



2015 Metrics on Human Research Protection Program Performance

Updated March 30, 2016

About the Metrics

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 2015 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 2015, 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 2015 data, the metrics are represented as the median, except where indicated as the mean.

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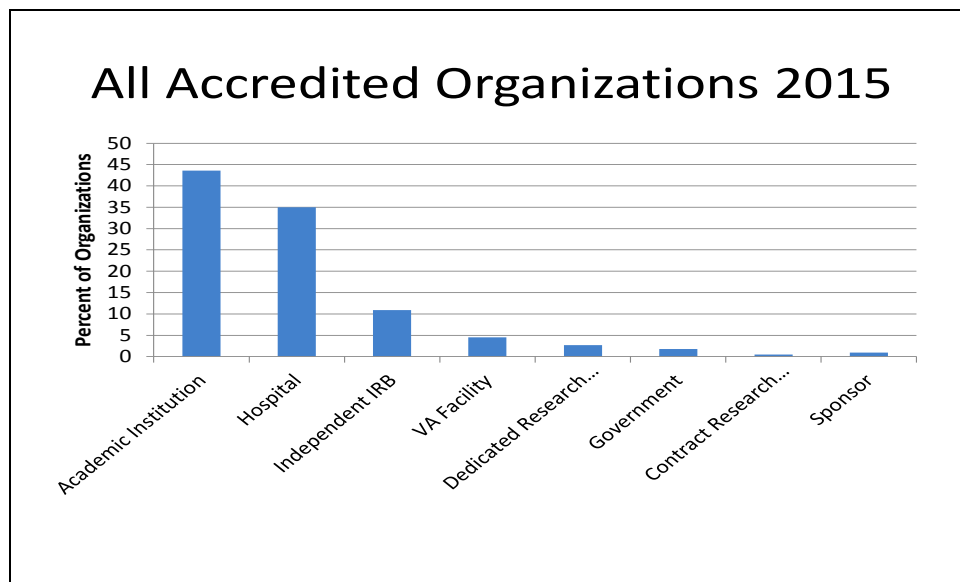
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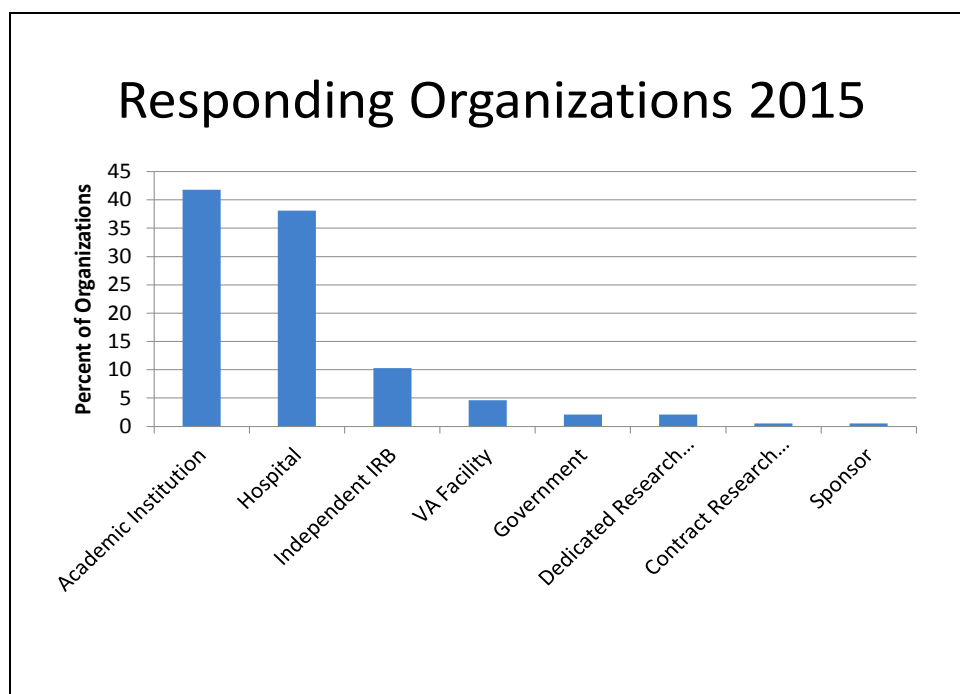
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General Description of Organizations



Slide 1: 44% of all accredited organizations are academic institutions, 35% are hospitals, 11% are independent IRBs, 5% are VA facilities, 3% are dedicated research sites or research institutes, 2% are government organizations, 1% are sponsor organizations, and 0.5% are contract research organizations.



Slide 2: 42% of organizations that responded in 2015 were academic institutions, 38% were hospitals, 10% were independent IRBs, 5% were VA facilities, 2% were government organizations, 2% were dedicated research sites or research institutes, 0.5% were contract research organizations, and 0.5% were sponsor organizations.

General Description of the Research Conducted or Overseen by Organizations

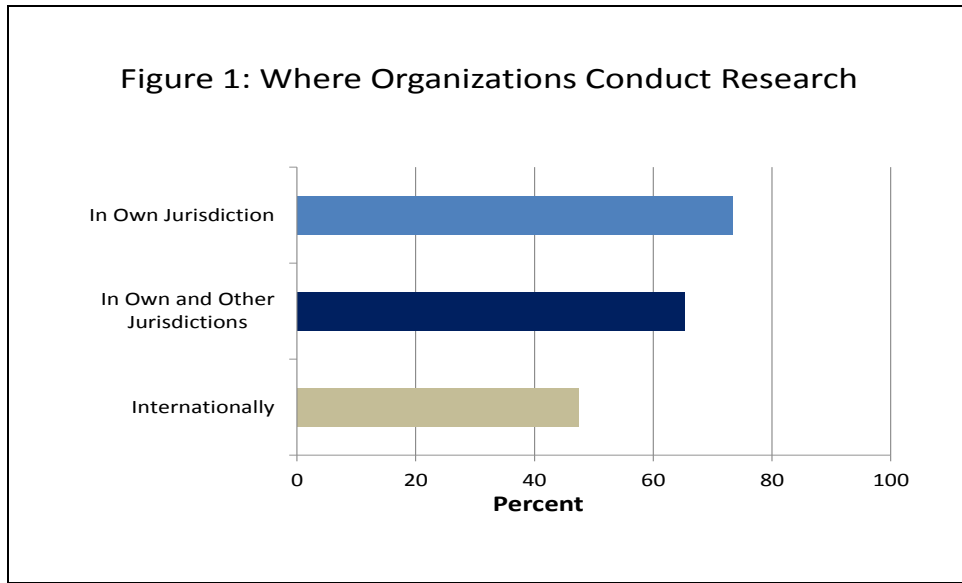


Figure 1: 73% of responding organizations conduct research in their own jurisdiction, 65% conduct research in their own and other jurisdictions, and 48% conduct research internationally.

