2019 Metrics on Human Research Protection Programs Performance

July 2020
About the Metrics

Improving the quality of human research protection programs (HRPP) is a top priority of AAHRPP. Effective and efficient systems of oversight by organizations provide better protections for research participants and produce higher quality research. And collectively, they raise the global bar to ensure research participants are safe and respected. AAHRPP is pleased to present the 2019 metrics for HRPP performance.

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 based off the most recent data reported by AAHRPP organizations as of December 31, 2019. Qualitative data was selected based on what most accurately reflected AAHRPP organizations in 2019. 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, IRB review times, to conformance with regulations and guidance, to financial and personnel resources.
Table of Contents

General Description of Organizations
Slide 6. All Accredited Organizations

General Description of Research
Slide 7. Where Organizations Conduct Research
Slide 8. Type of Research Organizations Conduct or Review
Slide 9. Specific Types of Research

Selected Types of Research
Slide 10. Organizations That Conduct Research With Vulnerable Populations

Sponsors of Research
Slide 11. Sponsors of Research
Slide 12. Federal Sponsors of Research
Slide 13. Regulations and Guidance Followed by Organizations

Reliance on the IRB
Slide 14. Use of IRBs
Slide 15. Use of External IRBs
Slide 16. Number of IRBs per Organization
Compensation of IRB Members
Slide 17. Compensation of IRB Members by Organizations
Slide 18. Financial Compensation of IRB Members

Characteristics of IRBs
Slide 19. Median Number of Active Protocols Organizations Oversee by Quartile
Slide 20. Median Number of Active Protocols Overseen by all Organizations
Slide 21. Mean Number of Active Protocols Organizations Oversee by Quartile
Slide 22. Mean Number of Active Protocols Overseen by all Organizations
Slide 23. Median Number of Active Protocols Overseen by an IRB Based on the Number of IRBs per Organization
Slide 24. Mean Number of Active Protocols Overseen by an IRB Based on the Number of IRBs per Organization

IRB Review Times
Slide 25. IRB Review Times by Type of Review
Slide 26. Five Year Trend in IRB Review Times

Use of Technology
Slide 27. Technology Use by Organizations with an IRB
Resources for the IRB
Slide 28. IRB Staffing and Funding Levels
Slide 29. Five Year Trends in Median IRB Budgets

Audits of the HRPP Conducted by Organizations
Slide 30. Number of Audits Conducted within the Past Year
Slide 31. Five Year Trends in Mean Number of Audits Conducted

Complaints Reported to the IRB
Slide 32. Five Year Trends in Mean Number of Complaints Reported

