Report of **Key Performance Metrics** for the IRB Review Process

Report #8
Period: April 1, 2010 – September 30, 2010

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Compiled by the Human Subjects Division
Office of Research

UNIVERSITY of WASHINGTON

Image: Lamp in front of Suzzallo Library

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INTRODUCTION and WHAT'S NEW

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.

Reliable and detailed metrics are a fundamental tool for accomplishing HSD strategic goals and specific objectives. This regular report fulfills one of those objectives, which is to provide researchers with publicly-available and reliable "turn-around time" metrics, to assist them in planning their research activities. Also, metrics will improve the IRB process by identifying bottlenecks, inefficiencies, and unnecessary steps.

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 2010. With each quarterly posting, comparisons to metrics from previous reporting periods will be made, as well as comparisons to the baseline. Additionally, with most quarterly postings, new metrics will be added for specific parts of the IRB Review Process.

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 those data were in the old HSD database and/or were obtained during the new database migration and implementation period.

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

What's new in this Report?

This report collapses two previously separate sections, "Time Taken by Researchers to Respond to Review Letters" and "Average Number of Review Letters per Application" into one new section "Turn-around Time for Researchers to Respond to HSD and IRB Correspondence."

This revision was made because for the past four reporting periods, there has been little to no change in median response time for each of the correspondence types, making it less useful to graph this metric for each reporting period. In the new graph, one can see at a glance the median number of business days researchers took to respond across each of the primary correspondence types (e.g., screening request, deferral letter, conditional approval letter, Minimal Risk review letter) for the current reporting period.

There has also been little to no change across the past four reporting periods in the average number of review letters for each type of application. For this reason, the average number of review letters for each type of application for the past four reporting periods has been used to calculate an "overall" average, which is referred to in the "Description" portion of this new section.

Additional information

Definitions: page 15
Visual representation of the IRB review process: Appendix A

Questions?

See the "Questions and Answers" at the end of this document.
For other questions, send an email to dora1g@u.washington.edu, or call Candy Grossman, Project Manager at 206-685-0561.

TABLE 1. Overall Turn-Around Time for Initial IRB Applications

	Full IRB Review	Minimal Risk Review	Exempt Status
Reporting period*	4/1/10 – 9/30/10	4/1/10 – 9/30/10	4/1/10 – 9/30/10
Median business days to completion of approval process**	68	20	5
Range	9 to 420	0 to 248	0 to 119
Number of applications (n)	89	290	300
Baseline***	71	21	3

Reporting periods are 6-month windows, which "slide" by 3 months from one reporting period to the next.

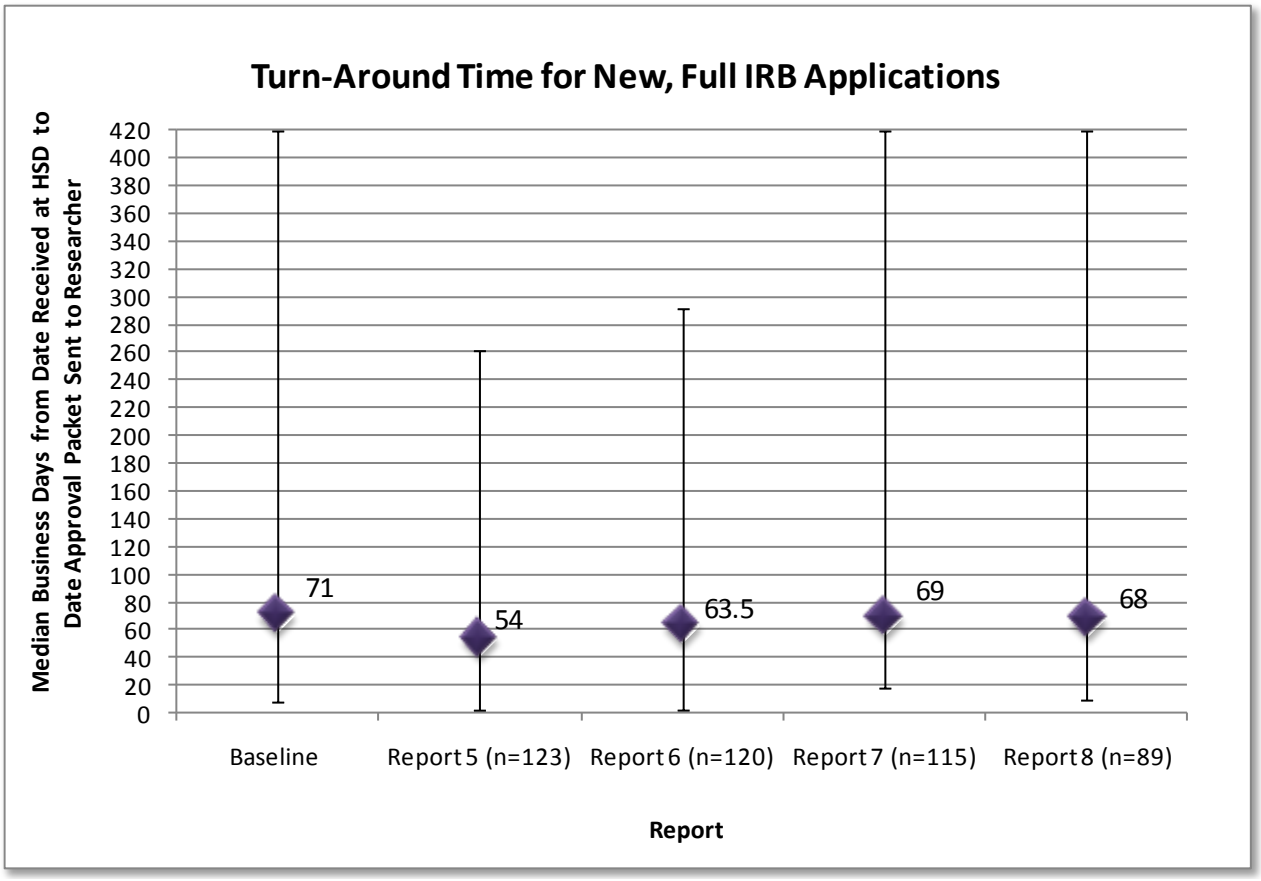
****HSD considers the approval process complete on the date when the approval packet is mailed to the researcher.***

*****For information on how the baseline was calculated, please see the "Questions & Answers" section at the end of this report.***

Note: Charts throughout this report contain data for the current reporting period as well as the past three reporting periods (listed below).

Reporting Period	Metrics Report
7/1/09 – 12/31/09	Report 5
10/1/09 – 3/31/10	Report 6
1/1/10 – 6/30/10	Report 7

FIGURE 1. Overall Turn-Around Time for Initial Applications Requiring Full IRB Review

