Report of
Key Performance
Metrics for the
IRB Review
Process
Report Period: July 1, 2008 to December 31, 2008

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Office of Research

UNIVERSITY of WASHINGTON
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INTRODUCTION

The Human Subjects Division (HSD) implemented a new database in February, 2008. The new database allows HSD, for the first time, to capture accurate and detailed data about performance and workload. As the database accumulates data, performance metrics can be calculated. This will help improve the IRB review process by identifying bottlenecks, inefficiencies, and unnecessary steps. Reliable and detailed metrics are a fundamental tool for accomplishing HSD strategic goals and specific objectives.

One objective is to publicly post reliable “turn-around time” metrics. This information has been requested by researchers for some time, but reliable data were not available from the previous database.

What are the metrics in this report?

For each of the following turn-around time metrics, we report four descriptive statistics: median (average), range, interquartile range (a measure of variability), and number of applications.

Overall turn-around time: the number of business days between the date when HSD receives an IRB application and the date when application receives Full Approval. The statistics are reported separately by type of application:

- New applications undergoing Full IRB review
- New applications undergoing “Minimal Risk” review
- New applications for a Certificate of Exemption

Review process steps: descriptive statistics for key components of the IRB review process, because of their importance to researchers. In this first report, one metric is included:

- Turn-around time for Conditional Approval of applications undergoing Full IRB review

All statistics are based on IRB applications received and approved between 7/1/08 and 12/31/08. Data for applications received before 7/1/08 are excluded because the data were in the old HSD database and/or were obtained during the database migration and implementation period. Further, data from the Veteran’s Administration IRBs are also excluded because of the impact of additional VA requirements.

What is next?

The initial goal is to provide basic information and to establish the baseline turn-around time for the overall review process. The baseline can be calculated when all of the applications received during this initial reporting period have completed the review process. These metrics will be updated quarterly throughout 2009, and more frequently in 2010. With each quarterly posting, comparisons to baseline will be made and new metrics will be added for specific parts of the IRB review process.

The overall goal is to help researchers better understand the amount of time and work involved in the IRB review process, so that they can more effectively plan their research. This includes providing information that suggests steps researchers can take to facilitate the review and approval of their applications.

Additional information
Definitions: page 11
Visual representation of the IRB review process: pages 5 and 6

Questions?
See the “Questions and Answers” at the end of this document.
For other questions, send an email to dora1q@u.washington.edu, or call Candy Grossman, Project Manager at 206-685-0561.
TABLE 1. Initial Applications Reviewed by a Full IRB

<table>
<thead>
<tr>
<th>Submission Type</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Full Approval Applications for Full IRB Review</td>
<td>Conditional Approval Applications for Full IRB Review</td>
</tr>
<tr>
<td>Reporting Period</td>
<td>7/1/08 - 12/31/08</td>
<td>7/1/08 - 12/31/08</td>
</tr>
<tr>
<td>Number of items (n)</td>
<td>36</td>
<td>59</td>
</tr>
<tr>
<td>Range of business days to approval</td>
<td>8 to 92</td>
<td>8 to 81</td>
</tr>
<tr>
<td>Median number of business days to approval</td>
<td>48</td>
<td>24</td>
</tr>
</tbody>
</table>

1 Includes applications that received Conditional Approval first and obtained Full Approval by 12/31/08

2 Includes 25 applications that are also reported as Full Approval, as they first received Conditional Approval
### Table 2. Initial Applications Reviewed as Minimal Risk or as Exempt

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>Applications for Minimal Risk Review</th>
<th>Applications for Exempt Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting Period</td>
<td>7/1/08 - 12/31/08</td>
<td>7/1/08 - 12/31/08</td>
</tr>
<tr>
<td>Number of items (n)</td>
<td>190</td>
<td>226</td>
</tr>
<tr>
<td>Range of business days to approval or granting of exempt status</td>
<td>0 to 95</td>
<td>0 to 50</td>
</tr>
<tr>
<td>Median number of business days to approval</td>
<td>15</td>
<td>3</td>
</tr>
</tbody>
</table>

3 Items that were received at HSD and approved on the same day are considered to have a turn-around time of “0” business days.
FIGURE 1. Turn-around Time for Full Approval of New Applications Receiving Full IRB Review

Full IRB New Applications Given Full Approval (n=36)

DESCRIPTION
A median of 48 business days was required to obtain Full Approval of new applications undergoing Full IRB review, for applications received and approved during the reporting period of 7/1/08 to 12/31/08. This turn-around time was highly variable, ranging from 8 to 92 business days.

