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# 2016 Metrics on Human Research Protection Program Performance for Hospitals

Updated April 24, 2017

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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 2016 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 2016, 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 2016 data, the metrics are represented as the median, except where indicated as the mean.

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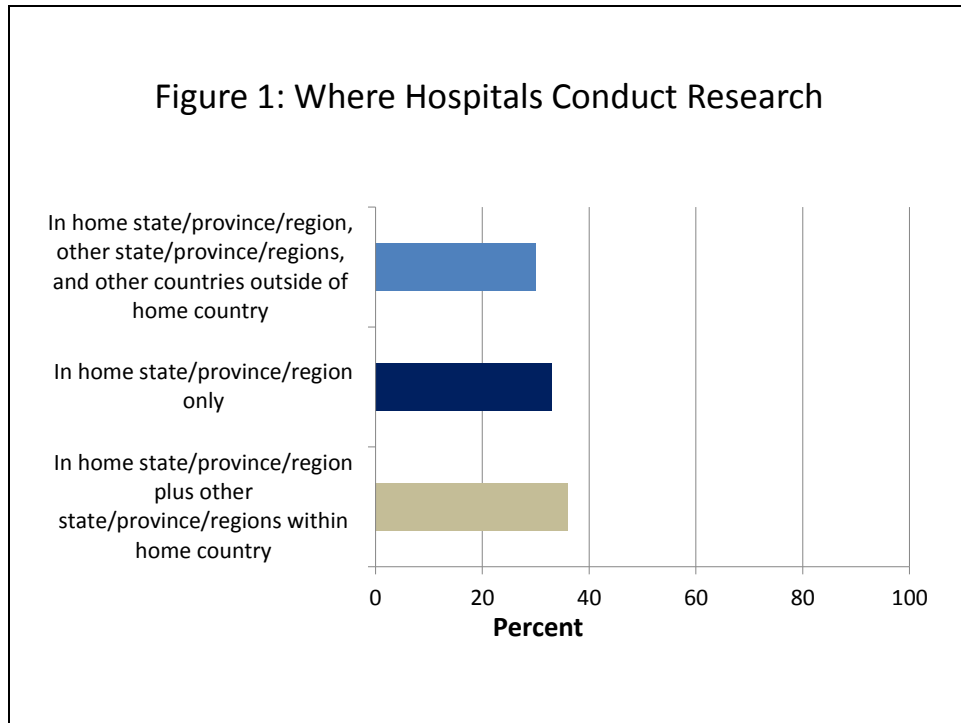
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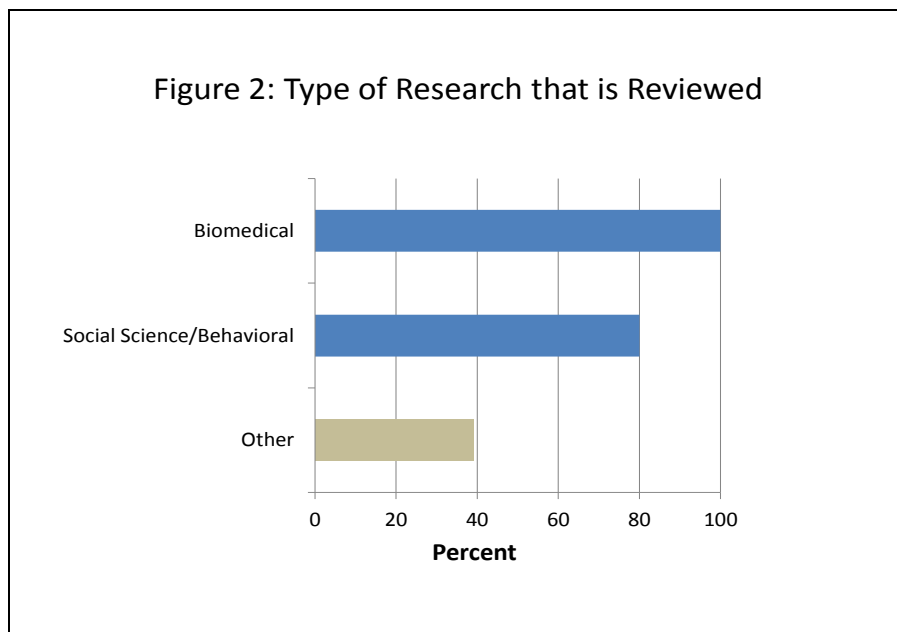
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# General Description of the Research Conducted or Overseen by Hospitals