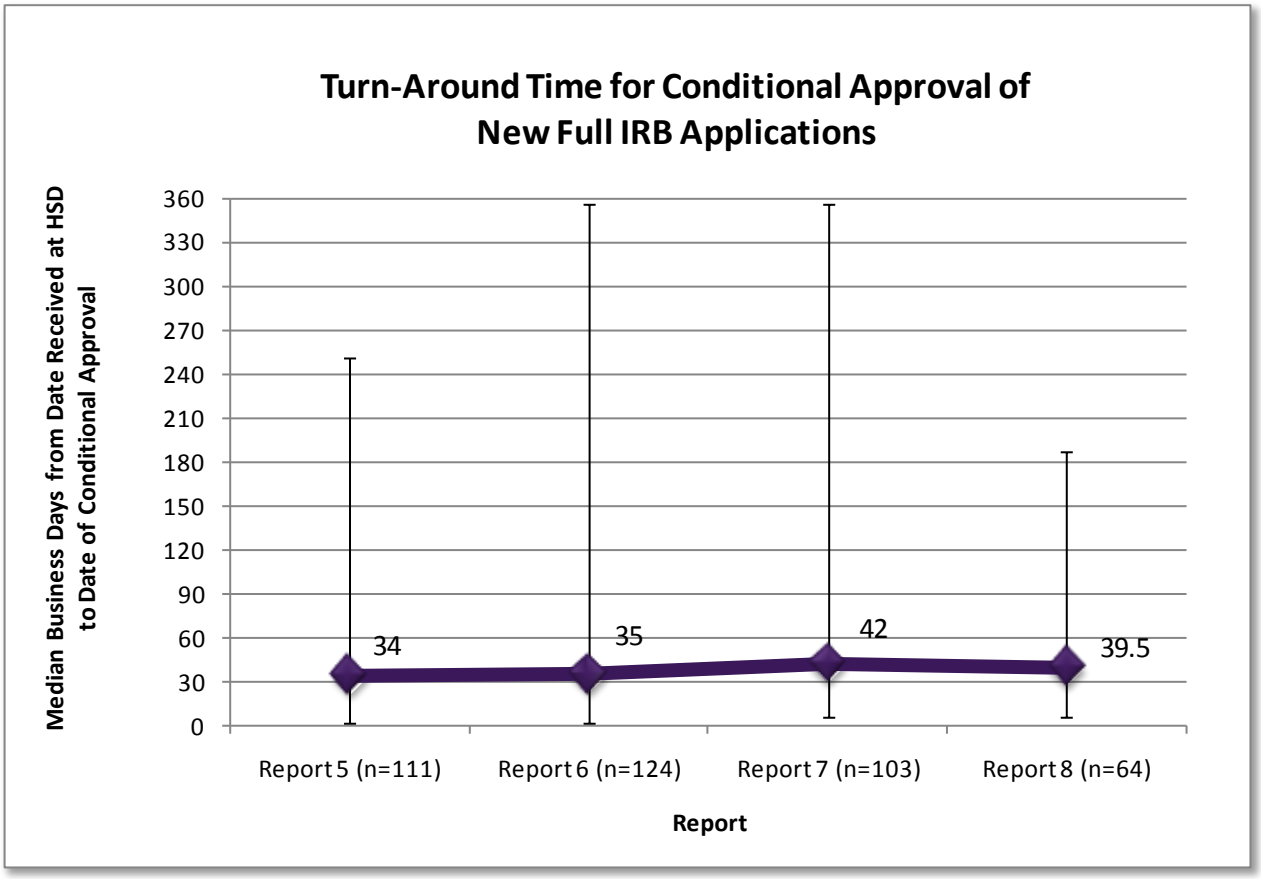


DESCRIPTION

This chart shows the average number of business days required to obtain Full Approval of new IRB applications undergoing Full IRB review, for the most recent four reporting periods as well as the baseline. The vertical bars show the range of the turn-around time.

For a visualization of the process, click on the above flowchart.

FIGURE 2. Time Required to Obtain Conditional Approval for Initial Applications Requiring Full IRB Review

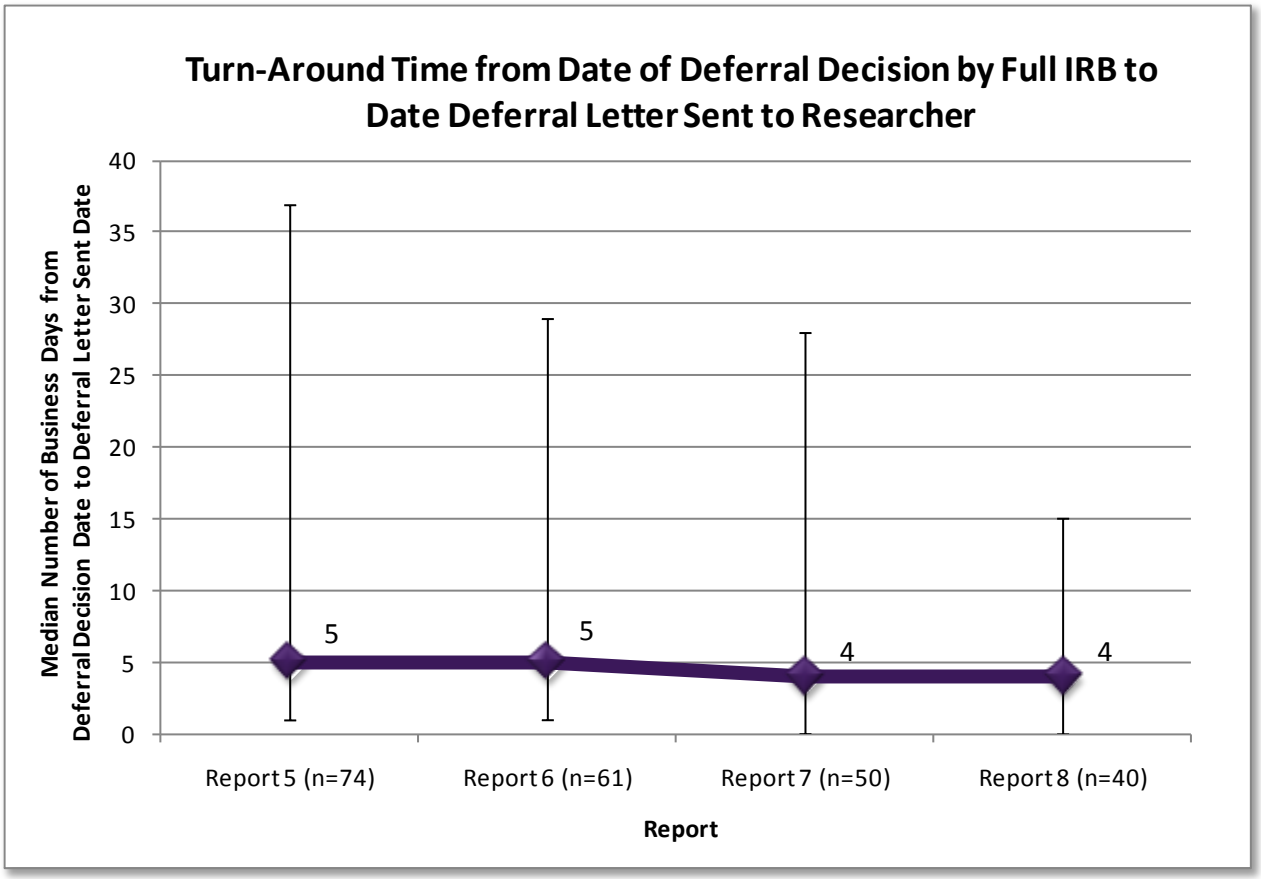


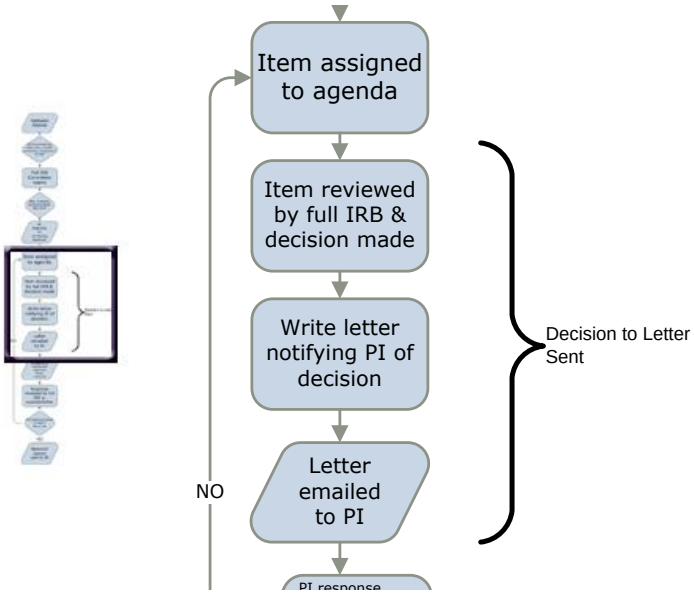
DESCRIPTION

This chart compares the average time required to obtain Conditional Approval for initial applications requiring Full IRB review for the most recent four reporting periods. The vertical bars show the range of the turn-around time. Conditional Approval is an important intermediate step toward Full Approval because it allows researchers to receive and start spending grant or contract funds.

For a visualization of the process, click on the above flowchart.

