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 12 primary and 10 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

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 if IRB review is required, the first step is to determine if 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 "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 number of cycles and response time (both investigator and IRB) during the review process are critical components of the review process.

A comparison of 2016 vs 2017 Full Board and Expedited Review New Submissions revealed the following:

Expedited New			Mean # of Days - Submission to Approval	Mean # of Days with IRB	% of Total Time	Mean # of Days with PI	% of Total Time
2017	45 days or less		23.76	16.04	68%	7.72	32%
	45 days or more		104.43	31.86	30%	72.57	70%
2016	45 days or less		26.76	17.8	67%	8.96	33%
	45 days or more		75.27	31.7	42%	43.57	58%
Full Board New			Mean # of Days - Submission to Approval	Mean # of Days with IRB	% of Total Time	Mean # of Days with PI	% of Total Time
2017	90 days or less		52	36.4	70%	15.6	30%
	90 days or more		246.33	100.67	41%	145.67	59%
2016	90 days or less		40	25.67	64%	14.33	36%
	90 days or more		165.5	48.5	29%	117	71%

- Studies experiencing review times above the "expected turn-around times" for both Full Board (90 days) and Expedited (45 days) identify a marked increase in the number of days spent with the PI.
  - In response to this, the Research Compliance Office realizes the need for additional education to help investigators navigate the overall submission and review process. Starting in March 2018, the Research Compliance Office has begun offering educational sessions 2 times per month (once at the Volker campus and once at the Hospital Hill campus). The schedule of sessions including dates, times and locations can be found here, http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/irb-education

