

# 2024 Metrics for AAHRPP-Accredited Human Research Protection Programs

**September 2025** 



## About the Metrics

AAHRPP is pleased to present the 2024 metrics for Human Research Protection Program (HRPP) performance. You will see some changes to the metrics that were based on feedback from a working group with representatives from accredited organizations. 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.

#### **Abbreviations Used and Definitions**

**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 Council for Harmonisation Good Clinical Practice

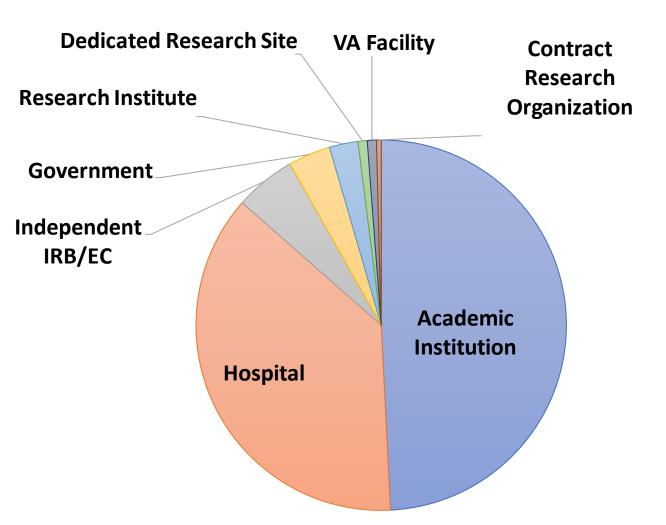
**VA** US Department of Veterans Affairs

Definitions of metrics, including how times are calculated, are available here.

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# Accredited Organizations By Type



#### Of the accredited organizations:

- 49.2% are academic institutions
- 37.3% are hospitals
- 5.3% are independent IRB/ECs
- 3.7% are governmental organizations
- 2.5% are research institutes
- 0.8% are dedicated research sites
- 0.8% are VA facilities
- 0.4% are contract research organizations