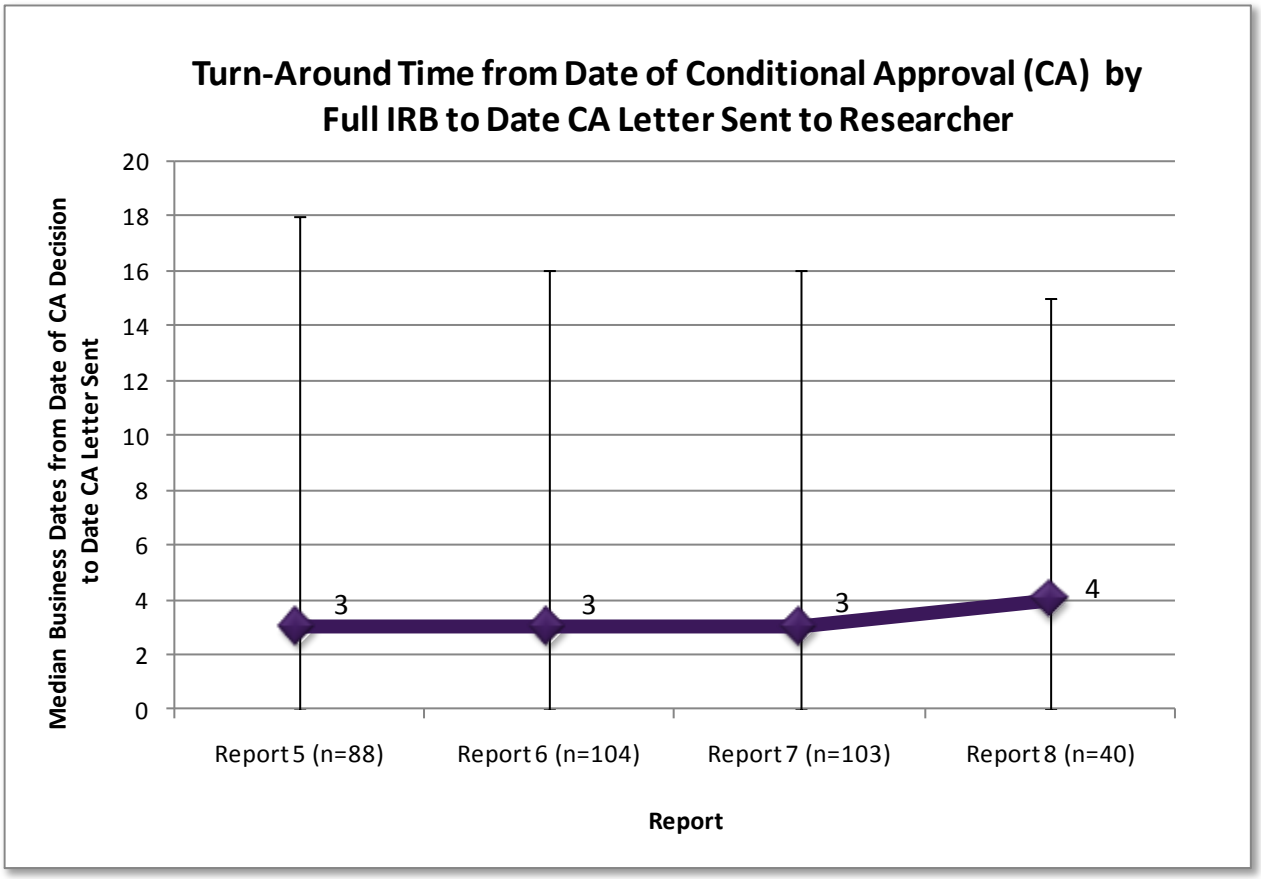
FIGURE 3. Time Required to Prepare IRB Review Letters to Researchers





Description and analysis continued on the next page.

FIGURE 4. Time Required to Prepare IRB Review Letters to Researchers (cont.)

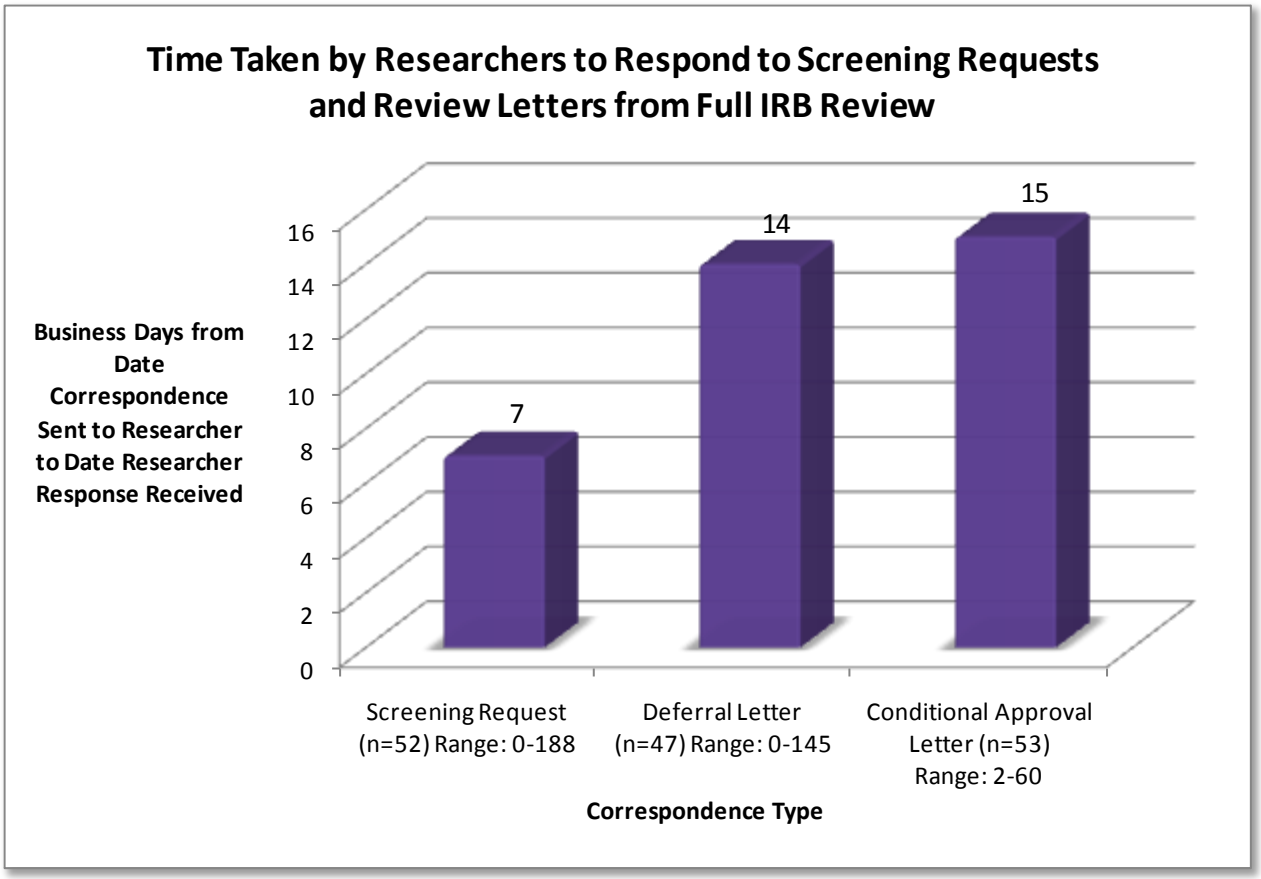


DESCRIPTION

These charts show, for the most recent four reporting periods, the average number of business days required to prepare and send two types of IRB review letters to researchers: deferral letters and 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. The vertical bars show the range of turn-around times.