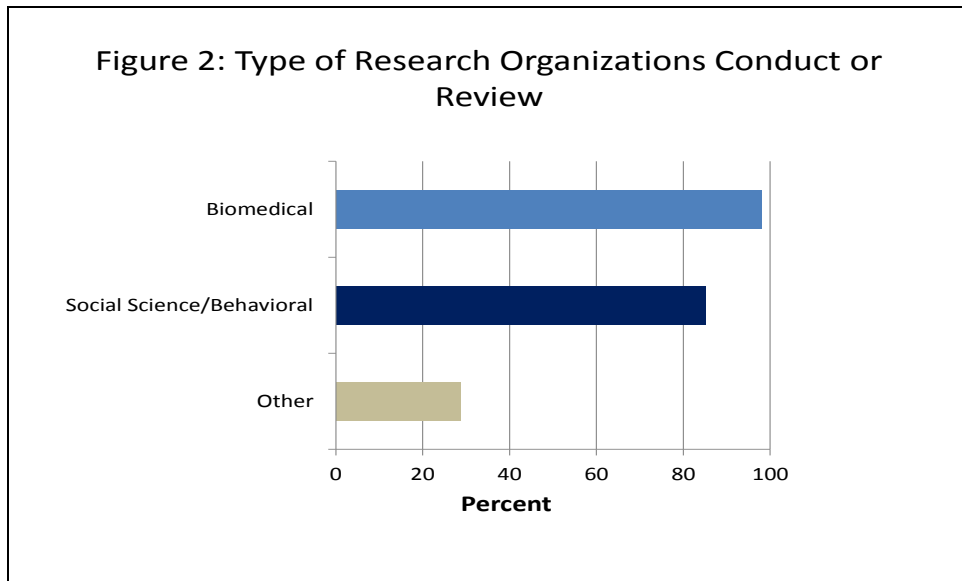


Figure 2: 99% of all organizations conduct biomedical research, 87% conduct social/behavioral research, and 29% conduct research falling into other categories.

Selected Types of Research Conducted or Overseen by Organizations

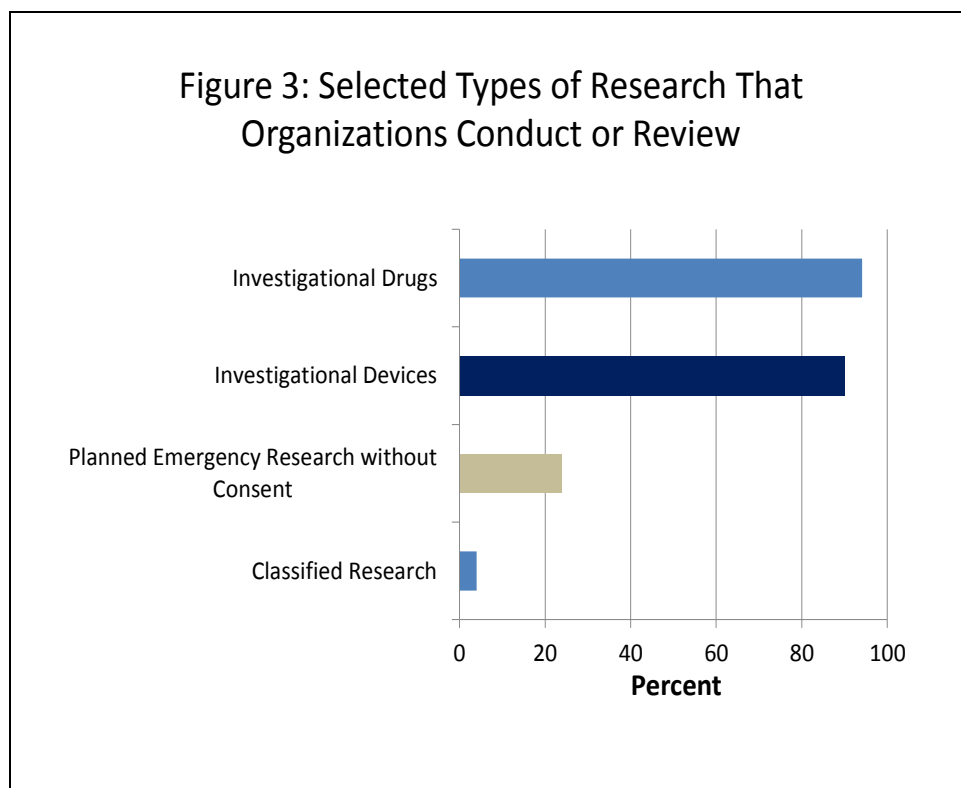


Figure 3: 94% of organizations conduct research involving investigational drugs, 90% conduct research involving investigational devices, 24% of organizations conduct planned emergency research without consent, and 4% conduct classified research.

Selected Types of Research Conducted or Overseen by Organizations

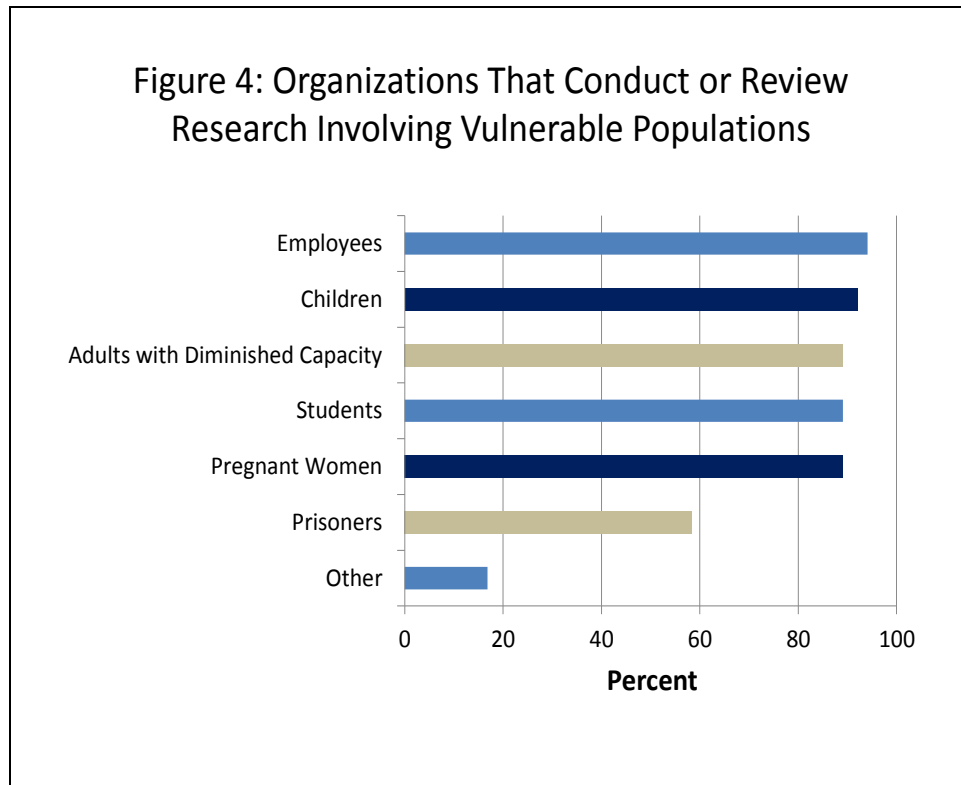


Figure 4: 94% of all organizations conduct research with employees, 92% conduct research with children, 89% conduct research with adults with diminished capacity, 89% conduct research with students, 89% conduct research with pregnant women, 58% conduct research with prisoners, and 17% conduct research with other vulnerable populations.

