Office of Research

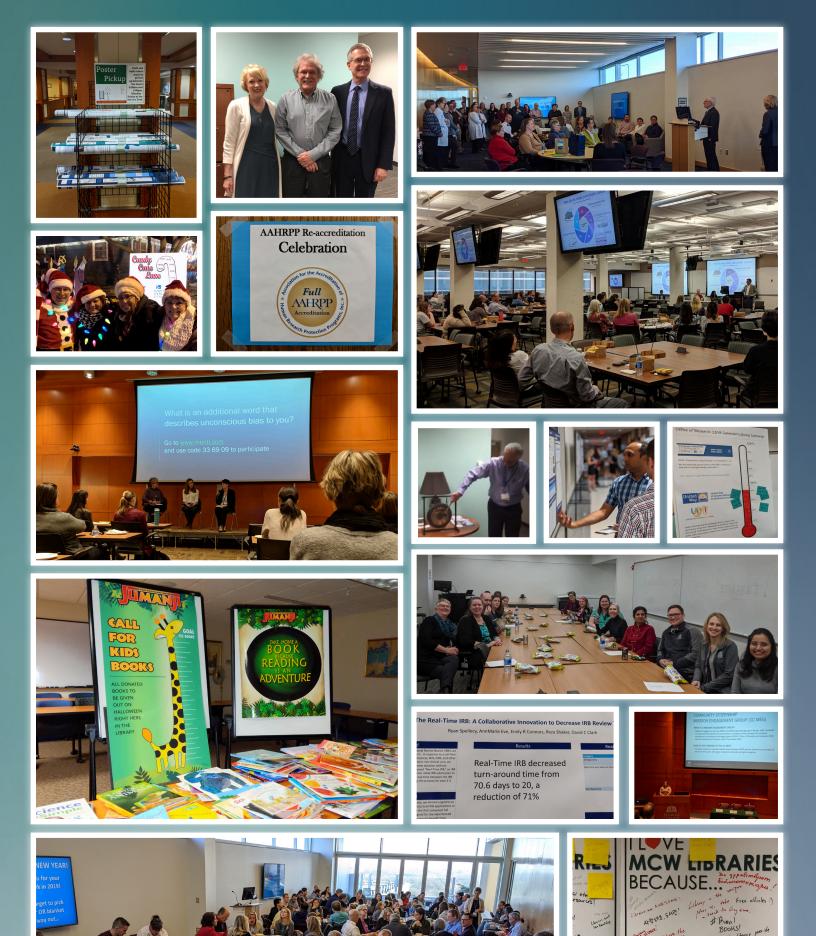


The Year In Review:

Highlights, accomplishments, and activities of the Office of Research in 2019



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Leadership Welcome

Dear Colleagues,

As we prepare for new opportunities in 2020 and beyond, the Office of Research is pleased to close out 2019 with a sense of optimism and accomplishment. Institutionally, the Research Mission has seen an exceptional level of growth and success in 2019. A few of these highlights measured for fiscal year 2019 include:

- Increased overall NIH funding by 12.5% to \$112 million
- Growth in clinical trial revenue to \$17.8 million, a 33% gain
- Increased publications in upper quartile journals by 27% to 1,163

It takes many gears to turn the wheels of discovery. High-quality, high-impact research requires a robust infrastructure that constantly evolves to promote the most efficient and productive programs possible. The Office of Research is always adapting, either by flexing priorities to meet changing needs, developing programs to pursue new opportunities, or identifying methods to improve operations.

If adapting to change is our modus operandi, then 2019 was no exception. This guide provides an outline of our efforts throughout the year, and we hope it illustrates our commitment to providing the best possible research experience at MCW.

Cheers to 2020!



Ann Nattinger, MD, MPH, MACP Associate Provost for Research Professor of Medicine Lady Riders Professor of Breast Cancer Research



Cecilia Hillard, PhD Associate Dean for Research Professor of Pharmacology Director, Neuroscience Research Center



Lisa Henk, MS Chief Administrator for Research Operations

2019 Headlines

Advancing Research Strategic Planning

The Office of Research is partnering with the Dean's Office to progress the Research Strategic Plan. Under the umbrella of the MCW Strategic Framework and in partnership with the School of Medicine, we are working to promote our shared goal of Accelerating Discovery. Our clinical partners, Froedtert Health, Children's Wisconsin, Versiti BloodCenter, and the Zablocki VA, have embraced our research mission as a differentiator among regional organizations. Research Strategic Planning is an all-hands-on-deck effort, and many have contributed to the initial phase by sharing their ideas, refining key points, and helping to identify future needs.

