Office of Research

COVID-19 Report & 2020 Year In Review

A dual summary highlighting the work of the Office of Research throughout the pandemic and during the calendar year.









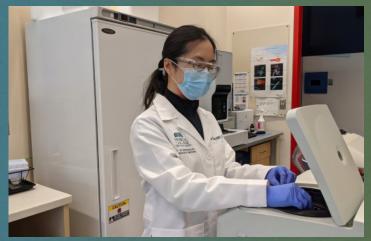


































Leadership Welcome

To our colleagues and friends,

What can be said about 2020 that has not already been expressed... It was an absolutely unprecedented year and an extremely challenging time, not only for all of us as research faculty and staff, but for each of us as people. We are all incredibly proud of the work we have been able to accomplish as an institution despite the ever-changing and difficult landscape we found ourselves in from mid-March of 2020 and on.

The Office of Research was heavily involved in navigating and addressing the impact of COVID-19 on research, actively participating in the complicated task of keeping everyone safe while limiting the impact of the pandemic on our research programs. Our teams worked diligently to support our research portfolio, but to also achieve several successes throughout the year and see through on previously committed plans and projects. For that reason, we are dually featuring a report of our COVID-19 work with our annual Year In Review.

We wish to thank everyone who has made contributions to the research mission and realized the importance of this work throughout the pandemic. There are so many wonderful things on the horizon—growth, change, optimism, and hard work, just to name a few. We are indeed fortunate to have the opportunity to support research and improve health for all.



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, MSChief Administrator for Research
Operations

The onset of the coronavirus pandemic required a swift response and quick action to mitigate any negative effects on our outstanding research programs. Throughout those first challenging weeks and though the duration of the pandemic, the Office of Research has worked in partnership with MCW leadership and the COVID-19 Response Task Force to safely and responsibly address concerns and needs. Each unit in the department took a proactive approach to ensuring research could continue to the extent possible, and that the MCW community as a whole had appropriate guidance and resources to navigate their work.

April 2020

A new Committee to Review Essential Experimentation was established to review scientific COVID-19 research applications for continuing critical work during hibernation and subsequent Critical Experimentation requests.

The IRB began an expedited approval process for COVID-19 related studies, including the approval for the first patients infused with Covid-19 convalescent plasma in collaboration with Froedtert Hospital and Versiti.

A new InfoScope page was developed to list available COVID-19 studies for clinical referrals.

Lab Hibernation and suspension of clinical research involving face-to-face contact with subjects that offered moderate or no potential benefit to patients continued through April, 2020, while Office of Research-led committees and representative leaders met frequently to discuss PPE needs, personnel concerns, ramp-up plans, and what the next several months of MCW research would look like.

March 2020

MCW Research Leadership began holding urgent meetings to plan pandemic response for lab and clinical research operations. The department developed a COVID-19 & MCW Research InfoScope page that was launched to house news and information.

The HRPP Office issued IRB Guidance to limit need for IRB reporting of precautions taken to protect research subjects (such as transitioning to virtual visits).

On March 17, a <u>Phase 1 Slow-Down</u> of Research Labs took effect. This limited new experiments, enacted a freezedown of cell lines and reductions in animal breeding and inventories. Non-critical lab personnel were then required to work remotely. In cooperation with the BRC, new animal orders were suspended.

On March 24, <u>Mandatory Lab Hibernation</u> was implemented for over 200 MCW research labs. More than 95 investigators submitted Critical Experimentation requests to continue lab work in a limited capacity. These requests were coordinated, reviewed, and vetted by the Office of Research.

An additional InfoScope page was created to provide updates on Research Core & Service Statuses.

Later in the month, the HRPP Office issued a <u>suspension of</u> any human subject research that had little to no potential benefit to subjects if and when face-to-face contact would be required. Subsequently, further suspension of human subject research was enacted to cease studies offering moderate potential direct benefit to subjects if and when face-to-face contact would be required. Together with clinical campus leaders, the Clinical Research Appeals Group was established to review requests for study continuation in cooperation with clinical partners.

Similar to peer institutions, department leadership issued a public statement on COVID-19 and MCW Research, and new COVID-19 research funding opportunities were posted publicly.

Department personnel coordinated collection and donation of substantial amounts of PPE from research labs to clinical partners.

