



# 2014 Metrics on Human Research Protection Program Performance for Hospitals

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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 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 Hospitals

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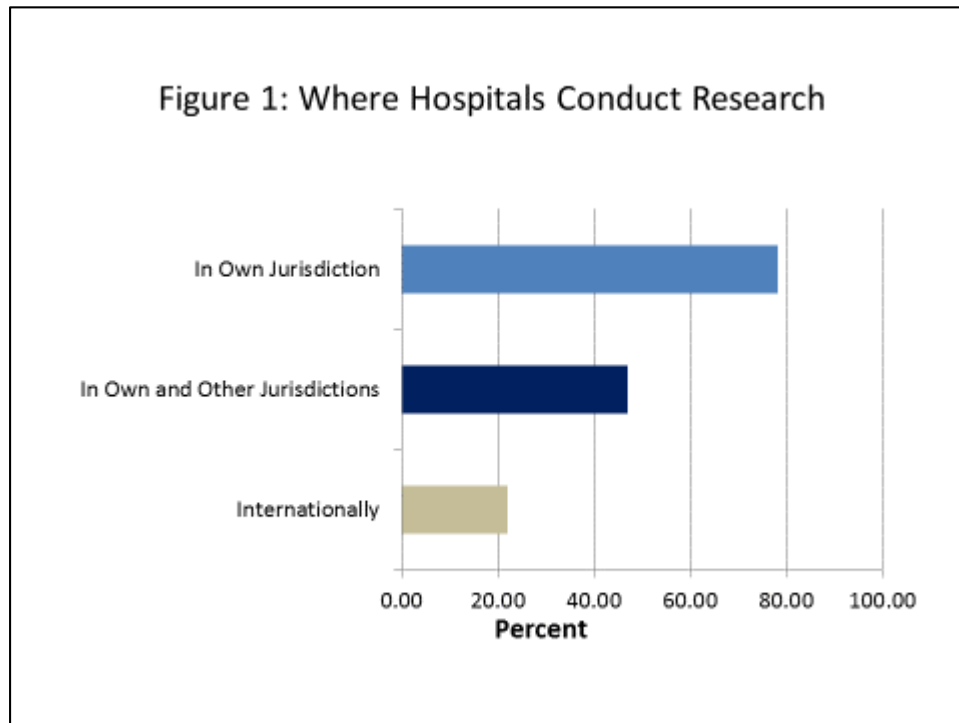


Figure 1: 78.1% of hospitals conduct research within their own jurisdictions; 46.9% conduct research within their own and other jurisdictions; and 21.9% conduct research internationally.