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

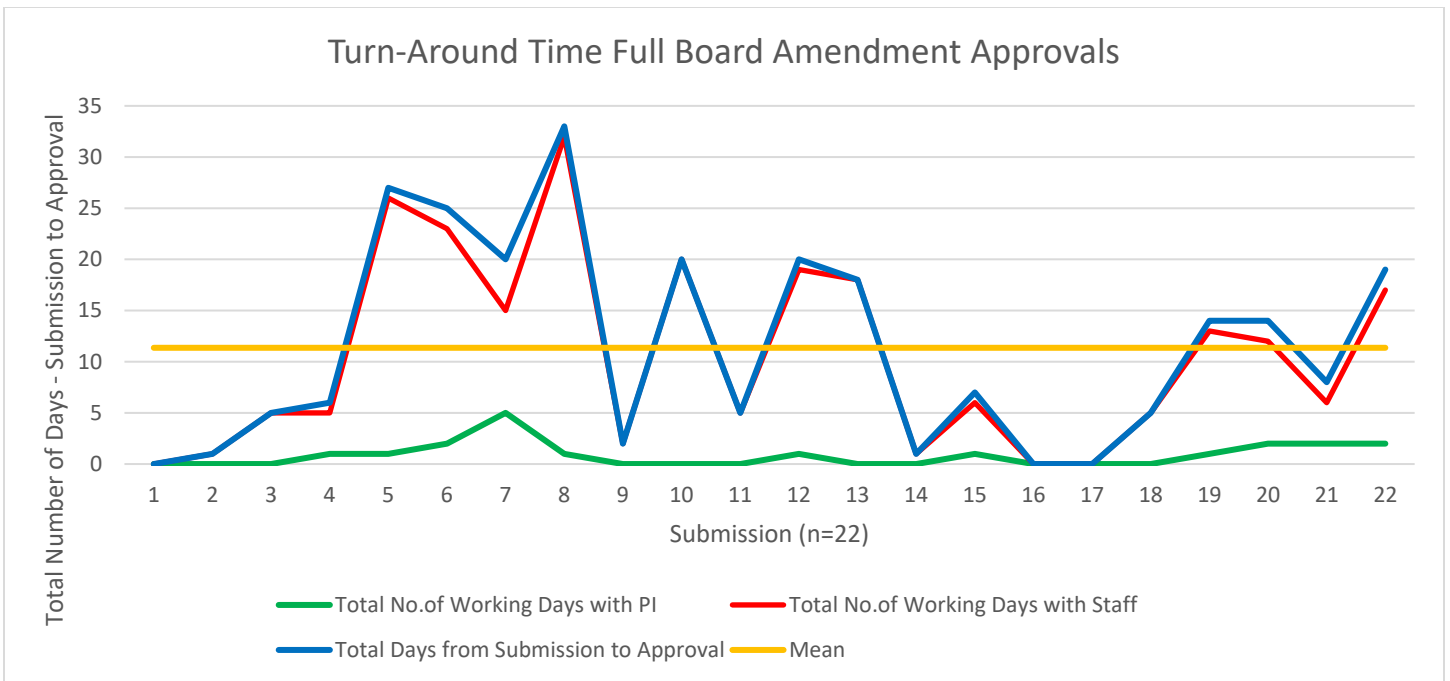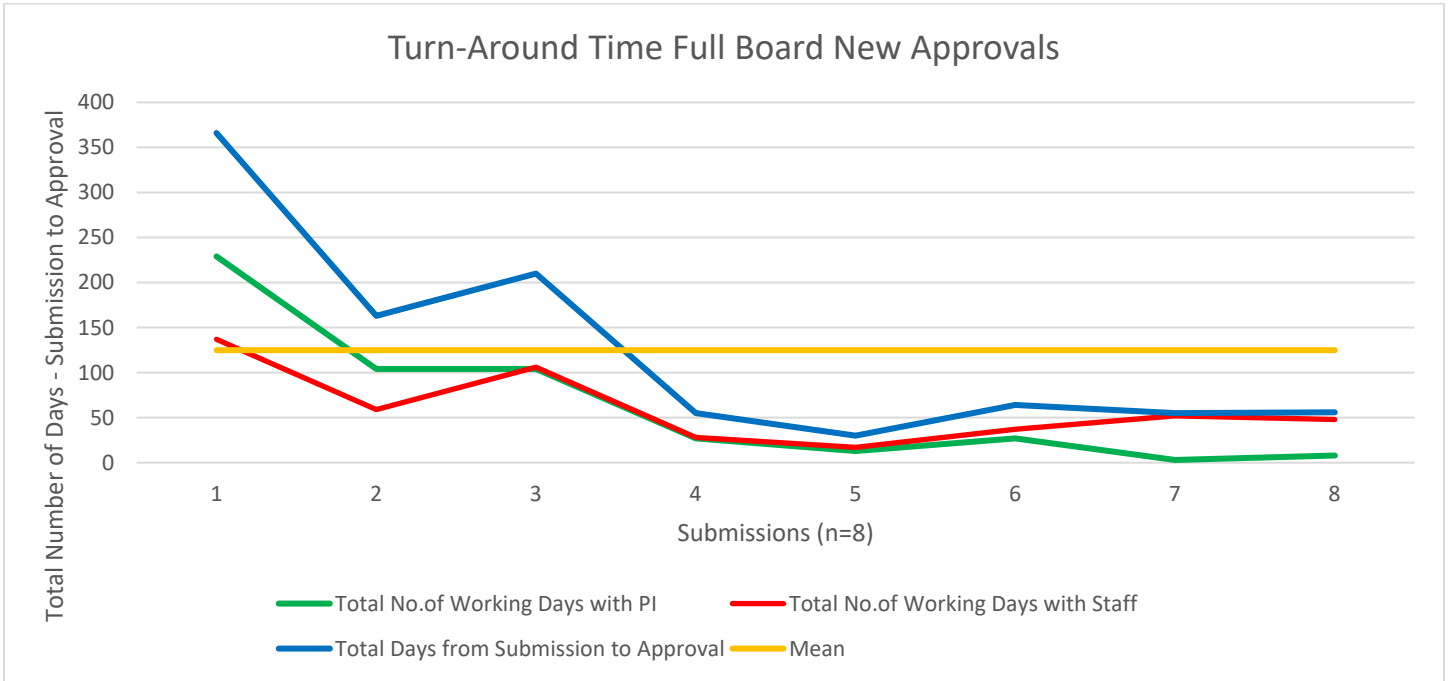| Full Board	Total Number of Actions			Mean Number of Days from Submission to Approval			Mean Number of Working Days with PI			Mean Number of Working Days with IRB/IRB Office		
	2015	2016	2017	2015	2016	2017	2015	2016	2017	2015	2016	2017
	125	61	55									
New Submissions	9	8	8	75	71	125	36	40	64	39	31	61
Amendments	36	25	22	12	9	11	6	1	1	6	8	11
Continuing Reviews	21	11	15	37	43	41	8	0	1	29	43	40
Protocol Violations	3	2	4									
Serious Adverse Events	56	15	6									

