IRB Review Process

The University of Missouri—Kansas City Institutional Review Board (IRB) fulfills its goal to review protocols and new information to determine whether regulatory criteria for approval are met (45 CFR 46.111), take action on protocols and act to protect subjects.

All projects that meet the federal definition of research with human subjects (45 CFR 46.102) must be reviewed and approved or receive a determination of exemption prior to initiation of the research. **The IRB staff initially screens submissions to determine the completeness and appropriate type of review.** Submissions may be returned to the study team for changes before being submitted for review or receiving a determination of exemption.

Types of Review

There are three (3) application paths for Human Subjects Research: Full Board, Expedited, and Exempt. The path is determined by:

- Level of risk to subjects associated with the project
- The type of research being conducted
- The sensitivity of the research questions or complexity of the research design
- The involvement of vulnerable populations as research subjects

Full Board Review

Federal regulations and institutional policy require IRB Full Board Review for applications where the research involves more than minimal risk to human subjects or has been referred to the committee by an expedited reviewer or the Chair.

The IRB at UMKC is composed of 13 primary and 8 alternate members of UMKC Faculty and Staff, Truman Medical Centers employees, and community members. The following are areas represented by UMKC, Dentistry, Education, Information Services, Medicine, Nursing, Pharmacy, Psychology, Student Affairs and University Libraries.

Full Board Review Process

Applications requiring full board review are reviewed by the full board at one of the two monthly convened meetings. IRB staff assign submissions to a primary and secondary IRB reviewer for presentation at the full board meeting. Investigators may be invited to attend the meeting to answer questions from the board. At the conclusion of the meeting, the board votes and issues a motion.

Expedited Review

Federal regulations (45 CFR 46.110) authorize the use of an expedited review process for:

- Minimal risk human subjects research that meets one or more of the OHRP Expedited Review Categories
- Minor changes to research previously approved by the full board

Expedited Review Process

Applications qualifying for expedited review are accepted and reviewed on a continuing basis by 2 or more IRB members. Expediting reviewers are experienced IRB members appointed to the role by the IRB Chair. The expedited reviewer has the authority to approve, require modifications for approval or refer a submission for full board review. Only the full board has the authority to disapprove a study.

Exempt Research Review

Per university policy, investigators must submit an exempt application for a determination by the IRB Administrative Office. Projects that meet the criteria for a federal exempt category (45 CFR 46.101 b) may be granted a determination of exemption. Most research receiving an exempt determination poses no more than minimal risk to the subjects.

Research involving prisoners or certain types of research with children (e.g. surveys, interviews/observations of public behavior where the investigator interacts with the children) does not qualify for exemption.

IRB Exempt Review Process

The IRB Administrative Office determination of exempt applications are limited in scope to the information necessary to determine if the proposed exemption applies. Projects receiving an exempt determination are not subject to the Continuing Review process. Amendments are required only if the changes to the project would alter the exemption criteria. An exempt determination does not lessen the researcher's ethical obligations to subjects as articulated in the Belmont Report or to the codes of conduct for specific disciplines.

Not Human Subjects Research

To determine whether or not IRB review is required, the first step is to determine whether or not the study is Human Subjects Research. Some projects that may require careful consideration for this type of determination include: oral histories, case studies, quality improvement studies, etc. Please see below for the regulatory definitions of research and of human subjects.

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

Human subject: a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through *intervention* or *interaction* with the individual, OR

(2) *Identifiable private information*

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject.

Identifiable private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

How to interpret the following turn-around time data

Establishing expectations for turn-around times is challenging as each review/determination depends on a variety of factors such as:

- How well the application was prepared
    - Incomplete or inconsistent answers
    - Missing materials
- Complexity of the study
- PI/Coordinator response time
- Number of IRB/IRB Office comment cycles
    - This is tied to the preparation of the application above. The number of clarifications, requests, and questions determine the number of cycles

The tables demonstrate the mean number of days for each application type with a break down to number of days with the PI and number of days with the IRB/IRB office.

The line charts show each application type submission and the number of days from submission to approval. This information is reflected in the table, however, outliers are shown giving a better representation of the number of studies under the mean.

Review Cycles – Once a protocol is received and sent back to the researcher for clarification, requests for additional information and/or questions that counts as 1 cycle.

