



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

2021 Metrics for AAHRPP-Accredited Human Research Protection Programs

June 2022



About the Metrics

AAHRPP is pleased to present the 2021 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.

Data were selected based on what most accurately reflected AAHRPP organizations in 2021.

Abbreviations Used

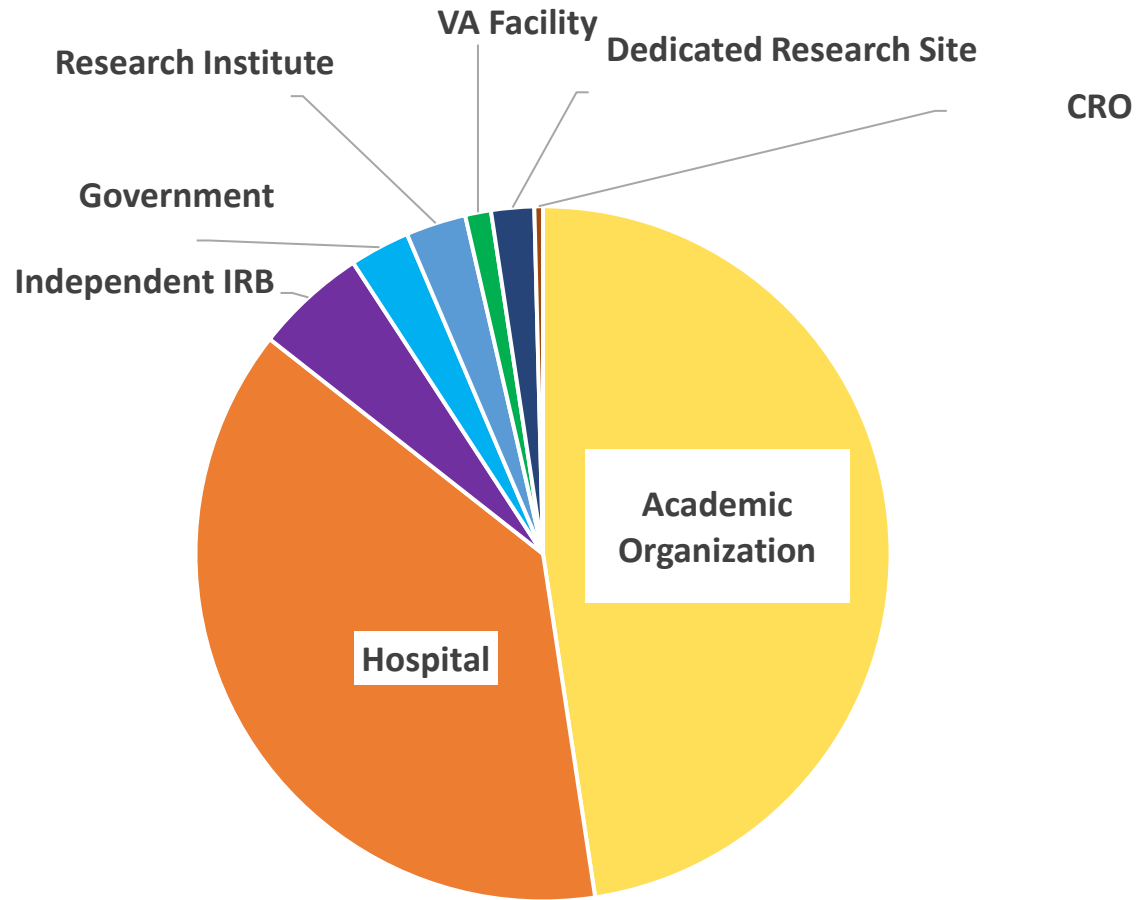
| | |
|---------|--|
| DHHS | US Department of Health & Human Services |
| DoD | US Department of Defense |
| ED | US Department of Education |
| DoE | US Department of Energy |
| DoJ | US Department of Justice |
| EPA | US Environmental Protection Agency |
| FDA | US Food and Drug Administration |
| ICH GCP | International Conference on Harmonisation Good Clinical Practice |
| VA | US Department of Veterans Affairs |



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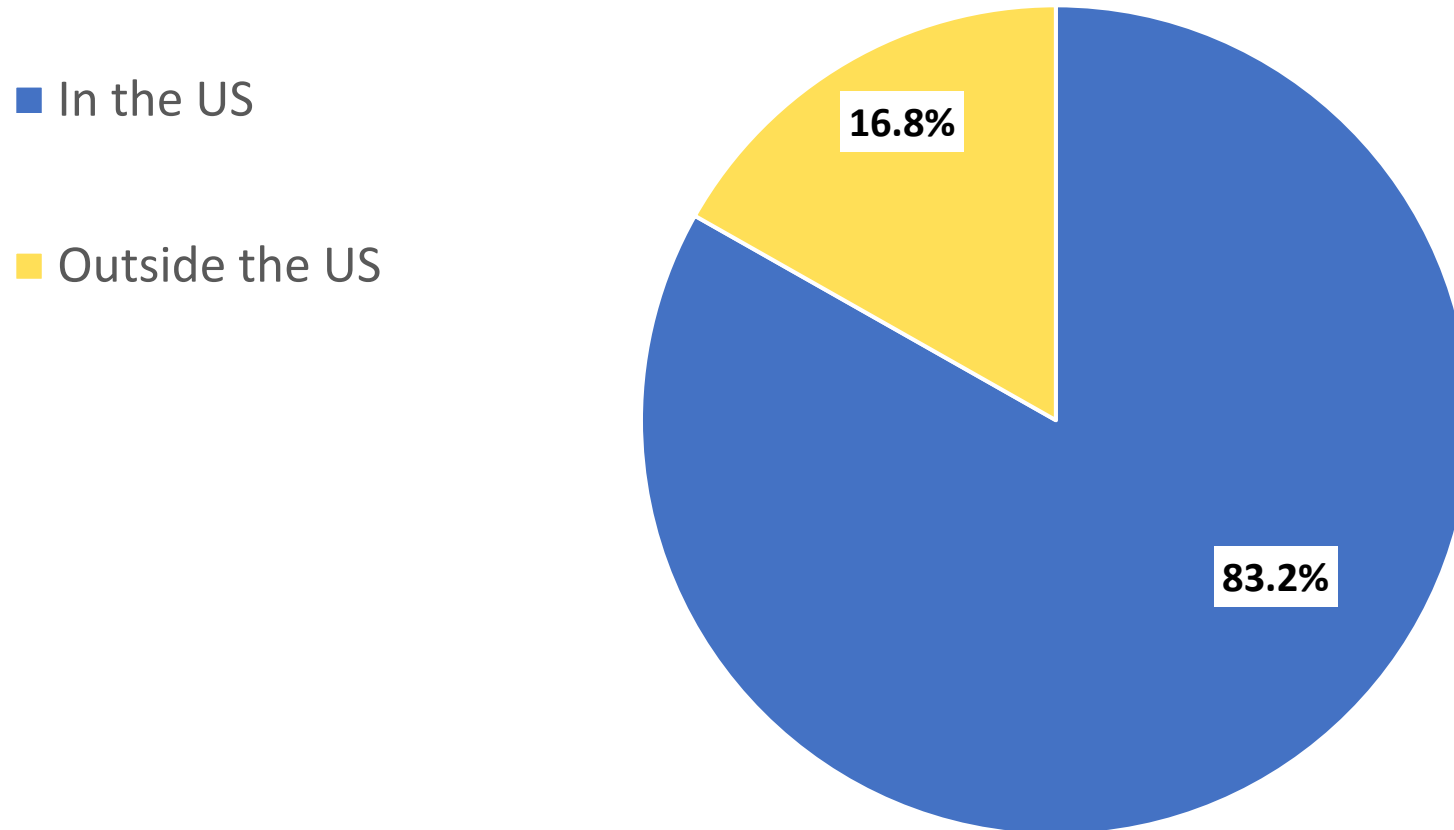
Accredited Organizations By Type



