



2018 Metrics on Human Research Protection Program Performance

June 7, 2019

About the Metrics

Improving the quality of human research protection programs (HRPP) is a top priority of AAHRPP. Effective and efficient systems of oversight within 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 2018 metrics for HRPP performance.

These metrics are collected from annual reports, as well as step 1 and step 2 applications, submitted by clients. All the metrics were based off the most recent data reported by AAHRPP clients as of December 31, 2018. From data supplied by our client organizations in 2018, 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 and conformance with regulations and guidance, to financial and personnel resources and IRB review times.

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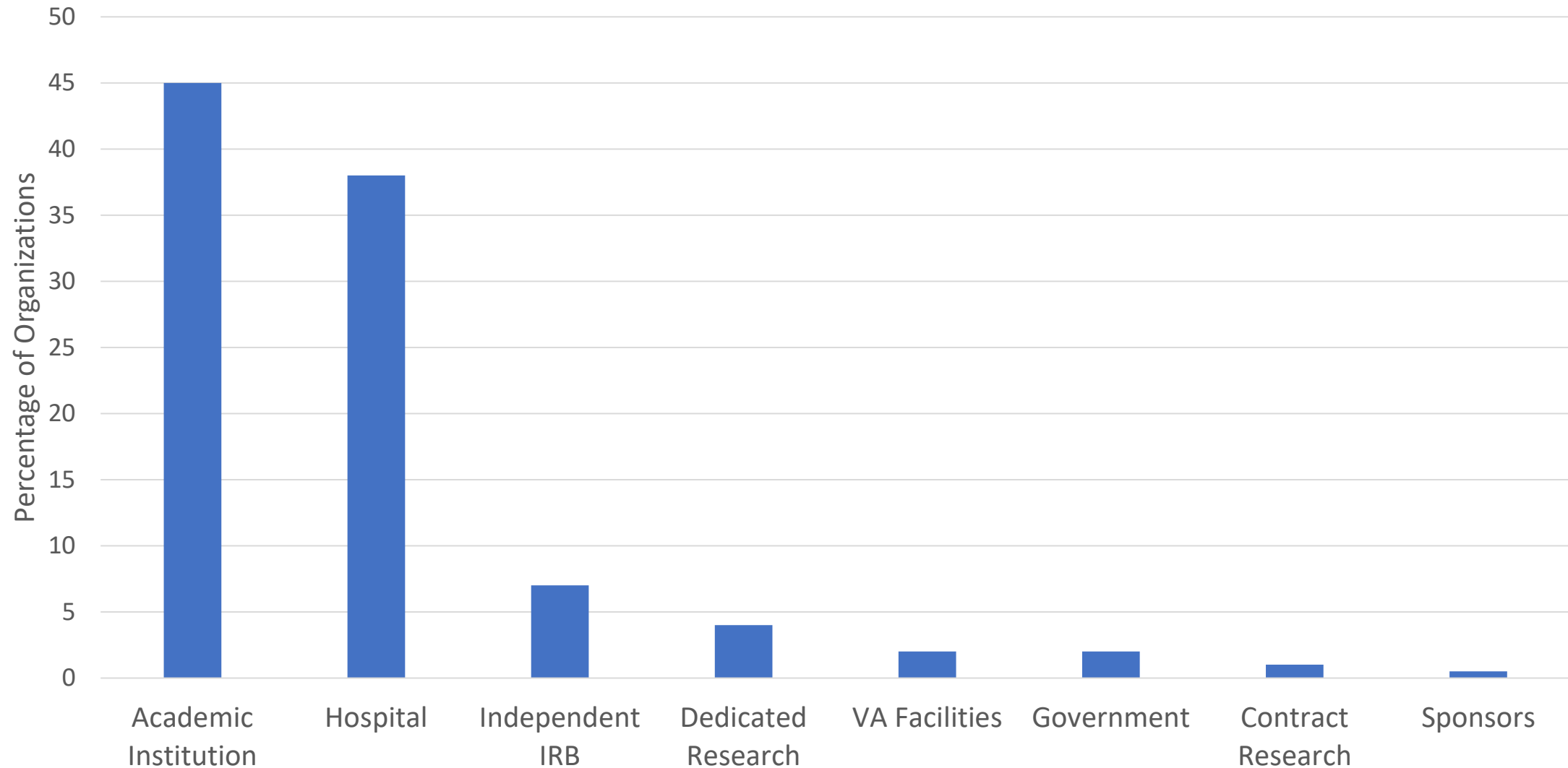
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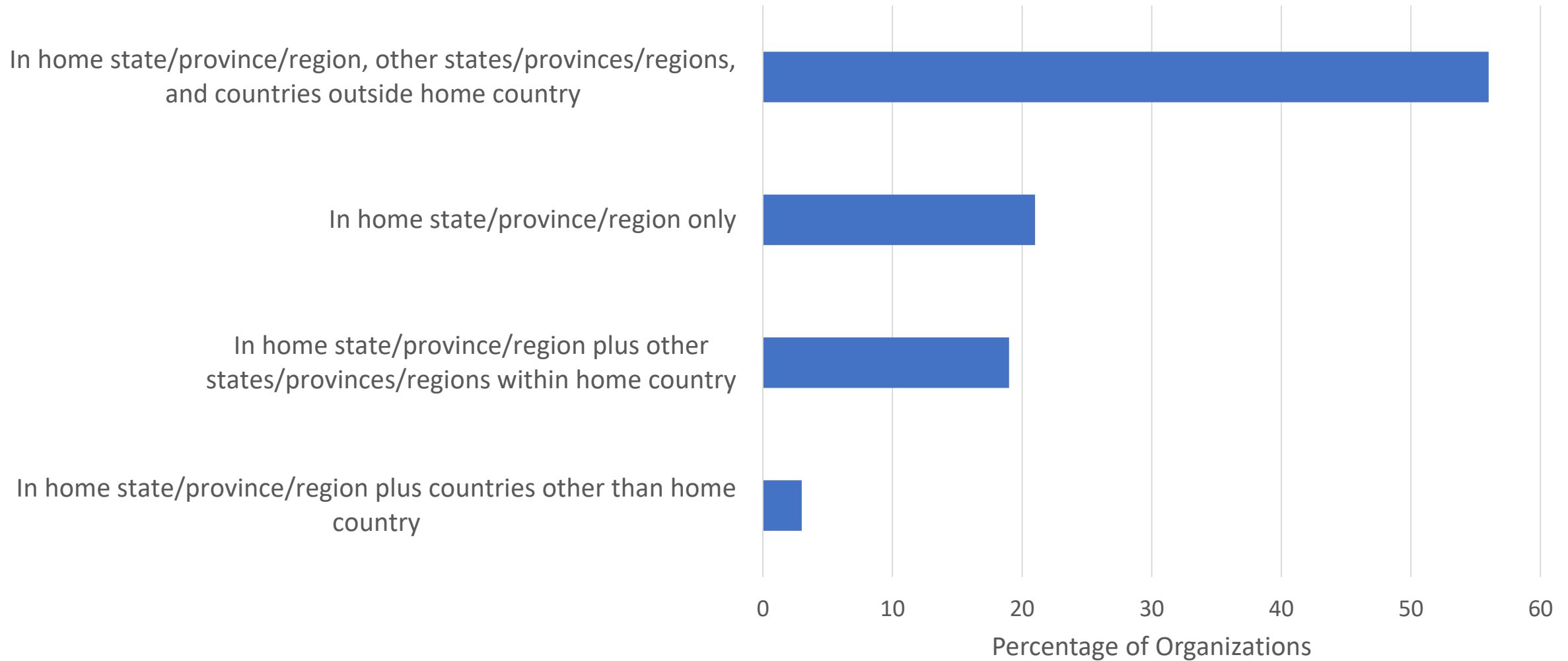
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All Accredited Organizations 2018



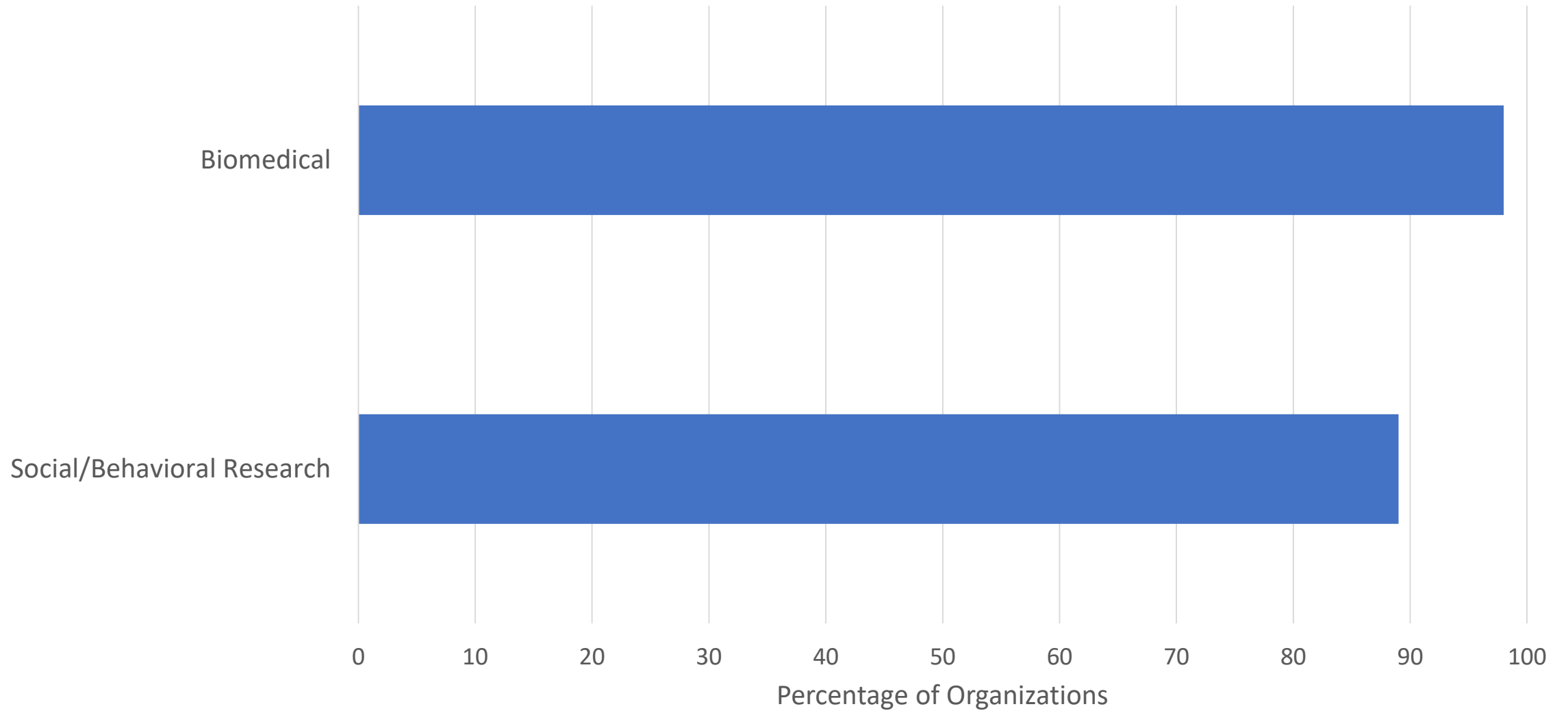
Of the 254 AAHRPP Accredited organizations, 45% are academic institutions; 38% are hospitals; 7% are independent IRBs; 4% are dedicated research facilities; 2% are VA facilities; 2% are governmental organizations; 1% are contract research facilities; 0.5% are sponsors.

