



From Bench to Bedside — APRIL 6, 2011

**WILD WORLD OF  
RESEARCH**

**"Happy TRIALS to You!"**





# WILD WORLD OF RESEARCH

— Wednesday April 6, 2011 - Albert Sabin Education Center: Fifth Third Auditorium

## AGENDA

**7:30 – 8:00**      **Registration**

**8:00 – 8:15**      **Introduction and Opening Remarks**

Timothy P. Cripe, MD, PhD 8:00 to 8:05  
Co-Medical Director,  
Office for Clinical and Translational Research

### **Opening Remarks**

Arnold W. Strauss, MD 8:05 to 8:15  
Rachford Professor and Chair of Pediatrics  
University of Cincinnati College of Medicine  
Director, Cincinnati Children's Research Foundation  
Chief Medical Officer, Cincinnati Children's Hospital Medical Center (Cincinnati Children's)

**8:15 - 9:45**      **Adhering to FDA Expectations 2011:  
Investigator Delegation and Study - Staff Training**

Erika Stevens, MA, senior manager advisory services, Ernst & Young  
Liz Wool, CCRA, CMT, president and CEO, QD-Quality & Training Solutions, Inc., *member, board of trustees,*  
*Association of Clinical Research Professionals (ACRP)*

Ms. Stevens is a senior manager in the Advisory Services practice of Ernst & Young. Erika has more than 15 years of clinical research experience, including more than 12 years in clinical research management serving in roles such as the director of the Clinical Trials Office, regulatory training manager, interim executive director of the Clinical Trials Office and director of Research Operations.

Prior to joining Ernst and Young, Erika served as the director of the Clinical Trials Office at Dartmouth Hitchcock Medical Center, where she led the promotion, development, management/operations and strategic plan for clinical trial research including the financial, regulatory, operations and compliance services to Dartmouth College and Dartmouth-Hitchcock facilities. She also served as the interim executive director of the Clinical Trials Office at Columbia University Medical Center, director of Research Operations at Washington University School of Medicine and worked in project management at the University Of Pennsylvania School Of Medicine.

Ms. Stevens sits on the editorial advisory board for *The Monitor*, the peer reviewed journal publication for Association of Clinical Research Professionals (ACRP) and she serves on the Global Planning Conference Planning Committee. She is also a frequent speaker on clinical research operations and compliance practices at national conferences. Additionally, Ms. Stevens is a published author whose work on patient oriented research has appeared in a variety of peer journals including the *American Journal of Obstetrics & Gynecology* and the *Journal of Mental Health and Aging*.

Ms. Wool possesses 21 years of experience in the product development industry including positions in biotech and pharmaceutical companies, investigational sites, CROs, and academia. This experience includes drugs, biologics and medical device clinical research. Ms. Wool's expertise is unique in that she has held a range of positions as a research nurse, various study manager positions, as well as director-level positions in clinical compliance and clinical operations. She is a sought after guest speaker for academic medical centers for GCP training courses, including investigator's supervisory responsibilities, CRC training courses and sponsor-investigator responsibilities for IND/IDE holders. She holds a faculty appointment at the University of California, Berkeley, University of California, teaching their Good Clinical Practices course.



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Ms. Wool is an ACRP member and is on the board of trustees. She is the immediate past-president of the ACRP Northern California Chapter that was awarded the Chapter of the Year award in 2009. She is a published author in the ACRP journal, *The Monitor* – “Good Training Practices: A Primer for Employee Training Plans,” 2008, and “Investigator Meetings: Focus on Protocol Execution Performance,” 2011. She served as the guest editor for *The Monitor* February edition titled, *Education and Training in the 21st Century: Paradigm Shift to Performance*.

## Objectives

1. Understand FDA expectations for investigator delegated responsibilities in clinical trials.
2. Describe the core elements for employee training plans for regulatory compliance.
3. Recognize the required site infrastructure training.

### 9:45 – 10:45 **The Good, the Bad and the Ugly**

True Definition of Clinical Trials  
Michael Spigarelli, MD, PhD

Dr. Spigarelli is an associate professor of Pediatrics and Internal Medicine at Cincinnati Children's in the Divisions of Adolescent Medicine and Clinical Pharmacology and co-medical director of the Office for Clinical and Translational Research. He has participated in numerous pre-clinical and clinical trials involving a wide range of diseases from acne to viral treatment. His clinical practice is focused on adolescent issues including eating disorders, puberty, gynecology, substance abuse and the interactions of medicinal agents and physiology. He directs the CTSA Recruitment Core, as well as the Cincinnati Children's Genomic Cohort Control project, which has recruited more than 1,000 healthy community participants between the ages of 3 and 17 in order to help understand the role of genetics in childhood diseases.

