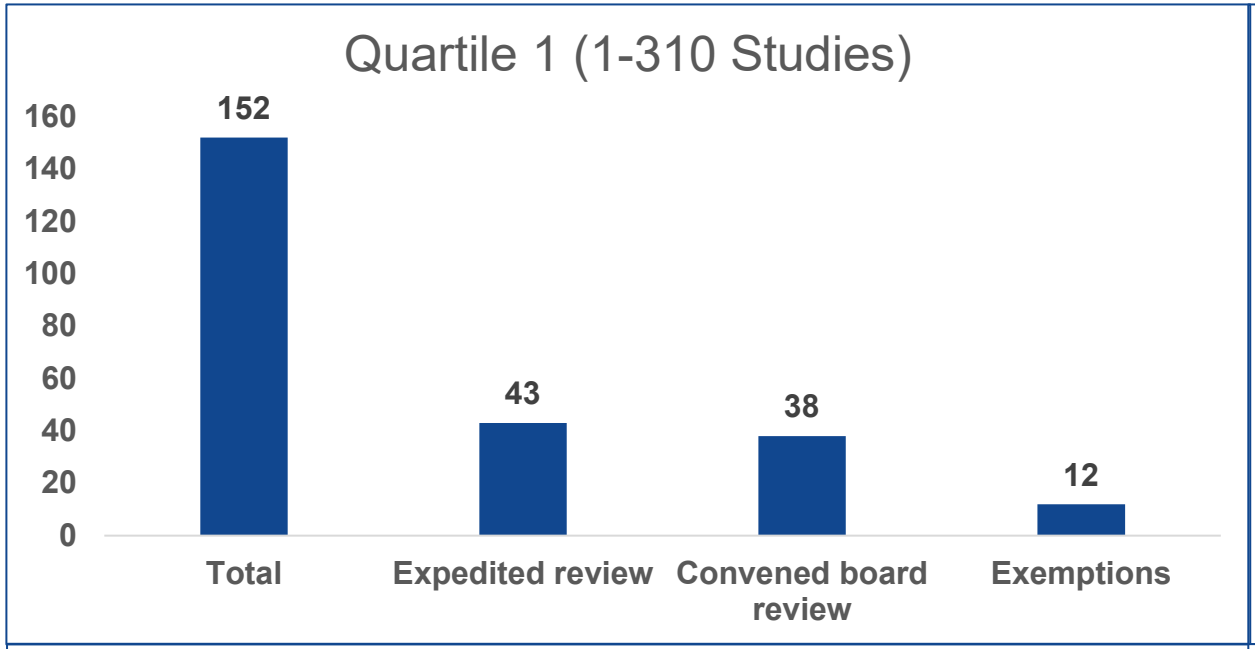


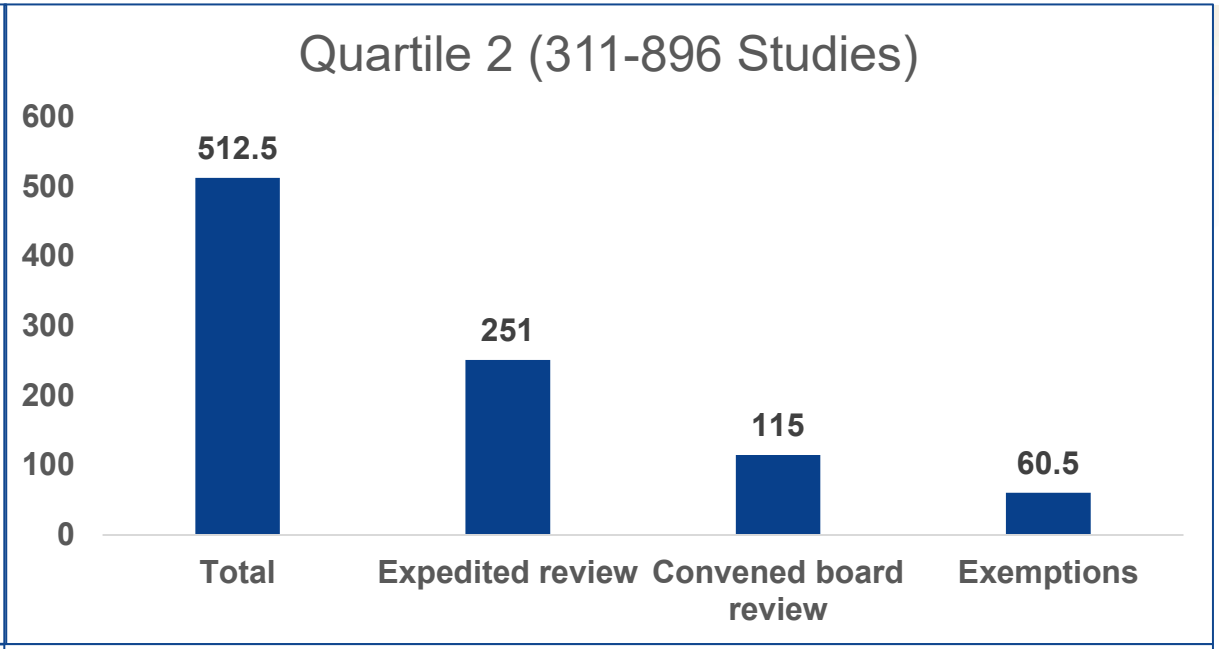
This chart shows the median number of active studies that organizations conduct, review, or manage by type of review.

