Marshfield Clinic
Research Foundation

**Research Matters** **May 2015**

*Research Matters is an internal monthly newsletter published by Marshfield Clinic Research Foundation.*

# Directors' Report

In today's column, I wanted to introduce readers to the MCRF Board of Trustees (BOT). It is composed of twenty members elected for three year terms. Regular meetings of the BOT are held five times annually. The Board is composed of eight physicians from Marshfield Clinic Class A members, one PhD senior scientist, the Clinic Executive Director, and ten public members from the community. The physician representatives to the BOT are elected annually at the April Clinic Class A Members meeting. The Clinic's Directors of Research and Education serve as ex officio members of the Board. The BOT has the critical responsibility of overseeing the research activities of MCRF, and holds the following responsibilities:

a. Oversight of the administration and distribution of trust arrangement funds from the Marshfield Clinic Research Foundation Fund (MCRF Fund).
b. Policy direction for research activities.
c. Assist in resource development (fund-raising).
d. Assist Clinic in community relations.
e. Advisory role to Clinic, where appropriate.

I am delighted to report that nine physicians were nominated for Board membership at the April Marshfield Clinic Class A physician member meeting. Three physician members of the BOT were elected and two community members were ratified. In terms of community members, Todd Hasenbank was ratified to serve a second term and John Laird was elected. Representing the physicians, Dr. Adedayo Onitilo was re-elected and Drs. Bob Haws and Roger Kulstad were also elected. We were delighted by the response to the call for nominations, and the willingness of several community and physician members to serve. Please join me in congratulating our newly elected and re-elected members. Our BOT members are:

Physician Members

- Jamie Boero, MD, PhD (Chair)
- John Braxton, MD
- Michael Caldwell, MD, PhD
- Thomas Fritsche, MD
- Robert Haws, MD
- Rezwan Islam, MD
- Roger Kulstad, MD
- Narayana Murali, MD
- Adedayo Onitilo, MD

Scientist Member

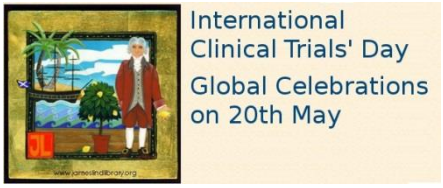
- Po-Huang Chyou, PhD

Community Members

- Andy Keogh, EdD (Vice – Chair)
- Matt Berrier
- Rene Daniels
- Todd Hasenbank
- Brian Kief
- Patricia Kleine
- John Laird
- Marty Reinhart
- Jim Schuh
- Jim Weber, PhD

# Associate Directors' Report

I recently returned from the Association of Clinical Research Professionals (ACRP) Global Conference in Salt Lake City. This conference focuses on the many facets of clinical trials, including their design, conduct, compliance, business and numerous other aspects. At over 2,000 attendees, it is not the largest conference focused on research, but does provide ample opportunity to learn and network with others. An experience I had while at the conference was the familiarity others had with MCRF. This was demonstrated by the speakers and attendees alike, including the plenary speaker Rebecca Skloot, author of *The Immortal Life of Henrietta Lacks*. Incidentally, if you have not read this book, I highly recommend you do so. It presents research ethics in a very real-world light. Our second plenary speaker, Simon Ibell, who suffers from a rare genetic disease, also knew of MCRF and our work. It was great meeting with him and gaining the perspective of an individual our work ultimately benefits.




Speaking of clinical trials, May 20th is International Clinical Trials Day. Why this particular day? It was on May 20, 1747 when James Lind, a surgeon in the British Royal Navy, started his study on the identification of an agent for the effective treatment of scurvy. At the time, scurvy was thought to be caused by "putrefaction" of the body. Acting more on a hunch that acids could be used as a cure, he investigated six agents, including cider, dilute sulfuric acid, vinegar, sea water, citrus fruits, and a paste of garlic, mustard seed and radish root. As we now know, scurvy is the result of Vitamin C deficiency, and as such the use of citrus fruits was found to be effective. This was not only a breakthrough in terms of the treatment of a disease that was the bane of sailors, but Lind's study is also considered the first prospective clinical trial. International Clinical Trials Day provides us the opportunity to recognize all those individuals involved in clinical research. In our part, we are having a celebration at our Full Foundation meeting. Clinical and medical research of all varieties has a very rich history, and I invite you to explore the online James Lind Library (http://www.jameslindlibrary.org/) to experience some of that history.

