AAHRPP

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

2023 Metrics for AAHRPP-Accredited Human Research Protection Programs

May 2024

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About the Metrics

AAHRPP is pleased to present the 2023 metrics for Human Research Protection Program (HRPP) performance. You will see some changes to the metrics that were based on feedback from a working group with representatives from accredited organizations. More changes to come next year. 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 submitted by AAHRPP organizations.

Abbreviations Used

DHHS	US Department of Health & Human Services
DoD	US Department of Defense
ED	US Department of Education
DoE	US Department of Energy
DoJ	US Department of Justice
EPA	US Environmental Protection Agency
FDA	US Food and Drug Administration
VA	US Department of Veterans Affairs

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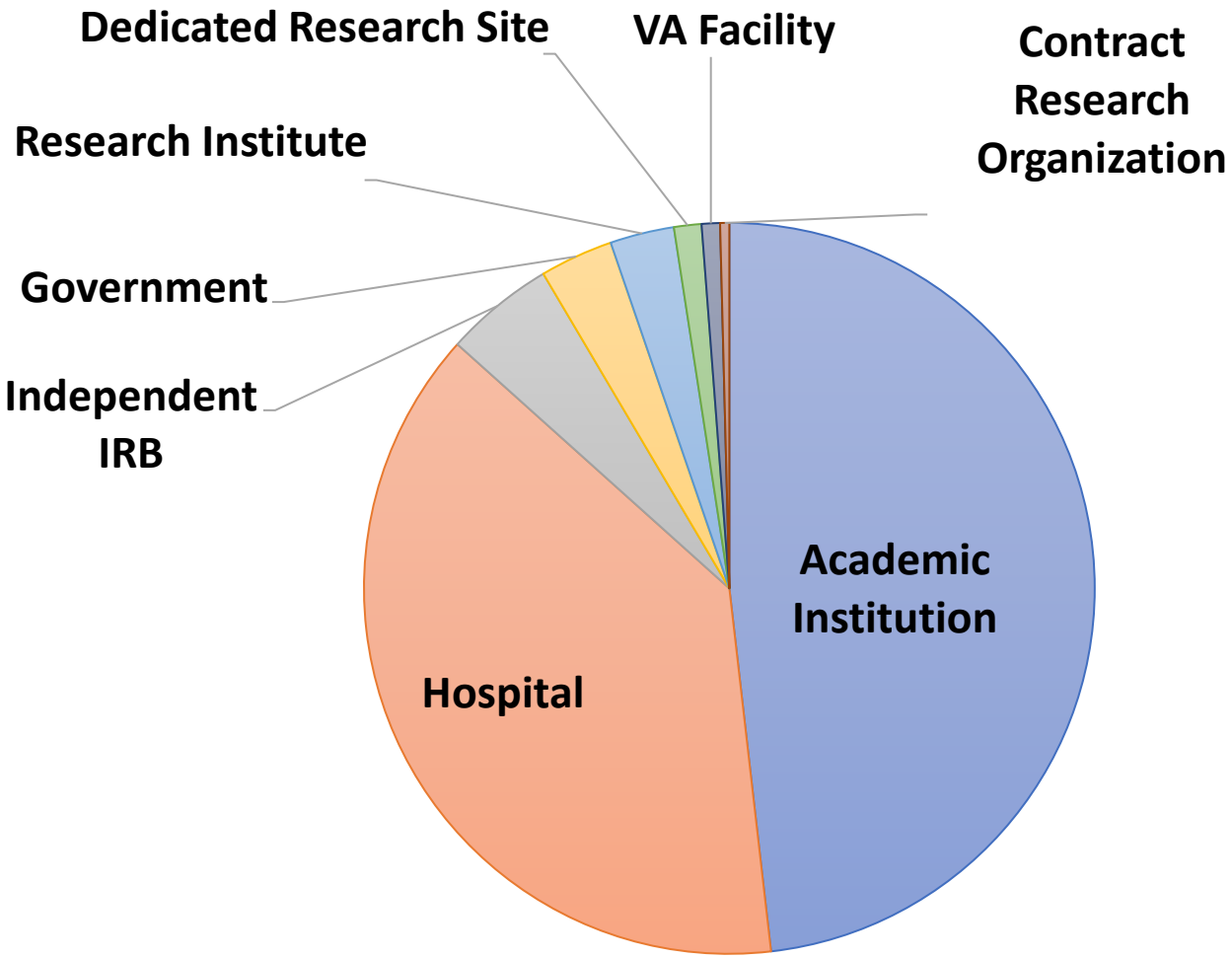
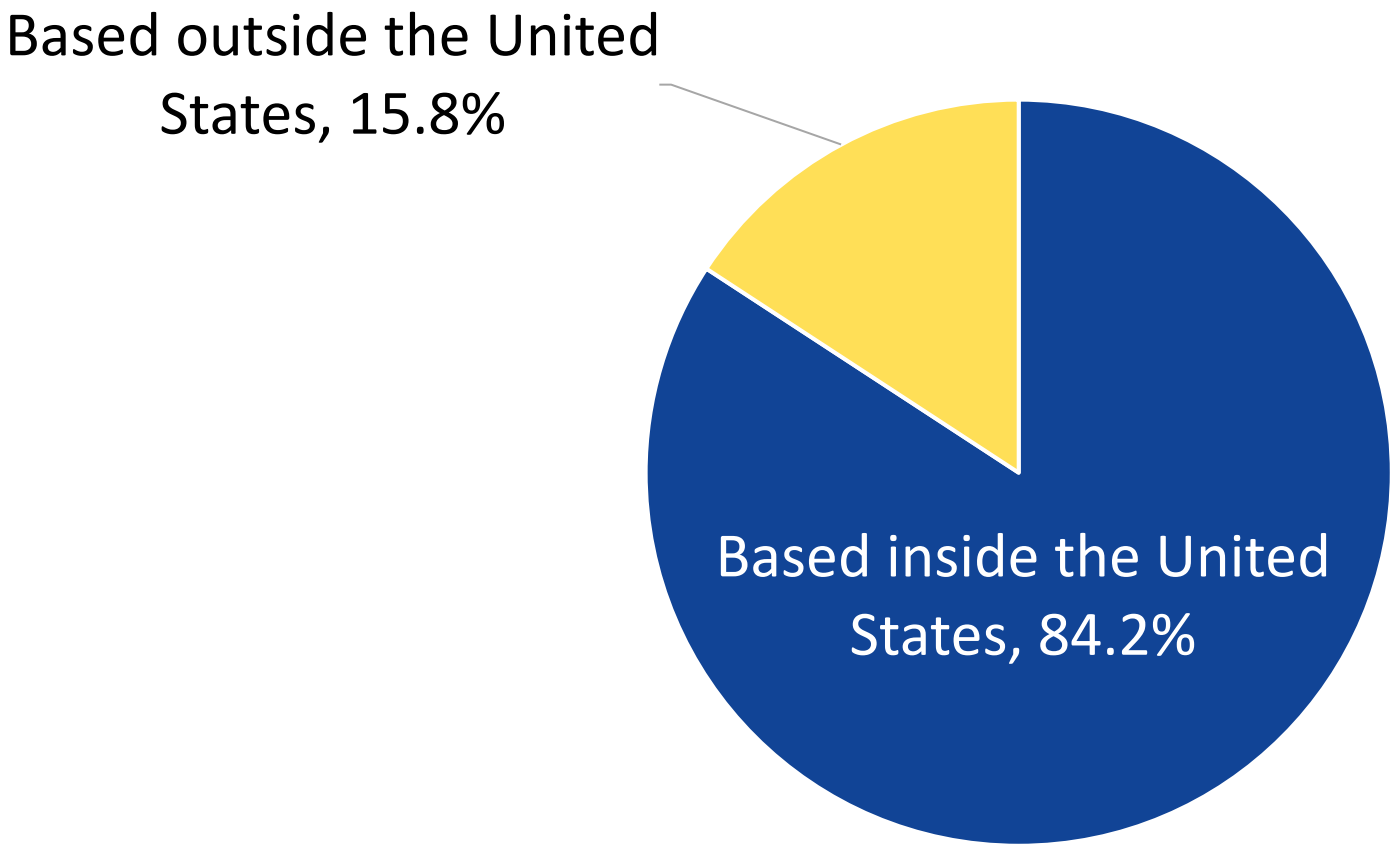
Accredited Organizations By Type



