

#### **2022 Metrics for AAHRPP-Accredited** Human Research Protection Programs

**Academic Organizations** 

May 2023



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

# **Metrics About Academic Organizations**

AAHRPP is pleased to present the 2022 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 academic organizations.

All the quantitative data were derived from the most recent reports submitted by academic 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
- ICH GCP International Conference on Harmonisation Good Clinical Practice
- VA US Department of Veterans Affairs





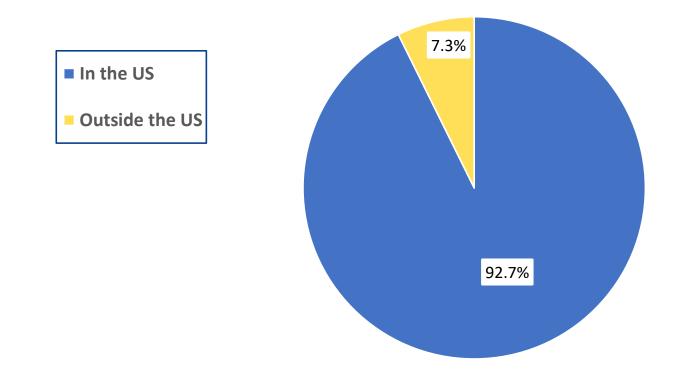


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### Where Accredited Academic Organizations are Based

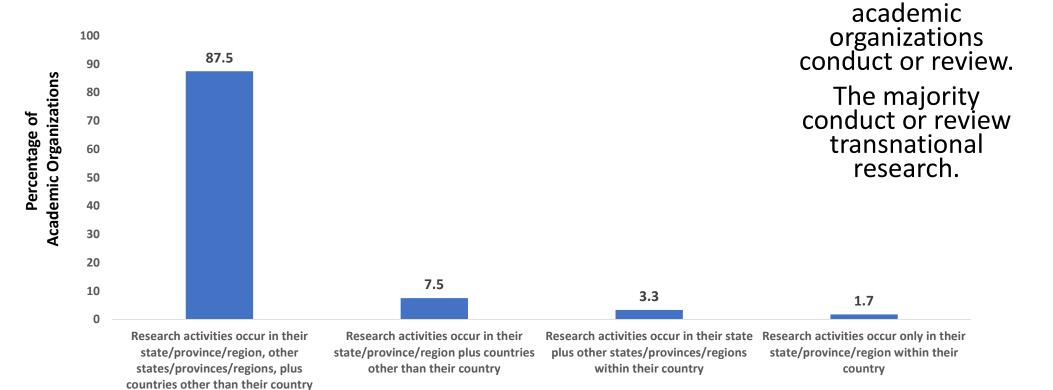




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### **Where Research Occurs**



This chart shows

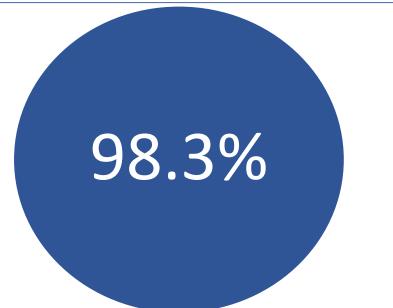
where research occurs that



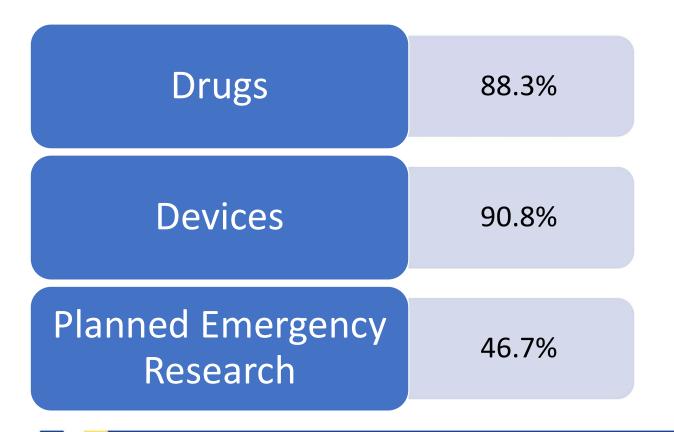
Most academic organizations conduct or review biomedical/clinical research Most academic organizations conduct or review social/behavioral/education research

