Western Michigan University
Homer Stryker M.D. School of Medicine

INSTITUTIONAL REVIEW BOARD
HUMAN RESEARCH PROTECTION PROGRAM

Time Period
From July 2022 / To June 2023

ANNUAL REPORT

EXECUTIVE SUMMARY

COMMITTEE PURPOSE

The medical school supports one IRB with members that are appointed by the Institutional Official. The IRB prospectively reviews and makes decisions concerning all human research conducted at, under the auspices of, or using the services or resources of the medical school unless another IRB has been designated by the medical school to do so. The medical school IRB also provides IRB review and oversight for other local entities, the terms of which are described in IRB Services or Authorization Agreements executed prior to performing IRB review and oversight. The medical school IRB is responsible for the protection of rights and welfare of human subjects, through review and oversight of safe and ethical research. It discharges this duty by complying with the requirements of federal and state regulations, the FWA, and applicable institutional policies.

PROPOSAL VOLUME

There was a total of 241 research protocols active end of fiscal year 2022/2023. For July 1, 2022, through June 30, 2023 there was a total of 336 submissions processed by the WMed IRB.

- 101 initial proposals submitted for initial IRB review;
- 53 continuing reviews (21 processed administratively);
- 31 closures (WMed IRB 19; CCR / external IRB 11; 2 other academic IRB);
- 104 personnel changes;
- 7 reports of new information;
- 39 modifications; and,
- 1 IRB approval expiration.

Following is the breakdown of types of initial reviews conducted:

- 6 protocols processed administratively and approved by an external IRB (4 CCR)
- 67 exempt determinations including limited reviews
- 8 non-exempt (including expedited and full board reviews)
- 18 non-human subjects research determinations
- 2 proposals withdrawn

We received 14 responses to our customer satisfaction survey. Scores were consistently high for overall satisfaction of the IRB experience. The responses for the electronic system were average and most had visited the IRB website. As a result of the feedback, we will:

- Work to provide additional guidance and update forms to further streamline the electronic submission process.
- Continue to make enhancements to the IRB website as this seems to be the best mechanism to communicate.
- Work to provide more frequent communication and educational opportunities to the research community.

BUILDING REVIEWER AND STAFF CAPACITY

- Anita Crawshaw, the IRB Coordinator left WMed in October 2022 for a new opportunity. Emily Norwood joined our team in February 2023 as the IRB Coordinator. Emily shares the FTE with the IACUC so has taken on many new initiatives to help our research compliance team. Em has attended several training sessions and is picking up the review processes very quickly.

GOALS

This upcoming year, the IRB will focus on improving existing tools and resources such as creating a guidance for survey submissions, update consent templates to improve readability, improve outcome letter templates to include investigator expectations, create new protocol templates for HCUP database queries and research registry projects, re-visit the policy/procedure for exempt closures, and continue to build on providing guidance and tools for researchers wishing to conduct community engaged research.

ABOUT THE IRB/HUMAN RESEARCH PROTECTION PROGRAM

The mission of the HRPP is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety, and well-being are protected.
- Provide guidance and support to the research community in the conduct of research with human subjects.
- Assist the research community in ensuring compliance with relevant federal, state, and local laws and regulations.
- Provide timely and high-quality education, review, and monitoring of human research projects.
- Facilitate excellence in human subjects' research.

The Western Michigan University Homer Stryker M.D. School of Medicine (WMed) Institutional Review Board (IRB) complies with applicable federal and state laws and regulations governing IRBs and research with human subjects. The WMed IRB has written procedures for initial and continuing review of research, prepares written minutes of convened meetings, and retains records pertaining to the review and approval process. These activities comply with the requirements of 21 CFR Parts 50 and 56, 45 CFR 46 and its subparts, and ICH Good Clinical Practice (GCP), as applicable. The WMed IRB has a Federalwide Assurance (FWA) and is registered with both the FDA and OHRP. Registration is current and the FWA expires on August 25, 2024.

The Human Research Protection Program (HRPP) carries out administrative duties involving the Institutional Review Board. The HRPP is supervised by Dr. Amy Shipley, Assistant Dean for Research Compliance, and Ms. Maureen Owens, Director of HRPP, under the oversight of the Associate Dean for Research, Greg Vanden Heuvel.

