Dear Colleagues,

As we break into 2019, the Office of Research is pleased to report that we had a productive and strategically oriented 2018. The year was heavy with efforts to build and grow in a number of ways, including new people, innovative programs, and thoughtful planning. In particular, the work being done as we prepare and share the Research Strategic Plan has been both inspiring and rewarding. It truly is an exciting time to be involved in thinking about what research at MCW could look like a few years from now.

Successful research is the number one priority of our Office, and supporting investigators is a responsibility not taken lightly. The importance of research to the institution is indelibly high, and the value of research to our partners and affiliates is increasingly visible. The Office of Research is committed to driving an innovative strategy, supporting a well maintained infrastructure, expanding the institutional capacity for research, and furthering MCW’s reputation as a hub for academic medicine.

Thank you to all of the faculty and staff who helped contribute to the research mission over the last year. Here’s to a successful 2019!

Ann B. Nattinger, MD, MPH, MACP
Associate Provost for Research
Senior Associate Dean for Research,
School of Medicine
Professor of Medicine

Cecilia J. Hillard, PhD
Associate Dean for Research
Director, Neuroscience Research Center
Professor of Pharmacology & Toxicology

Marja T. Nevalainen, MD, PhD
Assistant Dean for Research
Director, Prostate Cancer Center of Excellence
Professor & Eminent Scholar, Pathology and Pharmacology & Toxicology

Lisa R. Henk, MS
Chief Administrator for Research Operations
Major Initiatives of 2018

Research Strategic Planning

Institutionally, MCW is undergoing a Strategic Planning process with regard to all missions. The process began in 2018, but sets the direction for 2020-2025. The Research Strategic Plan provides a blueprint for our successful future, and putting together such a document requires a great deal of effort and collaboration from all research stakeholders. Manatt, a highly regarded consulting firm, conducted an in-depth review of the current research environment, assessing the institutional infrastructure, organization, challenges, opportunities, and scientific strengths. Following ongoing review and discussion, the Plan will be published in spring, 2019. New subcommittees will form throughout 2019 to tackle the various components of the Plan.

Clinical Research Development

The Office of Research made significant effort to ensure the ongoing success of clinical research. In addition to supporting preparation for the highly anticipated Epic Research Module, our newly created position—Manager of Research Operations Quality & Effectiveness, Jennifer Brown—and the new Human Research Operations Committee (HROC) have been established to facilitate growth.

The Office of Research and the Finance Department co-sponsored the implementation of the MCW Compensation Card in the fall. This MCW-branded reloadable debit card offers an alternative, easy-to-use payment method for clinical research participants. The rollout included a new system implementation, Forte Payments, for administrators and clinical research staff to manage card access.

A policy enhancement has eliminated the need to collect a social security number from a research study participant receiving an individual gift card/cash payment of $60 or less.

The MCW IRB and the Froedtert Health Office of Clinical Research and Innovative Care Compliance (OCRICC) hired new staff to continue providing the best service possible amidst significant growth in clinical research.

Reducing Regulatory Burden

Dr. Nattinger charged an Ad Hoc Committee to Reduce Regulatory Burden to assess areas at MCW that are institutionally regulated to a greater degree than that which is required by an external agency. Joe Thulin, DVM, and Cece Hillard, PhD, co-chaired the committee and released a series of recommendations for consideration and potential implementation.

The eBridge Budget Overhaul project, a coordinated effort between system analysts, developers, and the Grants & Contracts Office, implemented a new Condensed Budget option for the Funding Module. For grant applications in which the sponsor requires minimal budget information, users can enter totals by category as opposed to a detailed line item budget—ideal for Modular Budgets.

Our Real-Time IRB has received national attention for its unique approach to reducing regulatory burden. Ryan Spellecy, PhD, in collaboration with David Clark, PhD, and AnnMarie Eve of our HRPP Office and the CTSI, published a paper in the Journal of Empirical Research on Human Research Ethics detailing our innovative real-time review mechanism.

