

## Director's Report



Frederick Wenzel,  
Interim Executive  
Director

Work on the strategic plan is continuing. The initial planning group consisting of the Center Directors and the Foundation leadership met on Thursday, August 18 to begin finalizing the plan for presentation to the larger planning group which will meet in the next several weeks. The plan calls for six principal strategies involving People, Quality, Growth, Service, Community Engagement and Financial Stability. The group also reviewed drafts of the mission and vision statements as well. I am pleased with the progress the group has made over the past several months and we are looking forward to integration of the Foundation's plan into the System's overall plan as well.

The Executive Committee Board of Trustees of the Foundation met on Monday, August 15 to review and approve the Foundation's budget for FY 2017. The Board considered recommendations for the Sebold Award which will be presented on October 11th. The Executive Committee was advised that the Foundation will change its name to avoid confusion with the name of the new philanthropy foundation that has been formed recently. A new name for the research group will be presented to the Board of Trustees in September.

This summer has seen a significant number of publications. Between July 16 and August 6 there were 11 papers published or in press. July was also a good month for grants. The Foundation received new and continuing funding in the amount of \$5,579,000,774 during the month. These awards went to Drs. Belongia, Bendixsen, Greenlee and Lee. Congratulations to all.

I was informed recently about a noteworthy collaboration that I would like to mention. The staff of the Institute for Oral and Systemic Health (IOSH) and the Institute for Quality Innovation and Patient Safety (IQIPS) are working with Family Health Center (FHC) leadership to identify and implement key areas of medical-dental care integration throughout the Marshfield Clinic Health System. The group is also working towards establishing an informatics platform and developing quality measures to support the quality improvement initiatives for FHC Dental Centers. Additionally, IOSH is collaborating with the IQIPS Virtual Care (Telehealth) Center on a pilot research study to establish a tele-dental approach which allows online patient-dentist interactions especially those which occur during non-traumatic dental visits to the emergency department.

Two other notable recent events were Dr. Belongia's invitation to participate in discussions including 50 international epidemiologists at the World Health Organization in Geneva, Switzerland in September where the group will consider "Live Attenuated Influenza Vaccine Effectiveness" and Dr. Peissig's invitation from the American Informatics Professional Association in Bethesda, Maryland where 100 thought leaders will gather in September to discuss the role and future of Informatics.

## Associate Director's Report



Steve Ziemba,  
Associate Director

As many readers of *Research Matters* are aware, I was recently appointed as the Interim Center Director for the Clinical Research Center (CRC). A number of people have asked why this change has occurred. A big part of the reason is that the nature of the work that occurs within the CRC requires a somewhat different leadership structure from that of our fellow Centers in MCRF.

Dr. Bob Haws is now the Medical Director for the CRC, and will work with physicians already involved, or interested, in clinical research. Administrative leadership is composed of Brian Zaleski and Melissa Slager. My role interacts with each of these individuals and CRC as a whole. This will also mean a change in the processes and policies of how CRC engages in the workings of clinical research. Our focus will be on customer service, which is an essential function of the Center. Customers include the clinical trial sponsors, who entrust us with their projects and reputation; our physician investigators, who entrust us to be ready and available to engage with them to conduct the clinical study, and to our patients, who to simply put it, trust us.

There are positive changes coming for CRC. Some will see results in the near future, whereas others will take longer. The CRC contains people and leadership with the knowledge and expertise to achieve these goals. We feel that the achievements to come will be a benefit not only to MCRF, but also the Marshfield Clinic and Marshfield Clinic Health System.

Finally, I've still retained the responsibilities of Associate Director of MCRF, though with a few changes there as well. However, there are similarities between the roles from an administrative standpoint. Between that and the fact that I work with an outstanding team of people, I feel quite comfortable in the two roles. I wanted to include that aspect as it has also been a question that has come up several times.

Thank you all again for all you do.

## Recent Publications, Grants, and Awards

This column is to highlight recent accomplishments of MCRF researchers and MC clinical investigators.

Please select the hyperlink to view recent [publications](#) and [grants](#).

If you have recently published an article or received a grant or an award and want it included in the next issue of *Research Matters*, please contact Patti Baer at [baer.patricia@mcrf.mfldclin.edu](mailto:baer.patricia@mcrf.mfldclin.edu)

For more, please visit <http://www.marshfieldresearch.org/>

## IRDL (ir-del)? What in the world does that stand for?

IRDL Director Jennifer Meece, PhD provides a brief primer on the MCRF laboratory

Although the Integrated Research and Development Laboratory (IRDL) was renamed nearly two years ago to better reflect the integrated nature of the research we support, many people still don't fully understand who we are and what we do.