Non-Compliance Reported to the IRB
Slide 33. Number of Cases of Non-Compliance Reported to the IRB in the Past Year
Slide 34. Five Year Trends in Mean Number of Reported Cases of Non-Compliance
Of the 258 accredited organizations in 2019, 46% are academic institutions; 36.8% are hospitals; 7.8% are independent IRBs; 2.3% are VA Facilities, 3.9% are dedicated research facilities or research institutes; 2.3% are governmental organizations; 0.4% are contract research facilities; 0.4% are sponsors.
Of the 258 accredited organizations, 58.5% conduct research in their home state/province/region, other states/provinces/regions, and countries outside their home country. 21.3% conduct research in their home state/province/region only. 17.4% conduct research in their home state/province/region and other states/provinces/regions within their home country. 2.7% conduct research in their home state/province/region and countries outside their own country.
Of the 258 accredited organizations, 99% conduct biomedical research; 91% conduct social science/behavioral research; 26% conduct other types of research.
Nine organizations conduct biomedical research but did not specify the type. Of the remaining 249 organizations, 94% conduct research on drugs, while 92.8% conduct research on biomedical devices. Seven organizations did not specify if they had or had not conducted emergency research without consent in the last 12 months of their most recent report. Of those who did, 22% did conduct emergency research without consent in the last 12 months.
Of all 258 organizations, 95.3% conduct research involving children; 94.2% conduct research involving adults unable to consent; 93% conduct research involving employees; 89.9% conduct research involving students; 87.2% conduct research involving pregnant women; 60.1% conduct research involving prisoners; 14.3% conduct research involving other vulnerable groups.
For all organizations, a median of 15.4% of research is federally funded; a median of 16.3% is industry funded; a median of 7.5% is externally funded; a median of 45% is internally funded.
215 Organizations revealed the source of their federal funding. Of those 215 organizations, 70.2% receive funding from the United States government only. 17.2% receive funding from both US and non-US governments. 12.6% receive funding from only non-US governments.
Of 258 organizations, 85.7% follow FDA regulations; 84.9% follow DHHS regulations; 78.2% follow state and local laws; 64.0% follow ICH regulations in some form; 58.1 follow DOD regulations; 34.4% follow country-specific laws outside the US; 33.7% follow DoEd regulations; 27.5% follow DOJ guidelines; 16.7% follow VA regulations; 16.7% follow EPA regulations; and 14.3% follow DoE regulations.
Of the 239 non-IRB organizations, 95% have their own IRB while 5% do not.
For all non-IRB Organizations, 18% do not rely on external IRBs for any protocols, 48% rely on external IRBs for less than 10% of protocols, 29% rely on external IRBs for more than 10% of protocols, 5% rely on external IRBs for all protocols.
For all accredited organizations, 5% have zero IRBs; 37% have one IRB; 23% have two IRBs; 13% have three IRBs; 8% have four IRBs; 4% have five IRBs; 3% have six; 3% have seven; and 4% have eight or more.
85% of organizations with an IRB (excluding private IRBs) compensate IRB chairs; 62% compensate IRB vice chairs; 44% compensate affiliated members; 63% compensate non-affiliated members.
Within AAHRPP organizations that compensate IRB chairs, 95% provide financial compensation for chairs; within AAHRPP organizations that compensate IRB vice chairs, 96% provide financial compensation for vice chairs; within AAHRPP organizations that compensate affiliated members, 84% provide financial compensation for affiliated members; within AAHRPP organizations that compensate non-affiliated members, 93% provide financial compensation for non-affiliated members.
Median Number of Protocols Overseen organized by Quartiles of AAHRPP accredited Orgs

### Median Number of Active Protocols for Organizations (0-310 Protocols)

- Reviewed by a Convened IRB: 39
- Reviewed by the Expedited Procedure: 38
- Exemptions: 5
- Total: 138

### Median Number of Active Protocols Overseen (311-876 Protocols)

- Reviewed by a Convened IRB: 180
- Reviewed by the Expedited Procedure: 259
- Exemptions: 27
- Total: 518

### Median Number of Active Protocols Overseen (879-2028 Protocols)

- Reviewed by a Convened IRB: 312
- Reviewed by the Expedited Procedure: 740
- Exemptions: 130
- Total: 1294

### Median Number of Active Protocols Overseen (2049+ Protocols)

- Reviewed by a Convened IRB: 1085
- Reviewed by the Expedited Procedure: 1916
- Exemptions: 359
- Total: 3501
Reviewed By a Convened IRB: 227
Reviewed by the Expedited Procedure: 435
Exemptions: 50
Total: 878

Median Number of Active Protocols Overseen by all Organizations

Protocols: 227, 435, 50, 878
Total Protocols: 20
### Mean Number of Active Protocols Organizations Oversee by Quartile

#### Mean Number of Active Protocols (0-310 Protocols)
- Reviewed By a Convened IRB: 67
- Reviewed by the Expedited Procedure: 67
- Exemptions: 16
- Total: 139

#### Mean Numbers of Active Protocols (311-876) Protocols
- Reviewed By a Convened IRB: 218
- Reviewed by the Expedited Procedure: 264
- Exemptions: 64
- Total: 552

#### Mean Numbers of Active Protocols (879-2028) Protocols
- Reviewed By a Convened IRB: 418
- Reviewed by the Expedited Procedure: 764
- Exemptions: 192
- Total: 1409

