



2013 Metrics on Human Research Protection Program Performance for Hospitals

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 Hospitals

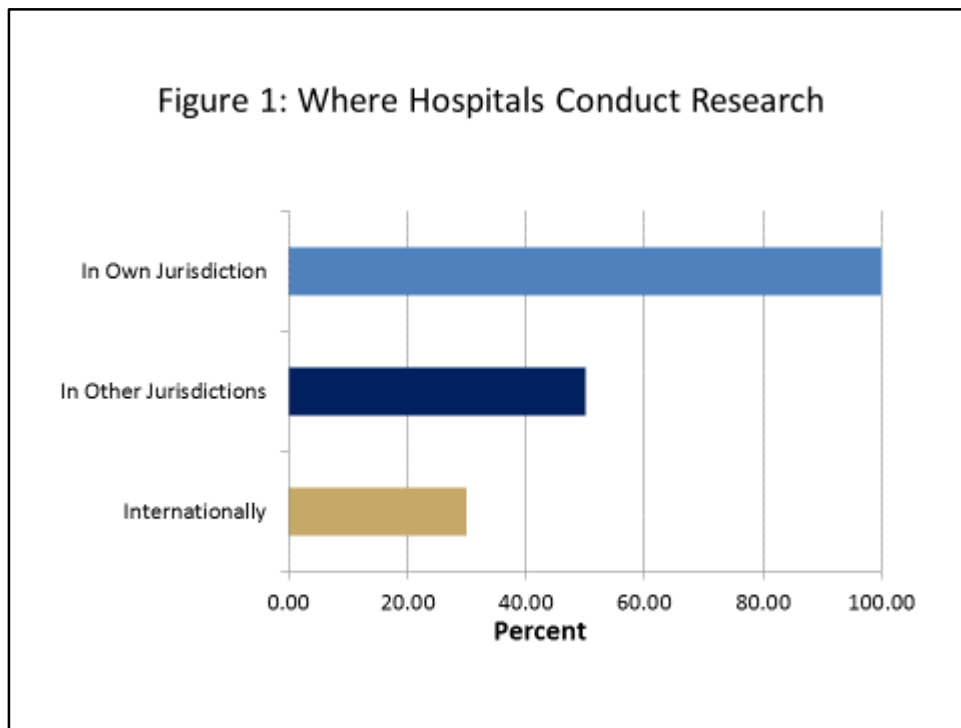


Figure 1: 100% of hospitals conduct research within their Own Jurisdictions, 50% conduct research within Other Jurisdictions, and 30% conduct research internationally.

