



# 2016 Metrics on Human Research Protection Program Performance

Updated April 24, 2017

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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 2016 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 2016, 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 2016 data, the metrics are represented as the median, except where indicated as the mean.

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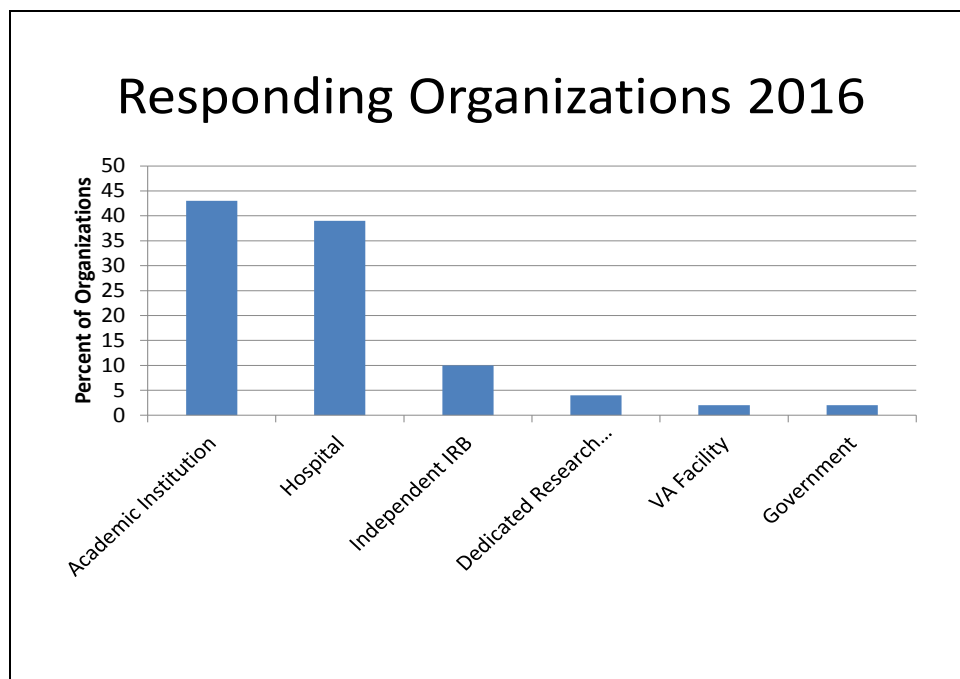
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## General Description of Organizations

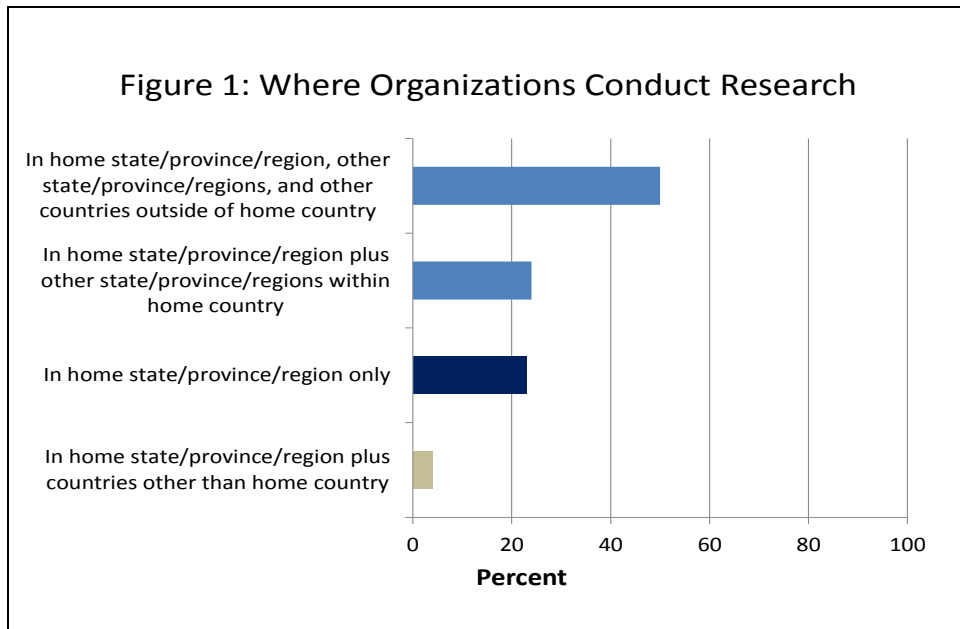


**Slide 1:** 43% of all accredited organizations are academic institutions, 38% are hospitals, 9% are independent IRBs, 4% are VA facilities, 3% are dedicated research sites or research institutes, 2% are government organizations, 1% are contract research organizations, and 0.5% are sponsors.

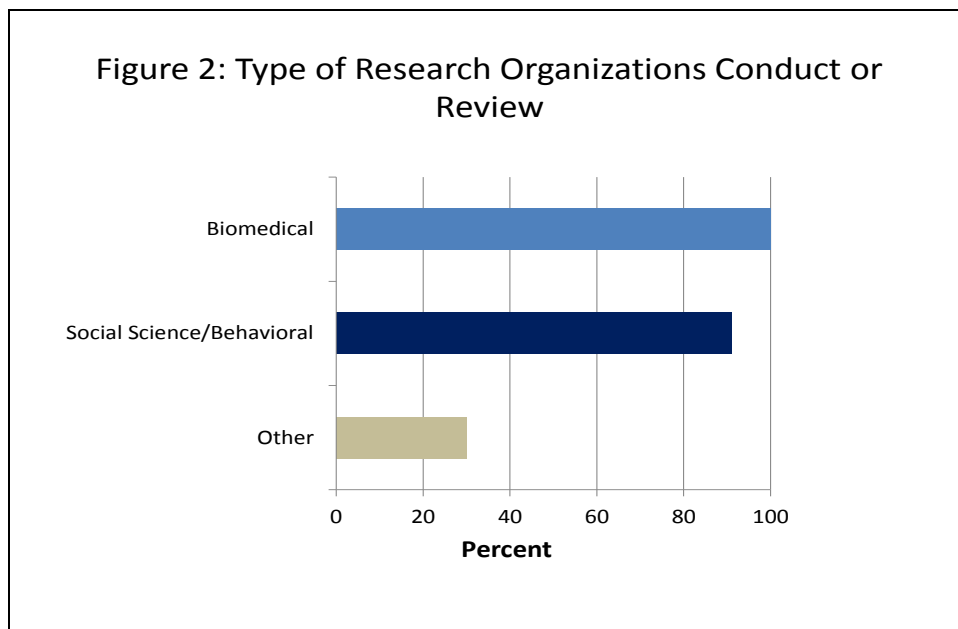


**Slide 2:** 43% of organizations that responded in 2016 were academic institutions, 39% were hospitals, 10% were independent IRBs, 4% were dedicated research sites or research institutes, 2% were VA facilities, and 2% were government organizations.

