



# 2019 Metrics on Human Research Protection Programs Performance

July 2020

# About the Metrics

Improving the quality of human research protection programs (HRPP) is a top priority of AAHRPP. Effective and efficient systems of oversight by organizations provide better protections for research participants and produce higher quality research. And collectively, they raise the global bar to ensure research participants are safe and respected. AAHRPP is pleased to present the 2019 metrics for HRPP performance.

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 based off the most recent data reported by AAHRPP organizations as of December 31, 2019. Qualitative data was selected based on what most accurately reflected AAHRPP organizations in 2019. AAHRPP has compiled an information database to help research organizations, researchers, sponsors, government agencies, and participants identify and support high-performing practices for HRPPs. The data range from types of research, IRB review times, to conformance with regulations and guidance, to financial and personnel resources.

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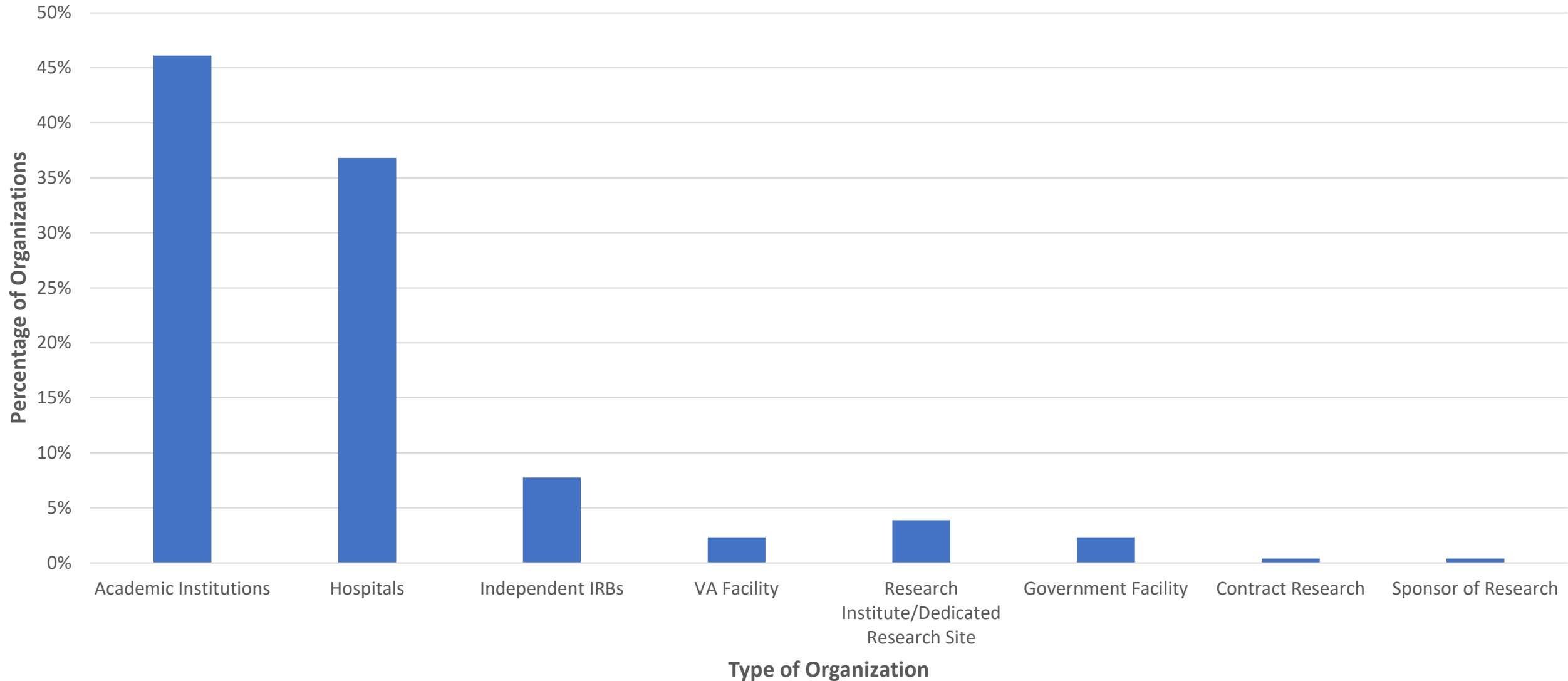
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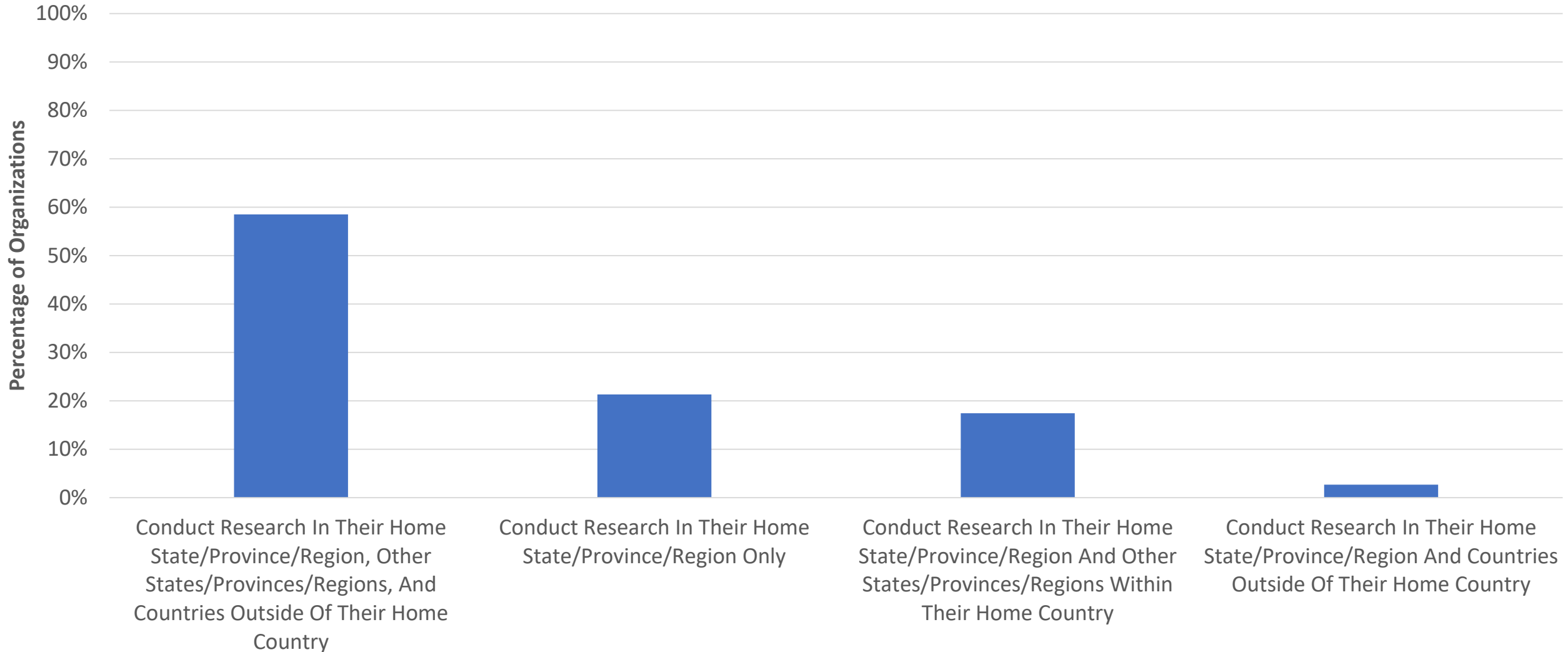
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## All Accredited Organizations 2019



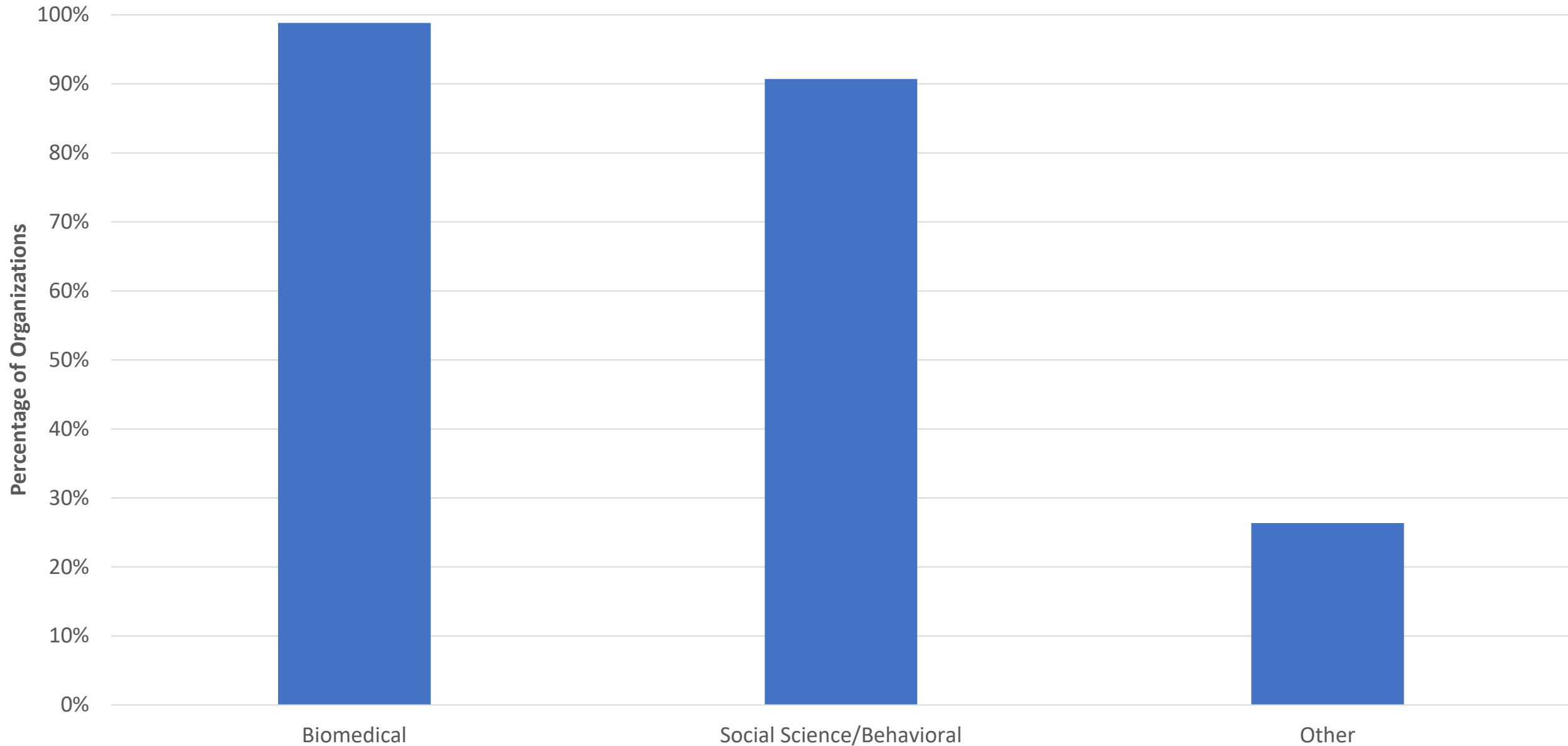
Of the 258 accredited organizations in 2019, 46% are academic institutions; 36.8% are hospitals; 7.8% are independent IRBs; 2.3% are VA Facilities, 3.9% are dedicated research facilities or research institutes; 2.3% are governmental organizations; 0.4% are contract research facilities; 0.4% are sponsors.

## Where Organizations Conduct Research



Of the 258 accredited organizations, 58.5% conduct research in their home state/province/region, other states/provinces/regions, and countries outside their home country. 21.3% conduct research in their home state/province/region only. 17.4% conduct research in their home state/province/region and other states/provinces/regions within their home country. 2.7% conduct research in their home state/province/region and countries outside their own country.

