



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

2020 Metrics for AAHRPP-Accredited Human Research Protection Programs

Hospitals

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 hospitals.

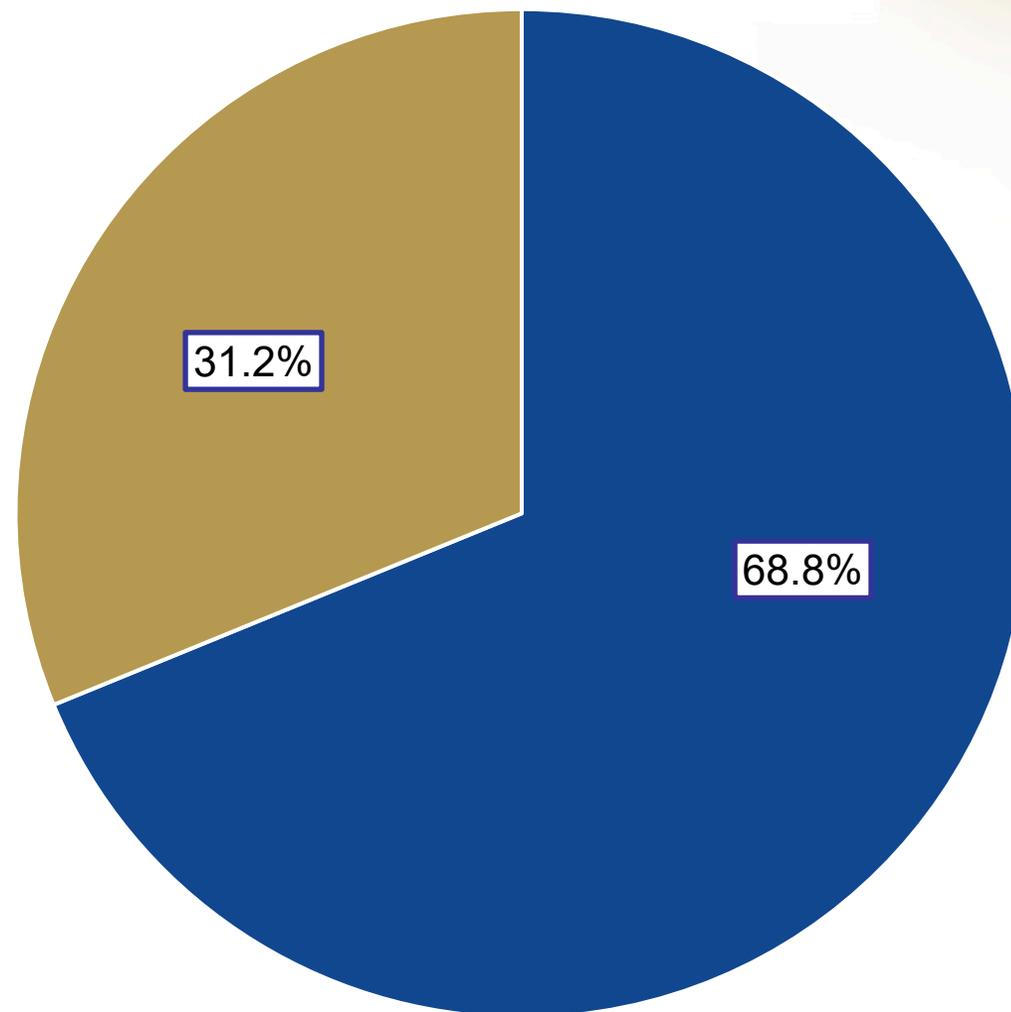
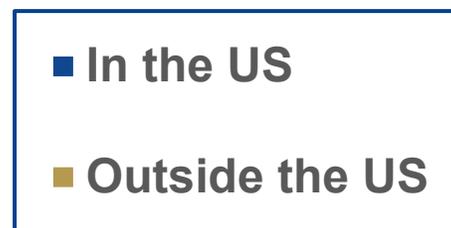
All the quantitative data were derived from the most recent reports by AAHRPP organizations.

Data were selected based on what most accurately reflected accredited hospitals in 2020.

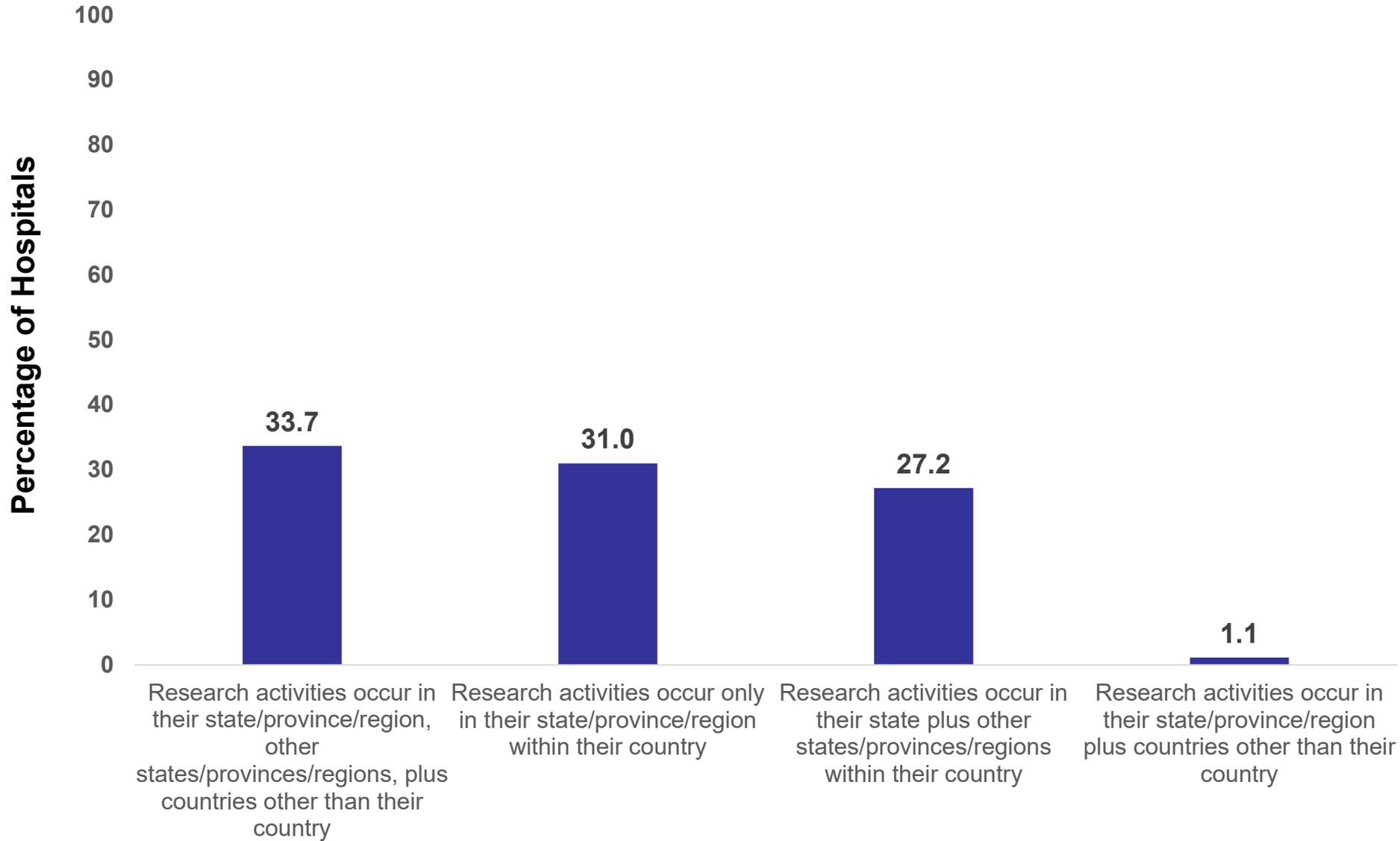
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Where Accredited Hospitals are Based



Where Research Occurs



This graph shows where research occurs that hospitals conduct or review.

