Report of

Key Performance Metrics

For the UW IRB Review Process

Report #21
Period: July 1, 2014 – December 31, 2014
Posted: February 27, 2015

Human Subjects Division
Office of Research
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INTRODUCTION

Background
Reliable metrics are a fundamental tool for accomplishing HSD strategic goals and specific objectives. This report fulfills one of those objectives: providing researchers with publicly available “turnaround time” metrics for planning research activities.

These metrics are updated twice yearly. New metrics calculations will occasionally be added.

Metrics Calculations
Each bi-annual report is based on a 6-month “window” of data.

Three descriptive statistics are reported for turn-around time metrics: median (average) number of business days, range, and number of applications. “Business days” do not exclude University Holidays or closures (e.g., snow days).

Additional information
Definitions: page 20
Visual representation of the IRB review process: Appendix A

Questions?
See the “Frequently Asked Questions” at the end of this document.
For other questions: Lauren White, Metrics and Reporting Specialist, (lawhite@uw.edu).
# OVERALL TURNAROUND TIME

## TABLE 1. Overall Turnaround Time (TAT) for Initial IRB Applications

<table>
<thead>
<tr>
<th>Reporting Period</th>
<th>Full IRB Review</th>
<th>Minimal Risk Review</th>
<th>Exempt Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median Business Days to Completion of Approval Process</strong>*</td>
<td>67</td>
<td>26</td>
<td>9</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>11 - 205</td>
<td>2 - 225</td>
<td>0 - 90</td>
</tr>
<tr>
<td><strong>Number of Applications (n)</strong></td>
<td>61</td>
<td>365</td>
<td>280</td>
</tr>
<tr>
<td><strong>Target TAT</strong></td>
<td>71</td>
<td>21</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Target Upper End of Range</strong></td>
<td>254</td>
<td>307</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*HSD considers the approval process complete on the date when the approval packet is mailed to the researcher.

**Targets for Turnaround Time and Range have been set using baseline data from 2009. For more information on how the baseline was calculated, please see the FAQ section at the end of this report.

**NOTE:** Figures and Tables throughout this report contain data for the current reporting period as well as the previous three reporting periods (listed below).
FIGURE 1. Overall Turnaround Time for Initial Application Requiring Full IRB Review

DESCRIPTION
This figure shows the median number of business days for review and Full Approval of new initial IRB applications requiring Full Board Review by a convened IRB for the current and previous three reporting periods. The vertical bars show the targeted median and range of turnaround times.
FIGURE 2. Distribution of Turnaround Times for Initial Applications Requiring Full IRB Review

DESCRIPTION
This figure shows the frequency distribution of turnaround times for the review and Full Approval of new, initial applications requiring Full Board Review by a convened IRB during the Reporting Period.
FIGURE 3. Time from Application Receipt to First Full IRB Review (“Agenda Date”)

DESCRIPTION
This figure shows the median number of business days between the date a new, initial IRB application requiring Full Board Review is received by HSD and the Agenda Date where it is first reviewed at a meeting of the convened IRB.

Many activities occur during this time period, including:
- Assignment of the application to a specific IRB.
- Creation of a data record in the HSD database.
- Screening of the application (staff read the entire application packet, write a screening email to the researcher, receive and screen the researcher’s response).
- Creation of the meeting agenda (prioritizing workload, assuring that a quorum will be present at the IRB meeting, identifying primary reviewers for each agenda item).
- Preparation and delivery of the agenda materials to the IRB members (staff scan all materials, including screening letters and responses; flash drives with scanned materials are delivered to IRB members).
- IRB members have about five business days (per regulations before the meeting to read and review the materials).

For more information on the process occurring during this period, see Section 2.2.3 of the SOP Initial Intake, found on the Policies, Procedures, and Guidance page of HSD’s website.
FIGURE 4. Distribution of Outcomes for the First Full IRB Review of Initial Applications

**DESCRIPTION**

This figure shows the distribution of outcomes from the first convened IRB meeting for initial applications for the current and previous three reporting periods. As shown, a small number of applications received Full Approval at the first Full IRB meeting, meaning that no subsequent IRB review or action is required. Applications with a review outcome of Deferral must be reviewed again by the Full IRB after the researcher’s response to the review letter is received. Applications with a review outcome of Conditional Approval undergo a verification process (no Full IRB meeting) after the researcher’s response to the Conditional Approval review letter is received.
# DETAILED ANALYSIS: Modifications to Studies Requiring Full Board Oversight

