



April 26, 2012

Research 2012:

We're Not in Kansas Anymore



From Bench to Bedside



Sponsored by the Office for Clinical and Translational Research



**Cincinnati
Children's**
Research Foundation

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Thursday, April 26, 2012 – Albert Sabin Education Center: Fifth Third Auditorium

Agenda

7:30-8:00 Registration

8:00-8:15 Opening Remarks

We're Off to See the Wizard

Tracy A. Glauser, MD

Associate Director of Clinical, Translational, Outcomes and Health Services Research

Cincinnati Children's Research Foundation

Professor of Pediatrics and Neurology

Cincinnati Children's Hospital Medical Center

8:15-9:30

The Trip Down the Yellow Brick Road May Be Scenic, but Should It Take So Long to Get to Oz?

Christine Pierre, founder, president and CEO of RxTrials, Inc.

Christine Pierre has been committed to human subject protection and clinical site operations for more than 20 years. She is founder and president of RxTrials Inc., an elite network of investigative sites that conducts inpatient and outpatient clinical research in a variety of therapeutic areas. RxTrials provides site support services to site and industry stakeholders. Christine also founded RxTrials Institute (RxTi) which provides education, training and consultation services with sponsors, CROs and other research professionals, and hosts the Site Solutions Summit, industry conferences and webinars.

Christine was the chair of the Association of Clinical Research Professionals (ACRP) in 2008, an editorial board member of Clinical Trials Advisor and eCliniqua, a member of the steering committee of the Clinical Trials Transformation Initiative (CTTI), and on the board of advisors for both the Center for Information & Study on Clinical Research (CISCRP) and Hands Across the Americas. In 2009, PharmaVOICE named Christine one of the "100 Most Inspiring People" in the life sciences industry, has been nominated as one of the top female business professionals in Maryland and in 2011 was recognized by the National Association of Professional Women as "Women of the Year." Christine co-authored the book *Responsible Research: A Coordinators Guide*, and has contributed to many other books within the clinical research industry. She holds a degree in nursing and has been committed to human subject protection and clinical site operations for more than 20 years.

Keynote Presentation

This interactive session leads off with historical site start-up, subject recruitment metrics and the reasons why some believe these "norms" are expected to continue. New data will then be presented from a recently completed industry collaborated project. This project collected and analyzed site start-up metrics to conclude the best predictors for start-up times required for different types of sites. Interventions for improved operational activities, leading to the "new norm" for start-up time and enrollment, will be discussed. Bring questions and lessons learned!

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Objectives

1. Describe three root causes historically contributing to prolonged study site start-up.
2. Describe three interventions to reduce study site start-up time or to plan for a more realistic study start-up period.

9:30-10:30*Professor Marvel Never Guesses... He Knows! - What Clinical Research Professionals Need to Know About NIH-Sponsored Research*

John "J.P." Clancy, MD, PhD

Dr. Clancy was born and raised in Iowa City, IA, and attended medical school at the University of Iowa. He completed his pediatric residency at the University of Virginia, followed by pediatric pulmonary medicine and research training at the University of Alabama at Birmingham (UAB). He served as the division director of Pediatric Pulmonary Medicine at UAB from 2002-2010, and is currently the Thomas Boat Endowed Chair in CF. He is internationally recognized for his translational research in cystic fibrosis, examining how the cystic fibrosis transmembrane conductance regulator (CFTR) mutations cause disease, and developing strategies to restore function. He has published more than 75 manuscripts and more than 200 abstracts, and regularly provides leadership in clinical and translational research through the international CF research community. He and his wife Tracy have three children (Aiden – 11, Maeve – 5, Holland - 4), and live in Clifton.

Objectives

1. Discuss the basic structure of the NIH and the process of grant submission, review and feed back for clinical research studies.
2. Distinguish the various names and types of NIH awards, such as "R," "U" and "K" awards.
3. Recognize the skills and expertise necessary for clinical research professionals and investigators to successfully conduct NIH-supported clinical research.

