



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

# 2021 Metrics for AAHRPP-Accredited Human Research Protection Programs

## Hospitals

June 2022



# Metrics About Hospitals

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 hospitals.

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

Data were selected based on what most accurately reflected accredited hospitals in 2021.

# Abbreviations Used

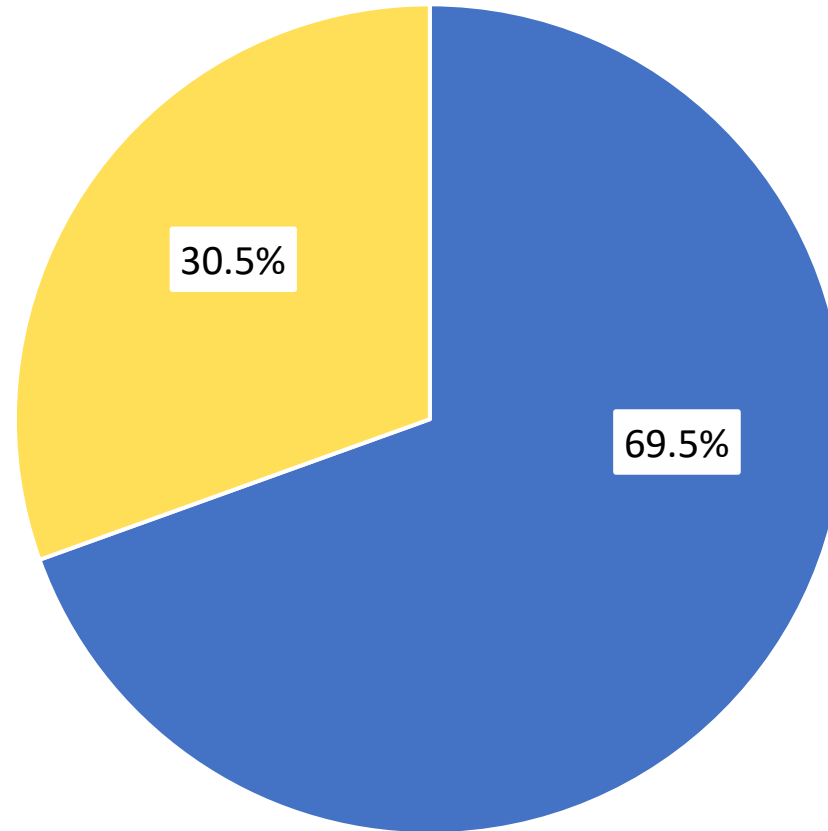
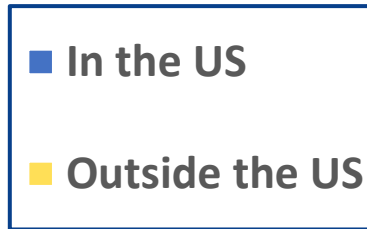
|         |  |
|---------|--|
| DHHS    | US Department of Health & Human Services                         |
| DoD     | US Department of Defense   |
| ED      | US Department of Education                                       |
| DoE     | US Department of Energy  |
| DoJ     | US Department of Justice   |
| 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                                |



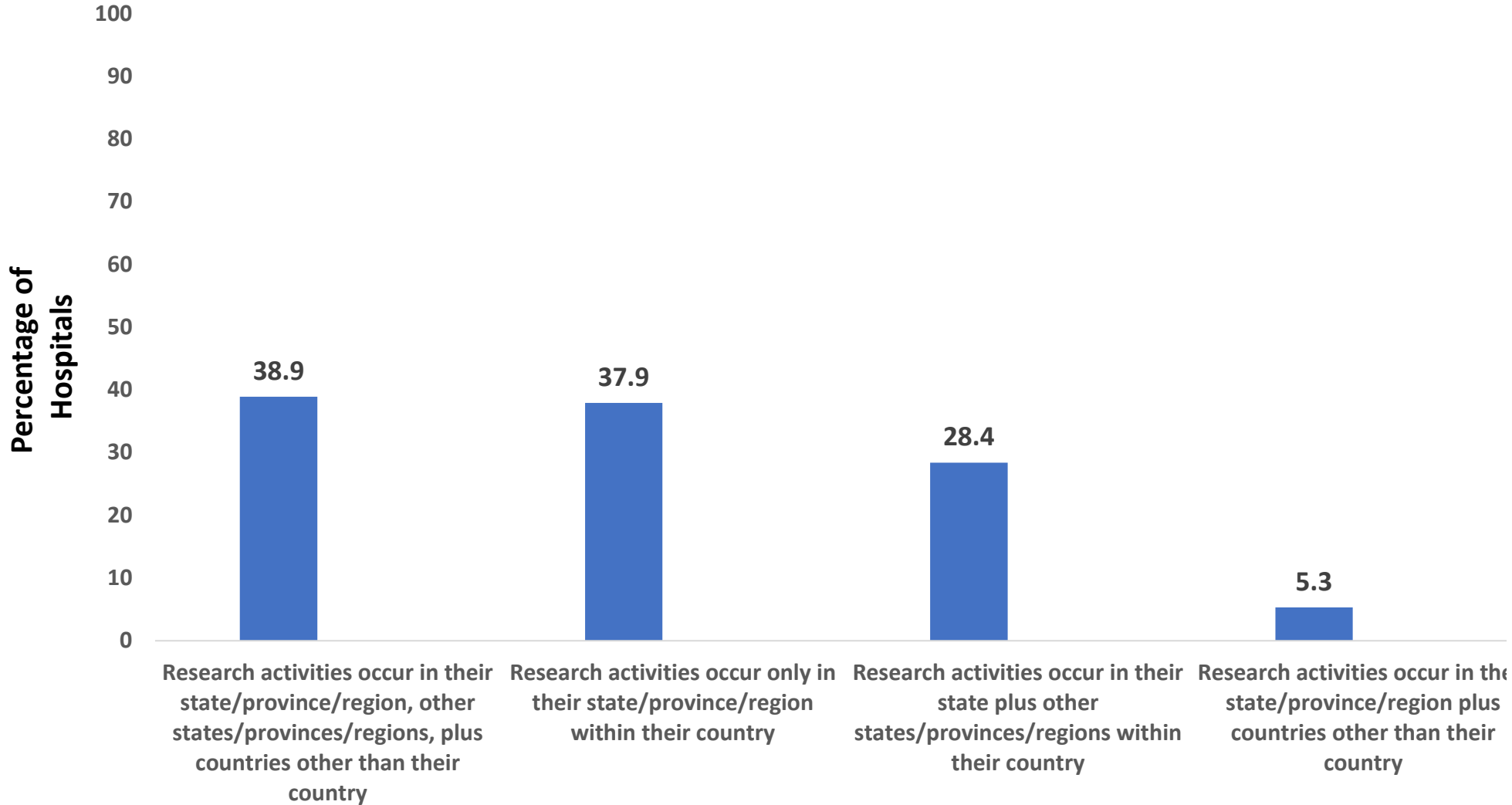
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# Where Accredited Hospitals are Based



