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

2022 Metrics for AAHRPP-Accredited Human Research Protection Programs

May 2023

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About the Metrics

AAHRPP is pleased to present the 2022 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 submitted by AAHRPP Organizations.

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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
ICH GCP	International Conference on Harmonisation Good Clinical Practice
VA	US Department of Veterans Affairs

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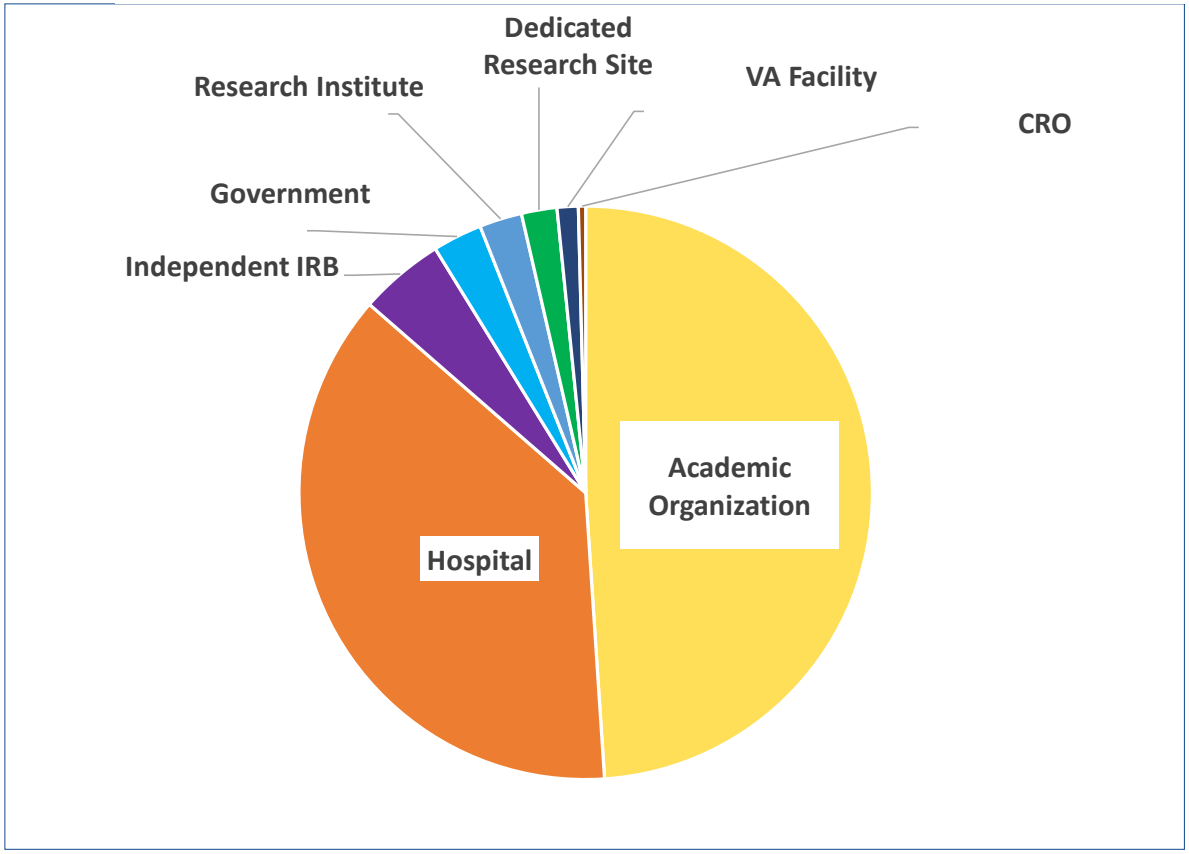
Accredited Organizations By Type



Of the 251 accredited Organizations:

- 49.0% are academic organizations
- 37.5% are hospitals
- 4.8% are independent IRBs
- 2.8% are governmental organizations
- 2.84 are research institutes
- 2.0% are dedicated research sites
- 1.2% are VA facilities
- 0.4% are contract research organizations

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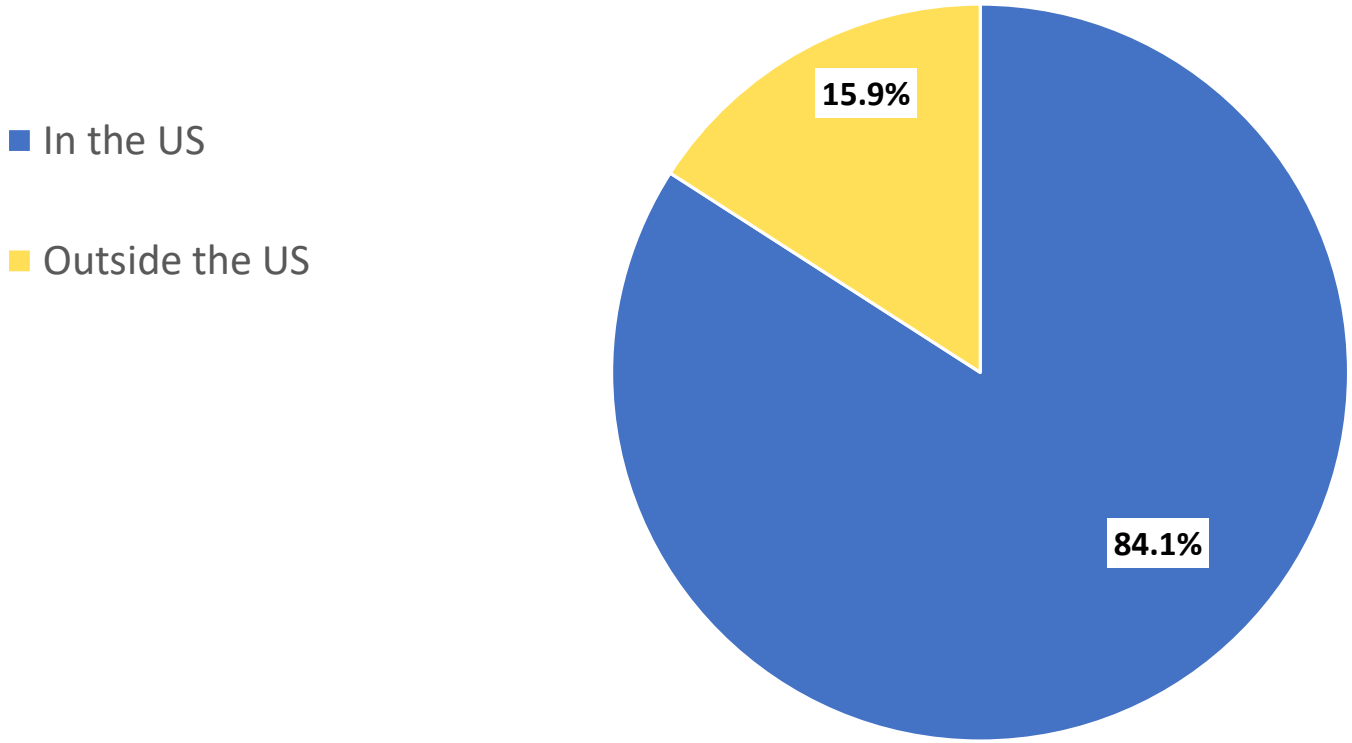
Where Accredited Organizations are Based