The lab roots go back to approximately 1998 which the "Core Lab" was founded in the Clinical Research Center under the joint mentorship of the then CRC Director, Dr. Kurt Reed, his able post-doctoral fellow, Dr. Sanjay Shukla, and 2 research associates. The idea behind the lab was to provide laboratory support for clinicians who had a lab project or idea, but weren't laboratory-minded or weren't well matched to working with laboratory scientists with existing programs.

As with all good ideas, the Core Lab continued to expand and grow and morph. FTE were added to support expansion of programs and other groups were rolled into the Core Lab to accommodate the changing structure of MCRF.

In 2007, a large and significant change occurred when Molecular Diagnostics group was incorporated and a full time director was hired.

Today in 2016, we are a vibrant group with a very diverse research and service portfolio - all of which would not be possible without our fabulous team: Anna Schotthoefer (Project Scientist), Steve Kaiser (Laboratory Operations Manager), Jennifer Anderson, Phillip Bertz, Wayne Frome, Sherri Guzinski, Lynn Ivacic, Tammy Koepel, Thao Le, Brooke Olson, Nan Pan, Ram Shrestha, Elisha Stefanski, Patrick Stockwell, and Kai Qi Zhang (Senior Research Associates); Derek Boehm, Erin Donnerbauer, Klevi Hoxha, and Rachel Schoone (Research Associates). Of note, among the Senior Research Associates, the average number of years of experience is 19.8 years!

IRDL has developed a strong financial and research portfolio. We perform clinical assays as a reference laboratory for Marshfield Labs, we provide service to the Clinical Research Center for sample processing, we serve as a reference lab testing respiratory specimens using a multiplex viral testing platform for national and international research and clinical trials, we serve as the stewards the PMRP cohort and other biobanks, and we perform basic research in fungal and tick-borne infectious disease as examples.

I'm very proud to have been a part of this growth and development and grateful for those who envisioned and supported the endeavor at its inception.



**The IRDL Team** (from l-r) 1<sup>st</sup> row: Erin Donnerbauer, Thao Le, Nan Pan; 2<sup>nd</sup> row: Elisha Stefanski, Tammy Koepel, Steve Kaiser; 3<sup>rd</sup> row: Sherri Guzinski, Derek Boehm, Phil Bertz; 4<sup>th</sup> row: Lynn Ivacic, Jen Meece, Klevi Hoxha; 5<sup>th</sup> row: Ram Shrestha, Kai Qi Zhang, Pat Stockwell. Not shown, Wayne Frome, Rachel Schoone, Brooke Olson, Anna Schotthoefer, Jennifer Anderson

## MCRF On The Move

“MCRF On The Move” is a recurring section of *Research Matters* where you can find information about the new roles, new locations, and new opportunities at MCRF.

CCEPH is currently seeking to hire the following **temporary positions** to work on their RSV and Influenza studies September 2016 – May 2017:

- Two **Clinical Trial Assistants**
- Eleven **Research Coordinator Associates**

CCEPH is also recruiting for their **0.5 FTE Administrative Secretary** position. This position is permanent.

Interested applicants should apply through HR’s [Employment Center](#) website.

## BIRC Welcomes New Programmer Analyst



Richard Duerr joined us as a Programmer Analyst in the BIRC-ICR group August 1. Richard graduated from UW-Oshkosh with a Bachelor’s in Computer Science. Richard’s hometown is Pittsville - “It is great to be back home again near family, friends and girlfriend. I enjoy programming, as well as video games, cooking, disc golf and spending time with friends. One of my personal projects is creating a personal web site, as well as an RTS video game that is planned for Windows, Mac, iPad and Android.”

## Auction to honor Dr. Emanuel, other ‘Champions’

The theme of this year’s [Auction of Champions](#), Sept. 15 at RiverEdge Golf Course, Marshfield, focuses on the origins the Auction and its support of youth agricultural projects in our rural communities. Proceeds will be dedicated to the champions of NFMC’s past, particularly Dr. Dean Emanuel, and applied toward research designed to keep farmers healthy, happy, and whole.

Besides meat from champion animals purchased at local fairs, the annual gala will feature new and exciting auction packages such as:

- A week stay in Kauai, Hawaii with airfare for two
- A 2016 Polaris Ranger 570 XP fullsize
- Brett Favre autographed football helmet
- Door County weekend and Trolley Tour
- Pizza and farm experience for 20 at Stoney Acres Farm in Athens, WI



Don’t miss the fun! [Register](#) today.

