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CALENDAR

Carle IRB

3rd Wednesday of the month

Scientific Review Committee

4th Wednesday of the month

Research Lunch 'N' Learn

November 6, 10 – 11 a.m.

Statistics and Study Design
Dan Bronson-Lowe, PhD, CIC
Biomedical Research Center
Conference Room
Mills Breast Cancer Institute

How Did We Do?

See something you liked or have a suggestion for future issue? We'd like to hear from you. Send your comments and/or suggestions to research@carle.com.

The 2013 Carle Research Institute Awards: Excellence in Research and Friend of Research

The Research Institute's Unit Partnership Council has begun a new initiative to recognize the exemplary work of Carle and University of Illinois physicians, professors and staff. During August many individuals were nominated for the Excellence in Research award and Friend of Research awards. These individuals have shown their dedication to the success of the Research Institute as well as to the success of the studies and the teams with which they work. Listed below are the 2013 awardees. Excellence in Research is for any principal investigator, co-investigator or sub-investigator that exemplifies expertise, professionalism, results, and collaboration in their research. Friends of Research are individuals who exemplify excellence in service and collaboration with researchers as well as patients.

Awards will be given at the Research Mixer in The Forum immediately following Foundation Day, Thursday, November 7, 2013

Excellence in Research



Aron Barbey, PhD

Dr. Barbey is assistant professor in the Department of Speech and Hearing Science at the University of Illinois. Dr. Anna Keck of the Carle's Research Institute nominated him for his work on their collaborative study "Nutrient Biomarker Patterns, Cognitive Function, and MRI Measures of Brain Aging," where they analyze the relationship between nutrient biomarkers and psychometric and imaging indices of brain health in non-demented elders. Dr. Barbey along with his multidisciplinary team is exceeding enrollment expectations per their grant timeline.



Brian Wheatley, MD

Dr. Wheatley is a vascular surgeon at Carle Foundation Hospital and an assistant clinical professor at the University of Illinois. Research study coordinator Tiffany McGeehon nominated Dr. Wheatley for his work on the CryoVein LimbSave study, which is a multicenter, prospective clinical trial that is evaluating below-the-knee bypass in patients with critical limb ischemia using CryoVein's cryopreserved saphenous vein allograft. Dr. Wheatley was able to complete 83 percent of his required enrollment before any other site began enrolling, and as result, Carle was designated as a site to collect photographic data. Carle will also become a competitive enrollment site once 100 percent enrollment has been obtained.

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The 2013 Carle Research Institute Awards: Excellence in Research and Friend of Research (cont.)

Friends of Research



Meagan O'Brien, MS

Meagan is an ophthalmic assistant in Carle Ophthalmology. She was nominated by Dr. Michael Tsipursky, MD, Ophthalmology at Carle, for her work on a project involving novel applications of photodynamic therapy in combination with anti-VEGF injections for resistant macular degeneration.



Travis Blunier, MS

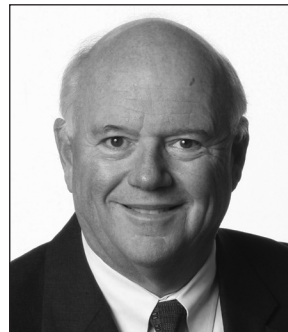
Travis is the Lab Cytology Pathology manager at Carle. Dixie Heath, director of Research Operations, and tissue-data management specialist Bre Stillwell nominated Travis for his exemplary work in helping to facilitate tissue collection and lab processing for numerous research projects. Travis is vital to the

success of the Tissue Procurement Services team and to the entire Research Institute.



Colleen Luce, RN

Colleen is a nurse in Orthopedics. Research study coordinator Kevin Osborne nominated her for her work on collaborative study with Dr. Stewart, PhD, University of Illinois. To date, she has consented almost all of the nearly 700 subjects in that study.



R. Bruce Wellman, MD, Chief Executive Officer, Carle Physician Group

Dr. Wellman was nominated by Dr. James Dougherty for providing steady and supportive leadership to all Carle-based research in his role as chief medical officer. Additionally, he serves as the institutional official, a position of significant

responsibility in the research compliance world.