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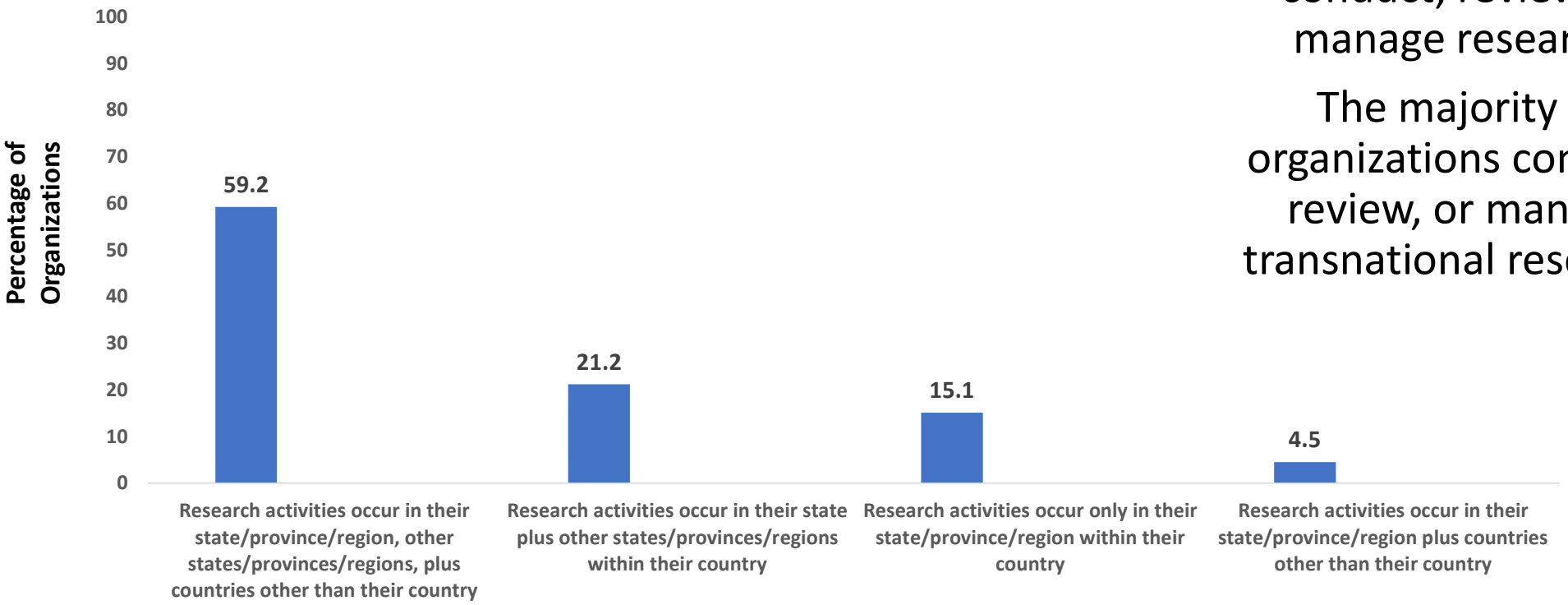
Where Research Occurs



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

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

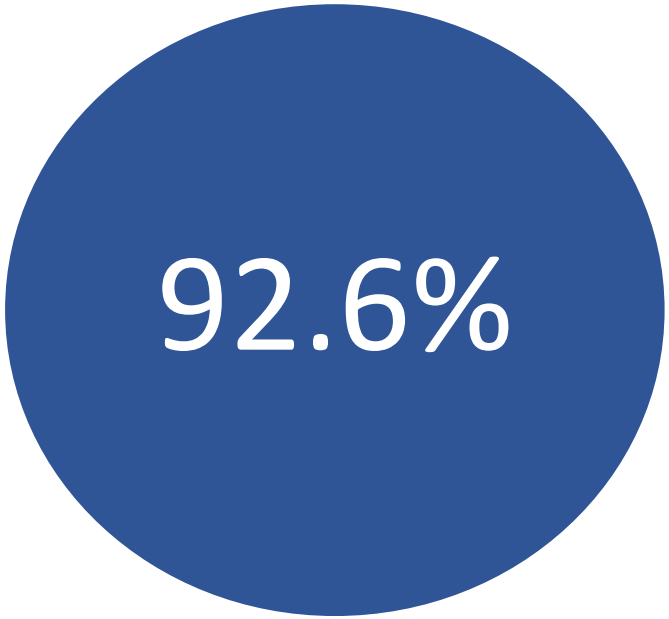
Research Type

Most Organizations conduct, manage, or review

biomedical/clinical research

Most Organizations conduct, manage, or review

social/behavioral/education research



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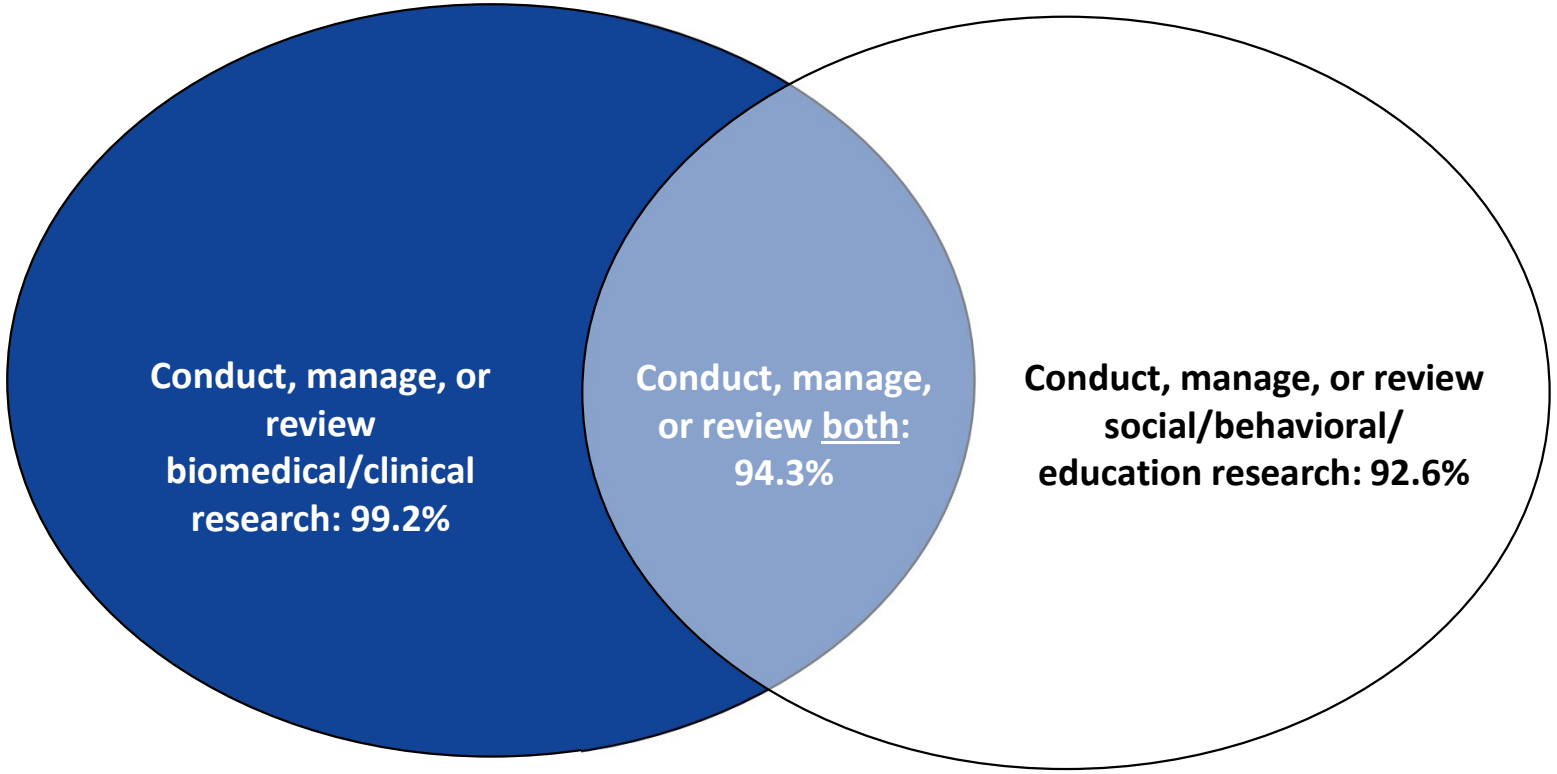
Type of Research Organizations Conduct, Manage, or Review



Biomedical/Clinical Research by Type

Drugs	93.0%
Devices	93.0%
Planned Emergency Research	40.8%

This table shows the type of biomedical/clinical research Organizations conduct or review.

