



2017 Metrics on Human Research Protection Program Performance for Academic Institutions

Updated May 2, 2018

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 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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General Description of the Research Conducted or Overseen by Academic Institutions

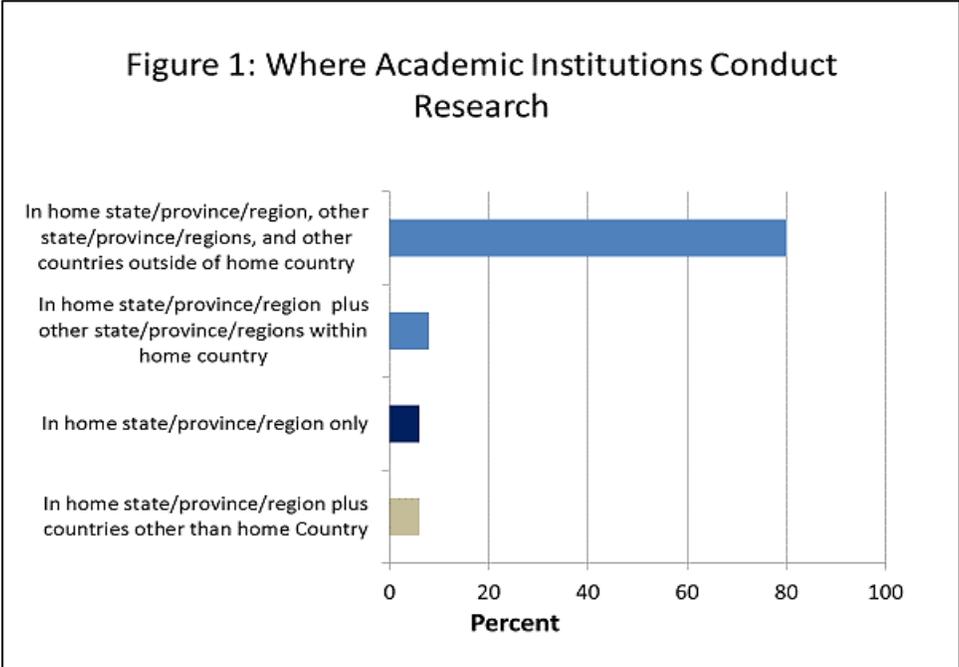


Figure 1: 80% of academic institutions conduct research within their home state/province/region; other states/provinces/regions within their home country, and countries other than their home country; 8% conduct research in their home state/province/region and other states/provinces/regions within their home country; 6% conduct research in their home state/province/region only; and 6% conduct research in their home state/province/region and countries other than their home countries.

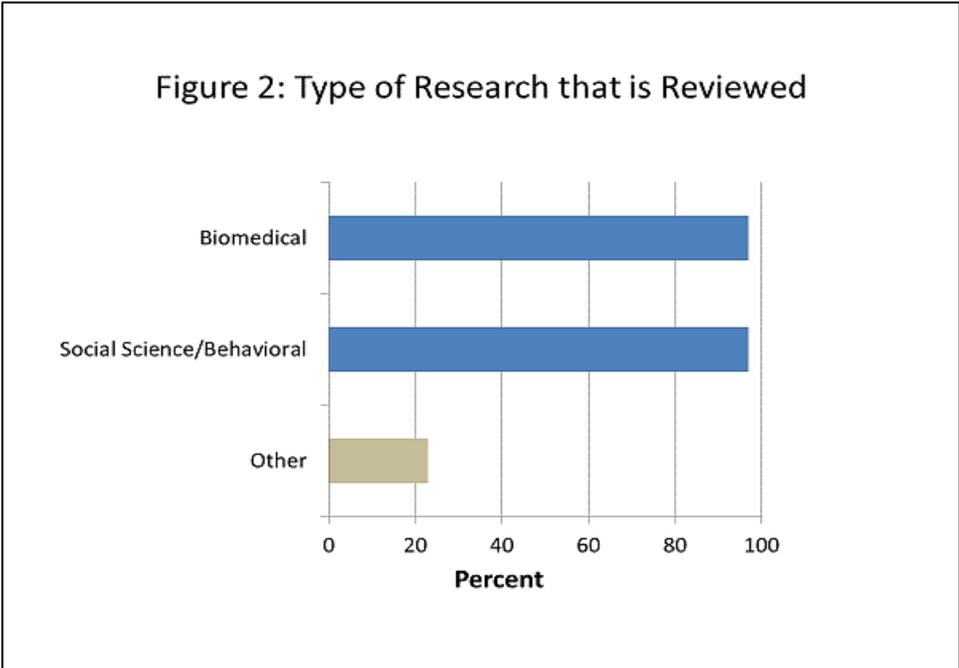


Figure 2: 97% of academic institutions conduct biomedical research; 97% conduct social science/behavioral research; and 23% conduct research falling into other categories.

