2020 Metrics for AAHRPP-Accredited Human Research Protection Programs

August 2020
AAHRPP is pleased to present the 2020 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 organizations.

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

Data were selected based on what most accurately reflected AAHRPP organizations in 2020.
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Accredited Organizations By Type

Of the 255 accredited organizations:

- 45.9% are academic organizations
- 37.6% are hospitals
- 7.1% are independent IRBs
- 2.7% are governmental organizations
- 2.7% are research institutes
- 2.0% are VA facilities
- 1.2% are dedicated research sites
- 0.4% are contract research organizations
- 0.4% are sponsors
Where Accredited Organizations are Based

- In the US: 83.9%
- Outside the US: 16.5%
Where Research Occurs

This graph shows where organizations conduct, review, or manage research.

The majority of organizations conduct, review, or manage transnational research.
Most organizations conduct, manage, or review biomedical/clinical research: 99.2%

Most organizations conduct, manage, or review social/behavioral/education research: 91.7%
### Biomedical/Clinical Research by Type

<table>
<thead>
<tr>
<th>Research Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>93.8%</td>
</tr>
<tr>
<td>Devices</td>
<td>91.8%</td>
</tr>
<tr>
<td>Other Biomedical</td>
<td>71.7%</td>
</tr>
<tr>
<td>Planned Emergency Research</td>
<td>27.6%</td>
</tr>
</tbody>
</table>

This table shows the type of biomedical/clinical research organizations conduct, review, or manage.

**Note**
- 52 organizations that conduct, manage, or review biomedical research did not further specify the type.
- 5 organizations did not identify whether they conducted, reviewed, or managed emergency research within the last 12 months of their most recent report.
This table shows the categories of vulnerable populations that participate in research conducted, reviewed, or managed by organizations.

Only 2 organizations indicated they do not conduct, review, or manage research involving any vulnerable populations.

Organizations identified a range of “other” vulnerable populations, such as veterans, non-English speakers, indigenous people, and socially disadvantaged.

<table>
<thead>
<tr>
<th>Vulnerable Populations</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>96.4%</td>
</tr>
<tr>
<td>Adults Unable to Consent</td>
<td>92.5%</td>
</tr>
<tr>
<td>Employees</td>
<td>92.1%</td>
</tr>
<tr>
<td>Students</td>
<td>86.9%</td>
</tr>
<tr>
<td>Pregnant Women</td>
<td>89.3%</td>
</tr>
<tr>
<td>Prisoners</td>
<td>63.1%</td>
</tr>
<tr>
<td>Other</td>
<td>16.7%</td>
</tr>
</tbody>
</table>
This table shows the percentage of organizations that conduct, review, or manage research by funding type that supports the research.

<table>
<thead>
<tr>
<th>Funding Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government or federally sponsored</td>
<td>95.6%</td>
</tr>
<tr>
<td>Industry sponsored</td>
<td>95.6%</td>
</tr>
<tr>
<td>Internally funded or unfunded</td>
<td>90.8%</td>
</tr>
<tr>
<td>Sponsored by other external sources</td>
<td>88.8%</td>
</tr>
</tbody>
</table>
Funding Distribution

This chart shows the median percentage of funding type that supports research organizations conduct, review, or manage.
This chart shows the percentage of organizations that apply specific regulations and guidelines to the research they conduct, review, or manage. Of the 251 organizations included:

- 84.9% - US FDA
- 84.5% - US Dept of Health & Human Services
- 69.2% - ICH GCP
- 61.4% - US Dept of Defense
- 35.9% - US Dept of Education
- 29.9% - US Dept of Justice
- 18.7% - US Environmental Protection Agency
- 15.9% - US Dept of Energy
- 15.5% - Veterans Affairs
Internal IRBs/ECs*

% of organizations that have internal IRBs: 95%

Median # of IRBs/ECs per organization: 2

Number of internal IRBs/ECs organizations support:
- 1 IRB: 37%
- 2 IRBs: 25%
- 3 IRBs: 15%
- 4 IRBs: 8%
- 5 IRBs: 4%
- 6 IRBs: 3%
- 7 or more IRBs: 8%

*Data exclude independent IRBs/ECs
Relying on External IRBs/ECs*

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

83.6%

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

- Rely on external IRBs/ECs for < 10% of active studies: 43%
- Rely on external IRBs/ECs for ≥ 10% of active studies: 41%
- Do not rely on an external IRB/EC: 16%

*Data exclude independent IRBs/ECs
% of organizations with internal IRBs/ECs that compensate IRB/EC members

90.1%

*Data exclude independent IRBs/ECs
This chart shows the median number of active studies that organizations conduct, review, or manage 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
Median Number of Active Studies Overseen (by Quartile)

Quartile 1 (1-310 Studies)
- Total: 152
- Expedited review: 43
- Convened board review: 38
- Exemptions: 12

Quartile 2 (311-896 Studies)
- Total: 512.5
- Expedited review: 251
- Convened board review: 115
- Exemptions: 60.5

Quartile 3 (911-2012 Studies)
- Total: 1342
- Expedited review: 618.5
- Convened board review: 323
- Exemptions: 195

Quartile 4 (2024-13284 Studies)
- Total: 4072.5
- Expedited review: 1877
- Convened board review: 1048
- Exemptions: 510
Active Studies: Internal vs. External IRB/EC

This chart shows the median number of active studies that organizations conduct, review, or manage by type of 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 organizations with IRBs/ECs.
This chart shows the median number of active studies organizations oversee based on the number of IRBs/ECs.

