

A Word from the Executive Director



It's good to note that frigid weather doesn't slow down the work of MCRF scientists and staff, except for circumstances out of their control. Frozen biological samples that were due to be sent out for analysis the week of the Arctic Vortex were held up due to a delayed dry ice shipment; how ironic is that? It's been another productive month. In the area of grants, Simon Lin, PhD, with many MCRF collaborators, most notably Bob Greenlee, PhD, and Murray Brilliant, PhD, among many other scientists and staff participated in a multi-center collaborative grant application to PCORI (Patient Centered Outcomes Research Institute). The application entitled "The Greater Plains

Collaborative" was funded as a Clinical Data Research Network and we are very excited to be a part of this groundbreaking work. With regards to publications, we are extremely pleased that MC and MCRF investigators continue to publish important work in top journals. This month we had TWO publications in the *New England Journal of Medicine* (NEJM), arguably the top medical science journal of all; congratulations to the authors and the staff who assisted with the projects described in the publications. In terms of community service, we applaud the Marshfield Epidemiology Research Center for their generous efforts as they came together with their 2nd annual food drive serving their mission to give the families of Marshfield hope during the holiday season. Finally, administratively, the Office of Research Integrity and Protections (ORIP) is to be commended for submitting a several hundred page application for consideration for AAHRPP (Association for the Accreditation of Human Research Protection Programs, Inc.) certification. AAHRPP Certification is a necessary step in continuing to participate in outstanding collaborative research with top academic institutions around the U.S. A tremendous amount of work went into this application.

And from Our Associate Director



Welcome to 2014! The New Year has already seen a number of accomplishments for MCRF. These accomplishments are discussed in this edition of Research Matters. Not only are these achievements notable in and of themselves, but they also demonstrate the strength of collaboration. On that note, I urge everyone to attend our next Full Foundation meeting. What's the connection? We will be dedicating the majority of the meeting to talking with everyone regarding your thoughts and general comments about MCRF. People have expressed pride in MCRF and the work they do, but also

frustrations and concerns. It is obvious that there is work to be done. We are focusing our next Full Foundation meeting on continuing the conversation with you to improve the culture of MCRF. On a related note, we will be holding a Winter Holiday party on Friday January 24th from 11:30am – 2:00pm, in Lawton R1A/B/C. Be sure to come over to enjoy good company and good food!

Recent Publications

New England Journal of Medicine

Marshfield Clinic and Marshfield Clinic Research Foundation scientists collaborated with investigators from across the country on a recent article published in the *New England Journal of Medicine*. Dr. Steve Yale and Dr. Michael Caldwell were primary authors on an article titled, “A Pharmacogenetic versus a Clinical Algorithm for Warfarin Dosing.” Several other Marshfield investigators contributed to the project: Diane Kohnhorst, Sandra Strey, James Burmester, John Schmelzer, Joseph Mazza, and Satay Bhupathi were included in the list of COAG investigators. This study compared a genotype-guided warfarin dosing strategy with a clinically based dosing strategy during the first 5 days of therapy among patients initiating warfarin treatment. The full article can be read here:

<http://www.nejm.org/doi/full/10.1056/NEJMoa1310669>

New England Journal of Medicine

Dr. Ed Belongia was one of the researchers in a multicenter, collaborative study funded by the Centers for Disease Control and Prevention (CDC). The study sought to determine the postlicensure risk of intussusception following administration of the monovalent rotavirus vaccine Rotarix to infants aged 4 to 34 weeks. The complete article “Risk of Intussusception after Monovalent Rotavirus Vaccination” can be found here:

<http://www.nejm.org/doi/full/10.1056/NEJMoa1311738>

Lupus

Marshfield Clinic staff Michael Sanfelippo, Dr. Akanksha Joshi, Sally Schwartz, Jessy Meister, and Dr. Jerry Goldberg submitted an article to the journal *Lupus*, titled, “Antibodies to Phosphatidylserine/Prothrombin Complex in Suspected Antiphospholipid Syndrome in the Absence of Antibodies to Cardiolipin or Beta-2-Glycoprotein I.” The purpose of their study was to determine if antibodies to the complex of phosphatidylserine and prothrombin (aPS/PT) could be identified in patients suspected of having antiphospholipid syndrome (APS) but without antibodies to cardiolipin (aCL), and also to determine if patients with only aPS/PT had evidence of either thrombotic disease or obstetrical complications. The complete article can be found here: <http://lup.sagepub.com/content/22/13/1349.long>

SAARC Abstract

Marshfield Clinic physician Dr. Rezwana Islam was selected to represent Marshfield Clinic, MCRF, and SCH staff as International Advisor for the 8th South Asian Association for Regional Cooperation (SAARC) Federation of Oncologists meeting held December 13-15, 2013, in Kathmandu, Nepal. Dr. Islam was also one of the authors of the abstract, “Is Microsatellite Instability (MSI) Associated with Differential DNA Methylation in Colorectal Carcinoma?” that was presented at the conference. Please read the [abstract](#) for more information.

Marshfield Clinic Part of Greater Plains Collaborative

Marshfield Clinic along with the Medical College of Wisconsin, the University of Wisconsin-Madison, and medical organizations in seven states formed the Greater Plains Collaborative (GPC), part of the Patient-Centered Clinical Research Network (PCORnet). This collaborative will use a newly created depository of patient medical information, allowing patients and their caregivers to make better-informed health care decisions. The other institutions involved in the GPC are University of Iowa Healthcare, the University of Kansas Medical Center, Children's Mercy Hospital in Missouri, the University of Minnesota Academic Health Center, the University of Nebraska Medical Center, the University of Texas Health Sciences Center at San Antonio, and the University of Texas Southwestern Medical Center. Simon Lin, MD, director of the Biomedical Informatics Research Center at Marshfield Clinic Research Foundation (MCRF) is the local Principal Investigator, and Bob Greenlee, PhD, Epidemiology Research Center, MCRF, Murray Brilliant, PhD, director of the Center for Human Genetics, MCRF, and Amit Acharya, PhD, Dental Informatics Scientist, MCRF, are co-investigators (photos, left to right below).



The \$7 million GPC is funded by the Patient-Centered Outcomes Research Institute (PCORI) for 18 months while the institutions build and solidify the collaborative and technological infrastructure required to undertake such large trials. Having interoperable systems across all institutions is challenging, calling for parallel systems for collecting and managing data, governance structures, common dictionaries of terms, and standard operating procedures.

“We face the decision all the time of treatment options versus surgery,” said Lin. “This collected information will help providers, patients and the patients’ families make the best decision.”

The collaboration’s benefits have far-reaching potential. Greenlee said developing this stockpile of data is important for patients, providers, insurers, health systems, and policy makers. “We’re looking to study health care in a comprehensive way,” Greenlee said. “It can be done independently, but there is a greater chance of making a meaningful difference collaboratively.”

Patient information in the network will be “de-identified,” meaning it will not contain any of the 12 elements that could be used to identify a person. Though patients cannot be identified, Brilliant wants the results of related studies to become public, so people know they’re contribution helps. “People donate blood, cells, and DNA, but they’re never told what it’s used for,” Brilliant said. “I want to let people know how their biological donations are improving the health of other people.”

The collaborative used the input from community members throughout the Midwest to determine which health issues to target. GPC identified three areas of interest to the community members polled – breast cancer, amyotrophic lateral sclerosis (ALS; also known as Lou Gehrig’s Disease), and obesity. *(continued on next page)*

Greater Plains Collaborative *(continued from previous page)*

A challenge for nearly all clinical research is accruing enough patients to make study results meaningful, particularly in cases involving rare diseases. PCORnet can give physicians in the cooperative access to patient histories otherwise not accessible, offering evidence for a treatment plan with the best potential.

Citing Internal Funds, Endowment Funds, and Disease Specific Restricted Funds for Research Projects

Has your project received funding from “internal funds,” endowment funds, or Disease Specific Restricted Funds (DSRF)? If it has, your project has been funded by philanthropic gifts to Marshfield Clinic Research Foundation. Please help us recognize this source of funding. It will greatly assist MCRF and the development department in communicating to donors the impact their gifts have made.

Please include a citation, such as: “This study was funded in part through philanthropic support of Marshfield Clinic Research Foundation’s [insert fund name here].” This information is generally provided in MCRF’s award letters and will be requested for all articles regarding projects that were awarded donated funds.

A couple of examples:

For a study funded through the Heart, Lung, and Blood DSRF: “This study was funded in part through philanthropic support of Marshfield Clinic Research Foundation’s Heart, Lung, and Blood Disease Specific Restricted Fund.”

For a study funded through an endowment such as the Steve J. Miller Distinguished Physician/Scientist Endowment in Agricultural Health and Safety: “This study was funded in part through philanthropic support of Marshfield Clinic Research Foundation’s Steve J. Miller Distinguished Physician/Scientist Endowment in Agricultural Health and Safety.”

If you have any questions about this citation, please contact Deb Hansen (x7-9130) or Pete Schmeling (x9-3238).

New Oral Systemic Health Journal Club

You may have noticed that you’ve been hearing more and more about Oral Systemic Health here at MCRF. For example, in October the Dental Informatics team sponsored a Regional Oral Systemic Health Conference, and there are many oral systemic research projects underway across the foundation, including a bio-repository for OSH studies. In an effort to bring together groups who are working in this field and to share and expand our separate areas of knowledge, Dental Informatics and the Center for Human Genetics have launched a new journal club.

This activity is open to anyone at Marshfield Clinic, Marshfield Clinic Research Foundation, or the Family Health Center. By participating in the journal club, you will have the opportunity to explore oral systemic health research through a variety of lenses including, clinical, dental, informatics, laboratory, microbial, epidemiological, social, etc. **Meetings take place the 2nd Tuesday of each month from 12-1pm.** You are welcome to bring your lunch. Articles are mailed to participants one week in advance. Upcoming topics include sleep apnea to be presented by Dr. Boero, cleft lip and palate by Dr. Carter, and oral pathogens by Dr. Shukla. Previous sessions have focused on Alzheimer’s disease, breathomics, and Chronic Obstructive Pulmonary Disease (COPD). *(continued on next page)*

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

Health Journal Club *(continued from previous page)*

For more information, please check out the journal club's SharePoint site, where you can find presentations, articles, and the calendar.

http://mcrfsp/sites/mcrf_home/Journal%20Club/SitePages/Home.aspx

To suggest a topic, volunteer to lead a session, or to be added to the OSHJC mailing list, please contact Dixie Schroeder at schroeder.dixie@mcrf.mfldclin.edu. The more varied the expertise we have at the table the better, so we hope to see you there.

Clinical Research Center "Points of Interest"

This is a new standing section for *Research Matters*, incorporating information that was previously distributed in the monthly CRC Newsletter.

Educational Opportunities

Topic	Presenter	Date/Time	Location	Notes
"Human Subjects Research GCP... Maybe it is Rocket Science!"	Shari Zeldin	January 30, 2014 10:00-11:30 am	<i>via video conference</i> Froehlke Weston 1B EC-RCC	Human Subjects Research
"Informed Consent as a Process"	Steve Ziemba	February 18, 2014 10:00-11:00am	<i>via video conference</i> Froehlke Weston 1B EC-RCC Rice Lake West	Informed Consent Process

SoCRA Education and Certification Preparation

SoCRA Certification for CCRP

- March 19, 2014 from 8:00am-12:00 pm
- R1A/B/C
- Register on SoCRA site and receive study materials <http://www.socra.org/html/certific.htm>

SoCRA Exam Self Study (Medical Device Review FDA)

- Overview of Regulatory requirements for Medical Devices
<http://fda.yorkcast.com/webcast/Viewer/?peid=040308365ec8405bad39b06de8561bdc1d>
- Training and Continuing Education
<http://www.fda.gov/Training/CDRHLearn/ucm162015.htm#overview>

SoCRA Educational Opportunities 2014

<http://www.socra.org/html/education.htm#onlinecourses>

GCP

- ["Good Clinical Practice: A Question & Answer Reference Guide", Barnett International](#)

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

2013 MCRF Summer Intern Receives Acceptance into Five Dental Schools



Adam Sorenson, a former Marshfield Clinic Research Foundation Summer Intern on the Dental Informatics team received acceptance into five dental schools: Marquette University School of Dentistry, University of Minnesota School of Dentistry, University of Iowa School of Dentistry, University of Louisville Dental School, and Case Western Reserve University School of Dental Medicine. He also was offered a summer research scholarship toward his tuition at the University of Minnesota School of Dentistry. He has decided to attend Marquette University School of Dentistry to begin in fall of 2014.

Sorenson, a native of Wausau, Wisconsin, is currently a senior at the University of Wisconsin-La Crosse, majoring in Biochemistry.

Sorenson's summer research project focused on conducting a formal usability evaluation of the Intelligent Tooth Charting System (iTooth), a touch-based electronic tooth chart developed on the iPad. Through this research, he traveled to Family Health Center dental centers and obtained feedback from dental professionals that will enable improvements to the application.

Sorenson's abstract was accepted at the annual 2014 Symposium on Human Factors and Ergonomics in Health Care in Chicago, Illinois.

MCRF has offered summer research internship opportunities to qualified students since 1974. Through the Summer Student Research Internship Program (SSRIP), students are matched with a research mentor and work on an independent project, contributing to all aspects of the research process during the 12-week program. At the end of the internship, students present their research at the annual research [symposium](#). Sorenson was 1 of 10 students selected out of over 100 eligible applicants last summer.

SSRIP is accepting applications for summer 2014 through January 15, 2014. Scientists interested in mentoring a student should approach their Center Director. The SSRIP will work with Center Directors and MCRF Administration to select mentors for 2014.

Epidemiology's 2nd Annual Holiday Food Drive

This holiday season Epidemiology brought generous efforts as they came together with their 2nd annual food drive. Exchanging gifts can be a traditional setting for some, while others just hope to share a meal. Upon contacting the local pantry this year, it was quickly reiterated just how prevalent hunger is right here in our home communities. St. Vincent De Paul shared how many families they served recently: 722 in September, 798 in October, and 754 in November. As a department, Epidemiology was honored to bring some holiday cheer to families in need.

The activity began by dividing Epidemiology into random teams. A point system encouraged donations of items of greatest need by the pantry: fruits, vegetables, peanut butter/jelly, boxed meals, cereals, grains, and more. Epidemiology was further incentivized to donate peanut butter, jelly, and bread when they learned of a local high school project, where older students sneak a PB&J sandwich into the backpacks of younger students who may be going home to an empty plate. The teams battled it out for 10 days and each member of the winning team received a gift card courtesy of Cattails Coffee. *(continued on next page)*

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

Holiday Food Drive *(continued from previous page)*



Once again as seen in the picture to the left, Epidemiology was very successful in serving their mission to give the families of Marshfield hope during the holiday season. Together, the group collected 354 items that were loaded up and delivered on December 20, 2013. This collection included ample fresh fruits and vegetables, an abundance of canned fruits and vegetables, juices, boxes of cereal, a good supply of grains, and so much more. With hopes to carry on an annual tradition, Epidemiology takes a stance against hunger with hopes to share a little holiday magic with the community.

In Addition:

- The next Board of Trustees meeting will be held on January 30, 2014 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Dr. Jim Burmester, Deb Hansen, Dr. Rezwan Islam, Dr. Simon Lin, Anne Nikolai, Sarah O'Brien, Kristina Reisner, Michael Sanfelippo, Pete Schmeling, Kelsey Schwei, Dixie Schroeder, Dr. Bob Steiner, Dr. Steve Ziemba

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A Word from the Executive Director



We are pleased to publish the final winter edition of Research Matters, though I may be accused of wishful thinking for that designation. As you can see from the stories below, research productivity continues at a commendable rate. Our staff and scientists continue to receive honors and awards, and to participate on national committees. We are especially pleased at the name changes for our core lab and epidemiology group. Finally, the note below on research misconduct, which occurred close to home, is a frank reminder of the critical importance of research integrity training and monitoring.

And from Our Associate Director



It seems that winter may be abating somewhat. Definitely a positive change after the cold and snow we have been experiencing. That said, I think we hope to see more positive change within MCRF. It certainly has started. The level of openness and collaboration, already present, has increased. I am pleased to also inform you that our consultant for cultural change, Amy MacDonald, will be visiting us again March 5th – March 7th. We are providing her the entire Full Foundation meeting, on March 5th at 10 am in the Froehle auditorium, to allow her the opportunity to communicate to all of you. She will also be meeting with the scientists and staff of MCRF, in a manner similar to her initial visit, to present her requests for change. This is an important milestone in the ongoing improvements of MCRF, and one I am sure everyone feels is welcome. Thank you again for the work you do.

Compliance Corner

Research Misconduct

The Department of Health and Human Services (DHHS) Office of Research Integrity (ORI) recently made a research misconduct determination involving a researcher in Wisconsin. ORI is the office that investigates allegations of misconduct in research funded or directed by the Public Health Service (PHS). This researcher was found to have constructed five false Western blot figures while a graduate student at the Medical College of Wisconsin and an assistant scientist at UW-Madison. He also was determined to have falsified quantitative data for summary bar graphs and statistics in related text. As part of a settlement with ORI, over the next three years, the researcher must be supervised during any involvement in PHS-funded research, any employer of the researcher who wants the researcher to be involved in PHS-funded research must certify to ORI that data, procedures and methodology are accurately reported, and the researcher cannot serve in any advisory capacity to PHS.

(continued on next page)

Compliance Corner *(continued from previous page)*

All investigators and staff at Marshfield Clinic must be aware of what constitutes research misconduct, and report suspected research misconduct as required by Clinic policy. Research misconduct is the “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”

- “Fabrication” is making up data or results, and recording or reporting them.
- “Falsification” is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- “Plagiarism” is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

A finding of research misconduct can be made for any misconduct that is not only committed intentionally or knowingly, but also misconduct that is committed recklessly.

Farm Center to Host OHIP Internship

The National Farm Medicine Center has become a host site of the Occupational Health Internship Program (OHIP), a program dedicated to helping students learn about the field of occupational safety and health. Applications are being taken at: <http://aoec.org/ohip/>.

The intern(s) will be working on dairy-related projects of the Upper Midwest Agricultural Safety and Health Center. Applicants must be bilingual in Spanish and English. Application deadline is March 14, 2014.

Since 2004, OHIP has played a crucial role in training, mentoring, and inspiring a new generation of occupational safety and health professionals, as well as providing worker organizations and unions with resources to strengthen their health and safety efforts to prevent job injury and illness. OHIP is housed within the Association of Occupational and Environmental Clinics and has training sites in the San Francisco Bay Area, Los Angeles, San Diego, Chicago, Boston, New York City, Denver, Wisconsin, and Minnesota.

Changes to IRB Exempt Research

A clarification has been made to the IRB Procedure, “Review of Exempt Projects.” Previously, once exempt from further IRB review, a project did not have to come back to ORIP unless the PI was planning to change the project in a way that would render the original exemption null. As of November 2013, investigators should submit a new IRB Exemption Request Form if there is any change to the activity, from what was described at the time of original exemption. ORIP will then determine whether exemption is still applicable under 45 CFR 46. 101(b). To learn more about IRB Exempt Research, attend ORIP’s Education Series Presentation on March 27th at 10AM in Laird 50.

CHG Researchers Attend NHGRI Workshop – eMERGE Network



On January 22, 2014, the National Human Genome Research Institute (NHGRI) held a workshop focused on the **e**lectronic **M**edical **R**ecords and **G**enomics (eMERGE) Network, in Bethesda, MD. NHGRI staff and experts from around the country were invited to attend and discuss the progress of the genomics community and future directions for eMERGE Phase III.

Two Center for Human Genetics (CHG) investigators, Drs. Murray Brilliant and Peggy Peissig, were invited to attend this workshop.

The agenda focused on eight areas:

- Discovery versus Implementation-Balancing;
- EHR and Clinical Phenotyping-Challenges and New Opportunities;
- EHR and Genomic Discovery-Beyond GWAS and Pharmacogenomics;
- Genomic Testing (genotyping/sequencing) – Actionability, Validation and Standards of Lab Reports;
- Informed Consent, Education & Governance – ELSI;
- Return of Genomic Results – Current Applications and Challenges;
- EHR Integration and Genomic Medicine Implementation – Big Data, Clinical Disseminations, Clinical Validities & Utilities; and
- Genomic Medicine in Pediatric Patients – Obstacles and Future Directions.

Dr. Murray Brilliant was part of the panel discussing the Genomic Testing and Actionability topic.

MCRF Dental Informatics Scientist Elected to Two Committees



Dr. Amit Acharya was recently elected to serve as the Vice Chairman of the Clinical Informatics subcommittee and a member of the Oversight Committee of the American Dental Association's (ADA) Standard Committee on Dental Informatics (SCDI). Dr. Acharya has been involved in various national standards development activities in the past and had recently contributed in the publication of the ANSI-ADA Specification 1067 for Standard Functional Requirements of an Electronic Record System for General Dentistry.

The ADA SCDI develops informatics specifications and technical reports to assist the dental profession with hardware and software selection, digital photography, interoperability, data security and more. The SCDI is comprised of 40 voting members from the profession, dental industry, academia, and the government. In 2001, the SCDI was reorganized into three subcommittees and 14 working groups working on the development or revision of 26 technical reports or specifications. The actual standards development occurs in its 19 working groups. The subcommittees are grouped according to the following general subject matters: Information Exchange, Clinical Informatics, and Knowledge Management.