> ***Each cycle, once it has been returned to the IRB/IRB office, can add an additional week to the review/determination turn-around.***

The following expected turn-around times are based on well-developed applications with a minimal number of review cycles (1-2 cycles) prior to determination/approval:

- **Not Human Subjects Research Determination**
    - 7 days
- **Exempt**
    - 14 days
- **Expedited Review**
    - 30 to 45 days
- **Full Board Review**
    - 60 to 90 days

Turn-Around Time Report

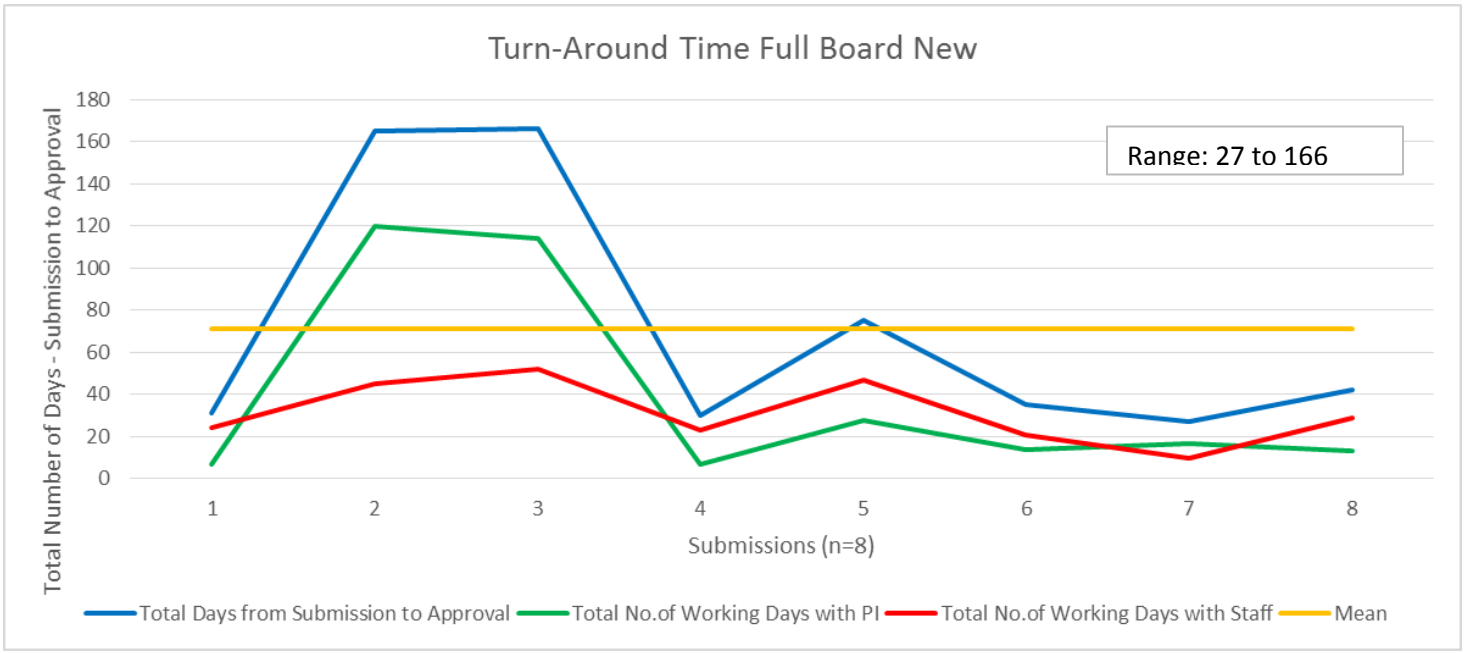
