

# 2023 Metrics for AAHRPP-Accredited Human Research Protection Programs

**Academic Organizations** 

**May 2024** 



### **About the Metrics**

AAHRPP is pleased to present the 2023 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. More changes to come next year. 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 AAHRPP organizations.

### **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

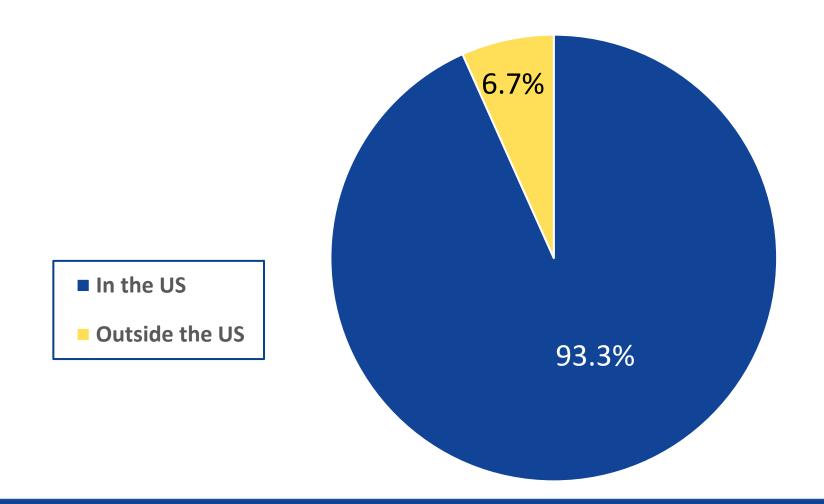
VA US Department of Veterans Affairs



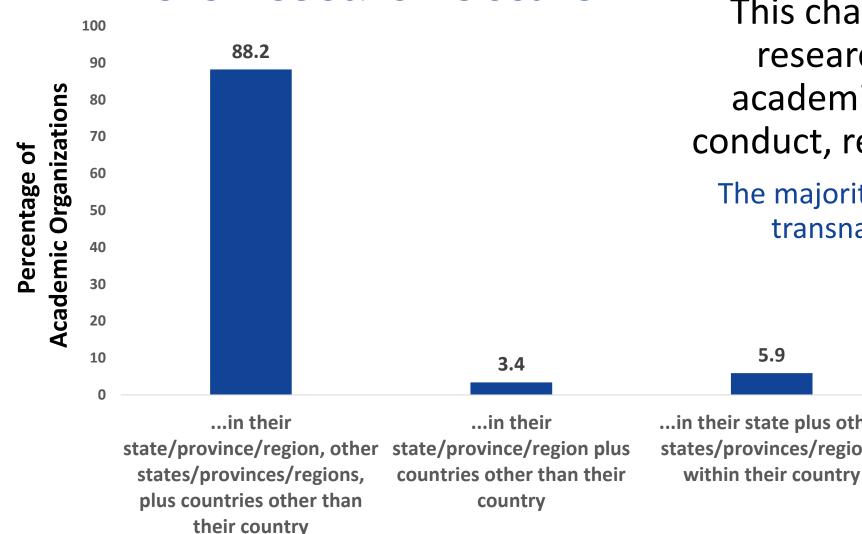
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### Where Accredited Academic Organizations are Based



### **Where Research Occurs**



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

The majority conduct or review transnational research.