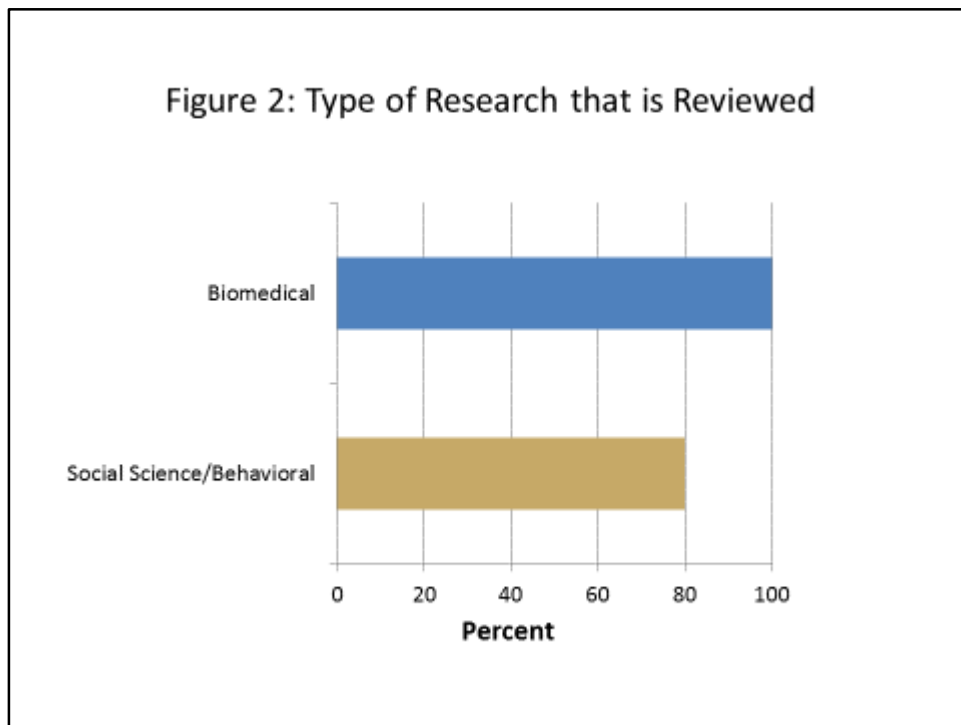


Figure 2: 100% of hospitals conduct Biomedical Research and 80% conduct Social Science/Behavioral Research.

Selected Types of Research Conducted or Overseen by Hospitals

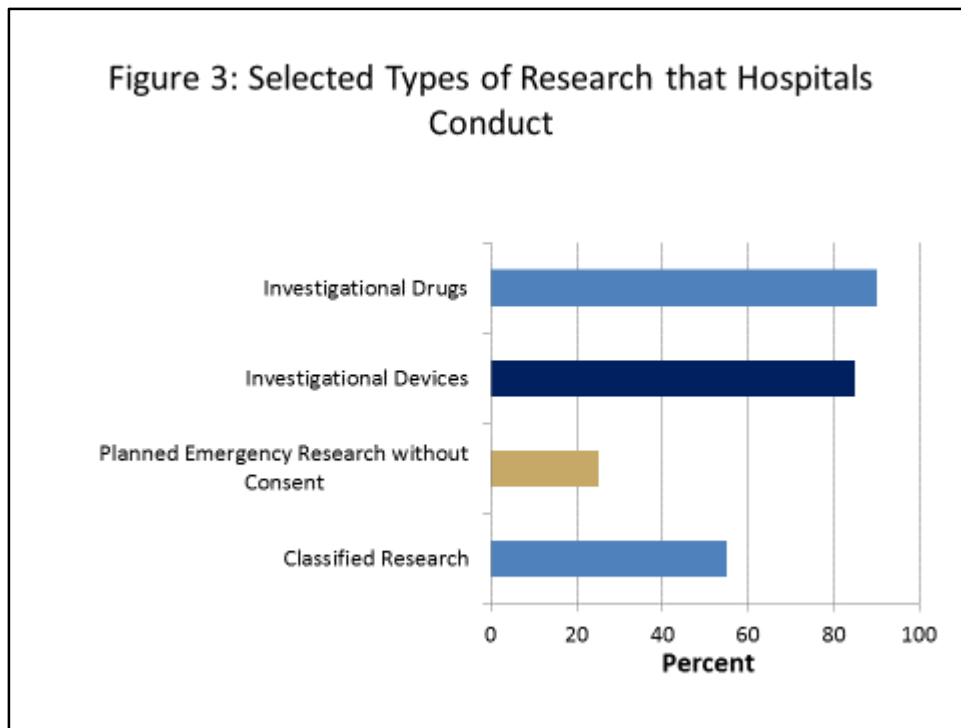


Figure 3: 90% of hospitals utilize Investigational Drugs, 85% use Investigational Devices, 55% conduct Classified Research, and 25% conduct Planned Emergency Research without Consent.