FACULTY LEADERSHIP

CHAIR AND VICE CHAIR

In August 2020, Dr. Parker Crutchfield assumed the role of IRB Chair. Of the 336 submissions received in this report period, Parker conducted 85 reviews total. Of the 101 initial submissions in this period, Parker reviewed 63 submissions. Dr. Crutchfield served as Vice-Chair since 2019 and was mentored by the founding Chair, Dr. Kelly Quesnelle.

Dr. Shibani Kanungo joined the IRB as Vice-Chair in August of 2020. Dr. Kanungo reviewed a total of 8 proposals during this report period, 3 submitted for initial review. Although the number of reviews was limited, the complexity of proposals reviewed was substantially greater. Dr. Kanungo was instrumental in providing a high-level of expertise in human subject protections for these non-exempt reviews. Drs. Crutchfield and Kanungo have worked with the IRB staff to increase the efficiency and effectiveness of the IRB review process.

IRB MEMBERS

In this review period, the IRB Committee had 8 members and 7 alternate members.

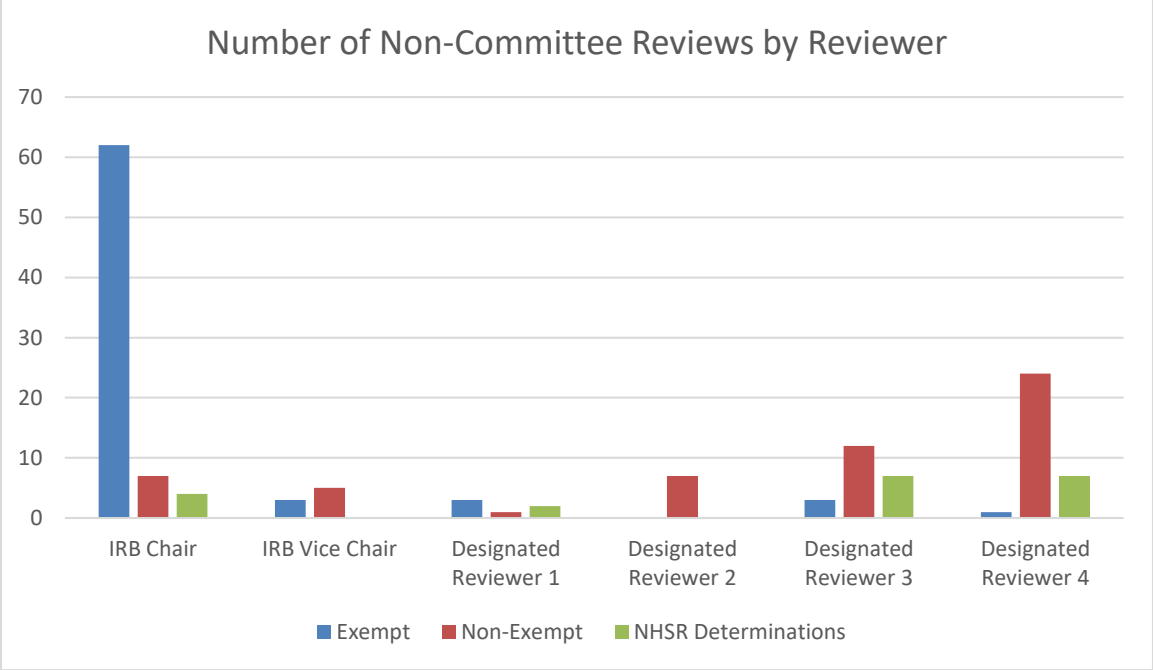
Figure 1 shows the number of reviews completed by WMed IRB reviewers by review type (exempt; non-exempt; NHSR) between July 1, 2022, and June 30, 2023.

Also, in this review period, 2 members resigned from the IRB, and 1 member moved to alternate status due to similar expertise. An alternate community member was recruited.

Brett Jagger, a physician alternate, left WMed in early January. A replacement is currently being recruited.

The Committee is an exceptional group of people: they are committed, sensitive to the complexities involving the protection of human research subjects, and helpful to the research community. A current roster of the IRB Committee can be found on page 7.

