

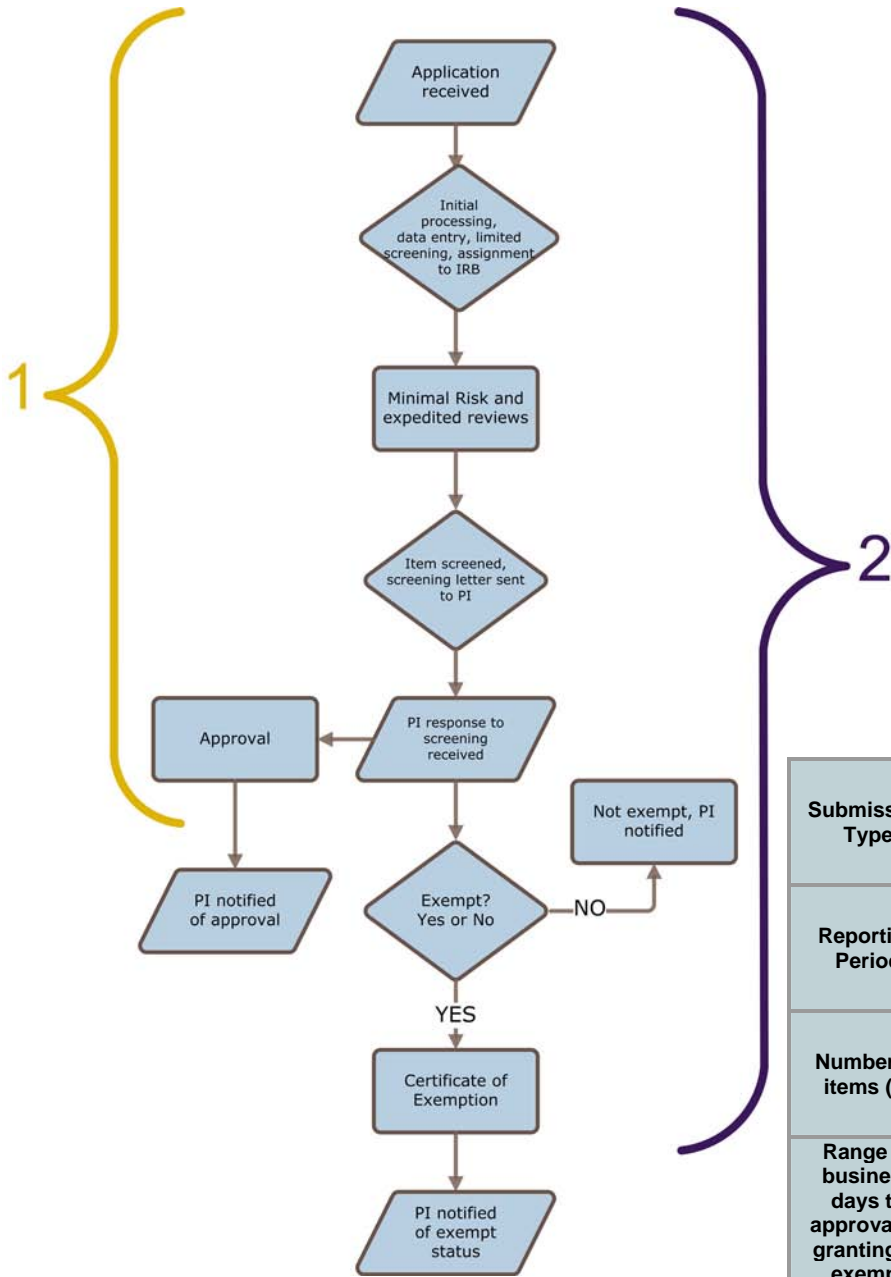








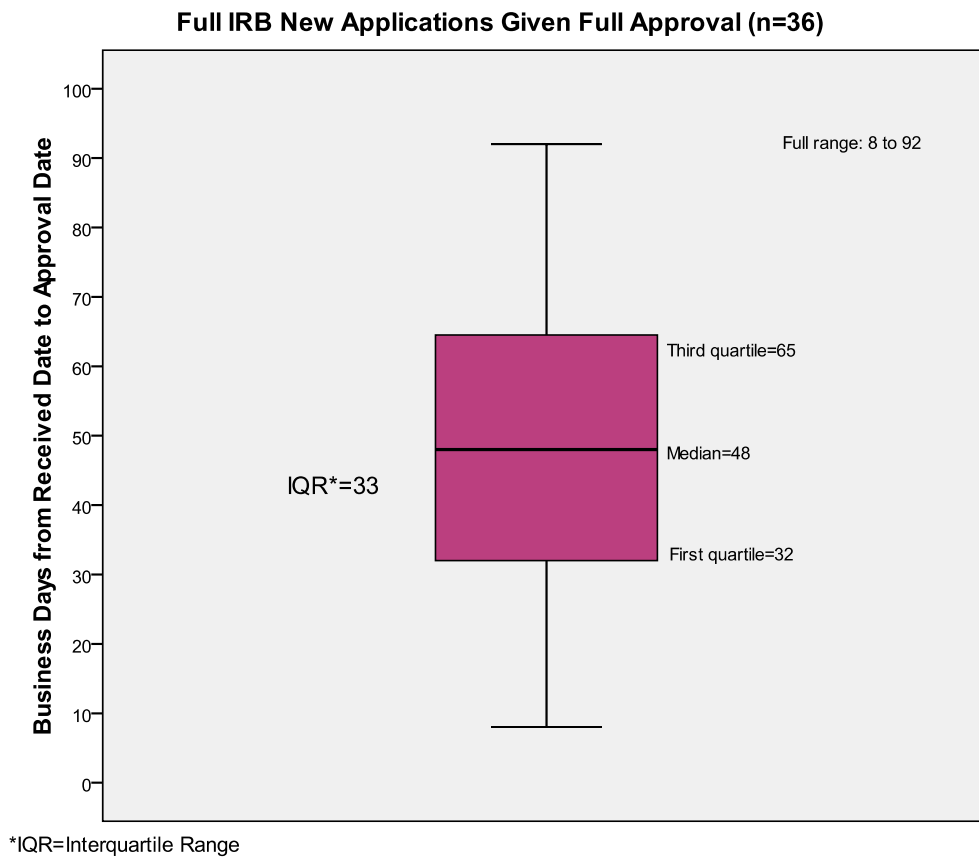
**TABLE 2. Initial Applications Reviewed as Minimal Risk or as Exempt**



	1	2
Submission Type	Applications for <b>Minimal Risk</b> Review	Applications for <b>Exempt</b> Status
Reporting Period	7/1/08 - 12/31/08	7/1/08 - 12/31/08
Number of items (n)	190	226
Range of business days to approval or granting of exempt status <sup>3</sup>	0 to 95	0 to 50
Median number of business days to approval	15	3

