



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

2021 Metrics for AAHRPP-Accredited Human Research Protection Programs

Academic Organizations

June 2022



Metrics About Academic Organizations

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 academic organizations.

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

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

Abbreviations Used

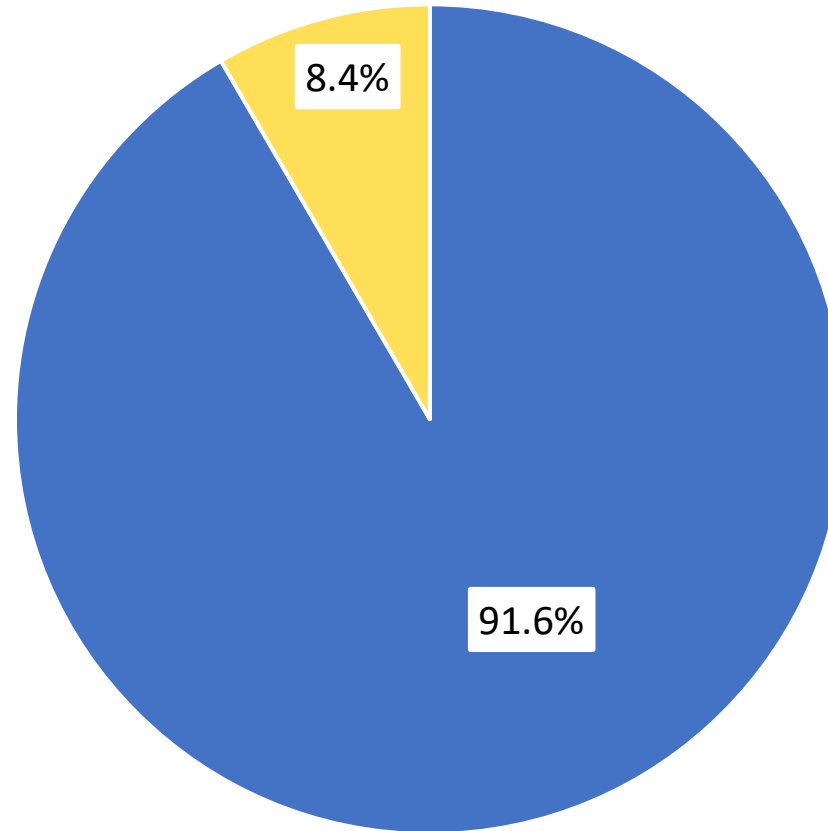
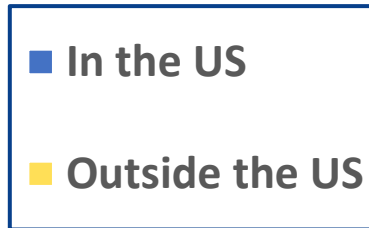
DHHS	US Department of Health & Human Services
DoD	US Department of Defense
ED	US Department of Education
DoE	US Department of Energy
DoJ	US Department of Justice
EPA	US Environmental Protection Agency
FDA	US Food and Drug Administration
ICH GCP	International Conference on Harmonisation Good Clinical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



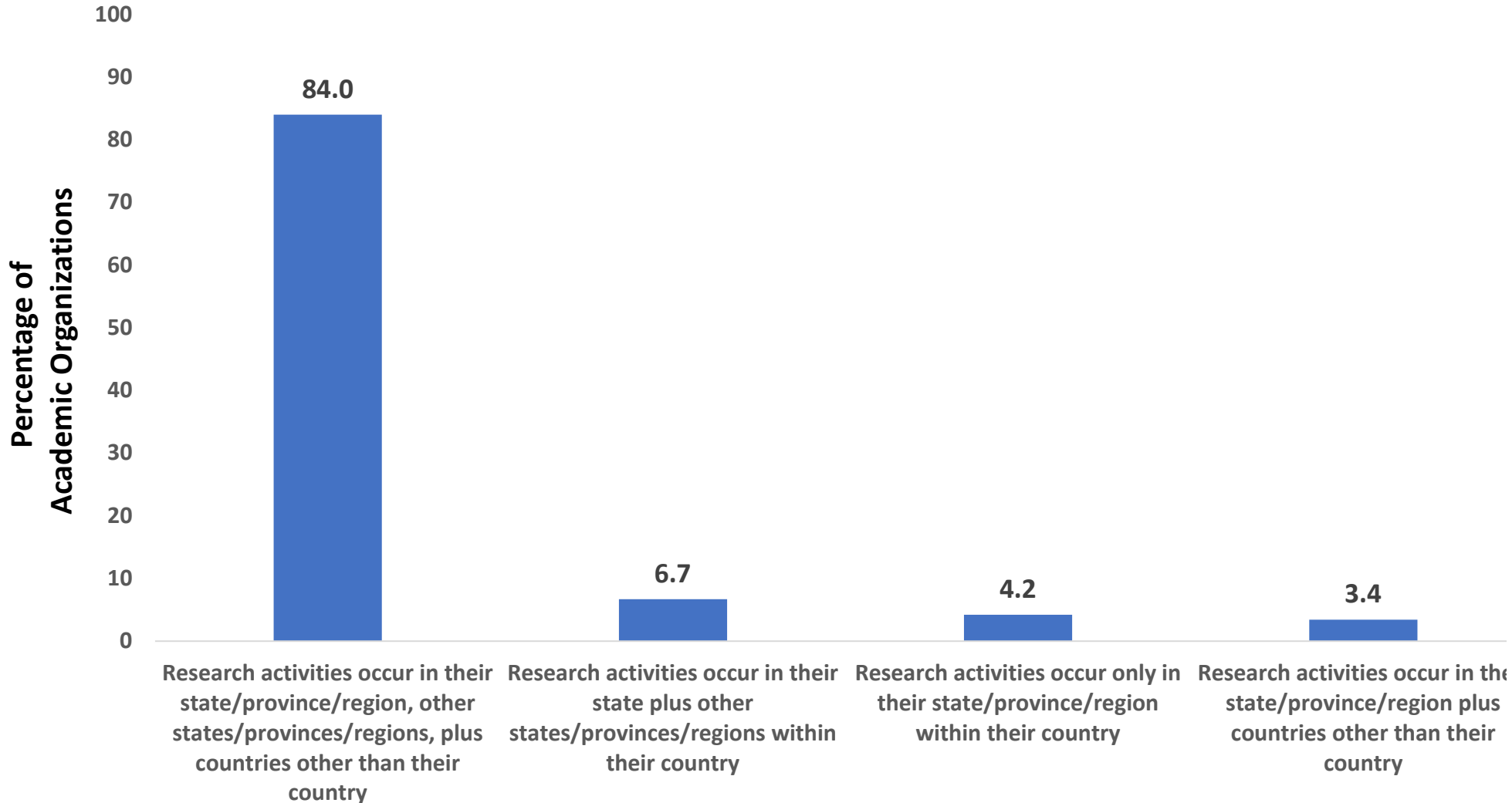
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Where Accredited Academic Organizations are Based



Where Research Occurs



This chart shows where research occurs that academic organizations conduct or review.

