



2016 Metrics on Human Research Protection Program Performance for Academic Institutions

Updated April 24, 2017

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 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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General Description of the Research Conducted or Overseen by Academic Institutions

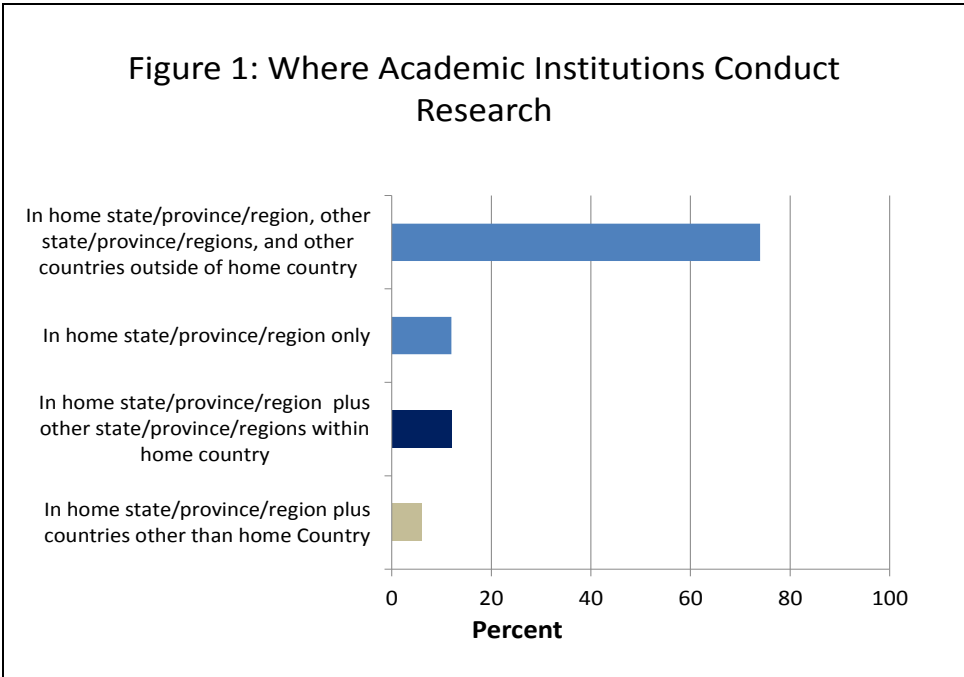


Figure 1: 74% of academic institutions conduct research home state/province/region, other states/provinces/regions within their home country, and countries other than their home country, 12% conduct research in their home state/province/region only, 12% conduct research in their home state/province/region and other states/provinces/regions within their home country, and 6% conduct research in their home state/province/region and countries other than their home countries.

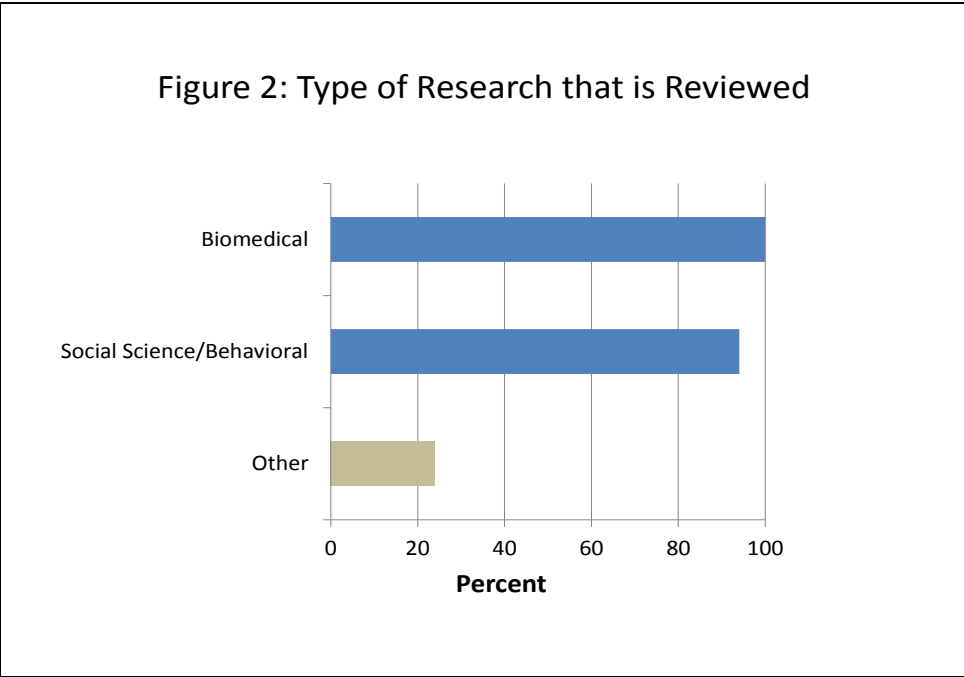


Figure 2: 100% of academic institutions conduct biomedical research, 94% conduct social science/behavioral research, and 24% conduct research falling into other categories.

