



2014 Metrics on Human Research Protection Program Performance

Updated May 15, 2015

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 2014 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 2014, 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 2014 data, the metrics are represented as the median, except where indicated as the mean.

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General Description of the Research Conducted or Overseen by Organizations

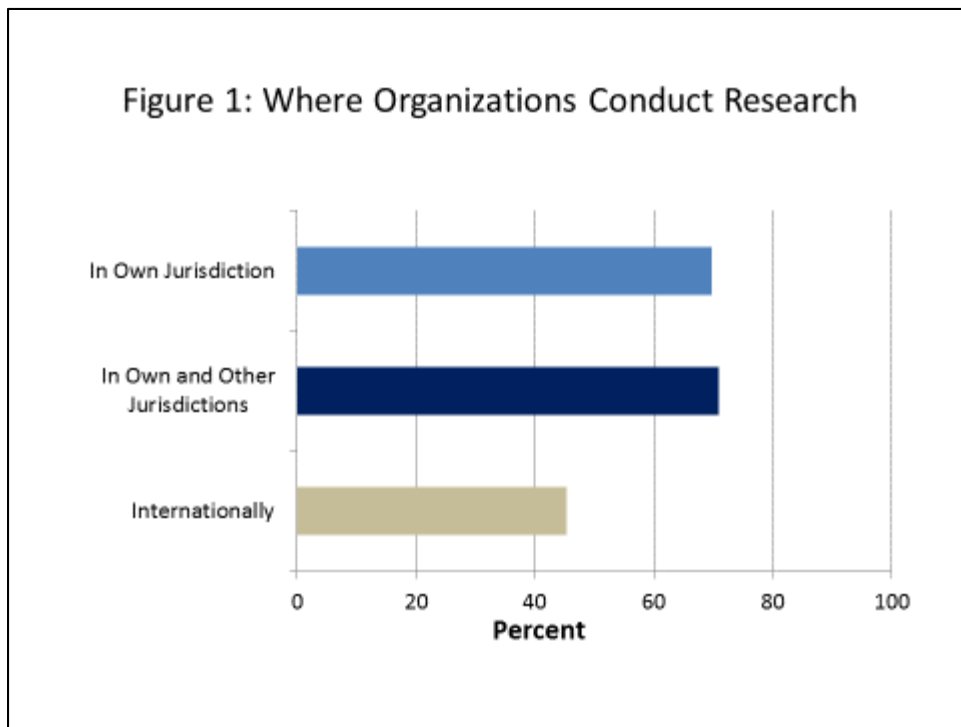


Figure 1: 69.8% of responding organizations conduct research in their own jurisdiction; 70.9% conduct research in their own and other jurisdictions; and 45.3% conduct research internationally.

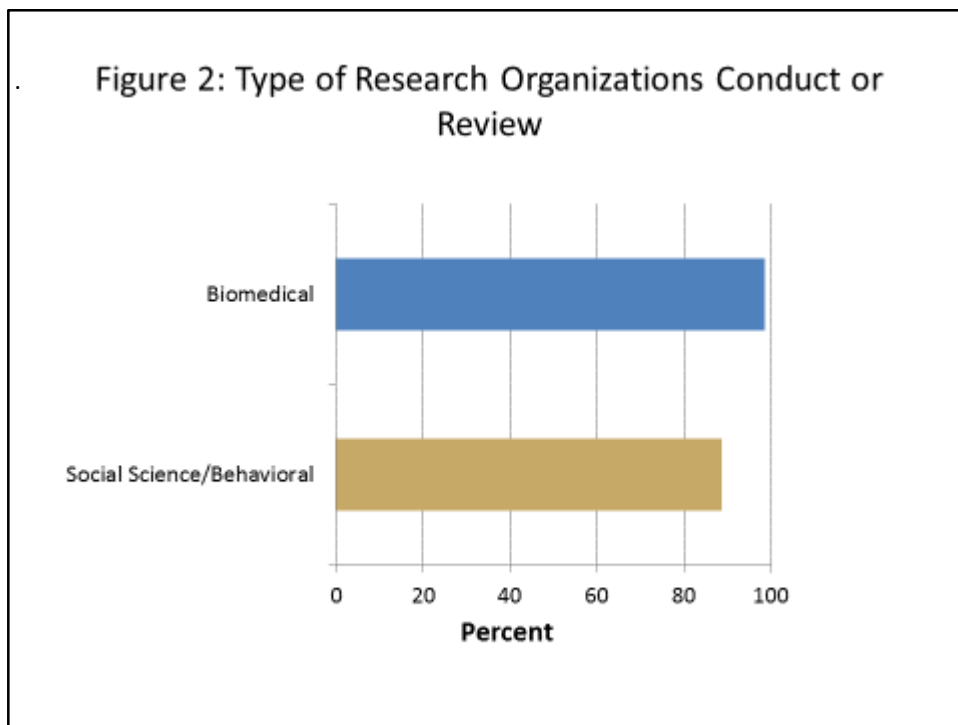


Figure 2: 98.8% of all organizations conduct biomedical research and 87.2% conduct social/behavioral research.