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Vulnerable Populations

Children	97.1%
Adults Unable to Consent	93.9%
Pregnant Women	93.1%
Employees	82.4%
Students	80.4%
Prisoners	61.2%
Other	24.1%

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.

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

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Funding Type

Industry sponsored	97.6%
Sponsored by other external sources	91.8%
Internally funded or unfunded	91.4%
Government or federally sponsored	83.3%

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

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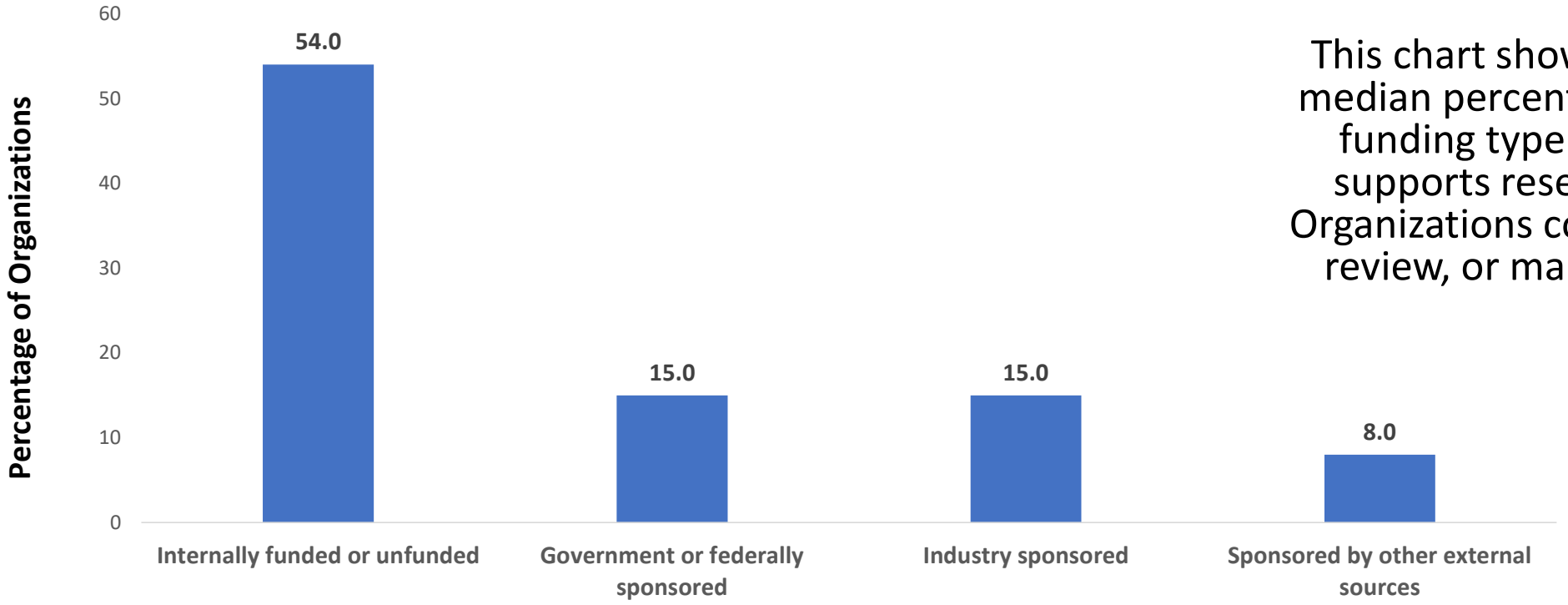
Funding Distribution



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

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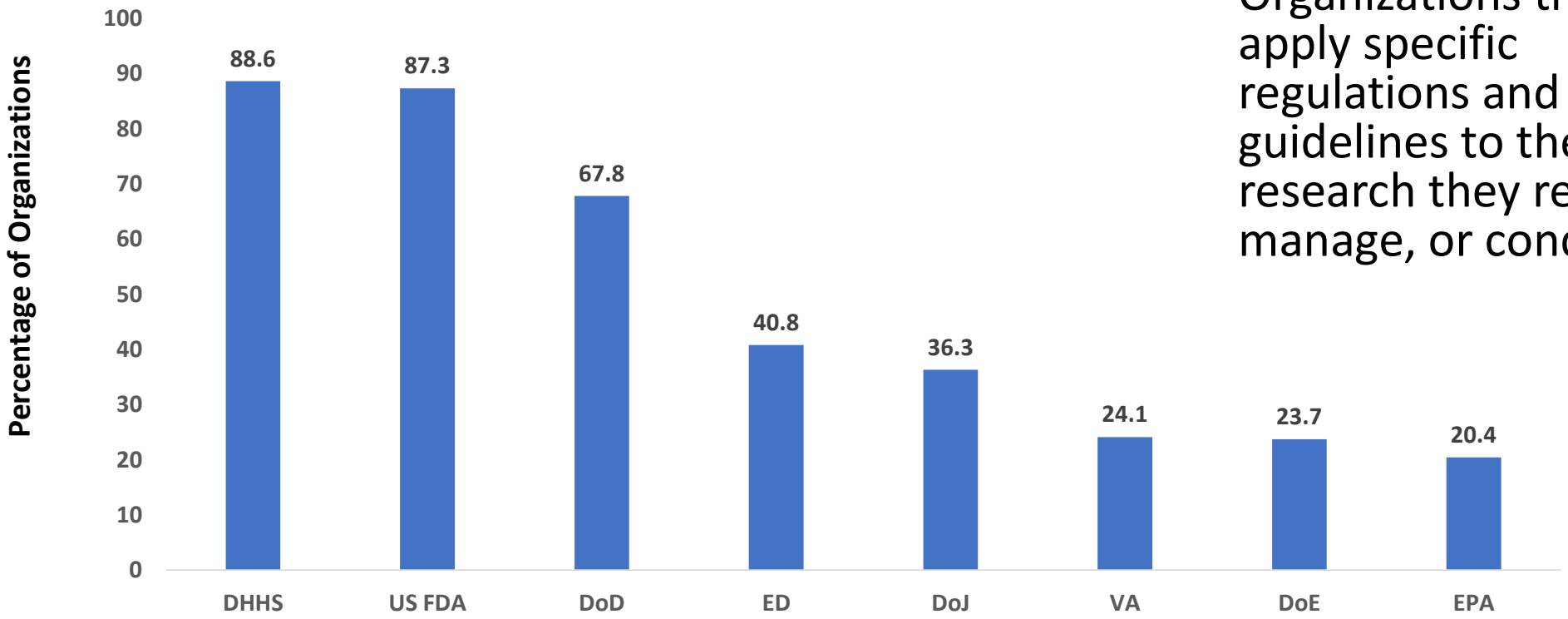
Regulations & Guidelines