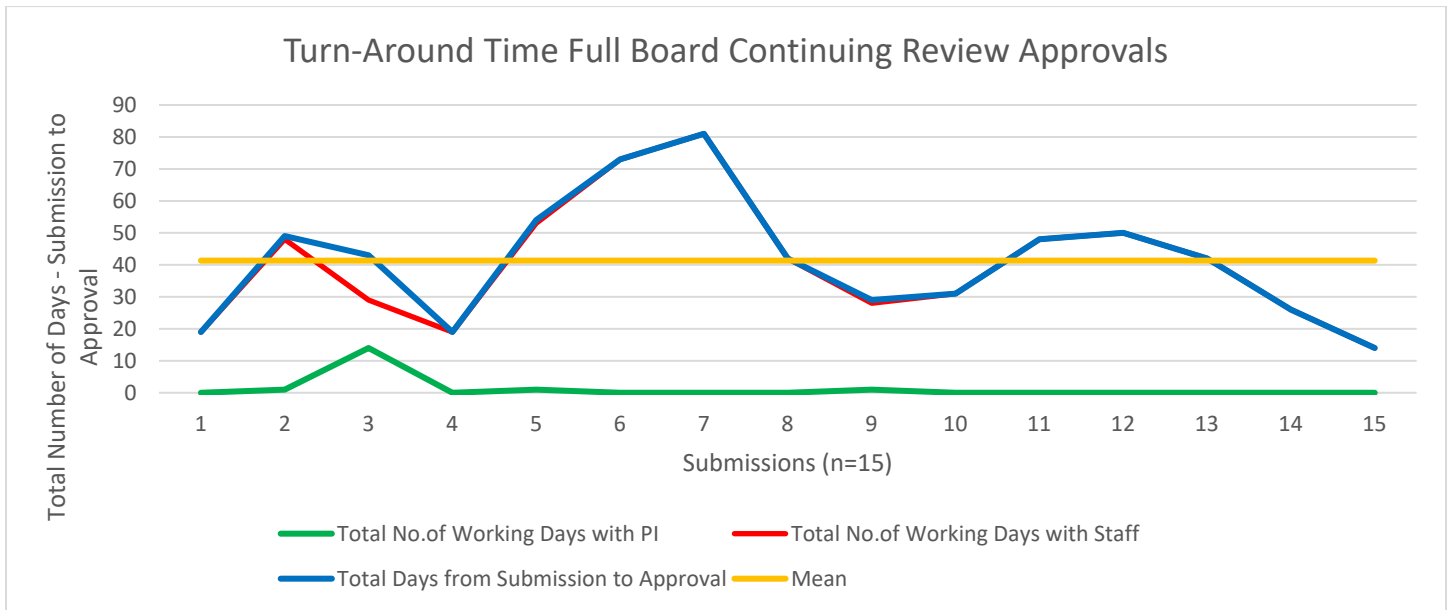| Full Board		Range	Total Days from Submission to Approval		Total No. of Working Days with PI		Total No. of Working Days with Staff	
			Mean	Median	Mean	Median	Mean	Median
Total # of Actions	55							
New Submissions	8	30-366	124.88	60	64.38	27	60.5	50
Amendments	22	1-33	11.36	7.5	0.86	0.5	10.5	6
Continuing Reviews	15	14-81	41.33	42	1.13	0	40.2	42
Protocol Violations	4							
Serious Adverse Events	6							

Analysis:

In 2017,

- The mean for Full Board new submissions was 125 days with 50% being approved within 60 days.
  - Time spent with the PI = 52%
  - Time spent with the IRB* = 48%
  - The range for Total Days from Submission to Approval increased from 27-166 in 2016 to 30-366 in 2017.
    - Overall time increased by 57%
    - PI Time increased by 62%
    - IRB time increased by 53%
  - 3 of the 8 applications were approved within 163 to 366 days
    - Of those, the average number of days with the PI was 146, while the average number of days with the IRB* was 101.
  - 5 of the 8 applications were approved within 30 to 64 days.
    - Of those, the average number of days with the PI was 16, while the average number of days with the IRB* was 36.
-
- The mean for Full Board amendments was 11 days with 64% being approved within 15 days.
- The mean for Full Board continuing reviews was 41 days with 87% being approved within 60 days.