Selected Types of Research Conducted or Overseen by Organizations

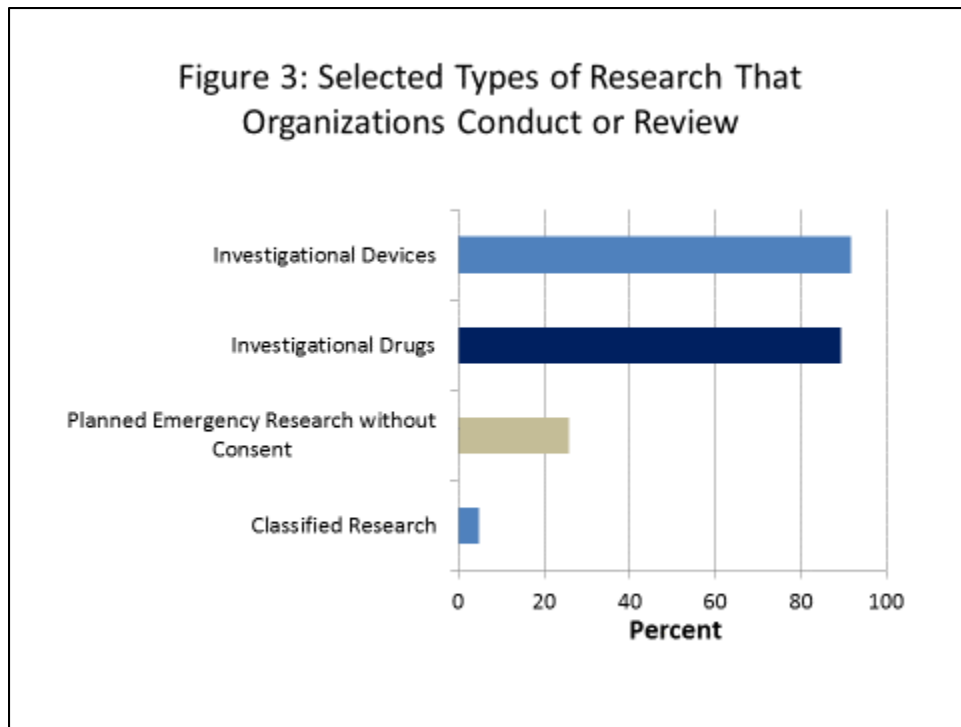


Figure 3: 91.8% of organizations conduct research on investigational devices; 89.4% conduct research on investigational drugs; 25.9% of organizations conduct research using planned emergency research without consent; and 4.7% conduct classified research.

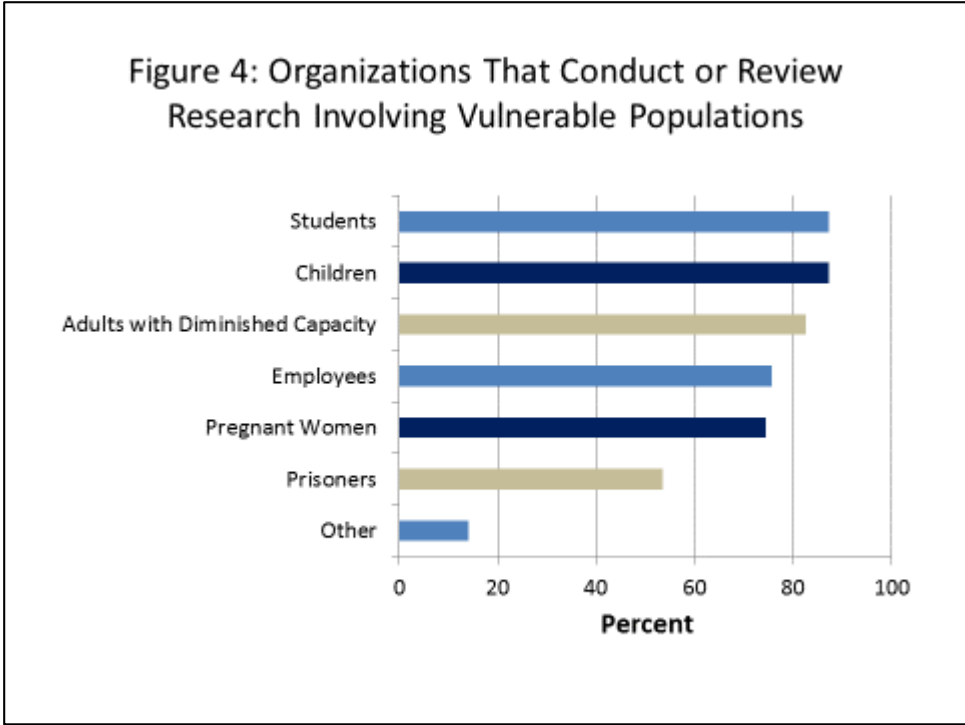


Figure 4: 87.3% of all organizations conduct research with students; 87.2% conduct research with children; 82.6% conduct research with adults with diminished capacity; 75.6% conduct research with employees; 74.4% conduct research with pregnant women; 53.5% conduct research with prisoners; and 14% conduct research with other vulnerable populations not listed in the survey.

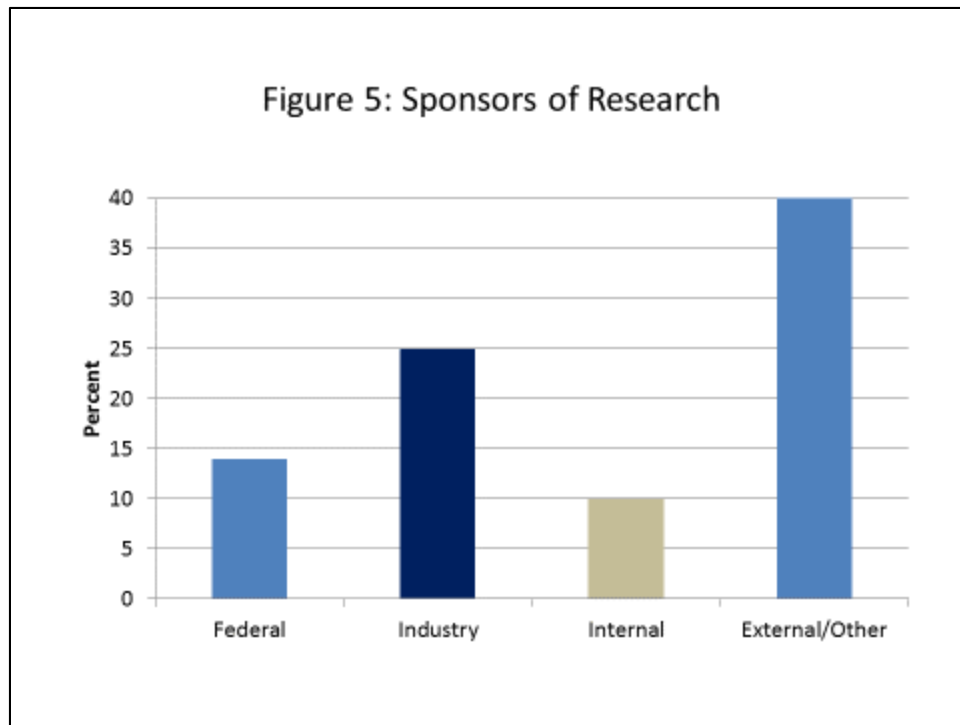


Figure 5: All organizations report a median of 14% federally-sponsored research; 25% industry-sponsored research; 10% internally-sponsored research; and 42% externally/other-sponsored research.

