



# 2017 Metrics on Human Research Protection Program Performance

Updated May 2, 2018

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# About the Metrics

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Improving the quality of human research protection programs (HRPP) is a top priority of AAHRPP. Effective and efficient systems of oversight with organizations provide better protections for research participants and produce higher quality research. And collectively, they raise the bar globally to ensure research participants are safe and respected. AAHRPP is pleased to present the 2017 metrics for HRPP performance.

The metrics are collected from annual reports and new applications from our current clients. From data supplied by our client organizations in 2017, 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. For the 2017 data, the metrics are represented as the median, except where indicated as the mean.

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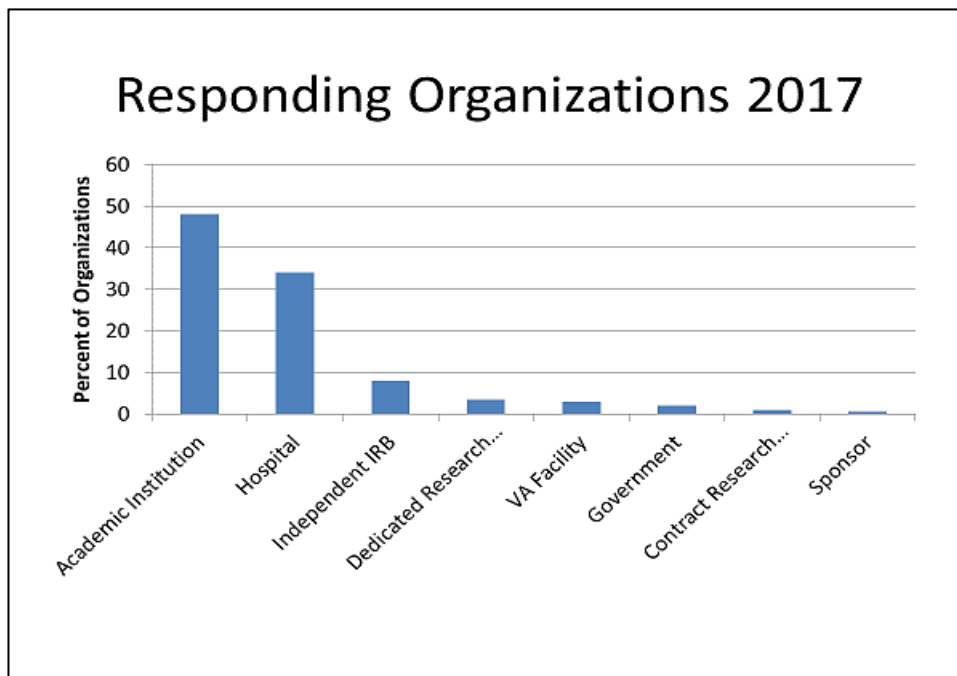
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## General Description of Organizations

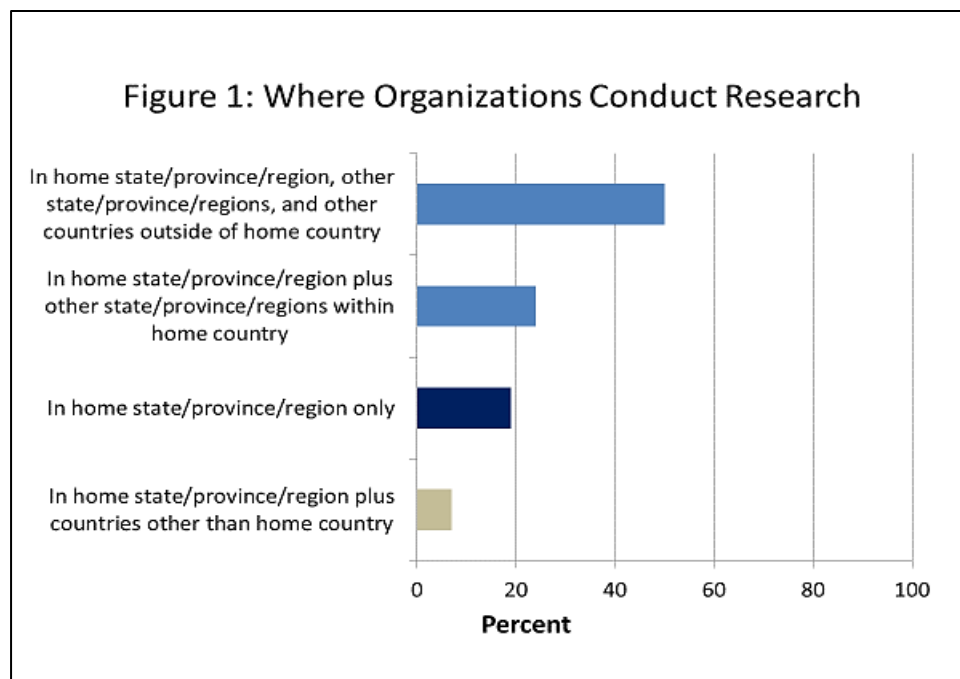


**Slide 1:** 43% of all accredited organizations are academic institutions; 39% are hospitals; 8.5% are independent IRBs; 3% are VA facilities; 3% are dedicated research sites or research institutes; 2% are government organizations; 1% are contract research organizations; and 0.5% are sponsors.

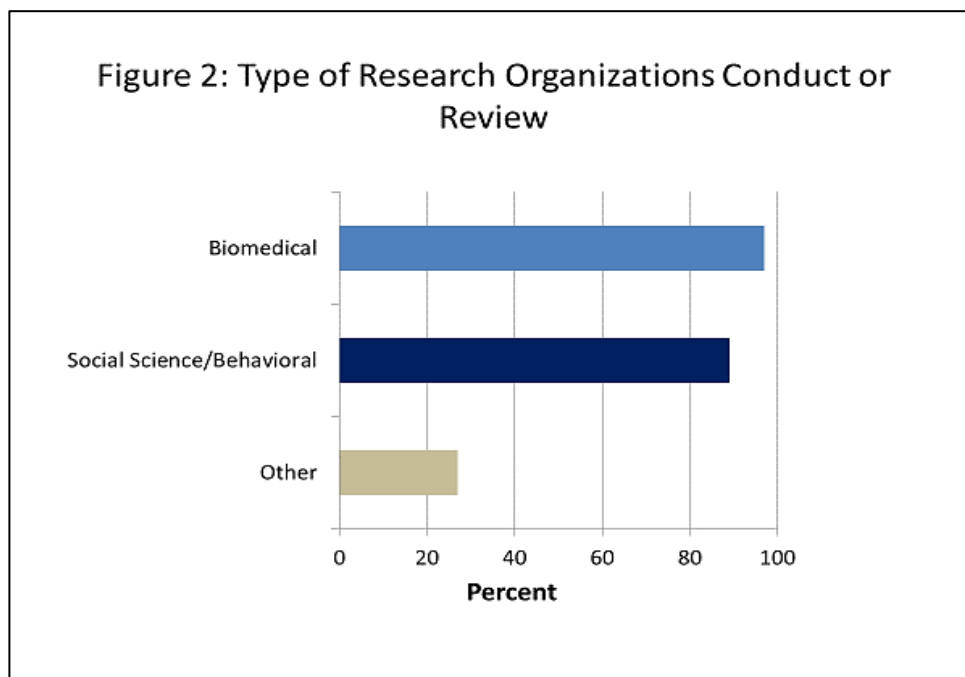


**Slide 2:** 48% of organizations that responded in 2017 were academic institutions; 34% were hospitals; 8% were independent IRBs; 3.5% were dedicated research sites or research institutes; 3% were VA facilities; 2% were government organizations; 1% were contract research organizations; and 0.5% were sponsors.