# Where Research Occurs



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

# Research Type

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

100%

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

92.6%

# Biomedical/Clinical Research by Type

Drugs

98.9%

Devices

98.9%

Planned Emergency  
Research

26.3%

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



# Vulnerable Populations

|                          |       |
|--------------------------|-------|
| Children                 | 96.8% |
| Employees                | 98.7% |
| Adults Unable to Consent | 90.5% |
| Pregnant Women           | 90.5% |
| Students                 | 84.2% |
| Prisoners                | 32.6% |
| Other                    | 11.6% |

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

# Funding Type

Industry sponsored

100%

Government or federally  
sponsored

96.8%

Internally funded or  
unfunded

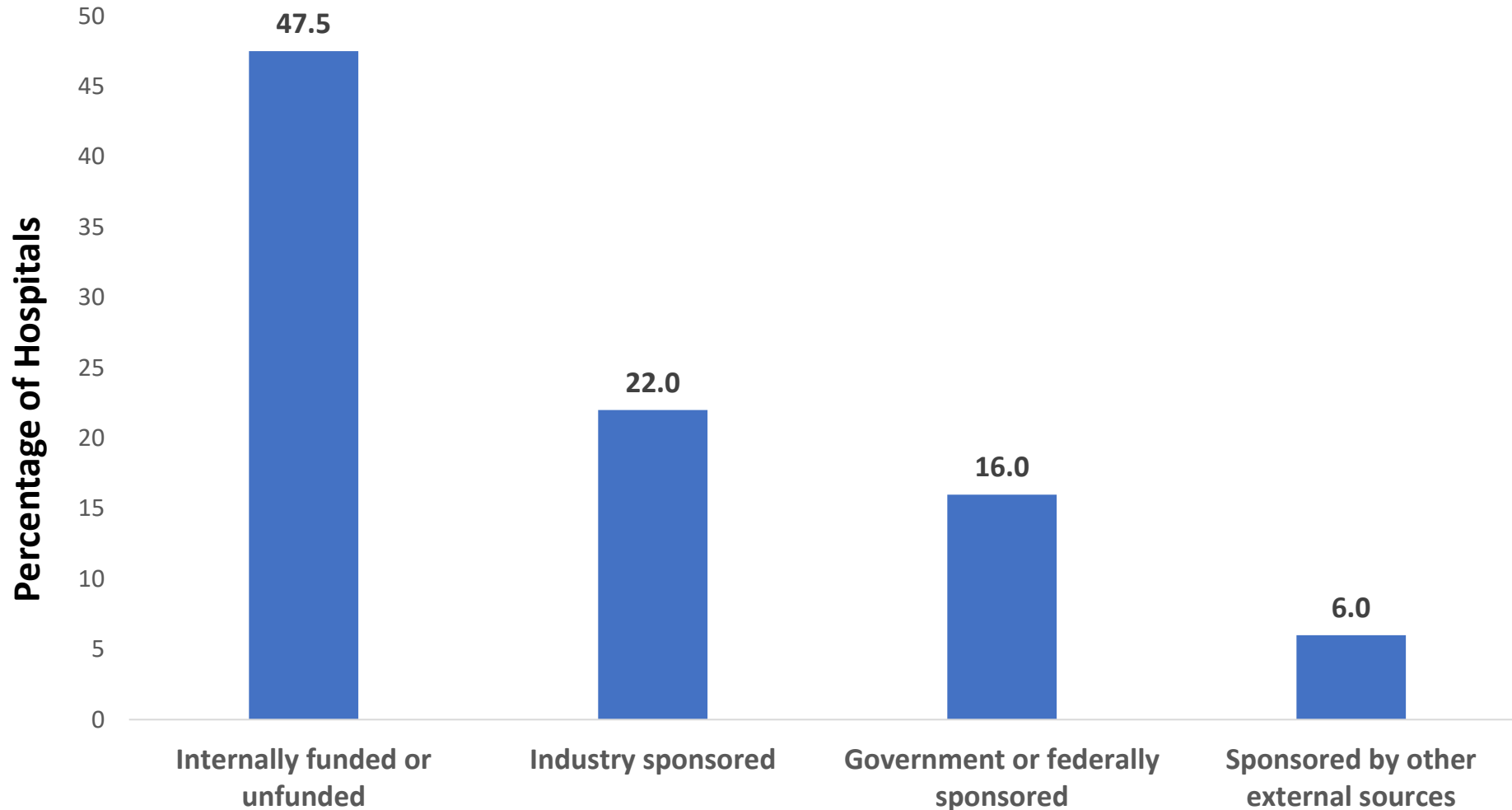
96.8%

Sponsored by other external  
sources

90.5%

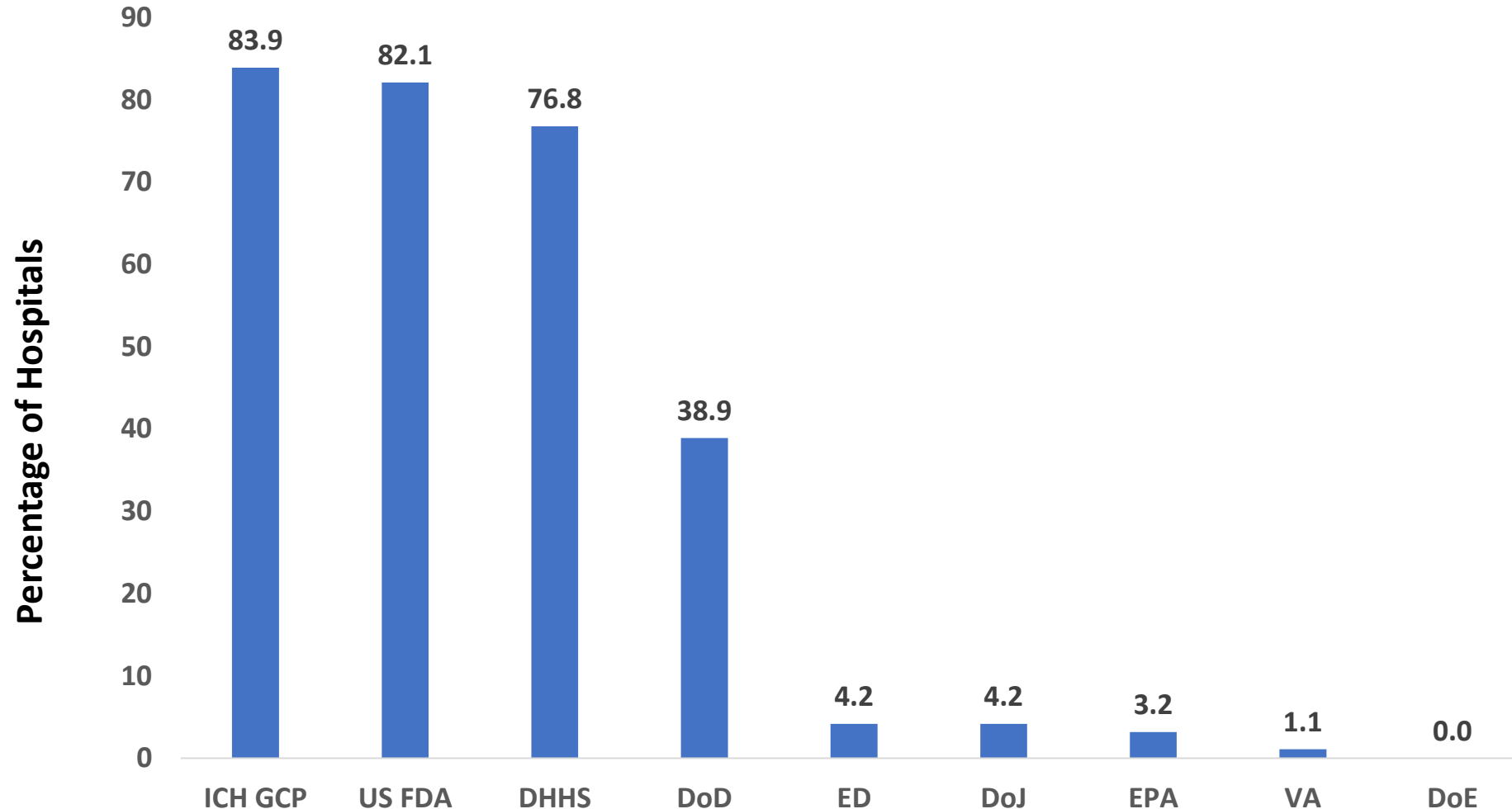
This table shows the percentage of hospitals that conduct or review research by funding type that supports the research.

# Funding Distribution



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

# Regulations & Guidelines



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

# Internal IRBs/ECs

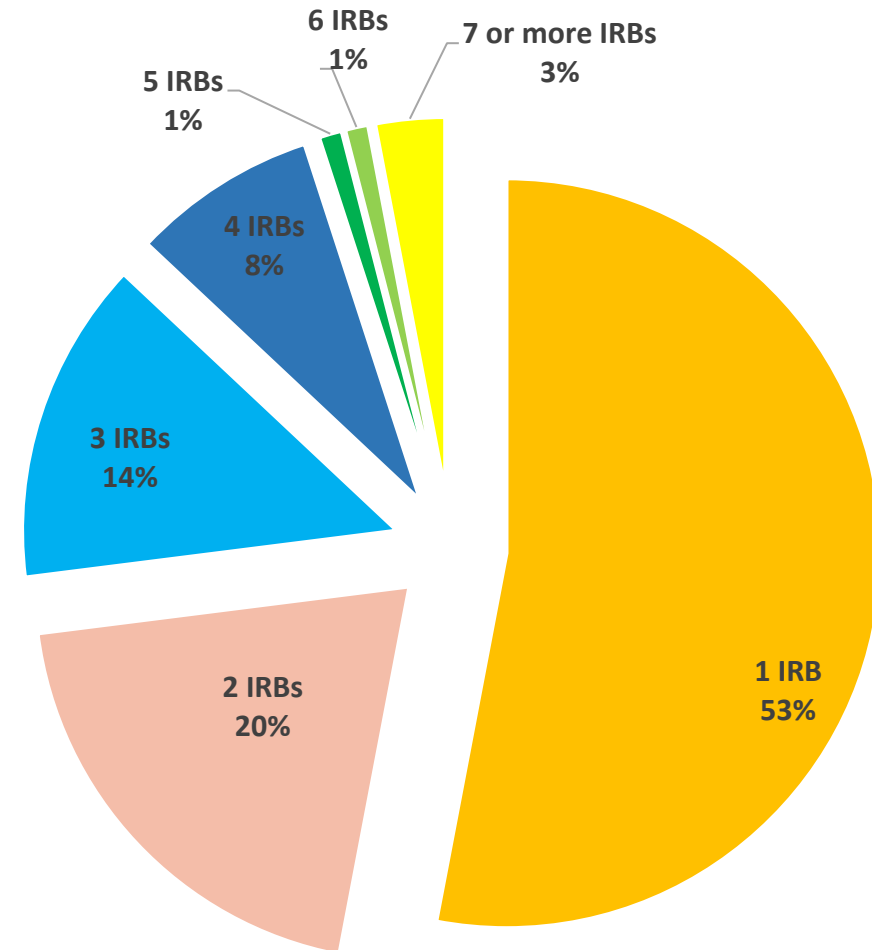
% of hospitals that  
have internal IRBs