Clinical Research Center “Points of Interest”

Educational Opportunities

“Informed Consent as a Process”	Steve Ziemba	February 18, 2014 10:00-11:00am	<i>via video conference</i> Froehlke Weston 1B EC-RCC Rice Lake West	Informed Consent Process
“Human Subjects Research GCP.... Maybe it is Rocket Science!”	Shari Zeldin	Archived on mediasite from January 30, 2014 presentation	http://mediasite.mfldcl.in.edu/Mediasite/Play/39ac9e0104014b0d90b5ec4c031a4f4f1d	Human Subjects Research Slides

ACRP (Association of Clinical Research Professionals)

- <http://www.acrpnet.org/>
 - ACRP 2014 Global Conference & Exhibition, April 26-29, 2014 (San Antonio, TX)
 - **Explore PI Certification** <http://www.acrpnet.org/MainMenuCategory/Certification/PICertification.aspx>
- Note* Many Sponsors accept certification with ACRP in lieu of annual GCP training

SoCRA (Society of Clinical Research Associates)

Certification for CCRP

- March 19, 2014 from 8:00am-12:00 pm
 - R1A/B/C at Marshfield Clinic Research Foundation
 - Register on SoCRA site and receive study materials <http://www.socra.org/html/certific.htm>
- Note* Many Sponsors accept certification with SoCRA in lieu of annual GCP training

- [SoCRA Chapter Meeting](#) Invitation
- [SoCRA Self-Study guide](#)

GCP

- [Guidance for Industry Investigator Responsibilities-Protecting the Rights, Safety, and Welfare of Study Subjects](#)

Center for Clinical Epidemiology & Population Health Announces New Name

MCRF Board of Trustees (BOT) approved a name change on January 30 for the center formally known as Marshfield Epidemiology Research Center (MERC). “There has been interest in renaming our center for the past couple years because ‘epidemiology research’ does not convey the scope of our work to most people,” says Edward Belongia, MD, Director of CCEPH. “We spent a great deal of time discussing options for a more descriptive center name, and I think the new name will be helpful for collaborators, reviewers, funding agencies and donors.” The new name makes it clear that CCEPH focuses on population health, but also recognizes their involvement in clinical research studies. Chair of the BOT, Jaime Boero, MD, stated during the January 30 meeting that the center can change their name as long as they keep doing the same great work. Belongia assured Boero that wouldn’t be a problem.

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

“Core Lab” Adopts New Name

On January 30, 2014 a name change for the MCRF Core Laboratory was adopted by the MCRF Board of Trustees. Core Lab will now officially be known as the Integrated Research and Development Laboratory (IRDL).

The IRDL was founded in 1998 as a small team of staff who primarily supported the needs of Marshfield Clinic physicians whose research ideas required skilled laboratory testing. Today, the laboratory supports over 50 active studies and has gained a national reputation for influenza research, provides stewardship of the Personalized Medicine Cohort, and supports clinical trial needs. Most recently, the IRDL has begun the process of bringing next generation sequencing to our research community.

We proposed a name that more accurately reflected the breadth and depth of the research and services we provide to Marshfield Clinic, MCRF, and external research partners. Since its inception, the IRDL mission has been to provide a central support to investigators. We have the ability to engage in all aspects of the research process from the start of an idea through publication. This is all possible because of the high quality, skilled support of a team of scientists and Research Associates who comprise the IRDL. The combined years of service to Marshfield Clinic is quite impressive with 264 years of experience. Members of the IRDL with years of service noted are: Wayne Frome (46), Lynn Ivacic (28), Phil Bertz (28), Donna David (27), Kai-Qi Zhang (22), Tammy Koepel (19), Nan Pan (16), Jennifer Anderson (14), Thao Le (14), Jennifer Meece (12) Patrick Stockwell (12), Sherri Guzinski (11), Elisha Stefanski (6), Brooke Olson (6), and Anna Schotthoefer (3).

Questions about support available and access to services from the IRDL can be directed to Jennifer Meece, PhD (meece.jennifer@mcrf.mfldclin.edu).

NFMC Visits Wisconsin Cranberry Growers Meeting



Matt Faber, Marshfield Clinic Development Officer, Scott Heiberger, Communications Specialist, and Tammy Ellis, Education Outreach Specialist (left to right in photo), attended the Wisconsin State Cranberry Growers Association conference, January 22, at the Holiday Inn Hotel and Convention Center, Stevens Point, Wis. Growers shared health and safety concerns unique to the cranberry industry, as well as issues common across other types of agriculture. The National Farm Medicine Center looks forward to working more with cranberry growers.

Winter Party

The Winter Party held on January 24th brought Marshfield Clinic Research Foundation staff together for good food and good conversation. A big “thank you” to those who contributed and made this possible: Dr. Ed Belongia, Dr. Murray Brilliant, Dr. Matt Keifer, Dr. Simon Lin, Dr. Richard Leer, Dr. Bob Steiner, Dr. Steve Yale, and Dr. Steve Ziemba!

Continuous Quality Improvements in the Marshfield Epidemiologic Study Area

The Marshfield Epidemiology Study Area (MESA) was formed in 1991 and is the oldest active research cohort in the Marshfield Clinic Research Foundation (MCRF). MESA is one of several more-visible research brands associated with MCRF. As a core research resource, MESA supports both scientist and clinician-led projects that involve population-level research questions.

Just as Marshfield Clinic providers continuously strive to improve the quality of care for their patients, a team of scientists and programmers in the Center for Clinical Epidemiology and Population Health continues to adopt innovative methods to improve the accuracy and usability of the MESA resource. This has become increasingly important as research informatics capabilities develop rapidly across the country in other large healthcare organizations and the scope of MCRF research continues to expand. To help ensure that MCRF is well positioned to compete for externally funded population health projects in the future, the MESA team is pursuing several key updates in 2014. These will result in: (1) improving the precision of MESA person-time estimates, (2) regularly communicating information on MESA population characteristics (e.g., demographics, disease rates) to interested stakeholders, and (3) improving epidemiologic research capacity/flexibility to build larger, more diverse cohorts that combine MESA data with other Marshfield Clinic sources such as non-MESA patients and Security Health Plan enrollees.

Several updates were recently completed that align MESA programming with new administrative procedures conducted in the Clinic related to tracking patient addresses. This work results in more precise identification of individuals who enter MESA and helps the MESA team more efficiently find questionable residents that may require manual validation. A statistical algorithm is currently being developed and will soon be validated against physical address confirmations in order to improve the accuracy of how long a given MESA resident should be considered an 'active' member of the MESA cohort. Results from this work will streamline current research processes that 'cap' MESA enrollment status. A further side benefit of this work will likely be closer alignment between MESA residency and U.S. census estimates of the number of people in our region.

Learnings from these MESA refinements will be applied in the regular release of reports that outline the MESA population profile, as well as the incidence and prevalence of select diseases. These reports will be shared at MCRF Scientific Seminars and posted on the CCEPH department website and SharePoint pages. They will help both internal and external research collaborators access and understand basic information on the MESA population. In collaboration with BIRC and other MCRF experts, the MESA team will also pursue ways to improve MCRF's capacity to assemble larger population cohorts beyond MESA. Some large research cohorts that overlap with MESA are currently available to MCRF scientists, including Vaccine Safety Datalink and the Virtual Data Warehouse (as part of the HMO Research Network), among others. In order to provide more robust support for projects that require larger sample sizes, the healthcare utilization patterns of broader pools will be explored to estimate the levels at which Marshfield Clinic captures their medical care. This activity will advance MCRF's capabilities in population-based research, providing more flexibility in assisting scientists on how to identify the right population for their given research projects.

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

New Staff

Research Specialist Joins Center for Human Genetics

Thomas (Nate) Person joined the Center for Human Genetics on January 27th as a research specialist. Nate will work with Dr. Max He on projects to develop novel and reliable statistical methods and computational tools for analyzing phenome-wide associate studies (PheWAS) data; “Big Data” framework to support translational research, statistical methods and computational tools for analyzing next-generation sequencing (NGS) data, and statistical tools for analyzing drug-wide association studies (DrugWAS) data derived from EMRs combining with different genetic data.

Nate was born and raised in Austin, Texas. He served in the US Air Force for many years and was stationed in Mildenhall, England for almost five years. After leaving the armed services, Nate pursued undergraduate studies at Angelo State University, Texas majoring in biochemistry followed by earning a master’s degree in Bioinformatics and Computational Biology from the University of Texas, Dallas. During his master’s program, he held several bioinformatics internships at the Los Alamos National Laboratory and the University of Texas Medical Center. Nate was employed at the University of Texas-Southwestern Medical Center prior to coming to Marshfield Clinic Research Foundation. In non-working hours, Nate enjoys bicycling and is looking forward to taking advantage of Wisconsin’s winter sport activities.

Anthropologist Joins National Farm Medicine Center



Casper “Cap” Bendixsen, PhD, has joined the National Farm Medicine Center/National Children’s Center as a project scientist. Bendixsen’s specialty is cultural anthropology. He’s helping the Farm Center to better understand the social and cultural fabric of rural populations, enhancing the center’s ability to tailor safety initiatives. He successfully defended his dissertation January 29 at Rice University, where he taught for three years. He holds a master’s degree in anthropology from Rice, and earned bachelor’s degrees in anthropology and philosophy from the University of Idaho. Bendixsen’s dissertation is titled, “Pastoralist Ethic and a ‘Spirit’ of Traditionalism: US Cowboys’ Livestock, Land and Kin.” He is a former professional rodeo cowboy and firefighter/emergency medical technician. His topics and areas of study include: agrarian ethics, traditionalism, masculinity, rhetoric and poetics, ethnography, and working class imaginations/intellectualism.

BIRC Analyst Reappointed as PCORI Panelist



Daniel Wall, BIRC Applications Analyst, has been reappointed to the Patient Centered Outcomes Research Institute (PCORI) Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options. In his role with that Advisory Panel, Wall represents patients, caregivers, and patient advocates. This Panel evaluates and prioritizes research questions and topics such as bipolar disorder, ductal carcinoma in situ, migraine headache, and osteoarthritis.

Farm Safety Campaign Wins Awards



The Cultivate Safety campaign, “Parent First, Farmer Second,” earned two first-place awards from the National Agri-Marketing Association (NAMA) Region IV. The campaign won for best print ad series and best radio ad series. The announcements were made January 23 at the NAMA awards dinner in Milwaukee. The goal of the ads is to demonstrate the passion and hard work that goes into being a farmer, but ultimately reminds us that a farmer’s most important job label is being a parent. The ads encourage farmers to put their children’s safety first.

The National Farm Medicine Center/National Children’s Center worked with Twin Cities agency broadhead on the campaign (<http://cultivatesafety.org>). “The research aim of the campaign,” said Principal Investigator Barbara Lee, PhD, “is to determine if working with an agricultural marketing firm is effective in reaching farm parents who can use the safety information to guide actions that minimize injuries and fatalities to children.”

In Addition:

- The next Full Foundation meeting will be held on March 5, 2014 at 10AM in the Froehle Auditorium. Amy MacDonald will be speaking.
- The next Board of Trustees meeting will be held on May 8, 2014 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Bobbi Bradley, Scott Heiberger, Linda Jaros, Cathy Marx, Dr. Jen Meece, Anne Nikolai, Melissa Ostrowski, Dr. Peggy Peissig, Dixie Schroeder, Dr. Bob Steiner, Marlene Stueland, Dr. Jeff VanWormer, Michelle Wellsandt, Dr. Steve Ziemba

Edited by: Alexis Tavano, MPH, tavano.alexis@mcrf.mfldclin.edu, ext. 1-8939.

Director's Report



Thank you to all who attended the Full Foundation meeting to hear from Dr. Brian Ewert. The recent announcement on financial measures within Marshfield Clinic has led to some degree of discussion and rumors within MCRF. We are looking to you to help discern truth from fiction, and to make sure that what you hear is, indeed, true. Our Full Foundation meeting was one means to help provide factual information, and we will be holding a follow-up session with Dr. Ewert to continue this discussion.

Healthcare systems, of all sizes, throughout the country are facing the same pressures we are. Some have been more severely affected than others. Fortunately, Marshfield Clinic has proactively identified the potential for severe consequences, and our Board of Directors and Senior Leadership are actively working to prevent such consequences from happening. This storm has been weathered before and we can navigate it again.

The greatest asset that MCRF has is its people. You are knowledgeable and committed to the work and mission of the organization. Let us know what ideas you may have to help better manage costs, increase revenues, or any other improvement that will be beneficial to MCRF. Thank you again for all you do.

Compliance Corner

Research Risk Assessment for 2014

Development of the Marshfield Clinic annual research risk assessment for 2014 has begun. As part of the process, Research Compliance Officer Melissa Ostrowski would like to thank MCRF leadership, researchers and staff for completing a survey about compliance hot topics and areas of concerns. She is reviewing the last risk assessment conducted at MCRF, the current regulatory environment, findings made by federal agencies, hot-topic issues noted in publications and at conferences, and local audit results. Ostrowski will present a draft of the assessment at the next Research Compliance Committee for consideration.

Research Institute Cited by FDA for Defects in Device Trials

A Las Vegas research institute, Advanced Magnetic Research Institute (AMRI) recently received a warning letter from the FDA after an inspection. AMRI was a sponsor for three studies evaluating the "Magnetic Molecular Energizer," a device intended to treat congestive heart failure, cerebral palsy, Alzheimer's, and brain and spinal cord injuries. The FDA found several violations of the regulations for investigational device exemptions, including that AMRI failed to obtain IRB approval, and promoted the device on its website as safe or effective for the purposes for which it was being investigated before the FDA approved it for commercial distribution. AMRI also failed to maintain required records or make reports, including reports of several serious adverse events. AMRI was given 15 days to submit proposed corrective actions and a monitoring plan.

KL2 Scholars Program

The KL2 Scholars Program provides promising young clinical and translational investigators the training, mentoring, and protected time to develop an independent research program. This program is funded by the NIH through ICTR's Clinical and Translational Science Award (CTSA) and currently includes 16 KL2 Scholars.

The University of Wisconsin Institute for Clinical and Translational Research (ICTR) is requesting KL2 Program Applications for June 2015 awards. The KL2 Program is a mentored career-development award intended to train and support junior faculty pursuing and actively engaged in clinical and/or translational research careers.

Key Dates

RFA Information Sessions will be held on **April 4, 2014** or **April 24, 2014** from 12:00-1:00pm in 2158 Health Sciences Learning Center to discuss the application process for 2015 KL2 Program awards. Potential applicants and their 2 proposed mentors are strongly encouraged to attend one of these sessions. (Note: there may be the possibility of teleconferencing these sessions for MCRF applicants.)

Monday, **June 2, 2014** is the Nomination Letter deadline. All MCRF KL2 candidates must be nominated by Dr. Bob Steiner.

Information sessions (2 options) for the Nominee and Mentors will be held on **June 4, 2014** or **June 18, 2014** from 12:00-1:00pm in 2158 Health Sciences Learning Center. MCRF Nominees and Mentors are encouraged to attend one of these sessions in person.

Monday, **August 4, 2014** is the Application due date, with an extended deadline of **September 2, 2014**, for new faculty with appointments starting between June 1, 2014 and June 1, 2015.

December 2014 is when Award announcements will be made. The cohort selected from this round of applications will start on **June 1, 2015**.

The RFA and application materials (including a sample Letter of Nomination) can be found at this link: <https://ictr.wisc.edu/KL2RFA>.

For more information regarding ICTR's KL2 Program, please visit <https://ictr.wisc.edu/> or contact ICTR Research Education and Career Development Administrative Director, Pam Asquith (psasquith@wisc.edu).

Researcher, Research Staff, and IRB Member Survey

The Office of Research Integrity & Protections (ORIP) would like to thank everyone who participated in the Researcher, Research Staff, and IRB Member survey last October. Eighty-eight individuals responded, for a response rate of approximately 30%. The survey asked respondents to rate (extremely satisfied, very satisfied, satisfied, somewhat satisfied, and not satisfied) the following areas:

- quality of interactions with IRB staff (responsiveness, friendliness, knowledge and communication)
- satisfaction with time from submission to decision from convened IRB; and
- satisfaction with time from submission to expedited review decision.

(Continued on next page)

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

Research Survey *(Continued from previous page)*

What we learned about these areas is that the great majority of respondents (85%-93%) were extremely satisfied, very satisfied, or satisfied. Friendliness of IRB staff rated the highest at 93% and time from submission to convened IRB review rated the lowest at 85%. In the latter category, 10% were somewhat satisfied and 4% were not satisfied.

Respondents were also asked to:

- describe positive and negative experiences with the IRB or IRB staff;
- suggest improvements to the IRB process; and
- suggest topics for future educational offerings.

We received many helpful comments in these areas and appreciate the honest and thoughtful input. We will be working to address the following themes that emerged from comments in the 'not satisfied' and 'negative experiences' areas:

- less frequent changes in policies/procedures;
- assistance in understanding form completion expectations;
- quicker processing/review times; and
- clarification on IRB requirements versus other regulatory requirements (ie, data transfer, HIPAA privacy)

ORIP looks forward to your continued feedback in future surveys and hopes you will consider participating if you did not do so in the inaugural survey.

Policy on Requests for Donated Funds

MC/MCRF is the beneficiary of donations from grateful patients that are expected to be used for conducting disease specific research. Through MCRF's Internal Funding policy:

http://srdweb1/clinic/policies/policy_details.asp?RecID=253, employees of MC can apply for access to these donated funds by submitting a research proposal to the Research Committee for scientific merit review. Please see the form, "[Research Committee – Full Proposal Application – Projects Requesting Funds](#)". The level of base funding available per project is currently \$50,000. (When practicing clinicians are participating in the research, an additional \$15,000 per project may be awarded to compensate for their time and effort.)

Effective October 1, 2013 pre-proposals are required to be submitted for review in advance of submitting a full proposal. Applications may be submitted any time prior to the start of each quarterly cycle, with new cycle dates beginning on the 16th of March, June, September and December. Applications are reviewed in the order they are received during the cycle, so it can be advantageous to submit proposals earlier in the cycle than later.

A listing of disease specific funds available can be found on the Research Mentor intranet landing page, with a link titled "Donated Funds Available for Research":

<http://mclweb/mcrf/?page=researchmentor>. Questions regarding this funding mechanism can be directed to Deb Hansen at ext. 79130.

Plan to Attend the Rich Seubert Celebrity Trap Shoot



Rich Seubert

Winter will be gone before we know it, and you know what happens in the spring... The **Rich Seubert's Celebrity Trap Shoot!** Join us for a fantastic day with current and former NFL greats to help raise support for cardiology research. New York Giants include Chris Snee, Kevin Boothe, Grey Ruegamer, Chris Bober, Jim Cordle, and Kevin Boss and Green Bay Packers include Tony Fisher, Bill Schroeder, Dexter McNabb, and Bill Ferrario.

The 6th Celebrity Trap Shoot will be **April 12, 2014** at the Eau Claire Rod & Gun Club in Eau Claire, WI. A reception with heavy hors d'oeuvres, raffles, and silent and live auction will follow at The Florian Gardens. There is plenty of excitement for the non-shooters as well. Guests can attend the entire day's event (trap shoot, lunch, and evening reception) or just the evening reception. There will be raffles and auctions featuring luxurious vacation packages, rare autographed sports memorabilia, guns, and more!

Shooting spots are limited, so register your team today. If you register to shoot by March 26th, you will be entered for a chance to win the Early Bird Prize!

If you plan to spend the weekend with us, blocks of rooms have been reserved under "Trap Shoot" at the Holiday Inn or The Metropolis Hotel in Eau Claire. Please visit www.marshfieldclinic.org/TrapShoot for the online registration link for both hotel and event registration.

Clinical Medicine & Research Announcements



Beginning with the next issue of *Clinical Medicine & Research*, the complimentary print version of the journal will no longer be provided to Marshfield Clinic's clinical care providers and MCRF's scientists and staff. The online version of *Clinical Medicine & Research* will remain available to Marshfield Clinic's and MCRF's employees, and the print version will be available for reading in the George E. Magnin Medical Library. Personal subscriptions to the print version of the journal can be ordered by emailing the Editorial Office at clinmedres@mcrf.mfldclin.edu.

If you would like to receive email notification of future issues and articles published online-ahead-of-print in the journal's *RAPID RELEASE* section, visit the journal's web site (www.clinmedres.org), click on the "Sign up for Email Alerts" link in the center of the homepage and enter the requested information.

The December 2013 issue of *Clinical Medicine & Research* (volume 11, number 4) presented original articles by Dr. Adedayo Onitilo and colleagues (Marshfield Clinic and MCRF) assessing prostate cancer risk in pre-diabetic men, and evaluating survivorship of breast and prostate cancer patients with diabetes. Dr. Carrie Black and colleagues (Marshfield Clinic and MCRF) presented a study of urinary calcium in primary hyperparathyroidism, and Dr. Tahir Tak and colleagues (Mayo Clinic) presented a review of EECF therapy in clinical practice. Read these articles and more from December 2013 on the *Clinical Medicine & Research* web site (www.clinmedres.org). Articles published online-ahead-of-print can be found by clicking the "View *RAPID RELEASE* articles" link in the center of the homepage.