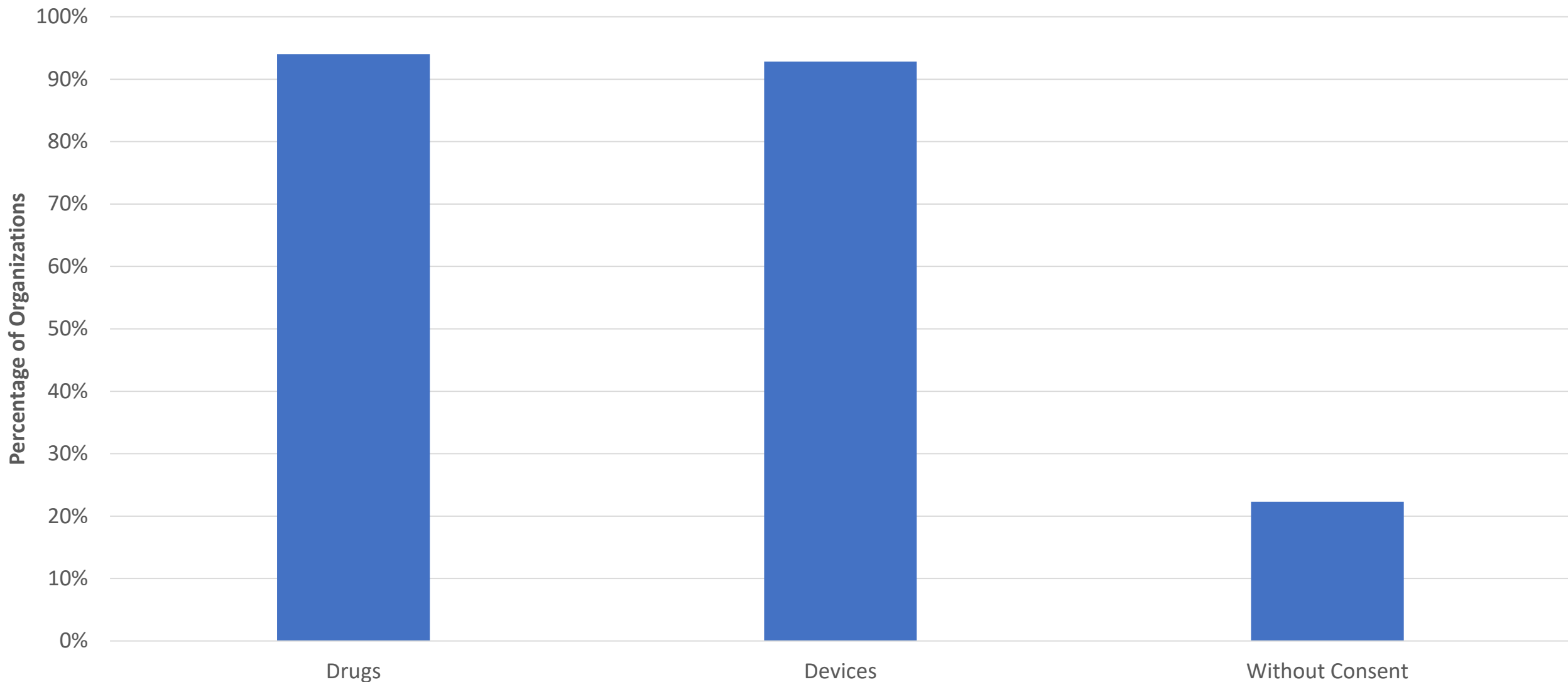
## Types of Research Conducted



Of the 258 accredited organizations, 99% conduct biomedical research; 91% conduct social science/behavioral research; 26% conduct other types of research.

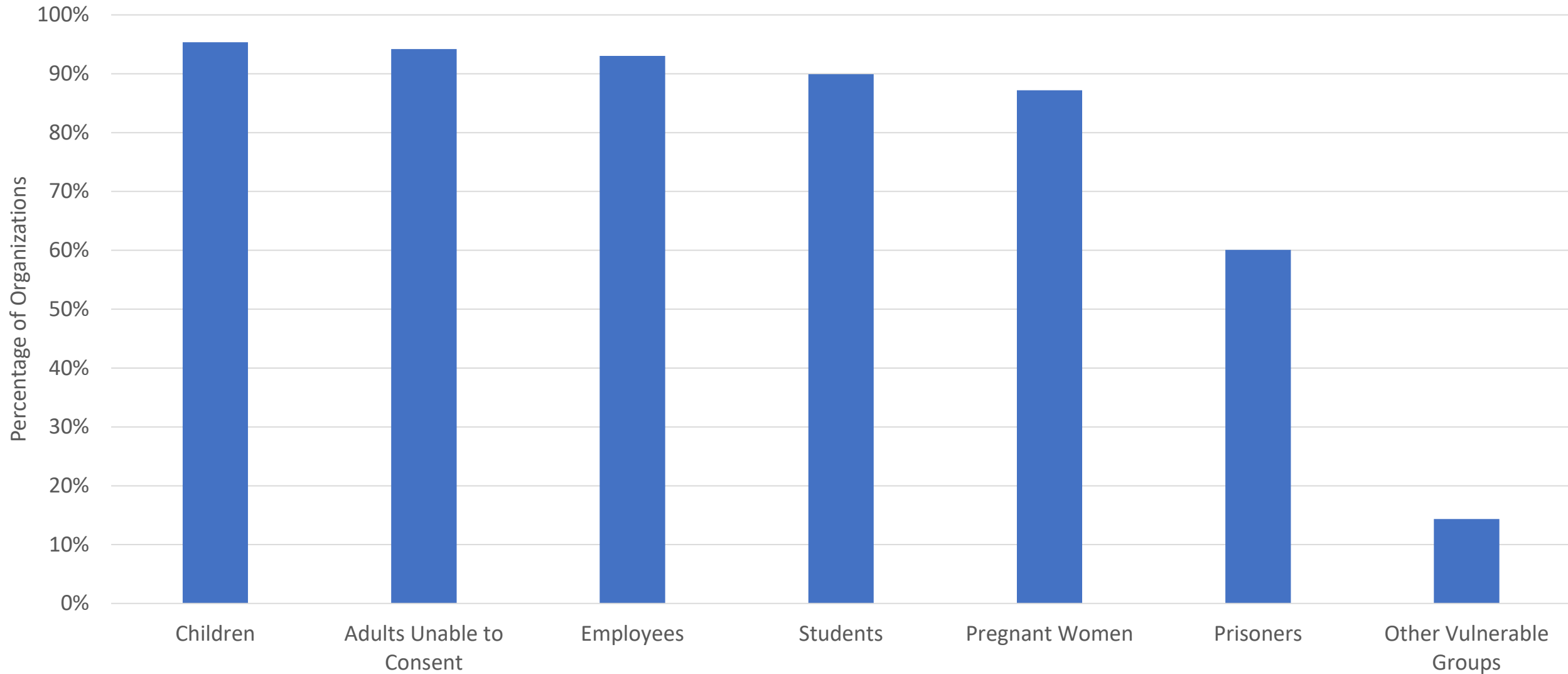


## Specific Types of Research



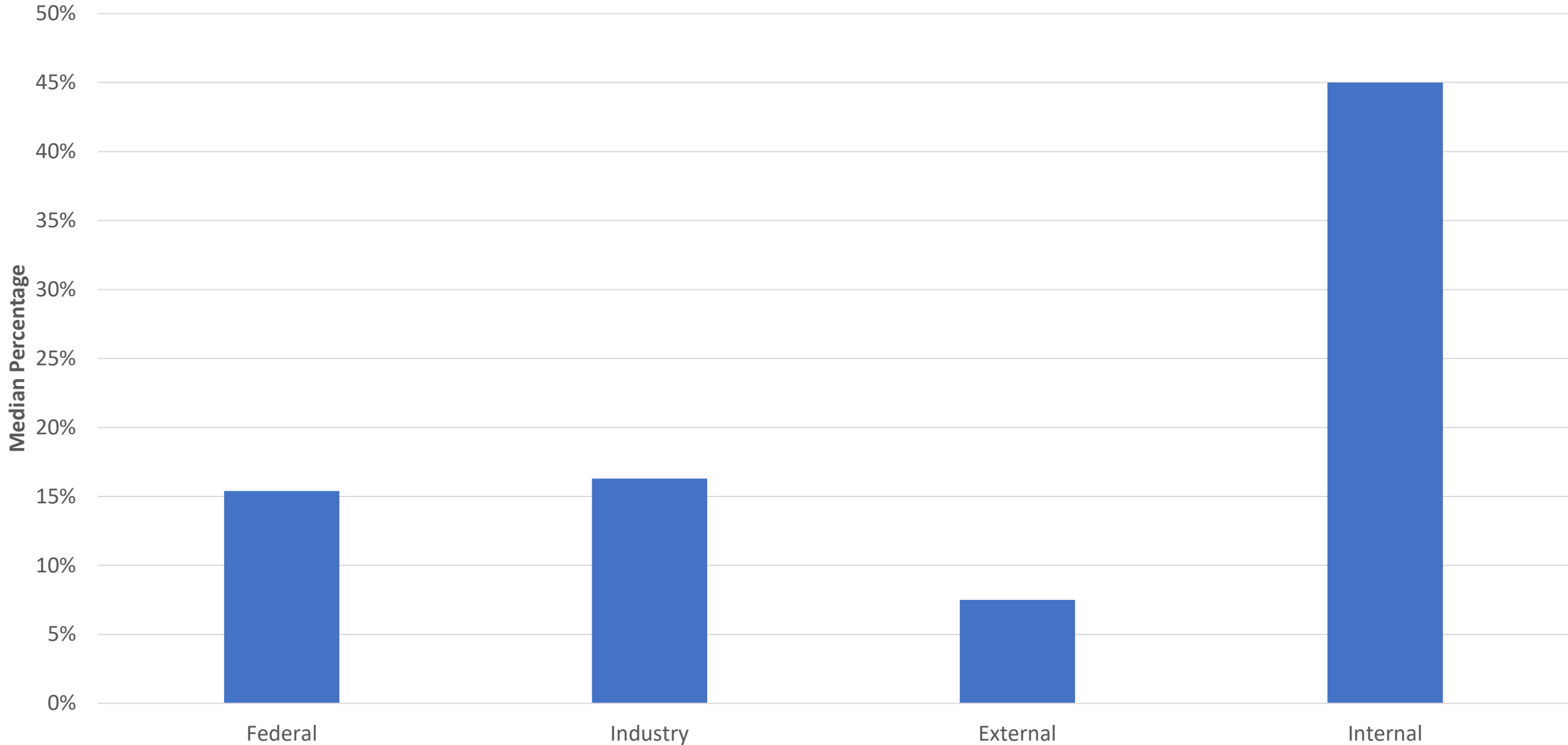
Nine organizations conduct biomedical research but did not specify the type. Of the remaining 249 organizations, 94% conduct research on drugs, while 92.8% conduct research on biomedical devices. Seven organizations did not specify if they had or had not conducted emergency research without consent in the last 12 months of their most recent report. Of those who did, 22% did conduct emergency research without consent in the last 12 months.

