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INTRODUCTION

The Human Subjects Division (HSD) implemented a new database in February, 2008. The new database allows HSD 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 HSD 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.

Metrics calculations
Each quarterly report is based on a 6-month sliding “window” of data. Data for applications received before 7/1/08 are always excluded because the data were in the old HSD database and/or were obtained during the new database migration and implementation period.

Four descriptive statistics are reported for turn-around time metrics: median (average) number of business days, range, interquartile range (a measure of variability), and number of applications. “Business days” currently does not exclude University holidays or closures (e.g., snow days).

What is next?
The initial goal is to provide basic information and to establish the baseline turn-around time for the overall 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 (once the baseline has been established) 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 about steps researchers can take to facilitate the review and approval of their applications.

Additional information
Definitions: page 16
Visual representation of the IRB review process: pages 4, 12 & 14

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. Overall Turn-Around Time for Initial IRB Applications

<table>
<thead>
<tr>
<th></th>
<th>Applications for Full IRB Review</th>
<th>Applications for Full IRB Review</th>
<th>Applications for Minimal Risk Review</th>
<th>Applications for Minimal Risk Review</th>
<th>Applications for Exempt Status</th>
<th>Applications for Exempt Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median business days to completion of approval process</strong></td>
<td>58.5</td>
<td>60</td>
<td>16</td>
<td>16</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>7 to 94</td>
<td>8 to 173</td>
<td>0 to 166</td>
<td>0 to 160</td>
<td>0 to 116</td>
<td>0 to 116</td>
</tr>
<tr>
<td><strong>Number of items (n)</strong></td>
<td>98</td>
<td>90</td>
<td>317</td>
<td>242</td>
<td>336</td>
<td>287</td>
</tr>
</tbody>
</table>

*HSD considers the approval process complete as of the date the approval packet is mailed to the PI.

**DESCRIPTION**

This table shows the average number of business days required to obtain Full Approval of new IRB applications undergoing Full IRB review, Minimal Risk review, or Requests for Exempt Status, for two consecutive reporting periods. (Reporting periods are 6-month windows, which "slide" by 3 months from one reporting period to the next.)
**DESCRIPTION**
This boxplot is a visual representation of the data provided in **Table 1** on the preceding page, for the most recent reporting period. It shows the average number of business days required to obtain Full Approval of new IRB applications undergoing Full IRB review.

**ANALYSIS**
Some of the factors that contribute to the high variability in overall turn-around time are (1) the length of time required to prepare the IRB review letters sent to researchers, and (2) the length of time that researchers take to respond to IRB review letters. These factors are shown in Figures 3 and 4.
**FIGURE 2. Time Required to Obtain Conditional Approval for Initial Applications Requiring Full IRB Review**

This boxplot shows the time required to obtain Conditional Approval for initial applications requiring Full IRB review. Conditional Approval is an important intermediate step toward Full Approval because it allows researchers to receive and start spending grant or contract funds.

**DESCRIPTION**

This boxplot shows the time required to obtain Conditional Approval for initial applications requiring Full IRB review. Conditional Approval is an important intermediate step toward Full Approval because it allows researchers to receive and start spending grant or contract funds.

**ANALYSIS**

Some of the factors that contribute to the high variability in obtaining conditional approval are (1) the length of time required to prepare the IRB review letters sent to researchers, and (2) the length of time that researchers take to respond to IRB review letters. These factors are shown in Figures 3 and 4.
FIGURE 3. Time Required to Prepare IRB Review Letters to Researchers

Turn Around Time from Date of Deferral Decision by Full IRB to Date Deferral Letter Sent to PI for New Applications (n=43)

*IQR=Interquartile Range

Description and analysis continued on the next page.
DESCRIPTION
These boxplots show the average number of business days required to prepare and send two types of IRB review letters to researchers (four days for Deferral letters; three days for Conditional Approval letters). The preparation process includes drafting the letter and then obtaining and incorporating feedback from the primary reviewer, the IRB committee chair, and other appropriate individuals before finalizing and sending the letter.

ANALYSIS
This analysis is an important step in examining key factors that contribute to overall turn-around time for IRB review and approval.

Deferral letters: The median dropped from five to four days and the Interquartile Range (a measure of variability) dropped from seven to three days for this reporting period compared with the last reporting period.

Conditional approval letters: The median stayed the same (three days) as for the last reporting period, but the range dropped considerably: it was zero to 36 days for the last reporting period compared with zero to 18 days for this reporting period.
FIGURE 4. Time Taken by Researchers to Respond to IRB Review Letters

Deferral Responses from PI (n=47)

* IQR=Interquartile Range

Full Range: 2 to 140

Third Quartile=31
Median=12
First Quartile=7

Description and analysis continued on the next page.
FIGURE 4. Time Taken by Researchers to Respond to IRB Review Letters (cont.)

DESCRIPTION
These boxplots show the average number of business days required for researchers to prepare and send their response to two types of IRB review letters (12 days for Deferral responses; 17 days for Conditional Approval responses).