Research Type

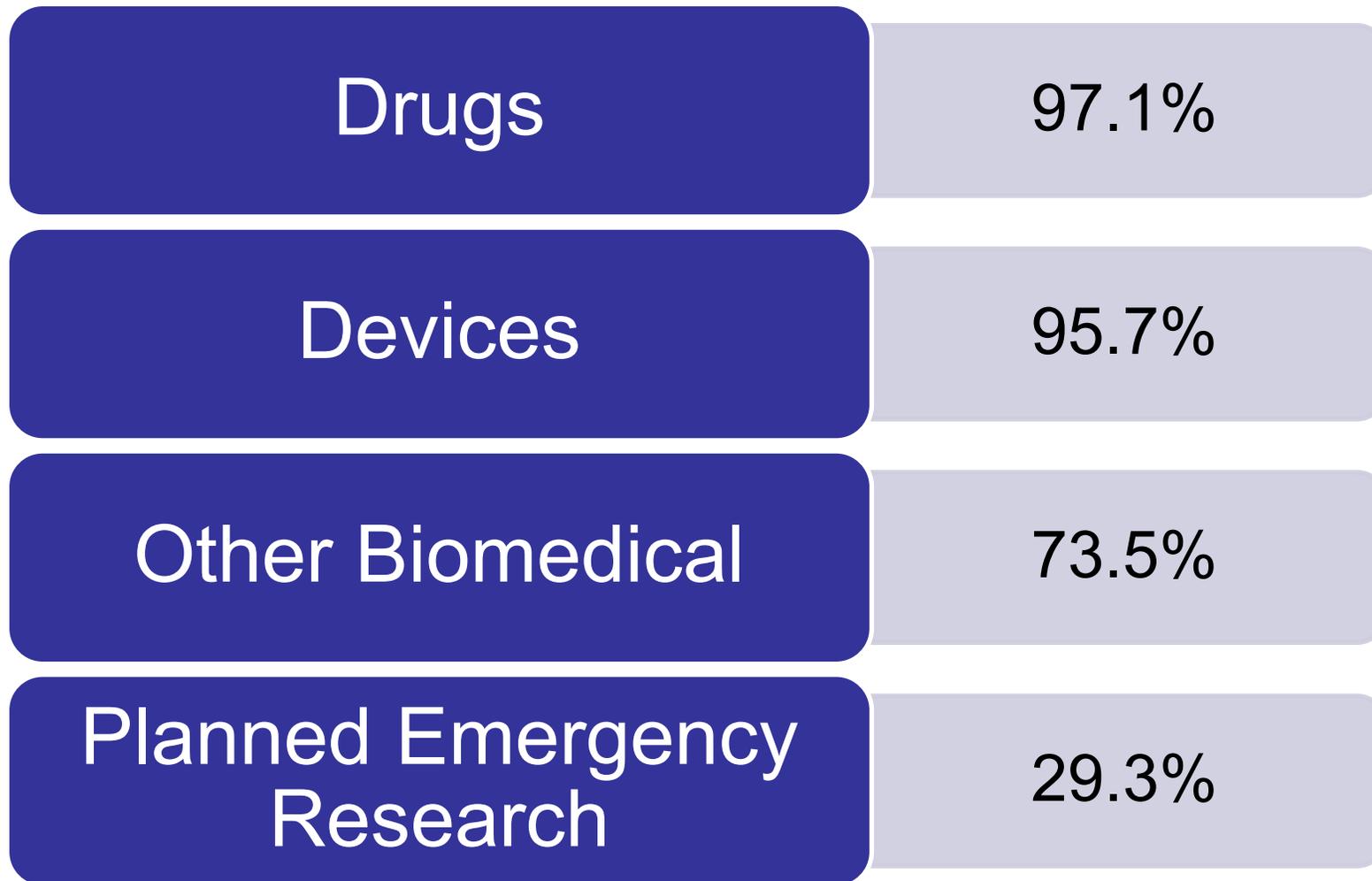
**All hospitals conduct or review
biomedical/clinical research**



**Most hospitals conduct or review
social/behavioral/education research**



Biomedical/Clinical Research by Type



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

Vulnerable Populations

Children	95.7%
Adults Unable to Consent	93.5%
Employees	91.4%
Pregnant Women	88.2%
Students	80.6%
Prisoners	35.5%
Other	15.7%

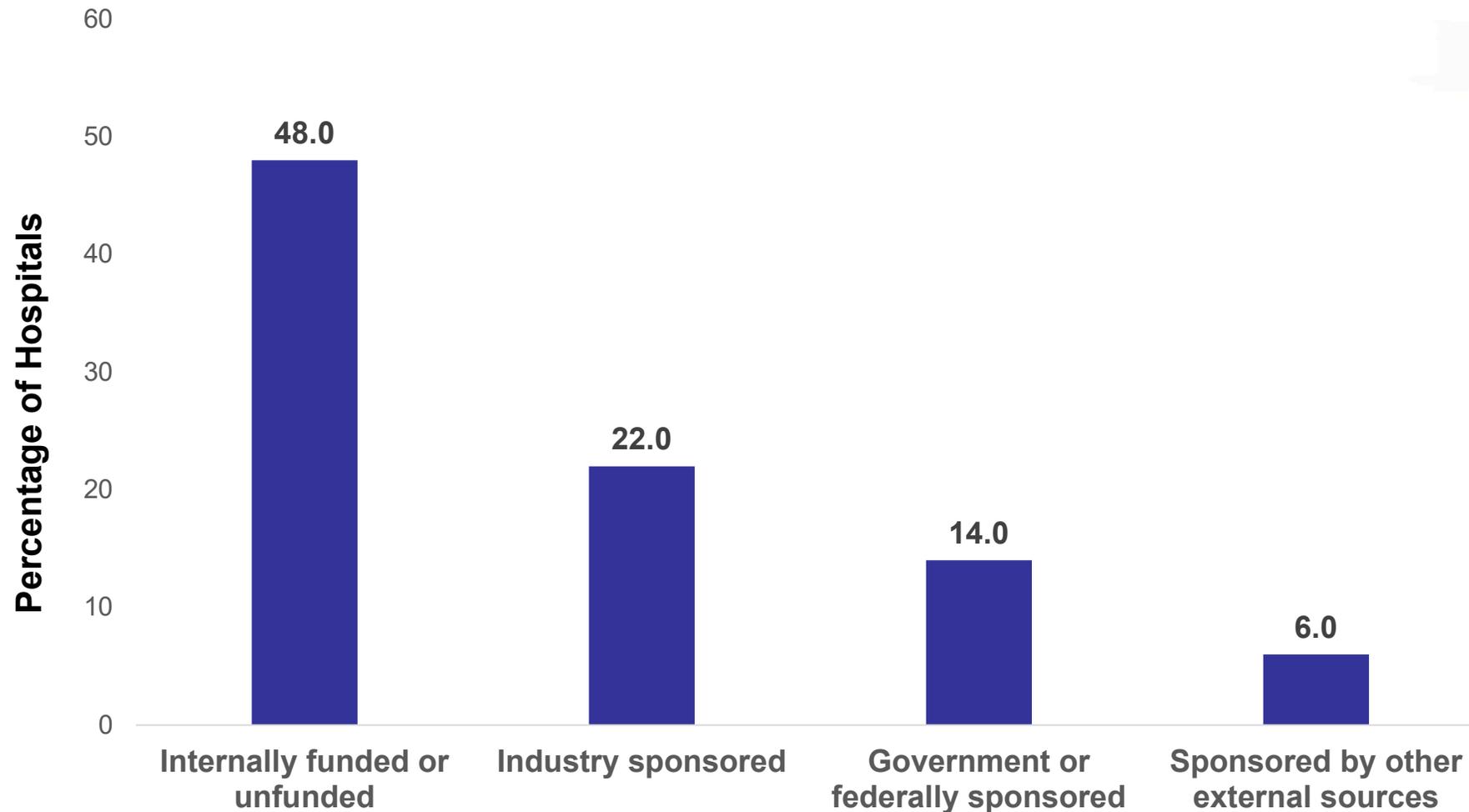
This table shows the categories of vulnerable populations that participate in research conducted or reviewed by hospitals.