Where Organizations Conduct Research



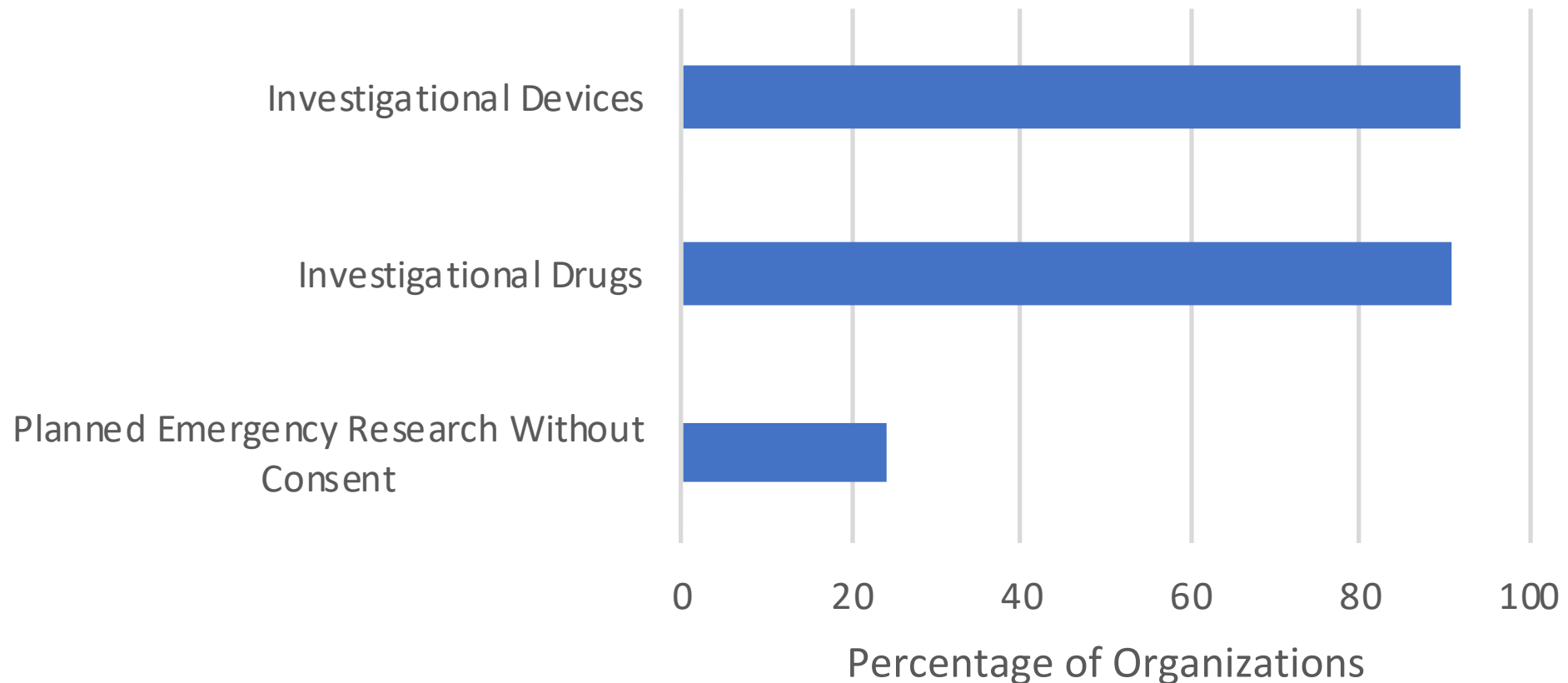
56% of responding organizations conduct research in their home state/province/region, other states/provinces/regions, and countries outside of their home country; 21% of responding organizations conduct research in their home state/province/region only; 19% of responding organizations conduct research on their home state/province/region and other states/provinces/regions within their home country; and, 3% of responding organizations conduct research in their home state/province/region and countries outside of their home country.

Type of Research Conducted or Reviewed by Organizations



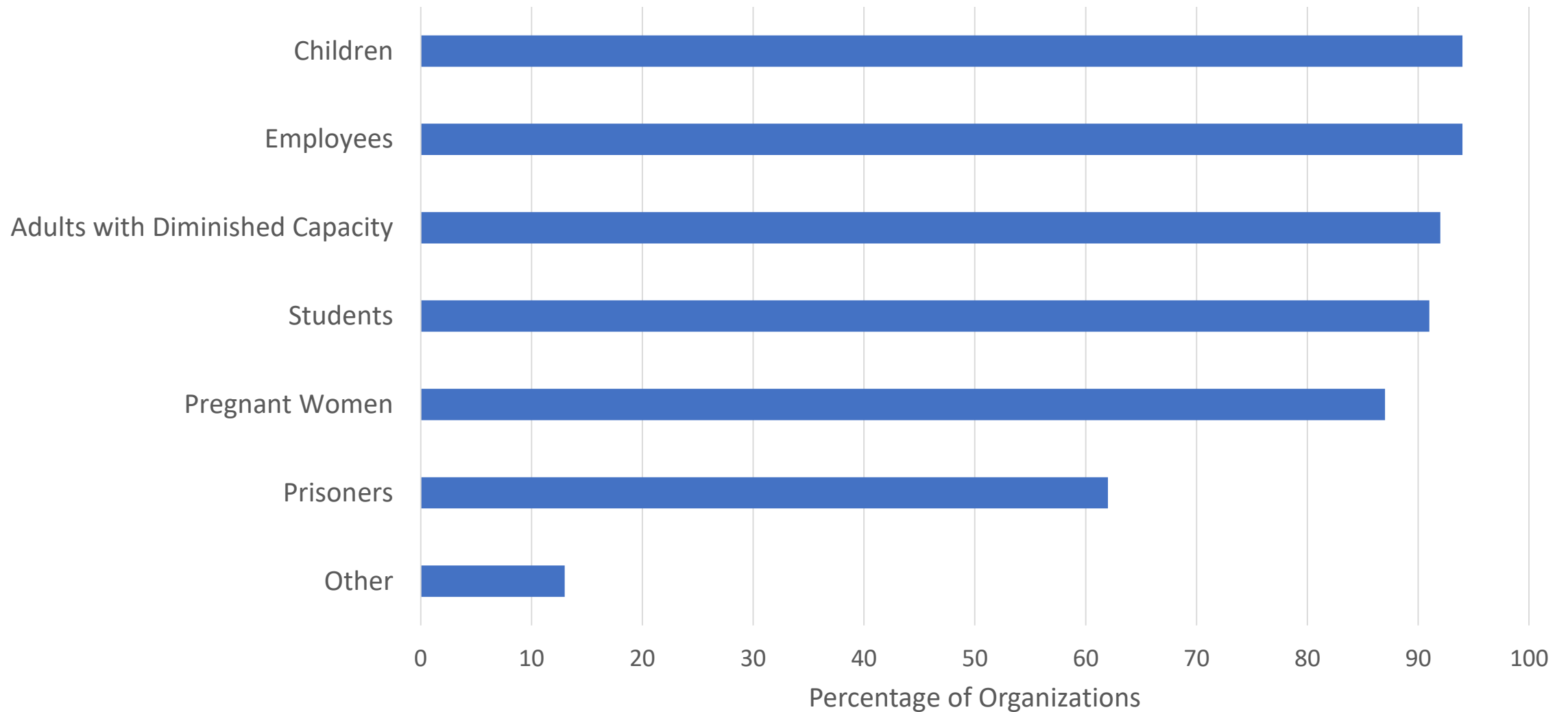
98% of responding organizations conduct biomedical research; 89% conduct social/behavioral research.

Selected Types of Research That Organizations Conduct or Review



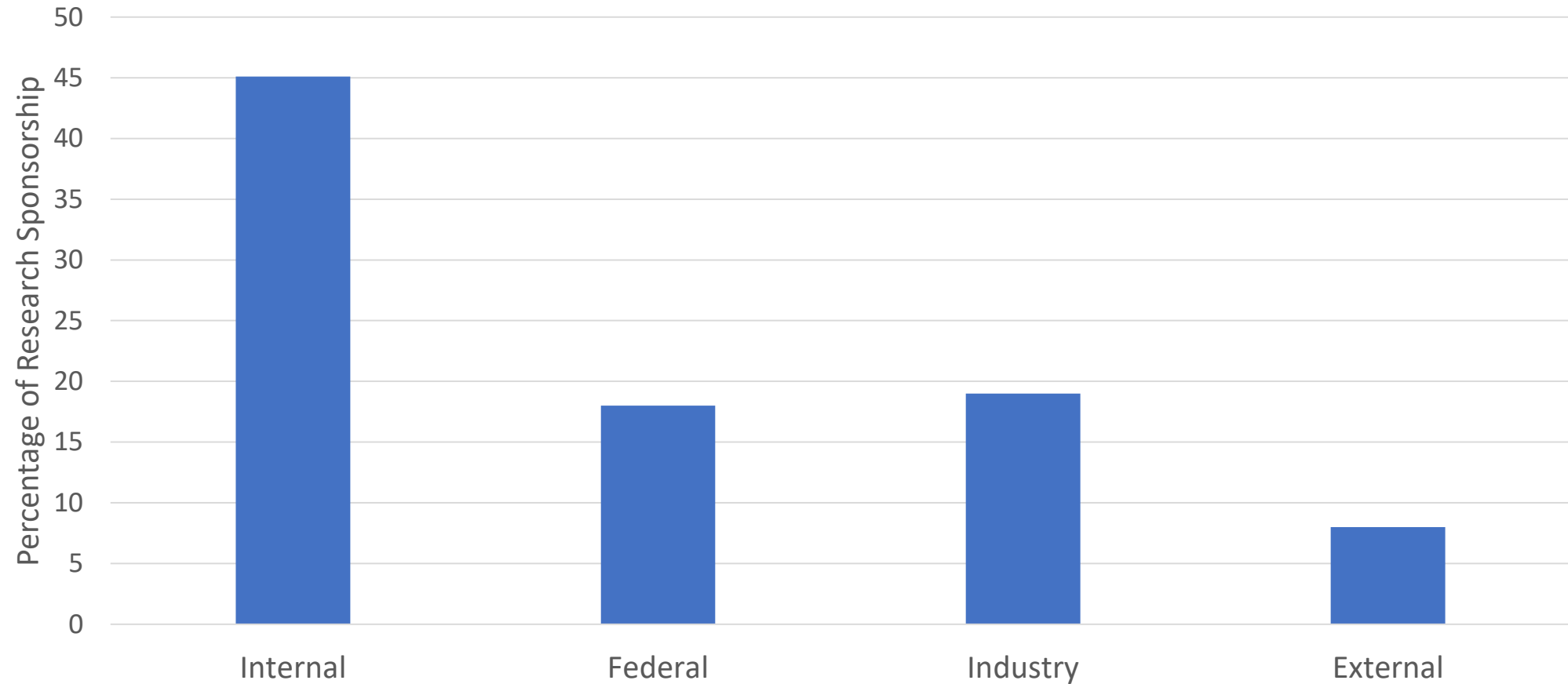
92% of responding organizations conduct research involving investigational drugs; 91% conduct research on investigational devices; and, 24% of responding organizations conduct planned emergency research without consent. Five organizations indicated they did biomedical research but did not specify which types.