Full Board Review

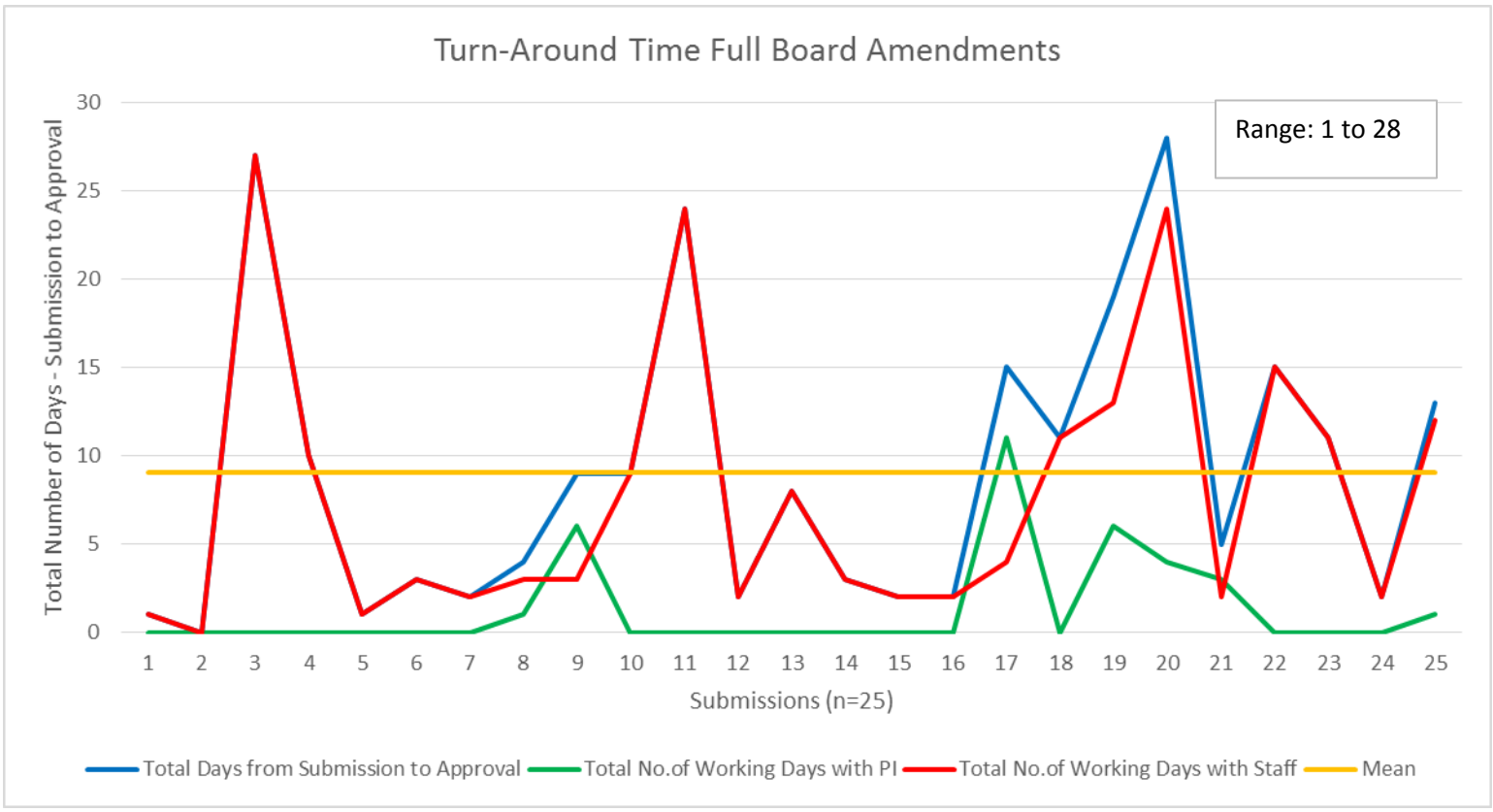
Full Board	Total Number of Actions		Mean Number of Days from Submission to Approval		Mean Number of Working Days with PI		Mean Number of Working Days with IRB/IRB Office	
	2015	**2016**	2015	**2016**	2015	**2016**	2015	**2016**
	125	**61**						
New Submissions	9	**8**	75	**71**	36	**40**	39	**31**
Amendments	36	**25**	12	**9**	6	**1**	6	**8**
Continuing Reviews	21	**11**	37	**43**	8	**0**	29	**43**
Protocol Violations	3	**2**						
Serious Adverse Events	56	**15**						