Finally, you may notice that this issue of *Research Matters* is being edited by yours truly. The reason is that Alexis Tavano, who oversaw this newsletter, has left MCRF for a position in the pharmaceutical industry. As with her other tasks and responsibilities, she did a great job with *Research Matters,* making it into a great conduit for communication throughout MCRF. We wish her the best.

## Recent Publications, Grants, and Awards

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

Please select the hyperlinks to view recent publications.

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 Steven Ziemba at Ziemba.steven@mcrf.mfldclin.edu

## Compliance Notes

**Changes Regarding Federally-Funded Research with Newborn Dried Blood SPOTS**

Effective March 16, 2015, any federally-funded research on newborn dried blood spots shall be considered research carried out on human subjects as defined at 45 CFR 46.102(f)(2). The human subject designation applies to newborn dried blood spots even if they are completely de-identified. In addition, prospective, written parental consent is required for all research uses of these samples.

The changes come about as part of the, “Newborn Screening Saves Lives Reauthorization Act of 2014” (Public Law No: 113-240). Under current interpretation of the Common Rule, completely de-identified samples do not meet the definition of a “human subject,” so the pursuant set of Institutional Review Board regulations do not apply. The second significant difference the new law sets forth is that upon review, an IRB has no ability to waive informed consent nor allow verbal parental consent via a waiver of written consent form.

While the research body affected by this change is very specific, I believe awareness of the issue it is important. It represents the first interpretation by the federal government that affords de-identified specimens the same protections as human research subjects.

## Annual Disclosure for Investigators Begins in May

*The message below is repeated from last month as a reminder on annual disclosure.*

Beginning the week of May 4th, be on the lookout for an “Action Required" email from sender “Conflict of Interest (Shared)”. This electronic request for annual disclosures of significant financial and associational interests will include a link to access the disclosure tool. Annual disclosures are due by June 5th.


As implemented last year due to AAHRPP accreditation requirements, the definition of *Investigator* includes anyone “involved in” the design, conduct or reporting of research. Previously the definition included those “responsible for” the design, conduct or reporting of research. All research staff is now subject to annual disclosure requirements.

An individual in the following situations would not be considered an *Investigator* and would not need to submit a disclosure:

- An individual who provides medical services that would normally be performed as part of routine clinical care. The clinician does not administer an investigational agent or use a research protocol to dictate the patient’s care. Data regarding adverse events that occur during that care may be collected by another investigator or research staff, but not by the clinician providing the medical service.
- An individual informs prospective subjects about the availability of research, or provides them with information about the research, but does not seek or obtain informed consent or act as an investigator’s representative.

For individuals who have not submitted an annual disclosure in the past, a brief online training will also be required. The training takes approximately 10 minutes to complete.

Questions or concerns should be directed to Patti Baer (ext 1-8840) in the Office of Research Integrity and Protections, or e-mail at conflict.interest@marshfieldclinic.org.

# IOSH Scientist Receives National Institutes of Dental and Craniofacial Research (NIDCR) RO3 Grant to Enhance Care of Dental Patients with Diabetes

Dr. Amit Acharya, Director of IOSH, recently received a RO3 grant of $322,500 from the NIDCR to support a two year study. IOSH researchers have teamed up with Columbia University researchers on this grant to conduct a secondary analysis of Electronic Health Record (EHR) data to enhance care of dental patients with diabetes as well as discover the best model(s) to identify existing undiagnosed diabetes and prediabetes among the patients and communities served by Marshfield Clinic Health System. In addition, the research team will determine the burden of a diabetic patient's level of glycemic control, disease duration, presence of other complications and comorbidities on his/her oral/periodontal status over time, response to non-surgical periodontal therapy, and healing following oral/periodontal surgery and/or tooth extractions.

"This important work will help us develop practical tools for identifying undiagnosed prediabetes/diabetes in a dental setting built upon better understanding of the complex relationship between dysglycemia and oral/periodontal disease and will give dental care teams actionable information to mitigate the deleterious effects of diabetes," said Dr. Acharya who serves as the principal investigator of this study.

According to the Centers for Disease Control and Prevention, "Diabetes mellitus is a major health concern as 8.3% of the U.S. population has diabetes and one quarter of those affected remain undiagnosed and prediabetes often precedes type 2 diabetes and is estimated to affect 35% of U.S. adults. About 9 out of 10 prediabetic individuals do not know that they have the condition " It is reported that the direct and indirect health care costs associated with diabetes in the U.S. are more than $200 billion a year. The American Diabetes Association endorses the fact that early identification of diabetes and prediabetes allows for interventions to improve outcomes.

