



2013 Metrics on Human Research Protection Program Performance

Updated August 1, 2014

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 2013 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 2013, 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 2013 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

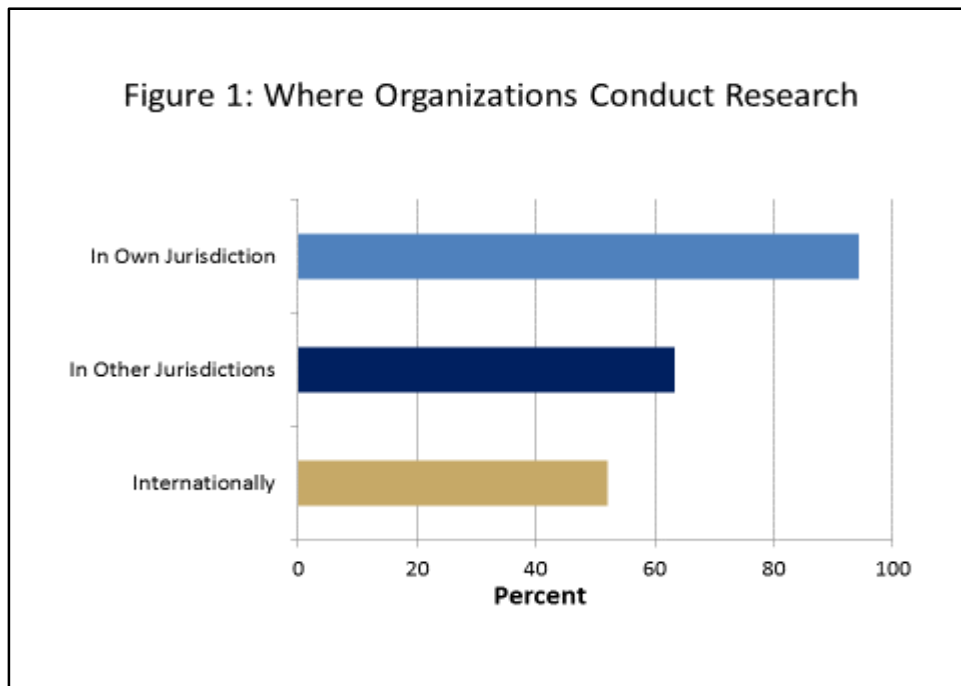


Figure 1: 94.4% of all organizations conduct research in their own jurisdictions, 63.4% in other jurisdictions, and 52.1% conduct research internationally.

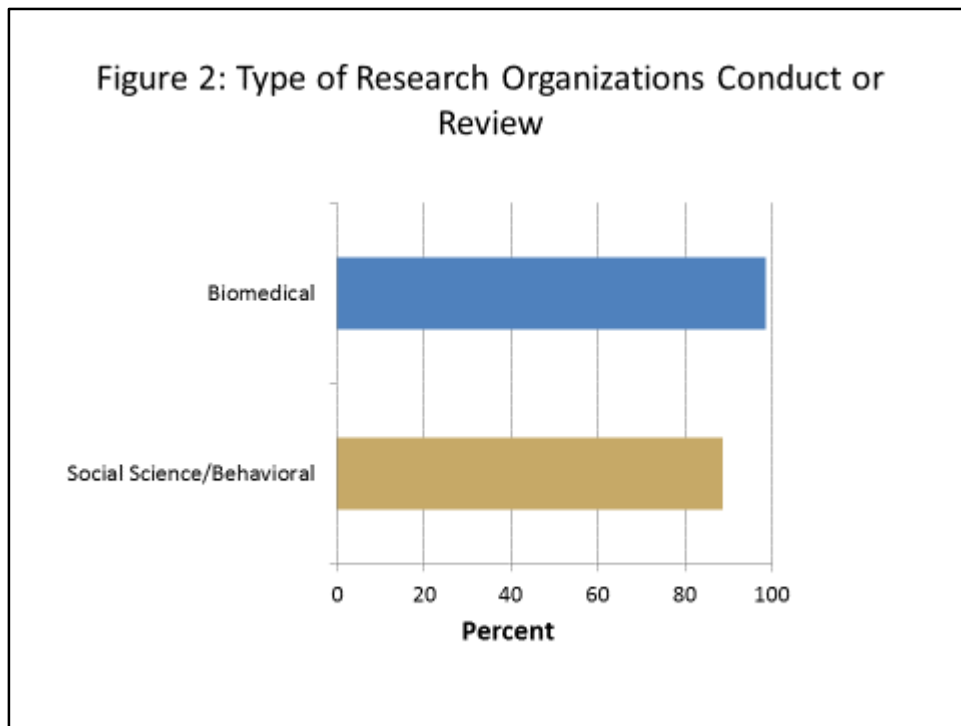


Figure 2: 98.6% of all organizations conduct Biomedical Research and 88.6% conduct Social Science/Behavioral Research.