Selected Types of Research Conducted or Overseen by Academic Institutions

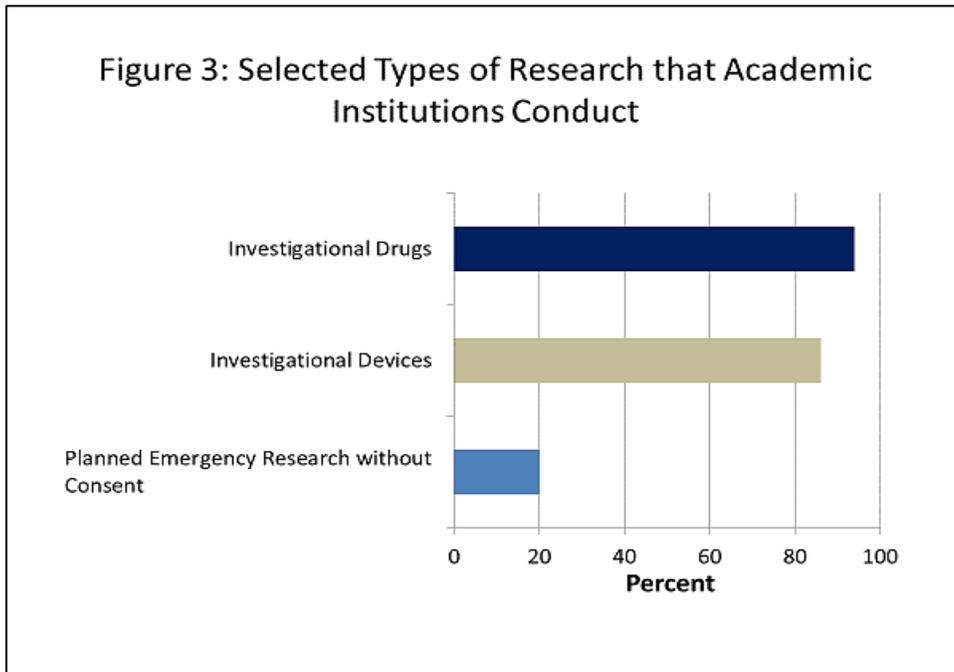


Figure 3: 94% of academic institutions conduct research involving investigational drugs; 86% conduct research involving investigational devices; and 23% conduct planned emergency research without consent.

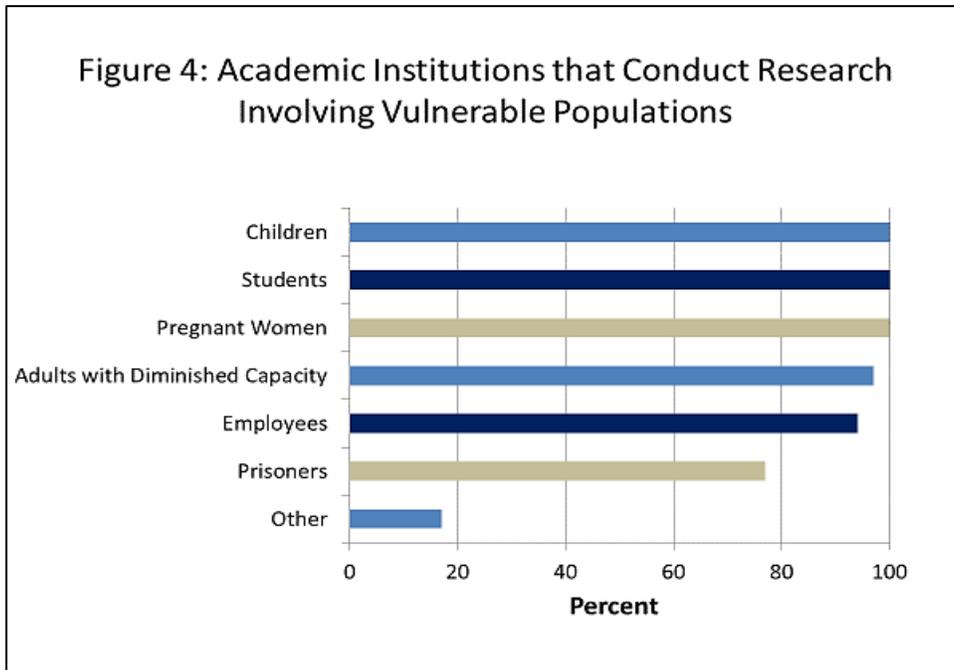


Figure 4: 100% of academic institutions conduct research with children; 100% conduct research with students; 100% conduct research with pregnant women; 97% conduct research with adults with diminished capacity; 94% conduct research with employees; 77% conduct research with prisoners; and 17% with other vulnerable populations.