Organizations that Conduct Research or Review Research Involving Vulnerable Populations



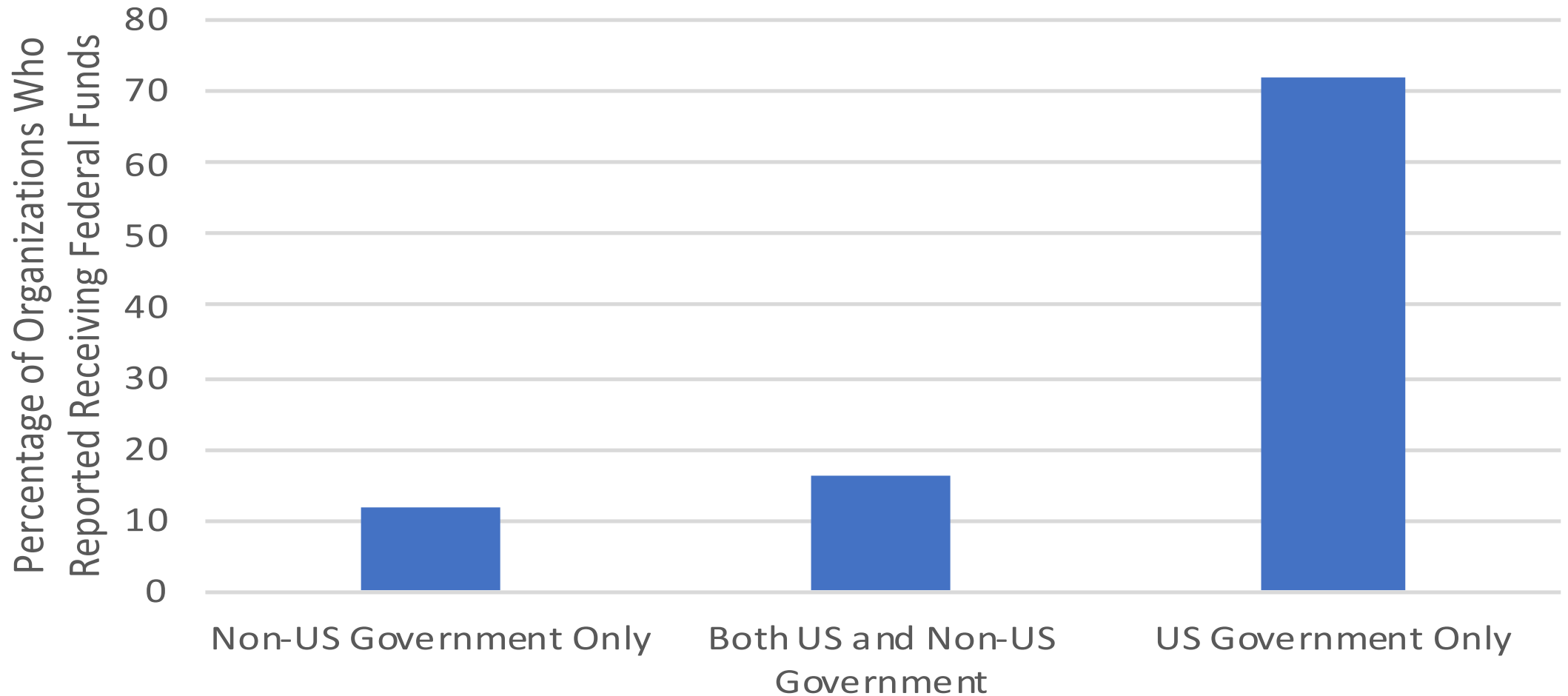
94% of organizations conduct research with children; 94% conduct research with employees; 92% conduct research with adults that have diminished capacities; 91% conduct research with students; 87% conduct research with pregnant women; 62% conduct research with prisoners; 13% conduct research with other vulnerable populations.

Sponsors of Research



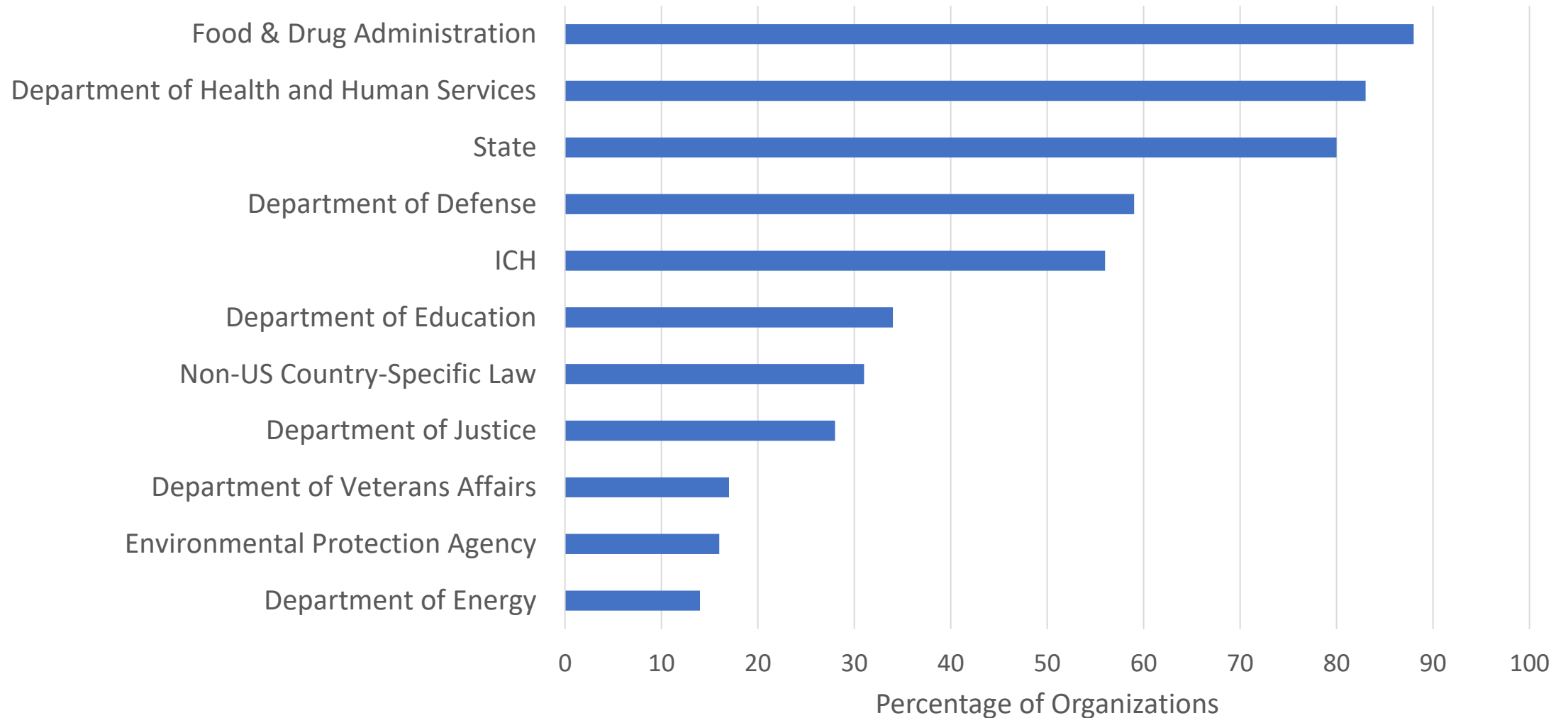
For all organizations a median of 45% of research is sponsored internally; a median of 18% of research is sponsored federally; a median of 19% of research is industry sponsored; a median of 8% of research is sponsored externally.

Federal Sponsors of Research



For all organizations receiving federal funds, 12% receive funds from only non-US governments; 16% receive funds from both US and non-US governments; and 72% receive funds from the US government only.

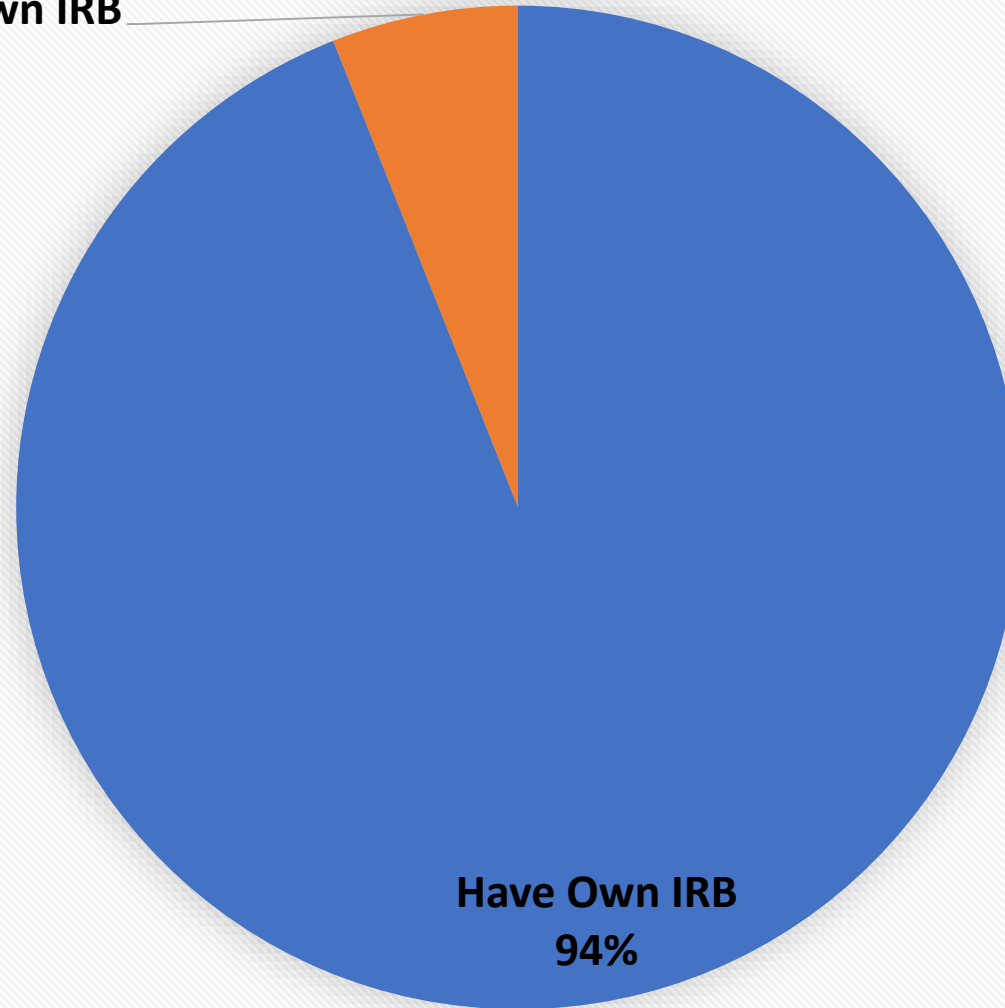
Regulations and Guidance Followed by Organizations



88% of all organizations follow FDA regulations; 83% follow DHHS regulations; 80% follow state and local government regulations; 59% follow DOD regulations; 56% follow ICH or follow ICH requested by a sponsor; 34% follow ED regulations; 31% follow non-US country-specific laws; 28% follow DOJ regulations; 17% follow VA regulations; 16% follow EPA regulations; and 14% follow DOE regulations.

