2012 Metrics on Human Research Protection Program Performance

Updated July 18, 2013
About the Metrics

Improving the quality of human research protection programs (HRPP) is a top priority for AAHRPP. Effective and efficient systems of oversight within 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 2012 metrics for HRPP performance.

From data supplied by 183 client organizations in 2012, 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. Averages, represented as means, are presented except where indicated.

Figures 19 and 20 on page 15 and Table 1 on page 16 were updated on July 18, 2013.

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General Description of the Research Conducted or Overseen by Organizations

Figure 1. Where Organizations Conduct Research

- 94.9 percent of organizations conduct research within the jurisdiction where they reside;
- 62.7 percent of organizations conduct research outside the jurisdiction within which they reside;
- 44.1 percent conduct research outside the country in which they reside.

Figure 2. Type of Research Organizations Conduct or Review

- 94.9 percent of organizations conduct biomedical research;
- 76.3 percent conduct social and behavioral science research.
Selected Types of Research Conducted or Overseen by Organizations

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

<table>
<thead>
<tr>
<th>Research Type</th>
<th>Percent of Organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigational Drugs</td>
<td>93.2%</td>
</tr>
<tr>
<td>Investigational Devices</td>
<td>79.7%</td>
</tr>
<tr>
<td>Planned Emergency Research without Consent</td>
<td>32.2%</td>
</tr>
<tr>
<td>Classified Research</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

Figure 3: 93.2 percent of organizations conduct or review research involving investigational drugs and 79.7 percent conduct or review research involving investigational devices. 32.2 percent conduct or review planned emergency research without consent under the U.S. FDA regulations. 1.7 percent of organizations report that they conduct classified research.

Figure 4: Organizations that Conduct or Review Research Involving Vulnerable Populations

<table>
<thead>
<tr>
<th>Vulnerable Population</th>
<th>Percent of Organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults with Diminished Capacity</td>
<td>91.5%</td>
</tr>
<tr>
<td>Employees</td>
<td>89.8%</td>
</tr>
<tr>
<td>Students</td>
<td>79.7%</td>
</tr>
<tr>
<td>Children</td>
<td>93.2%</td>
</tr>
<tr>
<td>Pregnant Women</td>
<td>84.7%</td>
</tr>
<tr>
<td>Prisoners</td>
<td>55.9%</td>
</tr>
</tbody>
</table>

Figure 4: Almost all organizations conduct or review research involving some vulnerable populations. 91.5 percent and 89.8 percent conduct research with adults with diminished decision-making capacity or with employees, respectively. 79.7 percent conduct or review research involving students, 93.2 percent with children, 84.7 percent with pregnant women, and 55.9 percent with prisoners.
Figure 5: 30.1 percent of research is federally sponsored, 41.8 percent of research is sponsored by industry and 22.9 percent by other sponsors.
Figure 6: Regulations and Guidance Followed by Organizations

Figure 6: 93.2 percent of organizations follow the FDA regulations and 89.8 percent follow the Department of Health and Human Services regulations. Other U.S. regulations that are followed by organizations are Department of Defense (47.5 percent); Department of Education (28.8 percent); Department of Justice (22 percent); Department of Energy (18.6 percent); Environmental Protection Agency (16.9 percent); and Department of Veterans Affairs (13.6 percent). 50.8 percent of organizations follow the ICH-GCP (E6) guideline; 27.1 percent follow the laws or guidance of other countries.
Figure 7: 27 percent of organizations that have a federalwide assurance check the box applying the Department of Health and Human Services regulations, including the subparts to all research; while 51 percent uncheck the boxes and 22 percent check the box applying only Subpart A to all research.

Note: Data include organizations that have a federalwide assurance and have the option to uncheck the boxes.

Figure 8: Compared to data provided by the Office for Human Research Protections (OHRP), a higher percentage of AAHRPP organizations uncheck all the boxes on the federal wide assurance than those registered with OHRP.
Reliance on the IRB

Figure 9: 85 percent of organizations have their own IRB.

Figure 10: Of those organizations that have their own IRB and rely on external IRBs, 65 percent rely on external IRBs for review of no more than 10 percent of their research portfolio.
Figure 11. Number of IRBs Organizations Have

- 1 IRB: 50%
- 2 IRBs: 22%
- 3 IRBs: 13%
- 4 IRBs: 6%
- 5+ IRBs: 7%

50 percent of organizations have one IRB.
Compensation of IRB Members

Figure 12: 74.8 percent of organizations compensate the IRB chairs, 52 percent compensate the vice chairs, 28.8 percent compensate the affiliated members and 49.4 percent compensate the non-affiliated members. Compensation includes payment to members, payment to departments of members, or release of time from other duties.