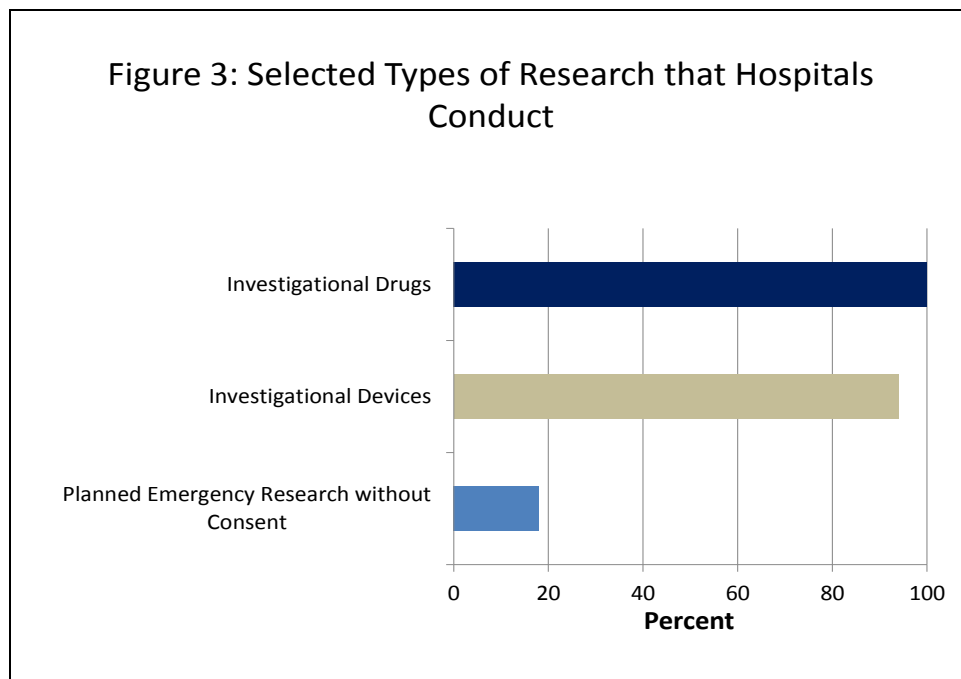


**Figure 1:** 82% of hospitals conduct research within their own jurisdictions, 39% conduct research within their own and other jurisdictions, and 18% conduct research internationally.

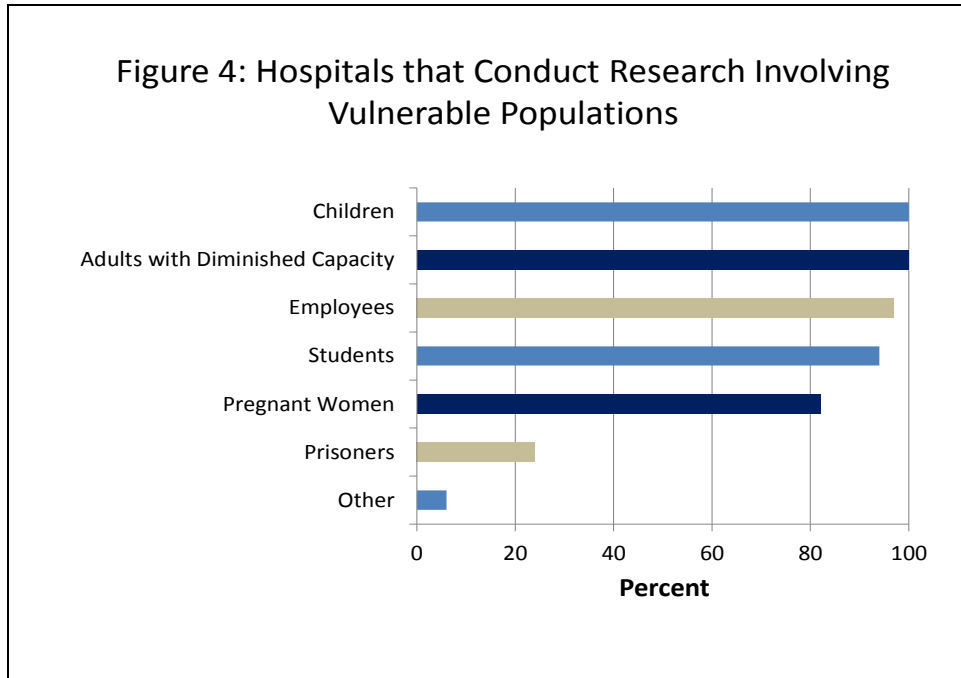


**Figure 2:** 100% of hospitals conduct biomedical research, 88% conduct social science/behavioral research, and 33% conduct research falling into other categories.