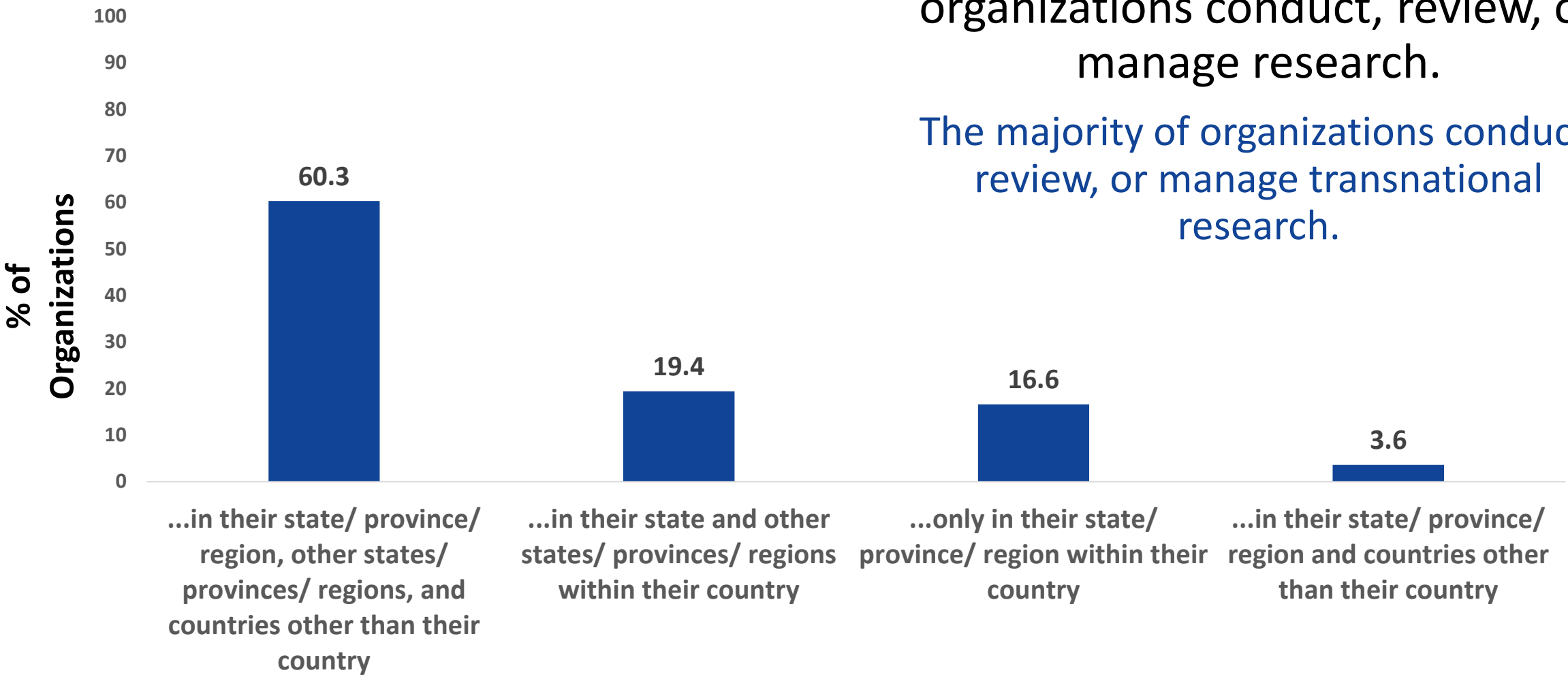
Of the 247 accredited organizations:

- 48.2% are academic institutions
- 38.5% are hospitals
- 4.9% are independent IRBs
- 3.2% are governmental organizations
- 2.8% are research institutes
- 1.2% are dedicated research sites
- 0.8% are VA facilities
- 0.4% are contract research organizations

Where Accredited Organizations are Based



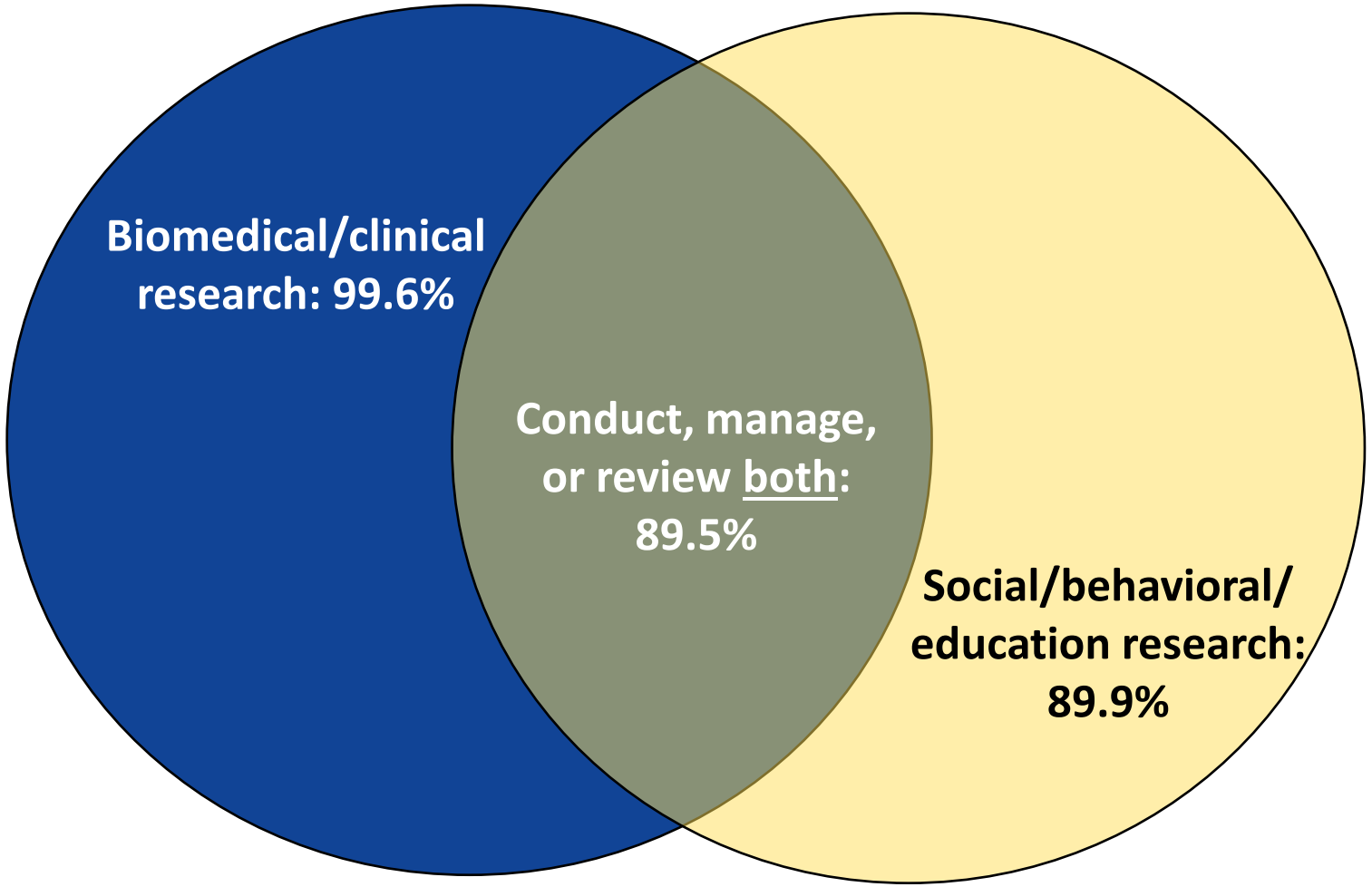
Where Research Occurs



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

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

Type of Research Organizations Conduct, Manage, or Review



Biomedical/Clinical Research by Type

Drugs	93.9%
Devices	93.9%
Planned Emergency Research	50.2%

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

Vulnerable Populations

Children	97.2%
Adults Unable to Consent	95.1%
Pregnant Women	92.7%
Prisoners	59.9%