## Research on Vulnerable Populations



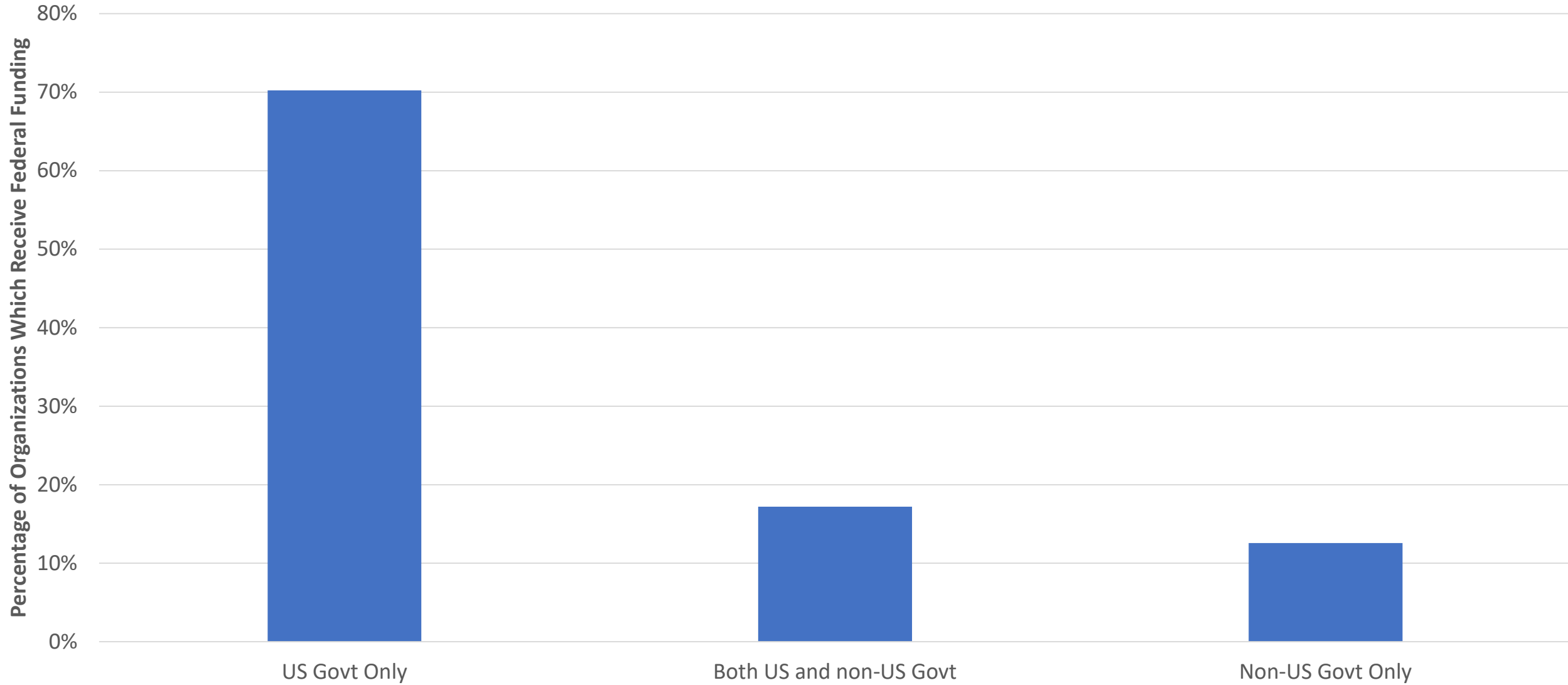
Of all 258 organizations, 95.3% conduct research involving children; 94.2% conduct research involving adults unable to consent; 93% conduct research involving employees; 89.9% conduct research involving students; 87.2% conduct research involving pregnant women; 60.1% conduct research involving prisoners; 14.3% conduct research involving other vulnerable groups.

## Median Sources of Funding



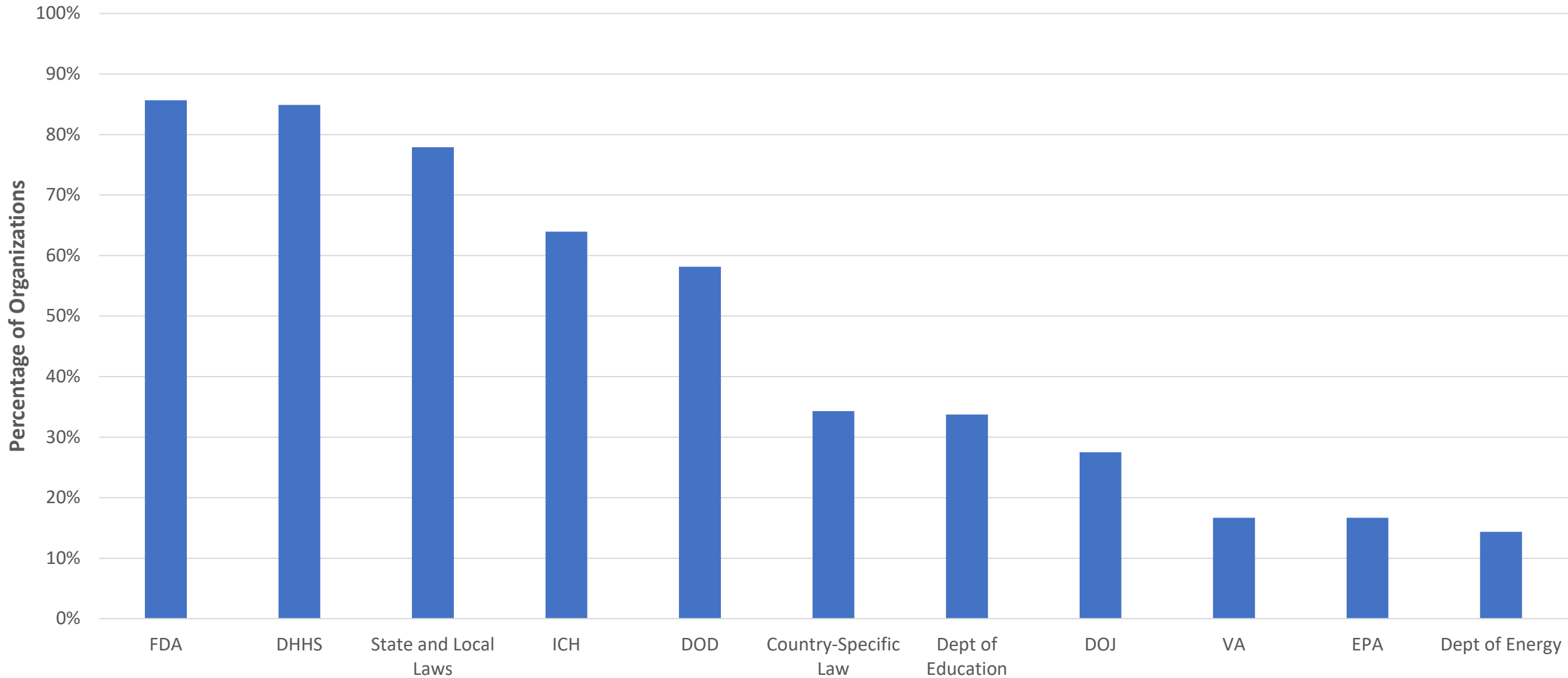
For all organizations, a median of 15.4% of research is federally funded; a median of 16.3% is industry funded; a median of 7.5% is externally funded; a median of 45% is internally funded.

## Sources of Federal Funding



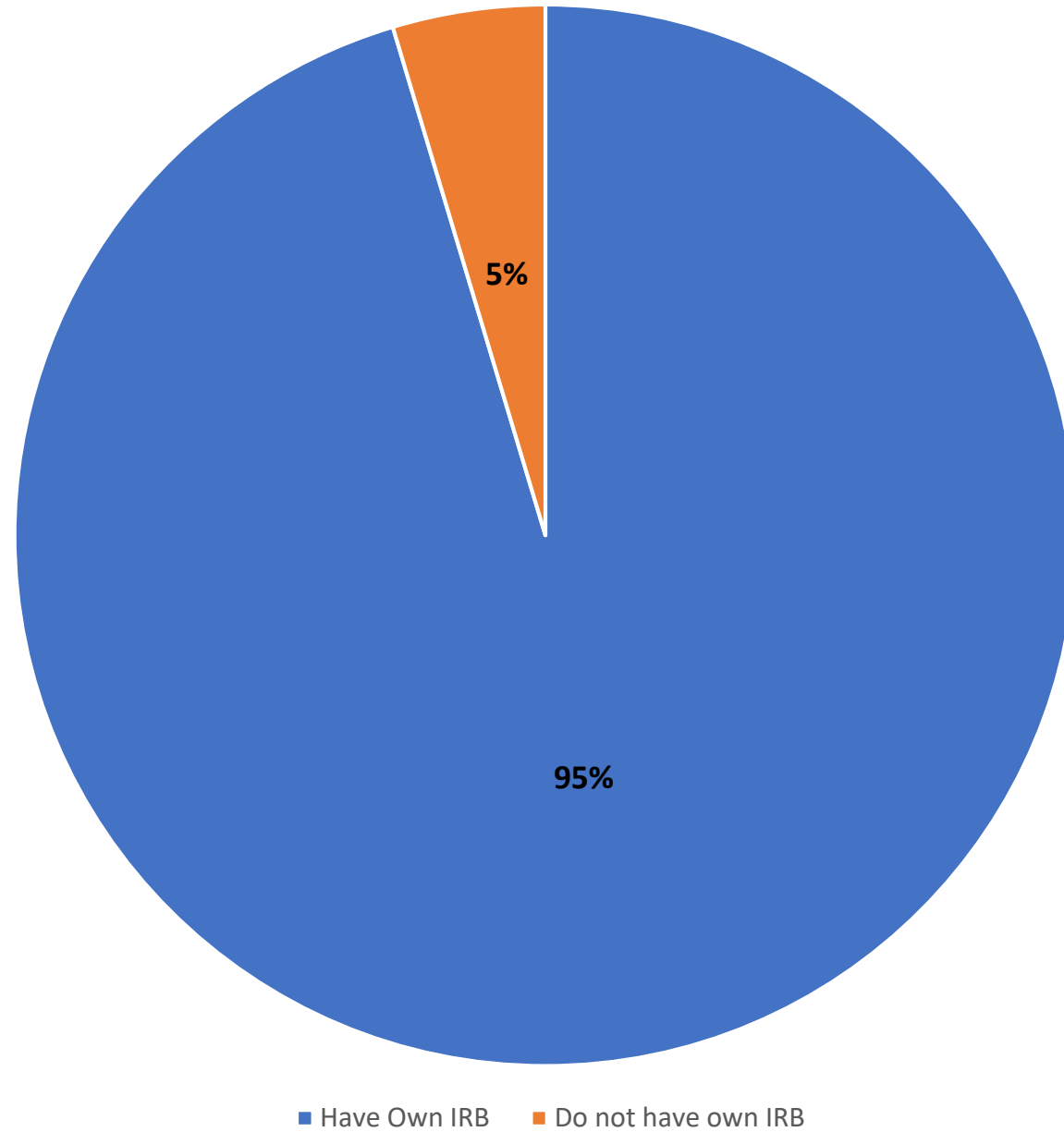
215 Organizations revealed the source of their federal funding. Of those 215 organizations, 70.2% receive funding from the United States government only. 17.2% receive funding from both US and non-US governments. 12.6% receive funding from only non-US governments.

## Regulations and Guidelines Followed

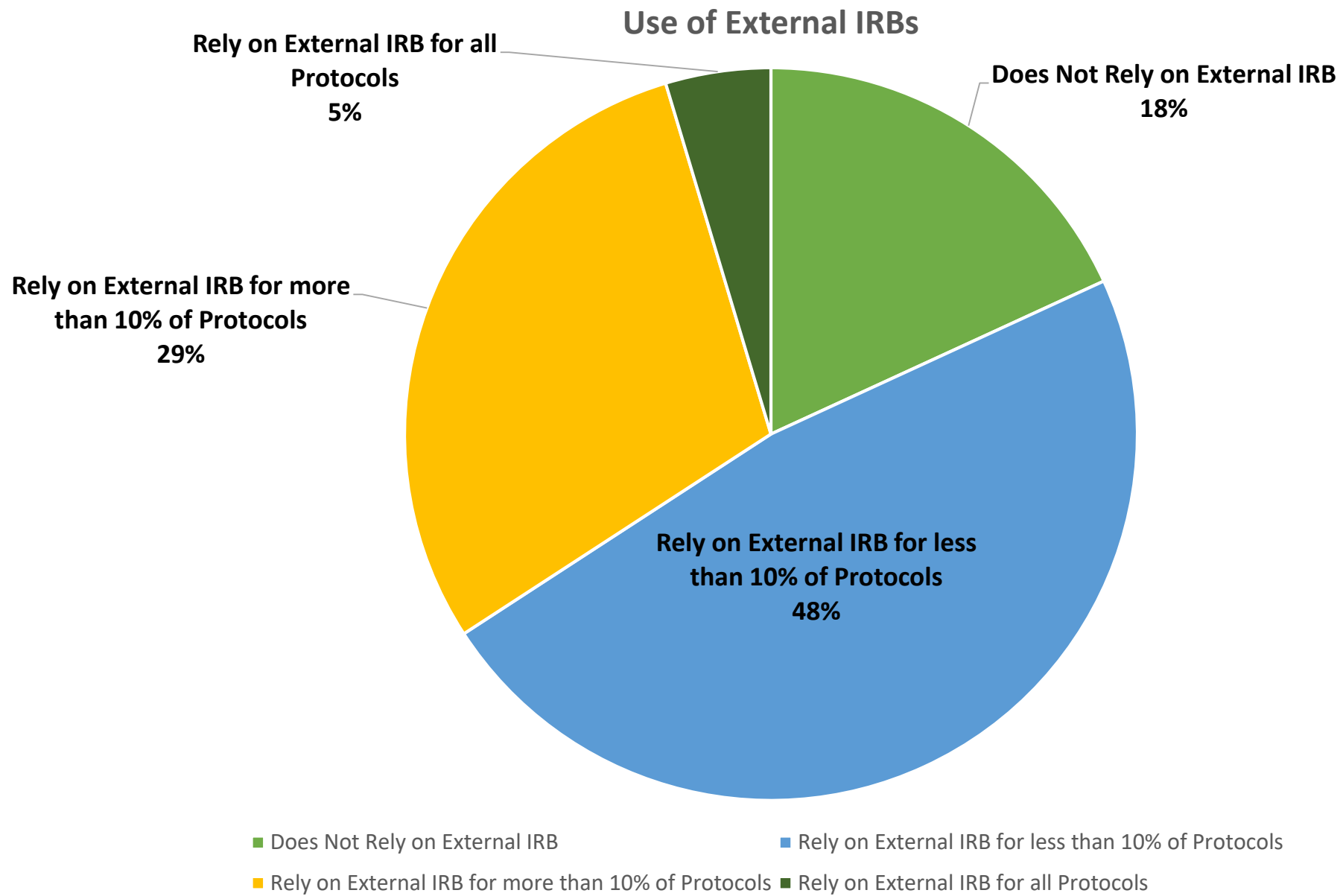


Of 258 organizations, 85.7% follow FDA regulations; 84.9% follow DHHS regulations; 78.2% follow state and local laws; 64.0% follow ICH regulations in some form; 58.1 follow DOD regulations; 34.4% follow country-specific laws outside the US; 33.7% follow DoEd regulations; 27.5% follow DOJ guidelines; 16.7% follow VA regulations; 16.7% follow EPA regulations; and 14.3% follow DoE regulations.