# General Description of the Research Conducted or Overseen by Organizations

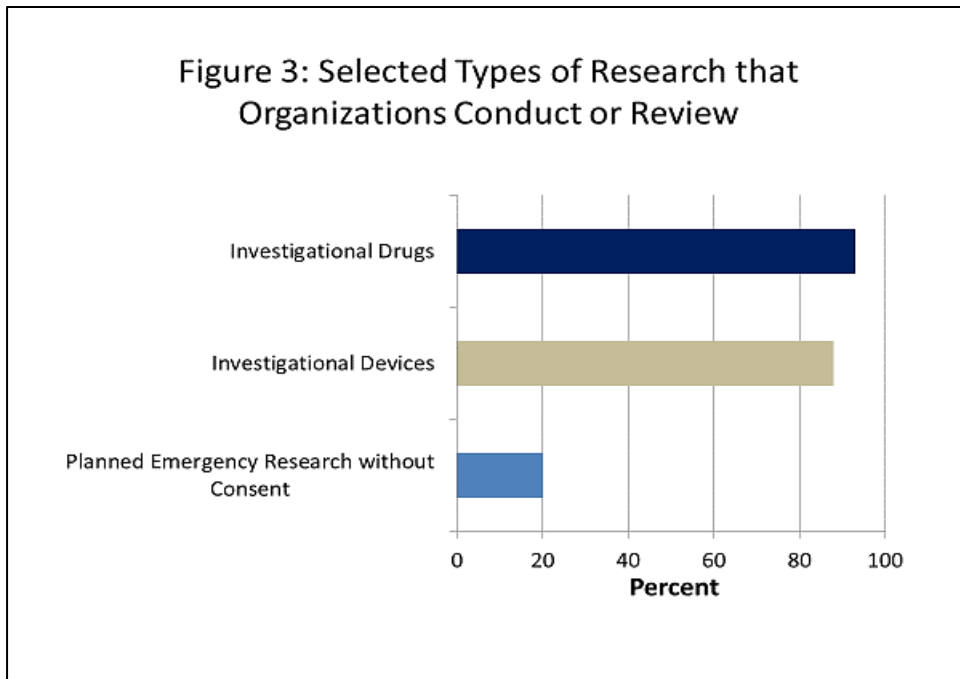


**Figure 1:** 50% of responding organizations conduct research within their home state/province/region, other states/provinces/regions within their home country, and countries other than their home country; 24% conduct research in their home state/province/region and other states/provinces/regions within their home country; 19% of responding organizations conduct research in their home state/province/region only; and 7% conduct research in their home state/province/region and countries other than their home countries.

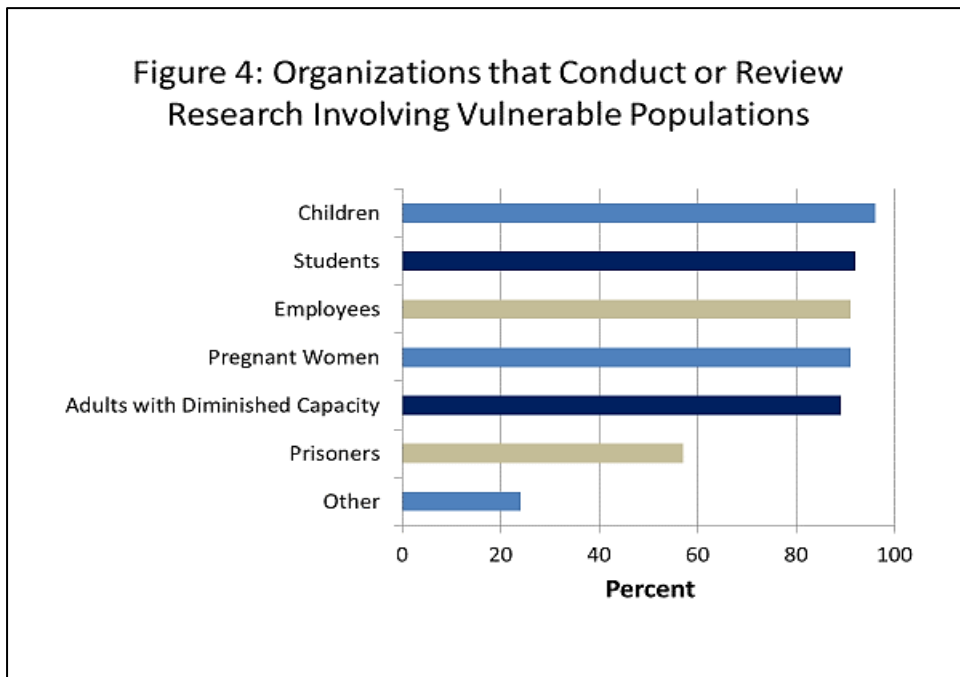


**Figure 2:** 97% of responding organizations conduct biomedical research; 89% conduct social/behavioral research; and 27% conduct research falling into other categories.

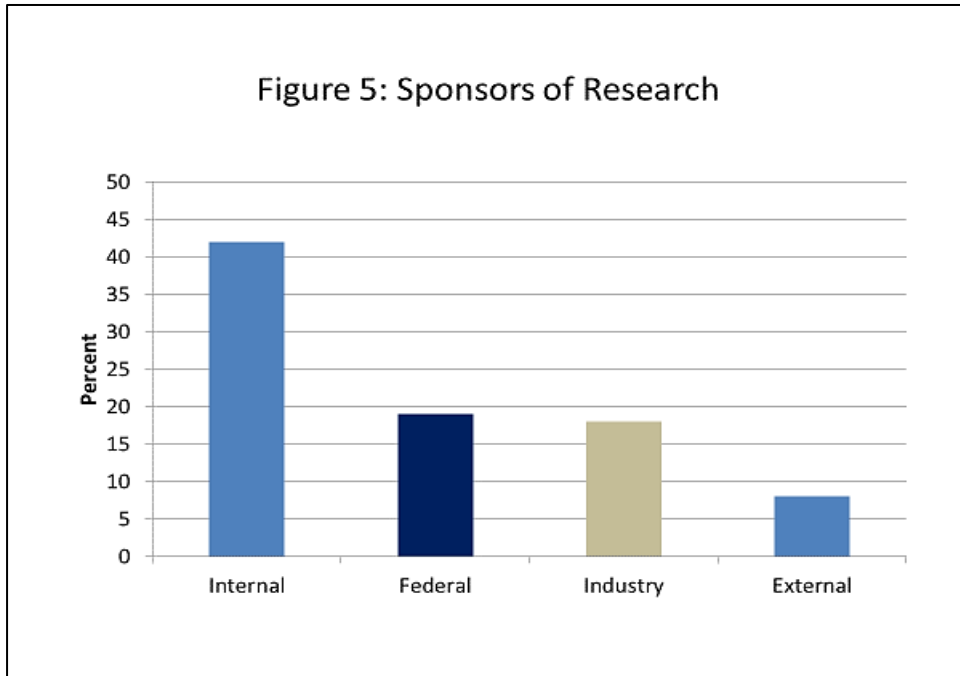
# Selected Types of Research Conducted or Overseen by Organizations



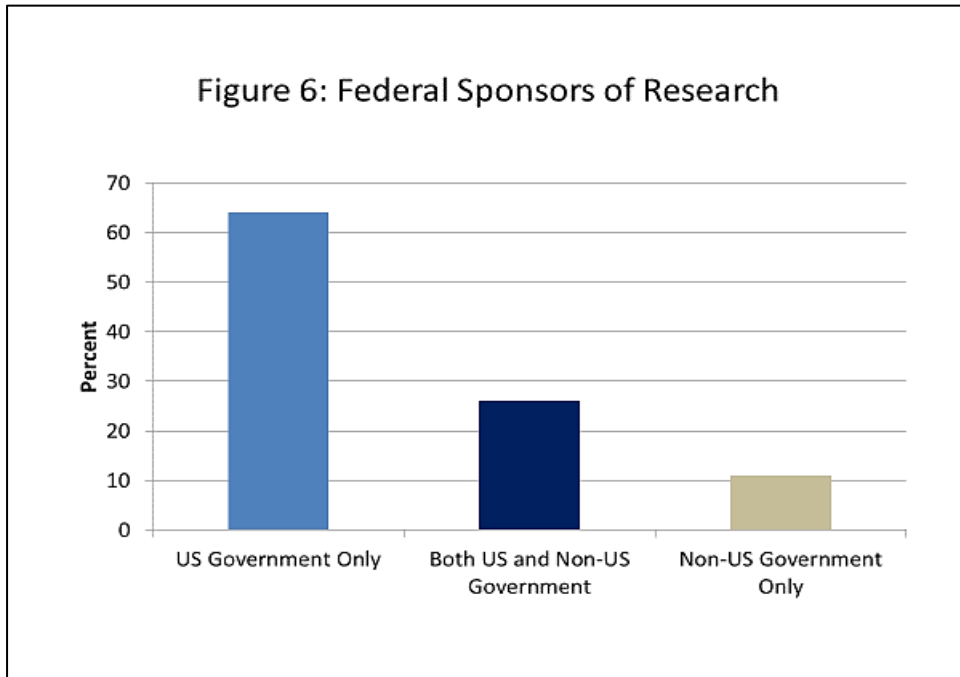
**Figure 3:** 93% of organizations conduct research involving investigational drugs; 88% conduct research involving investigational devices; and 16% of organizations conduct planned emergency research without consent.