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

FIGURE 5. Turn-around Time for Researchers to Respond to HSD and IRB Correspondence



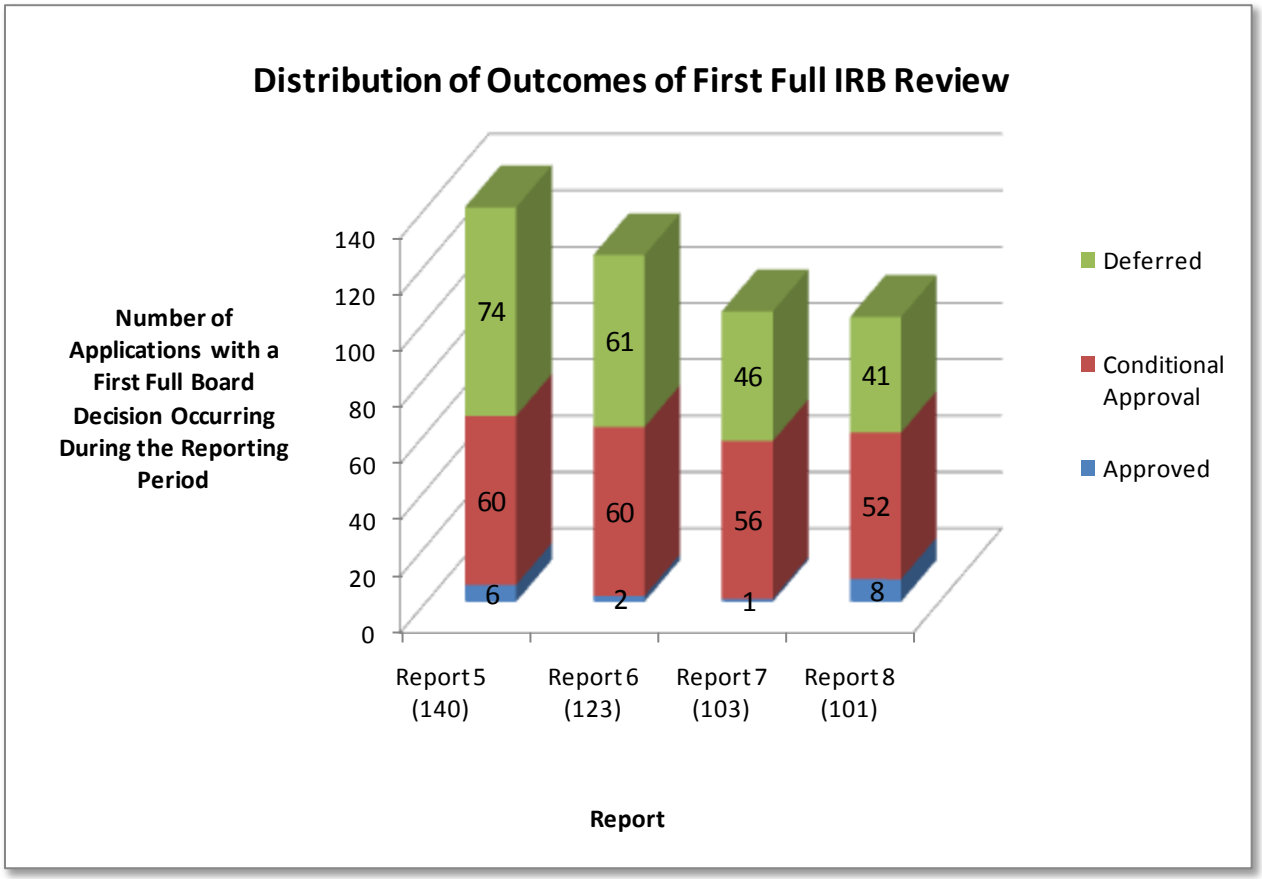
DESCRIPTION
This chart shows the median business days for researchers to respond to three types of formal correspondence from HSD staff and the IRB: screening requests, deferral letters and conditional approval letters. The range of response times and number of responses received during the reporting period are indicated across the bottom of the chart.

ANALYSIS
The information in this chart is helpful in understanding the factors that affect the overall turn-around time for an application, particularly when considered in conjunction with the volume of correspondence typical for most new applications. A new full IRB application requires on average 2.33 review letters, usually including a screening request followed by a deferral letter and/or conditional approval letter. A higher-than-average number of review letters typically is the result of one or more of the following:

- The research has some challenging ethical issues;
- The information provided in the application (or response letters) was not clear to the IRB;
- The information provided in the application (or response letters) was not complete, sufficiently detailed, or consistent throughout the application materials.

When the average number of review letters per application and the amount of time researchers take to respond to each letter are considered together, it can be observed that roughly 4.5 weeks (or about one third) of the overall turn-around time of 68 business days (13 weeks) is due to the time it takes researchers to respond to correspondence from HSD and the IRB. As indicated by ranges listed in the bar chart above, some responses take as long as 188 days (about 37 weeks) to reach the IRB, further increasing the turn-around time significantly for those specific applications. This information may provide some context for researchers when considering the typical progress of their own applications.

FIGURE 6. Distribution of Outcomes for the First Full IRB Review of Initial Applications

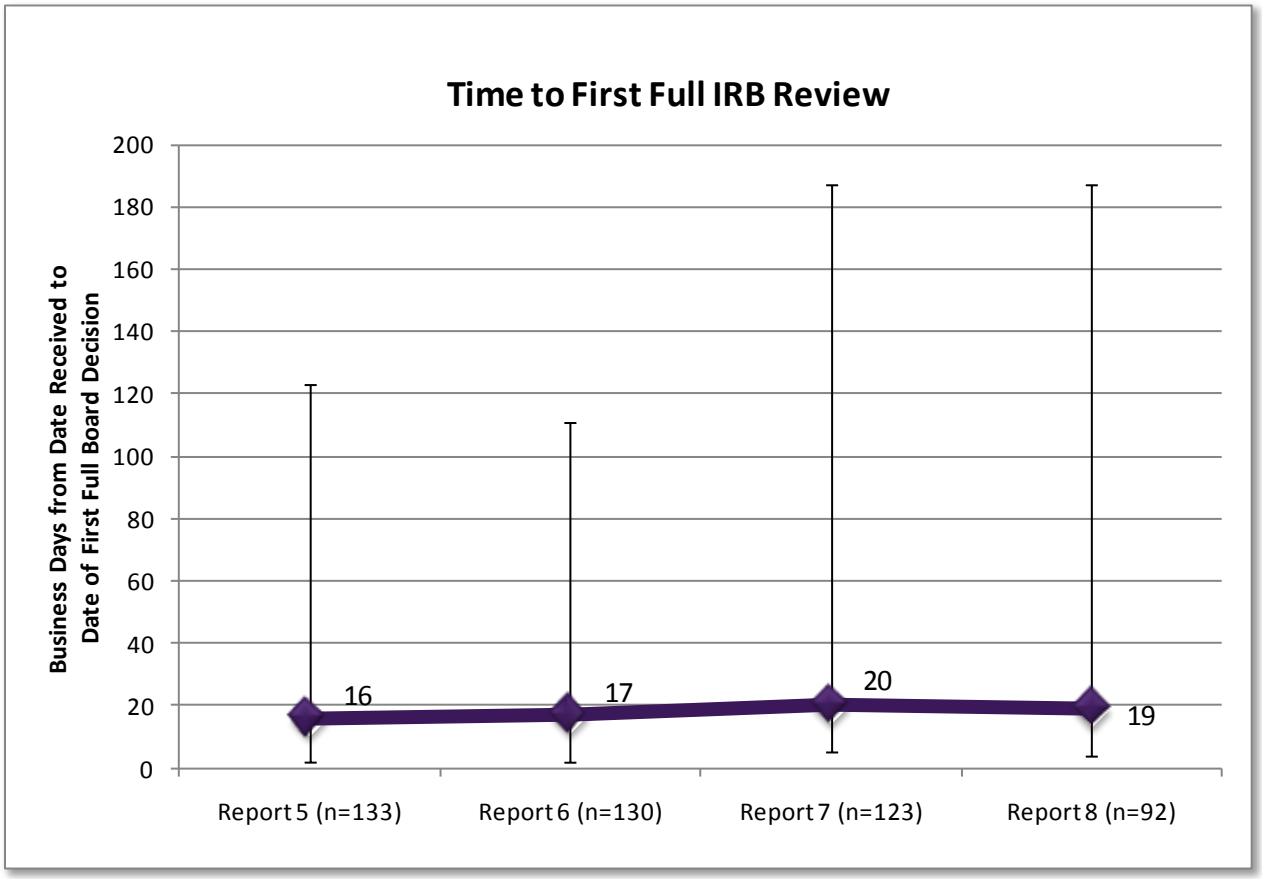


DESCRIPTION

The purpose of this chart is to show the distribution of outcomes from the first Full IRB review for initial applications, for the most recent four reporting periods. As shown, a small number of applications (ranging from less than 1% to 8%) 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 (ranging from 41% to 53% in these reporting periods) 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 (ranging from 43% to 55%) undergo an expedited review process (no Full IRB meeting) after the researcher's response to the review letter is received.