## Dr. Amit Acharya elected to serve on the American Dental Association's Standards Committee in a leadership role



Dr. Amit Acharya, Director of IOSH was recently elected to serve as the Interim Chairman of the Clinical Informatics subcommittee of the American Dental Association's (ADA) Standard Committee on Dental Informatics (SCDI). The ADA SCDI develops informatics standards and technical reports to assist the dental profession with hardware and software selection, digital photography, interoperability, data security and more. In 2001, the SCDI was reorganized into three subcommittees (Information Exchange, Clinical Informatics and Knowledge Management) and 14 working groups working on the development or revision of 26 technical reports or specifications. Dr. Acharya has been involved in ADA SCDI national standards development activities since the last decade and more recently has been serving as the Vice-Chairman of the Clinical Informatics subcommittee and a member of the Oversight Committee of the ADA SCDI. Dr. Acharya had recently contributed in the publication of the ANSI-ADA Specification 1067 for Standard Functional Requirements of an Electronic Record System for General Dentistry and is currently the working group chairman of the ADA Technical Report No. 1084 for Core Set of Reference for Communication among Dental Information Systems.

## IOSH Administrator Selected to Represent Marshfield Clinic in the Next Leadership Marshfield Program

Dixie Schroeder, MBA, was recently selected to represent Marshfield Clinic in the next Leadership Marshfield Program, which begins in September. The purpose and objective of Leadership Marshfield is to identify current and potential leaders in the community and provide a training program that will enhance their ability to function as more effective leaders. Class participants participate in a series of eight informative one-day programs and develop group projects designed to meet each individual's interests and community needs.



Dixie intends to bring more awareness to the importance of oral health as well the need to support families of individuals with mental health challenges throughout our community.



**LEADERSHIP  
MARSHFIELD**

Leadership Marshfield is a program of the Marshfield Area Chamber Foundation supported by the Leadership Council, volunteers, Chamber staff, and a strong Alumni network. Fritz Wenzel was one of the original founders of this program nearly 25 years ago.

## National farm safety group to meet at Foundation

The Agricultural Safety and Health Council of America (ASHCA) Board of Directors is meeting next week (Aug. 29-30) at the Research Foundation, hosted by the National Farm Medicine Center. ASHCA is an industry-driven, not-for-profit organization with members from producer groups, agribusiness, insurance, academia and government.

“The Farm Center was privileged to be the incubator for ASHCA until it was ready to move to Washington, D.C.,” said Barbara Lee, Ph.D., who served as ASHCA’s Executive Director while the organization was based in Marshfield. “Now, nearly a decade later, ASHCA is widely recognized and supported by major agricultural businesses and national farm organizations.”

ASHCA President Frank Gasperini, executive director of the National Council of Agricultural Employers, gave a presentation at Froehle Center in September 2015. Gasperini addressed immigration reform and other priority issues facing growers.



*This image is being shown on Clinic monitors the week of August 29th.*

## Cranberry growers surveyed for Lyme study



*Iris Reyes, NFMC, and Robert Walker, Upper Midwest Agricultural Safety and Health Center (UMASH), administered surveys to cranberry growers Aug. 10 at the Wisconsin State Cranberry Growers Association Field Days in Black River Falls.*

Lyme disease and other tick-borne diseases are on the rise and are commonly reported in Minnesota and Wisconsin. The Marshfield Clinic Research Foundation, the National Farm Medicine Center, University of Minnesota and the Upper Midwest Agricultural Safety and Health Center (UMASH) are working together on a pilot project to assess knowledge, attitudes and practices among workers in occupations considered high-risk in the upper Midwest, including cranberry growers. The long-term goal of this project is to advance the knowledge of the ecology, epidemiology, and social determinants of tick-borne diseases, as well as identifying effective strategies for infection prevention and clinical case management.

## 2017 HCSRN Spring Conference Call for Submissions

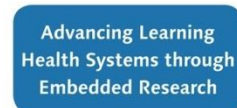
The Health Care Systems Research Network (HCSRN) [2017 Spring Conference](#) will be held in San Diego March 21-23.

Marshfield Clinic Research Foundation has been a member of the HCSRN (formerly the HMO Research Network) since 2005, and MCRF investigators and staff have contributed to the science at the annual meeting every year since. MCRF co-hosted the annual meeting in 2008 and in 2016.