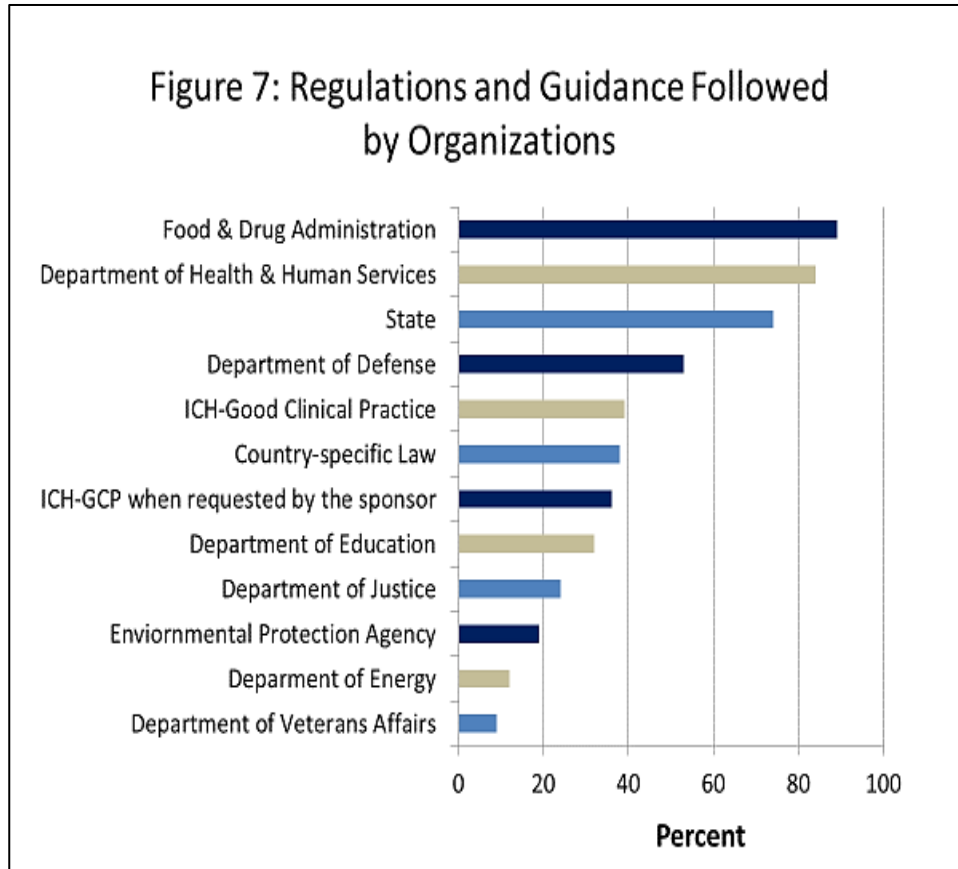
**Figure 4:** 96% of all organizations conduct research with children; 92% conduct research with students; 94% conduct research with employees; 91% conduct research with pregnant women; 89% conduct research with adults with diminished capacity; 57% conduct research with prisoners; and 24% conduct research with other vulnerable populations.



**Figure 5:** For all organizations, a median of 42% of research is internally sponsored; a median of 19% of research portfolios is federally sponsored; a median of 18% of research is industry sponsored; and a median of 8% of research portfolios is externally sponsored.

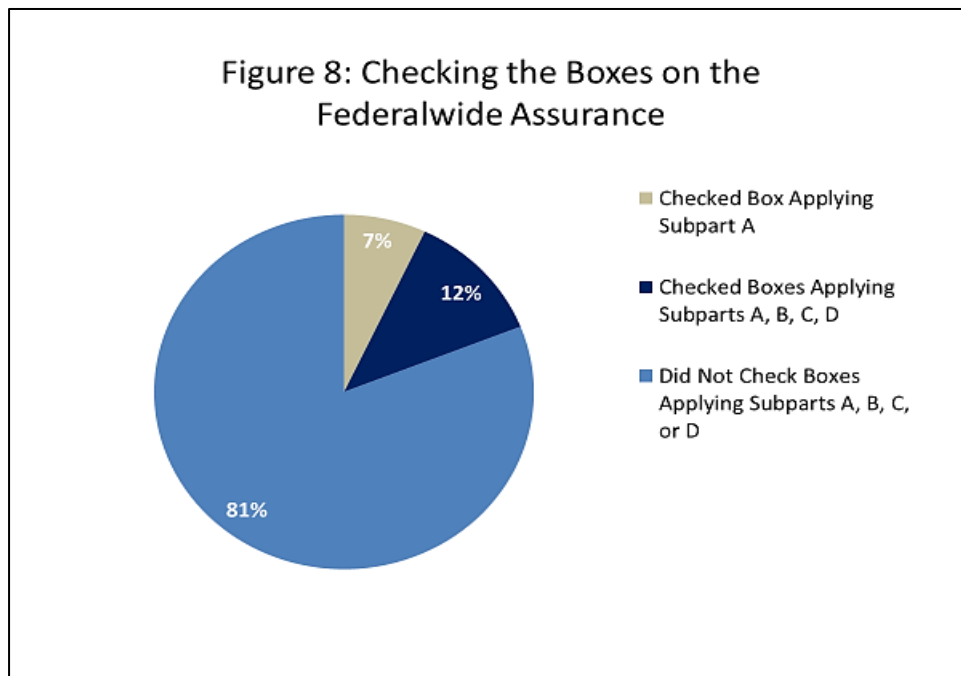


**Figure 6:** For all organizations receiving federal funds, a mean of 64% of research is sponsored by the US government only; a mean of 26% of research portfolios is sponsored by both US and non-US governments; and a mean of 11% of research is sponsored by only non-US governments.

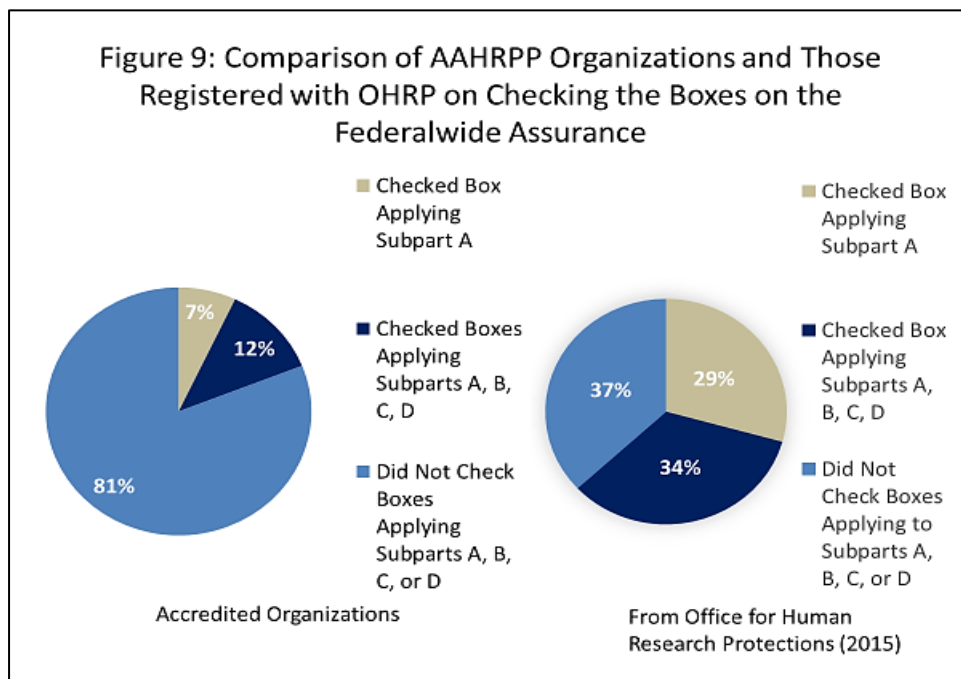


**Figure 7:** 89% of all organizations follow FDA regulations; 84% follow Department of Health and Human Services regulations; 74% follow regulations or guidelines of their state; 53% follow Department of Defense requirements; 39% follow the ICH- Good Clinical Practice guideline; 38% follow Country-specific regulations or guidelines; 36% follow the ICH- Good Clinical Practice guideline when requested by the sponsor; 32% follow Department of Education requirements; 24% follow Department of Justice requirements; 19% follow Environmental Protection Agency requirements; 12% follow Department of Energy requirements, and 9% follow Department of Veterans Affairs requirements.