Note:
- Median number of studies include those reviewed by both internal and external IRBs/ECs.
This chart shows the median review times by review process for organizations that have internal IRBs/EC or are independent IRBs/ECs.

Note:
- Exemption review times are for organizations regardless of whether they have an internal IRB/EC.
This chart shows the median expedited review times for organizations that have internal IRBs/EC or are independent IRBs/ECs.
This chart shows the median review times for convened board review for organizations that have internal IRBs/ECs or are independent IRBs/ECs.
This chart shows the median review times for exemption determinations for organizations regardless of whether they have an internal IRB/EC.
### IRB/EC Technology

<table>
<thead>
<tr>
<th>Feature</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Database for submission tracking</td>
<td>92.1%</td>
</tr>
<tr>
<td>Online application submission</td>
<td>90.4%</td>
</tr>
<tr>
<td>Online protocol/materials distribution to IRB/EC members</td>
<td>93.7%</td>
</tr>
<tr>
<td>Online review functions</td>
<td>89.5%</td>
</tr>
<tr>
<td>Does not use an electronic system</td>
<td>2.9%</td>
</tr>
</tbody>
</table>

This table shows the technology organizations that have IRBs/ECs use to support IRB/EC tracking, submission, distribution and the specific functions used.

Note:
- 2 organizations did not provide information about any IRB/EC technology they may use
This table breaks down IRB/EC staffing and budgets by the size of the research portfolio (exempt, expedited, and convened reviews) overseen by internal IRBs/ECs.

### Note:
- Data from organizations without internal IRBs/ECs are not included
- 2 organizations did not provide information

<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>1007</td>
<td>7</td>
<td>143.9</td>
<td>$495,740</td>
</tr>
<tr>
<td>0-100</td>
<td>43</td>
<td>2.5</td>
<td>6.1</td>
<td>$127,000</td>
</tr>
<tr>
<td>101-500</td>
<td>251</td>
<td>2.9</td>
<td>35.9</td>
<td>$229,056</td>
</tr>
<tr>
<td>501-1000</td>
<td>711</td>
<td>5</td>
<td>101.6</td>
<td>$400,000</td>
</tr>
<tr>
<td>1001-2000</td>
<td>1352</td>
<td>9</td>
<td>193.1</td>
<td>$677,735</td>
</tr>
<tr>
<td>2001-4000</td>
<td>2538</td>
<td>14</td>
<td>362.6</td>
<td>$1,218,921</td>
</tr>
<tr>
<td>4001+</td>
<td>6224</td>
<td>24</td>
<td>889.1</td>
<td>$2,492,229</td>
</tr>
</tbody>
</table>
Audits of Researchers

Median # of researchers per organization: 414
Median # of research staff per organization: 323
% of organizations that reported that audits of investigators occurred: 89.4%

Internal:
- "for cause"
  • Median: 1
  • Total: 1036

- random
  • Median: 12.5
  • Total: 11487

Regulatory agency inspections
  • Median: 0
  • Total: 356
Audits of IRBs/ECs

% of organizations that reported that audits of IRB/EC records occurred: 79.7%

Internal: "for cause"
- Median: 0
- Total: 369

Internal: random
- Median: 3
- Total: 4336

Regulatory agency inspections
- Median: 0
- Total: 55
<table>
<thead>
<tr>
<th>Number of active studies</th>
<th>Median # &amp; Total reported</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>Median</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>1</td>
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<tr>
<td></td>
<td>Total</td>
<td>197</td>
<td>11869</td>
<td>1501</td>
<td>882</td>
<td>2209</td>
</tr>
<tr>
<td>0-100</td>
<td>Median</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>0</td>
<td>43</td>
<td>18</td>
<td>7</td>
<td>32</td>
</tr>
<tr>
<td>101-500</td>
<td>Median</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>2</td>
<td>610</td>
<td>107</td>
<td>35</td>
<td>323</td>
</tr>
<tr>
<td>501-1000</td>
<td>Median</td>
<td>0</td>
<td>3.5</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>34</td>
<td>1345</td>
<td>94</td>
<td>28</td>
<td>170</td>
</tr>
<tr>
<td>1001-2000</td>
<td>Median</td>
<td>0</td>
<td>13</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
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<td>51</td>
<td>4808</td>
<td>313</td>
<td>292</td>
<td>695</td>
</tr>
<tr>
<td>2001-4000</td>
<td>Median</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>34</td>
<td>1383</td>
<td>245</td>
<td>110</td>
<td>401</td>
</tr>
<tr>
<td>4001+</td>
<td>Median</td>
<td>0</td>
<td>67</td>
<td>5</td>
<td>2</td>
<td>7.5</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>76</td>
<td>3663</td>
<td>724</td>
<td>410</td>
<td>586</td>
</tr>
</tbody>
</table>

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

*Only includes data from organizations that have internal IRB/ECs or are independent IRBs/ECs.