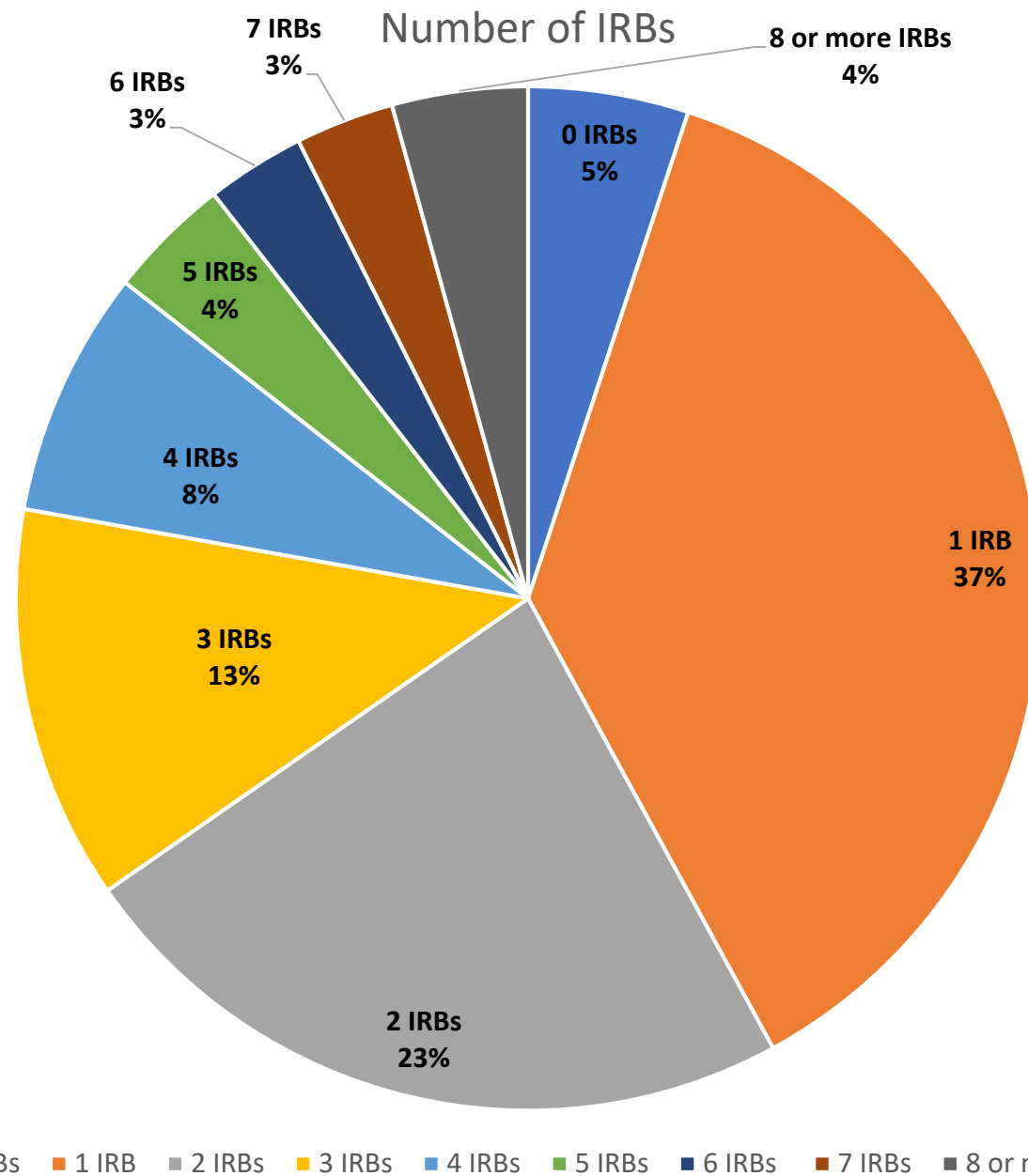
## Use of IRBs



Of the 239 non-IRB organizations, 95% have their own IRB while 5% do not.



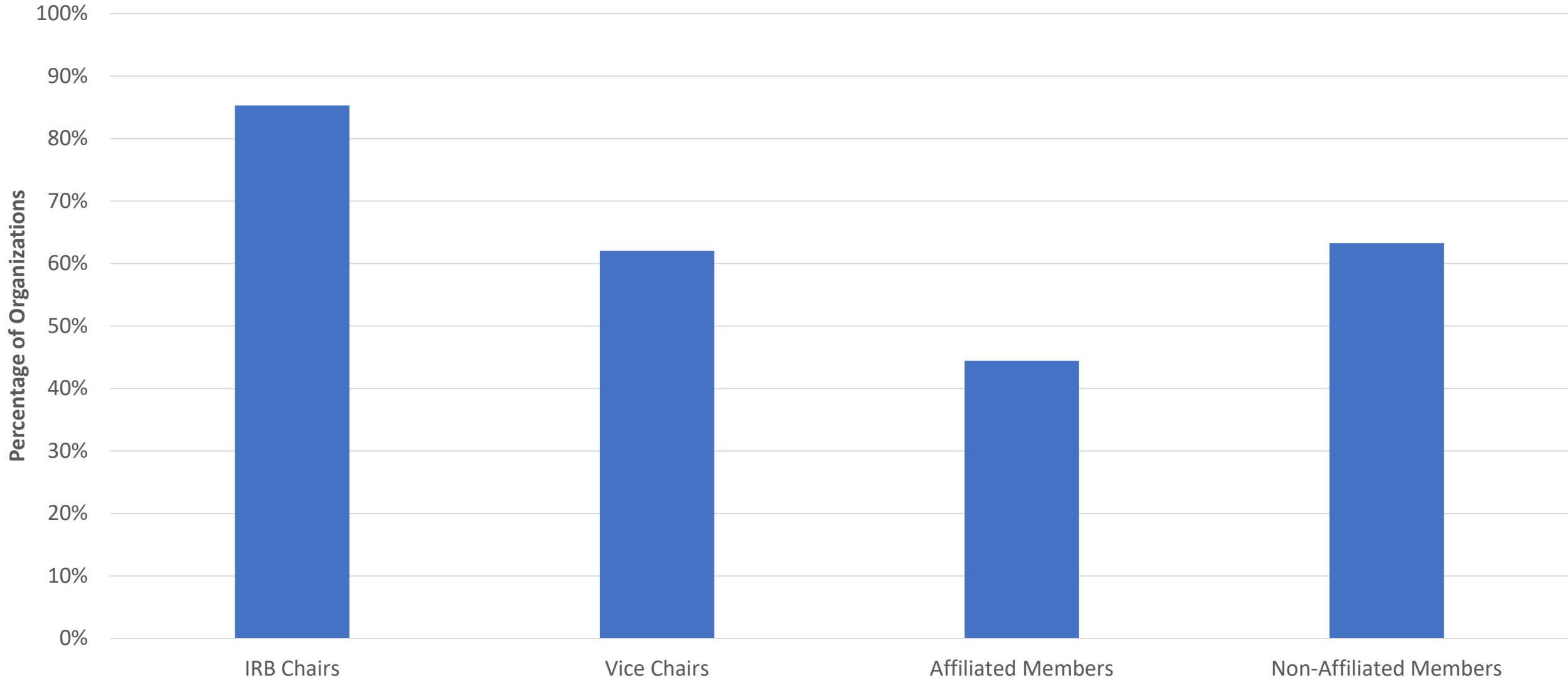
For all non-IRB Organizations, 18% do not rely on external IRBs for any protocols, 48% rely on external IRBs for less than 10% of protocols, 29% rely on external IRBs for more than 10% of protocols, 5% rely on external IRBs for all protocols.



For all accredited organizations, 5% have zero IRBs; 37% have one IRB; 23% have two IRBs; 13% have three IRBs; 8% have four IRBs; 4% have five IRBs; 3% have six; 3% have seven; and 4% have eight or more.