The 2017 Conference organizers are now accepting submissions for scientific posters and also for panel presentations. Abstracts for scientific poster presentations should focus on research findings, whereas proposals for panel presentations should focus on the methods, challenges and approaches used during conduct of research. Individuals are invited to apply to contribute to one of the pre-identified panel topics or to create their own full panel on the topic of their choice. The Conference Committee encourages panel presentation submitters to also submit related scientific poster abstracts that complement their panel presentation submissions. [Click here](#) for more details on the two different submission options.

Don't delay! Scientific poster and panel presentation submissions will be accepted until Sunday, September 25, 2016. Please note this deadline is a little earlier than in some years. All submitters will be notified of their status by Friday, December 2, and all presenters will be required to register by Friday, December 16, 2016. Register for the conference before December 16, 2016 to receive the Early Bird Rate. Registration rates increase by \$100 after December 16.

Robert Greenlee, PhD, MPH, Research Scientist, Center for Clinical Epidemiology & Population Health is the local MCRF site Principal Investigator and a member of the HCSRN Governing Board.



## USA Today: farm children safer, but die too often

The National Children's Center was featured prominently in an article posted Aug. 11 by [USA Today](#). The article cited a National Children's Center fact sheet showing a long-term decline in rate of non-fatal injuries to children on farms, but a steady occurrence of fatal injuries. It quoted Dr. Bryan Weichelt and Marsha Salzwedel, highlighting their agricultural backgrounds and current safety work.

In addition to Gannett News Service, the article was distributed nationally by the Associated Press. After four days, versions of the article had appeared on 82 newspaper websites including the Milwaukee Journal Sentinel and a dozen other Wisconsin papers, the Minneapolis Star Tribune, Detroit Free Press, Cincinnati Inquirer, Arizona Republic, Indianapolis Star, Washington Times and others. Combined "circulation" estimate of these news outlets: 60.8 million (unique visitors).



*Gary and Holly Stankowski of Mosinee were also interviewed for the USA Today story.*

## Compliance Notes

### OHRP & FDA Issue DRAFT Joint Guidance for Comment



Linda Jaros,  
Research  
Compliance Officer

Earlier this month the Department of Health and Human Services Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA) published joint draft guidance to address required and recommended policies for IRBs to have in place for research that is regulated by either or both agencies. It is entitled, [“Institutional Review Board \(IRB\) Written Procedures: Guidance for Institutions and IRB.”](#) Such joint guidance has been rare from the two agencies and represents a favorable trend. Risk of non-compliance can be higher when institutions and individual researchers work with divergent sets of regulations and policies. This draft guidance addresses policies already required by 45 CFR 46.103(b)(4)&(5) and 21 CFR 56.108 (a)&(b). What is new

is the recommendation that IRB written policies and procedures incorporate approximately 59 additional human subjects protection topics. Due to respect for the numerous existing published federal guidances, and the desire to meet AAHRPP’s rigorous accreditation standards, MCRF currently has most if not all of the recommendations addressed. Below is a sample of documentation recommendations from the draft guidance:

- Institutional process for determining which activities require IRB review
- IRB operational details, such as timelines and materials to be submitted to the IRB for both convened and expedited review
- Various aspects of informed consent including document control systems in place to ensure correct versioning and processes in place for evaluating waivers of alterations of consent
- Additional safeguards that are expected to be in place for vulnerable subjects and how an IRB determines when those safeguards are required
- How the IRB assesses whether the sponsor or investigator have appropriately identified the need for an IND/IDE
- Requirements for implementing cooperative IRB review arrangements
- Handling of subject complaints, concerns, and questions
- Definition of a minor change in research and criteria used to determine whether convened IRB review is required versus expedited

The public comment period is open until October 3, 2016.



## Sponsored Programs Update

### New Procurement Requirements Coming Soon

Office of Management and Budget (OMB) Uniform Guidance that went into effect for federal awards issued after December 26, 2014 had initially allowed for implementation of new procurement requirements to start the first full fiscal year after the effective date. This would have been October 1, 2016 for MCRF/MC. However, OMB recently issued a grace period extension to allow for implementation to begin with the start of second full fiscal year, which will now be October 1, 2017. Some procurement practices are already in place and more will follow as we get closer to the deadline.