Selected Types of Research Conducted or Overseen by Organizations

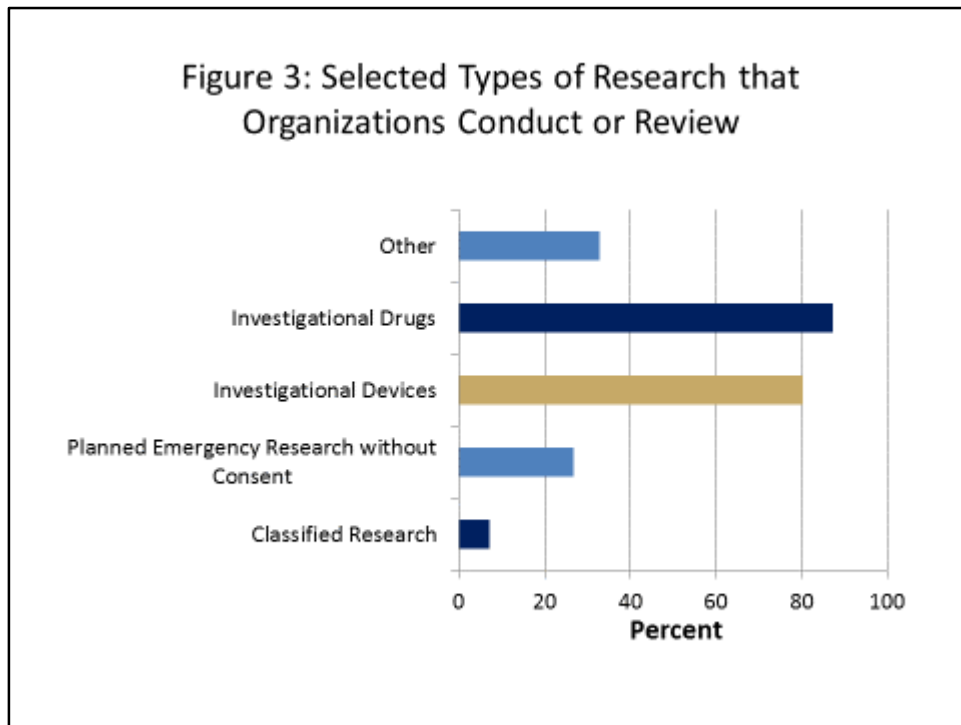


Figure 3: 87.3% of organizations utilize Investigational Drugs, 80.3% utilize Investigational Devices, 26.8% of organizations conduct research with Planned Emergency Research without Consent, and 7.2% conduct Classified Research.

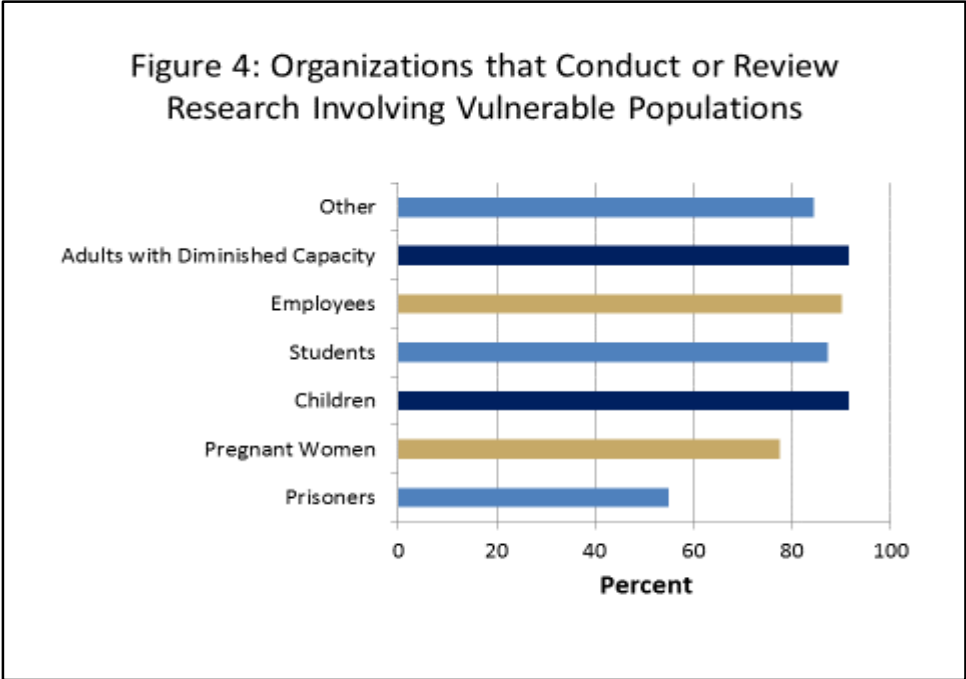


Figure 4: 91.5% of all organizations conduct research involving Children, 91.5% conduct research involving Adults with Diminished Capacity, 90.1% conduct research involving Employees, 87.3% conduct research involving Students, 77.5% conduct research involving Pregnant Women, 54.9% conduct research involving Prisoners, and 84.5% conduct research involving populations not listed in the survey.

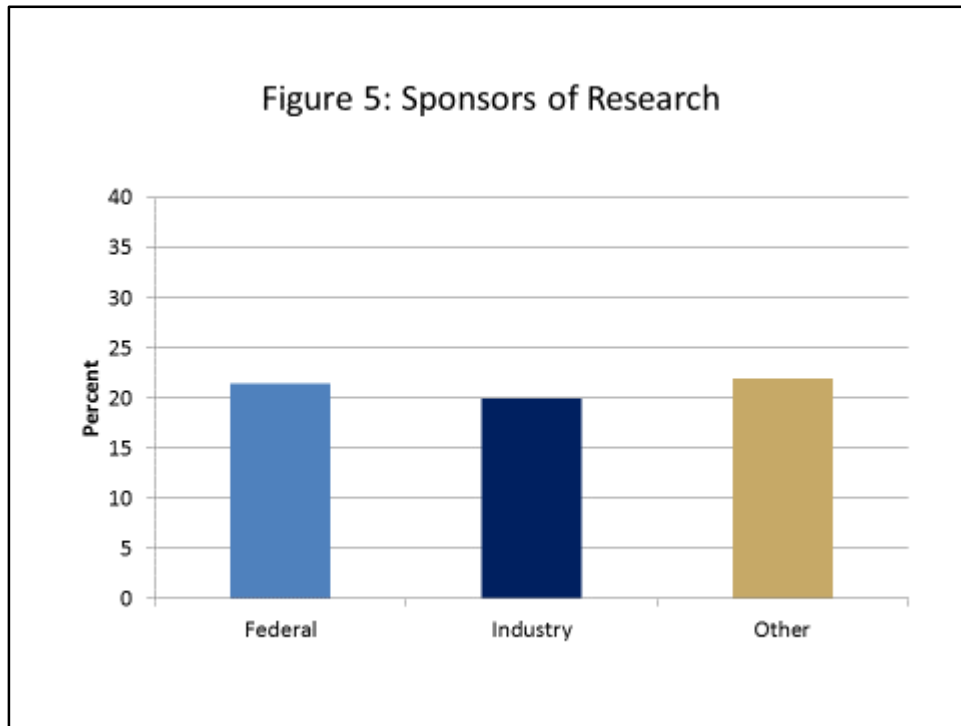


Figure 5: 21.5% of research is federally sponsored, 20% of research is sponsored by industry and 22% by other sponsors.



