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

INSTITUTIONAL REVIEW BOARD
HUMAN RESEARCH PROTECTION PROGRAM

Time Period
From July 2024 / To June 2025

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 2024/2025. For July 1, 2024, through June 30, 2025, there was a total of 521 submissions processed by the WMed IRB.

- 104 initial proposals submitted for initial IRB review;
- 32 continuing reviews (18 processed administratively);
- 97 closures (WMed IRB 92; CCR / external IRB 3; 2 other academic IRB);
- 211 personnel changes;
- 3 reports of new information;
- 10 modifications;
- 48 requests for re-determinations/re-approvals; and
- 16 responses to review board modifications

Following is the breakdown of types of initial reviews conducted:

- 7 protocols processed administratively and approved by an external IRB (3 Psychiatry; 3 CCR; 1 Other)
- 74 exempt determinations including limited reviews
- 5 non-exempt (including expedited and full board reviews)
- 18 non-human subjects research determinations

We received 10 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 WMed research community.

GOALS

This upcoming year, the IRB will focus on reducing workload to make time for improving existing tools and resources such as creating a guidance for submissions in the electronic system, use AI to update consent templates to improve literacy level, re-visit the policy/procedure for exempt updates, consider ways to reduce workload balance (personnel changes), and continue to build on providing guidance and tools for researchers.

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 February 4, 2030.

The Human Research Protection Program (HRPP) carries out administrative duties involving the Institutional Review Board. The HRPP is supervised by the Senior Director, Research Compliance, and Ms. Maureen Owens, Director of HRPP, under the oversight of the Senior Associate Dean for Research, Dr. Robert Sawyer.

FACULTY LEADERSHIP

CHAIR AND VICE CHAIR

In August 2020, Dr. Parker Crutchfield assumed the role of IRB Chair. Of the 419 submissions received in this report period, Parker conducted 89 reviews total. Of the 104 initial submissions in this period, Parker reviewed 65 submissions. Dr. Crutchfield also served as Vice-Chair since 2019 and was mentored by the founding Chair, Dr. Kelly Quesnelle.

Dr. Kevin Ault was appointed Vice-Chair of the IRB in February 2025. While his participation has so far been primarily limited to attending meetings, there are plans to expand his involvement in the near future. Dr. Ault brings extensive experience from his previous IRB roles at other institutions, and we are thrilled to have him as part of the team.

IRB MEMBERS

In this review period, the IRB Committee had 9 members and 6 alternate members.

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.

EMERGENCY PREPAREDNESS AND RESPONSE PLAN

The plan approved was effective in 2023/24. WMed continues to have leadership in place that takes disaster preparedness seriously and have dedicated appropriate resources to continue this in 2024/25.

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 assistance and consultation to Principal Investigators on issues of concern for IRB review (pertinent to 45 CFR 46 and the Belmont Report).

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 left WMed for retirement in May 2025. Ms. Madeline Rosenberger joined the HRPP team as an HRPP Specialist in June 2025 handling iMedRIS user requests, 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 and IRB members.

ACTIVITIES IN

MEETINGS

The IRB met 6 times in fiscal year 2024/2025 for full board meetings. 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

2023-2024	108
2024-2025	104

Of the 104 IRB protocols submitted in this reporting period, 7 involve industry sponsored projects, 2 received funding from WMed (pilot grant), and 2 are federally funded (single IRB).

FDA REGULATED RESEARCH

The WMed HRPP oversees several Humanitarian Use Device approvals maintained for affiliated hospital systems, 3 compassionate use approvals, and 17 clinical trials, 13 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 signed on to version 3 of the SMART IRB reliance agreement in March of 2025. 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 Senior Director Research Compliance (.8 FTE), HRPP Director (1 FTE), an HRPP specialist (1 FTE), .2 effort for IRB Chair, .1 effort for Vice-Chair and a .3 FTE for conflicts of interest committee chair. 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, 2024– June 30, 2025

1. Maintained AAHRPP accreditation
2. Revised all IRB documents with new email and URL
3. Developed and distributed resources for researchers to use to promote greater health literacy
4. Support DEI initiatives by attending various webinars and conferences applying knowledge gained to our program.
5. Revised the protocol templates to achieve greater compliance with requirements of initial submission.
6. Updated aspects of our pre-review procedures.