HSD has analyzed the reasons for Deferral outcomes. One major factor is the IRB's need for a wide array of information that is not provided by the current IRB application form. This analysis resulted in a current HSD process improvement initiative: major revision of the standard IRB application form. When implemented, this should significantly increase the frequency of Conditional or Full Approval decisions and/or reduce the amount of "back and forth" correspondence.

FIGURE 7. Time from Application Receipt to First Full IRB Review ("Agenda Date")



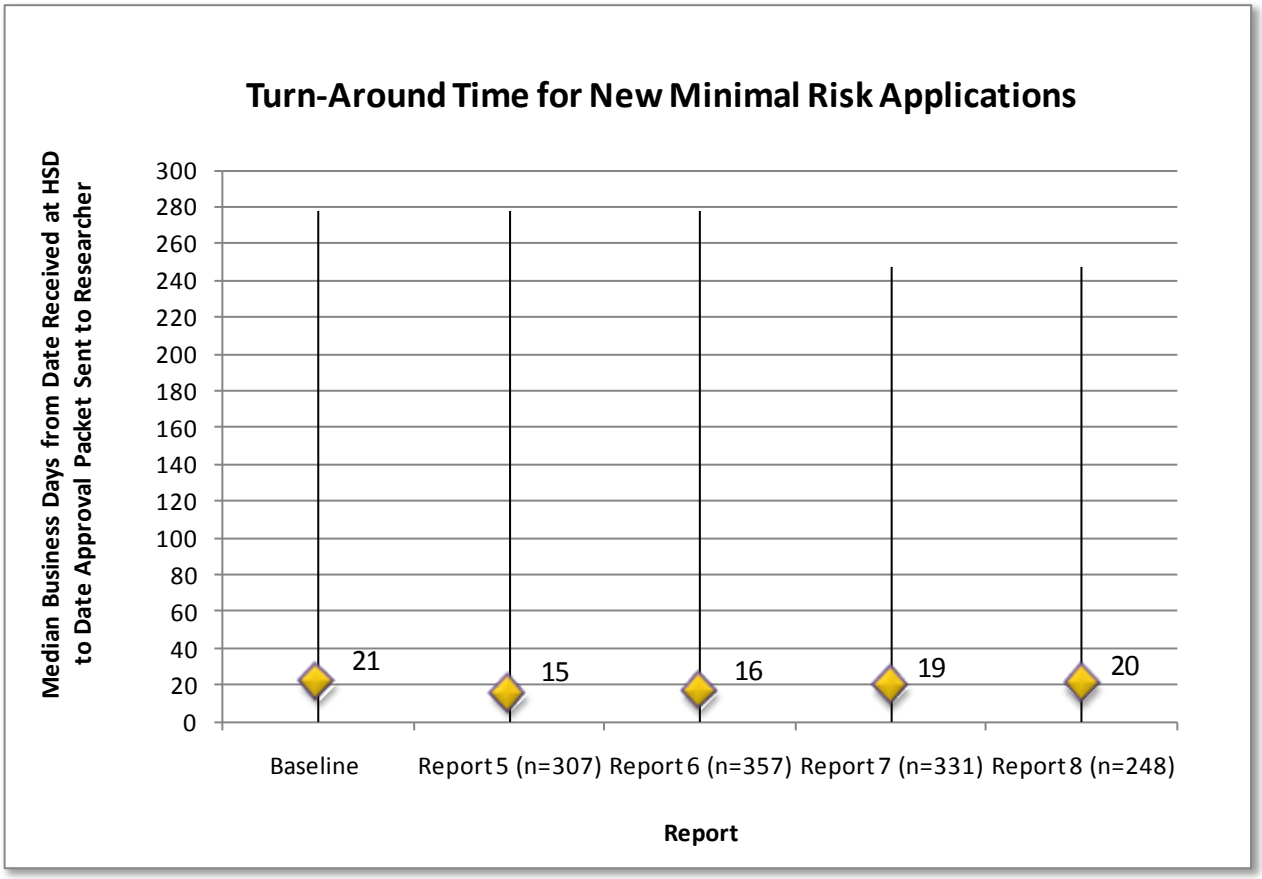
DESCRIPTION

This figure shows that an average of 19 business days elapsed between the time when an IRB application requiring full IRB review was received by HSD and the date when it was reviewed by the full 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 5 days (per regulations) before the meeting to read and review the materials.

FIGURE 8. Overall Turn-Around Time for Initial Applications Receiving Minimal Risk Review

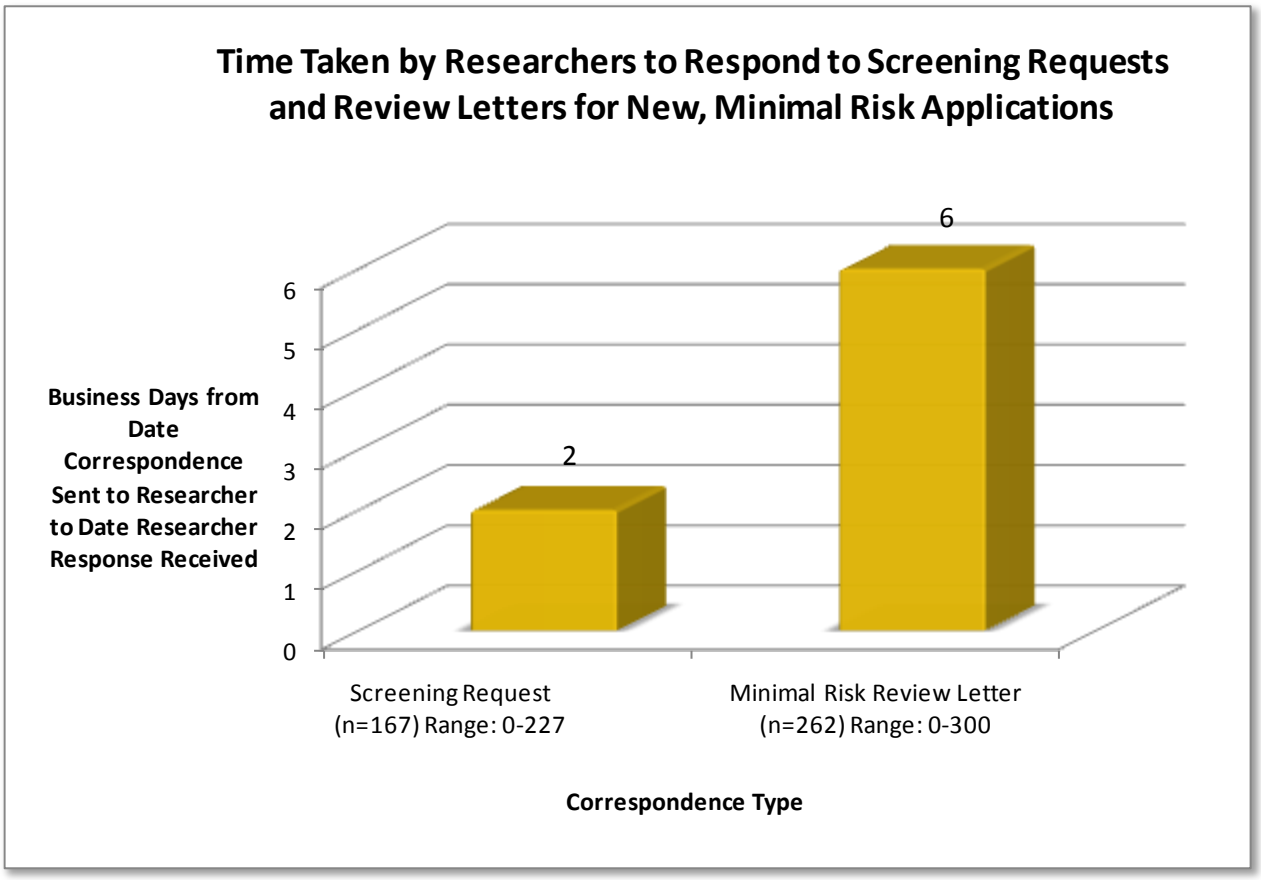


DESCRIPTION

This chart shows the average number of business days required to obtain Full Approval of new IRB applications undergoing Minimal Risk review for the most recent four reporting periods as well as the baseline. The vertical bars show the range of turn-around times.

