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.

Application Types

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 11 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, Research Services 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. 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 one 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 46.104) 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 research exemption status. 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: 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 that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

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

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) Interaction includes communication or interpersonal contact between investigator and subject.

(4) 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

(5) Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

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 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

NOTE: A change in the configuration of eProtocol reporting caused all non-active (closed) studies to be excluded from the reporting metrics. A decrease in total actions in every category of submission will be noticed and therefore the data presented here should be viewed under that context. In total there are 192 "Actions" across each category that are not factored into the data presented here.

Full Board		Range	Total Days from Submission to Approval Mean		Total No.of Working Days with PI Mean	% time	Total No.of Working Days with Staff Mean	% time
Total # of Actions	55							
New Submissions	3	6-73	43		36	84%	7	16%
Amendments	16	0-25	16		10		6	
Continuing Reviews	8	13-91	35		19		16	
Protocol Violations								
Serious Adverse Events								

Expedited Review		Range	Total Days from Submission to Approval Mean		Total No.of Working Days with PI Mean	% time	Total No.of Working Days with Staff Mean	% time
Total # of Actions								
New Submissions	33	14-418	70		51	73%	20	27%
Amendments	75	0-50	9		4	44%	5	56%
Continuing Reviews	39	1-61	19		10	53%	10	47%
Protocol Violations								
Final Reports								

Exempt		Range	Total Days from Submission to Determination Mean		Total No.of Working Days with PI Mean	% time	Total No.of Working Days with Staff Mean	% time
Total # of Actions	112							
New Submissions	56	1-133	22		14	64%	7	36%
Amendments	55	0-26	4		1	25%	3	75%
Protocol Violations								

Not Human Subjects Research		Range	Total Days from Submission to Determination Mean		Total No.of Working Days with PI Mean	% time	Total No.of Working Days with Staff Mean	% time
Total # of Actions								
New Submissions	136	1-26	10		6	60%	4	40%
Amendments								
Final Reports								

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	2018	2015	2016	2017	2018	2015	2016	2017	2018	2015	2016	2017	2018
Total Actions	125	61	55	27												
New Submissions	9	8	8	3	75	71	125	43	36	40	64	36	39	31	61	7
Amendments	36	25	22	16	12	9	11	16	6	1	1	10	6	8	11	6
Continuing Reviews	21	11	15	8	37	43	41	35	8	0	1	19	29	43	40	16
Protocol Violations	3	2	4													
Serious Adverse Events	56	15	6													

Full Board		Total Days from Submission to Approval		Total No.of Working Days with PI		Total No.of Working Days with Staff	
		Range	Mean	Mean	% time	Mean	% time
Total # of Actions	55						
New Submissions	3	6-73	43	36	84%	7	16%
Amendments	16	0-25	16	10		6	
Continuing Reviews	8	13-91	35	19		16	
Protocol Violations							
Serious Adverse Events							

Analysis:

In 2018,

- The mean for Full Board new submissions was 43 days with 66% being approved within 60 days.
  - Time spent with the PI = 84%
  - Time spent with the IRB* = 16%
  - The range for Total Days from Submission to Approval decreased from 30-366 in 2017 to 6-73 in 2018.
- The mean for Full Board amendments was 16 days with 65% being approved within 15 days.
- The mean for Full Board continuing reviews was 35 days with 63% being approved within 30 days.

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

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		Range	Total Days from Submission to Approval Mean	% time	Total No.of Working Days with PI Mean	% time	Total No.of Working Days with Staff Mean	% time
Total # of Actions								
New Submissions	33	14-418	70		51	73%	20	27%
Amendments	75	0-50	9		4	44%	5	56%
Continuing Reviews	39	1-61	19		10	53%	10	47%
Protocol Violations								
Final Reports								

Analysis:

In 2018,

- The mean for Expedited Review new submissions was 70* days with 69% being approved within 45 days.

  *Removing 5 outliers the mean for expedited review new submissions was 41 days

Total No. of Working Days with Staff	Total No. of Working Days with PI	Total Days from Submission to Approval
20	201	221
24	394	418
55	152	207
14	141	155
39	121	160

  - Time spent with PI = 73%
  - Time spent with IRB** = 27%
  - The range for Total Days from Submission to Approval was 14-418
    - Removing the same 5 outliers reduces the range to 14-110.
    - 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 9 days with 80% being approved within 14 days.

- The mean for Expedited Review continuing reviews was 19 days with 88% being approved within 45 days, 74% being approved within 30 days and 49% being approved in 15 days.

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

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	2018	2015	2016	2017	2018	2015	2016	2017	2018	2015	2016	2017	2018
Total Actions	207	144	149	111												
New Submissions	129	94	87	56	23	21	28	22	14	15	20	14	9	6	8	7
Amendments	78	50	61	55	5	4	5		2	2	2		3	3	3	

Exempt		Total Days from Submission to Determination		Total No.of Working Days with PI		Total No.of Working Days with Staff	
		Range	Mean	Mean	% time	Mean	% time
Total # of Actions	112						
New Submissions	56	1-133	22	14	64%	7	36%
Amendments	55	0-26	4	1	25%	3	75%
Protocol Violations							

Analysis:

In 2018,

- The mean for Exempt new submissions was 22 days with 56% being determined within 14 days.
  - The range for Total Days from Submission to Determination was 1-133.
  - Time spent with PI = 64%
  - Time spent with IRB Staff = 36%
- The mean for Exempt amendments was 4 days with 84% being determined within 5 days.

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	2018	2015	2016	2017	2018	2015	2016	2017	2018	2015	2016	2017	2018
Total Actions	78	141	129	135												
New Submissions	78	132	108	135	13	13	9	10	7	7	6	6	6	5	3	4
Amendments		9	10			8	3			0	1			2	2	

Not Human Subjects Research		Total Days from Submission to Determination		Total No.of Working Days with PI		Total No.of Working Days with Staff	
	Range	Mean		Mean	% time	Mean	% time
Total # of Actions							
New Submissions	136	1-26	10	6	60%	4	40%
Amendments							
Final Reports							

Analysis:

In 2018,

- The mean for Not Human Subjects Research new submissions was 10 days with 56% being determined within 10 days.
    - Time spent with PI = 60%
    - Time spent with IRB Staff = 40%
    - The range for Total Days from Submission to Approval was 1-26 days

In 2018 the IRB and IRB office maintained a total of 999 active protocols (inclusive of all application types outlined in this report). To demonstrate some of the complex research studies reviewed by the IRB, the following is provided for Active Protocols:

- Industry sponsored clinical trials = 20
- Subject to FDA Device Regulations = 5
- Subject to FDA Drug Regulations = 5
- Subject to Subpart B = 38
    - Subpart B includes pregnant women, human fetuses and neonates
- Subject to Subpart C = 6
    - Subpart C includes prisoners
- Subject to Subpart D = 34
    - Subpart D includes children