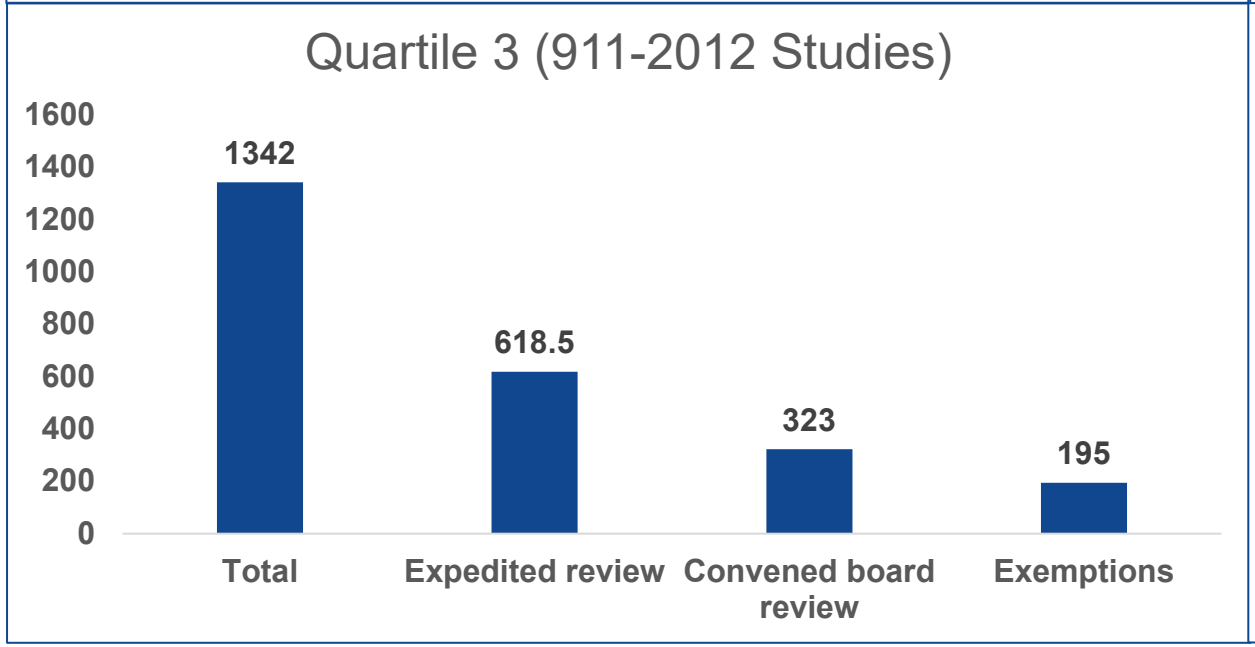
Note:

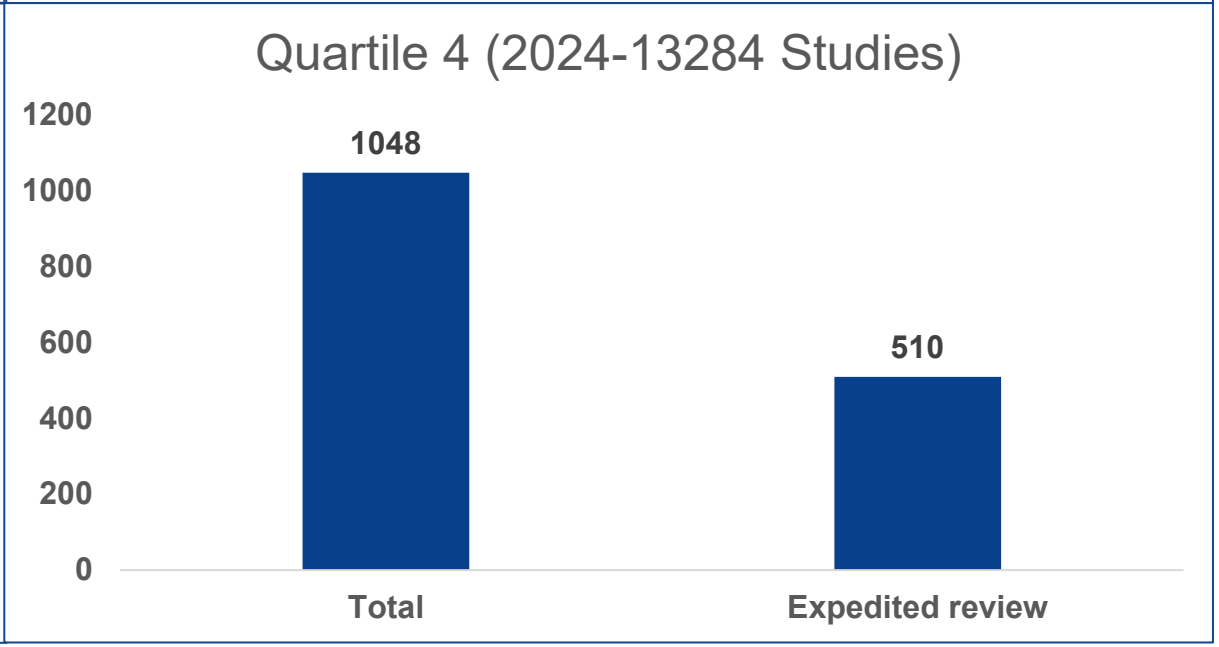
- Exemptions are based on the number of determinations made by an organization within 12 months of their most recent report to AAHRPP
- Total number of studies includes those reviewed by both internal and external IRBs/ECs in the case of organizations with IRBs/ECs