# General Description of the Research Conducted or Overseen by Organizations

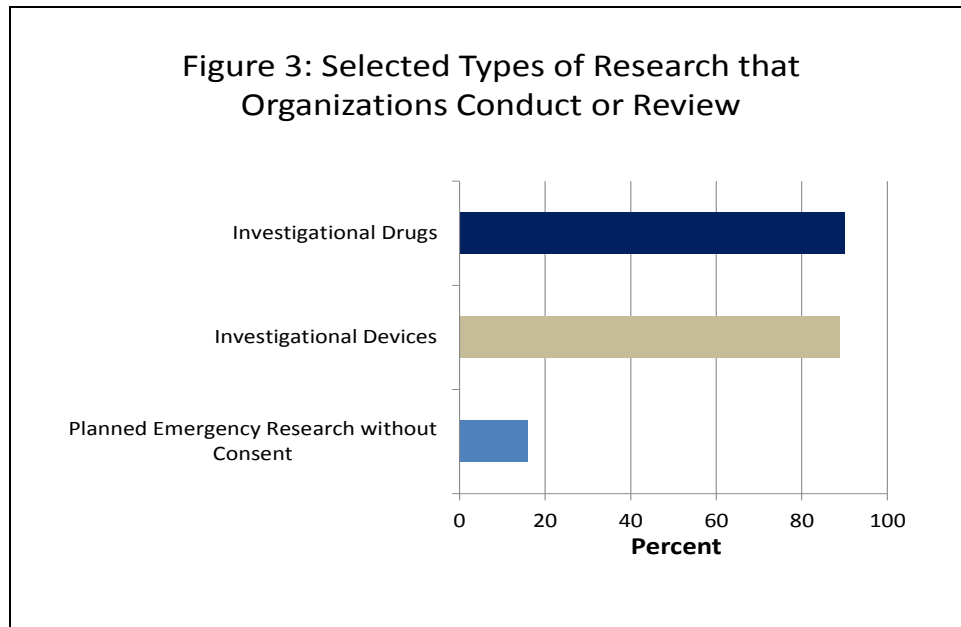


**Figure 1:** 50% of responding organizations conduct research home state/province/region, other states/provinces/regions within their home country, and countries other than their home country, 24% conduct research in their home state/province/region and other states/provinces/regions within their home country, 23% of responding organizations conduct research in their home state/province/region only, and 4% conduct research in their home state/province/region and countries other than their home countries.

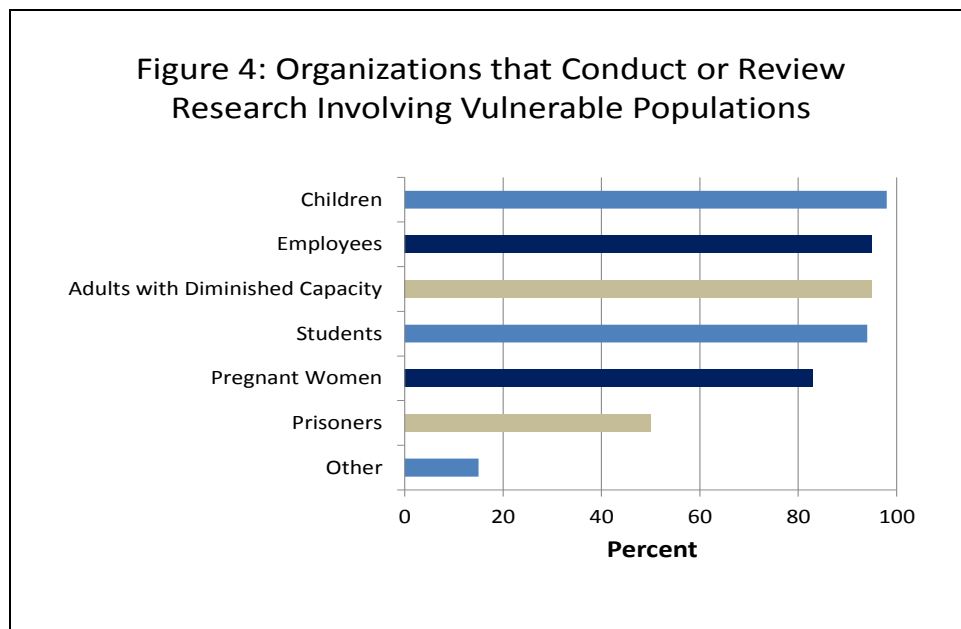


**Figure 2:** 100% of responding organizations conduct biomedical research, 91% conduct social/behavioral research, and 30% conduct research falling into other categories.

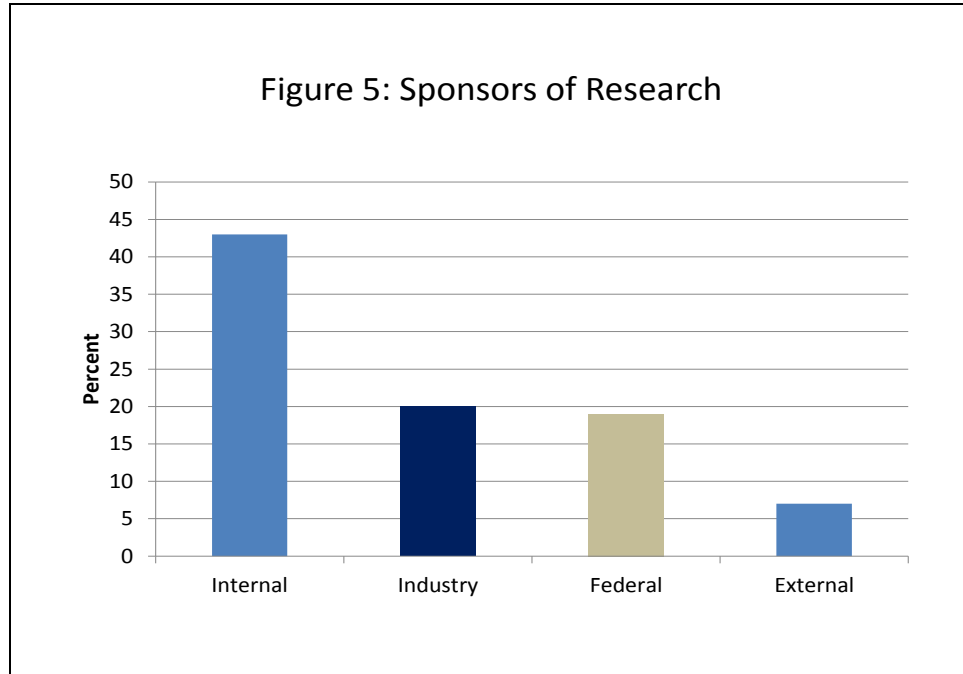
# Selected Types of Research Conducted or Overseen by Organizations



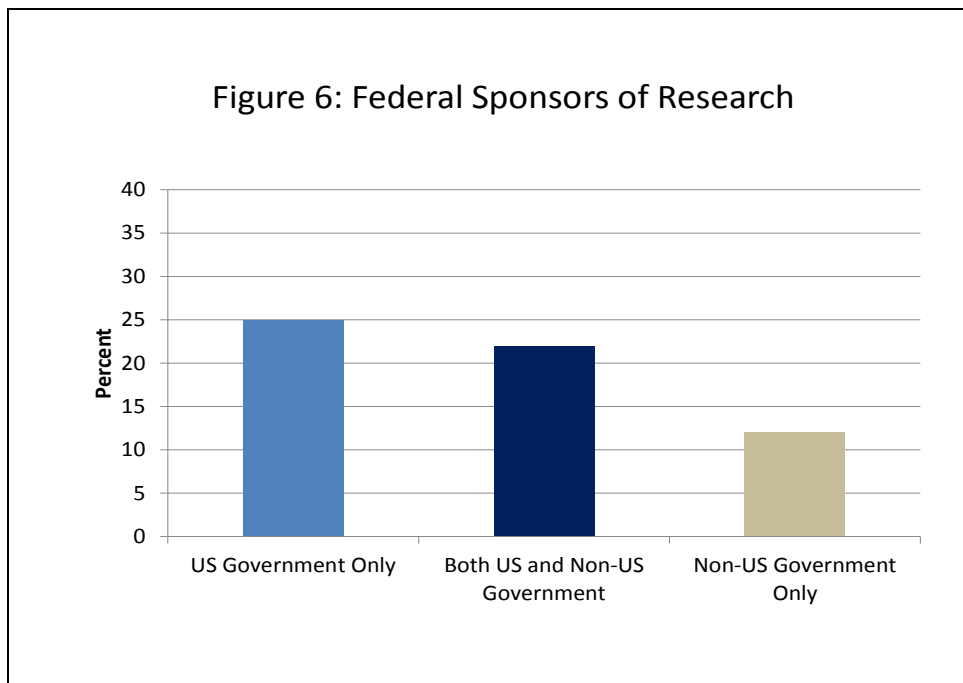
**Figure 3:** 90% of organizations conduct research involving investigational drugs, 84% conduct research involving investigational devices, and 16% of organizations conduct planned emergency research without consent.