May 2020

On May 4, research labs entered <u>Phase A of COVID-19 Lab Ramp-Up Plan</u>. The PI + 1 additional person were allowed in labs with physical distancing precautions in place including recommended shift work and staggered experimentation. Animal breeding was still not permitted, however requests for exemption were considered. Decontamination, hand-washing, wearing of face coverings, and other precautions remained in place.

A Clinical Reactivation Subcommittee was established, including members of Office of Research, CTSI, OCRICC, A-TRU, and key clinical research leaders. Guidance for Reactivation of Clinical Research was released requesting that departments prioritize studies that offer critical to moderate benefit to patients. Campus announcements were released regarding reactivation in the coming weeks, and the Clinical Reactivation Subcommittee began meeting to assess priority studies for reactivation.

Research leaders continued conversations to develop a COVID-19 testing program for research personnel and to plan and coordinate availability of PPE for research labs. Committees continued to convene and assess the financial status of the institutional research portfolio and discuss strategies for recovery and reimagining of research.













June 2020

The <u>Clinical Research Reactivation Plan entered Phase A</u> on June 3, which permitted critical studies to reengage as evaluated by the Clinical Reactivation Subcomittee.

<u>Lab Reactivation entered Phase B</u> on June 8. The PI + 2 additional people were allowed in labs with physical distancing precautions in place. Animal breeding continued to be restricted with requests for exemption considered.

MCW Libraries further developed the <u>COVID-19 LibGuide</u>, a continuously updated resource for related information and publications.

A new BSL3 Facilities and Procedures Work Group was established to evaluate capacity of Biosafety Level 3 Facilities, potential workflows, and safety concerns for working with SARS-CoV-2.

A new COVID-19 Grant Pursuit page was published to InfoScope to allow like-minded investigators and potential collaborators to make connections, and to share more broadly a snapshot of MCW COVID-19 research.

July 2020

The <u>Clinical Research Reactivation Plan entered Phase B</u> on July 6, in which departments could permit their study portfolios to incrementally re-open. New studies were also permitted.

The Lab Research Personnel Surveillance Testing Program was initiated on July 13. PCR viral tests were offered every 2 weeks for asymptomatic individuals through Internal Occupational Health to identify and isolate any potential cases on campus. Antibody blood tests were offered every 90 days for asymptomatic individuals through Internal Occupational Health to potentially detect prior cases.

The MCW Tissue Bank, in partnership with the Office of Research, the department of Pathology, and the Adult TRU and CTSI, began offering COVID-19 research biospecimens to investigators. In addition to autopsy samples, a process was initiated to collect samples from COVID-19-positive, consented patients, with samples being processed, banked, and distributed to the MCW community.

With the increased interest in working with COVID-19-positive patients, new site-specific research committees were established in the Medical Intensive Care Unit, Emergency Department, and on inpatient units. The Office of Research helped facilitate these groups with Froedtert Hospital leadership.

December 2020

The Office of Research submitted an application to the state for MCW to be a COVID-19 Vaccination site. Office of Research personnel partnered with the School of Pharmacy, Froedtert Hospital, Facilities, and the COVID-19 Task Force to stand up the MCW COVID-19 Vaccination Clinic. The group coordinated receipt and cold storage of the vaccine product, and assembled a team to accept patients, administer vaccines, and track doses in the Wisconsin Immunization Record.

Several faculty, staff, and student immunizers were recruited from School of Pharmacy and departments including Medicine, CTSI, and the Office of Research.

The first shipment of the Pfizer-BioNTech vaccine was received on December 21. The MCW Clinic was set up on the 1st floor of the Hub building and offered the first doses of vaccine on December 22.

August - November 2020

A new stage, Phase B2, was incorporated into the Lab Reactivation Plan in response to investigator needs to increase productivity and in the context of personnel adhering to the existing guidance while on campus. This moderate increase in flexibility was initiated on August 10. The PI + 4 additional people were allowed in labs with physical distancing precautions in place. Routine animal breeding and ordering was permitted, and surgical/procedural support services were again offered by the BRC.

"Close Quarters" work, that which must be done within the 6-foot bubble of physical distancing, has special guidance released for PPE and safety considerations. Committees continued to convene to begin reimagining research-related work: including virtual work options, safety protocols and guidelines, and what future research would look like.

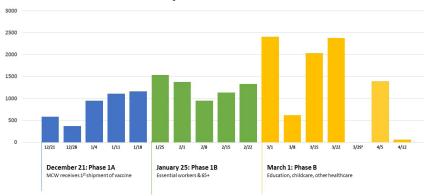
Follow-up testing under the Surveillance Testing Program was made available through the GSPMC and Adult TRU.