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

Former Summer Intern Completing First Year of Medical School



Former Summer Intern Shea Kruger, now Shea Jorgensen, is in the second semester of medical school at University of Iowa Carver College of Medicine. Her husband, Michael Jorgensen, also a former Summer Intern, is likewise attending medical school at University of Iowa and is in his second year. Kruger worked on the genetics of C-reactive protein (CRP), a biomarker used to detect inflammatory states, while interning at MCRF in 2011. “Dr. Dart was the best mentor imaginable and really pushed me to dig deeply into the science as well as the clinical impact that research has,” said Kruger of her experience at MCRF. “I can’t say enough about the positive experience I had!” After her internship at MCRF, Kruger completed a genetics internship at University of Michigan in 2012, followed by research into delirium in the hospice setting through University of Iowa. Kruger is planning to practice medicine but hopes to continue to have a research component in her career.

For more information about the Summer Student Research Internship Program, see this link: http://www3.marshfieldclinic.org/visitors/pages/default.aspx?page=educational_opportunities or contact Bobbi Bradley at ext. 9-3658.

Upcoming Conferences/Short Courses through UW-Madison

The following Land O’Lakes conferences are available for registration:

- June 9-12: 56th Annual International Industrial Pharmaceutical Research and Development Conference – “Particle Engineering in API and Drug Product Design”
- July 21-24: 15th Annual Bioanalytical Conference – “Adapting to Diverse Bioanalytical Technologies and a New Regulatory Guidance”
- August 4-7: 54th Annual Pharmaceutical Analysis Conference – “Innovations in Pharmaceutical Analysis & Quality: Solutions in a Climate of Change”
- September 8-11: 17th Annual Drug Metabolism and Pharmacokinetics and Applied Drug Development Conference – “Challenges in Developing Protein Therapeutics, Using Biomarkers, and Evaluating Drug Transporters”

Link to all conferences above:

<http://ce.pharmacy.wisc.edu/course/category.php?id=2&perpage=5>

In addition, UW-Madison is offering 3 unique short courses for the new Applied Drug Development Certificate Program. Those interested in learning more about this program can click here: <http://ce.pharmacy.wisc.edu/mod/coursepage/view.php?id=2827>

Per Dr. Eric Buxton (ebuxton@pharmacy.wisc.edu) one core course for the above program is under development for an online format, expected to be available either this fall or spring of 2015. One elective course is already online – “A Practical Review of Cardiovascular Physiology, Pharmacology and Safety” (<http://ce.pharmacy.wisc.edu/2014CardiovascularSCInfo>), and starts on April 1st. This course meets weekly through the end of May. “For the foreseeable future it will be necessary to attend at least 2 core courses in person. We are working on adding more elective online courses as well,” said Buxton.

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

New Staff

NFMC Hires Dairy Worker Safety Trainer



The National Farm Medicine Center has hired a bilingual community outreach trainer to conduct free health and safety training for Hispanic dairy workers on Wisconsin farms.

Yurany Ninco Sanchez comes to the Farm Center from Family Health/La Clinica in Wautoma, WI, where she worked as an outreach coordinator and nurse with migrant farm workers and their families. Ninco Sanchez holds a bachelor's degree in health care administration from the University of Wisconsin Stevens

Point. She also has a bachelor's degree in nursing from the University of Antioquia, Medellin, in her native Colombia.

Ninco Sanchez will deliver training approved by the Occupational Safety and Health Administration (OSHA) and endorsed by the University of Wisconsin River Falls and the Mexican Consulate in St. Paul, MN.

"We are delighted that we could attract someone as qualified as Yurany to this highly specialized position," said NFMC Director Matthew Keifer, MD, MPH. "Our Hispanic workforce is growing in dairy and in agriculture overall. Yurany will help the Farm Center reach that important community, and provide them with culturally and linguistically appropriate health and safety training."

Lesson topics include Introduction to Hazards, Animal Handling, Machinery and Equipment, Workers' Rights and Responsibilities, and Chemical Safety and Confined Spaces.

The trainings are offered free to qualified farms with grant-funding through the Upper Midwest Agriculture Safety and Health Center. Trainings are delivered on-the-farm with flexible scheduling. For complete information, go to: <http://www.marshfieldclinic.org/nfmc/seguridad>.

In Addition:

- The next Full Foundation meeting will be held on May 1, 2014 at 10AM in the Froehlke Auditorium.
- The next Board of Trustees meeting will be held on May 8, 2014 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Diane Austin, Tiffany Halan, Deb Hansen, Scott Heiberger, Melissa Ostrowski, Sherry Salzman, Dr. Steve Ziemba

Edited by: Alexis Tavano, MPH, tavano.alexis@mcrf.mfldclin.edu, ext. 1-8939.

Directors' Report



It is with tremendous pleasure that we celebrate Dr. Adedayo Onitilo's achievement being named a 2014 recipient of the Wisconsin Women's Health Foundation's *Champion in Women's Health – Cancer* award. This is a well-deserved honor for Dr. Onitilo, a true champion for women's health. In addition, we are delighted to share with you the exciting news that Dr. Richard Dart has been named President of the Wisconsin Medical Society (WMS). This is wonderful news for Dick and an acknowledgement of his numerous contributions to medicine in our state, but also great news for Marshfield Clinic. Finally, I call your attention to the section in the newsletter

on biosketches. We should be doing everything we can to increase our success rate on grant applications. Standardizing our approach to biosketch preparation is one way to make sure that our ancillary material optimally supports our science on grant applications.



There has been a lot of talk lately in the healthcare and research fields on the extended focus of the importance of research in healthcare. The relationship of research to healthcare goes beyond the inherent role of healthcare research; that is, investigating the causes, prevention and treatment of disease. Some areas of importance include patient centeredness, costs and quality.

A growing area is the inclusion of costs as an area of study. Healthcare costs as an area of research interest spans a wide area. A direct application is the understanding of cost effectiveness in a clinical study of different treatments. Such may be the focus of a comparative effectiveness study, or even within patient-centered outcomes research such as through the Patient Centered Outcomes Research Institute (PCORI). Quality is another area where interest within the industry has arisen on application of research methodologies. The concept of quality in healthcare is a broad area of focus. Regardless, it has a direct impact on costs via such diverse areas as adherence to standards, patient satisfaction, and efficiency, among others.

So why discuss this topic here? As we move forward with areas of research interest, you will likely see a greater emphasis on the inclusion of such aspects as cost effectiveness, impact on quality, and patient centeredness in grant announcements and among study sponsors. It also opens a door of opportunity for us as researchers, in working with the Marshfield Clinic Health System in improving care and quality, as well as reducing costs, for both the health system and the patients we serve.

Dr. Onitilo Honored as a 2014 Champion in Women's Health



Marshfield Clinic physician and researcher, Adedayo Onitilo MD, MSCR, FACP has been named a 2014 recipient of the Wisconsin Women's Health Foundation's *Champion in Women's Health – Cancer* award.

"Dr. Onitilo is an accomplished hematologist/oncologist with extensive clinical and research background in cancer, particularly breast cancer," said Dr. Steven Ziembra. "His tireless and selfless effort in breast cancer transcends a number of areas and we are pleased to have his work recognized by the Wisconsin

Women's Health Foundation."

Much of Dr. Onitilo's research is focused on breast cancer. He is the Principal Investigator on several studies of breast cancer prevention, control, and treatment, some international in scope. His significant contributions to the breast cancer knowledge base include mammography use, genetic biomarkers, and the influence of diabetes type II treatment on breast cancer management – findings he has used in his practice.

The Wisconsin Women's Health Foundation is a nonprofit organization founded in 1997 by Wisconsin's former first lady, Sue Ann Thompson after her diagnosis of breast cancer. The Foundation is dedicated to helping Wisconsin women and their families reach their healthiest potential through health education, resources, community and professional grants, and scholarships.

Wisconsin Medical Society Inaugurates New President



Dr. Richard Dart became one of only five Marshfield Clinic physicians to be named President of the [Wisconsin Medical Society \(WMS\)](#) since its foundation in 1841. Dr. Dart succeeds Dr. Timothy McAvoy. The WMS is the largest association of medical doctors in the state and a trusted source for health policy leadership.

In an interview with *The Pulse*, Dr. Dart said, "We (the Society) are facing more issues than have confronted medicine in many decades. This also provides both challenges and opportunities to participate in as effective, responsive, and responsible of a manner as possible. As Wisconsin Medical Society president, to assist and participate in helping get the 'message out' and to be a part of the Society leadership team is a very humbling, yet exciting, privilege and opportunity."

Dr. Dart has served as a member of the Society's Board of Directors and in several other leadership roles during his 40-year tenure with the Society. He is also an adjunct clinical professor of medicine at the University of Wisconsin School of Medicine and Public Health's Marshfield Campus and serves as an attending physician at the St. Vincent Free Clinic in Marshfield.

Dr. Dart is a graduate of the University of Illinois, College of Medicine and is board certified in internal medicine and nephrology. Dr. Dart retired from Marshfield Clinic as a nephrologist after serving from 1973 to 2007. Currently he serves as an Emeritus Research clinician in the Center for Human Genetics at the Marshfield Clinic Research Foundation.

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

Guidance on Creation of Quality Biosketches

A review criterion for grant reviewers is 'Investigator'. Reviewers are tasked with evaluating whether the proposal demonstrates relevant PI and research team expertise to carry out the research study. Biosketches are an important venue in the grant for demonstrating:

- 1) your expertise, training, and experience, and
- 2) your specific roles on the grant that is being submitted.

The following checklist summarizes points you will want to quality assess when creating your biosketch:

- 1) Did you follow the specific instruction for formatting the biosketch for this particular grant application?
 - a. The current general NIH guidelines specify a 4-page limit, but some RFAs state a different page limit, so check the RFA for instructions.
 - b. Margins should be one-half inch on all sides, black type, font style Arial, Helvetica, or Georgia, up to 6 lines and 15 characters per inch.
- 2) Headers:
 - a. Education and Training:
 - i. Include undergraduate and graduate degrees, year of completion, field of study, fellowship training, if appropriate
 - ii. List in chronological order from earliest to latest
 - b. Position title: include all relevant titles, eg, Department Chair, Cardiovascular Medicine; Professor, Cardiology

Information should be consistent with information in eRA Commons

- 3) *Customized* Personal statement:

Demonstrates the relevant experience/qualifications/expertise that makes you stand out as an appropriate expert to perform the specific role for this specific project.

 - a. Did you consistently use 'first person' throughout this section?
 - b. Did you take the opportunity to highlight previous collaborative efforts of the research team?
 - c. Did you highlight your leadership qualities and emphasize past leadership experience, if your current role is a leadership role?
 - d. Did you reflect enthusiasm/excitement about the project and its relative contributions?
 - e. Is everything you stated relevant to your specific role in the project?
 - f. Did you make sure not to include any personal information?
- 4) Section B: Positions/Honors
 - a. List positions/employment chronologically with current position last. List dates, places, and position titles.
 - b. Honors/other experience or professional memberships: list ending with most recent last.
 - c. Avoid abbreviations of what may be unfamiliar terms to reviewers.
 - d. Include any memberships on federal advisory committees, grant review panels, etc.

(continued on next page)

Biosketches *(continued from previous page)*

5) Section C: Selected Publications

NIH limits the number of publications you can show to **15**. If you have more than 15 publications, label section as “Selected peer-reviewed publications” and show the 15 publications as a subset of the total (eg, 15 of 100 total publications). There are several recommendations for selecting the most appropriate publications, such as:

- a. NIH biosketch webpage offers the following guidance: **5** most relevant to the current application; **10** additional recent publications of importance to the field (in chronological order)
- b. Show **5** publications for each of the following categories:
 - i. 5 most recent
 - ii. 5 of highest importance to the area of study the proposal addresses (high impact publications in your field of study)
 - iii. 5 with highest relevance to the research proposed in the grant
 - iv. Or, list 15 publications that are either most relevant or most recent

Note any distinctions/awards associated with any publication

- c. Number publications
- d. Use a consistent citation format; highlight your name
- e. Select peer-reviewed original publications accepted for publication, rather than reviews
- f. Do NOT include manuscripts under review or in preparation. Relevant data from unpublished work needs to be summarized as preliminary data in the “Approach” section of the grant.
- g. Remember to list PMID numbers for publications funded with NIH support that were published after 4/2008.

For publically accessible citations, URLs or PMIDs may be listed after the full reference. Be consistent with presenting all online articles in this manner.

For further information on this subject, please contact Dr. Ingrid Glurich at ext. 9-3072 (Glurich.Ingrid@mcrf.mfldclin.edu).

Recent and Upcoming Publications

Disease Surveillance Using the FDA Adverse Event Reporting System

Scientists from FDA and the Marshfield Clinic Research Foundation demonstrated the potential utility of the FDA Adverse Event Reporting System (FAERS) for identifying disease characteristics, in addition to its traditional applications in drug safety monitoring. In this pilot study, data-mining approaches were used to identify 115 potential sex-biased diseases from FAERS (a public database that contains patient demographic information for more than 4 million adverse event cases reported between 1997-2011). Of these identified diseases, 53 have been reported in the literature, with 50 showing the sex-biased effect (94% concordance with FAERS). Finally, eight of these diseases were selected and further confirmed through analysis of patient electronic medical records (EMRs). *(continued on next page)*

Disease Surveillance (continued from previous page)

This approach could be further applied to other publically available disease surveillance databases and to study other disease risk factors, such as age or ethnicity. The study was published online in *Clinical Pharmacology & Therapeutics* (2014, [Exploring the FDA Adverse Event Reporting System to Generate Hypotheses for Monitoring of Disease Characteristics](#)) by the Nature Publishing Group. The research data warehouse from Marshfield Clinic Research Foundation played a critical role in this study by providing clinical evidence to the disease signals. Scientists and staff members at the Biomedical Informatics Research Center who contributed to this study included: Crystal Jacobson as acknowledged contributor, Dr. Aaron Miller as co-author, and Dr. Simon Lin as the senior author.

Blood Pressure Control and Cardiovascular Outcomes in ALLHAT



Richard Dart, MD, Emeritus Research Clinician in the Marshfield Clinic Research Foundation's Center for Human Genetics was part of a multi-site team (Louisiana State University Health Science Center, Mayo Clinic, University of Texas School of Public Health, Kaiser Permanente Georgia, National Institutes of Health, Howard University Hospital, and the VA Medical Center in Dayton, OH) that evaluated the relationship between body mass index and blood pressure levels. The article will be published in an upcoming issue of the *Journal of Hypertension*,

but can be read [here](#).

HMO Research Network Conference

The HMO Research Network (HMORN) 20th Annual Conference was hosted by Kaiser Permanente Colorado and held from April 1-April 3, 2014 in Phoenix, Arizona. This was the 9th year that Marshfield Clinic Research Foundation (MCRF) was included in the meeting. The overall conference theme was 'Embedded Research to Improve Health', and among many other activities, there were a variety of presentations and opportunities to meet with program staff from the U.S. Patient Centered Outcomes Research Institute (PCORI).

At the meeting, MCRF representatives engaged with network colleagues in a variety of ways, including presenting posters and podium talks, moderating conference sessions, speaking on panel discussions, leading and participating in study team meetings, and working on various HMORN governance working groups. The thirteen Marshfield attendees included representation from Research Administration, Center for Clinical Epidemiology and Population Health, Biomedical Informatics Research Center, the Office of Scientific Writing and Publications, and a Wisconsin Academy of Rural Medicine student.

Noteworthy conference activities for MCRF representatives included:

- Robert Greenlee moderated a concurrent session on colorectal cancer and led a study team meeting for his Longitudinal Study of Implantable Cardioverter Defibrillators.
- Linda Jaros was part of an IRB panel discussion and represented Marshfield on the IRB Administrator working group.
- David McClure gave a podium presentation on the HMORN Rural Health Scientific Interest Group.

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

HMORN *(continued from previous page)*

- Deb Multerer was the coordinator of the Virtual Data Warehouse (VDW) Implementation Group Meetings.
- Will Ray gave a podium presentation on the Marshfield Dictionary of Clinical and Translational Science.
- Rachel Stankowski presented a poster on mammography and all-cause mortality.
- Trista Stankowski-Drengler presented a poster on determining health needs of an underserved population.
- Robert Steiner moderated the Junior Investigator Award plenary session, and was the Marshfield delegate to the HMORN Governing Board meeting.
- Alexis Tavano represented Marshfield on the Research Administrator working group.
- Jeff VanWormer presented a poster on improving aspirin utilization for cardiovascular disease prevention and was one of the Marshfield representatives at the VDW Implementation Group Meetings, which also included Valerie McManus and Aaron Miller.
- Steve Ziemba presented a poster on distress in rural breast cancer patients.

Conference proceedings from the 2014 meeting are to be published in a future issue of our own *Clinical Medicine & Research*, which will include all scientific abstracts from the poster and podium presentations, and the full list of co-authors for each.

Next year's HMORN conference will be hosted by Kaiser Permanente of Southern California, and will be held in Long Beach, California from March 11-13, 2015. MCRF will be co-hosting the 2016 conference along with Henry Ford Health System, with the meeting to be held in Atlanta, Georgia from April 13-15, 2016.

Compliance Corner

What is the Research Compliance Committee and What is its Function?

The DHHS Office of Inspector General has outlined the elements of an effective compliance program. One of those elements is formation of a compliance committee responsible for developing, operating, and monitoring the compliance program. Marshfield Clinic's Integrity & Compliance Committee fulfills this role for Marshfield Clinic, including MCRF. The Research Compliance Committee (RCC) complements the work of the Integrity & Compliance Committee by focusing on research compliance.

The RCC meets quarterly. The Research Compliance Officer (RCO) chairs the committee, and the Associate Director of MCRF is the vice chair. Voting members include the Director and Administrator of each MCRF Center, two physicians active in research, an office-based MCRF scientist, a lab-based MCRF scientist, a Patient Financial Services representative, and the Corporate Compliance Officer. The committee reviews new and revised regulations and guidelines, new and revised institutional policies and procedures, annual risk assessments, and monitoring and auditing results. It also considers whether institutional compliance education and other corrective actions are adequate.

(continued on next page)

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

Compliance Corner *(continued from previous page)*

The RCC welcomes input from all Marshfield Clinic researchers and staff on items that the committee should consider. If there are regulatory matters or concerns that you believe the RCC should review, please contact RCO Melissa Ostrowski at ext. 1-7040 (Ostrowski.Melissa@mcrf.mfldclin.edu) or your Center Administrator or Office Director to discuss.

In Addition:

- The next Full Foundation meeting will be held on May 1, 2014 at 10AM in the Froehlke Auditorium.
- The next Board of Trustees meeting will be held on May 8, 2014 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Dr. Richard Dart, Dr. Ingrid Glurich, Dr. Bob Greenlee, Dr. Simon Lin, Melissa Ostrowski, Pete Schmeling, Dr. Bob Steiner, and Dr. Steve Ziemba

Edited by: Alexis Tavano, MPH, tavano.alexis@mcrf.mfldclin.edu, ext. 1-8939.

Directors' Report



Well, I'm told winter is finally over. We still had snow on our property until 10 days ago. I do see signs of spring, so maybe we really are done with winter for a few months. In addition to the good news that warmer weather is here, we also have good news on the research front that we hope you will take the time to read below. I truly enjoyed seeing the photo of the signing of the Agritourism bill knowing that our NFMC colleagues were instrumental in its passing. Finally, I invite you all to participate in the Oral Systemic Health journal club. Scientists are beginning to appreciate how important oral health is to development and control of system disease. Happy reading!



Doubtless everyone reading this edition of *Research Matters* is aware of the financial challenges facing all of Marshfield Clinic. MCRF is no exception. There will be change and decisions to make. However, and it may be a bit of a cliché, but this also brings with it opportunity. The greatest is that such change will help us be more competitive, as MC is not the only organization in the industry having to face these same hurdles. It will also reinforce the need for us to work as a unit, something which has been ongoing and showing results already.

You may often hear during times like this that “change is needed” and “we will emerge better and stronger”. These are certainly true. However, the process itself is certainly stressful. Be sure to take care of yourself. Enjoy your time outside of work, in order to be that more able to handle the priorities and stresses when you come back in. As Dr. Steiner states above, spring is here. Enjoy it! Myself, I hope to get in some time bike riding.

Recent Publications, Grants, and Awards

This is a new column to highlight recent accomplishments of MCRF researchers and MC clinical investigators. Please select the hyperlink below to view recent publications. When applicable, links to grants and awards will also be included.

[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 Alexis Tavano at ext. 1-8939 or tavano.alexis@mcrf.mfldclin.edu.

ICTR Funding Opportunities

The ICTR Translational Technologies and Resources (TTRC) Core offers short-term, low-dollar awards (up to \$5,000) to advance the translation of discovery into therapy. Applicants must document an urgent need for services based on recent extramural grant review, or milestones for therapeutic development. Requests are redeemable only at one of the ICTR-TTRC resource areas.

The application due date for the third round of voucher awards is **June 1, 2014**, to be awarded in July 2014.

Further information can be found at: <https://ictr.wisc.edu/FundingOpportunities>, or contact Peggy Hatfield (pmhatfie@wisc.edu, 608-261-1939).