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

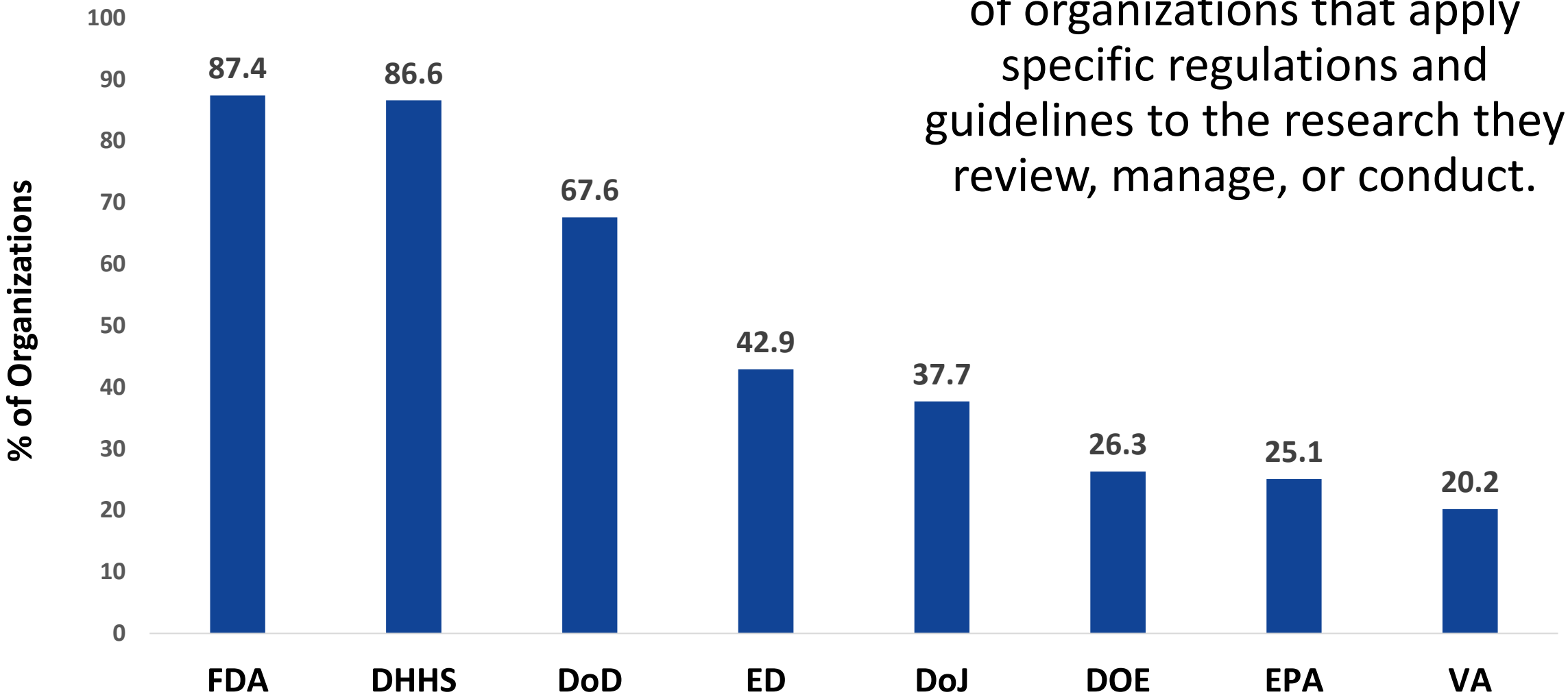
Only 1 organization indicated they do not conduct, review, or manage research involving any vulnerable populations.

Funding Type

Industry sponsored	93.9%
Sponsored by other external sources	91.5%
Internally funded or unfunded	91.9%
Government or federally sponsored	81.0%

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

Regulations & Guidelines



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

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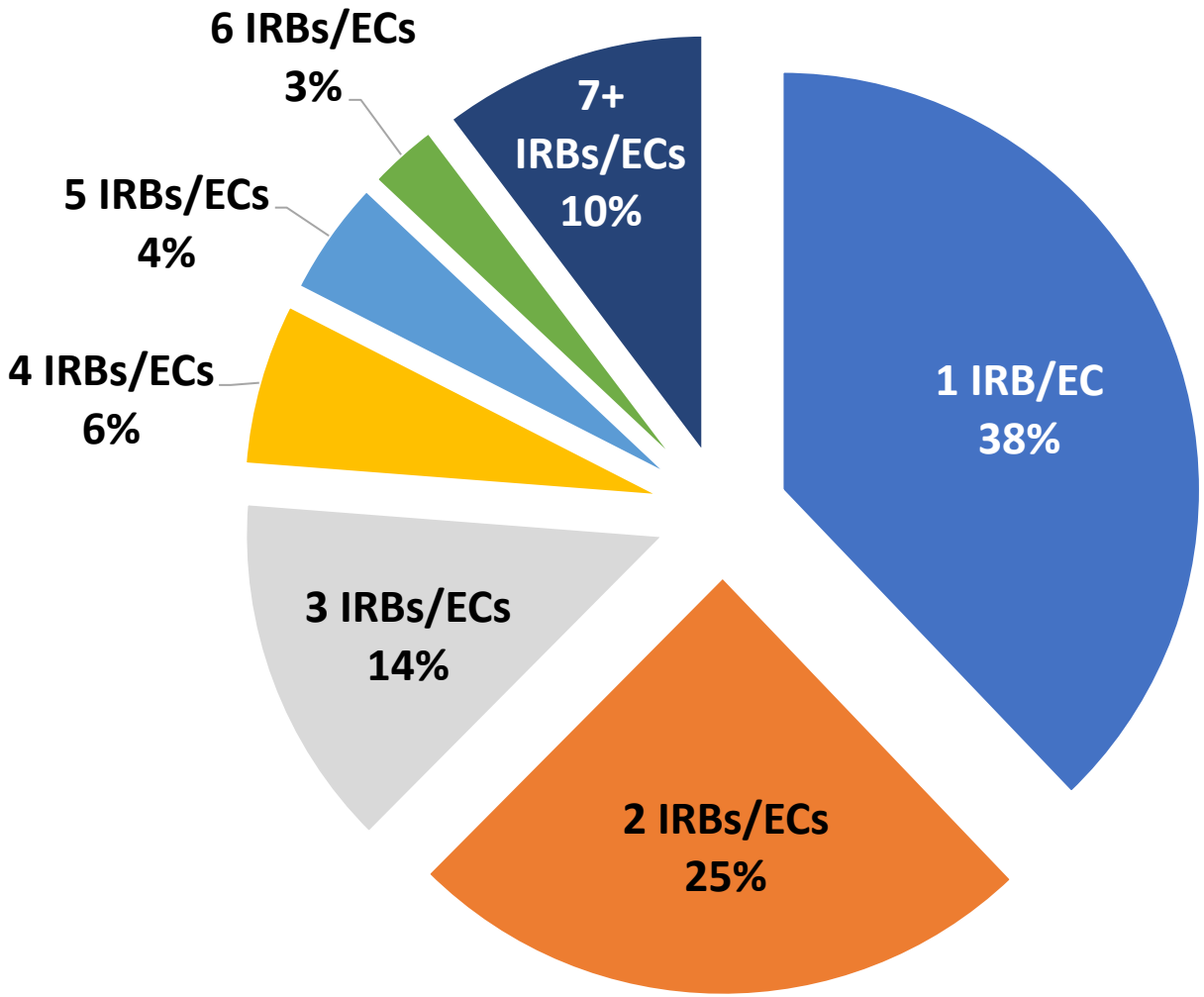
Internal IRBs/ECs*

% of organizations that have internal IRBs/ECs	95.3%
Median # of IRBs/ECs per organization	2