  * Time spent with the IRB means time spent with the IRB office staff and members of the IRB

Turn-Around Time Full Board New Approvals

Submissions (n=8)

- Total No.of Working Days with PI
- Total No.of Working Days with Staff
- Total Days from Submission to Approval
- Mean

Turn-Around Time Full Board Amendment Approvals

Submission (n=22)

- Total No.of Working Days with PI
- Total No.of Working Days with Staff
- Total Days from Submission to Approval
- Mean

Turn-Around Time Full Board Continuing Review Approvals

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**	2017	2015	2016	**2017**	2015	**2016**	2017	**2015**	2016	**2017**
	272	**330**	299									
New Submissions	73	**92**	81	65	40	**59**	35	**19**	36	**30**	20	**23**
Amendments	113	**111**	117	10	8	**8**	2	**1**	2	**8**	7	**7**
Continuing Reviews	79	**74**	89	30	28	**35**	11	**4**	4	**19**	23	**31**
Protocol Violations	6	**3**	9		37			**0**			37	
Serious Adverse Events	1	**50**			12			**1**			11	

| Expedited Review			Total Days from Submission to Approval		Total No.of Working Days with PI		Total No.of Working Days with Staff	
		Range	Mean	Median	Mean	Median	Mean	Median
Total # of Actions	299							
New Submissions	81	3-221	58.62	37	35.74	17	22.88	22
Amendments	117	1-55	8.27	4	1.73	0	6.55	4
Continuing Reviews	89	1-123	34.85	30	4.28	0	30.57	26
Protocol Violations	9							
Final Reports	3							

Analysis:

In 2017,

- The mean for Expedited Review new submissions was 59 days with 57% being approved within 45 days.
  - Time spent with PI = 61%
  - Time spent with IRB* = 39%

- o The range for Total Days from Submission to Approval increased from 6-188 in 2016 to 3-221 in 2017.
- o 64 of the 81 applications were approved in 90 days or less.
  - ▪ Of those, the average number of days with the PI was 15, while the average number of days with the IRB* was 20.
- o 17 of the 81 applications took longer than 100 days.
  - ▪ Of those, the average number of days with the PI was 115, while the average number of days with the IRB* was 34.
- The mean for Expedited Review amendments was 8 days with 84% being approved within 14 days.
- The mean for Expedited Review continuing reviews was 35 days with 73% being approved within 45 days.

* Time spent with the IRB means time spent with the IRB office staff and members of the IRB