Figure 6: 83.3% of all organizations follow FDA regulations or guidelines, 78.6% follow regulations or guidelines of their State, 78.6 % follow Department of Health and Human Services regulations or guidelines, 71.4% follow ICH- Good Clinical Practice regulations or guidelines, 59.5% follow Department of Defense regulations or guidelines, 42.9% follow Country-specific regulations or guidelines, 26.2% follow Department of Justice regulations or guidelines, 21.4% follow Department of Energy regulations or guidelines, 16.7% follow Environmental Protection Agency regulations or guidelines, 14.3% follow Department of Veterans’ Affairs regulations or guidelines, and 11.9% follow Other regulations or guidelines.

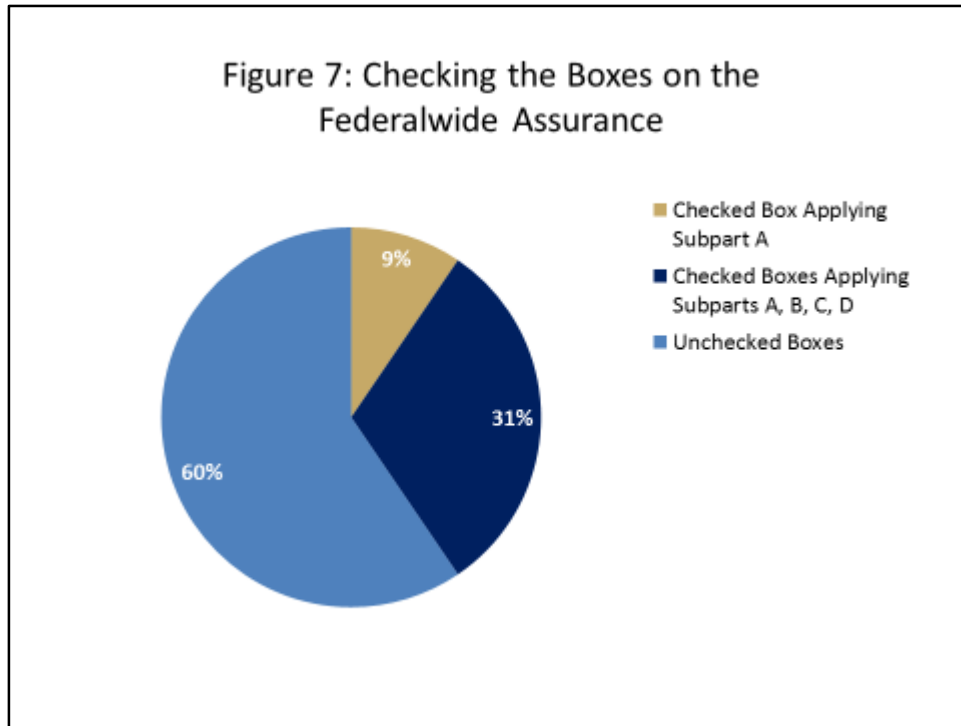


Figure 7: 60% of all organizations Uncheck the Box regarding Federalwide Assurance, 31% of all organizations Check boxes Applying to All Subparts (A, B, C, D), and 9% Checked the Box Only for Subpart A.

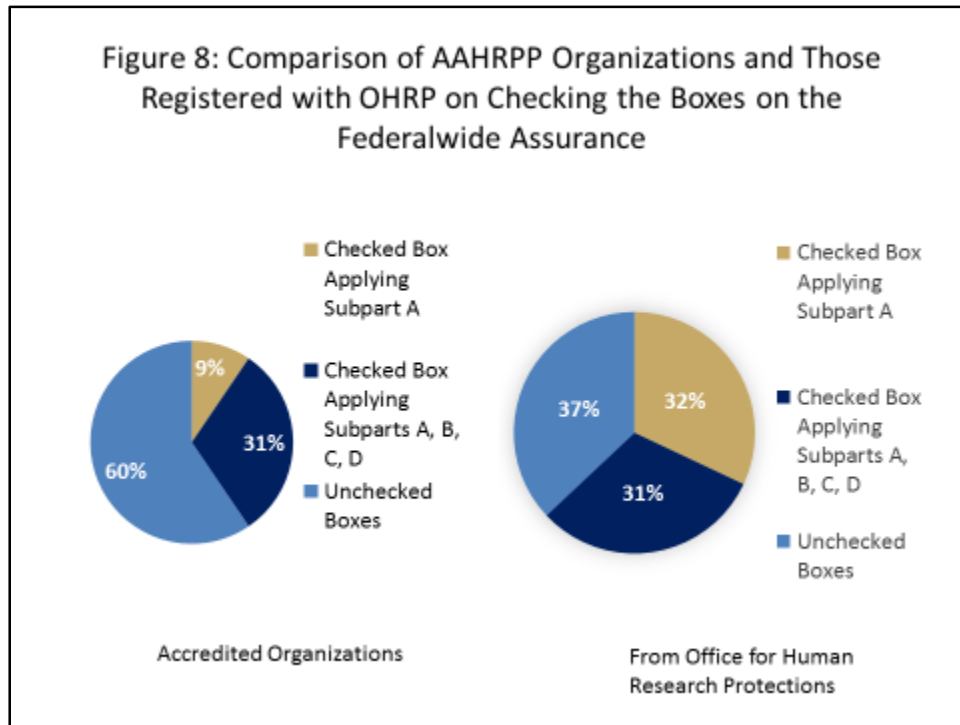


Figure 8: Compared to percentages provided previously by OHRP, more organizations accredited by AAHRPP or applying for AAHRPP accreditation unchecked the box.