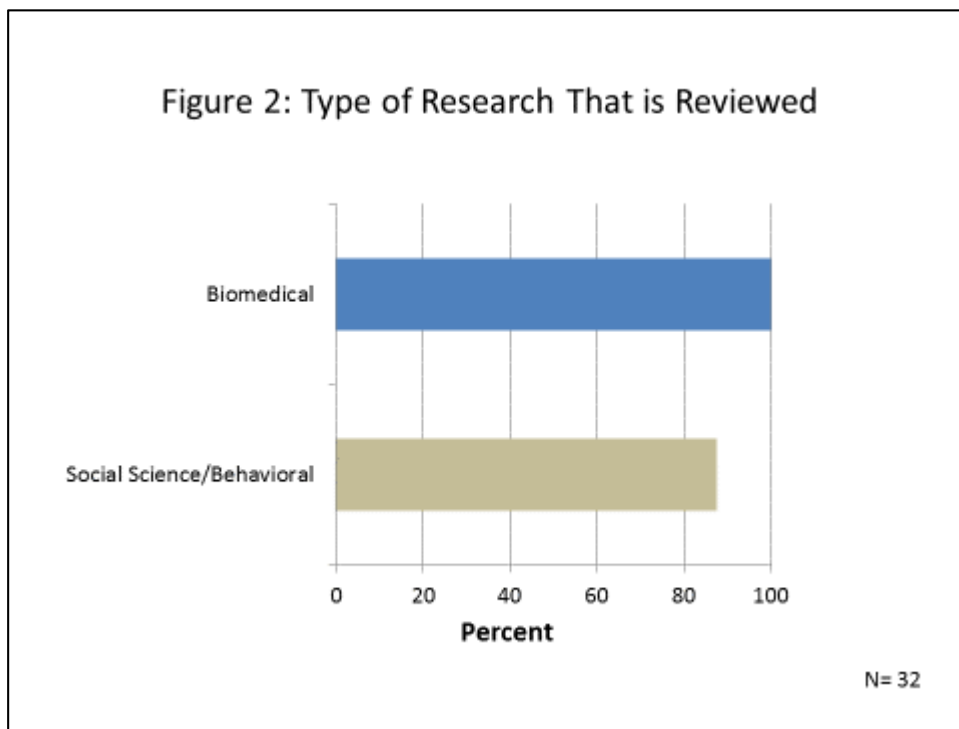
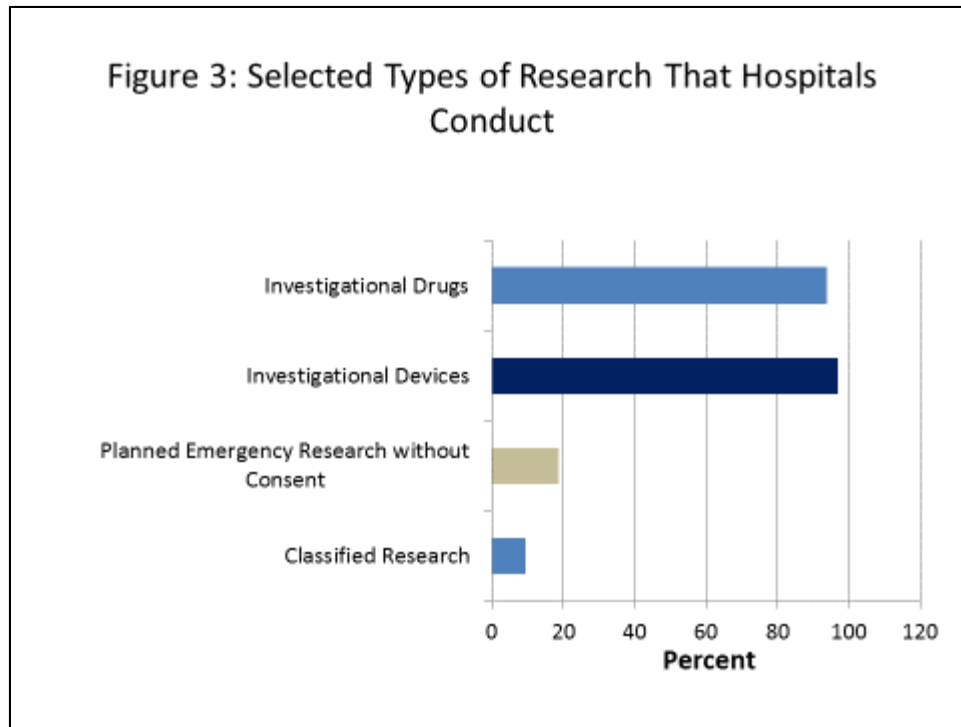


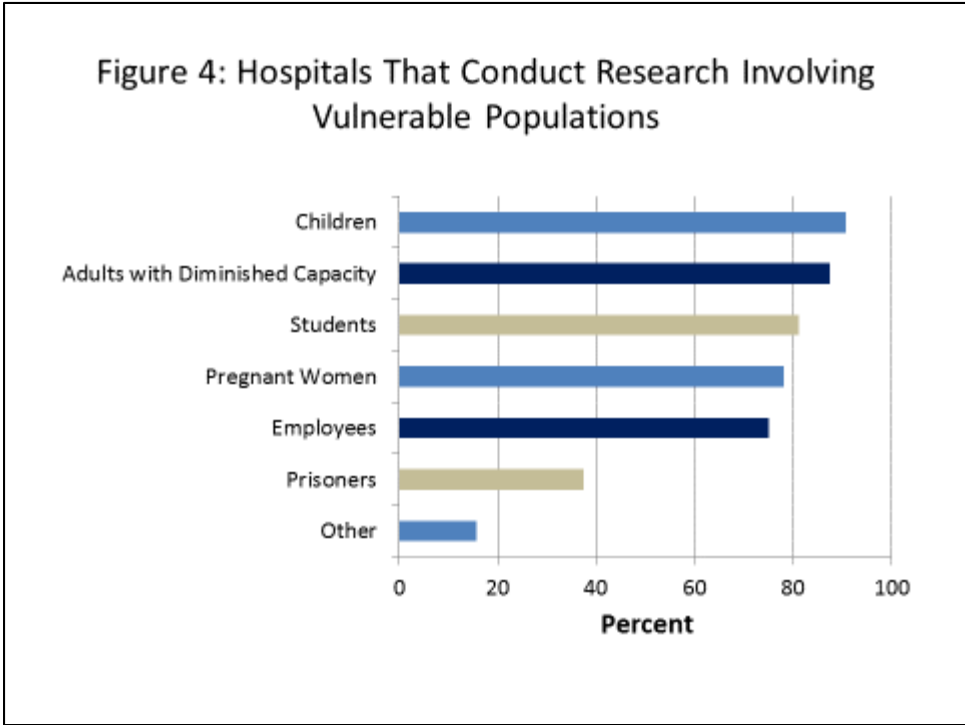
Figure 2: 100% of hospitals conduct biomedical research; 87.5% conduct social/behavioral research.

