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# 2017 Metrics on Human Research Protection Program Performance for Hospitals

Updated May 2, 2018

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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 2017 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 2017, 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 2017 data, the metrics are represented as the median, except where indicated as the mean.

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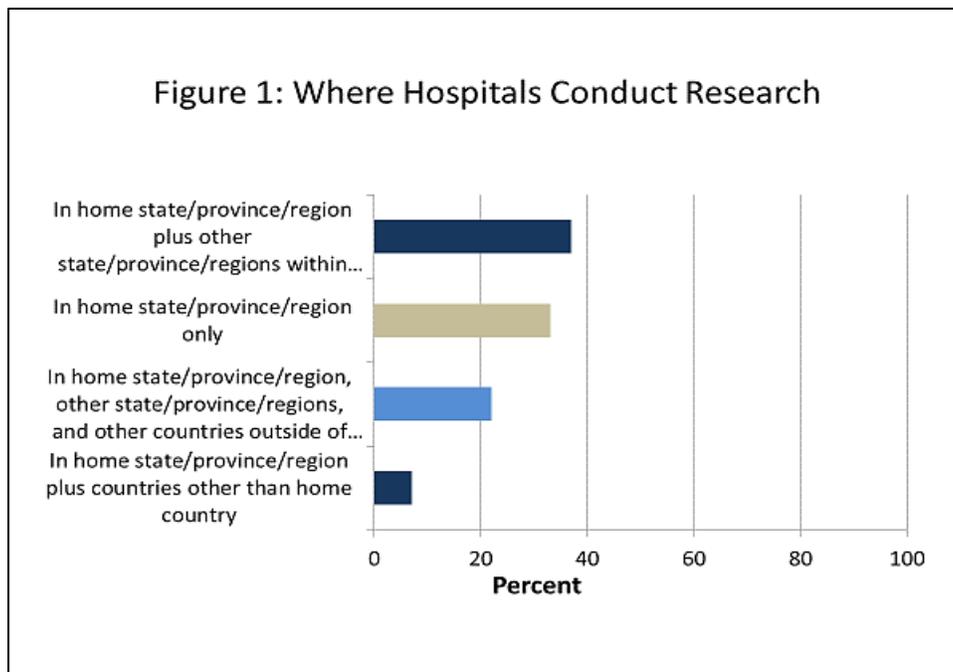
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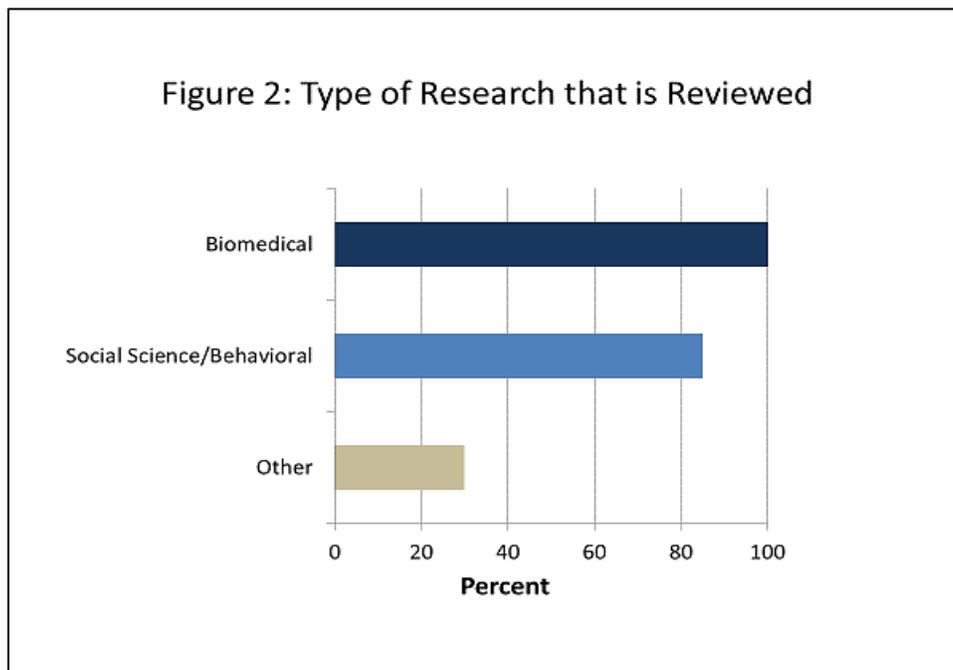
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# General Description of the Research Conducted or Overseen by Hospitals