Median Number of Active Studies Overseen (by Quartile)

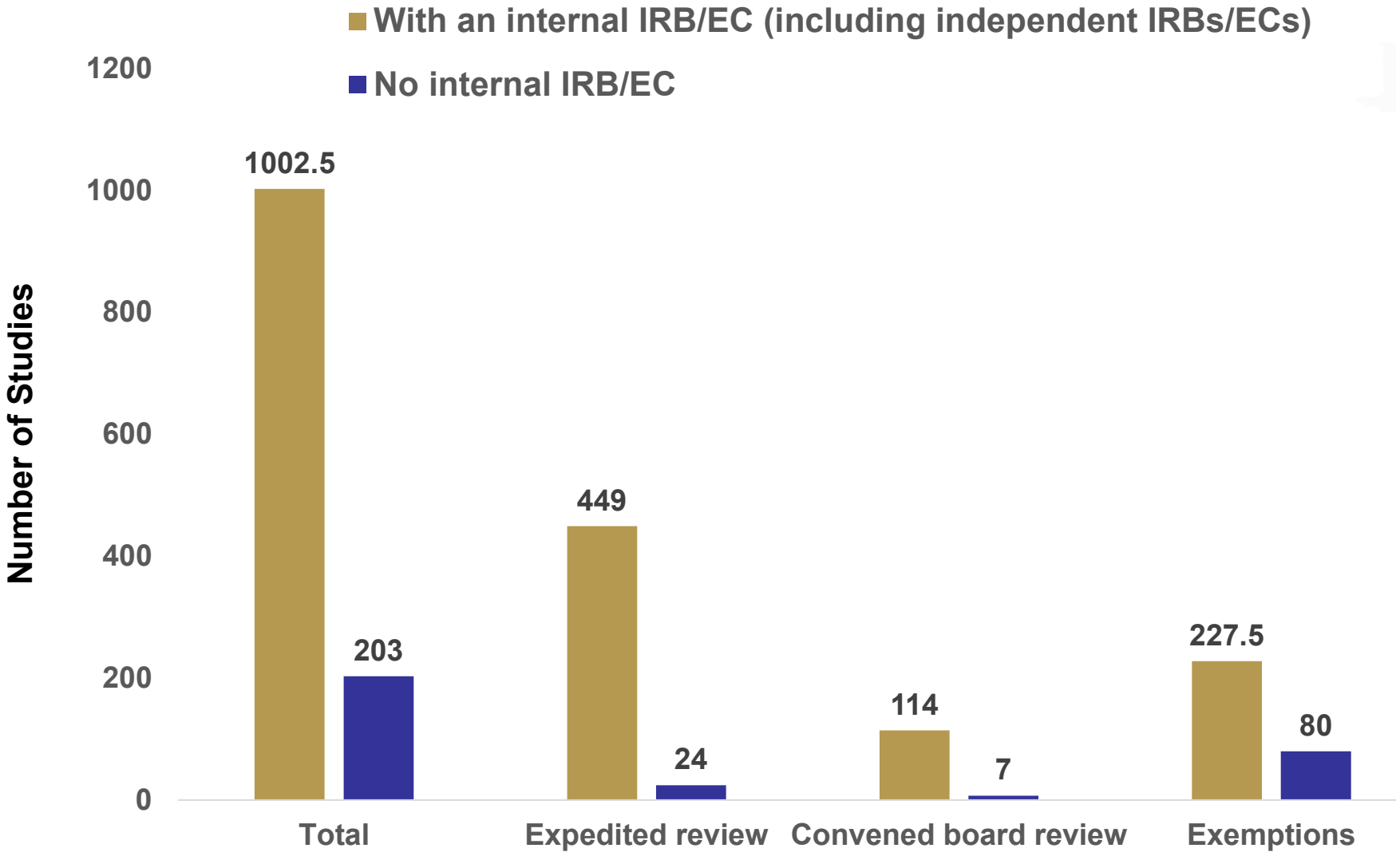








Active Studies: Internal vs. External IRB/EC

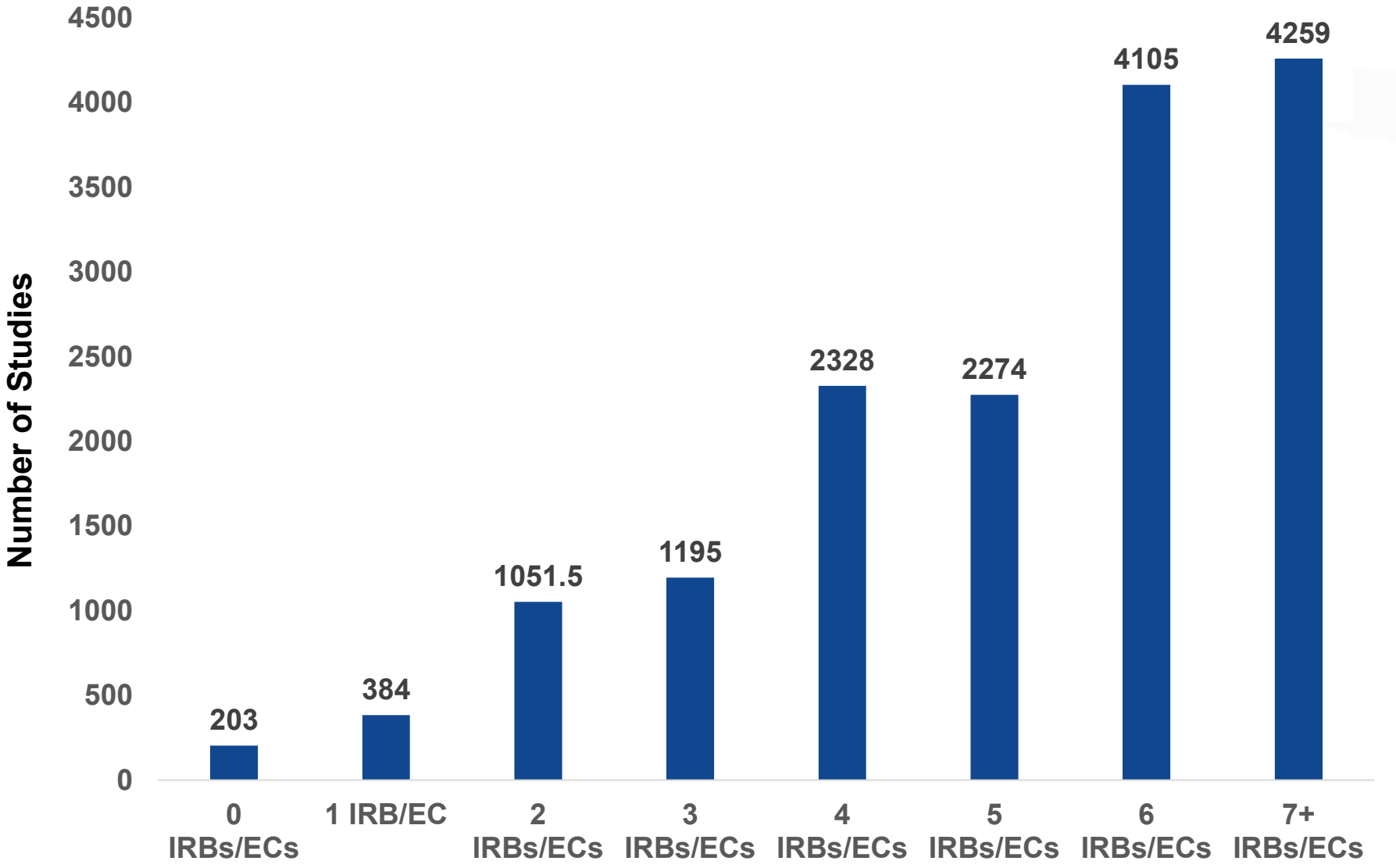


This chart shows the median number of active studies that organizations conduct, review, or manage by type of review based on whether they have an internal IRB/EC.

Note:

- Exemptions include the number of determinations made within 12 months of their most recent AAHRPP report
- Total number of studies includes those reviewed by both internal and external IRBs/ECs in the case of organizations with IRBs/ECs