Research Performance Exceed Expectations

In fiscal year 2019, the institution <u>surpassed target</u> <u>achievement</u> for our two research mission goals, which were to increase institutional research grant revenue and to increase total MCW-authored publications in top quartile journals. Research grant revenue, which includes external grants, awards, contracts, and clinical trials, is crucial to fiscal success and productivity. In FY18, total research revenue was \$133.7 million. In FY19, overall research grant revenue rose by 9.5% to more than \$146 million. On the other hand, peerreviewed publications provide direct measure of our scientific contributions and reach. MCW's publishing productivity also exceeded expectations in FY19 with a 27.2% increase in publications in top quartile journals to 1163.

\$265K Awarded to Faculty in 2019 through the Office of Research

The department awarded <u>three grants of \$30K</u> to faculty researchers in the first cycle of opportunities made available through an investment by the Advancing a Healthier Wisconsin Endowment. These cyclical opportunities will continue to be offered in 2020 and beyond. The Research Affairs Committee also awarded seven pilot grants of \$25K to new faculty investigators. The Research Affairs Committee opportunities have traditionally been made available for spring and fall cycles.

Record Funding in Clinical Trials

MCW Clinical Trial funding totaled over \$18 million in fiscal year 2019—the highest levels ever recorded for the institution. These totals, calculated by HERD survey data., are reported to the National Science Foundatoin. Year over year since 2014, total expenditures have been trending upward. MCW had the most clinical trial funding in Wisconsin in FY18 and we hope that remains true for FY19. Benchmarking data will be available later in 2020.

Human Research Protection Program Re-accredited with Distinction



The MCW HRPP Office, which has been accredited by the Association for the Accreditation of Human Research Protection Programs since 2011, <u>received a full three-</u> <u>year AAHRPP re-accreditation for</u> <u>both adult and pediatric research in</u>

2019. The organization noted zero negative findings out of 64 elemental areas during their rigorous site visit in the spring, and noted our Quality Assurance program, community engagement efforts, and IRB Committee Member support as strengths of the MCW HRPP. In recognition of our innovative Real Time IRB review process, our program received the special honor of accreditation awarded with Distinction.

New Members Join Society for Research Excellence

The <u>Society for Research Excellence</u> inducted eight new members at the 2019 Convocation ceremony: William Drobyski, MD, Cecilia Hillard, PhD, Quinn Hogan, MD, Mingyu Liang, MB, PhD, Ann Nattinger, MD, Daisy Sahoo, PhD, Reza Shaker, MD, and Cheryl Stucky, PhD. The Society, coordinated through the Office of Research, was founded in 2017 and has a current membership of 27 faculty. This expanded group is strategizing new ways to both elevate the national reputation of MCW as a biomedical research hub in the Midwest, and to support our current investigators with valuable programs and opportunities.

2019 Headlines

Patent Policy Revision Increases Inventor Share of Licensing Income

The Patent and Copyright policy was revised to increase the share of licensing income paid to MCW inventors to 35%. Faculty, staff, and students work with the OTD to develop and potentially patent their inventions, and the OTD in turn negotiates with industry partners to commercialize these patents in exchange for revenues. The net income resulting from these partnerships had been distributed to the inventor at a rate of 25% for amounts greater than \$5,000. The new 35% rate went into effect on July 1, due largely to the efforts of Kevin Boggs, Director of the OTD.

OCRICC Enhancements and Revised Workflows

The Office of Research partners with Froedtert Health's Office of Clinical Research and Innovative Care Compliance on a regular basis. Together, these MCW and FH teams support clinical investigation and strive to make it better. OCRICC made <u>significant modifications</u> to improve their workflows, including a revised website, streamlined application, and new resources including the FH Operational Feasibility Tool and the FH Research Chargemaster, the latter of which is available on the <u>Office of Research InfoScope site</u>. These efforts have nearly eliminated the back log, and have already reduced the median turnaround time for OCRICC approval to about 30 days.