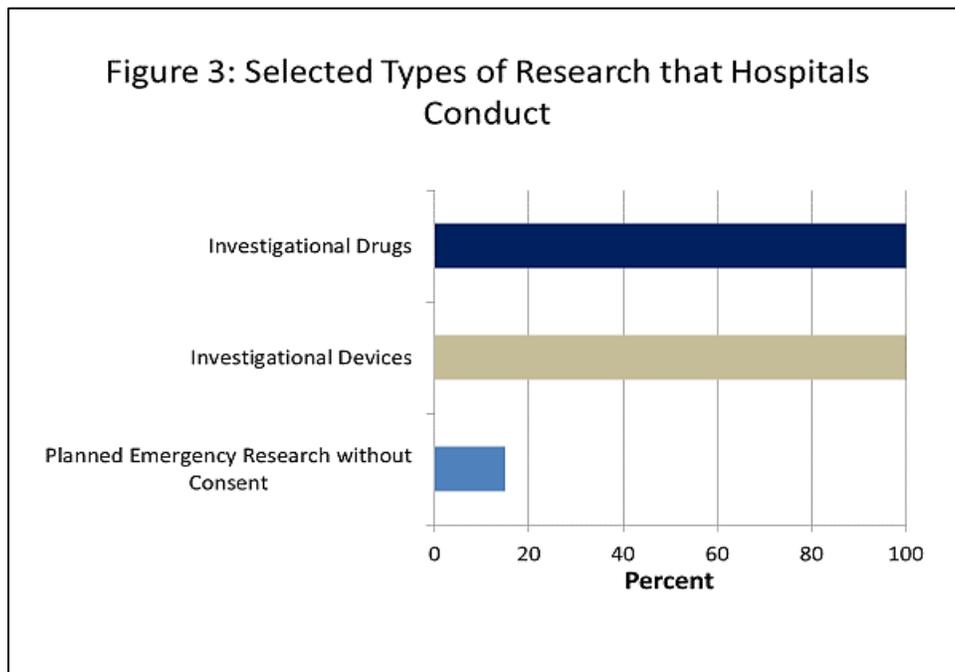


**Figure 1:** 37% of hospitals conduct research in their home state/province/region and other states/provinces/regions within their home country; 33% conduct research in their home state/province/region only; 22% conduct research in their home state/province/region, other states/provinces/regions within their home country, and countries other than their home country; and 7% conduct research in their home state/province/region plus countries other than their home country.

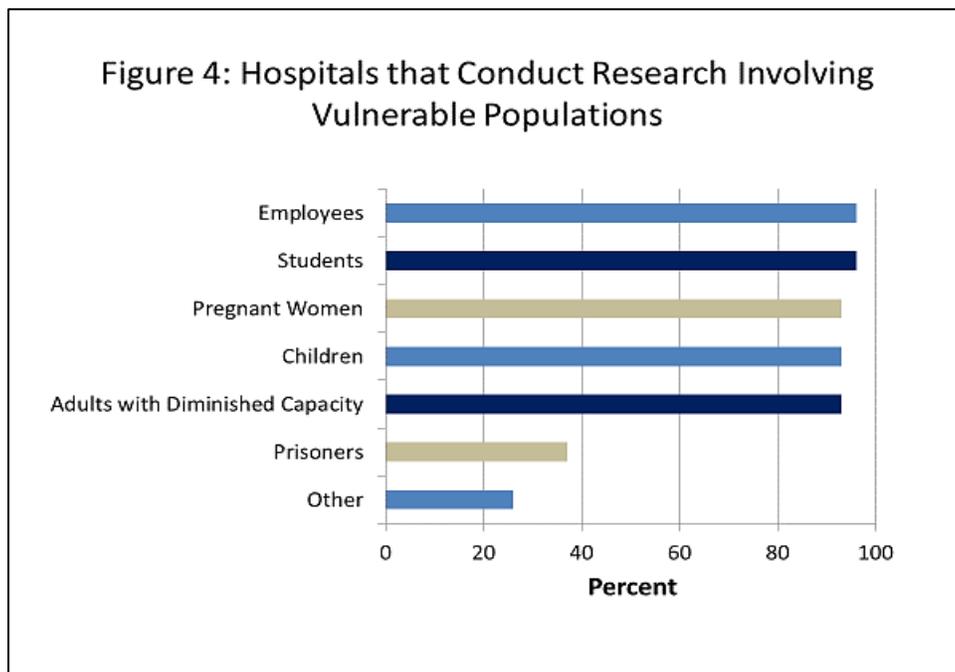


**Figure 2:** 100% of hospitals conduct biomedical research; 85% conduct social science/behavioral research; and 30% conduct research falling into other categories.

## Selected Types of Research Conducted or Overseen by Hospitals

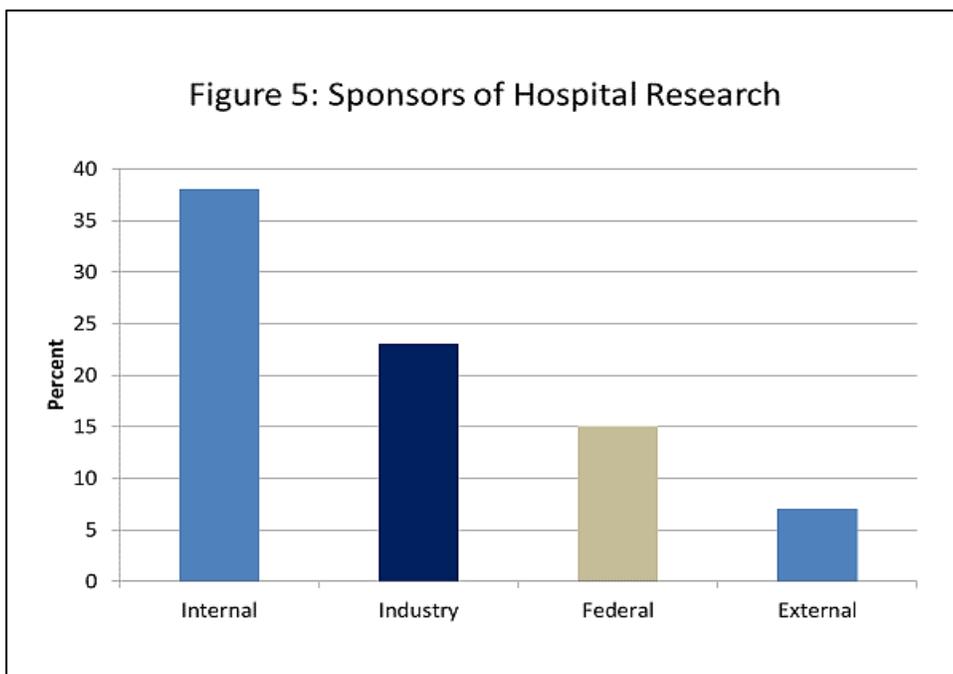


**Figure 3:** 100% of hospitals conduct research involving investigational drugs; 100% conduct research involving investigational devices; and 15% conduct planned emergency research without consent.