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# 99.2%







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

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### **Vulnerable Populations**

Children	100%	
Adults Unable to Consent	96.7%	
Pregnant Women	96.7%	
Employees	89.2%	
Students	89.2%	
Prisoners	86.7%	
Other	24.2%	

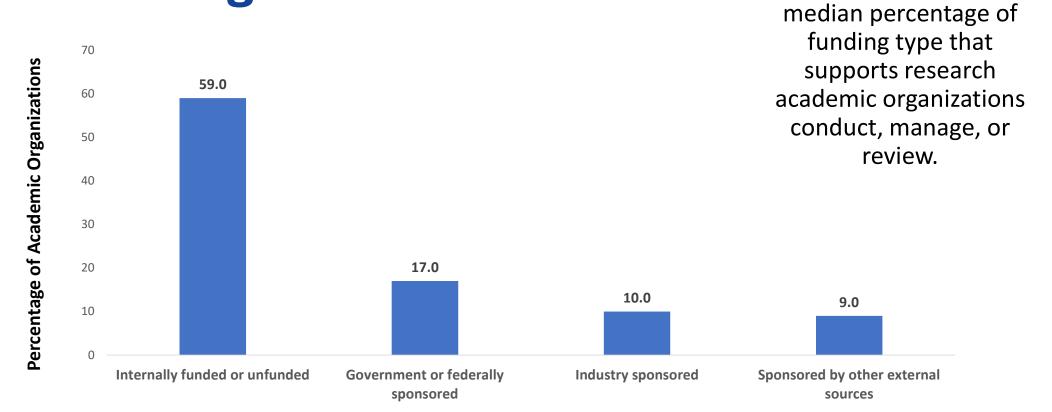
This table shows the categories of vulnerable populations that participate in research conducted or reviewed by academic organizations. Populations Organizations also identified as vulnerable (i.e., "Other") include Native Americans, neonates of uncertain viability, those who are educationally or economically 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.

Internally funded or unfunded	100%
Industry sponsored	99.2%
Sponsored by other external sources	97.5%
Government or federally sponsored	95.0%

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



# **Funding Distribution**



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This chart shows the

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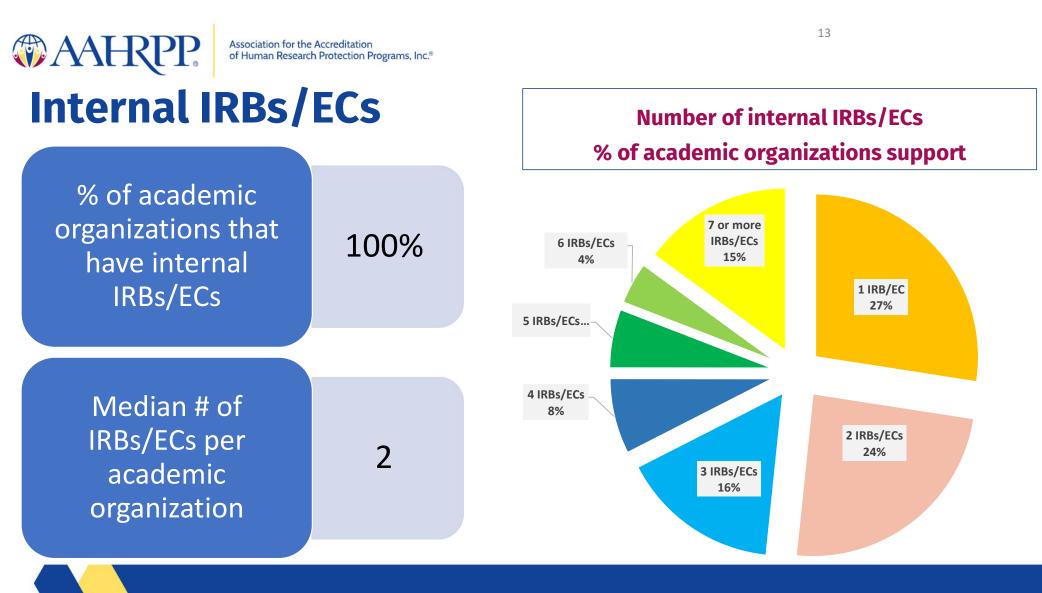
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## **Regulations & Guidelines**