GOALS FOR July 1, 2024 – June 30, 2025

1. Develop guidance for when external researchers wishing to do research or post their research opportunities in WMed facilities.
2. We will expand upon tools and resources available for community engaged research to improve health literacy and outreach activities.
3. We will update the policies and procedures for exempt closures.
4. 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.
5. We will continue to provide education to the IRB staff and members.
6. We will implement more robust guidance and tools for electronic consent.
7. We will fully implement a new policy and procedures for identifying research conflicts of interest.
8. We will continue to monitor the emergency preparedness and response plan; resources allocated to the HRPP; IRB composition; and outreach activities.

WMed IRB
COMMITTEE MEMBERS
July 2024 – June 2025

CHAIR / Vice-CHAIR				
Name	**Term**	**Department**	**Phone**	**Email**
Parker Crutchfield, PhD	2	WMed Faculty Bioethics	269-337-4244	parker.crutchfield@wmed.edu
Kevin Ault, MD	1	WMed Faculty OB / GYN	269-337-4570	Kevin.ault@wmed.edu

MEMBERS		
Name	**Term**	**Department**
Christine McNett, CIP	1	WMed HRPP/IRB Staff
Neil Hughes, MD	1	WMed Faculty
Donna Moyer, PhD, MSN	4	Bronson Methodist Hospital Nursing Representative
Theresa McGoff, MBA, RN, CCRP	1	WMed Biomedical Informatics
Adam Warner, PharmD	2	Bronson Methodist Hospital Representative
Alexandra Bayer, PhD	1	Social Behavioral and Educational Research
Michael Evans, BA	3	Kalamazoo Literacy Council – Community Member

ALTERNATES		
Name	**Term**	**Department**
Eric Edewaard, MD	1	WMed Faculty
Jagadeesh Kalavakunta, MD	4	Hospital Representative
Daniel Foley	3	Data Manager Harvard University
James Springstead, PhD	4	Community Faculty / WMU
Maureen Owens, MM, CIP	1	Regulatory
Keshia Dickason	1	Community Member

ANNUAL STATISTICS

Figure 2 shows the number of initial submissions by review type for fiscal year 2023/2024.

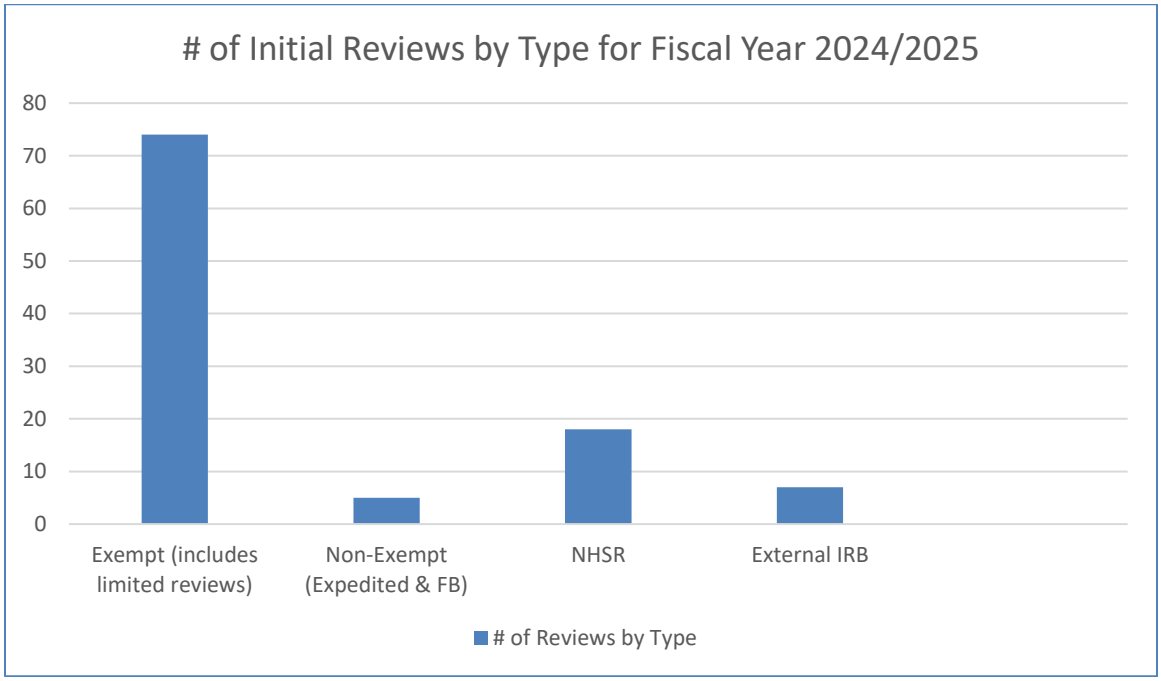

Figure 3 shows the number of submissions received by the IRB per month.