An Office of Research PPE Service Center was established to secured inventory of PPE including masks, gloves, and hand sanitizer at competitive rates. A store room was stocked and an iLab ordering site was launched for easy and efficient transactions.





Doses Administered per Week in MCW C-19 Clinic

















January - March 2021

In January, the MCW Clinic team vaccinated Phase 1A employees, healthcare workers, and other affiliated essential health care personnel. Clinical MCW volunteers were recruited to assist with vaccine administration and compounding, and non-clinical MCW volunteers signed up to support the clinic, including check-in, sanitizing, and post-monitoring.

The Office of Research began hosting a National Guard and State of Wisconsin team on site utilizing MCW as a cold-storage vaccine inventory hub supplying regional sites.

In February, the MCW Clinic vaccinated Phase 1B eligible personnel, including employees 65+, as well as local fire, police, and unaffiliated health care workers. The team coordinated training of MCW Medical Students as vaccinators in partnership with Academic Affairs.

In March, the MCW Clinic vaccinated Phase 1C eligible personnel, including MCW employees, community members, and unaffiliated education workers and individuals with underlying health conditions. Capacity in the clinic allowed MCW to offer employees the opportunity to nominate an eligible individual for vaccination.

April 2021

The MCW Clinic vaccinated additional community members and finalized second doses, with the clinic sunsetting on April 14. Nearly 20,000 doses were administered, fully vaccinating roughly 10,000 people, and with zero wasted doses at the end of all clinic days. In total, 219 School of Medicine and School of Pharmacy students were trained in the MCW clinic.

New Phase C guidance was developed under the revised Research Reactivation Plan to go into effect May 1. Under the new guidance, additional personnel were permitted in labs with a new 3-foot physical distancing requirement. All suspensions on clinical research were lifted, and on-campus activities for clinical research support staff, including consent, recruitment, and special data analysis, were permitted. 3-ply disposable masks were required to be worn in labs, ancillary research areas, and clinical spaces, as well as other MCW-wide precautions.

Research Headlines

Unique Office of Research Awards through AHW

Through an investment by the Advancing a Healthier Wisconsin Endowment, the Office of Research has been able to offer unique funding opportunities to address specific institutional funding needs. The Office of Research awarded three Competitive Resubmission grants of \$50,000 for faculty who previously submitted R01-level grant applications that were scored but not funded: Kajana Satkunendrarajah, PhD (Neurosurgery); Guan Chen, MD, PhD (Pharmacology & Toxicology) and Brian Hoffmann, PhD (Biomedical Engineering). In addition, three Limited Needs grants of \$30,000 were awarded to faculty to purchase special equipment or software needed to enable or augment existing studies in need of resources: Jacek Zielonka, PhD (Biophysics); Suresh Kumar, PhD (Pathology) and Nita Salzman, MD, PhD (Pediatrics). The AHW team also developed a new RFA to support the coalescing of teams to pursue Program Project Grants (PPGs) and were able to release the RFA in early 2021.

Research Affairs Committee Awards

Over the spring and fall cycles, seven MCW junior faculty were awarded pilot grants of over \$30,000 each. These funds support the development of preliminary results so that these promising investigators can competitively seek extramural funding. The Committee reviewed 36 applications total, making awards to the following faculty members: Gwen Hoben, MD (Plastic Surgery); Vanessa McFadden, MD (Pediatrics); Emma Morrison, PhD (Biochemistry); Patrick Murphy, MD (Surgery); Jenna Sarvaideo, DO (Medicine); Ravi Singh, PhD (Pathology) and David Gazeley, MD (Medicine), who received the focused Lupus award. The RAC Pilot grant continues to be an excellent mechanism for new faculty in pursuit of RO1-level funding.

Society for Research Excellence



The MCW Society for Research Excellence inducted six new members in 2020: William B. Campbell, PhD (Pharmacology & Toxicology); Julia Dickson-Gomez, PhD (Institute for Health & Equity); Stephen W. Hargarten,

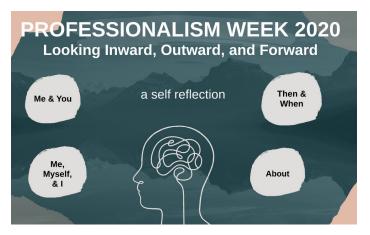
MD, MPH (Emergency Medicine); Julian H. Lombard, PhD (Physiology); Michael McCrea, PhD (Neurosurgery) and Gilbert C. White, MD (Medicine). The Society of Research Excellence helps support institutional programs such as review of applications for limited grant opportunities.