Turn-Around Time Expedited Review Amendment Approval

Turn-Around Time Expedited Continuing Review Approval
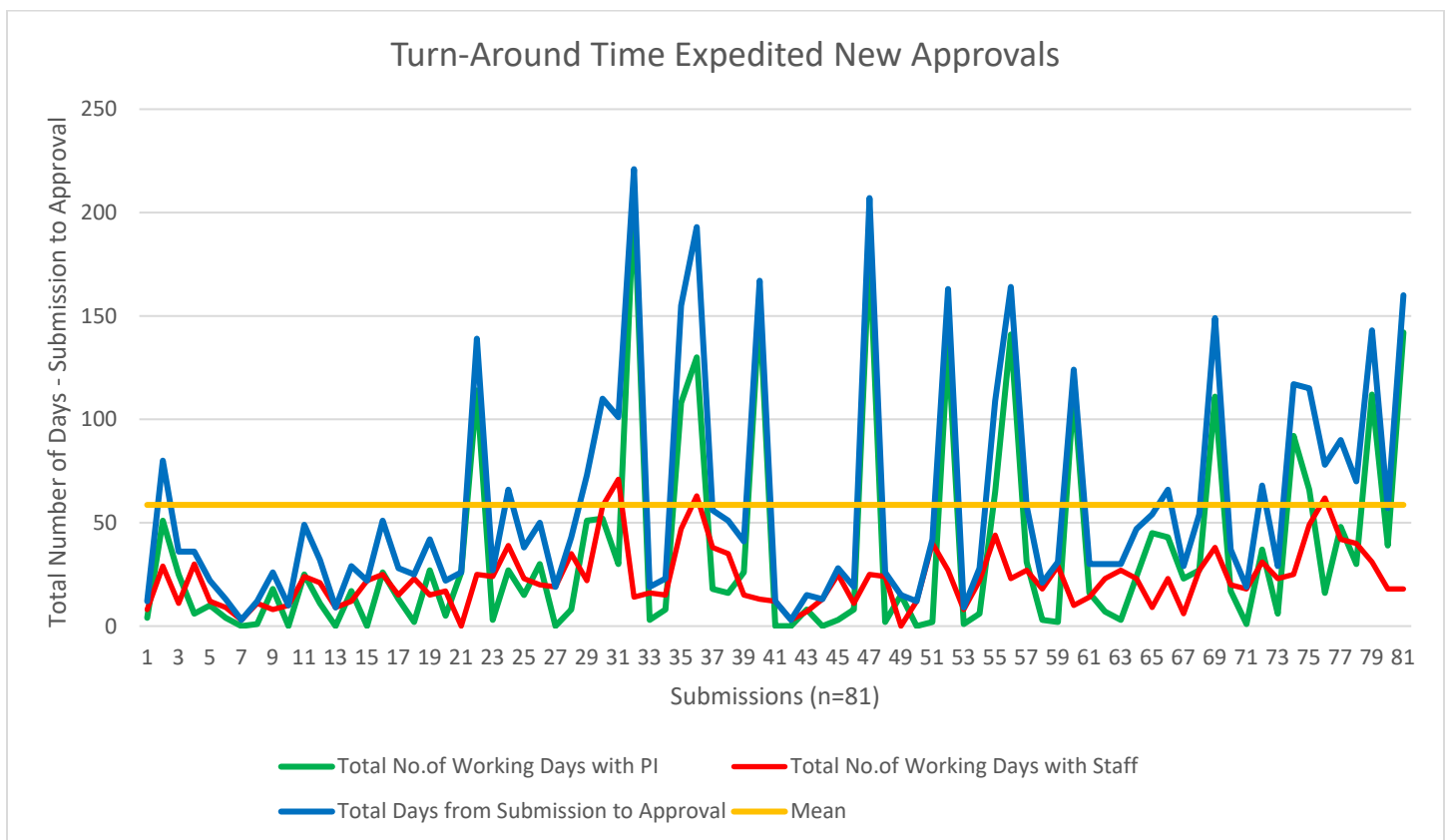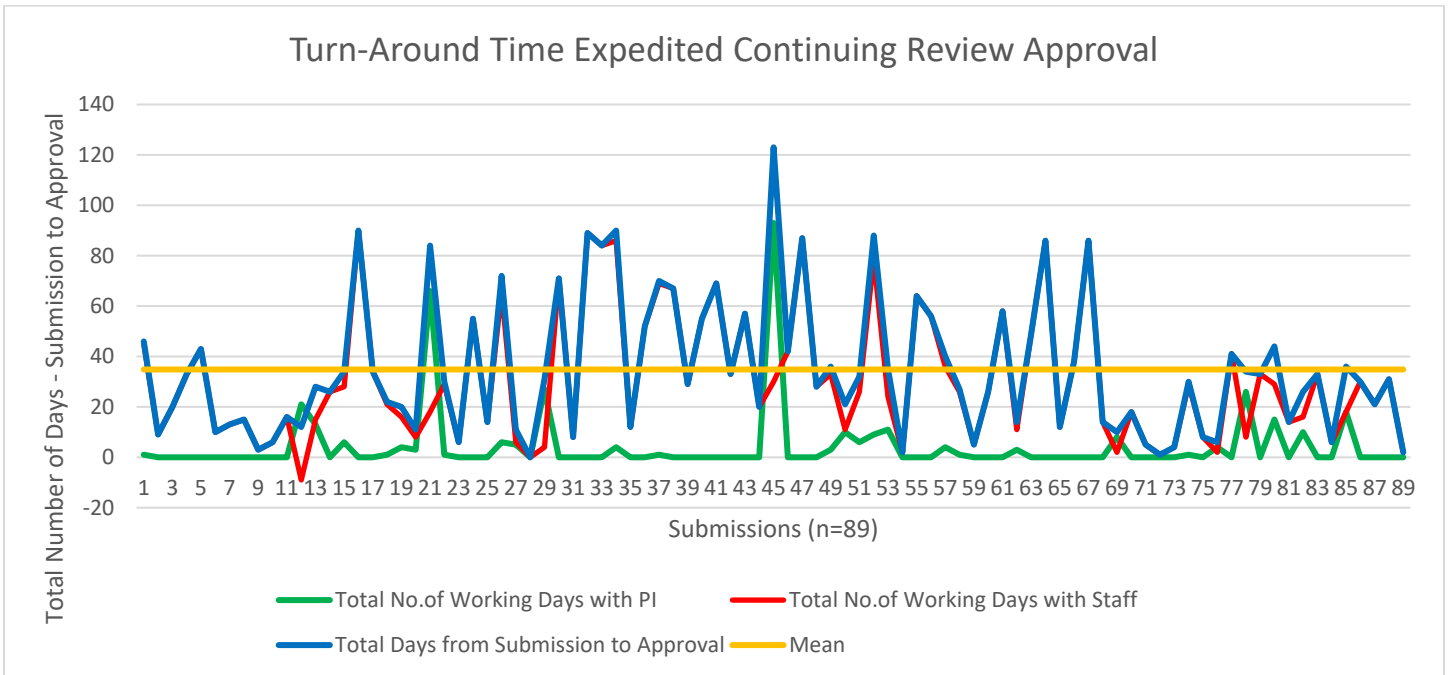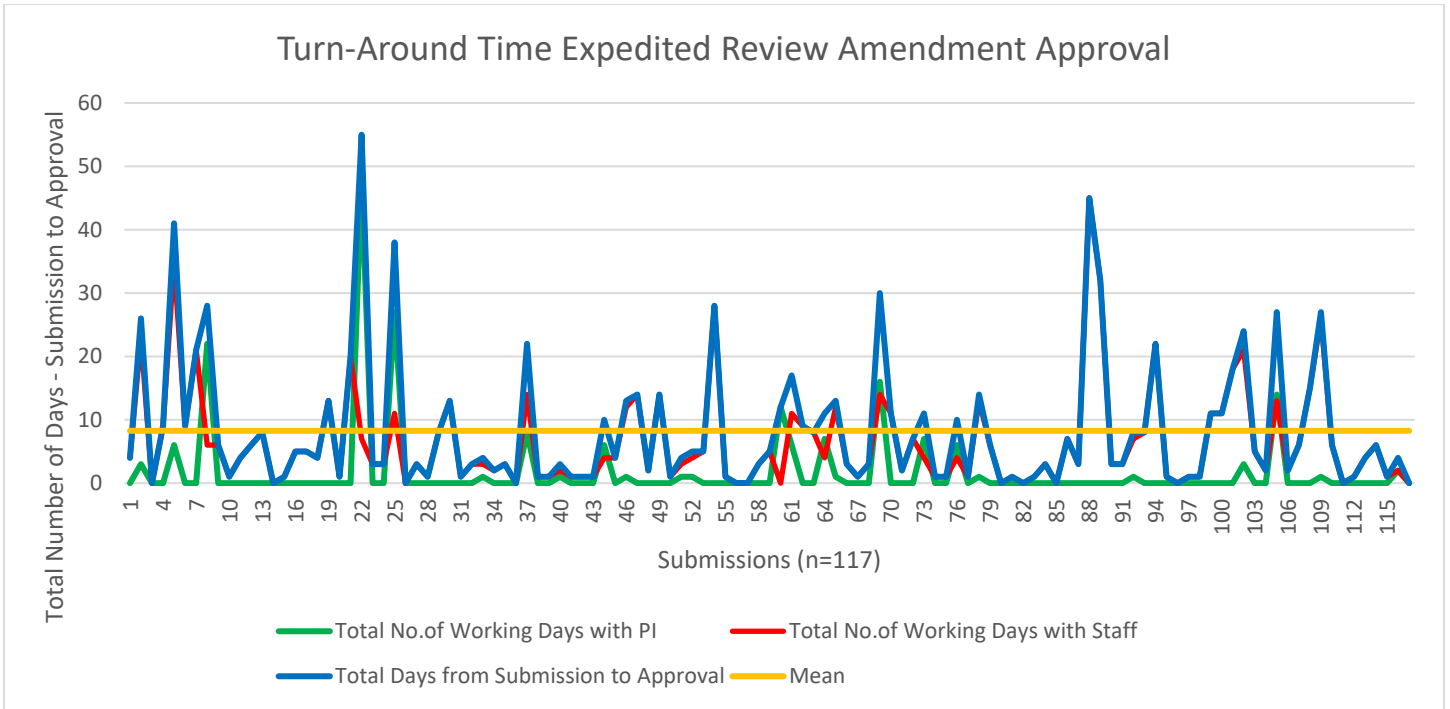
Exempt Determinations

