2021 Metrics for AAHRPP-Accredited Human Research Protection Programs

Academic Organizations

June 2022
AAHRPP is pleased to present the 2021 metrics for Human Research Protection Program (HRPP) performance. AAHRPP provides these data to help research organizations, researchers, sponsors, government agencies, and participants identify and support high-performing practices for HRPPs.

These metrics are collected from Annual Reports, as well as Step 1 and Step 2 applications, submitted by accredited academic organizations.

All the quantitative data were derived from the most recent reports submitted by academic organizations.

Data were selected based on what most accurately reflected academic organizations in 2021.
Abbreviations Used

DHHS  US Department of Health & Human Services
DoD   US Department of Defense
ED    US Department of Education
DoE   US Department of Energy
DoJ   US Department of Justice
EPA   US Environmental Protection Agency
FDA   US Food and Drug Administration
ICH GCP International Conference on Harmonisation Good Clinical Practice
VA    US Department of Veterans Affairs
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Where Accredited Academic Organizations are Based

- In the US: 91.6%
- Outside the US: 8.4%
This chart shows where research occurs that academic organizations conduct or review.

The majority conduct or review transnational research.
Research Type

Most academic organizations conduct or review biomedical/clinical research

99.2%

Most academic organizations conduct or review social/behavioral/education research

97.5%
This table shows the type of biomedical/clinical research academic organizations conduct or review.

<table>
<thead>
<tr>
<th>Research Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>89.8%</td>
</tr>
<tr>
<td>Devices</td>
<td>89.8%</td>
</tr>
<tr>
<td>Planned Emergency Research</td>
<td>36.4%</td>
</tr>
</tbody>
</table>
This table shows the categories of vulnerable populations that participate in research conducted or reviewed by academic organizations. Populations Organizations also identified as vulnerable (i.e., “Other”) include Native Americans, neonates of uncertain viability, those who are educationally or economically disadvantaged, military personnel and veterans, non-English speakers, hospitalized persons, individuals who are physically disabled or impaired, participants who are institutionalized, individuals who are engaged in or intending to engage in illegal or stigmatizing behavior, and undocumented or refugee populations.
This table shows the percentage of academic organizations that conduct or review research by funding type that supports the research.

<table>
<thead>
<tr>
<th>Funding Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internally funded or unfunded</td>
<td>100%</td>
</tr>
<tr>
<td>Government or federally sponsored</td>
<td>98.3%</td>
</tr>
<tr>
<td>Industry sponsored</td>
<td>98.3%</td>
</tr>
<tr>
<td>Sponsored by other external sources</td>
<td>97.5%</td>
</tr>
</tbody>
</table>
This chart shows the median percentage of funding type that supports research academic organizations conduct, manage, or review.
This chart shows the percentage of academic organizations that apply specific regulations and guidelines to the research they conduct, manage, or review.
Internal IRBs/ECs

% of academic organizations that have internal IRBs: 100%

Median # of IRBs/ECs per academic organization: 2

Number of internal IRBs/ECs % of academic organizations support:
- 1 IRB: 26%
- 2 IRBs: 24%
- 3 IRBs: 13%
- 4 IRBs: 10%
- 5 IRBs: 7%
- 6 IRBs: 4%
- 7 or more IRBs: 16%
Relying on External IRBs/ECs

% of academic organizations with internal IRBs/ECs that also use external IRBs/ECs

92.4%

Use of external IRBs/ECs by academic organizations with internal IRBs/ECs

- Do not rely on an external IRB/EC 7.6%
- Rely on external IRBs/ECs for < 10% of active studies 54.5%
- Rely on external IRBs/ECs for ≥ 10% of active studies 44.5%
% of academic organizations with internal IRBs/ECs that compensate any IRB/EC members

91.5%
This chart shows the median number of active studies that academic organizations conduct or review by type of review.

Note:
- Exemptions are based on the number of determinations made by an organization within 12 months of their most recent report to AAHRPP.
- Total number of studies includes those reviewed by both internal and external IRBs/ECs in the case of organizations with IRBs/ECs.
This chart shows the median number of active studies academic organizations oversee based on the number of IRBs/ECs they have.

