



APRIL 29, 2013

RESEARCH

FROM BENCH

ROCKS

TO BEDSIDE



Research Foundation

Sponsored by the Office for Clinical and Translational Research



# FROM BENCH TO BEDSIDE

APRIL 29, 2013

2013 Annual Research Symposium Sponsored by  
CINCINNATI CHILDREN'S RESEARCH FOUNDATION  
OFFICE FOR CLINICAL AND TRANSLATIONAL RESEARCH (OCTR)

7:30 – 8:00      **Registration - Breakfast**

8:00 – 8:15      **Opening Remarks**

Arnold Strauss, MD  
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

## Morning Sessions – Investigator Focused

8:15 – 9:45

(two 40-minute segments)

*Conflict of Interest in Human Research – Don't Get Caught Dancing to the 'Jailhouse Rock'*

Michael Barnes, PhD  
JP Clancy, MD  
Joan Gates, JD

- High profile cases that placed Conflict of Interest under the microscope (Dr. Clancy)
  - Jessie Gelsinger gene therapy example
  - Recent examples from *The New York Times*
- Principles and interpretations relevant to Conflict of Interest in research (Ms. Gates)
  - Types
  - Regulations
  - Management
- Real world vignettes (Ms. Gates and Dr. Clancy)

*Genetics-based Research and Human Subjects Protection – 'The Times They Are A-Changin''*

- Real life case – new genetic information identified during a 'gene screen' – what to do with this information (Dr. Clancy and Dr. Barnes)
- The landscape of regulations regarding human subject protection and genetic research (Dr. Clancy)
  - Past
  - Present
  - Future
- How can Cincinnati Children's help you?
  - IRB
  - Cincinnati Biobank Core Facility (Dr. Barnes)

Dr. Barnes is currently assistant professor in the Division of Rheumatology and director of the Cincinnati Biobank Core Facility at Cincinnati Children's. In this position he supports institutional needs for sample collection, processing, storage and distribution. He also leads an institutional effort called Better Outcomes for Children to obtain consent from patients to use residual clinical samples for research. He is extensively involved in biobanking efforts internationally and participates in various working groups for the International Society of Biological and Environmental Repositories (ISBER). Prior to this position, Dr. Barnes provided gene expression analysis for studies of juvenile idiopathic arthritis. Dr. Barnes earned his PhD from the University of Cincinnati College of Medicine, Department of Molecular Genetics, Biochemistry and Microbiology in 2001 for studies of the complement resistance phenotype of *Bordetella pertussis*.



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Dr. Clancy is medical director of the Office for Clinical and Translational Research, research director for the Division of Pulmonary Medicine, and professor in the UC Department of Pediatrics. Prior to accepting his Cincinnati Children's positions, he served as the division director of Pediatric Pulmonary Medicine at University of Alabama Birmingham, 2002-2010. He is internationally recognized for his translational research in cystic fibrosis (CF), examining how the cystic fibrosis transmembrane conductance regulator (CFTR) mutations cause disease, and for developing strategies to restore function.

Dr. Clancy has been the primary or co-mentor of more than 20 fellows, graduate students and junior faculty. He has been the initial recipient of two endowed chairs, including the Raymond K. Lyrene Chair in Pediatric Pulmonary Medicine at the University of Alabama (2005), and the Tom Boat Chair in Cystic Fibrosis Clinical and Translational Research at Cincinnati Children's (2011). Dr. Clancy 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 attended medical school at the University of Iowa and completed his pediatric residency at the University of Virginia, which was followed by pediatric pulmonary medicine and research training at the University of Alabama at Birmingham (UAB).

Ms. Gates is currently counsel for Cincinnati Children's research enterprise. She provides counsel, advice and guidance regarding a wide variety of academic research related legal issues. Prior to joining Cincinnati Children's, Joan held leadership and legal positions in both the private and public sector, including within a large multi-state law firm. Joan is licensed to practice law in Ohio and earned her Juris Doctorate from Salmon P. Chase College of Law, Order of Curia, magna cum laude in May 2000, where she was a Commonwealth for Legal Studies Scholar. She graduated from the Cincinnati Academy of Leadership for Lawyers program in May 2007 and is currently a board member of the Greater Cincinnati Minority Counsel Program.