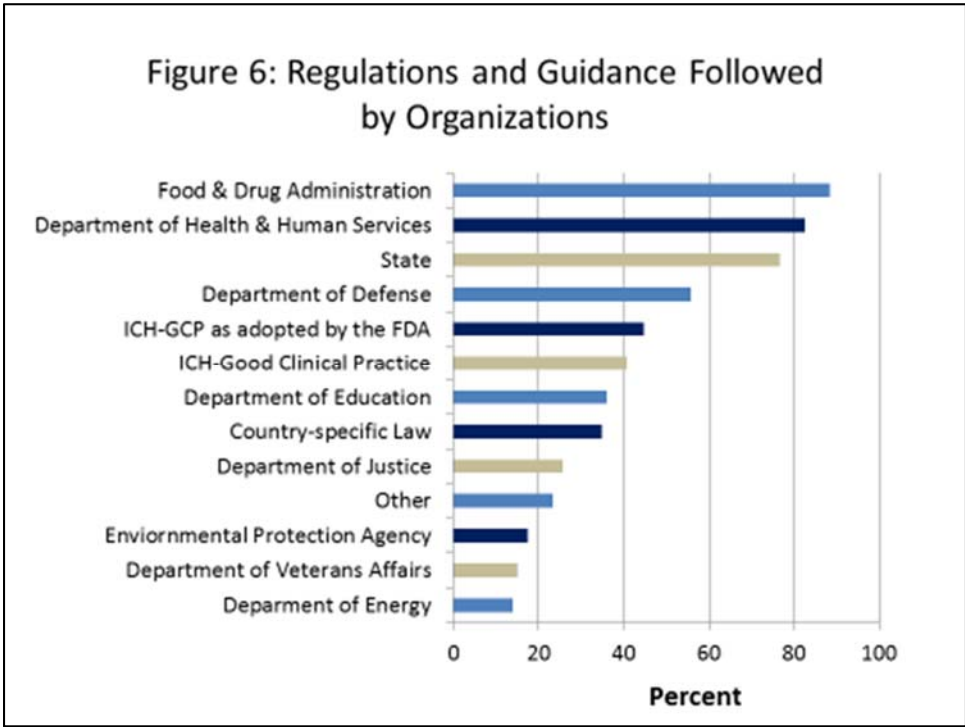


Figure 6: 88.4% of all organizations follow FDA regulations; 82.6% follow Department of Health and Human Services regulations; 76.7% follow State law; 55.8% follow Department of Defense regulations or guidelines; 44.7% follow ICH- Good Clinical Practice regulations or guidelines as adopted by the FDA; 40.7% follow ICH- Good Clinical Practice guidelines; 36% follow Department of Education regulations or guidelines; 34.9% follow country-specific laws, regulations or guidelines; 25.6% follow Department of Justice regulations or guidelines; 23.3.% follow other regulations or guidelines; 17.4% follow Environmental Protection Agency regulations or guidelines; 15.1% follow Department of Veterans’ Affairs regulations or guidelines; and 14% follow Department of Energy regulations or guidelines.

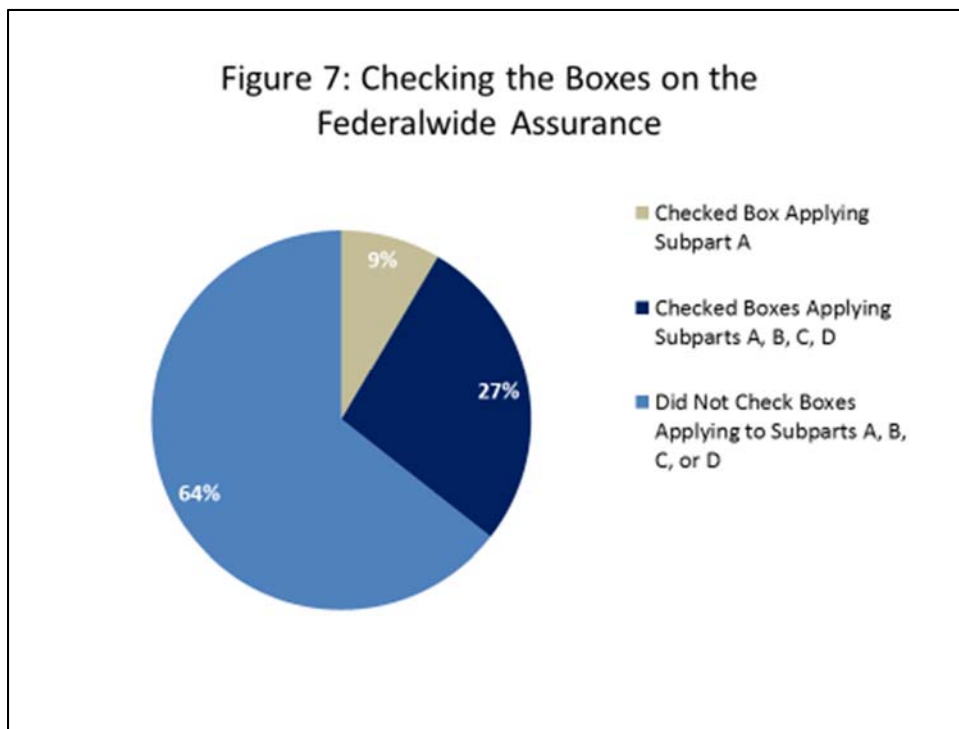


Figure 7: 64.4% of all organizations did not “check the box” to apply subparts A, B, C, or D on their Federalwide Assurance; 27.1% of all organizations did “check the box” to apply to all subparts (A, B, C, D); and 8.5% “checked the box” for subpart A only.