Figure 1



EMERGENCY PREPAREDNESS AND RESPONSE PLAN

The plan approved was effective in 2022/23. WMed continues to have leadership in place that takes disaster preparedness seriously and have dedicated appropriate resources to continue this in 2023/24. Our Emergency Preparedness Management Plan was evaluated by site visitors in February of 2023 without incident.

HRPP DIRECTOR

Maureen Owens serves as the Director for HRPP. Ms. Owens oversees all staff activities for the HRPP / IRB office. This includes review of incoming IRB submissions for appropriateness of selected review type, advising staff on assignment of submissions to IRB reviewers, and communication between reviewers and researchers as needed. Ms. Owens provides a great deal of assistance and consultation to Principal Investigators on issues of concern for IRB review (pertinent to 45 CFR 46 and the Belmont Report). Ms. Owens was instrumental in the re-accreditation of the WMed HRPP starting with the process at the beginning of this fiscal year and completing re-accreditation in June 2023.

Ms. Owens oversees all activities related to Institutional Authorization Agreements and Clinical Trials. She also makes presentations on the IRB to WMed researchers. Ms. Owens also works with IRB reviewers to ensure consistency of reviews and serves as an expert for the board on the federal regulations.

STAFF

Ms. Christine McNett continues as an IRB specialist handling iMedRIS IRB submissions, trainings, and monthly reports. She handles administrative closures for faculty departures, works closely with the research support services team providing IRB guidance, handles the agenda's/meeting minutes, and communicates routinely with research staff. Because we were without an IRB coordinator for much of the year, Chris picked up all tasks and kept the office of the IRB running smoothly. Chris continues to earn education credits for the CIP (Certified IRB Professional) by attending conferences and webinars.

Mx. Emily Norwood, the IRB Coordinator, assists with maintaining records. They help in the tracking of CITI training, periodically and proactively contacting researchers about their lapsed training. Emily addresses questions or concerns regarding IRB protocols and navigating the electronic system. In this role, they were responsible for pre-reviewing IRB submissions, renewals, and closures. They work with renewals for expedited and full board studies. Emily handled administrative closures for expired IRBs. They also provided support to researchers and the IRB members in promoting the conduct of ethical human research.

The IRB staff conduct all pre-reviews and post-reviews for exempt and expedited proposals using a checklist. They also process and assign incoming studies for IRB review. The specialist/coordinator assists with the review process for exempt IRB determinations, changes in key research personnel, and modifications.

The IRB agreed to provide administrative support to the IACUC in January of 2023. Therefore, the IRB coordinator position was split between the IACUC and the IRB. A post approval monitoring/regulatory specialist position was put on hold due to budget constraints.

ACTIVITIES IN

MEETINGS

The IRB met 7 times in fiscal year 2022/2023 for full board meetings. IRB members discussed research articles and educational materials as time allowed but specifically education on the FDA proposed changes to HSP regulations to harmonize with the 2018 common rule, reviewed the OHRP exploring payment for research participants, and covered the WMed HRPP disaster management plan. The minutes of the IRB Full Board Meetings are shared with the IO and affiliates as appropriate.

PROFESSIONAL DEVELOPMENT

Staff development is a critical component of the work of the HRPP. Ms. Owens and staff members attended several webinars and short courses offered by OHRP, AAHRPP, and Public Responsibility in Medicine & Research (PRIM&R). Information from conferences was shared with the IRB.

PROTOCOLS

The number of IRB proposals submitted has stayed consistent since implementing the electronic system and the revised Common Rule. We actively continue to improve the quality of proposals by working closely with the other research support services groups. This also reduced the amount of time spent in pre-review and protocols returned for changes.

Year	Research Protocols
2020-2021	127
2021-2022	139
2022-2023	101

Of the 101 IRB protocols submitted in this reporting period, 7 involve industry sponsored projects, 4 received funding from WMed (pilot grant), 2 are federally funded, and 2 other projects received funding from a private foundation.

The total number of initial submissions being slightly lower from years past was due to the new project request and triage where the IRB staff are assisting earlier in the development process allowing for greater quality of submissions versus quantity. We also heard from many investigators that the clinics being short staffed has prevented them from working on their research projects.