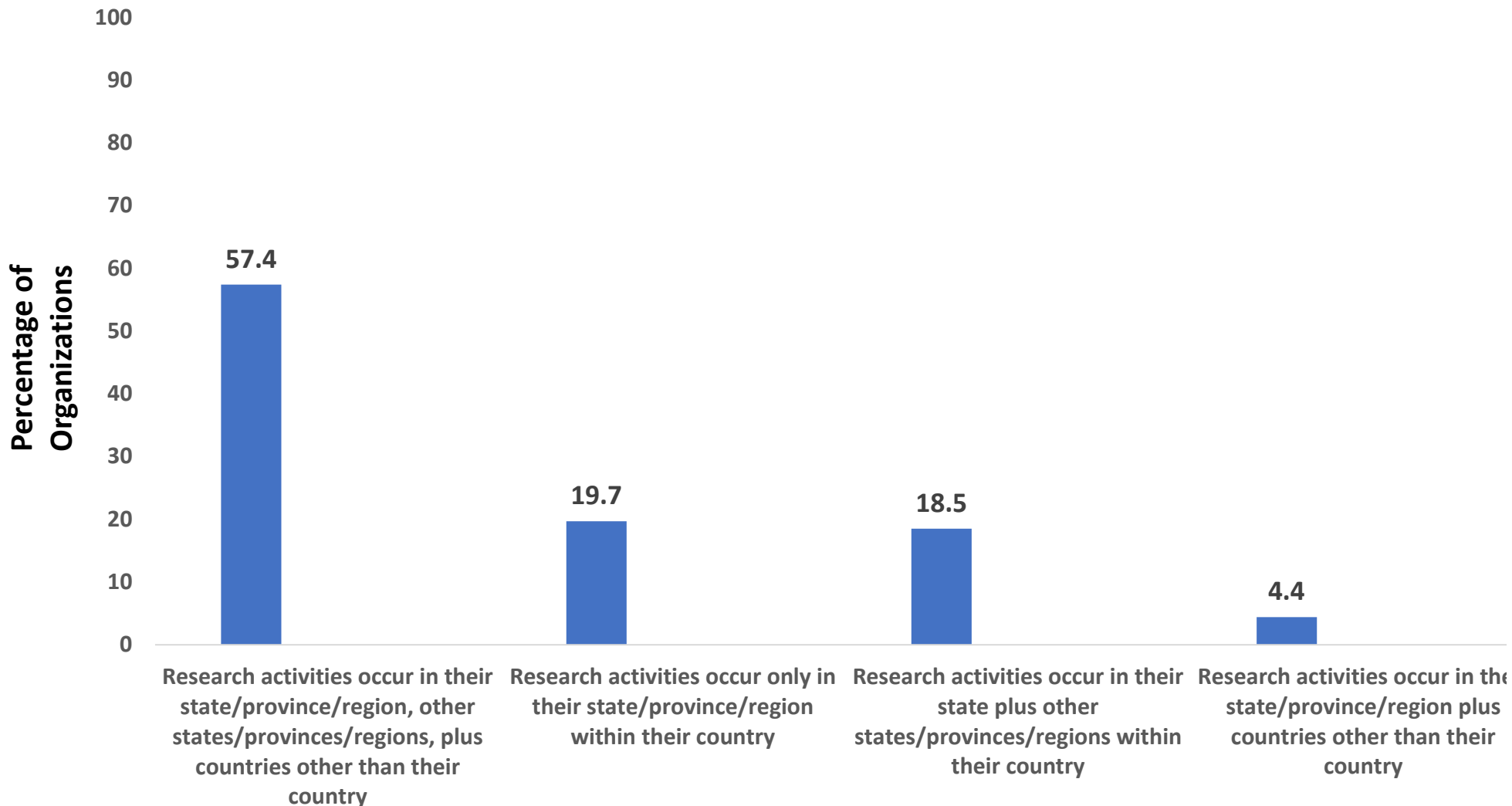
Of the 250 accredited organizations:

- 47.6% are academic organizations
- 38.0% are hospitals
- 5.2% are independent IRBs
- 2.8% are governmental organizations
- 2.8% are research institutes
- 2.0% are dedicated research sites
- 1.2% 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.

Research Type

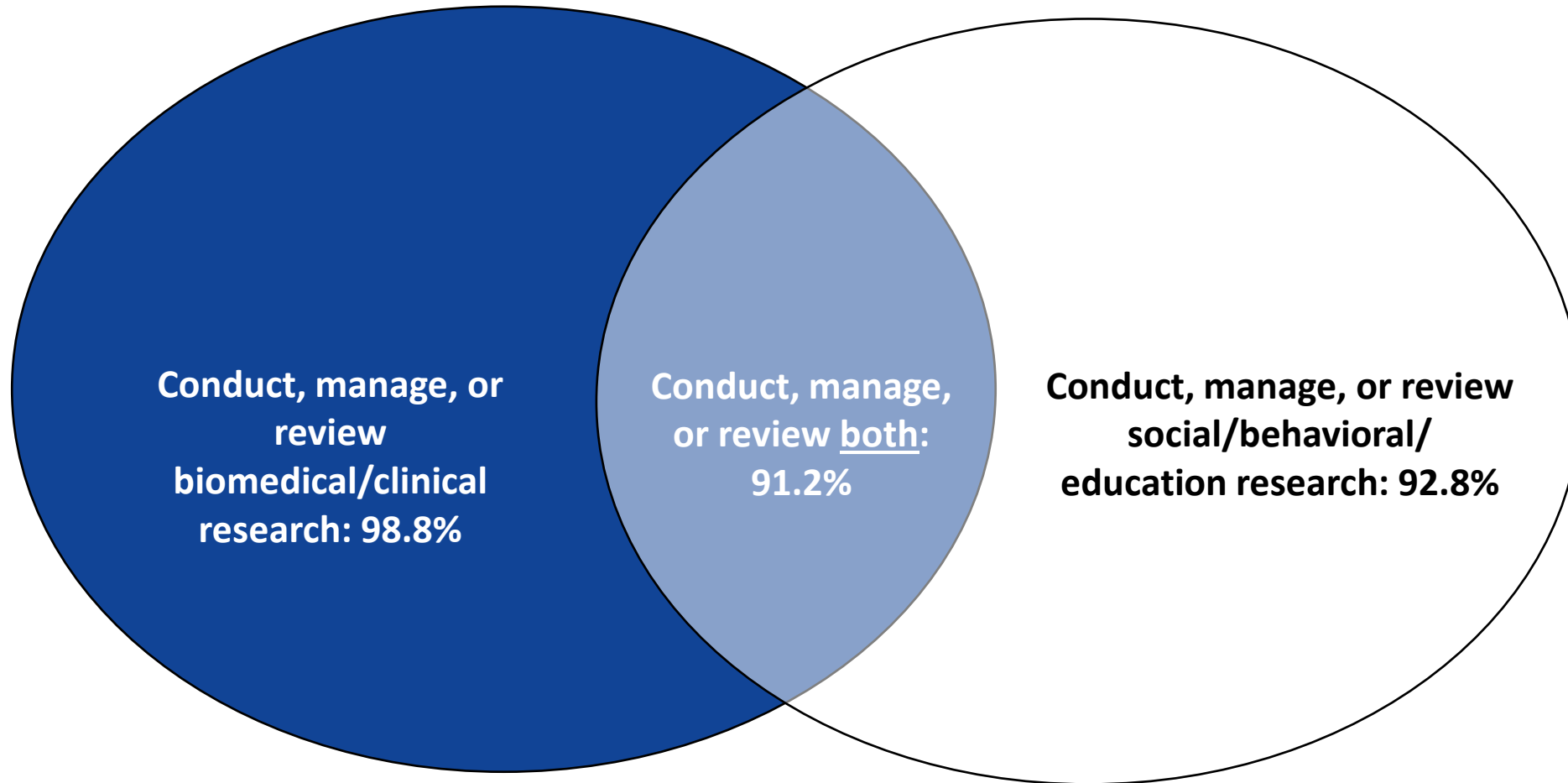
**Most organizations conduct, manage, or review
biomedical/clinical research**

98.8%

**Most organizations conduct, manage, or review
social/behavioral/education research**

92.8%

Type of Research Organizations Conduct, Manage, or Review



Biomedical/Clinical Research by Type

Drugs

94.0%

Devices

91.9%

Planned Emergency
Research

28.8%

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

Vulnerable Populations

| | |
|--------------------------|-------|
| Children | 96.0% |
| Pregnant Women | 92.0% |
| Employees | 92.8% |
| Adults Unable to Consent | 91.6% |
| Students | 89.6% |
| Prisoners | 60.0% |
| Other | 22.0% |