For a visualization of the process, click on the above flowchart.

FIGURE 9. Turn-Around Time for Researchers to Respond to Review Letters from Minimal Risk IRB Review



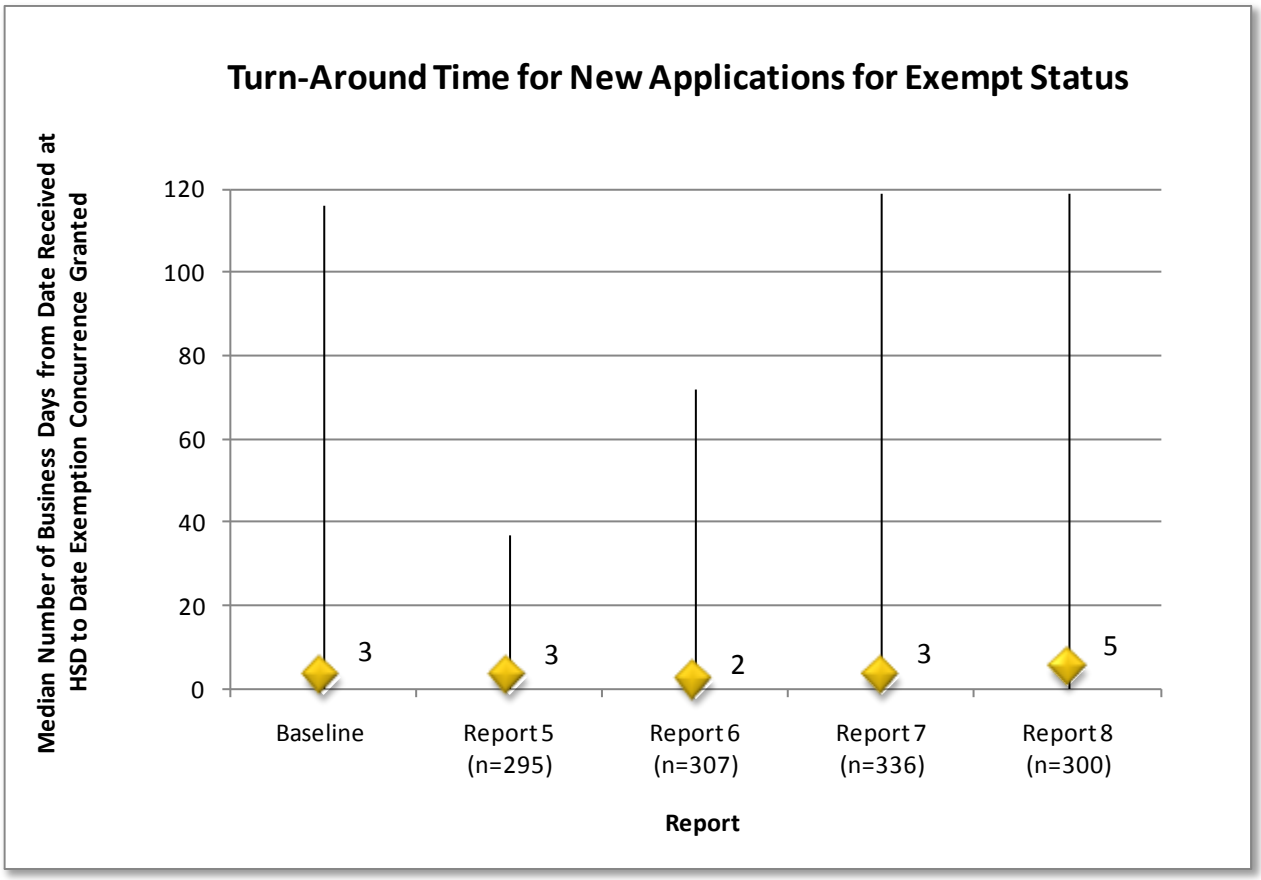
DESCRIPTION
This chart shows the median business days for researchers to respond to two types of formal correspondence from HSD staff and the IRB: screening requests and Minimal Risk review letters. The range of response times and number of responses received during the reporting period are indicated across the bottom of the chart.

ANALYSIS
The information in this chart is helpful in understanding the factors that affect the overall turn-around time for an application, particularly when considered in conjunction with the volume of correspondence typical for most new applications. A new Minimal Risk application requires on average 1.3 review letters. A higher-than-average number of review letters typically is the result of one or more of the following:

- The research has some challenging ethical issues;
- The information provided in the application (or response letters) was not clear to the IRB;
- The information provided in the application (or response letters) was not complete, sufficiently detailed, or consistent throughout the application materials.

When the average number of review letters per application and the amount of time researchers take to respond to each letter are considered together, it can be observed that roughly 1.5 weeks (or a little over a quarter) of the overall turn-around time of 20 business days (4 weeks) is due to the time it takes researchers to respond to correspondence. As indicated by ranges listed in the bar chart above, some responses take as long as 300 days (about 60 weeks) to reach the IRB, further increasing the turn-around time significantly for those specific applications. This information may provide some context for researchers when considering the typical progress of their own applications.

FIGURE 10. Overall Turn-Around Time for Review of Exemption Applications

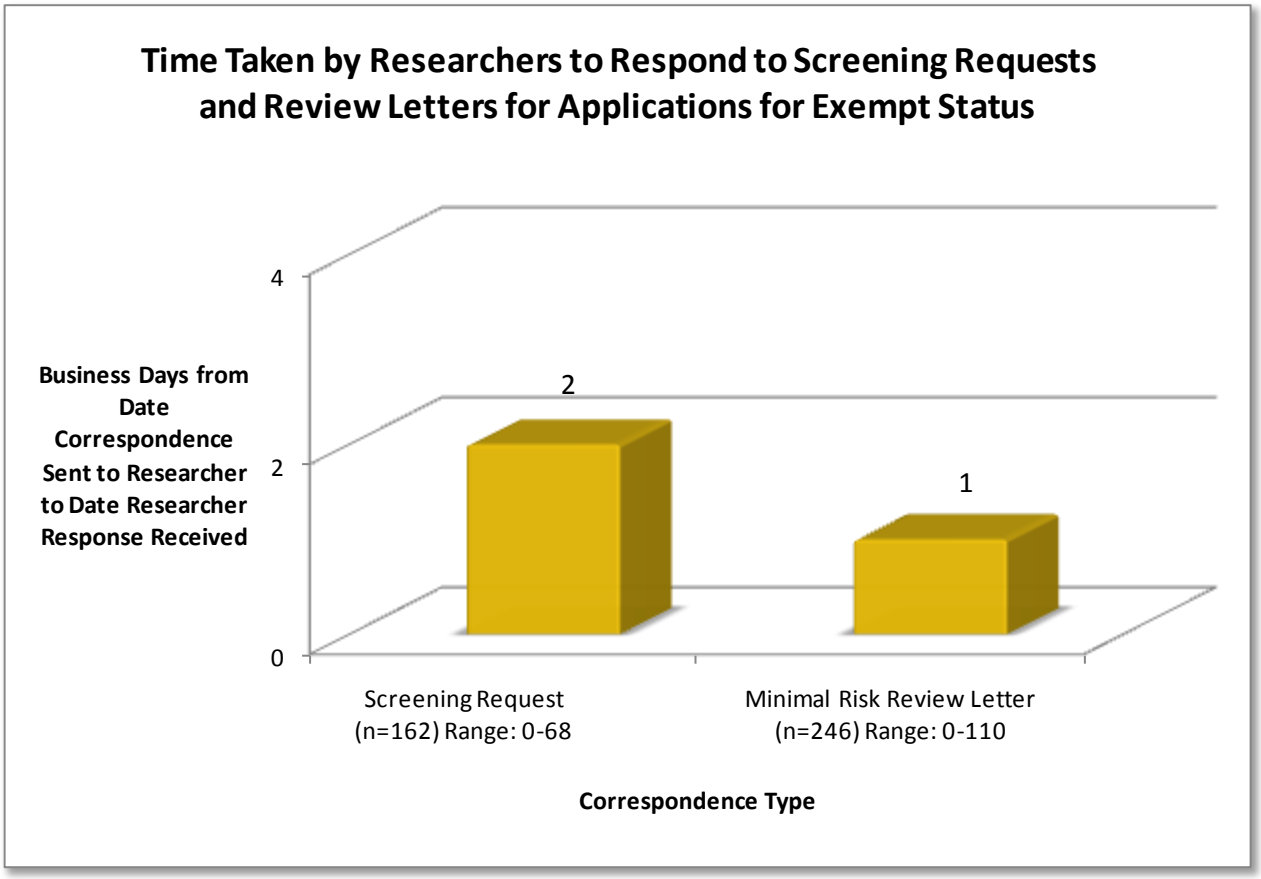


DESCRIPTION

This chart shows the average number of business days required to obtain a Certificate of Exemption, for the most recent four reporting periods as well as the baseline. The vertical bars show the range of turn-around times.