FDA REGULATED RESEARCH

The WMed HRPP oversees several Humanitarian Use Device approvals maintained for affiliated hospital systems, 2 compassionate use approvals, and 25 clinical trials, 22 approved via a central IRB.

FEDERAL FUNDING

The WMed HRPP currently oversees 9 research projects funded by the federal government. Per the NIH Single IRB Review policy, 3 utilize the single IRB review model.

Western Michigan University Homer Stryker M.D. School of Medicine recently joined the SMART IRB. SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.

BUDGET

The HRPP budget includes salaries for the HRPP Director (1 FTE), an IRB specialist (1 FTE), and a .6 FTE for the IRB coordinator, .2 effort for IRB Chair, .1 effort for Vice-Chair and a .3 FTE for management of research conflicts of interest. The budget allows some funds for professional memberships, travel to educational conferences, and a modest amount for relevant journals, books, and supplies.

ACCOMPLISHMENTS AND GOALS

We continue to improve the functionality of the HRPP and IRB by helping investigators with the

least restrictive necessary level of IRB review, continuing to pre-screen proposals for completeness before they are submitted and given to reviewers, and continue to help every IRB member with training and educational opportunities.

ACHIEVED July 1, 2022– June 30, 2023

1. Achieved re-accreditation through 2028
2. Developed and distributed resources for researchers to use to promote greater health literacy (recruitment flyer pre and post revision, list of health literacy web links, instructions to add the readability stats in word documents)
3. We continue to support DEI initiatives by attending various webinars and conferences applying knowledge gained to our program.
4. We revised the protocol templates to achieve greater compliance with requirements of initial submission.
5. We updated aspects of our pre-review procedures.
6. We created and executed training on emergency preparedness planning.
7. With the assistance of administration streamlined the protocol development process and research opportunities for students including enhancements to the WMed research website.
8. Assisted with quantifying student research opportunities for LCME.

GOALS FOR July 1, 2023 – June 30, 2024

1. We will expand upon tools and resources available for community engaged research to improve health literacy and outreach activities.
2. We will update the policies and procedures for exempt closures.
3. We will solicit additional feedback beyond our survey from the research community on satisfaction of their experience with our services and where improvements could be made.
4. We will improve guidance and forms to increase the level of customer satisfaction with the electronic system.
5. We will continue to provide education to the IRB staff and members.
6. We will continue to examine methods for increasing the flexibility of our IRB reviews and policies.
7. We will expand our post approval monitoring program by increasing the number of periodic reviews conducted for both exempt and non-exempt studies.
8. We will implement more robust guidance and tools for electronic consent.
9. We will update templates (protocol; outcome letter; consents).
10. We will re-visit the policy and procedures for identifying research conflicts of interest.
11. We will continue to collaborate with Informatics, HIM, Compliance, and Clinical Affairs to ensure the workflow of collecting/storing clinical information for all clinical activities supporting WMed's community outreach projects complies with all federal, state, and WMed regulations for data security, patient privacy, and research activities.
12. We will continue to monitor the emergency preparedness and response plan; resources allocated to the HRPP; IRB composition; and outreach activities.
13. We will continue to strive for a 5-day period of review for initial and subsequent review of exempt and expedited proposals.

WMed IRB
COMMITTEE MEMBERS
July 2022 – June 2023

CHAIR / Vice-CHAIR				
Name	**Term**	**Department**	**Phone**	**Email**
Parker Crutchfield, PhD	2	WMed Faculty Bioethics	269-337-4244	parker.crutchfield@wmed.edu
Shibani Kanungo, MD, MPH, FAAP, FACMG	1	WMed Faculty Peds/Bioethics	269-337-6472	shibani.kanungo@wmed.edu

MEMBERS		
Name	**Term**	**Department**
Christine McNett, CIP	1	WMed HRPP/IRB Staff
Jagadeesh Kalavakunta, MD	3	Ascension Borgess Hospital Representative
Donna Moyer, PhD, MSN	3	Bronson Methodist Hospital Nursing Representative
Theresa McGoff, MBA, RN, CCRP	1	WMed Biomedical Informatics
Adam Warner, PharmD	1	Bronson Methodist Hospital Representative
Michael Evans, BA	2	Kalamazoo Literacy Council – Community Member