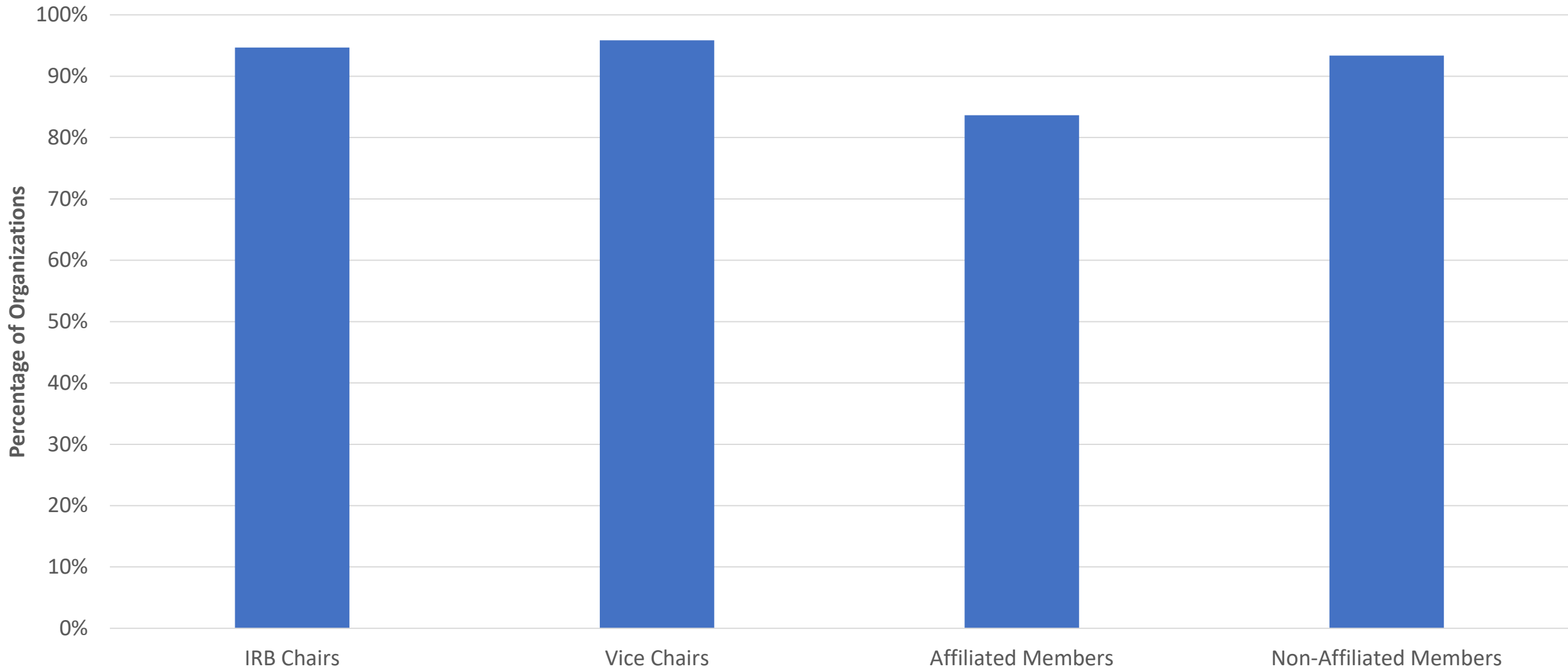


## Compensation of IRB Members



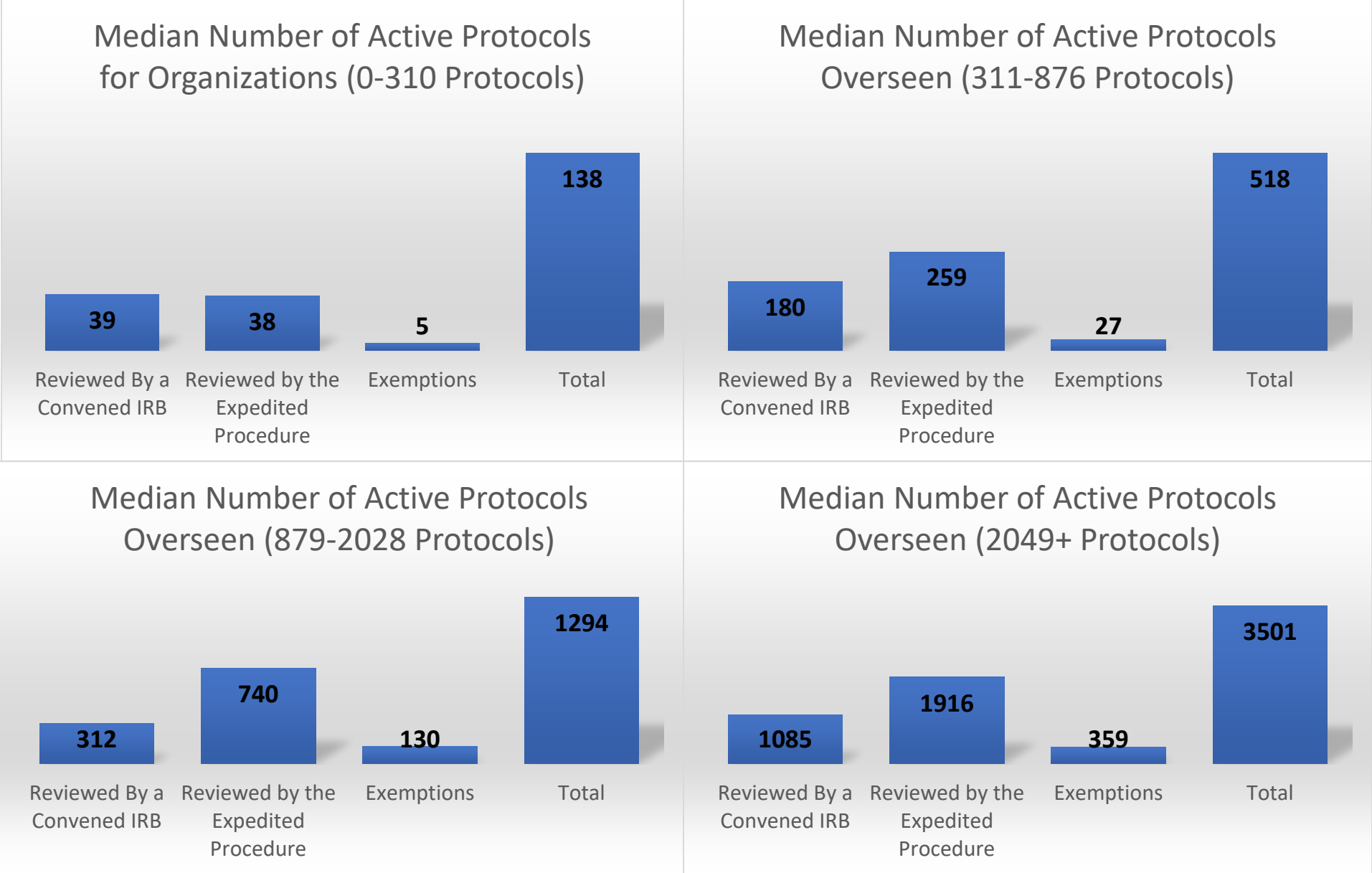
85% of organizations with an IRB (excluding private IRBs) compensate IRB chairs; 62% compensate IRB vice chairs; 44% compensate affiliated members; 63% compensate non-affiliated members.

## Financial Compensation of IRB Members

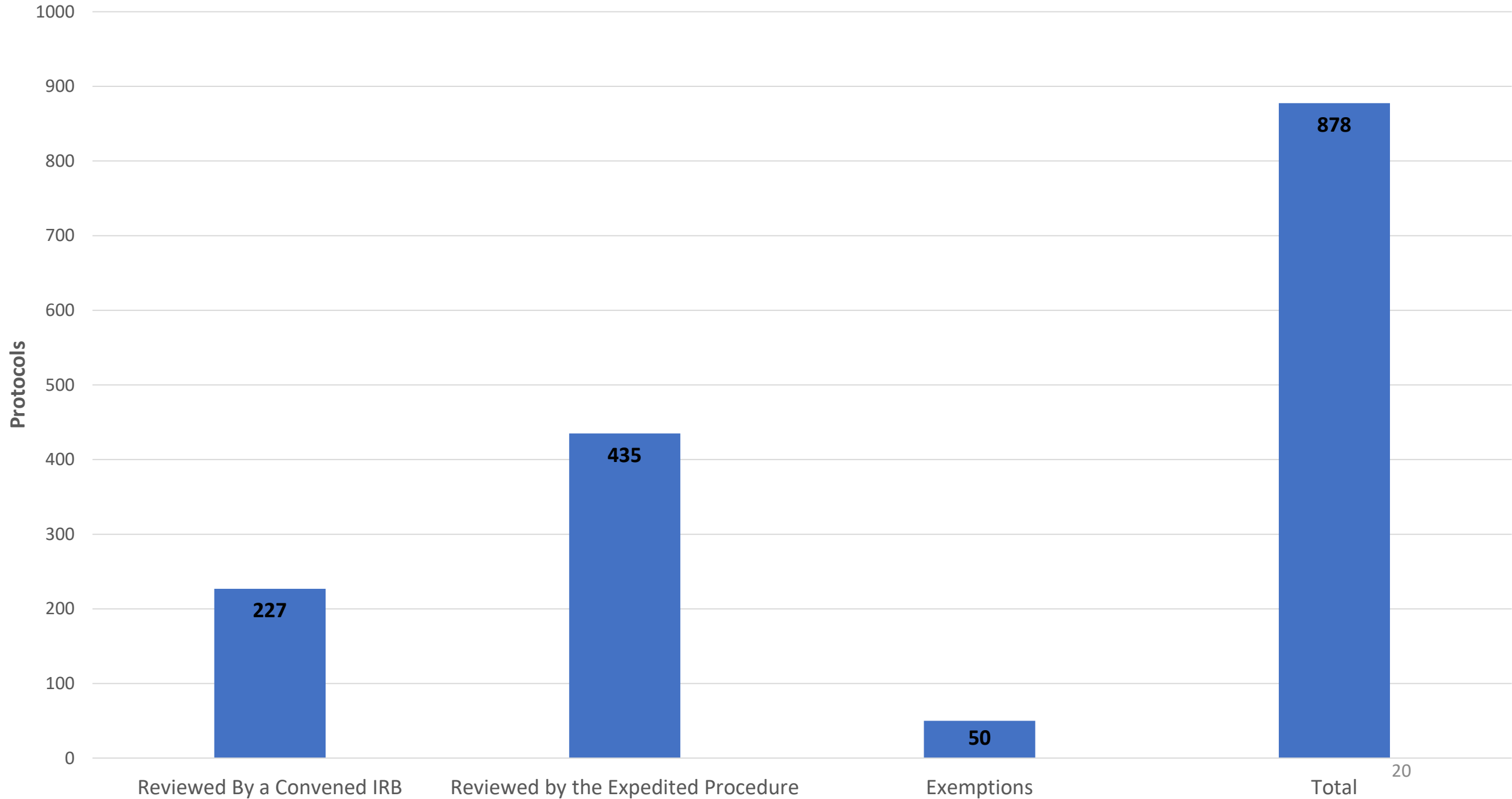


Within AAHRPP organizations that compensate IRB chairs, 95% provide financial compensation for chairs; within AAHRPP organizations that compensate IRB vice chairs, 96% provide financial compensation for vice chairs; within AAHRPP organizations that compensate affiliated members, 84% provide financial compensation for affiliated members; within AAHRPP organizations that compensate non-affiliated members, 93% provide financial compensation for non-affiliated members.

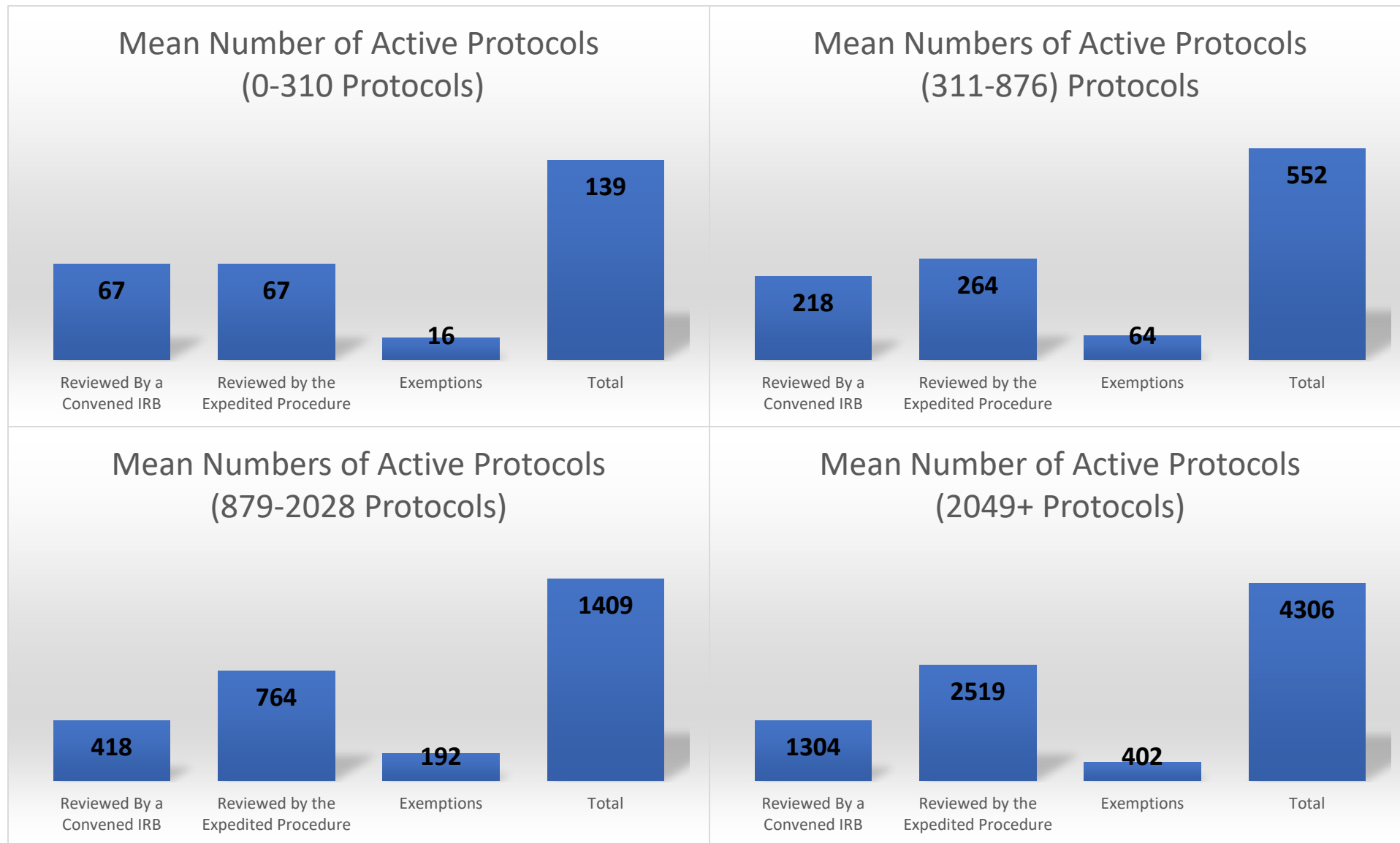
# Median Number of Protocols Overseen organized by Quartiles of AAHRPP accredited Orgs



