

## Director's Report



Frederick Wenzel,  
Interim Executive  
Director

I would like to wish a belated Happy Holidays to all especially those who have provided great support to the research group over the past year. The cooperation we have received from everyone has been outstanding and I want to thank you all.

The draft of the strategic plan initiated in April 2016 has been completed and on January 10th of the new year we will meet with a number of members of the staff to begin the process of operationalizing the plan. While the plan itself is of great importance, I can't emphasize enough the importance of bringing these strategies into an operational mode. Without that step, strategic plans are simply something placed on a shelf to gather dust until the next time around. The first challenge will be to select those actions that are of high priority in the upcoming year. There are more actions laid out than can be accomplished, so priorities will have to be established. In conjunction with setting priorities, we will be identifying those responsible for seeing to it that the actions are carried out. Timelines will have to be established along with action evaluation, which is also a key part of the planning process. At some point all staff members of the Foundation along with others from the Clinic will be involved.

The Institutional Review Board (IRB) members had their first opportunity to review iRIS, the new software which will enable the board to receive all of its information electronically. The plan is to institute the new system in January 2017. It will not only eliminate the reams of paper brought to the meeting by board members and staff, but will enable the board to make their comments and reviews electronically before the meeting. They will also be able to make notes electronically during the meetings as the discussions proceed. Training for staff members and investigators will continue in the following months.

The first two national cancer care delivery research (CCDR) projects ever approved as part of the Wisconsin NCI Community Oncology Research Program (WiNCORP) are being readied for opening at Marshfield Clinic by Drs. Onitilo and Greenlee. One project will evaluate the extent and predictors of negative financial impacts from advanced cancer among patients in the Clinic's oncology service. The other will be a pragmatic clinical trial evaluating a guideline-based standing order intervention for colony stimulating factor to prevent febrile neutropenia in cancer patients on high and intermediate risk chemotherapy regimens. These projects represent good examples of some of the health services research being carried out in the research foundation. Implementation of two new cancer control projects is also in the planning stage within WiNCORP. The first examines the potential of aspirin to prevent recurrence of breast cancer and the second will study new imaging techniques in breast cancer. These studies will be of significant consequence not only to the patients at Marshfield, but regionally and nationally as well.

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## Director's Report *(continued from previous page)*

Barbara Lee, PhD received the prestigious Heritage Award recently for her work in the National Farm Medicine Center (NFMC) dealing with farm safety, especially that involving children. Barbara was lauded for her long-standing interest in this area and we at the Foundation are very proud of the work that she has done over the years and add our congratulations. In addition to her current research work, she is also serving as Interim Director of NFMC.

Foundation staff members are also involved to a great extent in the development of proposals for a trauma program which would bring a Trauma 1 status to the hospital. Plans for a pilot project in Precision Medicine are being developed as well. More details on these projects will be presented in the next issue.

## Associate Director's Report



Steve Ziemba,  
Associate Director

We are very much in the Holiday season and approaching the end of an exciting year. The accomplishments of MCRF are a tribute to the knowledge, hard work, dedication and commitment of our scientists and staff. That said, we do need time to enjoy our families and pursuits outside of work. Be sure to use this time of year to get away from your desk and computer, even if for a short period of time. I plan to see a movie, read a book, and perhaps get out and do some snowshoeing. Stepping away from work can help us in terms of physical and mental health, and oddly enough, help with the quality and productivity of our work as well.

There are other aspects to this as well. We need to enjoy what we have. Unfortunately it took the passing of a friend of mine in November to fully realize and understand that aspect. We had met for dinner one week, and the next he was no longer with us, leaving behind a young family. Sorry to make it somber, but in the end such events emphasize the need to savor what we have now. Take this time of year to do so. Thank you 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)

## Master's Graduate Congratulations



We are pleased to congratulate Elham Saqheb for successful completion of her final master defense December 2nd, with the thesis title "Stage-Specific Predictive Models for Cancer Survivability". Elham will be graduated this month from UW-Milwaukee with a Master of Computer Science degree where she has been developing machine learning strategies and data analytics components to make stage-specific predictive models for cancer survivability. Elham is a Research Programmer Analyst with the BIRC team.