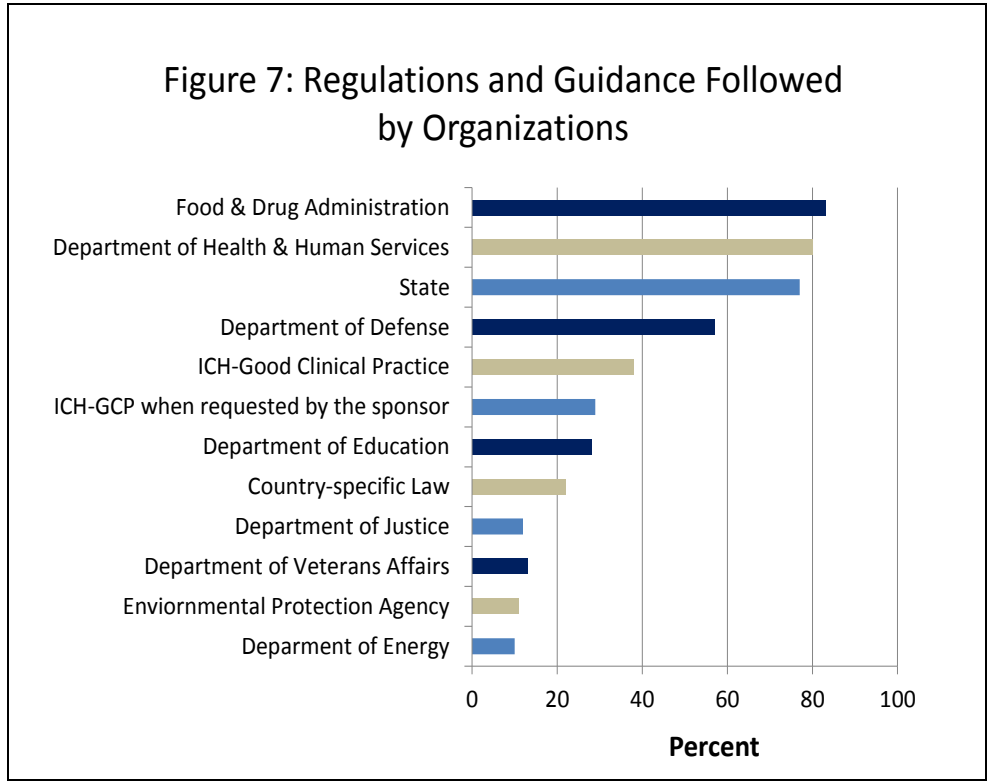
**Figure 4:** 98% of all organizations conduct research with children, 95% conduct research with employees, 95% conduct research with adults with diminished capacity, 94% conduct research with students, 83% conduct research with pregnant women, 50% conduct research with prisoners, and 15% conduct research with other vulnerable populations.



**Figure 5:** For all organizations, a median of 43% of research is internally sponsored, a median of 20% of research is industry sponsored, a median of 19% of research portfolios is federally sponsored, and a median of 7% of research portfolios is externally sponsored.

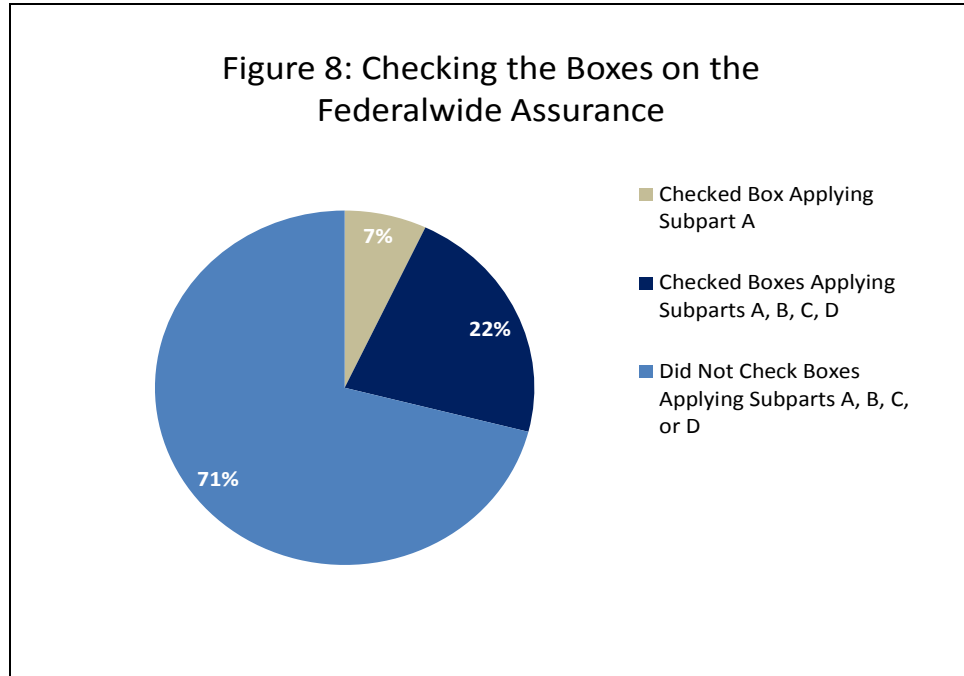


**Figure 6:** For all organizations receiving federal funds, a median of 25% of research is sponsored by the US Government only, a median of 22% of research portfolios is sponsored by both US and Non-US governments, and a median of 12% of research is sponsored by only Non-US Governments.

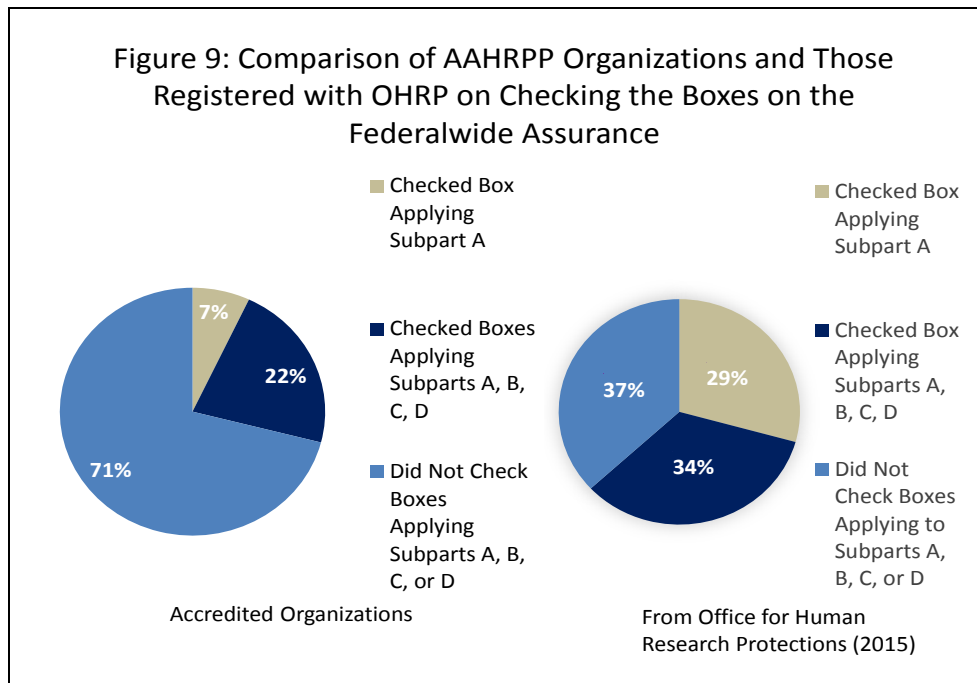


**Figure 7:** 83% of all organizations follow FDA regulations, 80% follow Department of Health and Human Services regulations, 77% follow regulations or guidelines of their state, 57% follow Department of Defense requirements, 38% follow the ICH- Good Clinical Practice guideline, 29% follow the ICH- Good Clinical Practice guideline when requested by the sponsor, 28% follow Department of Education requirements, 22% follow Country-specific regulations or guidelines, 12% follow Department of Justice requirements, 13% follow Department of Veterans Affairs requirements, 11% follow Environmental Protection Agency requirements, and 10% follow Department of Energy requirements.