<sup>3</sup> 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**



## 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.

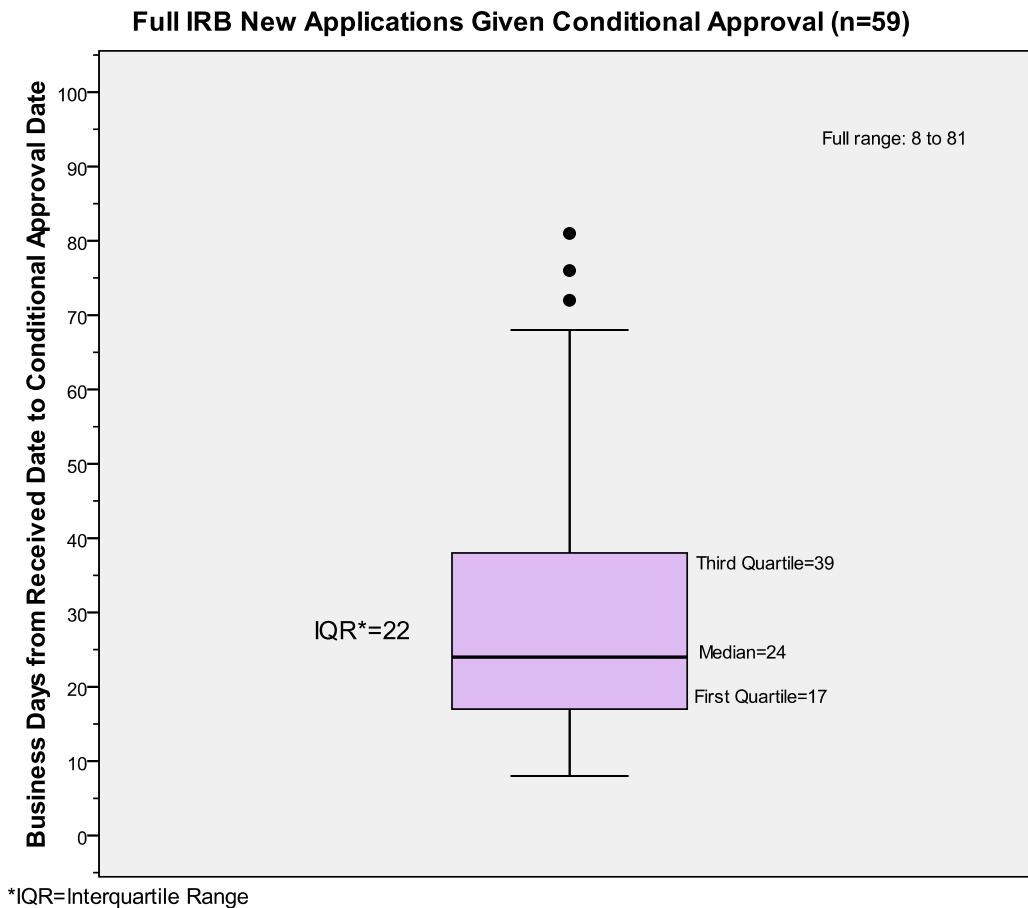
## ANALYSIS

- 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**



### DESCRIPTION

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.