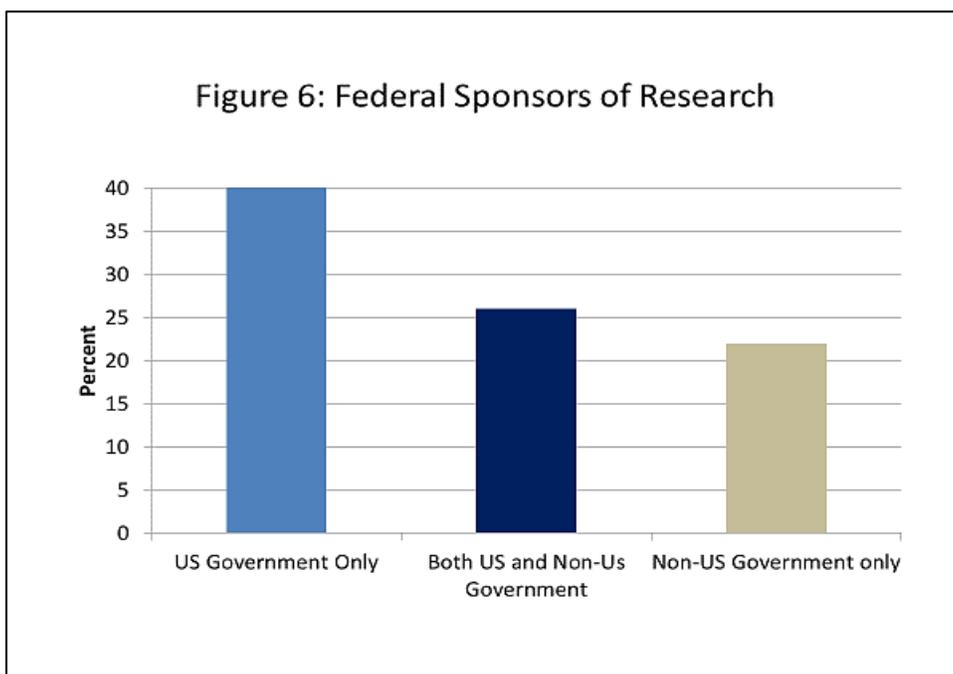


**Figure 4:** 96% of hospitals conduct research with employees; 96% conduct research with students; 93% conduct research with pregnant women; 93% conduct research with children; 93% conduct research with adults with diminished capacity; 37% conduct research with prisoners; and 26% conduct research with other vulnerable populations.

## Sponsors and Regulators of Hospital Research

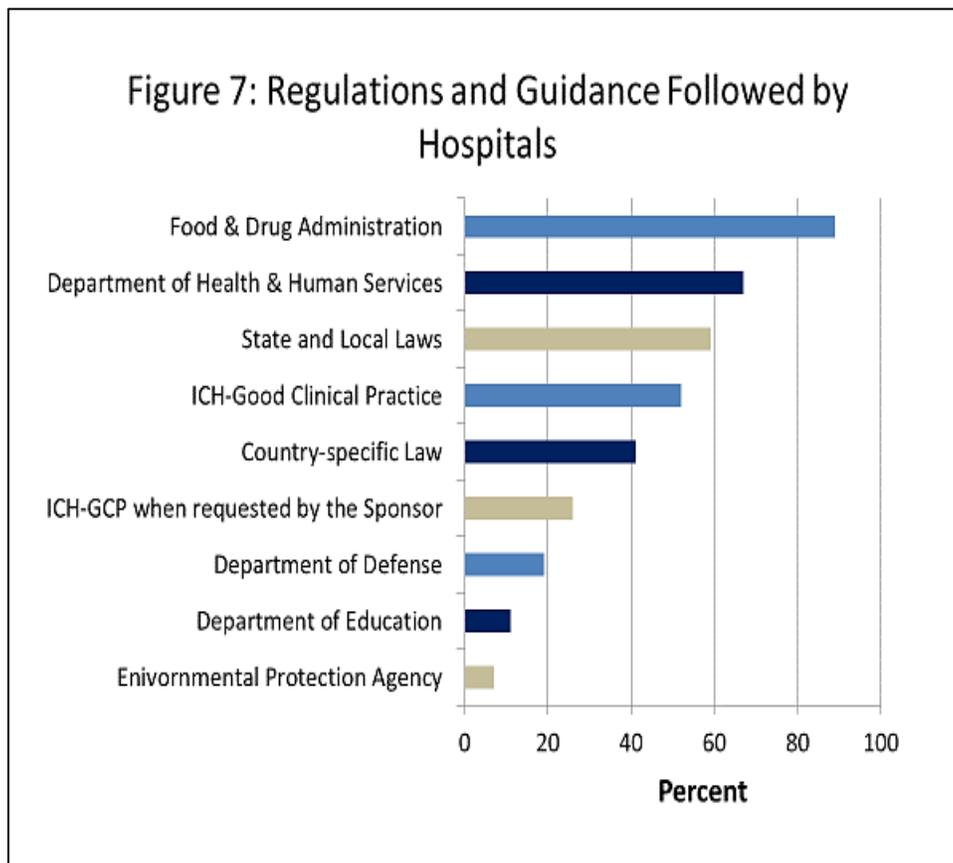


**Figure 5:** For hospitals, a median of 38% of research is internally sponsored; a median of 23% of research is industry sponsored; a median of 15% of research is federally sponsored; and a median of 7% of research is externally sponsored.