ANALYSIS
- The high variability is largely due to whether a specific application was deferred and/or conditionally approved before being fully approved.
- As shown on page ten, 51 new applications had not yet been granted approval as of 12/31/08. These reviews should be completed and captured in the next quarterly report (May 2009). Because these applications are taking longer to receive approval, the median turn-around time is likely to increase in the next report.
- In 2004 (the most recent available metrics), the median turnaround time for Full Approval or Conditional Approval was 61 days (range 4 to 381). The inclusion of Conditional Approval in that 2004 evaluation means that turn-around time for Full Approval was likely considerably higher than 61 days.

NEXT STEPS
- Turn-around time metrics are being developed for specific steps of the review process. Some of these will be added to each subsequent metrics report, to provide a detailed picture of how specific steps contribute to the overall amount of time it takes for a new application to receive approval. The overall goal is to provide regular reports of the average turn-around time required for each step of the review process.
- When all of the applications that were received during the initial reporting period have completed the review process, those turn-around times will be considered the baseline to use for setting goals and determining effects of process improvement efforts.
FIGURE 2. Turn-around Time for Conditional Approval of New Applications

A median of 24 business days was required to obtain Conditional Approval of new applications undergoing Full IRB review. This turn-around time was highly variable, ranging from 8 to 81 days.

ANALYSIS
- **The high variability** is almost entirely due to whether a specific application received an outcome of deferral at the first Full IRB meeting at which the application was reviewed. A deferral requires preparation of, and response to, a significant review letter, followed by a second review by a full IRB at one of its regularly-scheduled bi-weekly meetings.
- As shown on page ten, 51 new applications received during this reporting period had not yet been granted approval as of 12/31/08. These reviews should be completed and captured in the next quarterly report (May 2009). Because these applications are taking longer to receive approval, the median turn-around time is expected to increase in the next report.
- HSD has not previously been able to isolate metrics for Conditional Approval, so there is no basis for comparison with previous time periods.

NEXT STEPS
- Turn-around time metrics are being developed for specific steps of the review process. Some of these will be added to each subsequent metrics posting, to provide a detailed picture of how specific steps contribute to the overall amount of time it takes for a new application to receive approval. The overall goal is to provide regular reports of the average turn-around time required for each step of the review process.
- When all of the applications that were received during this initial reporting period have completed the review process, those turn-around times will be considered the baseline to use for setting goals and determining effects of process improvement efforts.
**DESCRIPTION**
A median of 15 business days was required to obtain Full Approval of new applications undergoing Minimal Risk review. Turn-around time was highly variable, ranging from 0 to 95 days.\(^4\) Turn-around time for Conditional Approval was not calculated because it is rarely used with Minimal Risk review.

**ANALYSIS**
Minimal Risk applications are not subject to the limitations of IRB meeting schedules and agenda size. This factor contributes to the lower turn-around time for these items as compared to that for full IRB applications. However, as shown on page ten, 52 Minimal Risk applications had not yet been granted approval as of 12/31/08. These reviews should be completed and captured in the next quarterly report (May 2009). Because these applications are taking longer to receive approval, **the median turn-around time is expected to increase**. Nonetheless, future turn-around time should still be significantly less than it was for the last available time period (2004), when the median was 37 days with a range of 1 to 327.

**NEXT STEPS**
As with applications requiring Full IRB review, the amount of time that researchers take to respond to screening letters or review letters plays a key role in the overall turn-around time for approval of Minimal Risk applications. In future quarterly reports, measures of these steps in the review process will be added.