For a visualization of the process, click on the above flowchart.

FIGURE 11. Turn-Around Time for Researchers to Respond to Review Letters from Exempt Review



DESCRIPTION
This chart shows the median business days for researchers to respond to two types of formal correspondence from HSD staff and the IRB: screening requests and Minimal Risk review letters. The range of response times and number of responses received during the reporting period are indicated across the bottom of the chart.

ANALYSIS
The information in this chart is helpful in understanding the factors that affect the overall turn-around time for an application, particularly when considered in conjunction with the volume of correspondence typical for most new applications. An application for exempt status requires on average .9 review letters. A higher-than-average number of review letters typically is the result of one or more of the following:

- The research has some challenging ethical issues;
- The information provided in the application (or response letters) was not clear to the IRB;
- The information provided in the application (or response letters) was not complete, sufficiently detailed, or consistent throughout the application materials.

When the average number of review letters per application and the amount of time researchers take to respond to each letter are considered together, it can be observed that roughly 1-2 days of the overall turn-around time of 5 business days is due to the time it takes researchers to respond to correspondence. As indicated by ranges listed in the bar chart above, some responses take as long as 110 days (about 22 weeks) to reach the IRB, further increasing the turn-around time significantly for those specific applications. This information may provide some context for researchers when considering the typical progress of their own applications.

DEFINITIONS

Agenda Date
The date when an application requiring full IRB review is first reviewed by a full IRB. 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 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 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.

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 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.

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 risk and that meet certain federally-defined criteria.

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.

QUESTIONS AND ANSWERS

1) Why does it take so long to receive IRB approval?
2) Your Metrics Report says the median number of days to conditionally approve a Full IRB new application is 39.5. Why is my application taking longer?
3) Is there anything I can do to speed my application through the approval process?
4) Will these turn-around times improve in the future?
5) Is one IRB faster than another, and how do I get my application placed with that committee?
6) How many HSD staff work on a single application? Or, how many IRBs are there?
7) How was the baseline calculated?

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 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 39.5. Why is my application taking longer?

"Median" means that half of the applications will take less than 39.5 days to obtain Conditional Approval and half of the applications will take more than 39.5 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) 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?

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 still expect our baseline numbers 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 seven 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.

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 weekdays 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.

APPENDIX A – IRB PROCESS FLOW CHARTS

Turn-Around Time for Initial Applications Requiring Full IRB Review

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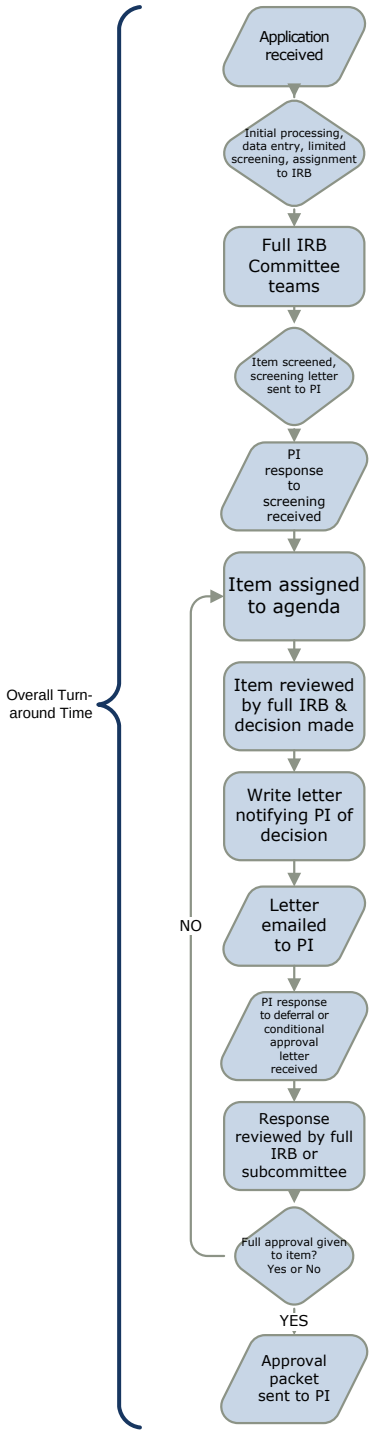

Time Required to Obtain Conditional Approval for Initial Applications Requiring Full IRB Review

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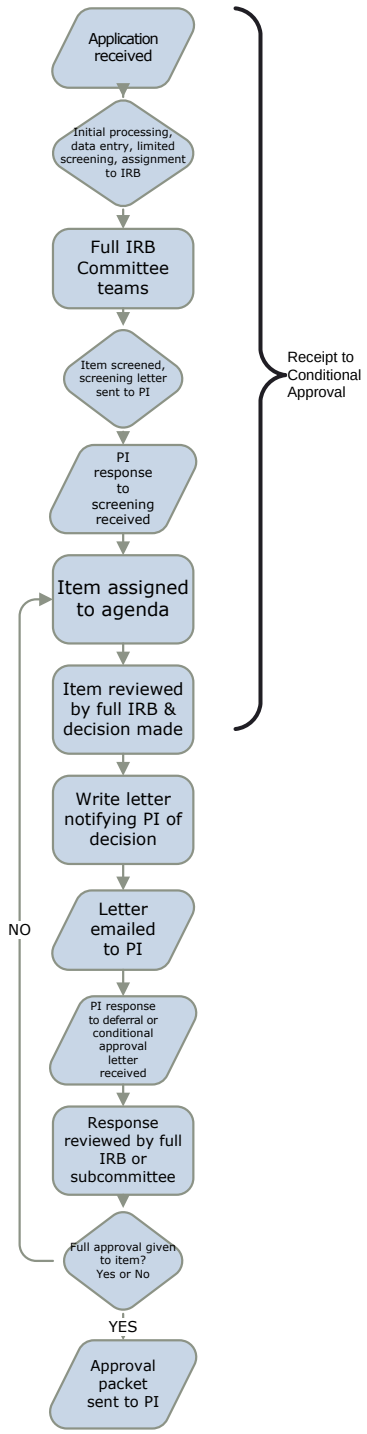