## Selected Types of Research Conducted or Overseen by Hospitals

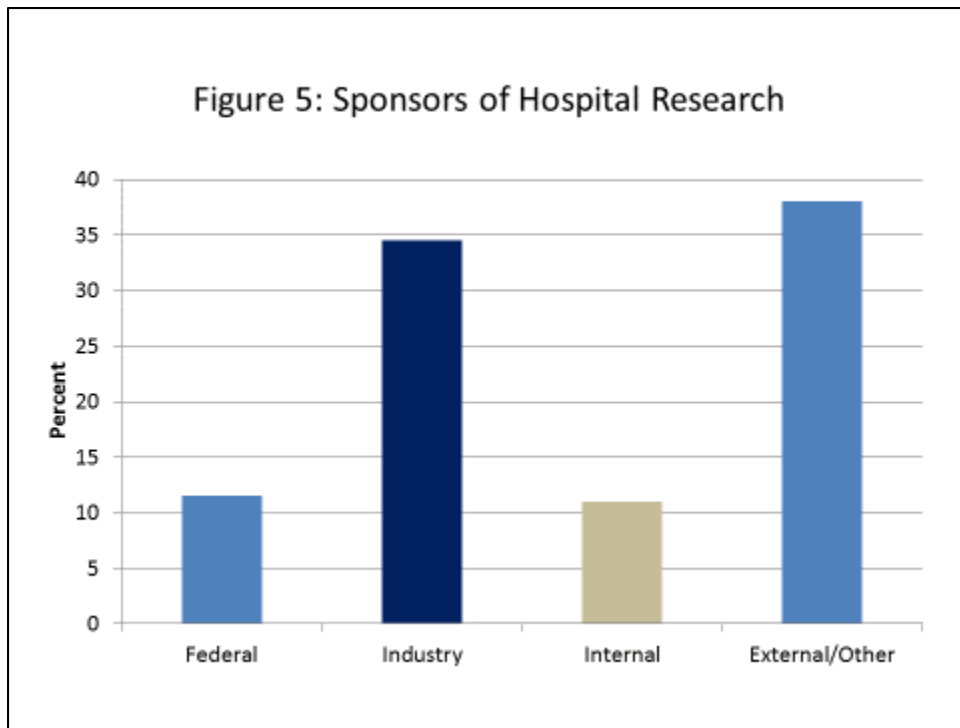
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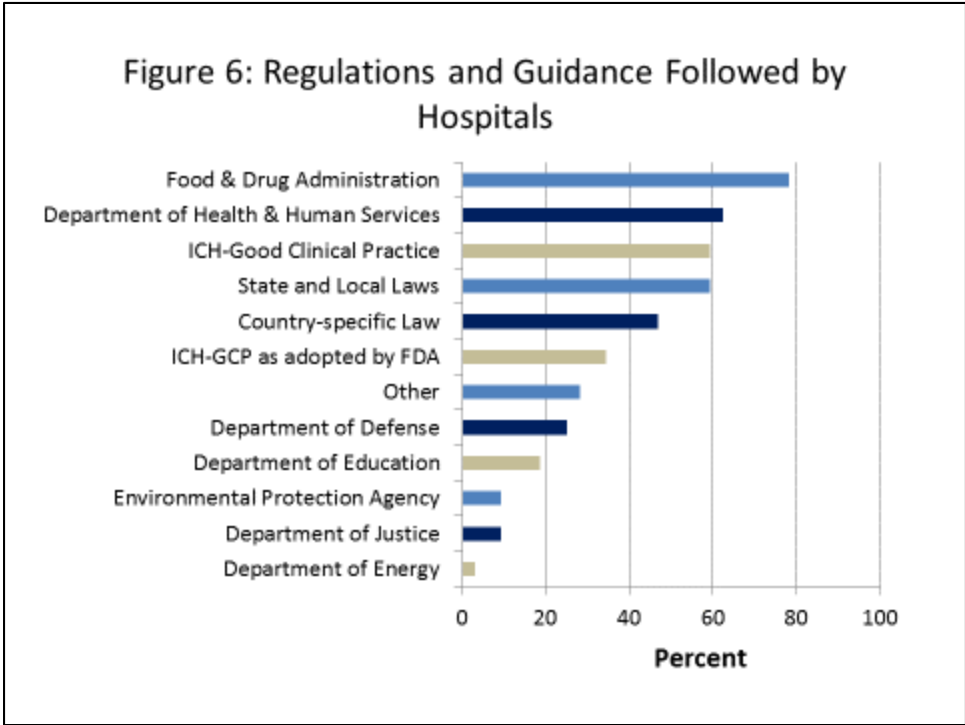
**Figure 3:** 93.75% of hospitals conduct research with investigational drugs; 96.9% conduct research using investigational devices; 18.75% conduct classified research; and 9.38% conduct planned emergency research without consent.