Key Leadership Change for Human Subject Research Protections Oversight

We were pleased to appoint Ryan Spellecy, PhD, as Assistant Provost for Research and Director of the Human Research Protection Program in December 2019. Dr. Spellecy, who has worked closely with our HRPP and has a significant background in human research ethics, conduct, and compliance, was a natural fit for this dynamic leadership role. David Clark, PhD, who directed the Human Research Protection Program since 2006, retired in 2019. Dr. Clark was granted Professor Emeritus status in recognition of his significant accomplishments and his great breadth of knowledge.

Working to Reduce Regulatory Burden

Much work has been done to reduce self-imposed administrative and regulatory burden. This refers to institutional requirements that are not explicitly required by law, regulation, or government policy. In 2019, the Office of Research established the <u>Committee for Self-Imposed</u> <u>Regulatory Burden</u> to enact and continue the work done by the 2018 ad hoc committee. Members represent a wide cross-section of departments, and the Committee is chaired by an expert in such work, Dr. Joe Thulin. In addition to this committee, Office of Research units are employing process improvement methods for researchers.

Another Successful Research Day

We were pleased to host MCW's annual <u>Research Day</u> event on September 19. The day's activities included a Team Science Session that highlighted three unique research collaborations, and a Keynote Talk on cardiovascular disease delivered by Kirsten Bibbins-Domingo, MD, PhD, MAS, Professor and Chair of Epidemiology and Biostatistics at the University of California-San Francisco. Additionally, 128 presenters were featured at our large poster session, and 18 awards were given to the top scoring abstracts.



Partnerships

The Academic Committee was founded in 2019 to unite key research stakeholders across Froedtert Health and MCW. Dr. Ann Nattinger, Dr. Jonathon Truwit, and Dr. Reza Shaker co-chair the committee, which works to identify and remove barriers to research.

The <u>Human Research Operations Committee</u> launched in 2019 for clinical research representatives to identify and propose improvements in human research operations at Froedtert & MCW. Members represent the Office of Research, Cancer Center, CTSI, and representatives from Froedtert Process Improvement, Froedtert Pharmacy, and the Office of Clinical Research and Innovative Care Compliance.

The Office of Research sponsored or supported multiple interdepartmental Leadership Academy Proposals: "Interdisciplinary Collaborative Research Network" and "Measuring Research Impact" (2019-2020), "MCW Research Administration Program" (2018-2019), and "Standardization of MCW Reported Data & Statistics" (2018-2019).

In partnership with Facilities, the Office of Research helped execute year 2 of 4 in identifying and coordinating swing space throughout Basic Science Building renovations.

The <u>Research Ambassadors</u> program launched in 2019 as an education and communication network for staff in Research Administration. The program, organized by AshLeigh Sanchez, currently includes 40 Ambassadors from several departments, divisions, and centers.



We expanded availability of the popular <u>MCW Engineering Core</u> to all campus users. To support the specialty work and technical support, we grew Core personnel with funding provided by AHW. The Core was also implemented in iLab.

Administrative staff collaborated with the Zablocki VA on a long term freezer storage space solution.

The Office of Research led a Cancer Crush team, raised funds for the United Way and UPAF through our Community Giving Campaign, and supported the Faculty Staff Gift Drive, of which Lisa Henk is Co-Chair of the Committee.

Kevin Boggs and Lisa Henk helped facilitate the Foxconn Smart Cities-Smart Futures contest. Kevin also helped review MCW-submitted ideas, two of which, led by Dr. James Bovie and Bradley Gershkowitz, went on to receive Grand Prizes.

The Payments project team worked to increase research participant's annual cumulative study payment threshold on the MCW <u>Payments Card to \$200</u> before a social security number is required, resulting in increased accessibility and use of the Card.

Jen Brown teamed up with the State of Wisconsin, UW-Milwaukee, Marquette University, and health service providers to establish the Milwaukee Refugee Research Collaborative.



Getting Things Done

Completed interface to pull IRB protocol data and review information from eBridge directly into OnCore, thereby limiting manual data entry and allowing better tracking of protocol activation metrics.