Funding Type

Industry sponsored	97.8%
Internally funded or unfunded	98.9%
Government or federally sponsored	94.6%
Sponsored by other external sources	90.3%

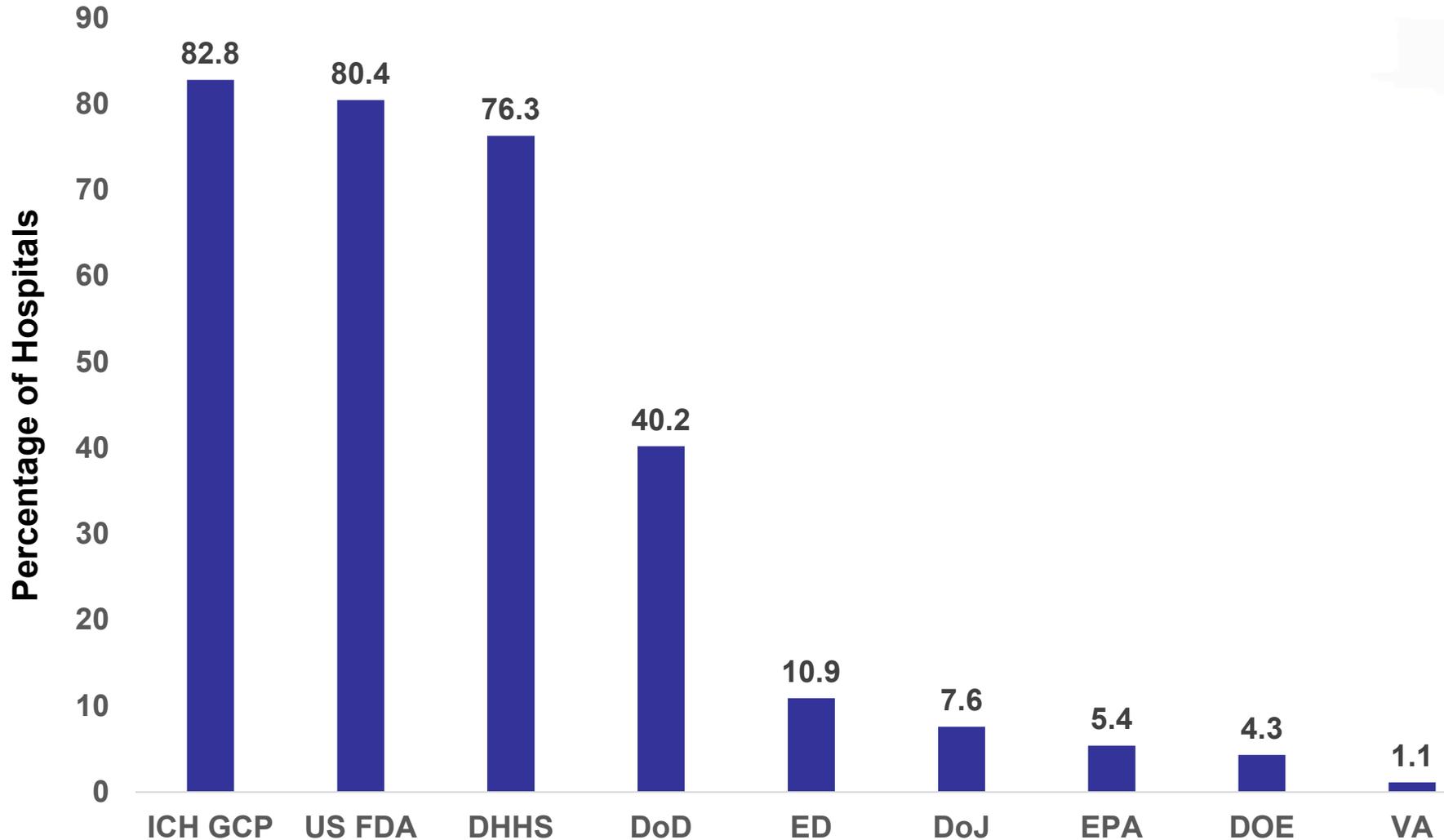
This table shows the percentage of hospitals that conduct or review research by funding type that supports the research.

Funding Distribution



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

Regulations and Guidelines



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

- 82.8% - ICH GCP
- 80.4% - US FDA
- 76.3% US Dept of Health & Human Services
- 40.2% - US Dept of Defense
- 10.9% - US Dept of Education
- 7.6% - US Dept of Justice
- 5.4% - US Environmental Protection Agency
- 4.3% - US Dept of Energy
- 1.1% – Veterans Affairs