...in their state plus other states/provinces/regions

...only in their state/province/region within their country

2.5

### **Research Type**

Most academic organizations conduct or review biomedical/clinical research

99.2%

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



### **Biomedical/Clinical Research by Type**

Drugs

90.8%

Devices

93.3%

Planned Emergency Research

56.3%

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

## **Vulnerable Populations**

Children

100%

Adults Unable to Consent

96.7%

Pregnant Women

96.7%

Prisoners

86.7%

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

99.2%

Industry sponsored

95.0%

Sponsored by other external sources

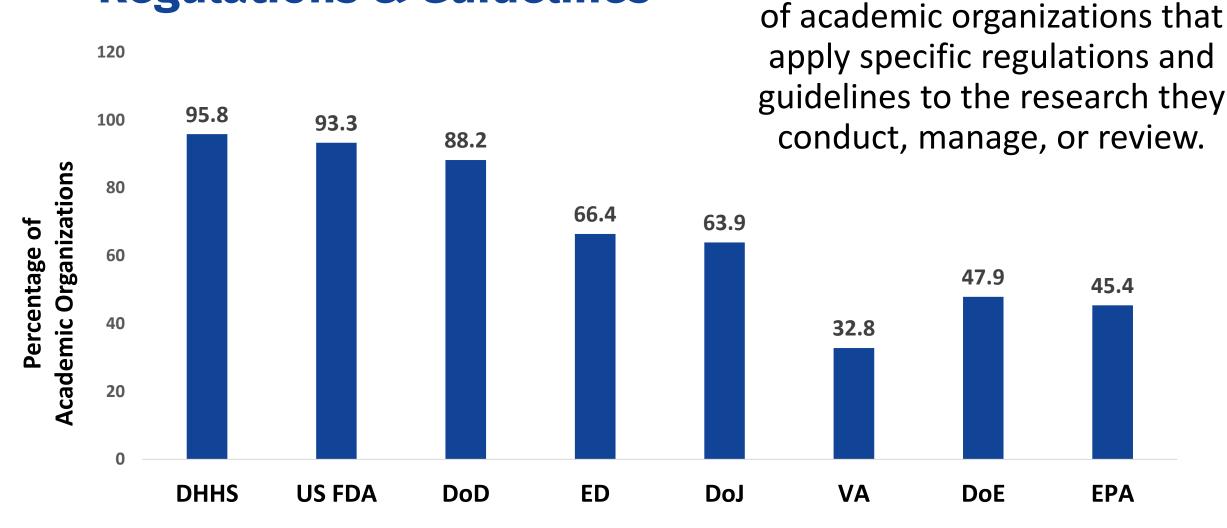
96.6%

Government or federally sponsored

92.4%

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

### **Regulations & Guidelines**



This chart shows the percentage

# Number of internal IRBs/ECs of academic organizations support

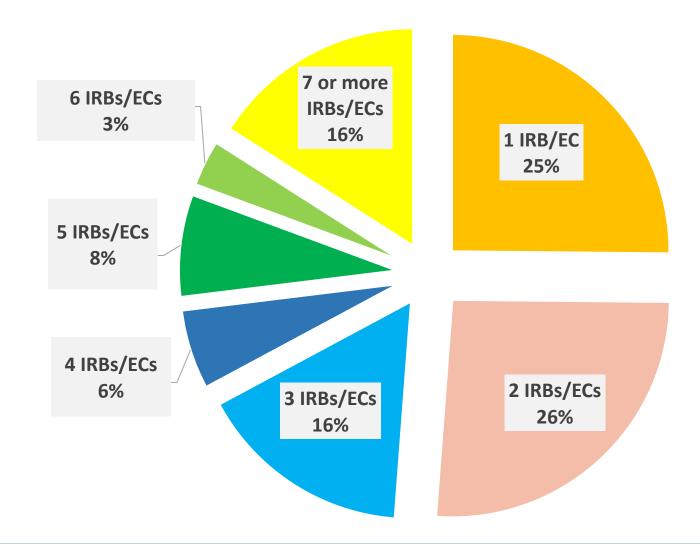
### **Internal IRBs/ECs**

% of academic organizations that have internal IRBs/ECs

100%

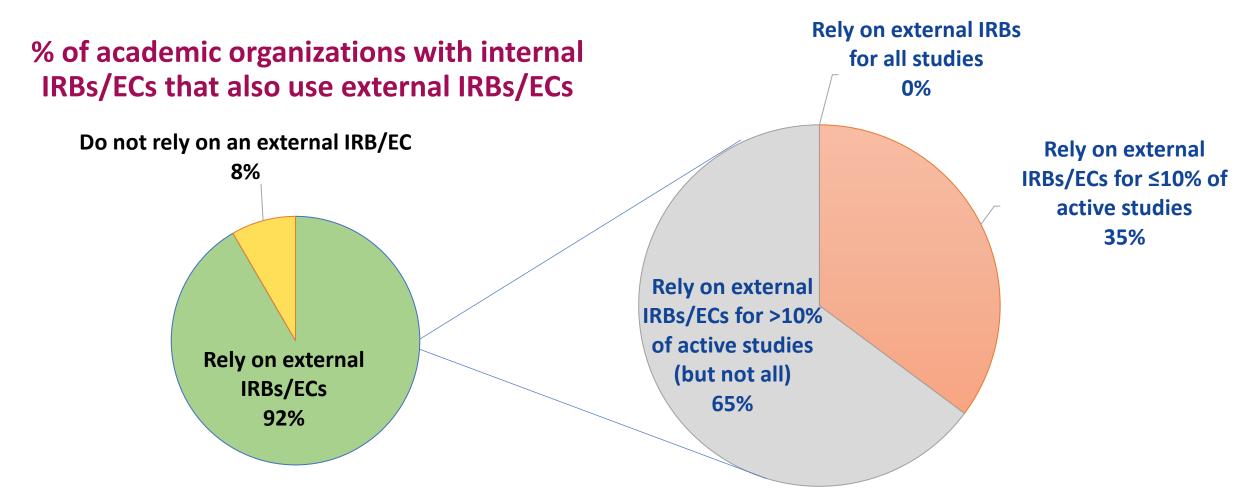
Median # of IRBs/ECs per academic organization