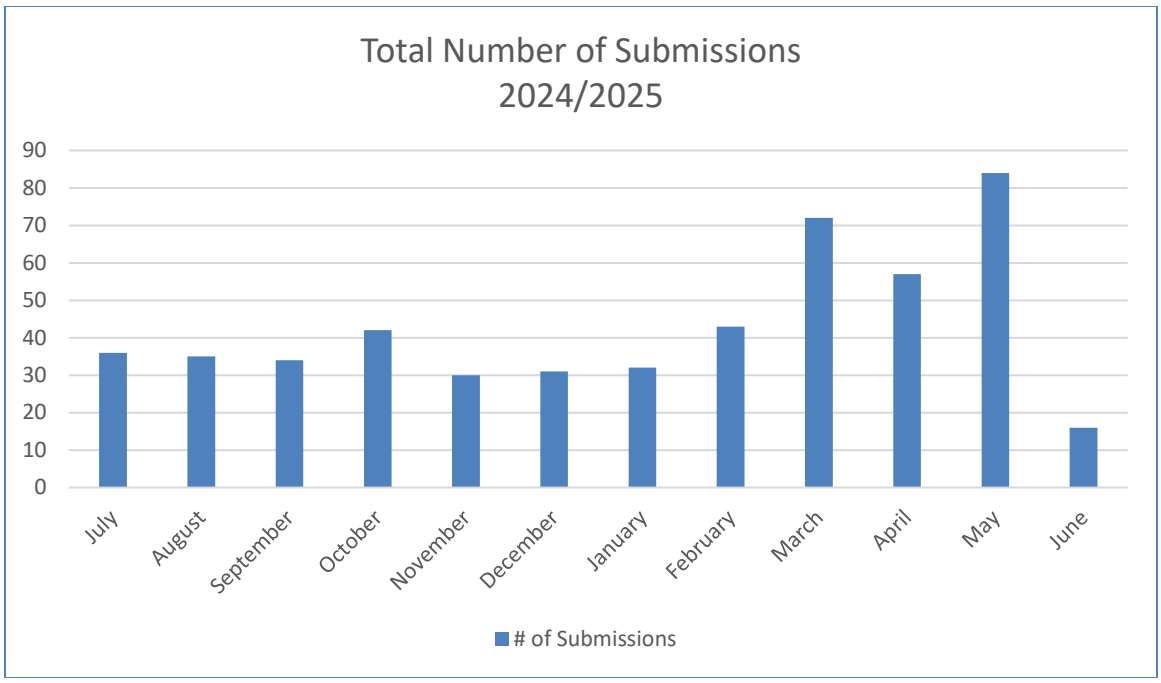

Figure 4 shows the number of submissions by review type.