Guidelines for Accessing Donated Funds

MC/MCRF is the beneficiary of donations from grateful patients that are expected to be used for conducting disease-specific research. Through MCRF's Internal Funding policy (http://srdweb1/clinic/policies/policy_details.asp?RecID=253), employees of MC can apply for access to these donated funds by submitting a research proposal to the Research Committee for scientific merit review. The "Research Committee Application - Projects Requesting Funds" is located at: http://srdweb1/clinic/policies/form_results.asp?FL=Yes&L=R&typeEntity=clinic. The level of base funding available per project is currently \$50,000. (When practicing clinicians are participating in the research, an additional \$15,000 per project may be awarded to compensate for their time and effort.)

Effective last October 1, pre-proposals are required to be submitted for review in advance of submitting a full proposal. Applications may be submitted any time prior to the start of each quarterly cycle, with new cycle dates beginning on the 16th of March, June, September, and December. Applications are reviewed in the order they are received during the cycle, so it can be advantageous to submit proposals earlier in the cycle rather than later.

A listing of disease-specific funds available can be found on the Research Mentor intranet landing page, with a link titled "Donated Funds Available for Research": <http://mclweb/mcrf/?page=researchmentor>. Questions regarding this funding mechanism can be directed to Deb Hansen (ext. 7-9130; hansen.debra@mcrf.mfldclin.edu).

Rich Seubert Celebrity Trap Shoot



From left: Brad Guse, BMO Harris Bank; Scott Sandberg, NFMC; Steve Schrodi, CHG; Casper Bendixsen, NFMC; and Brian Forrest, Maple Ridge Dairy

The 7th annual Rich Seubert Celebrity Trap Shoot occurred at the Eau Claire Rod & Gun Club on April 12th, and raised over \$154,000. As seen in the photo to the left, three MCRF staff members were among those participating in this year's event. To date, the Trap Shoot has raised over \$1 million for heart research at Marshfield Clinic. Seubert created an endowment at MCRF to benefit heart research in honor of his grandmother, Celine Seubert.

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

Wisconsin Institute Agreement Signed

In December 2013, MCRF signed an annual membership agreement with the Milwaukee Institute. The Milwaukee Institute is an independent not-for-profit research, education and public policy organization whose goals include providing world-class technical computing, storage, communications and collaboration facilities in support of economic development through scientific, engineering and technology leadership in the Great Lakes region, particularly in SE Wisconsin. This membership gains MCRF 10,000 core hours, 40 GB storage, and 40 GB of network bandwidth to their MGRID (<http://www.mkei.org/mgrid>) high performance computing system along with some basic consultations/professional services.

This service gives MCRF Researchers and other organizations additional options for high performance computing needs. For example, the Medical College of Wisconsin has been running jobs around genomics (alignment and methylation) as well as protein identification and best practices and methods for said identification. Their simulation and complex computation work utilize open source code including Bowtie, Cufflink, Tophat, R, and Bayesian analysis code from Wolfram.

Gov. Walker Signs Agritourism Bill



Gov. Scott Walker has signed into law the Ag-Tourism Limited Liability bill, which places limits on liability for persons offering agricultural tourism activities. The bill reached Walker's desk with help from the National Children's Center for Rural and Agricultural Health and Safety, part of the National Farm Medicine Center, Marshfield Clinic Research Foundation.

The National Children's Center will work with the Wisconsin Agricultural Tourism Association (WATA) to educate agritourism operators about the new law. "The law is great for the agritourism industry, but we need to remember that it doesn't provide blanket immunity," said the Center's Marsha Salzwedel. "Farmers still need to post signs for hazards and follow other safety best practices."

Agritourism resources published by the National Children's Center contain guidelines, checklists, signs and other resources that will help operators be in compliance (www.safeagritourism.com). Salzwedel will work with WATA at upcoming education sessions, sharing strategies to keep visitors safe on farms.

The bill passed the full Assembly 85-9. The bill passed the Senate on a voice vote April 1. WATA initiated the push, telling Gov. Walker that 22 other states already had such a liability law. Walker asked WATA to lead the effort and said he would sign it when it came across his desk.

WATA will be hosting an Ag-Tourism Education Series around the state that will include a focus on farm safety. More details on the new law and information about acquiring signage can be found on the WATA membership website, www.luv-r-ag.com. The bill was co-authored by Rep. Lee Nerison and Rep. Travis Tranel.

Marsha Salzwedel, who leads agritourism safety initiatives at the National Children's Center, attended the signing as an ex-officio member of the WATA Board. Questions? E-mail nccrahs@mcrf.mfldclin.edu, or call Salzwedel at 715-389-5226.

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

Oral Systemic Health Journal Club

With the emerging evidence of the connection between oral and overall health, the Institute for Oral and Systemic Health (IOSH) sponsors this journal club to provide Marshfield Clinic providers, researchers, educators and staff the opportunity to discuss the science behind the potential oral and systemic health connections as well as to evaluate research methodologies and its applicability to clinical care.

Presenters who volunteer to lead a session are requested to send a link or copy of two articles on the chosen topic to the OSH Journal Club Coordinator, Neel Shimpi, at least one week prior to the journal club. If you would like to present a topic, or to be included in the email invitation, please contact Neel Shimpi at shimpi.neel@mcrf.mfldclin.edu.



The Oral Systemic Health Journal Club sessions are scheduled to take place from 12:00pm-1:00pm in the Laird North Conference Room ML2A on the following dates: June 10th, July 8th, July 15th, August 12th, October 14th, and December 9th. A light lunch will be provided.

Compliance Corner

Research Quality and Compliance Reviews Have Begun

The Research Compliance department has begun new compliance and quality reviews of randomly selected research studies, as well as reviews of administrative processes at MCRF. The reviews are aimed to ensure legal, regulatory, contractual, and institutional requirements are being met in the course of research. The goal is to help Principal Investigators (PI) and Center/Office/study team management identify and implement appropriate corrective and preventative actions when concerns are identified. Risk areas identified in the annual research risk assessment and work plan will also be targeted.

The reviews are not intended to be punitive in nature, and time commitment of study or administrative staff should not be great, as they do not have to sit with the reviewer, and reviews will be primarily of documentation. Staff may have to provide additional documentation or answer some questions as needed by the reviewer. After the review is completed, a meeting will be scheduled with the PI to obtain any additional information needed, and to discuss the results and next steps.

We face real financial, legal, and reputational risks if we do not comply with all of the requirements, and admittedly the requirements are complex. We appreciate your cooperation and input as we strive to improve our processes, with the ultimate goal of improving the quality and integrity of the research. Please contact Melissa Ostrowski, Research Compliance Officer, with any questions (ext. 1-7040; ostrowski.melissa@mcrf.mfldclin.edu).

NIH and AHRQ Policy on Resubmissions Released

On April 17, 2014, clarifications were released to the National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ) Policy for Application Resubmission. The policy, found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>, states:

“Effective immediately, the NIH and AHRQ will accept a new (A0) application following an unsuccessful resubmission (A1) application. The subsequent new application need not demonstrate substantial changes in scientific direction compared to previously reviewed submissions, and must not contain an introduction to respond to the critiques from the previous review.

NIH's policy for accepting overlapping applications remains in effect (see NOT-OD-09-100). The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- a new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping resubmission (A1) application.
- a resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- an application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101).

The NIH time limit for accepting resubmission (A1) applications remains in effect (see NOT-OD-12-128 and NOT-OD-10-140). The NIH will not accept a resubmission (A1) application that is submitted later than 37 months after submission of the new (A0) application that it follows.

The NIH policy for New Investigator R01 resubmission deadlines, described in Guide Notice NOT-OD-11-057, remains in effect. A New Investigator whose new (A0) R01 application was reviewed in the Center for Scientific Review or the National Institute of Mental Health, and was unsuccessful, may submit a resubmission (A1) R01 application by the next New Investigator resubmission due date (April 10, August 10, or December 10). New Investigators who wish to submit a new (A0) R01 application following an unsuccessful resubmission application must use the standard due dates, regardless of the previous submission history for that project, unless they are eligible for Continuous Submission (see NOT-OD-14-028).

MCRF to Welcome Summer Research Interns May 27

This summer marks the 40th anniversary of the MCRF Summer Student Research Intern Program (SSRIP). Through this program, undergraduate and graduate students have a chance to put their education into practice as they work side-by-side with scientists who are experts in their fields for 12 weeks during the summer. Each student will work on a mentored, independent project, tailored to their skill level. At the end of the summer, students will present their work at the annual Research Symposium on Thursday, August 14, 8:00AM – 12:30PM in the Froehlike Auditorium. Please mark your calendar to attend! There will be something of interest to everyone. In the past, some of the student's work has even led to publication in scientific journals. *(continued on next page)*

Summer Research Interns *(continued)*

SSRIP is supported entirely through philanthropy. Thanks to the generosity of many community partners, Clinic employees, foundations, businesses and a major sponsorship by The Boldt Company, the program has the financial resources to host up to 10 students each summer. Since its inception, SSRIP has had over 224 students.

Directed by Huong McLean, PhD, MPH and Bobbi Bradley, MPH, SSRIP will run May 27 – August 15. We are proud to announce this year's 2014 Summer Interns and Mentors:

BIRC – Institute for Oral and Systemic Health (IOSH)

David Kirkhoff, St. Olaf College, Northfield, MN, Biology (2015)

Project: Dental-Clinical System Redesign

Mentors: Kelsey Schwei, MS and Amit Acharya, BDS, MS, PhD

Krista Koehler, University of Minnesota-Twin Cities, Biology (2015)

Project: Oral Cancer Risk Assessment Tool

Mentors: Neel Shimpi, BDS, MM and Amit Acharya, BDS, MS, PhD

CCEPH

Charles Garber, University of Michigan, Epidemiology (2015)

Project: Longitudinal Study of Implantable Cardioverter Defibrillators

Mentor: Robert Greenlee, PhD, MPH

CHG

Bethany Blank, University of Wisconsin-Stevens Point, Biology (2015)

Project: Measuring the Capabilities of New DNA Sequencing Technology

Mentor: Steven Schrodi, PhD

Ethan Heinzen, University of Minnesota-Twin Cities, Mathematics (2015)

Project: Developing Big-data Framework and Evaluating Performance

Mentor: Max He, PhD

Ran Zhao, University of Wisconsin-Green Bay, Human biology (2015)

Project: Genetic Variants in ARMS2 and Risk of Age Related Macular Degeneration

Mentor: Scott Hebring, PhD

IRDL

Matthew Buchholz, University of Wisconsin-Stevens Point, Wildlife Ecology: Research and Management (2014)

Project: Fungal Infections in Humans and Animals

Mentor: Jennifer Meece, PhD

NFMC

Jessica Perkins, State University of New York at Buffalo, Master of Public Health (2014)

Project: Agriculture and a Culture of Safety: Mapping Spheres of Influence

Mentors: Casper Bendixsen, PhD and Matthew Keifer, MD

Project/Mentors to be determined

Colleen Bramwell, Saint Augustine's University, Raleigh, NC, Biology (2016)

James Bychinski, University of Wisconsin-Madison, School of Pharmacy (2016)

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

Annual Disclosure Requirement Expanding to Include All Research Staff

Requests for annual disclosures of significant financial and associational interests were sent electronically to MCRF *Investigators* on May 12th.

As mentioned during a recent Full Foundation meeting, due to AAHRPP accreditation requirements, the definition of “*Investigator*” has expanded to include 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 and a link will be provided in the request email.

Questions or concerns should be directed to Patti Baer (ext 1-8840) or Diane Austin (ext 7-9134) in the Office of Research Integrity and Protections, or e-mail at conflict.interest@marshfieldclinic.org.

Lyme Disease

Stop Lyme disease with new resources from National Farm Medicine Center

Get the facts about Lyme disease and other tick-borne illnesses with a handy new set of printed resources from the National Farm Medicine Center (NFMC).

An estimated 300,000 Americans are diagnosed with Lyme disease each year, according to the Centers for Disease Control and Prevention. Wisconsin has one of the highest incidence rates. Ninety-five percent of U.S. Lyme cases are diagnosed in 13 states throughout the Upper Midwest and Northeast.

Although untreated Lyme disease is potentially serious, “the risk of Lyme disease is no reason to stop your outdoor activities,” said Anna Schotthoefer, PhD. “All it takes is your common sense and a little awareness.”

Dr. Schotthoefer, of the Integrated Research and Development Laboratory, Marshfield Clinic Research Foundation, worked with Tammy Ellis of NFMC to update the resources. *(continued on next page)*

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

Lyme Disease *(continued)*

The bacterium that causes Lyme disease is carried only by the Deer (blacklegged) tick. This tick prefers mice and deer as hosts, but will settle for humans and other animals when a blood meal is needed. The bacterium is transmitted during the bite and blood draw, a process that can take 24 to 48 hours. The bacterium usually enters the victim late in the process. Not all Deer ticks are infected with the bacterium that causes Lyme disease, and only an infected tick can transmit the disease.

When returning from a suspected tick environment, carefully check yourself, children, and pets for ticks. Scrub off well in a shower and check again in a few hours.

Early symptoms of infection mimic the flu – headaches, chills, nausea, fever, aching joints, and fatigue. In approximately 70 to 80 percent of cases, there is a bull's-eye shaped rash at the bite site, which appears 3 to 30 days after the bite.

Check out the following new resources online at http://www3.marshfieldclinic.org/nfmc/?page=nfmc_lyme_disease. To obtain hard copies, phone 1-800-662-6900 or email nfmcsh@mcrf.mfldclin.edu.

- Tick ID Business Card: Reflects actual tick sizes and appearances for the common Wisconsin ticks – Deer, Wood, and a newcomer, the Lone Star tick. The wallet-sized card includes diseases the ticks transmit, precautions, symptoms, and instructions on how to remove an attached tick.



- Tick ID card: Includes information that is on the Tick ID Business Card, plus a map of confirmed Wisconsin Lyme cases by county.
- Tick ID Field Guide: Provides more in-depth information; emphasizes the importance of “time” in preventing disease – time devoted to proper clothing and repellents, time for checking your body for ticks, the window of time you have to seek medical help and prevent the disease, and the time to maintain your property in a way to minimize tick habitat. The Field Guide includes information specific to pregnant women, farmers, hunters, fishermen, outdoor workers, and parents.

Clinical Research Center “Points of Interest”

- WI SoCRA Chapter Spring Meeting, June 5th (5:30-7:00 pm) in Marshfield Room ML2A.
Speaker – Dr. Steve Ziemba, Associate Director of MCRF
Title: *Informed Consent in Theory and Practice*
Objectives:
 - Understand the theory of informed consent in clinical research
 - Compare the theory to actual practice as taken from the literature
 - Utilizing this comparison, recognize best practices*Note: You do not have to be a SoCRA member to attend.*
- Grand Rounds, June 27th. Topic: “Misconduct in Research”, by Melissa Ostrowski, Dr. Steve Ziemba and Dr. Bob Steiner
http://srdweb1/clinic/dept/coe/CME/Grand_Rounds_Marshfield/MisconductInResearch.asp
- Promotion: Brian Zaleski has accepted the position of Center Administrator in the Clinical Research Center. Dr. Steve Ziemba said, “Brian brings with him a background in clinical trial contracts and budgets, as well as firsthand knowledge of the Clinical Research Center. I am confident that he will be a great asset in moving Clinical Research forward.”
- Introducing *Clinical Researcher*, formerly known as “The Monitor”
<http://www.acrpnnet.org/MainMenuCategory/Resources/Clinical-Researcher/April-2014.aspx>
- Resignation: Angie Hommerding resigned from her Investigational Drug Program (IDP) pharmacist position. Hommerding’s last day at the Clinic was May 9th.

In Addition:

- The next Full Foundation meeting will be held on July 10th at 10AM in the Froehlke Auditorium.
- The next Board of Trustees meeting will be held on August 28th 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Patti Baer, Ryan Frahm, Deb Hansen, Scott Heiberger, Dr. Simon Lin, Dr. Huong McLean, Anne Nikolai, Melissa Ostrowski, Dixie Schroeder, Dr. Bob Steiner, Bryan Weichelt, Dr. Steve Ziemba

Edited by: Alexis Tavano, MPH, tavano.alexis@mcrf.mfldclin.edu, ext. 1-8939.

Directors' Report



One of my greatest joys as Executive Director of MCRF is learning that one of our scientists has been successful with a major research grant proposal. This joy intensifies when that scientist is a junior scientist. I am personally delighted that Dr. Scott Hebring has been awarded a prestigious K-type career development award from the National Institutes of Health. These awards are made only to outstanding scientists with great potential, who also work in an environment that is conducive to the successful implementation of their research plan. Therefore, both Scott and his mentors, including Dr. Murray Brilliant and others, deserve credit for the successful application, and we at MCRF can take pride in knowing that peer reviewers and NIH staff recognize that we have an excellent research environment at MCRF.



We are undergoing a great deal of change in MCRF, and there are some changes that I am very happy to present to you. Later in this newsletter you'll see that Dr. Bob Haws has been named the new Director of CRC. He'll be working with Brian Zaleski, the newly named CRC Administrator, in promoting clinical trials and reaching out to clinician-investigators. Similarly, Dr. Doug Reding, the recipient of the Ebenreiter Endowment, has accepted the role of Principal Investigator for the MCRF Community Clinical Oncology Program (CCOP). This dynamic and important oncology clinical research program was developed from the ground up by Dr. Matthias Weiss. In addition to CRC, we have also seen changes in BIRC leadership. I want to welcome Dr. Peggy Peissig to her role as Interim Center Director for BIRC, and Dr. Amit Acharya as the Director of IOSH. Each of these individuals brings with them the knowledge, expertise, and passion that will help all of MCRF succeed.

Recent Publications, Grants, and Awards

This column is to highlight recent accomplishments of MCRF researchers and MC clinical investigators. Please select the hyperlink below to view recent publications:

[Publications](#)

In addition, work done on warfarin pharmacogenetics by MCRF researchers (Dr. Jim Burmester, Dick Berg, Dr. Steve Yale, Carla Rottscheit, Dr. Ingrid Glurich, Dr. John Schmelzer, and Dr. Michael Caldwell) was included in a review article in a prominent journal: Scott SA, Lubitz SA. Warfarin pharmacogenetic trials: is there a future for pharmacogenetic-guided dosing? *Pharmacogenomics*. 2014;15(6);719-22.

Dr. Scott Hebring received a grant from DHHS, NIH, National Library of Medicine for "GWAS – Development and Application of Phenome-wide Scan of Heritability (PheSH)". See the [article](#) below for more information. (*continued on next page*)

Pubs, Grants, and Awards *(continued from previous page)*

When available, awards will also be included. 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 Alexis Tavano at ext. 1-8939 or tavano.alexis@mcrf.mfldclin.edu.

MCRF Scientist Awarded NIH Grant



Recently, Dr. Scott Hebbring, an Associate Research Scientist in the Center for Human Genetics, was awarded an Early Independence Award (K22) from the National Institutes of Health. This grant is designed to study disease heritability. Heritability is the proportion of a disease that can be explained by genetics. For example, some forms of breast cancer are highly heritable due to genetic mutations. Dr. Hebbring and his group have recently assembled one of the largest populations of twins in the United States called the Marshfield Clinic Twin Cohort (MCTC), consisting of nearly 20,000 Marshfield Clinic patients. What sets MCTC apart is that all patients are linked to an electronic medical record (EMR) system. Twin siblings represent a unique family relationship, particularly with identical twins where both siblings share identical genes. As such, twins represent an ideal group to study disease heritability. Using MCTC, Hebbring will screen thousands of diseases in search of conditions with strong heritable properties using the Marshfield Clinic EMR system.

In addition to twins, other family structures, such as well-defined extended families consisting of children, parents, grandparents, and other blood relations, can be used to measure heritability. Hebbring and his group have begun to assemble participants of the Personalized Medicine Research Project (PMRP) into extended families based on available questionnaire and genetic data. Like MCTC, PMRP consists of nearly 20,000 Marshfield Clinic patients linked to an extensive EMR system. Of the 20,000 patients, 12,000 can be linked to families, with the largest family consisting of 35 members and three generations. As a complement to MCTC, heritability will also be measured for thousands of diseases using these family structures. The goal of these heritability screens is to identify diseases that can be further studied at the genetic level so that genetics can be more widely applied to personalized medicine.

CRC Welcomes Dr. Bob Haws as New Center Director



Dr. Bob Haws has accepted the role of Center Director for the Clinical Research Center (CRC), effective June 1st. Haws is a well-respected pediatric nephrologist and an experienced researcher. Haws will be working to encourage the growth of clinical research among clinicians, with the goal of making clinical trials more efficient from the administrative perspective while maintaining study integrity, patient safety, and regulatory compliance. To that end, Haws will be working with the newly appointed CRC Center Administrator, Brian Zaleski and Dr. Steve Ziemba.

Haws takes over the CRC from Dr. Steve Yale, who ably led the CRC for several years. Under Yale's guidance, a number of very successful programs were instituted in the CRC. We wish Dr. Yale the best of luck in his future endeavors, and welcome Dr. Haws.

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

Welcome to Dr. Doug Reding as New Oncology Research Director



Dr. Doug Reding has accepted the role of Oncology Research Director. He is a well-respected oncologist and researcher, with work encompassing farm cancer, environmental exposure and his work leading the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening study and National Lung Screening Trial, each of which have redirected the screening and detection of cancer nationally. Dr. Reding will be working in the development of our oncology research program. As we await the decision of the upcoming NCORP grant awards, which is replacing the current national CCOP program,

Dr. Reding will be working with our research partners at St. Vincent's in Green Bay and Gunderson Health System in La Crosse to bring cancer clinical trials to Wisconsin residents across the state.