**Figure 4:** 90.6% of hospitals conduct research with children; 87.5% conduct research with adults with diminished capacity; 81.25% conduct research with students; 78.1% conduct research with pregnant women; 75% conduct research with employees; 37.5% conduct research with prisoners; and 15.6% conduct research with other vulnerable populations.

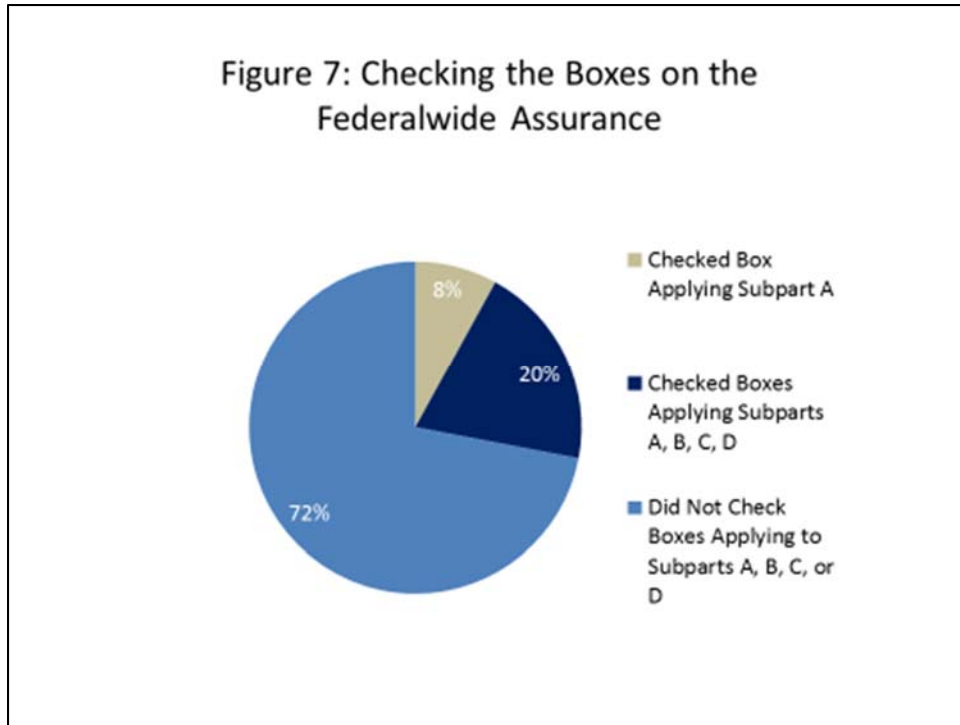


**Figure 5:** Hospitals report a median of 34.5% of industry-sponsored research; 10.95% of internally-sponsored research; and 38% of externally/other-sponsored research.