Use of IRBs

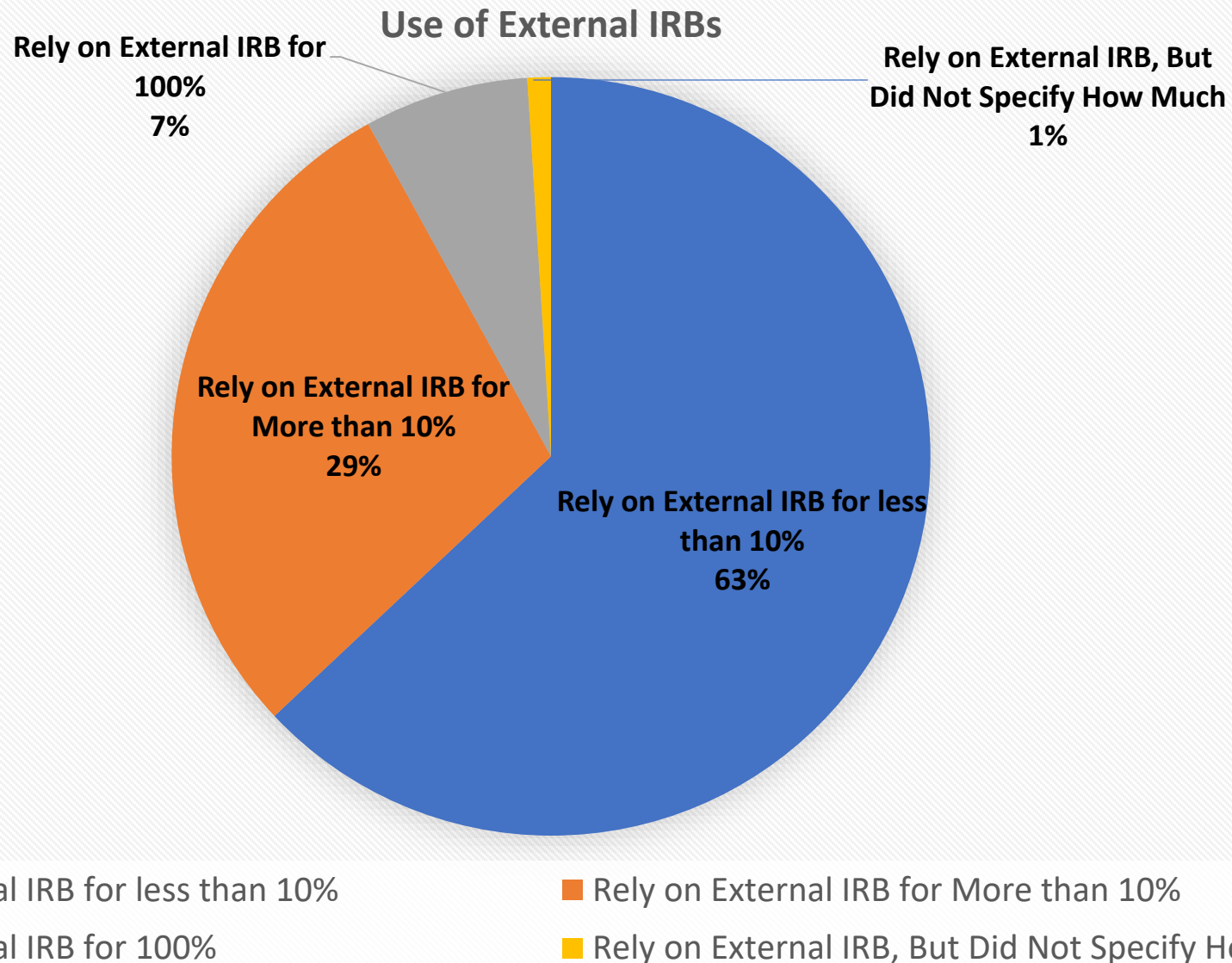
Do Not Have Own IRB
6%



Have Own IRB
94%

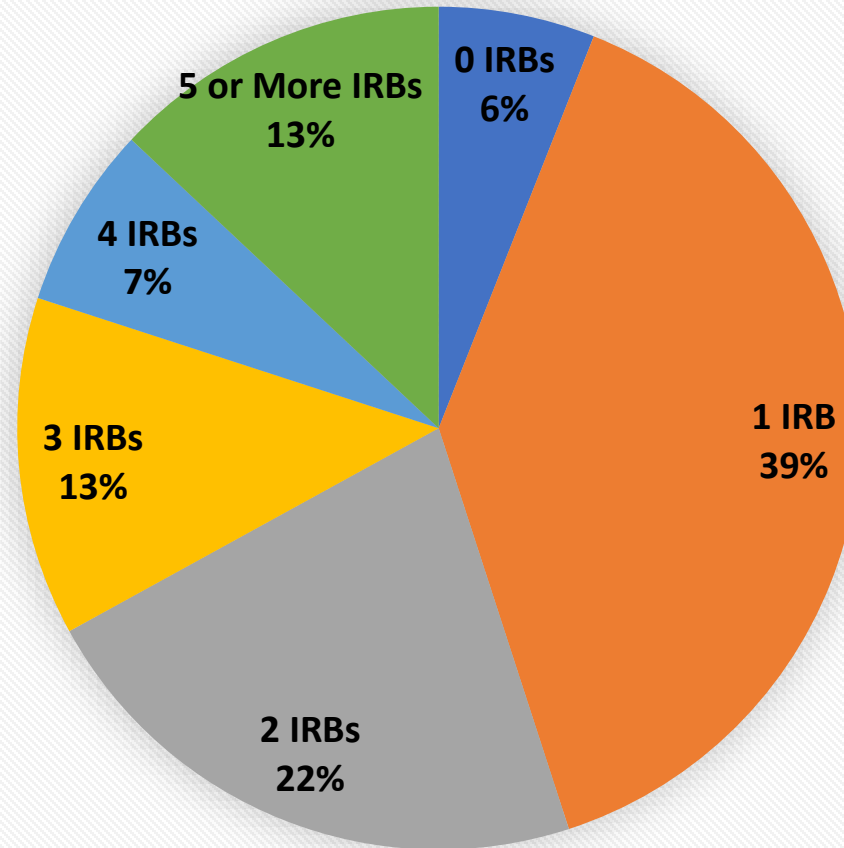
■ Have Own IRB ■ Do Not Have Own IRB

94% of all organizations have their own IRB while 6% do not.



189 accredited organizations reported using an external IRB. 63% of organizations that rely on an external IRB use external IRBs for 10% or less of their protocols; 29% of organizations rely on external IRBs for more than 10% of protocols; 6% of organizations that rely on external IRBs use them for 100% of protocols. 2% of organizations that use an external IRB did not specify for what percent of protocols.