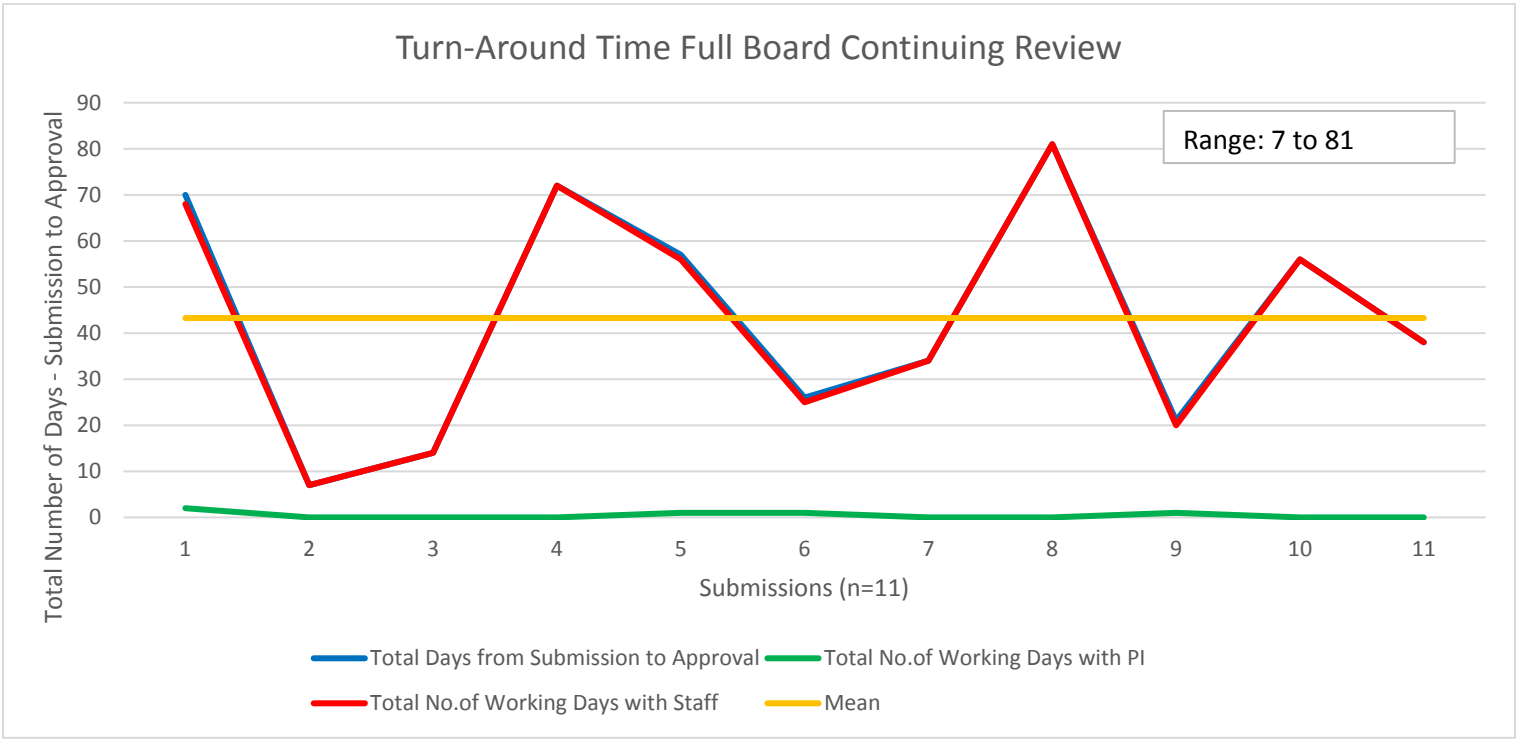
Analysis:

In 2016,

- The mean for Full Board new submissions was 71 days with 63% being approved within 60 days.
- The mean for Full Board amendments was 9 days with 84% being approved within 15 days.
- The mean for Full Board continuing reviews was 43 days with 73% being approved within 60 days.




Turn-Around Time Full Board Amendments
Range: 1 to 28
Total Number of Days - Submission to Approval
0
5
10
15
20
25
30
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Submissions (n=25)
Total Days from Submission to Approval
Total No.of Working Days with PI
Total No.of Working Days with Staff
Mean


Turn-Around Time Full Board Continuing Review
Range: 7 to 81
Total Number of Days - Submission to Approval
0
10
20
30
40
50
60
70
80
90
1 2 3 4 5 6 7 8 9 10 11
Submissions (n=11)
Total Days from Submission to Approval
Total No.of Working Days with PI
Total No.of Working Days with Staff
Mean