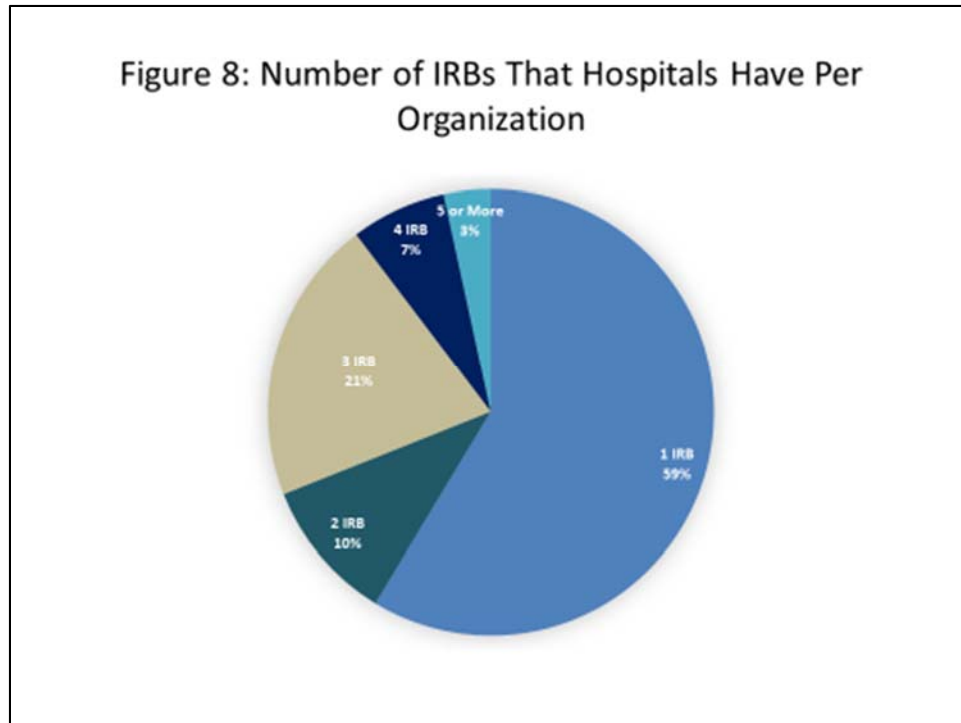


**Figure 6:** 78.1% of hospitals follow FDA regulations; 62.5% follow Department of Health and Human Services regulations; 59.4% follow ICH- Good Clinical Practice guidelines; 59.4 follow State law; 46.9% follow country-specific laws, regulations or guidelines; 34.4% follow ICH- Good Clinical Practice regulations or guidelines as adopted by the FDA; 28.1.% follow other regulations or guidelines; 25% follow Department of Defense regulations or guidelines; 18.75% follow Department of Education regulations or guidelines; 9.4% follow Environmental Protection Agency regulations or guidelines; and 9.4% follow Department of Justice regulations or guidelines; 3.1% follow Department of Energy regulations or guidelines.