Where Accredited Organizations are Based

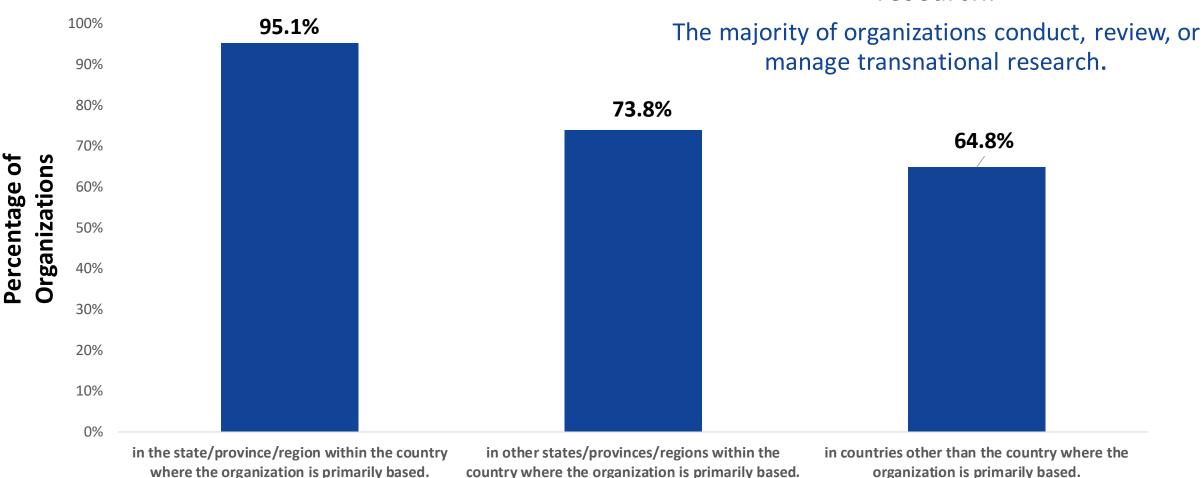
Based outside the United States, 16.8%

Based inside the United States, 83.2%



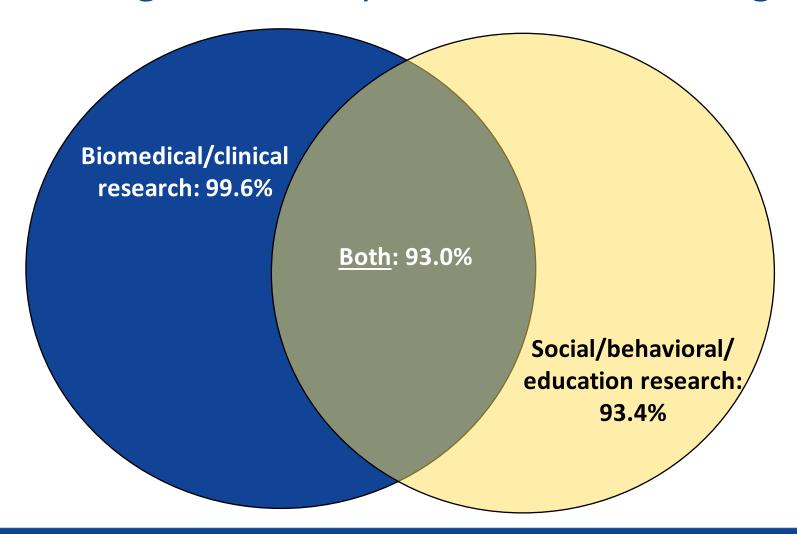
## Where Research Occurs

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



Research occurs...

#### Type of Research Organizations Sponsor, Conduct, Manage, or Review



## Biomedical/Clinical Research by Type

Drugs/biologics / dietary supplements

93.4%

**Devices** 

93.0%

Planned Emergency Research

51.6%

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

## **Vulnerable Populations**

Children 97.1% Adults Unable to Consent 94.3% 93.0% **Pregnant Individuals** 60.7% Prisoners

This table shows the categories of vulnerable populations that participate in research organizations sponsor, conduct, review, or manage.

Only 3 organization indicated they do not conduct, review, or manage research involving any vulnerable populations.