**Figure 8:** 71% of all organizations did not check boxes applying Subparts A, B, C, or D, 22% 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. Use of IRBs

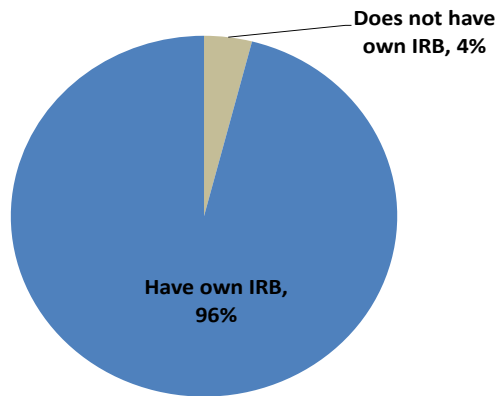


Figure 10: 96% of all organizations have their own IRB; 4% do not have their own IRB.

Figure 11. Use of External IRBs

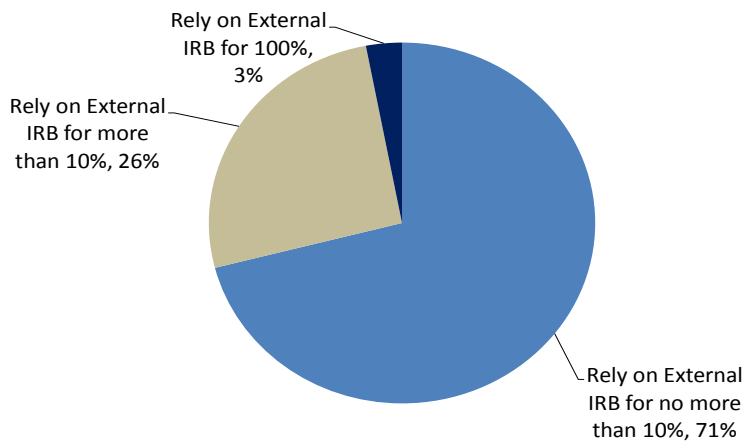
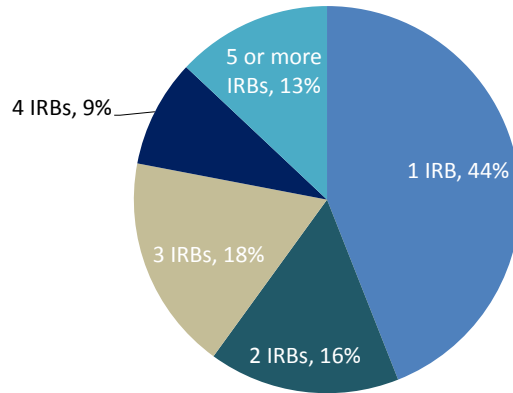
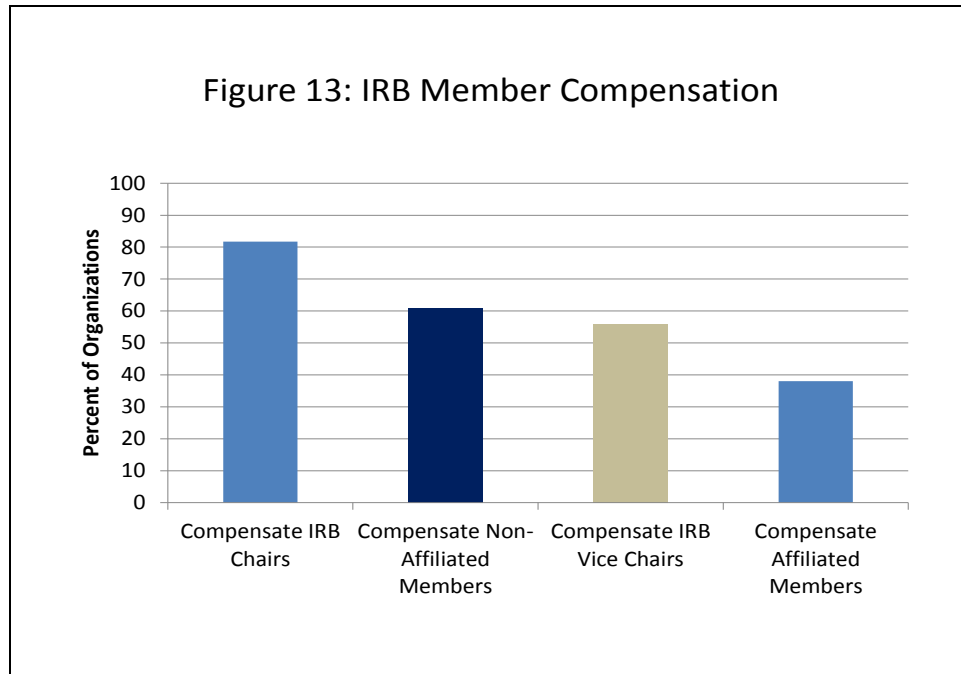


Figure 11: 71% of all organizations use external IRBs for a maximum of 10% of total protocols, 26% of organizations rely on external IRBs for more than 10% of total protocols, and 3% of all organizations rely on external IRBs for 100% of total protocols.

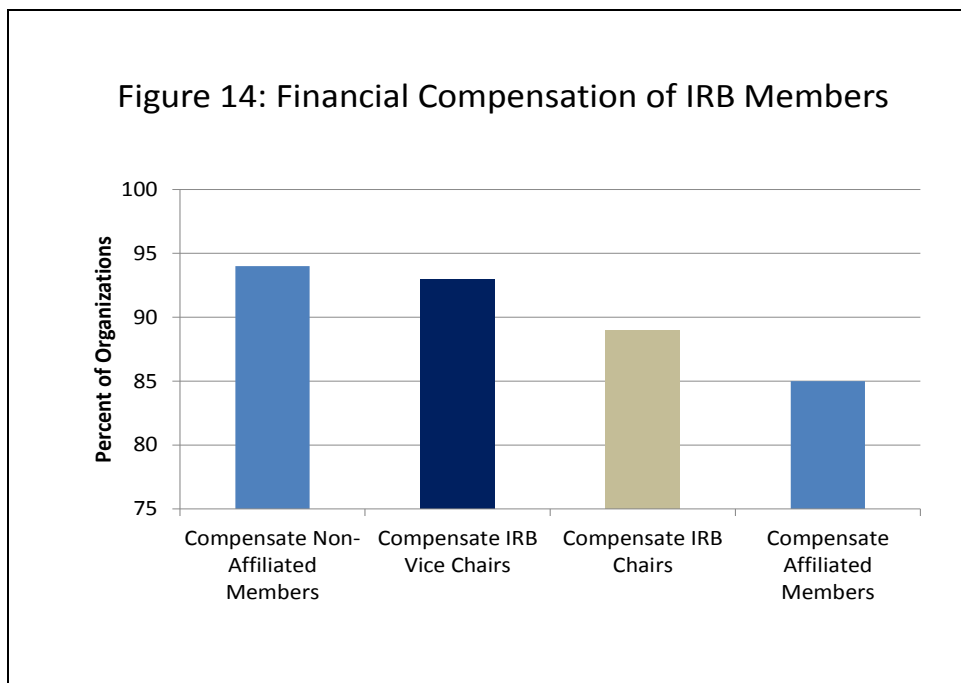
Figure 12: Number of IRBs per Organization