At the conclusion of this session, the symposium attendee will be able to:

1. Define the clinical research terms that are used and frequently misused.
2. Identify areas of clinical research that can be readily improved by adequate preparation.
3. Discuss individual research questions as they apply to conference participants.

### 10:45 – 11:00 **Break**

### 11:00 – 12:15 **Recruitment and Retention Toolbox Part I – fundamentals**

- Essential participant recruitment basics for all studies – Mark Schuller, MA
- How to recruit diverse and difficult to reach populations - Lori E. Crosby, PsyD, and Monica Mitchell, PhD
- Study participant retention skills and resources - Kate Haralson, BS, and Jennie Noll, PhD

Dr. Crosby is an associate professor in the Division of Behavioral Medicine and Clinical Psychology at Cincinnati Children's Hospital Medical Center (CCHMC), co-director of INNOVATIONS in Community Research and Program Evaluation and training director for the O'Grady Residency in Psychology. Her clinical work with families has been recognized nationally as she was invited to participate on a National Heart, Lung and Blood Institute work group to develop health objectives for patients with sickle cell disease (SCD) that mirror the healthy people 2010 objectives. Dr. Crosby has served as a co-investigator on a number of multi-site SCD studies focusing on topics such as adherence to medical regimens, disease management, transition to adult care, and clinical trials examining medication and psychological treatments. Currently, she is the coordinator for the SCD Transition Program and is involved in a number of quality improvement initiatives around chronic pain.

Ms. Haralson received a BS in psychology from Boise State University. She is a project coordinator in the Division of Behavioral Medicine and Clinical Psychology for a 25-year longitudinal study of females who were abused as children, and serves as Accurint services support for the CCTST. She has seven years of experience in behavioral research, and five years of experience working specifically with high-risk populations.



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Dr. Monica J. Mitchell is an associate professor in the Department of Psychology at the University of Cincinnati and holds joint appointments at CCHMC and the Child Policy Research Center. Dr. Mitchell also serves as co-director of INNOVATIONS in Community Research and Program Evaluation, which conducts program evaluations and consults with agencies on community-based research. She also serves as the co-director of the CCTST Community Engagement Core, which works to improve relationships between academic researchers and community members by engaging community physicians in research and translation of evidence-based practice, and by training/educating researchers and community members in community-engaged research in order to build capacity and an understanding of the benefits and risks of research involvement. Dr. Mitchell is the principal investigator on several studies examining treatment adherence, disease management and quality of life in pediatric sickle cell disease.

Dr. Noll received her PhD in developmental psychology and quantitative methods from the University of Southern California. As a professor of pediatrics, she also functions as the director of research in CCHMC's Division of Behavioral Medicine and Clinical Psychology. In addition, she serves as a research subject advocate chair of the Regulatory Arm and Safety Subcommittee in the CCTST. She has worked as PI and Co-PI on an ongoing longitudinal multi-generational study of the impact of sexual abuse on female development, which has maintained over 96% of participants during the past 25 years. She is presently the principal investigator on a large NIH R01 grant focused on teen pregnancy prevention in 514 high-risk adolescents.

Mr. Schuller is a senior associate of clinical research marketing for the Clinical Trials Office. Mr. Schuller has more than 25 years of experience in marketing and communications including positions at Cincinnati Children's, Hoxworth Blood Center and two Cincinnati advertising agencies. Mr. Schuller also has eight years of experience as a donor and apheresis coordinator for the National Marrow Donor Program helping to coordinate more than 70 donor/patient matches. He has developed and executed marketing and recruiting tactics for more than 300 Cincinnati Children's studies and won communication awards from the International Association of Business Communicators, Public Relations Society of America and Cincinnati Editors Association. Mr. Schuller earned a Master of Arts degree in communication and speech from the University of Cincinnati.

## Objectives

At the conclusion of this session, the symposium attendee will be able to:

1. Repeat three to five tactics of effective clinical research study participant recruitment to refine their individual recruitment practices.
2. Identify at least three strategies that have been used to effectively recruit diverse and hard-to-reach populations.
3. Recall several retention skills and resources, including how to build rapport with participants and gain access through IRB approval to retention services.

**12:15 – 1:15**      **Lunch**

**1:15 – 2:45**      **Breakout Session 1**

Clinical Data Management: Will it Really Help My Work?

- Introduction to the CCHMC Data Management Initiative - Rick Ittenbach, PhD
- What is Data Management and How Can It Improve My Work? - Cyndie Baker, BS, LPN
- Why Is Clinical Data Management Necessary? - Cyndie Baker, BS, LPN
- Putting Good Clinical Data Management Practices into My Research - Rachel Akers, MPH
- Data Management Options and Resources Within the Hospital - Eileen King, PhD
- How to Move Forward from Here (Contacts and Communication) - Eileen King, PhD

Ms. Akers has been a CCHMC staff member for nearly 10 years, managing the Data Management Center (DMC) within the Division of Biostatistics and Epidemiology (DBE). She received her Master of Public Health in epidemiology from the University of Alabama at Birmingham and has focused her career on study design, research methods and data management practices. She is a member of the Society for Clinical Trials, the Society for Clinical Data Management and the Drug Information Association.