percentage of academic organizations that apply specific regulations and guidelines to the research they conduct, 120 95.8 100 90.8 87.5 Academic Organizations manage, or review. 80 Percentage of 65.0 61.7 60 43.3 42.5 40 34.2 20 0 DHHS **US FDA** DoD ED DoJ VA DoE **EPA** 

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This chart shows the

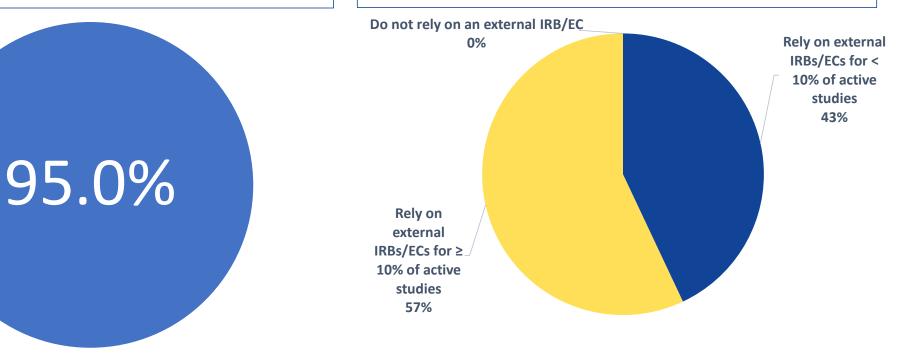




**Relying on External IRBs/ECs** 

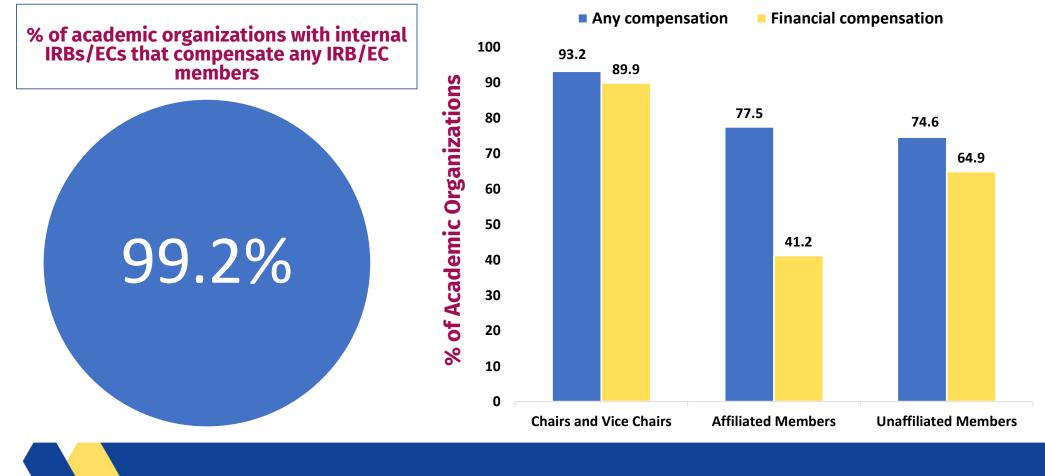
#### % of academic organizations with internal IRBs/ECs that also use external IRBs/ECs