Internal IRBs/ECs

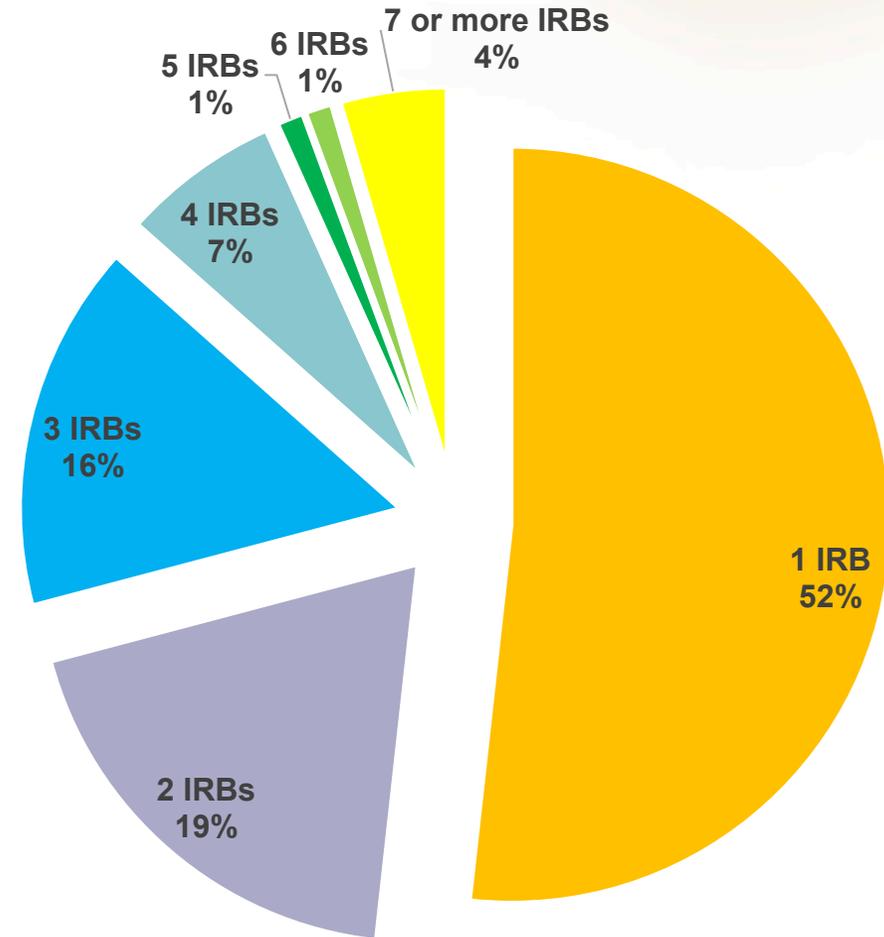
% of hospitals that
have internal IRBs

95.7%

Median # of
IRBs/ECs per
hospital

1

Number of internal IRBs/ECs % of hospitals support



Relying on External IRBs/ECs

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

71.9%

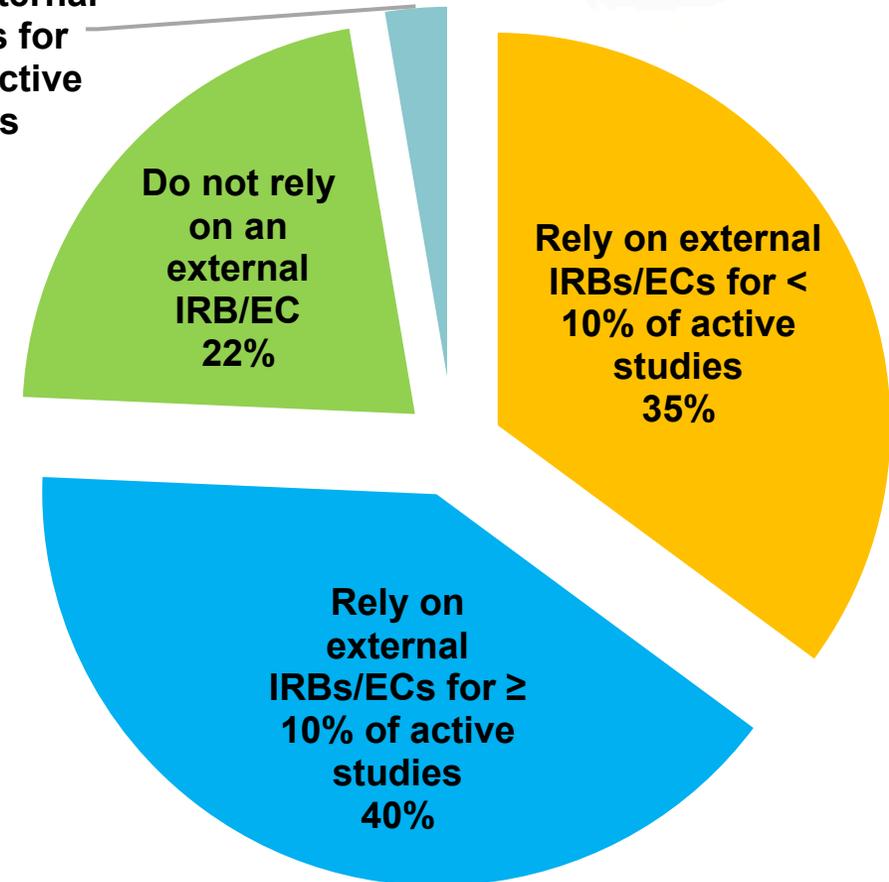
Use of external IRBs/ECs by hospitals with internal IRBs/ECs

Rely on external IRBs/ECs for 100% of active studies
3%

Do not rely on an external IRB/EC
22%

Rely on external IRBs/ECs for < 10% of active studies
35%

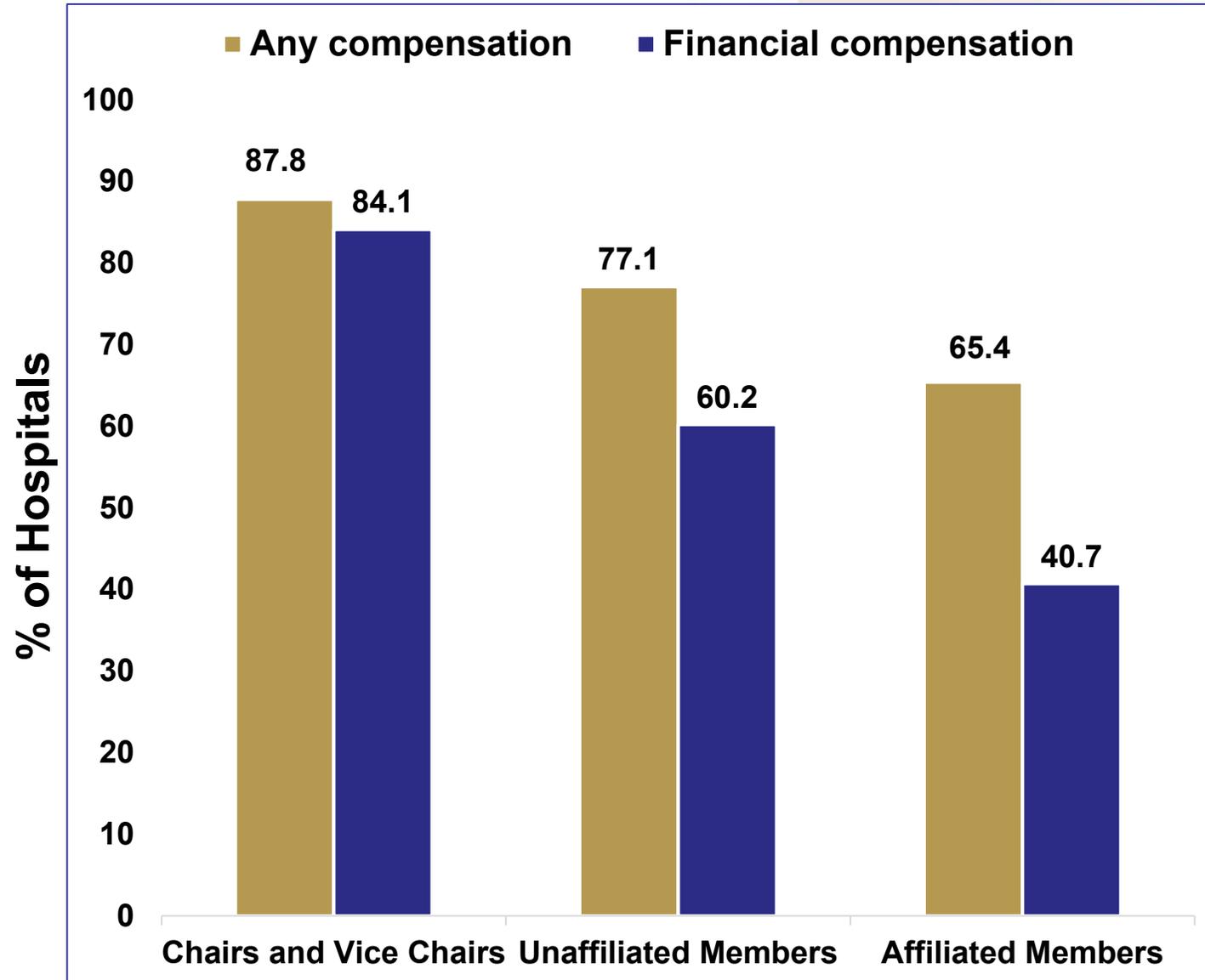
Rely on external IRBs/ECs for \geq 10% of active studies
40%