Sponsors and Regulators of Academic Research

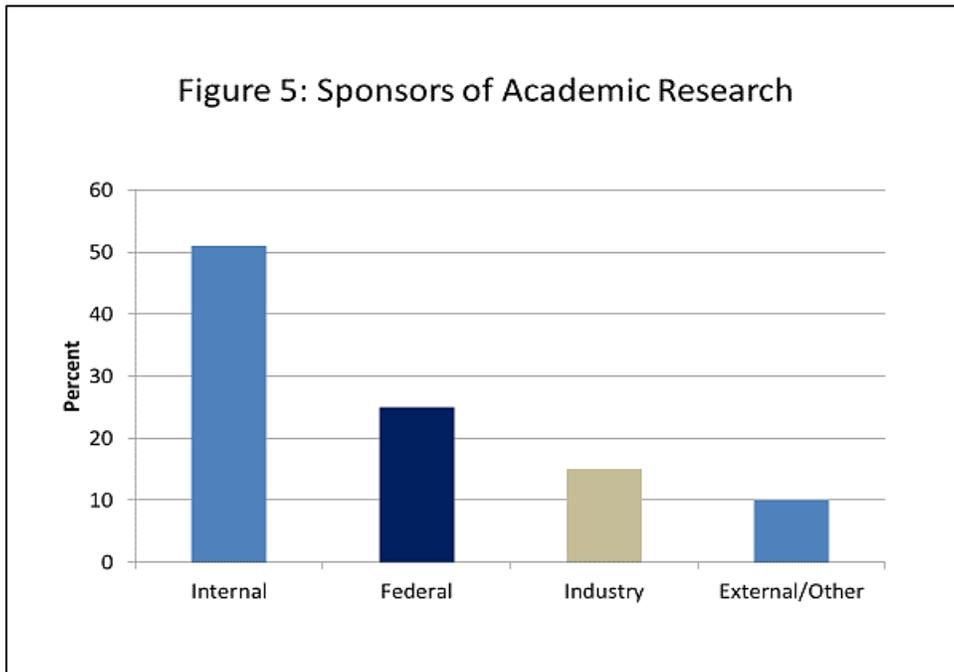


Figure 5: For academic institutions, a median of 51% of research is internally sponsored; a median of 25% of research portfolios is federally sponsored; a median of 15% of research is industry sponsored; and a median of 10% of research portfolios is externally sponsored.

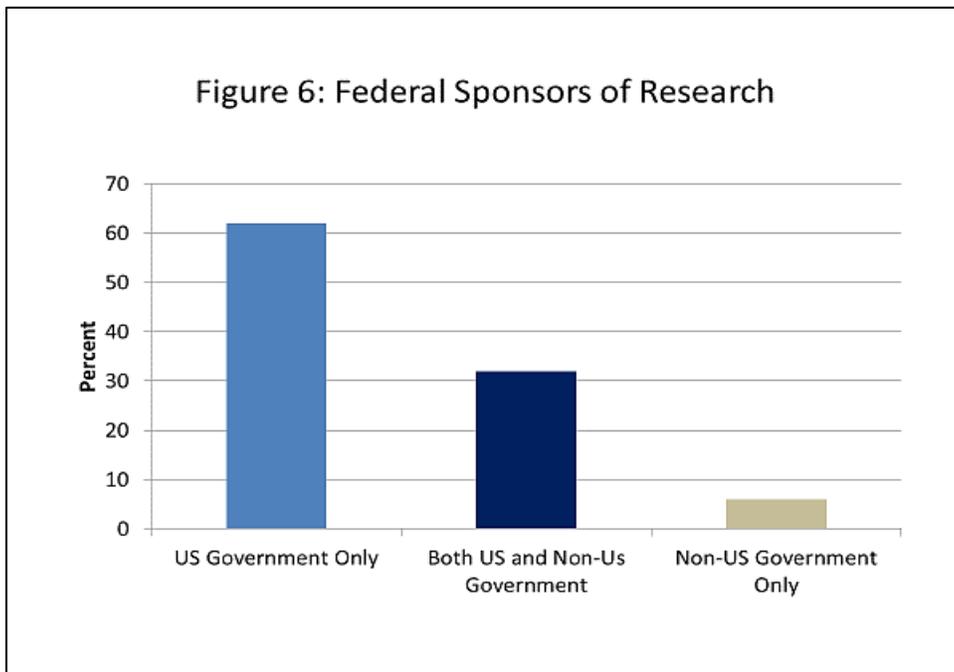


Figure 6: For academic institutions receiving federal funds, a median of 21% of research is sponsored by the US Government only and a median of 19% of research portfolios is sponsored by both US and Non-US governments.

