

2022 Metrics for AAHRPP-Accredited Human Research Protection Programs

Hospitals

May 2023





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 hospitals.

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



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







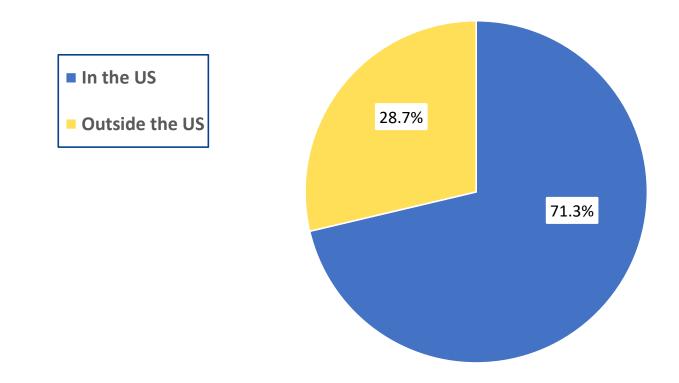
Table of Contents

General Description of Organizations	Slide 5: Where Accredited Hospitals are Based	Research Review: Number of Studies	 Slide 16: Active Studies Overseen: All Hospitals Slide 17: Active Studies: Internal vs. External IRB/EC
General Description of Research	 Slide 6: Where Research Occurs Slide 7: Research Type Slide 8: Biomedical/Clinical Research by Type Slide 9: Vulnerable Populations 		Slide 18: Review Times
Research Funding and Regulations	 Slide 10: Funding Type Slide 11: Funding Distribution Slide 12: Regulations & Guidelines 	Resources and Budget	 Slide 19: IRB/EC Technology Slide 20: IRB/EC Staffing and Budget
Use of IRBs/ECs	 Slide 13: Internal IRBs/ECs Slide 14: Relying on External IRBs/ECs Slide 15: Compensating IRB/EC Members 	Audits, Reportable Events, and Conflicts of interest	 Slide 21: Audits of Researchers Slide 22: Audits of IRBs/ECs Slide 23: Unresolved Complaints, Noncompliance, & Unanticipated Problems Slide 24: Conflicts of Interest



