

Directors' Report



Dr. Bob Steiner,
MCRF Exec. Dir.

As I write this column, I've just returned from the seventh RICH SEUBERT CELEBRITY TRAP SHOOT.

As aptly described by our Marshfield Clinic Development team, Rich Seubert is a big man with a "Giant" heart. That's why he established an endowment to support cardiology research, in the name of his beloved grandmother, Celine Seubert.

Rich is a local boy (Rozellville, Columbus Schools), who made it big, playing for the Giants in the NFL. Thankfully, he's never forgotten his roots. Heart disease is the leading cause of death in Wisconsin.



Rich Seubert

It kills one in three and has likely touched virtually every one of you reading this. More than 25 years ago, it touched former New York Giants offensive lineman Rich Seubert's family. His grandmother Celine lived much longer than expected thanks to a heart transplant that was only possible because of pioneering cardiology research. To support further cardiology research and improve the lives of other families, Rich, in partnership with Marshfield Clinic, annually hosts the premier celebrity shooting event. Rich always brings in former teammates and other Green Bay Packers to join the festivities.



Patrick Flannigan (Professional Shooter), Kevin Barry (Former Green Bay Packer), Rich Seubert

The event has already raised more than \$1 million for the Celine Seubert Endowment for Cardiology Research. This fabulous event began Friday evening in Chippewa Falls with a VIP dinner event hosted by Leinenkugel's. It was great to see Jake Leinenkugel and our CEO, Dr. Sue Turney, along with many other community leaders and Marshfield Clinic physicians at the event. There are a whole host of fabulous sponsors, and I am unable to thank them all individually in this short paragraph, but know that you are appreciated. The event continued on Saturday at the Eau Claire Rod and Gun Club, which this year hosted over 215 shooters, including yours truly. Having never picked up a shotgun in my life until this week, I was delighted to hit 17 of 50 clay pigeons. Steve Ziemba participated as well, and shot in the 20's despite little more experience than me; maybe this is the start of a friendly rivalry. Many thanks to NFMC's Cap Bendixsen, Matt Keifer, and honorary NFMC member Jim Lee for giving us expert instruction, encouragement, and role modeling. They all shot very well, and Matt even won an award for his marksmanship.

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Rob Wickersham, Brian Forrest, Bob Steiner, Cap Bendixsen, Jerry Meissner, Brady Guse, Steve Ziemba, Jim Lee, Brad Guse, Matt Keiffer

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However, nobody shot as well as our new Marshfield Clinic Health System COO Dan Ramsey, who shot a perfect 25 out of 25 in his final round. I just hope no professional trapshooting scouts were there. Finally, the weekend culminated in a dinner and auction at Florian Gardens in Eau Claire. Dinner was fabulous and the auction lively and I'm guessing record-setting. The event raised over \$177,000! I very much enjoyed the weekend and look forward to participating every year that I can. I'm sure I'm going to miss thanking some important contributors, and I apologize for that. I do want to specifically thank Rich Seubert, Matt Schneider, Tiffany Halan, and the entire Development team, who worked tirelessly to make sure the weekend went off without a hitch. The current holder of the Endowment, Shereif Rezkalla, MD carries on a great tradition of outstanding cardiology research at Marshfield Clinic and MCRF and we look forward to many more years of wonderfully supported cardiology research in the future.



Dr. Steve Ziemba,
MCRF Assoc. Dir.

One of the joys I have working at MCRF is the exposure to science and scientific progress, both internally and via external speakers and collaborations. Although my role is administrative, my education and career started in biology and health sciences, and frankly, my interest has never left. In my previous place of employment, I enjoyed attending cancer conferences and other talks, and was one of the very few to be able to attend conferences (we had a multi-year travel ban in place); as such travel was covered by grant dollars for studies I was involved in. I don't see such extremes here, although the budget has gotten tighter over the past year, and certainly travel has taken

a hit. The point is that we have tremendous opportunities in terms of staying current on happenings in the field, with such events as the Scientific Seminar, Infectious Disease Journal Club, Oral Systemic Health Journal Club, Inventor Forum, and Grand Rounds, among other presentations, talks, and special events. I try to attend at least some of these when I can. Considering schedules, I would urge you to attend as well, when the opportunity is available. Upcoming events specific to MCRF may be found at <http://www.marshfieldresearch.org/events/upcoming>. MCRF may be on the small side in terms of size for nationally recognized research organizations, but its range of speakers, talks, and presentations demonstrate that it is every bit as dynamic.