FY20 Research Mission Goal Success

Despite the challenges brought on by the pandemic, MCW research teams achieved all but one of six mission goals in fiscal year 2020. This included diversification of the grant portfolio by increasing non-NIH funding by 2.37%, increasing NCI funding by 8%, and increasing interventional accruals to pediatric and adult cancer clinical trials by 8%. This success positions the research mission to continue a growth trajectory with uninterrupted progress.

Professionalism Week: A Self Reflection Activity

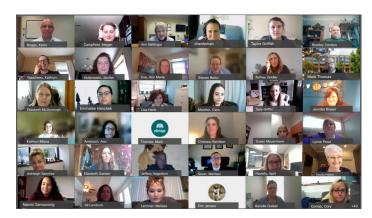
In the spirit of the PW2020 theme of "Looking Inward, Outward, and Forward," the Office of Research was pleased to host a special digital activity for all MCW faculty and staff. In the vein of self-reflection, thoughtfulness, and positive intention, we issued an anonymous assessment for individuals to consider themselves in terms of attitude, awareness, and progression. The results of the assessment were published in an interactive web format and shared with campus during Professionalism Week in October.



Smart Cities—Smart Futures Winners

Early in 2020, we congratulated the winning teams of MCW that advanced through Foxconn's Smart Cities—Smart Futures competition, which included two Grand Prize-winning projects. Joseph Bovi, MD, let a team from MCW including Christopher Schultz, MD, Fernando Santos-Pinheiro, MD, Jennifer Lindstedt, APNP, and Carolyn Brausch, RN. Bradley Gershkowitz, MCW medical student, led a team including fellow students Keayra Morris and Elizabeth Moore, as well as faculty mentors Brad Crotty, MD, and Melek Somai, MD. MCW also had three teams qualify for Round 2, those captained by Thomas Chelimsky, MD (finalist), Vasil Kukushliev (finalist), and Gopika SenthilKumar.

Adapting to Change



Office of Research units maintained a continuity of coverage throughout the pandemic. The Radiation Safety unit maintained campus presence during the first few weeks when only frontline workers were in clinical environments. Other units pivoted to remote work with zero down time, offering a continuity of research systems support, library reference services, IRB and IAUC committee meetings, and review of grant proposals. The Library also produced a Remote Work LibGuide, which assisted personnel and teams in navigating resources away from campus, and continued Clinical Medical Librarianship for clinical and research staff, including highlevel searches, dissemination of information, active support of research and publication, and virtual consultations.

The MCW HRPP Office was instrumental in directing clinical research teams to safely operate at the onset of COVID-19. This included directing a partial shutdown of clinical research, but also in developing and issuing new guidance for obtaining consent while minimizing person-to-person contact. This included offering numerous options for study teams, including RedCap, email, phone, and others.

New COVID-19 research quickly sprang up among MCW investigators, often resulting in new regulatory applications. The Office of Research maintained intake of new approval requests, including 116 new COVID-19-related funding proposals and 122 new COVID-19-related protocols, the latter of which were expedited for agile responsiveness.

MCW Librarians worked on several literature searches for MCW Leadership and the MCW COVID-19 Task Force. Subjects included pandemic planning, COVID-19 transmission modeling, school transmission, hydroxychloroquine, infodemic, working remotely, reopening, and disaster relief impact on mental health of staff.

MCW Librarians partnered with the Office of Diversity and Inclusion to develop an Anti-Racism LibGuide that will provide access to a searchable, ODI selected, anti-racism resource list. This guide will also feature links to ODI workshops and events and other helpful resources that support MCW's commitment to becoming an anti-racist institution.

The Office of Research was pleased to host a departmental effort to raise funds for the United Way of Greater Milwaukee and Waukesha County and the United Performing Arts Fund during the 2020 Community Giving Campaign. Through virtual trivia sessions and a photography contest, the department raised over \$4,800 dollars during the campaign, with 26.5% participation.