ALTERNATES		
Name	**Term**	**Department**
Brett Jagger, MD, PhD	1	WMed Faculty
Melissa Olken, MD, PhD	3	WMed Faculty
Daniel Foley	2	Data Manager Harvard University
James Springstead, PhD	3	Community Faculty / WMU
Maureen Owens, MM, CIP	1	Regulatory
Barbara Mulder, BSN, MS, RN	1	Ascension Borgess Hospital Nursing Representative
Keshia Dickason	1	Community Member

ANNUAL STATISTICS

Figure 2 shows the number of initial submissions by review type for fiscal year 2022/2023.

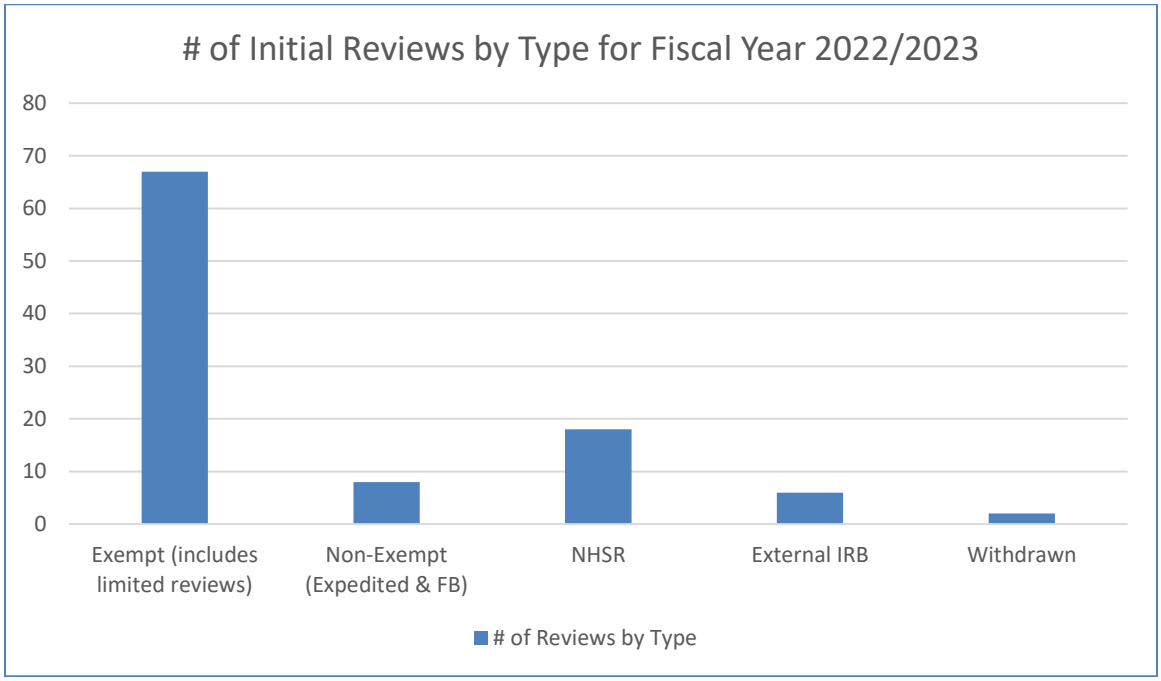


Figure 3 shows the number of submissions received by the IRB per month.