Marshfield Clinic Attains AAHRPP Accreditation

After a process that lasted approximately two years, Marshfield Clinic was granted Full Accreditation by the Association for the Accreditation of Human Research Programs (AAHRPP). Accreditation was effective December 2014, and is good for three years. Accreditation involves a set of objective standards used to evaluate the quality and level of protection that an organization provides research participants. Marshfield Clinic's research participants can be reassured knowing that we have attained the highest level. Benefits to the organization include respect from peers that comes with AAHRPP Accreditation, a competitive edge with research sponsors looking for sites, a reduced risk of non-compliance from having comprehensive policies and procedures, and an ongoing commitment to continuous quality improvement of the research program which ongoing Accreditation requires.



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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](#). There were no grant awards for March.

MCRF Associate Director Steve Ziemba, PhD, has earned certification as a Certified Principal Investigator (CPI). This certification, previously available only to physicians but recently expanded to other doctoral level researchers in the biomedical sciences, is made available by the Association of Clinical Research Professionals (ACRP). To become certified, an applicant must document a minimum of two years of experience performing duties essential to the role of a principal investigator and pass a comprehensive written examination. The exam covers topics such as addressing scenarios that may occur during a clinical trial, research design methodology, compliance, and research administration, among other areas. Ziemba indicated his interest in the CPI designation was to both challenge himself professionally, as well as gain a better understanding of the role of the investigator.

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.

Compliance Notes



FDA Issues Draft Guidance

Last month the U.S. Food and Drug Administration (FDA) issued a new draft Guidance, "Use of Electronic Informed Consent in Clinical Investigations." The introduction states the federal Office of Human Research Protection (OHRP) is working to harmonize with this Guidance. The implication is that when finalized, contents of the Guidance will apply to all federally-funded and all FDA-regulated research.

Electronic processes discussed include: websites, video, audio, text, and graphics. Regardless of the consent platform, specific processes will be required:

- Systems that ensure responses cannot be altered
- Methods to determine the person giving consent is actually the participant
- Mechanisms available for asking questions

When there is new study information available for participants, researchers must determine how to best: present updated consents, allow adequate opportunity to ask questions, provide copies of the amended electronically signed document to participants, and archive the consents appropriately. The draft Guidance states that HIPAA Authorization may be obtained electronically as long as the signature is valid, and as long as participants are given a copy of the signed Authorization.

An IRB must review and approve all electronic informed consent processes to ensure they are adequate to protect the rights and welfare of research participants.

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Migrant Clinicians Network Names NFMC Director, Specialist to “Top 30” List



Migrant Clinicians Network (MCN) has placed National Farm Medicine Director Matthew Keifer, MD, MPH, and Community Outreach Specialist Yurany Ninco Sanchez on its list of “30 Clinicians Making a Difference,” part of the Network’s 30th anniversary celebration.

Dr. Keifer and Ninco Sanchez are featured on the [30 Clinicians Making a Difference webpage](#). Dr. Keifer's profile details his extensive work in preventing pesticide

overexposure. Ninco Sanchez' profile follows her from her work as an interpreter and coordinator for a mobile clinic serving migrants, to her current project promoting safety for dairy workers as part of *Seguridad en Las Lecherias*, a five-year project funded by the Upper Midwest Agricultural Safety and Health Center.

Migrant Clinicians Network is a non-profit organization that works to “create practical solutions at the intersection of poverty, migration, and health.” You can read more about MCN's work on [their website](#).

Peissig Chairs Session at AMIA Joint Summit



Peggy Peissig, PhD, Director of Biomedical Informatics Research Center, served on the Clinical Research Informatics Scientific Program Committee for the 2015 American Medical Informatics Association (AMIA) Joint Summits on Translational Science, March 23 – 27 in San Francisco and served as session chair.

The AMIA Joint Summits serve as the primary forum to connect with leaders in the field of informatics who are advancing translational science at the nexus of bioinformatics and clinical research. The theme of the 2015 Joint Summits was “accelerating precision medicine and patient-centered outcomes research through discovery, development and delivery.” This meeting brought together translational scientists and informatics researchers and practitioners from academia, industry, government and non-profit sectors to share knowledge and best practices, and to forge interdisciplinary collaborations across boundaries. Equally emphasizing discovery and impact, this Joint Summit highlighted translational research from bench to bedside, practice, and communities. The past year of 2014 witnessed multiple exciting events for the Clinical Research Informatics community, including the launch of the nationwide Patient-Centered Outcomes Research Network (PCORnet), the continued increase in the use of electronic health records in physician offices in the United States, the rise in sharing results of clinical trial studies, and the establishment of the NIH Big Data to Knowledge (BD2K) center.