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\(^4\) Items that were received at HSD and approved on the same day are considered to have a turn-around time of “0” business days.
FIGURE 4. Turn-around Time for Granting Exempt Status to Exempt Applications

Exemption Applications (n=225)

The filled black circles represent statistically-identified outliers; asterisks represent statistically-identified extreme outliers.

DESCRIPTION
A median of 3 business days was required to review the 226 Exempt applications that were received and granted exempt status between 7/1/08 and 12/31/08. The range of 0 to 50 days indicates that the length of this review process is highly variable.

ANALYSIS
• As shown on page ten, of the 258 Exemption applications for which review was completed, 22 (9%) were found to be Not Human Subjects Research and 10 (4%) did not meet the criteria for Exempt status.
• In 2004 (the last time period for which HSD has metrics), the median time to grant Exempt status was 7 business days, with a range of 0 to 110.
• The large range is partly due to the inclusion of applications that were initially submitted as Minimal Risk applications using the standard IRB application (UW 13-11 form) but that were determined, after extensive screening and correspondence, to be qualified for Exempt status.

NEXT STEPS
The amount of time that researchers take to respond to screening letters or review letters plays a large role in the overall turn-around time for approval of Exempt applications. Measures of these steps in the review process will be added to future quarterly reports.

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5 Items that were received at HSD and approved on the same day are considered to have a turn-around time of "0" business days.
## TABLE 3. Status of All New Applications Received – 7/1/08 through 12/31/08

### Full IRB Applications

<table>
<thead>
<tr>
<th>Status</th>
<th>Number of Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Approval 6</td>
<td>36</td>
</tr>
<tr>
<td>Conditional Approval</td>
<td>34</td>
</tr>
<tr>
<td>Approval in Principle</td>
<td>15</td>
</tr>
<tr>
<td>Deferred (awaiting PI response &amp; IRB re-review)</td>
<td>21</td>
</tr>
<tr>
<td>Assigned to IRB meeting (screening completed)</td>
<td>21</td>
</tr>
<tr>
<td>Screening underway</td>
<td>9</td>
</tr>
<tr>
<td>Pending (no screening or review activity yet)</td>
<td>0</td>
</tr>
<tr>
<td>Closed or withdrawn after partial review 7</td>
<td>7</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>143</strong></td>
</tr>
</tbody>
</table>

6. Includes applications that received Conditional Approval first and obtained Full Approval by 12/31/08.

7. Replaced by different type of application; determined to be “Not Human Subjects Research;” or researcher requested withdrawal before review was completed.

### Minimal Risk Applications

<table>
<thead>
<tr>
<th>Status</th>
<th>Number of Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Approval</td>
<td>190</td>
</tr>
<tr>
<td>Conditional Approval</td>
<td>6</td>
</tr>
<tr>
<td>Approval in Principle</td>
<td>18</td>
</tr>
<tr>
<td>Not Human Subjects Research</td>
<td>8</td>
</tr>
<tr>
<td>Screening (screening letter sent, awaiting PI response/review of response)</td>
<td>25</td>
</tr>
<tr>
<td>Reviewed (IRB review letter sent, awaiting response/review of response)</td>
<td>36</td>
</tr>
<tr>
<td>Pending (no screening or review activity yet) 8</td>
<td>1</td>
</tr>
<tr>
<td>Closed or Withdrawn 9</td>
<td>11</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>295</strong></td>
</tr>
</tbody>
</table>

8. This one application was received at HSD on 12/31/08.

9. Replaced by different type of application, or researcher requested withdrawal before review was completed.

### Exempt Applications

<table>
<thead>
<tr>
<th>Status</th>
<th>Number of Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt Status Granted</td>
<td>226</td>
</tr>
<tr>
<td>Not Human Subjects Research or Not Research</td>
<td>22</td>
</tr>
<tr>
<td>Not Qualified for Exempt Status (review completed)</td>
<td>10</td>
</tr>
<tr>
<td>Screening (screening letter sent, awaiting PI response/review of response)</td>
<td>4</td>
</tr>
<tr>
<td>Review (review letter sent, awaiting response/review of response)</td>
<td>4</td>
</tr>
<tr>
<td>Closed 10</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>271</strong></td>
</tr>
</tbody>
</table>

10. Replaced by different type of application; research cancelled by researcher; or researcher did not respond to IRB correspondence.
DEFINITIONS

Approval
The Full IRB vote or subcommittee decision to approve an application, with no contingencies or conditions that must be met. Also referred to as Full Approval in this report to distinguish from Conditional Approval.