93.7%

Median # of  
IRBs/ECs per  
hospital

1

## Number of internal IRBs/ECs % of hospitals support

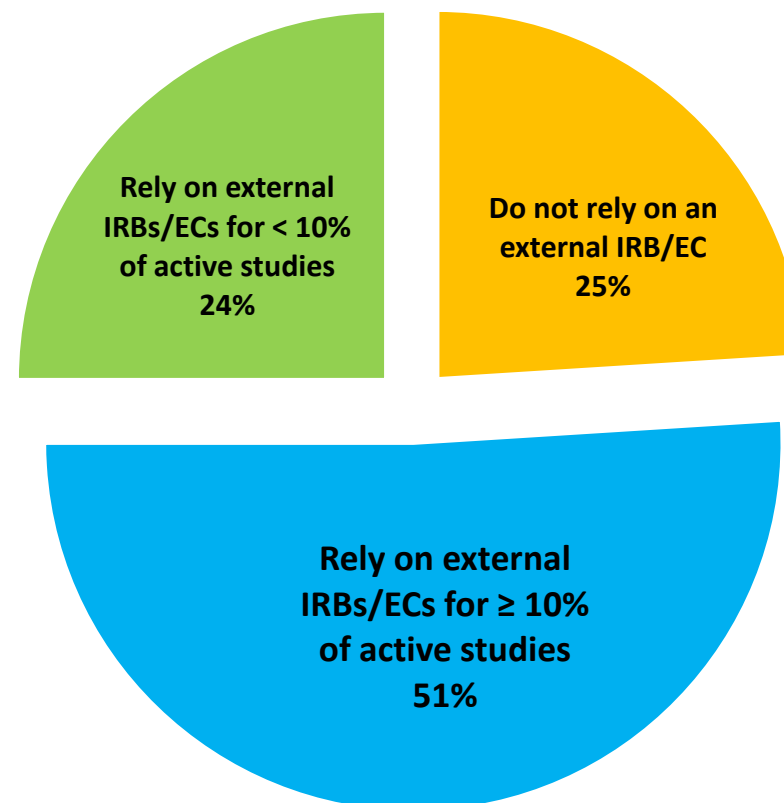


# Relying on External IRBs/ECs

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

**74.2%**

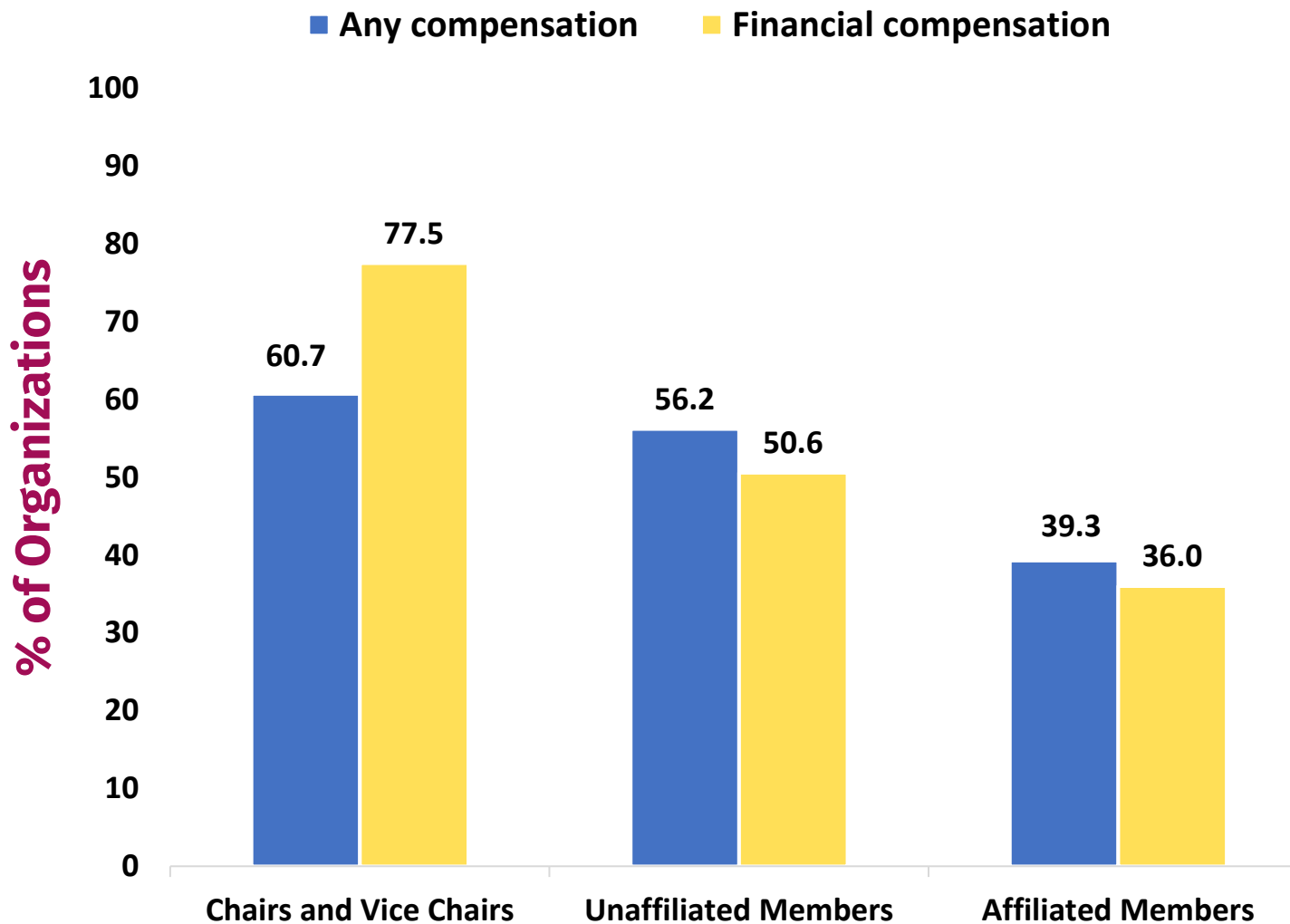
**Use of external IRBs/ECs  
by hospitals with internal IRBs/ECs**