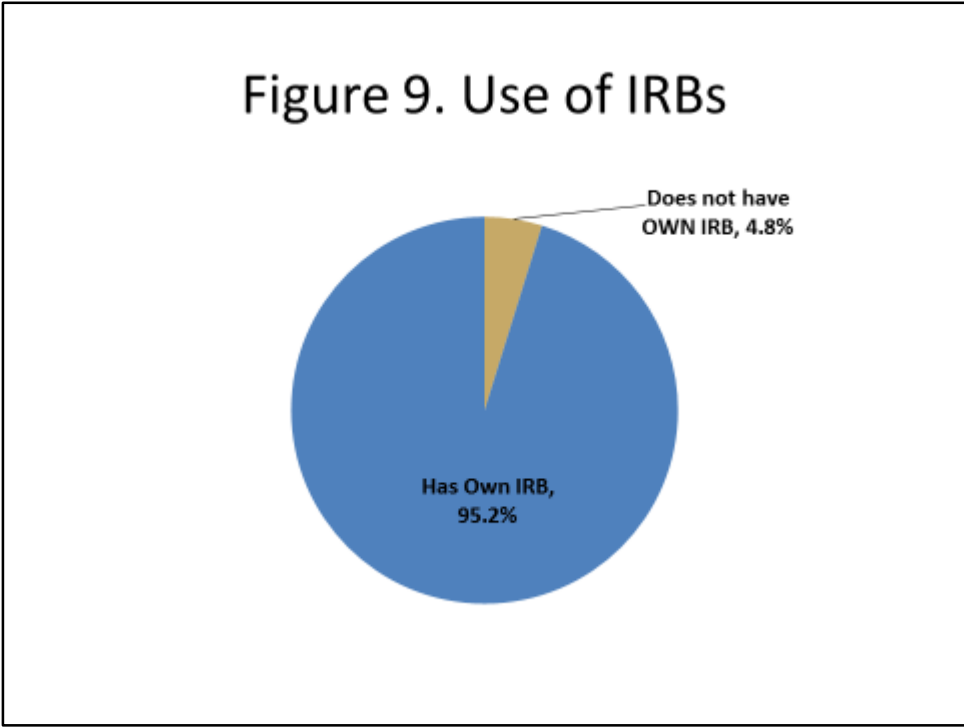


Figure 9: 95.2% of all organizations have their Own IRB while 4.8% do not have their Own IRB.

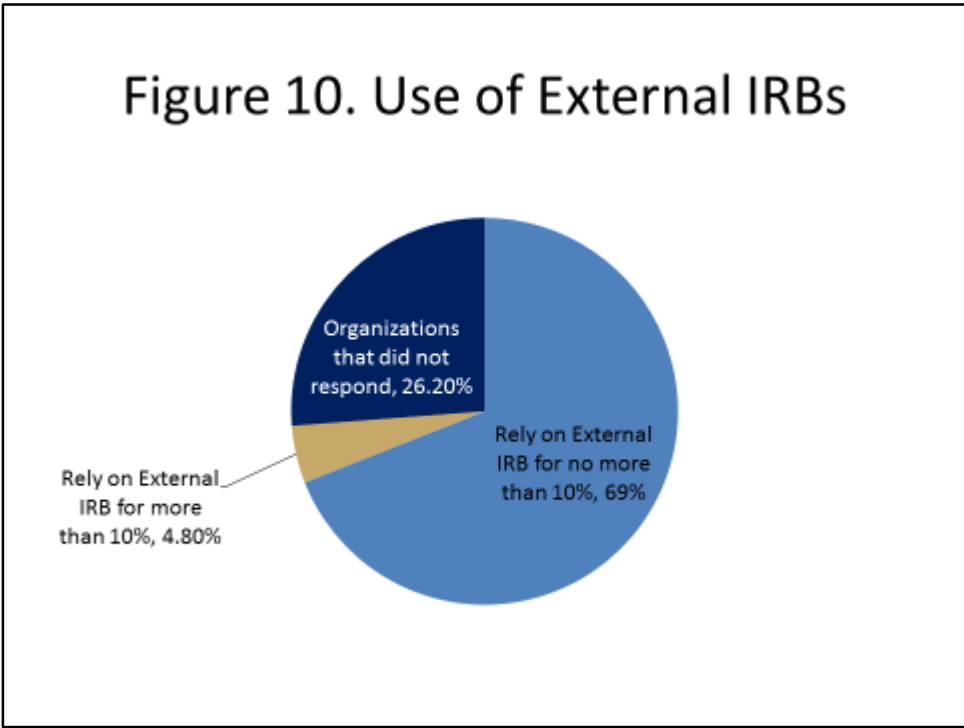


Figure 10: 69% of all organizations use External IRBs for a maximum of 10% of total protocols, 4.8% of organizations rely on External IRBs for more than 10% of total protocols, and 26.2% of all organizations did not respond.

Figure 11: Number of IRBs Organizations Have

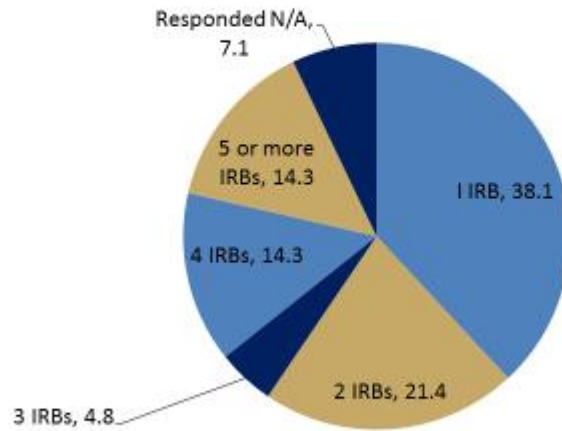


Figure 11: 38.1% of all organizations have One IRB, 21.4% have Two IRBs, 4.8% have Three IRBs, 14.3% have Four IRBs, 14.3% have Five or More IRBS, and 7.1% of all organizations did not respond.