Enhanced MRI research procedures by incorporating Research MRI Safety Committee Review into AUA and PRO eBridge SmartForms. Additionally, transitioned online portion of MRI Safety Training from D2L to our new training server for a more user-friendly experience.

Hosted Focus on Five sessions with Grants & Contracts Office Analysts to provide informal discussion forums to address issues of previous NIH Grant Cycles. 125 research and grants personnel representing over 20 departments attended the sessions.

Collaborated with Finance to establish <u>natural account for</u> <u>OCRICC administrative review fee</u>, thereby exempting the regulatory charge from being subject to F&A.

Launched the Office of Technology Developments' tri-annual newsletter, <u>Developments</u>.

Coordinated financial review in collaboration with external vendor and MCW Compliance to analyze reconciliation of funds for clinical studies, results of which identified over \$187,000 of uncollected revenue.

Increased outlet and electricity capacity in the Todd Wehr Library student study areas by 65%.

Created <u>Research Management LibGuide</u>, a collection of guidance and resources for clinical research personnel.

Developed Research Metrics in line with Space Guiding Principles to identify Research Grant Dollars per Assignable Square Foot as appropriate calculation.

Developed <u>Standard Operating Procedure</u> for use of EPIC CareEverywhere to clarify appropriate use of patient medical records for clinical research.

Enabled new process for select continuation funding proposals to be contained in a single eBridge funding proposal to clarify processes for subcontracts, amendments, modifications, and other events.

Dissolved the Hazardous Chemical Committee and replaced it with an expanded Hazard Communication Process. Particularly Hazardous Substances are identified within the AUA SmartForm and then appropriate guidance is provided to study teams electronically.

Established policy outlining procedures for reporting outcomes on ClinicalTrials.gov, which led to significant reduction in non-compliance. Identified department-based Subject Matter Experts to facilitate CT.gov reporting.

New condensed internal grant workflow that bypasses Grants & Contracts Office review in eBridge in favor of direct submission to internal sponsor.

Generated a full year of purposeful content and relevant news on departmental Twitter channels for <u>@MCW_Research</u> and <u>@MCW_GCO</u>, averaging over 10K Tweet Impressions (views) per month.

Expanded support for the <u>iLab Core Management System</u> and grew the MCW portfolio, which now includes 20 shared resources.

Launched <u>Research Conference Calendar</u> as a new shared Outlook tool for learning and collaboration tool among investigators and research teams.

Completed RFID tagging of all Library assets and successfully instituted a 24/7 Self-Checkout Station.

Promotional effort to increase awareness and adoption of <u>OnCore Clinical Trials Management System</u> with revised website and monthly drop-in sessions. Expanded system clientele to include Herma Heart Institute and Departments of Medicine and Neurology.

People In The News



Ann Nattinger, MD, MPH, MACP, Associate Provost for Research, was appointed to the GRAND Steering Committee of the Association for Academic Medical Centers (AAMC). GRAND, the Group on Research Advancement and Development, provides a national forum on the promotion, support, development, and conduct of biomedical research in medical schools and teaching hospitals. The Steering Committee is an elected group that identifies success strategies, recognizes trends and plans meaningful development opportunities for administrative research leaders at medical schools nationwide. Dr. Nattinger was also appointed to the Program Committee of the Research Group of the Associate of Academic Health Centers.

Kevin Boggs, MBA, PhD, Director of the Office of Technology Development, participated on a panel at the 5 Lakes Forum, an annual learning and networking event for regional tech and startup leaders. To close out the event, Dr. Boggs reviewed "The Future of Innovation in the Great Lakes" with fellow panelists Erik Iverson, Managing Director for Wisconsin Alumni Research Foundation, and Lisa Johnson, CEO of BioForward. The panel answered questions about start-ups and discussed the growing opportunities in the Midwest and Milwaukee.





Our experts presented at the Forte Fall Onsemble, a popular conference for clinical research professionals. **Ryan Spellecy, PhD, AnnMarie Eve,** and **Sara Griffin** of our Human Research Protection Program, along with Dr. Nirav Shah, Department of Medicine, gave a talk on the benefits and efficiencies of our innovative Real Time IRB program.



Sandi Johnson, OnCore System Administrator, also presented at Onsemble. Sandi discussed the importance of design and user experience for study websites, demonstrating our OnCore Clinical Trials Management system.