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

Industry sponsored

96.8%

Government or federally
sponsored

95.6%

Internally funded or
unfunded

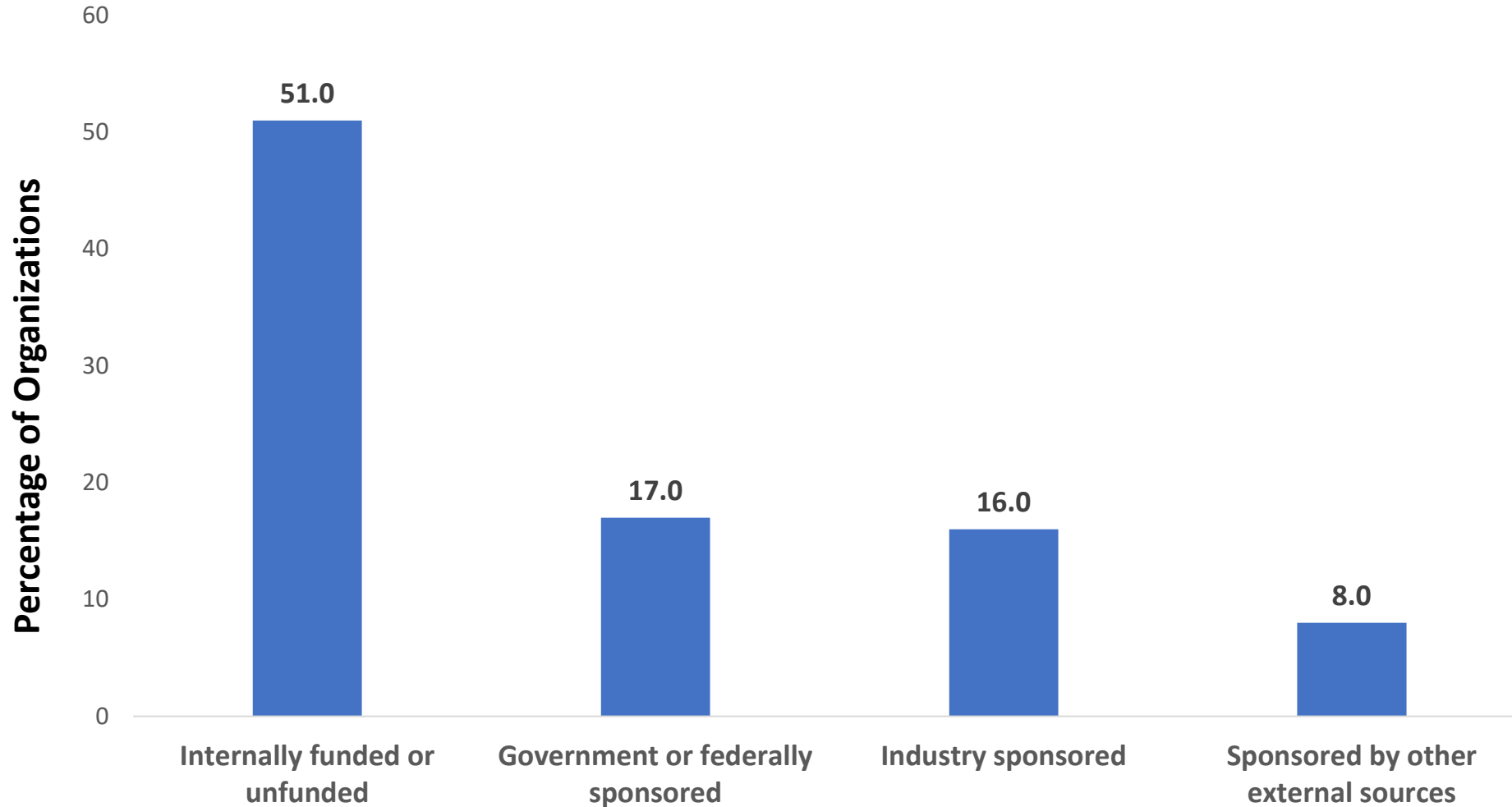
90.0%

Sponsored by other external
sources

90.0%

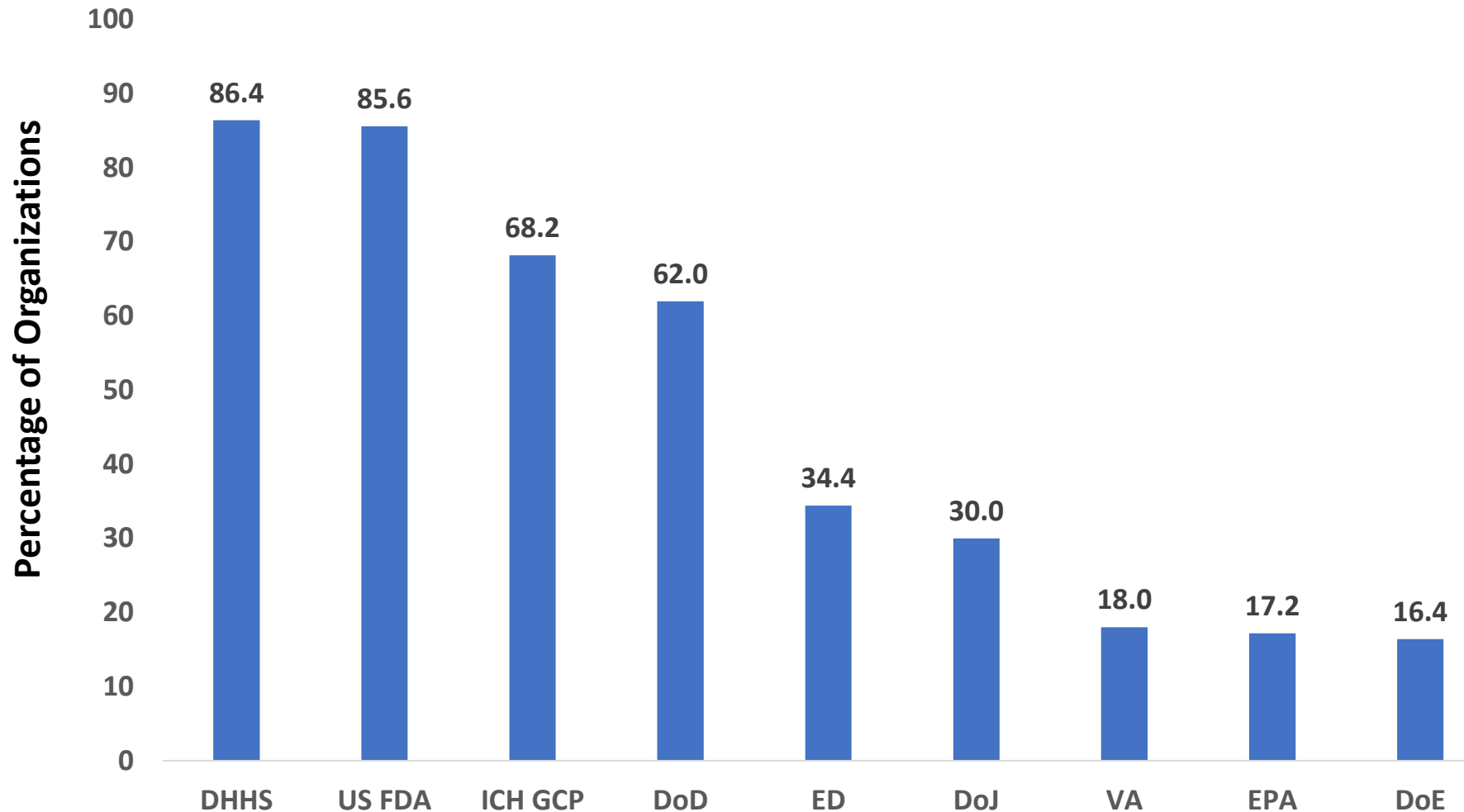
This table shows the percentage of organizations that conduct, review, or manage research by funding type that supports the research.

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 review, manage, or conduct.