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Ms. Baker is a senior specialist, clinical data management for the DBE. Cyndie's focus is on the continued development of the DMC, as well as institutional support and education. She has worked more than 12 years in clinical research, working as a site study coordinator, data associate at a CRO and over 7 years as a data manager at an orthopedic device company. Ms. Baker received her nursing education through the United States Army, and her Bachelor of Science in biology/chemistry from Bowling Green State University.

Dr. Ittenbach is an associate professor of pediatrics in the DBE. He has been involved in clinical data management for the past eight years and is currently chairing CCHMC's Data Management Initiative, which is an institution wide initiative to study, enhance, and streamline clinical data management operations. Dr. Ittenbach is also director of the new Scale Development Unit with the DBE, a unit designed to offer scale development expertise to investigators wishing to develop new clinical measures for use with children.

Dr. King is an associate professor in the DBE and is currently the acting director of the DMC within DBE. Dr. King has 23 years of experience in health care and pharmaceutical research, which includes management responsibility for statistical and data management support of research studies. She leads the data coordinating center activities for several research networks within the James M. Anderson Center at CCHMC. Dr. King received her PhD in statistics from Texas A&M University.

## Objectives

1. Define clinical data management and identify key roles, responsibilities and functions of clinical data managers.
2. Introduce CCHMC researchers to fundamentals of Good Clinical Data Management Practices and know when to implement them.
3. Identify clinical data management options and resources for support and collaboration within the institution.

## Breakout Session 2

### Participant Compensation: Ethics, Taxes and Common Practices

Daniel Brummett, CPA

Lauren Hoctor, MSN, BSBA, RN

Melinda Muenich, RN, MBA

Mr. Brummett is currently the tax compliance officer at CCHMC. He is responsible for the strategic direction and oversight of the external tax reporting function at Cincinnati Children's as well as an in-house technical resource for Human Resources, Legal Department, Senior Management, and the board of trustees related to tax-exempt status, employee benefits, Form 990 reporting, employee vs. independent contractor determinations, payroll and accounts payable policies and procedures, and community benefit analysis. He is a certified public accountant licensed in Kentucky and Ohio with more than 12 years of experience serving tax-exempt and governmental entities. Mr. Brummett received a bachelor's degree in business administration with an accounting emphasis from Campbellsville University and is a member of the American Institute of Certified Public Accountants.

Ms. Hoctor is a 1983 graduate of Miami University's School of Business, and her first career in market research and database analytics focused on secondary research. She graduated from the Christ Hospital School of Nursing in 2004, and earned a Master of Science degree in nursing with a concentration in health care law from Xavier University in 2010. Ms. Hoctor has worked for CCHMC for five years, is a member of our Pediatric Sexual Assault Nurse Examiner team, and joined the CCHMC IRB two years ago as a human protections analyst.

Ms. Muenich is the director of the Office for Clinical and Translational Research at Cincinnati Children's. She is responsible for managing daily operations, business development and strategic planning. Ms. Muenich has a diverse and extensive background in the health care industry including 20 years of operations management, experience in business development, marketing, physician services, corporate health program development, and quality process improvement/design. Ms. Muenich received her nursing diploma from the Deaconess School of Nursing, a BA in communications from Xavier University, and her MBA from the University of Cincinnati.



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1. Consider ethics and theory in the development of research participant compensation plans.
2. Understand the implications of government tax regulations on research participant compensation processes.
3. Apply guidelines to determine acceptable compensation and associated documentation of study fund distribution.

2:45 – 3:00

## Break

3:00 – 4:30

## Breakout Session 3

### Audit Trends: Issues, Findings and Remedies

Dawn Lowe Gooden, MS, CQA

Ms. Lowe-Gooden is the research compliance manager in the Office of Research Compliance and Regulatory Affairs (ORCRA) at CCHMC. Dawn has 20 plus years of quality assurance, compliance and regulatory experience in pharmaceutical testing and manufacturing, blood and tissue banking, and in academic health care settings. Ms. Lowe-Gooden has extensive hands-on knowledge of internal and external auditing as well as experience with inspections from regulatory agencies. She obtained a Master of Science in pharmaceutical sciences from the University of Cincinnati and is certified through the American Society of Quality as a certified quality auditor.