Selected Types of Research Conducted or Overseen by Academic Institutions

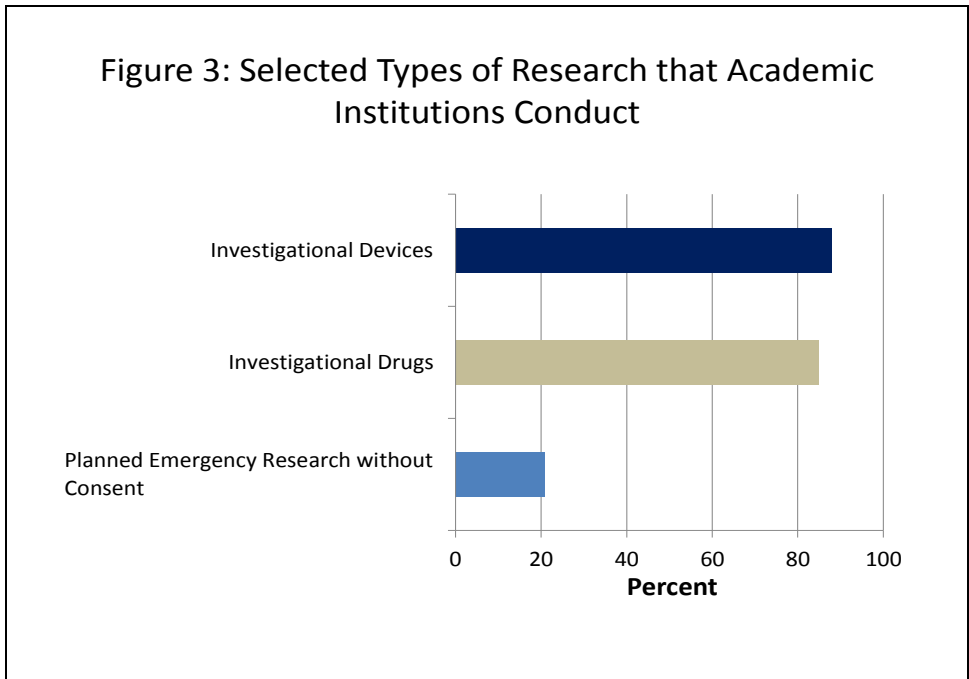


Figure 3: 89% of academic institutions conduct research involving investigational devices, 85% conduct research involving investigational drugs, and 21% conduct planned emergency research without consent.

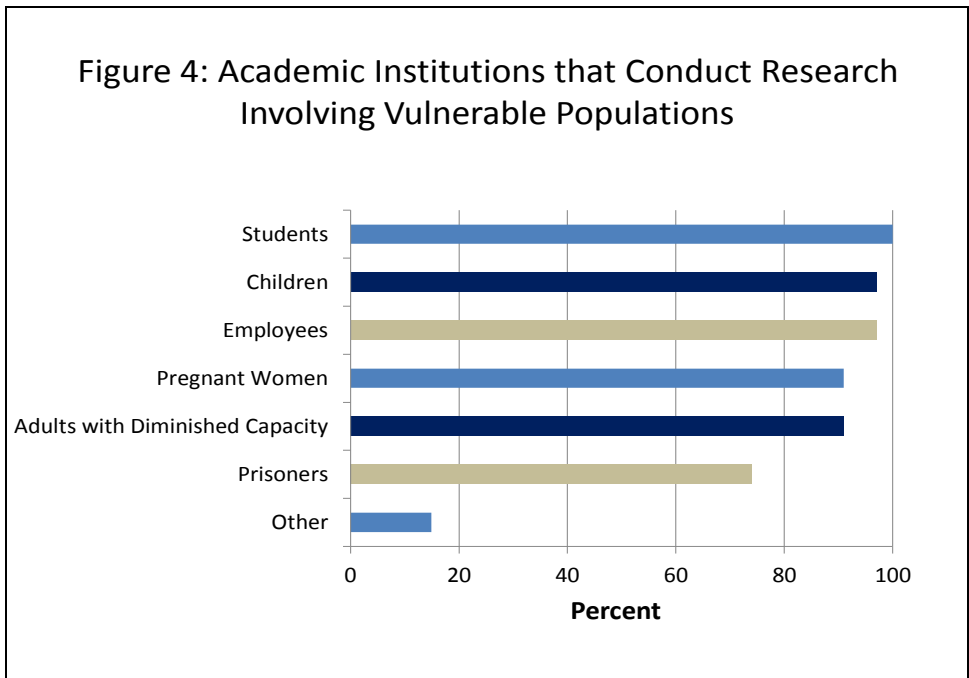


Figure 4: 100% of academic institutions conduct research with students, 97% conduct research with employees and children, 91% conduct research with adults with diminished capacity and pregnant women, 74% conduct research with prisoners, and 12% with other vulnerable populations.