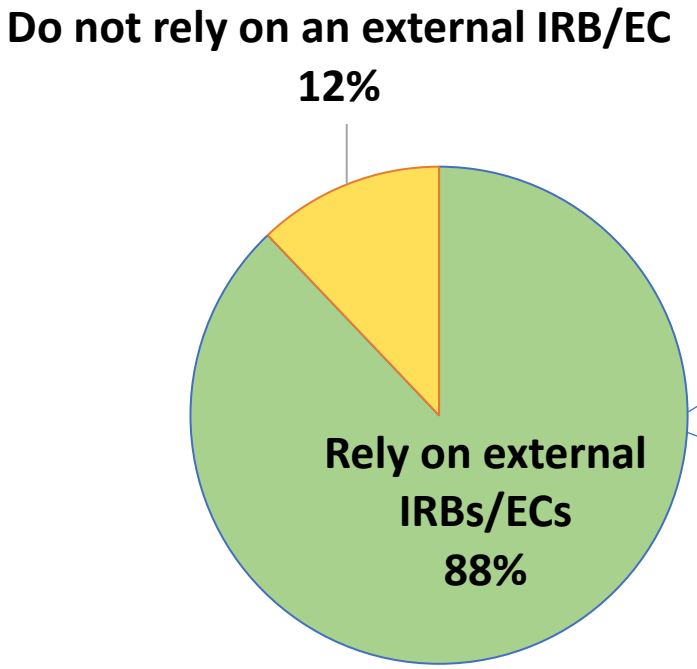
Number of internal IRBs/ECs organizations support