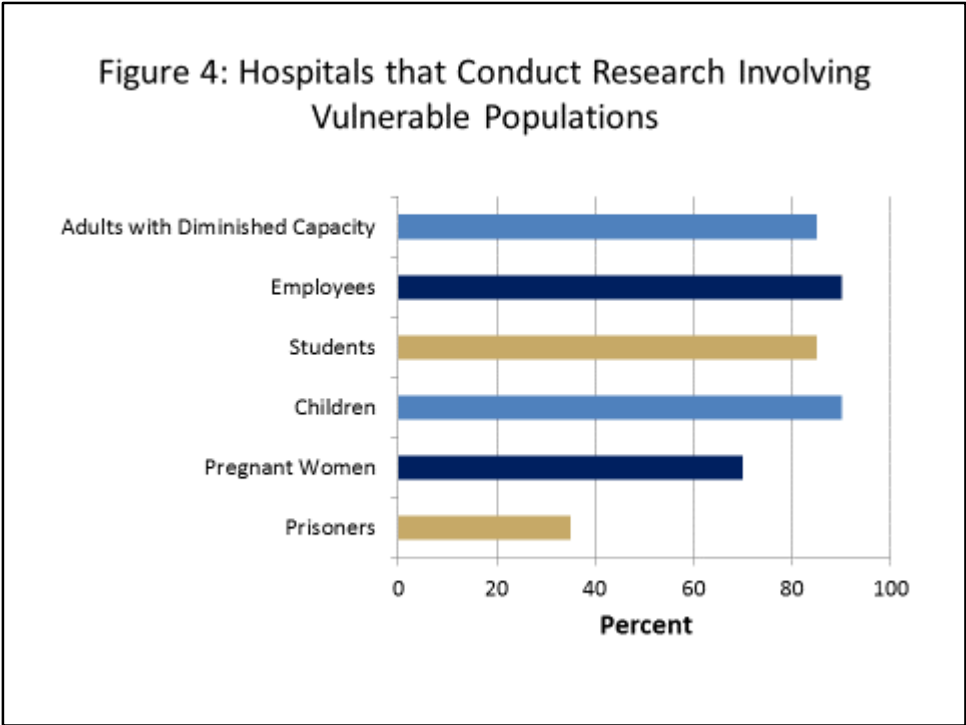


Figure 4: 90% of hospitals conduct research involving Employees, 90% also conduct research involving children 85% involving Adults with Diminished Capacity, 85% also conduct research involving Students, 70% conduct research involving Pregnant Women, and 35% conduct research involving Prisoners.

Sponsors and Regulators of Hospital Research

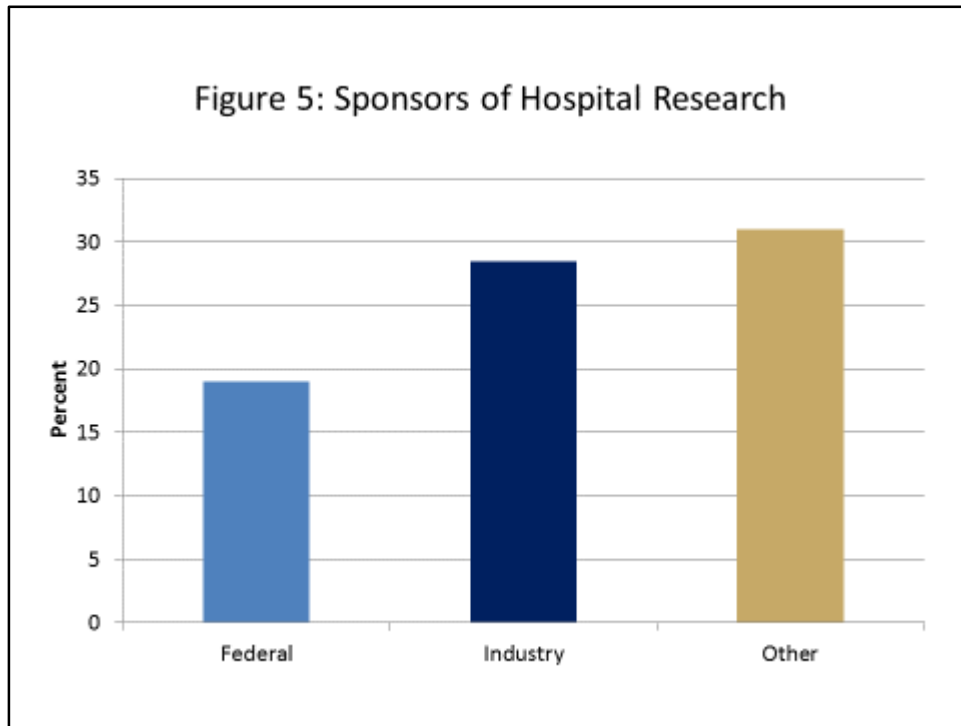


Figure 5: 19% of hospital research is federally sponsored, 28.5% of hospital research is sponsored by industry, and 31% by other sponsors.