## MCRF Welcomes New Staff Members



**Justin Marsh** joined **BIRC** November 14th in a NEW Programmer Analyst position specifically targeted for boosting our Web and Application based product portfolio. Justin has a Computer Science degree from River Falls and experience with OOP and many of the latest web technologies. Previously he worked as a Web Developer for Aladtec Inc. creating a SaaS scheduling application. While there, he also designed and implemented a proprietary online Business Intelligence suite for internal company use that utilized PHP, JavaScript, and a broad range of APIs and data formats. More recently he was a Software Engineer for I See Me! LLC, a maker of premium personalized children's books.



**Jacob Patitucci** has recently joined the **Research Analytics team** in **BIRC** as a Research Programmer/ Analyst. Jake obtained a Bachelor of Science in molecular biology and bioinformatics from the University of Wisconsin-Parkside in 2006. After graduating, Jake was a technician in the lab of Kelly Henrickson, MD at the Children's Hospital of Wisconsin where he developed PCR and sequencing-based diagnostic tests for infectious diseases as well as maintaining research databases. Here he was able to further develop his skills while advancing the specificity of the hospital's viral diagnostics. Since then, he has performed basic science research studying synaptic remodeling as well as working in small biotech start-up companies developing assays for the detection of various veterinary diseases. Jake is very excited for his transition to a primarily informatics role and is looking forward to working with the outstanding researchers and clinicians here at Marshfield Clinic.

## BIRC Post-Doc Fellow Presents at ISVC



Ahmad P. Tafti, postdoctoral scholar in the Biomedical Informatics Research Center (BIRC) at Marshfield Clinic Research Foundation will present December 13 at ISVC 2016, the 12th International Symposium on Visual Computing. The title of the presentation is: "OCR as a Service: an experimental evaluation of Google Docs OCR, Tesseract, ABBYY FineReader, and Transym."

ISVC is one of the longstanding computer vision conferences purposes to provide a scientific forum for researchers and scientists all around the world to present their latest ideas and developments in the area of visual computing and machine vision. ISVC 2016 will be held in Las Vegas, Nevada.

## Barbara Lee honored with Marshfield Clinic Heritage Award

Barbara Lee, R.N., Ph.D., director of the National Farm Medicine Center (NFMC), and recognized leader in agricultural safety and health, particularly childhood agricultural injury prevention, was honored Dec. 13 with the Marshfield Clinic Heritage Award.

“Barb’s compassion, dedication and commitment to challenge unsafe conditions and make farms safer have made a true difference for adults and children around the world,” said Dr. Narayana Murali, executive director of Marshfield Clinic.



“It is such an honor and privilege to receive the Heritage Award,” Lee said. “I want to thank Marshfield Clinic, the Research Foundation and wise leaders past and present who created the environment where research, public health, and community outreach are encouraged, and where staff working on these issues can make a difference.”

Lee joined a prestigious group of previous Heritage Award winners that include former Congressman and Secretary of Defense Melvin Laird; former Secretary of the Army Robert Froehle; and Clinic physicians and researchers George Magnin, M.D., Russell Lewis, M.D., Dean Emanuel, M.D., and James Weber, Ph.D.

### Heritage Foundation Award Recipients

1998	Melvin R. Laird
1999	Robert F. Froehle
2000	George E. Magnin, M.D.
2001	Chester “Chet” L. Krause
2002	Tommy G. Thompson
2003	Russell F. Lewis, M.D.
2004	Lee Sherman Dreyfus
2005	David R. Obey
2006	Dean A. Emanuel, M.D.
2007	Philip M. Farrell, M.D., Ph.D.
2008	Mark D. Bugher
2009	Dennis G. Maki, M.D.
2010	Sister Jomary Trstensky, O.S.F.
2011	D. David “Dewey” Sebold
2012	James L. Weber, Ph.D.
2013	Frederick “Fritz” Wenzel
2014	Gregory R. Nycz
2015	Charles W. Nason
2016	Barbara Lee, Ph.D.

The Heritage Award was the latest in a long list of prestigious honors Lee received that reflect the breadth and depth of her passion and expertise. She also received the Gwen D. Sebold Research Fellowship Award for Outstanding Medical Research from Marshfield Clinic in 2003. Additionally, she was named one of the “50 Distinguished Alumni” of the University of Wisconsin – Milwaukee College of Nursing, and received the Agricultural Safety and Health Council of America’s Leadership Award.