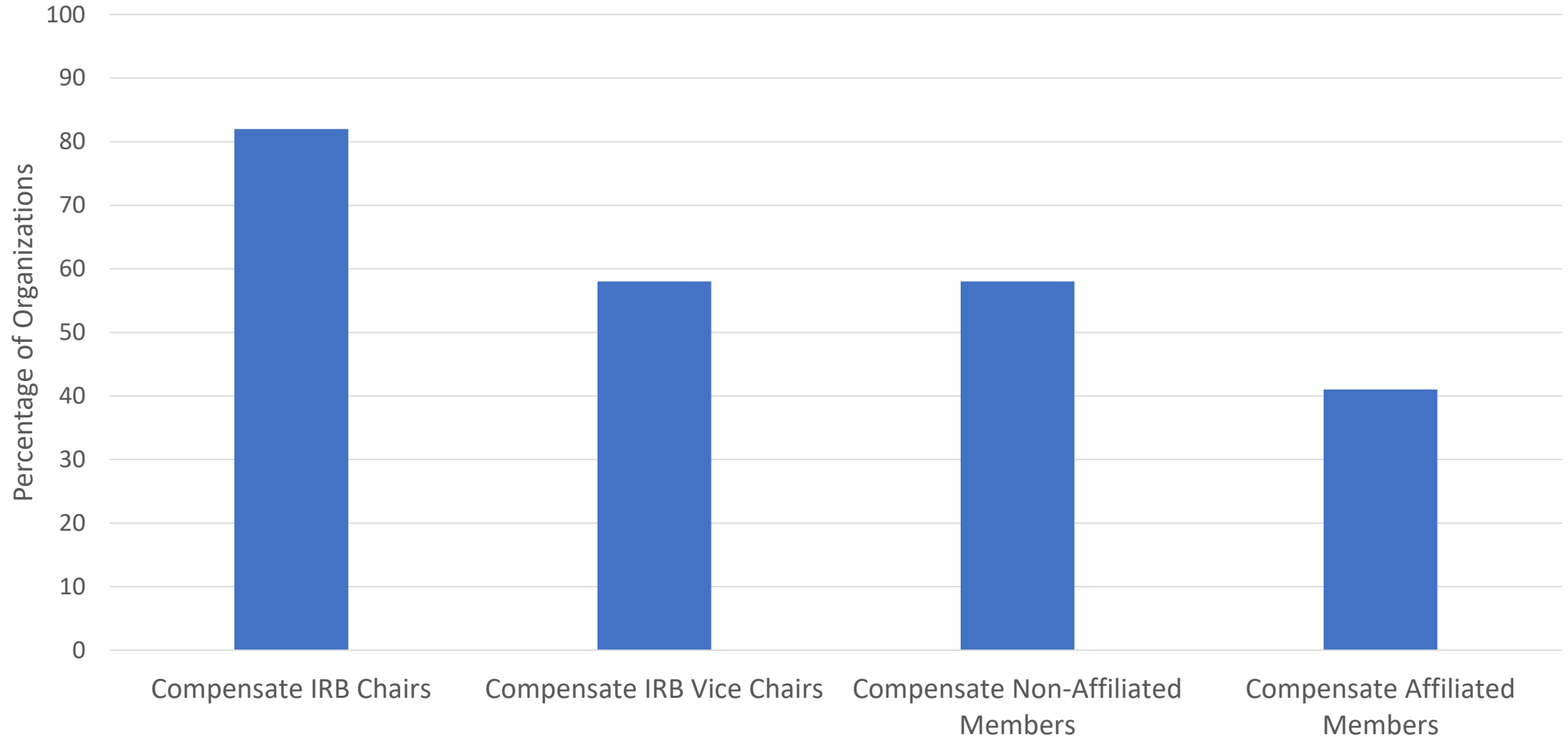
Number of IRBs per Organization



■ 0 IRBs ■ 1 IRB ■ 2 IRBs ■ 3 IRBs ■ 4 IRBs ■ 5 or More IRBs

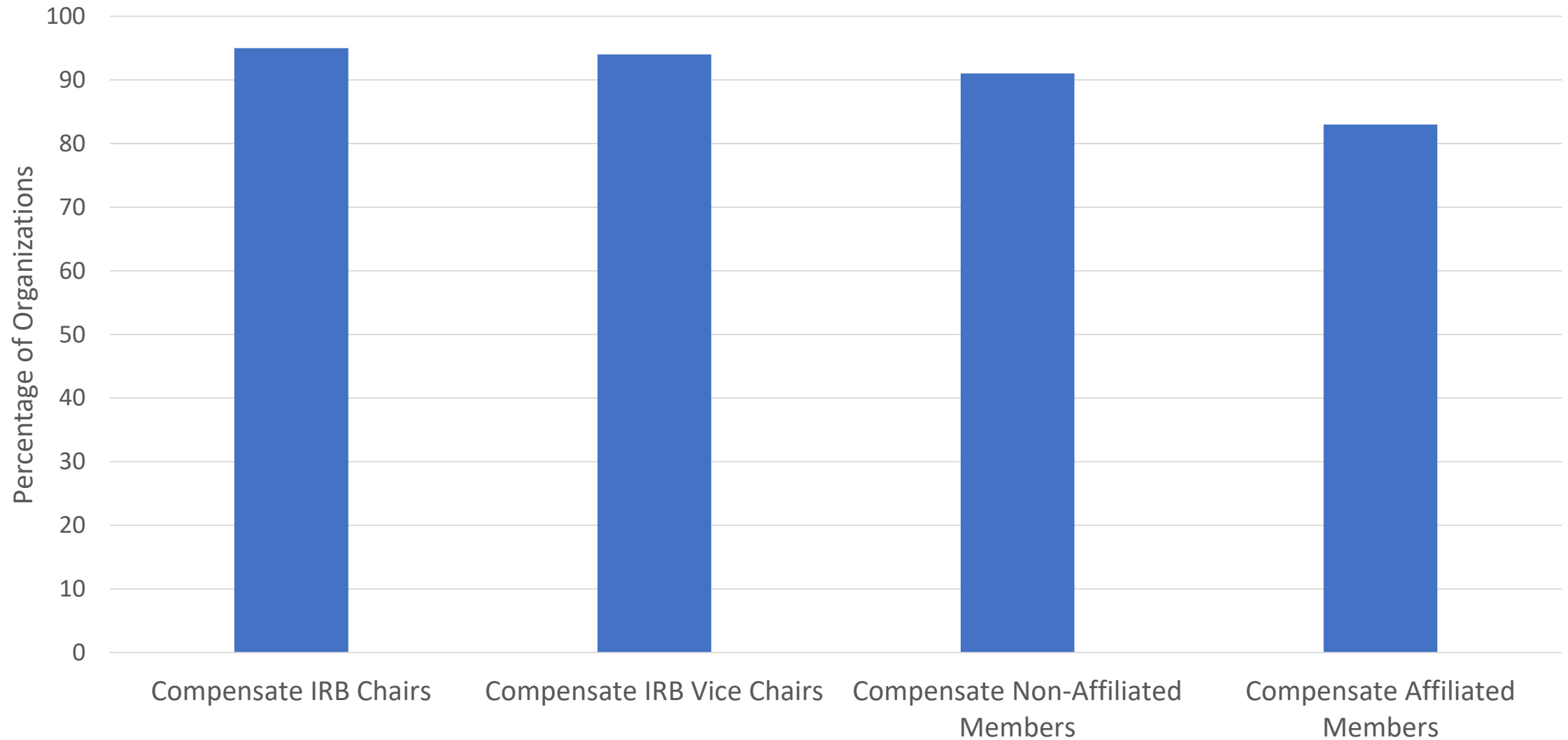
39% of all organizations have one IRB of their own; 22% have 2; 13% have 3; 7% have 4; 13% have 5 or more; and, 6% rely on external IRBs only.

IRB Member Compensation



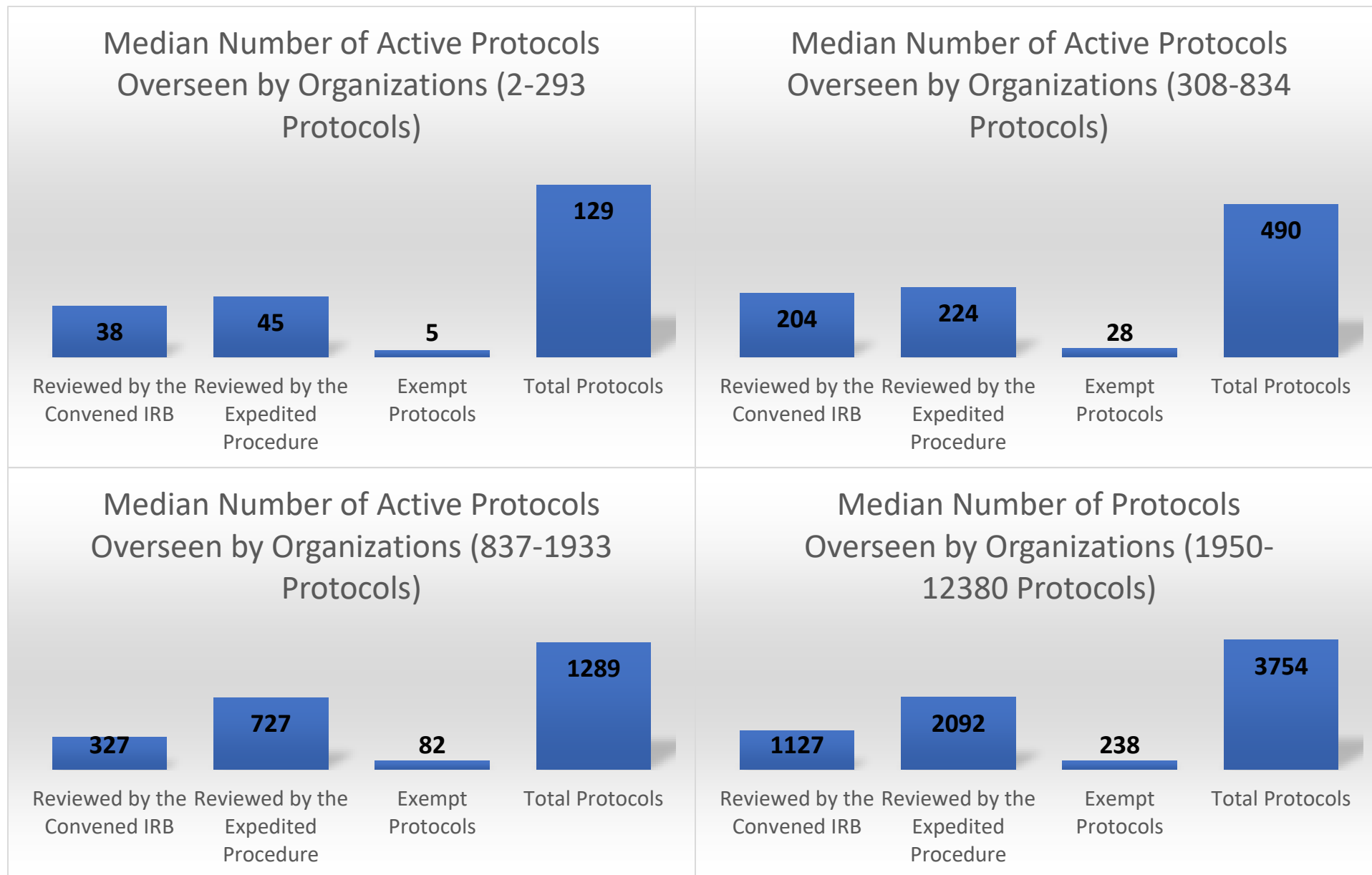
For all organizations (excluding independent IRBs), 82% of organizations with an IRB compensate IRB chairs; 58% compensate IRB vice chairs; 58% compensate non-affiliated members; 41% compensate affiliated members.

Financial Compensation of IRB Members



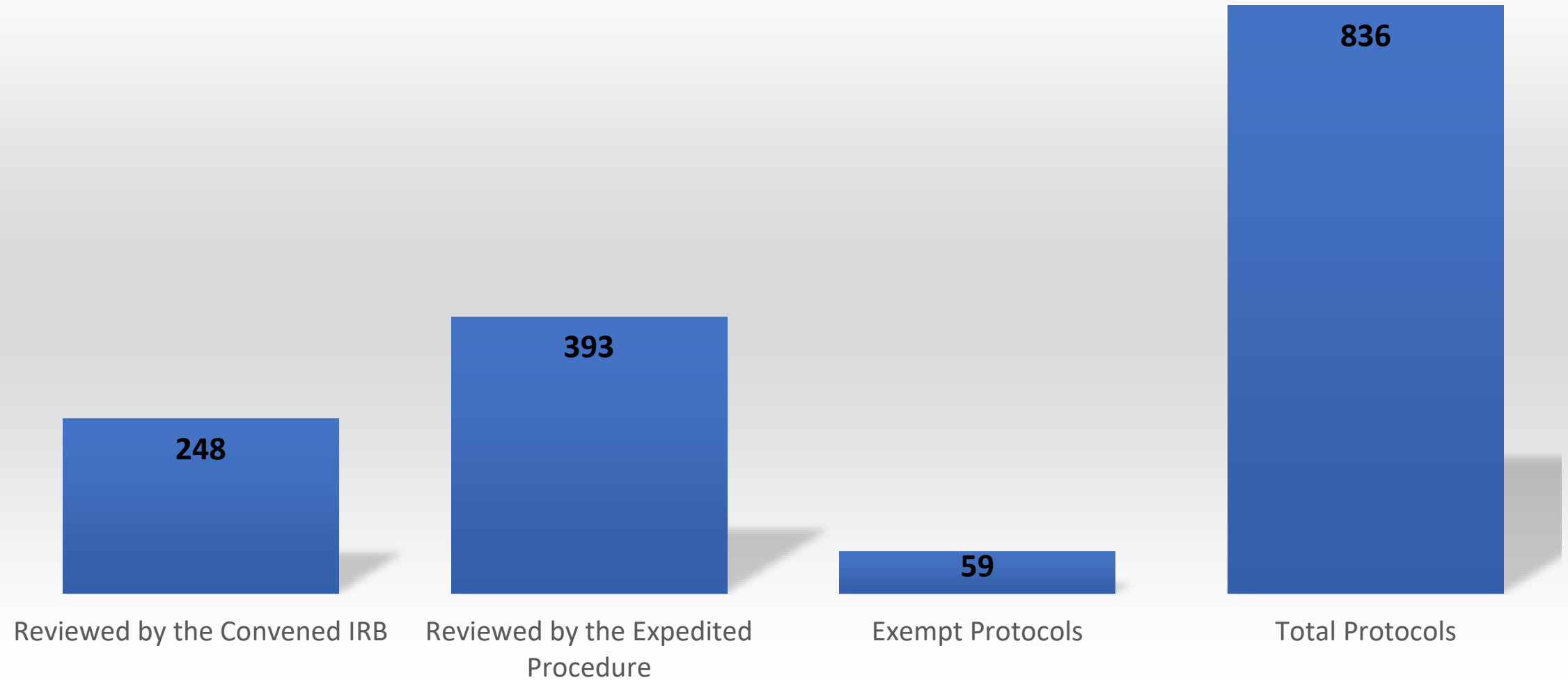
Within AAHRPP Organizations that compensate IRB chairs, 95% provide financial compensation for chairs; within AAHRPP organizations that compensate IRB vice chairs, 94% of organizations provide financial compensation for vice chairs; within AAHRPP organizations that compensate non-affiliated members, 91% of organizations provide financial compensation for non-affiliated members; within AAHRPP organizations that compensate affiliated members, 83% provide financial compensation for affiliated members.