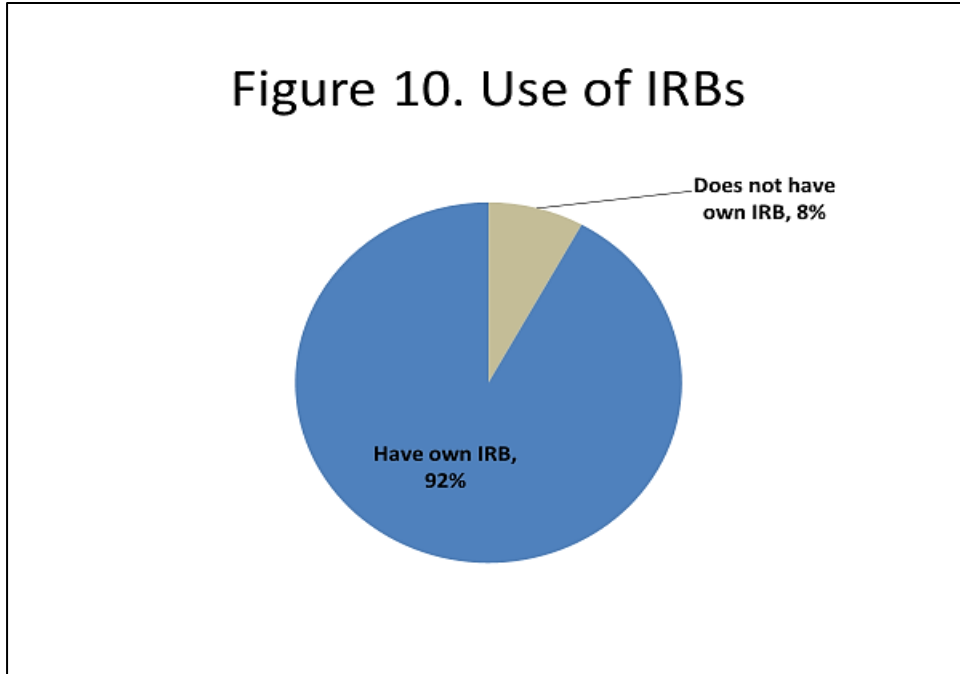




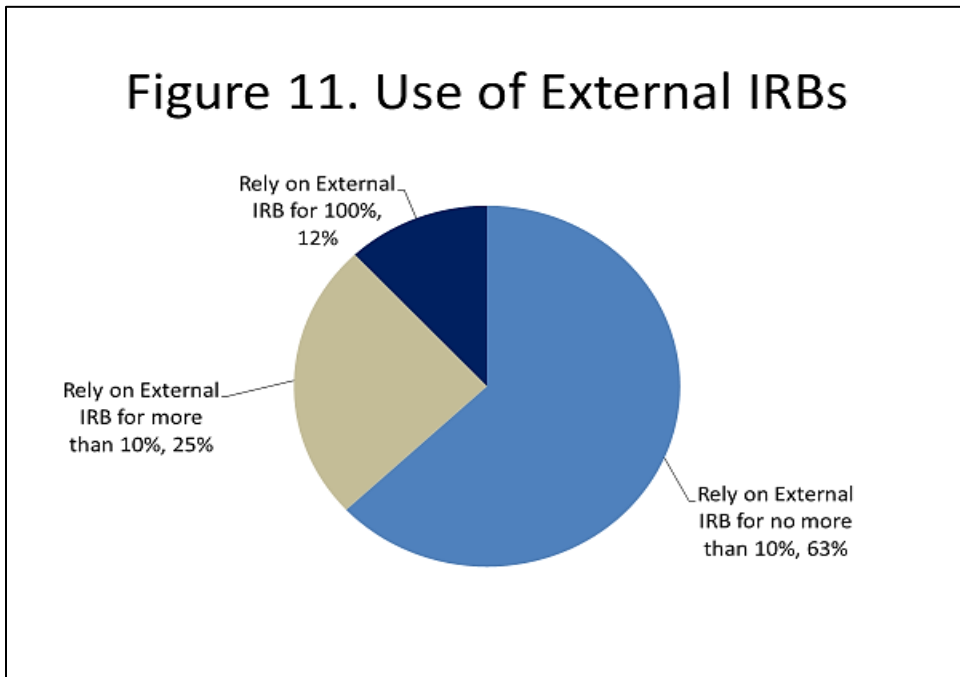
**Figure 8:** 81% of all organizations did not check boxes applying Subparts A, B, C, or D; 12% of all organizations check boxes applying all Subparts (A, B, C, D); and 7% checked the box only applying Subpart A.



**Figure 9:** Compared to percentages provided by OHRP, more organizations accredited by AAHRPP or applying for AAHRPP accreditation unchecked the box.

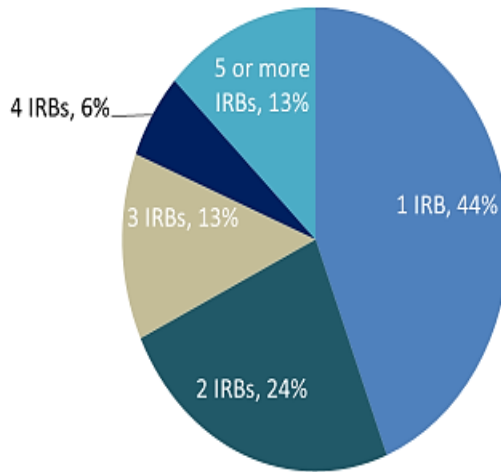


**Figure 10:** 92% of all organizations have their own IRB; 8% do not have their own IRB.

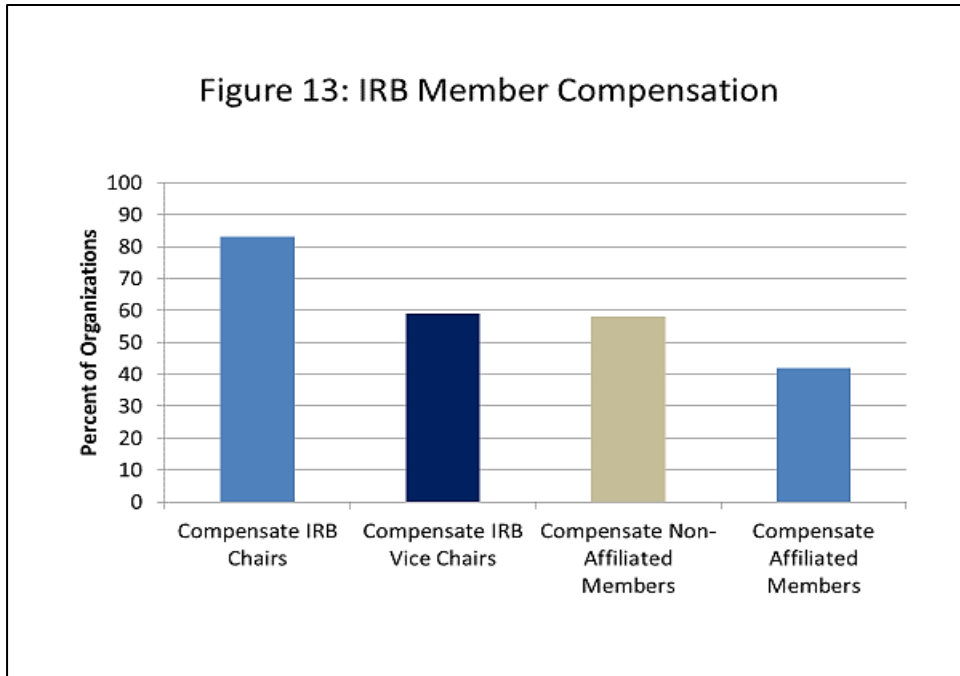


**Figure 11:** 63% of all organizations use external IRBs for a maximum of 10% of total protocols; 25% of organizations rely on external IRBs for more than 10% of total protocols; and 12% of all organizations rely on external IRBs for 100% of total protocols.

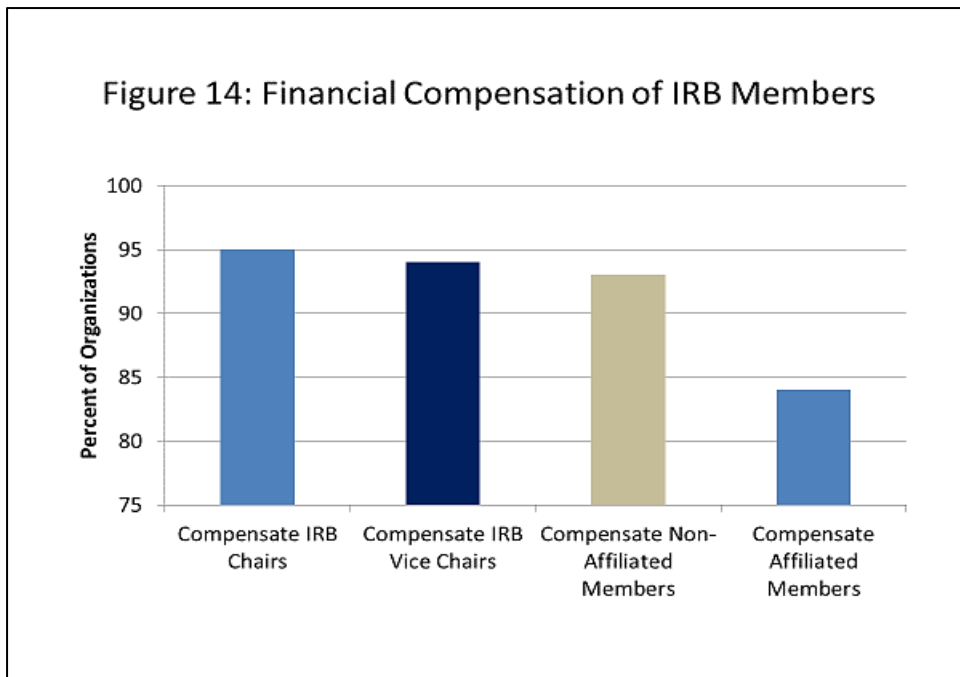
Figure 12: Number of IRBs per Organization