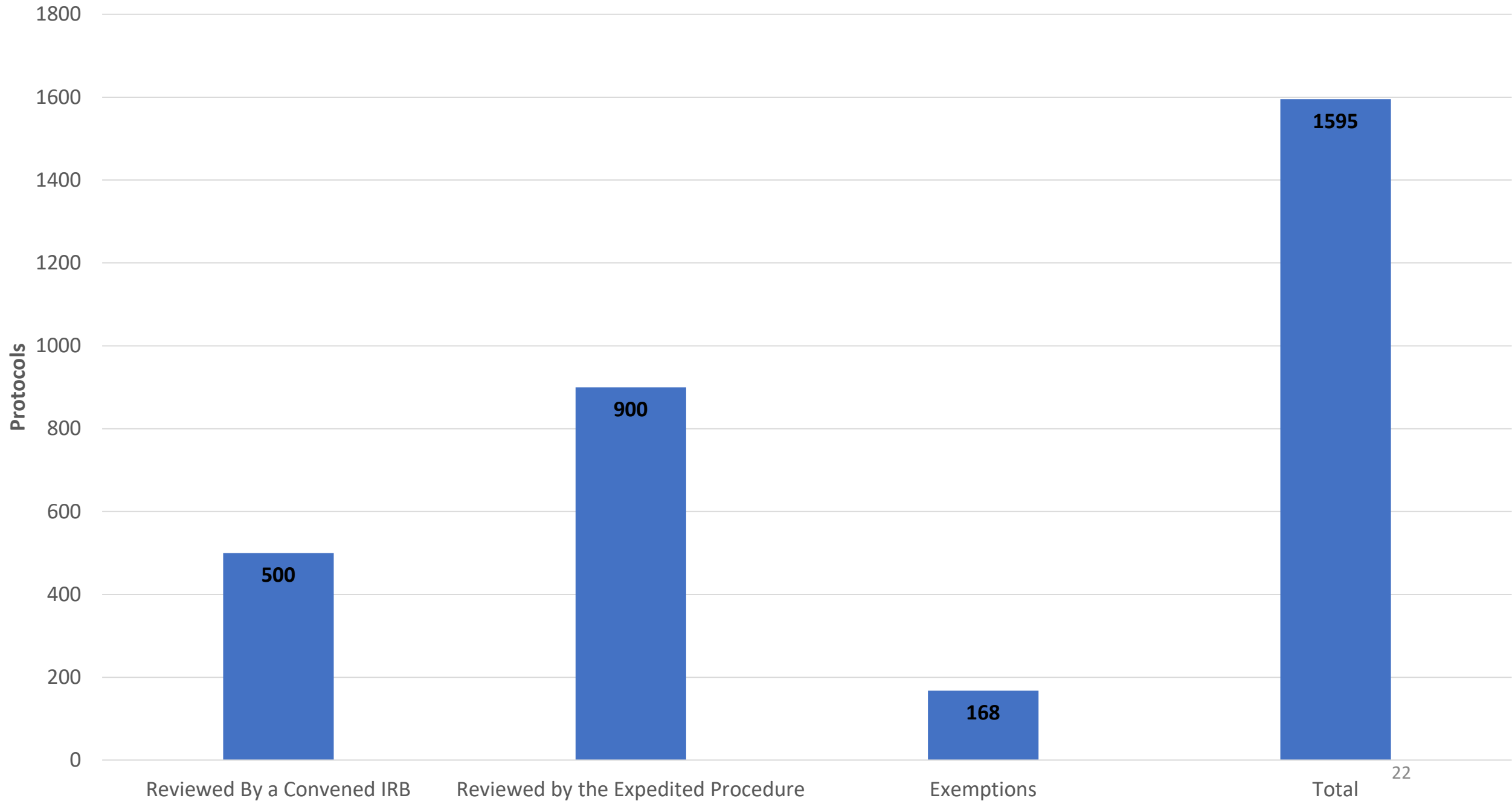
# Median Number of Active Protocols Overseen by all Organizations



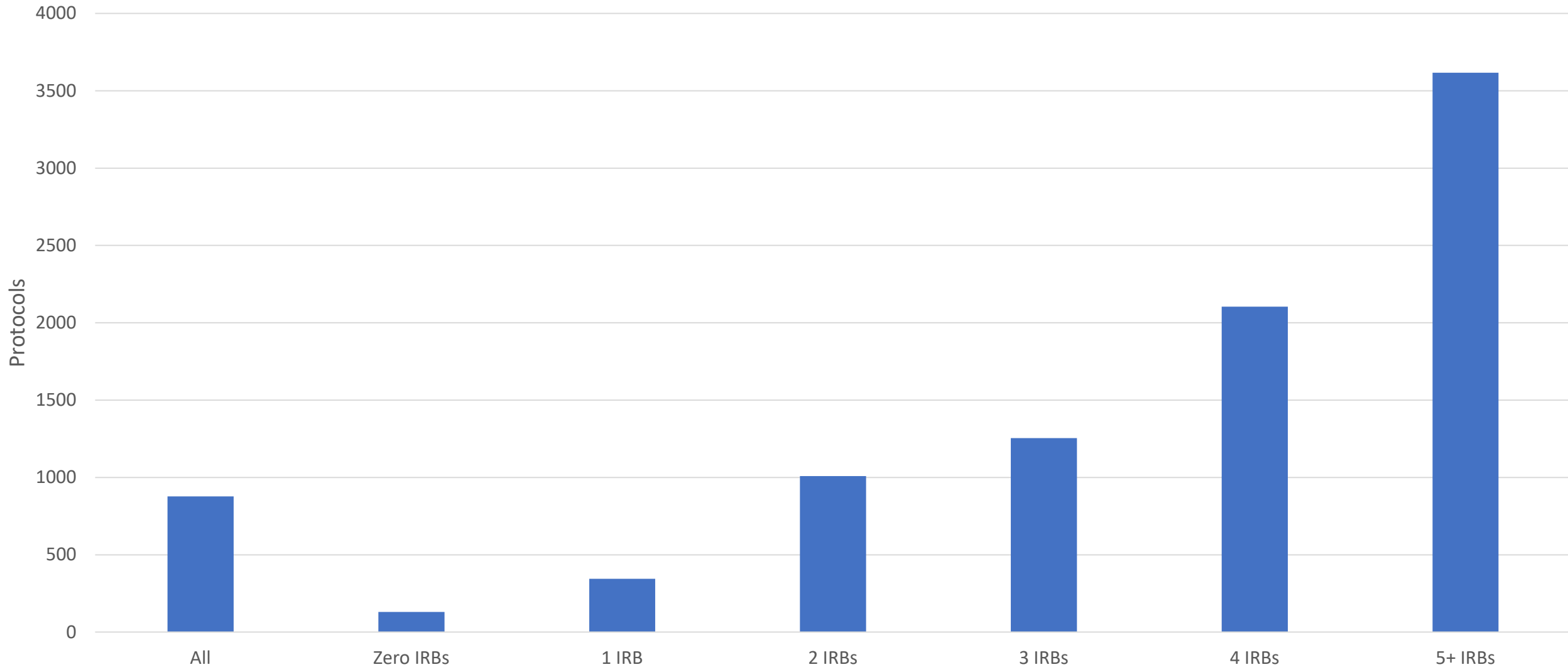
## Mean Number of Active Protocols Organizations Oversee by Quartile



# Mean Number of Protocols Overseen by all Organizations

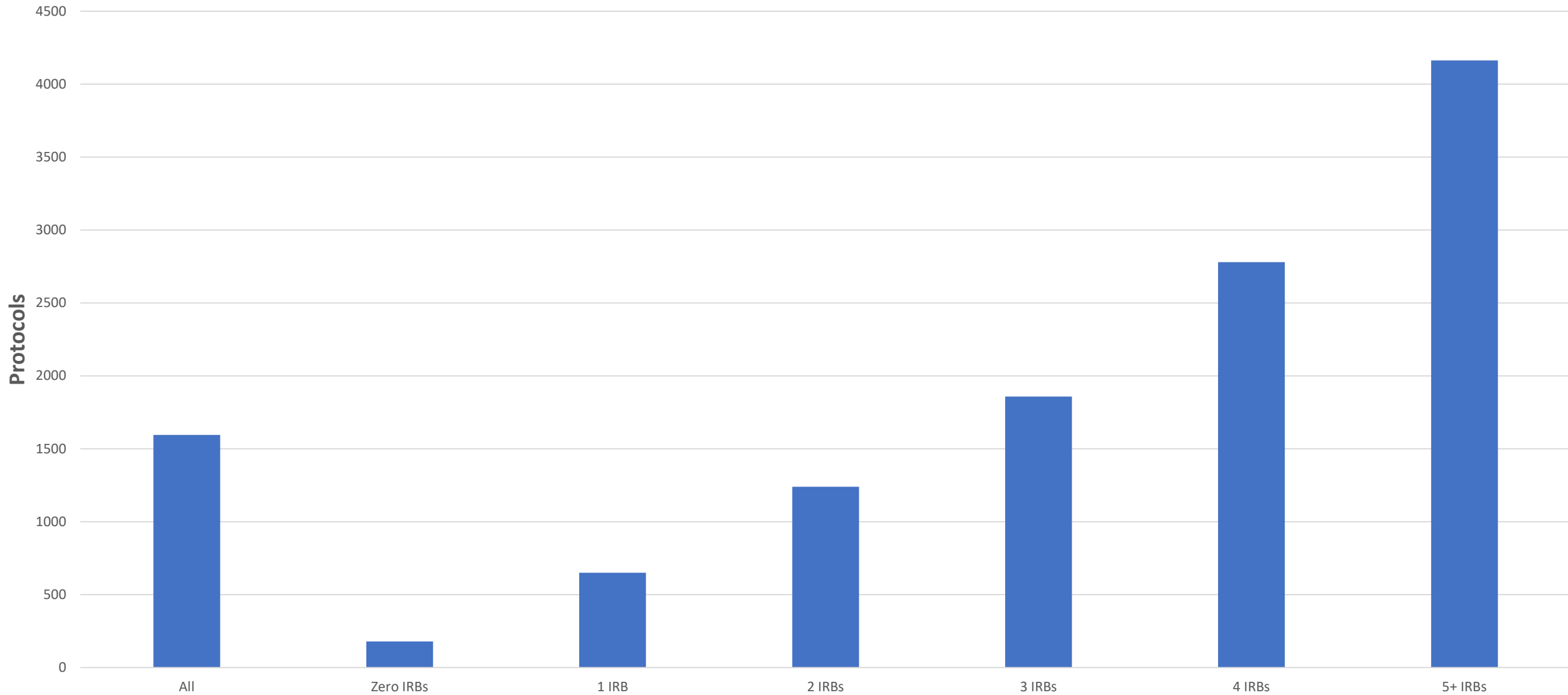


Median Number of Active Protocols overseen by IRBs per Organization



A median of 878 protocols were overseen by all organizations; a median of 130 protocols were overseen by organizations without an IRB; a median of 345 protocols were overseen by organizations with one IRB; a median of 1009 protocols were overseen by organizations with two IRBs; a median of 1255 protocols were overseen by organizations with three IRBs; a median of 2105 protocols were overseen by organizations with four IRBs; a median of 3617 IRBs were overseen by organizations with five or more IRBs.