Median Number of Protocols Overseen Organized by Quartiles of AAHRPP Accredited Orgs

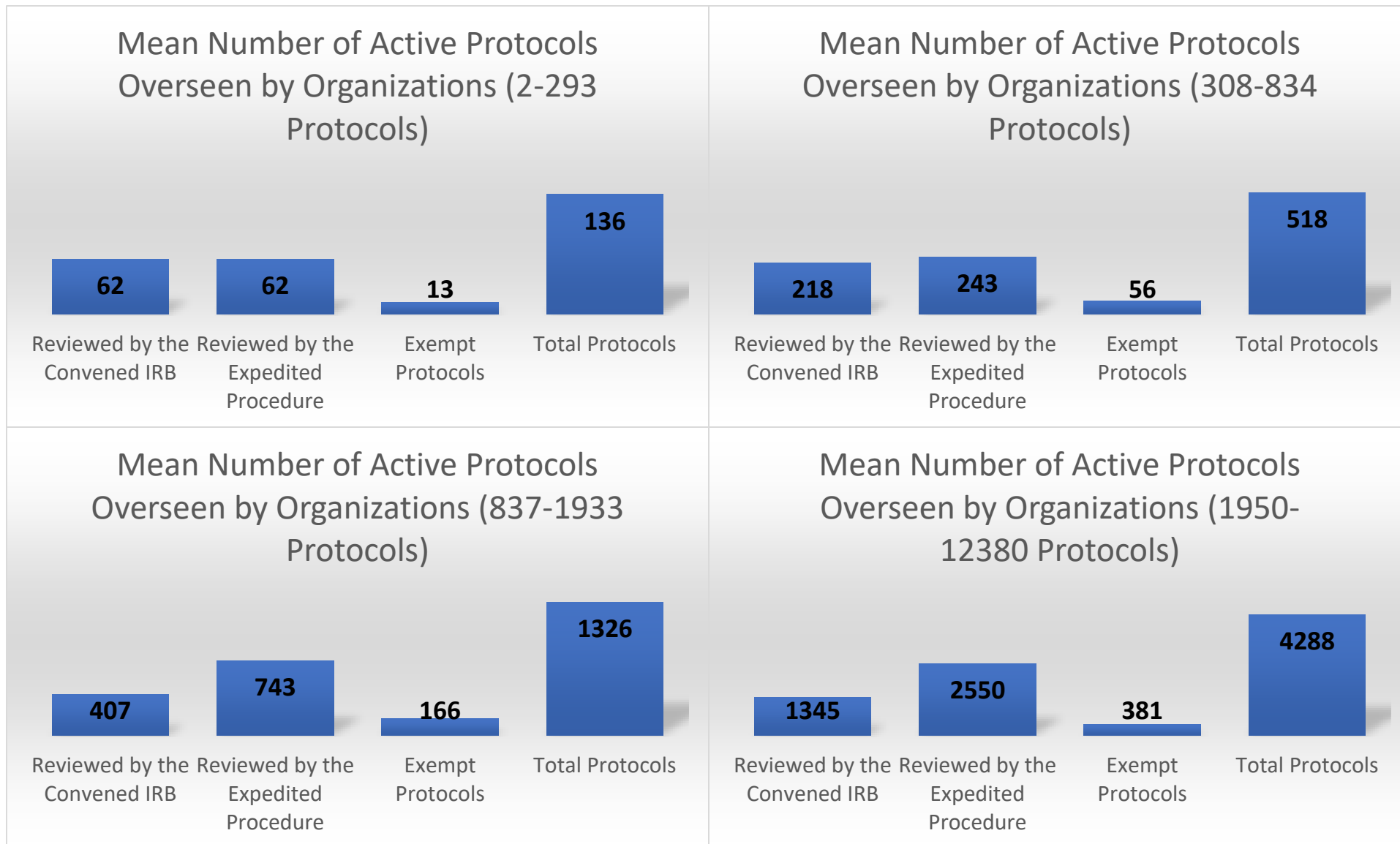


Each chart represents one quarter of accredited organizations.

Median Number of Active Protocols Overseen by all Organizations

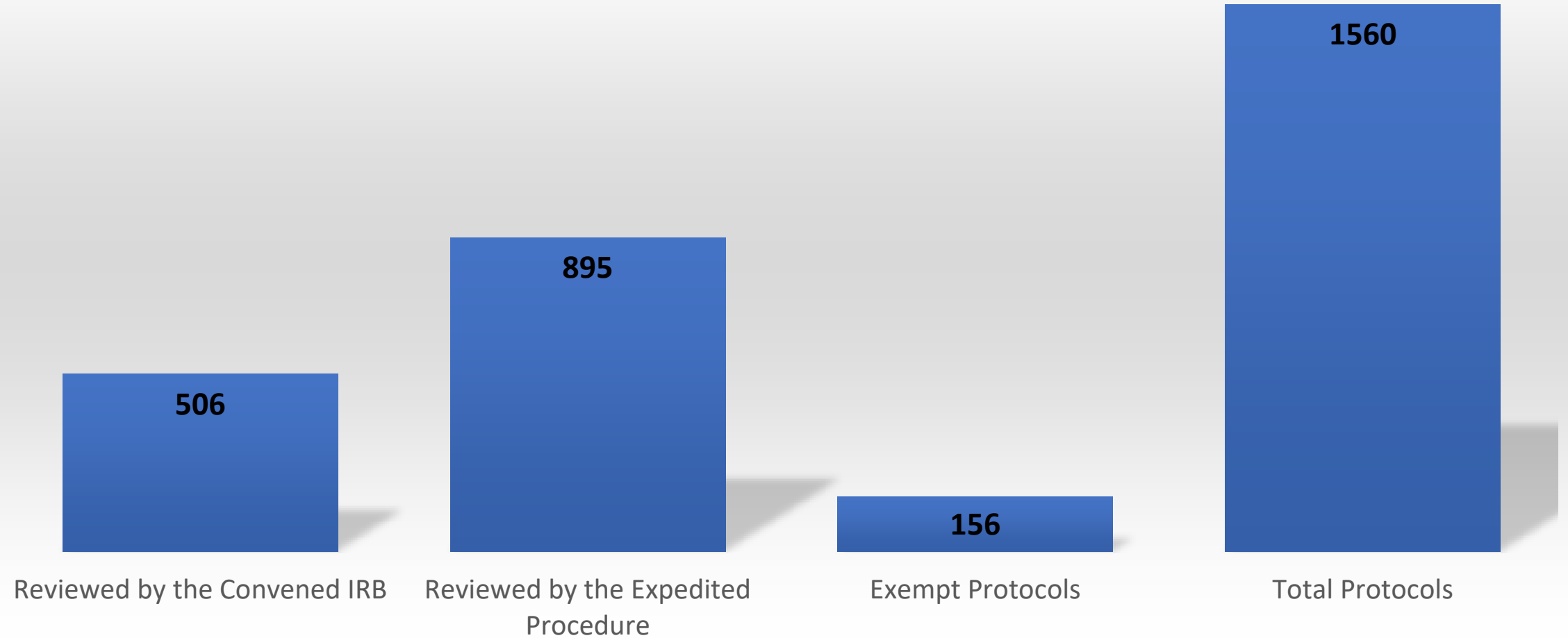


Mean Number of Active Protocols Organizations Oversee by Quartile

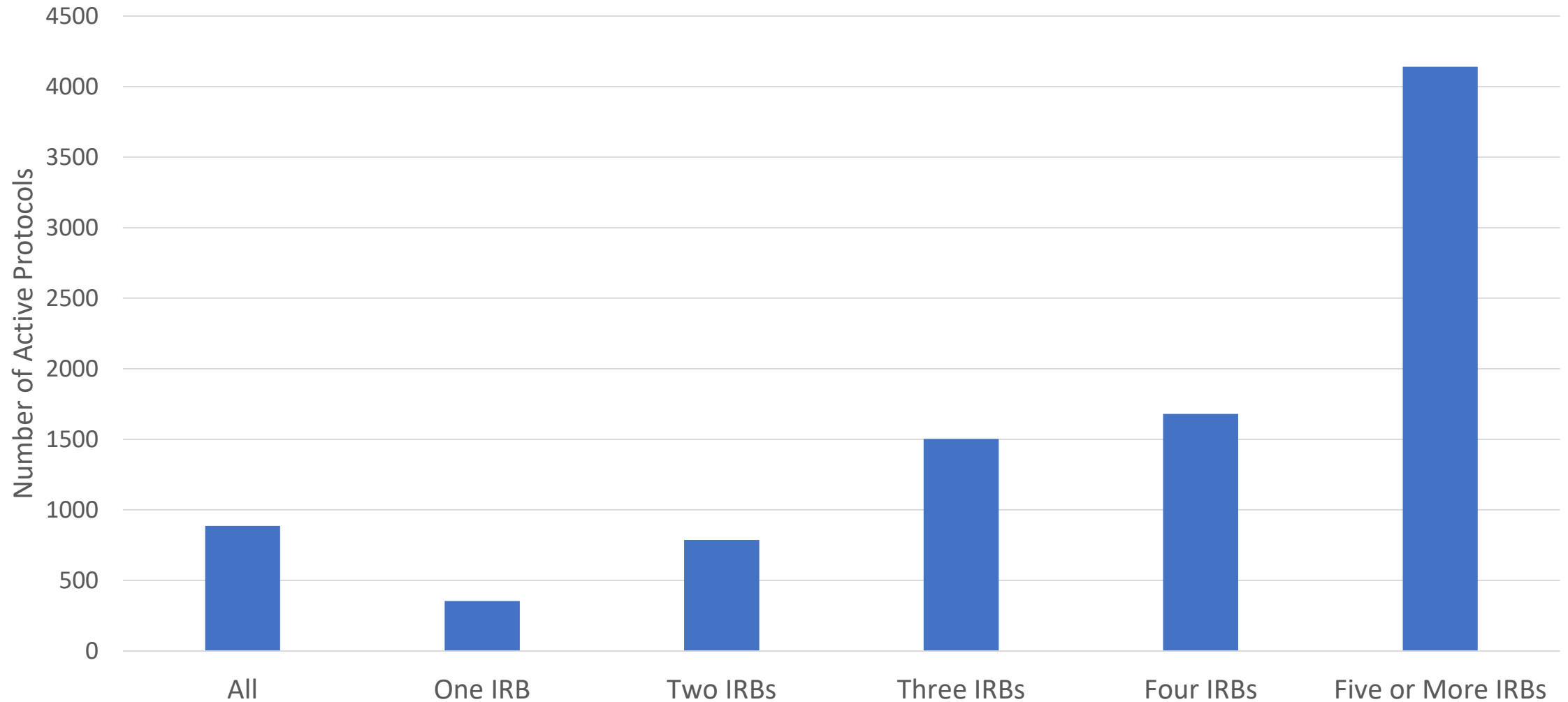


Each chart represents one quarter of accredited organizations.