2



### Relying on External IRBs/ECs

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

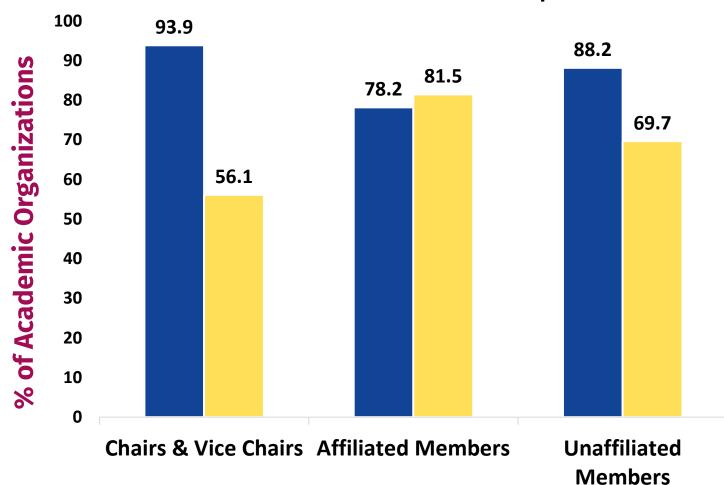


# **Compensating IRB/EC Members**

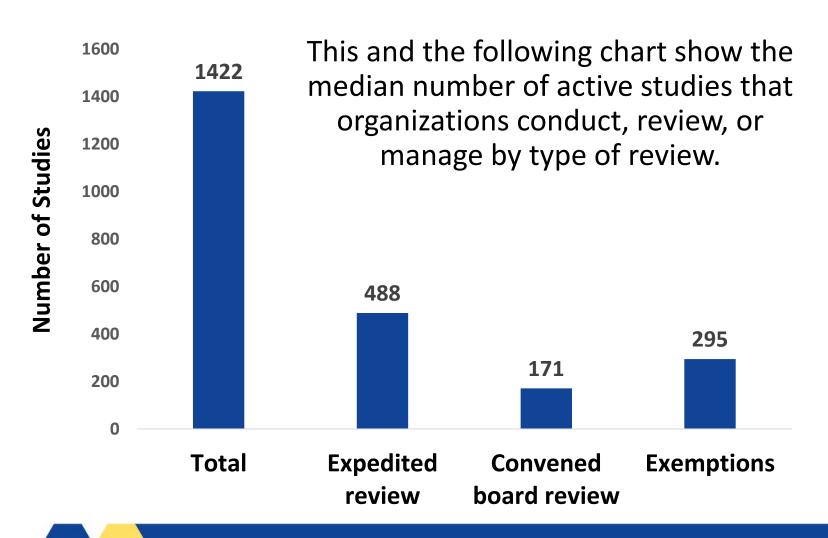
- **■** Financial compensation
- Non-Financial compensation

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





### **Active Studies Overseen: All Academic Organizations**

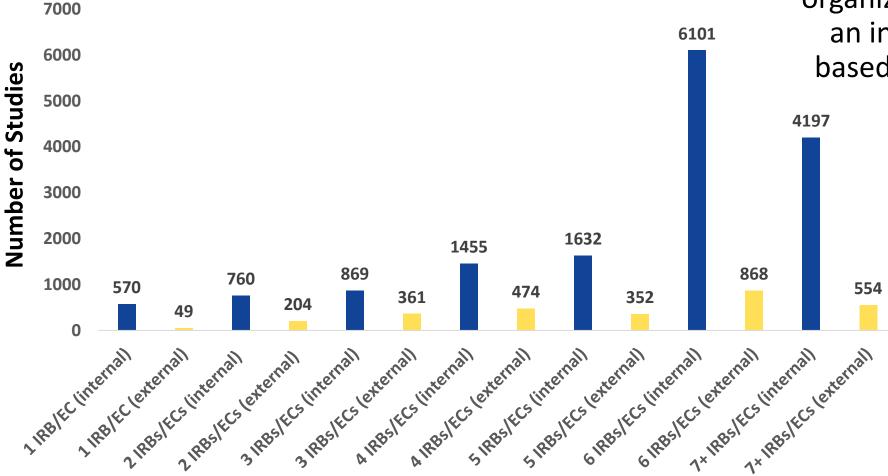


Exemptions are based on the number of determinations made by an organization for a 12-month period (e.g., the year prior to the AAHRPP report).