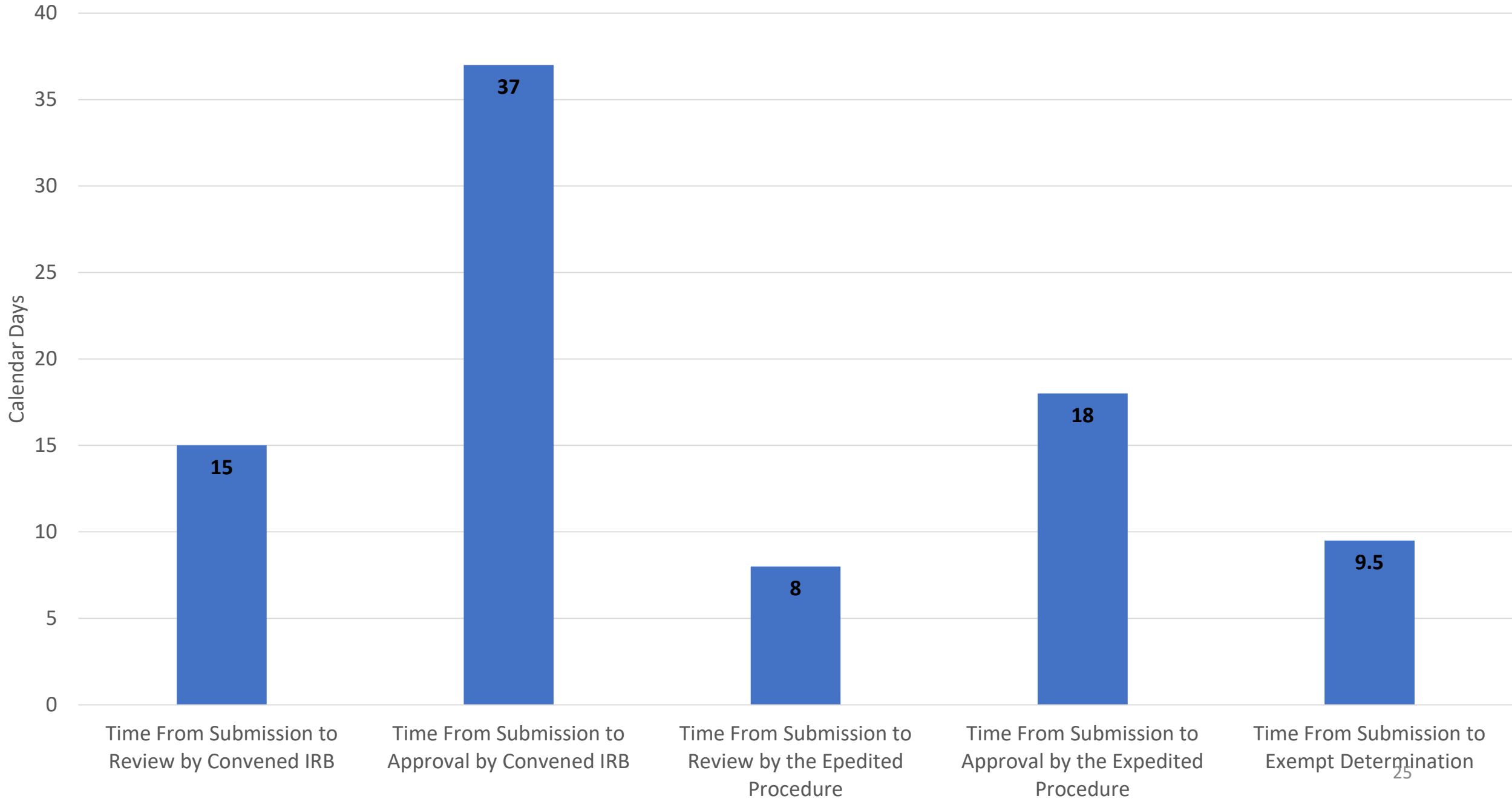
Mean Number of Active Protocols Overseen by IRBs per Organization



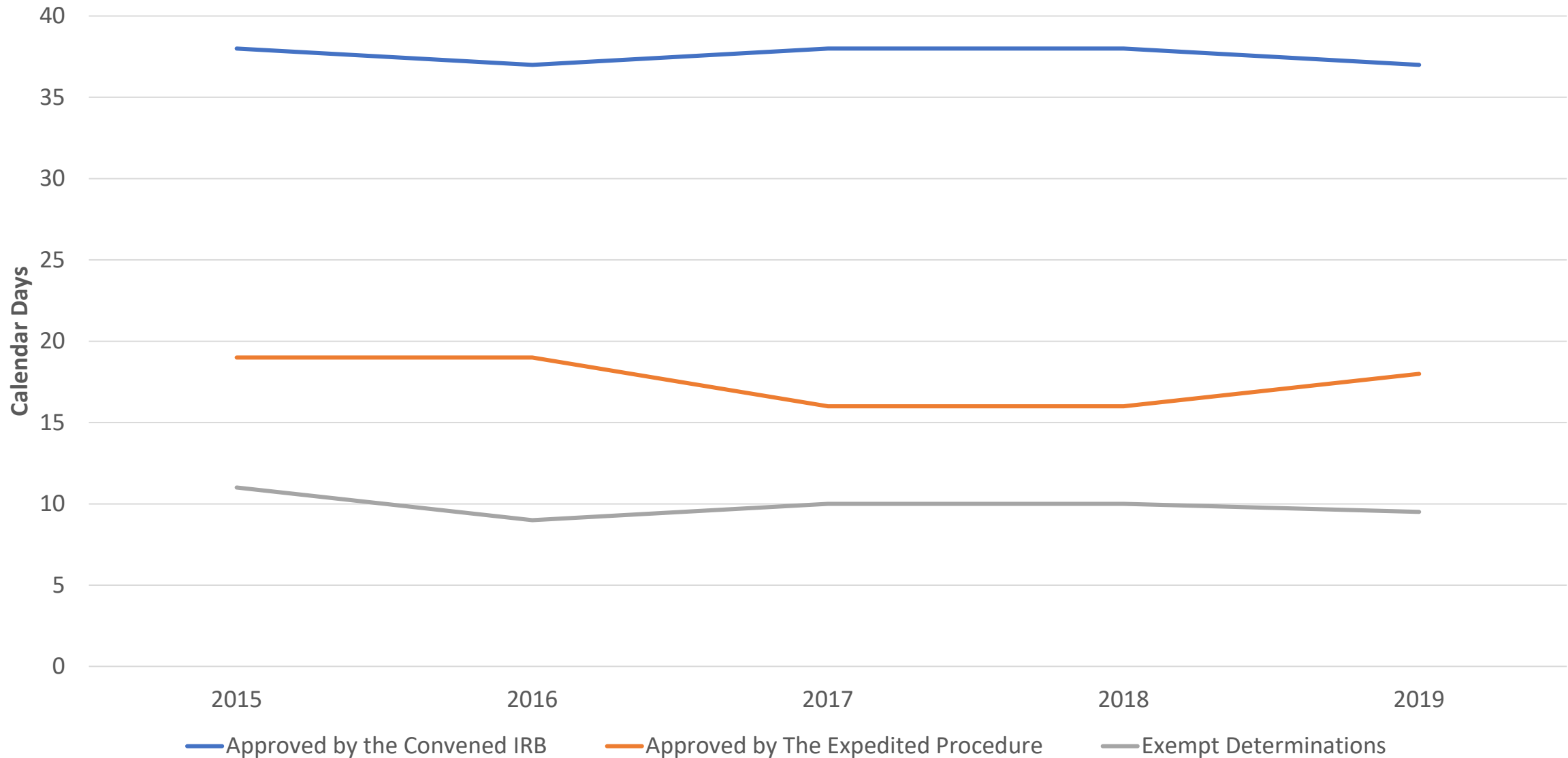
A mean of 1595 protocols were overseen by all organizations; a mean of 179 protocols were overseen by organizations without an IRB; a mean of 649 protocols were overseen by organizations with one IRB; a mean of 1239 protocols were overseen by organizations with two IRBs; a mean of 1857 were overseen by organizations with three IRBs; a mean of 2780 protocols were overseen by organizations with four IRBs; a mean of 4162 protocols were overseen by organizations with five or more IRBs.



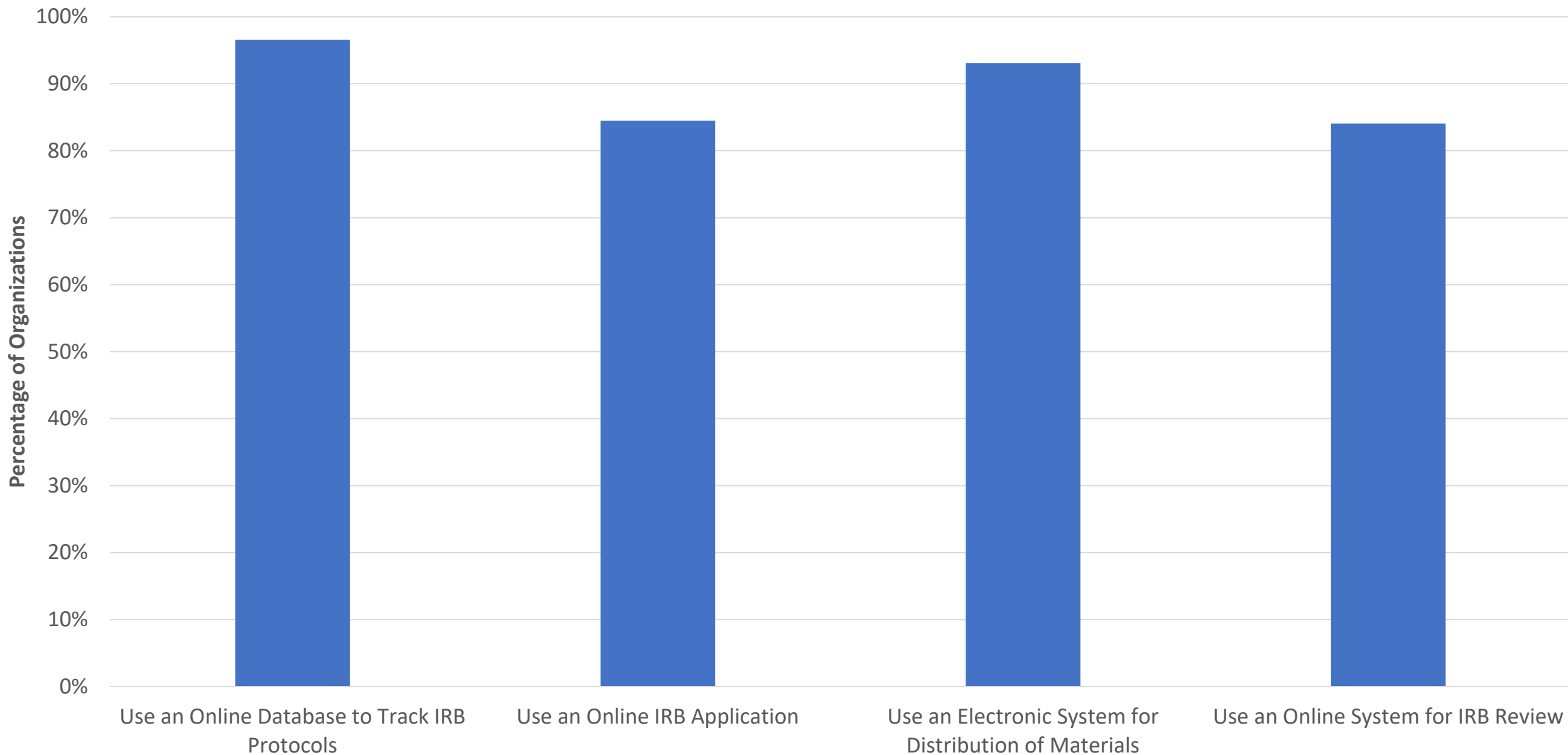
# Median IRB Review Times by Type of Review