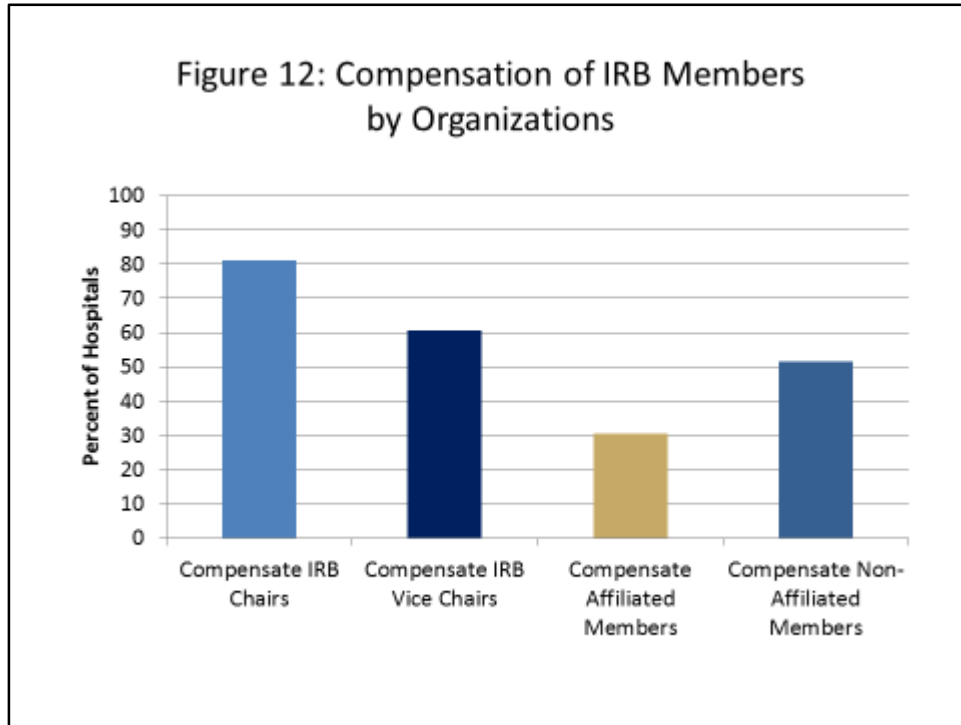


Figure 12: 81% of all organizations Compensate IRB Chairs, 60.7% compensate IRB Vice Chairs, 30.6% Compensate Affiliated Members, and 51.6% Compensate Non-Affiliated Members.

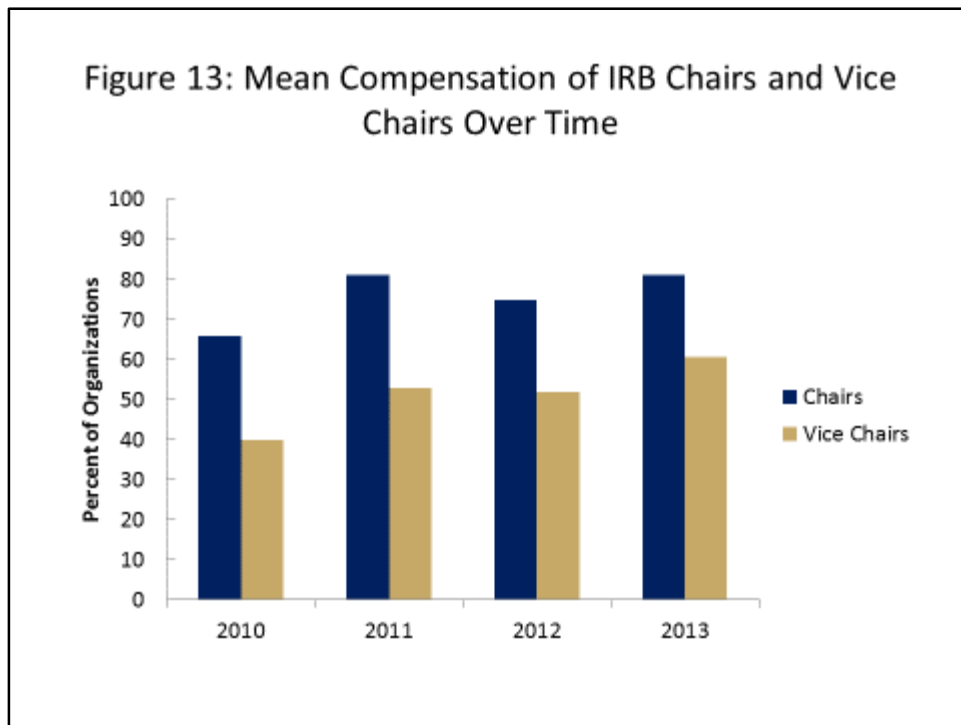


Figure 13: Generally the number of all organizations that compensate IRB Chairs and IRB Vice Chairs has increased since 2010.

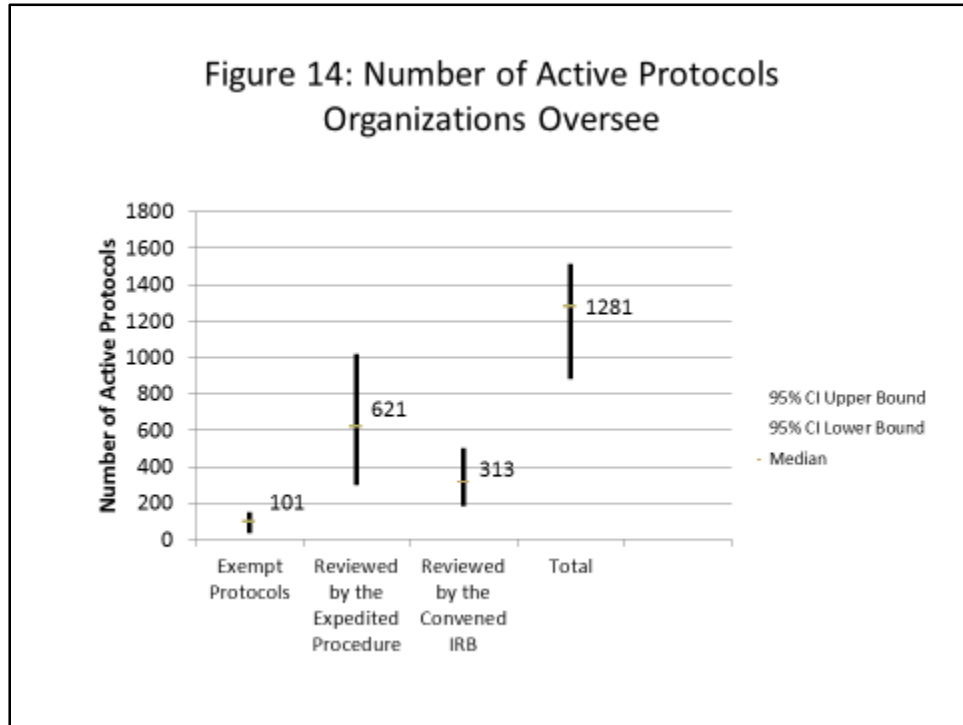


Figure 14: A median of 101 Exempt Protocols are overseen by all organizations, a median of 621 protocols are Reviewed by the Expedited Procedure, a median of 313 protocols are Reviewed by the Convened IRB, and a median of 1281 Total Protocols are overseen by all organizations.