The majority conduct or review transnational research.

Research Type

**Most academic organizations
conduct or review
biomedical/clinical research**

99.2%

**Most academic organizations
conduct or review
social/behavioral/education research**

97.5%

Biomedical/Clinical Research by Type

Drugs

89.8%

Devices

89.8%

Planned Emergency
Research

36.4%

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

Vulnerable Populations

Children	99.2%
Students	99.2%
Adults Unable to Consent	96.6%
Employees	96.6%
Pregnant Women	96.6%
Prisoners	87.4%
Other	13.9%

This table shows the categories of vulnerable populations that participate in research conducted or reviewed by academic organizations. Populations Organizations also identified as vulnerable (i.e., “Other”) include Native Americans, neonates of uncertain viability, those who are educationally or economically disadvantaged, military personnel and veterans, non-English speakers, hospitalized persons, individuals who are physically disabled or impaired, participants who are institutionalized, individuals who are engaged in or intending to engage in illegal or stigmatizing behavior, and undocumented or refugee populations.

Funding Type

Internally funded or
unfunded

100%

Government or federally
sponsored

98.3%

Industry sponsored

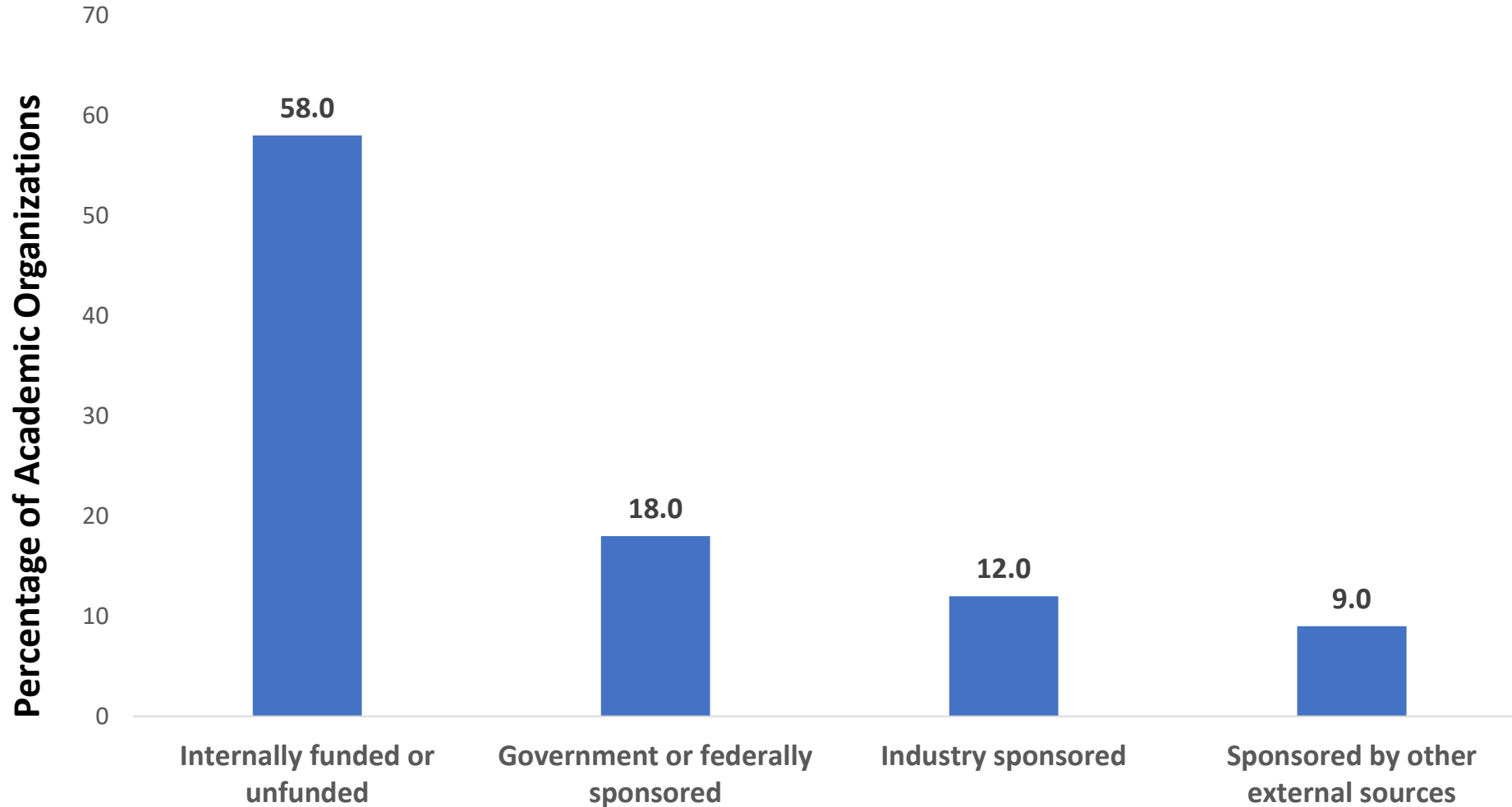
98.3%

Sponsored by other external
sources

97.5%

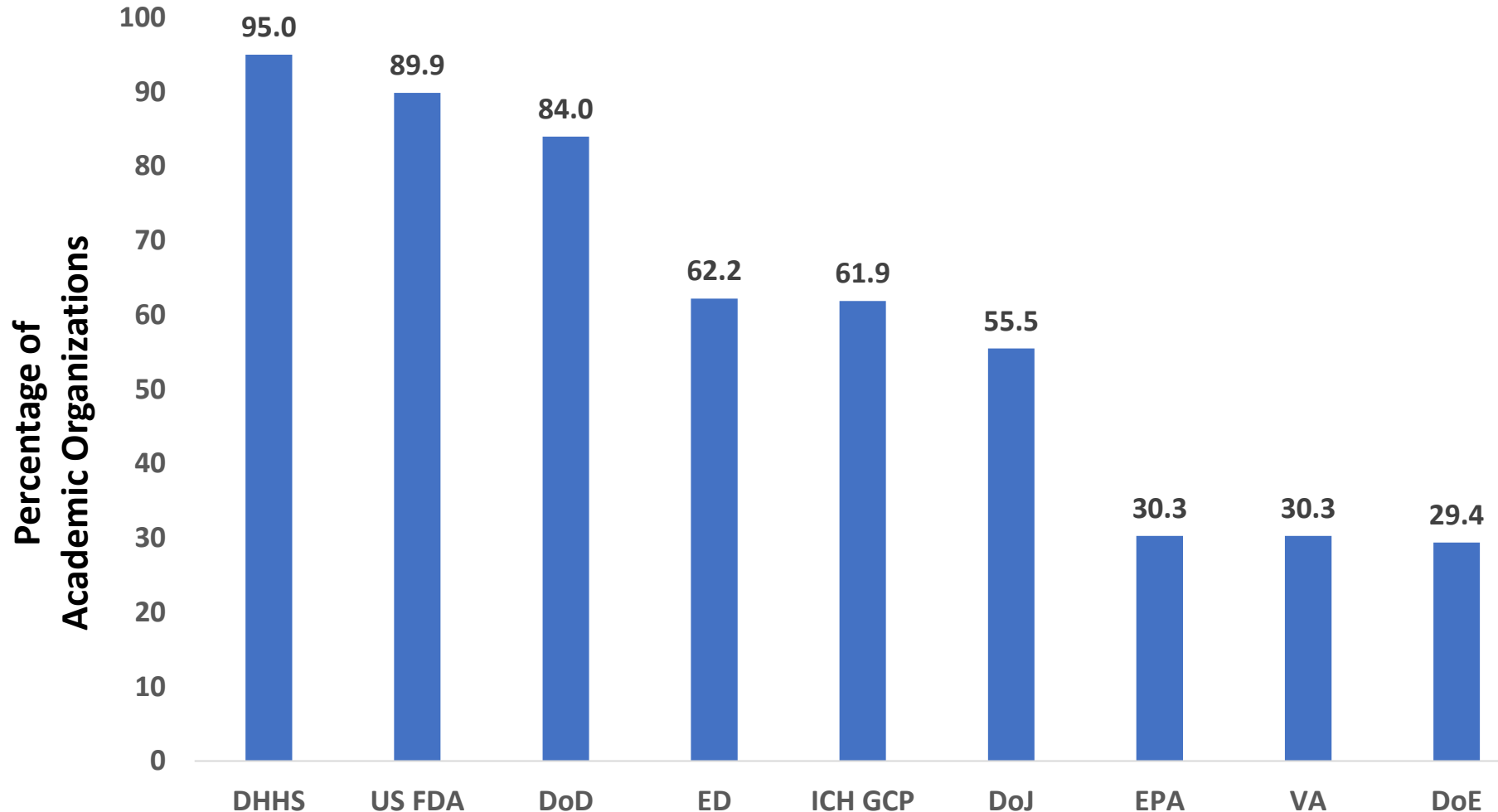
This table shows the percentage of academic organizations that conduct or review research by funding type that supports the research.

Funding Distribution



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

Regulations & Guidelines



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

Internal IRBs/ECs

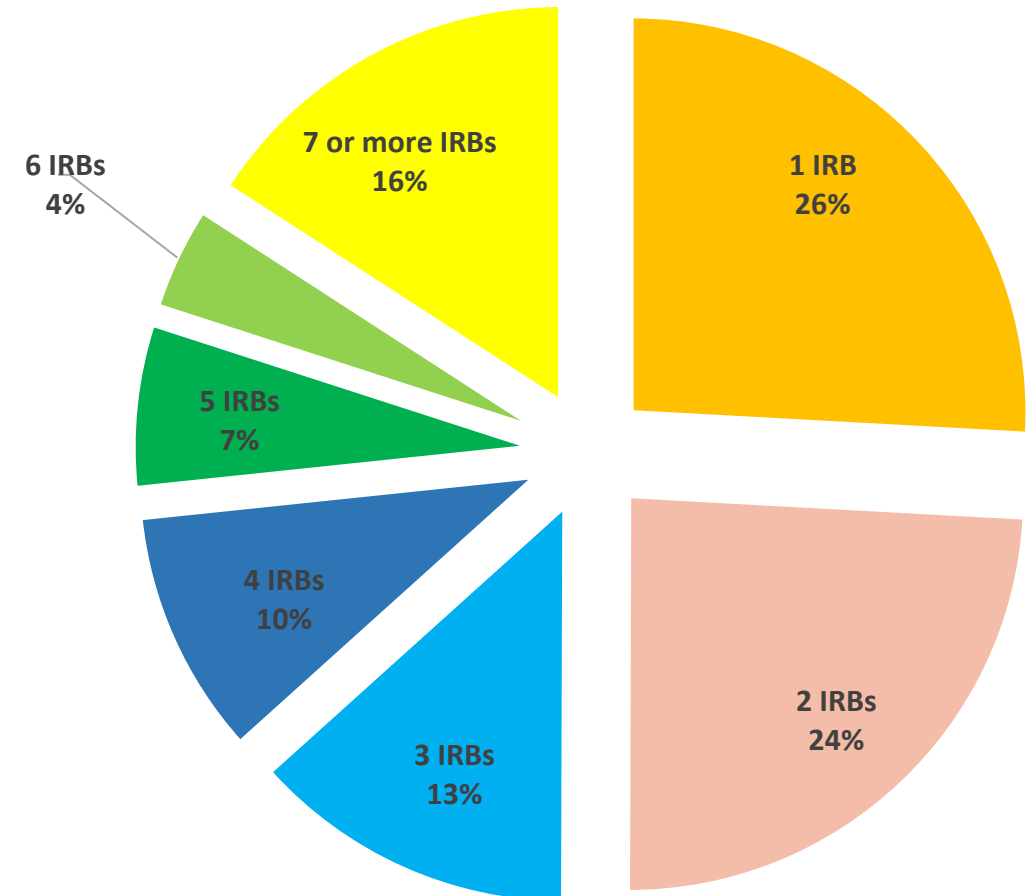
% of academic organizations that have internal IRBs

