

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

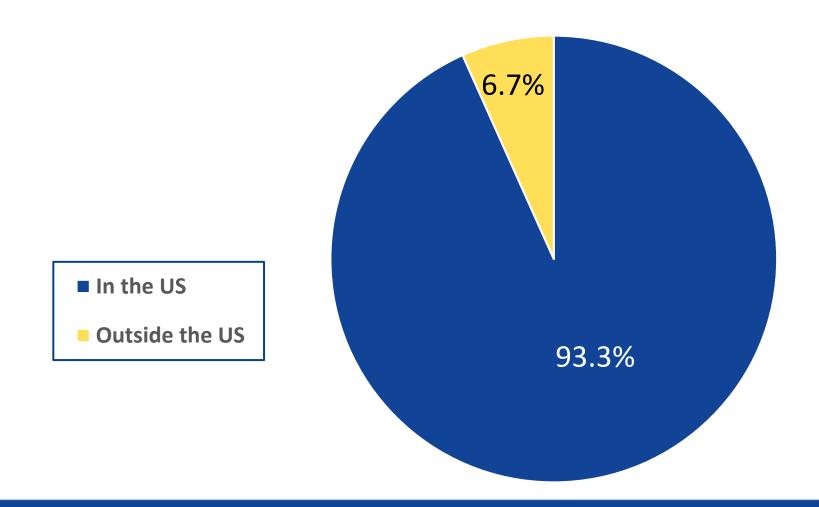
VA US Department of Veterans Affairs



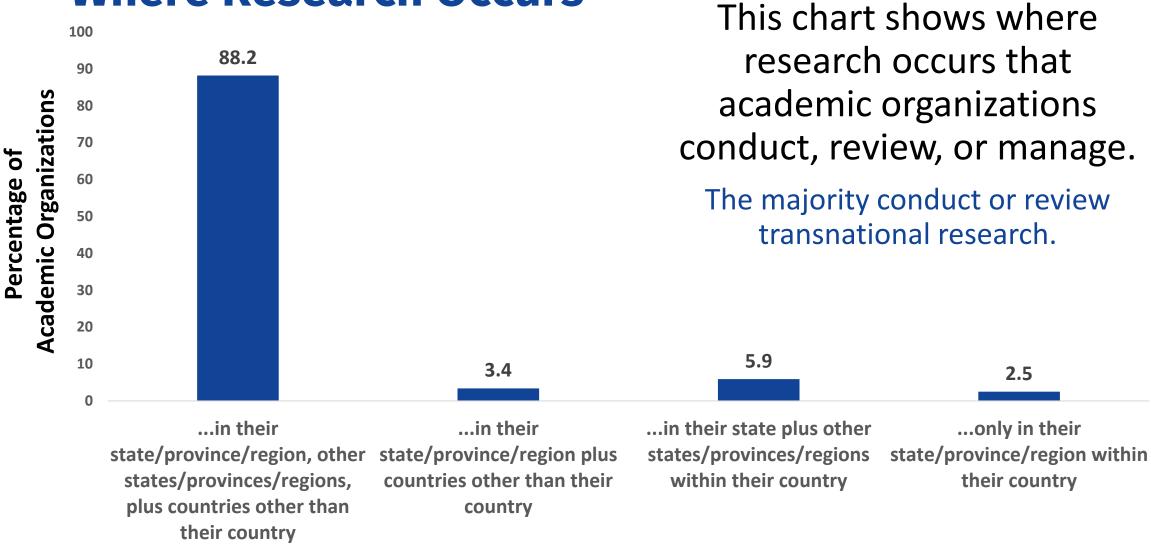
Table of Contents

General Description of Organizations	Slide 5: Where Accredited Academic Organizations are Based	Research Review: Number of Studies	Slide 15: Active Studies Overseen: All
General Description of Research	 Slide 6: Where Research Occurs Slide 7: Research Type Slide 8: Biomedical/Clinical Research by Type Slide 9: Vulnerable Populations 		 Academic Organizations Slide 16: Active Studies Per IRB/EC Slide 17: Review Times
Research Funding and Regulations	 Slide 10: Funding Type Slide 11: Regulations & Guidelines 	Resources and Budget	 Slide 18: IRB/EC Technology Slide 19: IRB/EC Staffing and Budget
Use of IRBs/ECs	 Slide 12: Internal IRBs/ECs Slide 13: Relying on External IRBs/ECs Slide 14: Compensating IRB/EC Members 	Audits, Reportable Events, and Conflicts of Interest	 Slide 20: Audits of Researchers Slide 21: Audits of IRBs/ECs Slide 22: Unresolved Complaints, Noncompliance, & Unanticipated Problems Slide 23: Conflicts of Interest