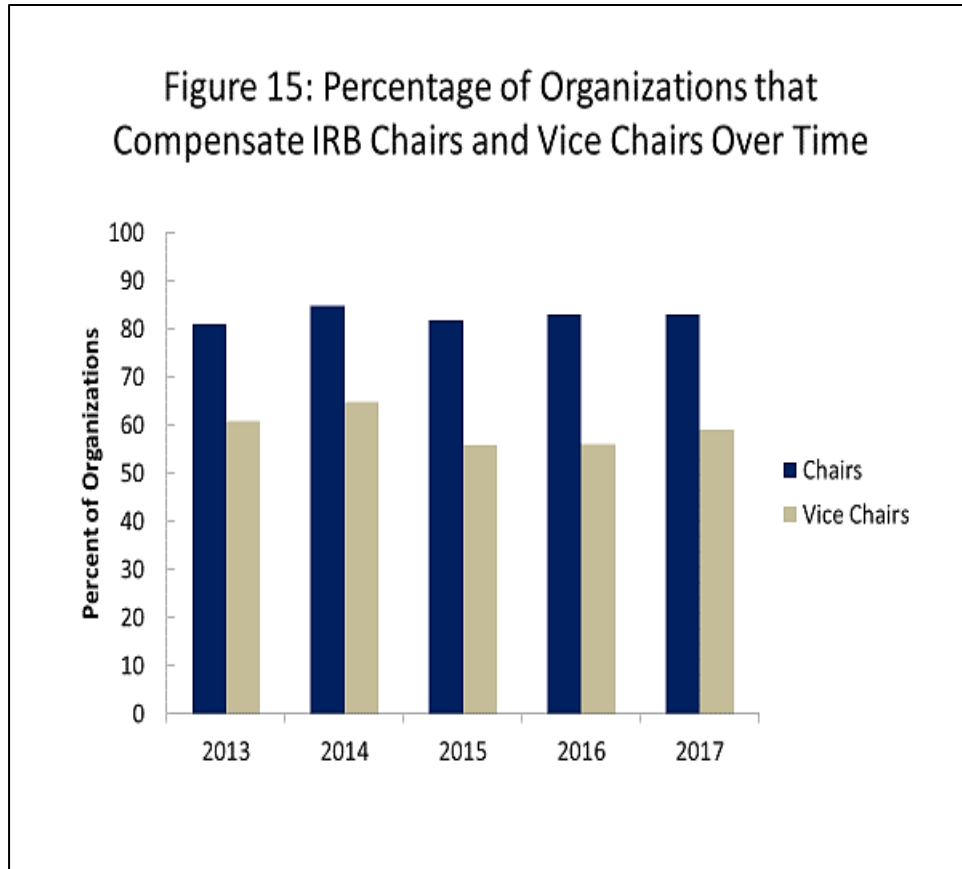
**Figure 12:** 44% of all organizations have one IRB; 24% have two IRBs; 13% have three IRBs; 6% have four IRBs; and 13% have five or more IRBs.



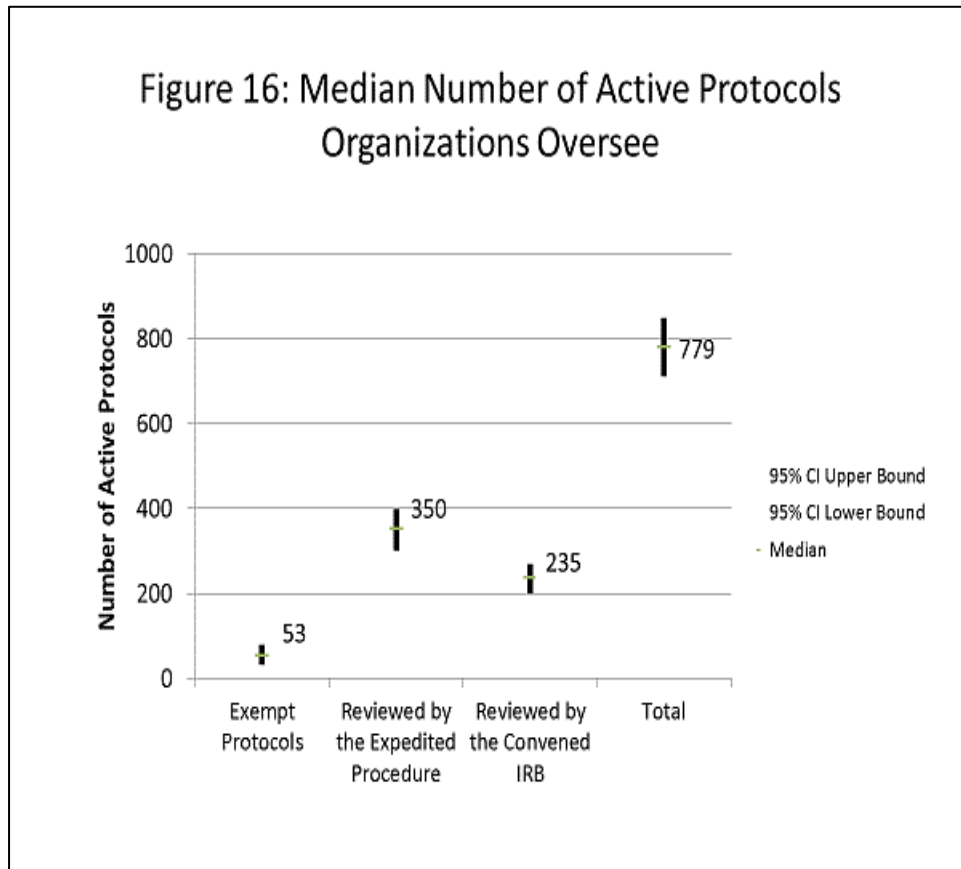
**Figure 13:** 83% of all organizations compensate IRB chairs; 59% compensate IRB vice chairs; 58% compensate non-affiliated members; and 38% compensate affiliated members.



**Figure 14:** Of organizations that compensate IRB members, 95% compensate IRB chairs financially; 94% compensate IRB vice chairs financially; 93% compensate non-affiliated members financially; and 84% compensate affiliated members financially.

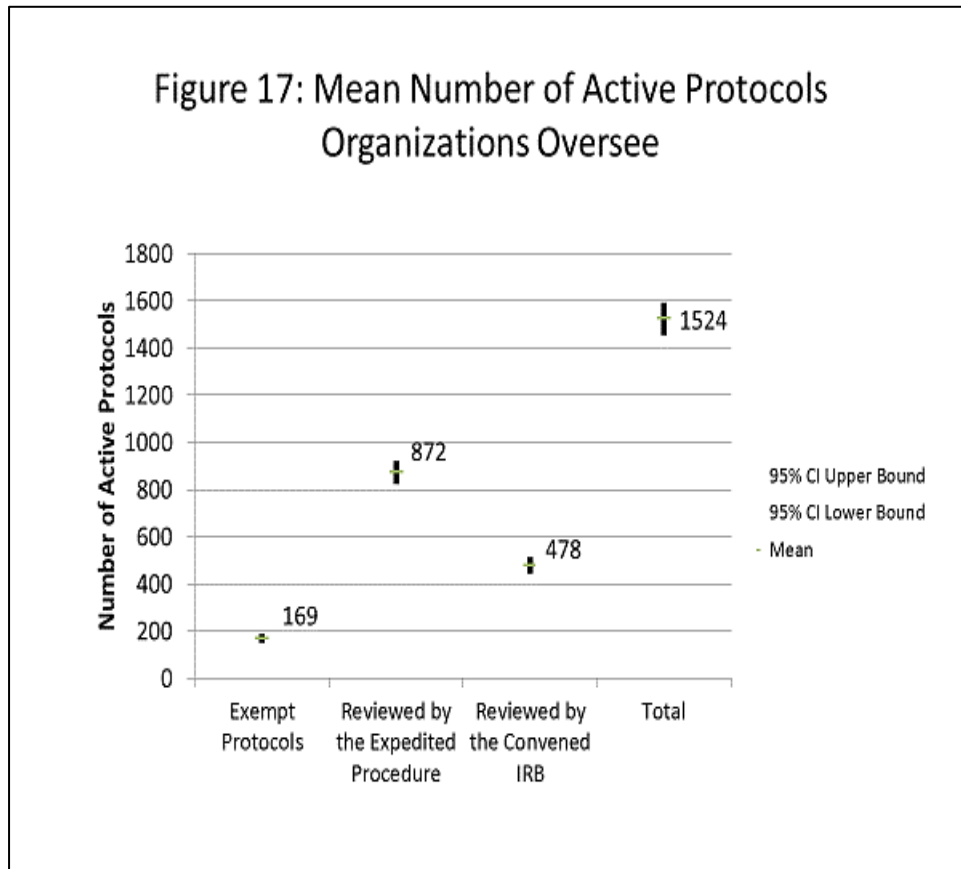


**Figure 15:** The percentage of organizations that compensate IRB chairs and vice-chairs has remained relatively consistent since 2013.