Internal IRBs/ECs*

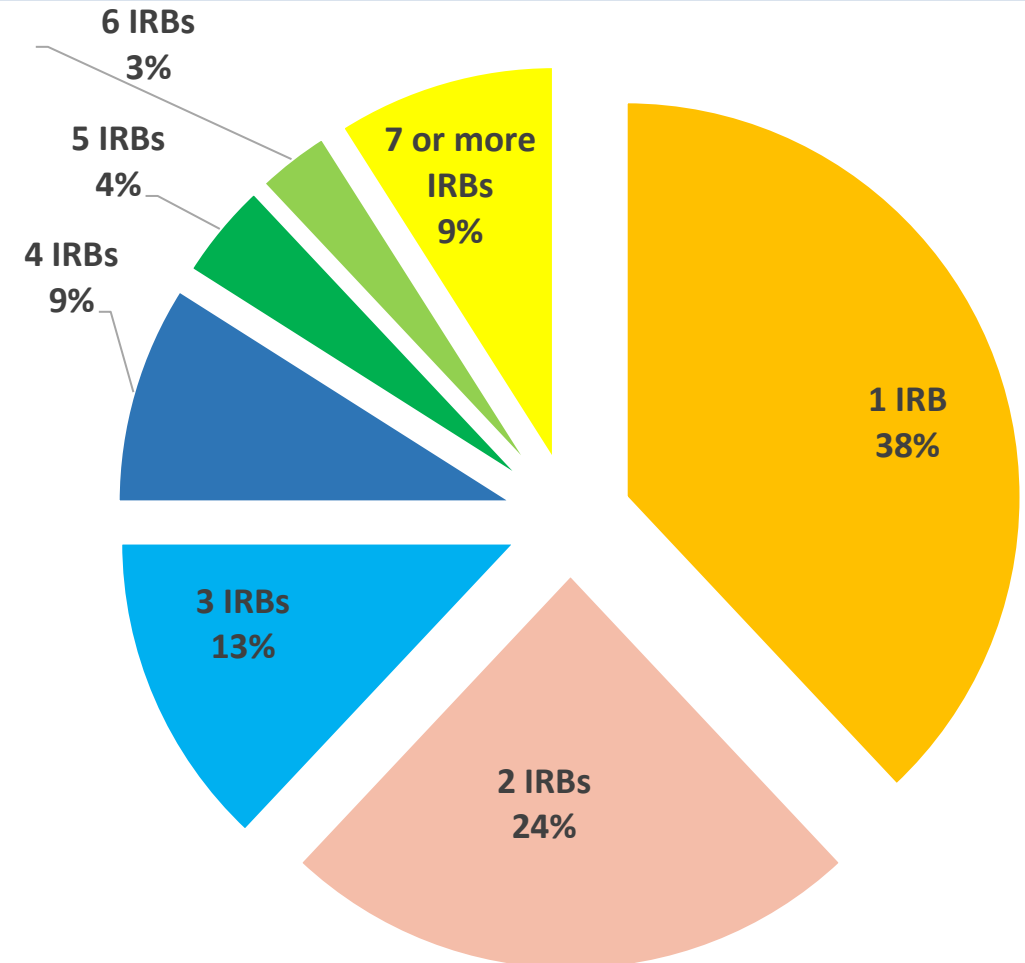
% of organizations
that have internal
IRBs

94.1%

Median # of
IRBs/ECs per
organization

2

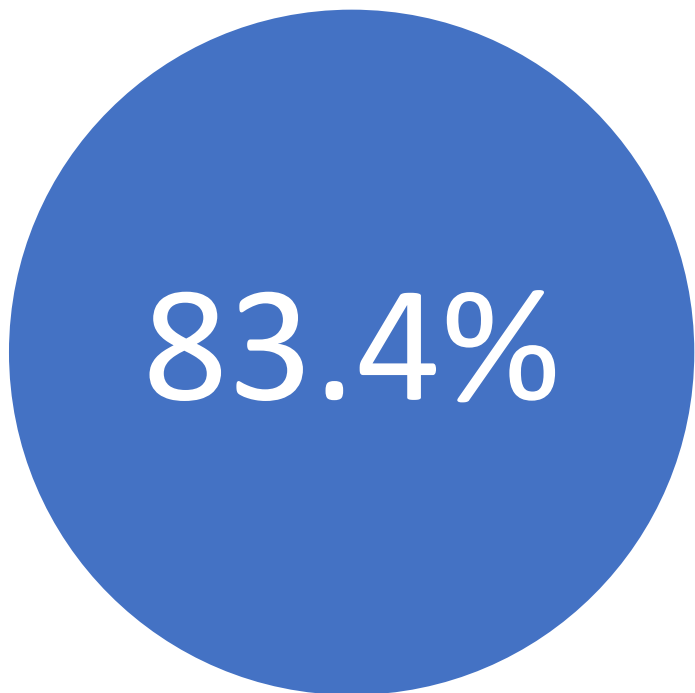
Number of internal IRBs/ECs organizations support