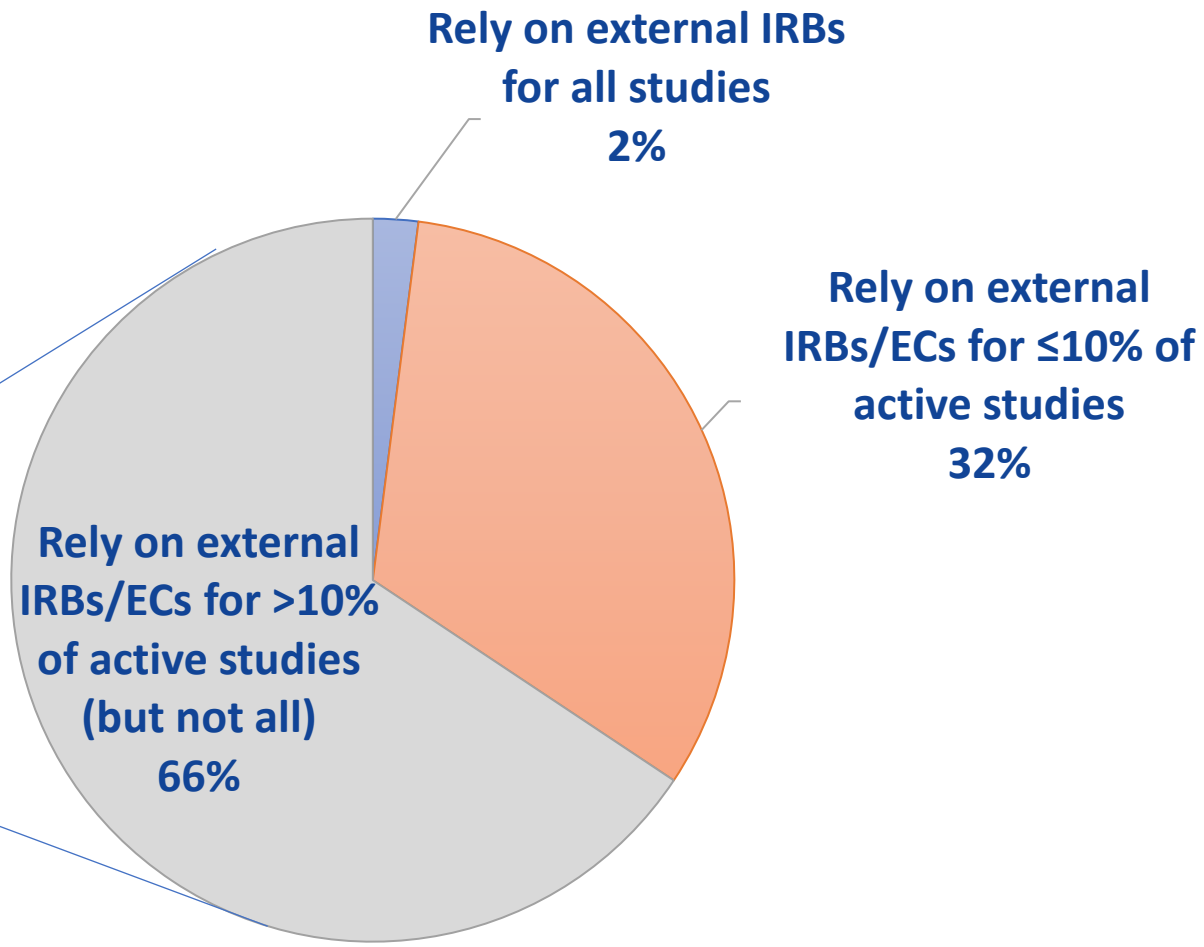
*Data exclude independent IRBs/ECs

Relying on External IRBs/ECs*

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

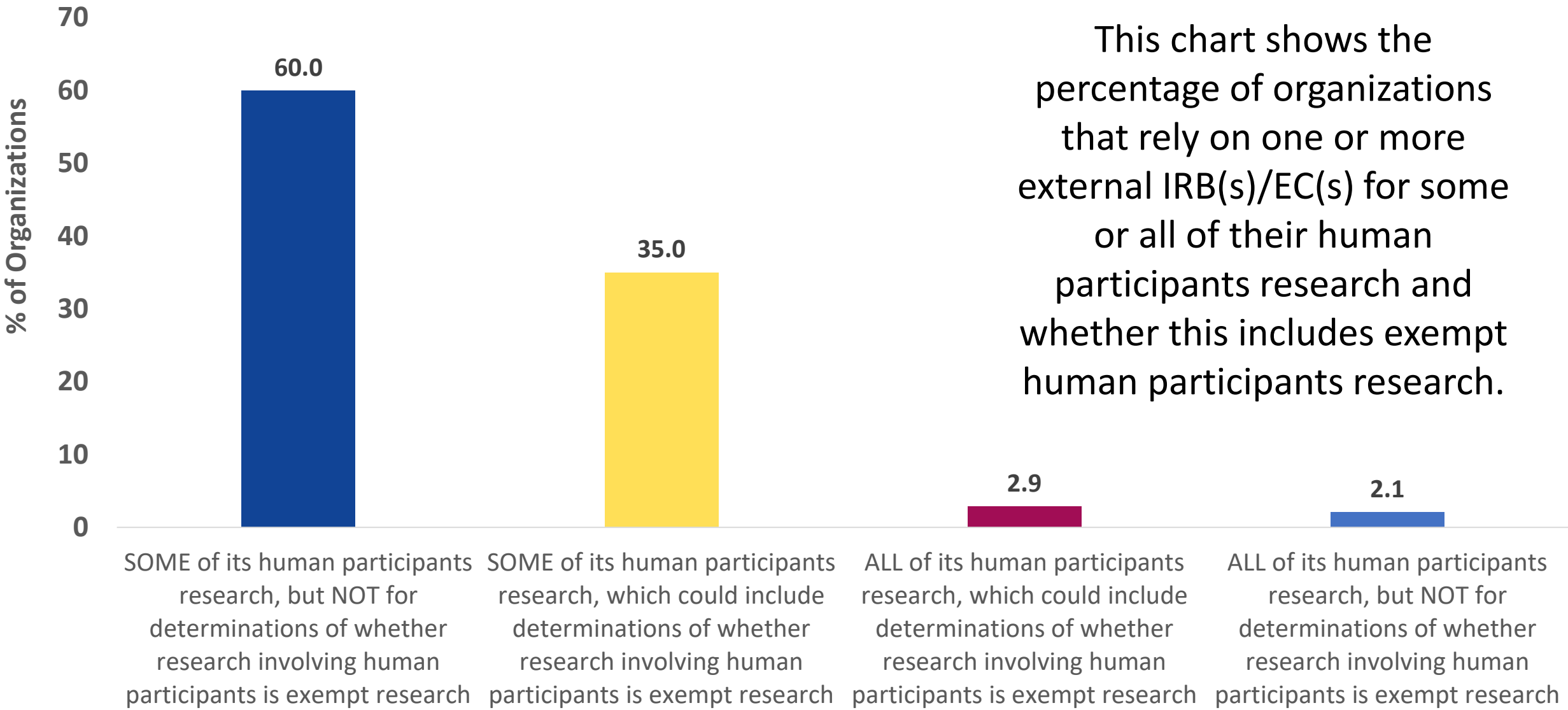


Use of external IRBs/ECs by organizations with internal IRBs/ECs



*Data exclude independent IRBs/ECs

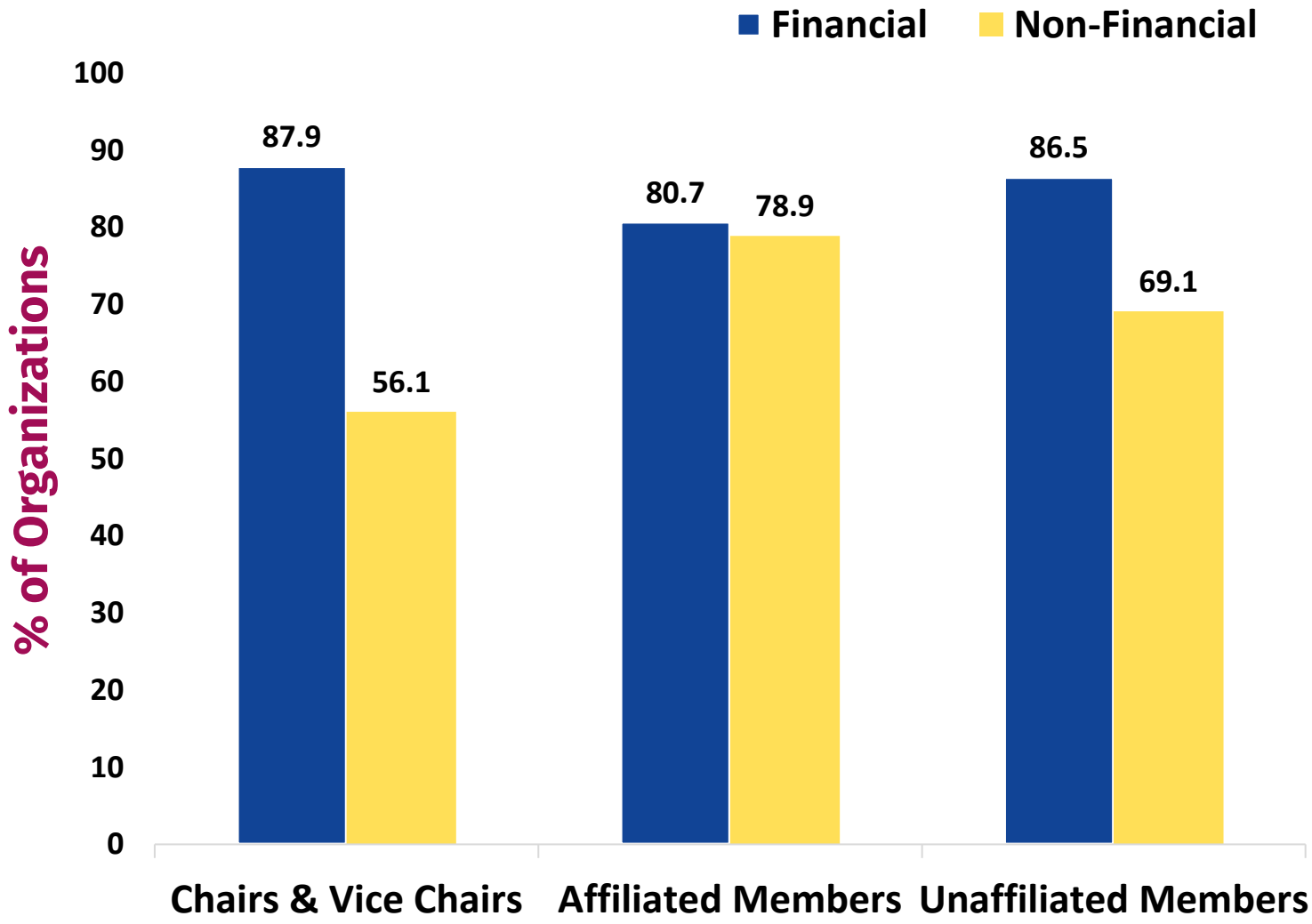
Research Reviewed by External IRBs/ECs



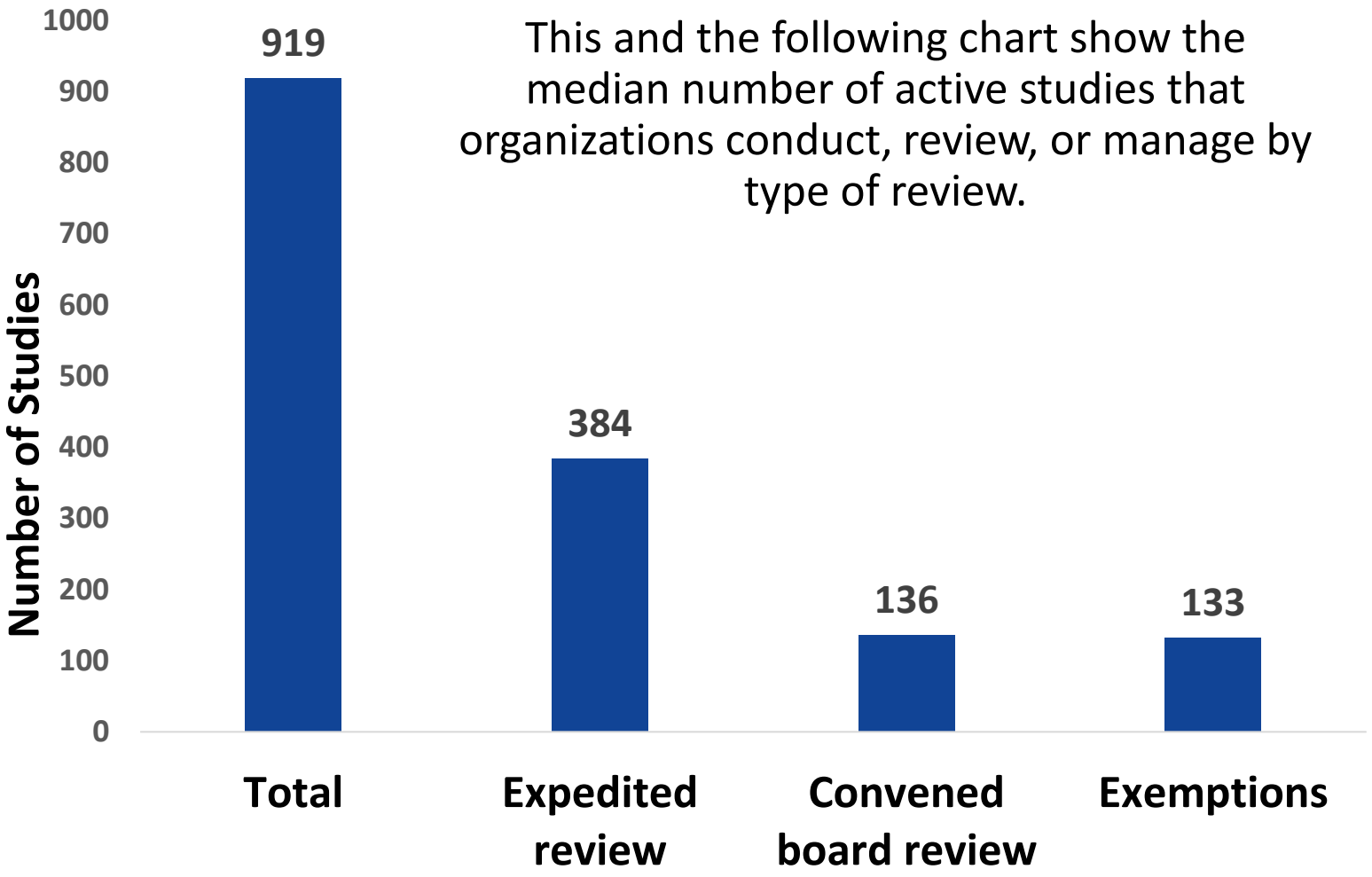
This chart shows the percentage of organizations that rely on one or more external IRB(s)/EC(s) for some or all of their human participants research and whether this includes exempt human participants research.