## Selected Types of Research Conducted or Overseen by Hospitals

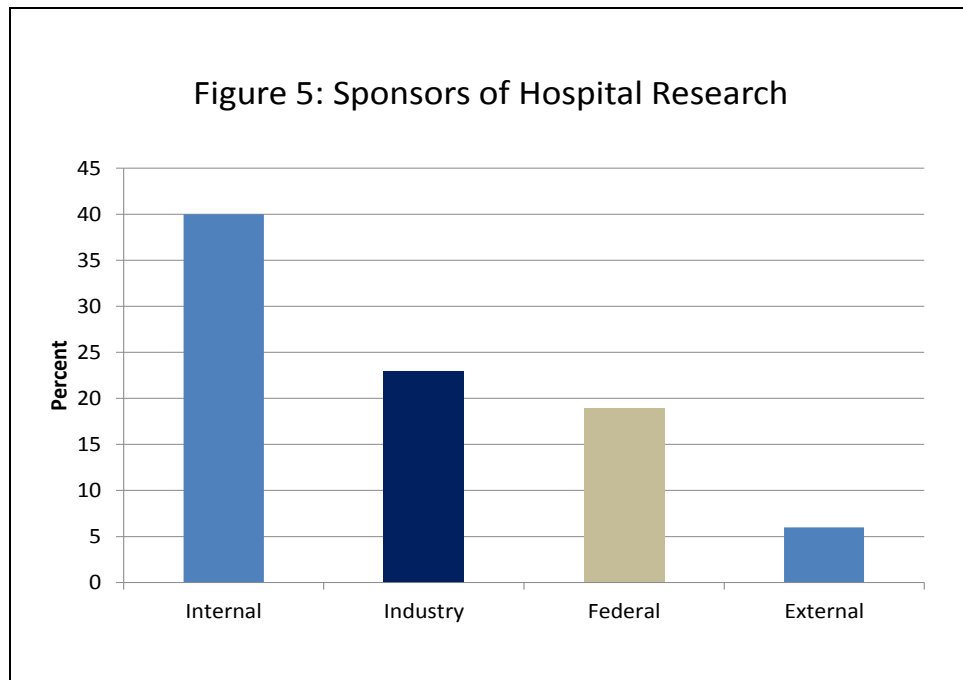


**Figure 3:** 100% of hospitals conduct research involving investigational drugs, 94% conduct research involving investigational devices, and 18% conduct planned emergency research without consent.

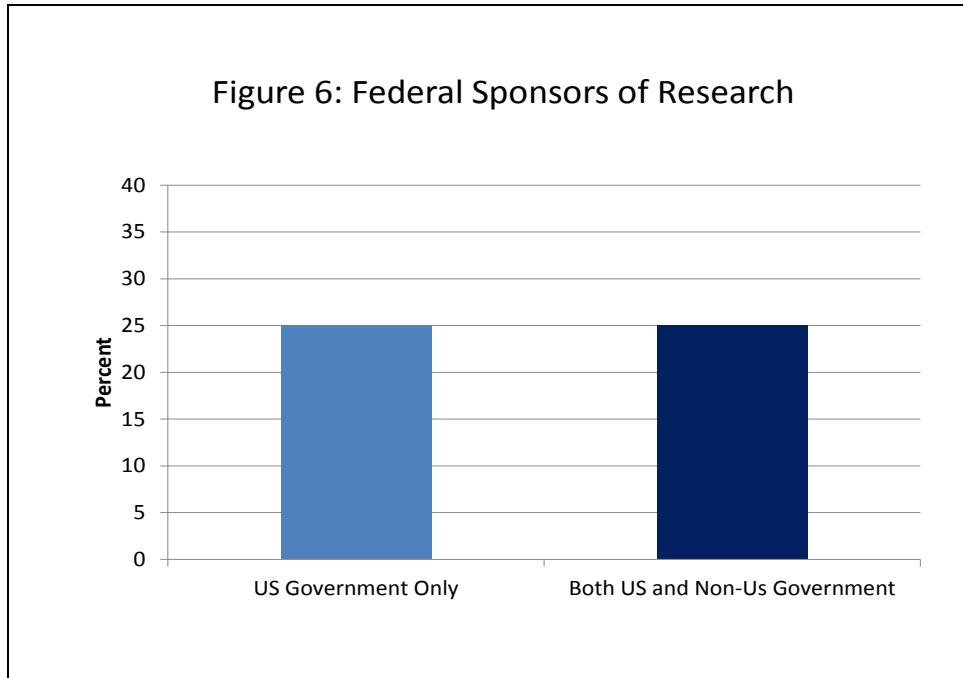


**Figure 4:** 100% of hospitals conduct research with children, 100% conduct research with adults with diminished capacity, 97% conduct research with employees, 94% conduct research with students, 82% conduct research with pregnant women, 24% conduct research with prisoners, and 6% conduct research with other vulnerable populations.