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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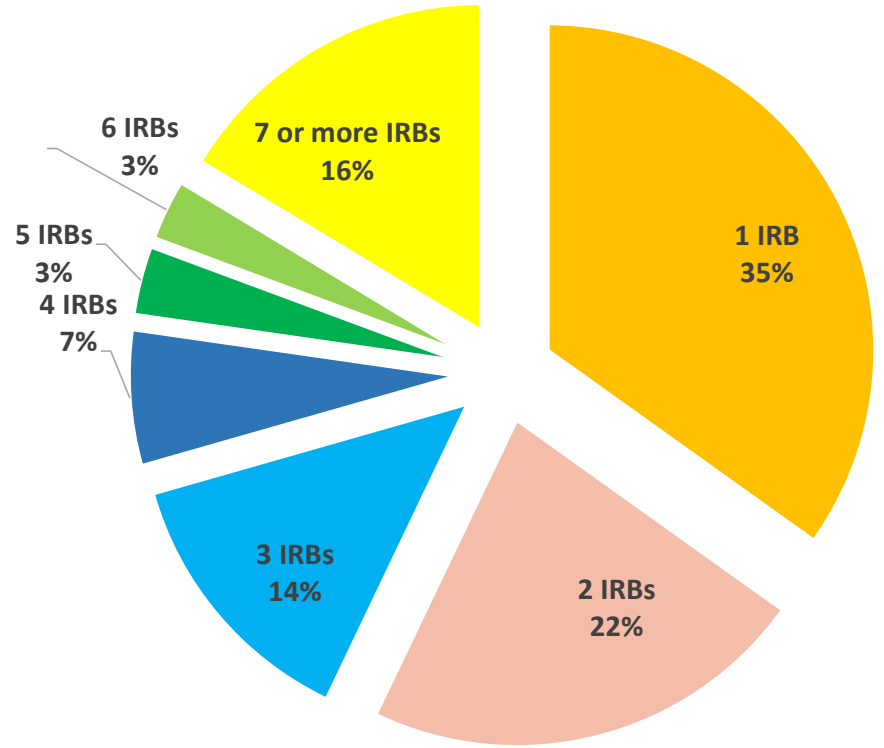
Internal IRBs/ECs*

% of organizations that have internal IRBs/ECs	90.6%
Median # of IRBs/ECs per organization	2

Number of internal IRBs/ECs Organizations support



*Data exclude independent IRBs/ECs

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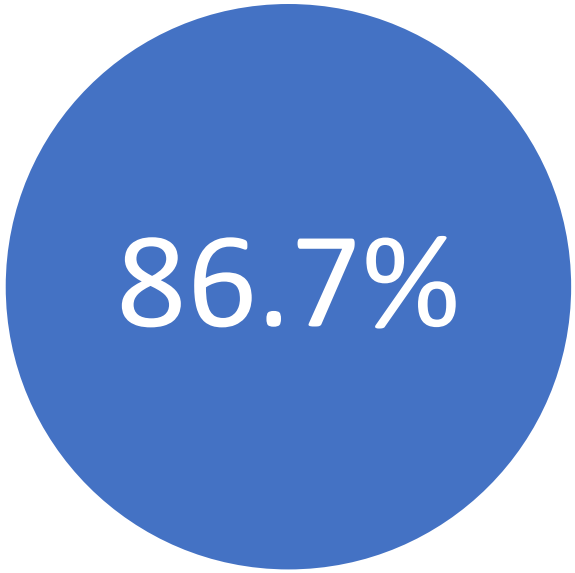
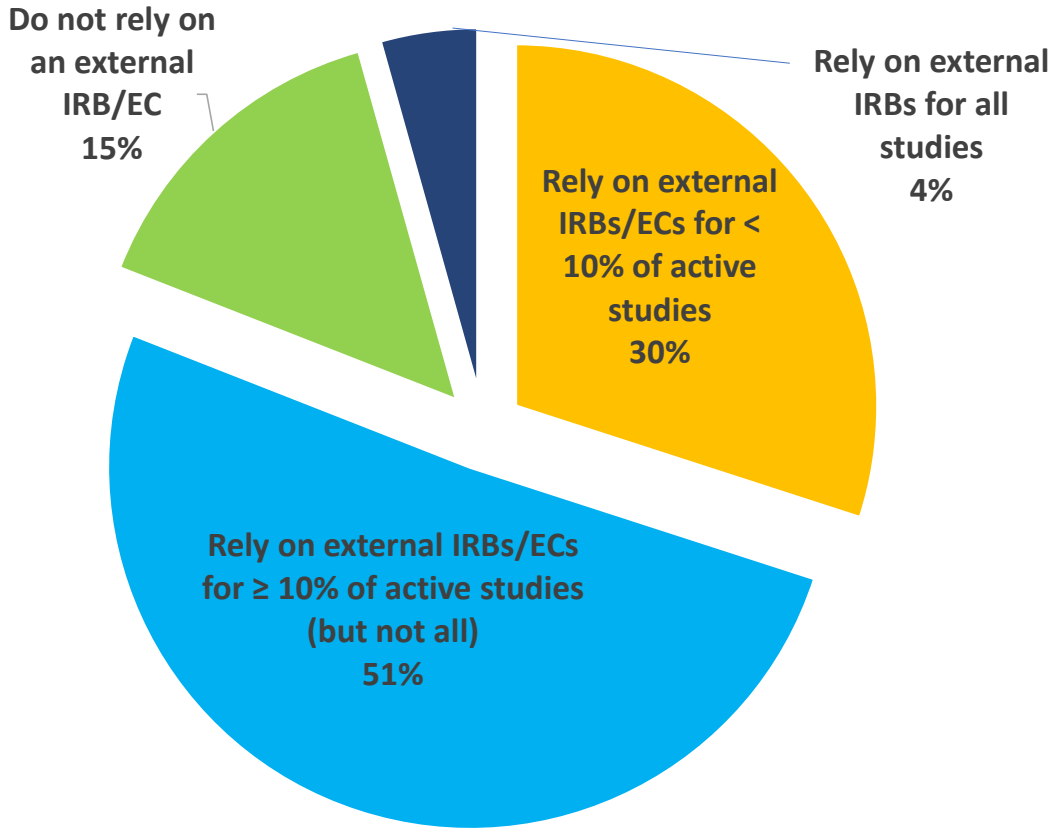
Relying on External IRBs/ECs*

% 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

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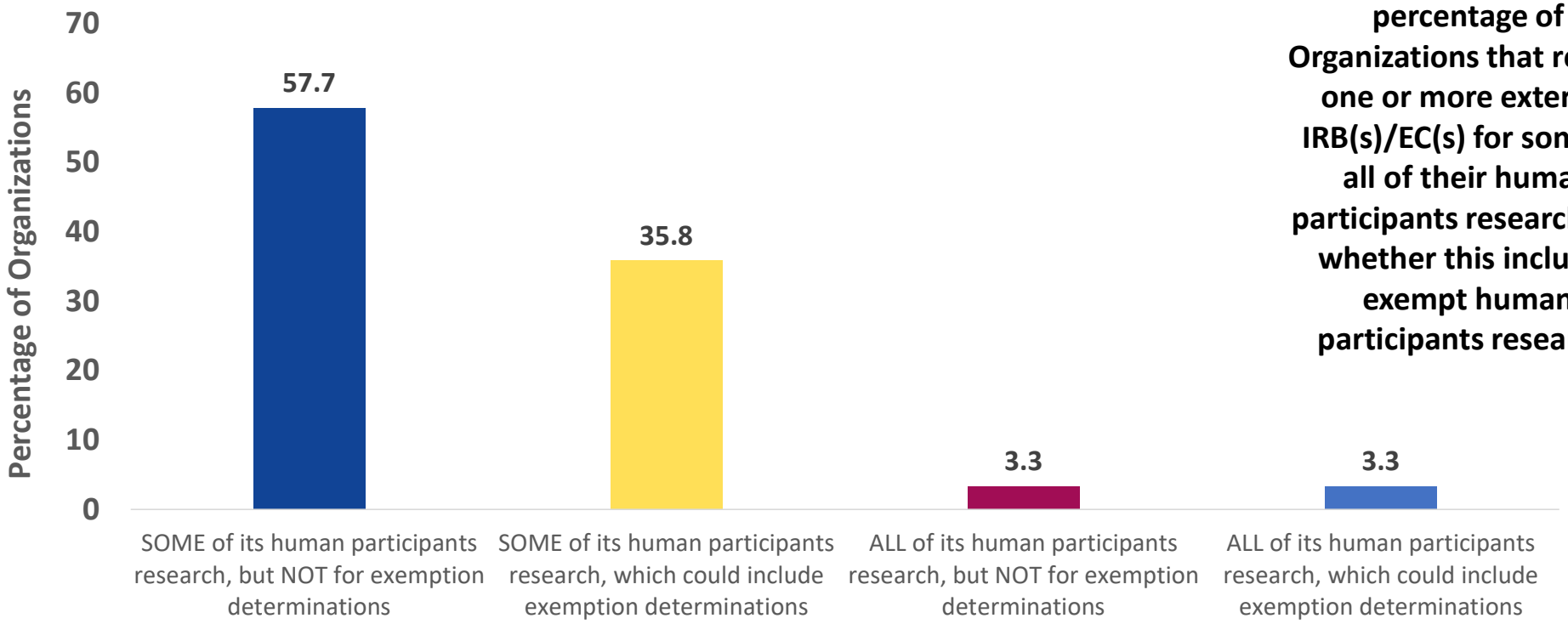
Research Reviewed by External IRBs/ECs



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.