Compensating IRB/EC Members

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



Active Studies Overseen: All Organizations



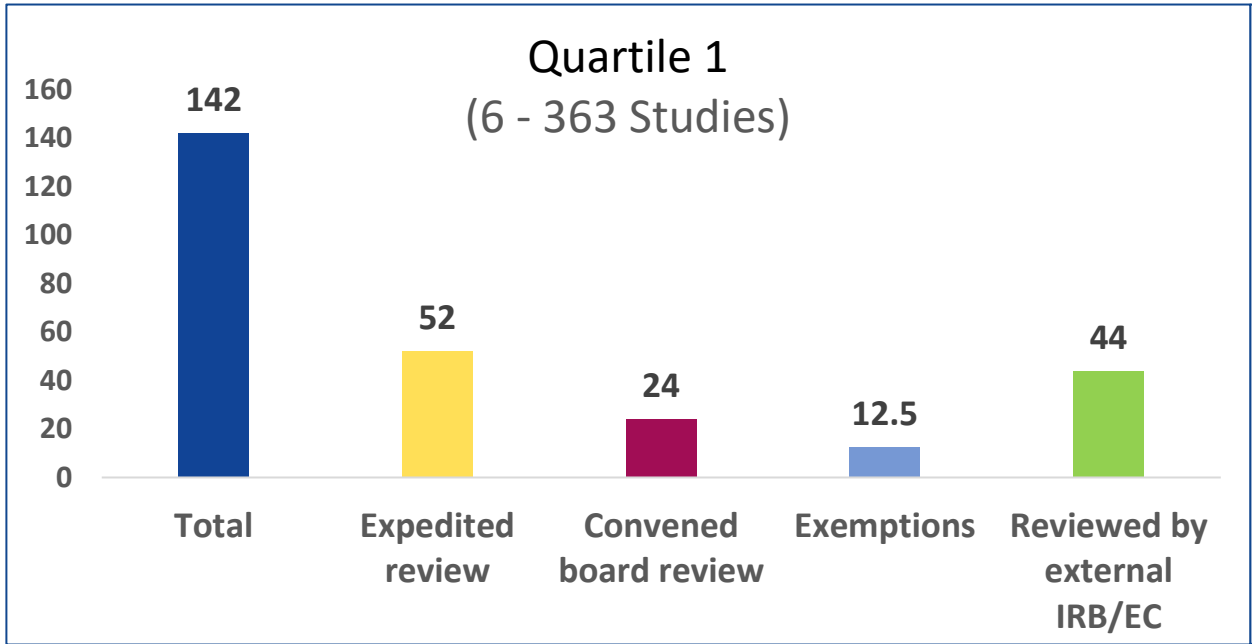
This and the following chart show the median number of active studies that organizations conduct, review, or manage by type of review.

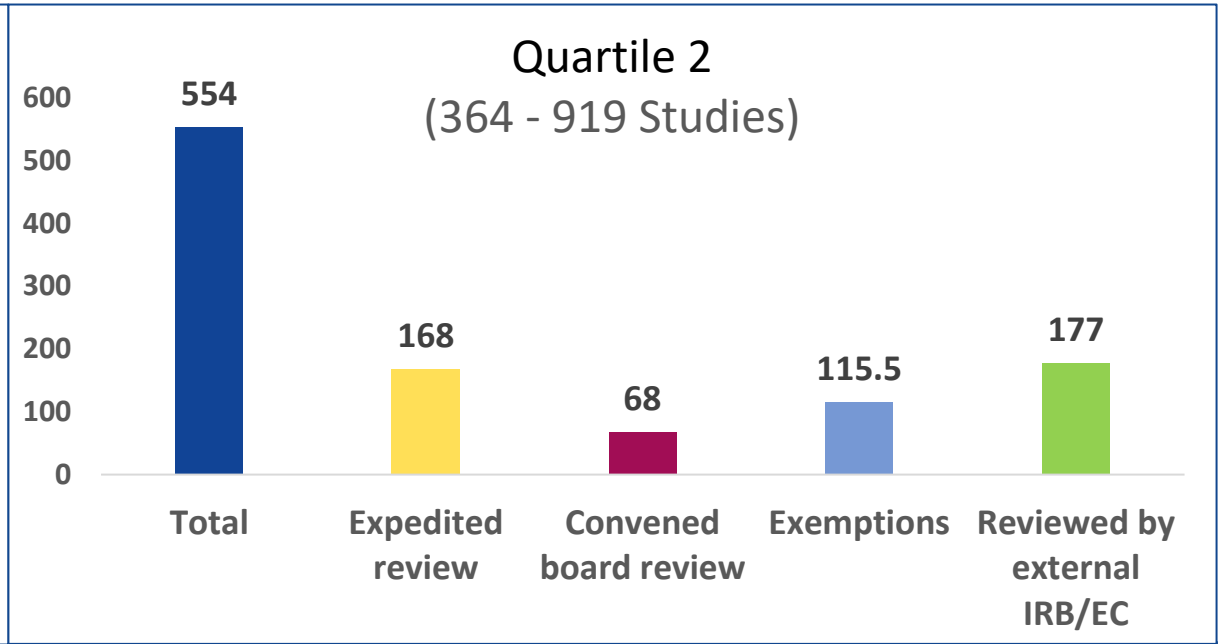
Exemptions are based on the number of determinations made by an organization for a 12-month period (e.g., the most year prior to the AAHRPP report).

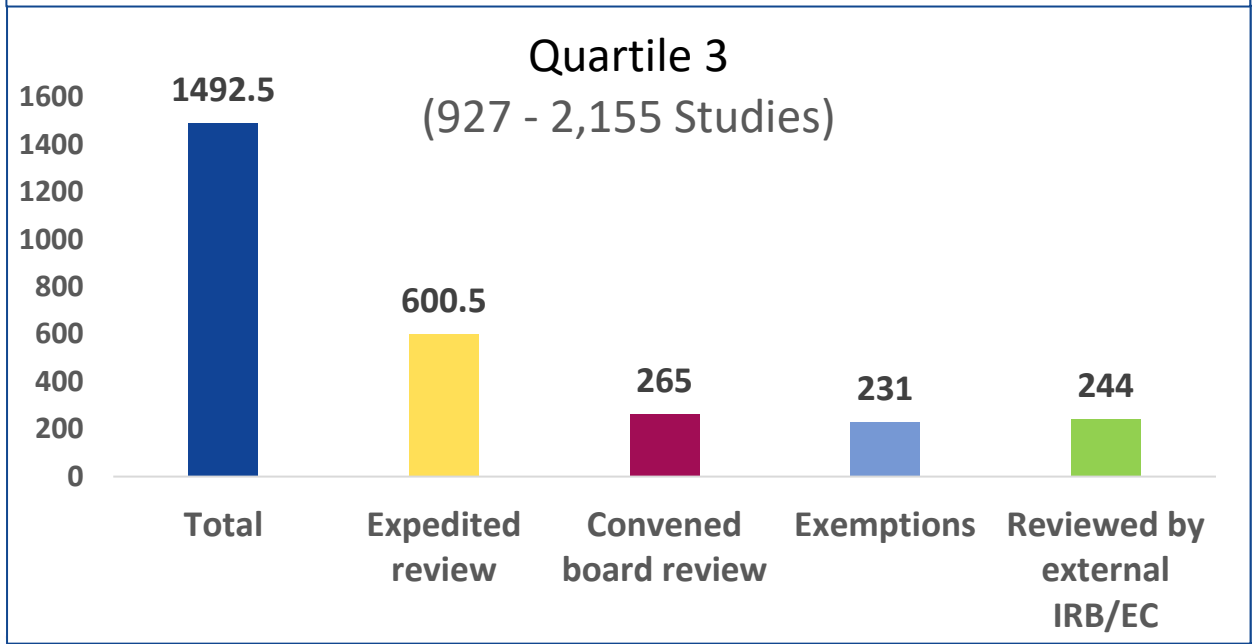
Expedited review and convened board review only include studies reviewed by an internal IRB/EC for organizations that have an internal IRB/EC and are not independent IRBs/ECs.