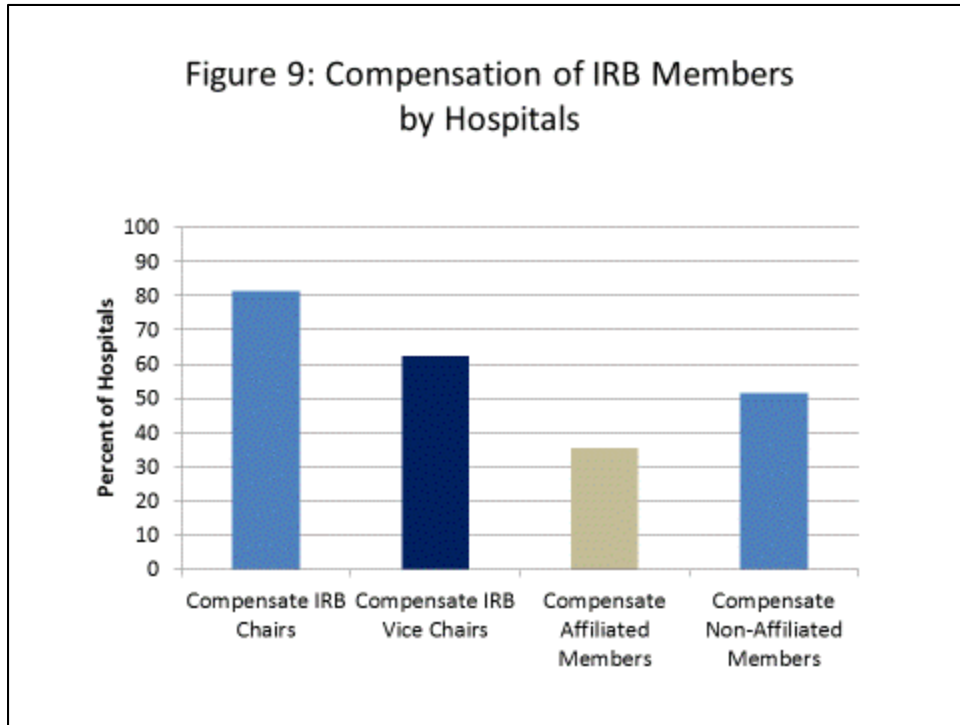




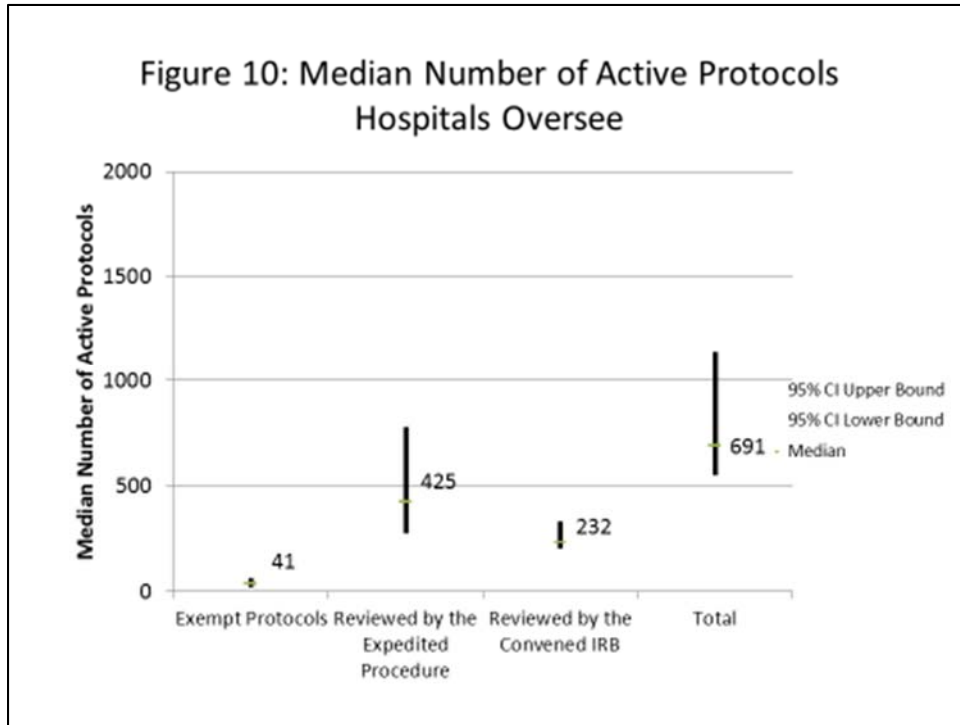
**Figure 7:** 72% of hospitals did not “check the box” to apply subparts A, B, C, or D on their Federalwide Assurance; 20% of all organizations did “check the box” to apply to all subparts (A, B, C, D); and 8% “checked the box” for subpart A only.



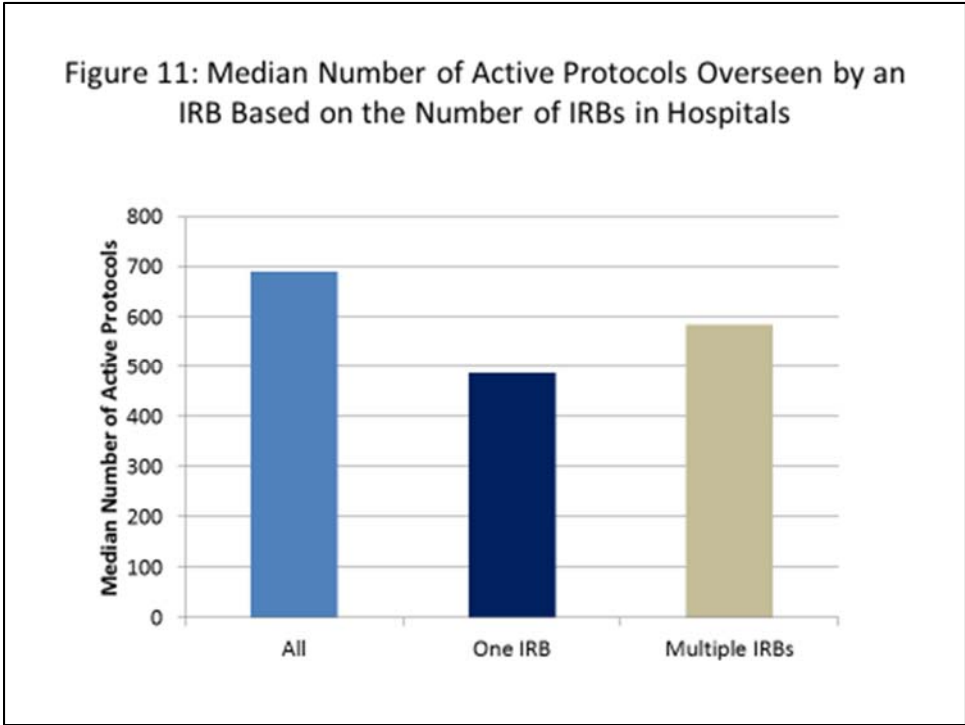
**Figure 8:** 58.6% of hospitals have one IRB; 10.3% have two IRBs; 20.7% have three IRBs; 6.9% have four IRBs; and 3.4% have five or more IRBs.