Where Accredited Academic Organizations are Based



Where Research Occurs



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

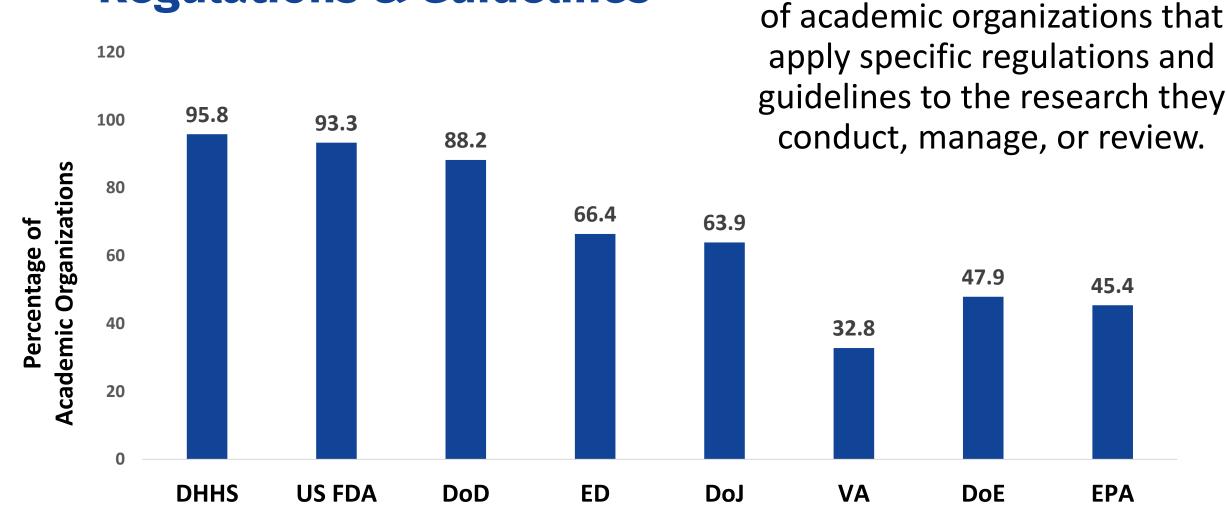
96.6%

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

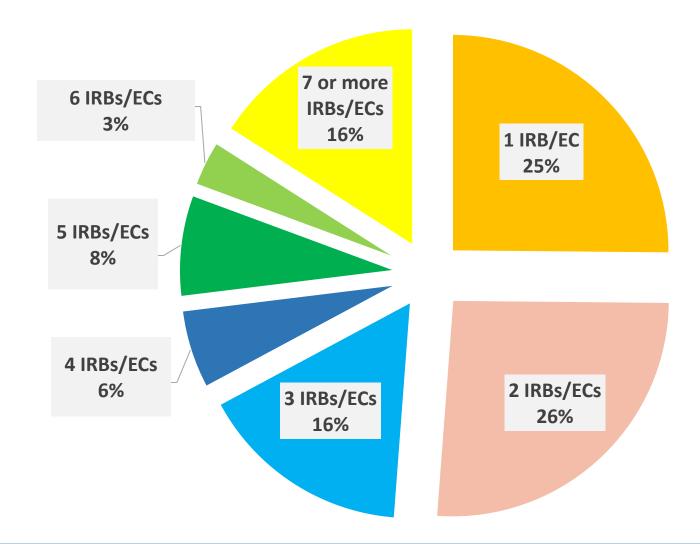
Internal IRBs/ECs

% of academic organizations that have internal IRBs/ECs

100%

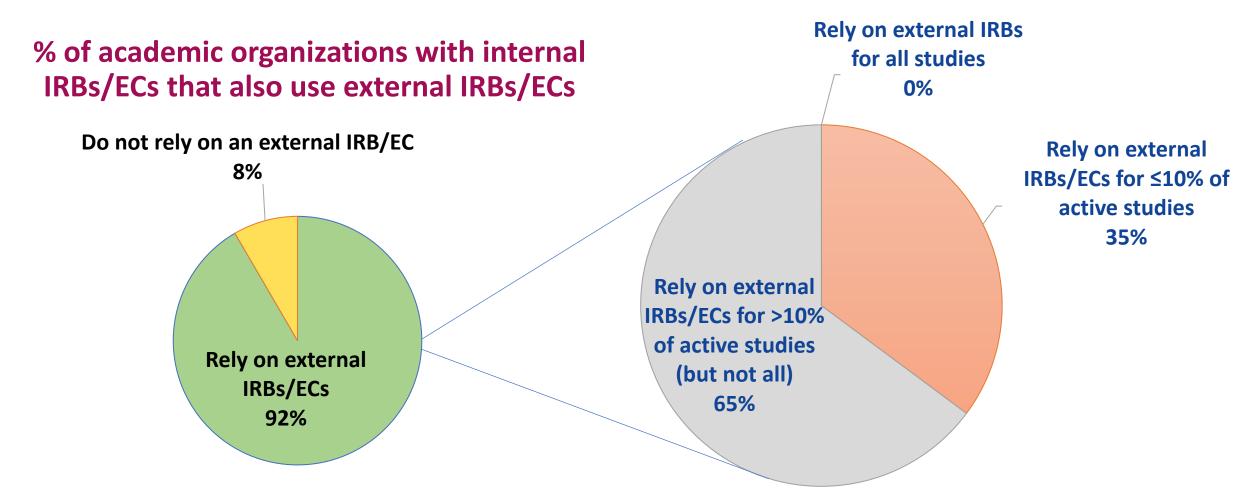