# **Funding Type**

Industry sponsored

96.7%

Sponsored by other external sources

94.7%

Internally funded or unfunded

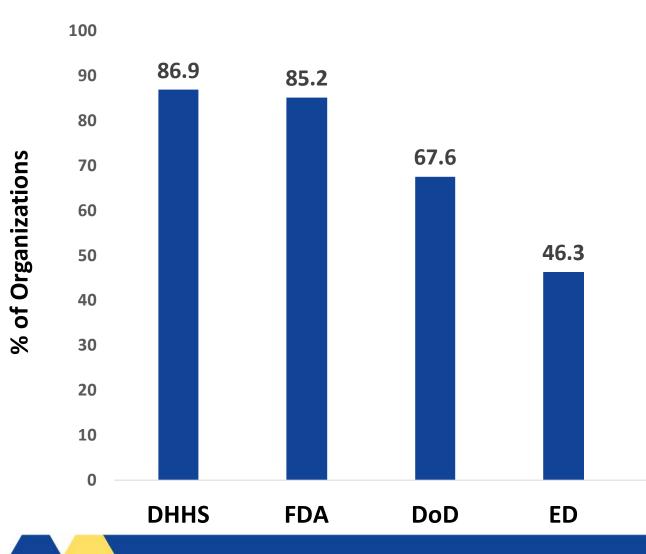
93.0%

Funded or sponsored by US Federal government

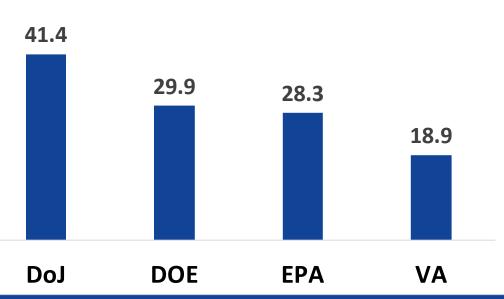
84.0%

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

# Regulations & Guidelines



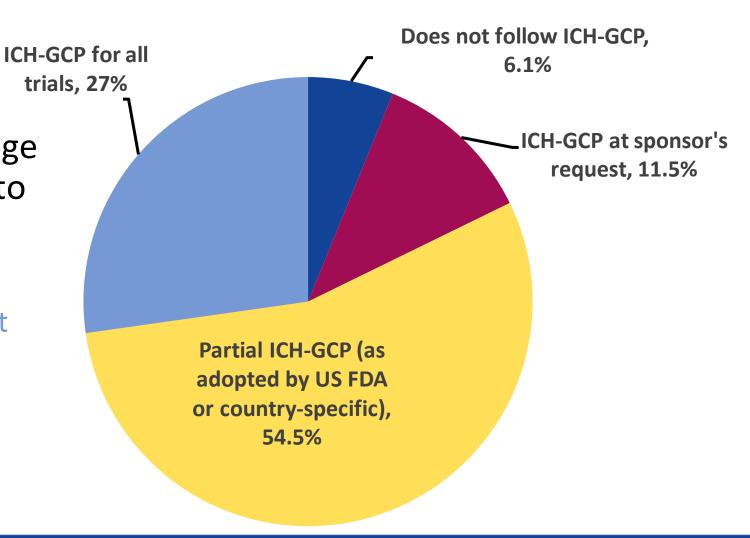
This chart shows the percentage of organizations that apply specific US regulations and guidelines to the research they sponsor, review, manage, or conduct.



# International Regulations & Guidelines

This chart shows the percentage of organizations that adhere to ICH-GCP guidelines.

About 6% of organizations do not adhere to ICH-GCP guidelines.



## Internal IRBs/ECs\*

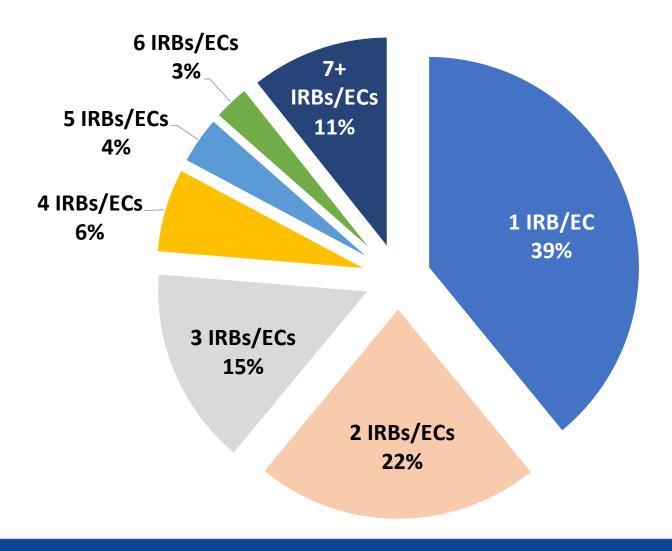
Number of internal IRBs/ECs organizations support

% of organizations that have internal IRBs/ECs

93.1%

Median # of IRBs/ECs per organization

2

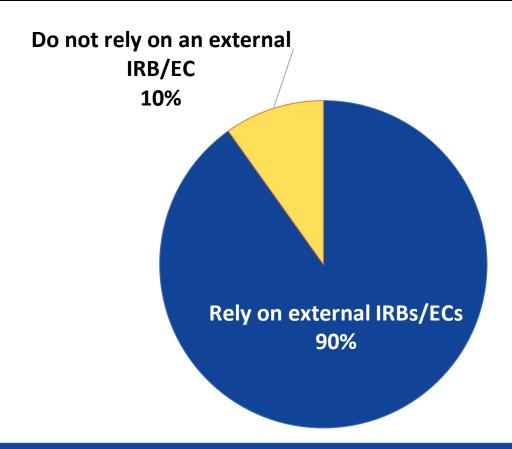


## Relying on External IRBs/ECs\*

Number of open studies reviewed by an external IRB/EC (median)