# Sponsors and Regulators of Hospital Research

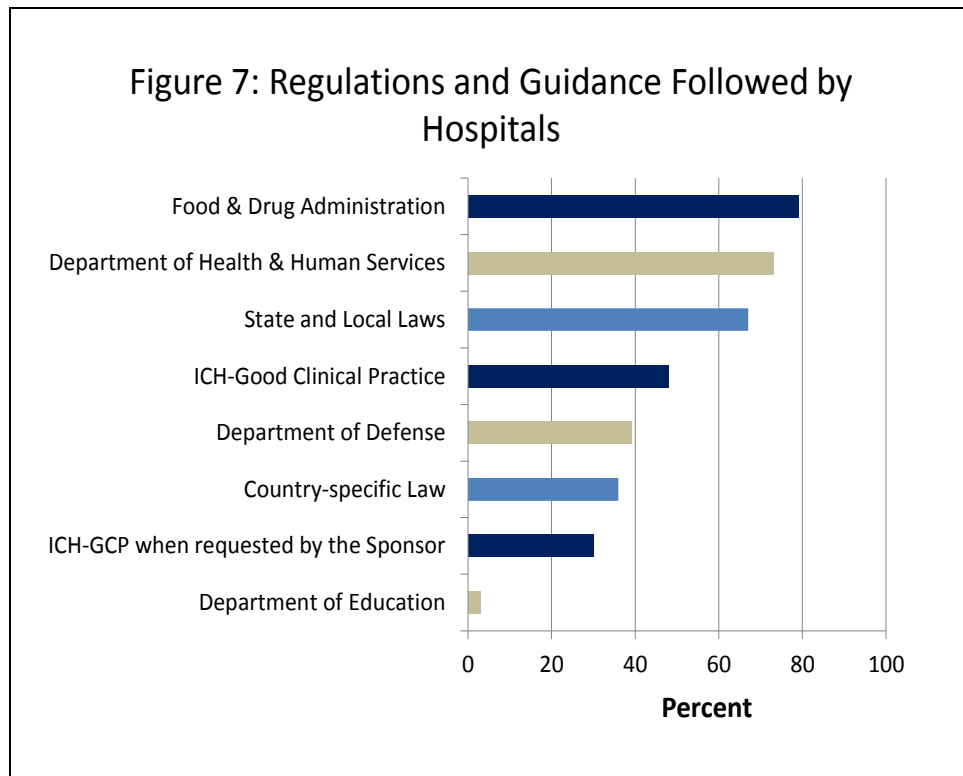


**Figure 5:** For hospitals, a median of 40% of research is internally sponsored, a median of 23% of research is industry sponsored, a median of 19% of research is federally sponsored, and a median of 6% of research is externally sponsored.

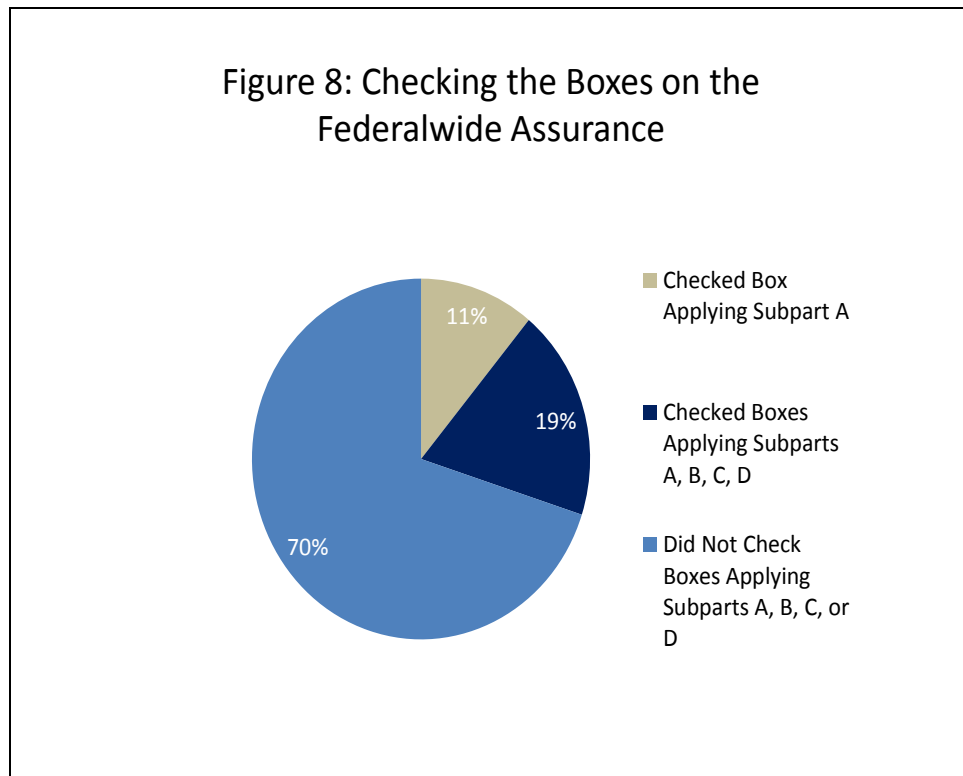


**Figure 6:** For hospitals receiving federal funds, a median of 25% of research is sponsored by the US Government only and a median of 25% of research portfolios is sponsored by both US and Non-US governments.