Marshfield Clinic’s Heritage Foundation was established in 1997 to honor individuals who have made significant contributions to the community in government, civic leadership, education, medicine, law or business. This Foundation annually presents an award to an individual who has made a difference.



## BIRC Contributes to AMIA 2016 Annual Symposium



Rajesh Koralkar, Research Programmer/Analyst Senior and Andrea Mahnke, BIRC Usability Analyst presented at the American Medical Informatics Association (AMIA) 2016 Annual Symposium November 12-16, 2016 in Chicago, IL. Also attending was Laurel Verhagen, Manager, Research Analytics.

AMIA is the professional home of leading informaticians: clinicians, scientists, researchers, educators, students, and other informatics professionals who rely on data to connect people, information, and technology. The AMIA mission is to improve health through informatics education, science and practice.

Posters presented:

Challenges and Triumphs: Developing an NLP Pipeline for Thyroid Ultrasound Reporting

**Rajesh Koralkar**, MSHI, **Eric LaRose**, BS, Yiqiang Song, M.S, David F. Schneider, MD, **Peggy L. Peissig**, PhD.

The study is an example of a novel natural language processing (NLP) application for extracting critical thyroid nodule features from thyroid ultrasonography (USG). This preliminary work will be extended by improving post-processing of multiple sentence logical groupings and then to another institution to test the generalizability of the NLP pipeline.

In Patient Usability Testing Results of a Patient-Centered Postoperative Wound Surveillance Smart Phone App Utilizing Digital Photographs

**Andrea N. Mahnke**, MS; Rebecca Gunther, MD; Sara Fernandes-Taylor, PhD; **Kate L. Baker**, MA; Jason T. Wiseman, MD; K. Craig Kent, MD

The study involved the design and testing of a patient-centered, outpatient wound surveillance program using smartphone digital photography to promote early recognition of SSI following discharge.

The Symposium also included a dedicated presentation session, educational activities, and networking events for high school students and high school teachers participating in educational and research partnerships with biomedical informatics researchers across the United States. High school students who participated in educational or research activities at biomedical informatics programs, were invited to submit presentations and abstracts for consideration in the [High School Scholars Program and Competition](#).

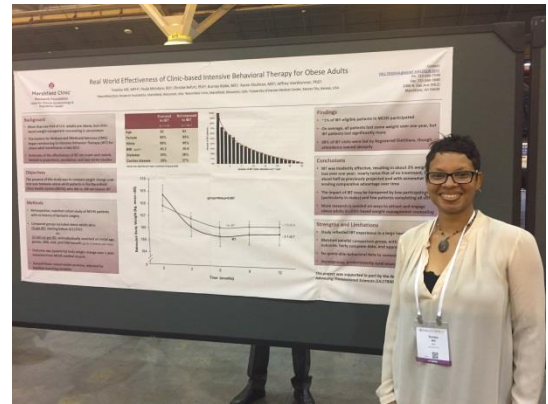
In addition to presenting at the Symposium, Andrea mentored an AMIA High School Scholar who participated in research at the University of California, San Francisco. The resulting presentation was titled A Multifaceted, Genetics-Based Drug Repositioning Study Across Several Diseases.



## CCEPH Epidemiologist Presents Research at Obesity Week

CCEPH Epidemiologist, Tenisha Hill, presented findings from a recent comparative effectiveness analysis at Obesity Week in New Orleans, Oct 31- Nov 4. Obesity Week is an international meeting focused on the basic science, clinical application, surgical intervention and prevention of obesity.

Tenisha's poster was on the real world effectiveness of clinic-based intensive behavioral therapy (IBT). Her study compared weight loss outcomes over one year between obese adult Marshfield Clinic patients who received IBT versus a matched comparison group of obese adults that did not receive IBT (i.e., usual care). Findings indicated that IBT was modestly effective, resulting in about 3% weight loss over one year, which was twice as much weight loss as no treatment. But IBT benefits seemed to erode over time, with few patients completing all allotted visits. More research is needed on ways to attract and engage obese adults in clinic-based weight management counseling, which is currently being studied in a large national trial that Tenisha manages for MCRF, the *Rural Engagement in Primary Care for Optimizing Weight Reduction (RE-POWER)* study.



Associated Marshfield Clinic authors include: Paula McIntyre, RD CD CDE, Burney Kieke, MS, Karen Shulman, MD, and Jeffery VanWormer, PhD.