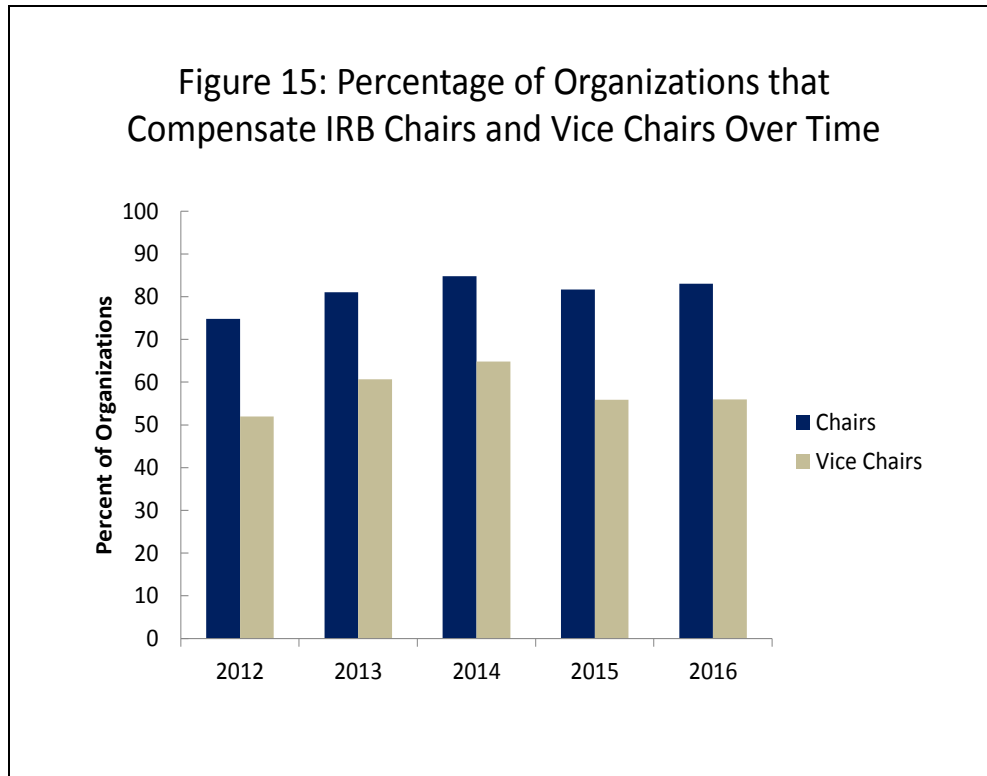
**Figure 12:** 44% of all organizations have one IRB, 16% have two IRBs, 18% have three IRBs, 9% have four IRBs, and 13% have five or more IRBs.



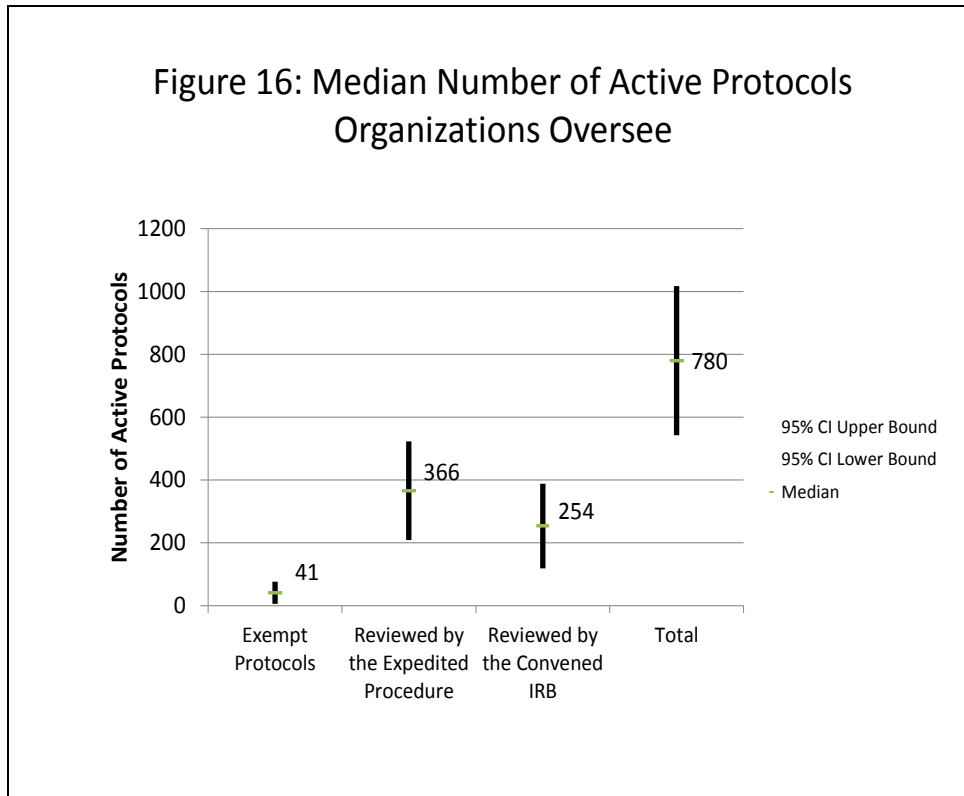
**Figure 13:** 83% of all organizations compensate IRB chairs, 61% compensate non-affiliated members, 56% compensate IRB vice chairs, and 38% compensate affiliated members.



**Figure 14:** Of organizations that compensate IRB members, 94% compensate non-affiliated members financially, 93% compensate IRB vice chairs financially, 89% compensate IRB chairs financially, and 85% compensate affiliated members financially.

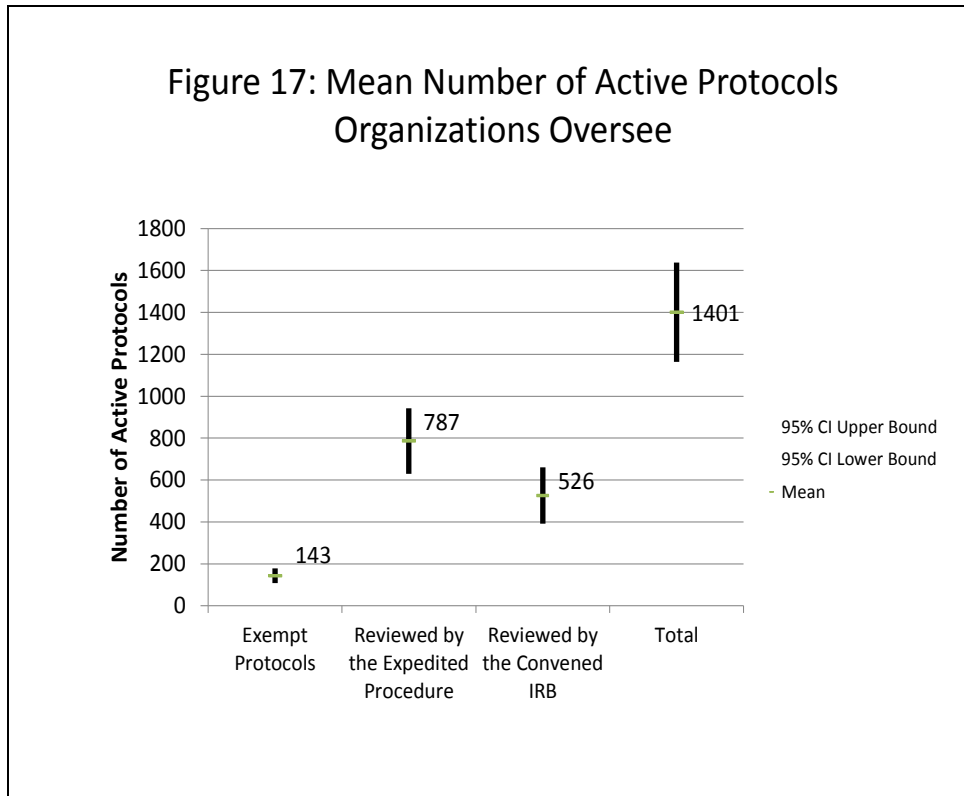


**Figure 15:** The percentage of organizations that compensate IRB chairs and vice-chairs has remained relatively consistent since 2012.