100%

Median # of IRBs/ECs per academic organization

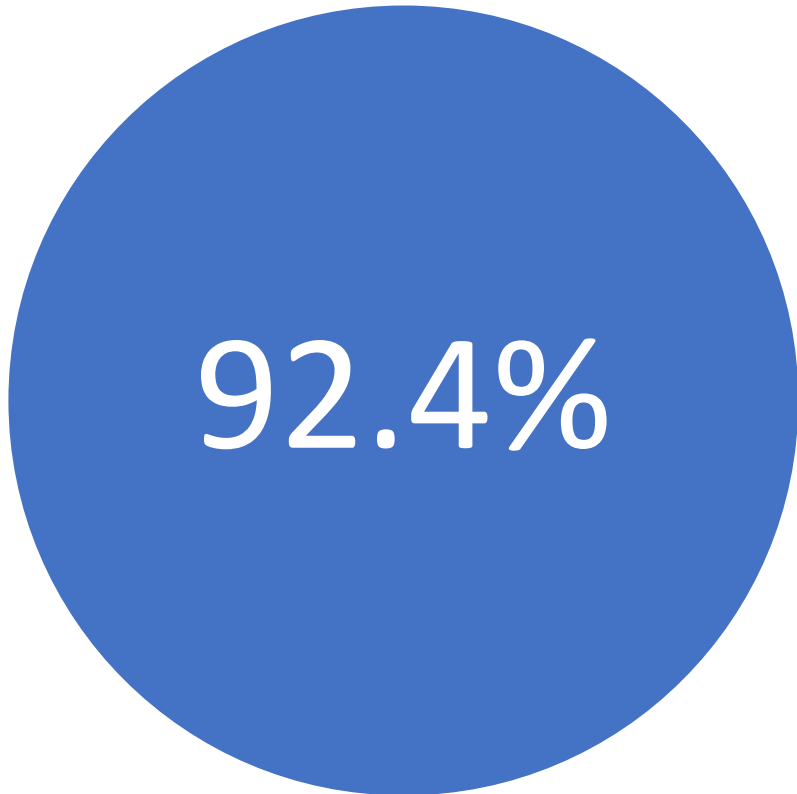
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Number of internal IRBs/ECs % of academic organizations support