of Human Research Protection Programs, Inc.®

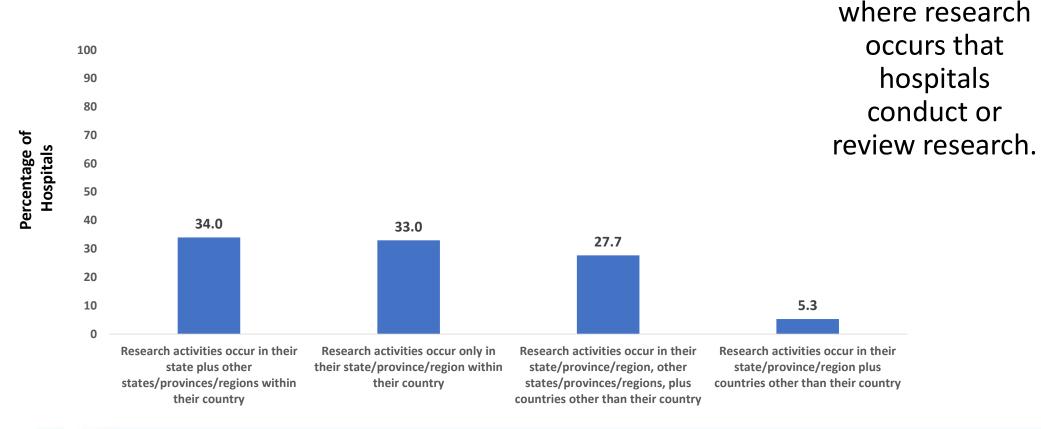
Where Accredited Hospitals are Based







Where Research Occurs



6

This chart shows

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

All hospitals conduct or review biomedical/clinical research

100%

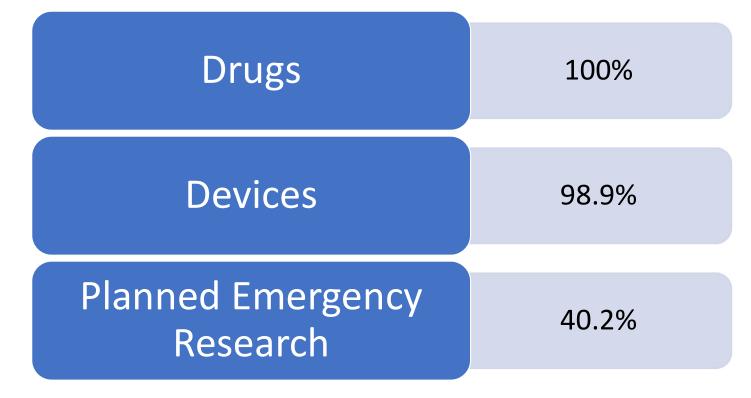
Most hospitals conduct or review social/behavioral/education research

7

91.5%



Biomedical/Clinical Research by Type



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



Vulnerable Populations

Children	96.8%	T
Adults Unable to Consent	93.6%	
Pregnant Women	92.6%	
Employees	80.9%	I
Students	73.4%	
Prisoners	34.0%	
Other	23.4%	

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

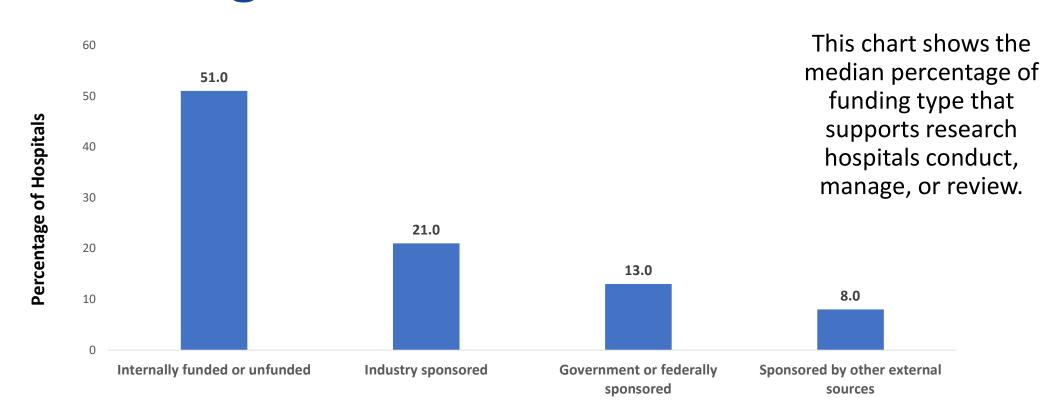


Industry sponsored	98.9%
Internally funded or unfunded	98.9%
Sponsored by other external sources	93.9%
Government or federally sponsored	73.4%