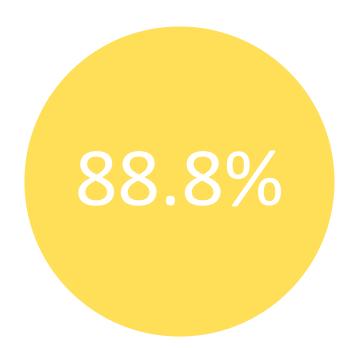
249

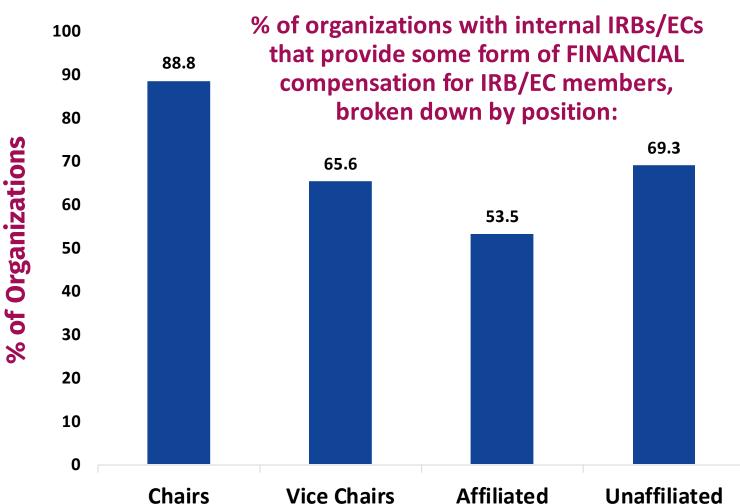
% of organizations with internal IRBs/ECs that also use external IRBs/ECs



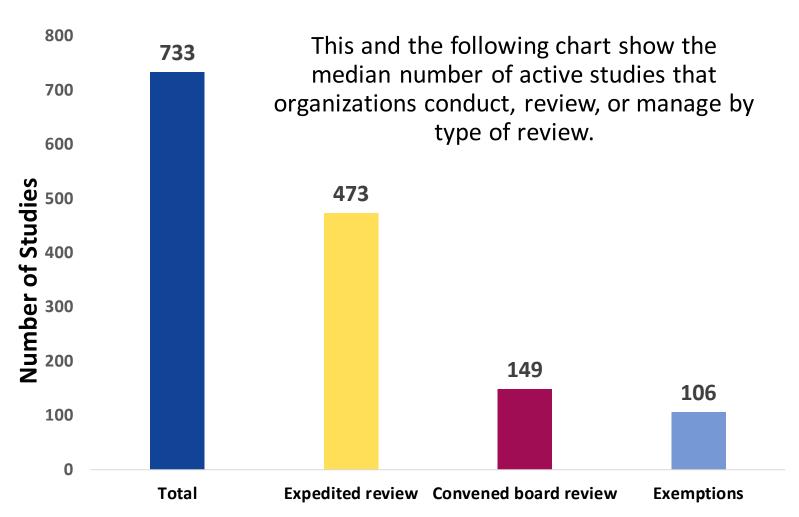
# Compensating IRB/EC Members

% of organizations with internal IRBs/ECs that provide some form of financial compensation to IRB/EC members