Figure 6: Regulations and Guidance Followed by Hospitals

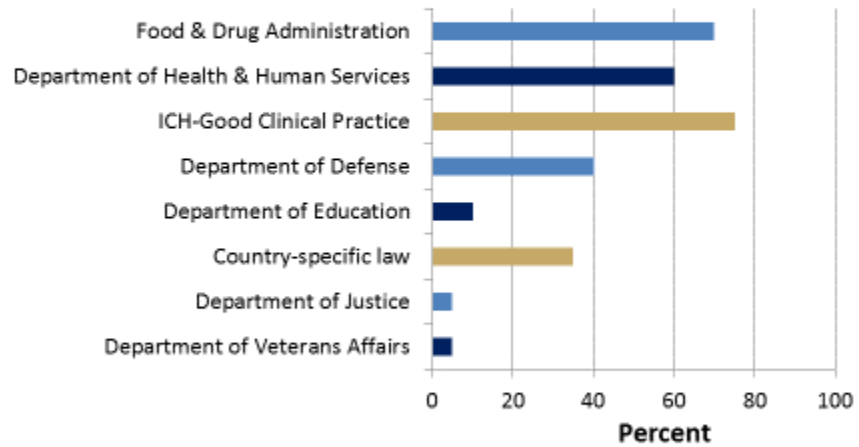


Figure 6: 70% of hospitals follow Food and Drug Administration regulations and guidelines, 75% follow ICH- Good Clinical Practices regulations and guidelines, 60% follow Department of Health and Human Services regulations and guidelines, 40% follow Department of Defense regulations and guidelines, 35% follow their Country-Specific regulations and guidelines, 10% follow Department of Education regulations and guidelines, 5% follow Department of Justice regulations and guidelines, and 5% follow Department of Veterans’ Affairs regulations and guidelines.