The Grants & Contracts Office promoted two of their highly skilled staff members to role of Analyst II in recognition of their significant experience and knowledge. **Neal Fitzgerald**, **JD**, has been with the GCO since 2017 and has consistently contributed to the unit amidst growth in volume and services. **Chelsea Spangenberg**, **MBA**, transferred to the GCO from Pediatrics in 2018 as Pre-Award Support Specialist and has provided exceptional support, both for the program and as an Analyst. GCO Analysts review and submit all pre-award, grants-related materials for the institution.

People In The News

Several MCW Librarians have been active in professional associations at both the local and national level. **Kathryn Mlsna, MLIS**, has served as Treasurer for the Midwest Chapter of the Medical Librarians Association (MLA-MC) since 2018-2019. **Elizabeth Suelzer, MLIS**, received the Academy of Health Information Professionals (AHIP) credential from the MLA, and is President Elect of the MLA-MC for 2019-2020. Liz is also Secretary for the Southeastern Wisconsin Health Science Library Consortium, a group for which our Librarians have also served as Presiding Officer—**Elizabeth Witkowski, MLIS**, (2019-2020) and **Eric Harding, MLS** (2018-2019). **Ashley Zeidler, MLIS**, is also President Elect of the Wisconsin Health Science Library Association for 2019-2020.

Librarians Elizabeth Suelzer, MLIS, Rita Sieracki, MLS, Elizabeth Witkowski, MLIS, and colleagues published a paper in *JAMA Network*

Open on a retracted article that is often cited in scholarly works. The 1998 article purported to show an association between the measles-mumps-rubella vaccine and autism, and though it has been retracted, it remains the ninth-most-cited scholarly publication indexed on the topic of autism. Our librarians also presented their work at the MLA-MC Annual Conference and won an award for their poster.

Jill Landrum, CRA, Manager in the Grants & Contracts Office, and Kathryn Mlsna, MLS, Assistant Director for Public Services & Education for the Library, joined Leadership Academy Teams in 2019-2020. Jill's team is tackling the Capstone Project "Inclusion for MCW Learners," while Kathryn's team is looking at "Measuring Research Impact." Additionally, AnnMarie Eve, Manager of the Human Research Protection Program, participated in Leadership Academy 2018-2019. With her team, she collaborated on the Capstone Project "Enhancing Recognition of Committee Service." The project identified strategies for promoting faculty committee service and elevating such work as a contribution to the research mission.





Two staff members of the administrative team, **Cory Corrao**, Administrative Coordinator, and **Derek Gordon**, Financial Analyst, were selected to lend their talents as mentors

to MCW's Administrative Professionals Mentoring Program. The Program provides learning and development opportunities to newly hired administrative professionals by pairing them with experienced administrative personnel.



Ann Amidzich, Intellectual Property Manager for the Office of Technology Development, was selected to join the Association of University Technology Managers (AUTM) Better World Project Committee. The Committee,

which includes members from Baylor, Emory, LSU, and other tech savvy organizations, works to promote the importance of academic research and technology on global health.







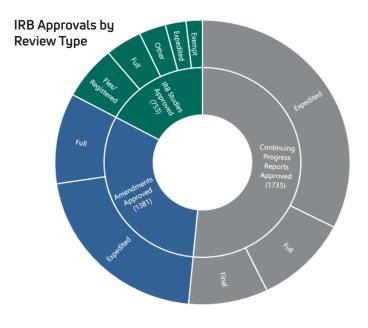




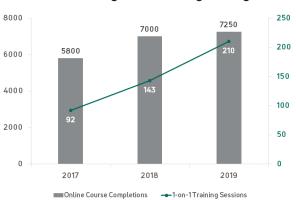


By The Numbers

The Human Research Protection Program oversaw a number of approvals by their six IRB Committees. A total of 3,869 IRB Studies, Continuing Progress Reports, and Amendments were approved in 2019. Additionally, 215 Reliance Agreements were executed.

