2021 Metrics for AAHRPP-Accredited Human Research Protection Programs

Hospitals

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 hospitals.

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

Data were selected based on what most accurately reflected accredited hospitals 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 Hospitals are Based

- **In the US**: 69.5%
- **Outside the US**: 30.5%
This chart shows where research occurs that hospitals conduct or review research.
Research Type

All hospitals conduct or review biomedical/clinical research

100%

Most hospitals conduct or review social/behavioral/education research

92.6%
## Biomedical/Clinical Research by Type

<table>
<thead>
<tr>
<th>Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>98.9%</td>
</tr>
<tr>
<td>Devices</td>
<td>98.9%</td>
</tr>
<tr>
<td>Planned Emergency Research</td>
<td>26.3%</td>
</tr>
</tbody>
</table>

This table shows the type of biomedical/clinical research hospitals conduct or review.
This table shows the categories of vulnerable populations that participate in research conducted or reviewed by hospitals.

<table>
<thead>
<tr>
<th>Population</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>96.8%</td>
</tr>
<tr>
<td>Employees</td>
<td>98.7%</td>
</tr>
<tr>
<td>Adults Unable to Consent</td>
<td>90.5%</td>
</tr>
<tr>
<td>Pregnant Women</td>
<td>90.5%</td>
</tr>
<tr>
<td>Students</td>
<td>84.2%</td>
</tr>
<tr>
<td>Prisoners</td>
<td>32.6%</td>
</tr>
<tr>
<td>Other</td>
<td>11.6%</td>
</tr>
</tbody>
</table>
This table shows the percentage of hospitals 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>Industry sponsored</td>
<td>100%</td>
</tr>
<tr>
<td>Government or federally sponsored</td>
<td>96.8%</td>
</tr>
<tr>
<td>Internally funded or unfunded</td>
<td>96.8%</td>
</tr>
<tr>
<td>Sponsored by other external sources</td>
<td>90.5%</td>
</tr>
</tbody>
</table>
Funding Distribution

This chart shows the median percentage of funding type that supports research hospitals conduct, manage, or review.

- Internally funded or unfunded: 47.5%
- Industry sponsored: 22.0%
- Government or federally sponsored: 16.0%
- Sponsored by other external sources: 6.0%
This chart shows the percentage of hospitals that apply specific regulations and guidelines to the research they review, manage, or conduct.
Internal IRBs/ECs

% of hospitals that have internal IRBs: 93.7%

Median # of IRBs/ECs per hospital: 1

Number of internal IRBs/ECs
% of hospitals support:
- 1 IRB: 53%
- 2 IRBs: 20%
- 3 IRBs: 14%
- 4 IRBs: 8%
- 5 IRBs: 1%
- 6 IRBs: 1%
- 7 or more IRBs: 3%
Relying on External IRBs/ECs

% of hospitals with internal IRBs/ECs that also use external IRBs/ECs

74.2%

Use of external IRBs/ECs by hospitals with internal IRBs/ECs

- Rely on external IRBs/ECs for < 10% of active studies: 24%
- Rely on external IRBs/ECs for ≥ 10% of active studies: 51%
- Do not rely on an external IRB/EC: 25%
% of hospitals with internal IRBs/ECs that compensate any IRB/EC members

85.4%
This chart shows the median number of active studies that hospitals conduct or review by type of review.

Note:
- Exemptions are based on the number of determinations made by an hospital 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 hospitals with IRBs/ECs
Active Studies: Internal vs. External IRB/EC

This chart shows the median number of active studies that hospitals conduct or review based on whether they have an internal IRB/EC.

Note:

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

Note
• Total number of studies for hospitals includes those reviewed by both internal and external IRBs/ECs
This chart shows the median review times by review process for hospitals.
<table>
<thead>
<tr>
<th>Technology</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Database for submission tracking</td>
<td>90.0%</td>
</tr>
<tr>
<td>Online protocol/materials distribution to</td>
<td>90.0%</td>
</tr>
<tr>
<td>IRB/EC members</td>
<td></td>
</tr>
<tr>
<td>Online application submission</td>
<td>85.6%</td>
</tr>
<tr>
<td>Online review functions</td>
<td>85.6%</td>
</tr>
<tr>
<td>Does not use an electronic system</td>
<td>2.2%</td>
</tr>
</tbody>
</table>

This table shows the technology hospitals 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>739</td>
<td>5.7</td>
<td>128.1</td>
<td>$329,358</td>
</tr>
<tr>
<td>0-100</td>
<td>48.5</td>
<td>1.5</td>
<td>32.9</td>
<td>$132,294</td>
</tr>
<tr>
<td>101-500</td>
<td>262</td>
<td>3</td>
<td>88.8</td>
<td>$161,837</td>
</tr>
<tr>
<td>501-1000</td>
<td>795</td>
<td>6.4</td>
<td>123.7</td>
<td>$552,000</td>
</tr>
<tr>
<td>1001-2000</td>
<td>1526</td>
<td>9</td>
<td>169.6</td>
<td>$645,750</td>
</tr>
<tr>
<td>2001-4000</td>
<td>2411.5</td>
<td>13.5</td>
<td>178.6</td>
<td>$698,819</td>
</tr>
<tr>
<td>4001+</td>
<td>6416</td>
<td>18.55</td>
<td>345.9</td>
<td>$3,200,000</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 hospitals.
Audits of Researchers

- Median # of researchers per hospital with active studies: 328
- Median # of research staff per hospital: 169
- % of hospitals that reported that audits of researchers occurred: 87.4%
- Internal: "for cause"
  - Median: 2
  - Total: 506
- Internal: random
  - Median: 11
  - Total: 3153
- Regulatory agency inspections
  - Median: 1
  - Total: 96
### Audits of IRBs/ECs

% of hospitals that reported that audits of IRB/EC records occurred (by internal or external sources):

**21.3%**

<table>
<thead>
<tr>
<th>Type of Audit</th>
<th>Median</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal: &quot;for cause&quot;</td>
<td>0</td>
<td>67</td>
</tr>
<tr>
<td>Internal: random</td>
<td>3</td>
<td>892</td>
</tr>
<tr>
<td>Regulatory agency inspections</td>
<td>0</td>
<td>20</td>
</tr>
</tbody>
</table>
This table is based on the 12 months prior to a hospital’s most recent report to AAHRPP and shows the median number of events per category.

<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>0-100</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>101-500</td>
<td>0</td>
<td>2.5</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>501-1000</td>
<td>0</td>
<td>11</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1001-2000</td>
<td>0</td>
<td>2.5</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>2001-4000</td>
<td>1</td>
<td>67.5</td>
<td>4</td>
<td>1.5</td>
<td>4</td>
</tr>
<tr>
<td>4001+</td>
<td>0</td>
<td>8</td>
<td>2.5</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
Conflicts of Interest

This chart shows the median number of COI-related disclosures, determinations, and reviews for hospitals within the last 12 months of their most recent AAHRPP report.

- Financial disclosures related to research involving human participants: 78.5
- Financial disclosures related to research involving human participants determined to indicate a financial COI: 4
- Studies with a financial COI management plan reviewed by the IRB/EC: 4