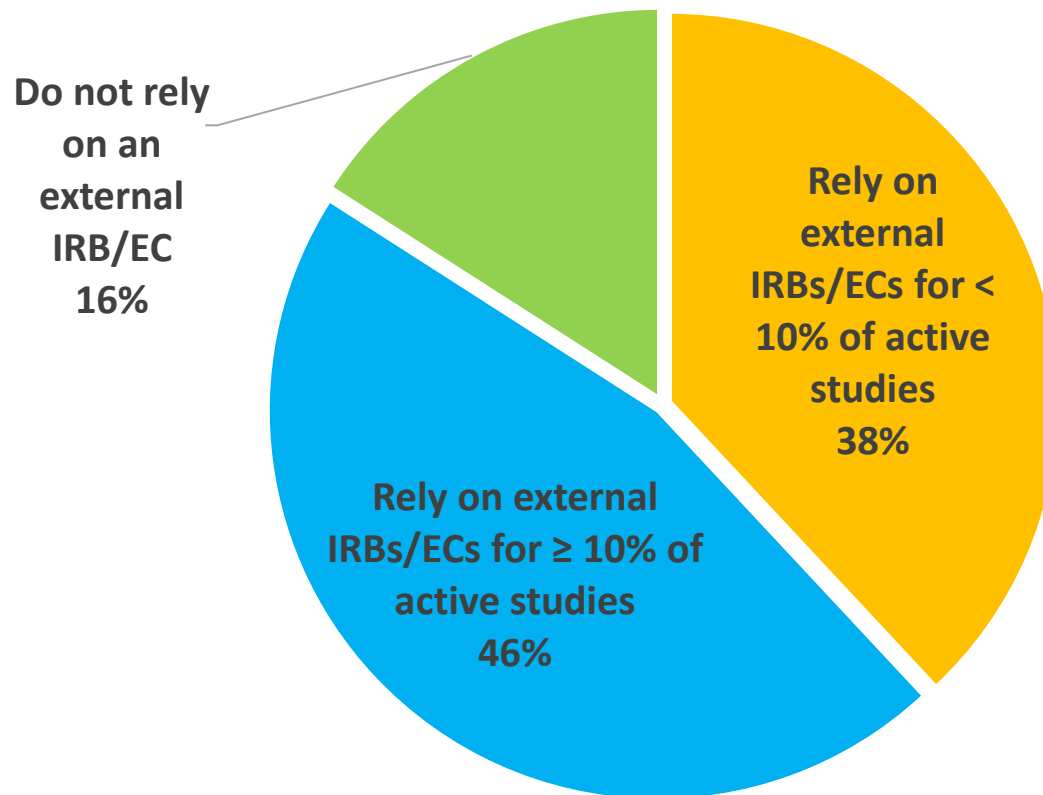
*Data exclude independent IRBs/ECs

Relying on External IRBs/ECs*

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



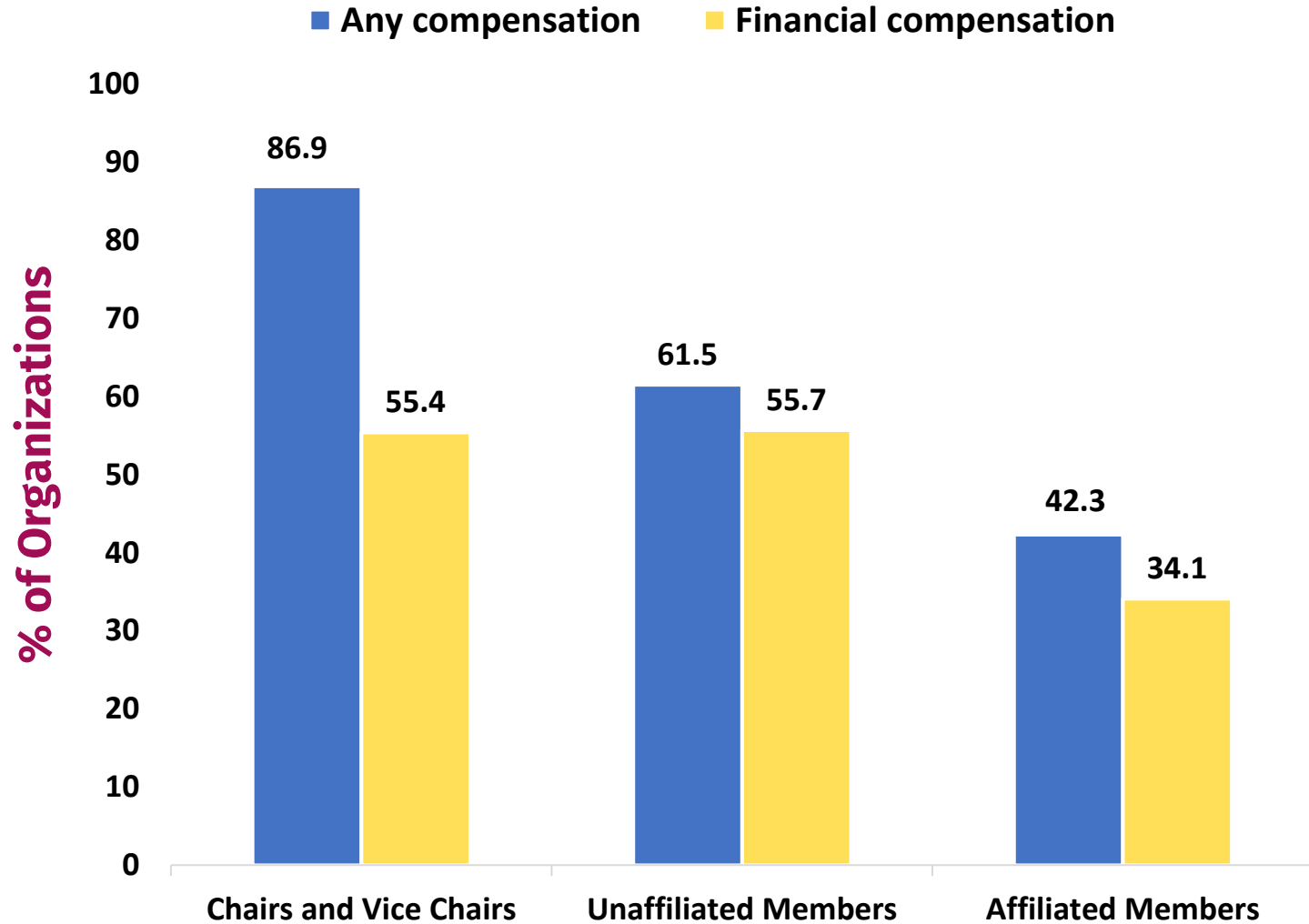
Use of external IRBs/ECs by organizations with internal IRBs/ECs



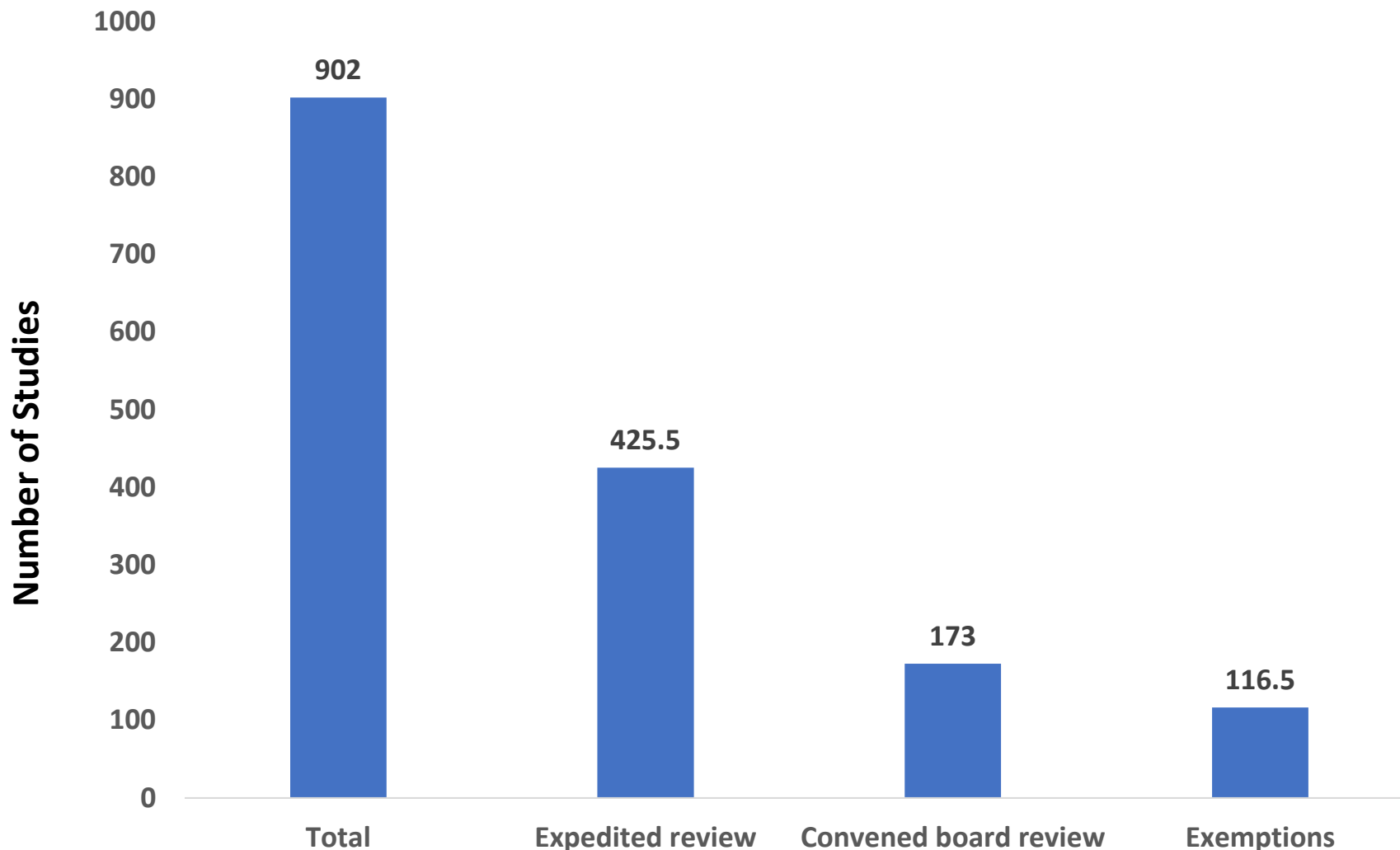
Compensating IRB/EC Members

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

87.8%



Active Studies Overseen: All Organizations



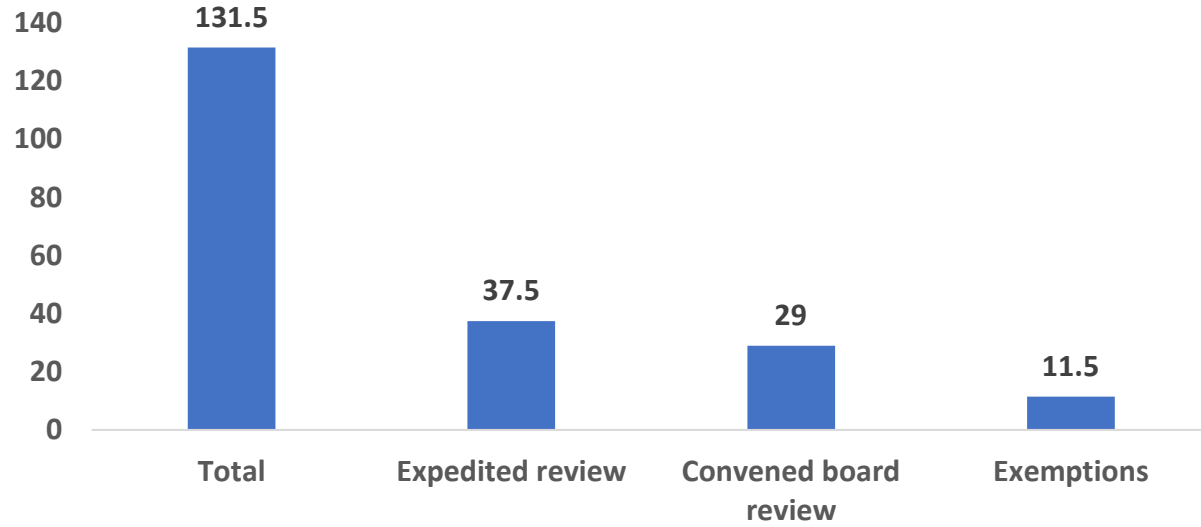
This chart shows the median number of active studies that organizations conduct, review, or manage by type of review.