## Objectives

1. Provide a general overview of findings documented during ORCRA quality reviews.
2. Discuss recommendations for corrective and preventive actions.
3. Provide tips for compliance and reporting to the IRB.

Panel: Tom Asplan, RQAP-GCP; Carla Hanekamp, RN; Jean Gibson, RN, CIP; Melissa Schneider; Elva Turner, BSEd, CCRC, CCRA (moderator)

## Breakout Session 4 – Sabin Center

### Recruitment and Retention Toolbox Part II - case studies

“Happiness and Hardship in Headache Study Recruitment”

Janelle Allen, MS

“Yesterday’s Children: Retaining a Birth Cohort of High Risk Lead-Exposed Subjects Followed for 32 Years”

Kim Dietrich, PhD

“Creative Recruitment of Parents of Teens with Developmental Disabilities”

Amie Duncan, MD

“Removing Roadblocks to Recruitment in a Rare Disease”

Leslie Korbee, BS

Mark Schuller, MA (moderator)

Ms. Allen is a Research Coordinator within the Center for Child Behavior and Nutrition Research and Training at CCHMC. She is responsible for managing the NIH funded “Drug and Non-Drug Treatment of Pediatric Chronic

Headache” and “Headstrong Intervention for Recurrent Pediatric Headache” studies and diabetes studies within her team, and also holds other responsibilities within the Pediatric Pain Program. During the past 11 years, she has completed research in developmental biology, neurophysiology / behavior, quality engineering: analytical / quality product review, molecular cardiovascular medicine, infectious diseases, and child behavior and nutrition.



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Ms. Allen serves on the advisory council of Clinical Research Professionals (CRP) as the chairperson of CRP education and as a member of the CRP membership sub-committee. She is a visiting faculty member within the Department of Zoology at Miami University, and also works in community and youth / young adult development within Butler and Hamilton Counties. Ms. Allen received a Bachelor of Science from Miami University in zoology, neuroscience, French and a Master of Science from Miami University in physiology and neuroscience (zoology).

Dr. Dietrich is professor of Environmental Health and Director of the Division of Epidemiology and Biostatistics at the UC College of Medicine, Department of Environmental Health. Dr. Dietrich has also served as associate director of the Cincinnati Children's Center for Environmental Health and Disease Prevention at CCHMC. He has served as a consultant to numerous local, state, national and international agencies and organizations concerned with the impact of environmental chemical exposures on the health and development of young children. His research has focused on the developmental effects of prenatal and early postnatal exposure to lead in infants, toddlers, school-age children, adolescents, and young adults. Dr. Dietrich is presently examining the relationship between early exposure to lead, genetic factors, and adult criminality in a long-standing prospective longitudinal birth cohort study. Among his other studies he is also examining the relationship between environmental factors that may determine pathways through puberty in girls as a risk factor for early developmental psychopathology and later pre- and post-menopausal breast cancer.

Dr. Duncan is a second year psychology postdoctoral fellow in the Division of Developmental and Behavioral Pediatrics. She is currently conducting a study on parental perspectives on the transition to adulthood in adolescents with developmental disabilities. Dr. Duncan is interested in identifying factors that impede or lead to a successful transition to adulthood and designing person-centered interventions to help adolescents with developmental disabilities, with a focus on autism spectrum disorders, achieve an optimum quality of life in adulthood.

Ms. Korbee is a medical writer / project manager for the Office for Clinical and Translational Research. Ms. Korbee has more than 18 years of experience with clinical trials including project management of a multi-center international study, regulatory management of IND studies, clinical trials management of a free standing respiratory research center, study management of a skin patch safety division of a consumer products research center, and clinical and device trials management of an orthopedic research entity focused on computer navigation in total joint surgery and spine surgery research. She has also managed hospital outpatient departments and medical practices, and authored or co-authored 10 scientific publications. Ms. Korbee received her BS from the University of Cincinnati and is a registered specialist in immunology through the American Society of Clinical Pathology.

## Objectives

At the completion of this session, attendees will:

1. Develop a clear understanding of approaches to research trial recruitment using EDC that were the most successful and least successful.
2. Recall the challenges posed by following a high-risk, inner-city cohort from conception to early adulthood from the perspective of recruitment, tracking, retention, and maintenance of mutual trust between investigators, staff and subjects.
3. Be able to identify alternative and novel recruitment strategies for research study subjects with developmental disabilities.
4. Gain understanding of alternate strategies for clinical trial recruitment for rare disease patient populations.

4:30

## Closing remarks and CME Evaluations

### 2011 Annual Research Symposium Planning Committee

Melinda Muenich, MBA, RN; Scott Powers, PhD, ABPP, FAHS; Dana Raab, RN, BSN, MS; Mark Schuller, MA; Michael Spigarelli, MD, PhD; Sheri Uber, MS, MBA