The Uniform Guidance outlines five methods of procurement:

- Micro-purchase: Purchases where the aggregate dollar amount does not exceed \$3,000 (or \$2,000 if the procurement is construction and subject to Davis-Bacon). When practical, the entity should distribute micro-purchases equitably among qualified suppliers. No competitive quotes are required if management determines that the price is reasonable.
- Small purchase: Includes purchases up to the Simplified Acquisition threshold, which is currently \$150,000. Informal purchasing procedures are acceptable, but price or rate quotes must be obtained from an adequate number of sources.
- Sealed bids: Used for purchases over the Simplified Acquisition Threshold, which is currently \$150,000. Under this purchase method, formal solicitation is required, and the fixed price (lump sum or unit price) is awarded to the responsible bidder who conformed to all material terms and is the lowest in price. This method is the most common procurement method for construction contracts.
- Competitive proposals: Used for purchases over the Simplified Acquisition Threshold, which is currently \$150,000. This procurement method requires formal solicitation, fixed-price or cost-reimbursement contracts, and is used when sealed bids are not appropriate. The contract should be awarded to the responsible firm whose proposal is most advantageous to the program, with price being one of the various factors.
- Noncompetitive proposals: Also known as sole-source procurement, this may be appropriate only when specific criteria are met. Examples include when an item is available only from one source, when a public emergency does not allow for the time of the competitive proposal process, when the federal awarding agency authorizes, or after a number of attempts at a competitive process, the competition is deemed inadequate.

## Upcoming Talks and Presentations

### Scientific Seminar (Froehlike Auditorium)

#### **Wednesday, September 14<sup>th</sup>**

12:05pm-1:00pm

“Gut microbiome and multiple sclerosis - From bathroom to bench to bedside”

Ashutosh K. Mangalam, PhD, Assistant Professor, Department of Pathology, University of Iowa

#### **Wednesday, September 21<sup>st</sup>**

12:05pm-1:00pm

“Understanding Risk Behaviors and Health Compliance: A Symbolic Interactionist Perspective”

Julie Sorensen, PhD, Director, Northeast Center for Occupational Safety and Health: Agriculture, Forestry and Fishing, New York Center for Agricultural Medicine and Health

### PreventionGenetics Seminar Series

All seminars take place in Helix Hall at PreventionGenetics from 12noon-1pm.

#### **Thursday, September 8<sup>th</sup>**

Speaker: Kerry Jedele, MD, Gundersen Health Systems

Topic: TBD

#### **Monday, September 12<sup>th</sup>**

Speaker: Adam Shapiro, MD, Montreal Children's Hospital

Topic: Primary Ciliary Dyskinesia and Related Ciliopathies

### Grand Rounds (12:00 - 1:00 p.m. in the Froehlike Auditorium)

#### **September 2nd, 16th and 23rd:**

No grand rounds.

#### **Friday, September 9th**

Brain Tumors

Mustafa K. Baskaya, MD, Associate Professor of Neurosurgery, Director of Skull Base Surgery Cerebrovascular and Skull Base Surgery, UW School of Medicine and Public Health, Department of Neurological Surgery

#### **Friday, September 30th**

Evidence-Based Approaches to Improving Outcomes for the Surgical Patient

Charles E. Edmiston, Jr., PhD, CIC, FIDSA, FSHEA, FSIS Emeritus Professor of Surgery, Department of Surgery, Medical College of Wisconsin

## In Addition:

- The next Full Foundation meeting is scheduled for September 29, 2016 at 8:30AM in the Froehlike Auditorium. Questions can be routed or emailed to Jeanette Normington at 1R3 or [normington.jeanette@mcrf.mfldclin.edu](mailto:normington.jeanette@mcrf.mfldclin.edu).
- The next Board of Trustees meeting will be held on September 29, 2016 at 6PM in the Laird 50 conference room.
- For the latest issue of the UW-Madison newsletter, *ICTR Today*, please click here: <https://ictr.wisc.edu/Newsletters>.
- For updates on the Wisconsin Network for Health Research (WiNHR), please visit: <https://ictr.wisc.edu/winhr>
- The Marshfield Clinic Research Foundation website can be accessed through this link: <http://marshfieldresearch.org/>. You will find in depth articles, news about upcoming presentations, and achievements by the staff. There are also links to each Center, with detailed information about the staff and projects.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Bobbi Bradley, Dr. Robert Greenlee, Scott Heiberger, Linda Jaros, Steve Kaiser, Dr. Jennifer Meece, Anne Nikolai, Bonnie Ohlsson, Dixie Schroeder, Michelle Wellsandt, Frederick Wenzel, Dr. Steve Ziemba

Edited by: Patti Baer, [baer.patricia@mcrf.mfldclin.edu](mailto:baer.patricia@mcrf.mfldclin.edu), ext. 1-8840.