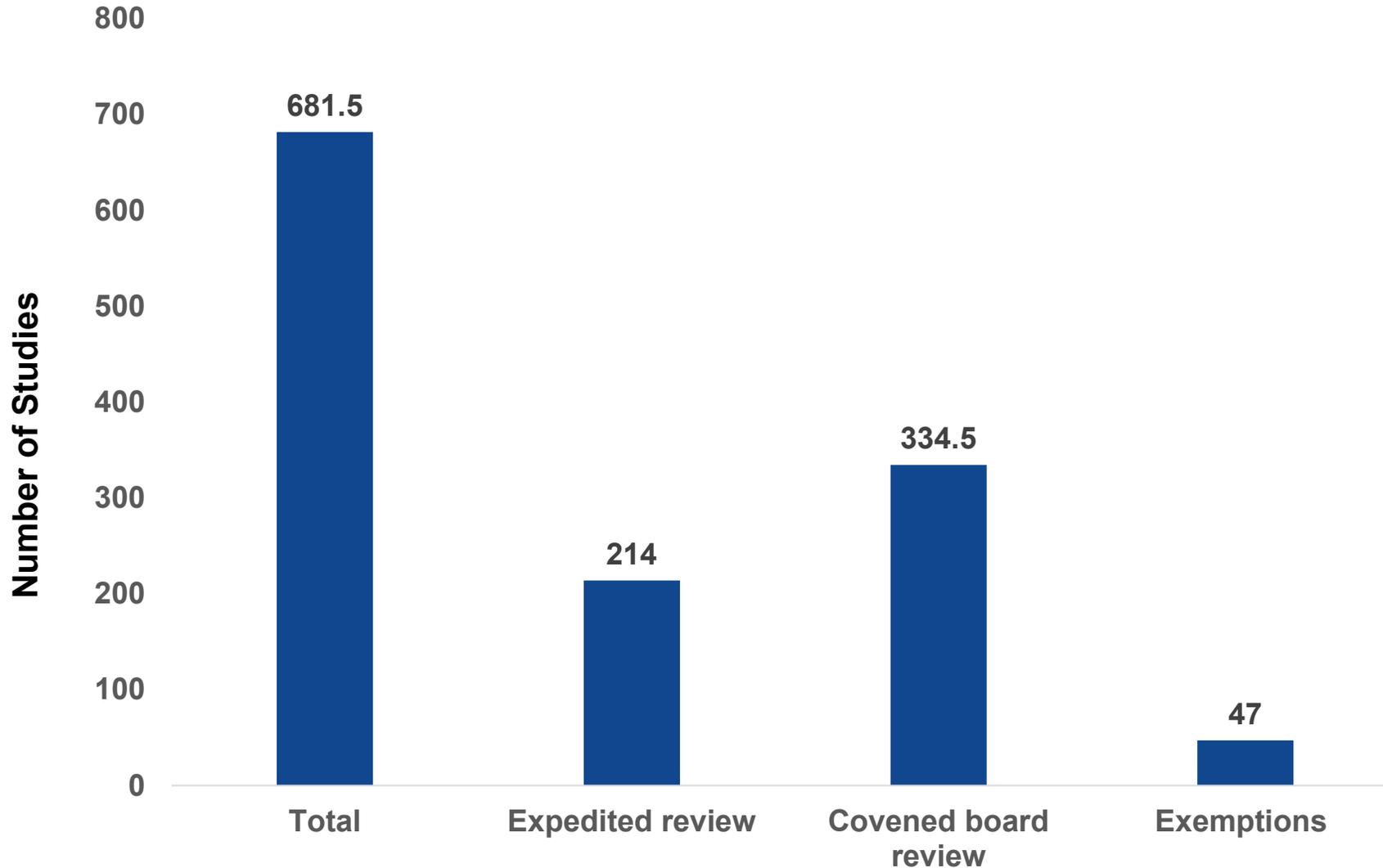
Compensating IRB/EC Members

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

87.8%



Active Studies Overseen: All Hospitals

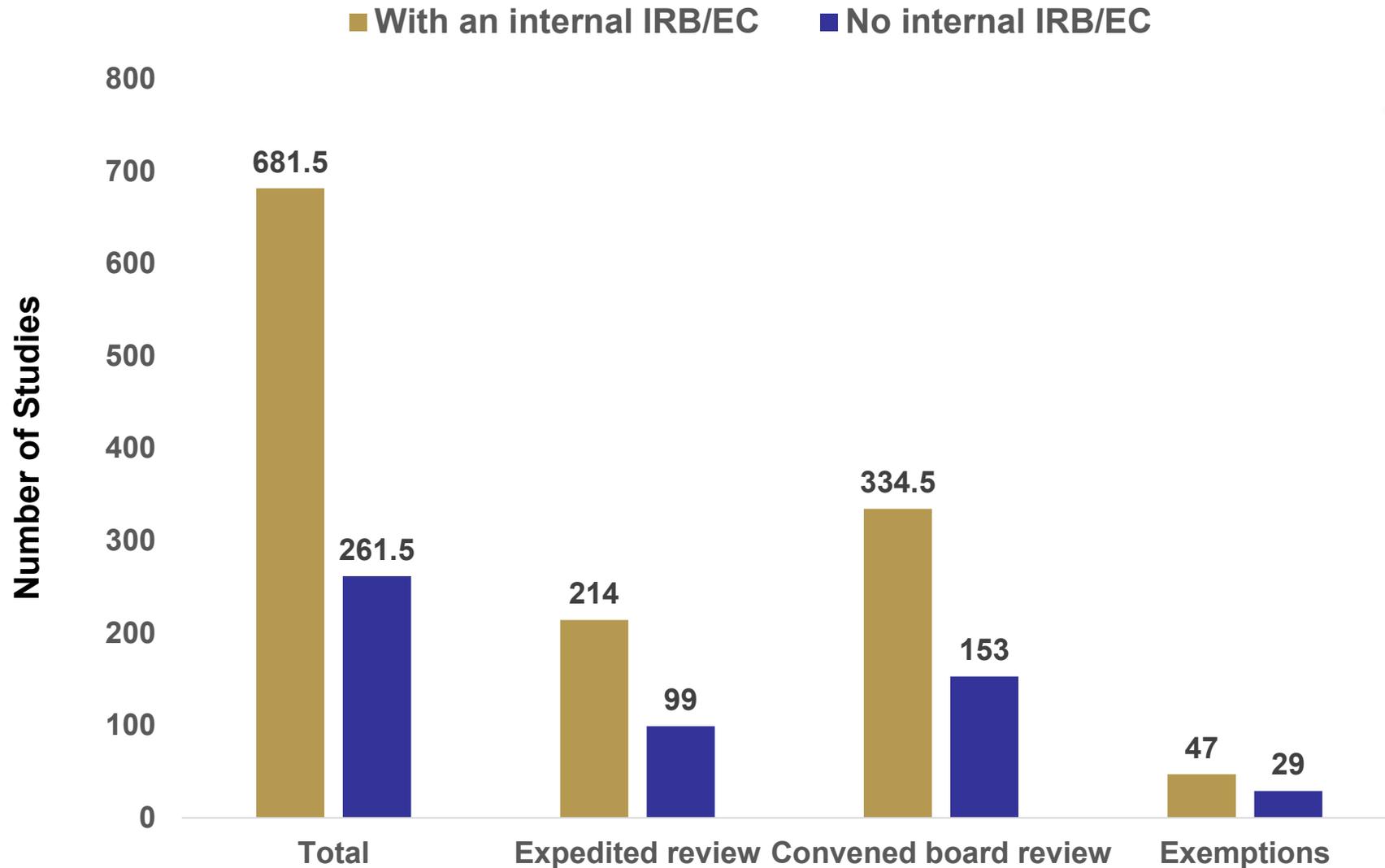


This chart shows the median number of active studies that hospitals conduct or review by type of review.

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: Internal vs. External IRB/EC