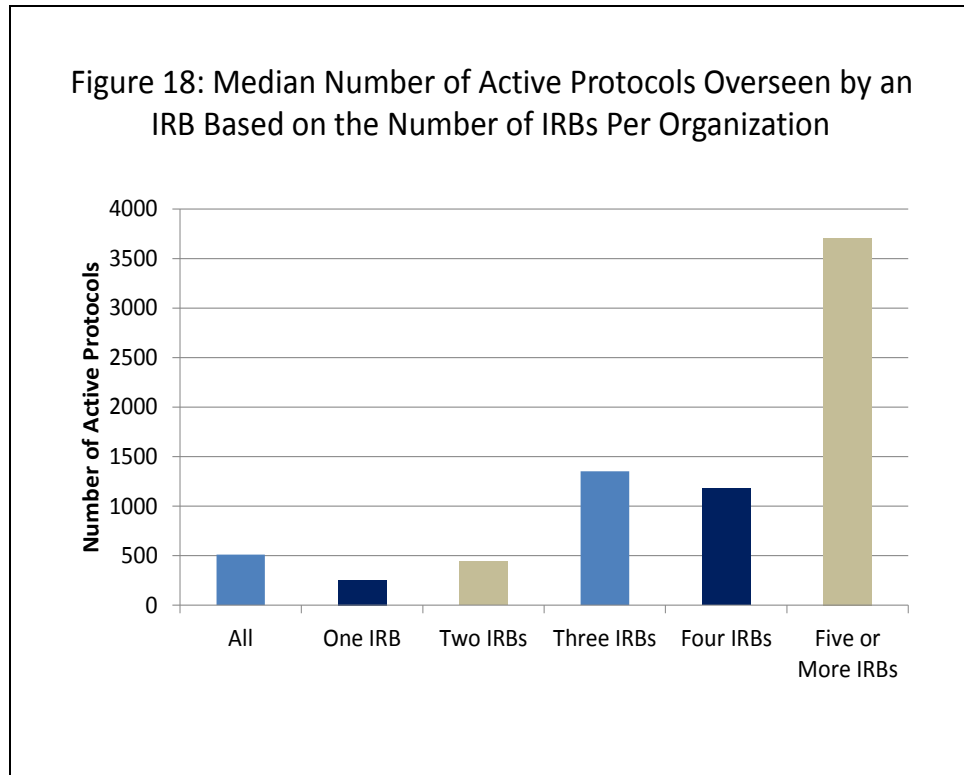
**Figure 16:** A median of 41 protocols were deemed exempt by all organizations\*, a median of 366 protocols were reviewed by the expedited procedure, a median of 254 protocols were reviewed by the convened IRB, and a median of 780 total protocols were overseen by all organizations.

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



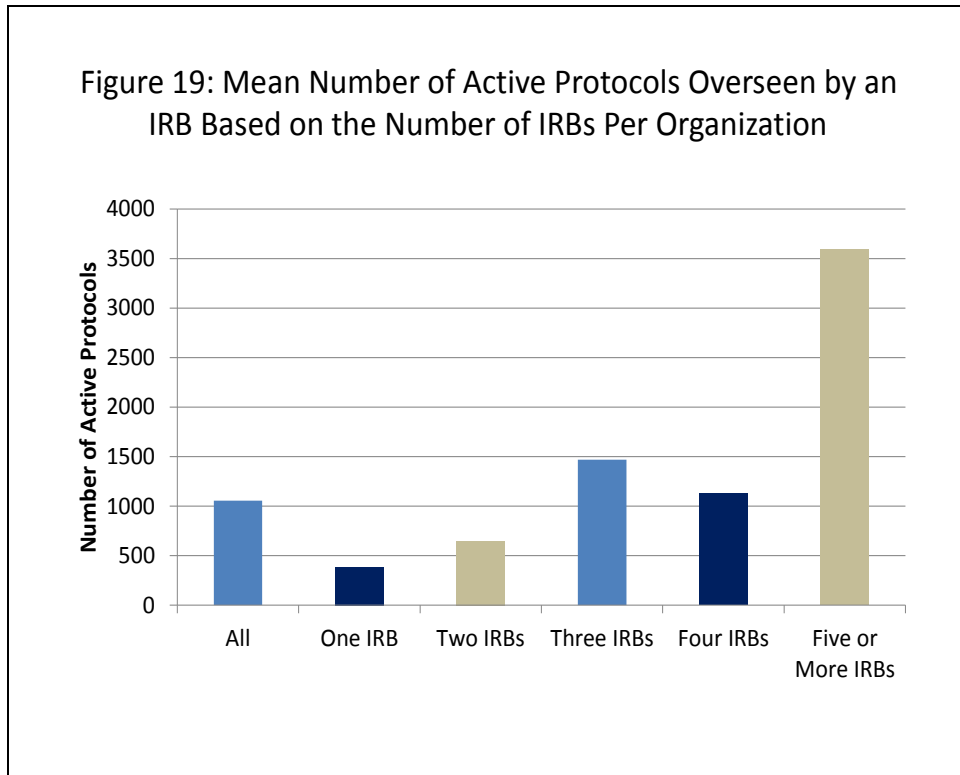
**Figure 17:** A mean of 142 protocols were deemed exempt by all organizations\*, a mean of 787 protocols were reviewed by the expedited procedure, a mean of 526 protocols were reviewed by the convened IRB, and a mean of 1401 total protocols were overseen by all organizations.

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



**Figure 18:** A median of 509 protocols were overseen by all organizations, a median of 254 protocols were overseen by organizations with one IRB, a median of 438 protocols were overseen by organizations with two IRBs, a median of 1352 protocols were overseen by organizations with three IRBs, a median of 1179 protocols were overseen by organizations with four IRBs, and a median of 3708 were overseen by organizations with five or more IRBs.





**Figure 19:** A mean of 1054 protocols were overseen by all organizations, a mean of 384 protocols were overseen by organizations with one IRB, a mean of 648 protocols were overseen two IRBs, a mean of 1468 protocols were overseen by organizations with three IRBs, a mean of 1131 protocols were overseen by organizations with four IRBs, and a mean of 3593 protocols were overseen by organizations with five or more IRBs.