Active Studies Per IRB/EC

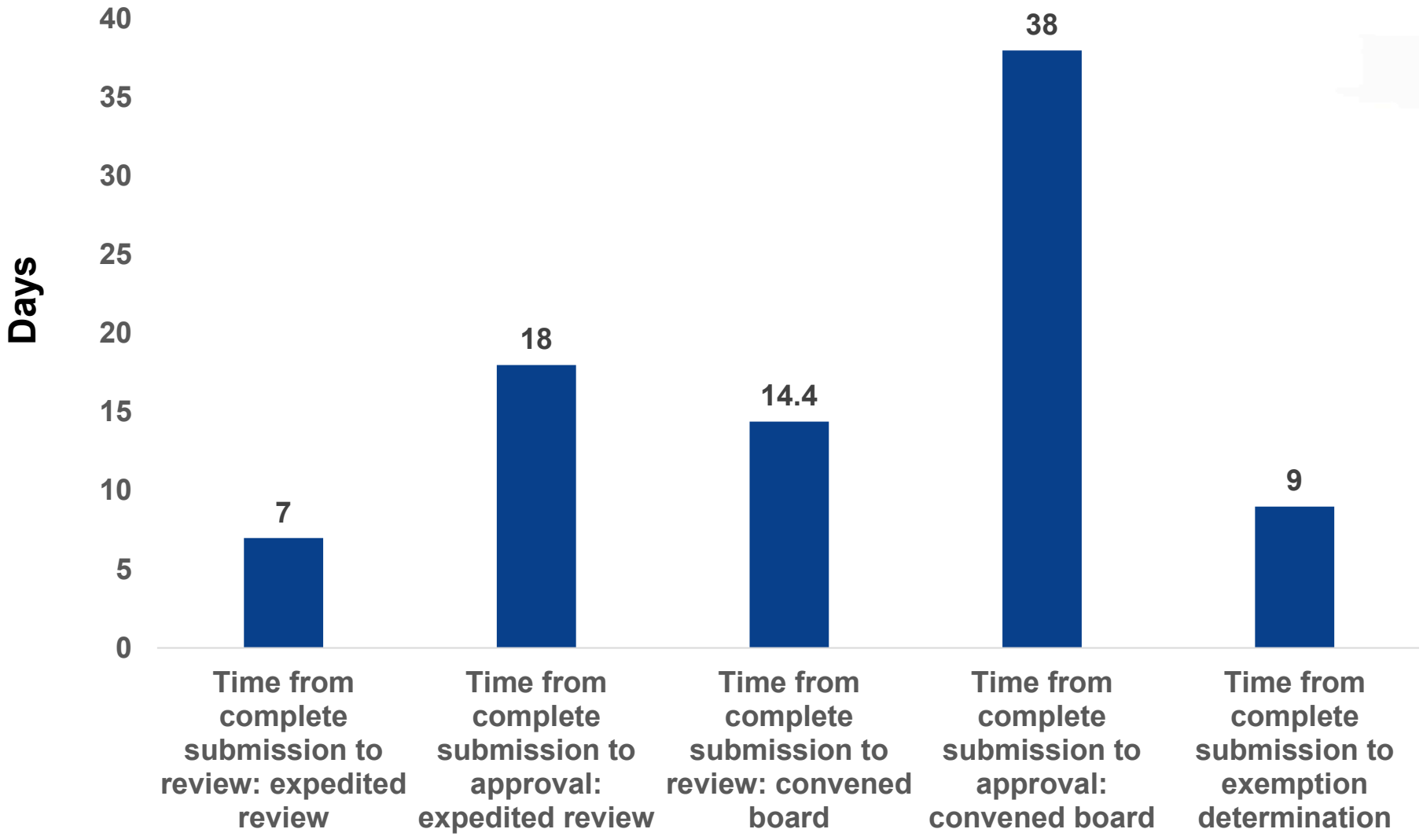


This chart shows the median number of active studies organizations oversee based on the number of IRBs/ECs.

Note:

- Median number of studies include those reviewed by both internal and external IRBs/ECs

IRB/EC Review Times: All Review Types

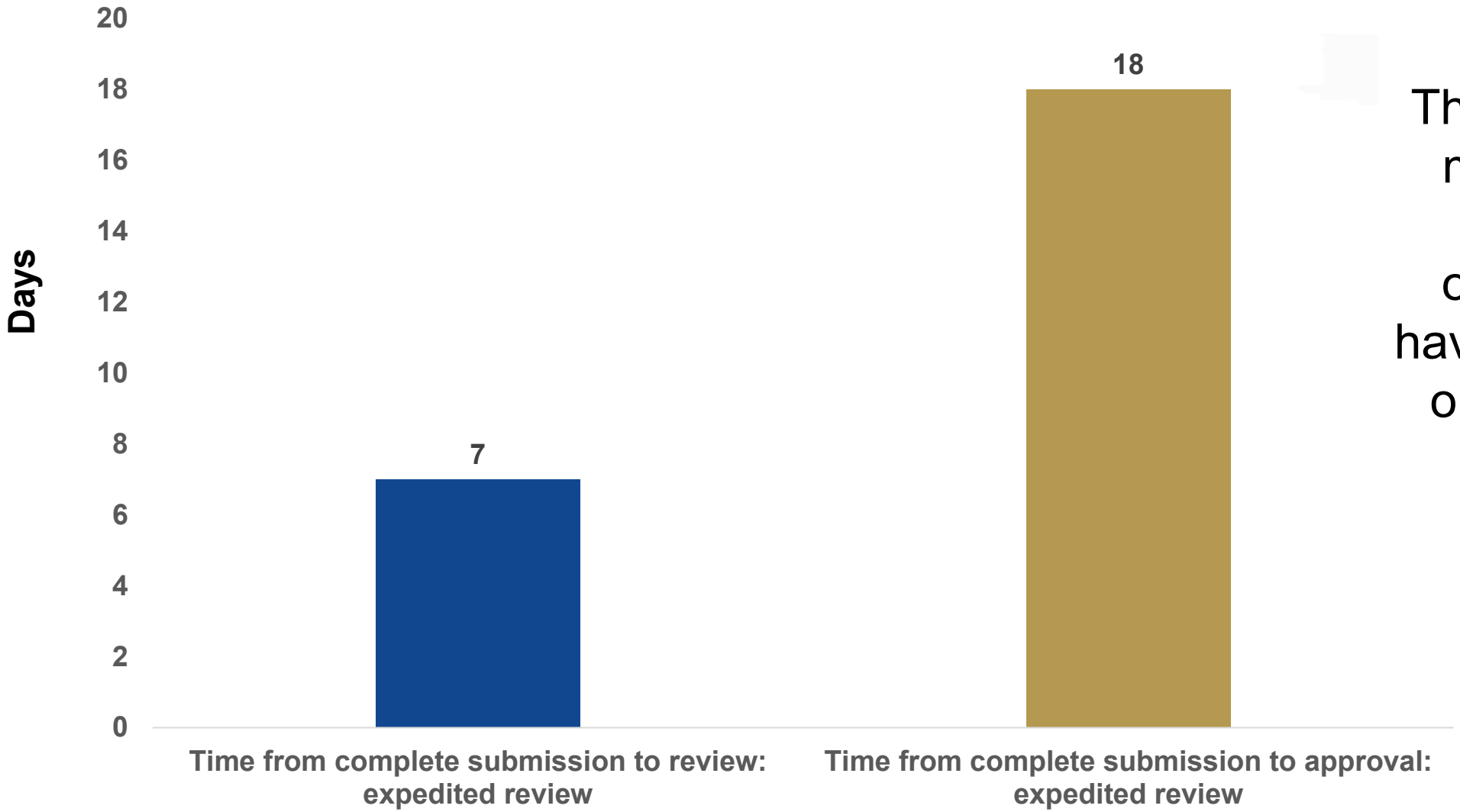


This chart shows the median review times by review process for organizations that have internal IRBs/EC or are independent IRBs/ECs.