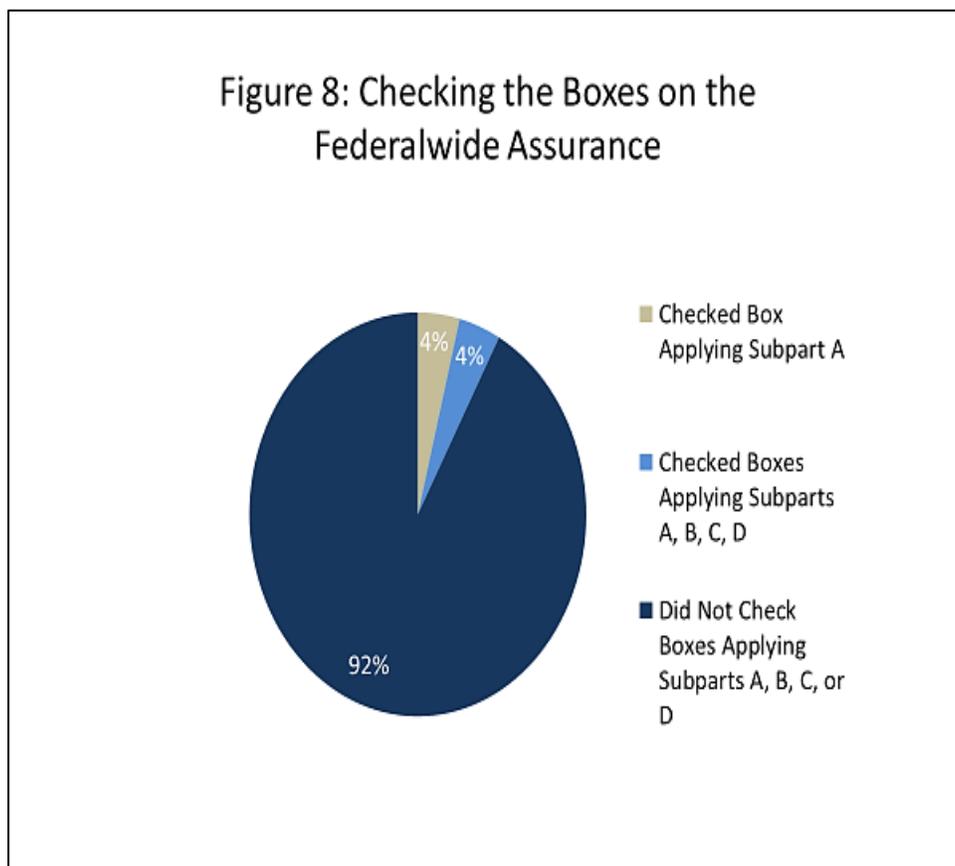


**Figure 6:** For hospitals receiving federal funds, a median of 52% of research is sponsored by the US government only; a median of 26% of research portfolios is sponsored by both US and non-US governments; and a median of 22% of research is sponsored by non-US governments only.

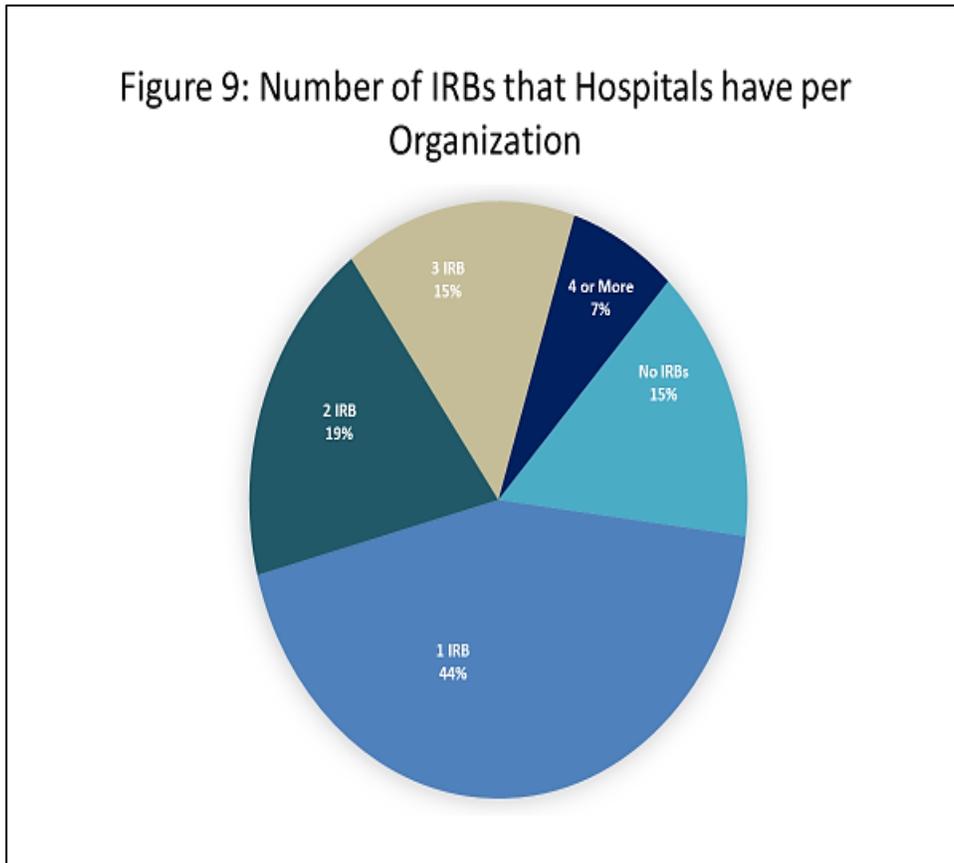
## Sponsors and Regulators of Hospital Research



**Figure 7:** 89% of hospitals follow FDA regulations; 67% follow Department of Health and Human Services regulations; 59% follow regulations or guidelines of their state; 52% follow the ICH-Good Clinical Practice guideline; 41% follow country-specific regulations or guidelines; 26% follow the ICH-Good Clinical Practice guideline when requested by the sponsor; 19% follow Department of Defense requirements; 11% follow Department of Education requirements; and 7% follow Environmental Protection Agency requirements.