Sponsors and Regulators of Academic Research

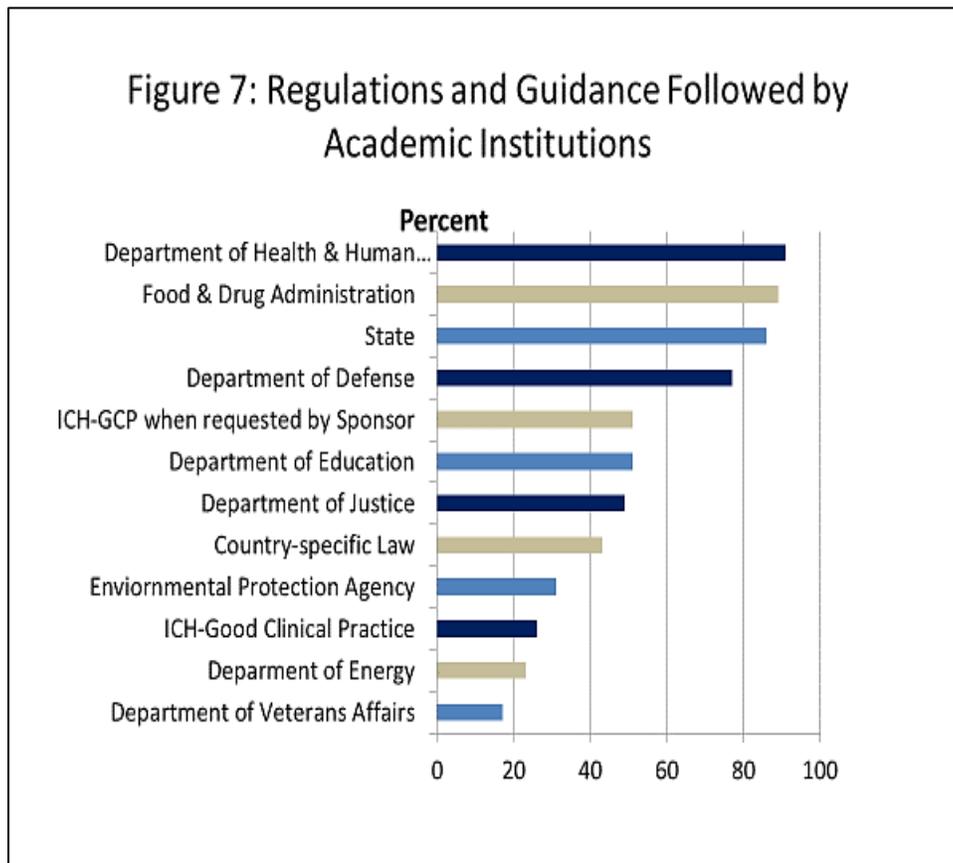


Figure 7: 91% of academic institutions follow Department of Health and Human Services regulations; 89% follow FDA regulations; 86% follow regulations or guidelines of their state; 77% follow Department of Defense requirements; 51% follow the ICH-Good Clinical Practice guideline when requested by the sponsor; 51% follow Department of Education requirements; 49% follow Department of Justice requirements; 43% follow Country-specific regulations or guidelines; 31% follow Environmental Protection Agency requirements; 26% follow the ICH-Good Clinical Practice guideline; 23% follow Department of Energy requirements; and 17% follow Department of Veterans Affairs requirements.

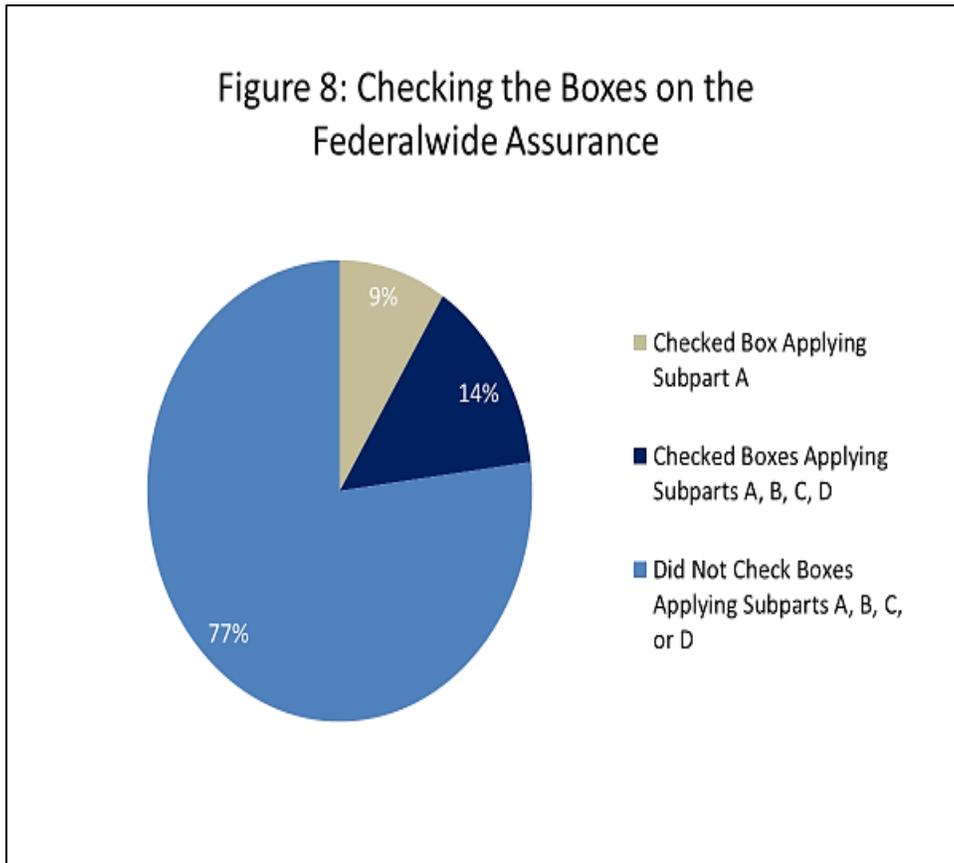


Figure 8: 77% of academic institutions did not check boxes applying Subparts A, B, C, or D; 14% checked the boxes applying all Subparts (A, B, C, and D); and 9% checked the box applying Subpart A only.

Figure 9: Number of IRBs that Academic Institutions have per Organization

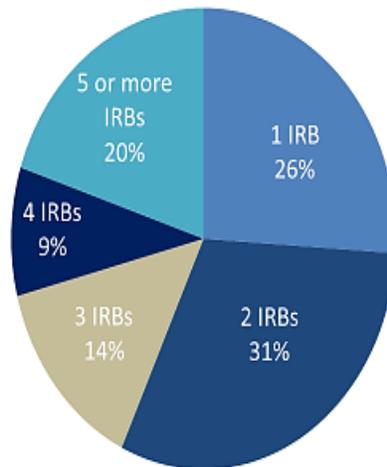


Figure 9: 26% of academic institutions have one IRB; 31% have two IRBs; 14% have three IRBs, 9% have four IRBs; and 20% have five or more IRBs.