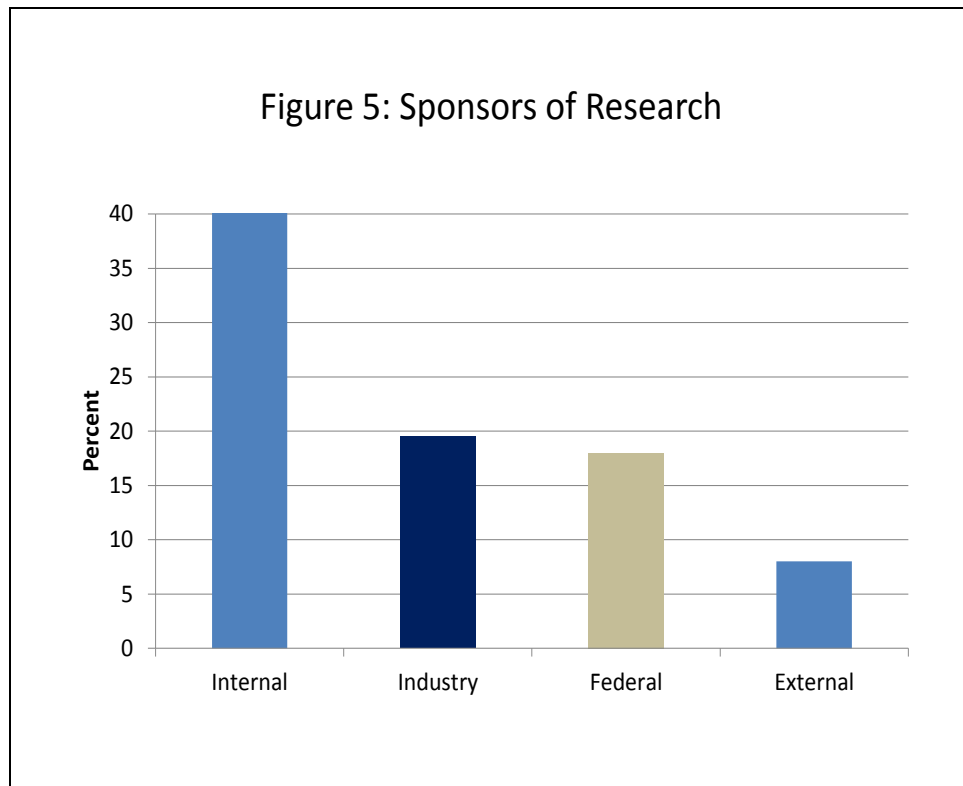


Figure 5: For all organizations, a median of 47% of research is internally sponsored, a median of 20% of research is industry sponsored, a median of 18% of research is federally sponsored, and a median of 8% of research is externally sponsored.

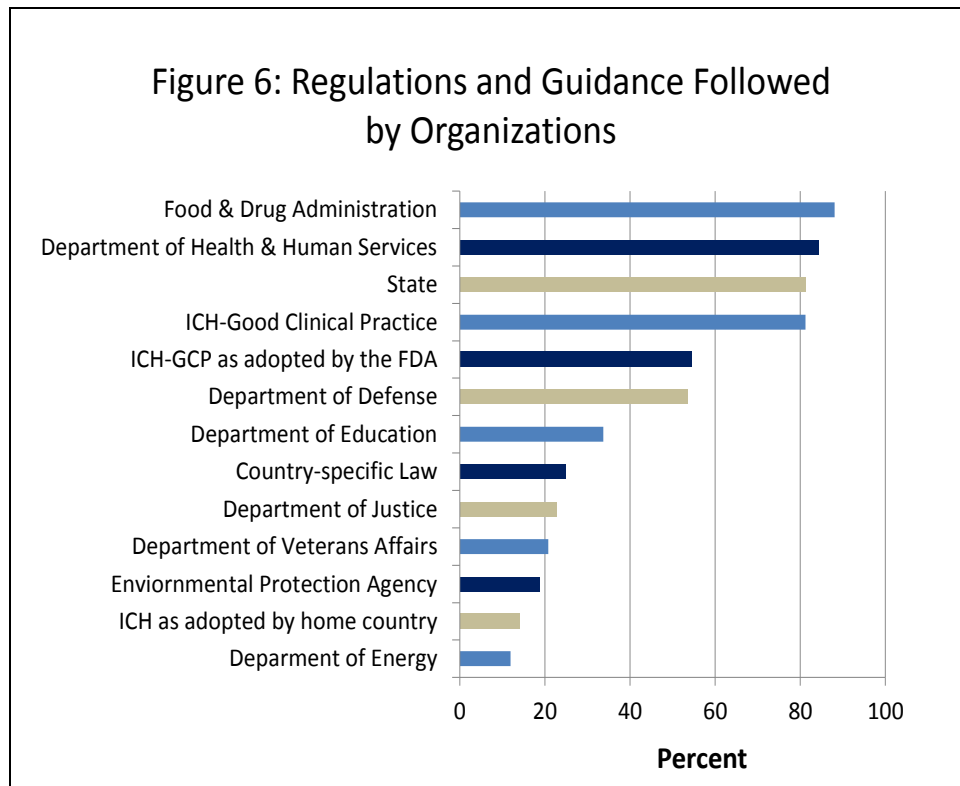


Figure 6: 88% of all organizations follow FDA regulations, 84% follow Department of Health and Human Services regulations, 81% follow regulations or guidelines of their State, 81% follow the ICH- Good Clinical Practice guideline, 55% follow the ICH- Good Clinical Practice guideline as adopted by the FDA, 54% follow Department of Defense requirements, 34% follow Department of Education requirements, 25% follow Country-specific regulations or guidelines, 23% follow Department of Justice requirements, 21% follow Department of Veterans Affairs requirements, 19% follow Environmental Protection Agency requirements, 14% follow the ICH-Good Clinical Practice guideline as adopted by their home country, and 12% follow Department of Energy requirements.

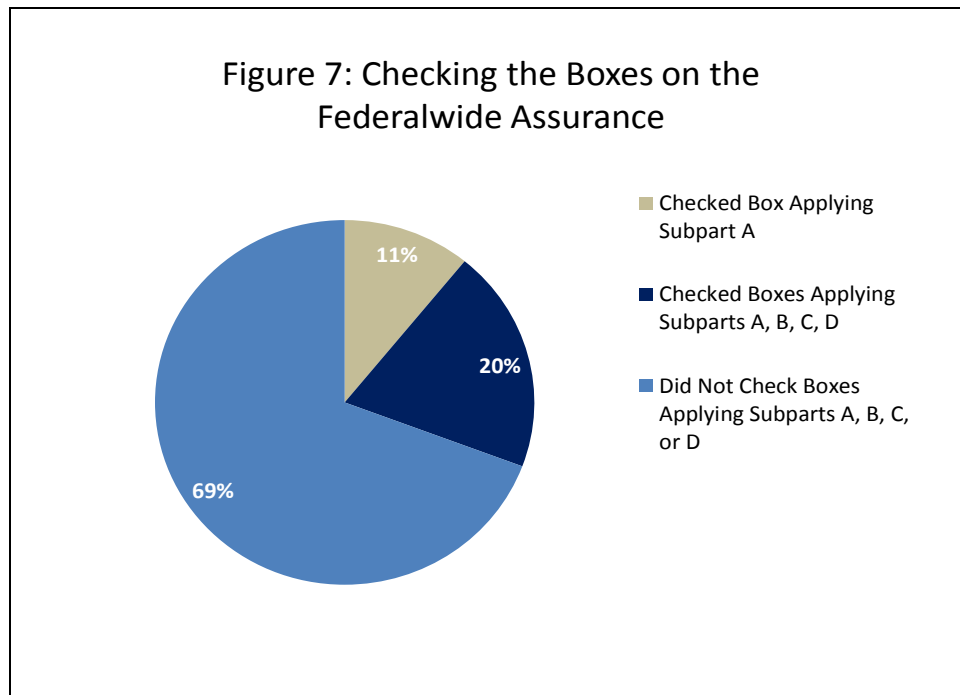


Figure 7: 69% of all organizations did not check boxes applying Subparts A, B, C, or D, 20% of all organizations check boxes applying all Subparts (A, B, C, D), and 11% checked the box only applying Subpart A.