Sponsors and Regulators of Academic Research

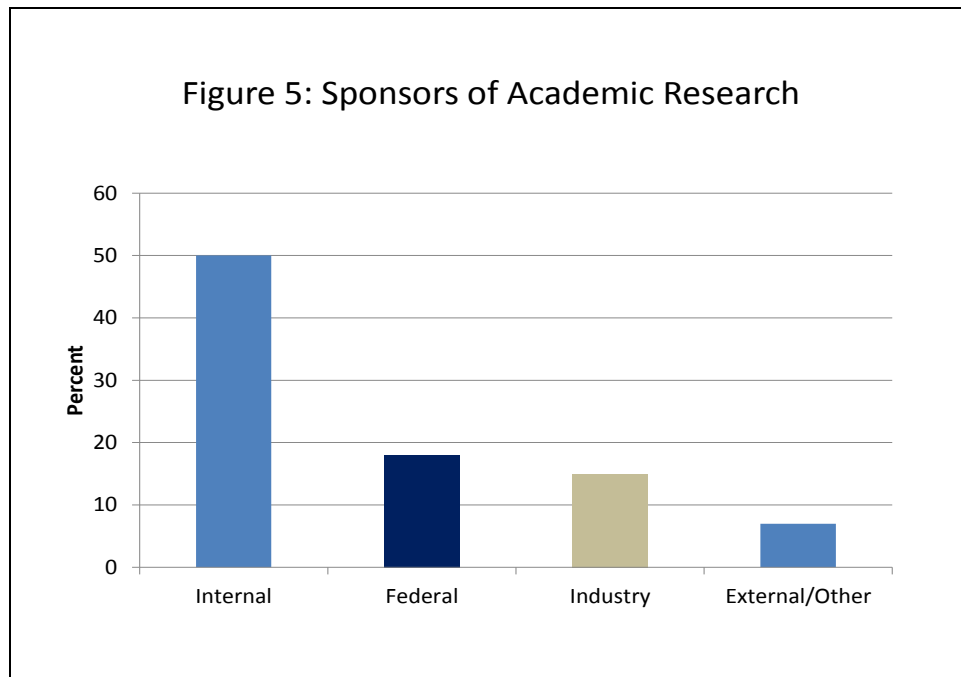


Figure 5: For academic institutions, a median of 50% of research is internally sponsored, a median of 18% of research portfolios is federally sponsored, a median of 15% of research is industry sponsored, and a median of 7% of research portfolios is externally sponsored.

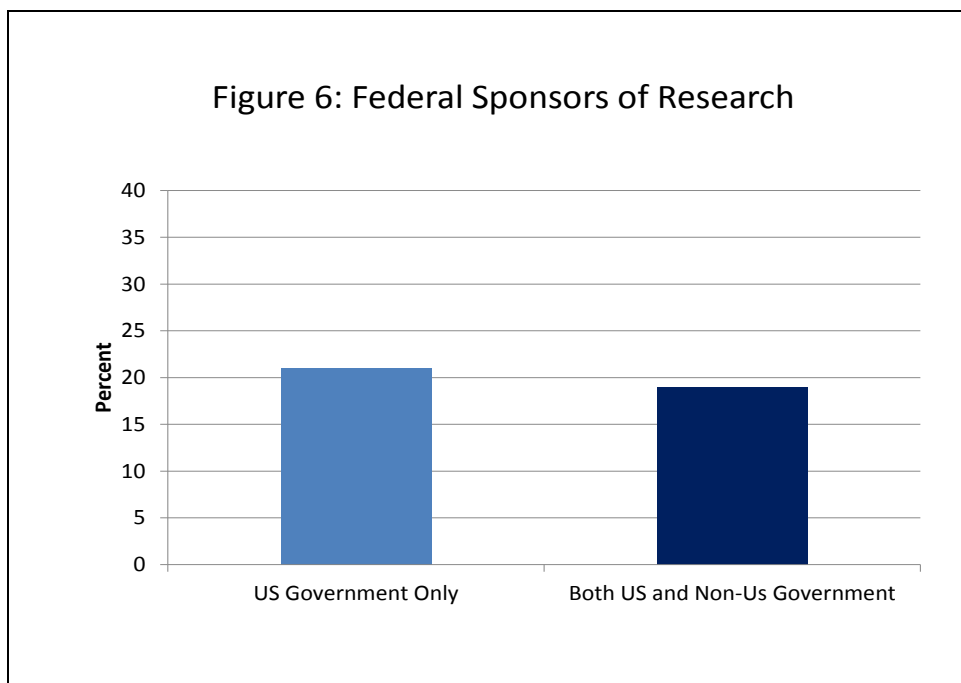


Figure 6: For academic institutions receiving federal funds, a median of 21% of research is sponsored by the US Government only and a median of 19% of research portfolios is sponsored by both US and Non-US governments.