## Sponsors and Regulators of Hospital Research

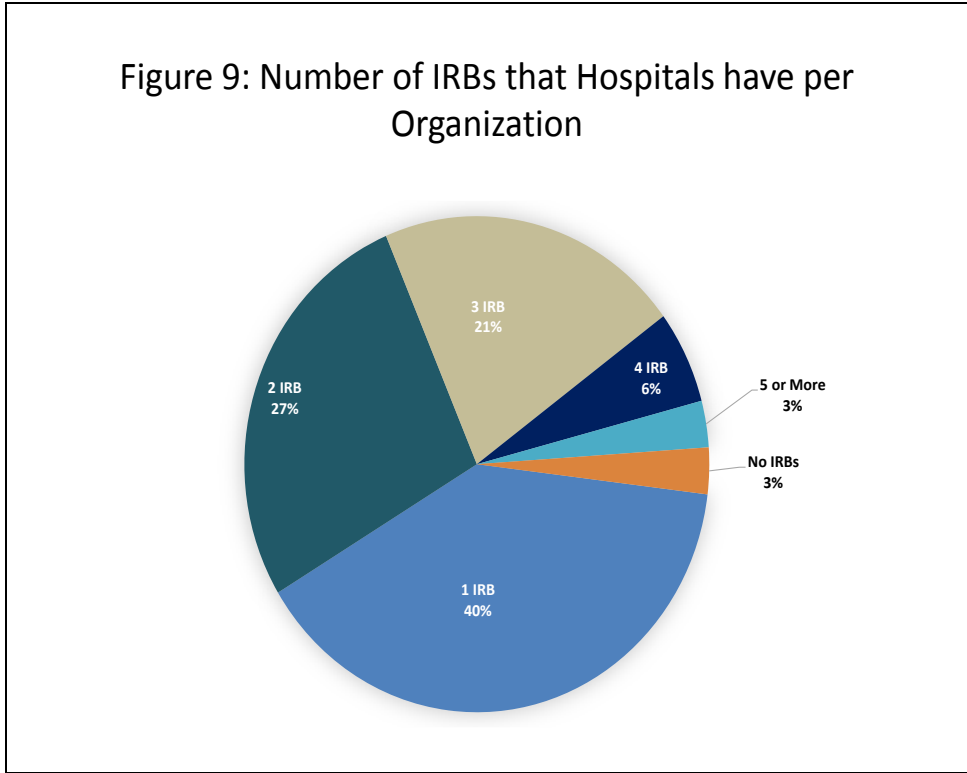


**Figure 7:** 79% of hospitals follow FDA regulations, 73% follow Department of Health and Human Services regulations, 67% follow regulations or guidelines of their state, 48% follow the ICH-Good Clinical Practice guideline, 39% follow Department of Defense requirements, 36% follow country-specific regulations or guidelines, 30% follow the ICH-Good Clinical Practice guideline when requested by the sponsor, and 3% follow Department of Education requirements.



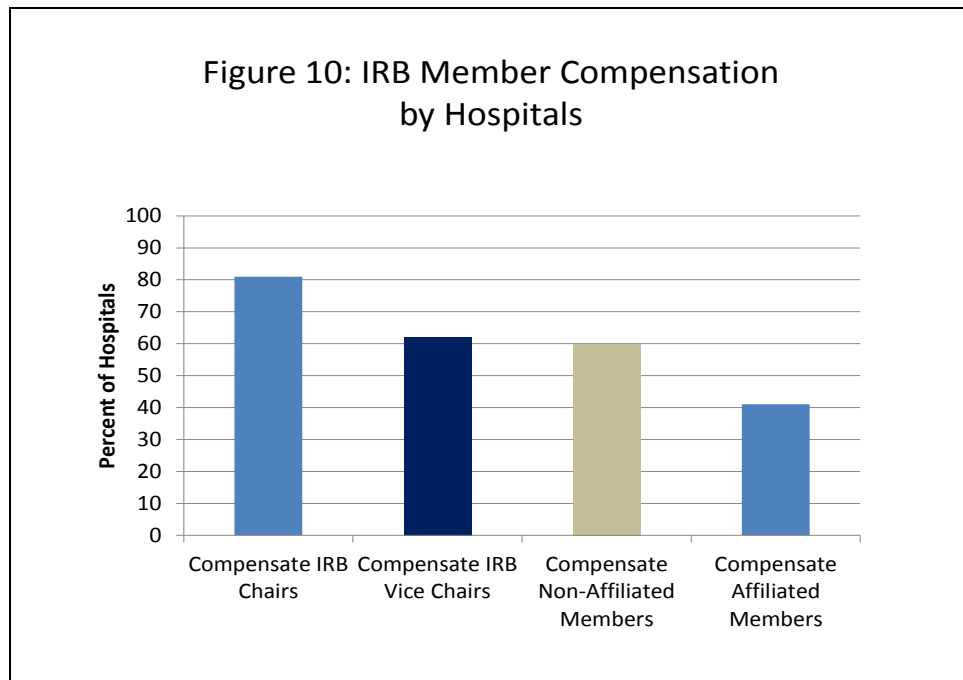
**Figure 8:** 70% of hospitals unchecked the boxes applying Subparts A, B, C, or D, 19% checked the boxes applying all Subparts (A, B, C, and D), and 11% checked the box only applying Subpart A.