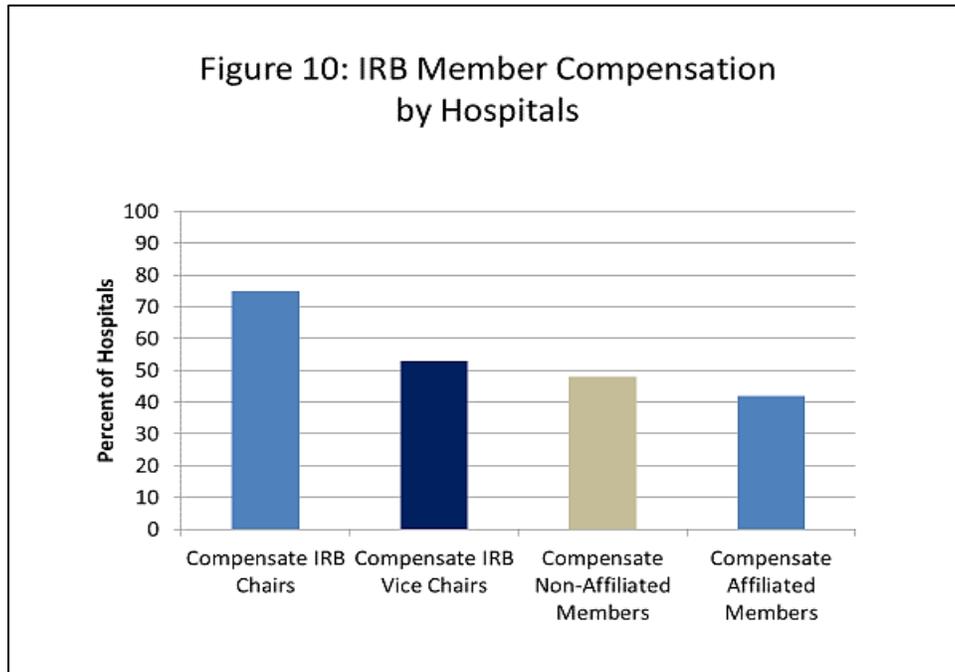


**Figure 8:** 92% of hospitals unchecked the boxes applying Subparts A, B, C, or D; 4% checked the boxes applying all Subparts (A, B, C, and D); and 4% checked the box applying Subpart A only.

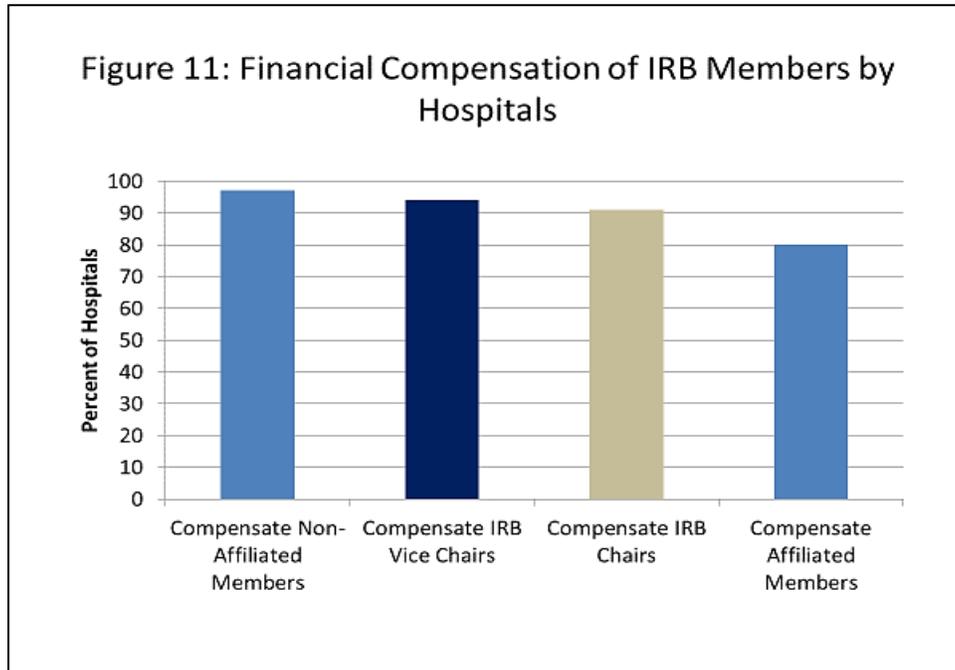


**Figure 9:** 44% of hospitals have one IRB; 19% have two IRBs; 15% have three IRBs; 7% have four or more IRBs; and 15% do not have an IRB.