Sponsors and Regulators of Academic Research

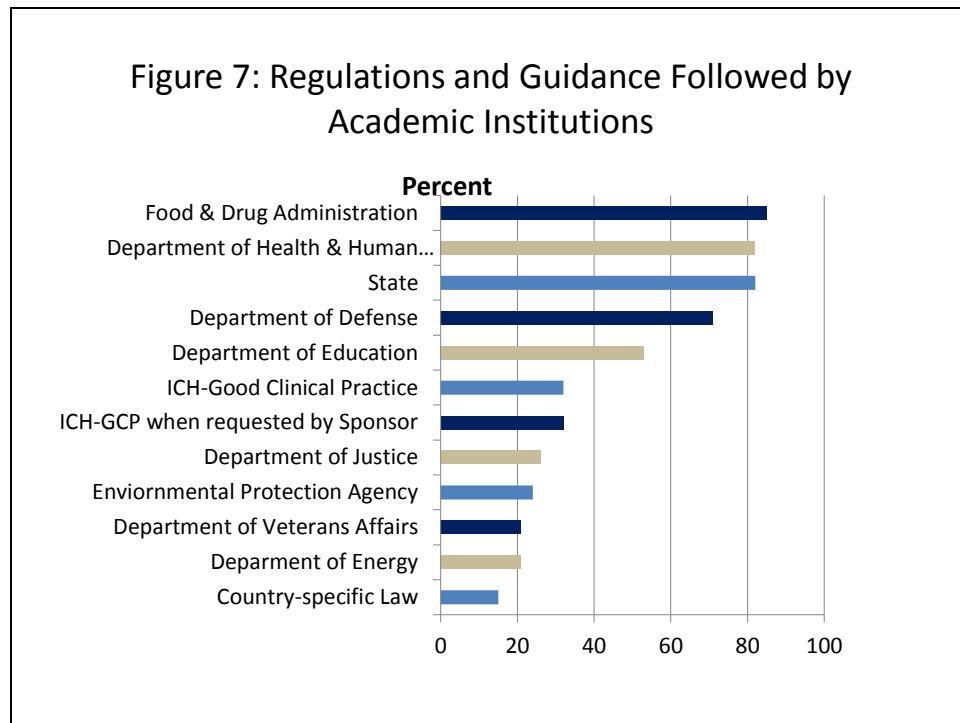


Figure 7: 85% of academic institutions follow FDA regulations, 82% follow Department of Health and Human Services regulations, 82% follow regulations or guidelines of their state, 71% follow Department of Defense requirements, 53% follow Department of Education requirements, 32% follow the ICH-Good Clinical Practice guideline, 32% follow the ICH-Good Clinical Practice guideline when requested by the sponsor, 26% follow Department of Justice requirements, 24% follow Environmental Protection Agency requirements, 21% follow Department of Veterans Affairs requirements, 21% follow Department of Energy requirements, and 15% follow Country-specific regulations or guidelines.

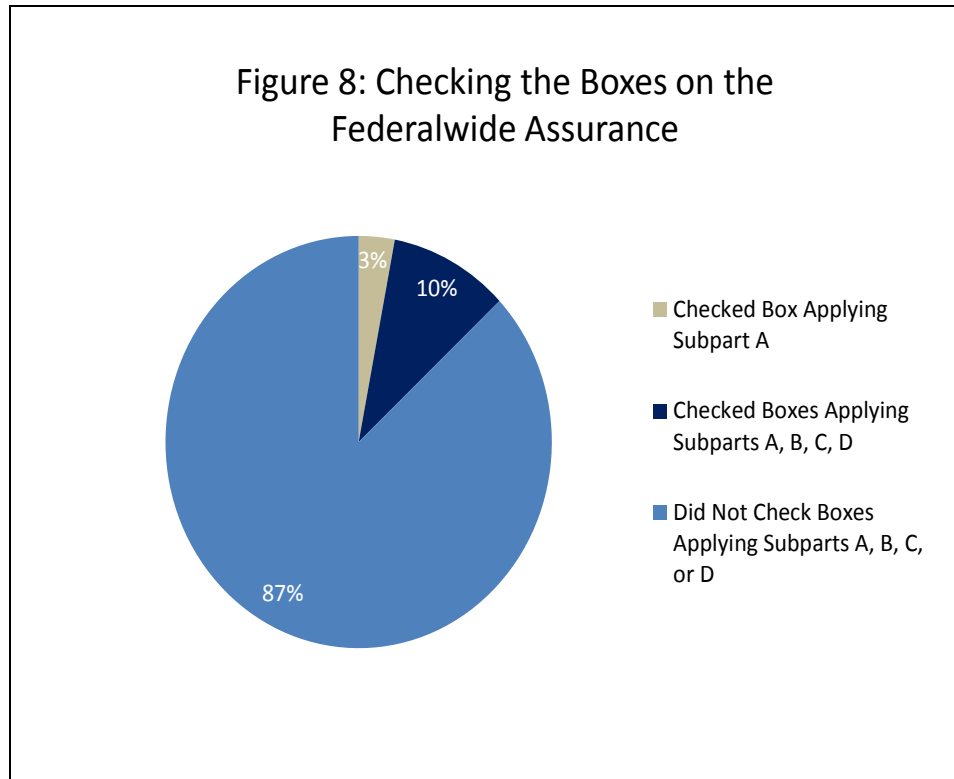


Figure 8: 87% of academic institutions did not check boxes applying Subparts A, B, C, or D, 3% checked the boxes applying all Subparts (A, B, C, and D), and 10% checked the box applying Subpart A only.

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

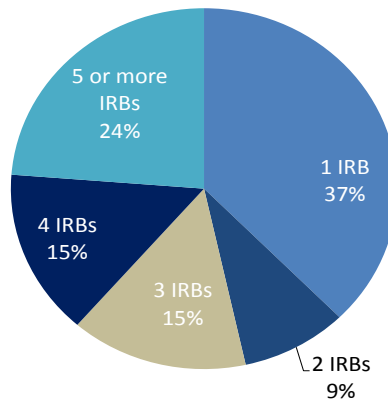


Figure 9: 37% of academic institutions have one IRB, 9% have two IRBs, 15% have three IRBs, 15% have four IRBs, and 24% have five or more IRBs.