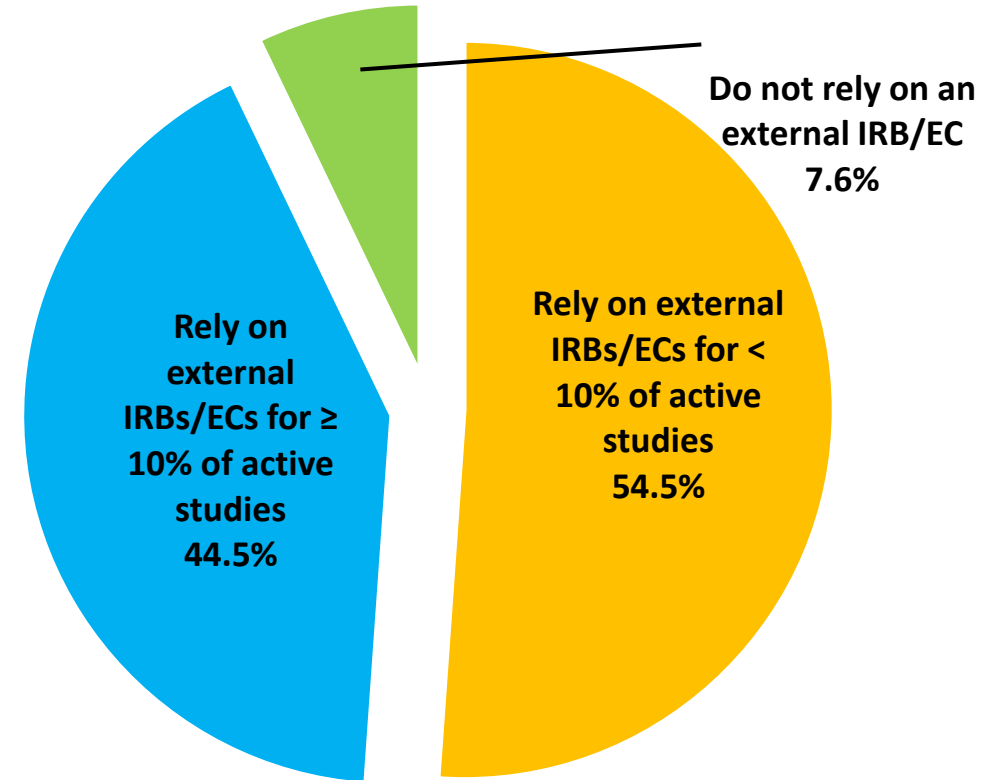


Relying on External IRBs/ECs

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



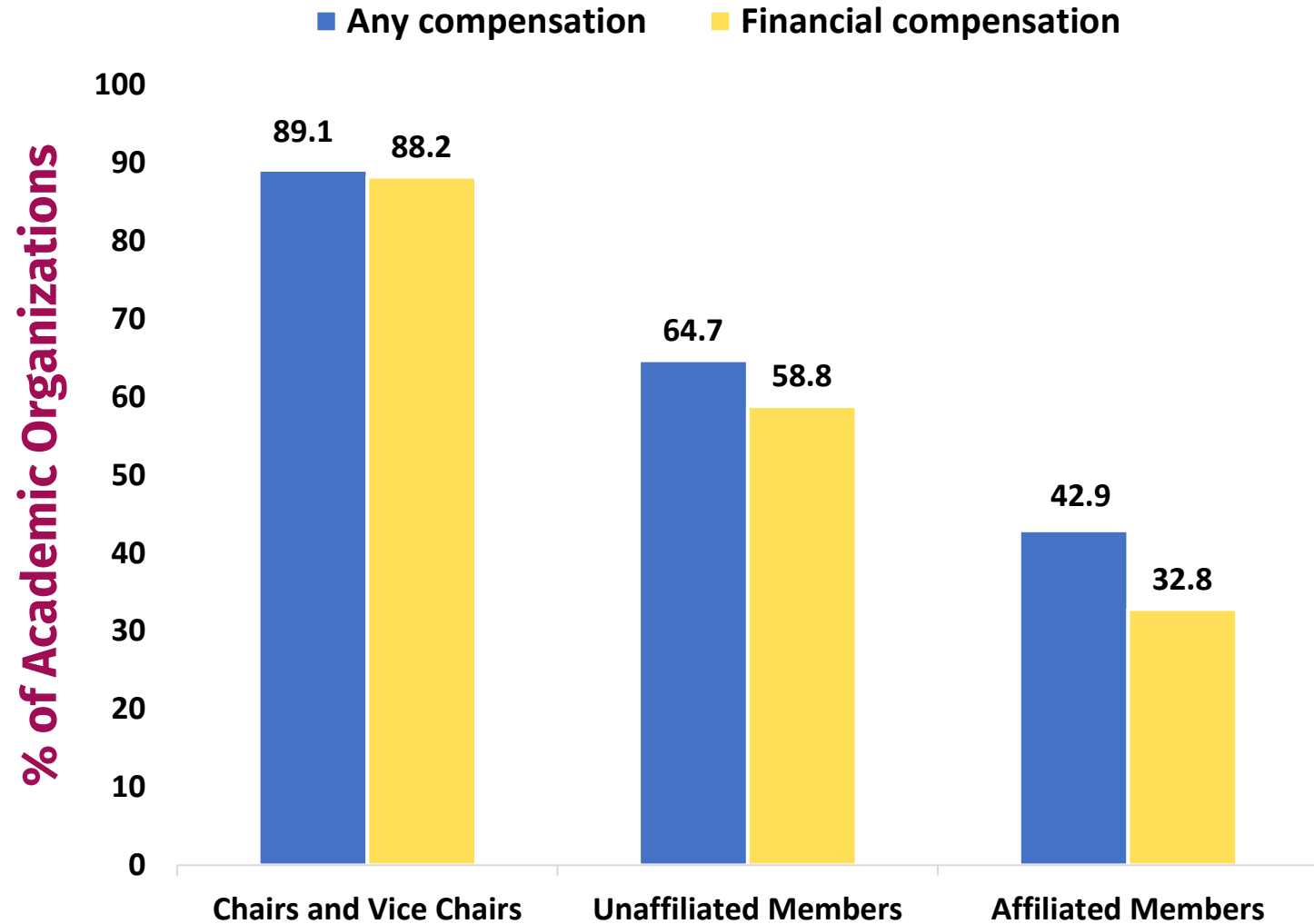
**Use of external IRBs/ECs
by academic organizations with internal IRBs/ECs**