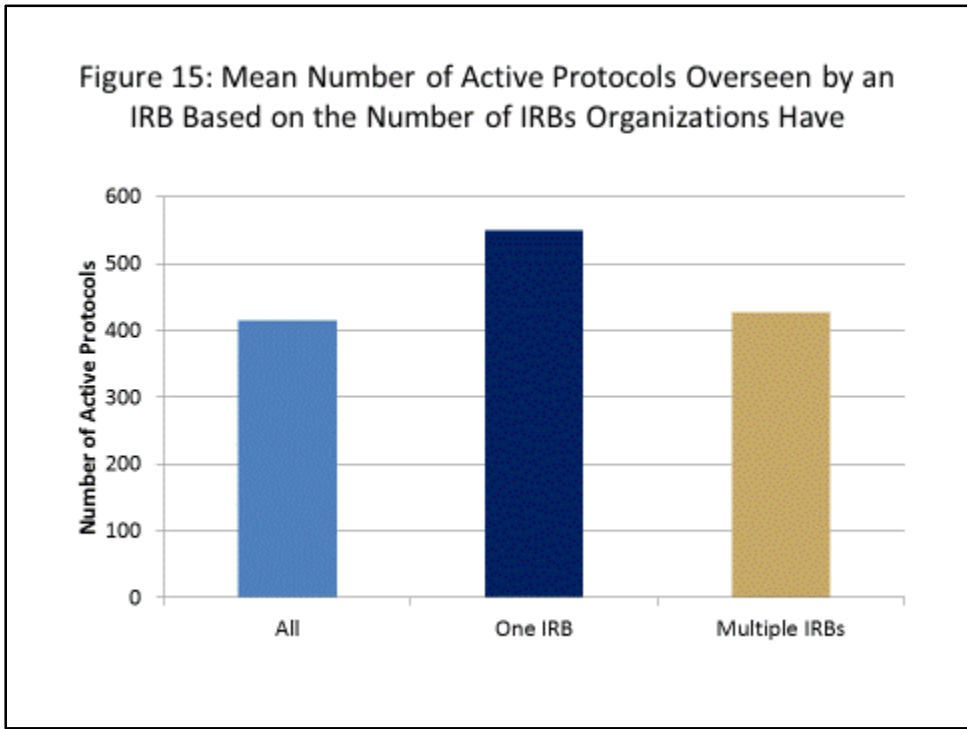


Figure 15: All organizations oversee a mean of 414.3 protocols per IRB, organizations with One IRB oversee a mean of 549.3 protocols and organizations with Multiple IRBs oversee a mean of 426.6 protocols per IRB.

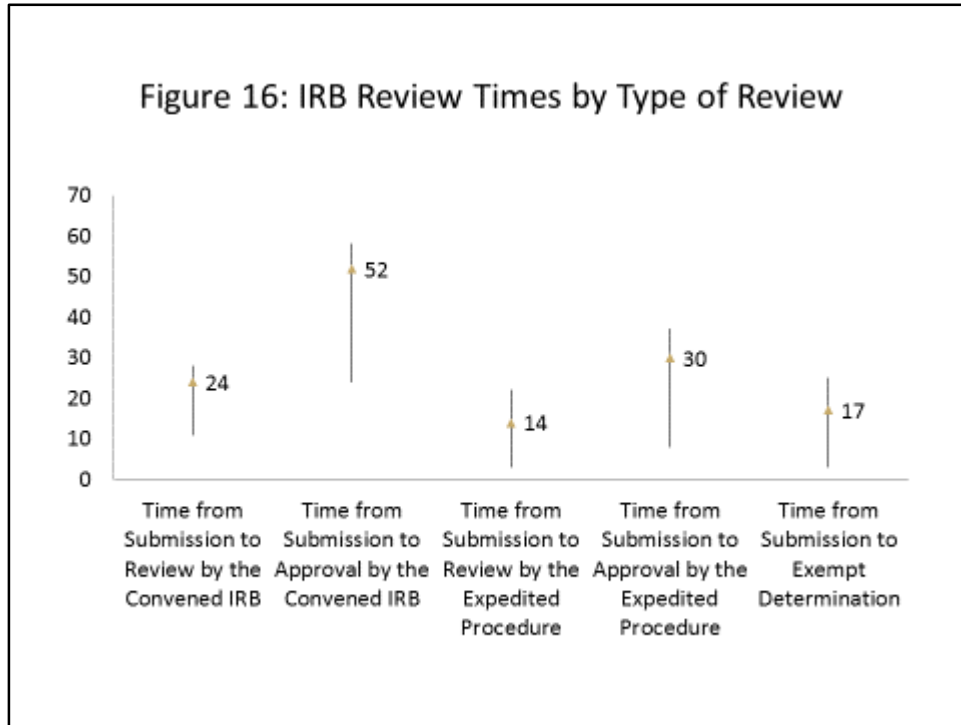


Figure 16: It takes all organizations a median of 24 Calendar Days from Submission to Review of a Protocol, a median of 52 Calendar Days from Submission to Protocol Approval, a median of 14 Calendar Days from Submission to Protocol Review by Expedited Procedure, a median of 30 Calendar Days from Submission to Protocol Approval by the Expedited Procedure, and a median of 17 Calendar Days from Submission to Exempt Protocol Determination.