Compensation of IRB Members

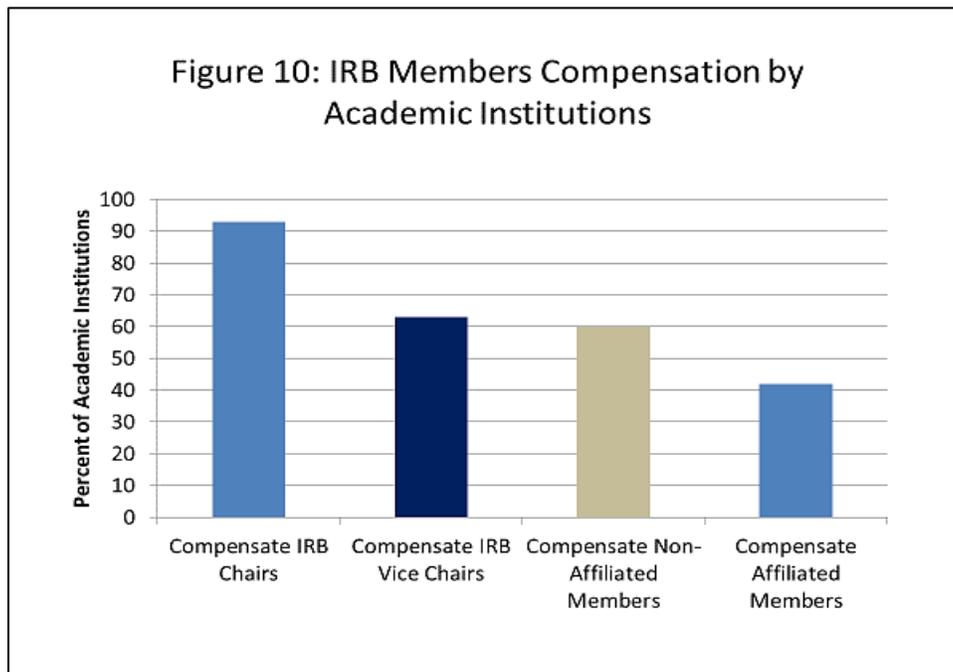


Figure 10: 93% of academic institutions compensate IRB chairs; 63% compensate IRB vice chairs; 60% compensate non-affiliated members; and % compensate affiliated members.

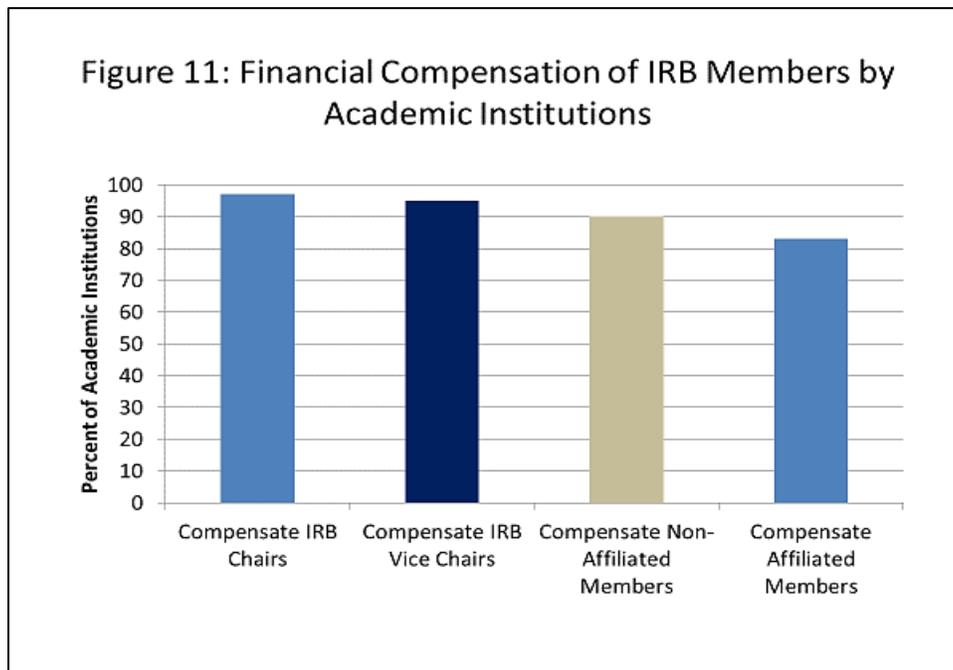


Figure 11: Of academic institutions that compensate IRB members, 97% compensate IRB chairs financially; 93% compensate IRB vice chairs financially; 90% compensate non-affiliated members financially; and 83% compensate affiliated members financially.