Exempt	Total Number of Actions			Mean Number of Days from Submission to Determination			Mean Number of Working Days with PI			Mean Number of Working Days with IRB/IRB Office		
	2015	**2016**	2017	2015	2016	**2017**	2015	**2016**	2017	**2015**	2016	**2017**
	207	**144**	149									
New Submissions	129	**94**	87	23	21	**28**	14	**15**	20	**9**	6	**8**
Amendments	78	**50**	61	5	4	**5**	2	**2**	2	**3**	3	**3**

Exempt		Range	Total Days from Submission to Determination		Total No.of Working Days with PI		Total No.of Working Days with Staff	
			Mean	Median	Mean	Median	Mean	Median
Total # of Actions	149							
New Submissions	87	1-201	27.64	14	20.13	6	7.52	6
Amendments	61	1-76	4.85	2	2.18	0	2.67	2
Protocol Violations	0							

Analysis:

In 2017,

- The mean for Exempt new submissions was 28 days with 51% being determined within 14 days.
  - The range for Total Days from Submission to Determination decreased from 1-338 in 2016 to 1-201 in 2017.
  - 45 of the 87 applications received a determination within 1-14 days
    - Of those, the average number of days with the PI was 2, while the average number of days with the IRB staff was 5.
  - 42 of the 87 applications received a determination within 15-201 days
    - Of those, the average number of days with the PI was 39, while the average number of days with the IRB staff was 10.
- The mean for Exempt amendments was 5 days with 90% being determined within 7 days.