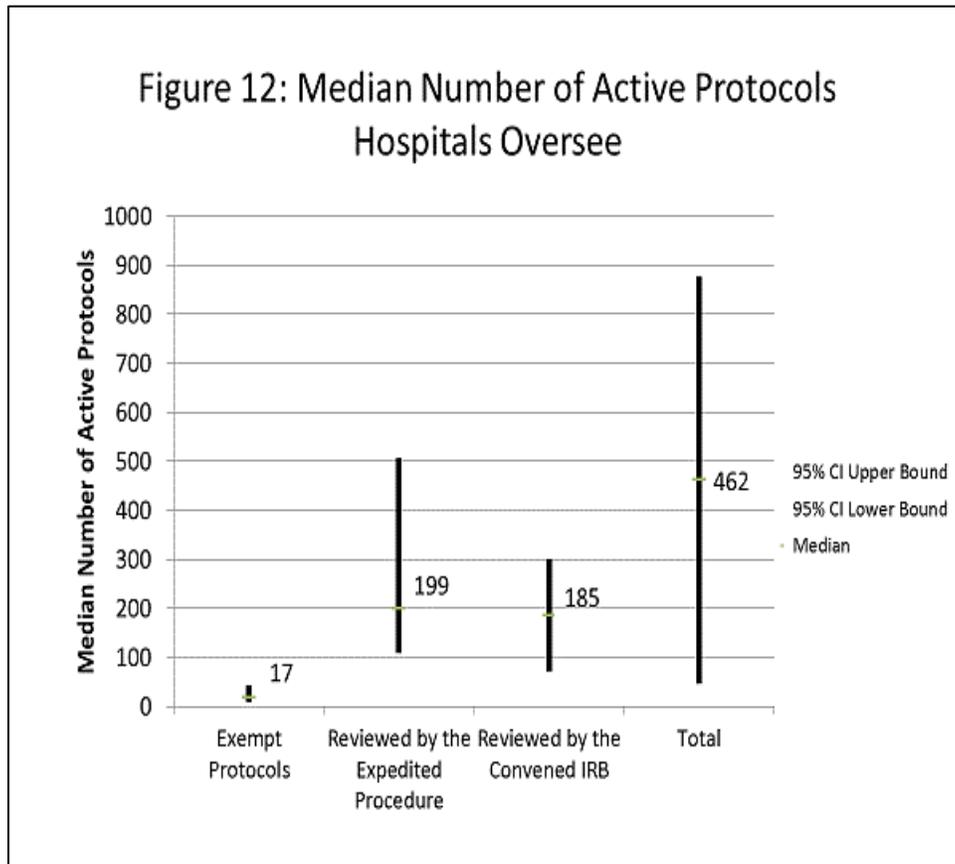
# Compensation of IRB Members



**Figure 10:** 75% of hospitals compensate IRB chairs; 53% compensate IRB vice chairs; 48% compensate non-affiliated members; and 42% compensate affiliated members.

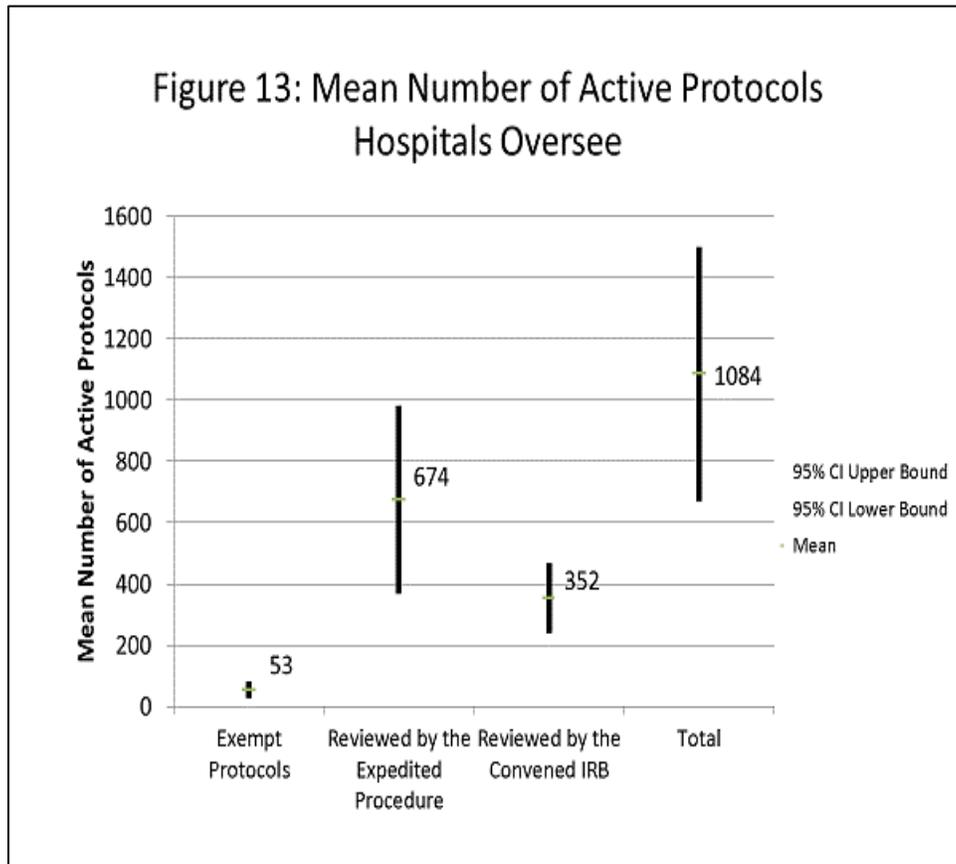


**Figure 11:** Of hospitals that compensate IRB members; 97% compensate non-affiliated members financially; 94% compensate IRB vice chairs financially; 91% compensate IRB chairs financially; and 80% compensate affiliated members financially.



**Figure 12:** A median of 17 protocols were deemed exempt by hospitals\*; a median of 199 protocols were reviewed by the expedited procedure; a median of 185 protocols were reviewed by the convened IRB; and a median of 462 total protocols were overseen by hospitals.