Note:

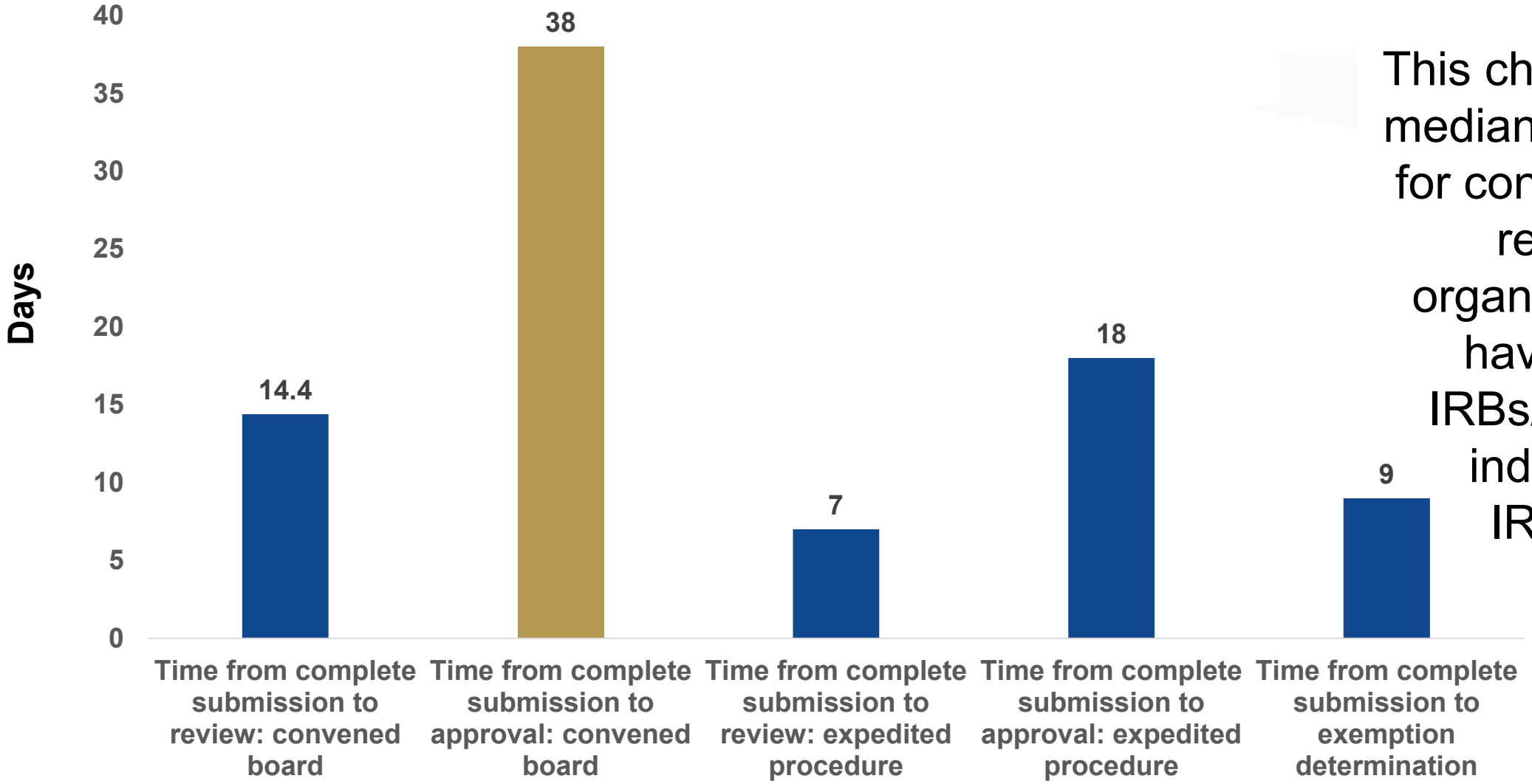
- Exemption review times are for organizations regardless of whether they have an internal IRB/EC