Compensation of IRB Members

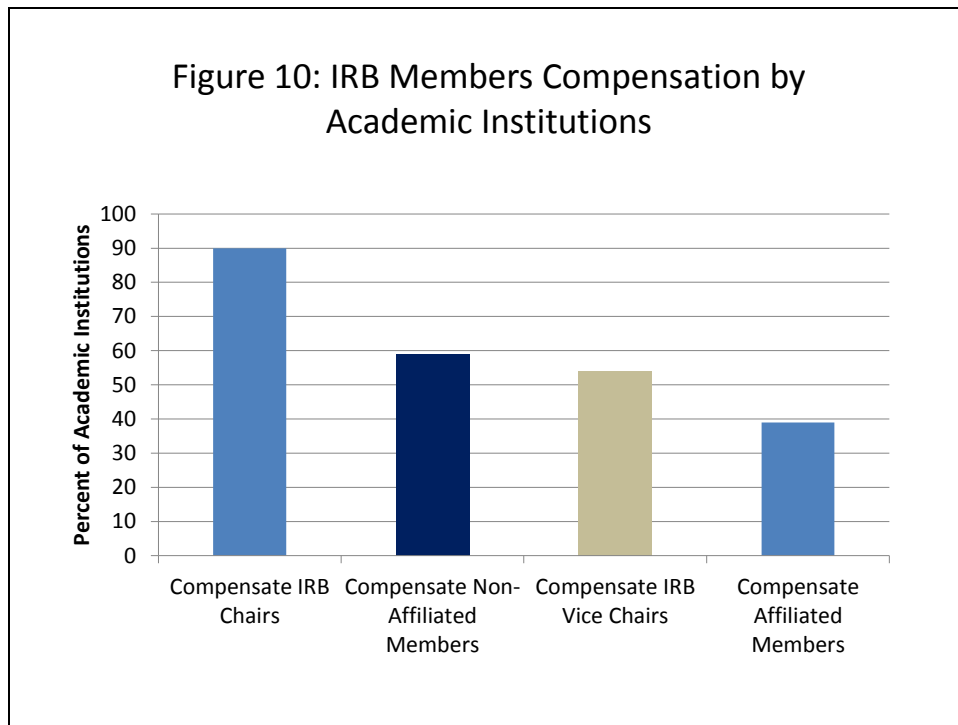


Figure 10: 90% of academic institutions compensate IRB chairs, 59% compensate non-affiliated members, 54% compensate IRB vice chairs, and 39% compensate affiliated members.

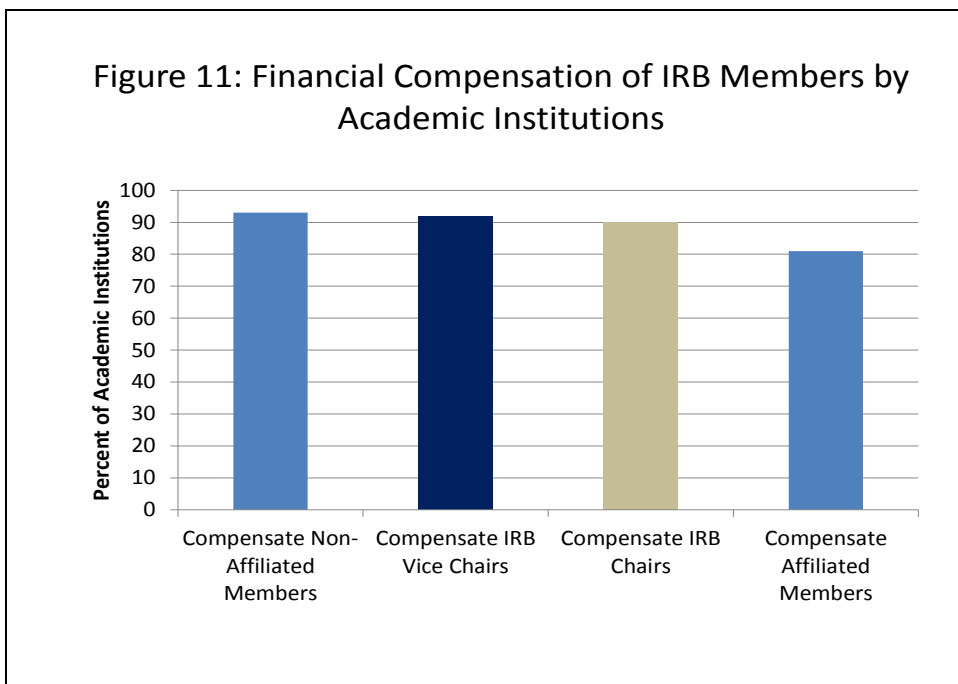


Figure 11: Of academic institutions that compensate IRB members, 93% compensate non-affiliated members financially, 92% compensate IRB vice chairs financially, 90% compensate IRB chairs financially, and 81% compensate affiliated members financially.