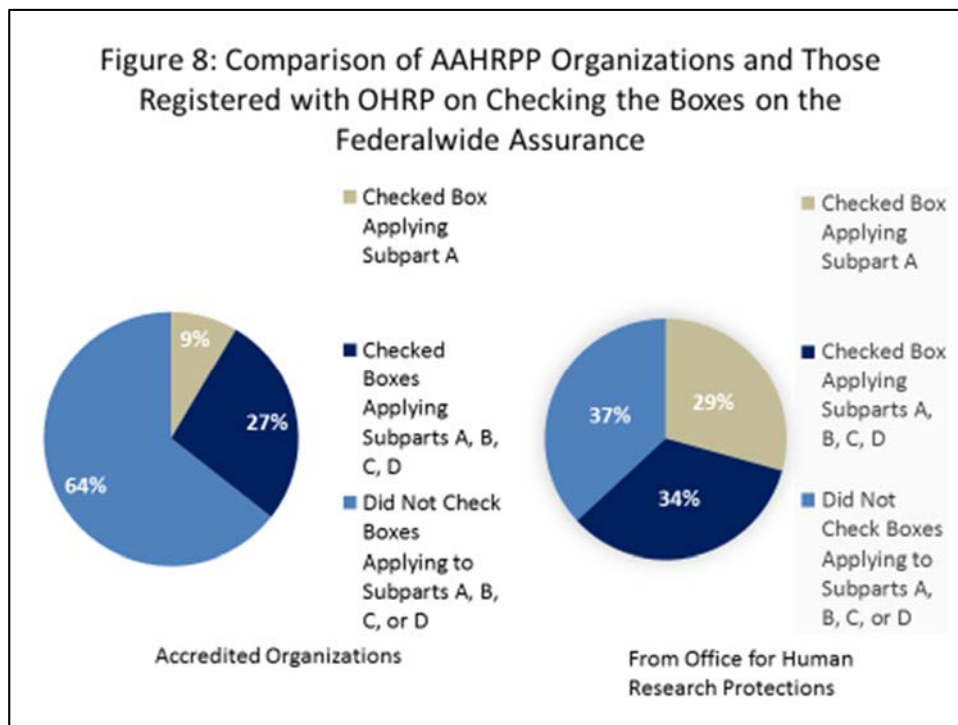


Figure 8: Compared to percentages provided by OHRP, more organizations accredited by AAHRPP or applying for AAHRPP accreditation have not “checked the box” for applying Subparts A, B, C, or D.

Figure 9. Use of IRBs

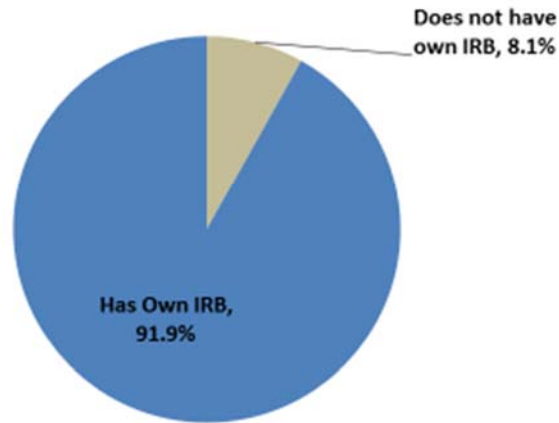


Figure 9: 91.9% of all organizations have their own IRB; 8.1% do not have their own IRB.

Figure 10. Use of External IRBs

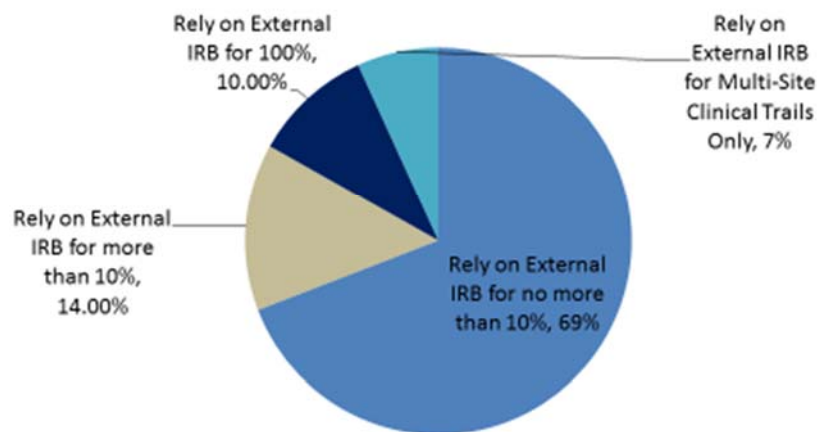


Figure 10: 69% of all organizations use external IRBs for a maximum of 10% of total protocols; 14% of organizations rely on external IRBs for more than 10% of total protocols; and 10% of all organizations rely on external IRBs for 100% of total protocols; 7% rely on external IRBs for multi-site clinical trials only.

Figure 11: Number of IRBs Per Organization

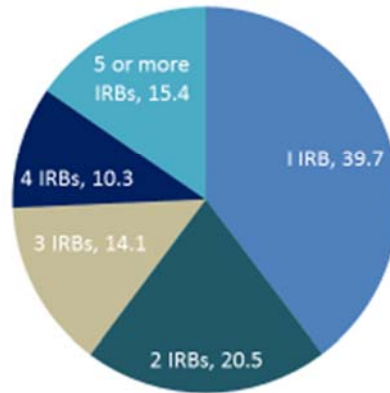


Figure 11: 39.7% of all organizations have one IRB; 20.5% have two IRBs; 14.1% have three IRBs; 10.3% have four IRBs; and 15.4% have five or more IRBs.