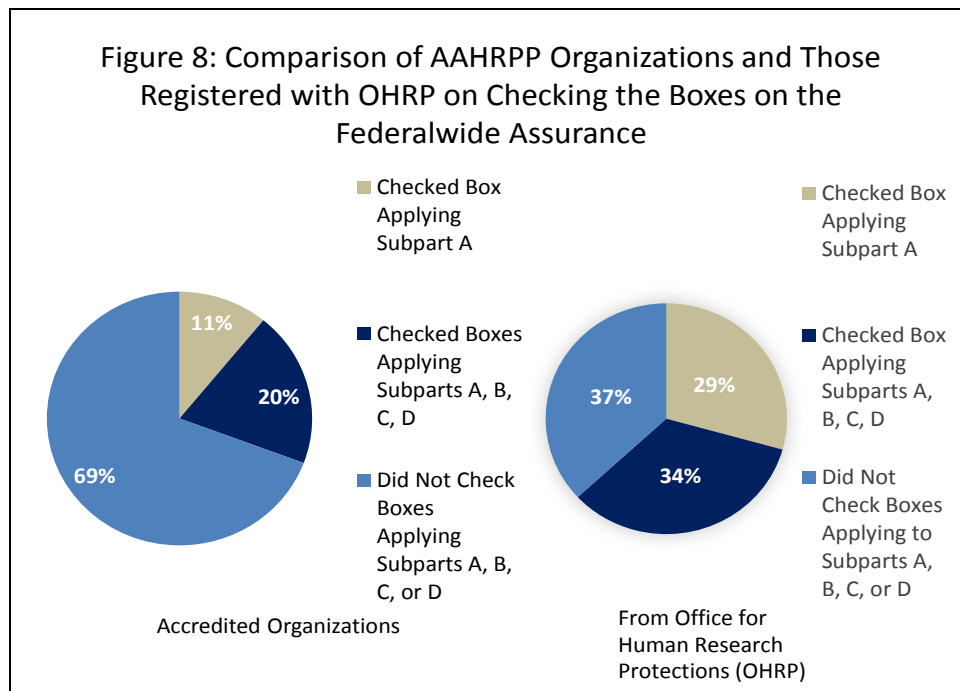


Figure 8: Compared to percentages provided by OHRP, more organizations accredited by AAHRPP or applying for AAHRPP accreditation unchecked the box.

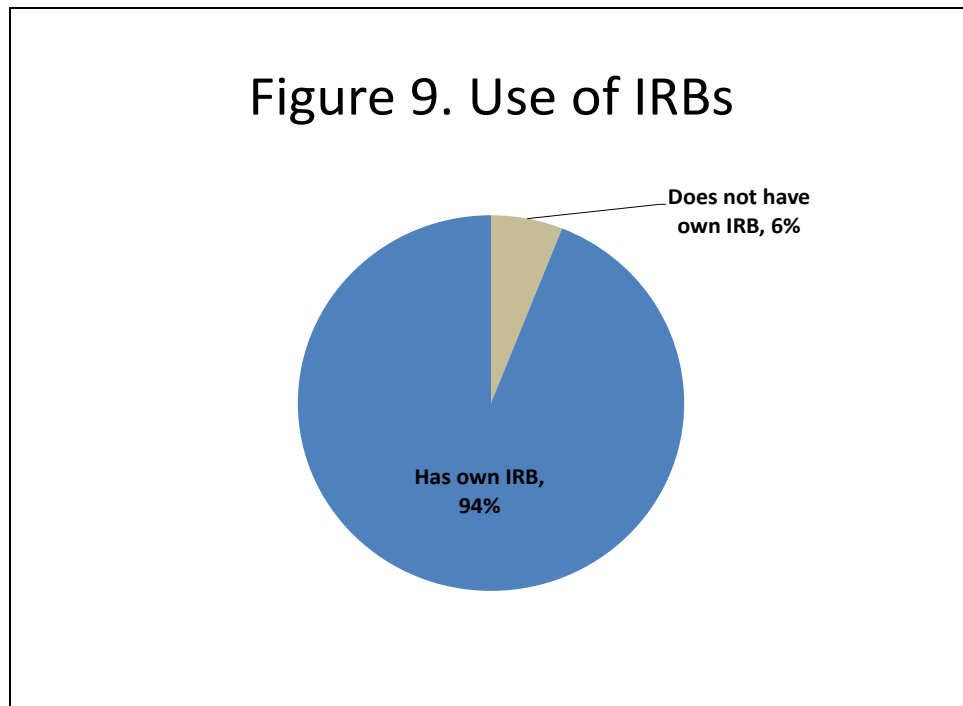


Figure 9: 94% of all organizations have their own IRB; 6% do not have their own IRB.

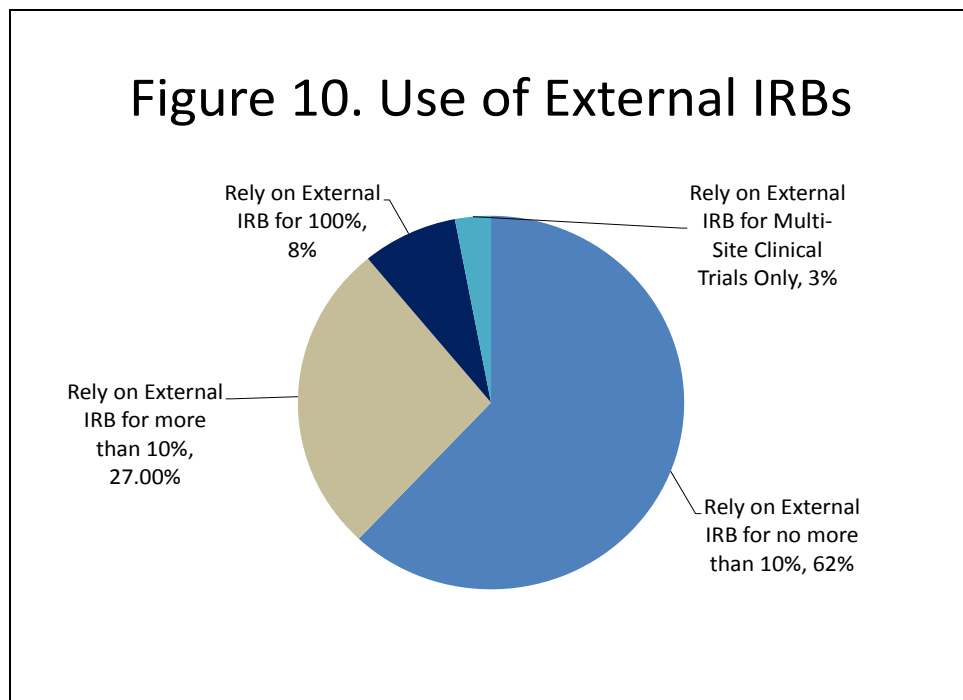


Figure 10: 62% of all organizations use external IRBs for a maximum of 10% of total protocols, 27% of organizations rely on external IRBs for more than 10% of total protocols, 8% of all organizations rely on external IRBs for 100% of total protocols, and 3% rely on external IRBs for multi-site clinical trials only.