Characteristics of IRBs

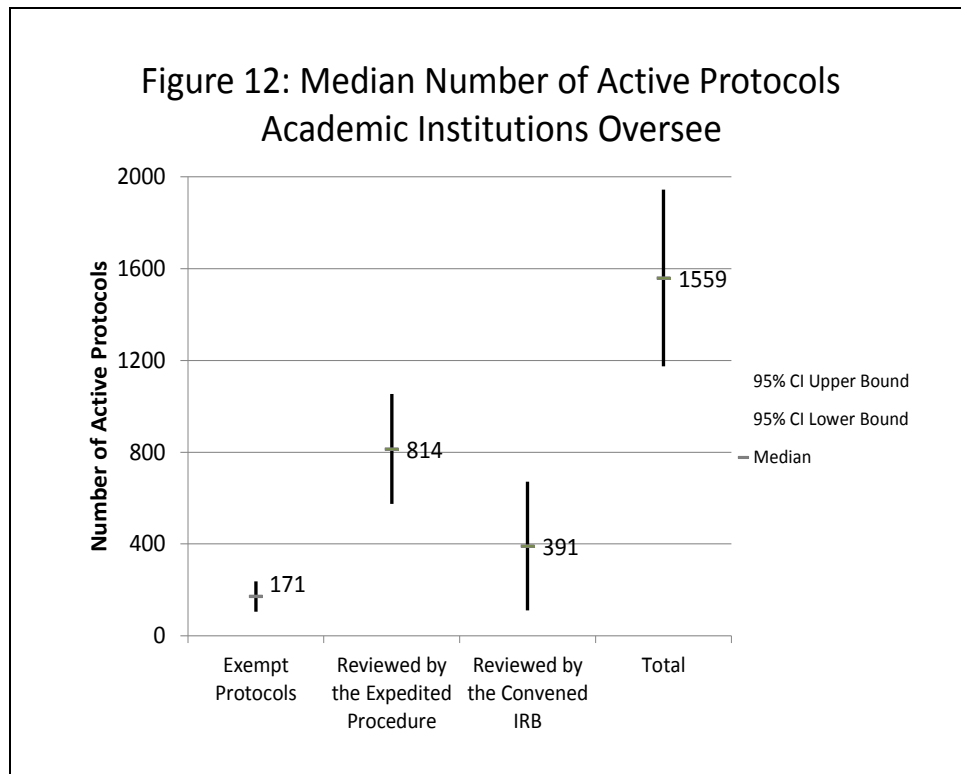


Figure 12: A median of 171 protocols were deemed exempt by academic institutions*, a median of 814 protocols were reviewed by the expedited procedure, a median of 391 protocols were reviewed by the convened IRB, and a median of 1559 total protocols were overseen by academic institutions.

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

Characteristics of IRBs

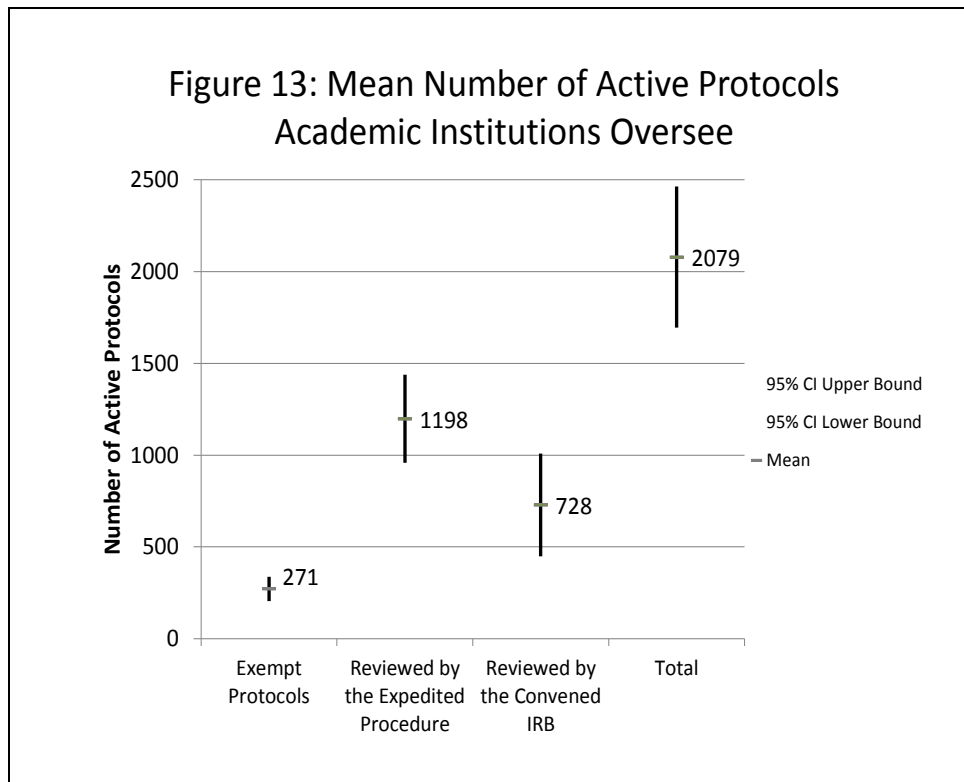


Figure 13: A mean of 271 protocols were deemed exempt by academic institutions*, a mean of 1198 protocols were reviewed by the expedited procedure, a mean of 728 protocols were reviewed by the convened IRB, and a mean of 2079 total protocols were overseen by academic institutions.