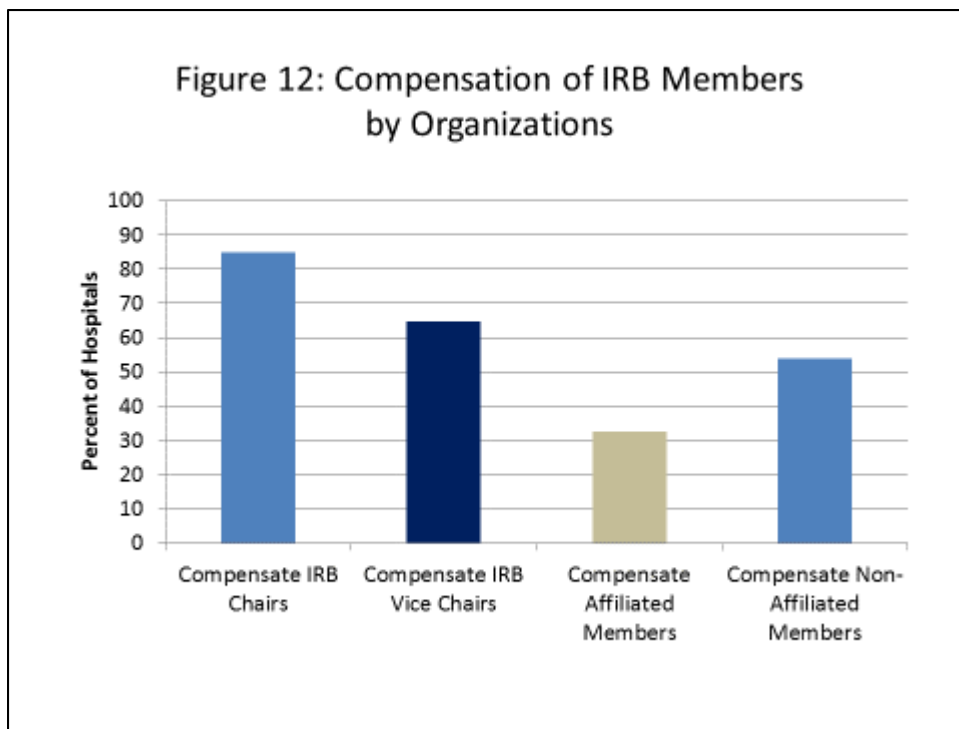


Figure 12: 84.8% of all organizations compensate IRB Chairs; 64.8% compensate IRB Vice Chairs; 32.7% compensate affiliated members; and 53.8% compensate non-affiliated members.

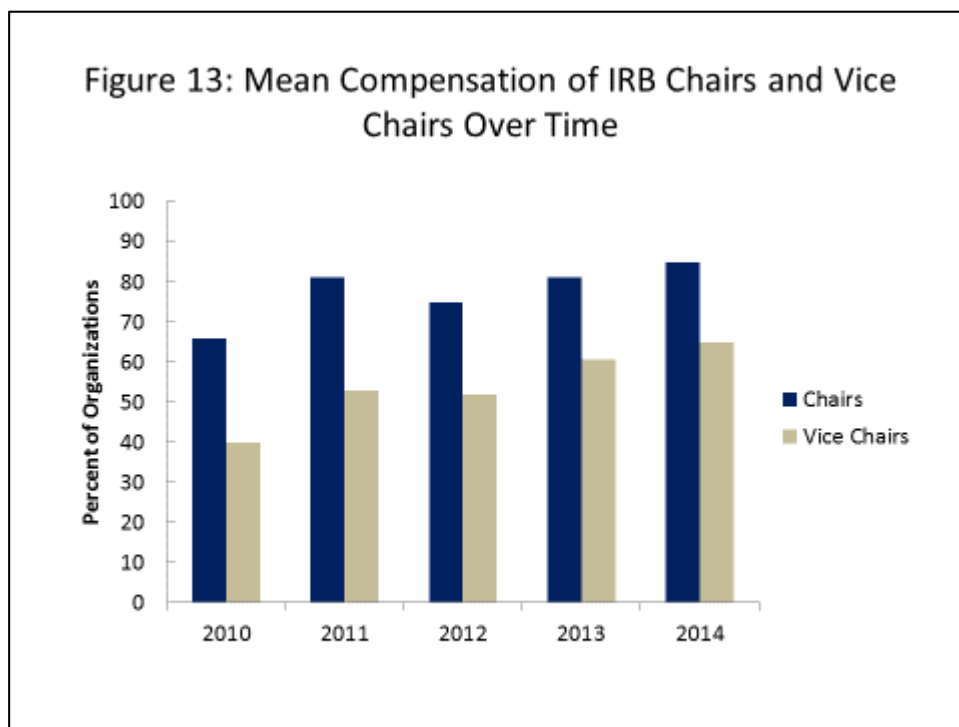


Figure 13: Generally the number of all organizations that compensate IRB Chairs and IRB Vice Chairs has increased since 2010.

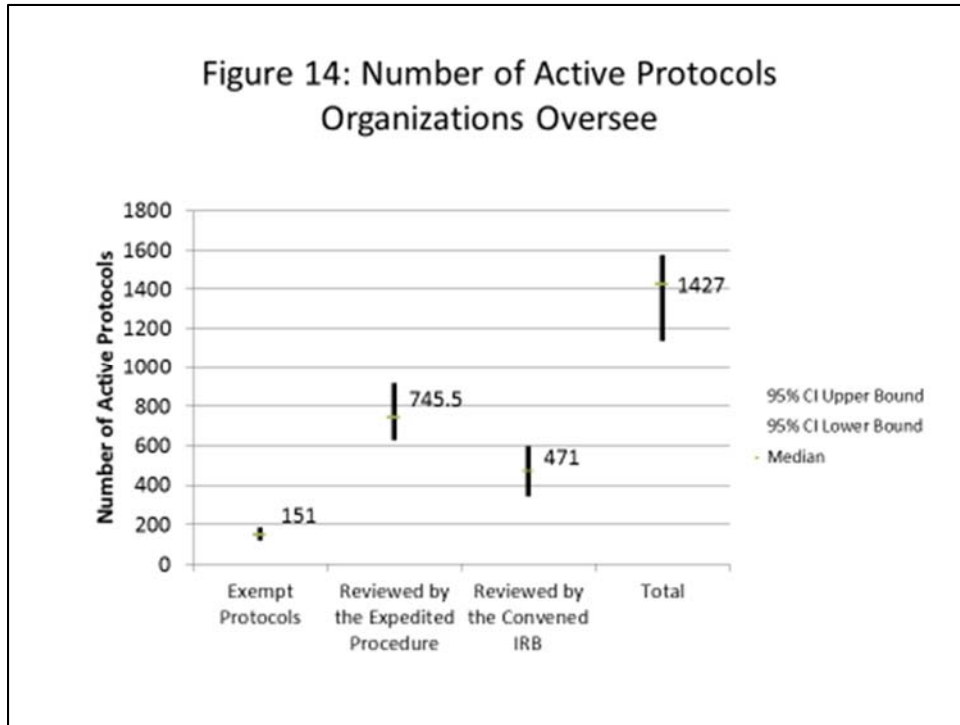


Figure 14: A median of 151 of protocols were deemed exempt by all organizations; a median of 745.5 protocols are reviewed by the expedited procedure; a median of 471 protocols are reviewed by the convened IRB; and a median of 1427 total protocols are overseen by all organizations.