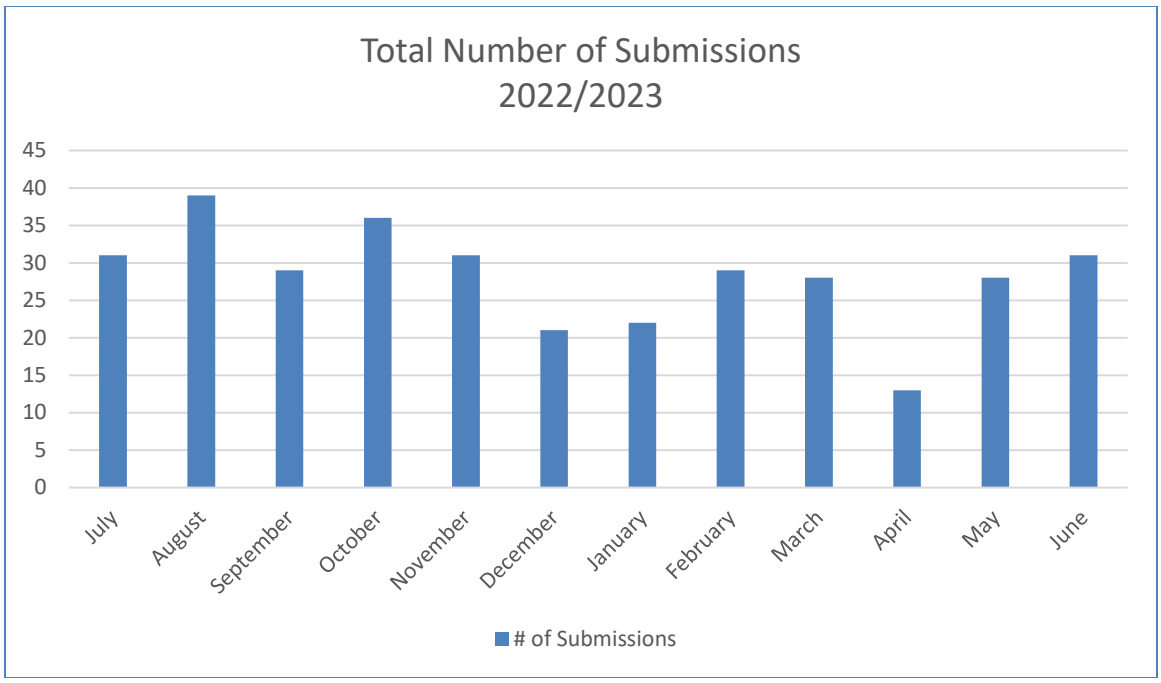


Figure 4 shows the number of submissions by review type.