### Five Year Trends in Median IRB Approval Times



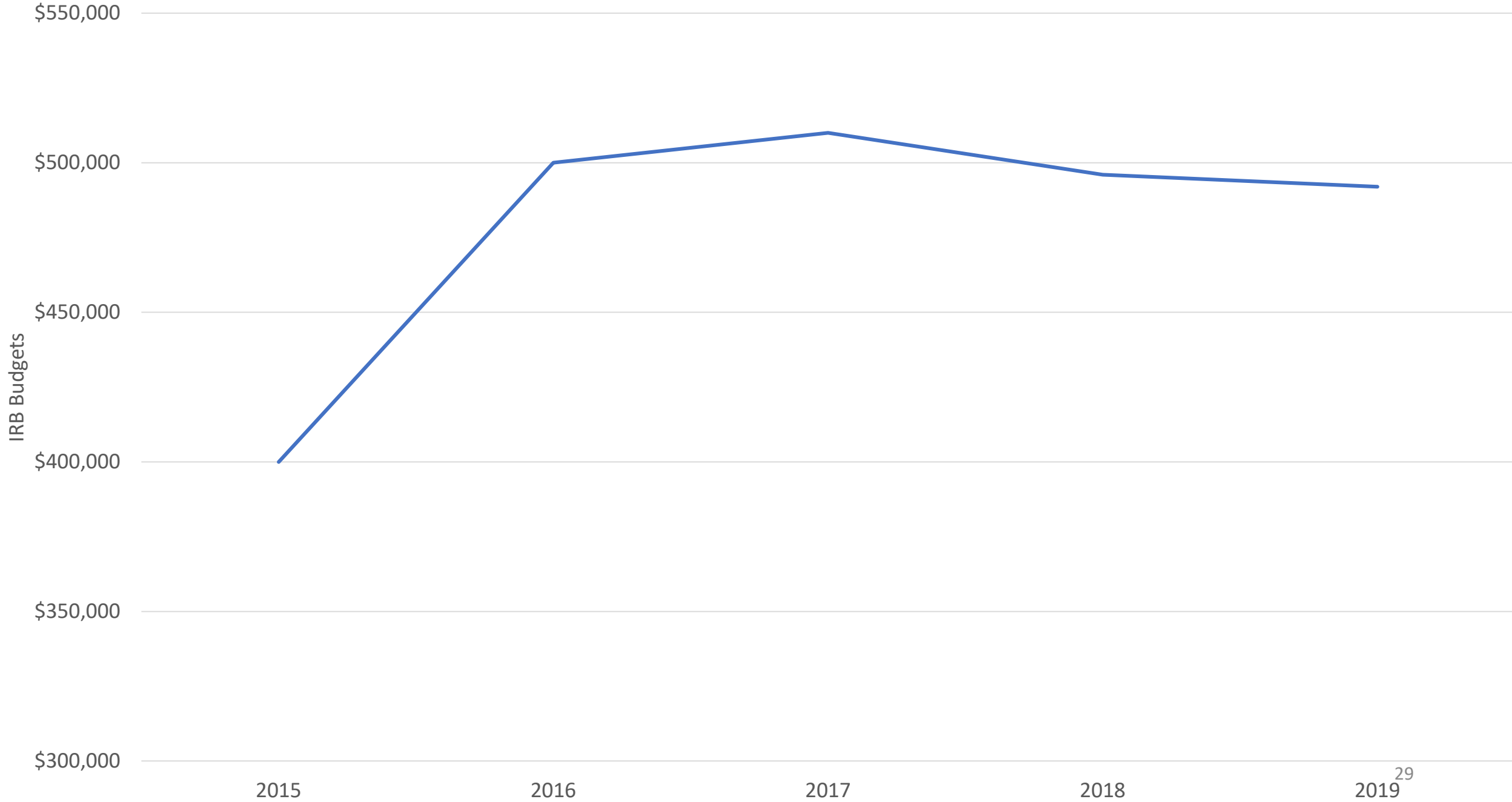
## Technology Use by Organizations



26 organizations did not answer this question. Of those who did, 97% use a database to track IRB protocols; 84% use an online IRB application; 93% use an electronic system for distribution of materials; 84% use an online system for IRB review.

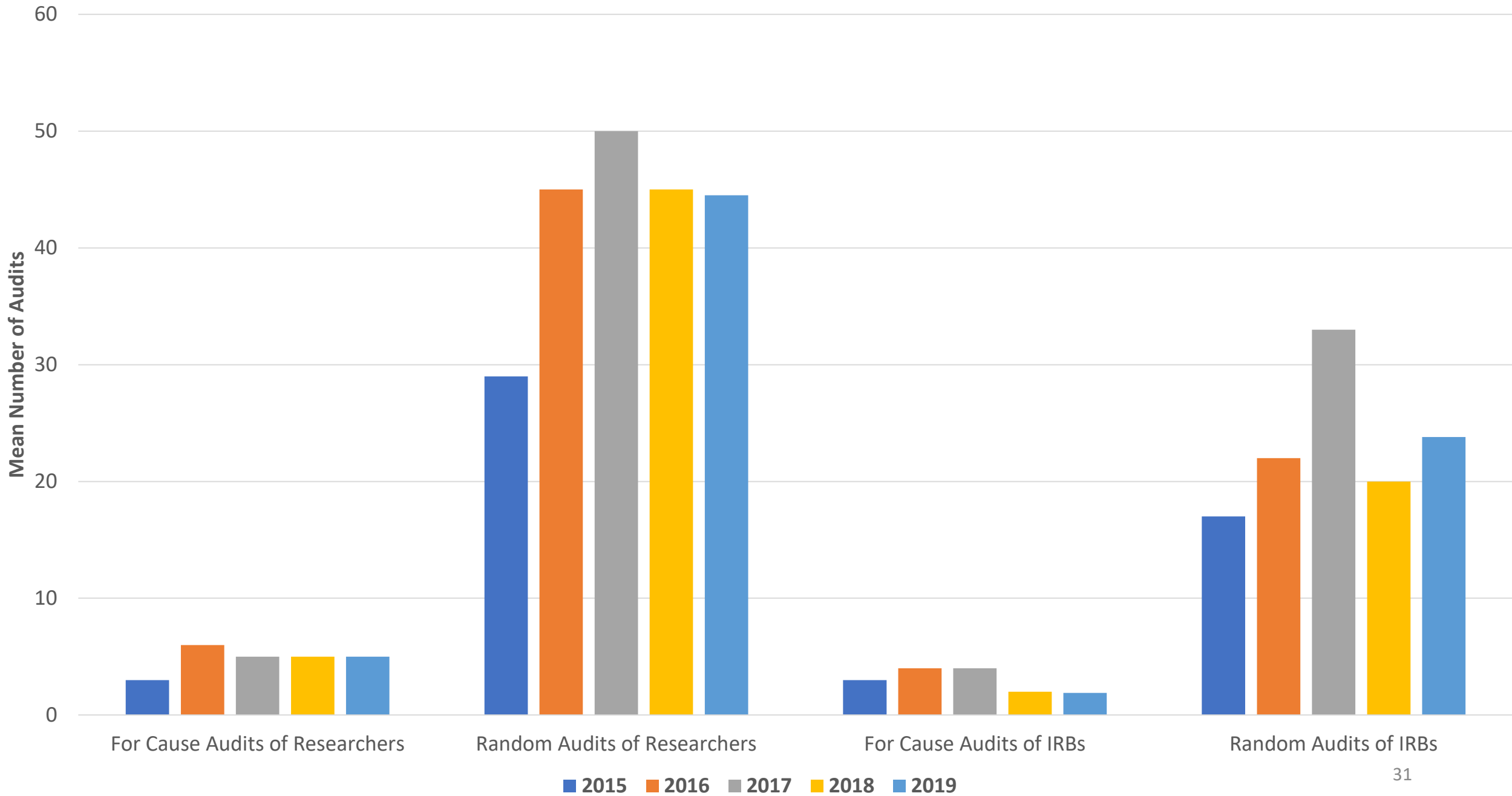
Number of Protocols	Median Number of Protocols	Median Number of Staff	Median Number of Protocols per Staff Member	Median IRB Budget
All	878	6.9	128.1	\$ 492,042.00
0-100	57	2	28.3	\$ 127,000.00
101-500	271	3.0	90.3	\$ 232,781.00
501-1000	688	4.9	141.0	\$ 375,000.00
1001-2000	1298	8.75	148.3	\$ 657,272.00
2001-4000	2667	16.0	166.7	\$ 1,293,559.00
4001+	5652	25.5	221.6	\$ 2,757,331.50 <sup>28</sup>

# Five Year Trend in Median IRB Budgets

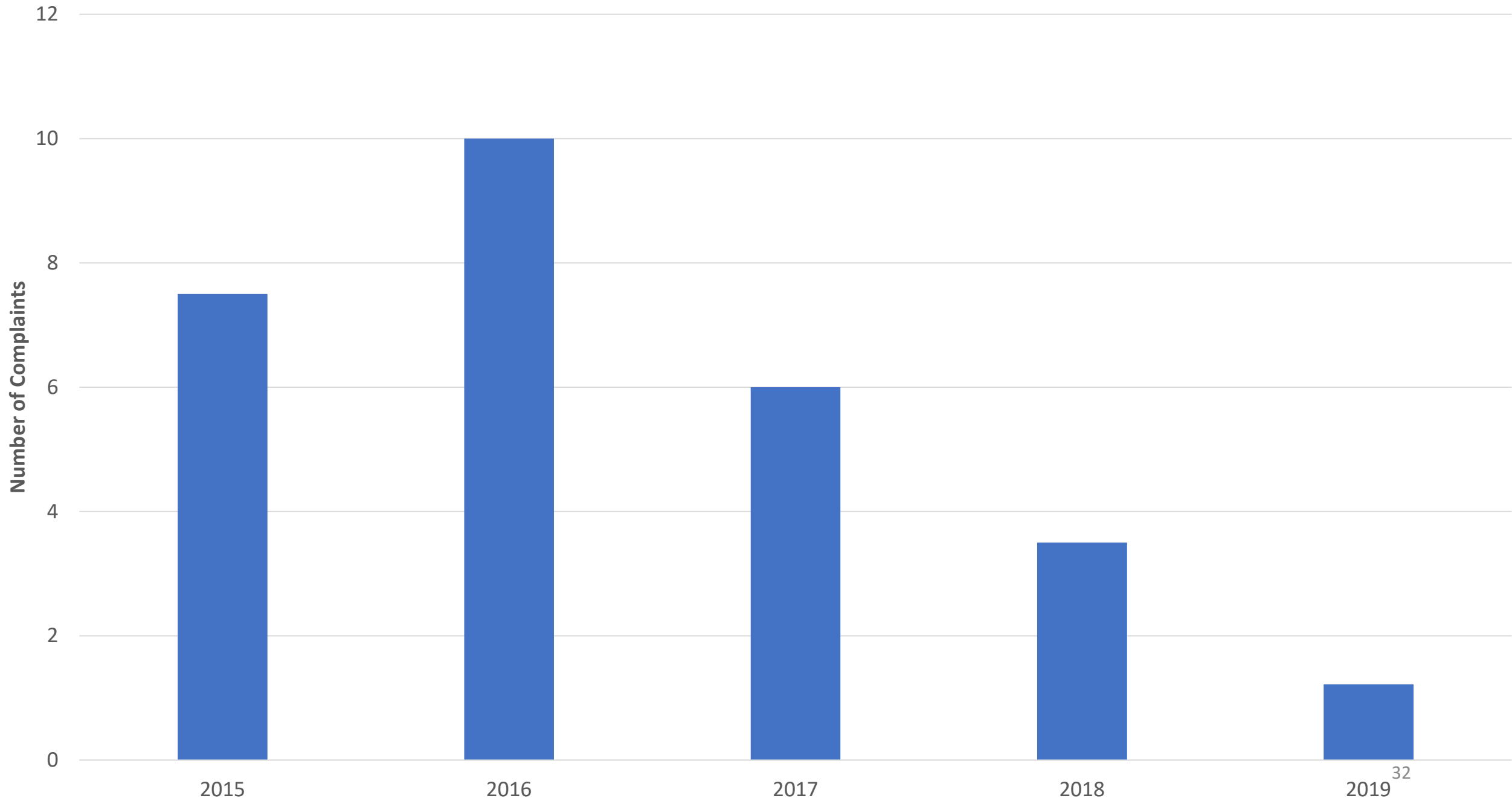


	For Cause Audits of Researchers	Random Audits of Researchers	For Cause Audits of IRBs	Random Audits of IRBs
Mean	5.0	44.5	1.9	23.8
Median	2	15	0	4 <sup>30</sup>

# Five Year Trend in Mean Number of Audits Conducted



## Five Year Trend in Mean Number of Complaints per Organization





Protocols	Median Number of Allegations of Non-Compliance	Median Number of Determinations of Serious Non-Compliance	Median Number of Determinations of Continuing Non-Compliance
0-100	0.5	0	0
101-500	1	0	0
501-1000	5.5	1	0
1001-2000	10	2	1
2001-4000	10	4	1
4000+	33	8	2

# Five Year Trend in Non-Compliance