Figure 15: Median Number of Active Protocols Overseen by an IRB Based on the Number of IRBs Per Organization

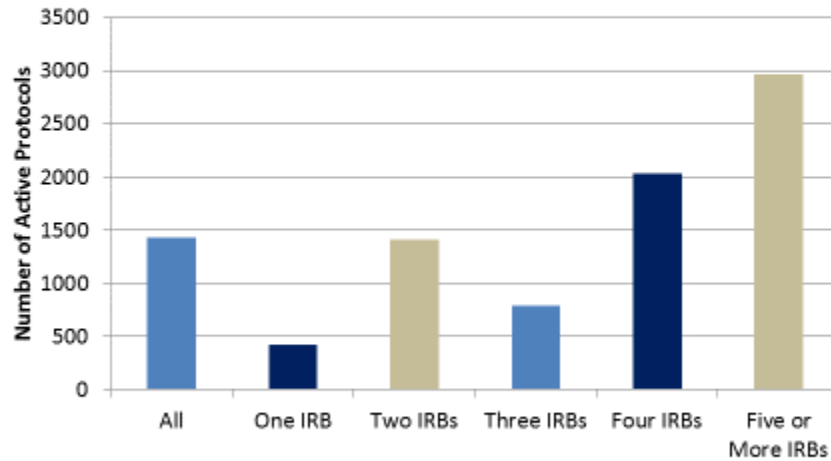


Figure 15: All organizations oversee a median of 1427 protocols; organizations with one IRB oversee a median of 420 protocols; organizations with two IRBs oversee a median of 1411 protocols; organizations with three IRBs oversee a median of 793 protocols; organizations with four IRBs oversee a median of 2031.5 protocols; and organizations with five or more IRBs oversee a median of 2970 protocols.

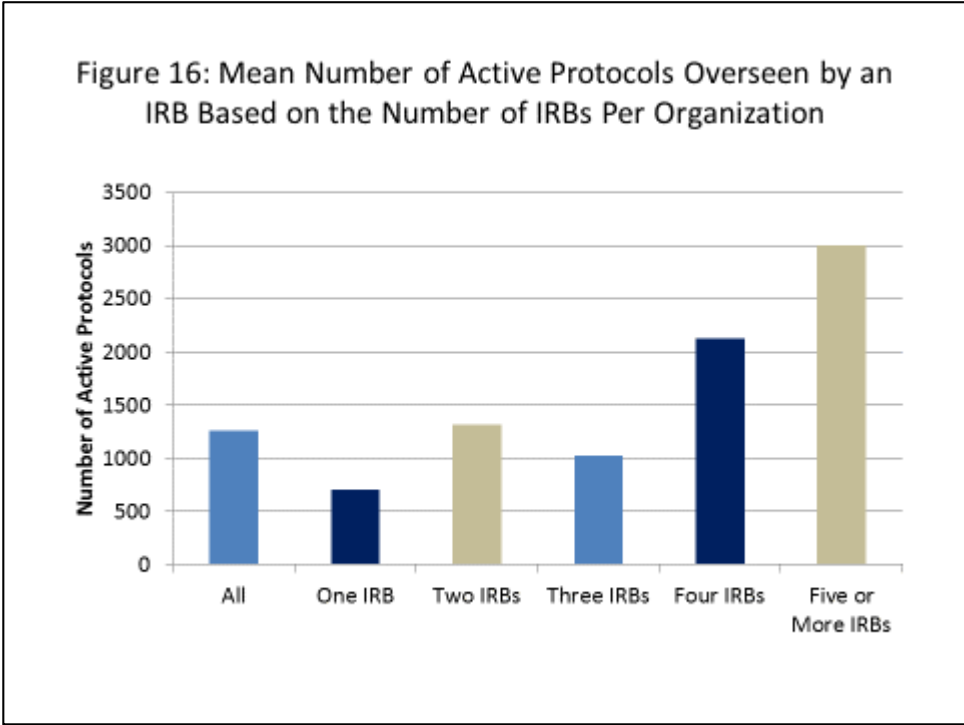


Figure 16: All organizations oversee a mean of 1258.94 protocols; organizations with one IRB oversee a mean of 707.71 protocols; organizations with two IRBs oversee a mean of 1316.63 protocols; organizations with three IRBs oversee a mean of 1025.27 protocols; organizations with four IRBs oversee a mean of 2128 protocols; and organizations with five or more IRBs oversee a mean of 3007.33 protocols.

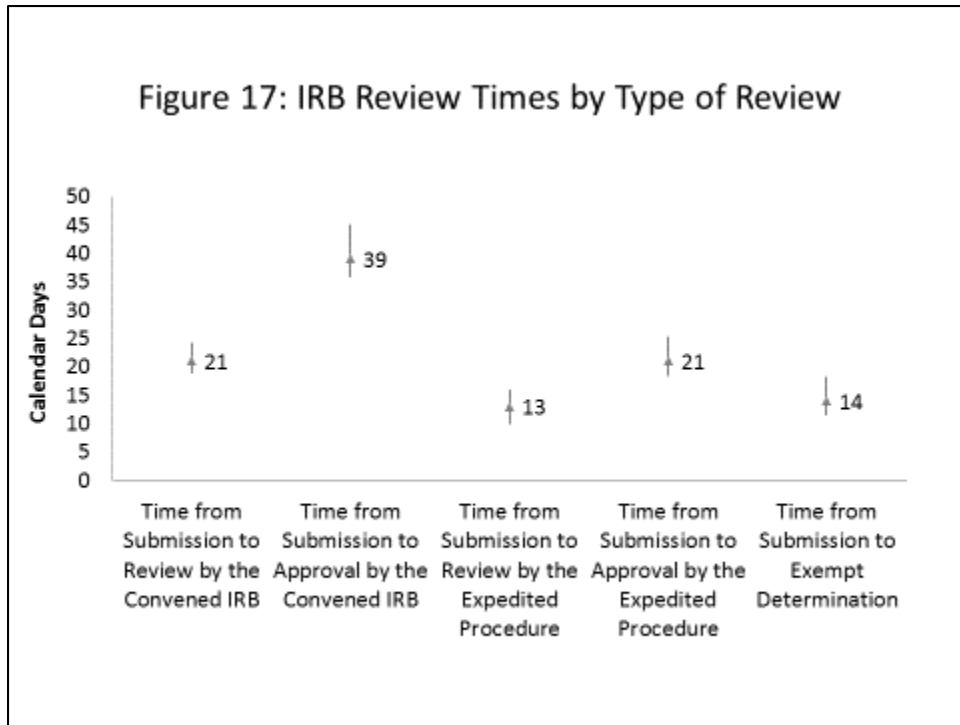


Figure 17: It takes all organizations a median of 21 calendar days from submission to review by a convened IRB meeting; a median of 39 calendar days from submission to protocol approval by convened meeting; a median of 13 calendar days from submission to protocol review by expedited review; a median of 21 calendar days from submission to protocol approval by the expedited review; and a median of 14 calendar days from submission to making determination of exemption.