ANALYSIS
This analysis is another important step in analyzing key factors that contribute to overall turn-around time for IRB review and approval.

Researcher response time for Deferral Response letters decreased for this reporting period compared with the last reporting period: 12 days versus 17 days. However, response time increased somewhat for Conditional Approval Response letters: from a median of 11 days to 13 days, and the Interquartile Range (a measure of variability) increased from 14 to 22 days.
FIGURE 5. Pie Chart Showing the Distribution of Outcomes for the First Full IRB Review of Initial Applications

Distribution of Outcomes for First Full IRB Review for New Applications (n=137)

For new applications received after 7/1/08 with a first full board review occurring between 1/1/09 and 6/30/09

- **Approved (n=7)**
- **Conditional Approval (n=81)**
- **Deferred (n=49)**
- **Disapproved (n=0)**

**DESCRIPTION**

The purpose of this pie chart is to show the distribution of outcomes from the first Full IRB review for initial applications. As shown, 5% received Full Approval at the first Full IRB review, meaning that no subsequent IRB review or action is required. Applications with a review outcome of Deferral (36%) 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 (59%) undergo an expedited review process (no Full IRB meeting) after the researcher’s response to the review letter is received.

**ANALYSIS**

In the coming year, HSD will analyze the reasons for Deferral outcomes with the goal of identifying contributing factors that can be addressed so as to lower the probability of a Deferral outcome.
FIGURE 6. Pie Chart Showing the Pattern of Full IRB Review Decisions for Initial New Applications Receiving a First Decision of Deferral

Pattern of Full Board Decisions for New Applications Receiving a First Decision of Deferral (n=31)

For full board applications reaching full approval between 1/1/09 and 6/30/09

The sample size for this analysis (n=31) is relatively small, with only six applications in the heterogeneous “All Other” category. A larger number (i.e., a longer analytic period) will be required in order to develop an understanding of this category.

DESCRIPTION
The purpose of this pie chart is to analyze the overall IRB review pattern for initial applications that had a Deferral outcome from the first Full IRB review. As shown, 16% received Full Approval at the second Full IRB review, meaning that no subsequent IRB review or action is required. About 65% received Conditional Approval at the second Full IRB review, meaning that an expedited review process (no Full IRB meeting) can be used to review the researcher’s subsequent response.

ANALYSIS
In the coming year, HSD will analyze the reasons for Conditional Approval outcomes following the initial Deferral outcome, with the goal of identifying contributing factors that can be addressed so as to increase the probability of a Full Approval outcome with the second IRB review.

The sample size for this analysis (n=31) is relatively small, with only six applications in the heterogeneous “All Other” category. A larger number (i.e., a longer analytic period) will be required in order to develop an understanding of this category.
**DESCRIPTION**
This boxplot is a visual representation of the data provided in Table 1 on page three. It shows the average number of business days required to obtain Full Approval of new IRB applications undergoing Minimal Risk review.

**ANALYSIS**
One factor that contributes to the high variability in overall turn-around time is the length of time that researchers take to respond to the IRB review letter. This factor is shown in Figure 8 (next page).
**FIGURE 8. Time Taken by Researchers to Respond to Minimal Risk IRB Review**

**DESCRIPTION**
This boxplot shows that researchers take an average of six business days to prepare and send their response to the Minimal Risk IRB review letter.

**ANALYSIS**
This analysis is an important step in analyzing key factors that contribute to overall turn-around time for Minimal Risk IRB review and approval. Though the average response time is quite low, the range of response times is extremely variable; the maximum response time was 148 business days or about seven months.
DESCRIPTION
This boxplot is a visual representation of the data provided in Table 1 on page three. It shows the average number of business days required to obtain a Certificate of Exemption.

ANALYSIS
One factor that contributes to the high variability in overall turn-around time is the length of time that researchers take to respond to the IRB review letter. This factor is shown in Figure 10 (next page).
FIGURE 10. Time Taken by Researchers to Respond to Exempt Review

DESCRIPTION
This boxplot shows that researchers take an average of only one business day to prepare and send their response to the Exemption review letter.

ANALYSIS
This analysis is an important step in analyzing key factors that contribute to overall turn-around time for Exemption review and approval. Though the average response time is remarkably low, the range of response times is extremely variable; the maximum response time was 112 business days or about five and one-half months.
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 Packet
The packet of materials that the Human Subjects Division sends to the researcher after an IRB application has been fully approved. It includes the formal documentation of IRB approval, typically in a box on the front page of the IRB application. If there is a consent form for the research, the Approval Packet also includes the formally-approved and stamped copy of the consent form. Researchers are required to copy this stamped version for use with the research subjects.

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.

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.

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.

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 – 327, in contrast with the current median of 15 days and range of 0-95 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.
- 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 received 2,034 new applications in 2008, and is responsible for continuing review and oversight of about 7,000 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 webpage) or send an email to hsdtrain@u.washington.edu with a 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 to still 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. The UW IRBs also have four subcommittees (Minimal Risk teams) that review Minimal Risk and Exemption applications. At least two HSD staff members typically work on each individual application, not including staff who do filing and data entry.