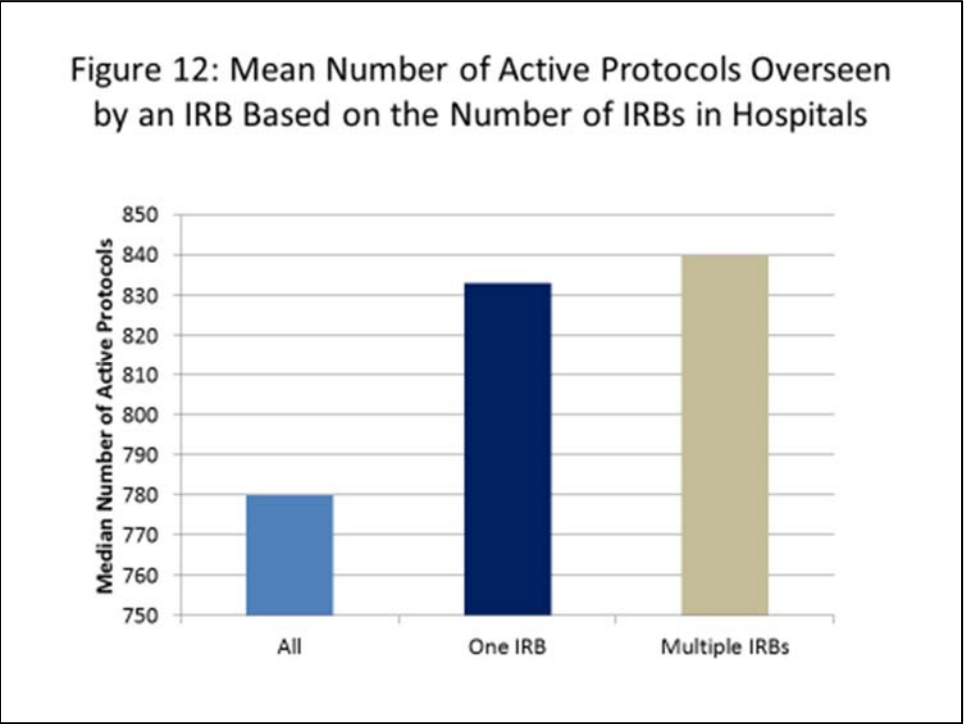
**Figure 9:** 81.25% of hospitals compensate IRB Chairs; 62.5% compensate IRB Vice Chairs; 35.5% compensate affiliated members; and 51.6% compensate non-affiliated members.



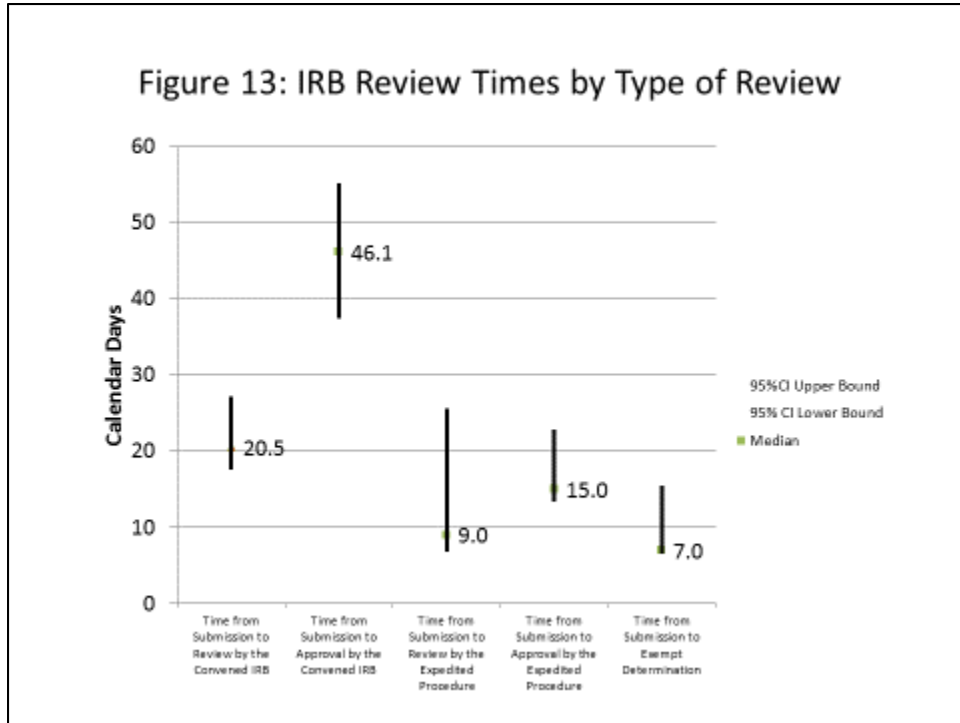
**Figure 10:** A median of 41 of protocols were deemed exempt by all organizations; a median of 425 protocols are reviewed by the expedited procedure; a median of 232 protocols are reviewed by the convened IRB; and a median of 691 total protocols are overseen by hospitals.