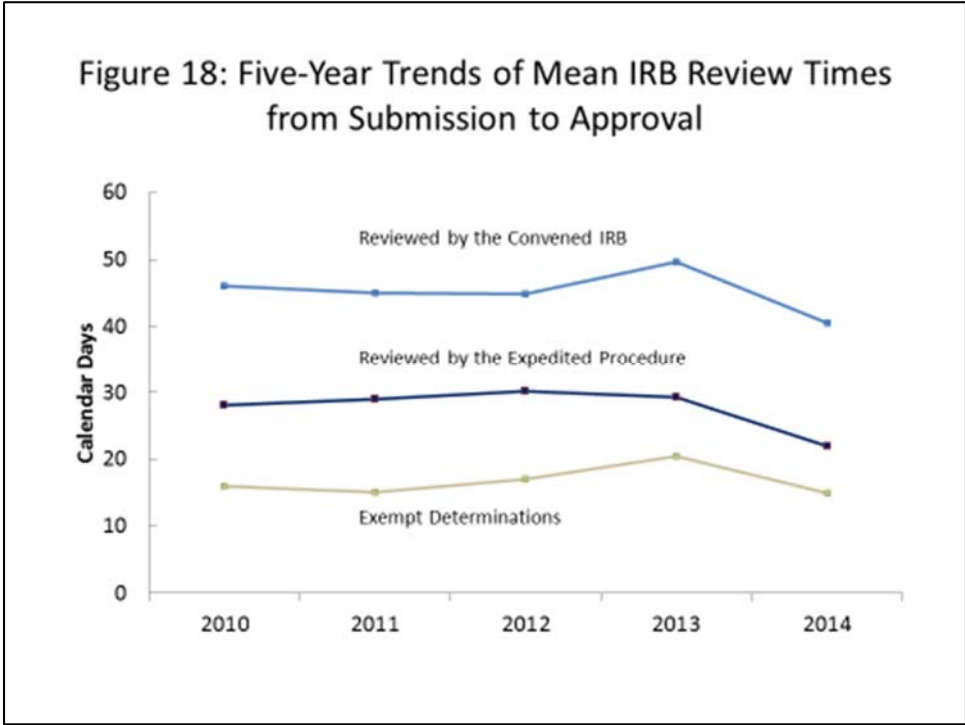


Figure 18: From 2010 to 2014 there was a decrease in review times for convened IRBs, exempt determinations and expedited reviews.

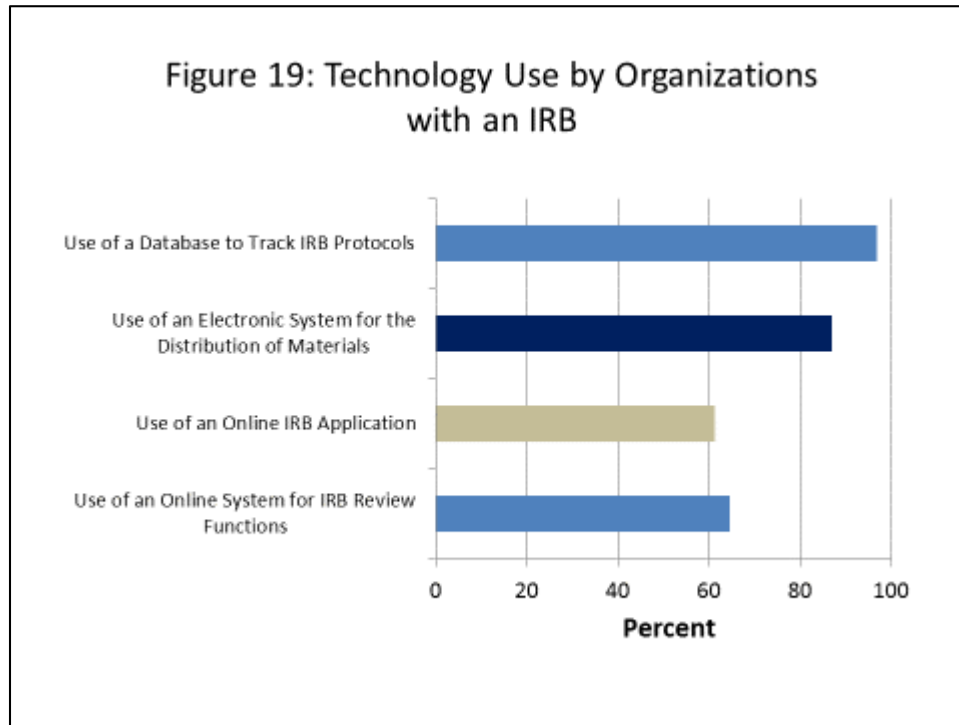


Figure 19: 96.8 % of all organizations use a database to track IRB protocols; 87.1% use an electronic system for distribution of materials; 61.3% use an online IRB application; 64.5% use an online system for IRB reviews.