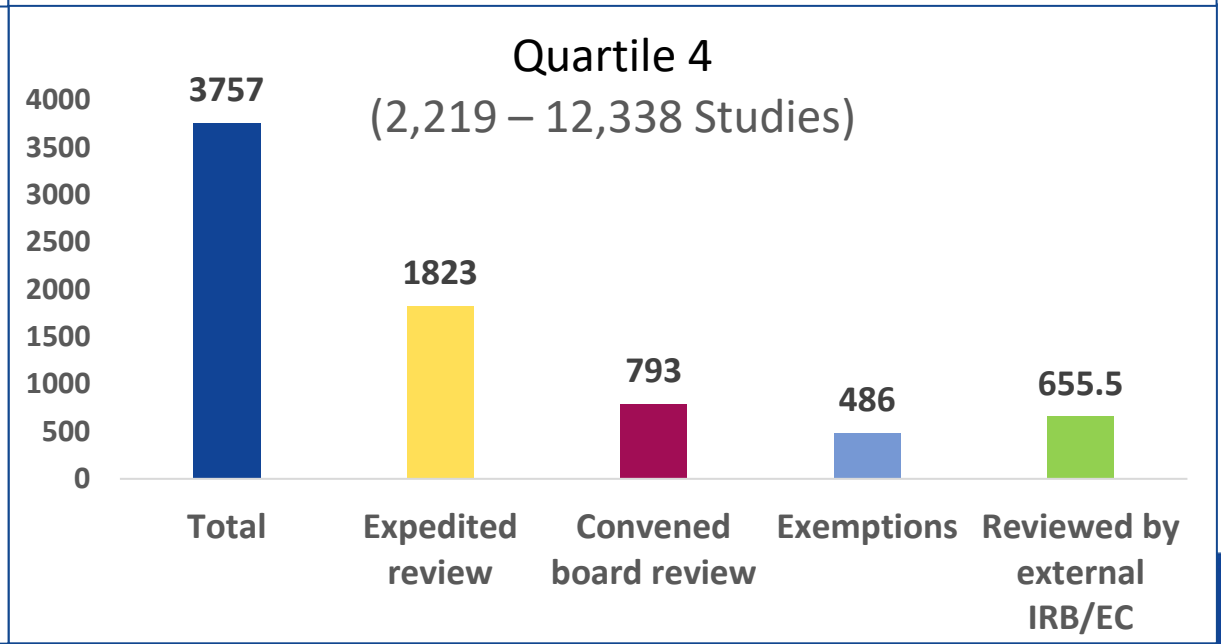
Total number of studies includes those reviewed by both internal and external IRBs/ECs in the case of organizations with IRBs/ECs.

Median Number of Active Studies (by Quartile)