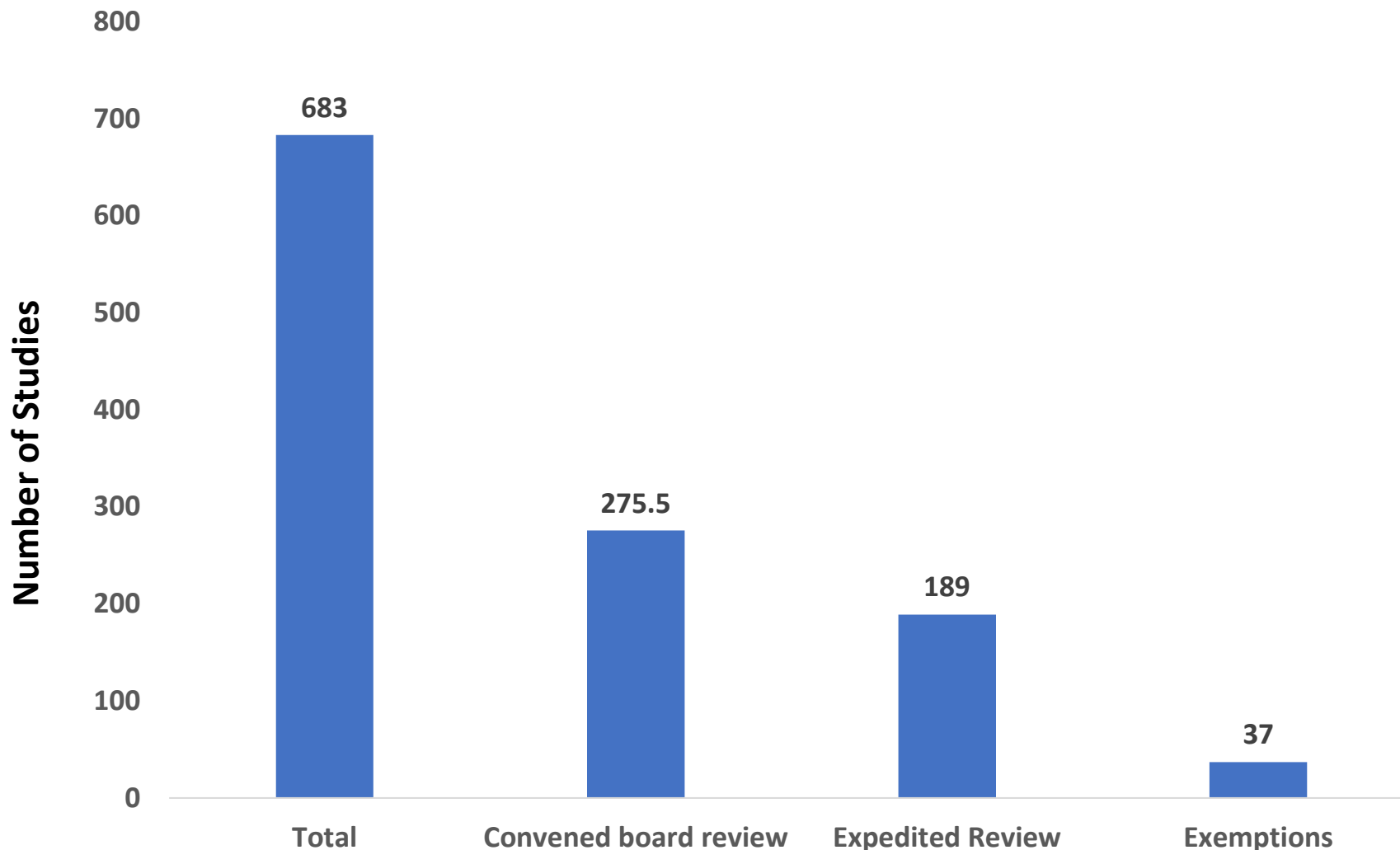
# Compensating IRB/EC Members

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

**85.4%**



## Active Studies Overseen: All Hospitals



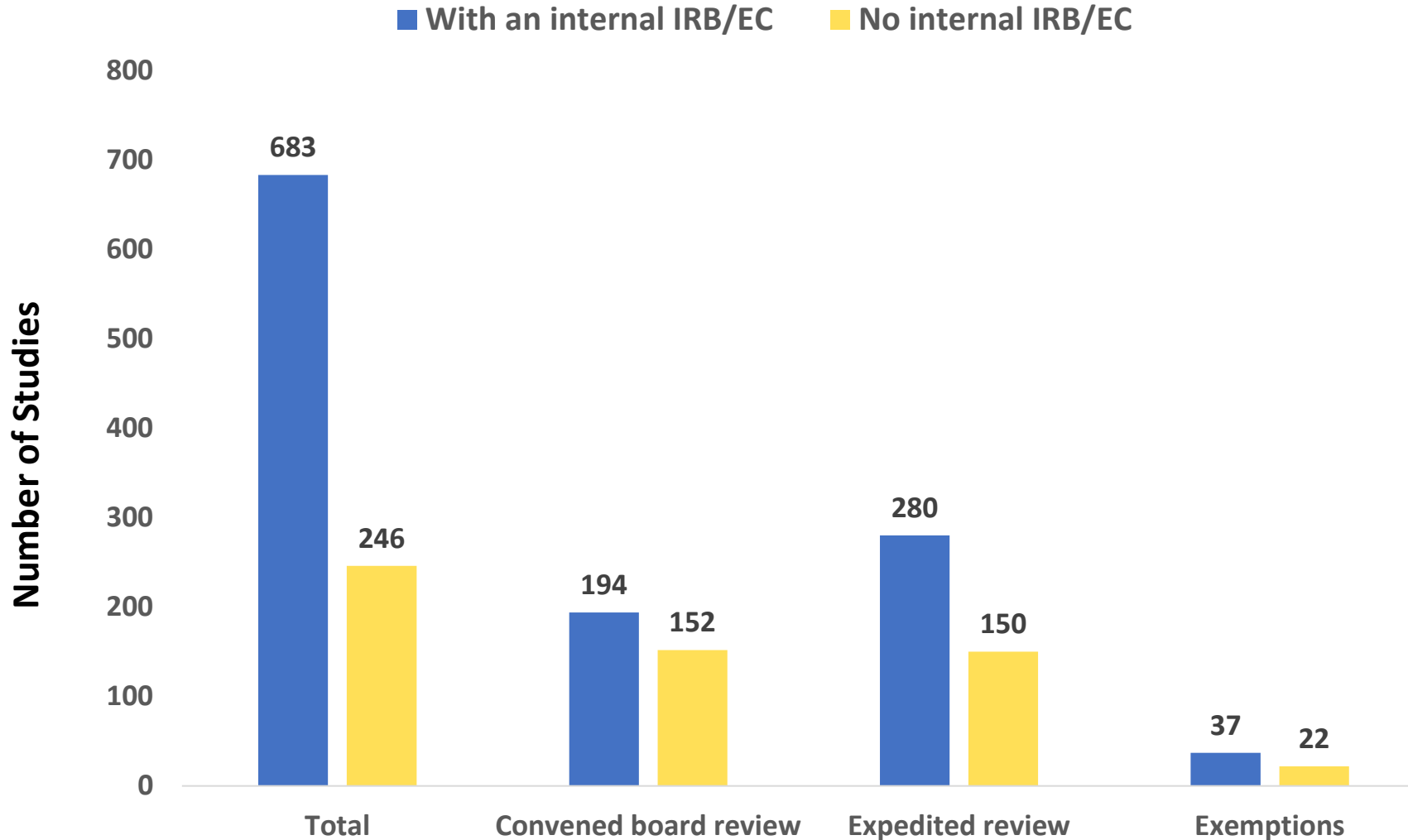
This chart shows the median number of active studies that hospitals conduct or review by type of review.

### Note:

- Exemptions are based on the number of determinations made by an hospitals 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 hospitals with IRBs/ECs