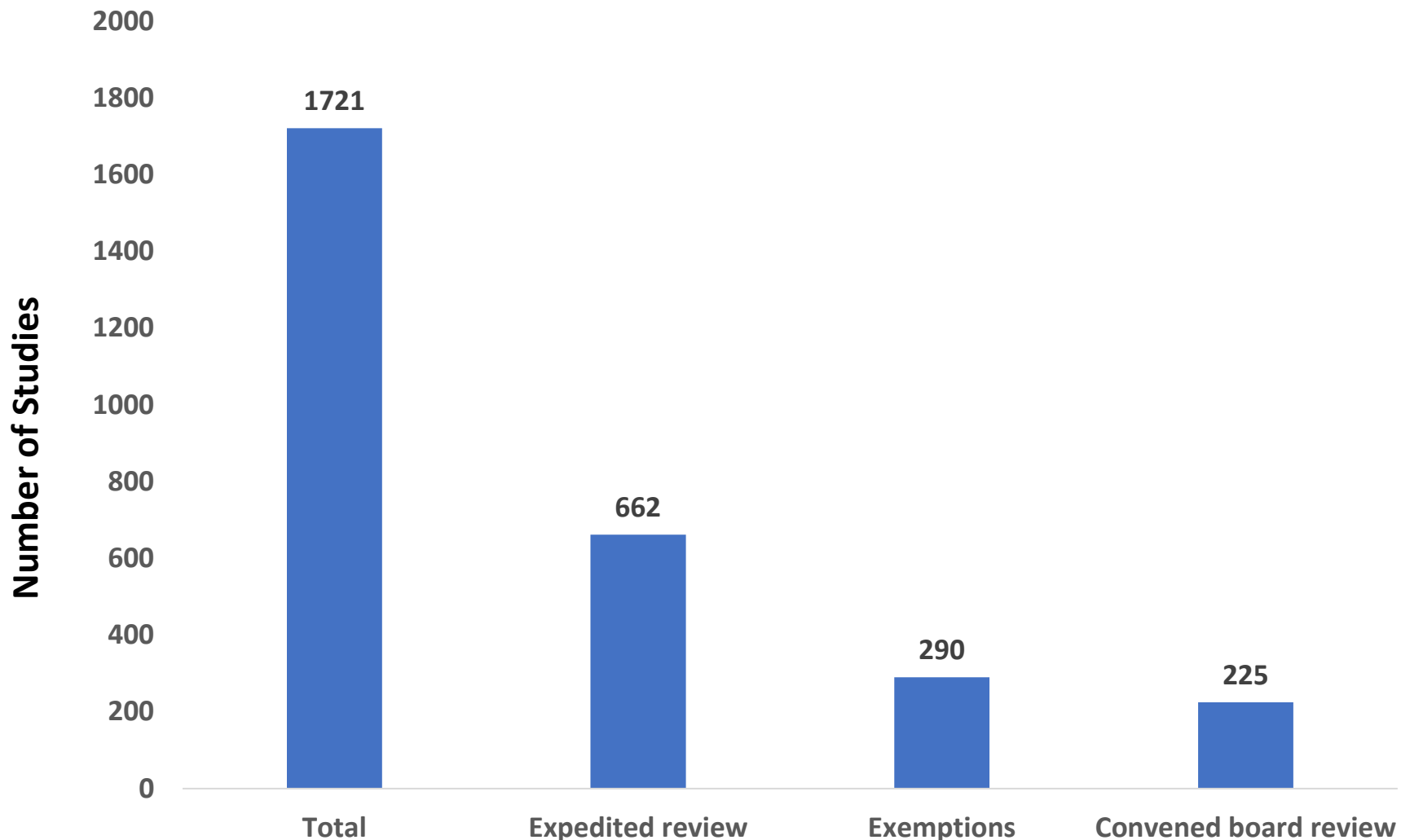
Compensating IRB/EC Members

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

91.5%



Active Studies Overseen: All Academic Organizations

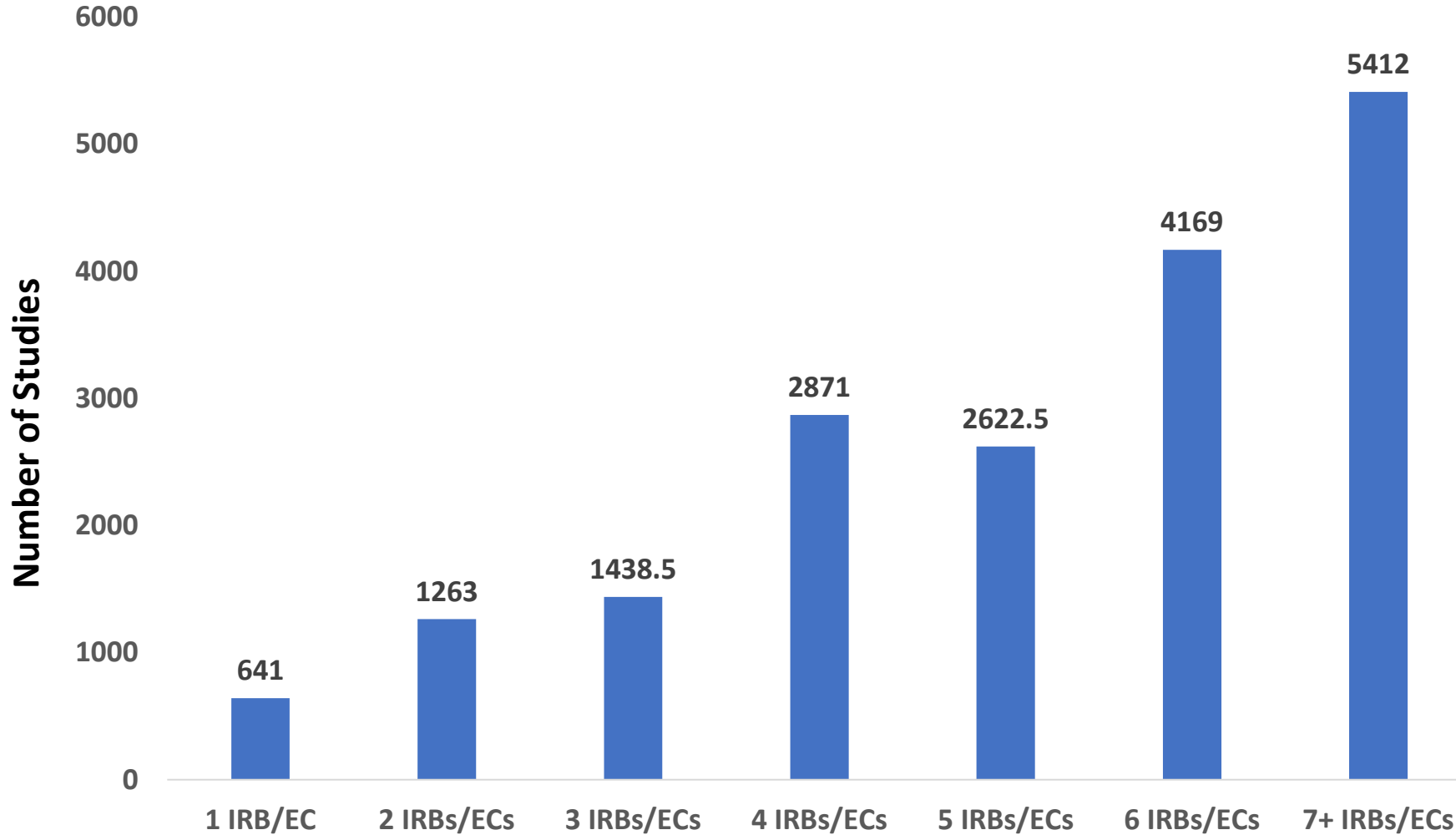


This chart shows the median number of active studies that academic organizations conduct or review by type of review.