Note

• Total number of studies for organizations includes those reviewed by both internal and external IRBs/ECs
This chart shows the median review times by review process for academic organizations.
## IRB/EC Technology

<table>
<thead>
<tr>
<th>Function</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Database for submission tracking</td>
<td>96.6%</td>
</tr>
<tr>
<td>Online application submission</td>
<td>94.1%</td>
</tr>
<tr>
<td>Online protocol/materials distribution to IRB/EC members</td>
<td>94.1%</td>
</tr>
<tr>
<td>Online review functions</td>
<td>89.9%</td>
</tr>
<tr>
<td>Does not use an electronic system</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

This table shows the technology academic organizations use to support IRB/EC tracking, submission, distribution, and the specific functions used.
# IRB/EC Staffing and Budget

<table>
<thead>
<tr>
<th>Number of Active Studies</th>
<th>Median Number of Studies</th>
<th>Median Number of Staff</th>
<th>Median Number of Studies per Staff</th>
<th>Median IRB/EC Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>1721</td>
<td>9.5</td>
<td>181.2</td>
<td>$670,000</td>
</tr>
<tr>
<td>0-500</td>
<td>248.5</td>
<td>2.8</td>
<td>89.5</td>
<td>$170,600</td>
</tr>
<tr>
<td>501-1000</td>
<td>775</td>
<td>5</td>
<td>155</td>
<td>$465,346</td>
</tr>
<tr>
<td>1001-2000</td>
<td>1467</td>
<td>8.5</td>
<td>172.6</td>
<td>$678,893</td>
</tr>
<tr>
<td>2001-4000</td>
<td>2852</td>
<td>13</td>
<td>219.4</td>
<td>$1,349,795</td>
</tr>
<tr>
<td>4001+</td>
<td>6133</td>
<td>23.4</td>
<td>262.4</td>
<td>$2,422,615</td>
</tr>
</tbody>
</table>

This table breaks down IRB/EC staffing and budgets by the size of the research portfolio (exempt, expedited, and convened reviews) overseen by academic organizations.
Audits of Researchers

Median # of researchers per organization with active studies: 870
Median # of research staff per organization: 1246
% of organizations that reported that audits of researchers occurred: 89.9%

Internal: "for cause"
• Median: 2
• Total: 387

Internal: random
• Median: 19
• Total: 5844

Regulatory agency inspections
• Median: 0
• Total: 110
## Audits of IRBs/ECs

<table>
<thead>
<tr>
<th>Category</th>
<th>Median</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal: “for cause”</td>
<td>0</td>
<td>253</td>
</tr>
<tr>
<td>Internal: random</td>
<td>6.5</td>
<td>3203</td>
</tr>
<tr>
<td>Regulatory agency inspections</td>
<td>0</td>
<td>25</td>
</tr>
</tbody>
</table>

% of organizations that reported that audits of IRB/EC records occurred (by internal or external sources): **78.2%**
Unresolved Complaints, Noncompliance, & Unanticipated Problems

<table>
<thead>
<tr>
<th>Number of active studies</th>
<th>Unresolved complaints</th>
<th>Investigations of alleged noncompliance</th>
<th>Serious noncompliance determinations</th>
<th>Continuing noncompliance determinations</th>
<th>Unanticipated problems determinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>0</td>
<td>10</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>0-500</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>501-1000</td>
<td>0</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1001-2000</td>
<td>0</td>
<td>26</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2001-4000</td>
<td>0</td>
<td>10</td>
<td>2.5</td>
<td>0.5</td>
<td>6</td>
</tr>
<tr>
<td>4001+</td>
<td>1</td>
<td>28</td>
<td>6</td>
<td>2.5</td>
<td>4.5</td>
</tr>
</tbody>
</table>

This table is based on the 12 months prior to an academic organization’s most recent report to AAHRPP and shows the median number of events per category.
This chart shows the median number of COI-related disclosures, determinations, and reviews for academic organizations within the last 12 months of their most recent AAHRPP report.