Figure 13: The percentage of organizations that compensate chairs and vice chairs increased from 2009 to 2011, but decreased slightly in 2012.
Figure 14: The median number of total active protocols overseen by organizations is 414; the median number of exemptions granted is 8. The median number of active protocols reviewed by the expedited procedure is 133 and the median number reviewed by the convened IRB is 136.

Notes: Data include organizations that have their own IRB. Data include active protocols (new and ongoing protocols) in 2012.

Figure 15: Overall, the median is 229 for active protocols per IRB. When an organization has one IRB, the median is 253 active protocols whereas when an organization has multiple IRBs, the median is 214 per IRB.
IRB Review Times

**Figure 16. IRB Review Times by Type of Review**

![Graph showing IRB review times by type of review](image)

**Figure 16:** Review times are reported as the time from submission of the protocol to the IRB office to review by the convened IRB; review by an IRB member using the expedited procedure; or review resulting in an exemption determination.

**Figure 17. Four-Year Trends of IRB Review Times from Submission to Approval**

![Graph showing four-year trends of IRB review times](image)

**Figure 17:** Overall, review times from submission to approval decreased between 2009 and 2012. However, between 2011 and 2012 the average time for review using the expedited procedure increased by one day, and for exempt determinations review time increased by two days. For review by the convened IRB review time remained relatively constant between 2011 and 2012.
Figure 18: 78.6 percent of IRBs do not disapprove proposed research projects.
Figure 19: 90 percent of organizations use a database to track protocols, 80 percent use an electronic system to distribute materials, 55 percent have an online IRB application, and 40 percent use an online system to perform IRB functions.

Figure 20: Use of databases has fallen slightly from 2009 to 2012, and use of online systems for IRB review functions fell from 2011 levels. Use of electronic systems for the distribution of materials has increased consistently since 2009.
## Table 1. IRB Staffing and Funding Levels

<table>
<thead>
<tr>
<th>Protocol Category</th>
<th>Average Number of Staff</th>
<th>Average Number of Protocols</th>
<th>Average Protocols per FTE</th>
<th>Average Dollars Budgeted for IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>18.2*</td>
<td>1,309.9</td>
<td>71.9</td>
<td>$932,267</td>
</tr>
<tr>
<td>1-100</td>
<td>4.3</td>
<td>39.8</td>
<td>9.3</td>
<td>$124,873</td>
</tr>
<tr>
<td>101-500</td>
<td>6.9</td>
<td>271.2</td>
<td>39.3</td>
<td>$336,437</td>
</tr>
<tr>
<td>501-1,000</td>
<td>12.7</td>
<td>788.2</td>
<td>62.1</td>
<td>$861,006</td>
</tr>
<tr>
<td>1,001-2,000</td>
<td>24.3*</td>
<td>1,550.5</td>
<td>63.8</td>
<td>$968,005</td>
</tr>
<tr>
<td>2,001-4,000</td>
<td>21.6</td>
<td>2,741.3</td>
<td>126.9</td>
<td>$1,345,269</td>
</tr>
<tr>
<td>4,000+</td>
<td>40.4</td>
<td>5,448.9</td>
<td>134.9</td>
<td>$3,354,933</td>
</tr>
</tbody>
</table>

Table 1: Data include all organizations. *One organization reported 248.5 FTEs. Excluding this outlier, the average number of staff for all organizations is 16.1 and the average number of staff for organizations with 1,001-2,000 active protocols is 16.8.

## Figure 21. Four-Year Trends in IRB Budgets

Figure 21: Budgets for IRBs decreased from 2009 to 2011; in 2012, they returned to levels similar to 2009.
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>5.2</td>
<td>36.7</td>
<td>2.7</td>
<td>48.4</td>
</tr>
<tr>
<td>Median</td>
<td>2.0</td>
<td>12.0</td>
<td>0.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Min</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Max</td>
<td>138</td>
<td>610</td>
<td>80</td>
<td>2,071</td>
</tr>
</tbody>
</table>

Table 2: The above data were derived from organizations that conduct research involving human participants. The data do not include the independent IRBs that oversee multiple investigative sites for each active protocol.