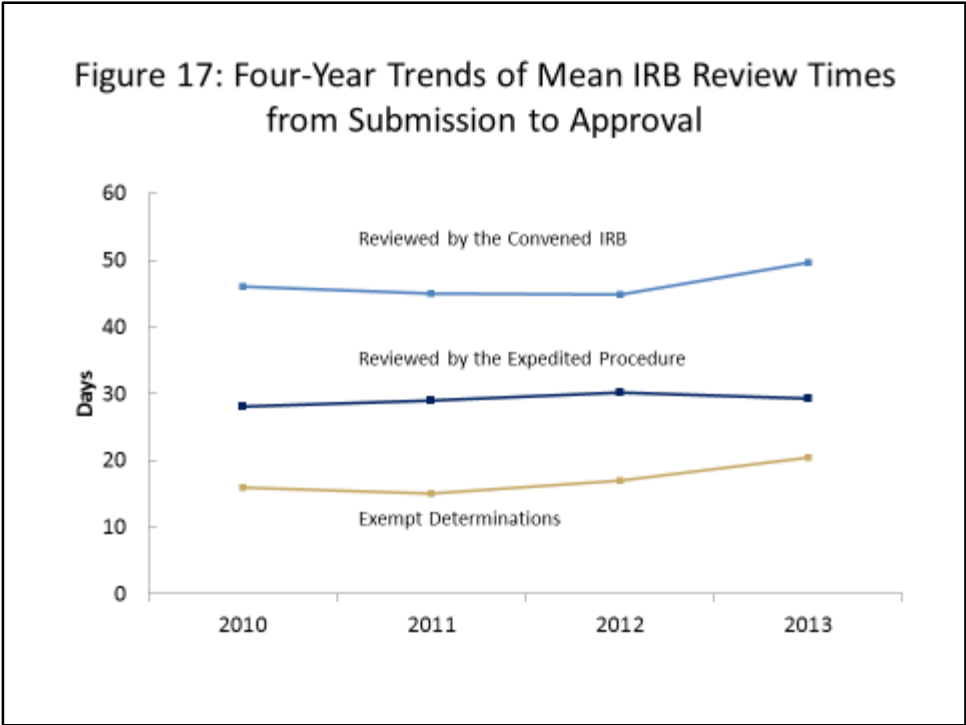


Figure 17: There was a decrease for Review Times for Expedited Review; Exempt Determinations and Convened IRB Review Times saw a slight uptick.

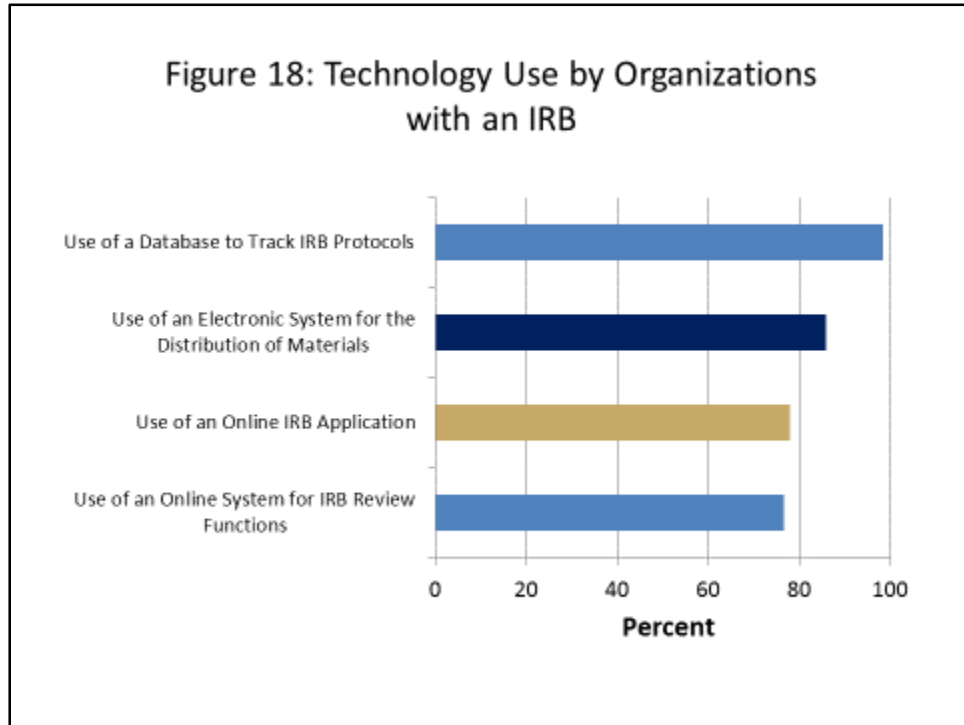


Figure 18: 98.4 % of all organizations use a Database to Track IRB Protocols, 85.9% use an electronic System for Distribution of Materials, 78.1% use an Online IRB Application, and 76.6% use an Online System for IRB Reviews.

Figure 19: Mean Technology Use by Organizations with an IRB – Four Year Trends

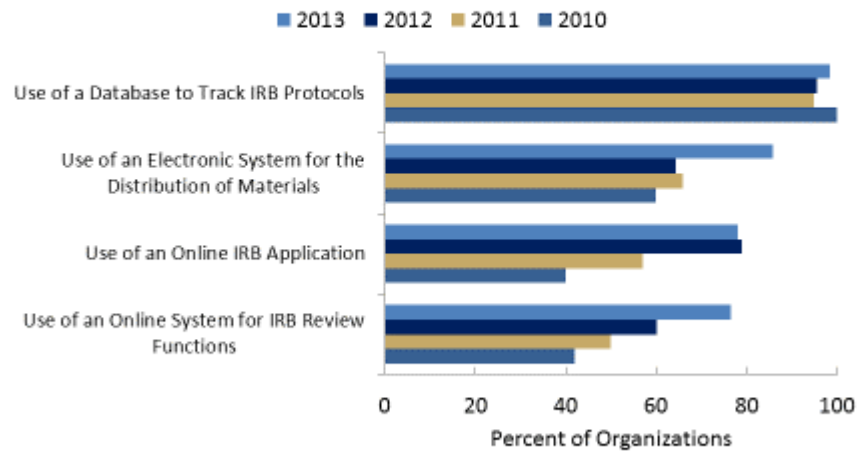


Figure 19: Use of a Database to Track IRB Protocols has steadily risen since 2011. Generally, since 2010, there has been an increase in organizations using Electronic Systems for Distribution of Materials as well as those that use an Online System for IRB Review Functions.