Note:

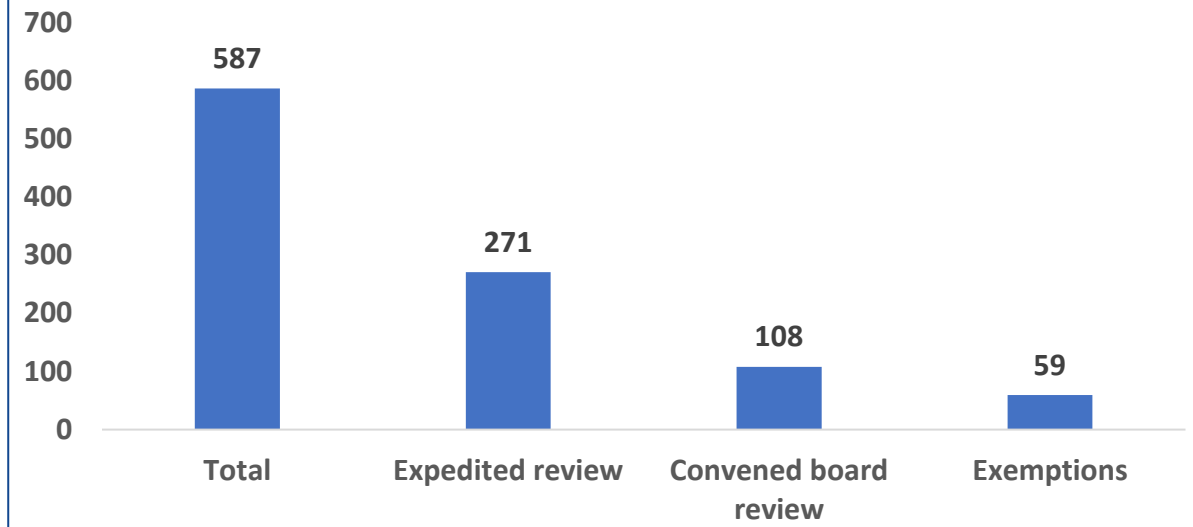
- Exemptions are based on the number of determinations made by an organization within 12 months of their most recent report to AAHRPP
- Total number of studies includes those reviewed by both internal and external IRBs/ECs in the case of organizations with IRBs/ECs

Median Number of Active Studies (by Quartile)

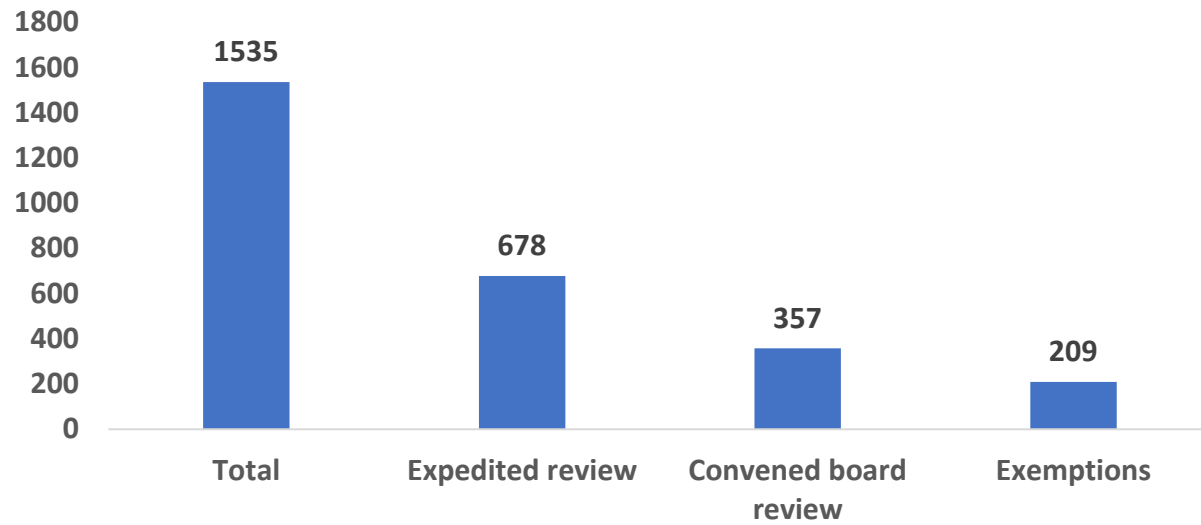
Quartile 1 (2-357 Studies)



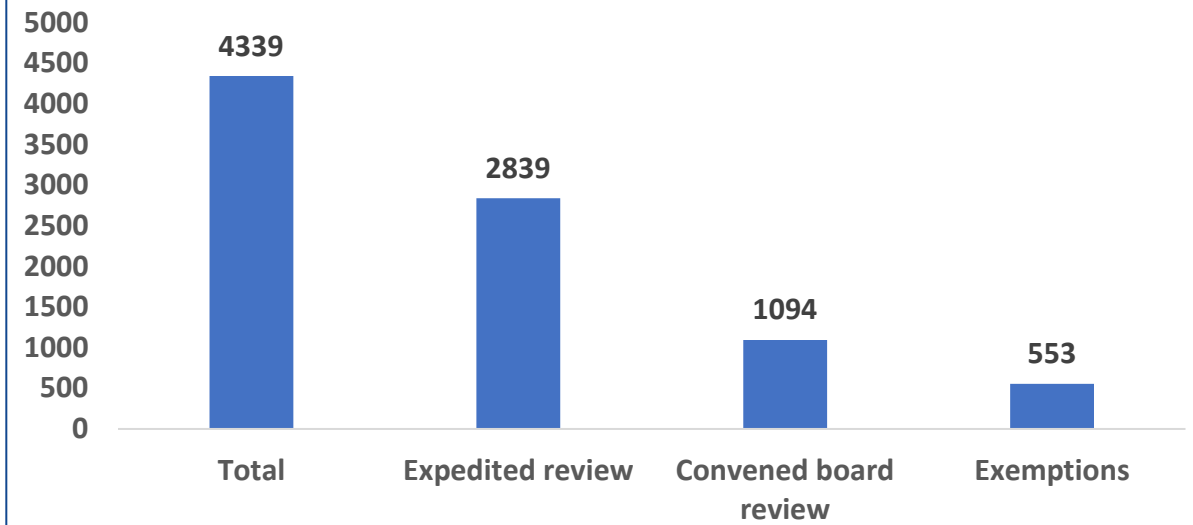
Quartile 2 (362-924 Studies)