IRB/EC Review Times: Expedited Review



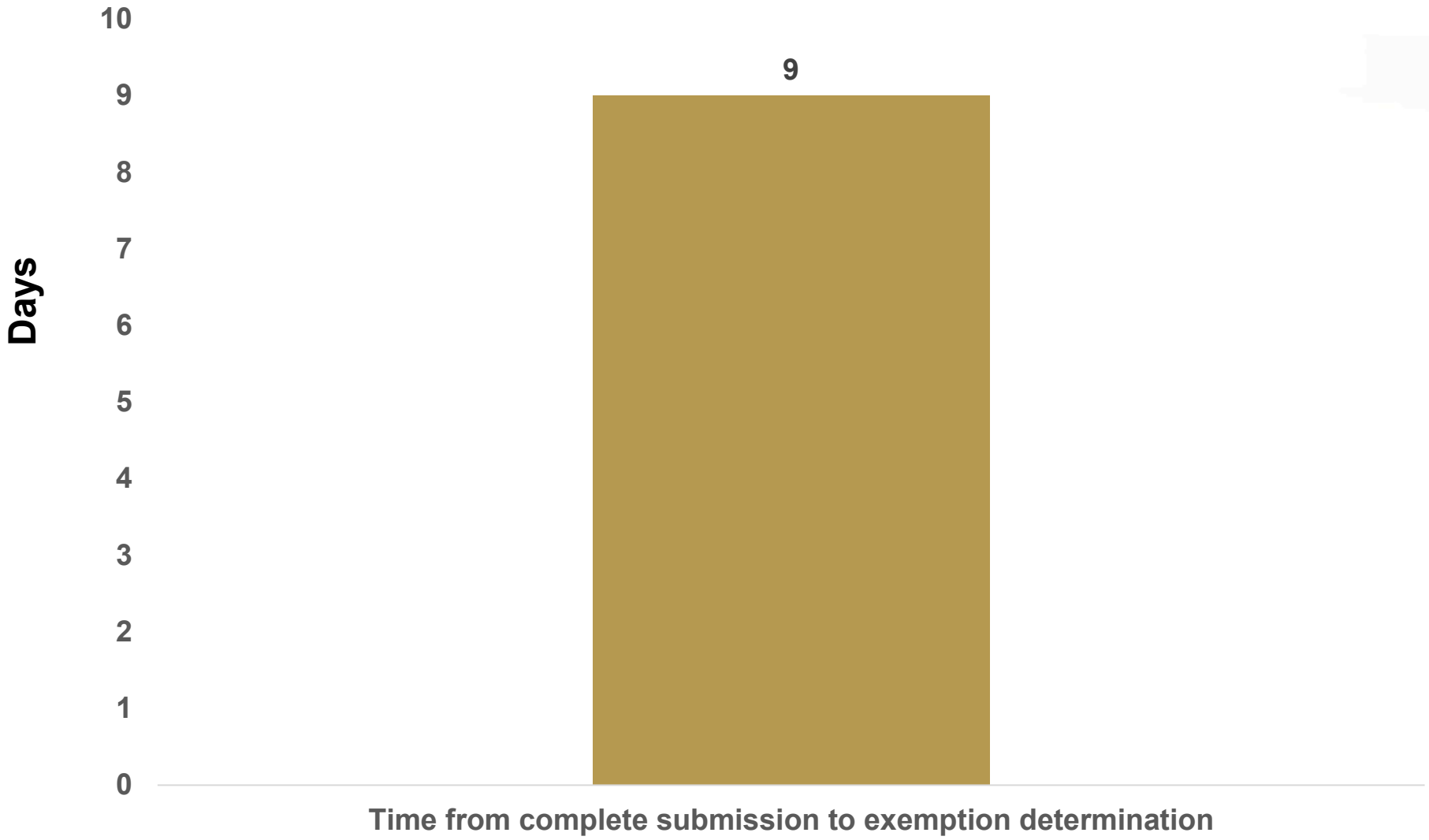
This chart shows the median expedited review times for organizations that have internal IRBs/EC or are independent IRBs/ECs.

IRB/EC Review Times: Convened Board Review



This chart shows the median review times for convened board review for organizations that have internal IRBs/ECs or are independent IRBs/ECs.

Review Times: Exemptions



This chart shows the median review times for exemption determinations for organizations regardless of whether they have an internal IRB/EC.

IRB/EC Technology

Database for submission tracking	92.1%
Online application submission	90.4%
Online protocol/materials distribution to IRB/EC members	93.7%
Online review functions	89.5%
Does not use an electronic system	2.9%

This table shows the technology organizations that have IRBs/ECs use to support IRB/EC tracking, submission, distribution and the specific functions used.

Note:

- 2 organizations did not provide information about any IRB/EC technology they may use

IRB/EC Staffing and Budget

Number of Active Studies	Median Number of Studies	Median Number of Staff	Median Number of Studies per Staff	Median IRB/EC Budget
All	1007	7	143.9	$495,740
0-100	43	2.5	6.1	$127,000
101-500	251	2.9	35.9	$229,056
501-1000	711	5	101.6	$400,000
1001-2000	1352	9	193.1	$677,735
2001-4000	2538	14	362.6	$1,218,921
4001+	6224	24	889.1	$2,492,229

This table breaks down IRB/EC staffing and budgets by the size of the research portfolio (exempt, expedited, and convened reviews) overseen by internal IRBs/ECs.