Figure 22: Four-Year Trends in Number of Audits Organizations Conducted

Figure 22: Random audits of researchers have increased slightly from 36.5 percent in 2009 to 36.9 percent in 2012. During the same period, random audits of IRBs increased from 22.5 percent to 48.2 percent. The above data were derived from organizations that conduct research involving human participants. The data do not include the independent IRBs that oversee multiple investigative sites for each active protocol.
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>Average Number of Protocol Deviations</th>
<th>Average Number of Protocol Deviations per 100 Protocols</th>
<th>Complaints</th>
<th>Average Number of Complaints per 1,000 Protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>142.7</td>
<td>9.3</td>
<td>4.2</td>
<td>3.2</td>
</tr>
<tr>
<td>1-100</td>
<td>38.5</td>
<td>85.7</td>
<td>1.1</td>
<td>24.5</td>
</tr>
<tr>
<td>101-500</td>
<td>65.9</td>
<td>21.9</td>
<td>1.0</td>
<td>3.6</td>
</tr>
<tr>
<td>501-1,000</td>
<td>107.3</td>
<td>12.5</td>
<td>1.2</td>
<td>1.5</td>
</tr>
<tr>
<td>1,001-2,000</td>
<td>222.6</td>
<td>13.1</td>
<td>6.0</td>
<td>3.8</td>
</tr>
<tr>
<td>2,001-4,000</td>
<td>254.8</td>
<td>6.9</td>
<td>7.8</td>
<td>2.8</td>
</tr>
<tr>
<td>&gt;4,000</td>
<td>386.5</td>
<td>3.3</td>
<td>15.7</td>
<td>2.9</td>
</tr>
</tbody>
</table>

Table 3: The above data were derived from organizations that conduct research involving human participants. The data do not include the independent IRBs that oversee multiple investigative sites for each active protocol.

Figure 23: Four-Year Trends in Numbers of Protocol Deviations and Complaints Reported

Figure 23: The numbers of reported protocol deviations increased from 2009 to 2012. Complaints increased slightly between 2009 and 2011, but in 2012 fell below their 2009 level. The above data were derived from organizations that conduct research involving human participants. The data do not include the independent IRBs that oversee multiple investigative sites for each active protocol.
**Table 4. Number of Cases of Non-Compliance Reported to the IRB in the Past Year**

<table>
<thead>
<tr>
<th>Protocol Category</th>
<th>Average Number of Allegations of Non-Compliance</th>
<th>Average Number of Allegations of Non-Compliance Per 1,000 Protocols</th>
<th>Average Number of Allegations of Serious Non-Compliance</th>
<th>Average Number of Allegations of Serious Non-Compliance Per 1,000 Protocols</th>
<th>Average Number of Allegations of Continuing Non-Compliance</th>
<th>Average Number of Allegations of Continuing Non-Compliance Per 1,000 Protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>22.2</td>
<td>16.7</td>
<td>3.4</td>
<td>2.6</td>
<td>1.1</td>
<td>0.8</td>
</tr>
<tr>
<td>1-100</td>
<td>4.9</td>
<td>114.8</td>
<td>1.5</td>
<td>33.4</td>
<td>0.5</td>
<td>11.1</td>
</tr>
<tr>
<td>101-500</td>
<td>5.2</td>
<td>19.3</td>
<td>2.0</td>
<td>7.5</td>
<td>0.8</td>
<td>2.9</td>
</tr>
<tr>
<td>501-1,000</td>
<td>11.8</td>
<td>14.6</td>
<td>2.2</td>
<td>2.8</td>
<td>0.6</td>
<td>0.7</td>
</tr>
<tr>
<td>1,001-2,000</td>
<td>11.1</td>
<td>7.7</td>
<td>4.6</td>
<td>2.9</td>
<td>1.3</td>
<td>0.8</td>
</tr>
<tr>
<td>2,001-4,000</td>
<td>59.3</td>
<td>21.6</td>
<td>4.6</td>
<td>1.7</td>
<td>1.6</td>
<td>0.6</td>
</tr>
<tr>
<td>&gt;4,000</td>
<td>81.5</td>
<td>15.2</td>
<td>9.7</td>
<td>1.8</td>
<td>2.7</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Table 4: The above data were derived from organizations that conduct research involving human participants. The data do not include the independent IRBs that oversee multiple investigative sites for each active protocol.

**Figure 24. Four-Year Trends in Number of Reported Cases of Non-Compliance**

![Bar chart showing the number of non-compliance cases from 2009 to 2012 (non-compliance investigations, serious non-compliance investigations, and continuing non-compliance investigations).]

Figure 24: The number of cases of non-compliance, cases of serious non-compliance, and cases of continuing non-compliance decreased from 2009 to 2011. From 2011 to 2012 cases of non-compliance and serious non-compliance increased, while cases of continuing non-compliance remained constant. The above data were derived from organizations that conduct research involving human participants. The data do not include the independent IRBs that oversee multiple investigative sites for each active protocol.