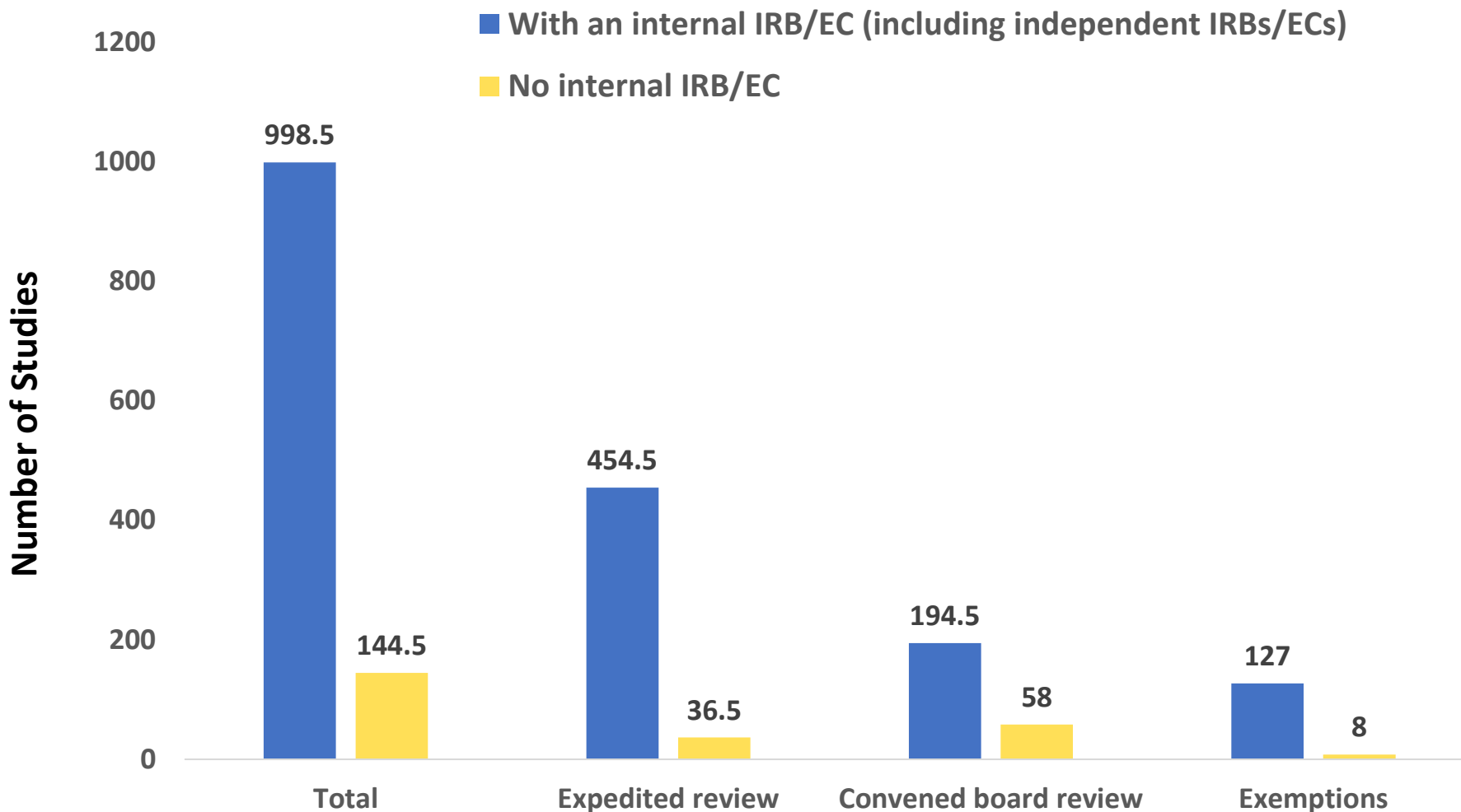
Quartile 3 (928-2368 Studies)



Quartile 4 (2455-13284 Studies)



Active Studies: Internal vs. External IRB/EC

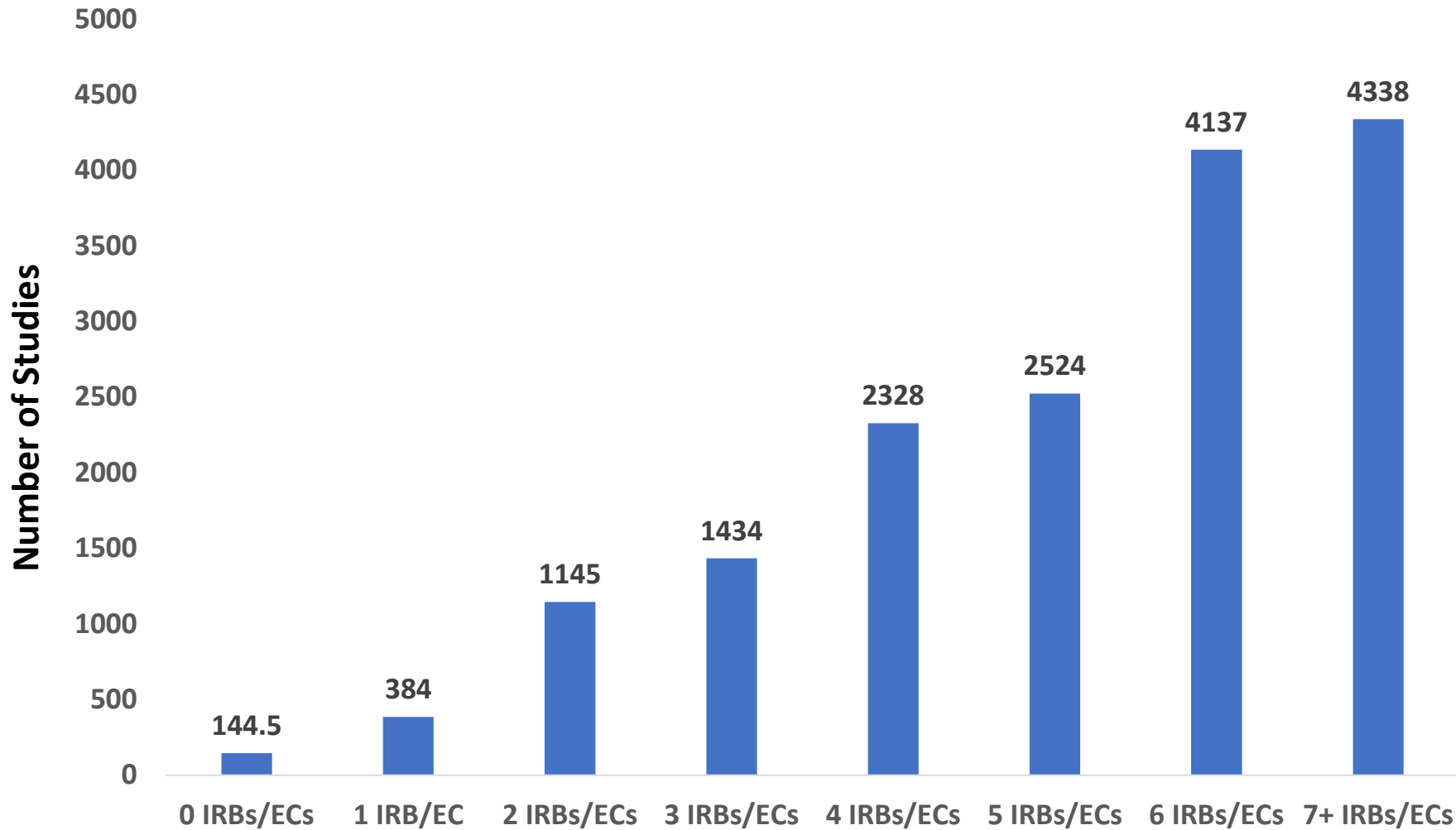


This chart shows the median number of active studies that organizations conduct, review, or manage by type of review based on whether they have an internal IRB/EC.