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

Characteristics of IRBs

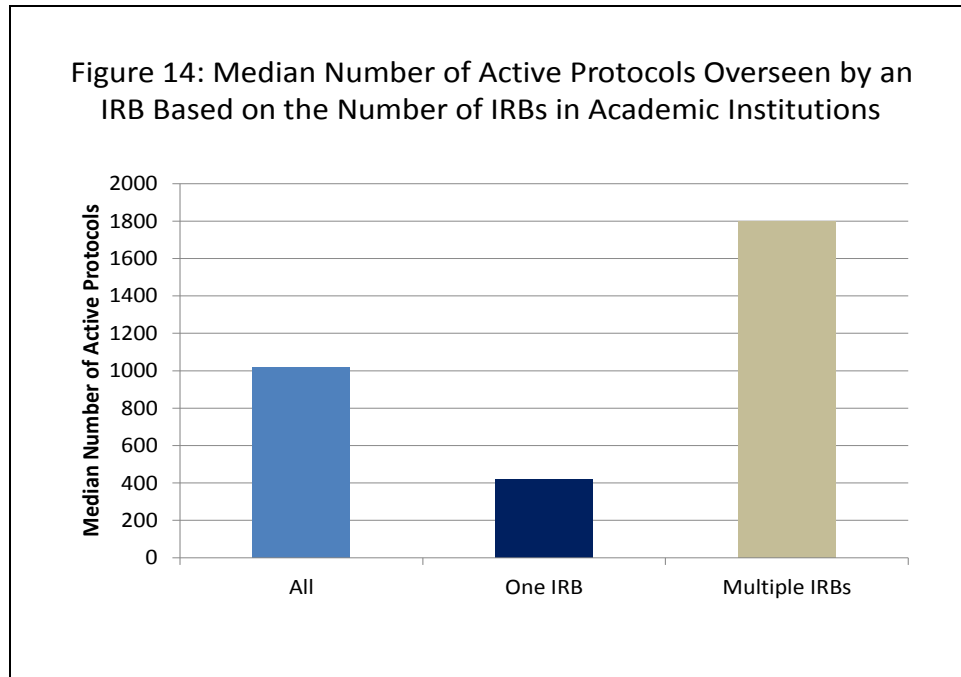


Figure 14: A median of 1017 protocols were overseen by academic institutions, a median of 420 protocols were overseen by academic institutions with one IRB, a median of 707 protocols were overseen by academic institutions with two IRBs, and a median of 1798 protocols were overseen by academic institutions with two or more IRBs.

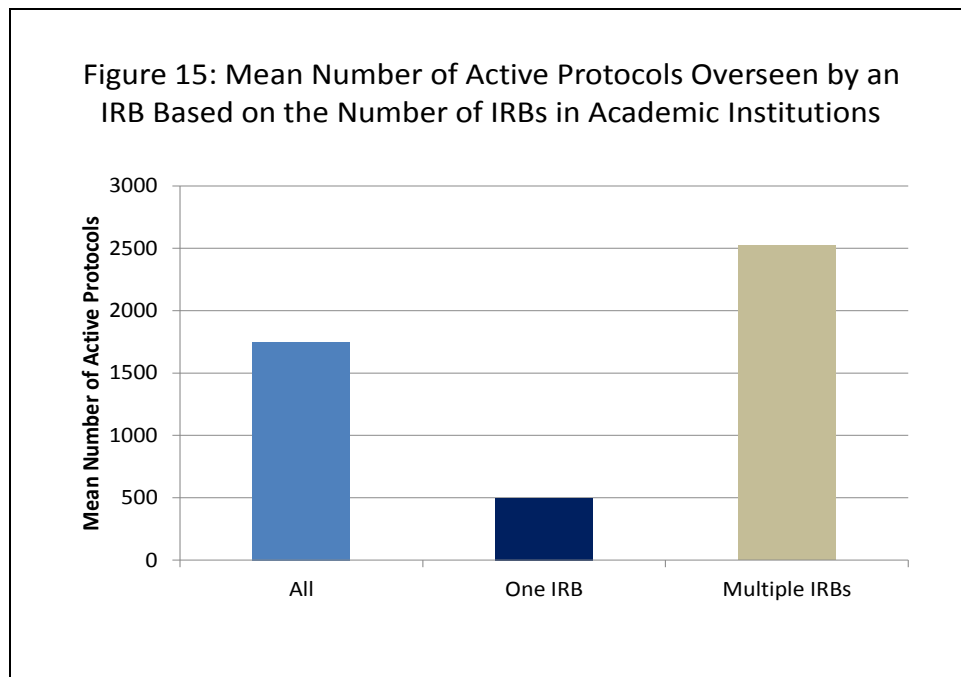


Figure 15: A mean of 1748 protocols were overseen by academic institutions, a mean of 498 protocols were overseen by academic institutions with one IRB, and a mean of 2521 protocols were overseen by academic institutions with two or more IRBs.