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	7.5	760	101.3	\$435,000
1-100	2.5	55	22	\$125,000
101-500	3.6	320.5	89	\$239,547
501-1000	5.5	700	127.3	\$371,000
1001-2000	10.25	1443.5	140.8	\$718,025
2001-4000	16.25	2691	165.6	\$1,358,246
4000+	23	5036.5	219	\$2,399,374

Figure 20: Five-Year Trends in Mean IRB Budgets

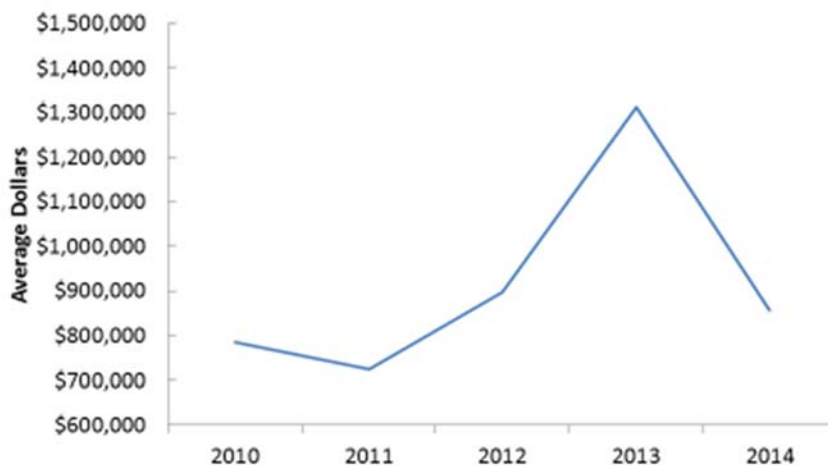


Figure 20: There has been a significant decrease in IRB budgets from 2013 to 2014.

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	4.7	30.5	1.9	17.9
Median	1	10	1	2
Min	0	0	0	0
Max	87	565	58	278

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

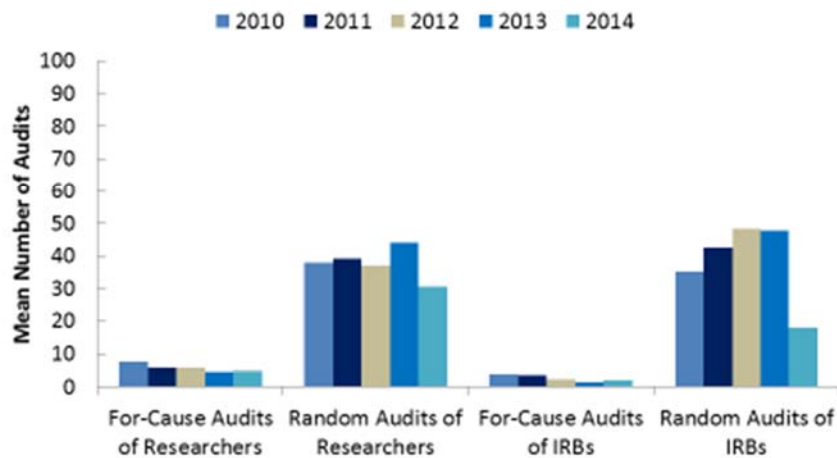


Figure 21: There has been a decrease in for-cause audits of research and for-cause audits of IRBs since 2010, the numbers remaining relatively consistent since 2013. Random audits of researchers reached the lowest number in five years as did random audits of IRBs.

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	64	1
1-100	12	0
101-500	34.5	0
501-1,000	34	0
1,001-2,000	97.5	2
2,001-4,000	113	4.5
>4,000	298	10

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

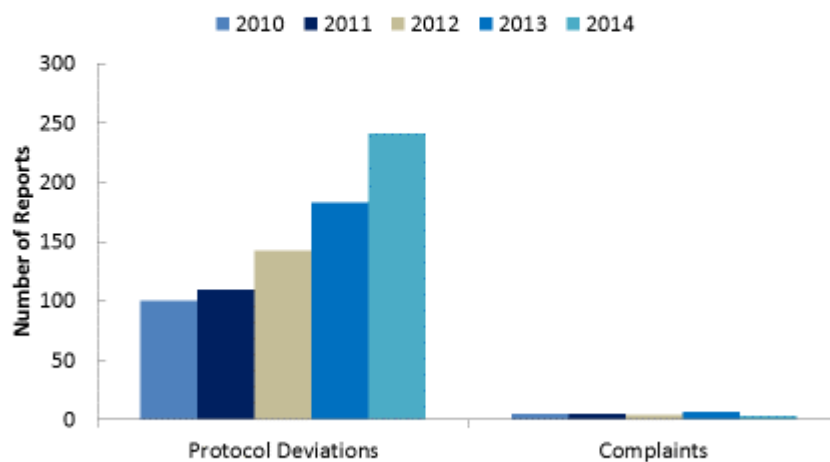


Figure 22: The number of protocol deviations has steadily increased since 2010, while the number of complaints has decreased in 2014.

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 Allegations of Serious Non-Compliance	Median Number of Allegations of Continuing Non-Compliance
All	5.5	1	0
1-100	3	.5	0
101-500	4	1	0
501-1,000	1.5	1	0
1,001-2,000	6	1	0.5
2,001-4,000	35	5	1
>4,000	39	7.5	1

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

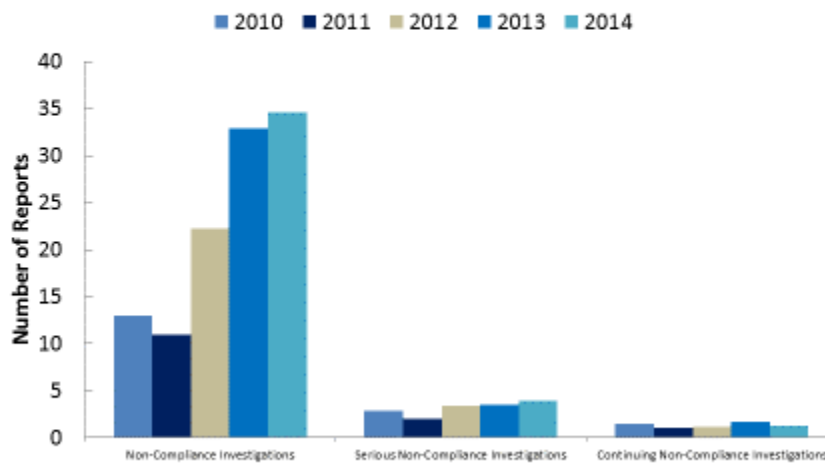


Figure 23: Investigations of alleged non-compliance have increased significantly since 2010; determinations of serious non-compliance have slightly increased since 2010; and determinations of continuing non-compliance have remained relatively consistent since 2010.



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