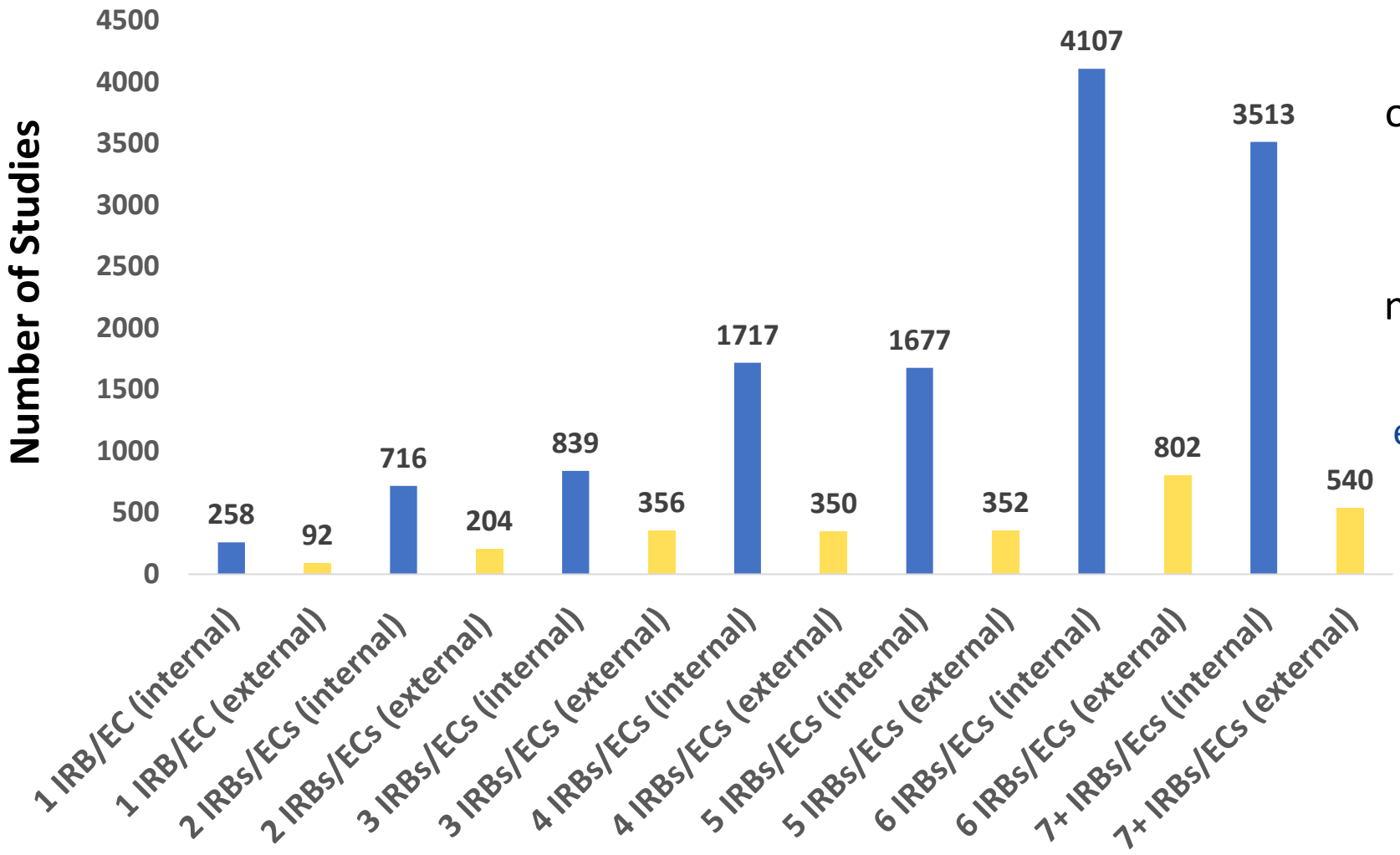








Active Studies Per IRB/EC

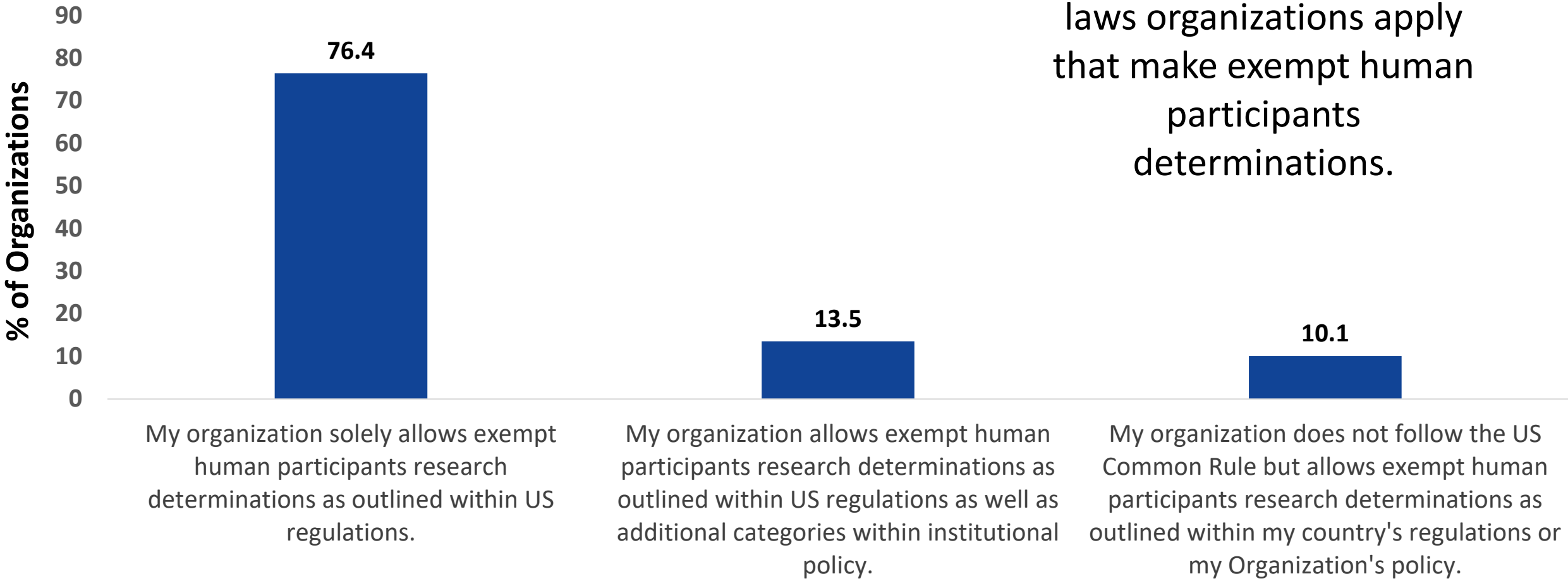


This chart compares the median number of active studies organizations oversee reviewed by an internal vs. external IRB/EC based on the number of internal IRBs/ECs they have. The data do not include independent IRBs/ECs.

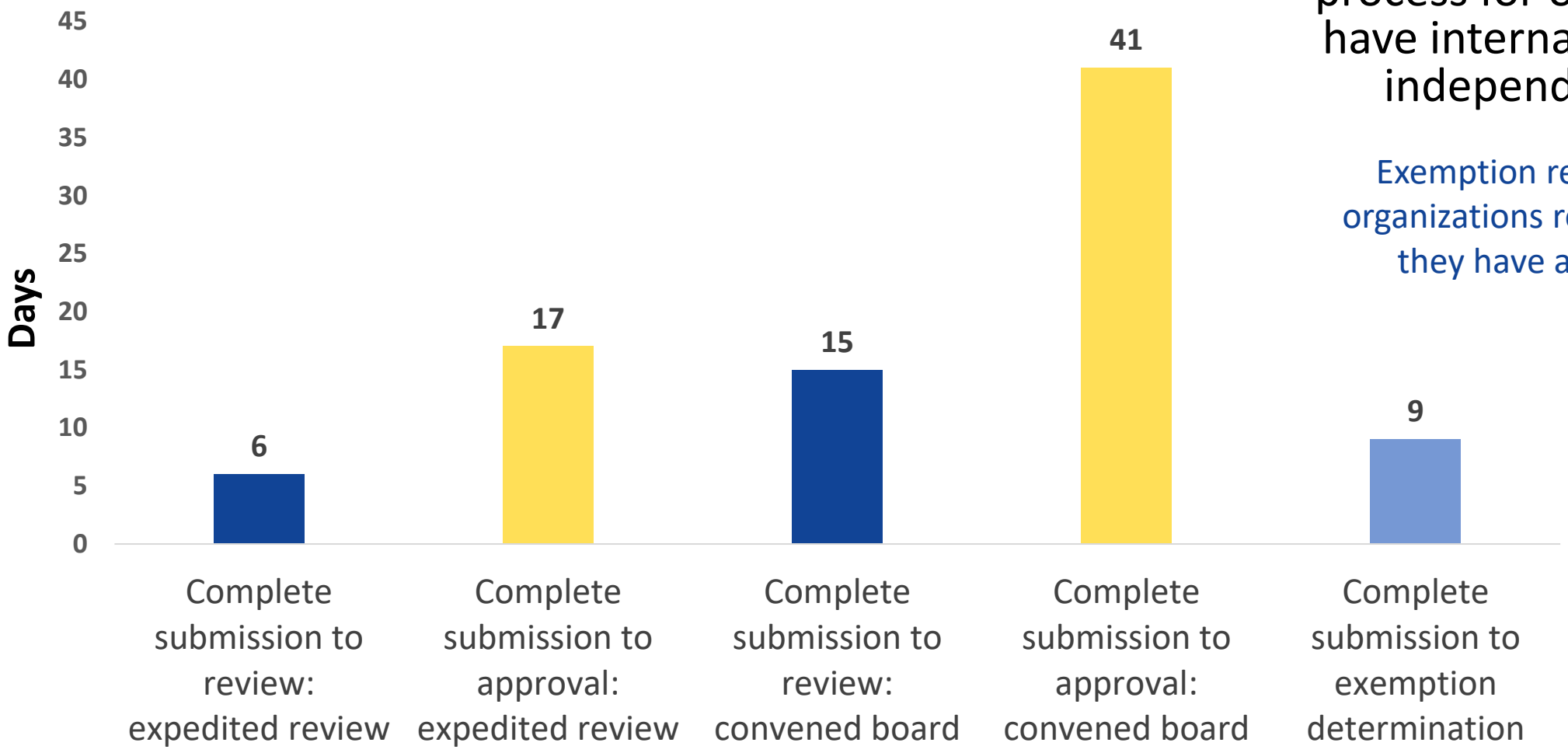
Median number of studies reflect exemption determinations that could be made by internal or external IRBs/ECs.

Policies and Procedures for Exempt Human Participants Research

This chart shows what policies, regulations, and laws organizations apply that make exempt human participants determinations.



Review Times



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

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

IRB/EC Technology

Online review functions	92.4%
Online protocol/materials distribution to IRB/EC members	91.1%
Online application submission	89.4%
Database for submission tracking	84.3%
Does not use an electronic system	1.3%

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

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	783	8.5	101.0	$628,500
0-100	42	2.0	21.3	$210,761
101-500	256	3.3	66.1	$287,279
501-1000	730	7.0	97.9	$599,000
1001-2000	1439	11.0	121.5	$1,031,885
2001-4000	2725	18.0	177.9	$1,719,535
4001+	5712	26.0	220.3	$2,837,898

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.

Data from organizations without internal IRBs/ECs are not included

Audits of Researchers

Percent of organizations that reported that audits of researchers occurred

85.4%

Internal: "for cause"	• Median: 1 • Total: 14,717
Internal: random	• Median: 11 • Total: 13,033
Regulatory agency inspections	• Median: 1 • Total: 842

Audits of IRBs/ECs

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

69.6%

Internal: "for cause"	• Median: 0 • Total: 658
Internal: random	• Median: 2 • Total: 9,385
Regulatory agency inspections	• Median: 0 • Total: 252

Unresolved Complaints, Noncompliance, & Unanticipated Problems

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.

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	6	1	0	1
	Total	347	15,027	1,980	1,473	2,442
0-100	Median	0	0	0	0	0
	Total	0	184	23	27	90
101-500	Median	0	2	0	0	0
	Total	11	1,143	91	53	251
501-1000	Median	0	8.5	1	0	0
	Total	37	2,993	142	55	294
1001-2000	Median	0	32	2.5	0.5	1
	Total	82	4,381	468	481	403
2001-4000	Median	0	16	2	0	6
	Total	21	3,602	620	280	1,068
4001+	Median	0	78	8	2	9
	Total	196	2724	636	577	336

Conflicts of Interest

This graphic shows the median number of studies with a financial management plan reviewed by an IRB/EC 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

Studies with a financial conflict of interest management plan were reviewed by an IRB/EC (internal or external)

5 *