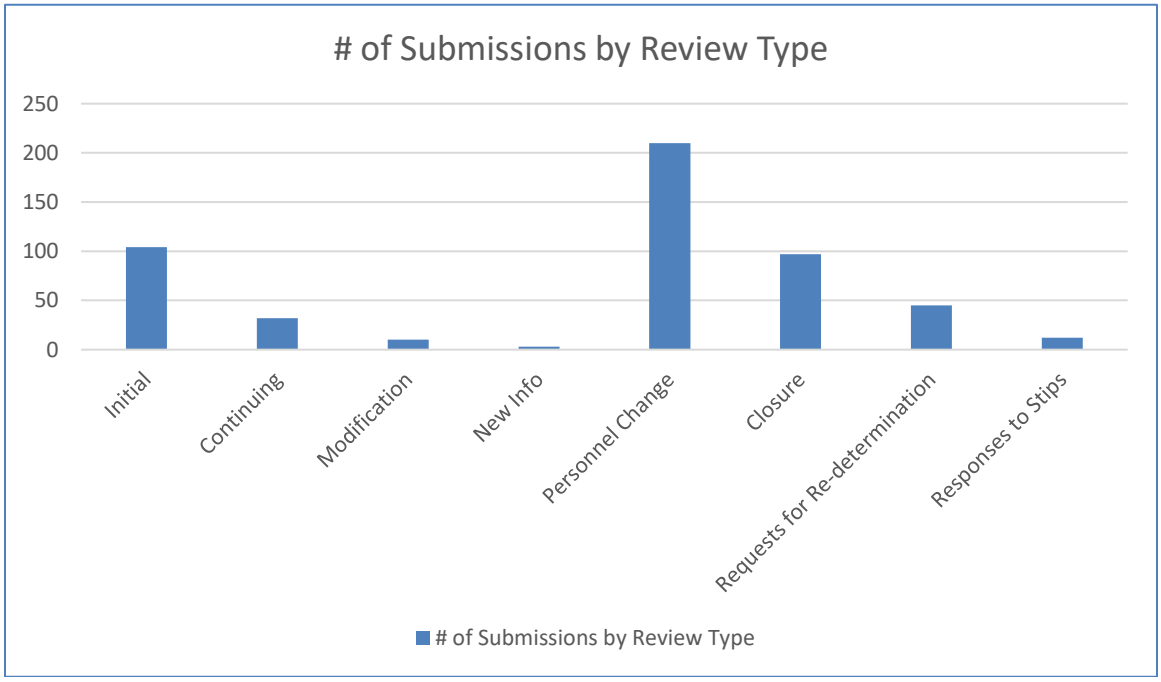

Figure 5 shows the number of reviews by reviewer per month

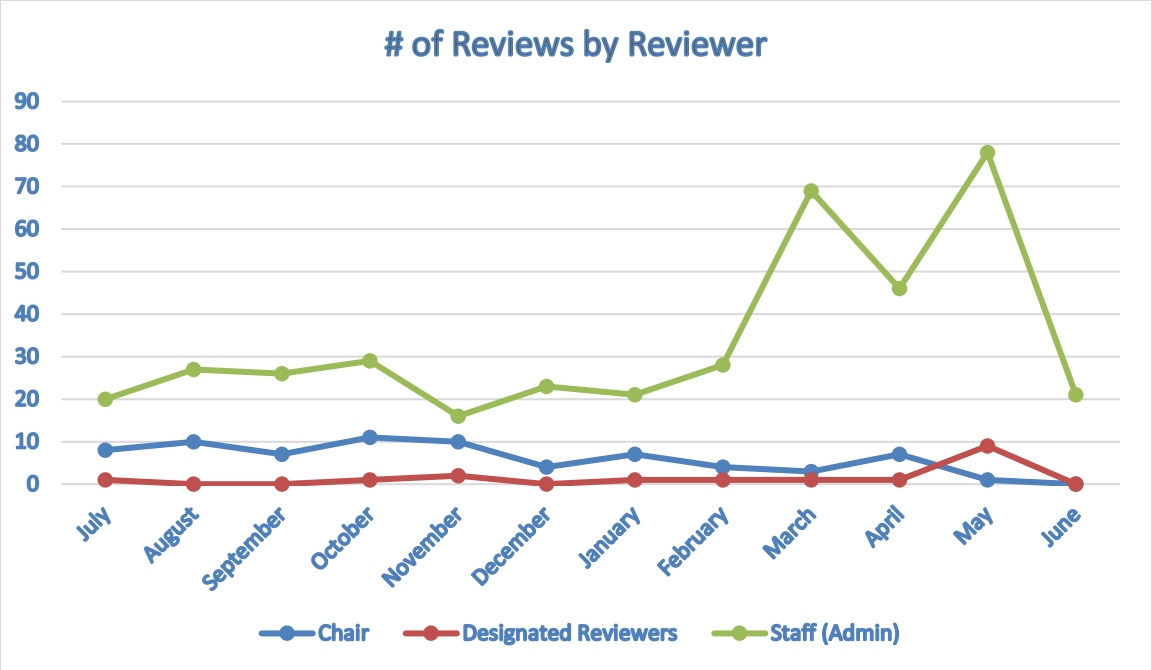

Figure 6 shows the number of active studies by department.

Current Active Human Subjects Research Studies by Department	
Department	**# of Active Studies**
Biomedical Informatics	15
Biomedical Sciences	28
CCR	9
Emergency Medicine	16
EMS and Disaster Medicine	1
Family Medicine	19
Family Medicine/Battle Creek Residency	5
Health Equity and Community Affairs	4
Hospice and Palliative Medicine Fellowship	1
Internal Medicine	11
Internal Medicine, Division of Infectious Disease	4
Internal Medicine-Pediatrics	7
Investigational Medicine	2
Medical Engineering	1
Medical Education	22
Medical Ethics	3
Obstetrics and Gynecology	4
Orthopaedic Surgery	12
Pathology	1
Pediatrics	15
Psychiatry	10
Radiology	1
Simulation Fellowship	1
Street Medicine	12
Student Affairs	1
Surgery	35

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