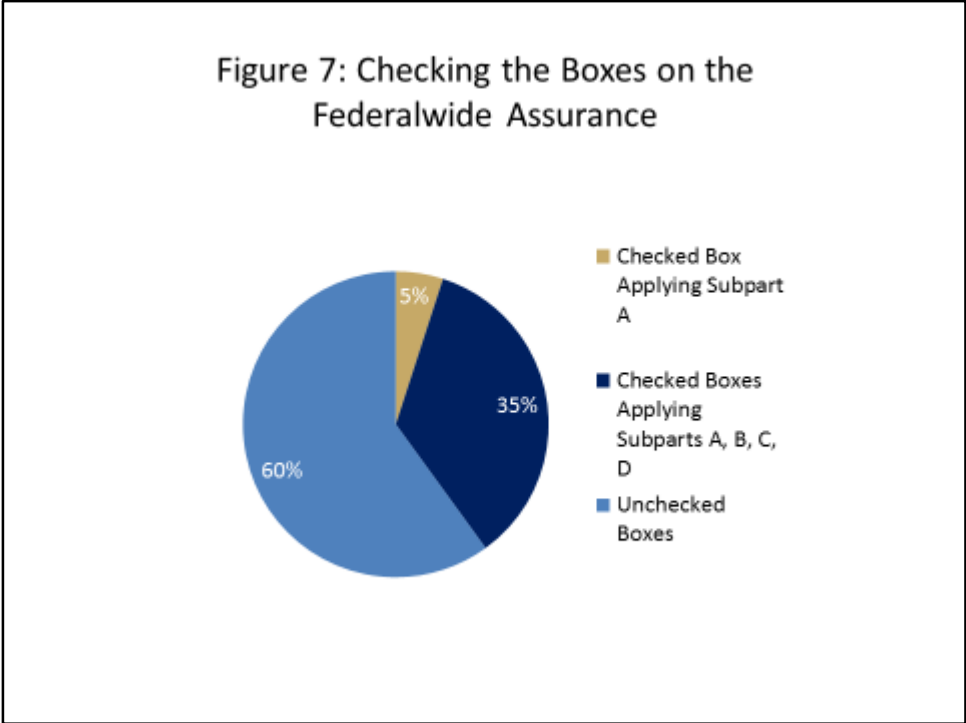


Figure 7: 60% of hospitals Unchecked the Boxes for Federalwide Assurance, 35% checked the boxes Applying to all Subparts (A, B, C, and D), and 5% checked the box only applying to Subpart A.

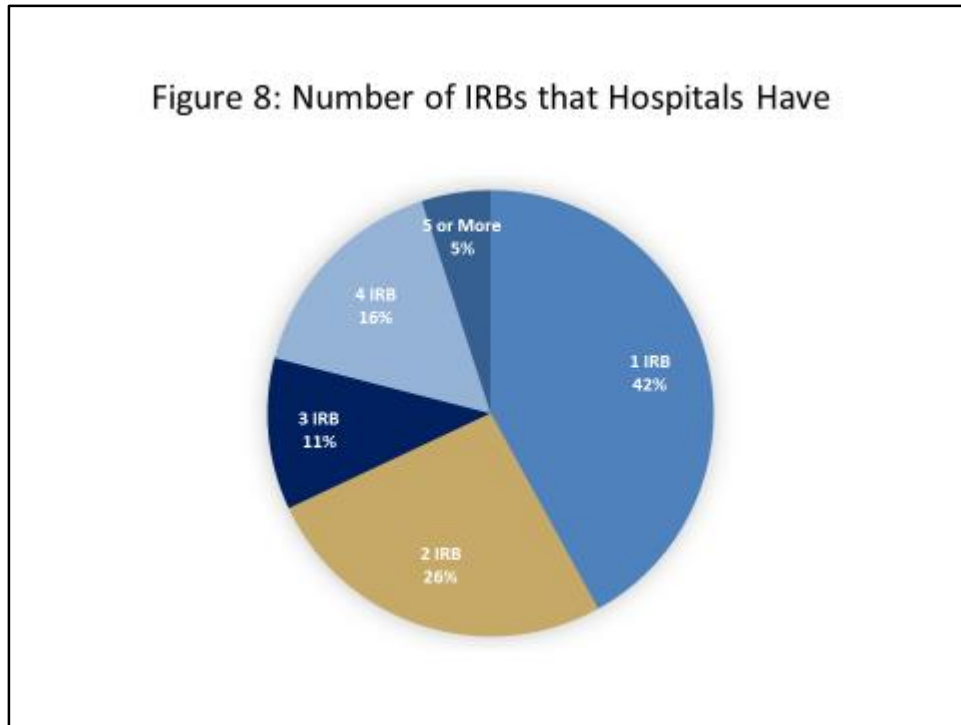


Figure 8: 42% of hospitals have One IRB, 26% have Two IRBs, 11% have Three IRBs, 16% have Four IRBs, and 5% have Five or More IRBs.