IRB FLEX Review, which initiated in 2017, allows minimal risk projects to undergo a streamlined review process and categorical registration. FLEX provides a simplified application process and a reduced new project review time. In 2018, the process was expanded to allow registered projects to submit amendments, reportable events, and closures under the FLEX mechanism.
Major Initiatives of 2018

System Improvements

The eBridge PI Dashboard was launched in April, centralizing activities and notices for investigators. The customized interface displays info for applications involving grants, human subject research, and animal use studies. The concept was developed from a 2016-2017 Leadership Academy Capstone Project from Ken Allen, DVM, Sommer Hatfield Nelson, JD, Mike Lawlor, MD, PhD, Kate Thompson and Tom Zahrt, PhD.

The iLab Core Management System went live in July and the MCW portfolio continues to grow. iLab provides a centralized virtual store for users to request core services. It is also integrated with Oracle, streamlining the payment and invoicing process to a few clicks and no paperwork. Current iLab cores include the MCW Tissue Bank, CRI Histology, Center for Imaging Research, and several others.

Research Space Optimization

The Research Space Guiding Principles, a formal document outlining the responsibility, operations, and oversight of research space, was published in September. Dr. Nattinger and Chief Operating Officer Chris Kops, CPA, MBA, chartered and convened an Ad Hoc Space Committee to develop the document. The Principles will direct ongoing space metrics and assessment.

In coordination with Facilities, Environmental Health & Safety, and the respective basic science departments, the Office of Research facilitated the continuation of research by coordinating moves and swing space throughout the renovations to the Basic Science Building. Thanks to all departments that hosted swing space labs to support moves.

To efficiently utilize existing space, the Office of Research established a newly refurbished Administrative Office location in Todd Wehr Library for the IACUC & Research Systems teams, as well as sprucing up of the existing office spaces on the 3rd floor MACC Fund building.

Supporting Innovation

As a result of the competitive FOA released by the Office of Research in FY17, the need for a collaborative resource in translational immunology research was evident. In FY18, Michael Dwinell, PhD, was named Founding Director of the new blue-level Center for Immunology, the goal of which is to develop therapeutic strategies that are applied in the clinic.

The Research Affairs Committee awarded New Faculty Pilot Grants to five faculty members in order to initiate new projects: Linda Olson, PhD; Josh Hunt, PhD; John Chan, PhD; Michael Lerch, PhD and Matthew Veldman, PhD. The Committee issues pilot award RFAs twice annually for awards of up to $25,000.

MCW investigators had the opportunity to submit requests for small equipment or software needed for a research project in their lab. The Office of Research and the Dean’s Office collectively awarded $135K in small equipment to 14 different faculty researchers to support ongoing projects.

Awardees Dawn Wolfgram, MD, Brian Smith, PhD, and Amy Prunuske, PhD, with their new equipment in action.
Accomplishments of 2018

The MCW animal care program received full AAALAC reaccreditation for the maximum of 3 years following a site visit in August, including a detailed evaluation of the IACUC and BRC facility.

Conducted External Stakeholder Feedback meetings with key departmental partners including Compliance, Finance, and Environmental Health & Safety to discuss administrative challenges, strengths, and opportunities.

The HRPP completed preparations for the Revised Common Rule, including implementation of a study transition plan. The eBridge team has also developed a 100% electronic audit process. As a result, many research teams will have fewer human research reporting requirements.

New eBridge enhancements for animal training, including conversion of Post Approval Monitoring, Core Certification and Continuing Education reminders and quick-access links, improve usability for animal researchers.

Improvements were made to the IBC website for easier navigating and additional resources.

Magnanimous Mentors of MCW, a Professionalism Week activity, published 150+ nominations from faculty and staff recognizing magnanimity in their colleagues.

The Radiation Safety Team accommodated needs of MCW investigators for evening and weekend coverage for inpatient research subjects being treated with investigational radioactive drugs.