## TABLES 2 and 3. Turnaround Time for Modifications to Studies Requiring Full IRB Review

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Reporting period</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median business days to completion of approval process</td>
<td>24</td>
<td>24</td>
<td>22</td>
<td>26</td>
</tr>
<tr>
<td>Range</td>
<td>7 - 165</td>
<td>1 - 274</td>
<td>2 - 184</td>
<td>6 - 142</td>
</tr>
<tr>
<td>Number of modifications (n)</td>
<td>109</td>
<td>101</td>
<td>119</td>
<td>104</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Reporting period</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median business days to completion of approval process</td>
<td>6</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Range</td>
<td>0 - 117</td>
<td>0 - 72</td>
<td>0 - 90</td>
<td>0 - 160</td>
</tr>
<tr>
<td>Number of modifications (n)</td>
<td>958</td>
<td>1014</td>
<td>884</td>
<td>647</td>
</tr>
</tbody>
</table>

**DESCRIPTION**

Table 2 shows the turnaround time for **Modifications** that require review by the full, convened IRB (required when the change is substantive and may alter the risks and/or benefits to the subjects). Table 3 shows the turnaround times for Modifications reviewed by a Subcommittee of the IRB, rather than at a convened IRB meeting. Modifications are eligible for Expedited Review via Subcommittee when the proposed changes are “minor” and will not alter the risks and/or benefits to subjects. Expedited review eligibility can be determined by researchers using the **WORKSHEET: Expedited Review Eligibility**.
FIGURE 5. Types of Modifications Requested for Studies Requiring Full IRB Review, Reviewed by the Convened IRB

*Types listed in order of descending frequency

DESCRIPTION

Figures 5 and 6 depict the types of changes requested in Modifications to approved studies requiring Full Board Review. Figure 5 displays the distribution of change types for Modifications reviewed by the Full, convened IRB. Figure 6 shows the distribution of change types for Modifications to studies requiring Full IRB oversight that are reviewed by an IRB subcommittee using the Expedited process. Modifications are eligible for Expedited Review via Subcommittee when the proposed changes are “minor” and will not alter the risks and/or benefits to subjects.
Types of Modifications Requested for Studies Requiring Full IRB Review, Reviewed by the Expedited Process

*Types listed in order of descending frequency

**DESCRIPTION**
See previous Figure.
FIGURE 7. Overall Turnaround Time for Initial Applications Receiving Minimal Risk Review

DESCRIPTION
This chart shows the average number of business days required to obtain Full Approval of new, initial IRB applications undergoing Minimal Risk review. The vertical bars show the range of turnaround times. Horizontal markers show the targeted median and range of turnaround times. For more information on Minimal Risk review, see the SOP Expedited Review on HSD’s website.
DESCRIPTION
This figure shows the frequency distribution of turnaround times for the review and approval of new, initial IRB applications undergoing Minimal Risk review for Report 21 (7/1/2-14 – 12/31/2014).
FIGURE 9. Median Turnaround Time for Initial Applications for Use of Identifiable Specimens/Data Compared to Initial Minimal Risk Applications

DESCRIPTION
This chart compares the turnaround time for “regular” Minimal Risk applications and applications for the Use of Identifiable Specimens/Data. The latter involves the review of medical records or specimens, retrospective or prospective, and does not involve collecting any other information from or about the research subjects. This type of research comprised 37% of this reporting period’s total Minimal Risk applications, and took a median of 15 business days to complete the approval process, compared with 33 business days for other Minimal Risk applications.
### TABLE 4. Turnaround Time for Modifications to Minimal Risk Studies

<table>
<thead>
<tr>
<th>Reporting period</th>
<th>Median business days to completion of approval process</th>
<th>Range</th>
<th>Number of modifications (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Report 18</strong>&lt;br&gt;1/1/13 – 6/30/13</td>
<td>11</td>
<td>0 - 175</td>
<td>558</td>
</tr>
<tr>
<td><strong>Report 19</strong>&lt;br&gt;7/1/13 – 12/31/13</td>
<td>6</td>
<td>0 - 205</td>
<td>536</td>
</tr>
<tr>
<td><strong>Report 20</strong>&lt;br&gt;1/1/14 – 6/30/14</td>
<td>5</td>
<td>0 - 156</td>
<td>610</td>
</tr>
<tr>
<td><strong>Report 21</strong>&lt;br&gt;7/1/14 – 12/31/14</td>
<td>8</td>
<td>0 - 120</td>
<td>598</td>
</tr>
</tbody>
</table>