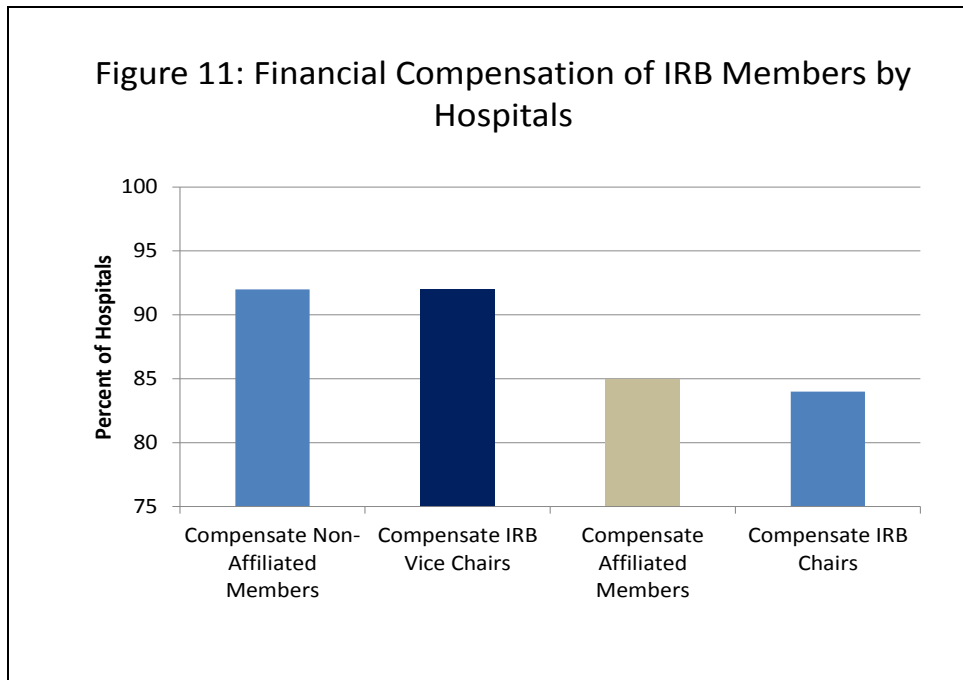


**Figure 9:** 40% of hospitals have one IRB, 27% have two IRBs, 21% have three IRBs, 6% have four IRBs, 3% have five or more IRBs, and 3% do not have an IRB.

# Compensation of IRB Members

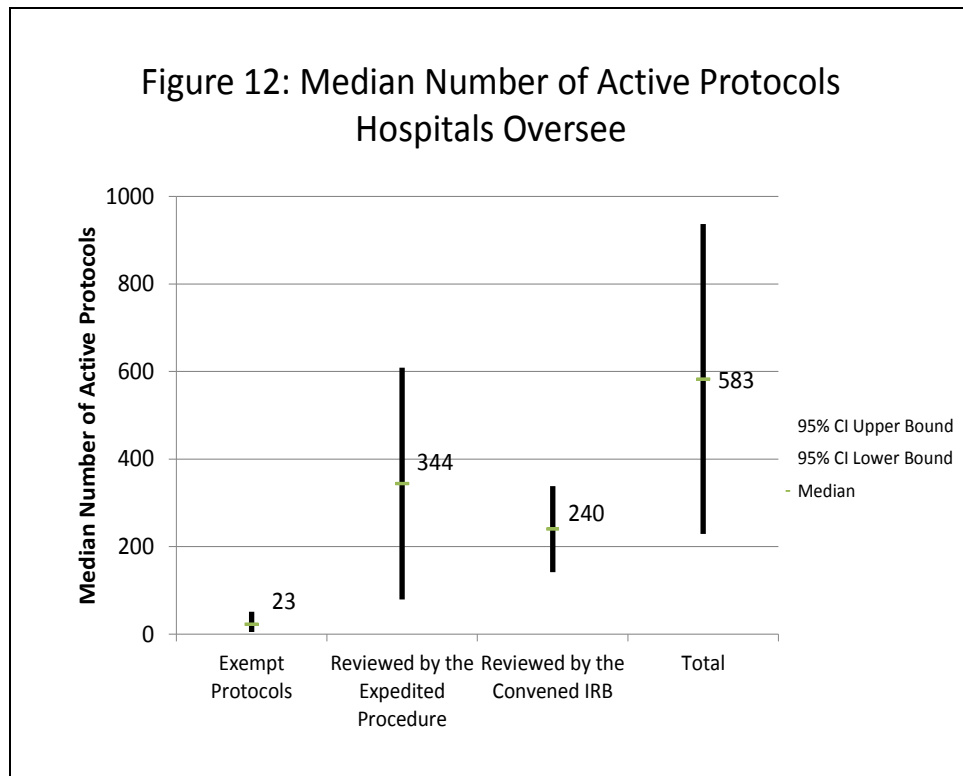


**Figure 10:** 81% of hospitals compensate IRB chairs, 62% compensate IRB vice chairs, 60% compensate non-affiliated members, and 41% compensate affiliated members.



**Figure 11:** Of hospitals that compensate IRB members, 92% compensate non-affiliated members financially, 92% compensate IRB vice chairs financially, 85% compensate affiliated members financially, and 84% compensate IRB chairs financially.