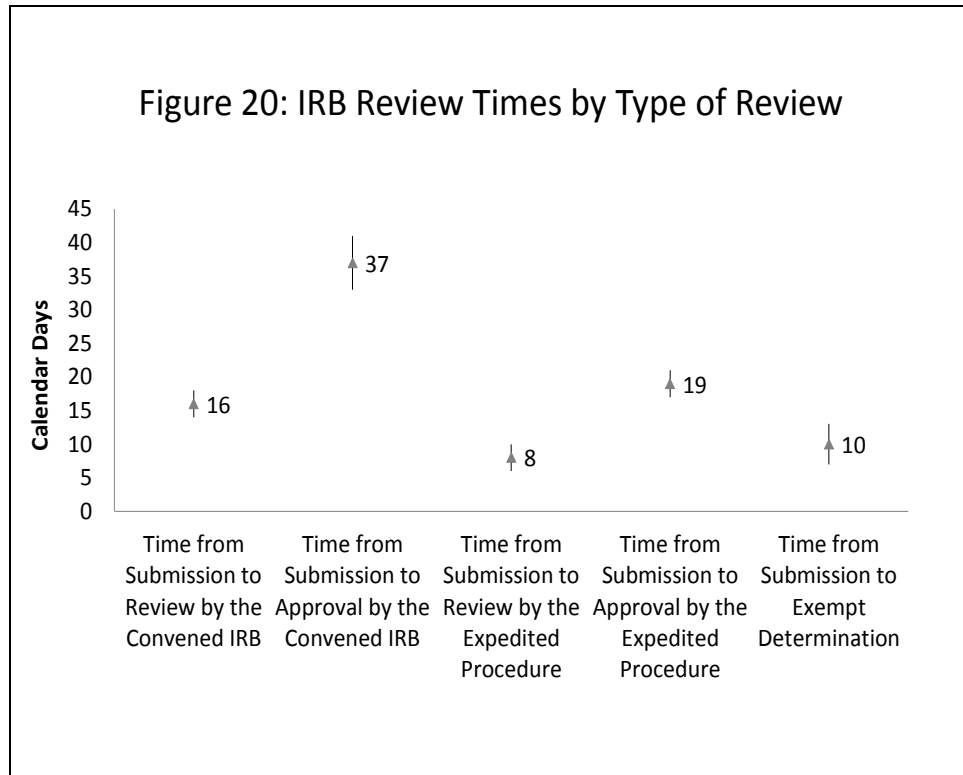
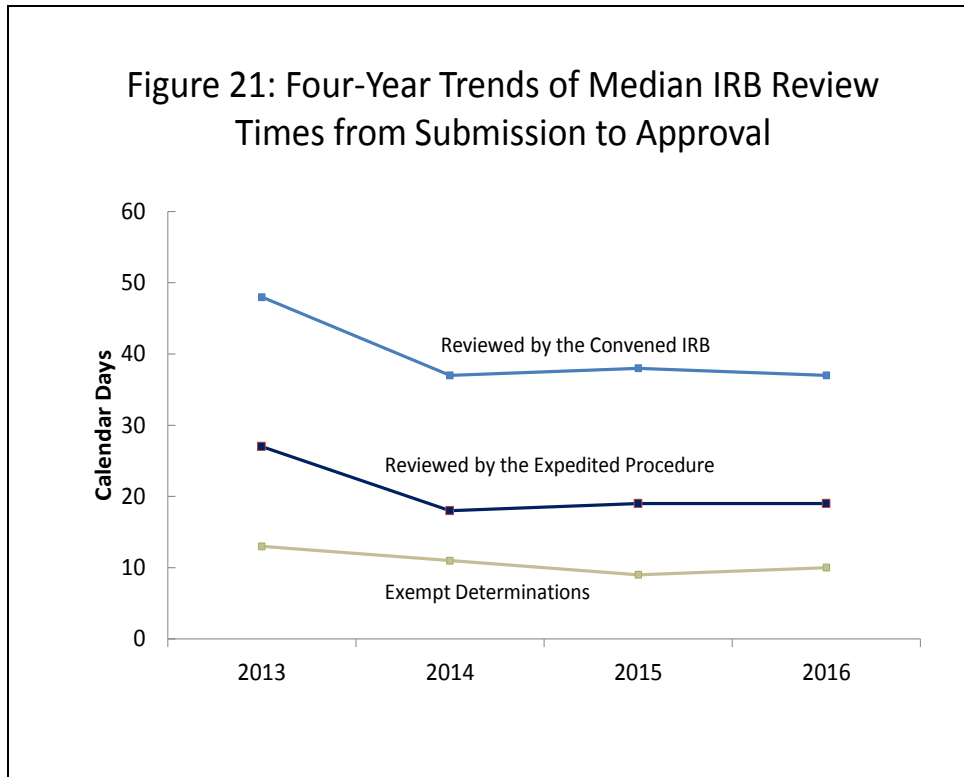
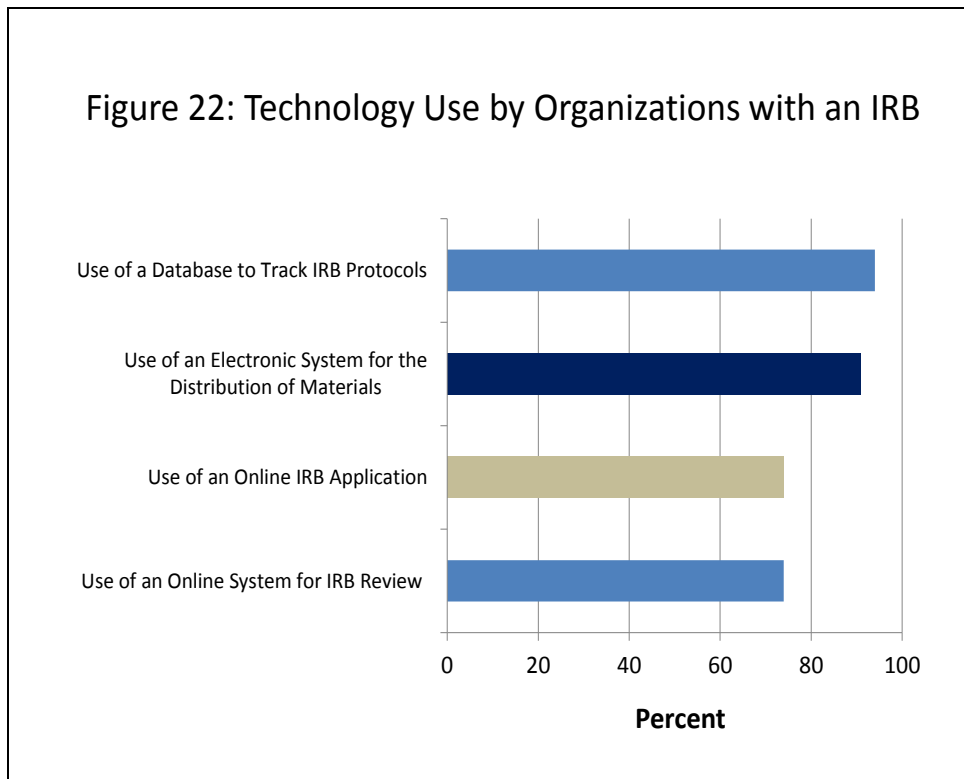


Figure 20: The time from submission to review by the convened IRB is a median of 16 calendar days, the time from submission to approval by the convened IRB is a median of 37 calendar days, the time from submission to review by the expedited procedure is a median of 8 calendar days, the time from submission to approval by the expedited procedure is a median of 19 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.

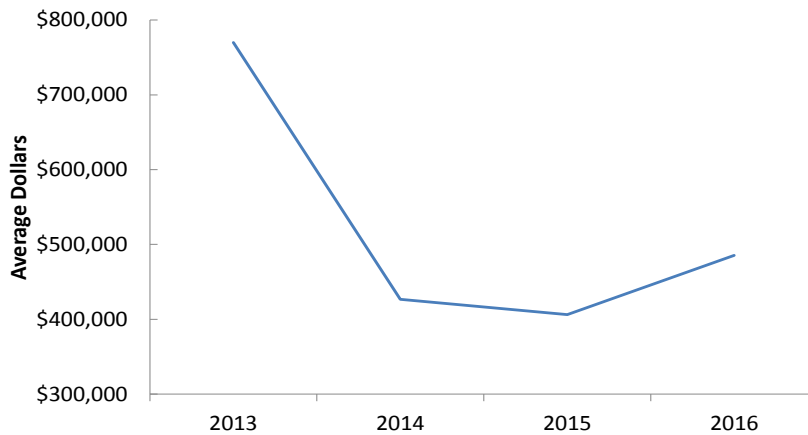


**Figure 22:** 94% of all organizations use a database to track IRB protocols, 91% use an electronic system for the distribution of materials, 74% use an online IRB application, and 74% use an online system for IRB review functions.

**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	865	123.6	\$485,436
1-100	2	37.5	18.75	\$100,800
101-500	4	271.5	67.9	\$352,288
501-1000	5.5	729.5	132.6	\$457,500
1001-2000	9	1379.5	156.8	\$596,013
2001-4000	18	2839	157.7	\$1,063,264
4000+	27	6344	235	\$2,215,500