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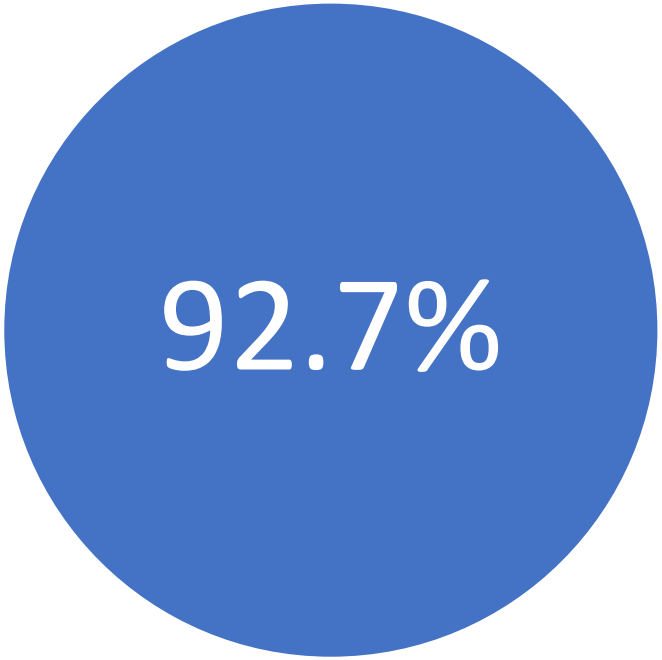
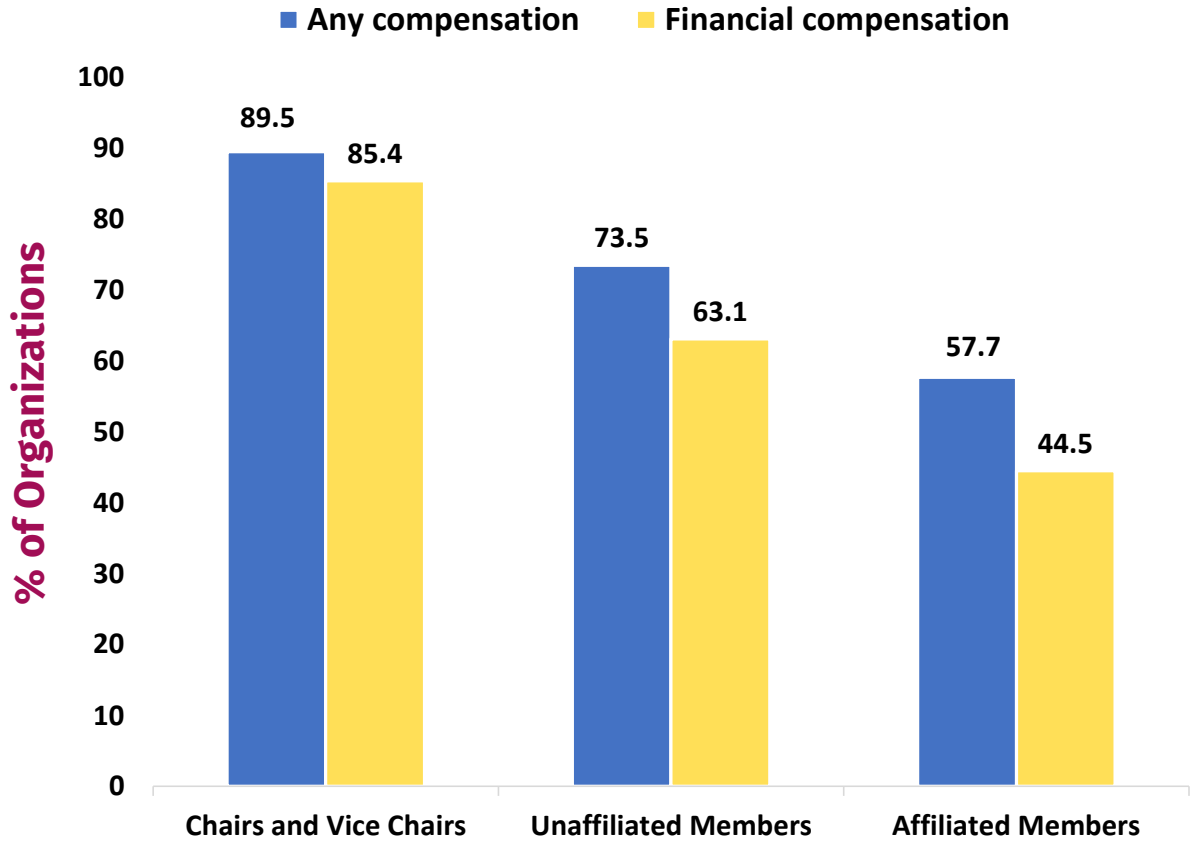
Compensating IRB/EC Members

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





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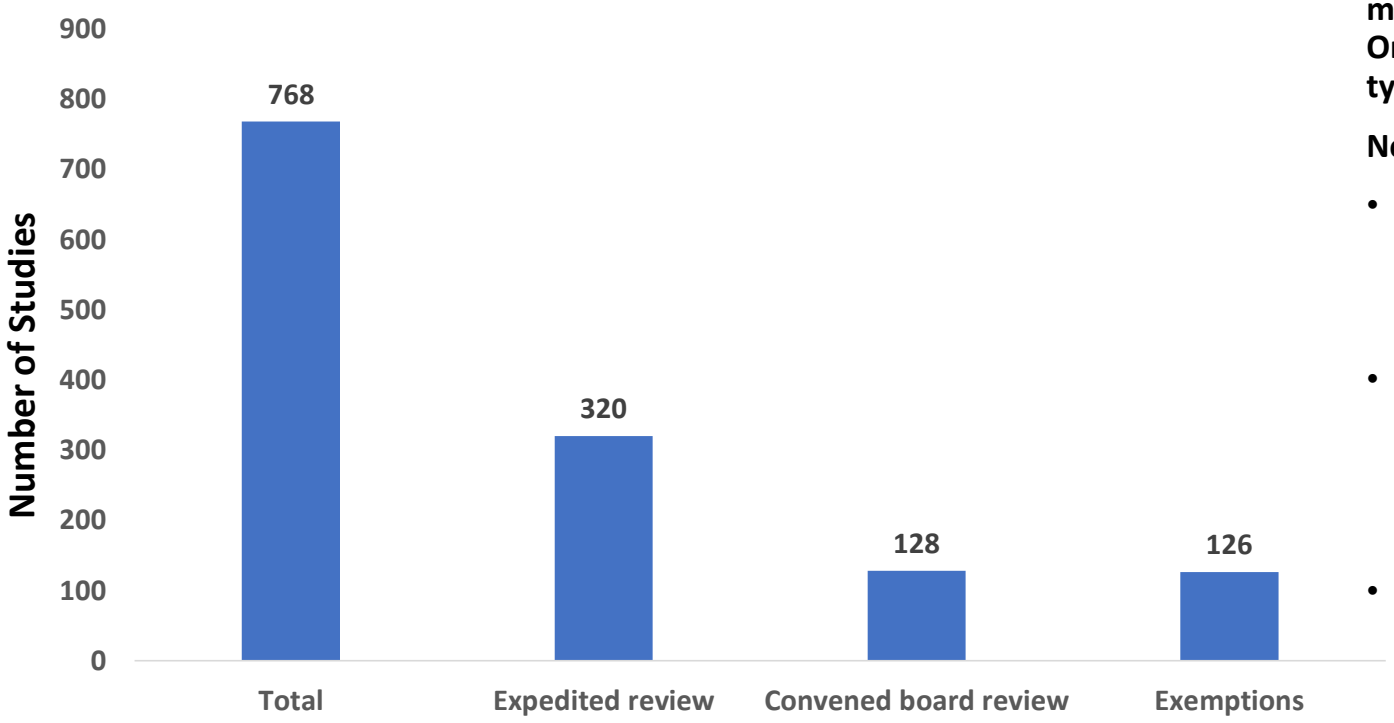
Active Studies Overseen: All Organizations