Dr. Reding is accepting the leadership of the program from Dr. Matthias Weiss, who has tirelessly worked to expand and strengthen our CCOP to become a national leader in oncology clinical trials. We wish Dr. Weiss all the best in the next stage of his career.

Welcome to New Leadership in BIRC



At the Biomedical Informatics Research Center (BIRC), Peggy Peissig, PhD, has taken over as Interim Center Director after the departure of Simon Lin, MD. Lin has been appointed Chief Research Information Officer at Nationwide Children's Hospital, headquartered in Columbus, Ohio. He was a major player in promoting the UW-MCRF bioinformatics partnership and we wish him well in this next phase of his career.

A longtime associate director of BIRC, Peissig recently returned to the MCRF, this time as a tenure track faculty member after earning a PhD in Clinical Investigation at UW. As an informatician specializing in EHR-based phenotyping and clinical informatics, Peissig is a natural choice to lead BIRC during this transition. She will be working with BIRC Research Administrator Lori Weigel, MBA. Peggy brings energy, enthusiasm, and knowledge and has already hit the ground running. Welcome back!

Amit Acharya, PhD, will direct the MCRF ICTR Biomedical Informatics core. Acharya previously held that position in an interim role for several months prior to Dr. Lin's arrival. Acharya is a Dental Informatics Scientist, respected nationally and internationally for his work. He directs the Institute of Oral and Systemic Health at Marshfield Clinic.

Clinical Medicine & Research Prepares for Possible Close of Business

This year, 2014, marks, perhaps, the final year of publication for *Clinical Medicine & Research* by Marshfield Clinic. Current fiscal constraints are making it difficult to continue this scholarly activity within the Clinic system. In preparation for the likelihood of closing the journal, we have suspended accepting submissions of new manuscripts; however, we will continue to process and review those manuscripts which we have requested revisions to and those that are currently in the later stages of peer review. If you have a revised manuscript to resubmit, please send the required documents to the journal's email account: clinmedres@mcrf.mfldclin.edu. During the next 6 months, we will be working to honor our commitment to those who have entrusted us with publishing their work.

All currently accepted articles, and those accepted in the next few months, will, at a minimum, be published in the Rapid Release section (electronic ahead of print) of the *Clinical Medicine & Research* web site (www.clinmedres.org). The possibility that a partnership with a commercial publisher will allow publication of the journal to continue is being explored, but in the meantime we must prepare for the potential close of the journal.

On a personal note, it truly has been my pleasure to work with everyone who has contributed to *Clinical Medicine & Research* as an author, a reviewer, an editorial board member, or as a supportive colleague. Each of you has helped bring *Clinical Medicine & Research* to the success it enjoyed. I am grateful for your support.

Sherry Salzman Scott
Senior Editor
Clinical Medicine & Research

A National Advisory Council Established for Institute for Oral and Systemic Health (IOSH)



An Advisory Council, consisting of nationally recognized experts and internal leaders, was created for the purpose of working with the Institute for Oral and Systemic Health, at the Marshfield Clinic Research Foundation, to carry out its mission “*To lead and*

pave the future of integrating medical-dental care delivery, oral-systemic research, inter-professional education and practice management through the application of informatics/information technology, applied, preventive and basic sciences to ultimately improve patient healthcare experience, improve quality of patient care and lower per capita healthcare cost.”

This [Advisory Council](#) (click hyperlink to see members) will advise and provide recommendations on matters that directly concern the IOSH's strategy, roadmap, research, software/product development, implementation, and training activities. To carry out the IOSH Advisory Council's purpose, the scope of its member activities shall include: providing information, analysis, and recommendations to IOSH through interactive dialogue and exchange of ideas and experiences to the IOSH Director and Key Staff. The output of these council meetings will serve to better inform the IOSH's strategy, policy development, grant development, training activities, and other external engagement functions.

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

McMillan-Warner Teams with National Farm Medicine Center on ROPS Retrofits



McMillan-Warner Mutual Insurance Company policyholders are now eligible for up to 100 percent reimbursement on the cost of retrofitting their tractors with rollover protective structures (ROPS), thanks to a new partnership with the National Farm Medicine Center Wisconsin ROPS Rebate Program. “Tractor overturns are one of the leading causes of farm-related deaths,” said Scott Krum, CEO of McMillan-Warner. “We feel strongly that each tractor should have a ROPS, and are excited to be part of this retrofit program.”

The National Farm Medicine Center program is open to any Wisconsin tractor owner, regardless if they are a McMillan-Warner policyholder, and reimburses owners up to 70 percent (maximum of \$865) toward the total cost of purchasing, shipping and installing individual ROPS. The newly formed partnership with The National Farm Medicine Center gives McMillan Warner Mutual policyholder’s an added benefit of receiving the remaining 30 percent of the retrofit cost (maximum of \$350).

A ROPS is an operator compartment structure (usually cab or rollbar) intended to protect farmers from injuries caused by overturns or rollovers. The ROPS system did not become standard on U.S. manufactured tractors until 1985, more than half the tractors in Wisconsin do not have this protection. A ROPS, when used with a seatbelt, is 99 percent effective in preventing injury or death in the event of an overturn.

Tractor owners can apply for the program via the ROPS hotline, 1-877-767-7748 (1-877-ROPSR4U), or the website, www.ropsr4u.com. The owner is asked to provide basic information about his or her farm and tractors. Program staff does all the leg work. Enrollees will be mailed retrofit options and costs for their particular tractor. Fifty ROPS have been installed during the first year of the program. A three-minute video about the ROPS program can be viewed at, http://www3.marshfieldclinic.org/nfmc/?page=nfmc_resources_rops_rebate.

BOTOX Used for Treatment of Hemiparetic Cerebral Palsy



Dr. Jill Meilahn, a Marshfield Clinic physician specializing in pediatric physical medicine and rehabilitation, is currently enrolling subjects with hemiparetic cerebral palsy into an industry-sponsored study to evaluate the use of BOTOX in the treatment of spasticity in children ages 2 to 18. BOTOX has been used “off-label” to treat spasticity in children since the 1980s, and is FDA-approved for use in adults. This multi-site international study evaluates the safety and efficacy of BOTOX treatment in children, with the goal of obtaining FDA approval for use in children. Says Meilahn, “Our MCRF with its research pharmacy, study coordinators and fabulous IRB system enabled us to be selected as one of the sites.” There are several protocols associated with this trial, with Marshfield Clinic looking to enroll 10 subjects into each. For more information regarding the study, please contact Sandy Freeman at ext. 7-9059 or freeman.sandra@mcrf.mfldclin.edu.

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

Compliance Corner

Research Misconduct Presentation at June 27 Grand Rounds

All Marshfield Clinic Research Foundation (MCRF) physicians, researchers, and staff are invited to attend an upcoming Grand Rounds presentation on Friday, June 27. The presentation will be led by MCRF Executive Director Dr. Robert Steiner, MD, and Research Compliance Officer Melissa Ostrowski, JD. The purpose of this presentation is to provide better understanding of what constitutes research misconduct, and the responsibilities of Marshfield Clinic physicians, researchers, and staff.

In 2013, the Department of Health and Human Services Office of Research Integrity received 425 allegations of research misconduct, the second year in a row with record high numbers. Research misconduct is the “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”

- “Fabrication” is making up data or results, and recording or reporting them.
- “Falsification” is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- “Plagiarism” is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

The presenters will outline what types of actions meet the definition of research misconduct under federal regulation, as well as Marshfield Clinic’s institutional policy, and how suspected misconduct is to be reported and investigated. Actual cases of research misconduct that have been discovered at other institutions will be outlined, as well as the risks implicated, and the tools and resources available to investigators and staff.

IOSH & MCIS to Sponsor Health Innovation Chats

In recent times, Health Informatics and Information Technology (HIIT) has been a key driver in facilitating major transformation in several aspects of the healthcare field. The Health Innovation Chat (HIC) is an effort to bring together folks interested in the area of HIIT from different corners of the Marshfield Clinic system to discuss specific technological ideas and its potential application to the healthcare field.

The Institute for Oral and Systemic Health (IOSH) will be sponsoring these chat sessions in collaboration with Marshfield Clinic Information Services (MCIS). The HICs will be held 6 to 8 times a year in either the Laird Center for Medical Research or the Fig Building. These chat sessions will be semi-moderated by a volunteering individual who introduces a topic of interest via a short presentation, demo, or a video during the first 15 minutes of the chat session. The introduction is followed by a 30 to 35 minute group discussion on how the topic relates to the healthcare field and what could be done around the topic with the different stakeholders in the audience (research, education, clinical care, IT, etc). *(continued on next page)*

Health Innovation Chats *(continued from previous page)*

Health Innovation Chats will take place from 12pm-1pm on the following dates:

- June 24: Conference Room FIC, Fig Building
- July 8: Conference Room ML2A, Laird North Research Building – near BIRC
- July 29: Conference Room FIC, Fig Building
- Sept. 9: Conference Room ML2A, Laird North Research Building – near BIRC
- November 11: Conference Room FIC, Fig Building



If you would like to present a topic or receive email invitations to the Health Innovation Chats, please contact the HIC Coordinator, Kelsey Schwei at ext. 1-6423 or schwei.kelsey@mcrf.mfldclin.edu.

In Addition:

- The next Full Foundation meeting will be held on July 10th at 10AM in the Froehlke Auditorium.
- The next Board of Trustees meeting will be held on August 28th 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Dr. Amit Acharya, Dr. Jim Burmester, Sandy Freeman, Dr. Scott Hebring, Scott Heiberger, Cathy Marx, Dr. Jill Meilahn, Melissa Ostrowski, Sherry Salzman, Dixie Schroeder, Dr. Bob Steiner, Dr. Steve Ziemba

Edited by: Alexis Tavano, MPH, tavano.alexis@mcrf.mfldclin.edu, ext. 1-8939.

Directors' Report



You will read in the following pages of several honors awarded to Marshfield Clinic and MCRF physicians, scientists, and staff. These awards and honors are very meaningful. We already enjoy a national reputation, but it's accomplishments like those listed in the pages of *Research Matters* that enhance our national and international reputation. Our reputation, in turn, is important in our ability to win research grants because familiarity is important, and to attract philanthropy. I applaud all of these outstanding achievements.



You've heard us talk about the work that has enabled MCRF to be a leader in research. This edition of *Research Matters* highlights only the most recent. The incredible thing about these accomplishments is that they occurred during a period of upheaval, demonstrating the quality and dedication of the scientists and staff that make MCRF what it is. We have come through a lot, and we are all the stronger for it. We have experienced loss during this time, but also greater collaboration and ingenuity, and I greatly look forward to the accomplishments that are yet to come.

Recent Publications, Grants, and Awards

This column is to highlight recent accomplishments of MCRF researchers and MC clinical investigators. Please select the hyperlink below to view recent publications:

[Publications](#)

In addition, Dr. Robert Greenlee, Research Scientist in the Center for Clinical Epidemiology and Population Health, was awarded a grant from the University of Kansas as site Principal Investigator for the Patient Centered Outcomes Research Institute (PCORI) Greater Plains Collaborative. This collaborative is a "network of 10 leading medical centers in seven states committed to a shared vision of improving healthcare delivery through ongoing learning, adoption of evidence-based practices, and active research dissemination." For more information, please see <http://pfaawards.pcori.org/node/20/datavizwiz/detail/4631>.

When available, awards will also be included. 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 Alexis Tavano at ext. 1-8939 or tavano.alexis@mcrf.mfldclin.edu.

Compliance Corner



Changes to Non-Compliance Reporting Requirements and New Reference Flow Chart Are Available

“Are all protocol deviations reportable to the Research Compliance Officer as potential non-compliance?” The answer is yes.

As part of policy changes for AAHRPP accreditation, there are new requirements for reporting potential non-compliance. The definition of non-compliance and the procedures for reporting are outlined in the policy “Non-Compliance in Human Participant Research.” A new process document also clarifies that any and all deviations from IRB-approved protocols are to be reported as potential non-compliance, “[Deviations from Protocol as Potential Non-Compliance](#).” This document can be found in Document Control. Staff are required to report any potential non-compliance to the Research Compliance Officer within 3 days of discovery by any staff member using the form, “[Potential Non-Compliance Determination Request](#).”

A new tool has been released to help investigators and staff to assess incidents and follow the policy requirements for reporting potential non-compliance and Unanticipated Problems Involving Risks to Subjects or Others. The flow chart outlines definitions and the processes to be followed, including any deadlines that apply. Investigators and staff can contact Melissa Ostrowski (ostrowski.melissa@mcrf.mfldclin.edu, Ext. 1-7040) for any questions about potential non-compliance, and Linda Jaros (jaros.linda@mcrf.mfldclin.edu, Ext. 9-3022) in ORIP for questions about Unanticipated Problems Involving Risks to Subjects or Others.

Fritsche Appointed Vice Chairholder in CLSI



Dr. Thomas Fritsche, Director of the Marshfield Clinic Division of Laboratory Medicine, was recently appointed as a Vice Chairholder of a Document Development Committee of the Clinical and Laboratory Standards Institute (CLSI). Fritsche has been active in a variety of CLSI activities for about 20 years and currently serves on several committees, including the Consensus Committee on Microbiology and the Subcommittee on Veterinary Antimicrobial Susceptibility Testing. CLSI develops the standards and guidance documents that are used throughout the United States and

Canada, and many other parts of the world when performing diagnostic laboratory tests for humans and animals. Use of these standards is required for Clinical Laboratories to receive payment from Medicare/Medicaid and insurance payers.

The document development committee for which Fritsche has been appointed vice chair will focus on development of standardized approaches for identification of bacterial and fungal pathogens producing infectious diseases. The focus will be on a new mass spectrometry approach that has high accuracy, fast turn-around time, and is low cost. Dr. Fritsche said, “This will be the first national guidance document on how the technology should be verified, implemented, and utilized in the laboratory to assure high quality results for patient care.” For more information on the scope of activities at CLSI, please go to their website: <http://clsi.org/>.

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

NFMC Communications Specialist Named to International Agriculture Safety Board



Scott Heiberger, a communications specialist with the National Farm Medicine Center (NFMC), Marshfield Clinic Research Foundation, has been named to the International Society for Agricultural Safety and Health (ISASH) Board of Directors. ISASH (isash.org/) is dedicated to professional development of agricultural safety and health professionals, and provides national and international leadership in preventing agricultural injuries and illnesses in the agricultural community. Heiberger is thought to be the first media or communications specialist on the board.

“This is an important liaison for NFMC, the National Children’s Center for Rural and Agricultural Health and Safety, and Upper Midwest Agricultural Safety and Health Center,” said Barbara Lee, PhD, NFMC senior research scientist. “This is a great show of support from agricultural safety professionals for the valuable role Scott has played in promoting safety via the media.”

Heiberger, a former newspaper journalist, joined the Farm Center in 2001. He handles media relations and publications, and is managing editor of the peer-reviewed *Journal of Agromedicine*. He has conducted journalists’ workshops across the United States – story-generating events that gather farm health researchers, child safety advocates, medical professionals, agricultural producers, and journalists for field trips and discussion focused on leading causes of childhood injuries on farms, and effective interventions to prevent these injuries.

Heiberger also assists in outreach for the Upper Midwest Agricultural Safety and Health Center (UMASH) at the University of Minnesota. He is presently finishing a UMASH-funded pilot study aimed at improving safety coverage in agricultural media. He is a member of the American Agricultural Editors Association and the National Association of Farm Broadcasting.

MC Selected to Participate in NIH-Funded StrokeNet Trial



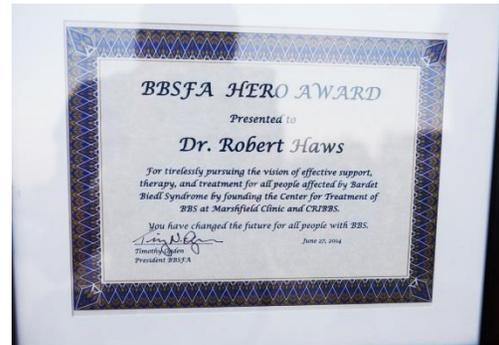
Marshfield Clinic has been selected to participate with the Regional Coordinating Center at UW-Madison in the Stroke Trials Network (StrokeNet) for stroke research. This Network is comprised of over 20 stroke centers across the country, with the purpose of “maximizing efficiencies to prioritize, harmonize, and streamline development of high-quality, multi-site clinical trials focused on key interventions in stroke prevention, treatment, and recovery.” Dr. Kenneth Madden, a neurologist at Marshfield Clinic, and Kathy Mancl, a Research Coordinator in the Marshfield Clinic Research Foundation’s Clinical Research Center, will be participating from Marshfield Clinic. Up to nine trials

covering prevention, acute care, and recovery are anticipated. For further information, please go to the following website:

http://www.ninds.nih.gov/research/clinical_research/NINDS_stroke_trials_network.htm.

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

MCRF CRC Director Recognized for Work with BBS Family Association



Dr. Bob Haws, above left with Tim Ogden, Bardet Biedl Syndrome Family Association (BBSFA) president, the newly appointed director for the MCRF Clinical Research Center, was recently recognized as the first “Hero of BBS” at a conference held at the University of Iowa at the end of June. Marshfield Clinic is the Bardet Biedl Syndrome (BBS) Center of Excellence and is under the direction of Haws. “It is exactly this type of involvement in development of an emerging Center of Excellence spanning patient care, research, and education and bringing in patients from around the nation and internationally (a destination medical center) that sets us apart from the local competition,” said Dr. Bob Steiner, MCRF Executive Director, of Haws’ recognition. The BBSFA is a patient advocacy organization for families impacted by this rare genetic disease that affects fewer than 2500 individuals in the United States. For more information on this disease, please see [https://www.marshfieldclinic.org/services/bardet-biedl-syndrome-\(bbs\)](https://www.marshfieldclinic.org/services/bardet-biedl-syndrome-(bbs)). Please also take a few minutes to watch the video at this link: <http://cribbs.marshfieldclinic.org/>. The Clinical Registry for Investigating Bardet-Biedl Syndrome (CRIBBS) was “launched” approximately 3 weeks ago and already has a significant number of people signed up to participate.

Aim for a Cure

The 3rd Annual “Aim for a Cure” Archery Shoot supporting cancer research will be held on August 2nd and 3rd. All staff are encouraged to participate or make a tax-deductible contribution to **AIM FOR A CURE** at Marshfield Clinic/Marshfield Clinic Research Foundation. Please see the [attached](#) for further information.

Save the Date: Research Foundation to Host Intern Symposium August 14th



Marshfield Clinic Research Foundation (MCRF) continues a 40-year tradition of concluding the Summer Student Research Internship Program with a Symposium on Thursday, August 14, from 8:00am until 12:00pm in Froehlike Auditorium at Marshfield Clinic Marshfield Center. A luncheon follows the presentations.

Directed by Huong McLean, PhD, and Bobbi Bradley, MPH, the summer internship provides a 12-week mentored research experience tailored to the student's skill level and is related to ongoing research at the Marshfield Clinic. The program enables students to put their education into practice as they work side-by-side with scientists who are experts in their fields.

The Summer Student Research Internship Program is supported entirely through philanthropy. Thanks to the generosity of many community partners, Clinic employees, foundations, businesses, and a major sponsorship by The Boldt Company, the program had the financial resources to host 10 students this year.

Staff, scientists, and physicians are invited to attend as many of the presentations as their schedules allow. The Symposium can also be viewed via MediaSite Live:

<http://mediasite.mfldclin.edu/Mediasite/Play/81631edbd8f842e585e475030379ea341d>.

Tentative Presentation Schedule:

8:00 AM	Welcome
8:15 AM	Matthew Buchholz (IRDL)
8:35 AM	Colleen Bramwell (CRC)
8:55 AM	Jessica Perkins (NFMC)
9:15 AM	Break
9:25 AM	David Kirkhoff (BIRC/IOSH)
9:45 AM	Krista Koehler (BIRC/IOSH)
10:05 AM	Charles Gaber (CCEPH)
10:25 AM	James Bychinski (CCEPH)
10:45 AM	Break
10:55 AM	Ranee Zhao (CHG)
11:15 AM	Bethany Blank (CHG)
11:35 AM	Ethan Heinzen (CHG)
11:55 AM	Closing

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

Research Specialist and Post-Doctoral Fellow Join Center for Human Genetics

Jeffrey (Jeff) Joyce joined the Center for Human Genetics (CHG) on June 9th as a Research Specialist. An Antigo, WI native, he received his Master's degree in Endocrinology - Reproductive Physiology at the University of Wisconsin – Madison. Jeff previously worked in clinical research for the Department of Ophthalmology & Visual Sciences at UW – Madison, managing multiple clinical trials and analyzing ocular images of eyes affected by cataracts, age-related macular degeneration, diabetic retinopathy, and ocular complications of AIDS. Joyce will be working closely with Drs. Murray Brilliant and Steve Schrodi on several genomic projects, including studying the risk factors and mechanisms responsible for developing various eye diseases. He will also oversee compliance for CHG. In his free time, Jeff enjoys sports, hunting, fishing, and spending time with his daughters.

Dr. Jixia Liu also recently joined CHG as a post-doctoral fellow working with Dr. Scott Hebring. Her current research includes the identification of novel gene-disease interactions using Phenome-wide Association Study, next generation sequencing, and molecular biology approaches.