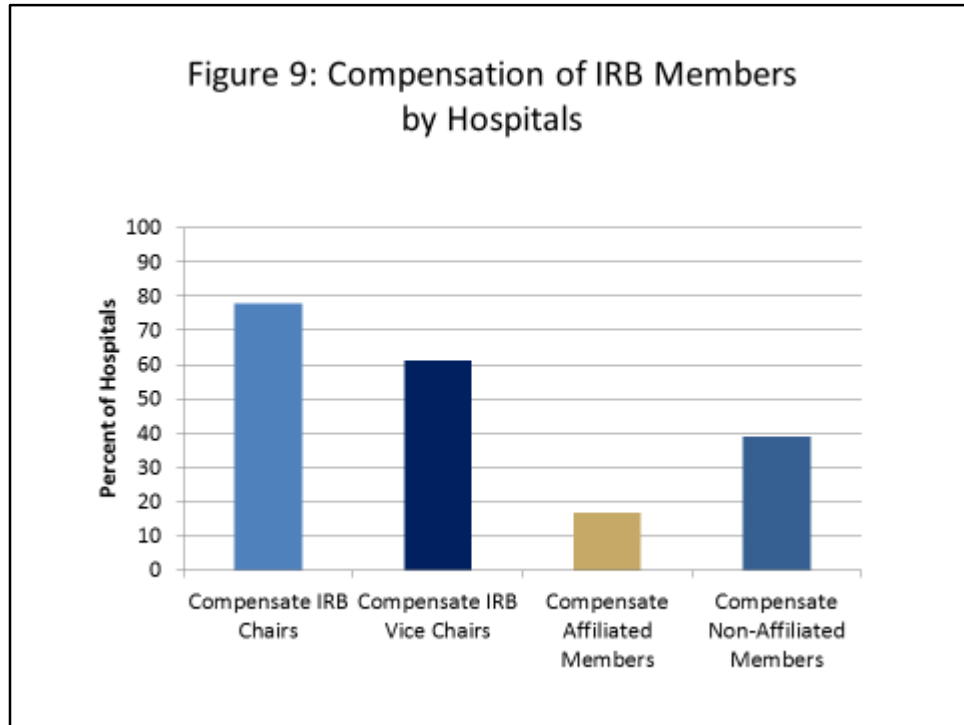


Figure 9: 77.8% of hospitals Compensate IRB Chairs, 61.1% Compensate IRB Vice Chairs, 16.7% Compensate Affiliated Members, and 38.9% Compensate Non-Affiliated Members.

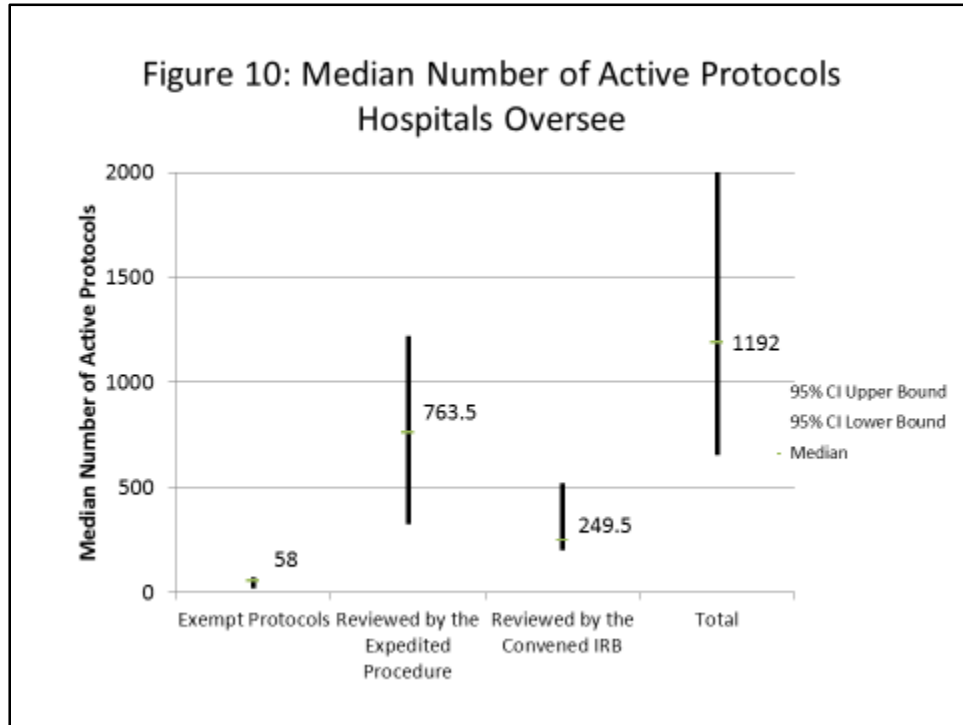


Figure 10: Hospitals oversee a median of 58 Exempt Protocols, a median of 763.5 Protocols are Reviewed by the Expedited Procedure, a median of 249.5 Protocols are Reviewed by the Convened IRB, and oversee a median of 1192 Total Protocols.