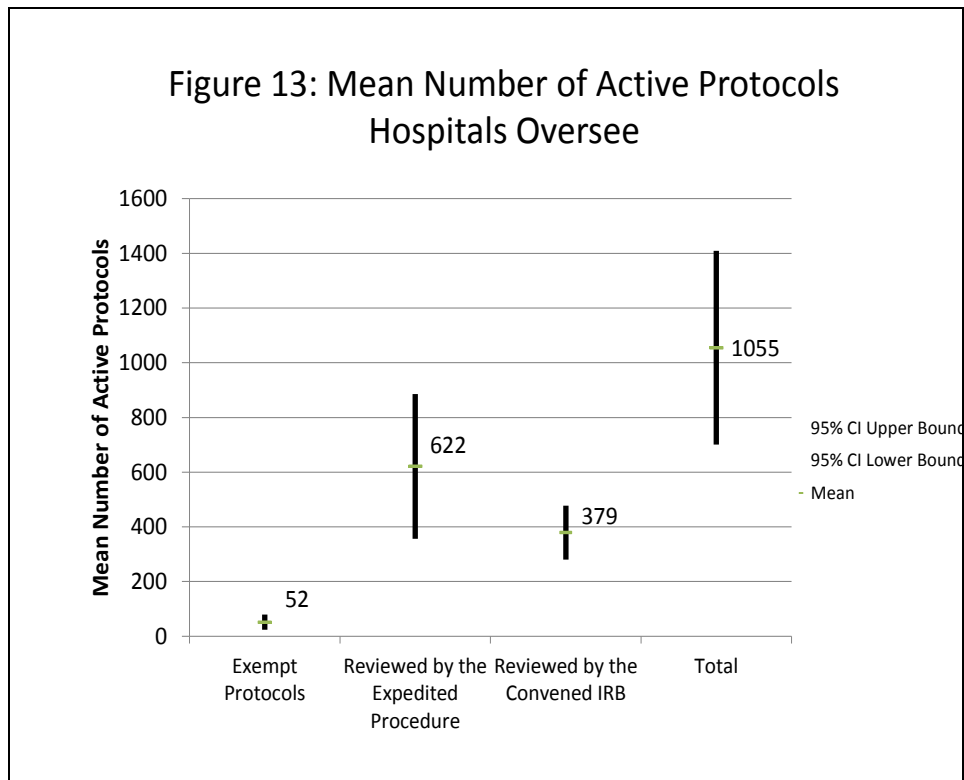
## Characteristics of IRBs



**Figure 12:** A median of 23 protocols were deemed exempt by hospitals\*, a median of 344 protocols were reviewed by the expedited procedure, a median of 240 protocols were reviewed by the convened IRB, and a median of 583 total protocols were overseen by hospitals.

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

## Characteristics of IRBs

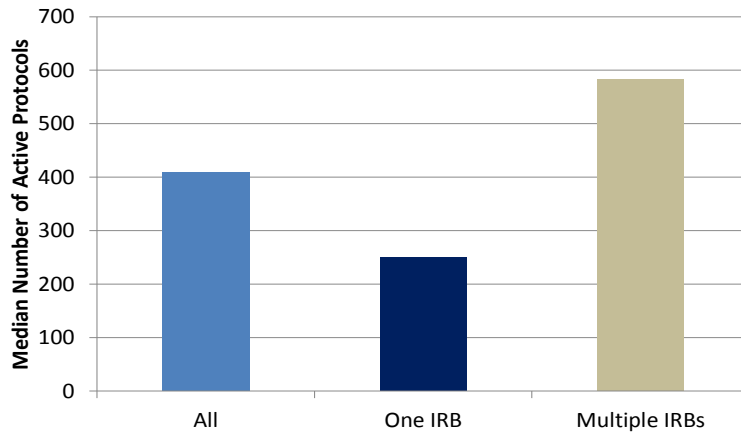


**Figure 13:** A mean of 52 protocols were deemed exempt by hospitals\*, a mean of 622 protocols were reviewed by the expedited procedure, a mean of 379 protocols were reviewed by the convened IRB, and a mean of 1055 total protocols were overseen by hospitals.

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

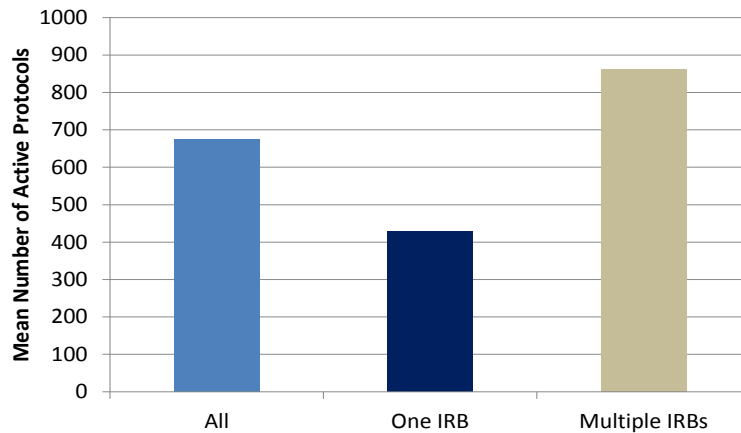
## Characteristics of IRBs

Figure 14: Median Number of Active Protocols Overseen by an IRB Based on the Number of IRBs in Hospitals