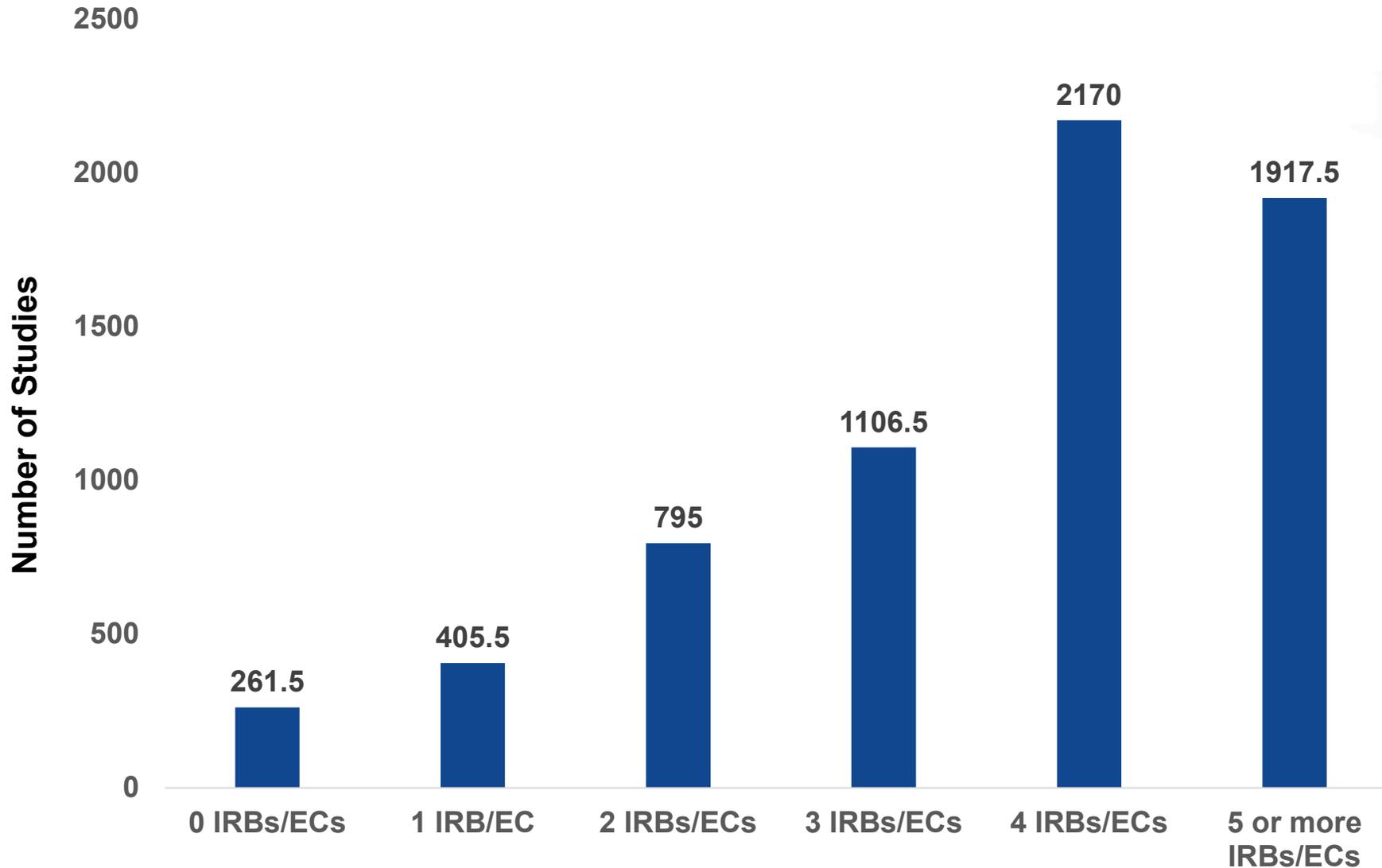


This chart shows the median number of active studies that hospitals conduct or review based on whether they have an internal IRB/EC.

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

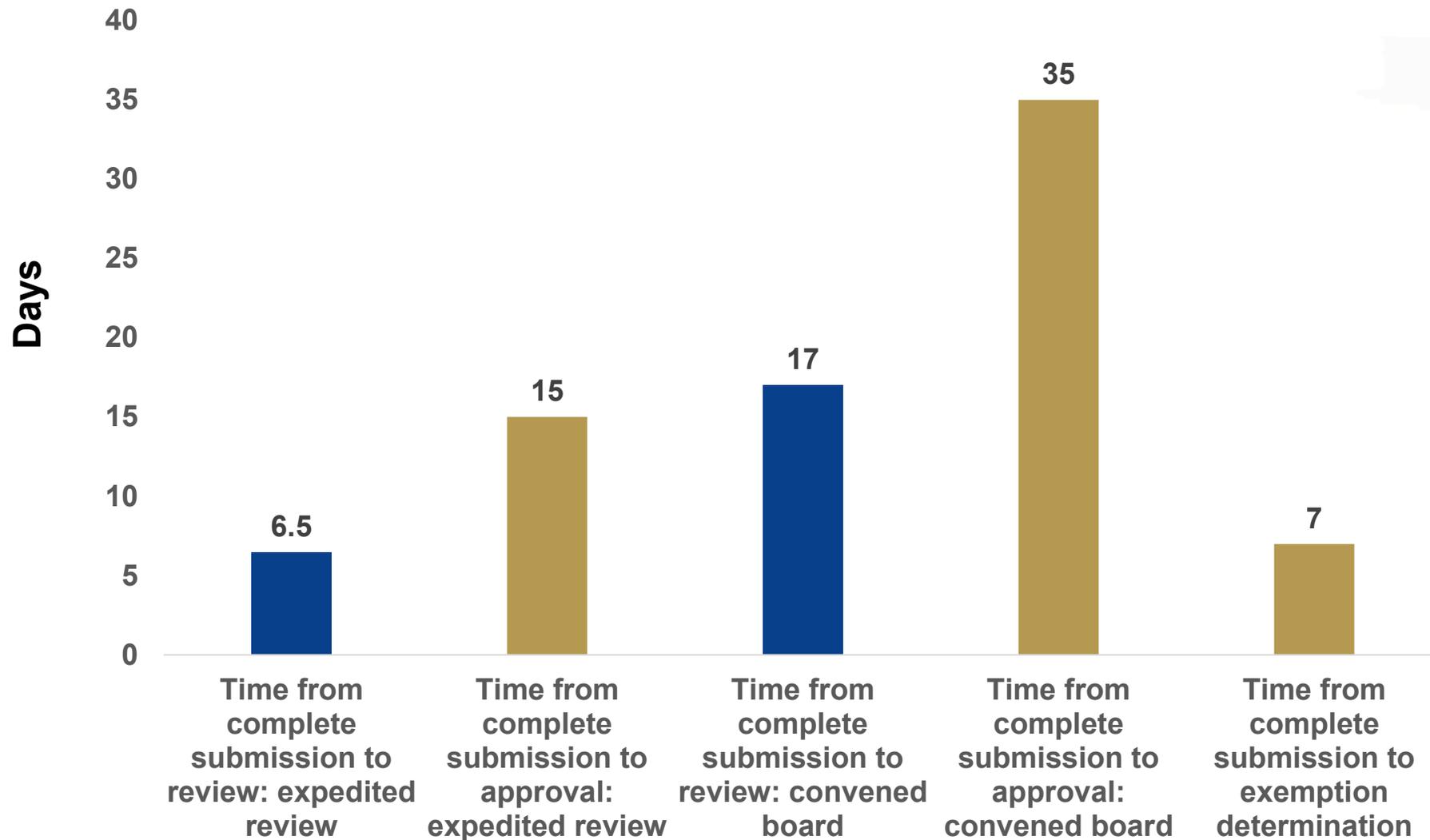


This chart shows the median number of active studies hospitals oversee based on the number of IRBs/ECs.

Note:

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

IRB/EC Review Times: All Review Types

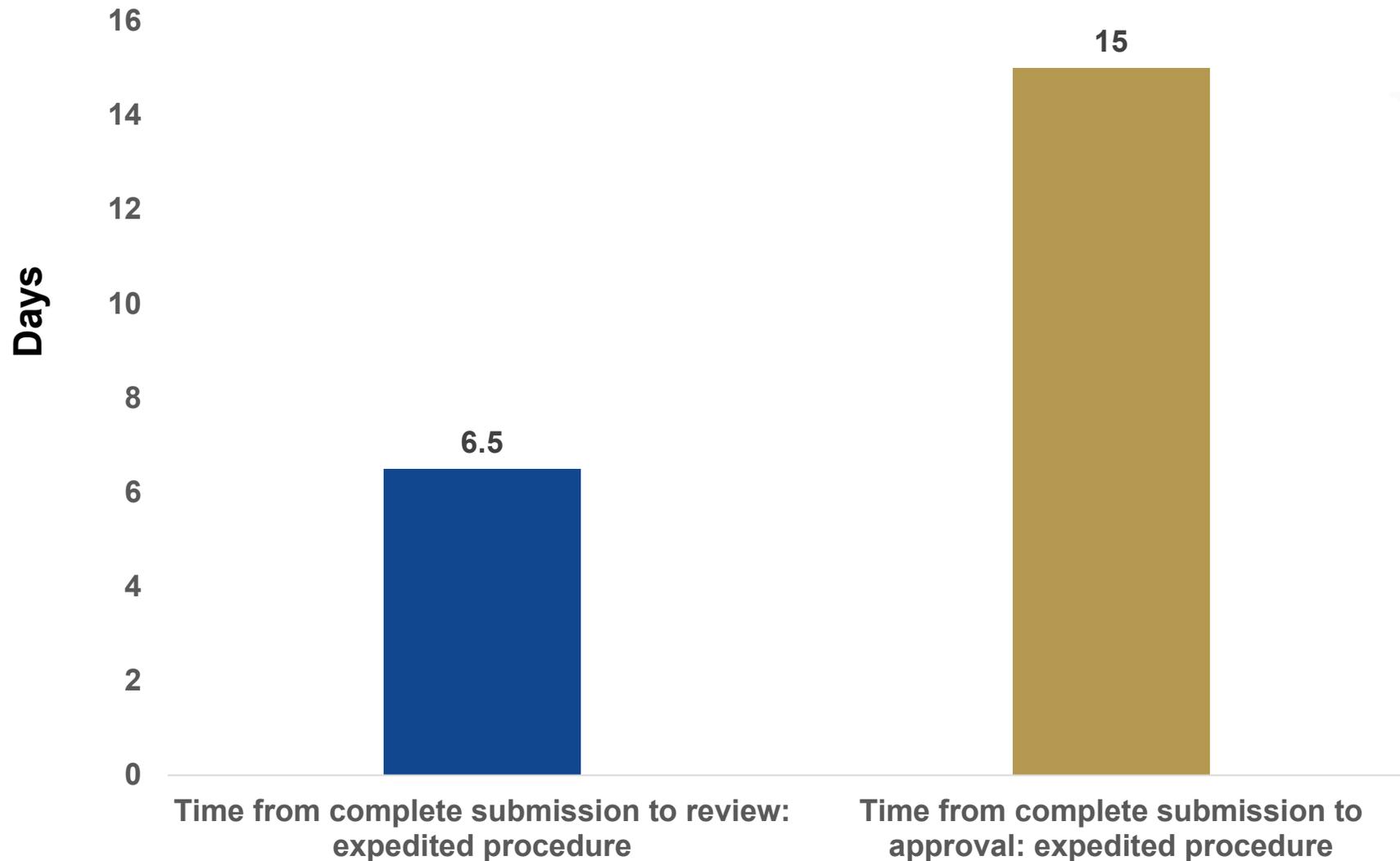


This chart shows the median review times by review process for hospitals that have internal IRBs/ECs.

Note:

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

IRB/EC Review Times: Expedited Review

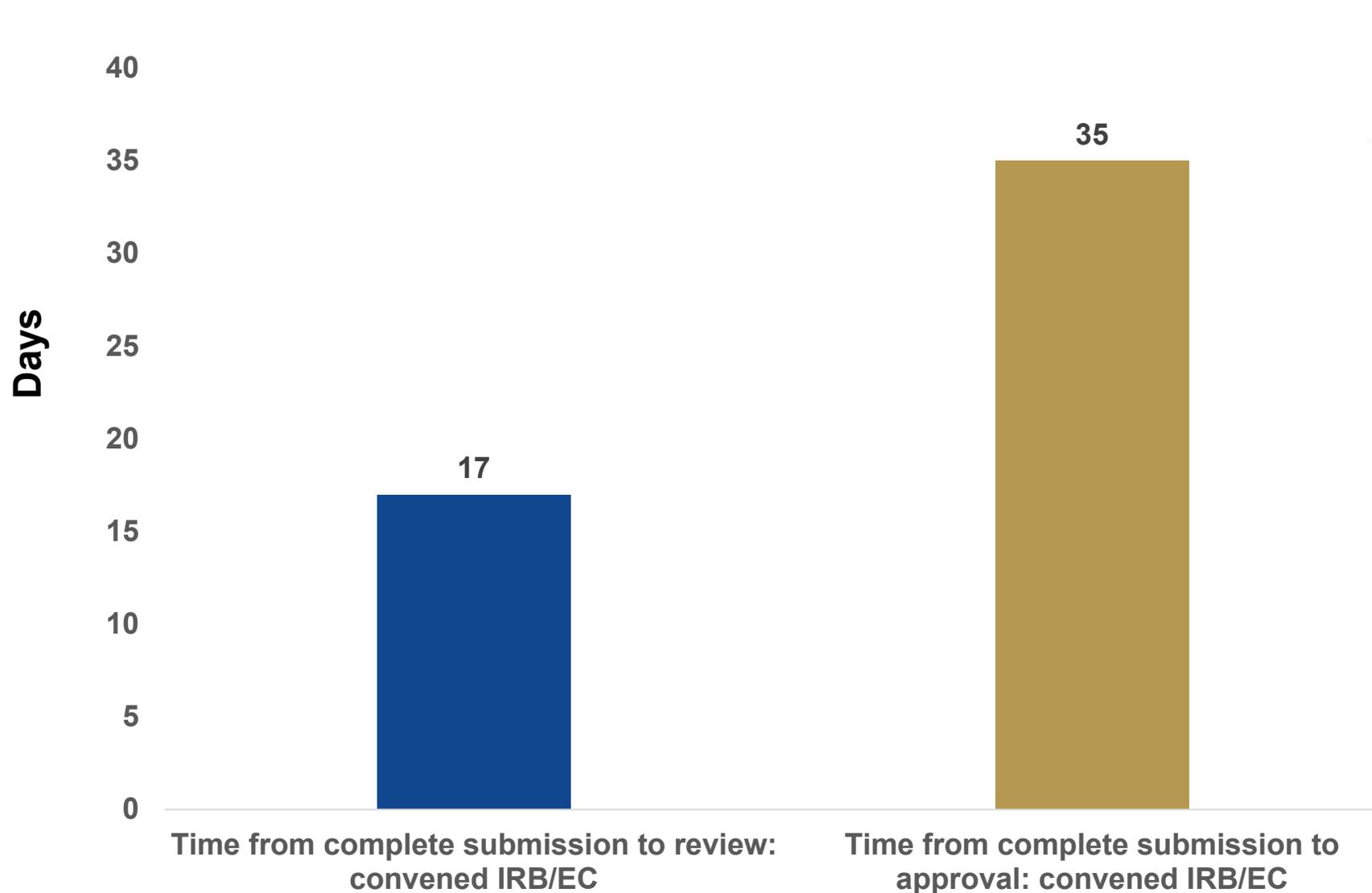


This chart shows the median expedited review times for hospitals that have internal IRBs/ECs.

Note:

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

IRB/EC Review Times: Convened Board Review

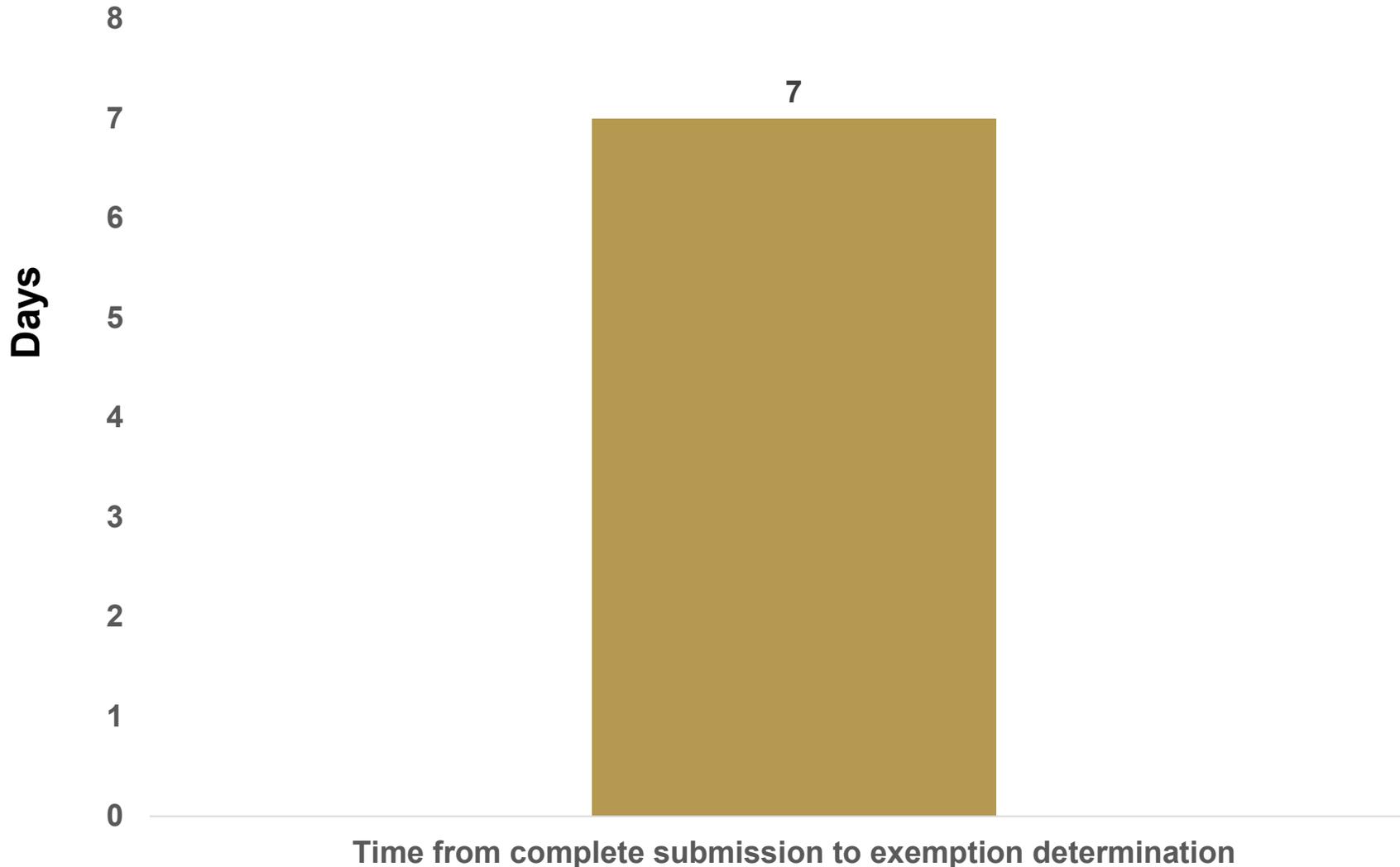


This chart shows the median convened board review times for hospitals that have internal IRBs/ECs.

Note:

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

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 86.5%

Online application submission 86.5%

Online protocol/materials distribution to IRB/EC members 89.9%

Online review functions 87.6%

Does not use an electronic system 4.5%

This table shows the technology hospitals 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	681.5	5	136.3	\$342,606
0-100	116	1.5	77.3	\$120,000
101-500	388	3	129.3	\$190,000
501-1000	719	4	179.8	\$385,144
1001-2000	1351	9	150.1	\$631,289
2001-4000	2330	15.5	150.3	\$849,580
4001+	9193.5	31.9	288.2	\$4,000,000

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

Note:

- Data from hospitals without internal IRBs/ECs are not included

Audits of Researchers

Median # of researchers with active studies per hospital:

321

Median # of research staff per hospital:

186

% of organizations that reported that audits of investigators occurred

88.2%

Internal:
"for cause"

- Median: 1
- Total: 394

Internal:
random

- Median: 11
- Total: 3277

Regulatory
agency
inspections

- Median: 0
- Total: 112

Audits of IRBs/ECs

% of hospitals
that reported that
no audits of
IRB/EC records
occurred:
79.8%

Internal:
"for cause"

- Median: 0
- Total: 41

Internal:
random

- Median: 2
- Total: 607

Regulatory
agency
inspections

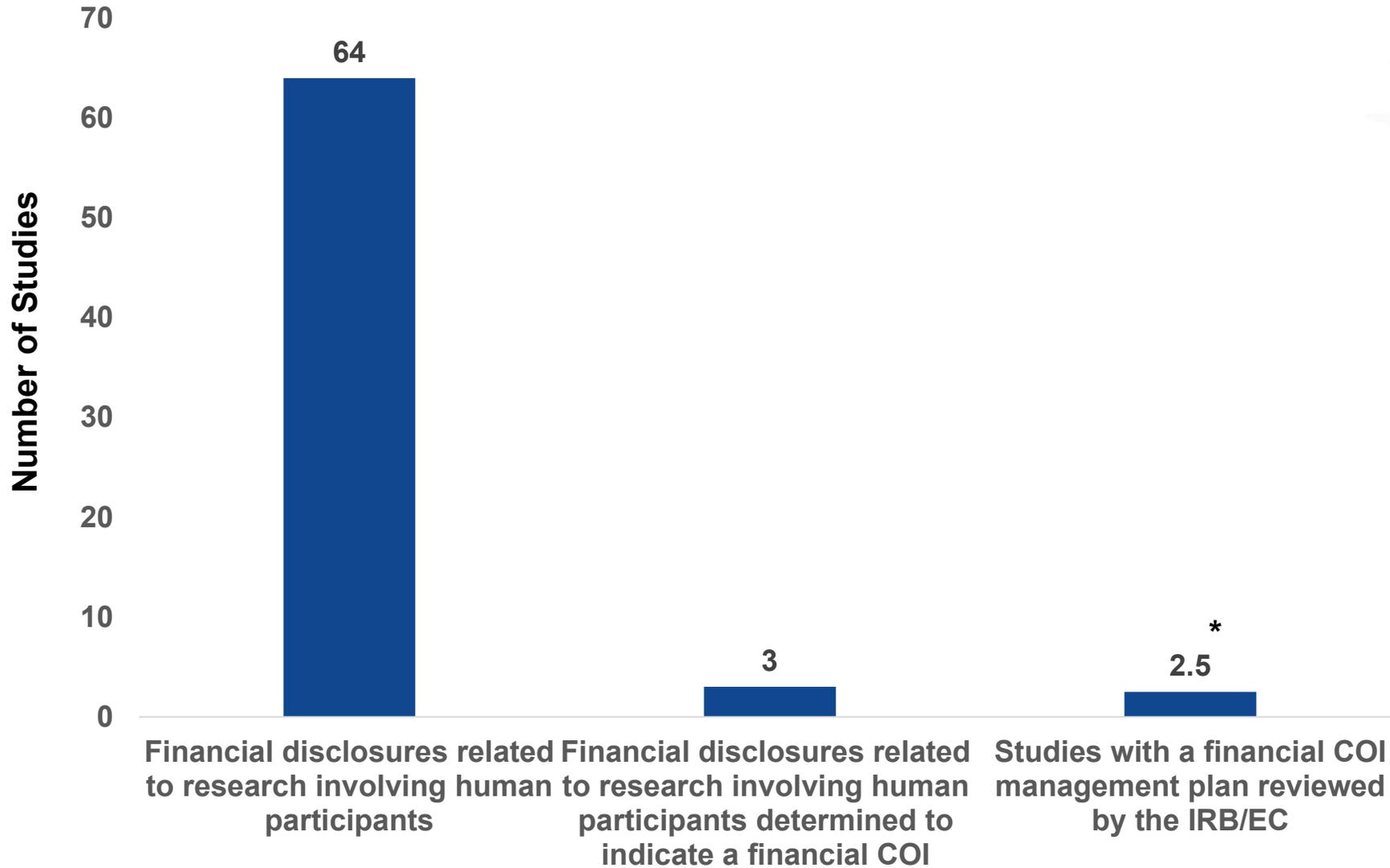
- Median: 0
- Total: 23

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	1	0	0	1
0-100	0	0	0	0	0
101-500	0	0	0	0	0
501-1000	0	4	1	0	1
1001-2000	0	5	1	0	0
2001-4000	0	7	4	0	4
4001+	0	119	1.5	0	10.5

This table is based on the 12 months prior to a hospital'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 hospitals 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