Approval Date
The date when the Full IRB voted or subcommittee decided to approve (or conditionally approve) an IRB application, except for exemption applications. For Certificates of Exemption, the approval date is the date when the IRB concurred with the exemption approval provided by the researcher’s department chair.

Approval in Principle
Approval that, at the IRB’s discretion, may be granted to satisfy funding agency requirements, without the IRB having reviewed all of the study procedures and consent documents. It allows researchers to receive funds from the funding agency, but does not allow researchers to screen for or recruit potential subjects, consent subjects, or perform any human subjects research procedures. A standard IRB application or exempt application must be reviewed and approved before the research activities can begin.

Certificate of Exemption
Status granted to studies that involve no more than minimal risk and that fall into one or more of the six categories of “exemption” defined by federal regulations. Exempt studies do not require periodic (e.g., annual) re-review and the standard requirements for obtaining subjects’ consent do not apply.

Conditional Approval
The Full IRB vote or subcommittee decision to approve an application, subject to the fulfillment of minor contingencies or conditions.

Full IRB
A review of an application that is performed by a majority of members of the entire IRB (the full board). This level of review is required for all applications that involve more than minimal risk to subjects and that do not meet the federally-defined criteria for allowing review by a subcommittee of the IRB.

Interquartile Range
The interquartile range is a summary measure of the spread (or variability, or statistical dispersion) in a set of numbers. It is also called the “midspread” or the “middle fifty.” It is essentially the range of the middle 50% of the data. Because it uses the middle 50%, it is not affected by outliers or extreme values.

Median
The median is a summary measure of the “average” value or central tendency in a set of numbers. To calculate the median: all of the numbers are arranged from lowest value to highest value; the value in the middle is the median. In other words, the median is the point that divides the distribution of scores in half. We use the median instead of the mean because (1) medians are less affected by outlier values in distributions; and (2) turn-around time values are skewed distributions, which are better represented by the median.

Minimal Risk
The term that the UW IRB uses to refer to IRB reviews performed by a subcommittee of the Full IRB. Federal regulations use the term “expedited” review to refer to this type of review. It can be used only for applications that involve no more than minimal risk to subjects and that meet certain federally-defined criteria.

Not Human Subjects Research/Not Research
An IRB determination that the research activity is not “human subjects research/not research” as defined by applicable federal regulations and therefore the research requires neither IRB review nor Exempt status.

PI
Principal Investigator – the lead researcher, defined by the IRB as the person’s whose name is on the IRB application.

Received Date
The date when the printed copies of the IRB application were received by the Human Subjects Division office.
1) **Why does it take so long to receive IRB approval?**

“Long” is relative, and conducting a quality review takes time. However, HSD has been working successfully to decrease the turn-around time by improving its processes. For example, in 2004 (the last time period for which HSD has metrics), the median turn-around time for Minimal Risk applications was 37 business days, with a range of 0 to 327, in contrast with the current median of 15 days and range of 0 to 95 days. A number of factors can add to the time required:

- Completeness of the initial application – did everything that is required for review come in with the application when first submitted to HSD and were all questions fully and appropriately answered?
- Complexity of the application – studies that involve multiple subject groups; use new methodologies and/or research techniques; require multiple stages and/or study sites; and/or raise significant ethical and/or safety issues can require additional time to review.
- Specific regulatory requirements – studies that involve vulnerable subjects or that use approaches for which there are specific regulatory requirements can require additional time to review to assure that all requirements are met by the researcher and the IRB.
- Applications that are deferred by a full IRB require preparation of, and response to, an often lengthy review letter, followed by a second review by a full IRB at one of its regularly-scheduled bi-weekly meetings.
- Applications that need to be transferred to a different level of review (for example, from Minimal Risk to Full IRB), or that have been submitted on the wrong type of application form.