Figure 11: Number of IRBs Per Organization

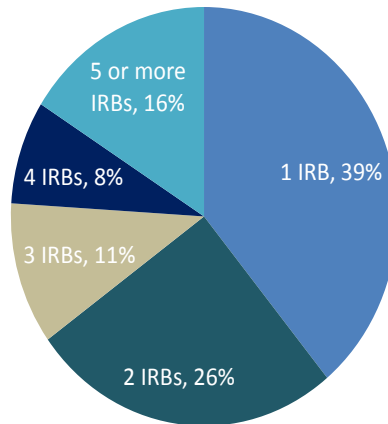


Figure 11: 39% of all organizations have one IRB, 26% have two IRBs, 11% have three IRBs, 8% have four IRBs, and 16% have five or more IRBs.

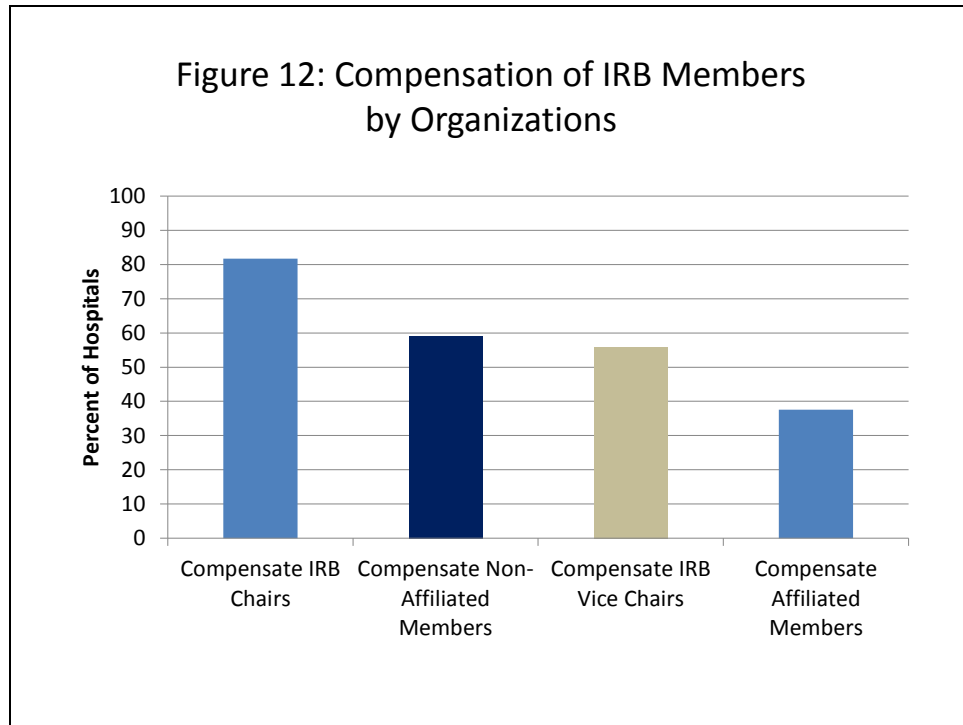


Figure 12: 82% of all organizations compensate IRB chairs, 59% compensate non-affiliated members, 56% compensate IRB vice chairs, and 38% compensate affiliated members.

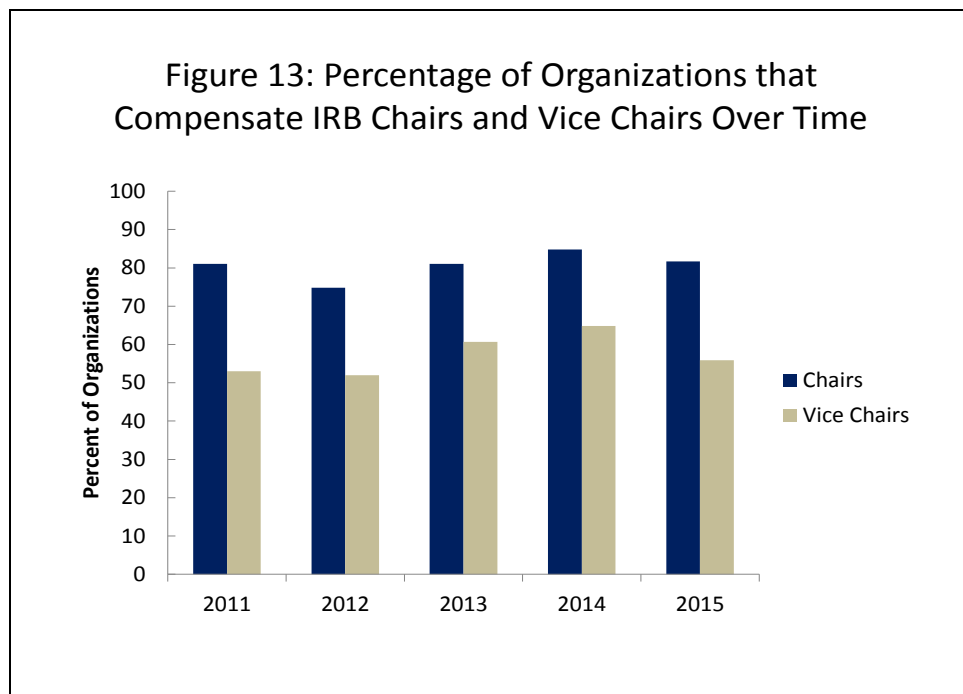


Figure 13: Since 2014, the mean compensation of IRB chairs and vice chairs has decreased to levels near 2011.