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

Active Studies Per IRB/EC

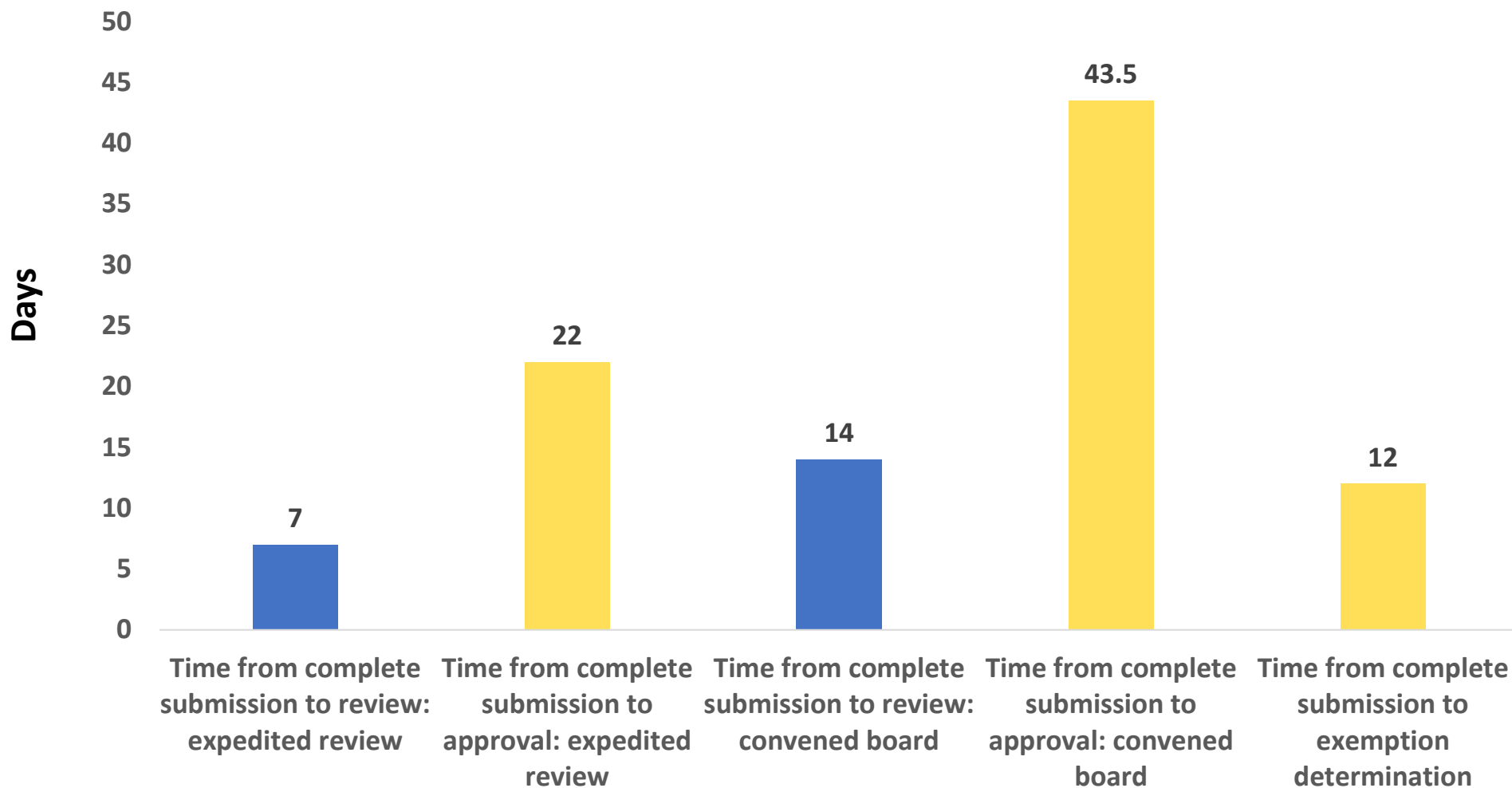


This chart shows the median number of active studies academic organizations oversee based on the number of IRBs/ECs they have.

Note

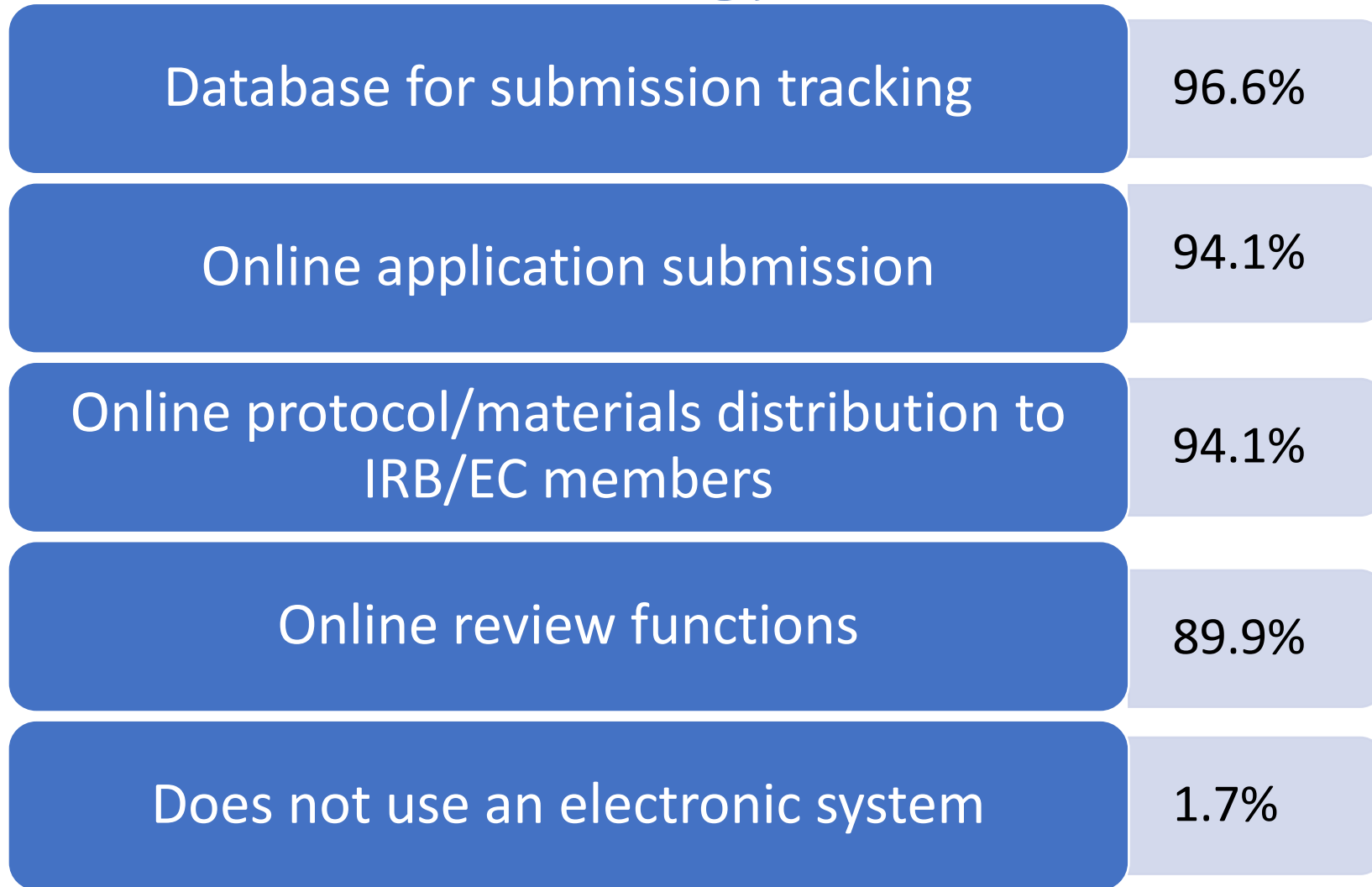
- Total number of studies for organizations includes those reviewed by both internal and external IRBs/ECs

Review Times



This chart shows the median review times by review process for academic organizations.