**DESCRIPTION**

This table shows the median turnaround time in business days for Modifications to Minimal Risk studies for the current and previous three reporting periods.
FIGURE 10. Types of Modifications Requested for Studies Receiving Minimal Risk Review

*Types listed in order of descending frequency

DESCRIPTION
This figure depicts the types of changes requested in Modifications to approved studies receiving Minimal Risk Review. Modifications are eligible for Expedited Review via Subcommittee when the proposed changes are “minor” and will not alter the risks and/or benefits to subjects.
FIGURE 11. Overall Turnaround Time for Review of Initial Applications for Exempt Status

DESCRIPTION
This chart shows the median number of business days required to obtain an Exempt Determination for Exempt Status Applications for the current and previous three reporting periods. The vertical bars show the range of turnaround times. For more information on Exempt research review, see SOP Exempt Determination, on HSD’s website.
FIGURE 12. Distribution of Turnaround Times for Initial Applications for Exempt Status

DESCRIPTION
This figure shows the frequency distribution of turnaround times for the review of Exempt Status Applications for Report 21 (7/1/2014 – 12/31/2014).
### Table 5. Industry Clinical Trials: Turnaround Times for Specific Start-Up Processes

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
<th>Median* (Business Days)</th>
<th>Range (Business Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSD receipt of researcher’s materials</td>
<td>HSD initial screening response</td>
<td>1</td>
<td>0 - 5</td>
</tr>
<tr>
<td>HSD receipt of researcher’s materials</td>
<td>Completion of HSD screening</td>
<td>14.5&lt;sup&gt;1&lt;/sup&gt;</td>
<td>0 - 293</td>
</tr>
<tr>
<td>Completion of HSD screening</td>
<td>IRB application submitted to WIRB</td>
<td>1&lt;sup&gt;2&lt;/sup&gt;</td>
<td>0 - 73</td>
</tr>
<tr>
<td>Application received by WIRB</td>
<td>WIRB approval granted</td>
<td>6.5&lt;sup&gt;3&lt;/sup&gt;</td>
<td>1 - 63</td>
</tr>
</tbody>
</table>

*Median turnaround times based on about 65 WIRB-reviewed studies that were approved by WIRB during the reporting period for Report 21 (7/1/14 – 12/31/14).

**Description**

1. This step requires information from other offices and a complete application before HSD can complete its screening and institutional sign-off for WIRB. It includes the time required for
   - HSD’s screening activities;
   - Sponsor response time and edits to consent forms and other documents;
   - Completion of contract negotiations by the Office of Sponsored Programs (OSP); and
   - Completion of the study budget by the Clinical Research Budget and Billing (CRBB) Office.

2. This step is performed by the study team and/or study sponsor.

3. This step represents the turnaround time for WIRB review.

For more information on reviews conducted by the Western Institutional Review Board (WIRB) see [SOP WIRB review, Researchers Procedures](#) on HSD’s website.
GLOSSARY OF HSD TERMS

**Agenda Date**
The date when an application requiring Full IRB Review is first reviewed by a Full IRB at a convened meeting. Also known as the “meeting date”.

**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 Exempt Status 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 Packet**
The packet of materials that the IRB sends to the researcher after an application has been fully approved. It includes the formal documentation of IRB approval, typically in a box on the application front page. The Approval Packet also includes the formally-approved and stamped copy of the consent form, which must be used with the research subjects.

**Conditional Approval**
The Full IRB or Subcommittee decision to approve an application, subject to the fulfillment of minor conditions.

**Deferral**
The decision (vote) by a Full IRB that indicates the following: (1) the IRB has questions about the research that have bearing upon the risk/benefit analysis of the research; (2) the IRB requires significant additional information or clarification in order to understand specific parts of the application; and/or (3) the IRB is requesting changes to the research in order to address regulatory requirements or concerns arising from the risk/benefit analysis.

**Exempt Status**
Status granted to studies that involve no more than Minimal Risk and that fall into one or more of the six categories of “Exemption” as defined by Federal regulations. Exempt studies do not require periodic (e.g., annual) re-review.