The IRB received 2034 new applications in 2008, and is responsible for continuing review and oversight of about 7000 currently approved and active studies, each with its own IRB application.

2) **Your Metrics Report says the median number of days to conditionally approve a Full IRB new application is 24. Why is my application taking longer?**

“Median” means that half of the applications will take less than 24 days to obtain Conditional Approval and half of the applications will take more than 24 days. Any individual application may be impacted by the factors described above in Question #1. Delays in responding to questions or requests from the IRB can also contribute to the overall time required for review.

3) **Is there anything I can do to speed my application through the approval process?**

Yes – the following recommendations can help to decrease the time required for review of your application:

- First and foremost, use the most current forms directly from the HSD web site (http://www.washington.edu/research/hsd/forms_paper.php) and read thoroughly the instructions on each form.
- If you have questions as you are completing an IRB application, contact an appropriate HSD administrator (see the HSD contact web page) or send an email to hsdtrain@u.washington.edu with a
QUESTIONS AND ANSWERS CONTINUED

brief description of the research or issue and your question, or to request a telephone or in-person consult. This can improve the application and potential turn-around time.

- To the extent possible, make sure that your application is complete. Include all necessary documentation and complete all questions asked. If a question on the application does not apply to your research, at least indicate “NA” or “Not Applicable.” Do not leave questions blank.
- When you receive questions or requests for additional information/materials from the IRB, respond as quickly and thoroughly as possible.
- If you are a student, make sure that you involve your Faculty Advisor in each step of the IRB submission process, including responding to requests and correspondence from the IRB.
- If you are a Faculty Advisor, be sure that you are involved in each step of your students’ IRB submission process.
- Find out if there is someone in your department who is designated to assist colleagues with preparing IRB applications and consult with that person prior to submitting your application.

4) Will these turn-around times improve in the future?

Yes – HSD has been putting significant effort and resources into strategic planning and process improvement efforts designed to make the IRB review process more efficient, consistent, and transparent. These efforts have begun to produce results, as shown by comparing the metrics reported here with the (few) metrics we were able to calculate with our old database in 2004.

However, we do expect that the median turn-around times reported in the next Metrics Report may be somewhat longer, because we have not yet completed the review process for all applications in our defined group of “baseline” applications (i.e., applications received between 7/1/08 and 12/31/08). These remaining applications in our baseline group are taking longer to receive approval, and therefore we expect the median and ranges of turn-around time to increase a bit for the baseline group. However, we expect those final baseline numbers still to be significantly better than the turn-around times we had in 2004 (the last time period for which we have metrics).

5) Is one IRB faster than another, and how do I get my application placed with that committee?

The review of one IRB is not necessarily faster than that of another. Over time, the average turn-around time across the IRBs is about the same. At any given point in time, each individual IRB is affected by increased or decreased volume of applications; complexity and quality of applications; staffing; and availability of IRB members. Applications requiring full IRB review are assigned to the IRBs on a rotating basis, with consideration given to the above factors, in order to facilitate appropriate reviews and optimal turn-around time. Minimal Risk applications are assigned to review teams based on the researcher’s academic department.

6) How many HSD staff work on a single application? Or, how many IRBs are there?

There are six IRBs at the UW for which HSD provides administrative support – three review biomedical research and three review social/behavioral research. There are also two IRBs at the Seattle VA that are supported by HSD. The UW IRBs also have four subcommittees (Minimal Risk teams) that review Minimal Risk and Exempt applications. At least two HSD staff members typically work on each individual application, not including staff who do filing and data entry.

HSD would appreciate your feedback on this document. If you have a moment, please take this short, anonymous survey: https://catalysttools.washington.edu/webq/survey/sherrye/72583