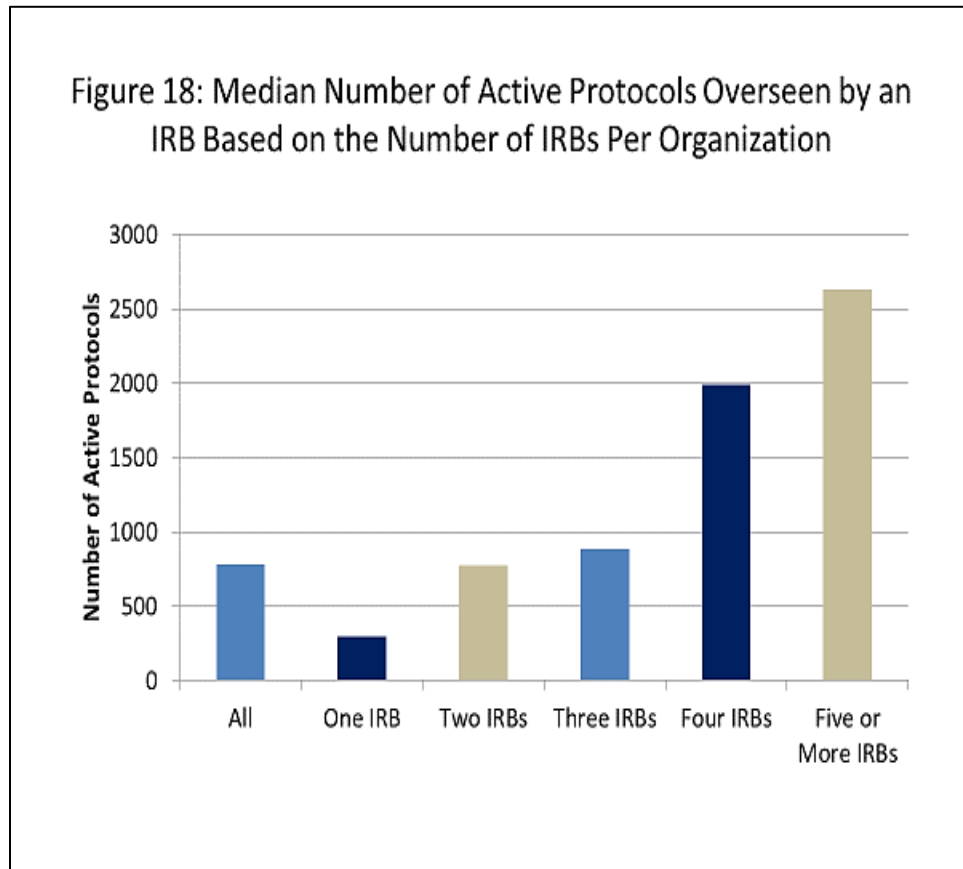
**Figure 16:** A median of 53 protocols were deemed exempt by all organizations\*; a median of 350 protocols were reviewed by the expedited procedure; a median of 235 protocols were reviewed by the convened IRB; and a median of 779 total protocols were overseen by all organizations.

\*Exempt determinations made within 12 months of an organization’s submission to AAHRPP.



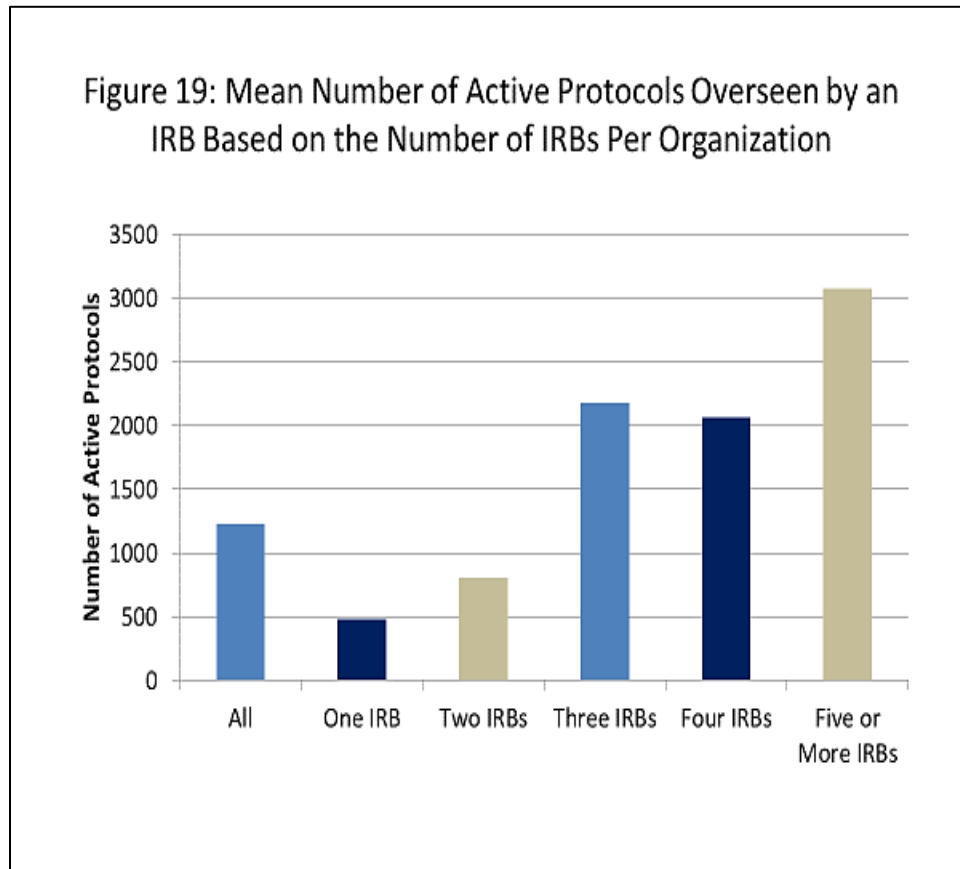
**Figure 17:** A mean of 169 protocols were deemed exempt by all organizations\*, a mean of 872 protocols were reviewed by the expedited procedure; a mean of 478 protocols were reviewed by the convened IRB; and a mean of 1524 total protocols were overseen by all organizations.

\*Exempt determinations made within 12 months of an organization’s submission to AAHRPP.

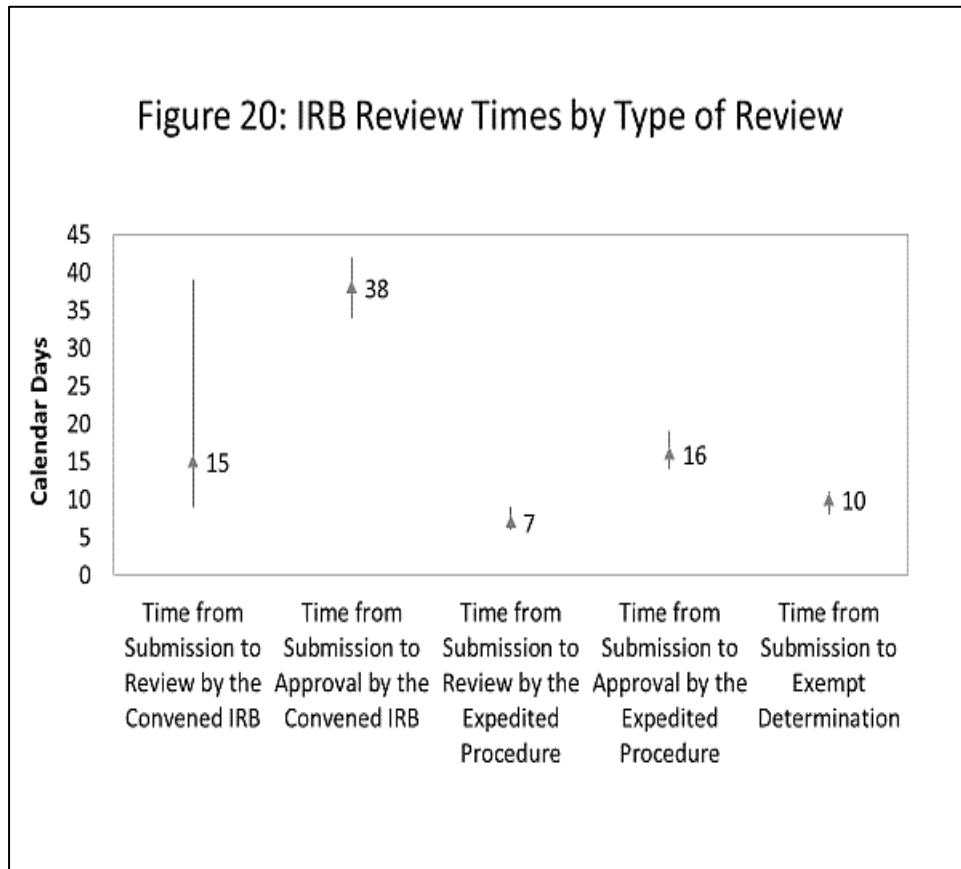


**Figure 18:** A median of 778 protocols were overseen by all organizations with an IRB; a median of 295 protocols were overseen by organizations with one IRB; a median of 777 protocols were overseen by organizations with two IRBs; a median of 883 protocols were overseen by organizations with three IRBs; a median of 1991 protocols were overseen by organizations with four IRBs; and a median of 2631 were overseen by organizations with five or more IRBs.