## Objectives

Conflict of Interest in Human Research: Don't Get Caught Dancin' to the 'Jailhouse Rock'

- Describe the various types of conflict of interest that can occur in medical research.
- Discuss the potential risks that conflicts of interest can create.
- Discuss the mechanisms to avoid and manage conflicts of interest in clinical research.

Genetics-based Research and Human Subjects Protection: 'The Times They Are A-Changin'

- Describe how genetic research regulations have changed with technological advancements.
- Explain the potential risks and unique challenges posed by genetic research relative to other types of clinical research.
- Discuss the Cincinnati Biobank Core, including its role in providing access to genetic and non-genetic research material.

9:45 – 10:30

*Achieving your study aims on time and on budget – 'Time Is On My Side'*

– project management tools and techniques for clinical research professionals  
Sophia Thurmond, BS

Ms. Thurmond is a senior project specialist in the Division of Pulmonary Medicine. She has more than eight years of experience managing research projects in regulated environments, including three years of clinical research project management at Cincinnati Children's. She manages the Pulmonary Outcomes Research Lab for the Division of Pulmonary Medicine, which includes the development and execution of a coordinated system that facilitates management of the portfolio of the Lab's research and quality improvement projects. She also manages the Collaborative Chronic Care Network (C3N) Project through the James M. Anderson Center for Health Systems Excellence. The C3N is funded by a Transformative R01 grant from the NIH to design and test a new system for transforming chronic care. Ms. Thurmond is passionate about improving quality of life and health outcomes for children and teaching others how they can help achieve this aspiration.



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## Objectives

- Define the role and responsibilities of the research project manager.
- Describe basic project management concepts.
- Demonstrate project management tools and processes for planning, execution and management of clinical research projects.

10:30 – 10:45 **Break**

## Keynote Speaker

10:45 – noon *Rockin' Drug Development through Collaborative Innovation*  
Kenneth A. Getz, MBA



Mr. Getz is the chairman of CISCRP (Center for Information and Study on Clinical Research Participation) – a nonprofit organization that he founded to educate and raise public and patient awareness of the clinical research enterprise. He is also the director of Sponsored Research and an associate professor at the Tufts Center for the Study of Drug Development, Tufts University School of Medicine where he conducts research programs on drug development management strategies and tactics, outsourcing, global investigative site and patient recruitment practices, trends and policies. Mr. Getz is also the founder and owner of CenterWatch, a leading publisher in the clinical trials industry and one of two businesses that he has sold.

A well-known speaker at conferences, symposia, universities, investor meetings and corporations, Mr. Getz has published extensively in peer-review journals, books and in the trade press. He is the author of two nationally recognized books for patients and their advocates entitled, *Informed Consent: A Guide to the Risks and Benefits of Volunteering for Clinical Trials* and *The Gift of Participation*, and is the recipient of several awards for innovation and scholarship. He has held a number of board appointments in the private and public sectors including serving on the Institute of Medicine's Clinical Research Roundtable, the DIA Foundation, the Consortium to Examine Clinical Research Ethics, and the Clinical Trials Transformation Initiative. He is on the editorial boards of *Pharmaceutical Medicine* and the *Drug Information Journal* and writes a bi-monthly column nominated for a Neal Award in 2010 for *Applied Clinical Trials*.

Mr. Getz holds an MBA from the J.L. Kellogg Graduate School of Management at Northwestern University and a bachelor's degree, Phi Beta Kappa, from Brandeis University. Prior to founding CenterWatch in 1994, he worked for more than seven years in management consulting where he assisted biopharmaceutical companies develop and implement business strategies to improve clinical development performance.

## Objectives

- Discuss trends and changes in the clinical research environment that are impacting the performance, efficiency and quality of work conducted by principal investigators and study staff.
- Review primary areas where there are opportunities to research sponsors and investigative sites to collaborate more effectively and ultimately improve quality and efficiency.
- Discuss opportunities to improve patient engagement and participation in clinical trials.

Noon - 12:45 **Lunch**



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## Afternoon Breakout Sessions – Coordinator Focused

12:45 – 1:45

1. *Historical Mistrust: Building Trust Between Medical Researchers and Their Research Participants – 'Honesty'*<sup>4</sup>

Melinda Butsch Kovacic, MPH, PhD

Charla Weiss, PhD

Dr. Butsch Kovacic is an epidemiologist who has clinical, translational and community-based participatory research projects. Her research group studies the genetic/epigenetic, environmental and socioeconomic basis of chronic diseases such as cancer, asthma and obesity, with specific interest in understanding how environmental exposures modify risk in vulnerable families. Her research is highly interdisciplinary with collaborators across the academic health center and in the community.