**Follow-up Info Request**
A request sent by HSD staff to the researcher requesting specific materials or information (e.g., clean, non-tracked version of consent form) that must be received prior to completion of the approval process.

**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.

**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 used by the UW for reviews performed by an IRB Subcommittee. Federal regulations use the term “Expedited” review. It can be used only for applications that involve minimal risks to subjects and that meet certain federally-defined criteria.

**Modification**
Federal regulations require researchers to obtain IRB Review and Approval before making any changes to their already-approved research. The request is submitted to HSD on a Modification form.

**Received Date**
The date when the printed copies of the IRB application were received by the Human Subjects Division office.

**Screening Request**
A request sent by HSD staff to the researcher after receipt of a new application to obtain missing information or clarification in order to either a) determine the level of review required (e.g., Expedited versus Exempt), or b) to better prepare the application for Full IRB review.
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 – 327. 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 require preparation of, and response to, an often lengthy review letter, followed by a second review by a full IRB at one of its 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.
- A considerable amount of available Minimal Risk review time is spent communicating with researchers about IRB applications that are eventually determined to not require IRB review because the described activities do not meet the federal regulatory definition of Human Subjects Research.

The IRB is responsible for continuing review and oversight of about 6,300 currently approved and active studies, each with its own IRB application.

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

“Median” means that half of the applications will take less than 24 business days to obtain Conditional Approval and half of the applications will take more than 24 business 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.
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:

- Always use the most current forms directly from the HSD web site ([http://www.washington.edu/research/hsd/forms/](http://www.washington.edu/research/hsd/forms/)) 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 webpage) or send an email to hsdinfo@uw.edu with brief description of the research or issue and your question, or 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 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?**

HSD puts significant effort and resources into strategic planning and process improvement efforts designed to make the IRB review process more efficient, consistent, and transparent. The results of these efforts are shown by comparing the metrics reported across our quarterly reports.

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, 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 Applications for both Full Board and Minimal Risk review are generally assigned to review teams based on the Principal Investigator’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 – four review biomedical research and two review social/behavioral research. The UW IRBs also have six subcommittees (Minimal Risk teams) that review Minimal Risk and Exemption applications. At least two HSD staff members typically work on each individual application.
7)  How was the baseline calculated?

The baseline for the turn-around time metrics for new applications requiring full IRB review, new applications for Minimal Risk review, and applications for Exempt status, was derived by tracking all new applications received between July 1, 2008 and December 31, 2008, until each reached a final status of either approved or closed. For those that reached a status of Full Approval, the turn-around time was calculated as the business days from the date received at HSD to the date the approval packet was sent to the researcher, whenever that occurred. As a result, both the median and the range for full IRB and Minimal Risk applications are higher for the baseline cohort than for the other reporting period cohorts, as the baseline includes more applications that took an exceptionally long time for review. For an explanation of reasons why review and approval can take longer than the median, please see Question 1 above in this section. Additionally, the applications included in the baseline will have been in earlier metrics reports, depending on when the approval packet was sent to researchers.
FIGURE 1: Process for Initial Application Requiring Full IRB Review

Application received

Initial processing, data entry, limited screening, assignment to IRB

Full IRB Committee teams

Item screened, screening letter sent to PI

PI response to screening received

Item assigned to agenda

Item reviewed by full IRB & decision made

Write letter notifying PI of decision

Letter emailed to PI

PI response to deferral or conditional approval letter received

Response reviewed by full IRB or subcommittee

Full approval given to item?

Yes or No

Approval packet sent to PI

Overall Turnaround Time

Time to first Full IRB Meeting

FIGURE 2: Process for Initial Applications Receiving Minimal Risk Review

Application received

Initial processing, data entry, limited screening, assignment to IRB

Minimal risk review

Item screened and/or reviewed, screen/review letter sent to PI

PI response to screen/review letter received

Approval

Approval packet sent to PI

Overall Turnaround Time
FIGURE 1: Process for Review of Exempt Research Applications

Application received

Initial processing, data entry, limited screening, assignment to IRB

Review

Item screened and/or reviewed, screen/review letter sent to PI

PI response to screen/review letter received

Exempt? Yes or No

Certificate of Exemption

Approval packet sent to PI

Overall Turn-around Time

Exempt? Yes or No

Certificate of Exemption

Not exempt, PI notified