Pushing the Boundaries: Scientific Innovation and Biomedical Ethics April 11-12, 2019

Preliminary Agenda

7:15 am - 5:00 pm Registration

7:15 am - 8:00 am Breakfast (Catered Full, all Registrants, Sabin Hall, Liberty Center)

8:05 am - 8:15 am Opening Remarks

Rick Ittenbach, PhD, Cincinnati Children's Hospital

Welcome

Margaret Hostetter, MD

B. K. Rachford Professor and Chair, Department of Pediatrics Cincinnati Children's Hospital and University of Cincinnati

8:20 am - 9:00 am Human Intestinal Models to Heal GI Patients

Session Chair: Holly Bante, PhD

Michael Helmrath, MD

Richard and Geralyn Azizkhan Chair of Pediatric Surgery

Associate Director of Clinical Translation. Center for Stem Cell & Organoid Medicine

Director, Surgical Research and Intestinal Rehabilitation

Cincinnati Children's Hospital

9:05 am - 10:20 am Regenerative Medicine: Navigating the Landscape of Emerging Treatments

Session Chair: Rick Ittenbach, PhD

Sarah Chan, PhD

Co-Director, Mason Institute for Medicine, Life Sciences and the Law

University of Edinburgh

10:25 am - 10:45 am Networking Break

10:50 am - 11:40 am Topical Breakout Sessions

Regenerative Medicine Breakthroughs (Liberty 1)

Session Chair: Jeremy Corsmo, MPH, CIP, Cincinnati Children's Hospital

Adult Neurogenesis as Potential Therapy

Agnes Luo, PhD

Associate Professor of Molecular Genetics, Department of Molecular Genetics, Biochemistry, and Microbiology, University of Cincinnati

 Craniofacial Muscle Stem Cells in Late Onset Muscular Dystrophy Katherine Vest, PhD

Ratifellile vest, PhD

Assistant Professor of Molecular Genetics, Department of Molecular Genetics, Biochemistry, and Microbiology, University of Cincinnati

Preparing for the Age of Precision Medicine: Engaging Adolescents in Selection and Return of Genomic Research Results (Liberty 2)

Session Chair: Michael Linke, PhD, University of Cincinnati

Adolescent Choices about Genomic Results

Melanie Myers, PhD

Associate Professor of Pediatrics

Director, Genetic Counseling Graduate Program

Division of Human Genetics, Cincinnati Children's Hospital and University of Cincinnati

Negotiating the Gray Zone When Returning Genomic Research Results to Adolescents

Cynthia A. Prows, MSN, APRN

Clinical Nurse Specialist, Division of Human Genetics

Cincinnati Children's Hospital

• Engaging Adolescents in Return of Results: A Bioethics Perspective

Holly Bante, PhD

Assistant Vice President for Ethics in Industry Engagement

Office of Research, University of Cincinnati

11:45 am - 1:00 pm Lunch (Registrants are on their own at Liberty Center)

1:05 pm - 2:15 pm Innovation, Rigor and the Best Interests of Study Participants:

Can We Have it All?

Session Chair: Maurizio Macaluso, MD, DrPH, Cincinnati Children's Hospital

Alex John London, PhD

Clara L. West Professor of Ethics and Philosophy

Director, Center for Ethics and Policy

Carnegie Mellon University

2:20 pm - 3:30 pm Topical Breakout Sessions

What is 'Right to Try' and How Does it Work? (Liberty 1)

Session Chair: Michael Linke, PhD, University of Cincinnati

• Right to Try in the Modern Era

Lyon Gleich, MD Vice President, Oncology, Medpace Cincinnati, OH

• Right to Try: The Institutional Perspective

Jeremy C. Corsmo, MPH, CIP

Senior Director, Office of Research Compliance and Regulatory

Affairs, Cincinnati Children's Hospital

So You Think Your Study is Ethical? (Liberty 2)

Session Chair Melanie Myers, PhD, Cincinnati Children's Hospital

• 'Not Bad, Just Drawn that Way...' Study Design is Not Ethically Neutral

Maurizio Macaluso, MD, DrPH

Professor of Pediatrics

Director, Division of Biostatistics and Epidemiology

Cincinnati Children's Hospital

Lies, Damned Lies, and Statistics: What is My Responsibility as a Biostatistician

Bin Huang, PhD

Professor of Pediatrics, Division of Biostatistics and Epidemiology Cincinnati Children's Hospital

• Manging the Science, the Project, and the 'Data'

Rick Ittenbach, PhD

Professor and Associate Director, Division of Biostatistics and Epidemiology Cincinnati Children's Hospital