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



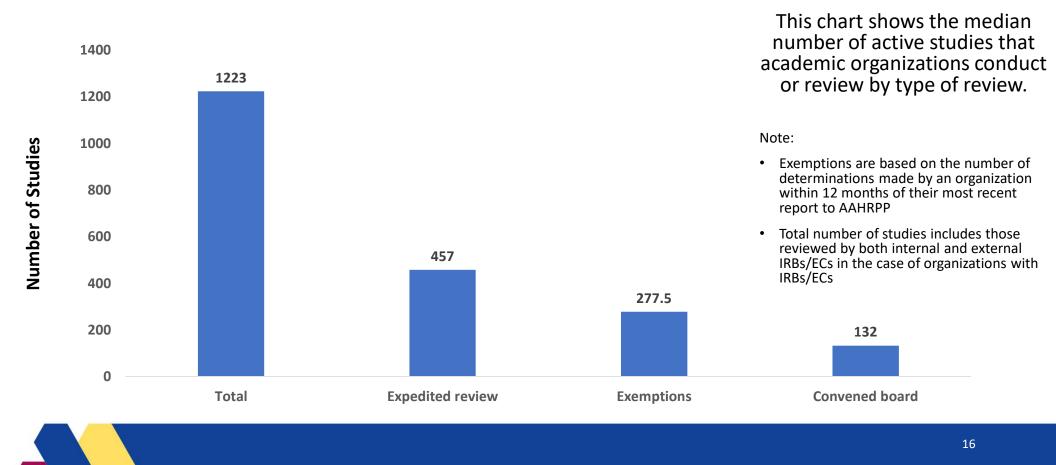


## **Compensating IRB/EC Members**



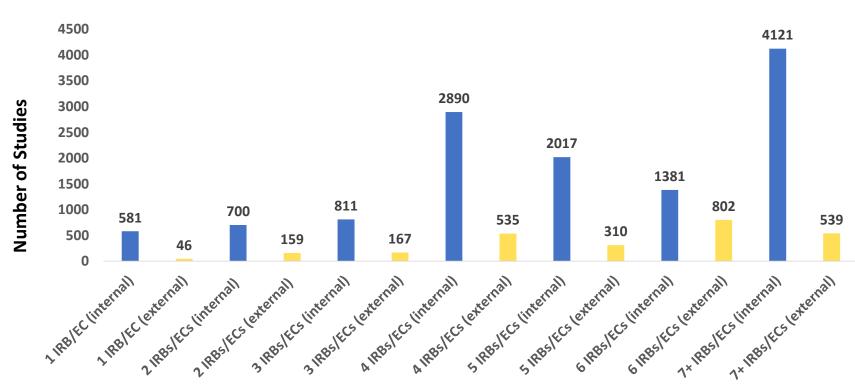


### **Active Studies Overseen: All Academic Organizations**





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

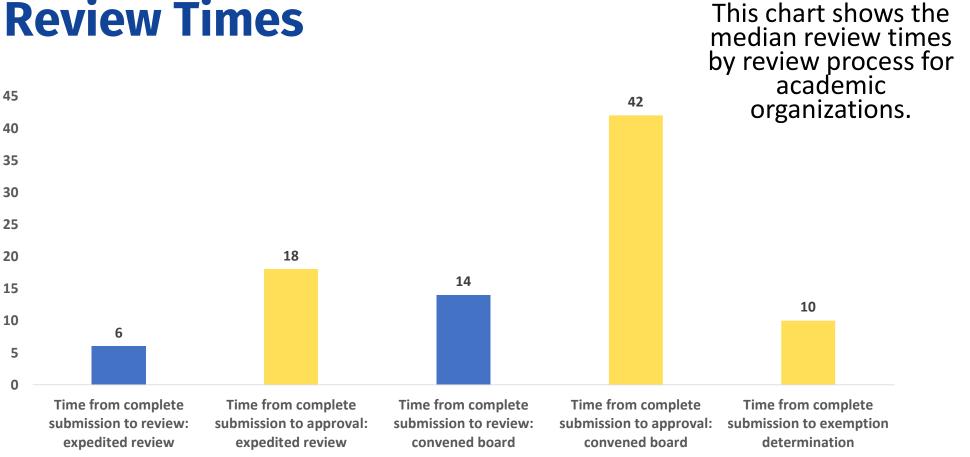


This chart compares the median number of active studies academic organizations oversee reviewed by an internal vs. external IRB/EC based on the number of internal IRBs/ECs they have.