Licensing agreements in 2018 include new partnerships with SDF Therapeutics (Brian Volkman, PhD), Manteia Medical Technologies (X. Allen Li, PhD), Nephraegis Therapeutics (William Campbell, PhD, and John Imig, PhD) and Lattice Four Pi Innovations (Joe Carroll, PhD).

MCW Libraries hosted 2 traveling poster exhibits from National Network of Libraries of Medicine. Surviving and Thriving: AIDS, Politics, and Culture included a discussion panel with the Center for AIDS Intervention Research. Confronting Violence: Improving Women’s Lives included a presentation and discussion with Angela Mancuso, Executive Director of The Women’s Center.

MCW Libraries partnered with Springer Nature, a major biomedical publisher, to host a panel discussion about scholarly publishing. Faculty authors shared their experiences and challenges with scholarly publishing.

The department raised $5,561 in the Community Giving Campaign and $1,058 for the inaugural Cancer Crush.

MCW Libraries was awarded a grant from the National Network of Libraries of Medicine to develop, oversee, and evaluate a program for teaching health literacy to adjudicated youth.

A new research policy, Scientific Review of Human Gene Transfer Studies, requires that HGT studies must pass a Scientific Review Committee (SRC). To this end, a new SRC for Non-Cancer HGT Trials under Dr. Parameswaran Hari has been established. The Cancer Center’s SRC reviews cancer-related HGT trials.

Constituted a Radioactive Drug Research Committee (with IRB) as required by the FDA to review certain studies involving radioactive materials that do not have an Investigational New Drug application.

The Office of Research got social! Follow us on Twitter: @MCW_Research and @MCW_GCO.

Grants & Contracts Office federal specialists hosted several Focus on Five sessions to share tips and advice, like items they picked up at the 2018 NIH Regional Seminar in Washington, DC.

Time-saving OnCore Custom Reports created, including a CHW-specific report and grouped accrual totals.

Electrical outlets and USB ports installed directly to table tops in the northeast section of the Todd Wehr Library, providing conveniently located access to power to meet the needs of our growing student body.

The Grants & Contracts Office hosted intern Noel Hincha for special administrative projects through Marquette’s Career Ready Internship Program.

The IACUC Office presented a 4-part series on Public Outreach, Education, and Engagement for Animal Research and streamlined the onboarding process for Summer Students participating in animal research.

Began MRI streamlined approval project to incorporate MRI-related questions directly into existing AUA & PRO SmartForms to eliminate separate MRI applications.

MCW Libraries & the Program in Chemical Biology licensed SciFinder®, a portal to chemistry and related information, and PatentPak®, an integrated workflow solution for searching full-text patents.
2018 Newsmakers

Joseph Thulin, DVM, Associate Professor and Director of the Biomedical Resource Center, was appointed to a term as President of the American College of Laboratory Animal Medicine. Dr. Thulin is a Diplomate of the ACLAM and has been on the Board of Directors since 2013. He was peer-elected to this 4-year leadership role. As President, he will preside over ACLAM meetings and oversee the organization’s affairs.

Ellen Sayed, MLS, MAcc, Director, MCW Libraries, was selected to serve as a mentor of the 2018-2019 NLM/AAHSL Leadership Fellows Program, which prepares emerging leaders for director positions in academic health science libraries. A jointly sponsored program between the National Library of Medicine and the Association of Academic Health Sciences Libraries, this competitive program matches fellows and mentors in a one-year leadership development program.

Marja Nevalainen, MD, PhD, Professor, Assistant Dean for Research, and Director of the Prostate Cancer Center for Excellence (left), and Debbie Scott, PhD, Enterprise Research Application Manager (right), participated together in Leadership Academy 2018. Dr. Ann Nattinger was the Executive Sponsor for their team and capstone project, “Enhancement of the MCW Research Mission.” The proposed program utilizes digital media boards to create an interactive Interdisciplinary Collaborative MCW Research Network. The project is currently in a pre-pilot stage for roll-out in 2019.