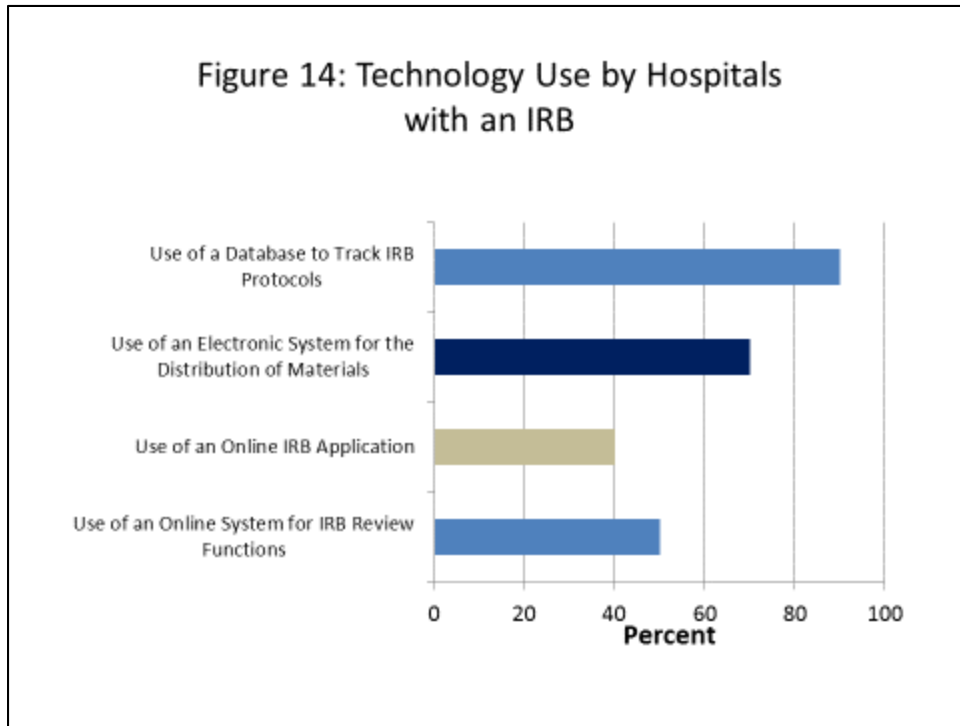
**Figure 11:** At hospitals, a median of 691 protocols are overseen by IRBs; a median of 420 protocols are overseen by one IRB; and a median of 585.5 protocols are overseen by multiple IRBs.



**Figure 12:** At hospitals, a mean of 780 protocols are overseen by an IRB; a mean of 833 protocols are overseen by one IRB; and a mean of 839.75 protocols are overseen by multiple IRBs.



**Figure 13:** It takes hospitals a median of 20.5 calendar days from submission to review by a convened IRB meeting; a median of 46.1 calendar days from submission to protocol approval by convened meeting; a median of 9 calendar days from submission to protocol review by expedited review; a median of 15 calendar days from submission to protocol approval by the expedited review; and a median of 7 calendar days from submission to making determination of exemption.



**Figure 14:** 90% of hospitals use a database to track IRB protocols; 70% use an electronic system for the distribution of materials; 40% use an online IRB application system; and 50% 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	4.35	464.5	106.78	\$335,172
1-100	1.75	43.5	24.86	\$148,774
101-500	3	313	104.33	\$254,642
501-1000	5.5	678	123.27	\$336,584
1001-2000	10.75	1498	139.35	\$786,025
2001-4000	-	-	-	-
4000+	45.37	8305	183.05	\$5,457,716





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