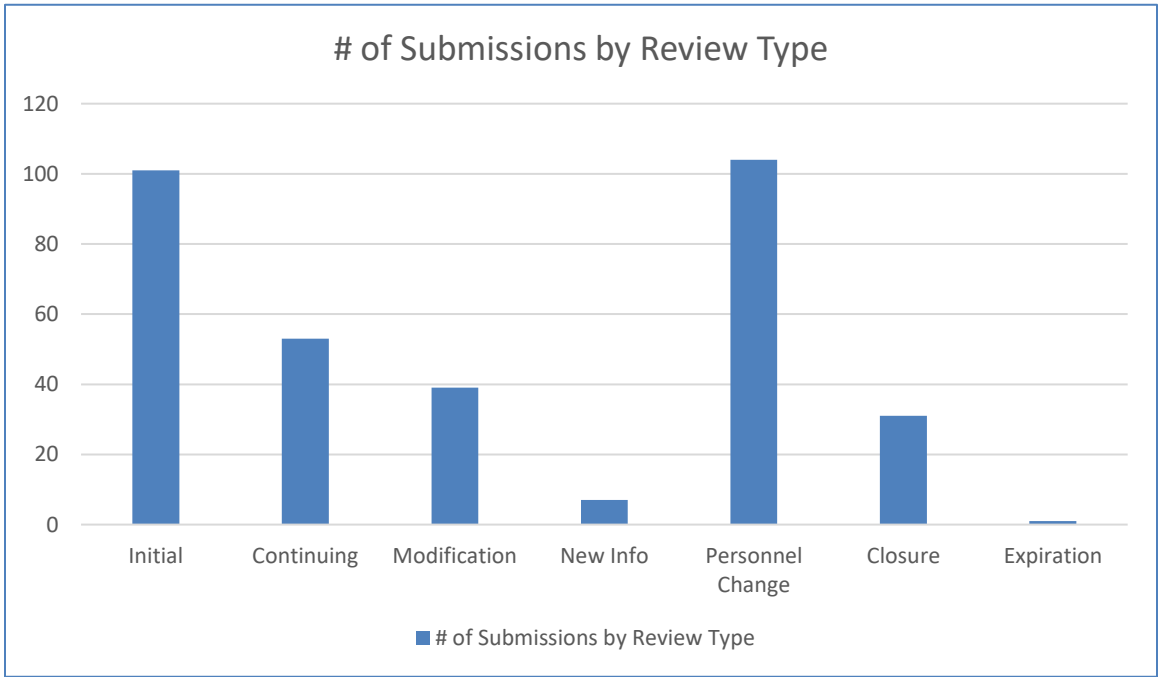


Figure 5 shows the number of reviews by reviewer per month

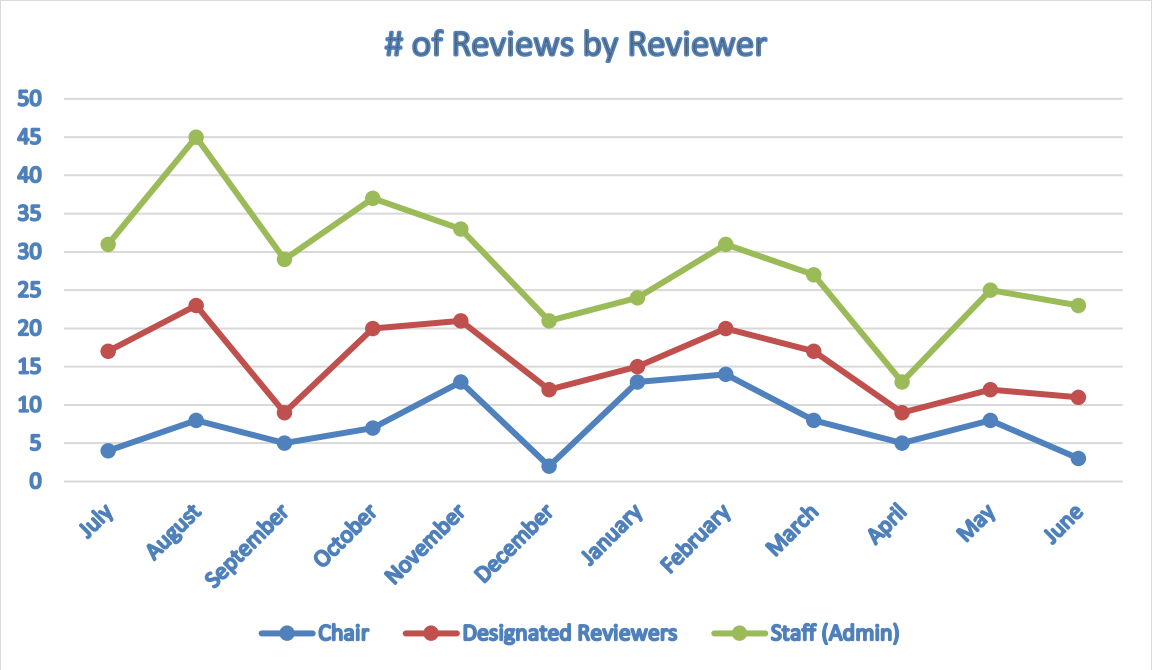


Figure 6 shows the number of active studies by department.

Current Active Human Subjects Research Studies by Department	
Department	**# of Active Studies**
Biomedical Informatics	9
Biomedical Sciences	30
CCR	58
Emergency Medicine	15
EMS and Disaster Medicine	1
Family Medicine	17
Family Medicine/Battle Creek Residency	3
Health Equity and Community Affairs	10
Hospice and Palliative Medicine Fellowship	1
Internal Medicine	17
Internal Medicine, Division of Infectious Disease	4
Internal Medicine-Pediatrics	8
Investigational Medicine	3
Library	1
Medical Education	14
Medical Ethics	5
Obstetrics and Gynecology	2
Orthopaedic Surgery	14
Pathology	3
Pediatrics	23
Psychiatry	2
Radiology	1
Student Affairs	1
Surgery	31

If you would like specific statistics for your department, contact Maureen Owens.

Figure 7 shows the number of initial reviews by institution that were submitted