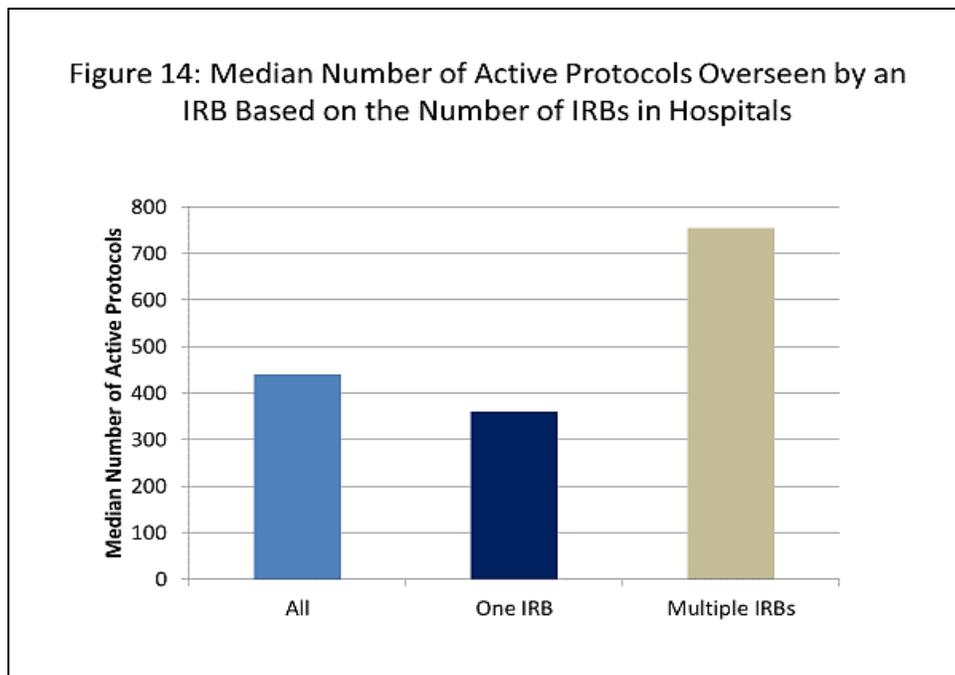
\*Exempt determinations made within 12 months of an organization’s submission to AAHRPP.



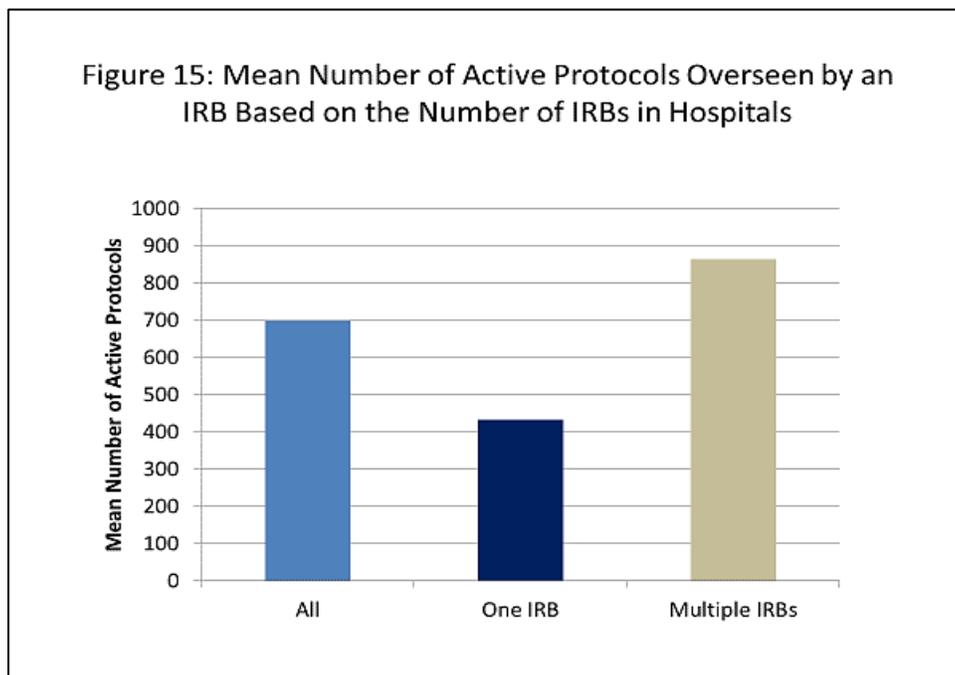
**Figure 13:** A mean of 53 protocols were deemed exempt by hospitals\*; a mean of 674 protocols were reviewed by the expedited procedure; a mean of 352 protocols were reviewed by the convened IRB; and a mean of 1084 total protocols were overseen by hospitals.