Mean Number of Active Protocols Overseen by all Organizations

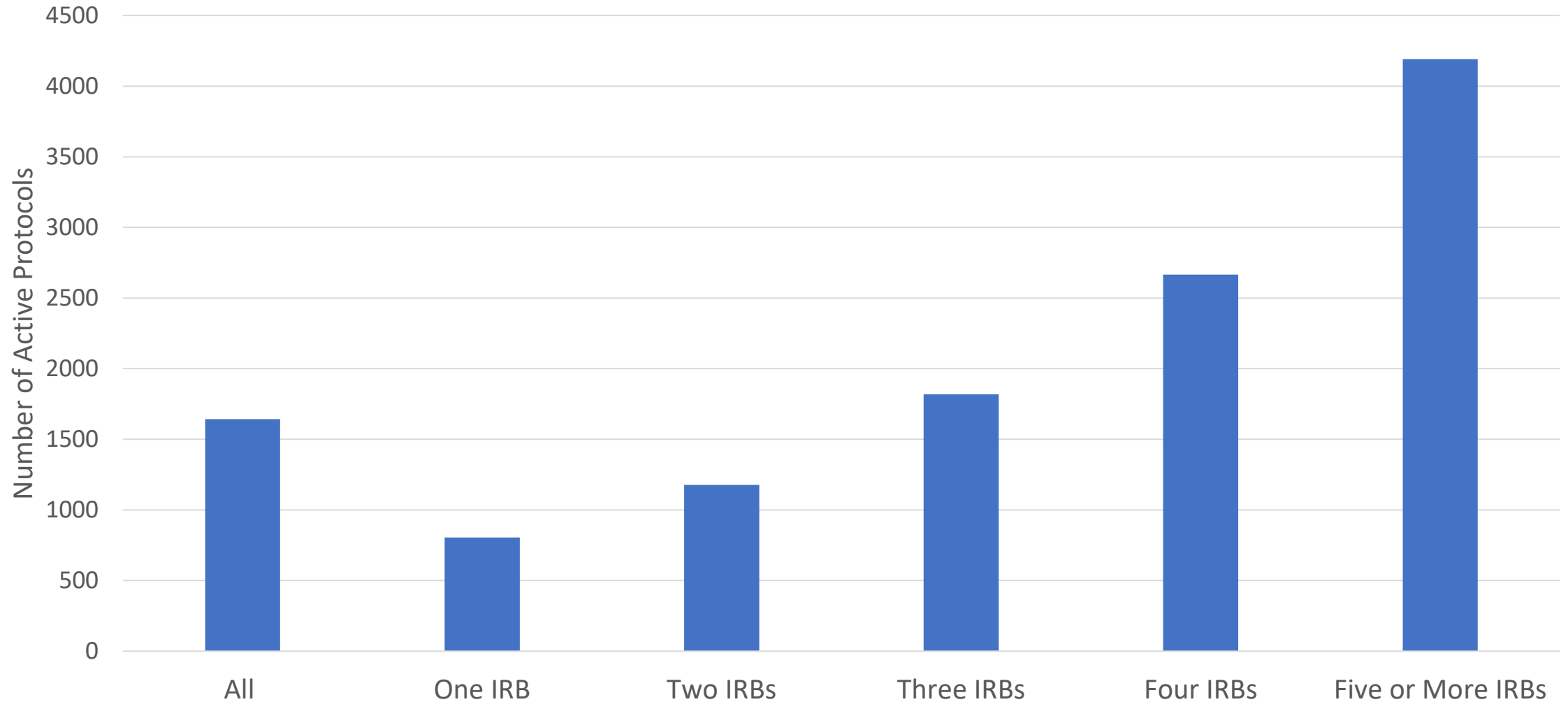


Median Number of Active Protocols Overseen by an Organization Based on the Number of IRBs per Organization



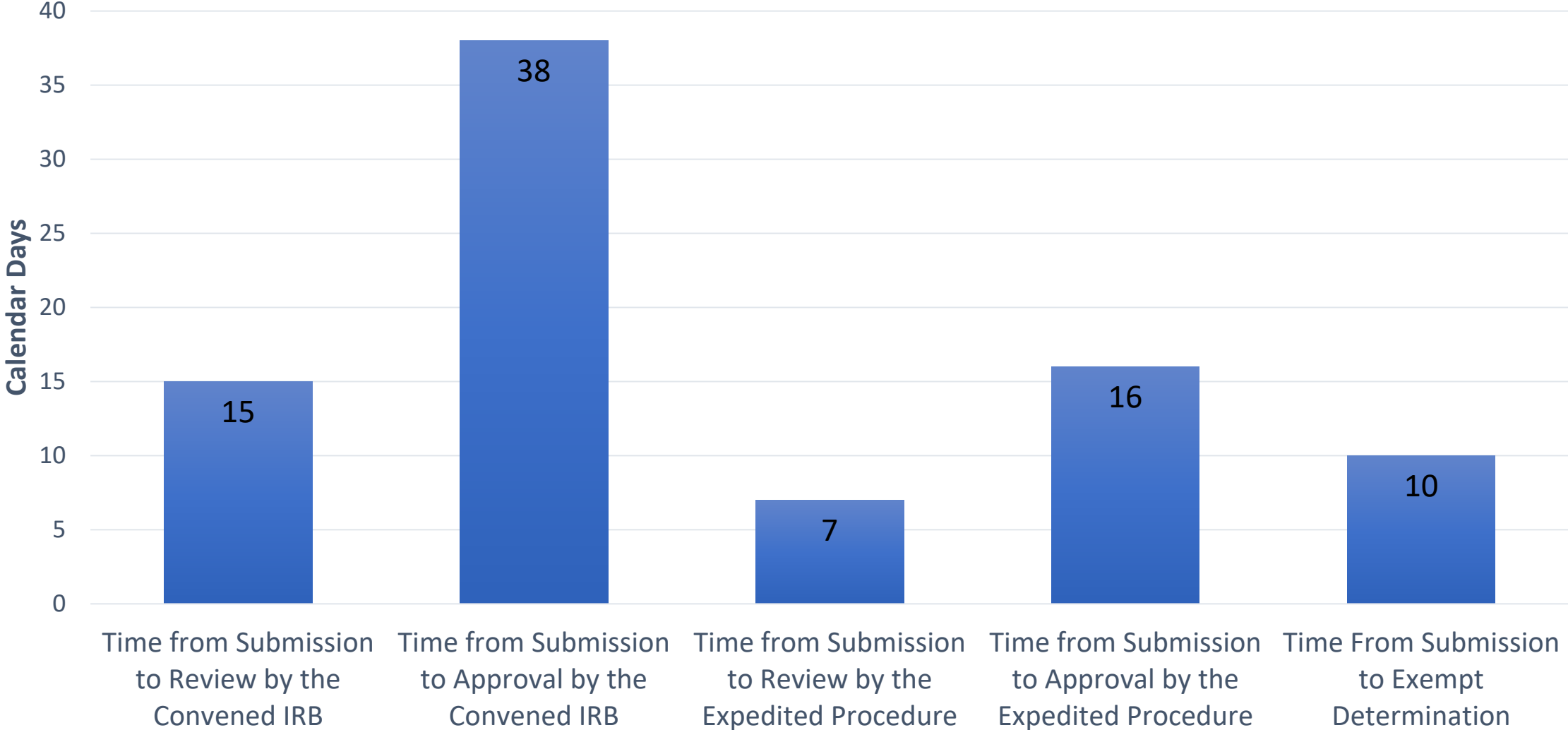
A median of 887 protocols were overseen by all organizations with an IRB; a median of 354 protocols were overseen by organizations with one IRB; a median of 787 protocols were overseen by organizations with two IRBs; a median of 1503 protocols were overseen by organizations with three IRBs; a median of 1680 protocols were overseen by organizations with four IRBs; a median of 4140 protocols were overseen by organizations with five or more IRBs.

Mean Number of Active Protocols Overseen by an Organization Based on the Number of IRBs per Organization

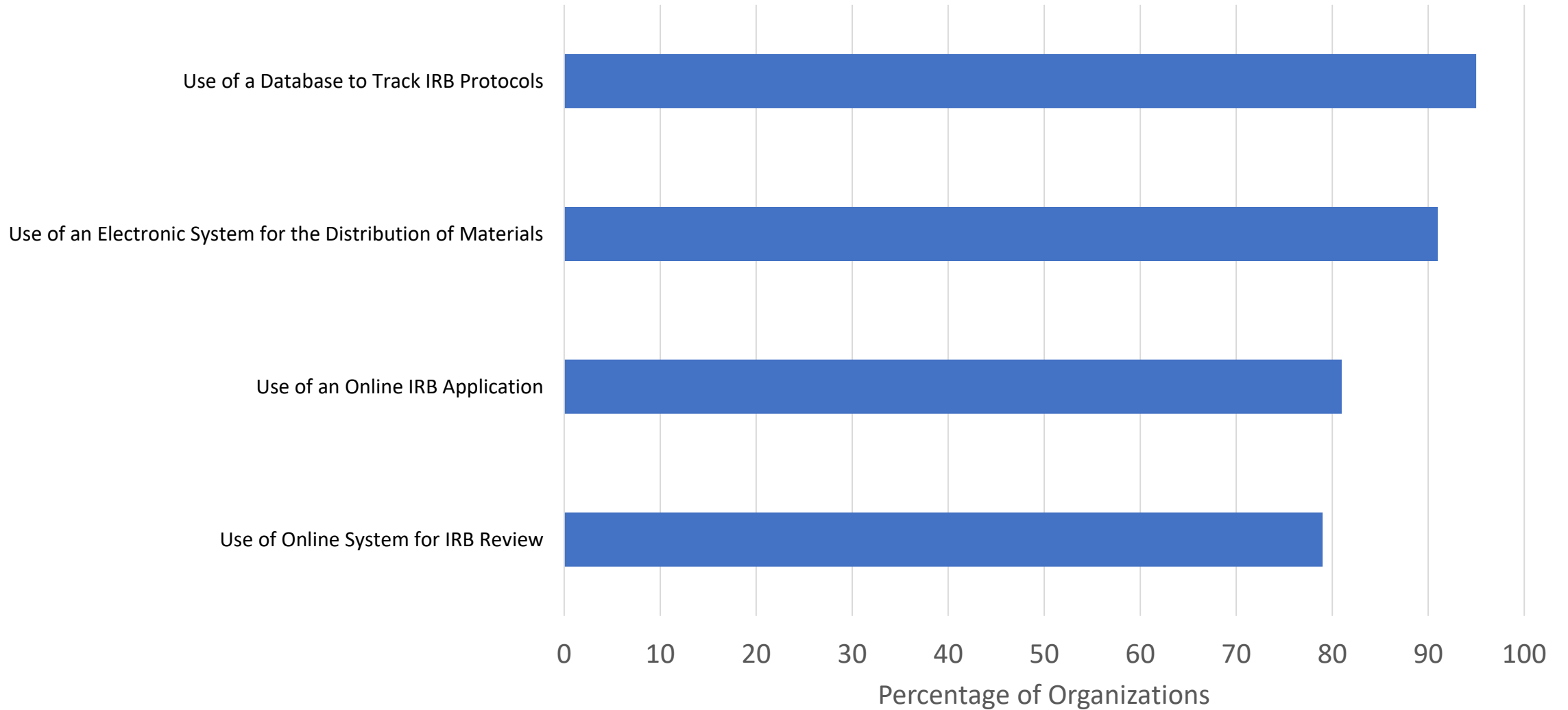


A mean of 1643 protocols were overseen by all organizations with an IRB; a mean of 805 protocols were overseen by organizations with one IRB; a mean of 1177 protocols were overseen by organizations with two IRBs; a mean of 1818 were overseen by organizations with three IRBs; a mean of 2666 protocols were overseen by organizations with four IRBs; a mean of 4192 protocols were overseen by organizations with five IRBs.