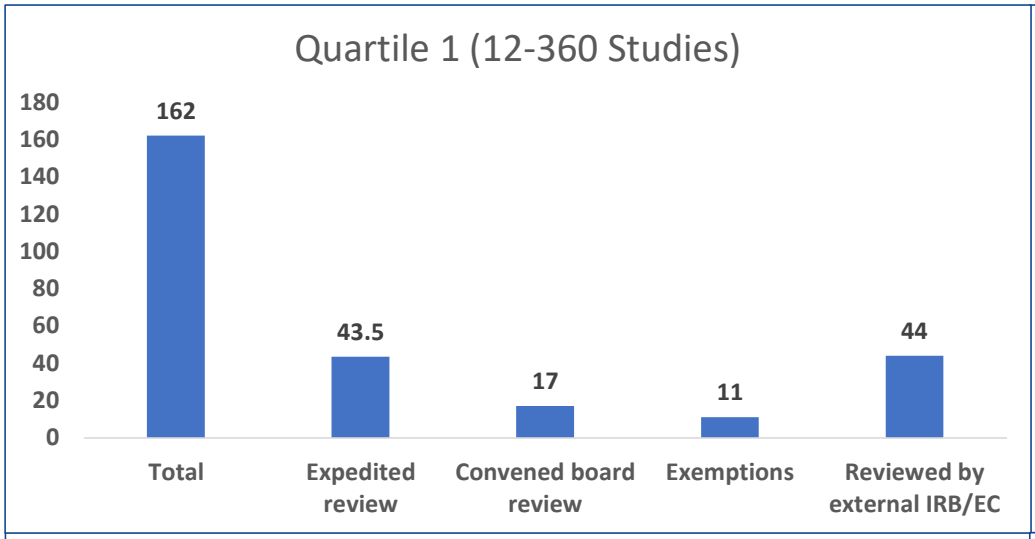


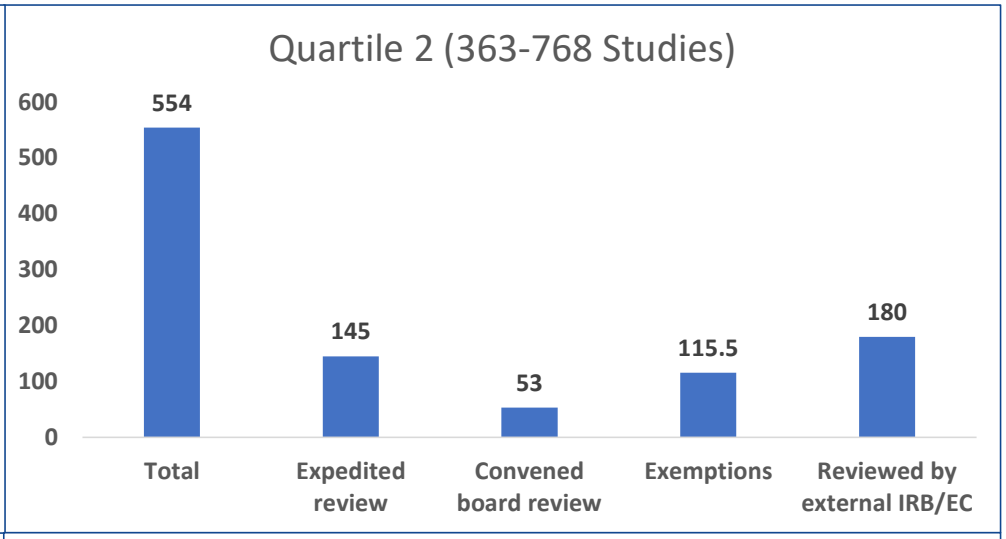
This and the following chart show the median number of active studies that Organizations conduct, review, or manage by type of review.

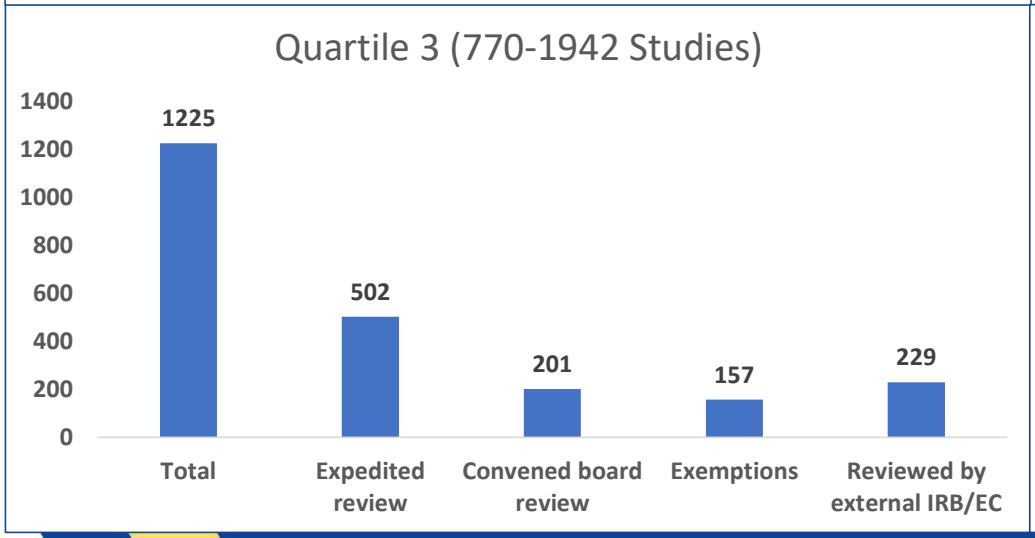
Note:

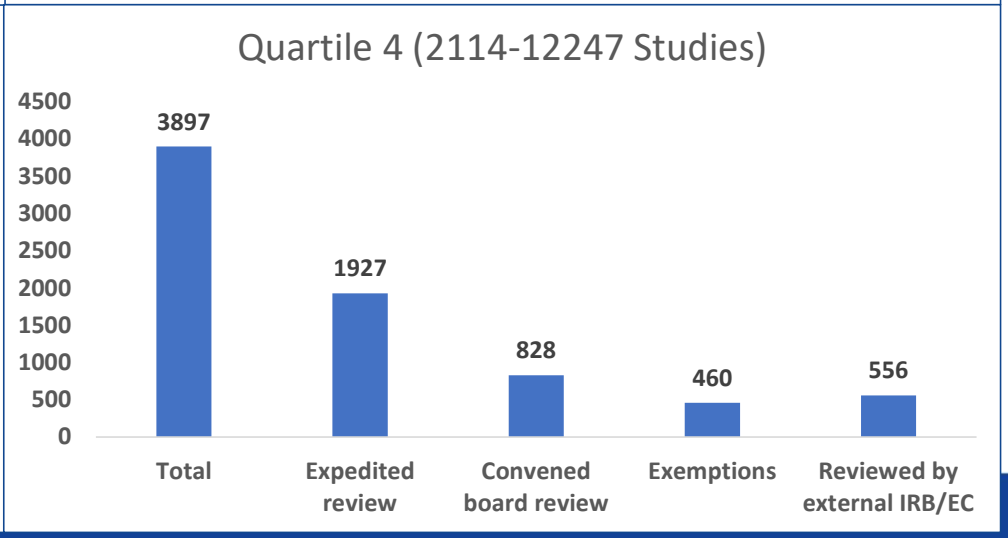
- **Exemptions are based on the number of determinations made by an Organization for a 12-month period (e.g., the year prior to the AAHRPP report)**
- **Expedited review and convened board review only include studies reviewed by an internal IRB/EC for Organizations that have an internal IRB/EC and are 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)