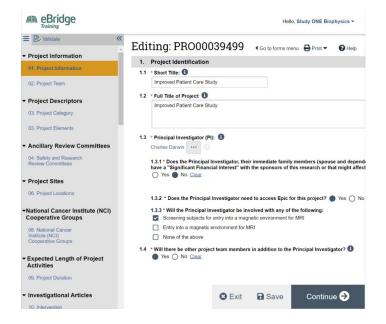
Staffin the Biomedical Resource Center supported operations in the animal facility seven days a week for the duration of the pandemic, providing on-site care and maintenance during hibernation and throughout research reactivation. The BRC also moved training classes online to the extent possible to meet the demands of socially distant work, which provided more convenient learning options for researchers. Classes that remained in-person due to content were adapted for new COVID-19 safety guidelines.





Making Research Better

The Research Systems team tackled major projects in 2020, including significant enhancements to the appearance and function of application SmartForms. SmartForms now have an improved left-panel navigation, sticky navigation buttons to Save, Continue, or Exit, and a Validation feature to scan for errors. Reviewer Notes are now integrated into the SmartForms, and an easily accessible Help feature with module-specific resources now appears in the main navigation. An overview of all changes can be reviewed in the preview video.

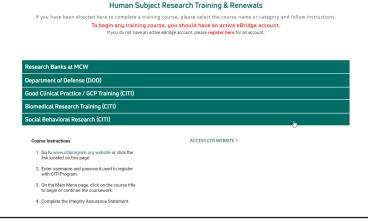


In cooperation with the HRPP, the Systems team launched a project to have Reliance Requests fully processed through eBridge. Reliance Requests allow an MCW protocol to rely on an external IRB. Now a single point in the PRO SmartForm for MCW research teams to submit a Reliance Request, it replaced every component of the former paper process. The SmartForm allows the user to identify all types of reliance on another IRB, including Commercial IRBs, CTSI Partner IRBs, National Cancer Institute (NCI) CIRB, National Marrow Donor Program (NMDP) IRB, and others. It also includes a new trackable and transparent reliance acceptance process and a new Reliance Dashboard. Additionally, the process to submit protocols in which MCW would serve as the single IRB was modified for the MCW PI and study team to only have to submit the protocol and details of local (MCW/FH/ Versiti) involvement for initial IRB approval. Relying external sites are now added after initial approval via subsequent amendments. This speeds up the initial approval and focuses each approval and amendment to the context of that request.

IRB fees, which are charged for studies that undergo review by our MCW IRB committees, underwent a billing implementation. Now, all IRB fees are assessed through iLab. The new process applies to 1) industry-sponsored for-profit research projects that meet the NIH definition of a clinical trial; 2) administrative review fees for projects deferred to another IRB; and 3) projects where MCW is serving as the single IRB of record for multi-site research. This transparent system allows departments to quickly and easily assess fees and attribute to sponsors as needed. The implementation has also significantly streamlined the billing and collection process within Office of Research administration.

Research-related Professional Billing underwent a standardization process change, under which all professional research-related charges are now submitted to CPS through the new MCW-Human Research Charge Notification form. This HIPAA-compliant Qualtrics form assures the required information for research claims management is received by Clinician Physician Services (CPS), regardless of whether the clinical trial involves a drug, device, or other biologic or who will be responsible for charges. The project was coordinated by the Office of Research in collaboration with CPS and MCW Corporate Compliance and successfully created a standardized process for the submission of MCW professional (provider) research-related charges.

Early in the year, <u>train.mcw.edu</u> was released as a new, centralized, easy-to-access and easy-to-navigate website for research training. This included safety, human research subjects, and compliance training. Over the year, it has expanded to include clinical trial support materials such as study start up documentation, research billing support, and CMS submissions. New content will continue to be made available. Train.mcw.edu will also host Toolboxes for clinical research onboarding and other key audiences.



Making Research Better

The **Epic Research Module**, which provides F&MCW researchers the ability to associate Froedtert patients and their visits with a specific research study, officially went live in the fall of 2020. The ERM can support enhanced research-related documentation associated with care & treatment, facilitate study recruitment and billing, and provide event notifications. A major advantage of the Epic Research Module will be the integration with OnCore CTMS, to automate study & subject tracking. The Office of Research worked diligently to bring this project to fruition, and our teams offered training and support before, during, and after go-live.