## Active Studies Overseen: All Organizations

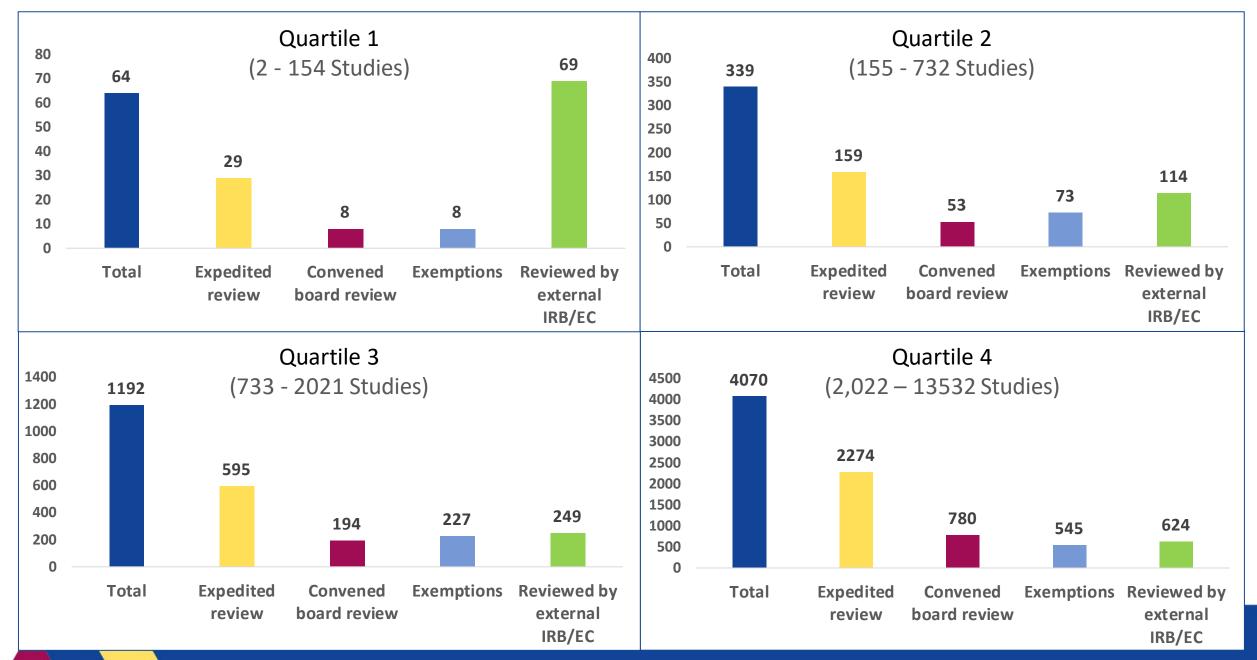


Exemptions are based on the number of determinations made by an organization for a 12-month period (e.g., the year prior to the AAHRPP report).

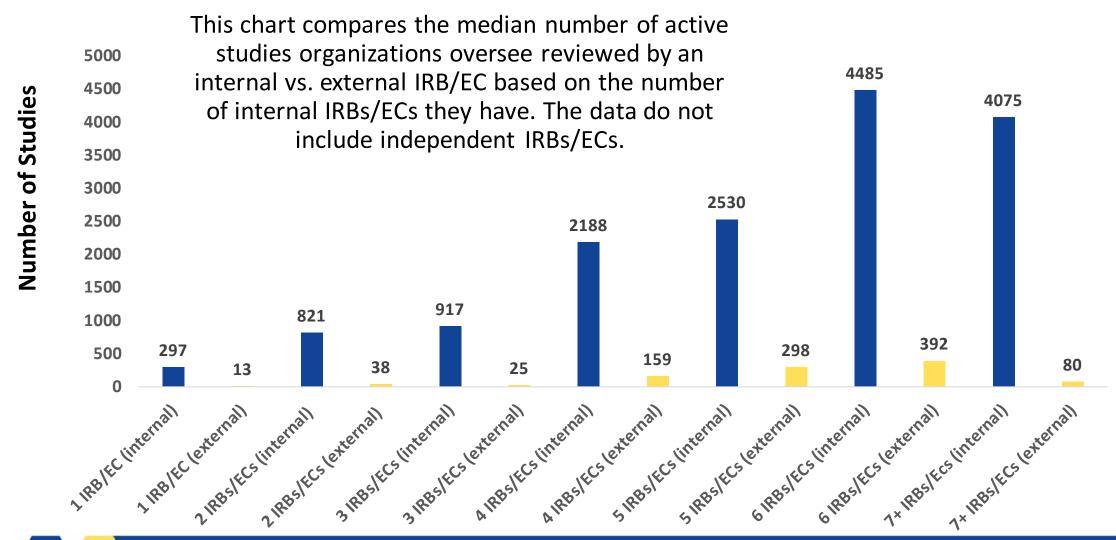
Expedited review and convened board review only include studies reviewed by an internal IRB/EC for organizations that have an internal IRB/EC and are not independent IRBs/ECs.

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

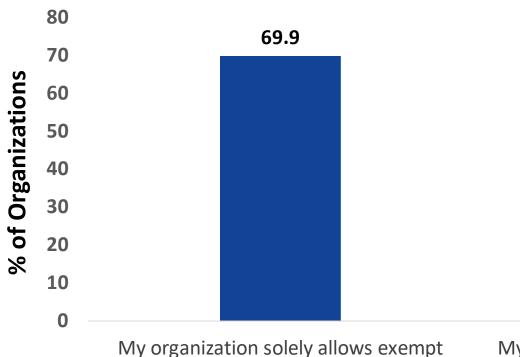
## Median Number of Active Studies (by Quartile)



#### Active Studies Per IRB/EC



## Policies and Procedures for Exempt Human Participants Research



My organization allows exempt human participants research determinations as outlined within US regulations as well as additional categories within institutional policy.