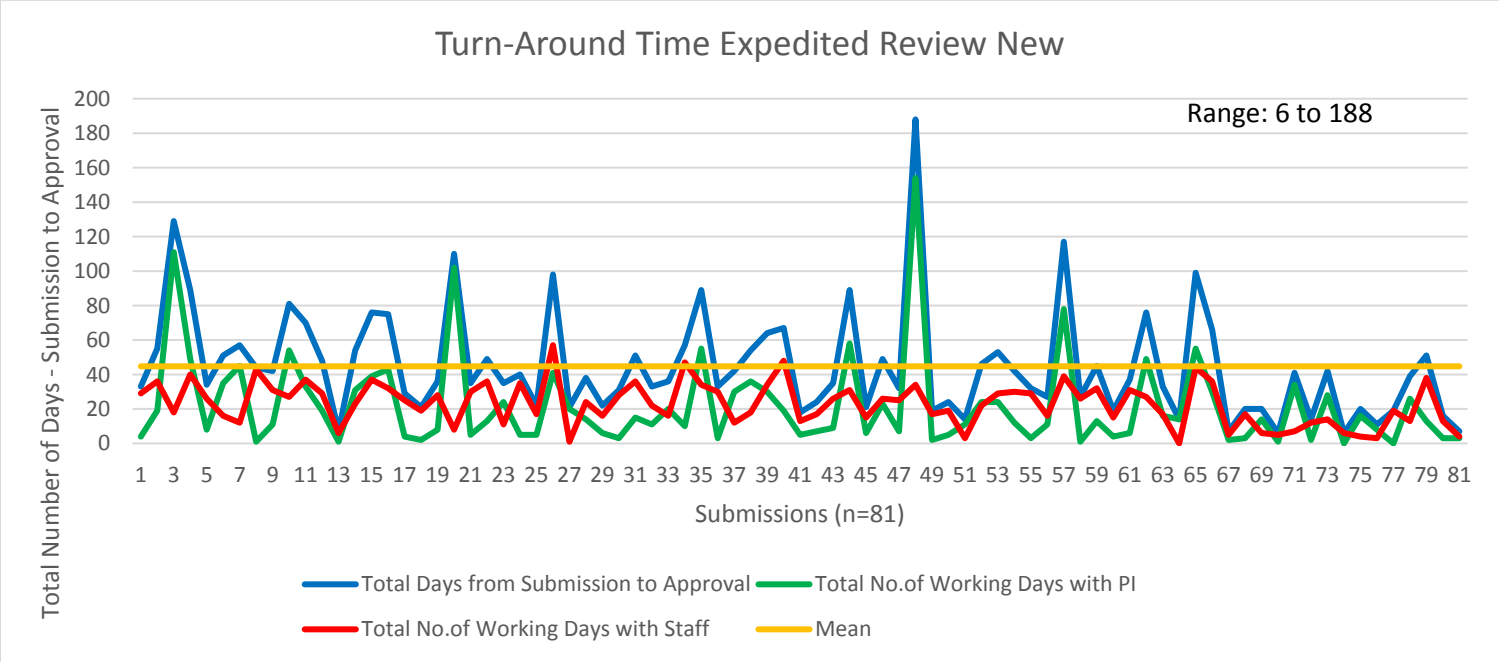
Expedited Review

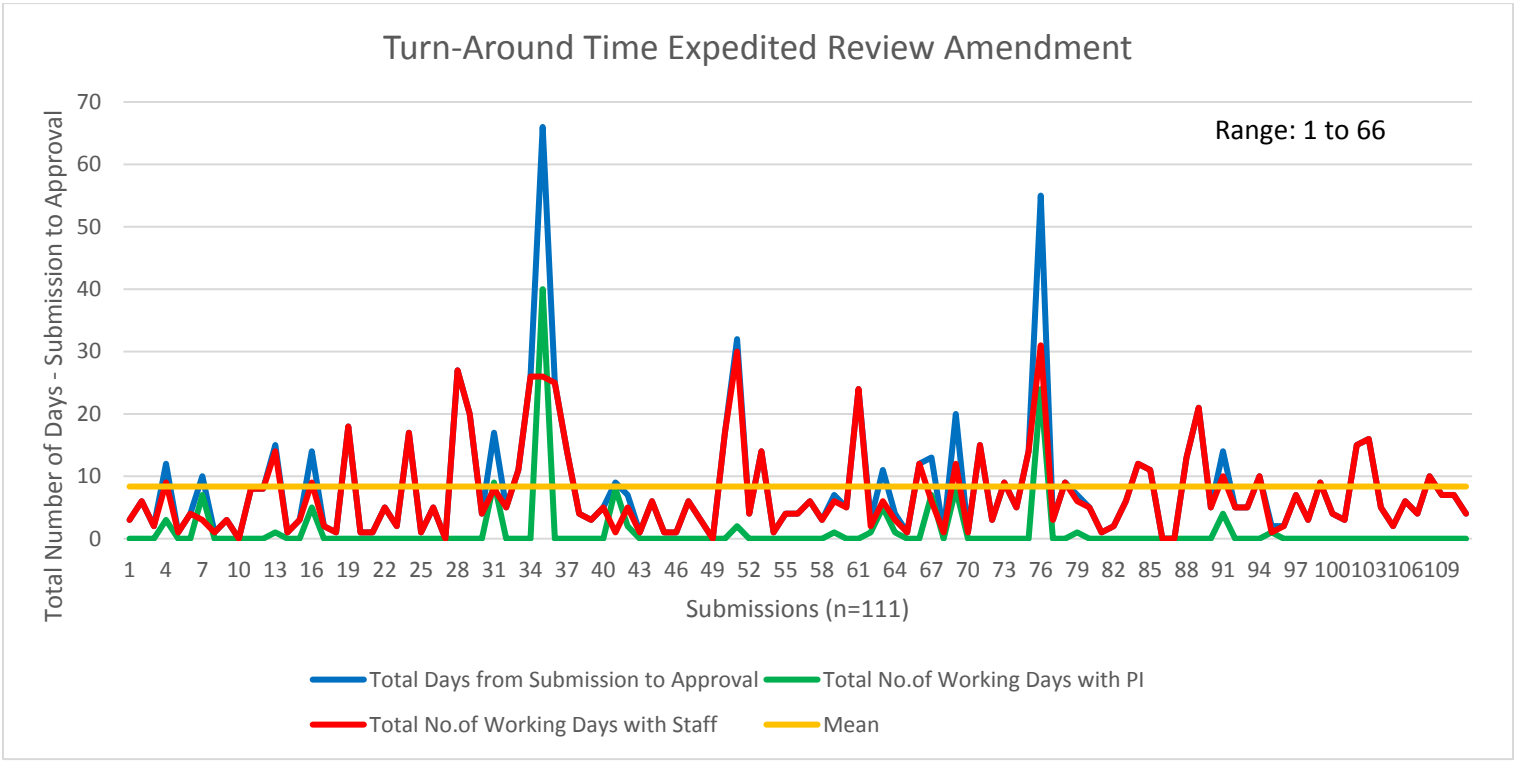
Expedited Review	Total Number of Actions		Mean Number of Days from Submission to Approval		Mean Number of Working Days with PI		Mean Number of Working Days with IRB/IRB Office	
	2015	2016	2015	2016	2015	2016	2015	2016
	272	330						
New Submissions	73	92	65	40	35	19	30	20
Amendments	113	111	10	8	2	1	8	7
Continuing Reviews	79	74	30	28	11	4	19	23
Protocol Violations	6	3		37		0		37
Serious Adverse Events	1	50		12		1		11