One of Dr. Butsch Kovacic's long-term goals is to improve the understanding of how the environment modifies chronic disease risk in genetically and/or economically vulnerable children. To this end, she is the principal investigator of an ongoing study that is evaluating associations between environment exposures and biomarkers of oxidative stress and whether or not these biomarkers will better predict risk of severe/uncontrolled childhood asthma compared to parental report of exposure alone. Dr. Butsch Kovacic will share how the use of Photovoice expands her research into a low-income and low-literacy Cincinnati community. Dr. Butsch Kovacic earned her PhD in biochemistry from the Ohio State University and her MPH from Harvard University School of Public Health.

Dr. Weiss is a consultant in the Office of Diversity and Inclusion at Cincinnati Children's. She works with the Office of Diversity and Inclusion to partner with colleagues throughout the institution to integrate the values of diversity and cultural competence into all aspects of healthcare delivery in order to provide a competitive advantage. Specifically, Dr. Weiss consults with the Office of Faculty Development to bolster the Department of Pediatrics' ability to attract and retain a diverse workforce. This, in turn, broadens the range of skills, knowledge, abilities and insights necessary to strengthen the delivery of world class pediatric healthcare. Dr. Weiss earned her PhD from the University of Michigan in education and psychology.

### Objectives

- State two historical reasons why individuals distrust medical researchers.
- Identify one method that may increase the trust level between medical researchers and their research participants.

2. *Social Media and Clinical Studies – 'Reach Out, I'll Be There'*<sup>6</sup>

Lorrie Duan, RN, BSN

Ms. Duan is the clinical research manager in the Division of Pulmonary Medicine at Cincinnati Children's. She has 30 years of experience in nursing including seven years in clinical research in Pulmonary Medicine. Ms. Duan and her team have developed the clinical research program that has grown to one of the largest programs in the country to meet the needs for our patients with cystic fibrosis, asthma and rare lung disease.

### Objectives

- Identify sources of social media that could be used in clinical research.
- Define the benefits of social media in recruitment of subjects into clinical trials

1:45 – 2:45 pm

1. *Alternative IRB Models for Multi-site Research – 'How Can I Be Sure?'*<sup>5</sup>

Jeremy Corsmo, MPH, CIP, CHRC



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Mr. Corsmo leads Cincinnati Children's Office of Research Compliance and Regulatory Affairs (ORCRA) institutional programs as research compliance officer and senior director. This principally includes Cincinnati Children's human research protection program, animal care and use in research program, research laboratory safety program, research compliance program and research integrity, education and conflict of interests program. He completed his undergraduate degree at Virginia Tech in microbiology and his master's degree in public health from the University of Massachusetts – Amherst. His research experience includes conducting toxicology laboratory research for the US EPA as well as conducting NIH and industry-funded clinical research in neuroscience and addiction medicine. Prior to joining Cincinnati Children's, Mr. Corsmo held a regulatory/compliance position with an international pharmaceutical company, a large domestic clinical research organization as well as one of the largest independent central IRBs in the US.

## Objectives

- Provide historical perspective of IRB oversight of multi-site research within a regulatory context.
- Discuss the most current federal and national thinking on IRB review in multi-site research.
- Differentiate and understand the current and future landscape with regard to IRB oversight of multi-site research including use of CIRB and various institutional reliance models.

2. *Social Media: What You Need to Know for Your Research Study Conduct – 'I Heard It Through the Grapevine'*,  
Kate Setter, BA  
Jackie Barnes, MA, CRP  
Kristen Safier, JD

Ms. Setter is a media relations associate in the Marketing and Communications Department at Cincinnati Children's, and is the social media manager for the institution's social media strategy. She supervises the medical center's corporate social channels including the Cincinnati Children's blog, Facebook, Twitter, YouTube, Google+ and most recently Pinterest. She has successfully worked to develop and increase Cincinnati Children's participation in social media applications and projects during the past four years. Prior to her Cincinnati Children's experience, she was employed at Convergys Corporation for five years working in public relations where she focused on national and international media relations. Ms. Setter graduated from Wilmington College with a BA in business administration and a minor in communications.