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



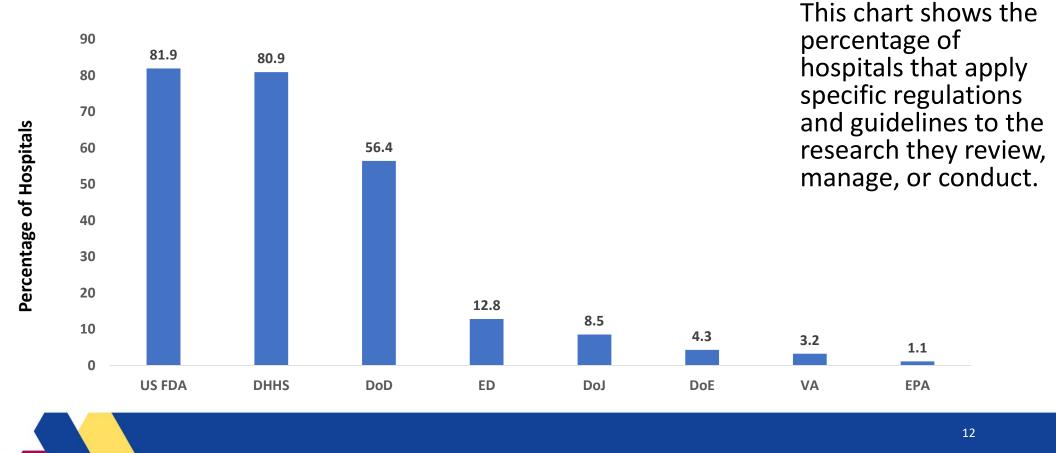


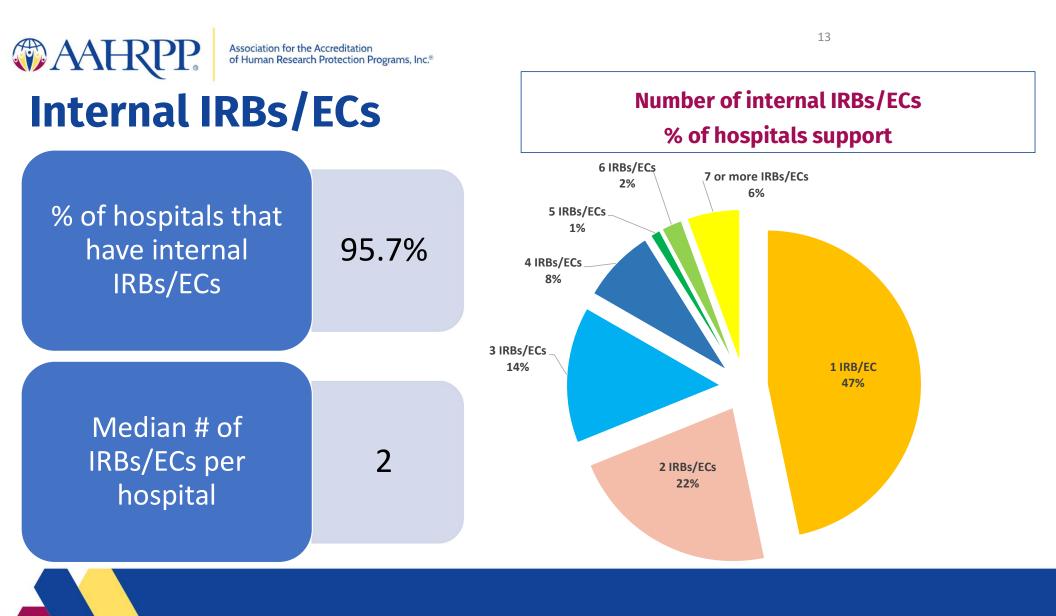


AAHRPP.

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

Regulations & Guidelines







Relying on External IRBs/ECs

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

77.0%

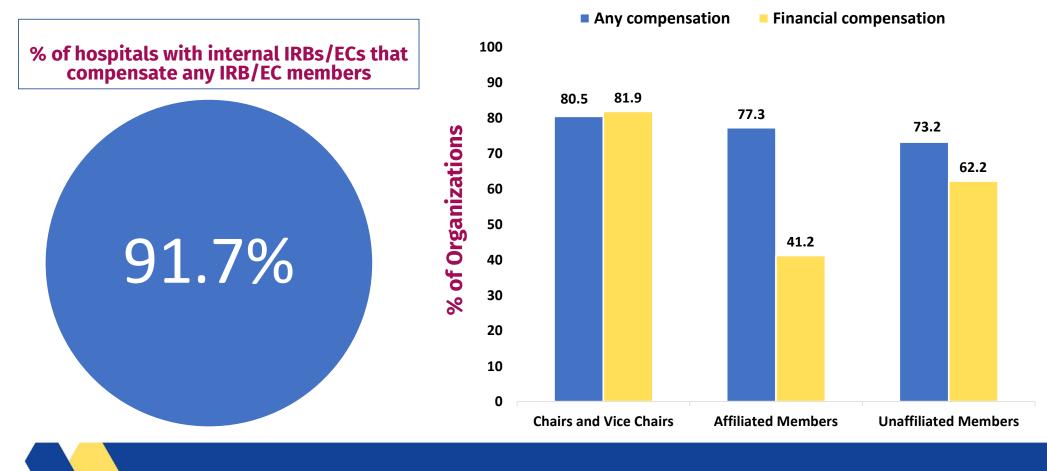
Use of external IRBs/ECs by hospitals with internal IRBs/ECs

Rely on external IRBs/ECs for < 109 of active studies 24% Do not rely on an external IRB/EC 25%

Rely on external IRBs/ECs for ≥ 10% of active studies 51%



Compensating IRB/EC Members



Number of Studies

Active Studies Overseen: All Hospitals

hospitals conduct or review by type of review. 700 648.5 Note: 600 Exemptions are based on the number of determinations made by an hospitals within 12 months of their most recent report to AAHRPP • 500 Total number of studies includes those reviewed by both internal and external IRBs/ECs in the case of hospitals with 400 IRBs/ECs 300 218 200 135 100 48 0 **Total Expedited Review Convened board Exemptions**