Much work was done around the OnCore Clinical Trials Management System in 2020. A new SOP was published around Data Entry and Quality Assurance Guidelines to increase accurate, timely, and complete data entry for protocol and subject information. The departments of Surgery, Neurology, and Medicine had their study portfolios fully implemented into OnCore, allowing them to take advantage of new and future integrations including the Epic Research Module. OnCore Drop-In Sessions, our informal training series, were brought back in virtual format. And the Physician SIP (Study Information Portal), which is currently in beta testing, began development. It will allow more study exposure to physicians leading to increased referrals.

The Grants & Contracts Office developed a new Human Subjects and Clinical Trials (HSCT) Information Guide in response to frequent questions concerning the SF424 Human Subjects and Clinical Trials form. GCO collaborated with the IRB team to create a guide that pulls together both internal (MCW PRO questions) and external (NIH, clinicaltrials.gov) sources of information for completing protocols.

The institutionally supported Pre-Award Support Services (PASS) Program in the Grants & Contracts Office is intended to assist clinical departments and their PIs with a variety of NIH grant application submissions. The total number of available slots for each NIH funding submission cycle expanded in 2020 and the program was able to offer assistance to a greater number of PIs per cycle.

The HRPP issued **new FDA guidance** to comply with new requirements that greater than minimal risk FDA-regulated studies had more extensive consent requirements.

The Early-Stage Research Regulatory Oversight Program was established in 2020 as an institutional effort to manage Investigational New Drug (IND) and Investigational Device Exemption (IDE) approvals. Led by Dr. Kristin Busse, the program provides education to faculty and staff on FDA granted IND and IDE's. Additionally, the program registers and tracks investigator held IND/IDE, and serves as liaison to the FDA and the Office of Human Research Protections (OHRP) for research teams and the institution.

The PI Eligibility policy was revised and republished to include all areas of research that outline specific eligibility requirements for Principal Investigators, including funding proposals, human subject protocols, animal use applications and Institutional Biosafety Committee applications.

The MCW Libraries implemented **Clio**, a new more cost effective system for inter library loan requests. Clio was implemented in February which resulted in greater convenience for users.

The Administrative team supported the SIMS upgrade project in coordination with Facilities, Finance, and Information Services to help deliver a high quality, user friendly version of the Space Information Management System.

The BRC formed its **Continual Improvement Steering Committee for Operational Excellence** (CISCOE). The CISCOE works to improve processes with a focus towards eliminating waste and ingraining Lean, as well as incorporating other continuous improvement methods into BRC culture and encouraging those doing the work to recommend changes. The inaugural committee is comprised of CISCOE Team Lead, Carly Saugstad, Megan Anderson, Sydney Buday, Megan Kreuter, Gail Morris and Kami Young.

The Office of Technology Development created and published the **Innovator's Start-Up Guide**, a resource that offers help and guidance for inventors who want to become entrepreneurs. The <u>Guide</u> was developed in collaboration with the MCW Legal Office and local industry professionals.



Our People



Joseph Thulin, DVM, MS, DACLAM, was named Assistant Provost for Research, Biomedical Resource Center, on January 1, 2020. Dr. Thulin has served as director of the BRC since 2007, and is an Associate Professor in the department of Physiology. He has raised the reputation of MCW's animal facility

as one of the most high-quality and operationally efficient in the region. This promotion recognized Dr. Thulin's significant contributions to animal research at MCW, and his expanded leadership in strategic planning efforts and administrative responsibilities.



Cecilia Hillard, PhD, Associate Dean for Research and Director of the Neuroscience Research Center, joined the Board of Directors of BioForward Wisconsin in 2020. BioForward is an independent organization that provides services and resources to support the state's biohealth industry, with the goal of providing meaningful

networking opportunities and educational programming to biohealth professionals, and to advocate for the importance of biohealth in Wisconsin and beyond. Dr. Hillard brings her expertise in pharmacology and her strong industry advocacy to the leadership of this important organization.





The MCW Librarians have not let COVID-19 slow down their activities in the local and state community of medical library science. Several MCW Librarians have been active in professional associations at both the local and national level. **Ashley Zeidler, MLIS**, took on the role of President for the Wisconsin Health Science Library Association. **Elizabeth Witkowski, MLIS**, was presiding officer for the Southeastern Wisconsin Health Science Library Consortium (SWHSL) for 2020. **Kathryn Mlsna, MLIS**, has served as Treasurer for the Midwest Chapter of the Medical Librarians

Association (MLA-MC) since the 2018-2019 academic year. **Elizabeth**

Suelzer, MLIS, is President of the MLA-MC for 2020-2021, as well as Secretary for the Southeastern Wisconsin Health Science Library Consortium (SWHSL). Suelzer was named 2020 WHSLA Librarian of the Year after being nominated in recognition of her efforts in the research of citation behavior around retracted articles. She was also interviewed in articles about retracted literature published in *Nature* and *Science* where she shared her knowledge and perspectives on citing retracted publications responsibly.