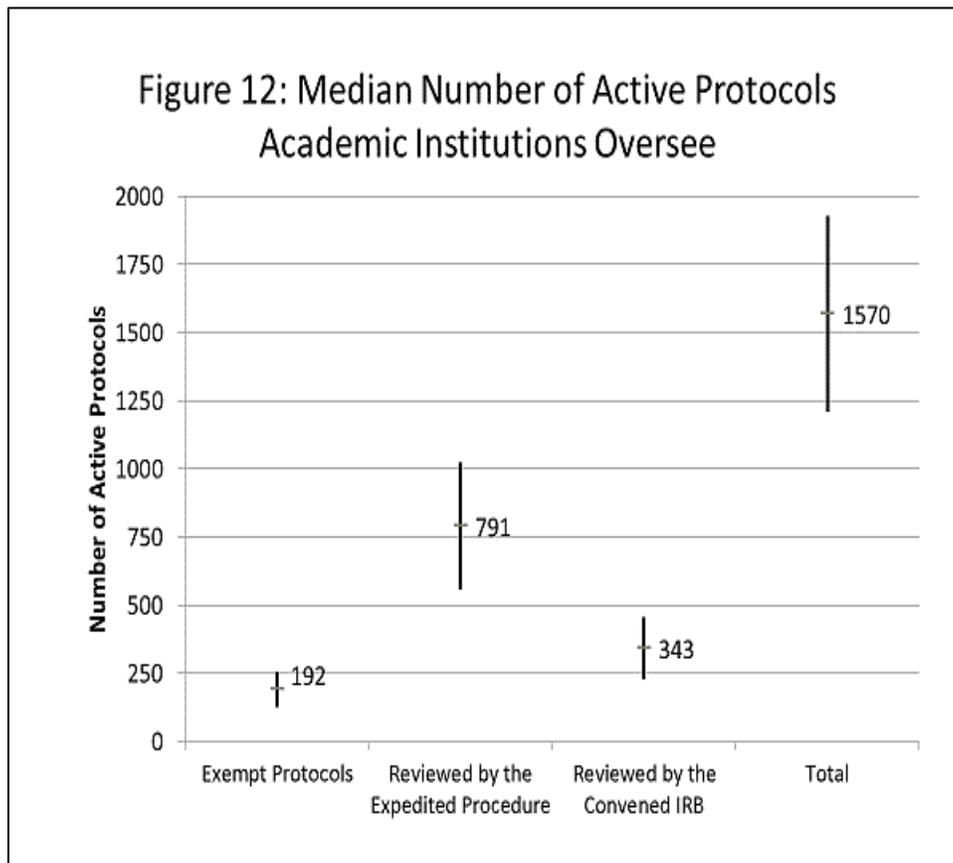


Figure 12: A median of 192 protocols were deemed exempt by academic institutions*; a median of 791 protocols were reviewed by the expedited procedure; a median of 256 protocols were reviewed by the convened IRB; and a median of 1570 total protocols were overseen by academic institutions.

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

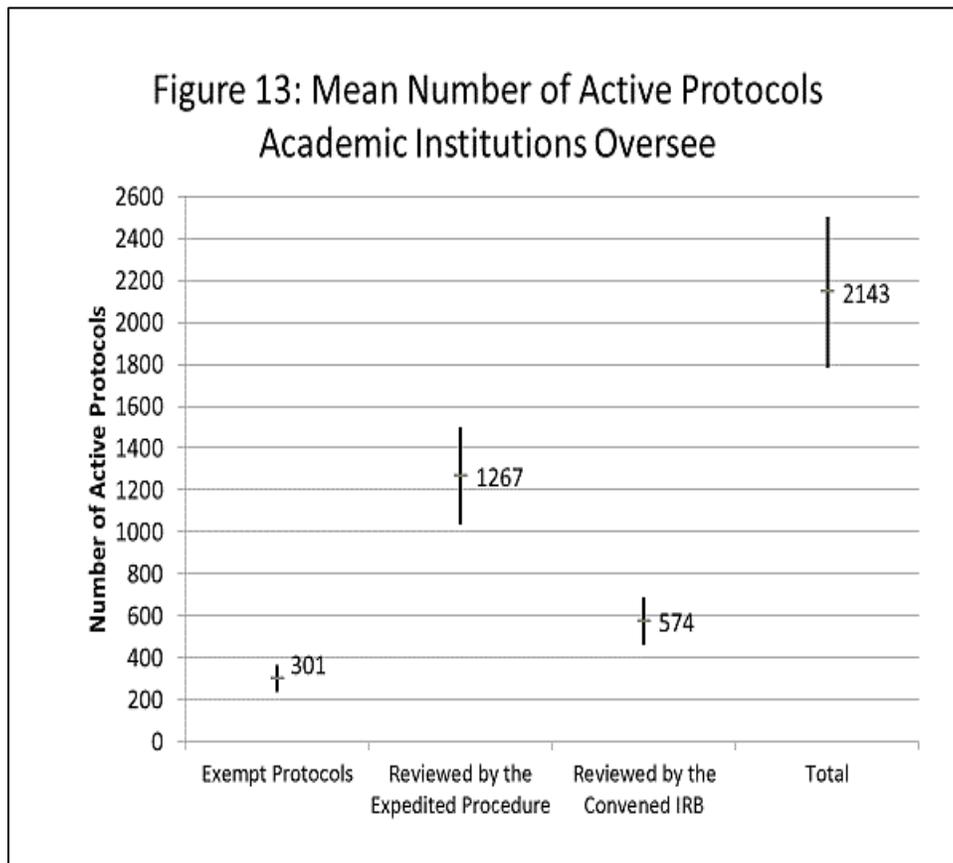


Figure 13: A mean of 301 protocols were deemed exempt by academic institutions*; a mean of 1267 protocols were reviewed by the expedited procedure; a mean of 574 protocols were reviewed by the convened IRB; and a mean of 2143 total protocols were overseen by academic institutions.