Overall Turn-Around Time for Initial Applications Receiving Minimal Risk Review

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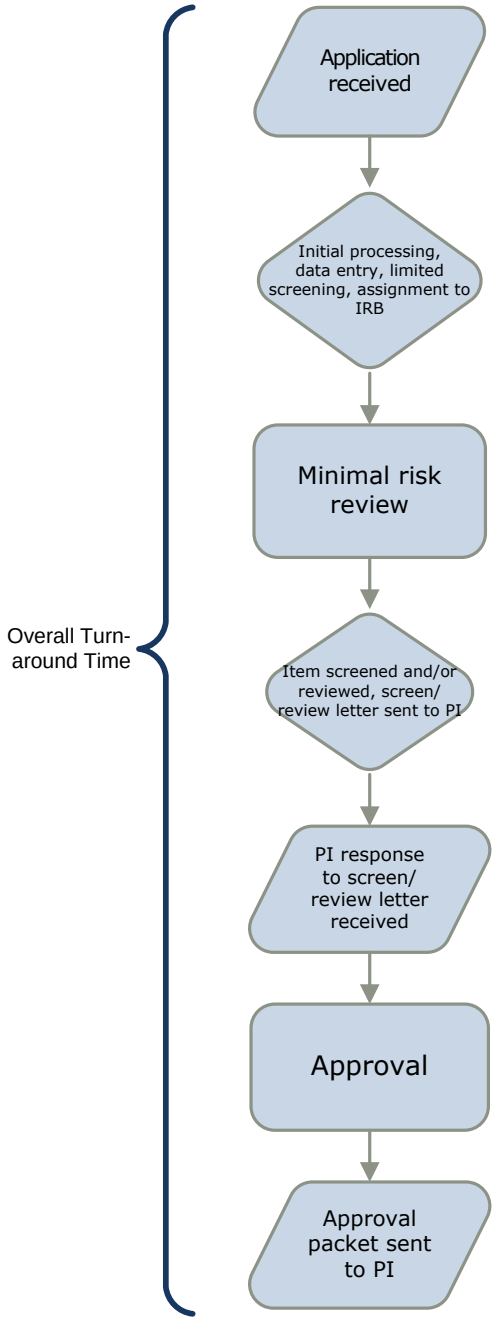
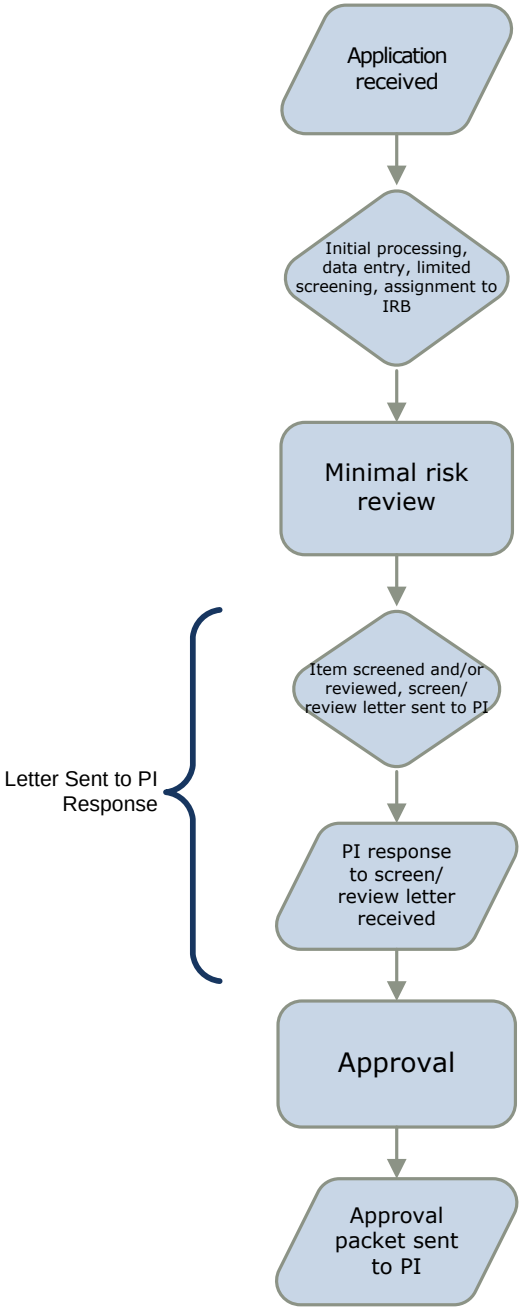


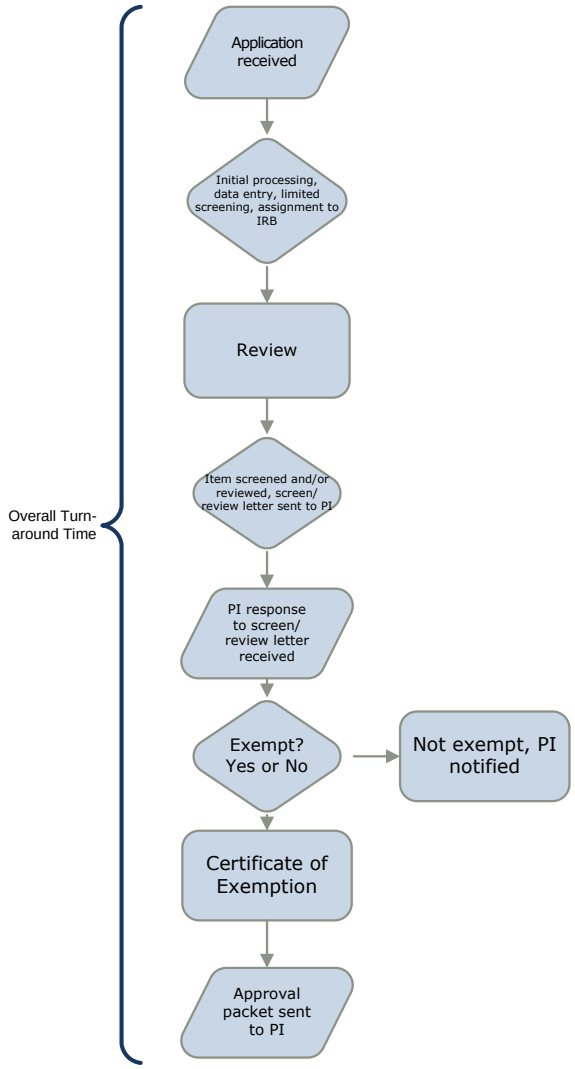
Time Taken by Researchers to Respond to Minimal Risk IRB Review

Back to Report



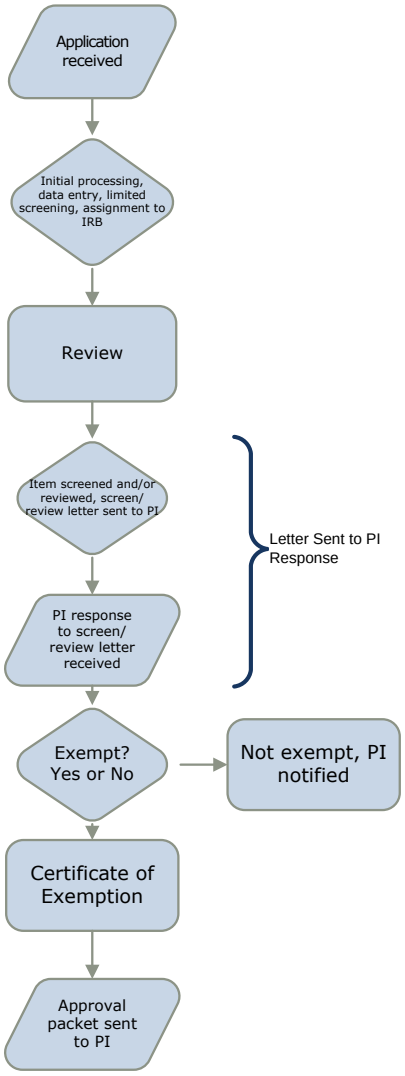
Overall Turn-Around Time for Review of Exemption Applications

Back to Report

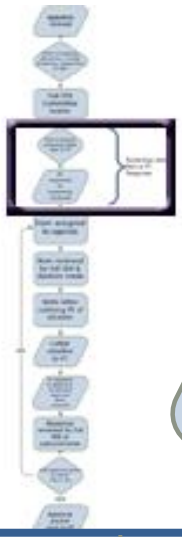


Time Taken by Researchers to Respond to Exempt Review

Back to Report



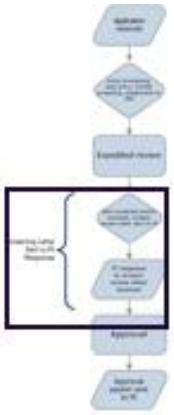
Time Taken by Researchers to Respond to Screening Requests – New, Full Applications



Item screened, screening letter sent to PI

PI response to screening received

Screening Letter Sent to PI Response



Screening Letter Sent to PI Response

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

PI response to screen/ review letter received

Time Taken by Researchers to Respond to Screening Requests – New, Minimal Risk Applications

Time Taken by Researchers to Respond to Screening Requests – New Applications for Exempt Status

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

PI response to screen/ review letter received

Screening Letter Sent to PI Response