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

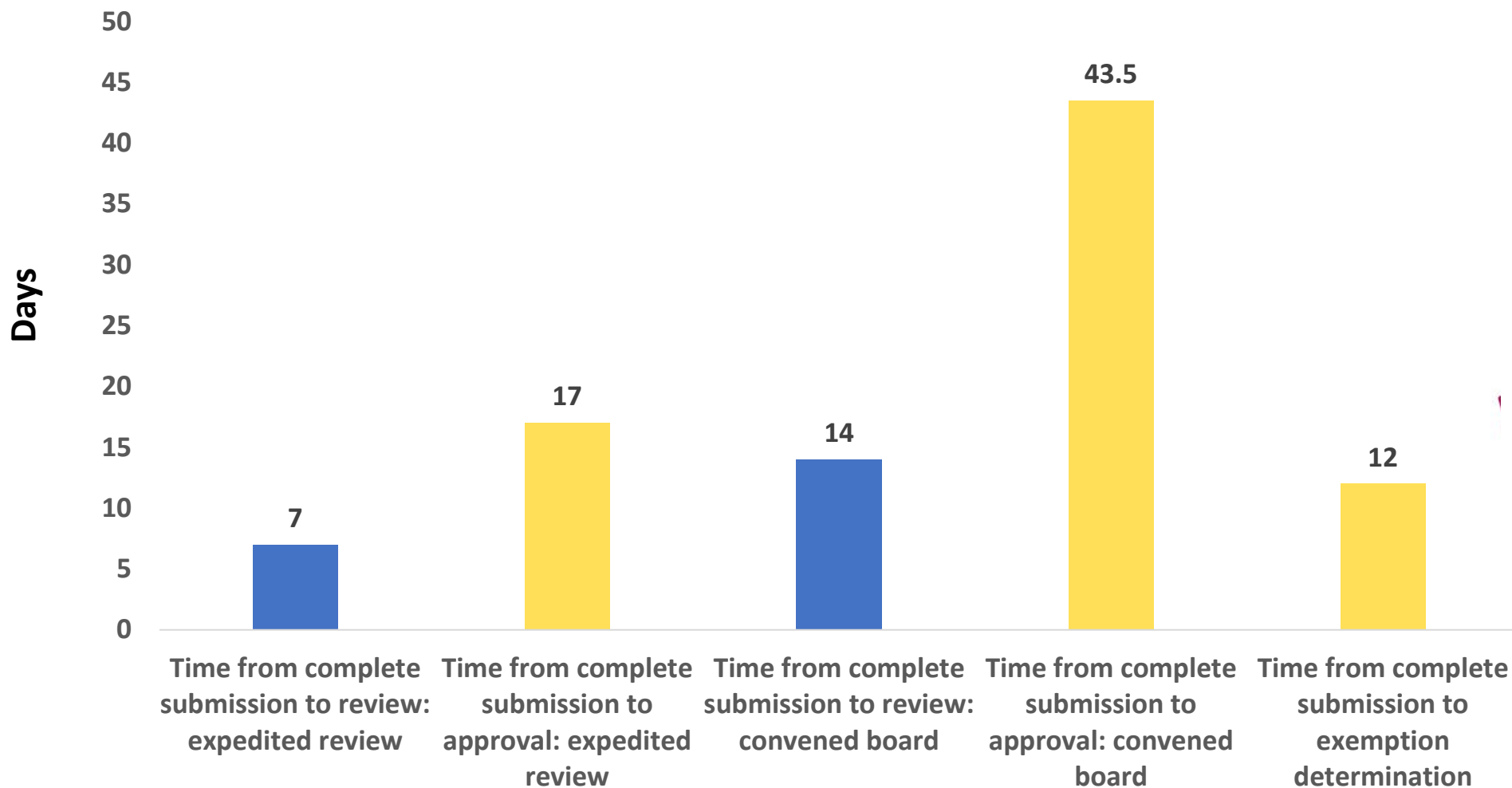


This chart shows the median number of active studies organizations oversee based on the number of IRBs/ECs.

Note:

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

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

IRB/EC Technology

Database for submission tracking

94.5%

Online protocol/materials distribution to
IRB/EC members

93.2%

Online application submission

91.1%

Online review functions

88.2%

Does not use an electronic system

2.1%

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 | 998.5 | 7 | 142.6 | \$542,932 |
| 0-100 | 47 | 2 | 23.5 | \$132,294 |
| 101-500 | 259 | 3 | 86.3 | \$190,430 |
| 501-1000 | 770 | 6 | 128.3 | \$522,932 |
| 1001-2000 | 1526 | 9 | 170.5 | \$674,583 |
| 2001-4000 | 2729 | 15 | 185.7 | \$1,303,358 |
| 4001+ | 6133 | 23.375 | 262.4 | \$2,490,849 |

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

Audits of Researchers

Median # of
researchers per
organization
with active
studies:

475.5

Median # of
research staff
per
organization:

396

% of
organizations
that reported
that audits of
researchers
occurred

86.8%

Internal:
"for cause"

- Median: 2
- Total: 940

Internal:
random

- Median: 12.5
- Total: 11,207

Regulatory
agency
inspections

- Median: 0
- Total: 213

Audits of IRBs/ECs

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

21.6%

Internal:
"for cause"

- Median: 0
- Total: 334

Internal:
random

- Median: 4
- Total: 4734

Regulatory
agency
inspections

- Median: 0
- Total: 48

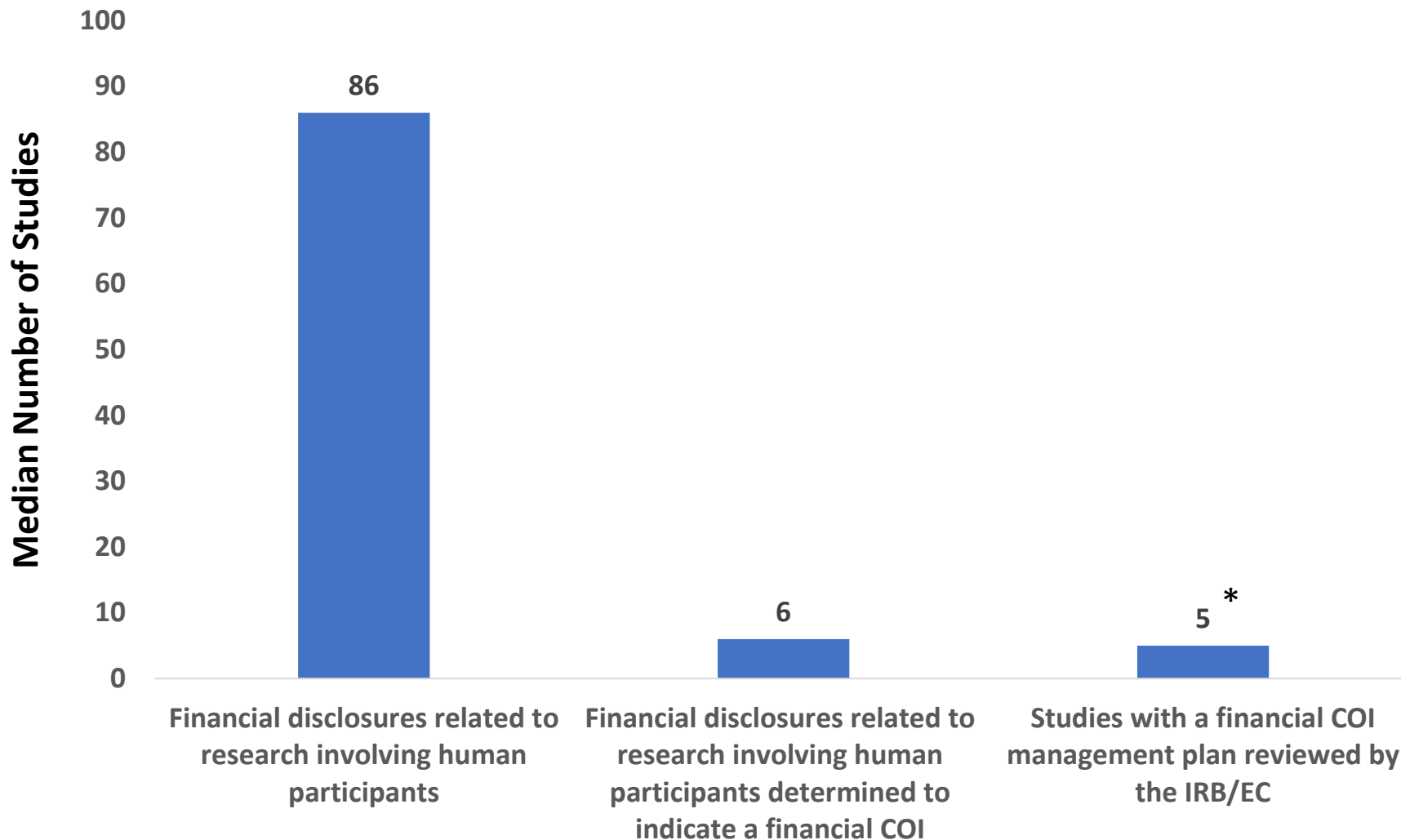
Unresolved Complaints, Noncompliance, & Unanticipated Problems

| 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 | 6 | 1 | 0 | 2 |
| | Total | 140 | 12009 | 1419 | 974 | 1760 |
| 0-100 | Median | 0 | 0 | 0 | 0 | 0 |
| | Total | 1 | 92 | 8 | 6 | 24 |
| 101-500 | Median | 0 | 4 | 1 | 0 | 1 |
| | Total | 0 | 2 | 1 | 0 | 0 |
| 501-1000 | Median | 0 | 4 | 1 | 0 | 1 |
| | Total | 25 | 2202 | 94 | 40 | 177 |
| 1001-2000 | Median | 0 | 11.5 | 2 | 1 | 1 |
| | Total | 23 | 3887 | 342 | 378 | 227 |
| 2001-4000 | Median | 0 | 10 | 4 | 1 | 5 |
| | Total | 21 | 2615 | 179 | 110 | 509 |
| 4001+ | Median | 1 | 28 | 6 | 2 | 8.5 |
| | Total | 64 | 2533 | 716 | 409 | 541 |

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