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.

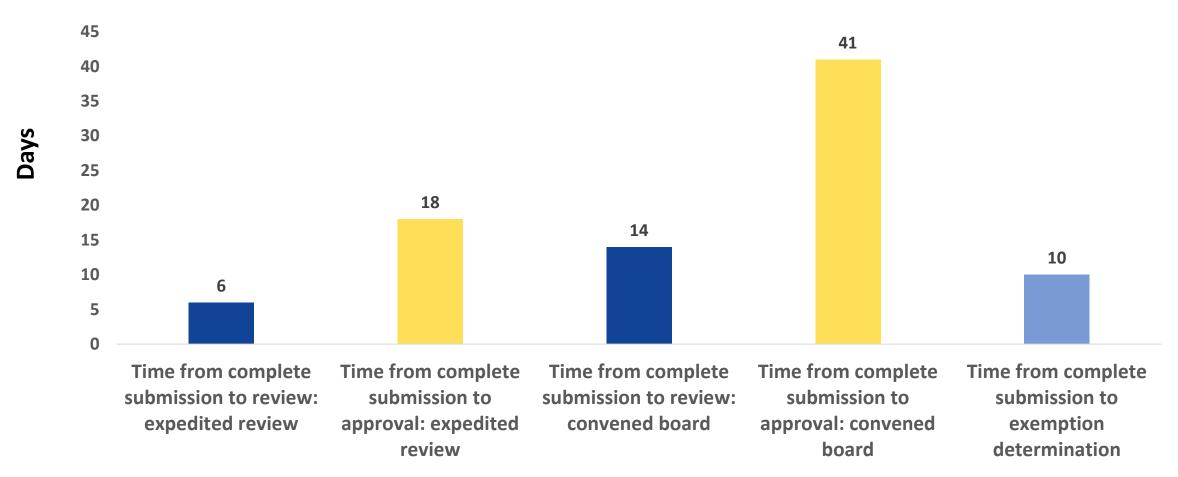
# **Active Studies Per IRB/EC: All Academic Organizations**



This chart compares the median number of active studies academic organizations oversee reviewed by an internal vs. external IRB/EC based on the number of internal IRBs/ECs they have.

### **Review Times**

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



## **IRB/EC Technology**

Online application submission	92.4%
Online protocol/materials distribution to IRB/EC members	92.4%
Online review functions	95.0%
Database for submission tracking	82.4%
Does not use an electronic system	0.8%

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	1437	10.0	143.7	\$925,237
0-500	239	3.0	79.7	\$294,916
501-1000	695	6.0	115.8	\$573,866
1001-2000	1437	10.0	143.7	\$977,337
2001-4000	2678	13.0	206.0	\$1,431,706
4001+	5678	23.8	238.3	\$2,517,398

#### **Corrected**

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**

% of academic organizations that reported that audits of researchers occurred

89.9%

Internal: "for cause"

• Median: 2

• Total: 4,325

Internal: random

• Median: 18

• Total: 8,521

Regulatory agency inspections

• Median: 1

• Total: 585

### **Audits of IRBs/ECs**

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

**78.2%** 

Internal: "for cause"

• Median: 0

• Total: 340

Internal: random

• Median: 5

• Total: 6,235

Regulatory agency inspections

• Median: 0

• Total: 41

#### Unresolved Complaints, Noncompliance, & Unanticipated Problems

Number of active studies	Unresolved complaints		noncompliance	Continuing noncompliance determinations	Unanticipated problems determinations
All	0	10.5	1	0	1
0-500	0	2	0	0	0
501-1000	0	5	1	0	1
1001-2000	0	33	3	1	1
2001-4000	0	15.5	2	1	3
4001+	0	77	6	1.5	10

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 graphic shows the median number of studies reviewed by an IRB/EC for academic 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 were reviewed by an IRB/EC (internal or external)