Dental providers have the opportunity to participate in the screening of people with undiagnosed diabetes and prediabetes as part of their commitment to oral and overall health. Currently, patients with unknown diabetes and prediabetes are passing through dental clinics, leaving clues to their status. Meanwhile, the disease goes unchecked and continues to damage these patients' health.

"This study will provide new and beneficial knowledge to the dental community that will fundamentally reframe the contact dental clinics have with their patients," Dr. Acharya said. "Dental care is hardly ever thought of as being lifesaving, but identifying those with previously undiagnosed diabetes and prediabetes and forecasting incident disease has the potential to save lives."

The results of this work will rapidly move beyond having theoretical impact as Greg Nycz, Director of Family Health Center's dental clinics at Marshfield Clinic indicated, "The dental clinics stand ready to accept the knowledge that this secondary analysis will generate into their practice." Dr. Acharya added, "The reason that such rapid translation will be possible at

Marshfield, and beyond, is that we will be basing our predictions/analyses on a very large, longitudinal set of clinical data from a real-world clinical setting captured within Marshfield Clinic's unique integrated medical-dental electronic health record "

## Marshfield Clinic Receives $250,000 for Breast Cancer Research

Thanks to ingenuity and spirit of philanthropy, Marshfield Clinic received $205,000 for breast cancer research.

V&H Trucks in Marshfield presented the contribution on Monday to Clinic leaders. The money was raised from the sale of "Reaching for a Cure," a custom-painted Wallboard Crane truck. The local business and long-time Clinic supporter designed the truck and then auctioned it off at a national trade show in April. The highest bidder was GMS Corporation of Tucker, GA. They plan to use the truck for local promotions and breast cancer awareness building.

## Center for Human Genetics Welcomes Post-Doctoral Fellow

Dr. Jamie Fox received a Computation and Informatics in Biology and Medicine (CIBM) post-doctoral fellowship through the National Library of Medicine and the University of Wisconsin – Madison to conduct a drug repurposing study under the mentorship of Dr. Scott Hebbring in the Center for Human Genetics. Her study will focus on identifying novel indications for the anti-diabetic drug Metformin. Using Phenome-Wide Association studies (PheWASs), she will analyze diabetes-linked genotypes and phenotypes to identify potential disease that may be targeted by Metformin. She will also conduct *in silico* molecular and biophysical analysis of diabetes linked genes, and analyze the effect of Metformin on type 2 diabetes-linked phenotypes within Marshfield Clinic's patient population.

Dr. Fox received her PhD in Biochemistry in 2014 from the Medical College of Wisconsin, Milwaukee, WI. Her PhD work focused on defining the structural and biophysical characteristic of the metamorphic cytokine, XCL1. Her previous research experience includes protein purification, nuclear magnetic resonance (NMR), fluorescence polarization, and cell-based assays.

## Clinical Research Center Welcomes New Staff

**Chris Mueller** –Chris began working with the Oncology Research program on May 4th as an Oncology Research RN. Chris holds a BSN from Chamberlain College of Nursing and has previous experience working with St. Joseph's Hospital (Registered Nurse) and Marshfield Clinic (Registered Nurse Oncology & Operations Manager).

**Dr. Marilyn Workinger** –Dr. Workinger joined CRC as an Emeritus Research Physician in mid-April. Dr. Workinger is also a casual staff speech-language pathologist. "I am using my time as an emeritus researcher to initiate and complete projects I envisioned but did not have time to do when working full-time as a clinician and administrator. I look at this as an opportunity to 'give back' to the Clinic and my profession."

**Arika Strand** – Arika has been promoted to Research Coordinator Associate. She previously held the title of Clinical Trials Assistant, and has been with MCRF since March 2014.

## In Addition:

- The next Full Foundation meeting is scheduled for July 9, 2015 at 2PM in the Froehlke Auditorium. Questions can be routed or emailed to Jeanette Normington at 1R3 or normington.jeanette@mcrf.mfldclin.edu.
- The next Board of Trustees meeting will be held on June 11, 2015 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.
- 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.

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## Don't Forget … Send Your Photos for Bike to Work Month!

http://mclweb.mfldclin.org/mcrf/?page=mcrf_updates