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

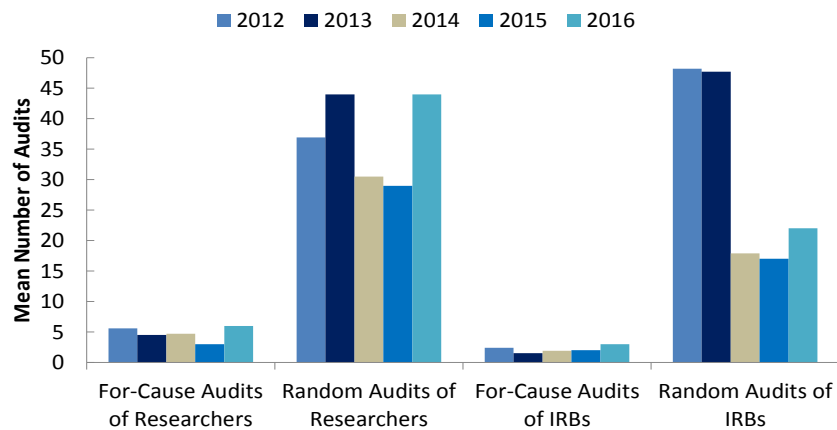


**Figure 23:** Median IRB budgets have slightly increased since 2015.

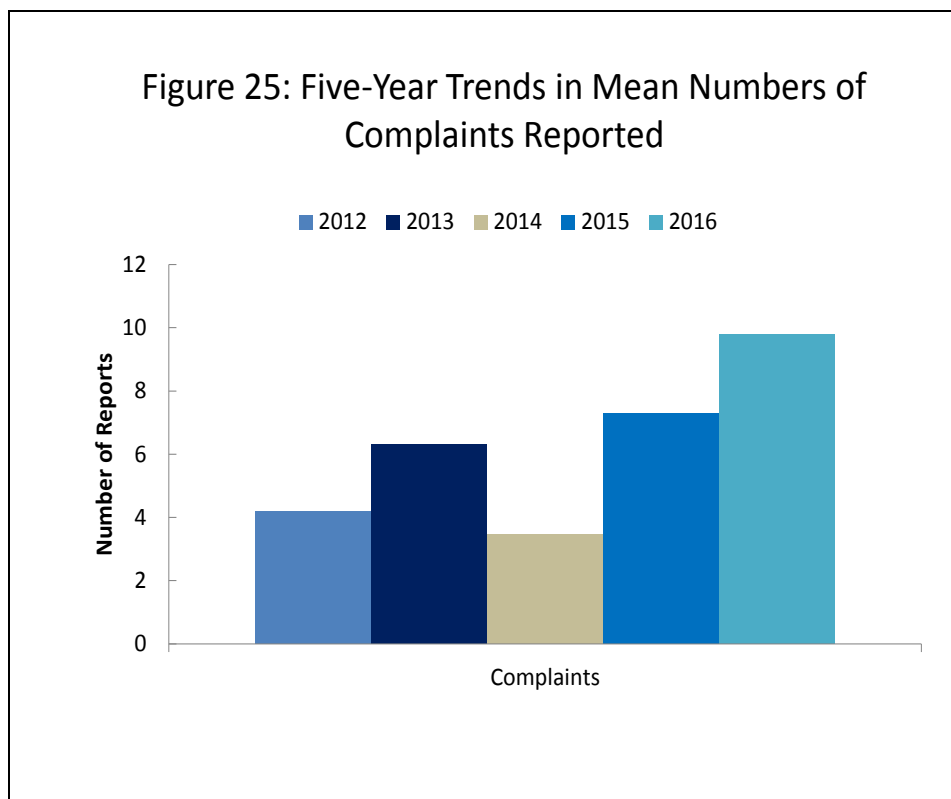
**Table 2. Number of Internal Audits Organizations Conducted within the Past Year**

	For-Cause Audits of Researchers	Random Audits of Researchers	For-Cause Audits of IRBs	Random Audits of IRBs
Mean	6	44	3	22
Median	1	15	0	4
Min	0	0	0	0
Max	149	860	162	506

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



**Figure 24:** For-cause audits of researchers and random audits of researchers have reached an all-time high in 2016. Random audits of IRBs and for-cause audits of IRBs have remained consistent since 2014.

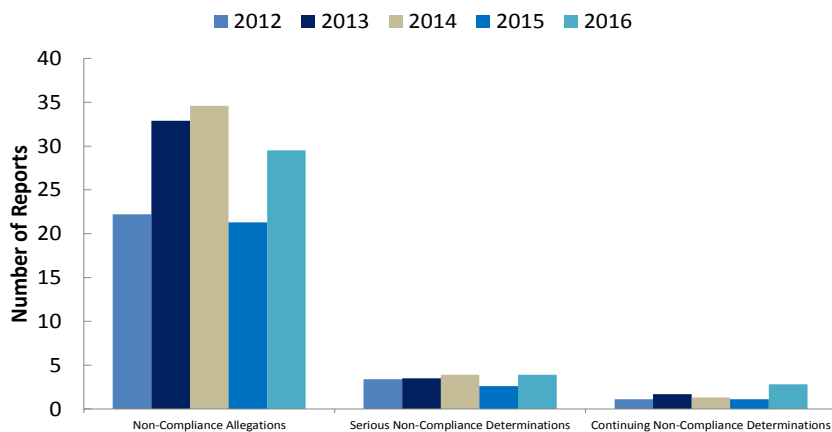


**Figure 25:** The number of complaints from research participants reached its highest total since 2012.

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

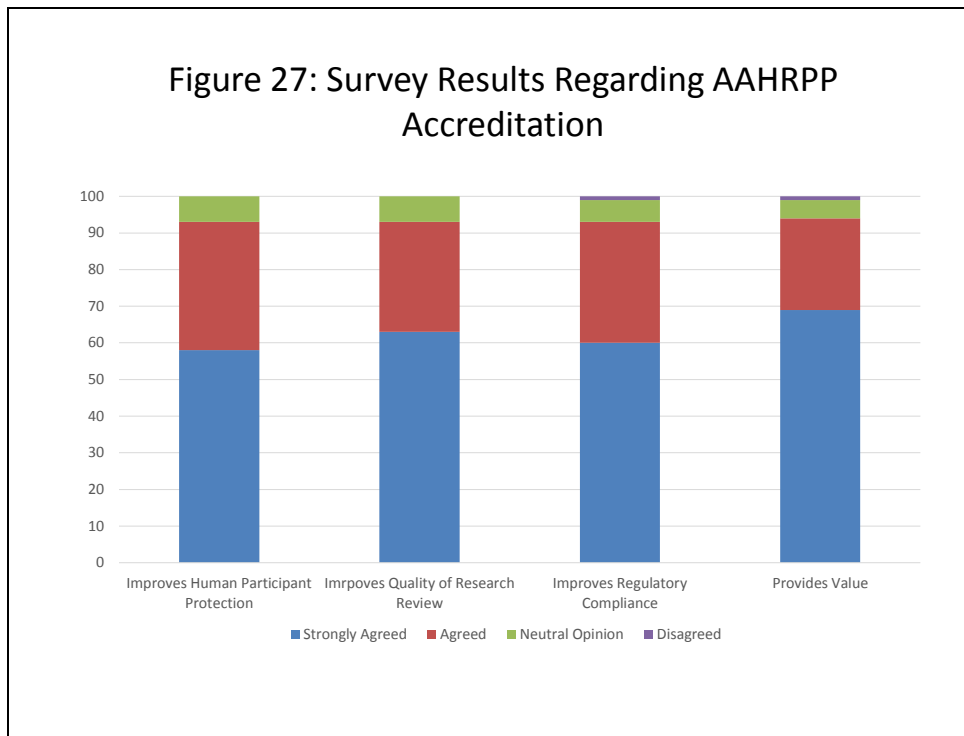
Protocol Category	Median Number of Allegations of Non-Compliance	Median Number of Determinations of Serious Non-Compliance	Median Number of Determinations of Continuing Non-Compliance
All	3	1	0
1-500	1	0	0
501-1,000	1	1	1
1,001-2,000	4	2.5	0.5
2,001-4,000	11	4	1
>4,000	16	4	2.5

**Figure 26: Five-Year Trends in Mean Number of Reported Cases of Non-Compliance**



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





**Figure 27:** 58% of responding organizations strongly agreed that AAHRPP Accreditation improves human participant protection, 35% agreed, and 7% had a neutral opinion. 63% of responding organizations strongly agreed that AAHRPP Accreditation improves the quality of research review, 30% agreed, and 7% had a neutral opinion. 60% of responding organizations strongly agreed that AAHRPP Accreditation improves regulatory compliance, 33% agreed, 6% had a neutral opinion, and less than 1% disagreed. 69% of responding organizations strongly agreed that AAHRPP Accreditation provides value to their organization, 25% agreed, 5% had a neutral opinion, and less than 1% disagreed.



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