Figure 11: Mean Number of Active Protocols Overseen by an IRB Based on the Number of IRBs Hospitals Have

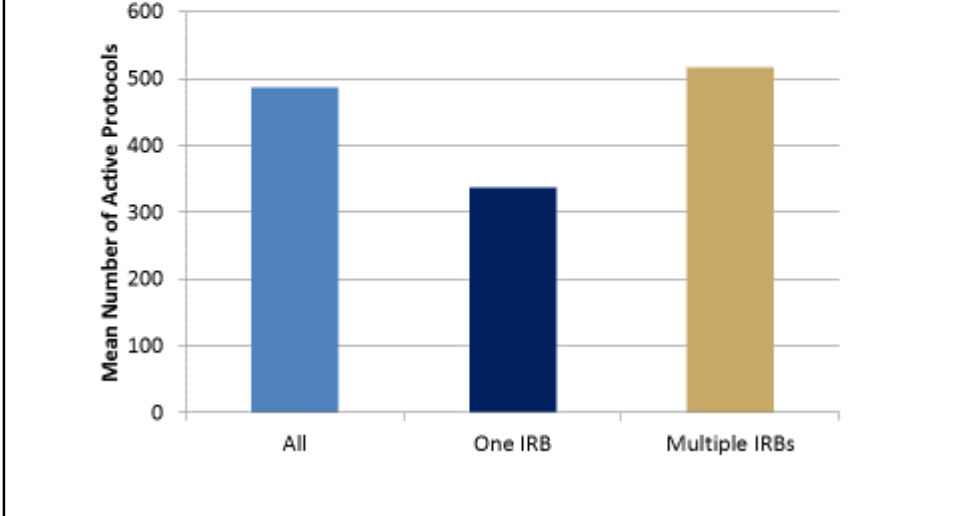


Figure 11: A Mean of 486.7 Protocols per IRB are overseen by all Hospitals, a mean of 337 Protocols are overseen by Hospitals with One IRB and a mean of 516.7 Protocols per IRB are overseen by Hospitals with Multiple IRBs.