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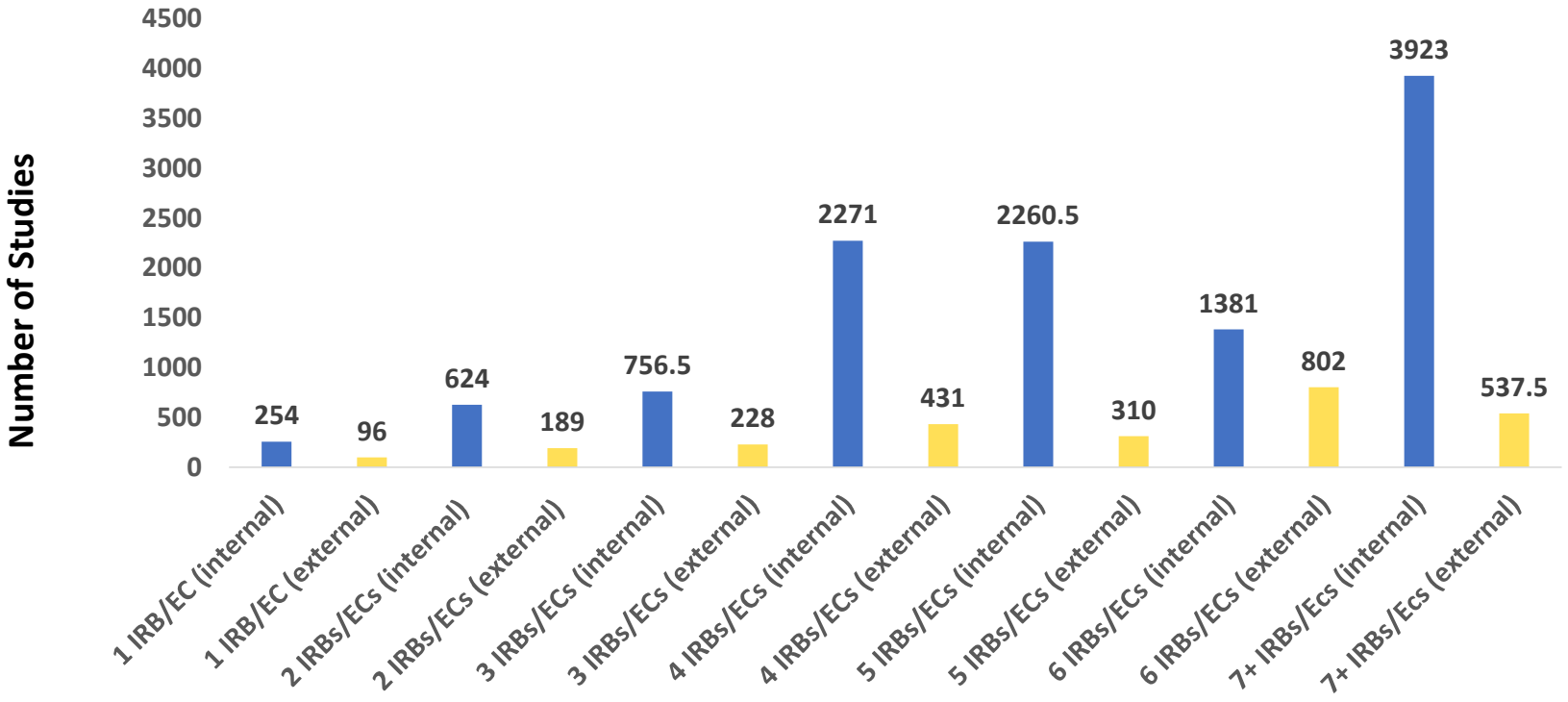
Active Studies Per IRB/EC



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.

Note:

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

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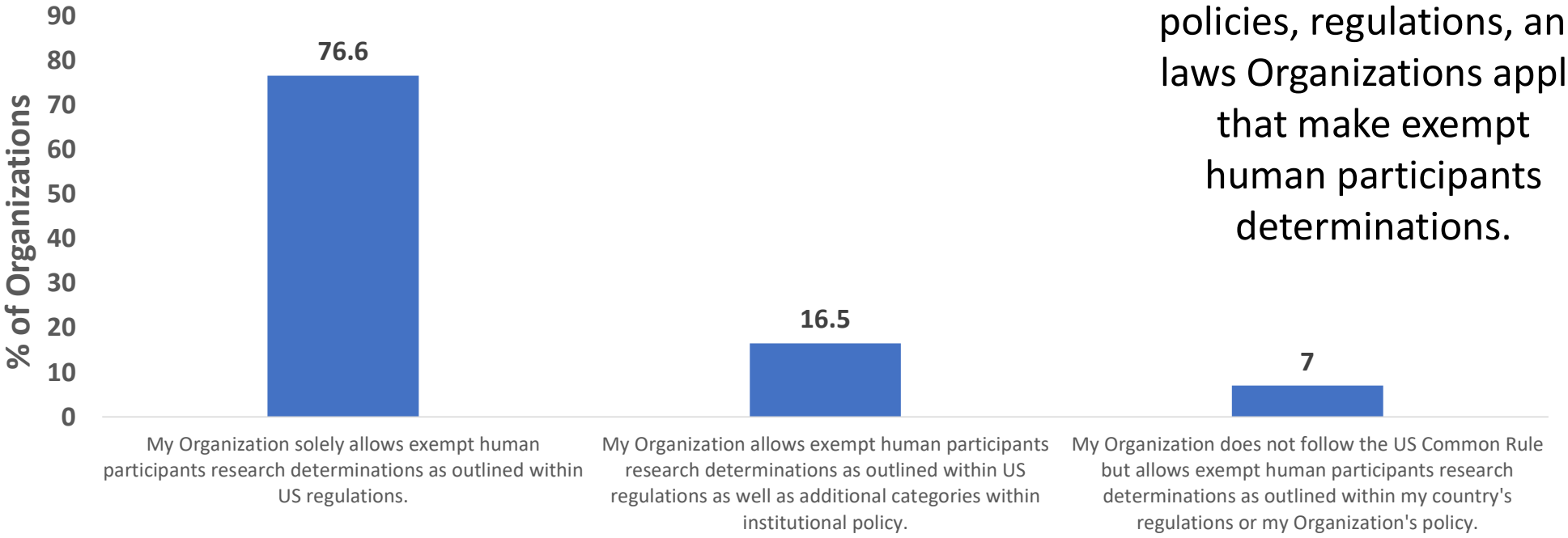
Policies and Procedures for Exempt Human Participants Research