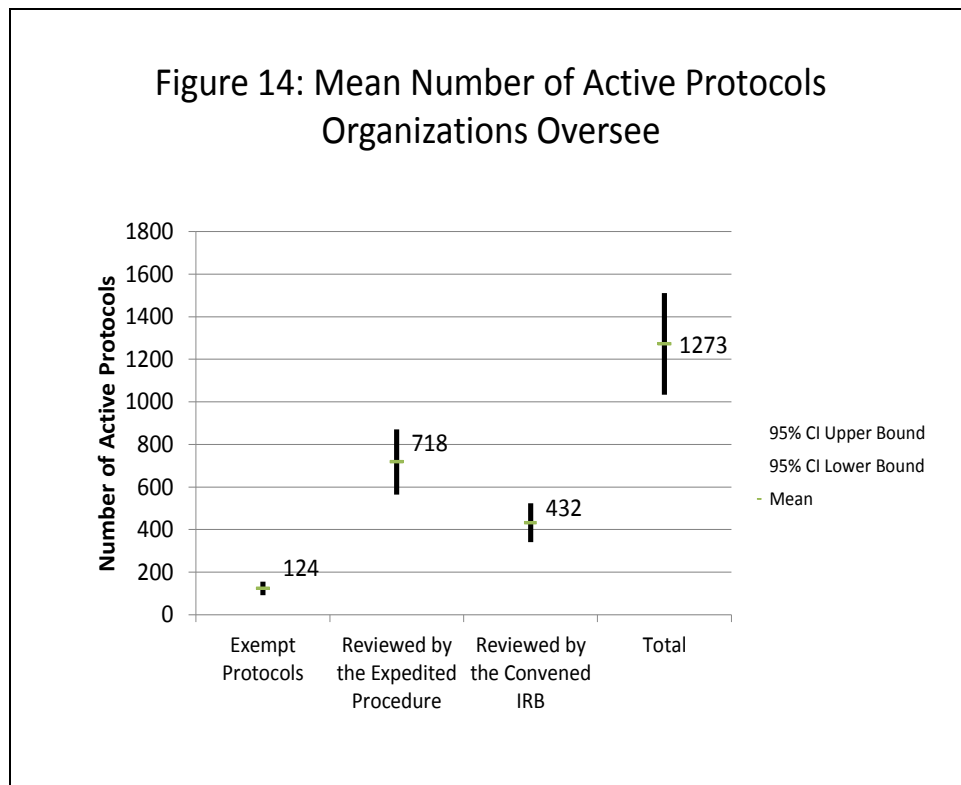


Figure 14: A mean of 124 protocols were deemed exempt by all organizations*, a mean of 718 protocols were reviewed by the expedited procedure, a mean of 432 protocols were reviewed by the convened IRB, and a mean of 1273 total protocols were overseen by all organizations.

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

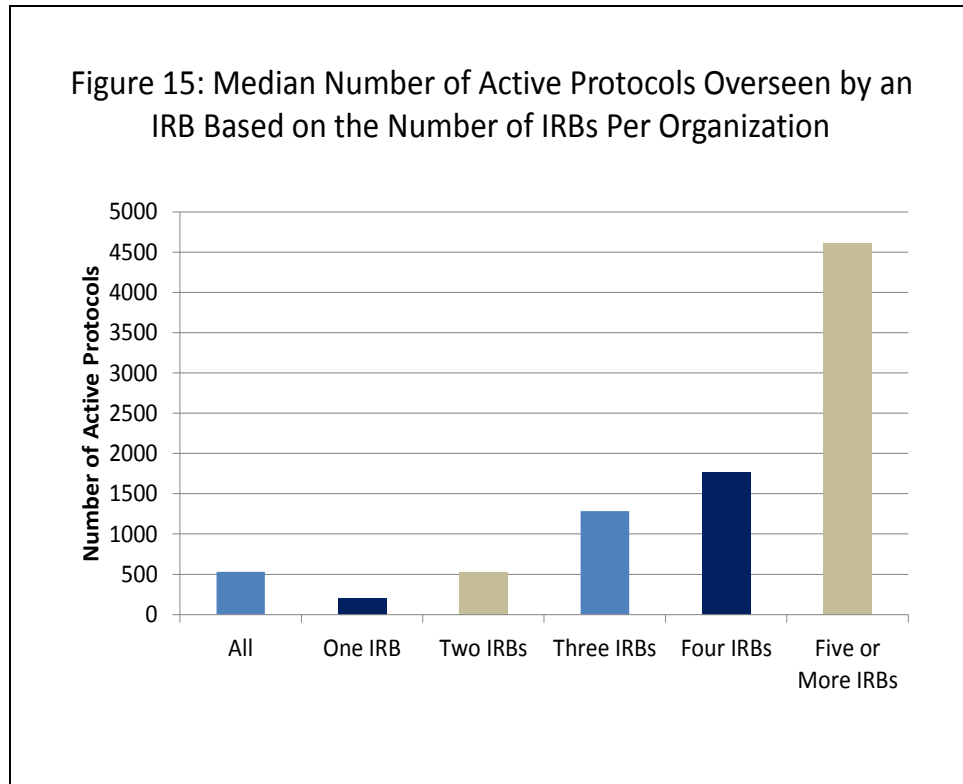


Figure 15: A median of 532 protocols were overseen by all organizations, a median of 212 protocols were overseen by organizations with one IRB, a median of 532 protocols were overseen by organizations with two IRBs, a median of 1283 protocols were overseen by organizations with three IRBs, a median of 1777 protocols were overseen by organizations with four IRBs, and a median of 4615 were overseen by organizations with five or more IRBs.

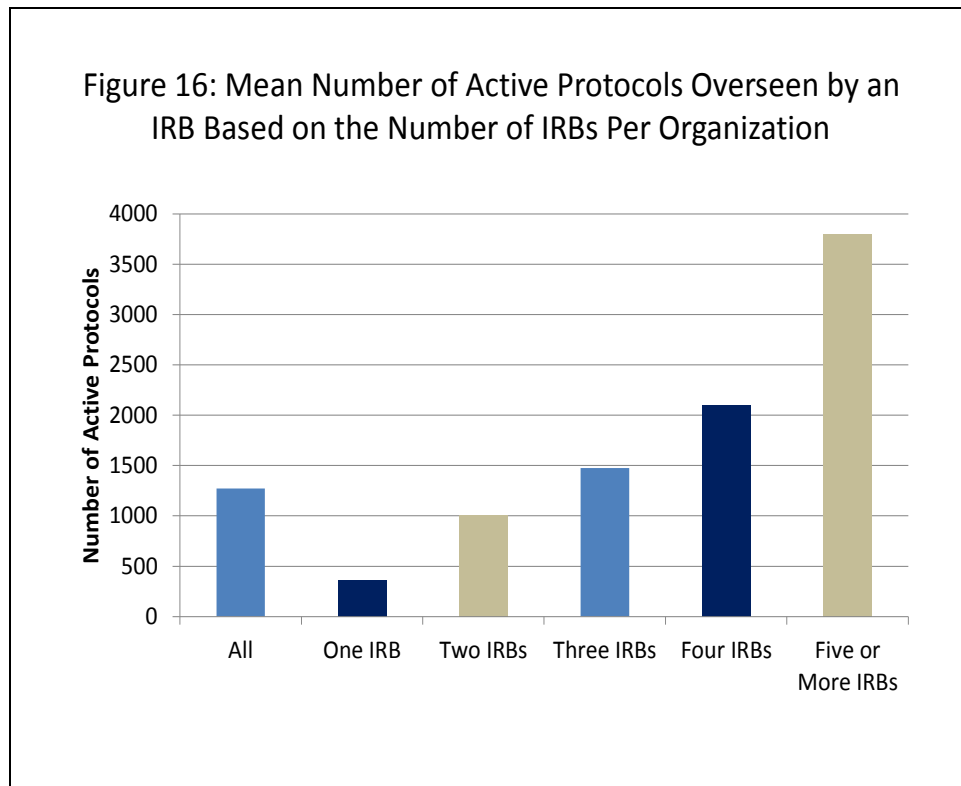


Figure 16: A mean of 1272 protocols were overseen by all organizations, a mean of 360 protocols were overseen by organizations with one IRB, a mean of 1005 protocols were overseen two IRBs, a mean of 1476 protocols were overseen by organizations with three IRBs, a mean of 2106 protocols were overseen by organizations with four IRBs, and a mean of 3806 protocols were overseen by organizations with five or more IRBs.