Note:

- Data from organizations without internal IRBs/ECs are not included
- 2 organizations did not provide information

Audits of Researchers

Median # of researchers per organization:	Median # of research staff per organization:	% of organizations that reported that audits of investigators occurred
414	323	89.4%

Internal: "for cause"	• Median: 1 • Total: 1036
Internal: random	• Median: 12.5 • Total: 11487
Regulatory agency inspections	• Median: 0 • Total: 356

Audits of IRBs/ECs

% of organizations that reported that audits of IRB/EC records occurred:

79.7%

Internal: "for cause"	• Median: 0 • Total: 369
Internal: random	• Median: 3 • Total: 4336
Regulatory agency inspections	• Median: 0 • Total: 55

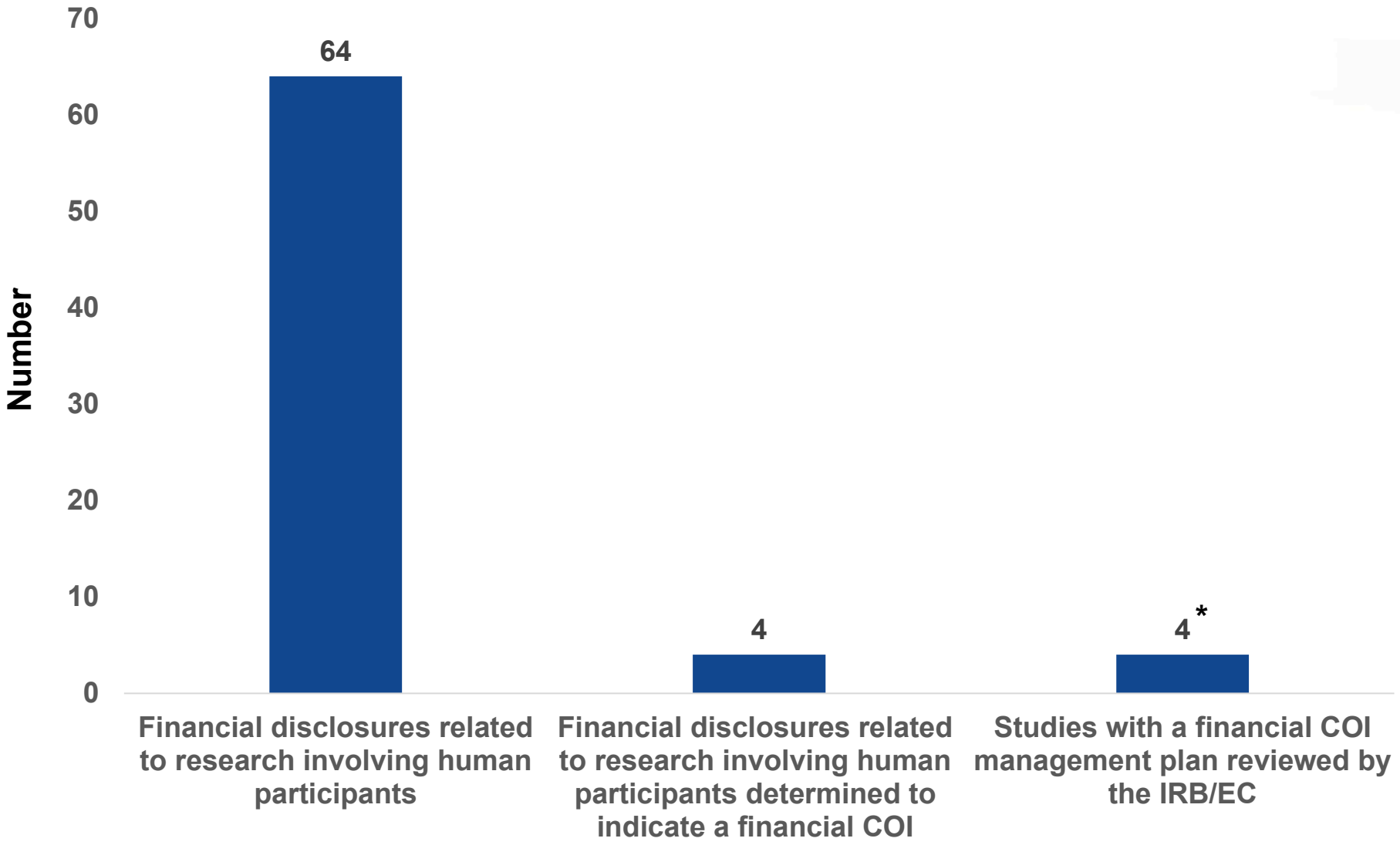
Unresolved Complaints, Noncompliance, & Unanticipated Problems

Number of active studies	Median # & Total reported	Unresolved complaints	Investigations of alleged noncompliance	Serious noncompliance determinations	Continuing noncompliance determinations	Unanticipated problems determinations
All	Median	0	4	1	0	1
	Total	197	11869	1501	882	2209
0-100	Median	0	0	0	0	0
	Total	0	43	18	7	32
101-500	Median	0	1	0	0	0
	Total	2	610	107	35	323
501-1000	Median	0	3.5	0	0	0
	Total	34	1345	94	28	170
1001-2000	Median	0	13	1	0	1
	Total	51	4808	313	292	695
2001-4000	Median	6	3	0	0	4
	Total	34	1383	245	110	401
4001+	Median	0	67	5	2	7.5
	Total	76	3663	724	410	586

This table is based on the 12 months prior to an organization's most recent report to AAHRPP.

The total represents all events across organizations for that category.

Conflicts of Interest



This chart shows the median number of COI-related disclosures, determinations, and reviews for organizations within the last 12 months of their most recent AAHRPP report.

*Only includes data from organizations that have internal IRB/ECs or are independent IRBs/ECs