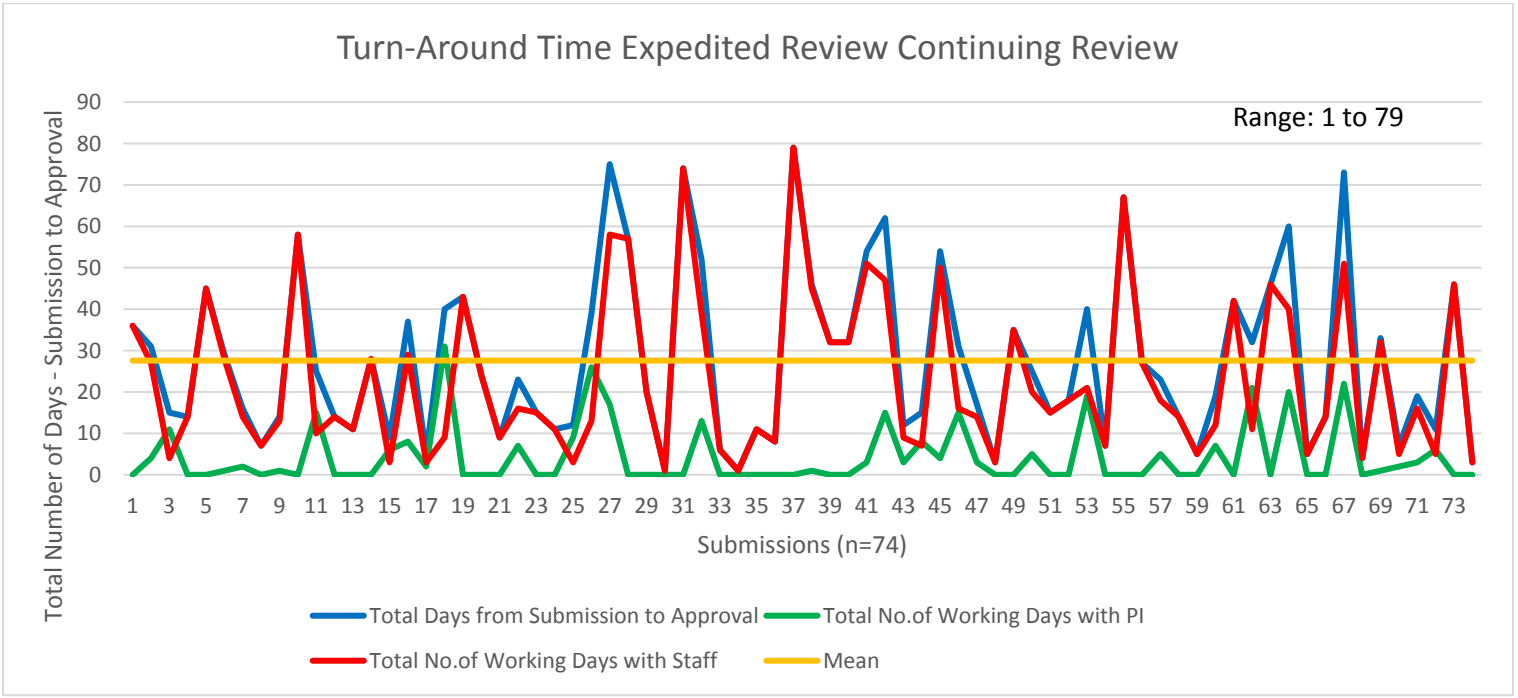
Analysis:

In 2016,

- The mean for Expedited Review new submissions was 40 days with 63% being approved within 45 days.
- The mean for Expedited Review amendments was 8 days with 84% being approved within 14 days.
- The mean for Expedited Review continuing reviews was 28 days with 80% being approved within 45 days.