Liu received her PhD in Biochemistry and Molecular Biology from Shanghai Jiao Tong University, China. She was a visiting fellow in the National Institute of Health and a research associate in the University of Minnesota and Rutgers University. Her previous research interests include the genetics of psychiatry disorders (schizophrenia and alcohol dependence), the application of next-generation sequencing in searching for disease-causing genes in limb development and stress-induced obesity using cell and mouse models, and the role of piRNAs in *Drosophila* evolution and mouse neurodevelopment. Her research experience is in genetics, genomics, epigenetics, computational biology, molecular biology, development, and stem cell biology. Liu has published 10 research papers in prestigious journals.

In Addition:

- The next Full Foundation meeting will be held on September 11th at 9:30AM in the Froehle Auditorium.
- The next Board of Trustees meeting will be held on August 28th 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Bobbi Bradley, Dr. Tom Fritsche, Scott Heiberger, Kathy Heintz-Dzikowich, Kathy Mancl, Cathy Marx, Jake Miller, Melissa Ostrowski, Pete Schmeling, Dr. Bob Steiner, Michelle Wellsandt, Dr. Steve Ziemba

Edited by: Alexis Tavano, MPH, tavano.alexis@mcrf.mfldclin.edu, ext. 1-8939.

Directors' Report



The MCRF Summer Student Research Internship Program (SSRIP) Research Symposium was one of my favorite events of the year. This is an opportunity for our summer interns to present the results of the research they conducted with mentorship by MCRF scientists and staff. Those of you who attended heard my enthusiastic endorsement of the Symposium and of the SSRIP, but I wanted to reiterate my comments for Research Matters. I was dazzled by the outstanding quality of the work accomplished and the presentations. I have renewed faith that we will have an excellent generation of new scientists.

This type of a program requires a major effort from many individuals. To mention a few key individuals and groups responsible for the great success of the SSRIP and the Symposium: Bobbi Bradley and Dr. Huong McLean as program leaders, the students, the students' families and friends, the donors who help fund the program, mentors, and Pete Schmeling and the Development team.



I think we can all agree that MCRF is a special place. There are amazing things happening here. You are all asked to do a lot...the time and effort dedicated to fulfilling our research mission, the use of your knowledge and skills, and the faith you have that MCRF will continue to grow and contribute to scientific knowledge in significant ways. I sincerely appreciate everything each and every one of you does on behalf of MCRF.

My wife and I recently had a conversation about our charitable giving. When we talked about our goals, it became clear that giving to MCRF was at the top of our list, so we decided to make two changes to our Project Shine Hour Club commitment. First, we decided to allocate all of our giving to MCRF Unrestricted Research so that MCRF could use these funds for the things that we can't pay for through grants. Second, we decided to increase our gift to a level that is the highest amount we've ever given to any organization. Why did we do these things? Simple – we believe in MCRF and the work we do together. We made this gift in honor of all of you knowing that great things will happen here because of your efforts.

It feels good to give to something so special. I hope you will consider joining us in supporting MCRF through Project Shine at a level that's meaningful to you.

Recent Publications, Grants, and Awards

This column is to highlight recent accomplishments of MCRF researchers and MC clinical investigators. Please select the hyperlink below to view recent publications: [Publications](#)

Grants



A grant from the National Cancer Institute's (NCI) newly formed National Community Oncology Research Program (NCORP) was recently awarded to Marshfield Clinic Research Foundation, along with Gundersen Health System of La Crosse and St. Vincent Cancer Center of Green Bay. The consortium will work together under the name Wisconsin National Community Oncology Research Program (WiNCORP). The grant is one of the largest MCRF has ever received. WiNCORP, which will be led at MCRF by Douglas Reding, MD, will work to improve access to cancer trials for more patients over the next five years. "The award demonstrates NCI's faith in our ability to continue strong enrollment of cancer patients in clinical trials to ensure they receive state-of-the-art oncology care. Working with our partners, we'll provide greater access to trials in the communities we serve," said Reding.



Huong McLean, PhD, Associate Research Scientist in the Center for Clinical Epidemiology and Population Health was recently awarded a grant from the Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases. McLean's project is "MMR3 Long-Term Follow-Up Study – Immunogenicity Associated with a Third Dose of Measles-Mumps-Rubella (MMR) Vaccine 5, 9, and 13 Years Following Vaccination". This study will be a continuation of a prior study that examined the immunogenicity and adverse events following receipt of a third dose of MMR vaccine. Participants from the original MMR3 study will be followed at multiple time points to assess the long-term duration of immunity to measles, mumps, and rubella after receipt of a third dose of MMR vaccine. The remarkable thing about this cohort is that some of the participants have been followed since 1994, when they received the second dose of MMR vaccine as part of another study to examine responses of different MMR vaccine schedules.



Sanjay Shukla, PhD, Research Scientist in the Center for Human Genetics, has received an award through the UW-Madison Institute for Clinical and Translational Research (ICTR) Basic and Clinical Pilot Awards program. Shukla will be collaborating with Michael Pulia, MD, Nasia Safdar, MD, PhD, and Kurt Reed from the UW School of Medicine & Public Health on a project entitled "*Methicillin-Resistant Staphylococcus aureus (MRSA) Colonization Detection as a Potential Strategy to Reduce Unnecessary Vancomycin Usage in the Emergency Department.*" This project is designed to determine if comprehensive MRSA colonization screening (multiple anatomic sites) has sufficient sensitivity to be used in screening for invasive MRSA infections.

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

Awards



Jessica Engel, DNP, RN, FNP-BC, AOCNP, has been nominated as one of only four finalists for the Oncology Nurse Excellence (ONE) Award, which will be presented at the annual conference in September. Dr. Adedayo Onitilo said, "She is an exceptional oncology nurse practitioner. Dr. Engel also consistently receives excellent patient satisfaction reviews and goes to great lengths to ensure optimal care for her patients. Dr. Engel's significant oncology research contributions make her a distinguished and deserving candidate." Engel also recently received the UW-Stevens Point Geographic

Information Systems Center Outstanding Partner Award for her work in mammography utilization in a largely rural region. For more information about the organization and the award, please follow this link: <http://www.theoncologynurse.com/>.

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 Alexis Tavano at ext. 1-8939 or tavano.alexis@mcrf.mfldclin.edu.

Compliance Corner

Important HIPAA Privacy Reminders



Research Principal Investigators and staff are reminded that we all have to do our part to ensure we are complying with the HIPAA Privacy and Security Rules when using or disclosing Protected Health Information (PHI) for Research. Breaches of PHI are taken seriously, as they not only can result in reporting to subjects or to the media, but also can lead to external audits by federal agencies and the potential for fines and imprisonment.

- Improper use of PHI can constitute a potential breach. PIs and research staff requesting or viewing data must ensure that the requests or viewing are consistent with the HIPAA authorization, HIPAA-approved waiver, or the "reviews preparatory" or "research on decedents" attestation for that specific research activity.
- Review the datasets prior to use or disclosure to ensure the data includes the identifiers that are allowed to be used or disclosed by the IRB-approved protocol/informed consent document/HIPAA authorization, and that the intended recipient is authorized to receive the data you are sending.
- If reviewing PHI for feasibility purposes under "reviews preparatory to research," you must file an attestation either through the Data Request with BIRC or by filing a separate attestation with ORIP. Among the statements attested is that the PHI will not be removed. This means PHI cannot leave the building or be taken off of Marshfield Clinic servers. Feasibility data can be shared only if: (1) in aggregate form, (2) it is completely de-identified by removing all 18 identifiers, or (3) the IRB grants a separate waiver of authorization to share the PHI.

(continued on next page)

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

Compliance Corner *(continued from previous page)*

- Always hit “Send Securely” when sending PHI in an email to an external source. Make sure there is an authorization, waiver, or other method that allows the recipient to receive the information. If the recipient cannot open the encrypted email, you can always fax the information as a secure alternative.

- If PHI is to be shared with another entity for the treatment of a subject, no separate authorization is required. However, a separate authorization is required to share any research-related data. An example where an authorization would be needed would be sharing information about unblinding a subject on a study conducted at Marshfield so that a subject can join a study at another institution.

- Data are only “de-identified” under HIPAA if all 18 HIPAA identifiers are completely removed. The HIPAA identifiers are:
 - Names
 - All geographic subdivisions smaller than a State (e.g., street address, city, county, precinct, zip code and their equivalent geocodes)
 - All elements of dates, except year, directly related to an individual including but not limited to birth date, admission date, discharge date, date of death; and for all ages over 89, all elements of date including year indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
 - Telephone numbers
 - Fax numbers
 - E-mail addresses
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers
 - Vehicle identifiers and serial numbers, including license plate numbers
 - Device identifiers and serial numbers
 - Web Universal Resource Locators (URLs)
 - Internet Protocols (IP) address numbers
 - Biometric identifiers including finger and voice prints
 - Full face photographic images and any comparable images
 - Any other unique identifying number, characteristic or code, except as otherwise permitted for re-identification purposes – this includes Medical History Numbers

NFMC Hosts Two Summer Interns



The National Farm Medicine Center (NFMC) hosted two students as part of a national summer internship program providing practical experience in the field of occupational safety. Ivanna Pereyra, Salisbury University, and Taylor Arnold, University of Memphis, spent eight weeks in Marshfield, WI., working primarily on *Seguridad en las Lecherias*, a project that is testing culturally appropriate occupational safety and health training for immigrant dairy workers.

Pereyra and Arnold came to the Farm Center as part of the Occupational Health Internship Program (OHIP), an initiative of the Association of Occupational and Environmental Clinics <http://aoec.org/ohip/>. Competition for internships was keen with just 34 positions nationwide for more than 400 applicants. Marshfield was the only rural location among nine training sites nationwide, and *Seguridad* was the only project focused specifically on agricultural safety and health among 17 projects.

“This has been a wonderful opportunity to have fresh young minds among us who can offer new perspectives and can ask questions that don’t occur to us but have relevance to our work,” said Matthew Keifer, MD, MPH, director of the National Farm Medicine Center, a program of Marshfield Clinic Research Foundation. “We hope that Ivanna and Taylor benefitted from their experience here as much as we have benefitted from their presence with us.”

“Our placement with NFMC and the *Seguridad* project gave us valuable inroads into the dairy industry,” wrote Pereyra and Arnold. “We were able to talk to numerous Hispanic workers, participate in safety trainings, and sit in on interviews and meetings with farm owners. Hearing multiple perspectives and having access to the various facets of the industry allowed us a much more nuanced view of the worlds of agriculture and occupational safety and health, and the complexities involved in merging the two worlds.”

Sebold Award Nominations Sought



William Hocking, MD, recipient of Sebold Award in 2013

MCRF and the Board of Trustees are accepting nominations for the 27th Gwen D. Sebold Research Fellowship Award. Nominations should be addressed to Jaime Boero, MD, Chair of the MCRF Board of Trustees, and routed to Jeanette Normington, 1R3. The nomination letters should be received by Friday, September 5th. The award will be presented at 5:30PM on Wednesday, November 12th in the Froehle Auditorium.

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

National Farm Medicine Center Plays Life-Saving Role at Wisconsin Farm Technology Days



Two significant threats to the farm population's well-being -- skin cancer and tractor rollovers -- were addressed by the NFMC during its largest outreach event of the year, August 12-14, at Wisconsin Farm Technology Days. More than 600 visitors received skin cancer screening and 75 individuals enrolled in the Wisconsin Rollover Protective Structure (ROPS) Rebate Program.

Twenty-four physicians, allied providers and staff from the Marshfield Clinic Dermatology Department, along with 10 Farm Center scientists and staff, volunteered for the three-day event held near Stevens Point.

NFMC Education Outreach Specialist Tammy Ellis began working with counterparts in Clinic Dermatology and Corporate Communications in March to ensure a smooth-running effort. "We tried to make it as easy as possible to take advantage of these services," Ellis said. "We had some people tell us that the last time they got screened for skin cancer was when we screened at Farm Tech Days in Clark County (2005) and Marathon County (2011). That shows how important this initiative is to central Wisconsin residents."

Said Dr. Erik Stratman, Chair of the Clinic Dermatology Department: "I don't think the farming community always seeks timely health care. This screening can provide the push they might need. I think we saved at least five lives today."

"Farmers are busy people," said Dr. Alexandra Carley, "and screening where they are makes sense." "Screenings also are valuable in that they give potential Marshfield Clinic patients a point-of-access to care," said Dr. Thomas McIntee.

Dr. Matthew Keifer, NFMC director, sees Farm Technology Days as a great opportunity for the Farm Center and Marshfield Clinic to cure disease. "Of all the cancers farmers are at risk for, skin cancer is the No. 1 cancer that can be diagnosed quickly and cured," Dr. Keifer said.

Dr. Barbara Marlunga and Ellis lead the Wisconsin Rollover Protective Structure (ROPS) Rebate Program, which has installed more than 70 ROPS in its first 18 months. Dr. Marlunga said promotion of the ROPS program is having an impact. Many farmers who enrolled during Farm Technology Days said they read about the program in special Farm Tech Days supplements published the week before in state ag magazines. "They came here to sign up -- they already knew about the program," Dr. Marlunga said.

In Addition:

- The next Full Foundation meeting will be held on September 11th at 9:30AM in the Froehle 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 August 28th 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Scott Heiberger, Bonnie Ohlsson, Melissa Ostrowski, Pete Schmeling, Dr. Rachel Stankowski, Dr. Bob Steiner, Dr. Steve Ziembra

Edited by: Alexis Tavano, MPH, tavano.alexis@mcrf.mfldclin.edu, ext. 1-8939.

Directors' Report



On Tuesday, September 9, I had the good fortune of being invited to present MCRF's Annual Report to the Marshfield Clinic Board of Directors and its new CEO, Dr. Susan Turney. Dr. Steve Ziemba and I took this as an opportunity to showcase all the great things that you in MCRF have accomplished this year. We also took the opportunity to inform the Board and CEO of the actions we took in response to the mandated budget cuts. Specifically, the outline of our presentation included:

- [Why MC Does Research](#) (an expanded Word [version](#))
- Introduction to MCRF
- MCRF: A Theme of Change
- Response to Budget Reductions
- Highlights and Accomplishments/Improving Recognition, Reputation, and Impact
- Strategic Planning: Moving Forward

We believe the presentation was well received, and that the Board and CEO are as proud of the accomplishments of MCRF this past year as we are. We hope to present the Annual Report to MCRF staff at an upcoming Full Foundation meeting, and to expand this presentation to an Annual Report available publicly.



Last month, you heard me talk about the importance of philanthropy to research, and how my wife and I decided to increase our contribution. This month, I want to continue that discussion by highlighting how philanthropy ultimately provides benefits to research, aside from the financial aspect.

When one considers how philanthropy benefits research, the first thought is the funding aspect it provides. This is certainly true and likely the most direct facet. However, philanthropy provides other benefits. Perhaps the greatest is the link it provides between research and the community. On the one hand is the opportunity to demonstrate to the community what research involves and what it provides. On the other is the opportunity for the community to become more involved and demonstrate their appreciation. Building from this is the sense of involvement of the community. When I meet an individual who is a participant on a study, I thank them for their involvement, for without it there would be no study. Similarly, the support of the community is a part of the infrastructure of research. *(continued on next page)*

Directors' Report *(continued from previous page)*

What does the community derive from supporting research through philanthropy? From a tangible aspect, it can be a sense of involvement, a way to say thank you, or helping to support something one feels is important. If you take a step back, though, what the community receives is a sense of hope. In contributing, they are a part of improving the lives of others with the same disease that a loved one was afflicted with, or trying to enhance how their care is provided, or even preventing the disease in the first place. This is, essentially, the foundation of the groups that focus on research philanthropy through the events, videos, or other means to tell their stories. One specific example that highlights this is a video I saw recently from our Golf For Research event. Take a few minutes to watch this video and I think you'll agree that the hope we provide through our work is something special.

Golf For Research Video: <http://youtu.be/47fzFcBFncM>

The research of MCRF has contributed in great ways to the medical field. There is still a long way to go, and philanthropy will be a vital piece of helping to make that happen.

Compliance Corner

Why Should You Care About Compliance?



A team mindset is essential to creating a culture of compliance in research. Admittedly, complying with all of the requirements that apply to our research is not easy. Compliance efforts are further complicated by the fact that many players are involved, and requirements are complicated and can vary by study or activity, and change over time.

The risks for non-compliance are real when requirements are not followed. There are potential risks to our subjects' rights and welfare, and the trust that they place in us. There are also risks to the integrity and privacy of the data, and to the institution. Warning letters, misconduct determinations, clinical trials billing fines, grant audit findings, and high-profile privacy breaches all are glaring real-world examples of what can happen. Your identification of risks, and input on compliance monitoring and auditing processes, will collectively help our efforts. Our primary goal is to ensure the rights and welfare of our patients and subjects are protected. Secondly, we aim to ensure that our research is of high quality and scientifically valid, which bolsters integrity and credibility.

We all need to do our part to work towards greater communication, collaboration, and consistency given reduced resources. Reach out to the Research Compliance Officer or to your Center or Office Director or Administrator when you have questions, or to report events. We can only fix what we know is a problem. Work to strengthen your relationships with your peers and your managers so you can feel comfortable working through issues as a team. Ask questions if you cannot find a certain policy or form. Do not be afraid to reach out to a Principal Investigator. He or she is ultimately responsible for the conduct of the research. If you feel uncomfortable doing so, consult with Center or Office leadership, or with the Research Compliance Officer. We are collectively responsible to ensure our projects are meeting all of the requirements.

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

ALS “Steps for Hope” Run/Walk and Ice Bucket Challenge



On Saturday, September 6th, over 300 people gathered at Wildwood Park in Marshfield to participate in the 1st Annual Amyotrophic Lateral Sclerosis (ALS) Steps for Hope event. This run/walk was organized by the Braun family in memory of their father and brother, John Braun.

With the goal of raising awareness for ALS and raising funds for ALS Research at Marshfield Clinic, the Braun family worked tirelessly for three months to plan and organize this inaugural event. Dr. Jaime Boero attended the event to speak about ALS and the importance of research in providing hope for future generations. ALS, often referred to as "Lou Gehrig's Disease," is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Marshfield Clinic would like to express our thanks to the Braun family for their enthusiasm and passion for ALS research.

As a way to promote the event, Darrin Braun challenged Jaime Boero, MD, PhD, Narayana Murali, MD, and his uncle, Gary Braun to participate in the Ice Bucket Challenge. In addition, Timothy Boyle, MD, Benjamin Lawler, MD, and Pete Schmeling also participated in the challenge, which took place on August 28th. Rules for this challenge, which raised millions of dollars for ALS research over the summer, are that those challenged must record a video of themselves announcing that they have accepted the challenge, nominate others for the challenge, and then have a bucket of icy water dumped over their heads. Click [here](#) for the video.



Ice Bucket Challenge (from left)
Timothy Boyle, MD (seated) with Bob Steiner, MD, pouring the ice water; Gary Braun with wife Edie; Jaime Boero, MD, PhD, with Steve Ziemba, PhD; Narayana Murali, MD, with children Tara and Suhaas; Benjamin Lawler, MD, with Karen Piel; and Pete Schmeling with Teresa Derfus.

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

IOSH Director Collaborates on IOM Discussion Paper



Dr. Amit Acharya, Director of Institute for Oral and Systemic Health (IOSH) was recently invited by the Institute of Medicine (IOM) to write a discussion paper on application of After Visit Summary (AVS) in the field of dentistry. Acharya collaborated with Alice M. Horowitz, PhD, RDH, from University of Maryland, Lindsey A. Robinson, DDS, from California Dental Association, and Man Wai Ng, DDS, MPH, from Harvard School of Dental Medicine, on this publication.

In dentistry, AVS can be thought of in both the context of a standalone dental practice and as a combined summary integrating oral health-related information with medical information. In this commentary, the authors explored the AVS from both perspectives and made a case for considering AVS as an important piece of the larger puzzle needed to improve oral health and general health literacy for all patients, as well as highlighted the success at Marshfield Clinic in developing AVS for dentistry as a case report.

“It was an honor to discuss the efforts going on here at Marshfield Clinic Research Foundation and Family Health Center of Marshfield, especially in an article invited by the Institute of Medicine as it reaches a wide national and international audience,” said Acharya.

Here is the link to the article:

<http://www.iom.edu/Global/Perspectives/2014/AfterVisitSummaries.aspx>

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](#) and [grants](#). No awards were submitted.

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 Alexis Tavano at tavano.alexis@mcrf.mfldclin.edu.

Celebrate Safety: ‘Like’ NFMC and Children’s Center on Facebook



In honor of National Farm Safety and Health Week, Sept. 21-27, show your appreciation for farm families and farm workers by “liking” the Facebook pages of the National Farm Medicine Center (www.facebook.com/farmmedicine) and National Children’s Center for Rural and Agricultural Health and Safety (www.facebook.com/nccrahs).

Since 1981, the National Farm Medicine Center has focused on the safety and well-being of those who live and work on farms. Meet the people and see the projects behind the Farm Center and its largest program, the National Children’s Center.