Jenna Bates

Jenna is a surgery scheduling specialist for Head and Neck Surgery at Carle. Research study coordinator Barbara Hall nominated Jenna for her efforts in providing patient population information in order for the Research Institute to consent subjects and

obtain tissue for collaborative studies with the University of Illinois.



Matt Wheeler, PhD

Dr. Wheeler is a professor at the University of Illinois Department of Animal Sciences. He is passionate about Carle and the University of Illinois and has been a huge advocate for collaborative work. He is helping develop research areas at Carle in sports medicine, oral maxillofacial

surgery and neurosurgery. Dr. Wheeler was nominated by Jerrad Zimmerman, MD, program director of the Carle Sports Medicine Fellowship Program.

REGISTRATION OF CLINICAL TRIALS:

Who should register and why

The website [ClinicalTrials.gov](https://www.clinicaltrials.gov) is a registry and results database that provides easy access to information about clinical studies to prospective study participants, healthcare professionals, researchers and other members of the public. The federal requirement to register a clinical trial applies to studies that are not only federally sponsored or industry sponsored, but to investigator initiated trials as well. Typically, registration is the responsibility of the sponsor of the trial, but, in some cases, the sponsor may designate the principal investigator to be responsible for the registration.

U.S. law requires that all “applicable clinical trials” initiated after 9/27/07 or ongoing as of 12/26/07 must register at [ClinicalTrials.gov](https://www.clinicaltrials.gov). Applicable clinical studies are investigational studies that use a drug, biologic or device as an intervention and would include the following:

- Controlled, clinical investigations (other than Phase I) of a drug or biologic subject to Food and Drug Administration (FDA) regulations,
- Device trials that are controlled trials with health outcomes of devices subject to FDA regulation (other than small feasibility studies), and
- Pediatric postmarket surveillance required by the FDA.

The consequence of not registering an applicable clinical trial may result in civil monetary penalties up to \$10,000/day, and, for federally funded studies, the withholding or recovery of grant funds.

A clinical investigation can still be considered an “applicable clinical trial” even if the study intervention does not require an IND or IDE. Examples of studies that do not have to be registered include the following:

- Phase 1 drug trials or studies in which investigational drugs are used as research tools,
- Observational research, or
- Studies that do not use drugs, biologics or devices such as behavioral interventions.

However, both the FDA and National Institutes of Health (NIH) encourage the registration of all trials and not just those that are required to register.

In addition, the International Committee of Medical Journal Editors (ICMJE) requires prospective registration of all interventional clinical trials in a public registry in order to be considered for publication in journals that adhere to ICMJE standards. The ICMJE defines a clinical trial as “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.” Note that this definition of clinical trial is broader than the definition of an applicable clinical trial and would include not only drugs and devices, but surgical procedures, behavioral treatments, dietary interventions and process-of-care treatments. Purely observational studies are not required to be registered. ICMJE accepts registration not only at [ClinicalTrials.gov](https://www.clinicaltrials.gov), but at several other trial registries as well. For more information, go to the ICMJE website.

Cancer Research Update: Learning Network to improve access to clinical trials through education and collaboration

In an effort to increase accrual (patients participating in clinical trials), particularly among racial minorities and the patient population over age 65, Carle Cancer Research has applied for and been granted the opportunity to participate in the National Cancer Clinical Trials Collaborative Learning Network with the Education Network to Advance Cancer Clinical Trials (ENACCT). This Learning Network seeks to improve access to cancer clinical trials through education and collaboration with communities, healthcare providers and researchers. Through a series of eight webinars with accompanying required homework and two on-site visits with ENACCT representatives, a team of clinical researchers, oncologists, and both the Mills Breast Cancer Institute coordinator and Radiation Oncology manager will work for four months to identify practical, patient-centered approaches to increase accrual overall as well as the specific populations

mentioned above. Webinars, consultation visits and self-assessments will be used as tools to develop a clinical trial recruitment and accrual process map and action plan that aids in the identification of weak links in the current processes. Understanding gaps in the current screening processes, securing physician buy-in, gleaning community support for research, enhancing communication within the Carle Cancer Center and to the community regarding new research options, and identifying inefficiencies and weaknesses through participation in the Learning Network will fortify the goals of the organization to maintain and grow its research opportunities. In alignment with the research-driven culture of Carle, the Cancer Research believes participation in this Learning Network will directly translate to broader and better options for cancer patients in our communities.