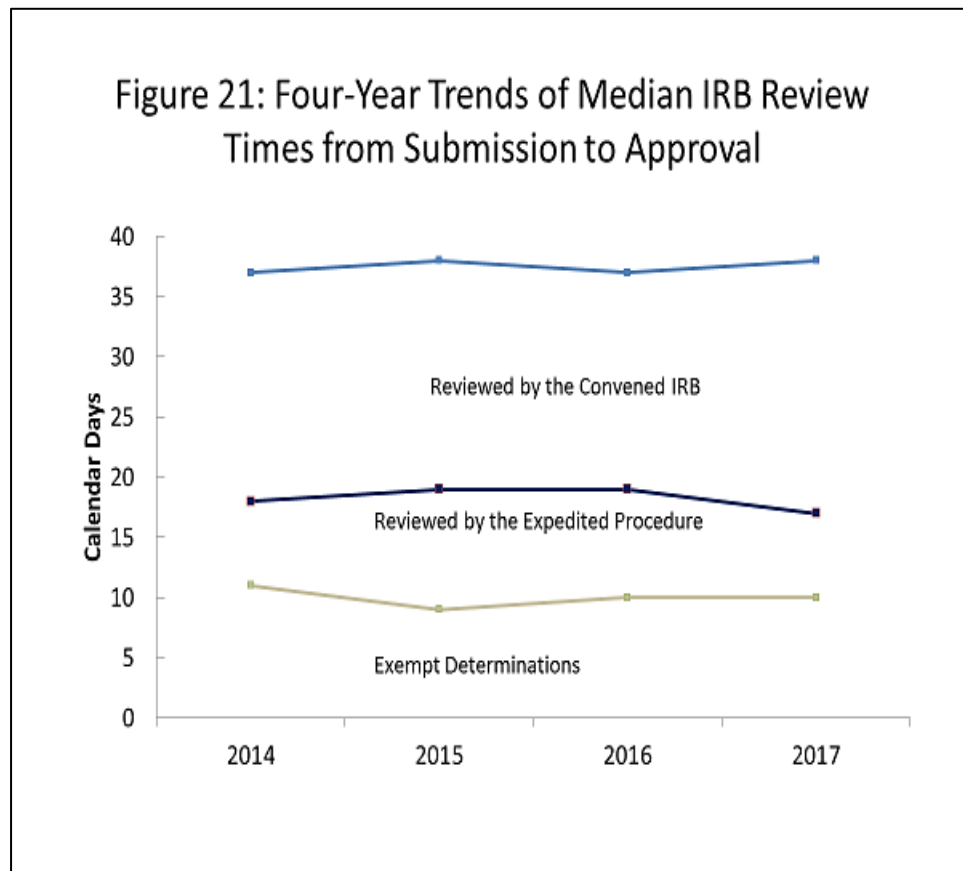




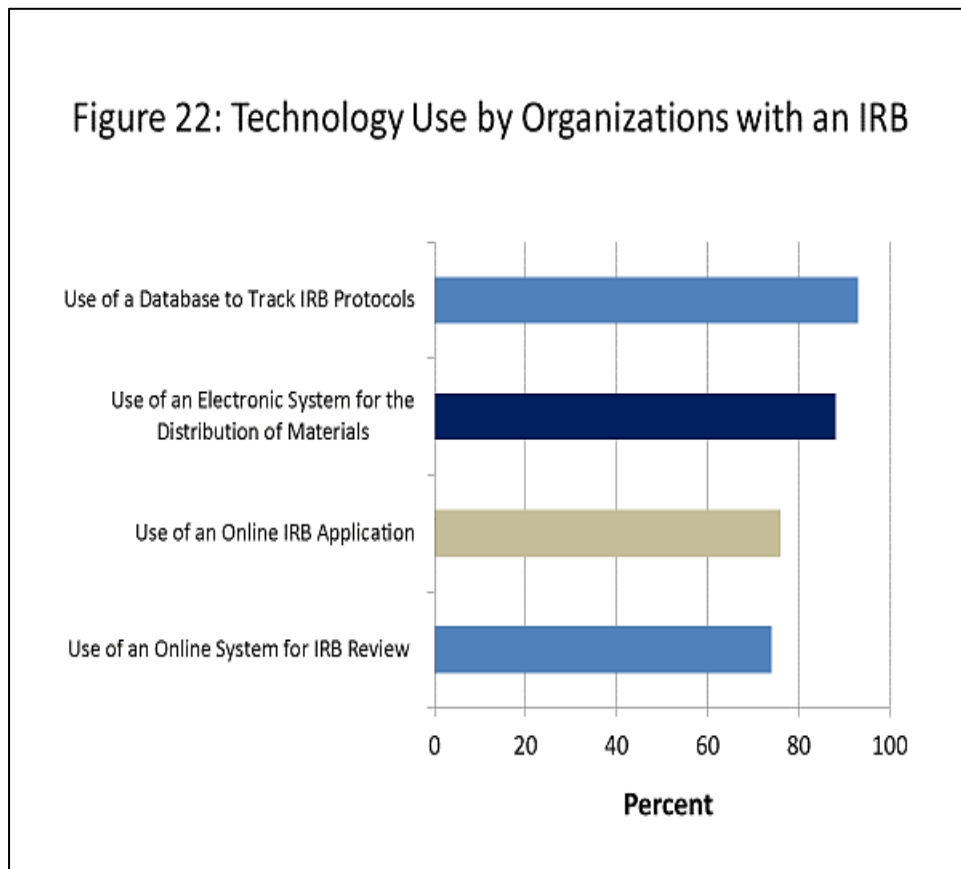
**Figure 19:** A mean of 1225 protocols were overseen by all organizations with an IRB, a mean of 478 protocols were overseen by organizations with one IRB; a mean of 806 protocols were overseen two IRBs; a mean of 2179 protocols were overseen by organizations with three IRBs; a mean of 2065 protocols were overseen by organizations with four IRBs; and a mean of 3075 protocols were overseen by organizations with five or more IRBs.



**Figure 20:** The time from submission to review by the convened IRB is a median of 15 calendar days; the time from submission to approval by the convened IRB is a median of 38 calendar days; the time from submission to review by the expedited procedure is a median of 7 calendar days; the time from submission to approval by the expedited procedure is a median of 16 calendar days; and the time from submission to exempt determination is a median of 10 calendar days.



**Figure 21:** Median review times have remained consistent since 2014.

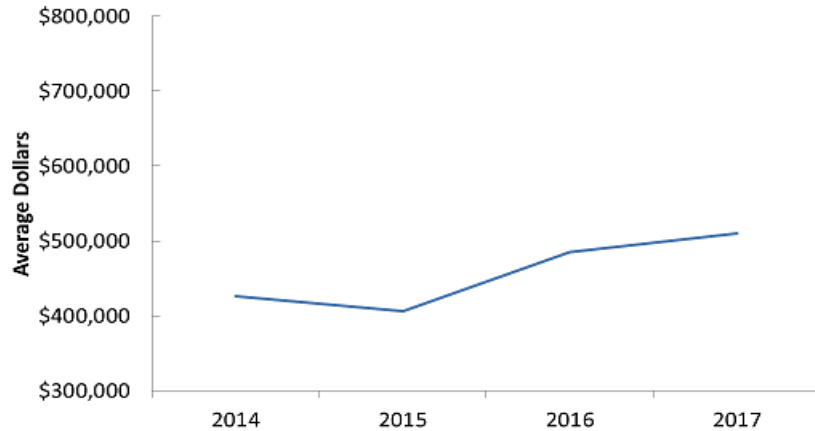


**Figure 22:** 93% of all organizations use a database to track IRB protocols; 88% use an electronic system for the distribution of materials; 76% use an online IRB application; and 74% use an online system for IRB review functions.