## Applications for Summer Research Internships Due January 16th

The Marshfield Clinic Research Foundation (MCRF) is still accepting applications for the 2017 Summer Research Internship Program. Applicants must be a full- or part-time continuing college or university junior or graduate student (including graduating seniors intending to go on to graduate/medical/dental school). Students are expected to work full-time for the duration of the program. In addition to earning an hourly wage, student interns are provided housing in Marshfield.

Students will work with research scientists on an independent project and contribute to all aspects of the research process. Students also lead a journal club discussion, prepare an abstract describing their research, and present their research findings at the annual Research Symposium on August 10th. Opportunities to attend medical Grand Rounds, scientific seminars, and shadow clinicians are also available.

Research areas include Biomedical Informatics, Clinical/Laboratory Research, Cultural/Medical Anthropology, Epidemiology, Genetics, Interactive Clinical Design, and Oral and Systemic Health.

For information about specific projects available this summer or to read more about the application criteria, please visit the [Summer Research Internship Program](#) website.

## 2017 ICTR Pilot Funding RFAs Announced

The UW-Institute for Clinical and Translational Research (ICTR) is offering several funding opportunities for the 2017 award cycle. Pilot funding programs include: Translational Basic & Clinical Research, Clinical & Community Outcomes Research, Dissemination Supplement, Dissemination & Implementation Research, and Stakeholder and Patient Engaged Research. Most require a Letter of Intent be submitted. Please check the individual program RFA for its due date.

For more information about the ICTR Pilot Award program and details about application requirements, please visit the [ICTR Funding Opportunities webpage](#).

## Compliance Notes



Linda Jaros,  
Research  
Compliance Officer

### Informed Consent of Adult Research Participants

Who can give consent for another adult person to participate in human subjects research? Informed consent, the living manifestation of “Respect for Persons” from the Belmont Report and Nuremberg Code is a critical principle of every human research project. In the simplest cases, an adult provides his or her own consent to enroll, after a research study has received approval from the IRB. However, what is research staff to do when someone, due to lack of capacity, is unable to give consent?

The IRB Application asks these necessary questions for investigators to lay out the plan for enrolling adults who are not able to consent for themselves. If a researcher intends to have the option to enroll such adults the IRB Appendix, “Adults Lacking Capacity to Consent,” is required. When a legally authorized representative (LAR) is the intended consentor, the Appendix asks, among other things, how this person will be identified and how the relationship will be documented. In Wisconsin, a LAR may be an individual designated as a valid and activated power of attorney (POA) for healthcare decisions or as a legal guardian. If the IRB approves enrollment for adults lacking capacity to consent, the corresponding signature lines for LAR on the informed consent document are to be completed. If the IRB has not approved this vulnerable population for inclusion in a particular research study, the LAR should not be signing consent and the vulnerable population is not to be consented. Keep in mind that the LAR is the only person designated to give consent after the option is approved by the IRB.

Recently at MCRF, a potential study participant asked study staff to allow his wife to sign the research consent form for him with the rationale that ‘she signs everything’. This serves as an important reminder to confirm LAR status if necessary. In this case the wife was neither the legal guardian nor activated POA for healthcare and her signature for consent would not be valid for enrolling her husband in research.

Additional detailed guidance on this topic is provided in the IRB resource guide, “[Adults Lacking Capacity to Consent](#).”

## Updates from ORIP/IRB



Lori Scheller,  
IRB Administrator

### **OHRP & FDA Issue Final Joint Guidance on Electronic Informed Consent**

Earlier this month the Department of Health and Human Services Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA) published a joint final guidance for Institutional Review Boards, Investigators and Sponsors to address the electronic informed consenting (eIC). The guidance document is entitled, "[Use of Electronic Informed Consent – Questions and Answers](#)". This guidance provides recommendations on the use of electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices and combinations. FDA's requirements are set forth in 21 CFR parts 11, 50 and 56 respectively. HHS requirements regarding the protection of human subjects are set forth in 45 CFR part 46. The information presented to the subject, processes used for obtaining informed consent, and documentation of the electronic informed consent (eIC) must meet the requirements of these and other applicable regulations.

