Ethics of Integrating Research and Clinical Care
March 23-24, 2017
Preliminary Agenda

Draft Date: 27 Jan 17

7:30 am - 12:00 pm  Registration
7:30 am - 8:15 am  Breakfast
Sabin Prefunction Area

8:15 am - 8:30 am  Welcome
William Ball, MD, Dean, University of Cincinnati College of Medicine

8:30 am - 9:00 am  Introductory Session
Title Pending
Jennifer S. Bard, JD, MPH, PhD, Dean and Nippert Professor of Law,
University of Cincinnati College of Law
Session Chair: Jane E. Strasser, PhD, University of Cincinnati

9:00 am - 10:15 am  Featured Presentation
Are Randomized Clinical Trials Comparing Standard of Care Treatments Truly Minimal Risk?
Scott Kim, MD, PhD, Department of Bioethics, National Institutes of Health
Session Chair: Richard F. Ittenbach, PhD, Cincinnati Children’s

10:15 am - 10:30 am  Break
Prefunction Area

10:30 am - 11:40 am  Phase I chemotherapy trials for children and adolescents: Who benefits?
James Geller, MD, Rachel Thienprayoon, MD, Cincinnati Children’s
Session Chair: Armand H. M. Antommaria, MD, PhD, Cincinnati Children’s

11:40 am - 1:00 pm  Networking Lunch

12:10 pm - 1:00 pm  Poster Session*
Prefunction Area
Sabin Auditorium
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| 12:10pm - 1:00pm | **Late Breaking Session** (Room D2.40)  
Revisions to the Common Rule: How Does it Impact Me?  
Session Chair: Joel Tsevat, MD, University of Cincinnati |
|              | Holly A. Bante, PhD, University of Cincinnati  
Michael J. Linke, PhD, Cincinnati Veterans’ Administration |
| 1:00 pm - 2:15 pm | **Featured Presentation**  
Notification and Authorization of Alternative Approaches in Pragmatic Clinical Trials of Commonly Used Medical Practices  
Kevin Weinfurt, PhD, Department of Psychiatry and Behavioral Sciences, Duke University School of Medicine  
Session Chair: Holly A. Bante, PhD, University of Cincinnati |
| 2:15 pm - 3:30 pm | **Evaluation and Communication of Risk for Clinical Research in the NICU**  
Session Chair: Michael J. Linke, PhD, Cincinnati VA Medical Center  
Hypothesis Generation Clinical Research: The Problem and Requirement For Risk, James Greenberg, MD, Cincinnati Children’s |
|              | Ethical Considerations with Research Involving a Vulnerable Populations: The Maternal Fetal Dyad, DonnaMaria Cortezzo, MD, Cincinnati Children’s |
|              | Risk Assessment in Clinical Research: Legal and Regulatory Considerations and the Problem of Hindsight Bias, David Russell, JD, Cincinnati Children’s |
| 3:30 pm - 3:50 pm | **Break**  
Prefunction Area |
| 3:50 pm - 5:00 pm | **Topical Sessions**  
**Breakout Session 1** (Room D2.22)  
Session Chair: James Heubi, MD  
Ethical Implications of Providing Oral Human Papillomavirus Results to Individuals with Fanconi Anemia Sharon Sauter, MS, Cincinnati Children’s  
Ancillary-Care Obligations and the Partiality of the Partial Entrustment Model: A Reply to Henry Richardson Alex Huffman, MS, University of Cincinnati |
|              | **Breakout Session 2** (Room D2.40)  
Session Chair: Joel Tsevat, MD  
Providers’ Response to Receiving Unsolicited Pharmacogenetic Research |
Results for their Pediatric Patients  Melanie Myers, PhD, Cincinnati Children’s
There is More to Understanding than Better Forms  Richard F. Ittenbach, PhD, Cincinnati Children’s

Breakout Session 3 (Room Sabin Auditorium)
Session Chair:  Armand H. M. Antommaria, MD
Using a Patient Centered Approach to Improve Pediatric Assent Forms
Michelle Dickey, APN, Cincinnati Children’s
Assenting Children and Teens, Julie Wijesooriya, Cincinnati Children’s,
The IRB Perspective, Robert Frenck, MD  Cincinnati Children’s

5:00 pm - 6:00 pm  Guest Reception, Open to all Registrants
Sabin Prefunction Area

Day 2

7:15 am - 8:00 am  Breakfast
Sabin Prefunction Area

8:00 am - 8:10 am  Welcome
Margaret K. Hostetter, MD, PhD, Chair, Department of Pediatrics, Cincinnati Children’s Hospital Medical Center
Session Chair:  Richard F. Ittenbach, PhD, Cincinnati Children’s

8:10 am - 9:25 am  Featured Presentation
First In Human Trials and Safety Assessment for Rare and Orphan Diseases
Andrew E. Mulberg, MD, Amicus Therapeutics
Session Chair:  James E. Heubi, MD, Cincinnati Children’s

9:25 pm - 10:20 am  Rare Disease Treatment Trials:  Hope for Patients with Diseases with no Existing Treatment
James E. Heubi, MD, Cincinnati Children’s
Laura K. Lentz, Continuum Clinical, Northbrook, IL
Session Chair:  Richard F. Ittenbach, PhD, Cincinnati Children’s

10:20 am - 10:40 am  Break
Sabin Prefunction Area
10:40 am - 11:40 am  Breakthroughs in Technology
Session Chair: Holly A. Bante, PhD, University of Cincinnati

SENSE: Bioethics Quandries in Neurological Medical Devices
George Shaw, MD, University of Cincinnati

Research and Clinical use of New Technologies in the Neuroscience ICU
Brandon F. Foreman, MD, University of Cincinnati

Commercialization Conundrums: Emerging and Evolving Ethical Conflicts as Technology Moves to Testing
Christopher J. Lindsell, PhD, University of Cincinnati

11:40 am - 11:45 am  Closing Remarks
Richard F. Ittenbach, PhD, Cincinnati Children’s

12:00 pm - 1:00 pm  CCTST Grand Rounds (Title Pending)
Andrew E. Mulberg, MD, Amicus Therapeutics
7051 UC Medical Sciences Building
Session Chair: James E. Heubi, MD

*Poster Session*
Session Chairs: Michael J. Linke, Armand H. M. Antommaria

(1) Is Medical Opportunity a Categorical Imperative? A Look at Single Patient Treatment Use in the 21st Century, Megan Bogia, BA, University of Pennsylvania

(2) The High Cost of New Technology: Ethical and Economic Considerations for Robotic Surgery, Andrea J. Redmann, MD, University of Cincinnati

(3) Exploring the Research Participants’ Perceptions and Experiences of the Informed Consent Process in Clinical Trials and Observations Studies at Karachi Pakistan, Dilshad Begum, MScN, RN, The Aga Khan University, Karachi, Pakistan

(4) Looking for a Collaboration Between Palliative Care and Oncology Phase 1 Researchers in the Perspective of Resolving Ethical Concerns, Stefania Langhi, MA, University of Turin, Turin, Italy

(5) Ethical Challenges of Including Minors in Protective Custody in Minimal Risk Research Studies, Vikash Patel, BA, Cincinnati Children’s