**Table 1: IRB Staffing and Funding Levels**

Protocol Category	Median Number of Staff	Median Number of Protocols	Median Protocols per FTE	Median Dollars Budgeted for IRB
All	7	872	125	\$510,113
1-100	2	61	31	\$79,278
101-500	3	259	86	\$179,173
501-1000	4	729	182	\$274,970
1001-2000	10	1557	156	\$862,364
2001-4000	16	2784	174	\$1,573,831
4000+	26	5684	219	\$2,415,561

**Figure 23: Four-Year Trends in Median IRB Budgets**

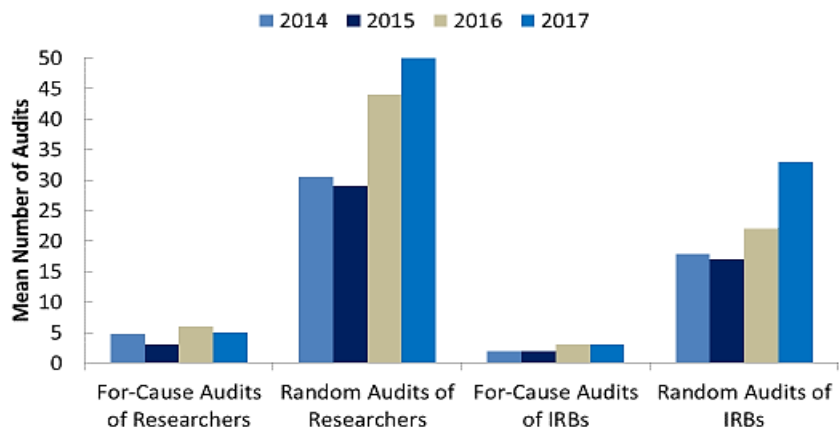


**Figure 23:** Median IRB budgets have increased since 2014.

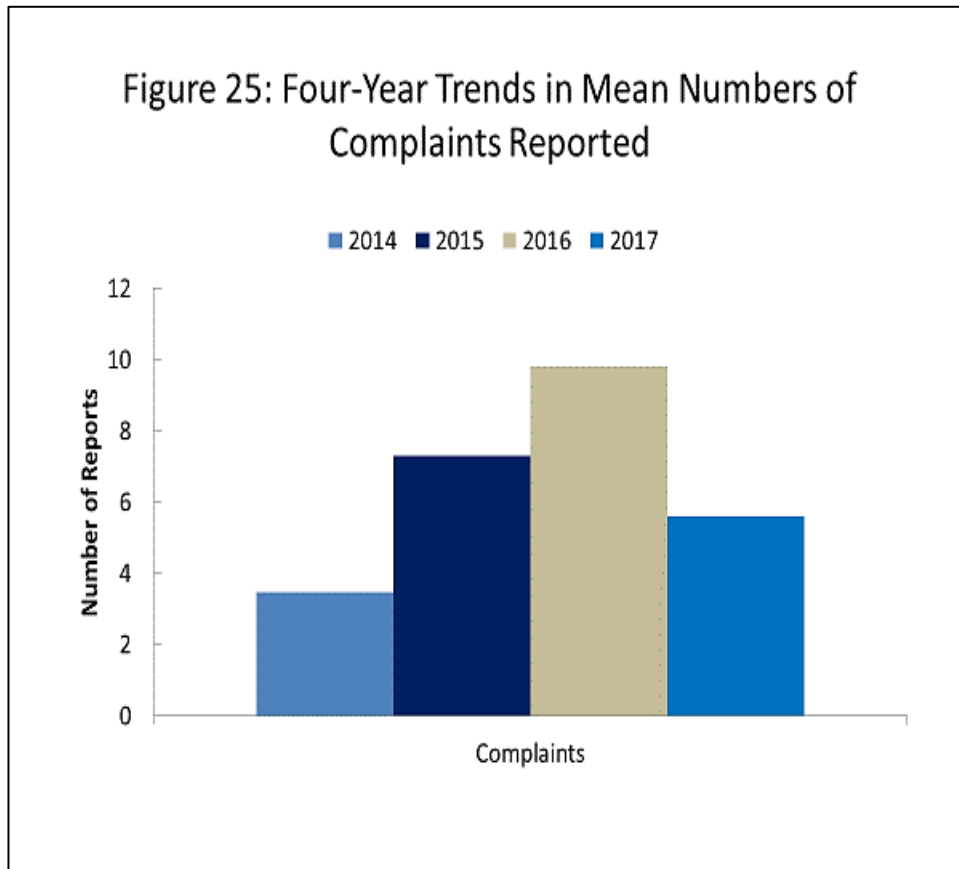
**Table 2. Number of Internal Audits Organizations Conducted within the Past Year**

	For-Cause Audits of Researchers	Random Audits of Researchers	For-Cause Audits of IRBs	Random Audits of IRBs
Mean	5	50	3	33
Median	1	15	0	4

**Figure 24: Four-Year Trends in Mean Number of Audits Organizations Conducted**



**Figure 24:** For-cause audits of researchers decreased in 2017. Random audits of researchers reached an all-time high in 2017. For-cause audits of IRBs have remained consistent since 2014. Random audits of IRBs increased in 2017.

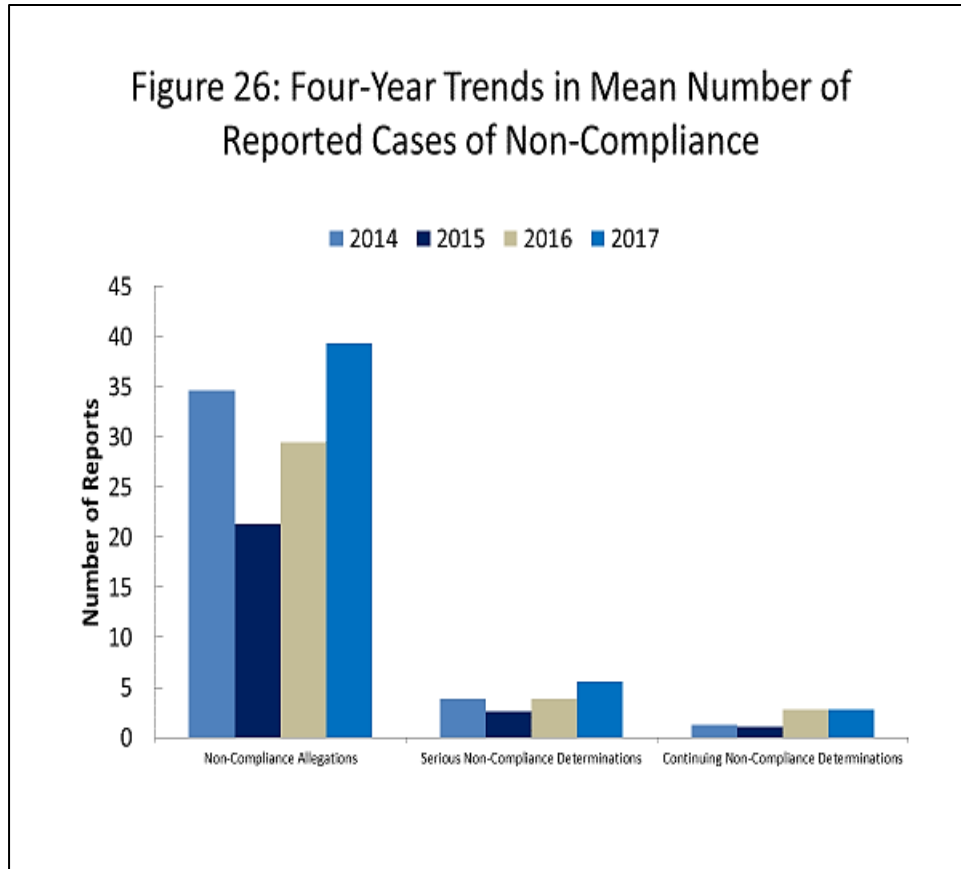


**Figure 25:** The number of complaints from research participants significantly decreased in 2017.

**Table 3. Number of Cases of Non-Compliance Investigated in the Past Year**

Protocol Category	Median Number of Allegations of Non-Compliance	Median Number of Determinations of Serious Non-Compliance	Median Number of Determinations of Continuing Non-Compliance
All	5	1	0
1-100	0	0	0
101-500	1	0	0
501-1,000	6	2	0
1,001-2,000	7	2	1
2,001-4,000	8	4	1
>4,000	33	8	3





**Figure 26:** Allegations of non-compliance, determinations of serious non-compliance, and determinations of continuing non-compliance have slightly increased since 2015.



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