# Active Studies: Internal vs. External IRB/EC

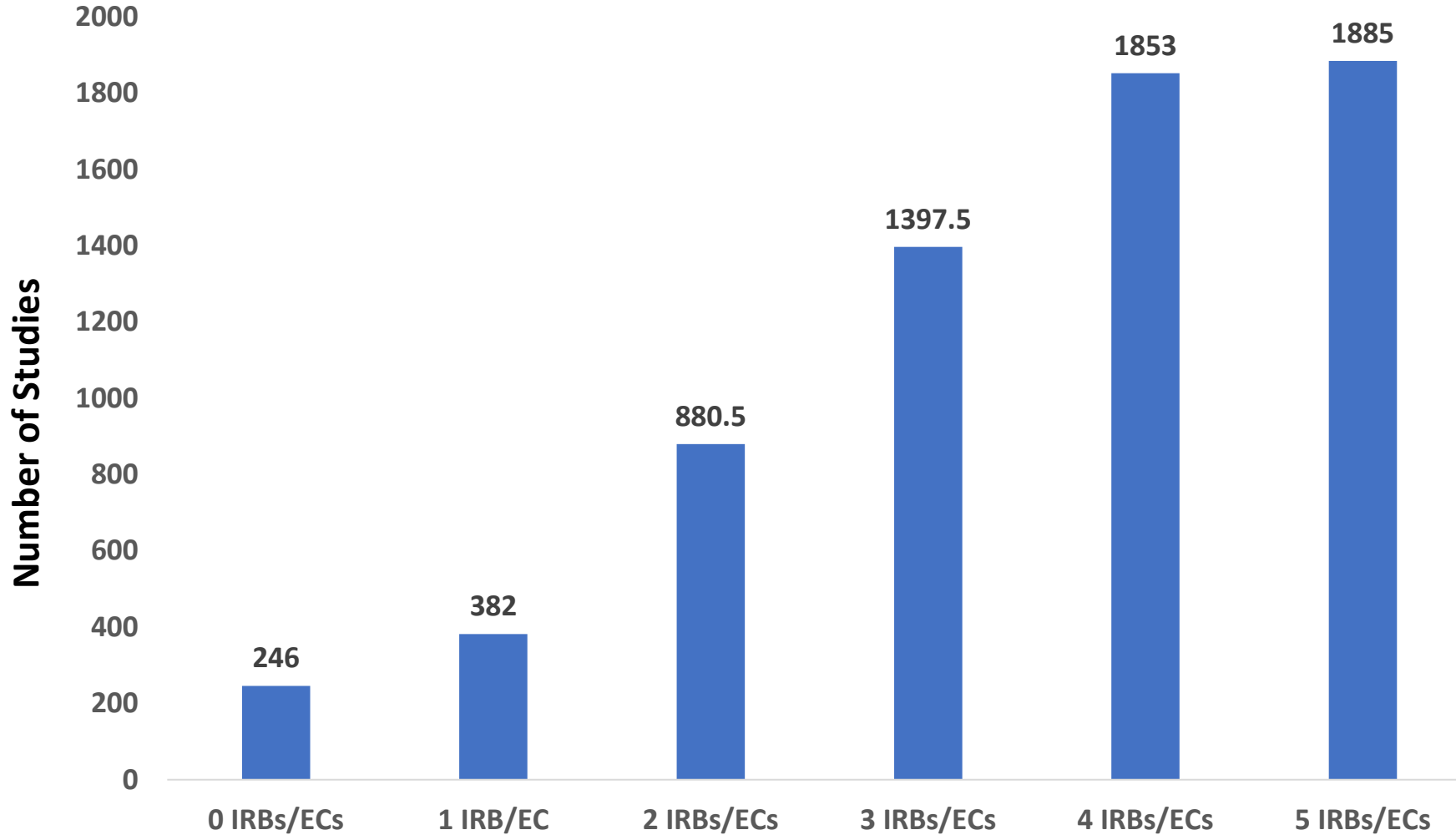


This chart shows the median number of active studies that hospitals conduct or review based on whether they have an internal IRB/EC.

### 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 hospitals with IRBs/ECs

# Active Studies