Leadership opportunities are plentiful in the emerging Precision Medicine landscape and AMIA is poised to make a positive and powerful contribution.

Annual Disclosure for Investigators Begins in May

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

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



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

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

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

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

Youth Garden Safety Featured in New Resource



As the popularity and diversity of community gardening grows, the National Children’s Center has introduced a resource booklet to help ensure a safe, positive gardening experience. “Community-Based Agriculture: Safety Guidelines for Youth Working in Gardens,” provides guidance for adults who are making decisions about what work is appropriate for children.

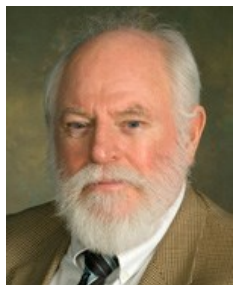
“Gardening can be such a positive experience and an excellent way to kick-start a child’s interest in agriculture,” said Bryan Weichelt, project manager for the National Children’s Center.

The booklet (<http://cultivatesafety.org/cba/>) draws upon previous research and resources from the National Children’s Center. It packages relevant content from the North American Guidelines for Children’s Agricultural Tasks and recommendations regarding hired adolescent workers. Many of the guidelines are available in Spanish.

The new booklet can help adults decide which tasks children should perform, what equipment they can use, what training they should receive, and how much supervision is needed, Weichelt said.

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Clinical Research Center (CRC) Welcomes New Staff



Ray C. Haselby, DO – Effective April 5, 2015 Dr. Haselby joined CRC as an Emeritus research physician. Dr. Haselby retired from the Marshfield Clinic in September, 2014 after 40 years of service. He started with the clinic in 1974 in Infectious Disease (ID) and was instrumental to the ID Journal Club at MCRF. He was a passionate Principal Investigator and Co-Investigator on multiple studies, as well as serving on the Board of Trustees for MCRF. Some highlighted areas of research interest include:

Clostridium difficile (C. diff), shingles vaccine, influenza, herpes zoster, respiratory syncytial virus (RSV), urinary tract infection (UTI), Lyme disease, pneumonia, human immunodeficiency virus (HIV), measles, mumps, and rubella (MMR), and methicillin-resistant *Staphylococcus aureus* (MRSA). On the lighter side, Dr. Haselby and his wife love to role play Mr. and Mrs. Claus.



Melissa Slager – Effective April 6, 2015 Melissa returned to MCRF as the CRC Manager-Research Studies. She most recently worked at Spaulding Clinical Research as a Quality Assurance Specialist/Auditor. Melissa previously worked in BIRC as a Research Project Coordinator and CRC in the roles of Research Quality Assurance Specialist and Assistant Manager of the Multispecialty Program.

Hannatu Amaza – Hannatu joined CRC in late March as a Multispecialty Research Coordinator Associate. Hannah comes to CRC from the Center for Clinical Epidemiology & Population Health. Hannatu's previous experience includes being a study technician at Covance and Primary Coordinator for REM Wisconsin (The MENTOR Network). She will be working with the cardiovascular team.



Integrating Oral Health into Primary Care



In a recent issue of [The Commonwealth Fund](#), the focus was on oral health. In an article titled, "In Focus: Integrating Oral Health into Primary Care", Dr. Amit Acharya, director of the Institute for Oral and Systemic Health in the MCRF Biomedical Informatics Research Center, discussed decision support tools that will help clinicians. One of these tools encourages primary care physicians to conduct oral examinations on their diabetic patients; another tool prompts blood glucose tests on patients with certain BMI levels and other characteristics that put them at risk for diabetes. Acharya said, "We wanted to see if we could control the inflammatory processes of gum disease by lowering the glycemic index for diabetic patients and vice versa."

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IOSH Researchers Present at the International Association of Dental Research Conference



Dr. Amit Acharya, Director of IOSH, Dr. Gary Pack, Post-doctoral Fellow, and Neel Shimpi, Research Specialist (photos, left to right), attended and presented research from Marshfield Clinic Research Foundation at the 93rd Annual meeting of International Association of Dental Research General Session & Exhibition in Boston, MA,

on March 9-15, 2015. This international research conference, which assembles around 4,000-6,000 health care professionals, was organized around exciting and diverse themes representing the major scientific headings in current dental and collateral research findings from around the world. The abstracts from these meetings are published online as Special Issues of the Journal of Dental Research (JDR).