As professionals with significant skills, training, and education in library science, the MCW Librarians also support researchers by conducting literature searches and systematic reviews. These technical projects thoroughly search and assess bodies of literature, and the collaborative efforts often result in publications. Several MCW librarians were acknowledged as authors this year. Elizabeth Suelzer, MLIS, Rita Sieracki, MLS, and Eric Harding, MLS, contributed to six papers in 2020 that appeared in peer reviewed journals.

Our People



The Office of Research and School of Pharmacy welcomed Kristin Busse, PharmD, BCPS, as Assistant Professor of Pharmacy Administration & Regulatory Sciences as well as Research Oversight Program Director. In addition to developing pharmacy curriculum, Dr. Busse provides leadership as a regulatory expert in support of early-stage development of investigator-initiated

clinical studies. As Program Director, she guides investigators and their teams in the disclosure, use, protection, and development of new discoveries and novel technologies, and help liaise with organizations such as the Food & Drug Administration (FDA) and the Office for Human Research Protections (OHRP). Kristin played an instrumental role in MCW's COVID-19 Vaccination Clinic.



The Office of Research Administrative team welcomed **Bradley Condon, CPA**, as Senior Financial Analyst in October, 2020. In this role, Brad's responsibilities include research mission reporting and lead iLab system support, as well as other data projects under the research mission. Brad joined MCW in 2008 as a Financial Analyst in Medicine, working on pre and post award

grants & research project finances. In 2015, he became Research Administrator for Radiology and the Center for Imaging Research (CIR). Brad has a Bachelor's Degree in Accounting from Carroll College and also holds a CPA license. He played a key role in data and reporting during the MCW COVID-19 Vaccination Clinic.



The Office of Research is very proud of our two staff members who achieved MCW service anniversary milestones in 2021. Lynne Prost, Business Manager for central administration, and Rita Sieracki, MLS, Reference Librarian, both celebrated 30 years of service to MC W. Both Lynne and Rita have been in their respective units for the duration of their tenure, and have made

tremendous contributions to the department. We thank them for their ongoing committment to the Office of Research and MCW.



Sue Mauermann, RN, CCRC, joined the administrative team of the Office of Research in the new role of Clinical Trial Budget Negotiation and Start-Up Specialist. This position, which is under the umbrella of the Office of Research

AHW grant, is designed to help identify barriers that delay study start-up. Sue is also working to improve workflows and processes to allow for more efficient and timely opening of clinical trials. In addition, Sue is developing resources for study teams, liaising with sponsors, and assisting with budget negotiations. Sue joined the Office of Research from the Department of Medicine, where she supported the Cardiovascular Division as a Compliance Coordinator. During the MCW COVID-19 Vaccination Clinic, Sue had an invalable role in administering vaccinations and training faculty, staff, and student vaccinators.

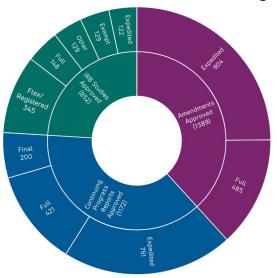


Landon Olp, PhD, joined the Office of Technology Development in the spring of 2020 as a Licensing Manager. In this role, Dr. Olp is responsible for evaluating the commercial viability and patentability of MCW's inventions as well

as supporting the commercialization of MCW's intellectual property. He brings both academic and industry experience to the OTD in biomedical research, product development, business development, and innovation methods. Prior to joining the OTD, he worked in R&D and Business Development at Streck, Inc. Landon received a bachelor's degree in Cell and Molecular Biology from Concordia University, Nebraska and a PhD in Virology from the University of Nebraska—Lincoln.

By the Numbers

Institutional Review Board Activity



The Institutional Review Boards expedited approval for 65% of Amendments and 64% of Continuing Progress Reports. Additionally, 345 studies, or 40% of all new studies, were eligible for FLEX review.