Median # of IRBs/ECs per academic organization

2



Relying on External IRBs/ECs

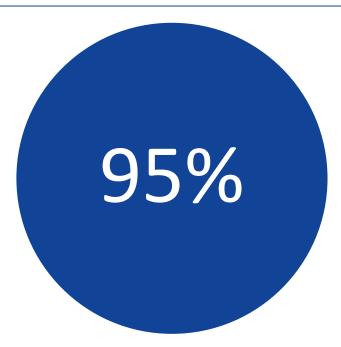
Use of external IRBs/ECs by academic organizations with internal IRBs/ECs

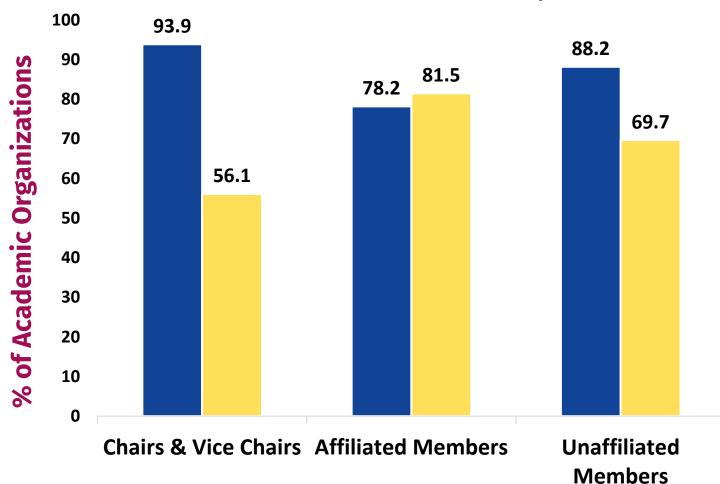


Compensating IRB/EC Members

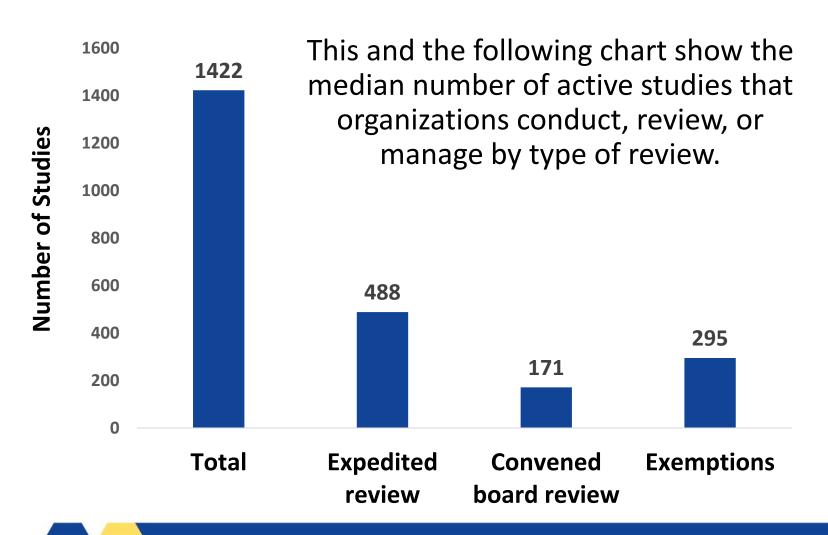
- **■** Financial compensation
- Non-Financial compensation