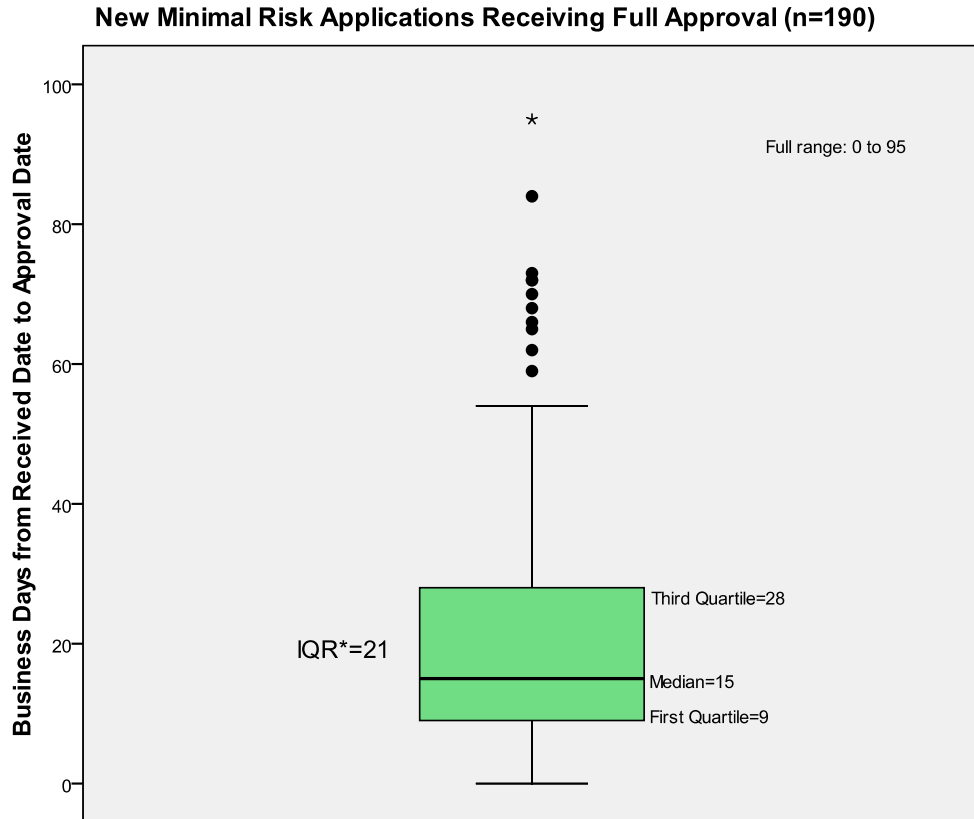
### ANALYSIS

- 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.

**FIGURE 3. Turn-around Time for Full Approval of New Minimal Risk Applications**



\*IQR=Interquartile Range

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

### 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.<sup>4</sup> 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.

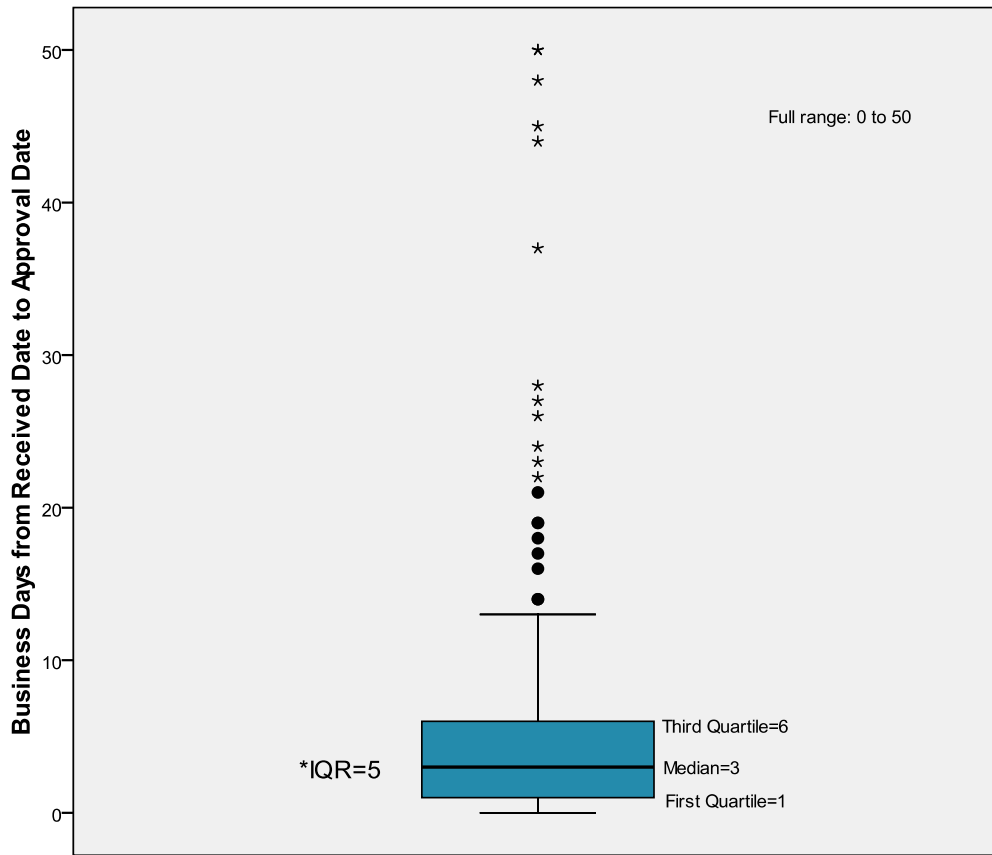
### NEXT STEPS

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.

<sup>4</sup> 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)**



\*IQR=Interquartile Range

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 <sup>5</sup> 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 – 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.

<sup>5</sup> 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**

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

**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.

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

**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.

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

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





## 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.