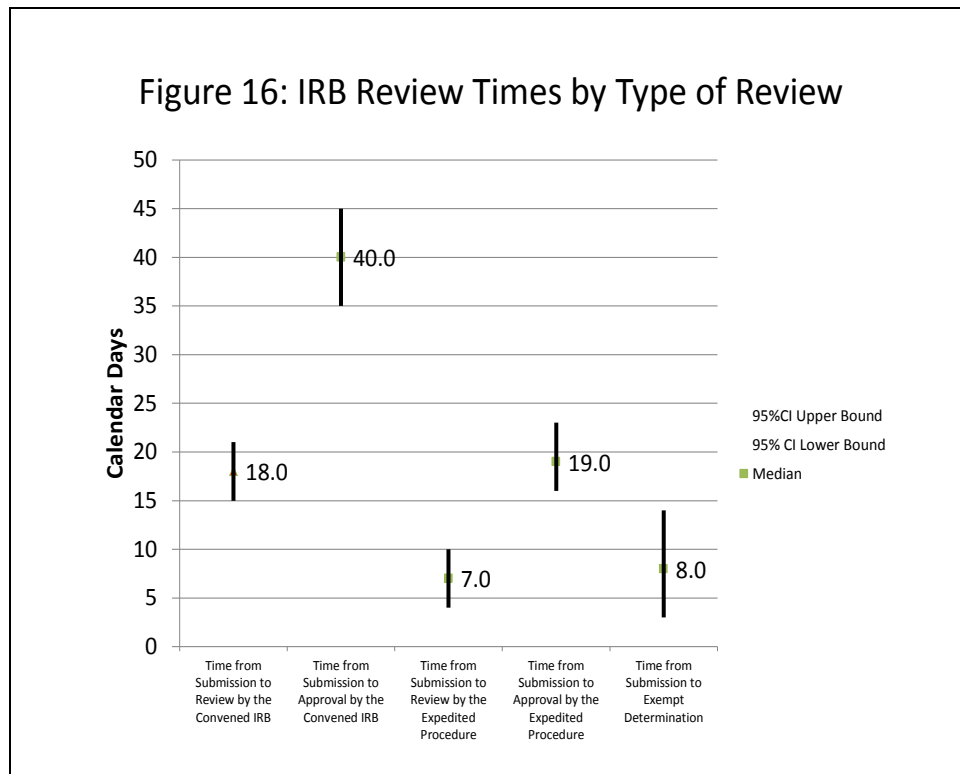
**Figure 14:** A median of 408 protocols were overseen by hospitals, a median of 249 protocols were overseen by hospitals with one IRB, and a median of 583 protocols were overseen by hospitals with two or more IRBs.

Figure 15: Mean Number of Active Protocols Overseen by an IRB Based on the Number of IRBs in Hospitals

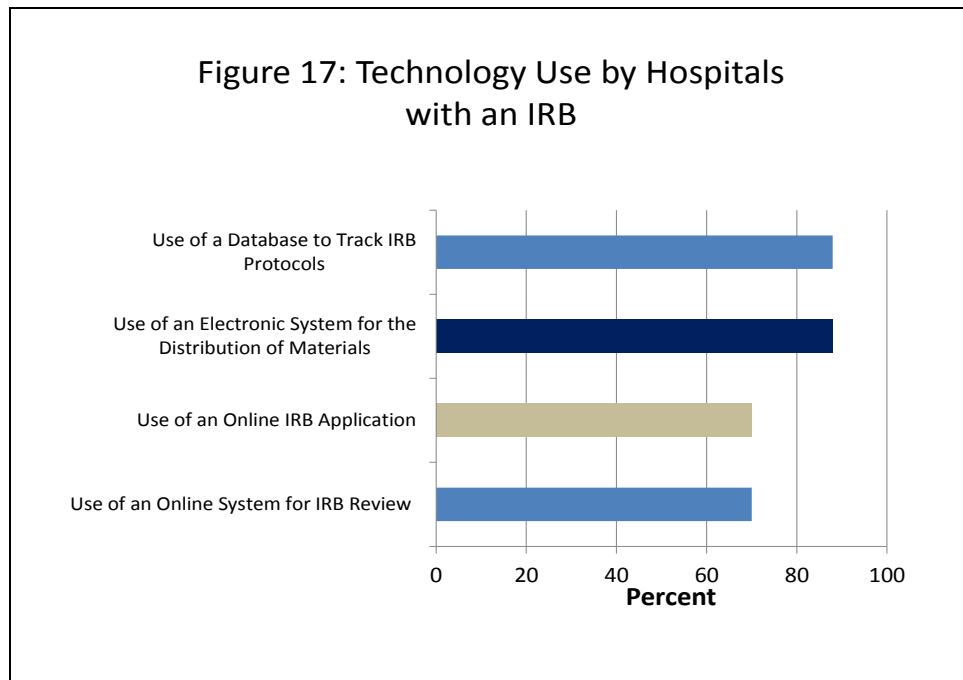


**Figure 15:** A mean of 674 protocols were overseen by hospitals, a mean of 430 protocols were overseen by hospitals with one IRB, and a mean of 863 protocols were overseen by hospitals with two or more IRBs.

# IRB Review Times



**Figure 16:** 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 40 calendar days, the time from submission to review by the expedited procedure is a median of 7 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 8 calendar days.



**Figure 17:** 88% of hospitals use a database to track IRB protocols, 88% use an electronic system for the distribution of materials, 70% use an online IRB application, and 70% 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	5.5	763	139	\$392,008
1-100	3	41	14	\$100,800
101-500	3	261	87	\$250,000
501-1000	4	716	179	\$404,320
1001-2000	10	1355	135.5	\$639,000
2001+	14	3251	232	\$831,801



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