17.1

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

13

My organization does not follow the US Common Rule but allows exempt human participants research determinations as outlined within my country's regulations or my Organization's policy.

determinations as outlined within US regulations.

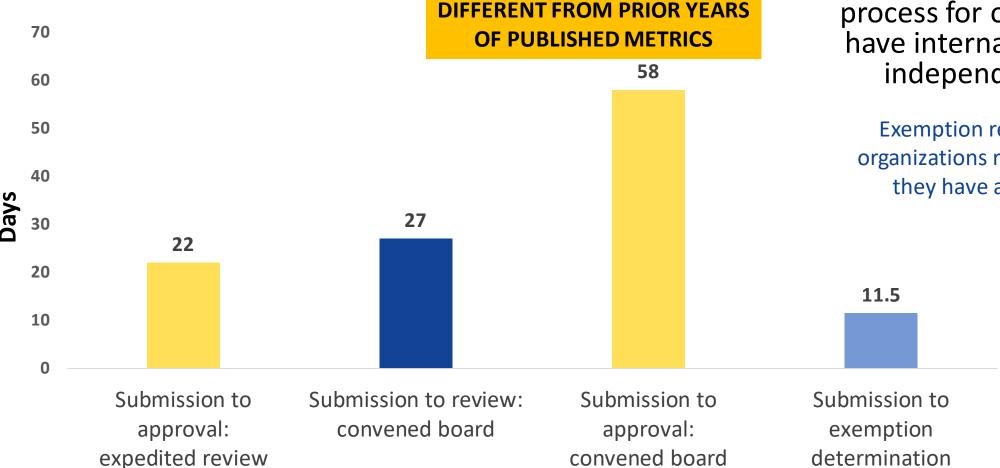
human participants research

**Review Times** 

## Data corrected December 2025

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

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



**NOTE: THE WAY REVIEW TIMES** 

WERE CALCULATED IS

# IRB/EC Technology

This table shows the technology used by organizations that have IRBs/ECs.

Only 4 organizations reported not using an electronic system.

# AAHRPP-Accredited organizations use technology...

that allows researchers to prepare and/or submit their applications for IRB/EC review.	94.4%
that allows IRB/EC members to review IRB/EC applications and supporting materials.	98.4%
that allows IRB/EC members and staff to communicate about IRB applications and other related materials.	93.0%
to document or record IRB/EC decisions and study- specific determinations within the system.	96.3%

# IRB/EC Staffing

Number of Active Studies	Median Number of Studies	Median Number of Staff	Median Number of Studies per Staff
All	691	9.0	103.6
0-100	41	2.0	13.5
101-500	262	6.0	65.8
501-1000	758.5	4.0	116.6
1001-2000	1433.5	11.0	106.2
2001-4000	2727.5	20.5	138.2
4001+	5843	23.6	231.0

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

Data from organizations without internal IRBs/ECs are not included

#### **Audits of Researchers**

% of organizations that reported - audits of researchers had occurred

79.5%

Internal: "for cause"

• Median: 1

• Total: 2022

Internal: random

• Median: 15

• Total: 15139

Regulatory agency inspections

• Median: 0

• Total: 129

## Audits of IRBs/ECs

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

1

**59%** 

Internal: "for cause"

• Median: 0

• Total: 234

Internal: random

• Median: 2

• Total: 6637

Regulatory agency inspections

• Median: 0

• Total: 588

#### Noncompliance & Unanticipated Problems

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.

Number of active studies	Median # & Total reported	Serious noncompliance determinations	Continuing noncompliance determinations	Unanticipated problems determinations
All	Median	1	0	1
	Total	1531	1017	2855
0-100	Median	0	0	0
	Total	23	28	75
101-500	Median	1	0	0
	Total	105	46	338
501-1000	Median	1	1	1
	Total	147	78	180
1001-2000	Median	2	0	2
	Total	331	64	298
2001-4000	Median	3	0	4
	Total	197	160	702
4001+	Median	6.5	1	9.5
	Total	728	641	1258

#### Conflicts of Interest

This graphic shows the median number of studies with a financial management plan reviewed by an IRB/EC 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

Studies with a financial conflict of interest management plan reviewed by an IRB/EC (internal or external)