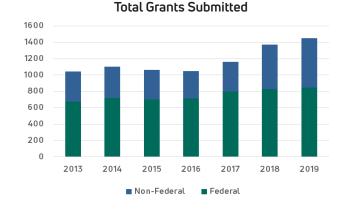


The **Research Systems** team saw an increase in activity with the expanded use of the OnCore and Payments systems. The Help Desk answered over 5,900 tickets in 2019, and the number of eBridge users is at an all time high, now nearly 8,000. The support team fixed 344 production issues and completed 10 projects across the portfolio. System training has shifted with the publishing of 6 new eLearning courses and 30 courses managed at the new site, train.mcw.edu.



Research Systems Training Activity

The **Grants & Contracts Office** experienced a large jump in agreement activity, which includes Industry Sponsored Clinical Trial Agreements, Non-Disclosure Agreements, and Material Transfer Agreements. Total agreement activity jumped from 1,076 in 2018 to 1,204 in 2019, a 12% increase.

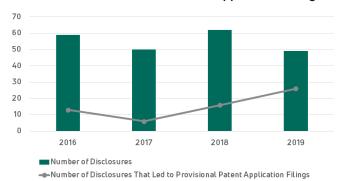


Faculty Support & Communication

Total Faculty Onboarded via Concierge	88
Total New Faculty Departments	26
Issues of Research Publication Series	12
Faculty Featured	56
Fellows, Staff & Students Featured	61
Issues of Research Pulse	13

The **Office of Technology Development** received 49 invention disclosures in 2019, filed 26 new patent applications, and received 14 new patents on behalf of MCW inventors. Additionally, the OTD signed off on 20 agreements as well as 5 licensing/option agreements.

Invention Disclosures & Patent Application Filings

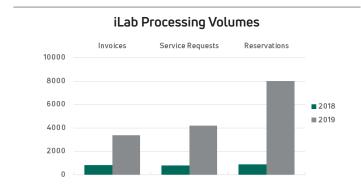


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By The Numbers

MCW Libraries experienced a busy year with a total Gate Count of 168,115. Our librarians facilitated over 2 million journal, eBook and Database usages and helped researchers with eleven systematic reviews, two of which were published. 76 classes were taught on topics including funding searches and the Faculty Collaboration Database, and the digital resource LibGuides were viewed 140,000 times. The Poster Printing service produced 1,509 posters--a 37% increase in volume from 2018.

Customers of the Libraries included over 10,000 MCW faculty, staff, nurses, APPs, students, residents, and fellows. In addition, another 10,000+ patients and their families, as well as the general public, were serviced at the MCW, Froedtert Health, and Children's Wisconsin locations.



The **iLab Support Team** coordinated the implementation of 14 new cores and shared into the system in 2019, adding to the current portfolio of 21 cores and shared research resources.

The **Radiation Safety Office** oversaw a significant amount of research and clinical activity in 2019. RSO personnel support all patient care applications of radioactive materials, including nuclear medicine, Gamma Knife, and room shielding.

Radiation Safety Activity

New Radioactive Materials Authorized Users	3
Authorized User Renewals	11
Radioactive Material Amendment Requests	8
Human-Use Applications Total	125
Human-Use Applications Requiring State Approval	39
Animal-Use Applications	24

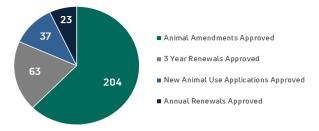
The **Biomedical Resource Center**, which employs about 40 technical staff and 10 administrative staff, cared for 36,236 animals. The team also coordinated 130 animal shipments and held 1,329 training opportunities.

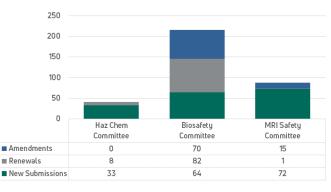
BRC Statistics

Total Board Days	4,956,705
Total Animals Annual	36,236
Mice	29,079
Rats	7,086
Average Daily Census	13,580
Mice	9,693
Rats	3,543

The Institutional Animal Care and Use Committee Office, which supports the IACUC, administratively processed 65 Animal Amendments, 363 Personnel Changes, and 309 Funding Changes. 71 in-lab visits and follow ups were completed uner the Post Approval Monitoring program.