The Office of Research veterinarians in the Biomedical Resource Center both received faculty promotions effective July 1:

Eric Jensen, DVM, was promoted to Associate Professor of Pediatrics. Dr. Jensen joined MCW in 2002 as a Clinical Veterinarian after several years in both private practice and at a pharmaceutical development lab. He received his initial faculty appointment in 2009.

Kenneth Allen, DVM, was promoted to Associate Professor of Microbiology and Immunology. Dr. Allen, who is a Diplomate of the American College of Laboratory Animal Medicine, joined MCW in 2005 as a Clinical Veterinarian. He received his initial faculty appointment in 2007.

Kalpa Vithalani, PhD, and James Antczak, PhD, have both been promoted to the role of Assistant Director in the Office of Technology Development. This well deserved promotion recognizes their demonstrated ability to contribute to the Office’s mission at a leadership level. Kalpa and Jim have assumed new responsibilities related to leadership, planning, and community outreach.

April Haverty, JD, received a promotion in line with the increased complexity, scope, and visibility of her role as the Director of the Grants and Contracts Office. Beyond leading GCO, April’s purview has expanded with regard to external partners.

Kathryn Mlsna, MLS, was promoted to Assistant Director, Public Service and Education. This title represents the greater breadth and scope of Kathryn’s leadership as she continues to contribute to the superior reputation of the MCW Libraries.

Sara Griffin and Tim Schafer have achieved the title of Certified IRB Professional (CIP). The CIP exam is supported by Public Responsibility in Medicine & Research (PRIM&R) as a way for those who support Institutional Review Boards to demonstrate knowledge and mastery in the application of the federal regulations regarding human subject research.
2018 by the Numbers

176,568
MCW Libraries
2018 Gate Count
6,252
Help Desk Tickets

4,989,013
Total BRC Animal Board Days

354
Total Animal Use Applications in State of Approved in FY18

7,000
Number of eLearning Course Sessions

7,468
Posters Printed in MCW Libraries

Number of Invention Disclosures to OTD

Total Grants Submitted by GCO

Average Readers per Issue of Research Pulse

371 Safety Committee Approvals in FY18

792 IRB Studies Approved

1,005
BRC Training Opportunities

84
Library Classes Taught

140
Researchers featured on MFRC Digital Board & Research Publication Series
2018 by the Numbers

The Institutional Animal Care and Use Committee approved 28 new Animal Use Applications, 225 Animal Amendments, 27 Annual Renewals, and 61 Three-Year Renewals. The IACUC Office administratively processed a combination of 1,086 personnel changes, funding updates, and Animal Amendments. The team also reviewed, revised, and renewed 8 IACUC Standards.

The Grants & Contracts Office submitted a record 1,644 total grant applications in 2018, the highest recorded annual figure. The GCO also reviewed 436 Material Transfer Agreements, 360 Non-Disclosure Agreements, and 280 Industry Sponsored Clinical Trial Agreements.

MCW Libraries taught 84 classes attended by 389 trainees, delivered 12,572 documents, facilitated nearly 1.8 million database usages, and printed 1,331 posters. Total gate count was over 176,000 and circulation was 4,839. The Libraries Liaison Program expanded to include four more departments, and five systematic reviews were completed and published in 2018.

Research Systems released the new Forte Payments system in 2018, in addition to eBridge and OnCore projects:

1. Grants Budget Overhaul
2. PI Dashboard
3. Electronic IRB Audit (Common Rule Prep)
4. IRB FLEX Amendment Capability
5. Primary & Secondary Appointments in Oracle Feed
6. Three SF424 Upgrades
7. 583 eBridge Production Issues Closed
8. OnCore Custom Reports
9. OnCore Project Prioritization Tool
10. Two OnCore Vendor Patch Upgrades

The training team taught 143 1-on-1 training sessions, published 10 eLearning courses, and published 4 new microlearning sites.

The Office of Technology Development licensed or optioned ten technologies and signed 33 agreements in FY18. In that time, 69 new patent applications were submitted for OTD technologies, and 12 had patents issued.