Turn-Around Time for Exempt New Determinations

Turn-Around Time for Exempt Amendment Determinations
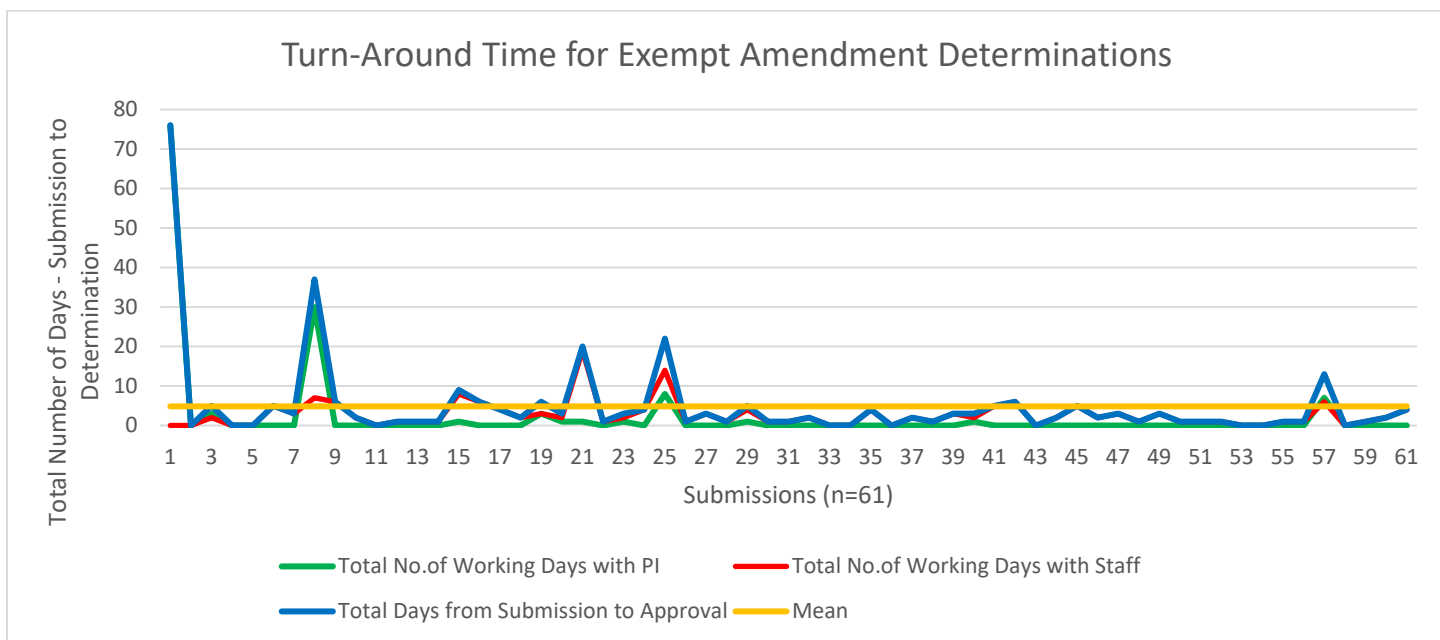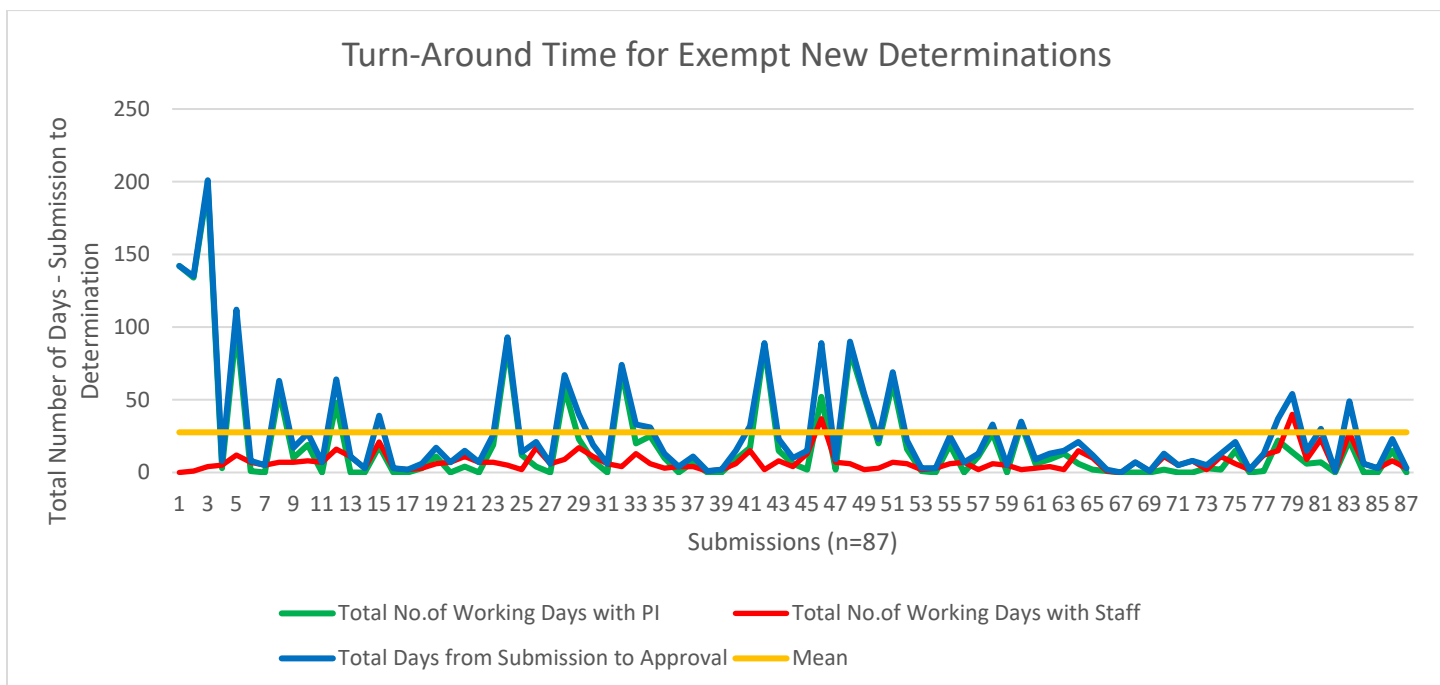
Not Human Subjects Research Determinations

Not Human Subjects Research	Total Number of Actions			Mean Number of Days from Submission to Determination			Mean Number of Working Days with PI			Mean Number of Working Days with IRB/IRB Office		
	2015	**2016**	2017	2015	2016	**2017**	2015	**2016**	2017	**2015**	2016	**2017**
	78	**141**	129									
New Submissions	78	**132**	108	13	13	**9**	7	**7**	6	**6**	5	**3**
Amendments		**9**	10		8	**3**		**0**	1		2	**2**

Not Human Subjects Research		Range	Total Days from Submission to Determination		Total No.of Working Days with PI		Total No.of Working Days with Staff	
			Mean	Median	Mean	Median	Mean	Median
Total # of Actions	129							
New Submissions	108	0-60	9.21	5	6.32	1	2.89	2
Amendments	10	0-16	2.9	1	0.8	0	2.1	1
Final Reports	11							

Analysis:

In 2017,

- The mean for Not Human Subjects Research new submissions was 9 days with 65% being determined within 7 days.