IRB/EC Technology



This table shows the technology academic organizations 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	1721	9.5	181.2	\$670,000
0-500	248.5	2.8	89.5	\$170,600
501-1000	775	5	155	\$465,346
1001-2000	1467	8.5	172.6	\$678,893
2001-4000	2852	13	219.4	\$1,349,795
4001+	6133	23.4	262.4	\$2,422,615

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



Audits of Researchers

Median # of
researchers per
organization
with active
studies:

870

Median # of
research staff
per
organization:

1246

% of
organizations
that reported
that audits of
researchers
occurred

89.9%

Internal:
"for cause"

- Median: 2
- Total: 387

Internal:
random

- Median: 19
- Total: 5844

Regulatory
agency
inspections

- Median: 0
- Total: 110

Audits of IRBs/ECs

% of organizations
that reported that
audits of IRB/EC
records occurred
(by internal or
external sources):

78.2%

Internal:
"for cause"

- Median: 0
- Total: 253

Internal:
random

- Median: 6.5
- Total: 3203

Regulatory
agency
inspections

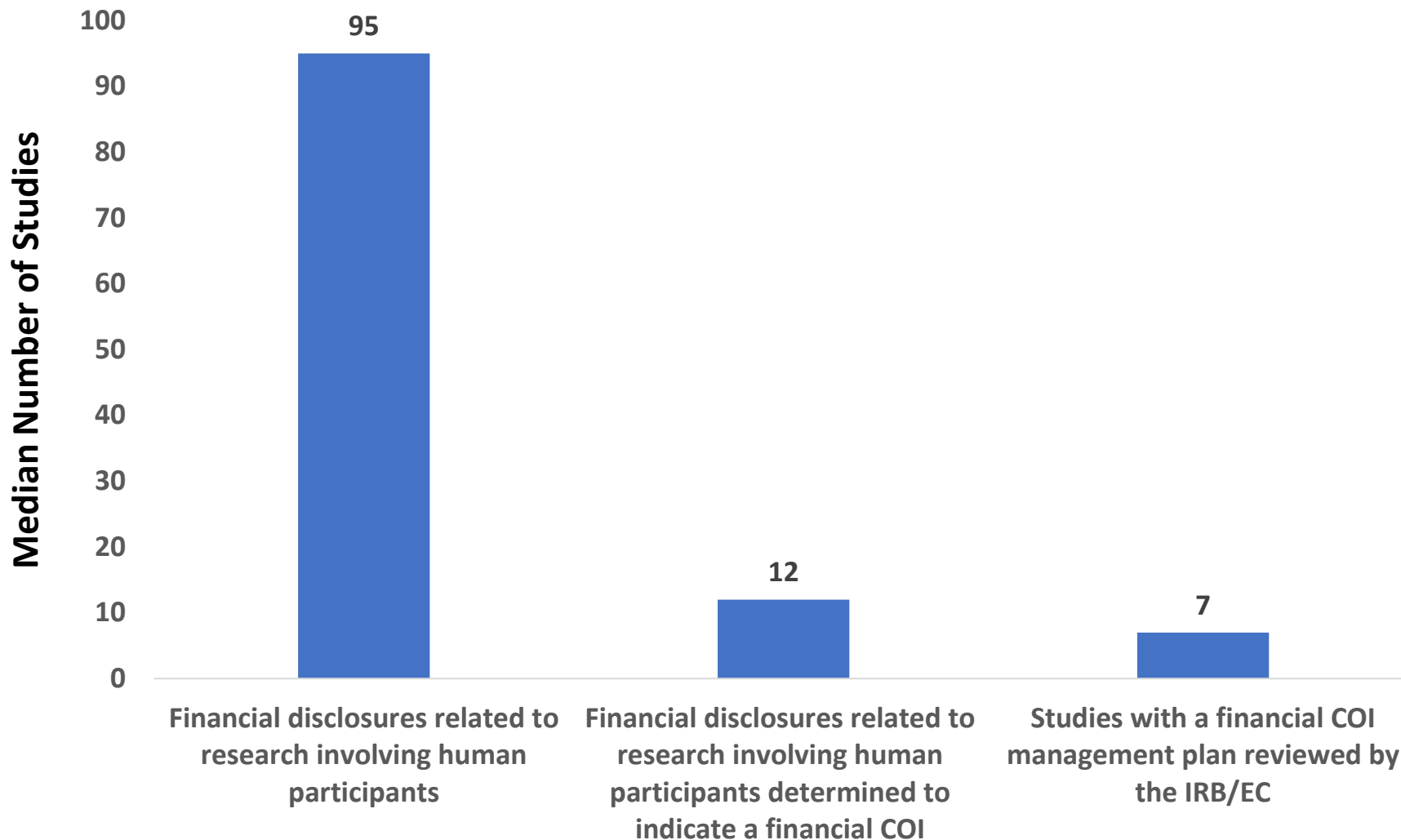
- Median: 0
- Total: 25

Unresolved Complaints, Noncompliance, & Unanticipated Problems

Number of active studies	Unresolved complaints	Investigations of alleged noncompliance	Serious noncompliance determinations	Continuing noncompliance determinations	Unanticipated problems determinations
All	0	10	2	1	2
0-500	0	2	0	0	1
501-1000	0	4	2	1	1
1001-2000	0	26	2	1	1
2001-4000	0	10	2.5	0.5	6
4001+	1	28	6	2.5	4.5

This table is based on the 12 months prior to an academic organization's most recent report to AAHRPP and shows the median number of events per category.

Conflicts of Interest



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