Approvals by Institutional Animal Care & Use Committee





Safety Committee Protocol Activity

Welcomed in 2019



Ryan Spellecy, PhD, was named Director of the Human Research Protection Program and Assistant Provost for Research effective December 1. Dr. Spellecy, the Ursula von der Ruhr Chair in Bioethics and Professor of Bioethics and Medical

Humanities and Psychiatry and Behavioral Health, has a significant background in human research ethics, conduct, and compliance. He received his PhD in Philosophy from the University of Utah and has been a member of the MCW faculty since 2002. During this time, he has served as chair of an IRB committee and has pioneered his own research program in informed consent, ethical issues in mental and behavioral health care, and communityengaged research ethics. He has authored numerous publications on informed consent, regulatory matters, and ethical concerns. Additionally, he spearheaded the Real-Time IRB program, an MCW-first, national development in making human research procedures more streamlined and transparent. Dr. Spellecy is also a passionate educator and has taught courses in the Center for Bioethics and Medical Humanities for many years, having earned the Outstanding Graduate School Teacher Award in 2015-2016.

Dr. Spellecy served as Co-Principal Investigator for an NIH-funded Blood and Marrow Transplant Clinical Trials Network national study evaluating informed consent for blood and marrow transplant trials. He also recently completed a study of the strengths and barriers in Milwaukee's African American community concerning participation in cancer clinical trials. Dr. Spellecy will maintain his research and teaching responsibilities in the Institute for Health and Equity in conjunction with his HRPP leadership role.



Emmalee Hanchek joined the Human Research Protection Program in March as an IRB Coordinator II and has been supporting the HRPP Institutional Reliance program. Previously, Emmalee worked as a research coordinator in Neurology and has prior experience in

Good Laboratory Practice quality assurance.



In the new position of Research Resource System Coordinator, **Rita Sigmund, MA**, joined the administrative team in March. Rita previously worked at the University of Iowa as a research scientist and core facility manager. In her current role, Rita is a part time

administrator for the iLab Core Management System.



Marcus Hendrickson, MS, joined the Human Research Protection Program in May as an IRB Coordinator II supporting the minimal risk IRB committee. Marcus earned his master's degree in Experimental Psychology from Western Illinois University, and has

previous experience as a human subjects pool coordinator.



The Human Research Protection Program welcomed **Cara Marzion** to their team in June, supporting the minimal risk IRB committee as an IRB Coordinator II. Cara has a bachelor's degree in Biological Science and an undergraduate certificate in Medical

Assisting. She is also pursuing her Master of Public Health as an MCW graduate student.

Welcomed in 2019



Melissa Lechner joined the Human Research Protection Program in June as an IRB Coordinator II in support of IRB Committee #4. Most recently, Melissa graduated from UW-Milwaukee with a bachelor's degree in Psychology and Sociology. She also has prior

experience in finance.



The Grants & Contracts Office welcomed **Erika Kyle** to their team in August as a Grants Analyst II. Erika moved to Milwaukee from Pittsburgh a few years ago, and previously worked in philanthropy, community relations, and events for various for-profit, non-

profit, and educational institutions.



Carrie Herdeman, CCRC, joined the Grants & Contracts Office in August as a Grants Analyst II. Carrie joined MCW in 2013. Before transferring to GCO, she supported the department of Obstetrics & Gynecology as a Clinical Research Coordinator, a role in which

she specialized in vulnerable populations research.



In August, **Chelsea Hamilton**, **MS**, joined the Grants & Contracts Office as a Grants Analyst II. Chelsea has a master's degree in Education with a focus on families. Chelsea has experience as a Grant and Outcomes Manager, and previously worked at

MCW as a Research Coordinator in Community Pediatrics.



Emily Fey, JD, joined the Grants & Contracts Office in September as a Contracts Analyst II. In this role, Emily reviews and negotiates MCW contracts related to clinical trials and research studies. Emily has previous experience in estate planning, trust administration,

family and asset protection planning, and probate law.



The Human Research Protection Program welcomed **Taylor Griffith** in September as an IRB Coordinator II in support of IRB Committee #1. Taylor earned her bachelor's degree in Economics and Mathematics from UW-Whitewater. She has previous

experience in nonprofit development.



Scott Brooks joined the Human Research Protection Program in October as an IRB Coordinator II supporting IRB Committee #6, which specifically reviews safety events and amendments for cancer studies. Most recently, Scott worked in the Applied

Research Lab at Versiti-Wisconsin as a lab supervisor.

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