16

This chart shows the median number of active studies that



2500

Number of Studies

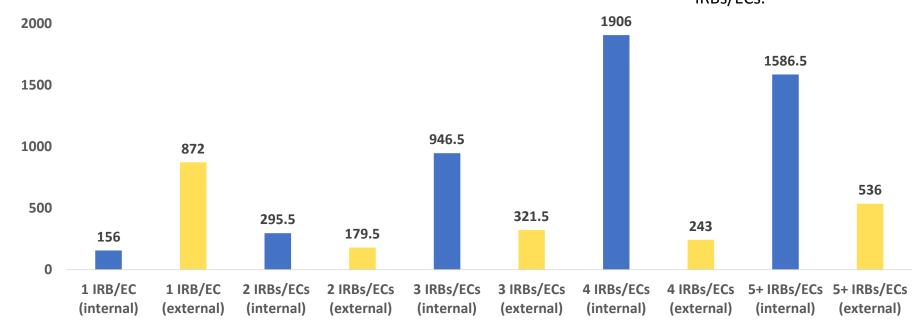
Association for the Accreditation of Human Research Protection Programs, Inc.®

Active Studies Per IRB/EC: All Hospitals

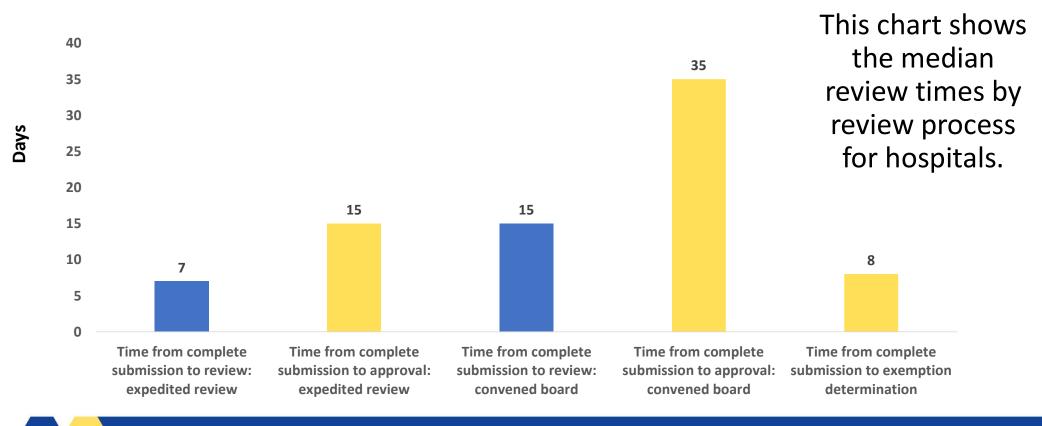
This chart compares the median number of active studies hospitals oversee reviewed by an internal vs. external IRB/EC based on the number of internal IRBs/ECs they have.

Note:

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









Online review functions	98.3%	This table shows the technology hospitals use to support
Online application submission	93.3%	IRB/EC tracking, submission, distribution, and the
Online protocol/materials distribution to IRB/EC members	88.8%	specific functions used.
Database for submission tracking	87.6%	
Does not use an electronic system	0%	