The guidance addresses the following questions and answers:

- 1) How should information in the eIC be presented to the subject
- 2) How and where may the eIC process be conducted
- 3) How and when should questions from subjects be answered
- 4) What steps may be taken to facilitate the subject's understanding of the information being presented
- 5) What steps may be taken to convey additional information, including significant new findings, to the subject during the course of the research
- 6) How can electronic signatures be used to document eIC
- 7) What methods may be used to verify the identity of the subject who will be electronically signing an eIC for FDA-regulated clinical investigations
- 8) What special conditions should be given to the use of eIC for pediatric studies
- 9) Should subjects receive a copy of their eIC and have an easy access to the materials and information presented to them in their eIC
- 10) What steps can be taken to help ensure privacy, security and confidentiality of the eIC information
- 11) Can HIPAA authorizations for research, which are frequently combined with informed consent documents, be obtained electronically
- 12) What eIC materials should the investigator submit to the IRB
- 13) What are the IRB's responsibilities in the eIC process
- 14) What eIC documentation does FDA require for submissions with applications.
- 15) What steps can be taken to ensure the system archives the eIC materials appropriately for FDA-regulated clinical investigations
- 16) What materials or documents with FDA require during an inspection



## CCEPH Holiday Giving

This Holiday Season has been especially fun and meaningful for the Center for Clinical Epidemiology and Population Health (CCEPH) team, who gathered together for a Food Drive in support of Soup or Socks (SOS). SOS is a United Way Program and an emergency Food Pantry. Other than their Director, SOS is staffed entirely by volunteers.

CCEPH donated 513 items and \$215 in cash! The CCEPH event included fun competition, breaking staff into 5 teams and assigning a point system to donations (higher needs were given higher points). Congratulations to 'Team Ladies & Bob' for taking first place. 'Ladies & Bob' was led by co-captains Maddie Minervini and Becky Pilsner and supported by members Deanna Cole, Bob Greenlee, Angela Harless, and Linda Heeren.



Many thanks to all of CCEPH for making a difference in our local community through generosity, enthusiasm and collegiality! Special thanks to Kate Lassa and Angela Harless for running the event.

## Upcoming Talks and Presentations

### Scientific Seminars (Froehlike Auditorium)

#### **Wednesday, January 4<sup>th</sup>**

12:05pm-1:00pm

“3D Surface Modeling of Microscopic Objects; a Computer Vision Adventure”

Ahmad P. Tafti, PhD, Postdoctoral Scholar, Biomedical Informatics Research Center (BIRC)-Marshfield Clinic Research Foundation

#### **Wednesday, February 15<sup>th</sup>**

12:05pm-1:00pm

“One Hour Proteomes and Deep Sequencing”

Joshua Coon, PhD, Professor of Chemistry and Biomolecular Chemistry, University of Wisconsin-Madison

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

#### **Friday, January 13<sup>th</sup>**

Earning MOC for participating in Clinic Initiatives: The Institutional MOC Program at Marshfield Clinic

Erik Stratman, MD, Marshfield Clinic Dermatology

#### **Friday January 20<sup>th</sup>**

Support and Medical Care for Youth with Non-Conforming Gender

James Meyer, MD, Pediatrics - Adolescent, Marshfield Clinic

## 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 for MCRF staff.

Marshfield Clinic's **Employee Referral Program (ERP)** is intended to reward employees who refer candidates for open positions. This program promotes the referral of candidates from external sources and provides employees who refer such candidates with the opportunity to earn a referral bonus in accordance with the program guidelines. Visit HR's [Employment Center](#) website to learn whether any ERP-bonus eligible positions currently available are appropriate for a qualified candidate you would like to refer.

## In Addition:

- The next Full Foundation meeting is scheduled for January 19, 2016 at 9:00AM 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 February 9, 2017 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/uw-ictr-today-newsletter-v9-n4-2016/>.
- 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/>.
- Archived issues of *Research Matters* are [available online](#).

Contributors to this issue: Patti Baer, Bobbi Bradley, Dr. Robert Greenlee, Scott Heiberger, Tenisha Hill, Linda Jaros, Dr. Huong McLean, Anne Nikolai, Bonnie Ohlsson, Lori Scheller, Dr. Jeff VanWormer, Michelle Wellsandt, Frederick Wenzel, Dr. Steve Ziemba

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*Wishing everyone the joy  
of the holiday season  
and a Happy New Year!*