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



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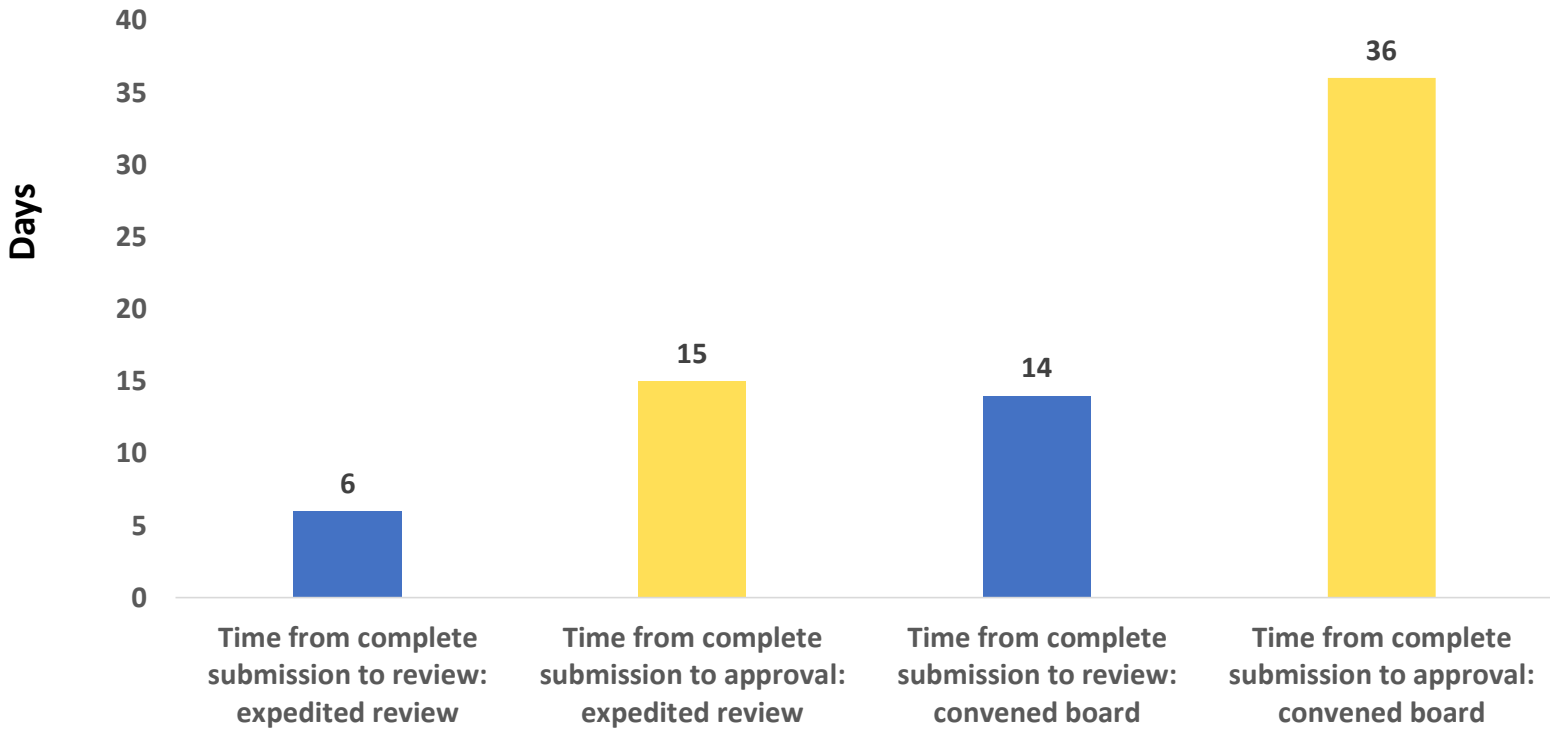
Review Times



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

Note:

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

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IRB/EC Technology

Online protocol/materials distribution to IRB/EC members	93.2%
Online review functions	91.9%
Online application submission	90.6%
Database for submission tracking	88.0%
Does not use an electronic system	0.4%

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

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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	823	7.5	109.7	$559,364
0-100	40	2	20.0	$150,870
101-500	265.5	3	88.5	$252,820
501-1000	683	6	113.8	$551,000
1001-2000	1400	10.8	129.6	$900,000
2001-4000	2838	15	189.2	$1,260,000
4001+	5898	23.7	249.4	$2,568,110

Corrected

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

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Audits of Researchers

% of Organizations that reported that audits of researchers occurred

88.6%

Internal: "for cause"	• Median: 1 • Total: 841
Internal: random	• Median: 10 • Total: 9921
Regulatory agency inspections	• Median: 0 • Total: 230

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Audits of IRBs/ECs

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

78.3%

Internal: "for cause"	• Median: 0 • Total: 443
Internal: random	• Median: 2.5 • Total: 5515
Regulatory agency inspections	• Median: 0 • Total: 75

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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	150	13871	1613	1224	2164
0-100	Median	0	0	0	0	0
	Total	0	112	11	2	12
101-500	Median	0	2	0	0	0
	Total	8	680	82	49	323
501-1000	Median	0	4	0	0	0
	Total	19	4071	165	89	304
1001-2000	Median	0	31	2	0	2
	Total	45	4060	327	487	386
2001-4000	Median	0	13	3	0	4
	Total	50	2841	533	241	851
4001+	Median	0	29	4.5	2	4
	Total	28	2107	495	356	288

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.

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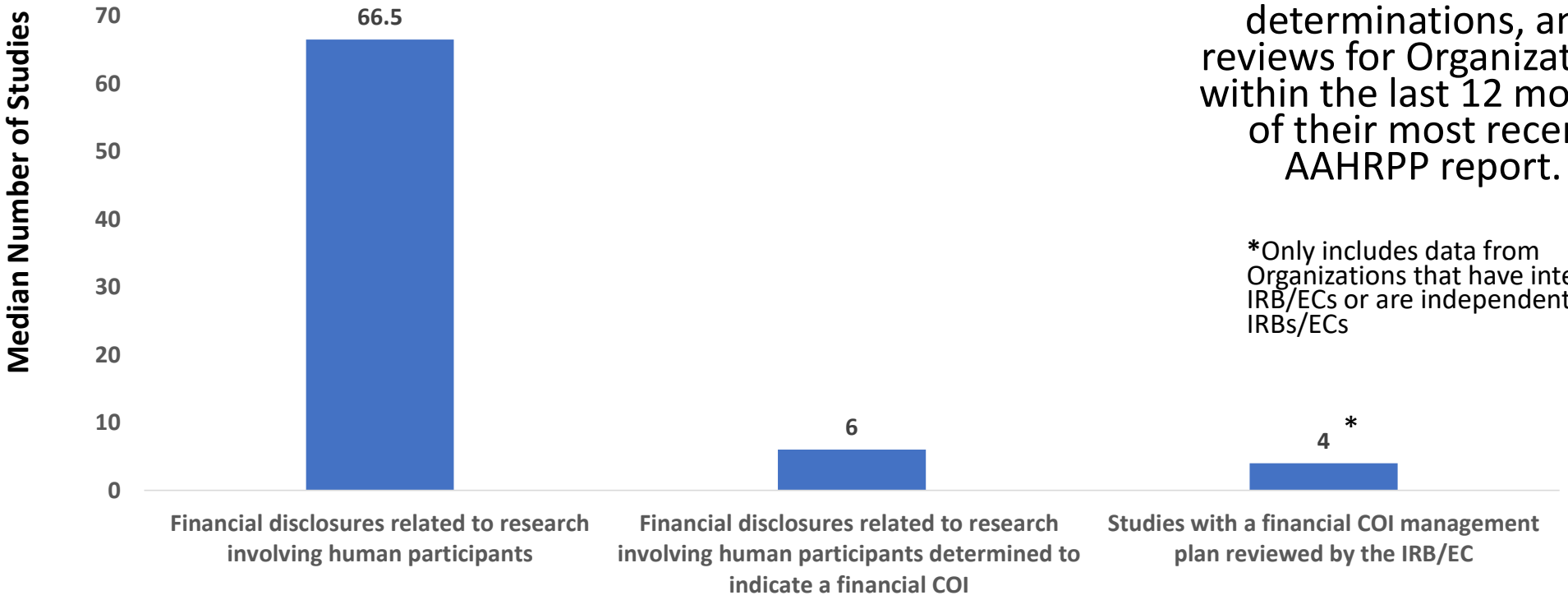
Conflicts of Interest



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