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 Organizations

Figure 1: Where Organizations Conduct Research

- 94.4% of all organizations conduct research in their own jurisdictions,
- 63.4% conduct research in other jurisdictions,
- 52.1% conduct research internationally.

Figure 2: Type of Research Organizations Conduct or Review

- 98.6% conduct Biomedical Research
- 88.6% conduct Social Science/Behavioral Research.
Selected Types of Research Conducted or Overseen by Organizations

Figure 3: Selected Types of Research that Organizations Conduct or Review

Figure 3: 87.3% of organizations utilize Investigational Drugs, 80.3% utilize Investigational Devices, 26.8% of organizations conduct research with Planned Emergency Research without Consent, and 7.2% conduct Classified Research.
Figure 4: Organizations that Conduct or Review Research Involving Vulnerable Populations

- Other: 87.5%
- Adults with Diminished Capacity: 91.5%
- Employees: 90.1%
- Students: 87.3%
- Children: 84.5%
- Pregnant Women: 77.5%
- Prisoners: 54.9%

Figure 4: 91.5% of all organizations conduct research involving Children, 91.5% conduct research involving Adults with Diminished Capacity, 90.1% conduct research involving Employees, 87.3% conduct research involving Students, 77.5% conduct research involving Pregnant Women, 54.9% conduct research involving Prisoners, and 84.5% conduct research involving populations not listed in the survey.
Sponsors and Regulators of Research

Figure 5: Sponsors of Research

Figure 5: 21.5% of research is federally sponsored, 20% of research is sponsored by industry and 22% by other sponsors.
Figure 6: 83.3% of all organizations follow FDA regulations or guidelines, 78.6% follow regulations or guidelines of their State, 78.6% follow Department of Health and Human Services regulations or guidelines, 71.4% follow ICH-Good Clinical Practice regulations or guidelines, 59.5% follow Department of Defense regulations or guidelines, 42.9% follow Country-specific regulations or guidelines, 26.2% follow Department of Justice regulations or guidelines, 21.4% follow Department of Energy regulations or guidelines, 16.7% follow Environmental Protection Agency regulations or guidelines, 14.3% follow Department of Veterans’ Affairs regulations or guidelines, and 11.9% follow Other regulations or guidelines.
Figure 7: Checking the Boxes on the Federalwide Assurance

Figure 7: 60% of all organizations Uncheck the Box regarding Federalwide Assurance, 31% of all organizations Check boxes Applying to All Subparts (A, B, C, D), and 9% Checked the Box Only for Subpart A.

Figure 8: Comparison of AAHRPP Organizations and Those Registered with OHRP on Checking the Boxes on the Federalwide Assurance

Figure 8: Compared to percentages provided previously by OHRP, more organizations accredited by AAHRPP or applying for AAHRPP accreditation unchecked the box.
Reliance on the IRB

Figure 9: Use of IRBs

- Has Own IRB, 95.2%
- Does not have OWN IRB, 4.8%

**Figure 9**: 95.2% of all organizations have their Own IRB while 4.8% do not have their Own IRB.

Figure 10: Use of External IRBs

- Rely on External IRB for more than 10%, 4.80%
- Organizations that did not respond, 25.20%
- Rely on External IRB for no more than 10%, 69%

**Figure 10**: 69% of all organizations use External IRBs for a maximum of 10% of total protocols, 4.8% of organizations rely on External IRBs for more than 10% of total protocols, and 26.2% of all organizations did not respond.
Figure 11: 38.1% of all organizations have One IRB, 21.4% have Two IRBs, 4.8% have Three IRBs, 14.3% have Four IRBs, 14.3% have Five or More IRBS, and 7.1% of all organizations did not respond.
Compensation of IRB Members

Figure 12: Compensation of IRB Members by Organizations

- 81% of all organizations compensate IRB Chairs
- 60.7% compensate IRB Vice Chairs
- 30.6% compensate Affiliated Members
- 51.6% compensate Non-Affiliated Members

Figure 13: Mean Compensation of IRB Chairs and Vice Chairs Over Time

- Generally, the number of all organizations that compensate IRB Chairs and IRB Vice Chairs has increased since 2010.
Figure 14: A median of 101 Exempt Protocols are overseen by all organizations, a median of 621 protocols are Reviewed by the Expedited Procedure, a median of 313 protocols are Reviewed by the Convened IRB, and a median of 1281 Total Protocols are overseen by all organizations.
Figure 15: All organizations oversee a mean of 414.3 protocols per IRB, organizations with One IRB oversee a mean of 549.3 protocols and organizations with Multiple IRBs oversee a mean of 426.6 protocols per IRB.
**Figure 16: IRB Review Times by Type of Review**

Figure 16: It takes all organizations a median of 24 Calendar Days from Submission to Review of a Protocol, a median of 52 Calendar Days from Submission to Protocol Approval, a median of 14 Calendar Days from Submission to Protocol Review by Expedited Procedure, a median of 30 Calendar Days from Submission to Protocol Approval by the Expedited Procedure, and a median of 17 Calendar Days from Submission to Exempt Protocol Determination.
Figure 17: There was a decrease for Review Times for Expedited Review; Exempt Determinations and Convened IRB Review Times saw a slight uptick.
**Figure 18: Technology Use by Organizations with an IRB**