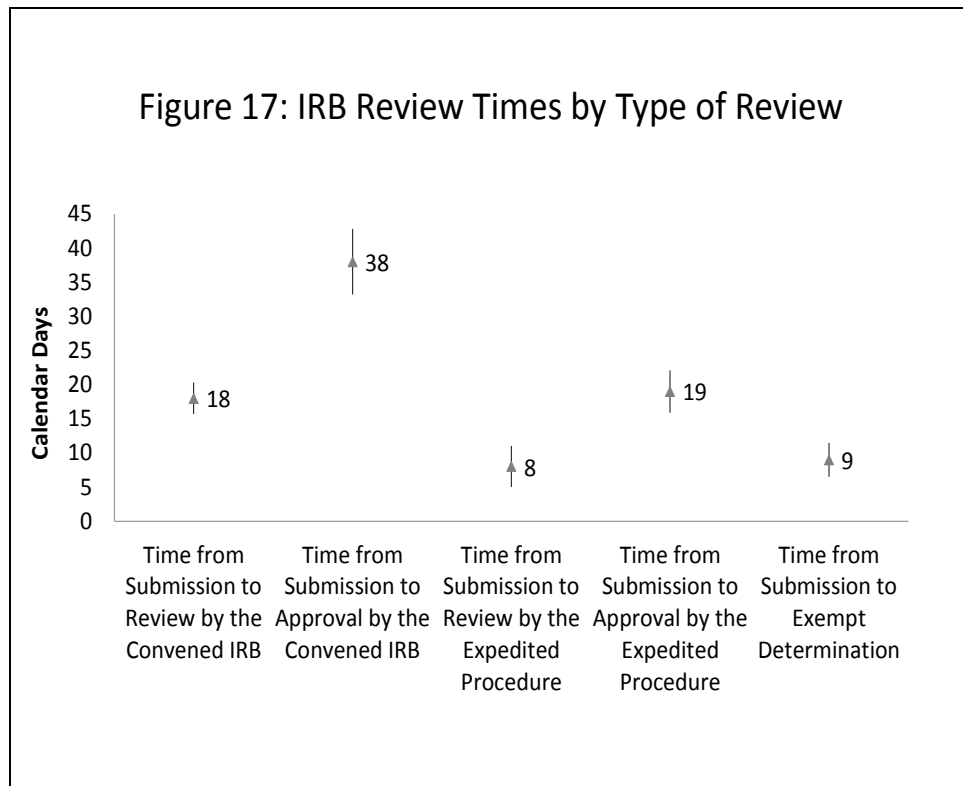


Figure 17: The time from submission to review by the convened IRB is a median of 18 calendar days, the time from submission to approval by the convened IRB is a median of 38 calendar days, the time from submission to review by the expedited procedure is a median of 8 calendar days, the time from submission 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 9 calendar days.

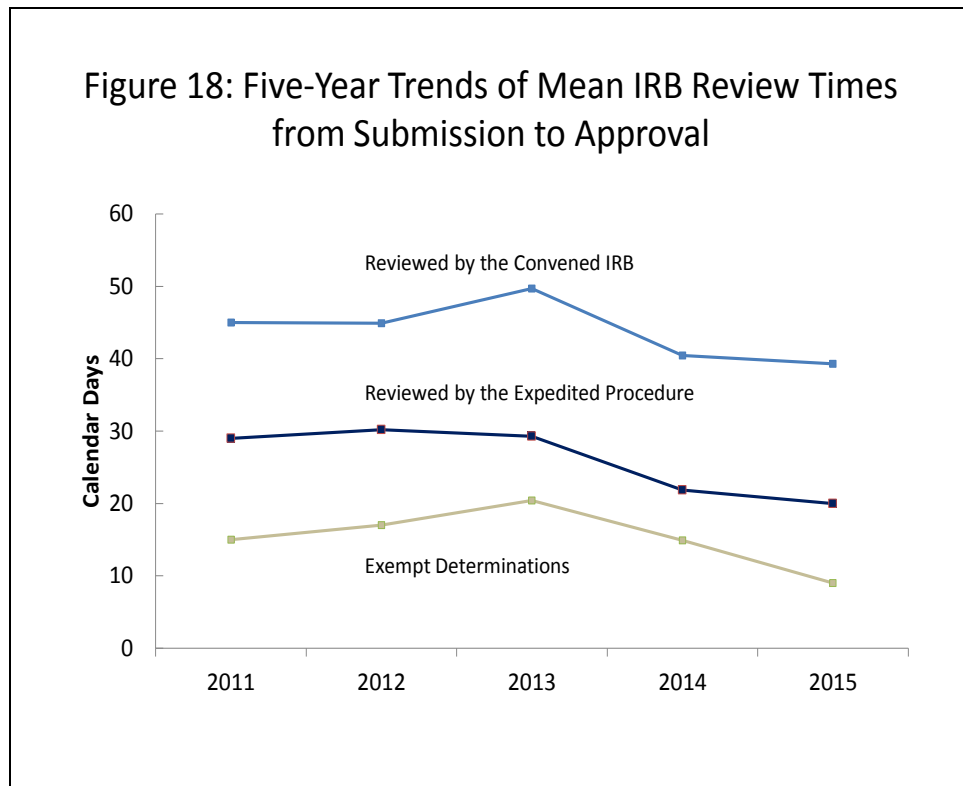


Figure 18: Since 2013, review times for convened, expedited, and exempt reviews have decreased across the board.

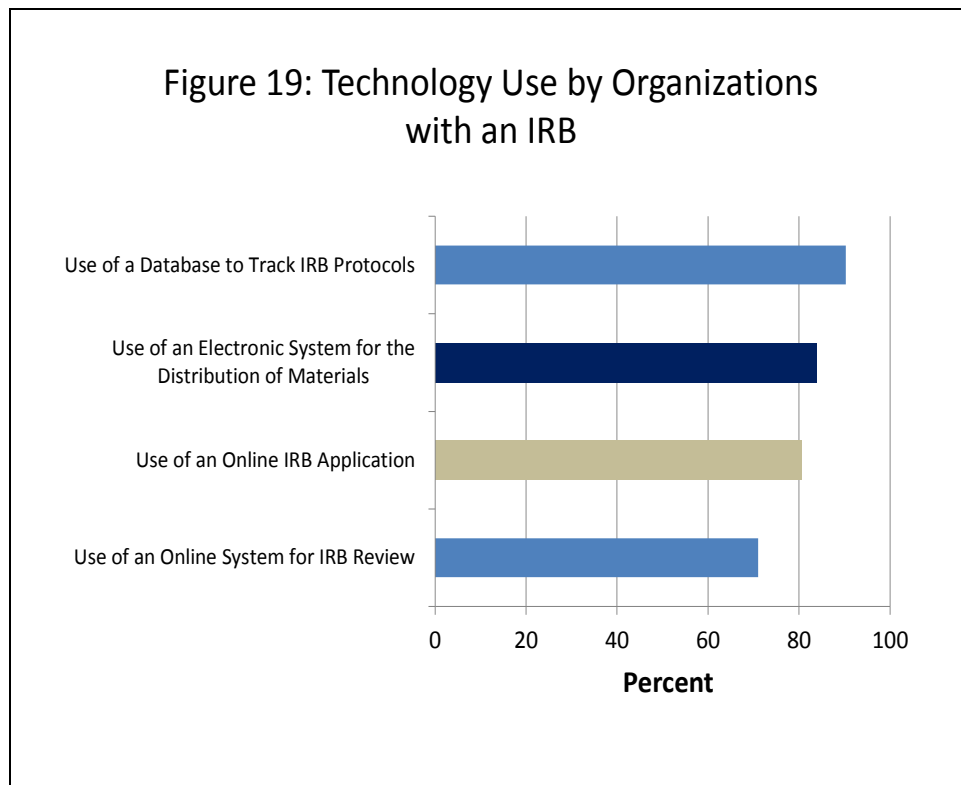


Figure 19: 90% of all organizations use a database to track IRB protocols, 84% use an electronic system for distribution of materials, 81% use an online IRB application, 71% use an online system for IRB reviews.