Publications

The following recent publications highlight Carle researchers in bold:

Bahl M, **Muzaffar M**, Vij G, Sosa JA, Choudhury KR, Hoang JK. Prevalence of the Polar Vessel Sign in Parathyroid Adenomas on the Arterial Phase of 4D CT. AJNR Am J Neuroradiol. 2013 Aug 14 [Epub ahead of print]

Holley JL, Schmidt RJ. Changes in fertility and hormone replacement therapy in kidney disease. Adv Chronic Kidney Dis. 2013 20(3):240-5.

Qu Y, **Ray PS**, Li J, Cai Q, Bagaria SP, Moran C, Sim MS, Zhang J, Turner RR, Zhu Z, Cui X, Liu B. High levels of secreted frizzled-related protein 1 correlate with poor prognosis and promote tumourigenesis in gastric cancer. Eur J Cancer. 2013 Aug 5 [Epub ahead of print]

Goss GD, O'Callaghan C, Lorimer I, Tsao MS, Masters GA, Jett J, Edelman MJ, Lilenbaum R, Choy H, Khuri F, Pisters K, Gandara D, Kernstine K, Butts C, Noble J, Hensing TA, **Rowland K**, Schiller J, Ding K, Shepherd FA. Gefitinib Versus Placebo in Completely Resected Non-Small-Cell Lung Cancer: Results of the NCIC CTG BR19 Study. J Clin Oncol. 2013 Aug 26 [Epub ahead of print]

Slater BJ, Willis AM, **Llano DA**. Evidence for layer-specific differences in auditory corticocollicular neurons. Neuroscience. 2013 229:144-54.

Cho JH, **Holley JL**. Squamous cell carcinoma of the bladder in a female associated with multiple bladder stones. BMC Res Notes. 2013 6(1):354.



The image shows the cover of a publication titled "CARLE SELECTED PAPERS". The cover features a blue and white abstract design with the Carle logo at the bottom. To the right of the cover, the text reads "Carle Selected Papers, Summer Issue Now Available".

Carle IRB - New Research Studies

Safety and Efficacy of the Cochlear™ Nucleus® CI422 Cochlear Implant in Adults
PI: Michael Novak, MD, Otolaryngology, Carle

A Registry of Caris Life Sciences® Molecular Intelligence Service™ (Biomarker Assessment Results) Intended for Correlation with Cancer Clinical Outcomes
PI: David Graham, MD, Oncology, Carle

Efficacy of Oxygen Systems in Pediatric Bronchiolitis
PI: Taylor Yardley, BSN, Pediatrics, Carle

Assuring Quality of Pediatric Assessment Frequency
PI: Ann Eckhardt, PhD, RN, House Officer, Carle

Assessing the Effectiveness of Advance Care Planning in Health Care Providers
PI: Jean Holley, MD, Nephrology, Carle

Investigating Causes of Feeding Intolerance/Problems and Necrotizing Enterocolitis in Premature Infants in the NICU Setting
PI: Kelly Tappenden, PhD, Food Science and Human Nutrition, University of Illinois

Subungual Squamous Cell Carcinoma Presenting as Chronic Paronychia: Report of 3 Cases and Review of the Literature
PI: Ike Uzoaru, MD, Pathology, Carle

Reviewing the Treatment Modalities for Sub-massive Pulmonary Embolism

PI: Scott Santeler, MD, Heart and Vascular Institute Procedure Center, Carle

Fatigue Countermeasures Program for Nurses
PI: Robin Grubbs, RN, Quality, Carle

Decrease falls by educating nurses to utilize hourly rounding
PI: Cricket Engelbrecht, RN, BSN, Emergency, Carle

Treatment related changes in cognition and brain function in hypothyroidism
PI: Arthur Kramer, PhD, Beckman Institute, University of Illinois

Lab-on-a-chip for point-of-care HIV/AIDS diagnostics
PI: Rashid Bashir, PhD, Bioengineering, University of Illinois

Physician Consultations: An Observation of Consultations Between Doctors in an EDt Setting
PI: John Lammers, PhD, Communication, University of Illinois