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

United Nations Human Rights Office Interviews Dr. Murray Brilliant



On July 28, 2014 a representative from the United Nations Human Rights Office came to Marshfield to interview and film Dr. Murray Brilliant, Director of the Center for Human Genetics, on the conditions of people with albinism in East Africa. The interview will be part of the UN agency's efforts to protect the rights and lives of people with albinism. Brilliant is an expert on the genetics of albinism, identifying three of the genes associated with the condition. One of the genes, OCA2, is associated with the most common form of albinism in Africa. Brilliant has described a common mutation in the OCA2 gene in Africa, implying that most Africans with albinism had a shared ancestor. His studies estimate that this ancestor lived about 2,500 years ago.

Africans with albinism are at a very high risk for skin cancer and because of a lack of treatment, most will die from this. Unfortunately, they face even more extreme peril in East Africa, where superstition holds that their bones, hair, and other body parts can be used magically. In the past, this was largely limited to grave robbing, but in the past few years living people are increasingly targeted and murdered for their body parts. Dr. Brilliant has worked to bring attention to their plight. You can view a Learning Channel Special, now on YouTube: (<https://www.youtube.com/watch?v=9YjzKusVu8>) about these people. This ancestral OCA2 mutation is carried by nearly 1 in 19 Tanzanians. Ironically, it is highly likely that it is also carried by at least a few of the murderers of people with albinism. Perhaps if the people of Tanzania knew that albinism is a manifestation of one of their ancestors, the murders would stop. Brilliant is scheduled to speak at the PanAfrican Summit on Albinism in Dar Es Salaam, Tanzania, in January, 2015.

Use of Donated Funds for Research

MC/MCRF is the beneficiary of donations from grateful patients that are expected to be used for conducting disease specific research. Through MCRF's Internal Funding policy: http://srdweb1/clinic/policies/policy_details.asp?RecID=253 employees of MC can apply for access to these donated funds by submitting a research proposal to the Research Committee for scientific merit review. The "Research Committee Application - Projects Requesting Funds" is located at: http://srdweb1/clinic/policies/form_results.asp?FL=Yes&L=R&typeEntity=clinic. The level of base funding available per project is currently \$50,000. (When practicing clinicians are participating in the research, an additional \$15,000 per project may be awarded to compensate for their time and effort.)

Pre-proposals are required to be submitted for review in advance of submitting a full proposal. Applications may be submitted any time prior to the start of each quarterly cycle, with new cycle dates beginning on the 16th of March, June, September and December. Applications are reviewed in the order they are received during the cycle, so it can be advantageous to submit proposals earlier in the cycle than later.

A listing of disease specific funds available can be found on the Research Mentor intranet landing page, with a link titled "Donated Funds Available for Research": <http://mclweb/mcrf/?page=researchmentor>. Questions regarding this funding mechanism can be directed to Deb Hansen (ext. 79130; hansen.debra@mcrf.mfldclin.edu).

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

Auction of Champions 2014: Safari!

Adventurers can expect to be surrounded in exotic elegance as they migrate through the auction tent, order a drink at one of the watering holes, or feast on their lion's share of a meal.

A sneak peek of live auction items include:



- Guess for your Lioness: a beautiful purse filled with dazzling jewelry that only Wickersham jewelry knows
- Safari Feast: a prime meat package including pork tenderloins, steaks, roasts, racks of lamb and more!
- Passport to Paradise: a six night, seven day vacation package, choosing from hundreds of resorts in more than 75 countries from around the world
- Migrate to Lambeau: You and 7 of your closest friends can enjoy experiencing one of the biggest rivalries of the season as the Packers take on the Vikings on October 2nd!

New this Year: Pre-event Raffle - Enjoy a one-week stay in beautiful Scariff, Ireland! Donated by Ann and Fergus McKiernan, these tickets are flying out of our doors. Package includes a one week stay in their traditional Irish cottage as well as a \$2000 travel voucher from High Street Travel. Tickets are \$100 each and only 150 are being sold. Although you need not be present to win, the lucky winner will be announced at Auction of Champions.

Tiffany Halan, Special Events Coordinator at Marshfield Clinic Development, said, "Our Auction of Champions committee, chaired by local dairy farmer Josh Meissner, has once again committed countless hours and resources into making this into what is sure to be another amazing evening. It is so inspiring to work beside this committee of about 40 people who are all dedicated to the same goal: improving health and safety in rural and agricultural communities."

The Auction is the National Farm Medicine Center's annual gala fundraiser. Since its inception in 1982, the Auction has raised more than \$3 million for Farm Center initiatives such as the Wisconsin ROPS Rebate Program, education, outreach, the Journal of Agromedicine and many other projects that benefit central Wisconsin's farm community.

Tickets are \$100 each to attend AOC. Register at www.marshfieldclinic.org/aoc

Reminder: PI Status and Change in Personnel

Federal guidelines specifically state that prior approval is required from the funding agency when the Principal Investigator or key personnel named in the award will withdraw from the project entirely, be absent from the project for a continuous period of 3 months or more, or will be reducing time committed to the project by more than 25 percent of the level of effort that was approved at the time of award. Many other funding agencies follow this same guidance, so please work with Sponsored Programs when there may be a potential for any of the situations listed above.

NFMC Year-in-Review Published



Learn the stories behind all National Farm Medicine Center/National Children's Center for Rural and Agricultural Health and Safety projects – and where the projects are headed. It's all in the year-in-review,

<http://www3.marshfieldclinic.org/proxy/MCRF-Centers-YearinReview2013.1.pdf>

Families Across the Country Supporting CRIBBS at MCRF

Volunteer Fundraising Events Supporting CRIBBS



The world's first rare disease registry for Bardet-Biedl Syndrome was launched at Marshfield Clinic Research Foundation at the end of June, 2014. To date, nearly 100 people from across the country have signed up to participate in the Clinical Registry Investigating BBS (CRIBBS). Funds are needed to ensure all of these interested individuals are able to enroll into the registry.

Realizing the future potential for BBS patients, members of the Bardet-Biedl Syndrome Family Association from across the country have rolled up their sleeves and are helping generate philanthropic support for CRIBBS. The

first of volunteer fundraiser events will take place in Minneapolis, MN on September 22 and the second in Atlanta, Georgia on October 23. Proceeds from both of these events will support CRIBBS at MCRF.

Bring Light to BBS – Minneapolis: <https://www.facebook.com/events/1462075820710171/>

Donation page: <http://cribbs.kintera.org/BringLight2BBSmpls>

Bring Light to BBS – Atlanta:

<https://events.r20.constantcontact.com/register/eventReg?oeidk=a07e9s4lkodd16769e6&oseq=&c=&ch>

Donation page: <http://cribbs.kintera.org/BringLight2BBSatlanta>

A video promo for the Minneapolis event is available here:

<http://www.youtube.com/watch?v=OM4-5271kUQ>

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

Epidemiologists Join CCEPH



Elizabeth Vickers, MPH, joined the Center for Clinical Epidemiology & Population Health (CCEPH) this summer as an Epidemiologist – Masters Prepared. Vickers completed her undergraduate work at Michigan State University in Biochemistry and Molecular Biology. She recently obtained a Master of Public Health from University of Michigan School of Public Health in Epidemiology. Prior to joining the CCEPH team, Vickers was an Influenza Research Assistant at the University of Michigan for a CDC-funded study to determine household influenza vaccine effectiveness in families/households. Vickers will be instrumental in the management of MCRF's participation in the CDC-funded Vaccine Safety Datalink and industry-funded infectious disease observational studies and clinical trials. She was drawn to Marshfield by the CCEPH's excellent reputation in performing epidemiologic research and by her passion for vaccine research. After moving to Marshfield, she has been able to rekindle her passion for the visual arts and is currently featured in the Flash Galleries Exhibits downtown.



Brian Chow, MD, FAAP, joined Marshfield Clinic and CCEPH on August 25 with a split appointment as an Infectious Disease Epidemiologist and Pediatrician. Chow received his undergraduate degree from Vanderbilt University in biomedical Engineering and his Medical degree from Case Western Reserve University School of Medicine. Chow recently completed a fellowship at The Warren Alpert Medical School of Brown University. He is trained in adult and pediatric infectious diseases, and has research interests in fungal infections in neonatal patients. He is currently involved in the Center's ongoing work in vaccine evaluation. As a clinician in practice, he continues to look for ways to apply scientific discoveries to patient care. Chow was attracted to Marshfield Clinic Research Foundation because it offered a unique opportunity to study the epidemiology of disease in a well-characterized population. In his spare time, Chow enjoys running and travel.

In Addition:

- The next Full Foundation meeting will be held on November 13th at 1:30PM in the Froehle 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 November 20th 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Dr. Amit Acharya, Bobbi Bradley, Dr. Murray Brilliant, Tiffany Halan, Deb Hansen, Scott Heiberger, Bonnie Ohlsson, Melissa Ostrowski, Pete Schmeling, Dixie Schroeder, Dr. Bob Steiner, Lori Weigel, Brooke Wolff, Dr. Steve Ziemba

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

Directors' Report



I'm writing this column from the American Society of Human Genetics (ASHG) meeting in San Diego. Yes, it's warm and beautiful here (I swam outside this morning). More importantly, the science at the meeting is outstanding. This is the top scientific meeting for human geneticists in the US. I'm not alone here from Marshfield; there are representatives here from Prevention Genetics, and several of our scientists from MCRF. In addition to myself, Drs. Steve Schrodi, Murray Brilliant, and Max He are here. It gives me great pleasure to report that MCRF has had a significant impact on the meeting this year. I was there mainly to listen, learn, and support, but also to attend the American

College of Medical Genetics Board meetings as an elected board member. Brilliant gave an invited presentation today reporting results of a study in which 300 individuals who were followed at Marshfield Clinic have had their complete genomes sequenced to see if sequencing can have an impact on patient outcomes. Max He was a co-author of that study, which was highly anticipated and will have a major impact on the field of human genetics in medicine. Brilliant co-authored several other abstracts presented at the meeting, as did Drs, Peggy Peissig and Scott Hebring. I am delighted to report that Scott was invited to present his work on PheWAS at a platform session. He explained to the audience how searching for text with natural language processing within clinic notes can be useful in addition to searching using diagnosis codes (the usual way) in identifying genetic contributions to disease. He made the lecture understandable and interesting, and indeed, there were great questions and laudatory comments from the audience. It's an honor to be chosen for one of these talks, I think I'd been attending the meeting for a dozen years before I was invited to present a platform session. Finally, a former scientist at MCRF and current Prevention Genetics CEO, Dr. Jim Weber, authored an article while working at MCRF in 1989 that was chosen this year as one of the top 10 articles in the 60 year history of the American Journal of Human Genetics, entitled "Abundant Class of Human DNA Polymorphisms which can be Typed Using the Polymerase Chain Reaction." This groundbreaking work has been cited 3600 times, and heralded the beginning of the mapping of the human genome. A special journal issue including that article and 9 others by luminaries in the field was handed out to all attendees at the meeting. We have reason to be proud to work at MCRF, and I'm returning home happy (even with the 45 degree temperature change). *(Continued on next page)*

Directors' Report *(Continued from previous page)*



October 7, 2014 marked one year since my first day with MCRF. It has been an extraordinary year to say the least, with *change* as the primary theme throughout. Our cultural environment, budgetary view, leadership, operational processes and other aspects are different than what they were a year ago. We now have a “New Normal”. Your persistence and contribution enabled us, as a Foundation, to adapt to these changes and incorporate them into the work we do. I can say that we have adapted because, not only has it been a year of changes; it has also been a year of accomplishments. Some have been internal in their development (CRIBBS Registry, IOSH), some on the state level (WiNCORP), and some national (Greater Plains Collaborative). The total number of accomplishments achieved this past year are too numerous to list in this one piece, and as you heard me express before, it is amazing the accomplishments that have been achieved during a year of change. As we regain our footing as the Marshfield Clinic Health System, I can just imagine what is yet to come. I, as well as Dr. Steiner, am looking forward to working with you in the coming years. Thank you again for all that 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](#).

Grants

See the article [below](#) for information on the recent National Children’s Center for Rural and Agricultural Health and Safety grant award.



Huong McLean, PhD, and Jeffrey VanWormer, PhD, Associate Research Scientists in the Center for Clinical Epidemiology and Population Health were recently awarded a two-year grant from the Centers for Disease Control and Prevention. The project will involve implementation and assessment of evidence- and systems-based interventions for providers to improve human papillomavirus (HPV) vaccination coverage among adolescent patients in the Marshfield Clinic system. McLean and VanWormer will work closely with Marshfield Clinic providers and IQIPS team, and Wisconsin Immunization Program on this project. “Increasing HPV vaccination rates to reduce cancer is one of the top National public health priorities, and we are excited that Marshfield Clinic will be a leader in these efforts,” said McLean. *(Continued on next page)*

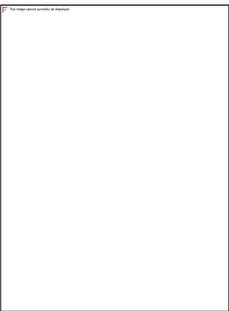
Recent Publications, Grants, and Awards (Continued from previous page)

Awards



As a follow up to an article in the August 2014 issue of *Research Matters*, Jessica Engle DNP, RN, FNP-BC, AOCNP, received the fourth annual Oncology Nurse Excellence award, presented Sept. 20 at the Academy of Oncology Nurse and Patient Navigators (AONN+) Navigation and Survivorship Conference in Orlando, FL. She was one of four nominees chosen for their leadership, compassion, and commitment to evidence-based practice. The more than 5,000 AONN+ members across the US voted for the winner. “I didn’t get the award for being on my own. It was because of the

opportunities I’ve had working with our research team, within our Oncology department and with the Clinic, and also because of all the other support I’ve received,” Engel said. “It’s nice to know people value the work you do and to be recognized for being what they think is a good example of how advanced-practice nurses can contribute to furthering patient care and oncology research. And it’s also nice to help get the Clinic name out at the national level in the nursing arena.”



Darla Egger, certified pharmacy technician, Investigational Drug, Marshfield Center, recently was named the 2014 Pharmacy Society of Wisconsin (PSW) Pharmacy Technician of the Year. Egger has 38 years of experience in the pharmacy field, including 32 years at Ministry Saint Joseph’s Hospital in Marshfield. She served two three-year terms as president of the PSW Technician Board and was on the PSW Task Force for developing technician credentialing recommendations and presenting recommendations to the Pharmacy Examining Board. The PSW award recognizes a Wisconsin pharmacy technician who has made significant contributions to pharmacy

technician practice, professional organizations and the community. “Darla is detail-oriented and consistently focuses on putting the patient first in everything she does,” said Sara Griesbach, PharmD, Director of Clinical Pharmacy Services. Egger was honored Aug. 23 at the PSW annual meeting awards banquet in Wisconsin Dells. She admitted feeling humbled when told she received an unprecedented 12 nominations for the award. “I’ve done a lot to promote technicians as the backbone of pharmacy health care,” Egger said. “Talk to any pharmacist and they’d tell you they would be lost without a technician.”

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 Alexis Tavano at tavano.alexis@mcrf.mfldclin.edu.

Hebbring Presents Use of Clinical Text Data for PheWAS Studies



Scott Hebbring, PhD, Associate Research Scientist in the Center for Human Genomics, presented “Application of Clinical Text Data for Phenome-Wide Association Studies (PheWASs)” at the American Society of Human Genetics (ASHG) meeting in San Diego. Hebbring’s work demonstrates that, for the first time, raw text data from clinical notes in an electronic medical record system can be used effectively to define a phenome. The study also validates that clinical text data, including drug data, can be applied to a PheWAS as an

alternative and complementary approach to a GWAS or ICD9-based PheWAS.

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

Compliance Corner

New NIH Policy for Genomic Data Sharing



Researchers involved in research that generates human or non-human genomic data, cell lines, or clinical specimens should be aware of a new U.S. National Institutes of Health (NIH) policy. This policy applies to NIH-funded research that generates such data, lines, or specimens, including GWAS, SNP arrays, and genomic sequence, and gene expression data. The policy is not limited to any funding level or mechanism, and currently excludes studies on fewer than 100 genomes.

For studies opened on or after August 26, 2014, NIH expects researchers to obtain informed consent from participants for broad sharing and future research using genomic and phenotypic data. This applies even if the data, lines, or specimens are de-identified. NIH will only consider compelling scientific reasons to grant any exception. Informed consent specific to future research is not required to submit, or for future research use of, data from de-identified specimens or lines that existed before August 26, so long as an IRB determines that the submission or use is consistent with the consent that was provided. The policy also defines when consent documents need to state whether future data access will be access-controlled or unrestricted. Additionally, any data submitted to designated repositories must be de-identified as defined by the HIPAA Privacy Rule, with a key held by the submitting institution.

The policy includes dates by which data has to be submitted, and defines how a committee reviews controlled access requests. It also states that for unrestricted access, investigators must assure they will not attempt to identify research participants and must acknowledge the data source. Institutions can request that data be removed for certain participants who withdraw, but NIH acknowledges that data that was already distributed cannot be retrieved.

CCEPH Researcher Participates in PCORI Obesity Trial



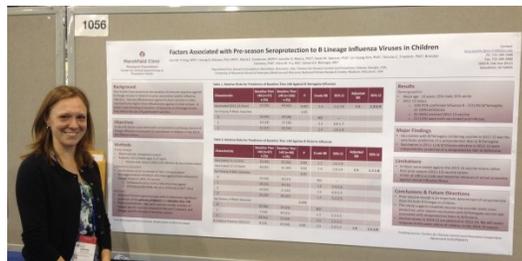
Jeffrey VanWormer, PhD, Associate Research Scientist in the Center for Clinical Epidemiology and Population Health (CCEPH) is part of the Greater Plains Collaborative healthcare consortium team that was recently awarded a 5-year grant from the Patient Centered Outcomes Research Institute. This new project is led by Christie Befort, PhD (Kansas University Medical Center), and will compare the impact of three obesity therapies in adult residents of the rural Midwest. This is a multisite, clinic-randomized trial with primary care

departments from several Marshfield Clinic centers participating, along with other clinic partners from Kansas, Nebraska, and Iowa. "Obesity is a persistent health condition that underlies many of the deadliest diseases of our time, particularly in rural areas like central and northern Wisconsin. In close cooperation with our partners in the Greater Plains Collaborative, Marshfield Clinic will help discover optimal models of delivering patient-centered primary care around weight management," said VanWormer.

CCEPH Scientists Presented Four Abstracts at IDWeek 2014 Conference

Three CCEPH scientists, Jennifer King, MPH; Huong McLean, PhD, MPH; and Melissa Simpson, DVM, PhD, attended and presented research from Marshfield Clinic at the third annual IDWeek Conference in Philadelphia, October 8-12, 2014. IDWeek is a joint meeting of the Infectious Diseases Society of America, the Society for Healthcare Epidemiology of America, the HIV Medicine Association, and the Pediatric Infectious Diseases Society that features the latest science and bench-to-bedside approaches in prevention, diagnosis, treatment, and epidemiology of infectious diseases. The meeting assembles healthcare professionals in infectious diseases and healthcare epidemiology and prevention from around the world. Posters presented by Marshfield Scientists include:

- Jennifer King, MPH, Huong McLean, MPH, PhD, Maria Sundaram, MSPH, Jennifer Meece, PhD, Sarah Spencer, PhD, Jin Hyang Kim, PhD, Thomas Friedrich, PhD, Brendan Flannery, PhD, Alicia M. Fry, MD, MPH, and Edward Belongia, MD. Factors Associated with Pre-Season Seroprotection to B Lineage Influenza Viruses in Children.



- Huong McLean, PhD, MPH, Jennifer King, MPH, Maria Sundaram, MSPH, Jennifer Meece, PhD, Sarah Spencer, PhD, Jin Hyang Kim, PhD, Thomas Friedrich, PhD, Brendan Flannery, PhD, Alicia M. Fry, MD, MPH, and Edward Belongia, MD. Factors Associated with Influenza A (H1N1) Vaccine Failure among Children Aged 5-17 Years.
- Melissa Simpson, DVM, PhD, Burney Kieke, MS, Maria Sundaram, MSPH, David McClure, PhD, Jennifer Meece, PhD, Frangiscos Sifakis, PhD, MPH, Robert Gasser Jr., MD, and Edward Belongia, MD. Seasonal Incidence of Medically Attended RSV and Influenza Illness in Children 6-59 Months Old.
- Maria Sundaram, MSPH, Huong McLean, MPH, PhD, Jennifer Meece, PhD, Richard K. Zimmerman, MD MPH, Mary Patricia Nowalk, PhD, Chyongchiou J Lin, PhD, Thomas Friedrich, PhD, Sarah Spencer, PhD, and Edward Belongia, MD. Antibody Response to Intradermal and High Dose Influenza Vaccine in 2012-13 among Adults Who Did Not Respond to Standard Dose Vaccine in 2011-12.

ORIP Administrator Passes Re-Certification Exam



Linda Jaros, Assistant Director ORIP/IRB Administrator, has passed the Certified IRB Professional (CIP) re-certification exam. The CIP certification is sponsored by Public Responsibility in Medicine and Research (PRIM&R). The CIP credential was developed to promote ethical research practices and programs by ensuring that professionals charged with their administration have demonstrated an advanced level of knowledge, understanding, and experience.

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

National Children's Center Receives Major Grant for Agriculture Safety



Farm parents, insurers, youth organizations, and others increasingly turn to the unique capabilities of the National Children's Center for Rural and Agricultural Health and Safety to help ensure the safety of the next generation of farmers.