Per IRB/EC

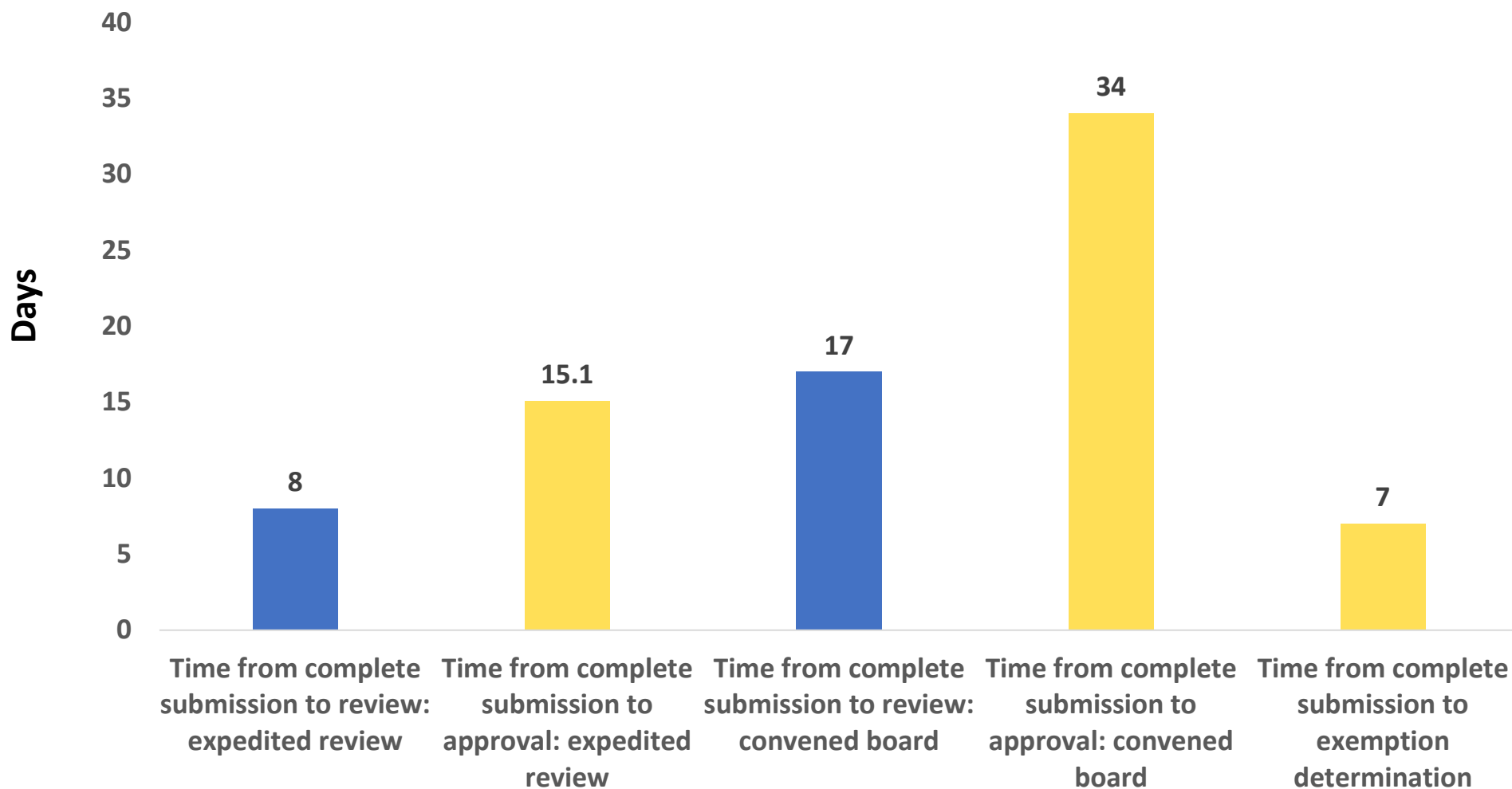


This chart shows the median number of active studies hospitals oversee based on the number of IRBs/ECs they have.

#### Note

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

# Review Times



This chart shows the median review times by review process for hospitals.