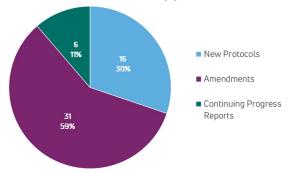
Biomedical Resource Center Census Stats

Total Board Days	4,572,565
Total Animal Annual	34,562
Average Daily Census	12,497
Mice Annual	28,963
Mice Average Daily Census	9,654
Rats Annual	5,513
Rats Average Daily Census	2,757
Training Opportunities	631
Animal Imports/Exports, Domestic & International	107

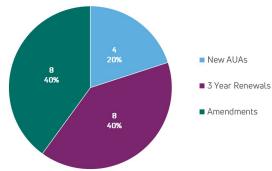
Despite COVID-19 having a significant impact on animal studies, the number of total board days was down just 7.7% from 2019 to 2020. The total animal annual census was down by 4.6% from 2019 to 2020.

The BRC technical support staff maintained continued committment and composure from the outset of the pandemic on, even during heightened precautions such as the state's Safer at Home order.

Human Submissions Approved with MRI

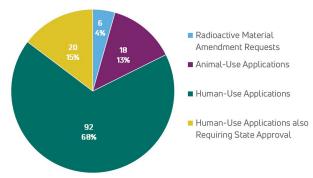


Animal Submissions Approved with MRI

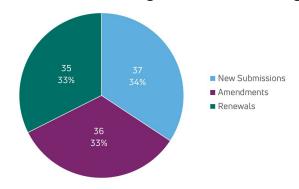


Note: MRI data is no longer stand-alone because MRI approvals were incorporated into the AUA and PRO SmartForms in 2019. The Hazardous Chemical Committee (HazChem) was dissolved in 2019 and replaced with the HazChem Communication protocol, therefore separate committee review numbers are no longer tracked.

Radiation Safety Activity

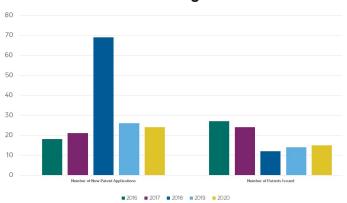


Institutional Biosafety Committee Activity



By the Numbers

MCW Patent Activity: 2016 - 2020



In MCW Fiscal Year 2020, the Office of Technology Development signed 11 license agreements, 4 of which were to faculty-related start-ups. That marks a 50% increase in total licenses and licenses to startups over the average from FY17-FY19.

MCW Libraries - Reference Users Served

Faculty	625
Staff	360
Medical Students	336
Graduate Students	13
Residents	170
Pharmacy Students	19
General Public	53

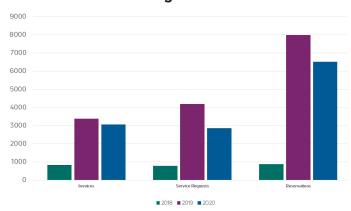
The MCW Libraries gate count was 62,904 for 2020. This included 981 items circulated, 1,256 documents delivered, 8,770 items borrowed or lent through Interlibrary Loan (ILL), 700 literature searches, and 3,237 reference questions answered. The Systems Support Team also responded to 1,219 questions for tech support during the pandemic.

Research Systems Stats

eBridge Development Production Issues Resolved	335
eBridge Help Desk Tickets Resolved	3,578
OnCore Help Desk Tickets Resolved	569
Online Trainings Completed	7,500+
Manual Entries in eBridge Avoided	4,514
Virtual 1-on-1 Trainings Completed	112
Forms Hosted (Qualtrics)	78
Total eLearning Courses Published	37
New Extensible Help Videos Integrated in eBridge	14

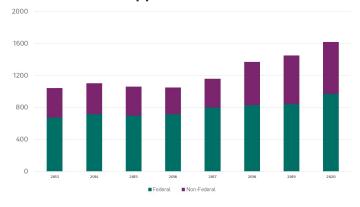
The Research Systems team adapted to the virtual environment, publishing 7 new eLearning courses as well as providing training support for the Epic Research Module, OnCore, and other projects. The team also supported major integration projects and significant upgrades.

iLab Activity: 2018 - 2020



The iLab support team implemented seven new cores/shared resources in the system in 2020, including the Office of Research PPE Ordering Service Center. The team continues to see growth in overall users.

GCO Grant Applications: 2013 - 2020



GCO Contract Activity: 2016 - 2020