IRB Review Times

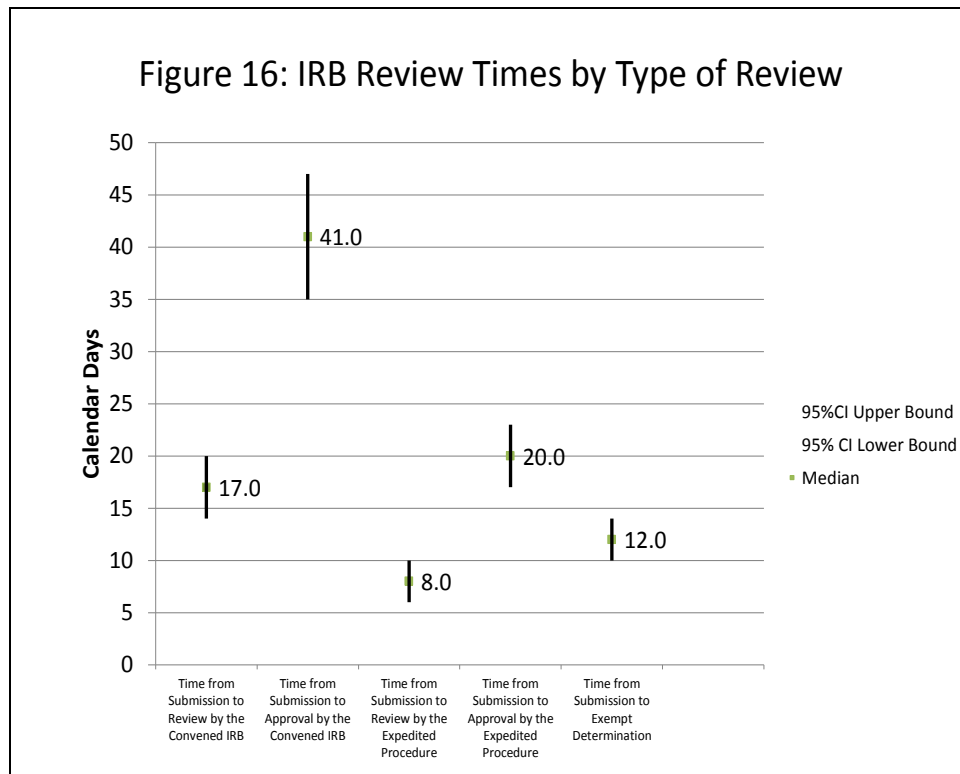


Figure 16: The time from submission to review by the convened IRB is a median of 17 calendar days, the time from submission to approval by the convened IRB is a median of 41 calendar days, the time from submission to review by the expedited procedure is a median of 8 calendar days, the time from submission 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.

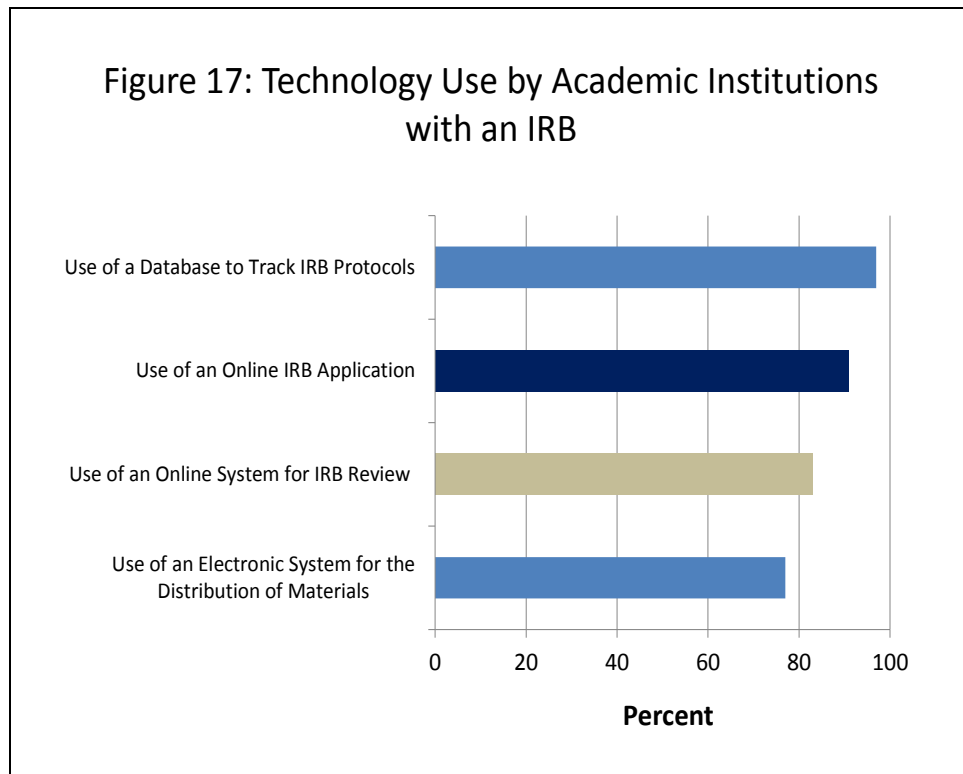


Figure 17: 97% of academic institutions use a database to track IRB protocols, 91% use an online IRB application, 83% use an online system for IRB review functions, and 77% use an electronic system for the distribution of materials.

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	13	2019	155.3	\$807,222
1-100	-	-	-	-
101-500	3	348	116	\$237,160
501-1000	5	823	165	\$425,000
1001-2000	9	1495	166	\$601,444
2001-4000	20	2777	139	\$1,584,279
4000+	32	5737	179	\$2,342,395



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