Note:

 Median number of studies reflect exemption determinations that could be made by internal or external IRBs/ECs.





Days

#### Association for the Accreditation of Human Research Protection Programs, Inc.® IRB/EC Technology

Online application submission	92.4%
Online protocol/materials distribution to IRB/EC members	92.4%
Online review functions	91.6%
Database for submission tracking	86.6%
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	1221	9.6	127.2	\$744,373
0-500	306	3	102	\$275,180
501-1000	683	6	113.8	\$554,946
1001-2000	1356	9.8	138.4	\$890,000
2001-4000	2865.5	16.7	171.6	\$1,352,671
4001+	5996	23.3	257.3	\$2,568,110

#### 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.

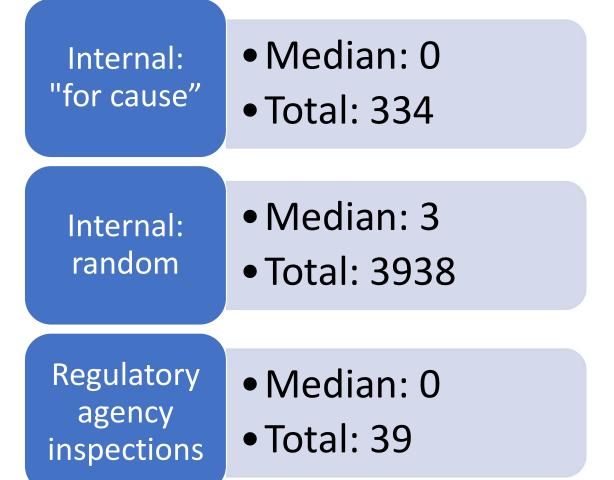


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Audits of Researchers	Internal: "for cause" • Total: 385
occurred	Internal: random • Median: 13 • Total: 5565
89.9%	Regulatory agency inspections • Median: 0 • Total: 114
	agency Tatal 114



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

**79%** 



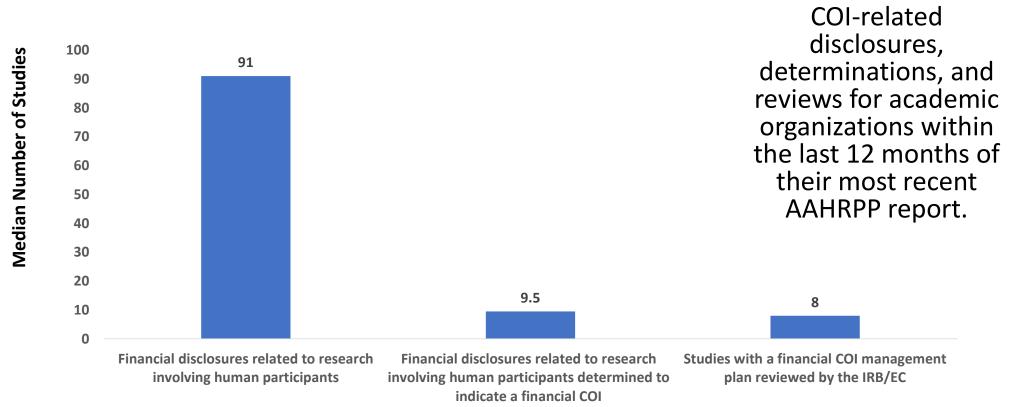


### **Unresolved Complaints, Noncompliance, & Unanticipated Problems**

Number of active studies	Unresolved		noncompliance	Continuing noncompliance determinations	Unanticipated problems determinations	Th base mon an orga
All	0	8.5	1	0	1	mo
0-500	0	2	0	0	0	r AA
501-1000	0	4	1	0	0	sł med
1001-200	0 0	32	2	0	2	ofe
2001-400	0 0	11.5	2	0	2.5	C
4001+	0	65	3	2	4	

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.





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This chart shows the

median number of