# IRB/EC Technology

Database for submission tracking

90.0%

Online protocol/materials distribution to  
IRB/EC members

90.0%

Online application submission

85.6%

Online review functions

85.6%

Does not use an electronic system

2.2%

This table shows the technology hospitals 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                      | 739                      | 5.7                    | 128.1                              | \$329,358            |
| 0-500                    | 48.5                     | 1.5                    | 32.9                               | \$132,294            |
| 501-1000                 | 262                      | 3                      | 88.8                               | \$161,837            |
| 1001-2000                | 795                      | 6.4                    | 123.7                              | \$552,000            |
| 2001-4000                | 1526                     | 9                      | 169.6                              | \$645,750            |
| 4001+                    | 2411.5                   | 13.5                   | 178.6                              | \$698,819            |

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



# Audits of Researchers

Median # of  
researchers per  
hospital with  
active studies:

328

Median # of  
research staff  
per hospital:

169

% of hospitals  
that reported  
that audits of  
researchers  
occurred

87.4%

Internal:  
"for cause"

- Median: 2
- Total: 506

Internal:  
random

- Median: 11
- Total: 3153

Regulatory  
agency  
inspections

- Median: 1
- Total: 96

# Audits of IRBs/ECs

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

**21.3%**

Internal:  
"for cause"

- Median: 0
- Total: 67

Internal:  
random

- Median: 3
- Total: 892

Regulatory  
agency  
inspections

- Median: 0
- Total: 20

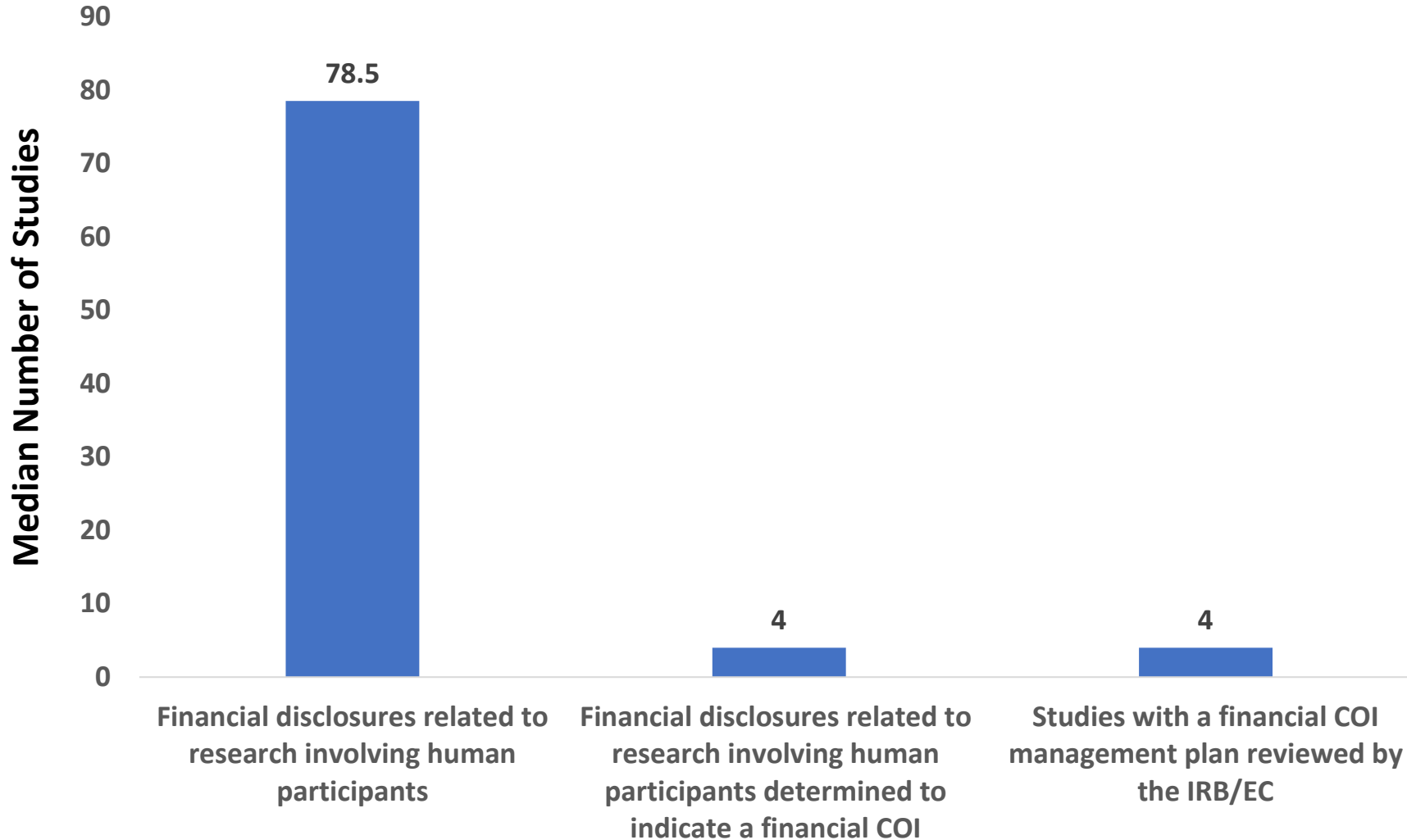
# Unresolved Complaints, Noncompliance, & Unanticipated Problems

| 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                                     |
| 0-100                    | 0                     | 0                                       | 0                                    | 0                                       | 0                                     |
| 101-500                  | 0                     | 2.5                                     | 0                                    | 0                                       | 0                                     |
| 501-1000                 | 0                     | 11                                      | 1                                    | 0                                       | 1                                     |
| 1001-2000                | 0                     | 2.5                                     | 1                                    | 0                                       | 2                                     |
| 2001-4000                | 1                     | 67.5                                    | 4                                    | 1.5                                     | 4                                     |
| 4001+                    | 0                     | 8                                       | 2.5                                  | 1                                       | 2                                     |

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.