Ms. Barnes has worked with the Divisions of Safe and Healthy Children, and Behavioral Medicine and Clinical Psychology for almost 13 years. She is currently assisting Jennie Noll, PhD, coordinating both qualitative and longitudinal quantitative studies as a clinical research coordinator IV. In 2012, Ms. Barnes coordinated the FADS (Female Adolescent Development Study), which examined high-risk sexual behaviors and teen pregnancy. Conclusions and interest from the FADS study helped launch the current study, TechnoTeens (addressed in Ms. Barnes presentation), which is currently examining high-risk internet behaviors in adolescents. Ms. Barnes received a Bachelor of Science degree in psychology from Xavier University and a Master of Science degree in sociology from the University of Cincinnati. Ms. Barnes has been published in the Journal of Interpersonal Violence, Child Abuse and Neglect, and the journal Pediatrics.

Ms. Safier is the deputy compliance officer at Cincinnati Children's. She manages Cincinnati Children's corporate compliance program, chairs the Integrity and Compliance Council, and serves as the privacy officer. Prior to joining Cincinnati Children's in February 2102, she was a practicing attorney for seven years representing hospitals, health care providers and physicians. She also taught women's studies at Miami University and law at the University of Dayton School of Law for three years. Ms. Safier's publication topics include education policy and legal trade. She received a BS in philosophy from Miami University, a MEd from the University of Pennsylvania and a JD from the University of Cincinnati.



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## Objectives

- Define social media.
- Describe how to apply for a Facebook page on the Cincinnati Children's web site and the importance of corporate branding.
- Discuss social media tactics with application to clinical research study recruitment and retention including IRB considerations.
- Identify and manage legal and compliance issues that may be raised when using social media in research studies.

2:45 – 3:00 **Break**

3:00 – 4:00 *Use of Micro-emotions in the Therapeutic Interaction with Children – 'Second That Emotion'*  
Dan Nelson, MD

Dr. Nelson is associate professor of Psychiatry, University of Cincinnati, Department of Psychiatry and medical director of the Child and Adolescent Psychiatric Units at Cincinnati Children's. He joined Cincinnati Children's in 1998 when he assumed the role of medical director for the Cincinnati Children's psychiatric unit. From 2005 to 2007, Dr. Nelson also directed both the child and adolescent psychiatric units at Cincinnati Children's. During the same time, he was medical director of the therapeutic interagency preschool program that specializes in the treatment of severely traumatized children.

Prior to joining Cincinnati Children's, Dr. Nelson was the director of the day hospital in residential treatment programs at The Children's Hospital at Oklahoma University Medical Center, Tulsa, Oklahoma, from 1991 to 1997. During these years he was the director of medical education for residents of medical students at that facility. Dr. Nelson was full-time teaching faculty and director of all resident education for the University of Oklahoma Health Sciences Center, Tulsa, in the Department of Psychiatry from 1994 to 1997.

Dr. Nelson's specialization in child development, trauma, and disasters led him to become the initial director at the family notification center after the Oklahoma City bombing. During the past 30 years he has specialized in both normal childhood development and child psychiatric illness including consulting and assisting in efforts to support mental-health in the victims of NYC Fire Department, 911, Hurricane Katrina, school shootings and multiple tornadoes. He is currently an acting consultant and board member of the National Center for School Crisis and Bereavement.

Dr. Nelson received his medical degree from the University of Oklahoma Health Science Center, Oklahoma City, Oklahoma, in May 1985, and completed advanced training in both general psychiatry and child and adolescent psychiatry at the University of Texas Health Science Center, San Antonio Texas in September 1990.

## Objectives

- Recognize the seven primary emotions and name them on sight.
- Identify if a patient is congruent for objective vs. subjective emotion.

4:00 – 4:15 **CME Evaluations**

## Name That Tune

1. Jailhouse Rock recorded by Elvis Presley
2. The Times They Are A-Changin' recorded by Bob Dylan
3. Time Is On My Side recorded by The Rolling Stones
4. Honesty? recorded by Billy Joel
5. How Can I Be Sure? recorded by the Young Rascals
6. Reach Out (I'll Be There) recorded by The Four Tops
7. I Heard It Through the Grapevine recorded by Marvin Gay
8. Second That Emotion recorded by Smokey Robinson and the Miracles

## 2013 Annual Research Symposium Planning Committee

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