In addition, researchers from the Universities of Michigan and Pittsburgh, along with IADR Global HQ staff and Internet2, convened a leadership session about Big Data for Oral Health Knowledge in conjunction with the 2015 IADR General Session in Boston. Dr. Acharya was one of the 50 international experts who were specifically invited to attend this event to explore some of the emerging challenges, such as development of standards for storage and retrieval of health data sets, dealing with increasingly larger data sets; how to bring team science and collaborations, such as practice-based networks (PBRNs) to bear on big data research questions, how to transfer data quickly, and meet HIPAA security requirements; how to use sensors and mobile devices to gather health data continuously on numerous patients and how these data should be categorized and stored; and the need for computational needs for complex data sets. Dr. Acharya was among several leading dental researchers from across the globe, including:

- Dr. Mary Marazita, Director of the Center for Craniofacial and Dental Genetics as well as Professor and Vice Chair of the Department of Oral Biology in the School of Dental Medicine at the University of Pittsburgh, Pittsburgh, PA;
- Dr. Ira Lamster, Professor, Health Policy & Management, Columbia University Mailman School of Public Health, New York, NY;
- Dr. Elsbeth Kalenderian, Associate Professor; Chair, Oral Health Policy and Epidemiology; and Chief of Quality at Harvard School of Dental Medicine, Boston, MA;
- Dr. Peter Polverini, Professor of Oral and Maxillofacial Pathology, Division of Oral Pathology/Medicine/Radiology and Periodontics and Oral Medicine at the University of Michigan School of Dentistry, Ann Arbor, MI;
- Dr. Christian Stohler, Dean of the Columbia University College of Dental Medicine and Senior Vice President of Columbia University Medical Center, New York, NY.

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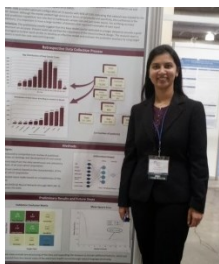
IOSH Presentation *(continued from previous page)*

Also present were industry partners from organizations such as Kaiser Permanente, ESPE, DentaQuest and Henry Schein; representatives from governmental organizations, such as NIH/NIDCR, WHO; representatives from organizations such as ADEA, IFDEA and IADR; and technology leaders, such as Laura Patterson, the CIO of the University of Michigan, and Michael Sullivan, Associate Director at Internet2.

Scientific presentations by the IOSH Researchers included:

Neel Shimpi, Research Specialist, gave an oral presentation on the topic 'Knowledge, Attitude and Behavior of Medical Providers towards Oral Health'. The study team consisted of Dixie Schroeder, Dr. Joseph Kilsdonk, Dr. Po-Huang Chyou, and Dr. Amit Acharya.

Dr. Gary Pack, Post-doctoral Fellow, presented his research in a poster format on 'Pleitropy, Neuroimaging and Dental Imaging that identifies genetic risk and inflammatory insult leading to Alzheimer's disease'. His study was mentored by Dr. Mark Craven from University of Wisconsin, Madison and Dr. Amit Acharya.



Neel Shimpi

Dr. Amit Acharya and Neel Shimpi presented their preliminary study results in a poster format on 'Development of Prototypical Design of Oral Cancer Risk Assessment Tool'. The study team consisted of Krista Koehler, Harshad Hegde, Dr. Gary Pack, and Dr. Po-Huang Chyou.

In Addition:

- The next Full Foundation meeting is scheduled for May 18, 2015 at 2PM 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 June 11, 2015 at 6PM in the Laird 50 conference room.
- For the latest issue of the UW-Madison newsletter, *ICTR Today*, please click here: <https://ictr.wisc.edu/Newsletters>.
- The Marshfield Clinic Research Foundation website can be accessed through this link: <http://marshfieldresearch.org/>. You will find in depth articles, news about upcoming presentations, and achievements by the staff. There are also links to each Center, with detailed information about the staff and projects.
- *Research Matters* is always accepting announcements. Your contributions are greatly appreciated.

Contributors to this issue: Patti Baer, Scott Heiberger, Linda Jaros, Anne Nikolai, Dixie Schroeder, Dr. Bob Steiner, Michelle Wellsandt, Dr. Steve Ziemba

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

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