Editing Genomes to Improve Human Health or Homo Sapiens? (Sabin Hall) Panel

Session Chair: Cynthia A. Prows, MSN, Cincinnati Children's Hospital

Leah Kottyan, PhD

Assistant Professor of Pediatrics, Cincinnati Children's Hospital

Sarah Chan, PhD

Co-Director, Mason Institute for Medicine, Life Sciences and the Law University of Edinburgh

Catherine Sherron, PhD

Professor and Chair, Philosophy, Thomas More University

3:35 am - 3:55 am Networking Break

4:00 pm - 4:45 pm Panel Breakout Sessions

Right to Try: Expanded Access for Compassionate Use (Liberty 1) Session Chair: Cynthia A. Prows, MSN, Cincinnati Children's Hospital

Trisha Wise-Draper, MD, PhD
Assistant Professor of Clinical Medicine
Department of Internal Medicine, University of Cincinnati

Jim Geller, MD

Professor of Pediatrics

Division of Oncology, Cincinnati Children's Hospital

Beyond the IRB: Ethical Responsibilities of Principal Investigators

(Liberty 2)

Session Chair: Holly Bante, PhD, University of Cincinnati

Carl Fichtenbaum, MD,
Professor of Clinical Medicine
Department of Internal Medicine, University of Cincinnati

Michael Linke, PhD Adjunct Professor of Medicine Department of Internal Medicine, University of Cincinnati

• The Price of Progress and Innovation: Protecting Those who Can't Speak in Preclinical Trials (Sabin Hall)

Session Chair: Jeremy Corsmo, MPH, CIP, Cincinnati Children's Hospital

Jane Strasser, PhD

Associate Professor, Infectious Diseases, Cincinnati Children's Hospital Associate Vice President, Office of Research Integrity, University of Cincinnati

George Babcock, MD

Professor Emeritus, Department of Surgery, University of Cincinnati

Andrew Norman, PhD
Professor of Pharmacology
Department of Pharmacology and Systems Physiology
University of Cincinnati

4:50 pm - 6:00 pm

Guest Reception, AC Hotel by Marriott at Liberty Center Open to All Registrants

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7:15 am - 12:00 pm Registration

7:30 am - 8:15 am Breakfast (Catered Full, all Registrants, Sabin Hall, Liberty Center)

8:15 am - 8:25 am Welcome

Andrew Filak, Jr. MD

Interim Senior Vice-President for Health Affairs and Dean

University of Cincinnati College of Medicine

8:30 am - 9:45 am Facing the Changing Ethical Landscape in Organ Transplantation

Session Chair: Rick Ittenbach, PhD, Cincinnati Children's Hospital

David C. Magnus, PhD

Director, Stanford Center for Biomedical Ethics

Stanford University

9:50 pm - 10:40 am Topical Breakout Session

Therapeutic Innovations in Transplantation

Session Chair: Jim Geller, MD, Cincinnati Children's Hospital

Liver Transplantation for Hepatoblastoma - Ethics of the Utilization of a Scarce Resource in a Challenging Disease Population

Greg Tiao, MD

Professor and Director, Division of General and Thoracic Surgery Cincinnati Children's Hospital

• Promise of Future Health Impact of Liver Organoids

Taka Tekebe, MD Assistant Professor
Division of Gastroenterology, Hepatology & Nutrition
Division of Developmental Biology, Cincinnati Children's Hospital
Department of Regenerative Medicine
Yokohama City University, Japan

10:45 am - 11:00 am Networking Break

11:05 am - 11:45 am Panel Session

• Ethics of Ovarian and Testicular Tissue Cryopreservation Research Session Chair: Holly Bante, PhD, University of Cincinnati

Andrew C. Strine, MD
Assistant Professor and Co-Director
Comprehensive Fertility Care and Preservation Program
Division of Pediatric Urology, Cincinnati Children's Hospital

Julie Sroga Rios, MD
Co-Director, Comprehensive Fertility Care and Preservation Program
Cincinnati Children's Hospital
Associate Professor, Department of Obstetrics and Gynecology
University of Cincinnati

Michelle McGowan, PhD Associate Professor, Ethics Center, Cincinnati Children's Hospital Departments of Pediatrics and Women's, Gender & Sexuality Studies University of Cincinnati

Olivia Frias, MSN, RN Registered Nurse III Comprehensive Fertility Care and Preservation Program Cincinnati Children's Hospital

11:50 am - 12:00 pm Closing Remarks

Rick Ittenbach, PhD

Professor and Associate Director, Division of Biostatistics and Epidemiology Ethics, Regulatory Knowledge and Support CCTST Co-Chair Cincinnati Children's Hospital