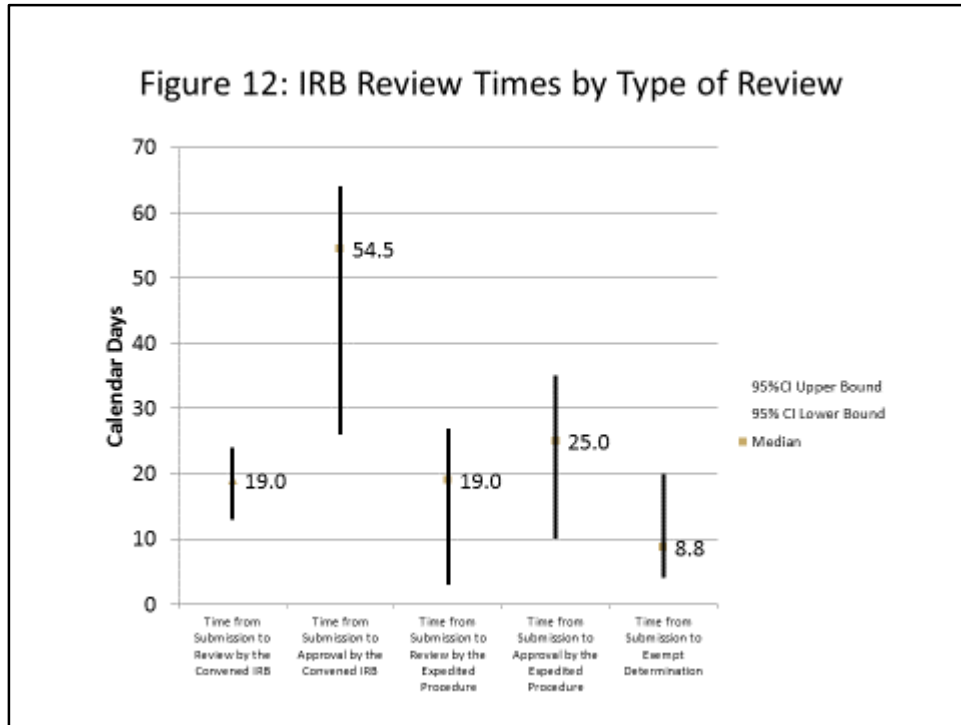


Figure 12: Hospitals take a Median of 19 calendar days from Submission to Protocol Review by the Convened IRB, a median of 54.5 calendar days from Submission to Protocol Approval, a median of 19 calendar days from Submission to Protocol Review by the Expedited Procedure, a median of 25 calendar days from Submission to Protocol Approval by the Expedited Procedure, and a median of 8.8 calendar days from Submission to Exempt Protocol Determination.

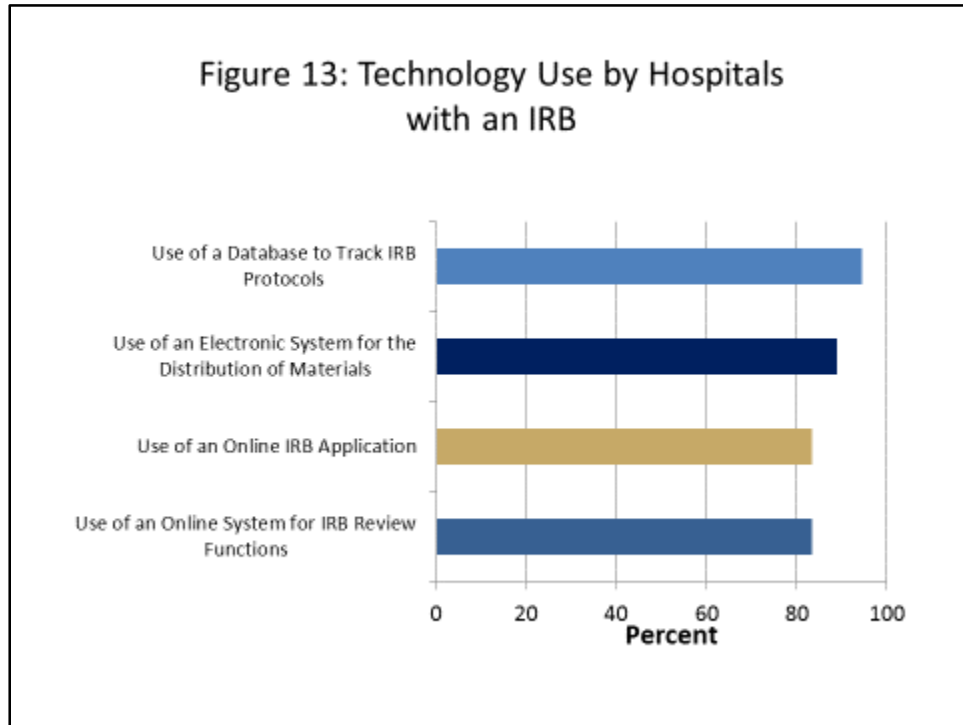


Figure 13: 94.4% of hospitals use a Database to Track IRB Protocols, 88.9% use an Electronic System for the Distribution of Materials, 83.3% use an Online IRB Application, and 83.3% use an Online System for IRB Review Functions.

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	8.9	1192	133.9	759,125
1-100	-	-	-	-
101-500	1.75	140	80	230,000
501-1000	4.6	654.0	142.2	\$414,314
1001-2000	13.8	1,192.0	86.4	\$950,000
2001-4000	11.0	2,235.0	203.2	\$1,288,569
4000+	44.5	7,680.0	172.5	\$5,256,638



AAHRPP®
Association for the Accreditation of
Human Research Protection Programs, Inc.®

2301 M Street, NW
Suite 500
Washington, DC 20037

(202) 783-1112 phone
(202) 783-1113 fax
www.aahrpp.org