#### Mean Number of Active Protocols (2049+ Protocols)
- Reviewed By a Convened IRB: 1304
- Reviewed by the Expedited Procedure: 2519
- Exemptions: 402
- Total: 4306
A median of 878 protocols were overseen by all organizations; a median of 130 protocols were overseen by organizations without an IRB; a median of 345 protocols were overseen by organizations with one IRB; a median of 1009 protocols were overseen by organizations with two IRBs; a median of 1255 protocols were overseen by organizations with three IRBs; a median of 2105 protocols were overseen by organizations with four IRBs; a median of 3617 IRBs were overseen by organizations with five or more IRBs.
A mean of 1595 protocols were overseen by all organizations; a mean of 179 protocols were overseen by organizations without an IRB; a mean of 649 protocols were overseen by organizations with one IRB; a mean of 1239 protocols were overseen by organizations with two IRBs; a mean of 1857 were overseen by organizations with three IRBs; a mean of 2780 protocols were overseen by organizations with four IRBs; a mean of 4162 protocols were overseen by organizations with five or more IRBs.
Median IRB Review Times by Type of Review

- Time From Submission to Review by Convened IRB: 15 calendar days
- Time From Submission to Approval by Convened IRB: 37 calendar days
- Time From Submission to Review by the Expedited Procedure: 8 calendar days
- Time From Submission to Approval by the Expedited Procedure: 18 calendar days
- Time From Submission to Exempt Determination: 9.5 calendar days
Five Year Trends in Median IRB Approval Times

- Approved by the Convened IRB
- Approved by The Expedited Procedure
- Exempt Determinations
26 organizations did not answer this question. Of those who did, 97% use a database to track IRB protocols; 84% use an online IRB application; 93% use an electronic system for distribution of materials; 84% use an online system for IRB review.
<table>
<thead>
<tr>
<th>Number of Protocols</th>
<th>Median Number of Protocols</th>
<th>Median Number of Staff</th>
<th>Median Number of Protocols per Staff Member</th>
<th>Median IRB Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>878</td>
<td>6.9</td>
<td>128.1</td>
<td>$492,042.00</td>
</tr>
<tr>
<td>0-100</td>
<td>57</td>
<td>2</td>
<td>28.3</td>
<td>$127,000.00</td>
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<tr>
<td>101-500</td>
<td>271</td>
<td>3.0</td>
<td>90.3</td>
<td>$232,781.00</td>
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<tr>
<td>501-1000</td>
<td>688</td>
<td>4.9</td>
<td>141.0</td>
<td>$375,000.00</td>
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<tr>
<td>1001-2000</td>
<td>1298</td>
<td>8.75</td>
<td>148.3</td>
<td>$657,272.00</td>
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<tr>
<td>2001-4000</td>
<td>2667</td>
<td>16.0</td>
<td>166.7</td>
<td>$1,293,559.00</td>
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<tr>
<td>4001+</td>
<td>5652</td>
<td>25.5</td>
<td>221.6</td>
<td>$2,757,331.50</td>
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Five Year Trend in Median IRB Budgets

IRB Budgets

2015 2016 2017 2018 2019
<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><strong>Mean</strong></td>
<td>5.0</td>
<td>44.5</td>
<td>1.9</td>
<td>23.8</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>2</td>
<td>15</td>
<td>0</td>
<td>4 (^{30})</td>
</tr>
</tbody>
</table>
Five Year Trend in Mean Number of Complaints per Organization

Number of Complaints

- 2015: 7
- 2016: 10
- 2017: 6
- 2018: 3
- 2019: 32
<table>
<thead>
<tr>
<th>Protocols</th>
<th>Median Number of Allegations of Non-Compliance</th>
<th>Median Number of Determinations of Serious Non-Compliance</th>
<th>Median Number of Determinations of Continuing Non-Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-100</td>
<td>0.5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>101-500</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>501-1000</td>
<td>5.5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1001-2000</td>
<td>10</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2001-4000</td>
<td>10</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>4000+</td>
<td>33</td>
<td>8</td>
<td>2</td>
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Five Year Trend in Non-Compliance