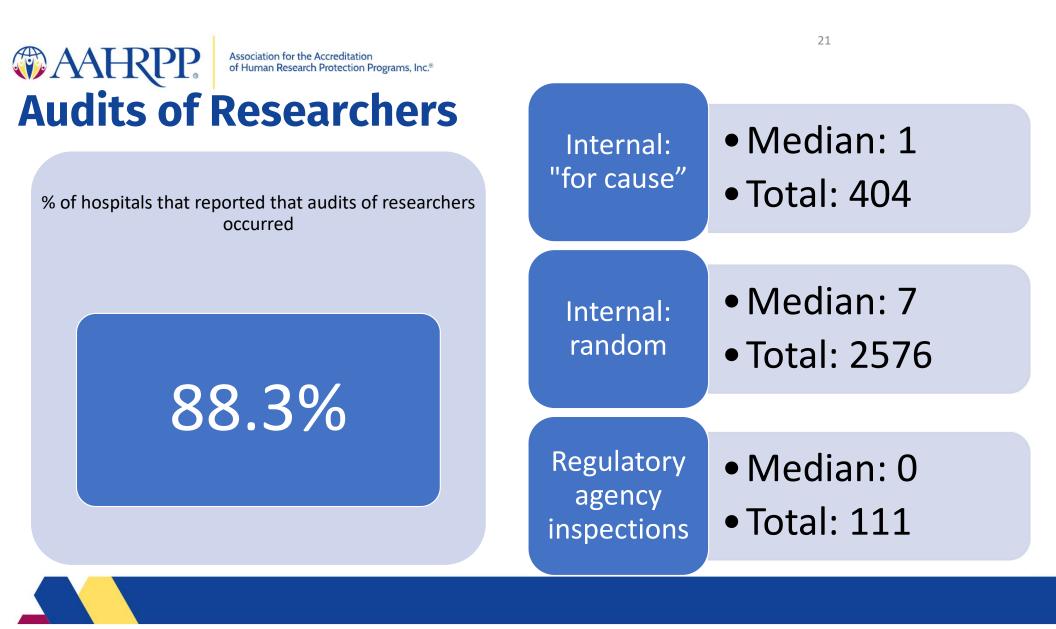
IRB/EC Staffing and Budget

Number of Active Studies	Median Number of Studies	Median Number of Staff	Median Number of Studies per Staff	Median IRB/EC Budget
All	648.5	4.5	144.1	\$350,000
0-100	34.5	1	34.5	\$120,506
101-500	218	3	72.7	\$164,864
501-1000	720.5	6.5	110.8	\$460,551
1001-2000	1533	10.4	147.4	\$925,087
2001-4000	2648	11	240.7	\$713,016
4001+	4986	21.9	227.7	\$1,800,000

Corrected

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





22 AAHRPP: Association for the Accreditation of Human Research Protection Programs, Inc.® **Audits of IRBs/ECs** • Median: 0 Internal: "for cause" • Total: 45 % of hospitals that reported that • Median: 2 Internal: audits of IRB/EC records occurred random • Total: 771 (by internal or external sources): Regulatory 70% • Median: 0 agency • Total: 30 inspections

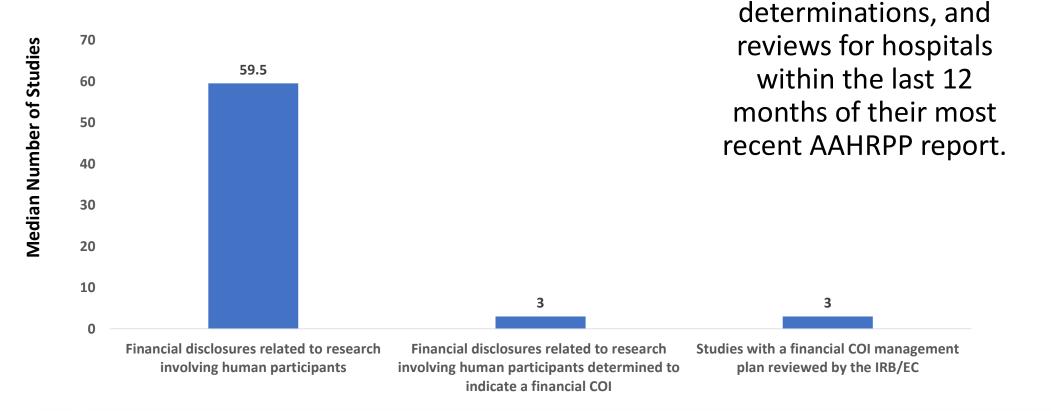


Unresolved Complaints, Noncompliance, & Unanticipated Problems

Number of active studies	Unresolved complaints	Investigations of alleged noncompliance	noncompliance	Continuing noncompliance determinations	•	base most pr hosp
All	0	1	0.5	0	0	recen AAF
0-100	0	0	0	0	0	sh media
101-500	0	1	0	0	0	ofe
501-1000	0	1.5	0	0	1	са
1001-2000	0	1.5	0.5	0.5	1	
2001-4000	0	5	3	0	4	
4001+	0	5	4.5	0	7.5	

This table is based on the nost recent year prior to a hospital's most recent report to AAHRPP and shows the median number of events per category.





This chart shows the

median number of COI-

related disclosures,