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





Active Studies Overseen: All Academic Organizations

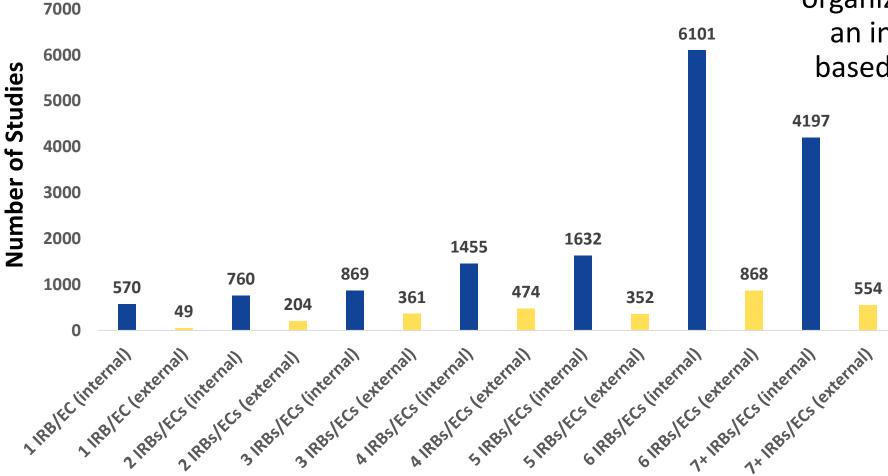


Exemptions are based on the number of determinations made by an organization for a 12-month period (e.g., the year prior to the AAHRPP report).

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.

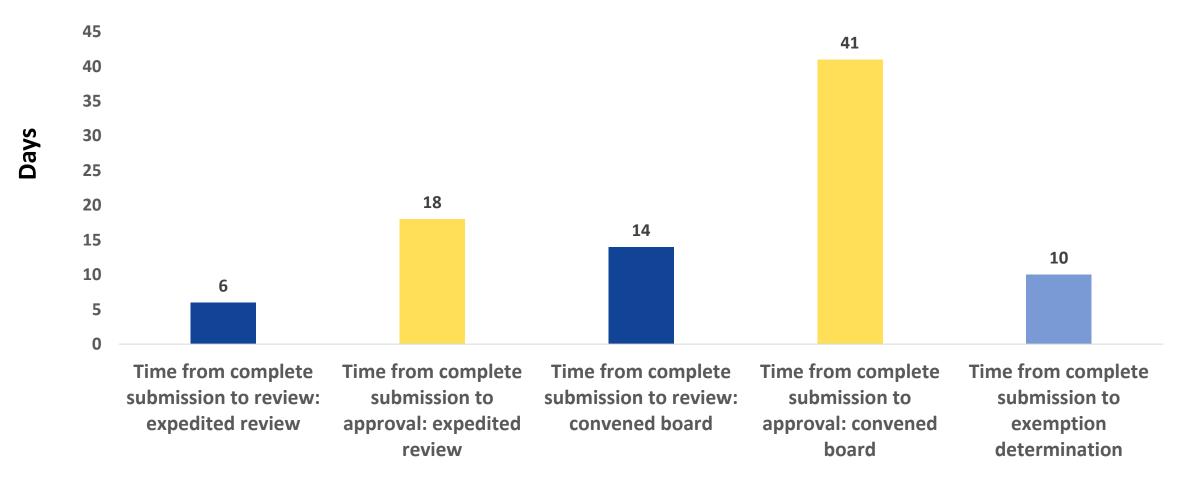
Active Studies Per IRB/EC: All Academic Organizations



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	1234.00	10.0	122.3	\$925,237
0-500	36.50	2.5	13.7	\$295,988
501-1000	309.00	3.2	70.3	\$358,138
1001-2000	751.00	5.9	104.6	\$630,000
2001-4000	1422.00	11.0	134.7	\$1,016,262
4001+	3235.50	20.0	164.1	\$1,639,070

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	Investigations of alleged noncompliance	noncompliance	Continuing noncompliance 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)