- Use of a Database to Track IRB Protocols: 98.4%
- Use of an Electronic System for the Distribution of Materials: 85.9%
- Use of an Online IRB Application: 78.1%
- Use of an Online System for IRB Review Functions: 76.6%

*Figure 18: 98.4% of all organizations use a Database to Track IRB Protocols, 85.9% use an electronic System for Distribution of Materials, 78.1% use an Online IRB Application, and 76.6% use an Online System for IRB Reviews.*
Figure 19: Use of a Database to Track IRB Protocols has steadily risen since 2011. Generally, since 2010, there has been an increase in organizations using Electronic Systems for Distribution of Materials as well as those that use an Online System for IRB Review Functions.
Table 1: IRB Staffing and Funding Levels

<table>
<thead>
<tr>
<th>Protocol Category</th>
<th>Median Number of Staff</th>
<th>Median Number of Protocols</th>
<th>Median Protocols per FTE</th>
<th>Median Dollars Budgeted for IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>9</td>
<td>1281</td>
<td>142.3</td>
<td>1,034,878</td>
</tr>
<tr>
<td>1-100</td>
<td>4</td>
<td>38</td>
<td>9.5</td>
<td>650,00</td>
</tr>
<tr>
<td>101-500</td>
<td>2</td>
<td>241</td>
<td>120.5</td>
<td>246,957</td>
</tr>
<tr>
<td>501-1000</td>
<td>3.3</td>
<td>772.5</td>
<td>234.1</td>
<td>399,532</td>
</tr>
<tr>
<td>1001-2000</td>
<td>11.5</td>
<td>1412.5</td>
<td>122.8</td>
<td>1,141,575</td>
</tr>
<tr>
<td>2001-4000</td>
<td>11.7</td>
<td>2308</td>
<td>197.3</td>
<td>1,685,000</td>
</tr>
<tr>
<td>4000+</td>
<td>21</td>
<td>5011</td>
<td>238.6</td>
<td>3,040,254</td>
</tr>
</tbody>
</table>

Figure 20: Four-Year Trends in Mean IRB Budgets

Figure 20: IRB budgets have increased since 2010.
Audits of the HRPP Conducted by Organizations

Table 2. Number of Internal Audits Organizations Conducted within the Past Year

<table>
<thead>
<tr>
<th></th>
<th>For-Cause Audits of Researchers</th>
<th>Random Audits of Researchers</th>
<th>For-Cause Audits of IRBs</th>
<th>Random Audits of IRBs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>4.5</td>
<td>44</td>
<td>1.5</td>
<td>47.7</td>
</tr>
<tr>
<td>Median</td>
<td>2</td>
<td>20.0</td>
<td>0.0</td>
<td>3</td>
</tr>
<tr>
<td>Min</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Max</td>
<td>26</td>
<td>480</td>
<td>29</td>
<td>1076</td>
</tr>
</tbody>
</table>

Figure 21: Four-Year Trends in Mean Number of Audits Organizations Conducted

Figure 21: There has been a decrease in For-Cause Audits of Research and For-Cause Audits of IRBs since 2010. Random Audits of Researchers and IRBs have increased since 2010.
Protocol Deviations and Complaints Reported to the IRB

Table 3. Number of Protocol Deviations and Complaints Reported to the IRB in the Past Year

<table>
<thead>
<tr>
<th>Protocol Category</th>
<th>Median Number of Protocol Deviations</th>
<th>Median Number of Complaints</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>99.5</td>
<td>2</td>
</tr>
<tr>
<td>1-100</td>
<td>11</td>
<td>0.0</td>
</tr>
<tr>
<td>1-1000</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>501-1,000</td>
<td>58</td>
<td>1.5</td>
</tr>
<tr>
<td>1,001-2,000</td>
<td>229.5</td>
<td>4.5</td>
</tr>
<tr>
<td>2,001-4,000</td>
<td>298</td>
<td>2</td>
</tr>
<tr>
<td>&gt;4,000</td>
<td>234</td>
<td>6.5</td>
</tr>
</tbody>
</table>

Figure 22: Four-Year Trends in Mean Numbers of Protocol Deviations and Complaints Reported

Figure 22: Reported Protocol Deviations have increased since 2010 while Complaints have remained relatively static.
Table 4. Number of Cases of Non-Compliance Reported to the IRB in the Past Year

<table>
<thead>
<tr>
<th>Protocol Category</th>
<th>Median Number of Allegations of Non-Compliance</th>
<th>Median Number of Allegations of Serious Non-Compliance</th>
<th>Median Number of Allegations of Continuing Non-Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>6</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1-100</td>
<td>3</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>101-500</td>
<td>8</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>501-1,000</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1,001-2,000</td>
<td>6</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2,001-4,000</td>
<td>9</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>&gt;4,000</td>
<td>2.5</td>
<td>2.5</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 23: Overall, Non-Compliance Investigations have increased since 2010. However, the number of Non-Compliance Investigations per 1,000 protocols has decreased since 2010. Since 2010 there has been a slight increase in Serious Non-Compliance Investigations. Serious Non-Compliance Investigations per 1,000 protocols has significantly decreased. Continuing Non-Compliance Investigations remained flat from 2010-2013 while significantly decreasing per 1,000 Protocols.

Figure 24: Four-Year Trends in Mean Number of Reported Cases of Non-Compliance