Median IRB Review Times by Type of Review



Technology Use by Organizations with an IRB

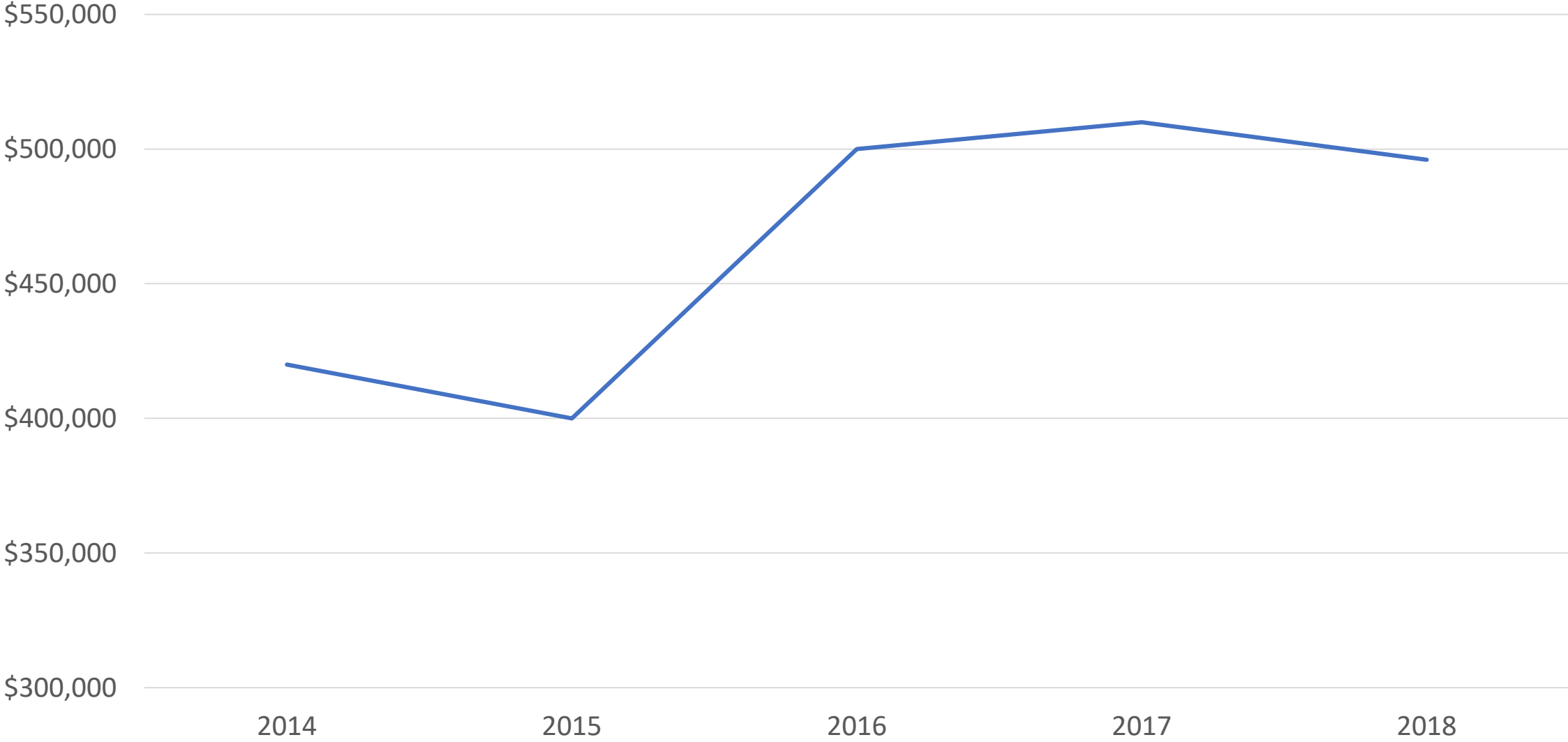


95% of all organizations use a database to track IRB protocols; 90% use an electronic system for the distribution of materials; 81% use an online IRB application; 79% use an online system for IRB review.

IRB Staffing and Funding Levels

Protocol Category	Median Number of Staff	Median Number of Protocols	Median Protocols per FTE	Median Dollars Budgeted for IRBs
All	7	871	119	\$496,298
1-100	2	42	21	\$82,896
101-500	3	296	99	\$240,140
501-1000	5	801	160	\$416,828
1001-2000	9	1,542	175	\$663,036
2001-4000	16	2,727	170	\$1,558,753
4000+	24	5,608	239	\$2,656,800

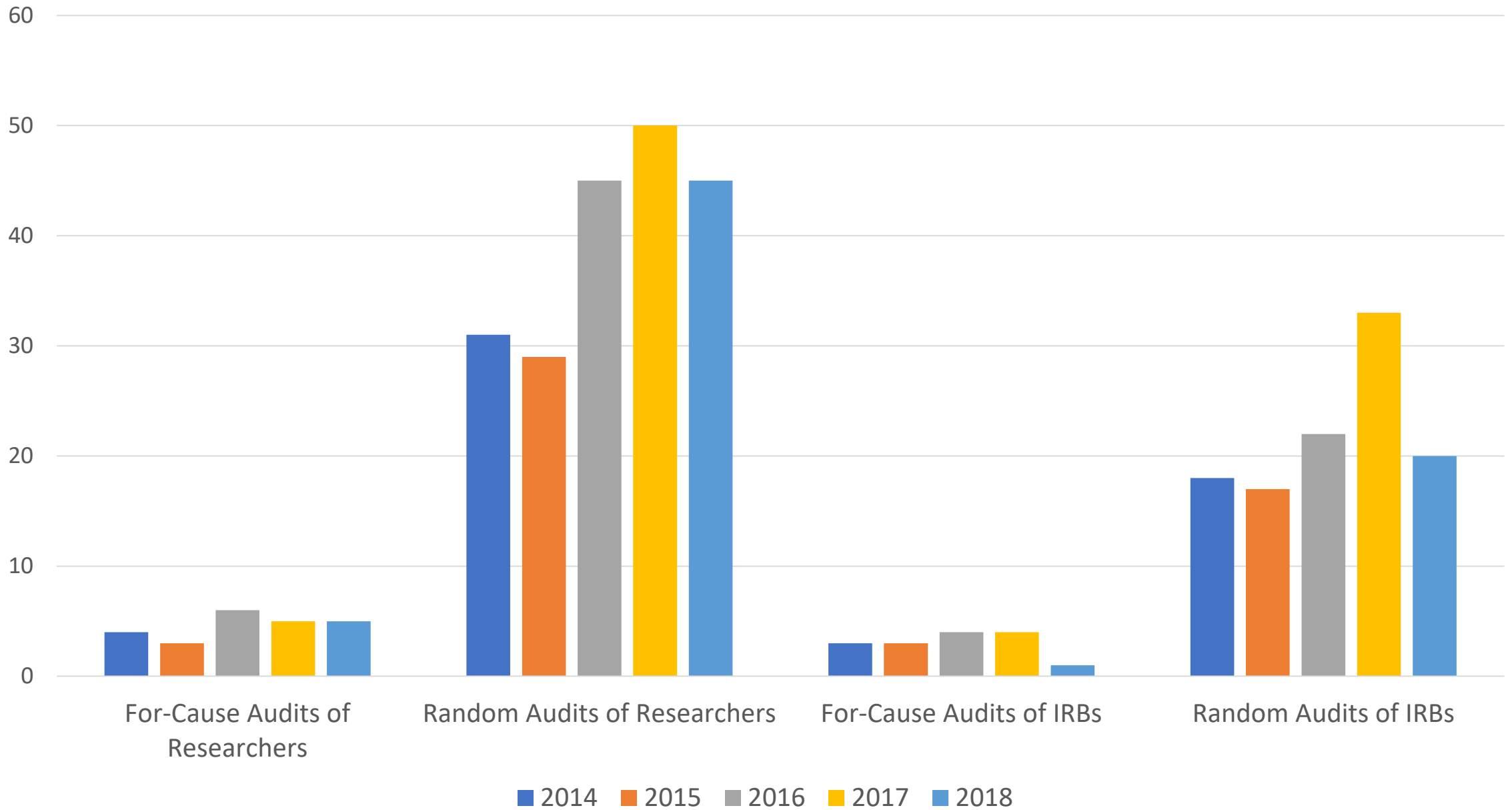
Five Year Trends in Median IRB Budgets



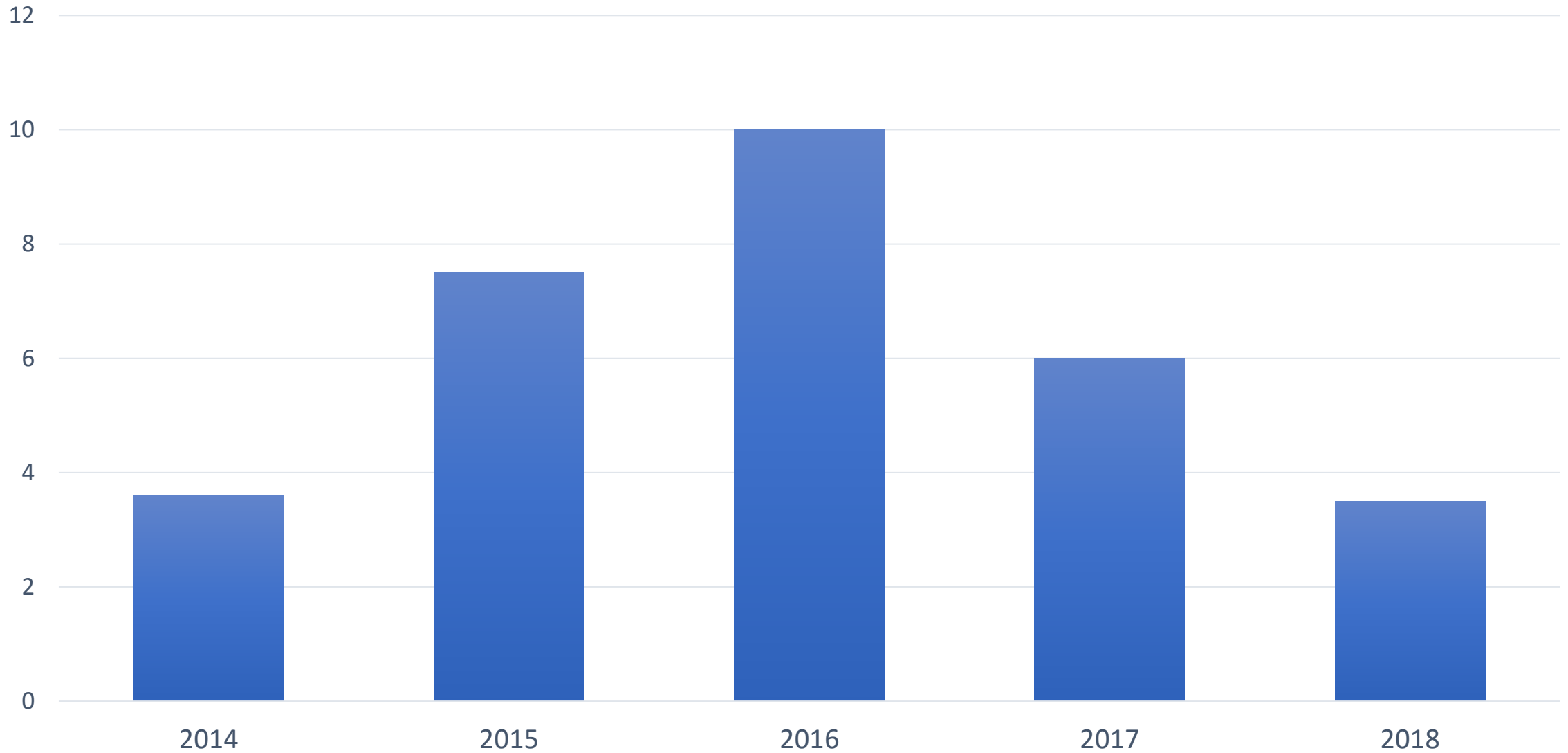
Number of Internal Audits Organizations Conducted within the Past Year

	For Cause Audits of Researchers	Random Audits of Researchers	For Cause Audits of IRBs	Random Audits of IRBs
Mean	5	45	1	20
Median	2	15	0	3

Five Year Trends in Mean Number of Audits Organizations Conduct



Five Year Trends in Mean Number of Complaints Reported



Number of Cases of Non-Compliance Reported to the IRB in the Past Year

Protocol Category	Median Number of Allegations of Non- Compliance	Median Number of Determinations of Non-Compliance
All	5	1
1-100	0	0
101-500	1	0
501-1000	6	1
1001-2000	13	1
2001-4000	11	6
4000+	36.5	6

Five Year Trends on Mean Number of Reported Cases of Non-Compliance