Turn-Around Time Expedited Review Amendment
Range: 1 to 66
Total Number of Days - Submission to Approval
0 10 20 30 40 50 60 70
1 4 7 10 13 16 19 22 25 28 31 34 37 40 43 46 49 52 55 58 61 64 67 70 73 76 79 82 85 88 91 94 97 100 103 106 109
Submissions (n=111)
Total Days from Submission to Approval
Total No.of Working Days with PI
Total No.of Working Days with Staff
Mean


Turn-Around Time Expedited Review Continuing Review
Range: 1 to 79
Total Number of Days - Submission to Approval
0 10 20 30 40 50 60 70 80 90
1 3 5 7 9 11 13 15 17 19 21 23 25 27 29 31 33 35 37 39 41 43 45 47 49 51 53 55 57 59 61 63 65 67 69 71 73
Submissions (n=74)
Total Days from Submission to Approval
Total No.of Working Days with PI
Total No.of Working Days with Staff
Mean

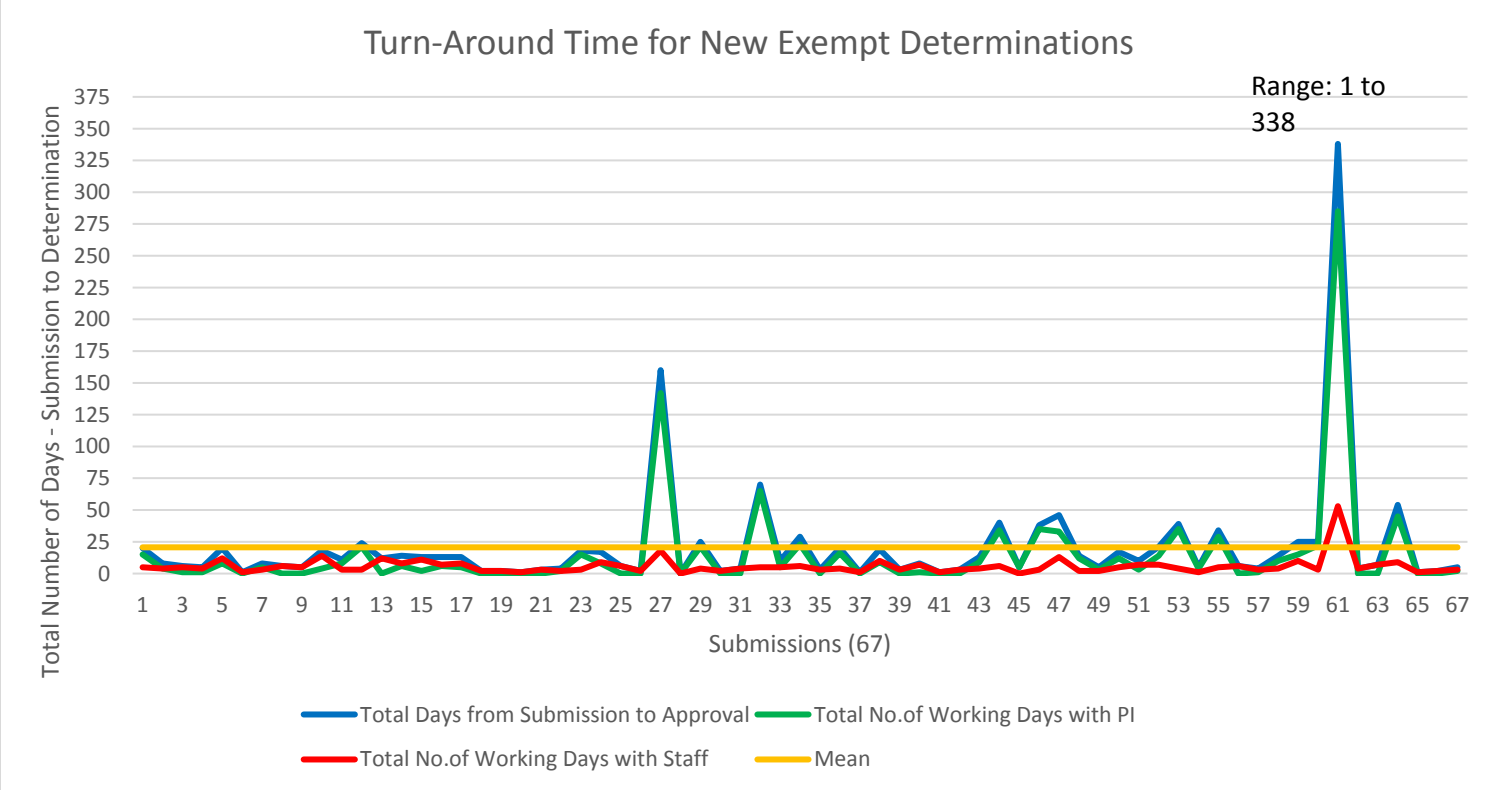
Exempt Determinations

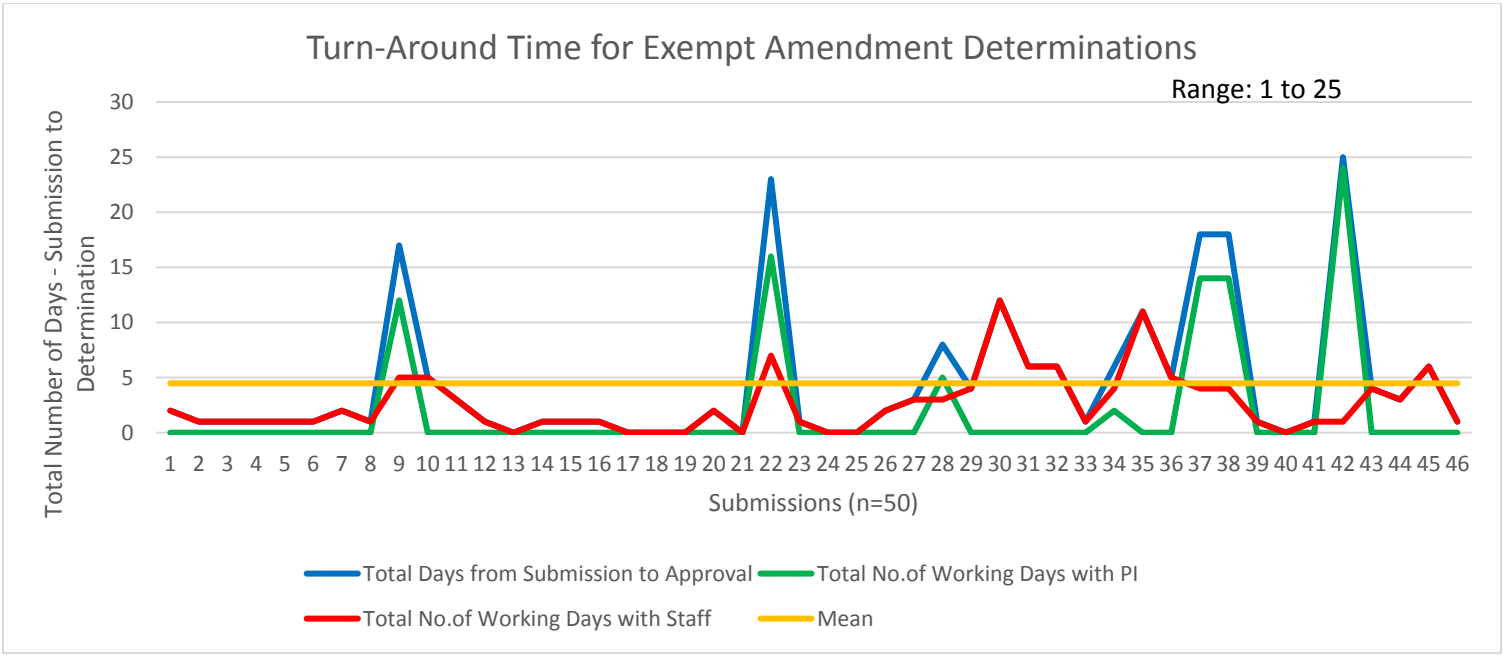
Exempt	Total Number of Actions		Mean Number of Days from Submission to Approval		Mean Number of Working Days with PI		Mean Number of Working Days with IRB/IRB Office	
	2015	2016	2015	2016	2015	2016	2015	2016
	207	144						
New Submissions	129	94	23	21	14	15	9	6
Amendments	78	50	5	4	2	2	3	3

Analysis:

In 2016,

- The mean for Exempt new submissions was 21 days with 66% being determined within 14 days.
- The mean for Exempt amendments was 4 days with 76% being determined within 7 days.




Turn-Around Time for Exempt Amendment Determinations
Range: 1 to 25
Total Number of Days - Submission to Determination
30
25
20
15
10
5
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46
Submissions (n=50)
Total Days from Submission to Approval
Total No.of Working Days with PI
Total No.of Working Days with Staff
Mean

Not Human Subjects Research Determinations

Not Human Subjects Research	Total Number of Actions		Mean Number of Days from Submission to Approval		Mean Number of Working Days with PI		Mean Number of Working Days with IRB/IRB Office	
	2015	2016	2015	2016	2015	2016	2015	2016
	78	141						
New Submissions	78	132	13	13	7	7	6	5
Amendments		9		8		0		2

Analysis:

In 2016,

- The mean for Not Human Subjects Research new submissions was 13 days with 63% being determined within 7 days.