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

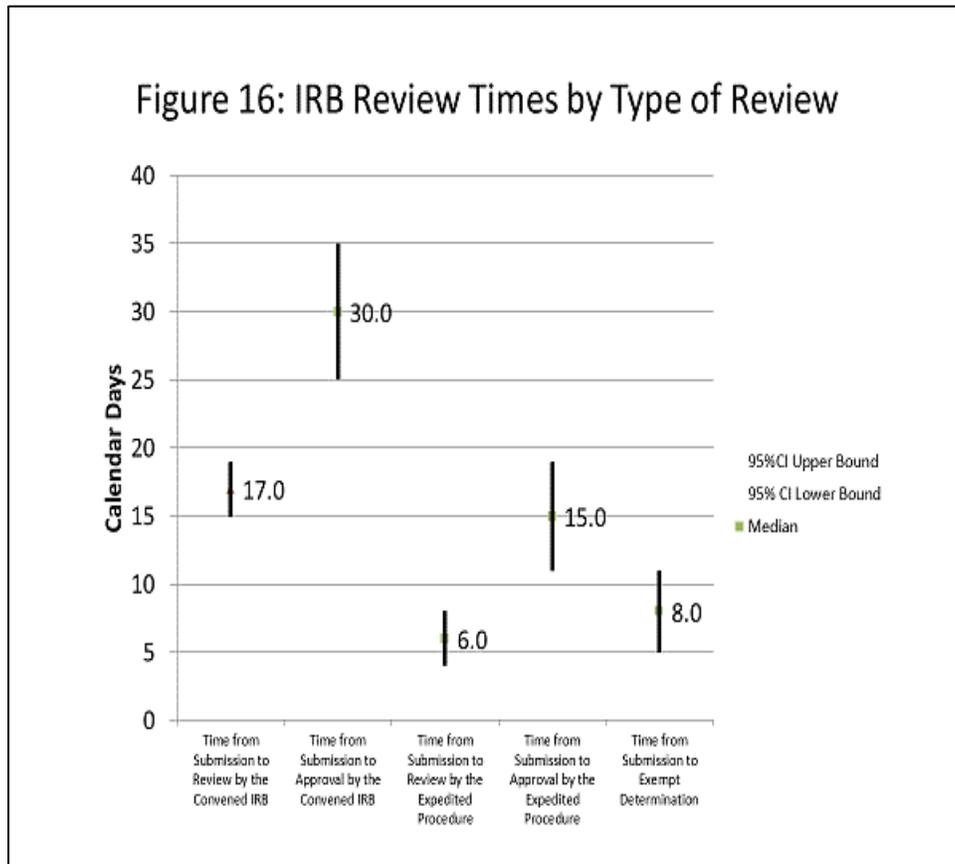
## Characteristics of IRBs



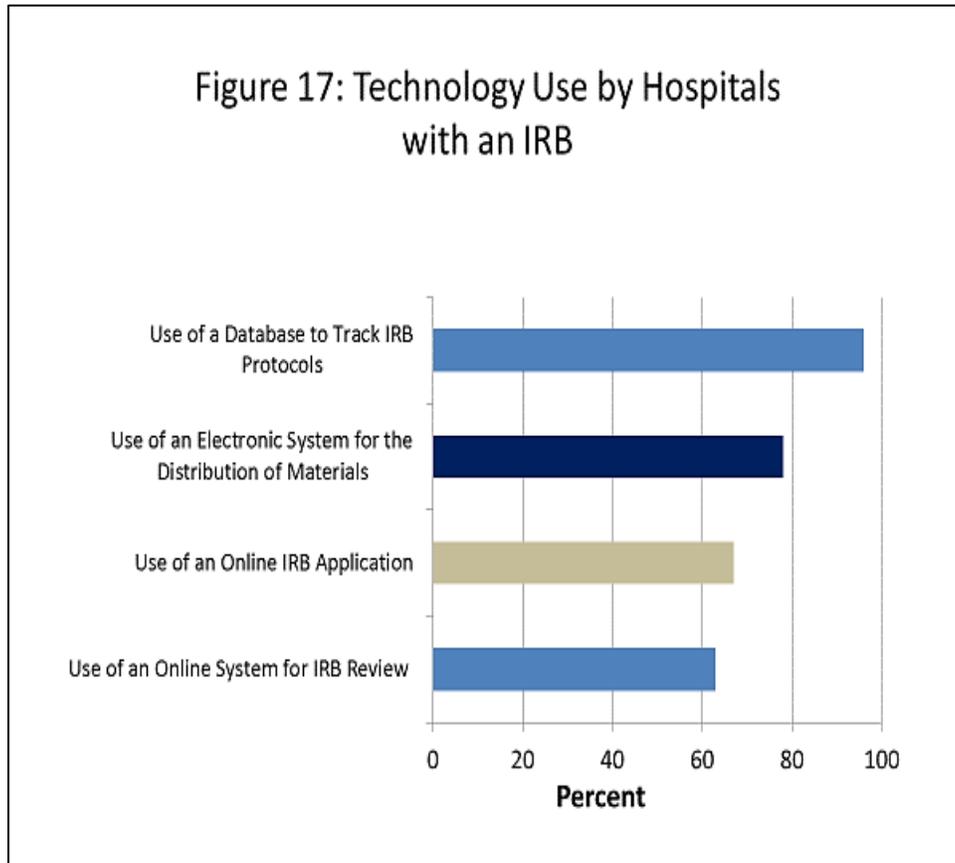
**Figure 14:** A median of 440 protocols were overseen by hospitals; a median of 360 protocols were overseen by hospitals with one IRB; and a median of 754 protocols were overseen by hospitals with two or more IRBs.



**Figure 15:** A mean of 698 protocols were overseen by hospitals; a mean of 432 protocols were overseen by hospitals with one IRB; and a mean of 1104 protocols were overseen by hospitals with two or more IRBs.



**Figure 16:** The time from submission to review by the convened IRB is a median of 17 calendar days; the time from submission to approval by the convened IRB is a median of 30 calendar days; the time from submission to review by the expedited procedure is a median of 6 calendar days; the time from submission to approval by the expedited procedure is a median of 15 calendar days; and the time from submission to exempt determination is a median of 8 calendar days.



**Figure 17:** 96% of hospitals use a database to track IRB protocols; 78% use an electronic system for the distribution of materials; 67% use an online IRB application; and 63% use an online system for IRB review.

**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	6	494	82	\$343,526
1-100	2	64	32	\$106,500
101-500	3	233	78	\$140,555
501-1000	6	859	143	\$406,200
1001+	10	2179	22	1,324,607



2301 M Street, NW  
Suite 500

(202) 783-1112 phone  
(202) 783-1113 fax

# Resources for the IRB

Washington, DC 20037

[www.aahrpp.org](http://www.aahrpp.org)

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