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	5	587	117	\$406,212
1-100	2	46	23	\$150,000
101-500	4	298	75	\$300,000
501-1000	4.7	699	148.7	\$428,276
1001-2000	12	1413	118	\$794,143
2001-4000	15	2190	146	\$1,326,719
4000+	25	5182	207	\$2,752,555

Figure 20: Five-Year Trends in Mean IRB Budgets

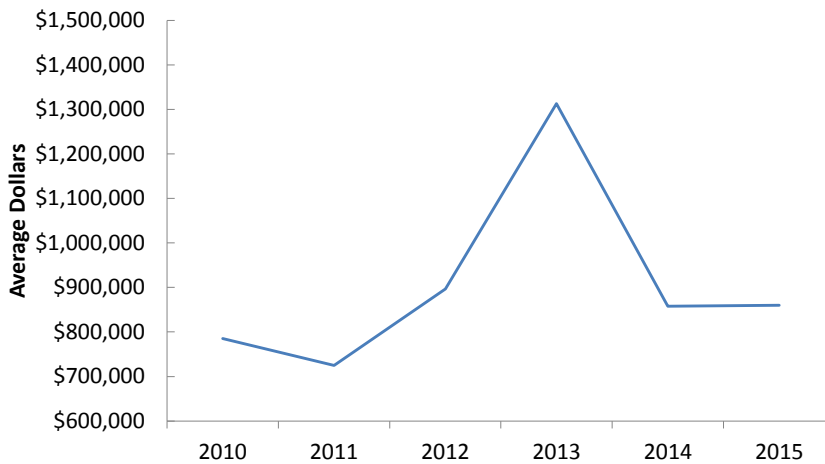


Figure 20: IRB budgets have remained nearly consistent from 2014 to 2015.

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	3	29	2	17
Median	1	7	0	3
Min	0	0	0	0
Max	48	489	33	362

Figure 21: Five-Year Trends in Mean Number of Audits Organizations Conducted

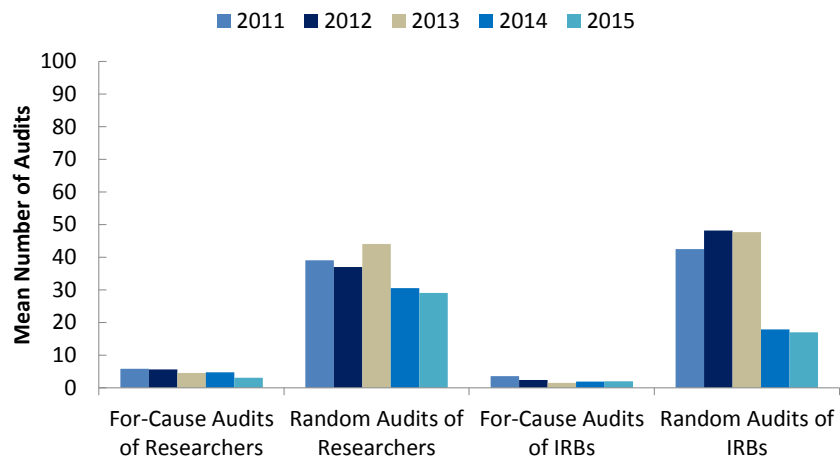


Figure 21: There has been a decrease in for-cause audits of researchers and for-cause audits of IRBs since 2011. Random audits of researchers has decreased since 2013. Random audits of IRBs in 2015 remained similar to the 2014's number.

Table 3. Number of Protocol Deviations and Complaints Reported to the IRB in the Past Year

Protocol Category	Median Number of Protocol Deviations	Median Number of Complaints
All	77	1
1-100	32	0
101-500	29	0
501-1,000	53	2
1,001-2,000	181	3.5
2,001-4,000	119	4
>4,000	567.5	17

Figure 22: Five-Year Trends in Mean Numbers of Protocol Deviations and Complaints Reported

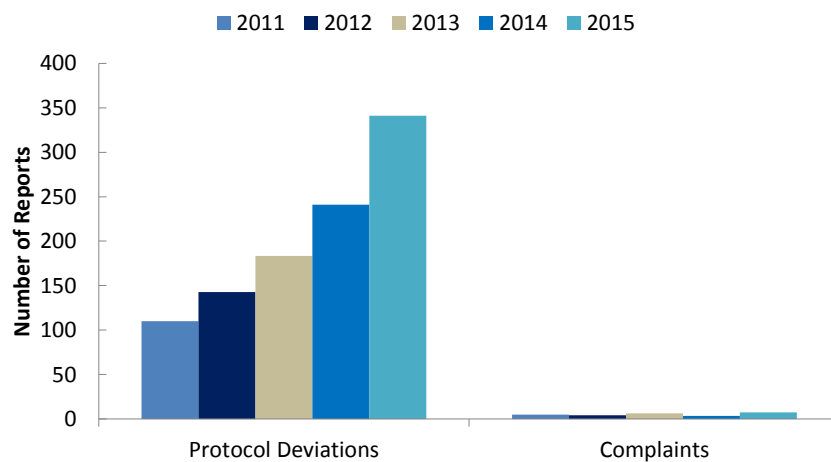


Figure 22: The number of Protocol Deviations has steadily increased since 2011, while the number of complaints remained similar in 2015.

Table 4. 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 Serious Non-Compliance	Median Number of Determinations of Continuing Non-Compliance
All	3	1	0
1-100	1	0	0
101-500	1	0	0
501-1,000	2	0	0
1,001-2,000	6	5	1
2,001-4,000	9	3	1
>4,000	31	5	1

Figure 23: Five-Year Trends in Mean Number of Reported Cases of Non-Compliance

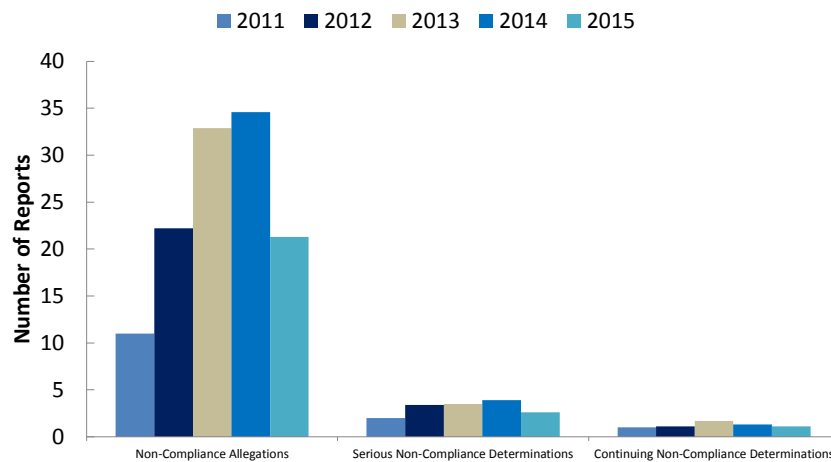


Figure 23: Allegations of non-compliance have decreased since 2014, returning to levels at or near those of 2012, while determinations of serious non-compliance and continuing non-compliance remained similar in 2015.



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