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

Characteristics of IRBs

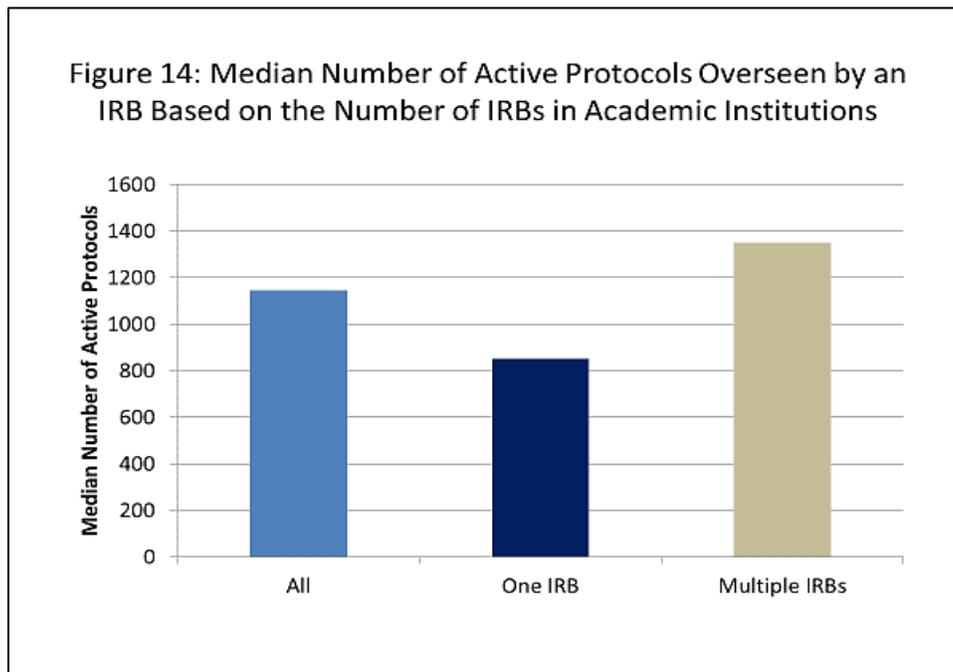


Figure 14: A median of 1144 protocols were overseen by academic institutions; a median of 852 protocols were overseen by academic institutions with one IRB; and a median of 1350 protocols were overseen by academic institutions with two or more IRBs.

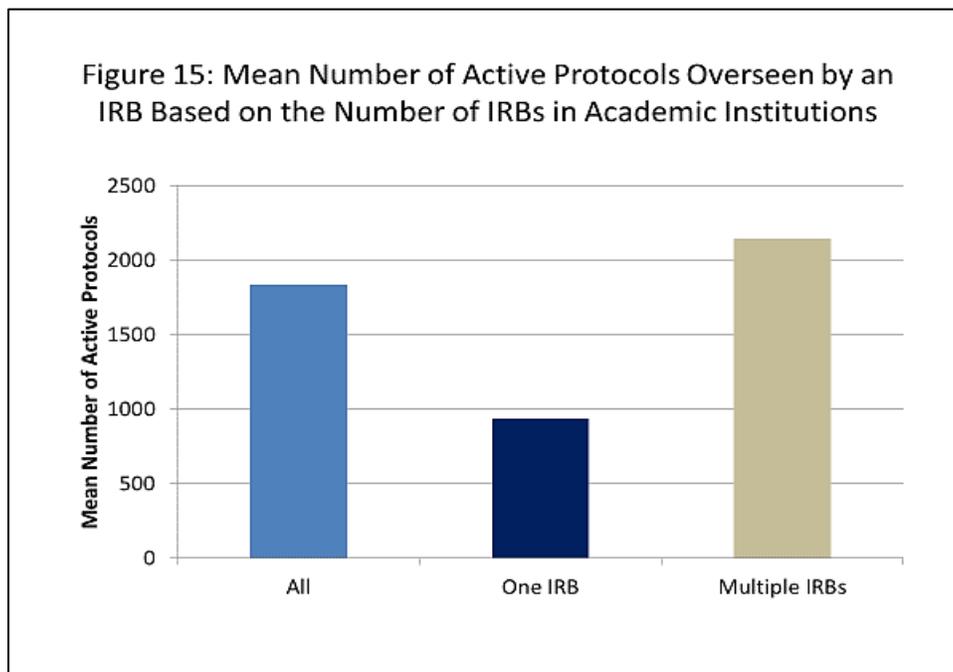


Figure 15: A mean of 1832 protocols were overseen by academic institutions; a mean of 938 protocols were overseen by academic institutions with one IRB; and a mean of 2142 protocols were overseen by academic institutions with two or more IRBs.