10:30-10:45**Break****10:45-11:45***If I Only Had a Voice: Engaging Patients and Families as Collaborators in Designing and Testing Interventions*

Michael Seid, PhD

Dr. Seid is director of Health Outcomes and Quality of Care Research in the Division of Pulmonary Medicine and a core faculty in the James M. Anderson Center for Health Systems Excellence at Cincinnati Children's. Dr. Seid applies behavioral and social science to answer the question, "What does it take to make sure the right treatment gets to the right child in the right way at the right time, every time?" In this quest, he collaborates broadly with patients and families, clinicians, social scientists, epidemiologists, designers, policy makers, computer engineers and developers, and creatives. With Peter Margolis, MD, PhD, he is co-principal investigator of the C3N Project, funded by a Transformative R01 grant from the NIH to design and test a new system for transforming chronic care. He has been principal and co-principal investigator of numerous large multi-disciplinary federally-funded research studies and publishes widely in such journals as *Medical Care*, *HSR: Health Services Research*, *Archives of Pediatrics and Adolescent Medicine*, *Pediatrics*, *American Journal of Medical Quality*, *Ambulatory Pediatrics*, and *Milbank Quarterly*.

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Objectives

1. Discuss the advantages of engaging patients and families as collaborators in research.
2. Describe how to involve patients and families.
3. Provide examples of insights/improvements from this research opportunity.

11:45-12:30 Lunch

Second Half "After the Twister"...

12:30-2:00 Breakout Session (1)

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REDCap – It's Not Just Data Capture Anymore

Matthew Schauseil, Systems Analyst
UC Health, Clinical Trials Office

Mr. Schauseil is an IT specialist with a dual appointment in the Office of Research and Graduate Education and the Clinical Trials Office. His responsibilities within both offices include database development and maintenance, web site development and other varied programming solutions. Mr. Schauseil takes pride in the opportunity to assist my co-workers, simplify lengthy and time consuming projects, as well as provide the data mining tools to assist with report generating.

Objectives

1. Identify study tracking resources within REDCap.
2. Utilize REDCap in study management, tracking and practical applications.
3. Describe how REDCap can be used for study visits and participant reimbursement.

Breakout Session (2)

Albert Sabin Education Center - D.2.46

Development and Implementation of Quality Management Program in Clinical Research

Amy Hoepfer, RN, CCRC and Rachel Akers, MPH, CCDM

Ms. Hoepfer is a quality manager for the Gamble Program for Clinical Studies in the Division of Infectious Diseases (ID). She has 17 years of nursing experience including 15 years of clinical research experience. She has been the quality manager in ID for the past 5 years overseeing quality management activities for NIH and industry studies. Ms. Hoepfer is a certified clinical research professional and has had several nationally accepted abstracts and poster presentations on the topic of quality management.

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Ms. Akers is the manager for the Cincinnati Children's Data Management Center. Ms. Akers provides oversight and direction to the data management personnel that support all of the data management activities for studies and clinical trials. Ms. Akers has more than 12 years of experience in clinical research and data management for NIH and industry sponsored studies.

Objectives

1. Discuss the ID clinical research program.
2. Provide an overview of the ID quality management plan.
3. Describe the components of a quality management plan.
4. Discuss the implementation and evaluation of a quality management plan and utilization of Data Management Center/Data Coordinating Center services.

2:00-2:15 Break

2:15-3:45 Breakout Session (1)

Albert Sabin Education Center - D.2.46

Technical Research Methods and Tools

Study Discussion: Coupled Biomechanical-Epidemiological Studies of Injury Risk Factors in School-Based Geographic Populations

Timothy Hewett, PhD, FACSM

Dr. Hewett is a professor and director of research at The Ohio State University Sports Health and Performance Institute. He is also a professor at Cincinnati Children's Hospital Sports Medicine Biodynamics Center and the University of Cincinnati. Dr. Hewett has a doctorate in physiology and biophysics and post-doctoral fellowships in biomechanics and molecular biology. Dr. Hewett has more than 165 peer-reviewed publications and has authored a book and multiple book chapters, is a permanent member of a National Institutes of Health Study Section, is on the editorial board for several medical journals and is an international expert in the field of injury prevention, especially of anterior cruciate ligament (ACL) injuries.