<table>
<thead>
<tr>
<th>Disclosures &amp; Patent Applications</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
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<tbody>
<tr>
<td>Total Disclosures</td>
<td>59</td>
<td>50</td>
<td>62</td>
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<tr>
<td>Number of Disclosures that Led to Provisional Patent Application Filings</td>
<td>13</td>
<td>6</td>
<td>16</td>
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The Human Research Protection Program approved 792 studies in 2018, 64% of which were Expedited, Exempt, or FLEX-registered. 1789 Continuing Progress Reports were approved, 86% of which were Expedited. 1,310 Amendments were approved, and 194 Reliance Agreements were executed.

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<th>New Studies Approved</th>
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<tr>
<td>Full</td>
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<td>Expedited</td>
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<td>Exempt</td>
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<tr>
<td>Flex/Registered</td>
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<td>NHSR</td>
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<tr>
<th>Continuing Progress Reports Approved</th>
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<tbody>
<tr>
<td>Full</td>
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<tr>
<td>Full 6-Year Renewal</td>
</tr>
<tr>
<td>Expedited</td>
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<tr>
<td>Expedited 6-Year Renewal</td>
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<tr>
<td>Final CPR</td>
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Biosafety Committee Approvals

- New Applications: 40
- Amendments: 57
- Renewals: 70

Haz Chem Committee Approvals

- Animal (Amendment): 2
- Animal (Renewal): 3
- Animal (New): 40
- Lab (New): 1
- Human (New): 1

MRI Safety Committee Approvals

- Amendments: 6
- Animal (New): 7
- Human (New): 48
<table>
<thead>
<tr>
<th>Name</th>
<th>Role and Details</th>
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<tbody>
<tr>
<td>Cory Corrao</td>
<td>Joined the Office of Research in January as Administrative Coordinator. Cory provides day-to-day assistance to the Associate Provost for Research, supports departmental operations in a multitude of ways, and assists in coordinating events and special projects. Cory previously worked in HR and Occupational Health at Froedtert Hospital.</td>
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<tr>
<td>Mark Kolmar</td>
<td>Joined the Research Systems team as OnCore Developer. This new role was created to meet the needs of our growing clinical trials program. Mark comes to MCW after a long history in Information Technology consulting. His experience is primarily in full-stack systems administration, DBA, and web application development support.</td>
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<tr>
<td>Ranelle Graber</td>
<td>Joined the Grants &amp; Contracts Office in April in the newly created role of GCO Expeditor. Ranelle has a BA in Government and Spanish Language &amp; Literature from Lawrence University with concentrations in International Law, Latin American Studies, and Economics. As GCO Expeditor, Ranelle handles first-tier grant-related questions.</td>
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<tr>
<td>Ashley Zelhoefer</td>
<td>Joined the Human Research Protection Program office in April as an IRB Coordinator II. Ashley has multiple years of IRB experience and fully supports IRB Committee III. She has two baccalaureate degrees from UW-Eau Claire, as well as a master’s degree in Clinical Science Psychology from the University of Northern Iowa.</td>
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<tr>
<td>Chelsea Spangenberg</td>
<td>Joined the Grants &amp; Contracts Office in June as the new Pre-Award Grant Submission Coordinator. Chelsea transferred to the Office of Research from the Pediatric Hematology/Oncology/BMT administrative team. Chelsea has a bachelor’s degree from UW-La Crosse, and graduated from UW-Whitewater in December earning her MBA.</td>
</tr>
<tr>
<td>Morgan Medina</td>
<td>Joined the Human Research Protection Program office in June as an IRB Coordinator I, providing front-line assistance for HRPP inquiries. Morgan has a Bachelor of Science degree in Kinesiology, and previously worked as a Rehabilitation Clerical Aide for outpatient physical therapy.</td>
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<tr>
<td>Elizabeth Witkowski</td>
<td>Welcomed in 2018, Elizabeth (Marcellus) Witkowski as the new Clinical Medical Librarian for CHW. Liz supports clinical and research resources for pediatric researchers, as well as CHW patients and their families. Liz holds a Master’s degree in Library and Information Science from the University at Buffalo, and has several years of experience in academic libraries.</td>
</tr>
<tr>
<td>Ann Amidzich</td>
<td>Joined the Office of Technology Development in the newly created role of Intellectual Property Manager. Ann manages the OTD IP database, maintains compliance with federal reporting requirements, and processes patent and licensing documentation. Ann has a bachelor’s degree in Criminal Justice and a paralegal certificate.</td>
</tr>
<tr>
<td>Mala Bobade</td>
<td>Joined the Human Research Protection Program Office as Quality Improvement Specialist in October. Within the QA/QI team, Mala conducts Routine Reviews and performs audits on approved human subject research projects. Mala has previously held positions as a Medical Officer, Clinical Research Coordinator, and MCW IRB Committee member.</td>
</tr>
<tr>
<td>Jennifer Brown</td>
<td>Joined the administrative team in the newly created role of Manager of Research Operations Quality &amp; Effectiveness. Jen has worked at MCW for 9+ years and has facilitated clinical research across Froedert and CHW. Jen will coordinate, execute and monitor quality assurance and quality improvement efforts for clinical and non-clinical research operations.</td>
</tr>
<tr>
<td>Nicholas Lim</td>
<td>Joined the MCW Libraries in December as the newest Reference Librarian. Previously, Nick worked as a librarian at Truman College (Chicago) for about 8 years. His family moved to Wisconsin from Chicago last year and he is excited about this new opportunity. In addition to his duties as a reference librarian, he works with data management for researchers, faculty, staff and students.</td>
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Four staff members on the eBridge development team officially transferred from the Information Services department to the Research Systems unit in May:

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<tr>
<th>Name</th>
<th>Role and Details</th>
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<tbody>
<tr>
<td>William (Will) Baye</td>
<td>An Enterprise Application Developer II. He has a degree in Management Information Systems from UW-Milwaukee. Will has been at MCW for 6+ years and has been working in system management for over 12 years.</td>
</tr>
<tr>
<td>Erika Krueger</td>
<td>An Enterprise Application Developer III. She has a Bachelor in Business Administration degree in Management Information Systems. Erika has been at MCW for over 7 years, with an additional 11 years of prior experience.</td>
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<tr>
<td>John Buzzell</td>
<td>An Enterprise Application Developer II. He has a bachelor’s degree in Computer Science. John has spent 3 years as a Developer here at MCW, and has an additional 2 years of prior experience.</td>
</tr>
<tr>
<td>Bijal Patel</td>
<td>An Enterprise Application Developer II. She has a Bachelor of Engineering degree in Information Technology. She has been at MCW for 3 years, but prior to that had 7 years of prior experience as a Developer.</td>
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</tbody>
</table>
Research Day – Sept. 24: Researchers from across campus gathered for a day of networking, science, and discovery. Our lunch hour Keynote Talk, “Molecular Architecture of the Circadian Clock in Mammals: Implications for Metabolism and Longevity” was delivered by Joseph Takahashi, PhD, a Howard Hughes Medical Institute investigator and Chair of Neuroscience at UT-Southwestern. Our poster session in the Hub Gallery featured 80+ researchers representing 24 different departments, institutes, and centers.

Cores Fair - Feb. 28: 40 campus cores and shared research resources participated in our open-house style networking event. Special guest Phil Hockberger, PhD, Associate VP for Research at Northwestern and recognized core facilities expert, visited campus for the Fair. He also presented at Research Council and answered questions during a Q&A session.

Gear Up for Success School Supply Drive: The Office of Research helped organize the July school supply drive for students at the Milwaukee Academy of Science.

Wisconsin Biohealth Summit: Ann Nattinger, MD, presented the Hector F. DeLuca Scientific Achievement Award to Allen Cowley, Jr., PhD, at the October 2018 Summit event in Madison. Kalpa Vithalani, PhD, is an executive member of the Biohealth board and helped nominate Dr. Cowley for this prestigious and competitive award.