Recognizing the role played by the National Children's Center in the steady decline of childhood agricultural nonfatal injury rates over the past decade, the National Institute for Occupational Safety and Health (NIOSH) announced Sept. 25 that it is awarding the Center a \$1.2 million per year competitive grant renewal for a five-year cycle.

NIOSH has funded the National Children's Center since 1997. It also is supported by Marshfield Clinic and through generous donations and other grants. The National Children's Center is a program of the National Farm Medicine Center, Marshfield Clinic Research Foundation (MCRF).

"This major award will significantly expand our efforts to integrate proven safety strategies into programs of organizations and businesses that are best positioned to influence the safety of children living and working on farms," said Barbara Lee, PhD, National Children's Center director. "We expect to facilitate partnerships with private sector organizations such as agricultural employer associations, insurance companies, bankers, and youth-serving groups. We want to ensure that optimal safety interventions and guidelines are sustained beyond the span of the grant period. Innovative approaches will address safety for beginning farmers and ranchers; child care services for migrant and seasonal farm worker parents; and supervisor training of youth hired for agricultural employment."

While the overall decrease in childhood nonfatal injury rates is encouraging, a child is killed in a farm accident an average of every three days, indicating there's work to be done. Also of concern is that the injury rate for children younger than age 10 is increasing.

The new NIOSH grant includes seven distinct projects, along with administrative, scientific, and evaluation oversight. Principal investigators from MCRF include Lee; Barbara Marlena, PhD; Matthew Keifer, MD; and Casper Bendixsen, PhD. External principal investigators include Amy K. Liebman, Migrant Clinicians Network; Dennis Murphy, PhD, Penn State University; and Diane Rohlman, PhD, University of Iowa.

Brilliant Presents on Whole Genome Sequencing at ASHG



Murray Brilliant, PhD, Director of the Center for Human Genetics, presented "Post-Mortem Whole Genome Sequencing: A Genomic Autopsy" at the American Society of Human Genetics (ASHG) meeting in San Diego. Brilliant's presentation, co-authored by Dr. Max He and Nate Person, discussed the analysis of the DNA sequence of 300 deceased individuals with nearly complete life-long medical records, with the goal of determining potential health benefits and savings in medical procedures and costs for each subject as if the lifetime genetic data of these people was available. This new project aims to understand if whole genome sequencing is currently beneficial, given the limits of today's knowledge.

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

Oncology Researchers to Present at UW Carbone Fall Conference

The UW Carbone Cancer Center will host the 13th Annual Symposium “Advances in Multidisciplinary Cancer Care – Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis” on Friday, October 24, 2014, at the Monona Terrace in Madison, Wisconsin.

This year’s Fall Cancer Conference will focus on issues identified in the recent IOM report on improving the quality of cancer care. <http://www.iom.edu/Reports/2013/Delivering-High-Quality-Cancer-Care-Charting-a-New-Course-for-a-System-in-Crisis.aspx>.



Dr. William Hocking and Mindy Gribble, RN, Marshfield Clinic Department of Oncology, will present a breakout session on care coordination titled “Shared Goals and Clear Roles: Coordinating the Cancer Journey.” Included in their presentation will be information about Marshfield Clinic’s WINGS Cancer Survivorship Program and the use of the Journey Forward Care plan templates as a care coordination tool. Hocking and Gribble are currently participating in

an ICTR research project in collaboration with Amye Tevaarwerk, MD, Oncology Department, University of Wisconsin School of Medicine and Public Health, Carbone Comprehensive Cancer Center, Wisconsin Institute for Medical Research (WIMR). The project is assessing the efficiency of cancer survivorship care plans for both patients and primary care providers with a special focus on the needs of patients from rural communities.

The Carbone conference is designed for individuals who are involved in cancer treatment and education of cancer patients and their families: oncology physicians, primary care physicians, oncology nurses, nurse practitioners, clinical research associates, health educators, social workers, psychologists, chaplains, and other interested health care professionals involved in cancer care. Patients, caregivers, and community members are also encouraged to attend. Peter Bach, MD, MAPP Director, Center for Health Policy and Outcomes, Memorial Sloan Kettering Cancer Center will present a key note address. Additional information and registration is available at www.uwhealth.org/cancerconference.

IOSH Receives R01 Supplement from NIDCR



The Institute for Oral and Systemic Health (IOSH) recently received an R01 supplement, in collaboration with the HealthPartners Institute for Education and Research (HPIER), from the National Institute for Dental and Craniofacial Research (NIDCR). Dr. Amit Acharya, Director of IOSH and Dental Informatics Scientist at BIRC, will serve as the Site Principal Investigator and will work closely with Dr. Bill Rush from HPIER to conduct human factors research studies to improve usability of the Dental Decision Simulation™ (DDS) software – which was recently developed as part of the R01 grant. IOSH will work closely with the usability analysts at the Interactive Clinical Design Institute (ICDI) to conduct the many research aspects of the grant. “This is a true testimony of the valuable expertise and resources that are available within BIRC and MCRF, that are attracting collaborators from other organizations to jointly work with us,” said Acharya. *(Continued on next page)*

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

R01 Supplement (Continued from previous page)

The purpose of DDS is to provide evidence-based training in a simulated clinical setting. DDS presents clinical cases that demonstrate concepts associated with one or more evidence-based guidelines. In this application, the dental professional will treat a virtual patient in accordance with these evidence-based guidelines. The dental professional's clinical care diagnosis and treatment plan will be compared with a care protocol based on the guidelines. Suggestions will be provided to the dental professional at the end of the exercise. These suggestions are to assist the dental professional in managing care in accordance with the evidence-based guidelines.

In Addition:

- The next Full Foundation meeting will be held on November 13th at 1:30PM in the Froehle 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 November 20th 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Dr. Murray Brilliant, Dr. Scott Hebring, Mindy Gribble, Sara Griesbach, Scott Heiberger, Kathy Heintz-Dzikowich, Linda Jaros, Dr. Huong McLean, Bonnie Ohlsson, Melissa Ostrowski, Dr. Bob Steiner, Lori Weigel, Michelle Wellsandt, Dr. Jeff VanWormer, Dr. Steve Ziemba

Edited by: Alexis Tavano, MPH, tavano.alexis@mcrf.mfldclin.edu, ext. 1-8939.

Directors' Report



Dr. Bob Steiner,
MCRF Exec. Dir.

The past month has been a busy one at the Research Foundation. We participated in the External Advisory Committee (EAC) meeting for ICTR (<https://ictr.wisc.edu/>). The EAC was very impressed with the success of ICTR and with the Marshfield partnership. Drs. Acharya, Brilliant, and Greenlee were presenters at the EAC meeting. I was in Madison again last week presenting at UW School of Medicine and Public Health (UWSMPH) Pediatric Grand Rounds. It was an honor to be back at my alma mater and a great opportunity to present an overview of one area of my research over the past 20 years, disorders of cholesterol synthesis. The Foundation was also delighted to host the Sebold Awards described in more detail below. We had two outstanding candidates this year such that the decision was made to have two awardees, Drs. Brilliant and Onitilo. The Awards presentation and ceremony were very moving, and it was tremendously gratifying to see samples of the work these two scientists have accomplished. Finally, we had our quarterly meeting of the Board of Trustees, the Board to which we report. I took the opportunity to present a brief Annual Report to the Board, similar to the presentation I gave to the Clinic Board of Directors in September. The Board was pleased with our accomplishments over the past year and we all look forward to an even more productive Fiscal Year 2015.



Dr. Steve Ziemba,
MCRF Assoc. Dir.

You have heard me talk previously about our present environment of change, within MCRF, MCHS, and the healthcare industry as a whole. We are still experiencing change, but now some of it will be of our own planning. I am happy to report to you that MCRF will be holding a Strategic Planning retreat on January 28 and 29, 2015. There are a few things to be aware of as we engage in this activity. The most important is that strategic planning is intended to be a broad, high-level process of determining the direction in which we want MCRF to go over the next three to five years. We are determining our future direction as a Foundation. The reason I bring this up is to address comments on strategic planning's role in everything from the Foundation as a whole (which it is), to individual departments, centers and even specific projects. Although strategic planning can have an influence on each of these, it is not intended to address the specifics of our day-to-day operations. Rather, its intent is for us to determine the nature of our current environment, where we are now, where we want to be, and how to make the best use of our resources to get to where we want to be.

Those present at the retreat will include MCRF leadership, representation from the Board of Trustees, clinician-investigators, and scientists' representation. As we get closer to our retreat date, please feel free to provide me with any topics you feel should be discussed, or let me know if you have questions on the process. Thank you again and have a great Holiday season.

Brilliant and Onitilo Honored with 27th Annual Sebald Award



Two of Marshfield Clinic's most accomplished researchers were honored by about 100 friends, family, and colleagues Wednesday, Nov. 12, as they were awarded the 27th Gwen D. Sebald Fellowship for Outstanding Research.

Murray Brilliant, PhD, senior research scientist at MCRF, and Adedayo Onitilo, MD, PhD, Weston Center and Marshfield Clinic Cancer Care at Saint Michael's in Stevens Point, were the 27th and 28th recipients of the prestigious award. It was the first time two people received the

fellowship in a single year. Dr. Onitilo (left) and Brilliant (right) were congratulated by Dewey Sebald (center).

At least 10 past recipients attended the award ceremony in the Froehlke Auditorium of the Laird Center. The fellowship has been given by D. David "Dewey" Sebald since 1988 to recognize an outstanding medical researcher and support continued research in his or her field.

"This is the 27th time we've been here to honor the memory of my sister, Gwen Sebald, who died 40 years ago of lung cancer," Sebald said, pausing for a moment to control his emotions. "We're also here to support the Marshfield Clinic Research Foundation (MCRF), its mission of improving human health and wellbeing, as well as honoring and recognizing Dr. Onitilo and Dr. Brilliant. You should be very pleased with everything said here this evening. You should be very proud. We are very proud of you and all you have done to advance the human condition."

The Center for Human Genetics congratulates Dr. Murray Brilliant on receiving the Gwen D. Sebald Research Fellowship Award for 2014. Dr. Scott Hebring and Dr. Steve Schrodi, Associate Scientists in the Center for Human Genetics, along with Dr. Peggy Peissig, Interim Director Biomedical Informatics Research Center, presented an overview of Dr. Brilliant's career. Brilliant was very appreciative of his family, mentors, colleagues, staff and friends helping him achieve his personal and professional goals. He even mentioned one of his high school teachers as being the catalyst to pursuing his love of science.

Dr. Adedayo Onitilo is also congratulated on receiving the Gwen D. Sebald Research Fellowship Award for 2014 by the several departments involved in his nomination, including the Oncology Service Line, Clinical Research Center, Office of Scientific Writing and Publication, and Clinical Medicine and Research. Several individuals stepped forward to describe Dr. Onitilo's impressive achievements in clinical and academic medicine and were even joined by Dr. Onitilo's father, Solomon Onitilo, who happened to be visiting from Nigeria at the time of the award presentation. Dr. Onitilo's heartfelt acceptance speech largely credited the team of clinical and research personnel who support him at work and his wife and three daughters who support him at home. Dr. Onitilo's entire family was in attendance and several colleagues, neighbors, and friends from Weston and Stevens Point travelled to the ceremony to offer their congratulations.

Recipients receive \$5,000 and a memorial plaque presented by Sebald in memory of Gwen who grew up in Dorchester, about 30 miles north of Marshfield. She joined Marshfield Clinic as a medical stenographer in 1955 and died in July 1974. View the Sebald presentation on [Mediasite](#).

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

Compliance Corner



Thank you to everyone who completed the voluntary survey on FDA-regulated research as part of our Annual Research Risk Assessment and Work Plan. Your anonymous input will help direct future education efforts and be shared with leadership to make any required operational improvements.

There are several recent regulatory documents that were released that may be of interest:

1. [U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#) (Office of Science and Technology Policy, September 24, 2014): The policy puts into place institutional requirements for government-funded or government-conducted life sciences research involving fifteen listed agents and toxins. (*Please note: a box asking for a username and password will pop up – click cancel and you will then be directed to the document. Apologies for the inconvenience.*)
2. [Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care](#) (DHHS Office of Human Research Protections, October 20, 2014): Draft guidance explains how to apply 45 CFR Part 46 to non-exempt research involving human subjects that is designed to evaluate treatments or procedures that are medically recognized standards of care
3. [Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories – Framework for Regulatory Oversight of Laboratory Developed Tests](#) (Food and Drug Administration, Center for Devices and Radiological Health, October 3, 2014): Draft guidance describes a framework for addressing regulatory oversight of a subset of in vitro diagnostic devices referred to as laboratory developed tests (LDTs). The guidance aims to instruct clinical laboratories about how the FDA intends to enforce authorities that apply to such laboratories as medical device manufacturers under the Federal Food, Drug, and Cosmetic Act. It describes FDA's priorities for enforcing premarket and postmarket requirements for LDTs, as well as the process by which FDA will phase in enforcement of FDA regulatory requirements over time.

I would like to announce that I have accepted a position as Senior Staff Attorney in Legal Services. My last day as Research Compliance Officer is December 1. I will miss working with all of you, and I want to thank you for your hard work and dedication to compliance in research. I do believe that we have made great strides in increasing awareness, collaboration, consistency and transparency to improve compliance as a whole. The rules and requirements imposed on research can be admittedly complex and onerous, and complying with them is not an easy task. Our research subjects and the scientific integrity of the research both stand to benefit from our compliance efforts, and I know that these efforts will continue. Thank you to everyone for doing their part.

My replacement is actively being recruited and the position should be filled soon. During the interim, you may contact Donna Andrew with questions or concerns (andrew.donna@marshfieldclinic.org; ext. 1-5410).

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](#) 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 Alexis Tavano at tavano.alexis@mcrf.mfldclin.edu.

BIRC Analysts Attend Eye Tracking Conference

Usability analysts from the Biomedical Informatics Research Center (BIRC), Kate Baker and Andrea Mahnke, recently attended a conference in Washington, D.C. entitled “Eye Tracking in User Experience Design.” As attendees, they heard industry leaders present projects where eye tracking played a pivotal role in improving the user experience (UX). Projects used eye tracking to study or improve: how users interact with web content; systems, in conjunction with usability testing; emotional response by pairing with physiological response data, eg, EEG, galvanic skin response (GSR) and pupil dilation; the UX of forms and surveys; the mobile experience; and low literacy web users.

Baker and Mahnke will apply the insights and ideas explored at the conference on upcoming projects with their collaborators inside the Foundation.

IRDL Scientist Speaks on Tick-borne Diseases

Anna Schotthoefer, PhD, of the Integrated Research and Development Laboratory (IRDL), spoke at the *Science in the Northwoods* conference hosted by field stations in the Northern Highlands region of Wisconsin (<http://scienceinthenorthwoods.org/>, Oct 15-17, 2014), about a collaborative study in which she and Jennifer Meece, PhD, have been involved with the Wisconsin Department of Natural Resources and Michigan Technological University on the effects of lakeshore development and habitat restoration on tick-borne diseases in Vilas County. The study is being supported by the MCRF Research Committee.

Schotthoefer also gave an invited talk at the Cambridge Healthtech Institute’s Inaugural “Targeting Tick-borne Diseases” conference in Boston, MA (Oct 29-30, 2014; <http://www.healthtech.com/Targeting-Tick-Borne-Diseases/>). The title of her talk was *Molecular Diagnosis of Human Anaplasmosis and Ehrlichiosis Using a Real-Time PCR Assay*, and it was based on work funded by the MCRF Research Committee and a manuscript published with Drs. Jennifer Meece, Tom Fritsche, Tim Uphoff, as well as other scientists at MCRF: <http://www.ncbi.nlm.nih.gov/pubmed/23637292>.

November is Lung Cancer Awareness Month

2014 is the 50th anniversary of the Surgeon General's report on Smoking and Health. The National Cancer Institute (NCI) has made this the year of Lung Cancer Research. Both studies below address the patient's smoking history.



Dr. Adedayo Onitilo (left) and Dr. Bilal Naqvi (center) are the Principal Investigators for Marshfield Clinic Lung Cancer Research, and Judith Petz (right) is the Oncology Research Nurse on these studies.

Lung-MAP (Lung Cancer Master Protocol):

MCRF is proud to be the first research group in

Wisconsin to be able to offer this study, which is a unique public-private collaboration among the NCI, five pharmaceutical companies, and other research foundations.

Lung-MAP is a large scale, phase II/III screening/clinical registration protocol that will use a genomic profile to screen patients with advanced stage lung squamous cell cancer moving to second-line therapy, and will use the screening results to direct each patient to the most appropriate one of five (or more) sub-studies.

Patients on each sub-study will be randomized to either standard of care (docetaxel or erlotinib) or biomarker-driven targeted therapy with an investigational agent.

The trial will initially test five experimental drugs, four targeted therapies and an anti-PD-L1 immunotherapy. It is anticipated that between 500 and 1000 patients will be screened per year for over 200 cancer-related genes for genomic alterations. The results of this test will be used to assign each patient to the trial arm that is best matched to their tumor's genomic profile. This innovative approach to clinical testing should improve access to promising drugs for patients.

For more information, please visit the website: www.Lung-MAP.org

ALCHEMIST – Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials – is a group of clinical trials to identify patients with early-stage non-small cell lung cancer who have tumors that contain uncommon genetic changes and to evaluate whether drug treatments aimed at those changes can improve patient survival. Further information on these trials can be found at: <http://www.cancer.gov/clinicaltrials/noteworthy-trials/alchemist>

For more information on these studies, please contact Judy Petz at ext. 1-7278.

NFMC's Reyes Serves as Co-Chair on APHA Committee and Fellow at MARPHLI



Iris Reyes, MPH, of the National Farm Medicine Center was selected to co-chair the Occupational Health and Safety Scholarship committee section of the American Public Health Association (APHA). The Scholarship committee provides funding to public health professionals, mostly students, to attend APHA's annual conference.

Reyes has been an active member of APHA, the largest public health organization in the world. She routinely presents NFMC projects and serves as a session moderator at the annual conference. "APHA is great because it provides a national stage to recognize our organization and our project efforts."

Further, Reyes was recently selected as a Fellow at the MidAmerica Regional Public Health Leadership Institute (MARPHLI). MARPHLI is based at the University of Illinois at Chicago School of Public Health. Starting its twenty-second year, MARPHLI is the oldest state-based public health leadership program in the United States. The Institute has expanded to serve the MidAmerica region, with teams representing Illinois, Indiana, Wisconsin, Michigan, and Ohio.

The MARPHLI program has graduated over 1000 fellows since its inception. It provides public health practitioners with critical leadership skills, and supports improvements in public health infrastructure through the process of applied action learning and team technical assistance projects. Individual and team learning occurs in the context of contemporary national trends in public health practice.

"I am thankful for NFMC's support for letting me pursue further training. I hope that with this fellowship, I can better contribute to the Clinic's mission." Reyes' fellowship is funded by the Center for Disease Control's Preventive Health and Health Services Block Grant through the Wisconsin Department of Health Services, Division of Public Health.

Annual Community Research Survey Input Invited

As part of MCRF's ongoing Association for the Accreditation of Human Research Protection Program (AAHRPP) quality improvement work, the Office of Research Integrity and Protections (ORIP) will be administering the second annual community survey regarding research. The intent of the survey is to serve as a mechanism for the public to reveal its awareness of research, what research-related topics might be of interest, and is also a way for MCRF to gather public perceptions and take steps toward enhancement. If you would like to suggest any questions, please email them to Linda Jaros (jaros.linda@mcrf.mfldclin.edu) and Anna Schotthoefer (schotthoefer.anna@mcrf.mfldclin.edu) by mid January. The survey will be made available via the new MCRF website and potentially by other means depending upon available funds.

Use of Donated Funding

MC/MCRF is the beneficiary of donations from grateful patients that are expected to be used for conducting disease specific research. Through MCRF's Internal Funding policy:

http://srdweb1/clinic/policies/policy_details.asp?ReclD=253, employees of MC can apply for access to these donated funds by submitting a research proposal to the Research Committee for scientific merit review. The "Research Committee Application – Projects Requesting Funds" is located at: http://srdweb1/clinic/policies/form_results.asp?FL=Yes&L=R&typeEntity=clinic. The level of base funding available per project is currently \$50,000. (When practicing clinicians are participating in the research, an additional \$15,000 per project may be awarded to compensate for their time and effort.)

Pre-proposals are required to be submitted for review in advance of submitting a full proposal. Applications may be submitted any time prior to the start of each quarterly cycle, with new cycle dates beginning on the 16th of March, June, September and December. Applications are reviewed in the order they are received during the cycle, so it can be advantageous to submit proposals earlier in the cycle than later.

A listing of disease specific funds available can be found on the Research Mentor intranet landing page, with a link titled "Donated Funds Available for Research":

<http://mclweb/mcrf/?page=researchmentor>. Questions regarding this funding mechanism can be directed to Deb Hansen at ext. 7-9130.

In Addition:

- The next Full Foundation meeting will be held on January 8, 2015 at 10AM 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 February 12, 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>.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Kate Baker, Deb Hansen, Kathy Heintz-Dzikowich, Linda Jaros, Cathy Marx, Bonnie Ohlsson, Melissa Ostrowski, Judy Petz, Iris Reyes, Dr. Rachel Stankowski, Dr. Bob Steiner, Michelle Wellsandt, Dr. Steve Ziemba

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