Objectives

1. Summarize the epidemiology and potential risk factors of knee and ACL injury risk.
2. Discuss theories relating to the gender gap in athletic knee injuries, including anatomic, hormonal and neuromuscular gender differences.
3. Design screening protocols to identify high-risk athletes that demonstrate neuromuscular control deficits.
4. Develop neuromuscular training interventions for decreasing ACL injury risk.

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*Thursday, April 26, 2012 – Albert Sabin Education Center: Fifth Third Auditorium***Breakout Session (2)**

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Behavioral Research with High Risk Populations

Robert T. Ammerman, PhD and Jenny G. Noll, PhD

Dr. Ammerman is professor of Pediatrics at Cincinnati Children's and scientific director, Every Child Succeeds. He received his PhD in 1986 in clinical psychology from the University of Pittsburgh. He is certified in cognitive and behavioral psychology from the American Board of Professional Psychology. Dr. Ammerman's research interests include enhancing early childhood prevention programs with a focus on maternal mental health, trauma, and social/emotional development in children. Dr. Ammerman is the recipient of grants from the National Institute on Mental Health, National Institute on Child Health and Development, Maternal and Child Health Bureau, National Institute on Disabilities and Rehabilitation Research, and Vira I. Heinz Foundation.

Dr. Noll is a professor of Pediatrics in the Divisions of Behavioral Medicine and Clinical Psychology with a joint appointment in Epidemiology and Biostatistics at Cincinnati Children's. Her primary program of research has focused on the bio-psycho-social health consequences of severe child abuse. Through long-term, prospective longitudinal study, Dr. Noll and her colleagues have published some of the most definitive research attesting to the abuse sequelae spanning a host of developmental outcomes including obesity, health-care utilization, teen pregnancy, premature delivery, sleep disturbances, stress-responsivity and cognitive abilities. Dr. Noll has forged a particular niche within the field of child maltreatment with her focus on the comprehensive assessment of sexual attitudes and activities, as well as variations in sexual development observed in teens abused as children. In her current R01, more than 500 females are being assessed longitudinally throughout adolescence in order to explicate pathways to aberrant sexual development that are directly attributable to the trauma of childhood abuse. Dr. Noll has conducted several longitudinal studies of abused populations spanning as many as 25 years and has been able to accomplish retention rates of up to 96 percent. She has ample experience recruiting large numbers of abused adolescents and has forged agreements and long-term relationships with protective service agencies who have granted access to these populations. Most recently, Dr. Noll has conducted research regarding adolescent internet use patterns, exposures to sexual media, online social behaviors and risk for internet-initiated victimization. Dr. Noll also holds a regulatory position as the Research Subject Advocate for Cincinnati Children's CTSA where she functions as the chair of the IRB and Safety Subcommittee for all CTSA studies throughout the health sciences campuses (i.e., Cincinnati Children's Hospital Medical Center, University Hospital, the VA Hospital and the University of Cincinnati Academic Health Center).

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Objectives

1. Discuss behavioral research methods, instrumentation, and procedures as they apply to high-risk populations studied in the home setting.
2. Describe the use of innovative assessments for assessing parent-child relationships and biological indicators of psychological functioning.
3. Describe data analytic approaches to longitudinal data collected in the context of behavioral research.

4:00 Closing and CME Evaluations

2012 Annual Research Symposium Planning Committee

Marianne Brunner, RN, BSN; Leslie Korbee, BS; Melinda Muenich, MBA, RN;
Scott Powers, PhD, ABPP, FAHS; Dana Raab, RN, BSN, MS; Mark Schuller, MA;
Sheri Selk, MS, MBA

... and Toto, too.