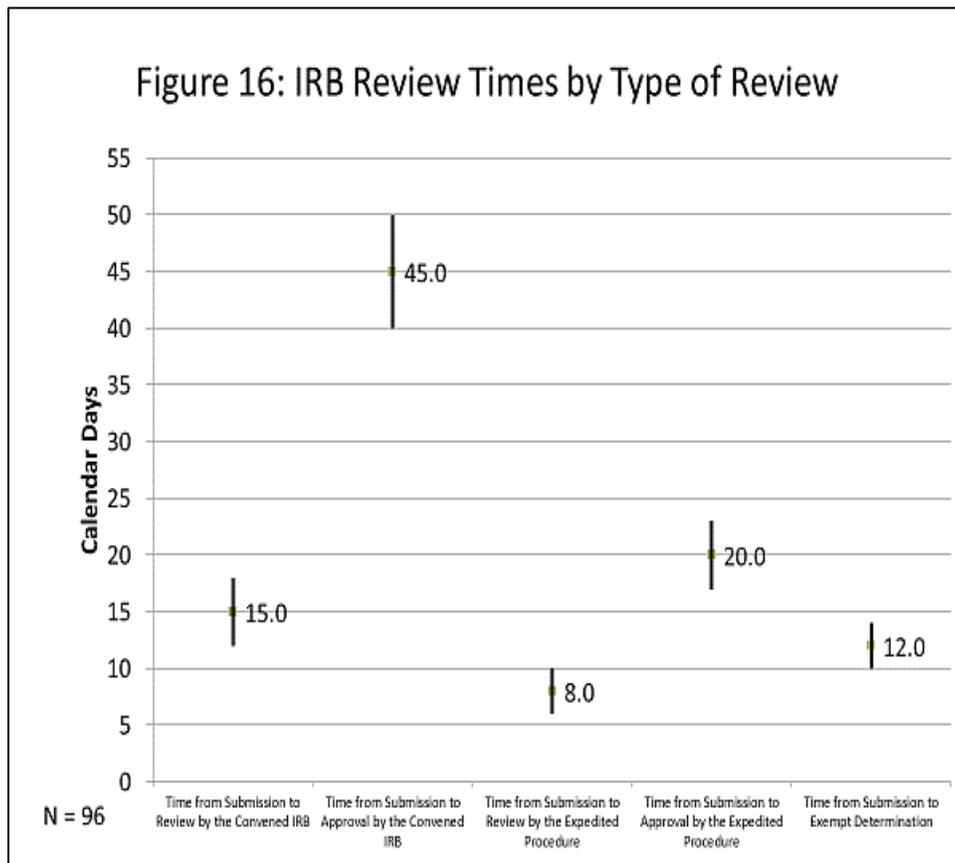


Figure 16: The time from submission to review by the convened IRB is a median of 15 calendar days; the time from submission to approval by the convened IRB is a median of 45 calendar days; the time from submission to review by the expedited procedure is a median of 8 calendar days; the time from submission to approval by the expedited procedure is a median of 20 calendar days; and the time from submission to exempt determination is a median of 12 calendar days.

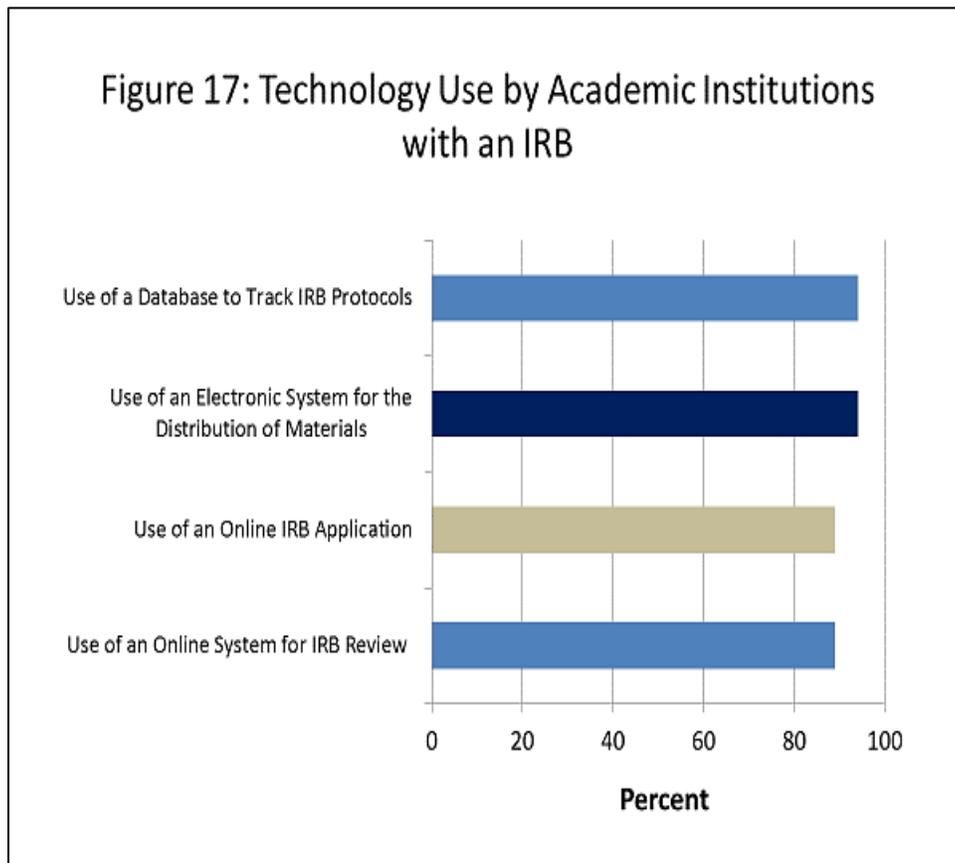


Figure 17: 94% of academic institutions use a database to track IRB protocols; 94% use an electronic system for the distribution of materials; 89% use an online IRB application; and 89% use an online system for IRB review functions.

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	12	1683	146	\$797,107
1-500	3	263	88	\$101,816
501-1000	4	736	184	\$404,150
1001-2000	9	1584	176	\$615,978
2001-4000	18	2662	148	\$1,573,831
4000+	25	5497	220	\$2,322,000



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