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	9	1281	142.3	1,034,878
1-100	4	38	9.5	650,00
101-500	2	241	120.5	246,957
501-1000	3.3	772.5	234.1	399,532
1001-2000	11.5	1412.5	122.8	1,141,575
2001-4000	11.7	2308	197.3	1,685,000
4000+	21	5011	238.6	3,040,254

Figure 20: Four-Year Trends in Mean IRB Budgets

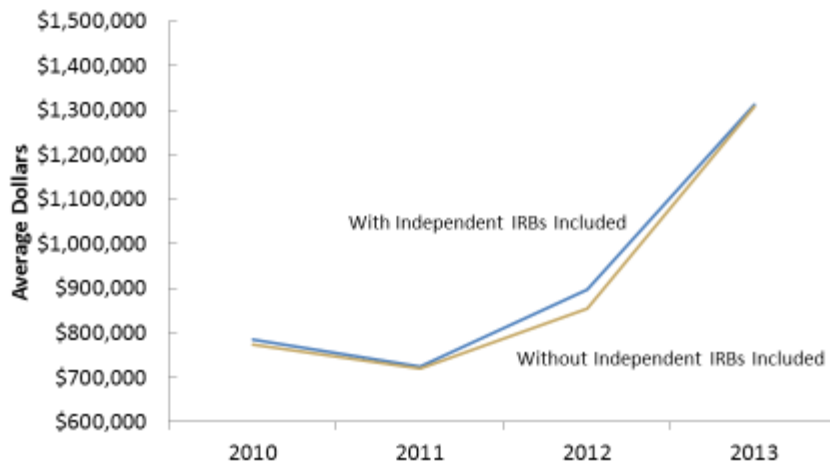


Figure 20: IRB budgets have increased since 2010.

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	4.5	44	1.5	47.7
Median	2	20.0	0.0	3
Min	0	0	0	0
Max	26	480	29	1076

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

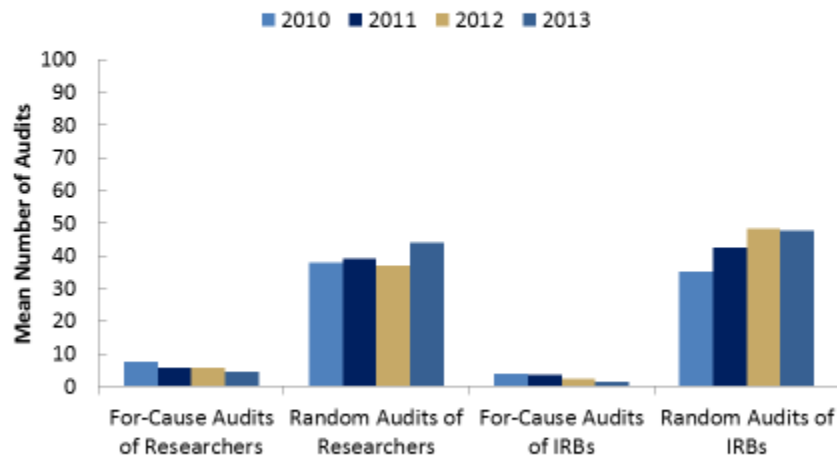


Figure 21: There has been a decrease in For-Cause Audits of Research and For-Cause Audits of IRBs since 2010. Random Audits of Researchers and IRBs have increased since 2010.

Protocol Deviations and Complaints Reported to the IRB

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	99.5	2
1-100	11	0.0
101-500	8	1
501-1,000	58	1.5
1,001-2,000	229.5	4.5
2,001-4,000	298	2
>4,000	234	6.5

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

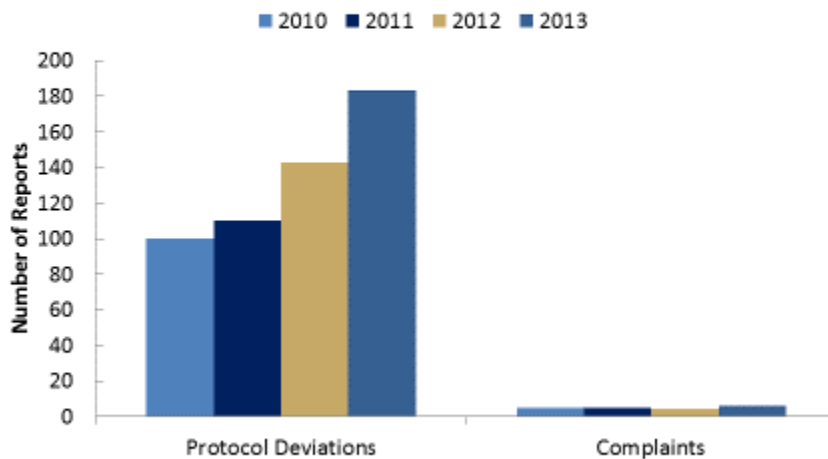


Figure 22: Reported Protocol Deviations have increased since 2010 while Complaints have remained relatively static.

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	6	1	0
1-100	3	0	0.0
101-500	8	0	0
501-1,000	2	1	0
1,001-2,000	6	1	0
2,001-4,000	9	3	1
>4,000	2.5	2.5	0

Figure 24: Four-Year Trends in Mean Number of Reported Cases of Non-Compliance

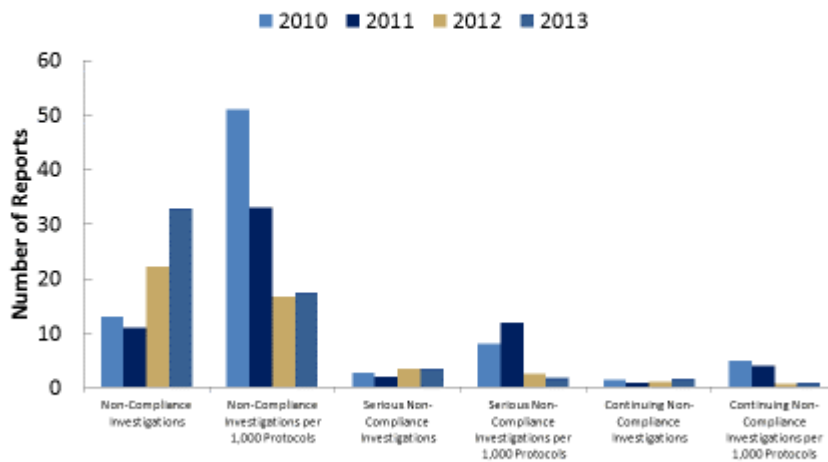


Figure 23: Overall, Non-Compliance Investigations have increased since 2010. However, the number of Non-Compliance Investigations per 1,000 protocols has decreased since 2010. Since 2010 there has been a slight increase in Serious Non-Compliance Investigations. Serious Non-Compliance Investigations per 1,000 protocols has significantly decreased. Continuing Non-Compliance Investigations remained flat from 2010-2013 while significantly decreasing per 1,000 Protocols.



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