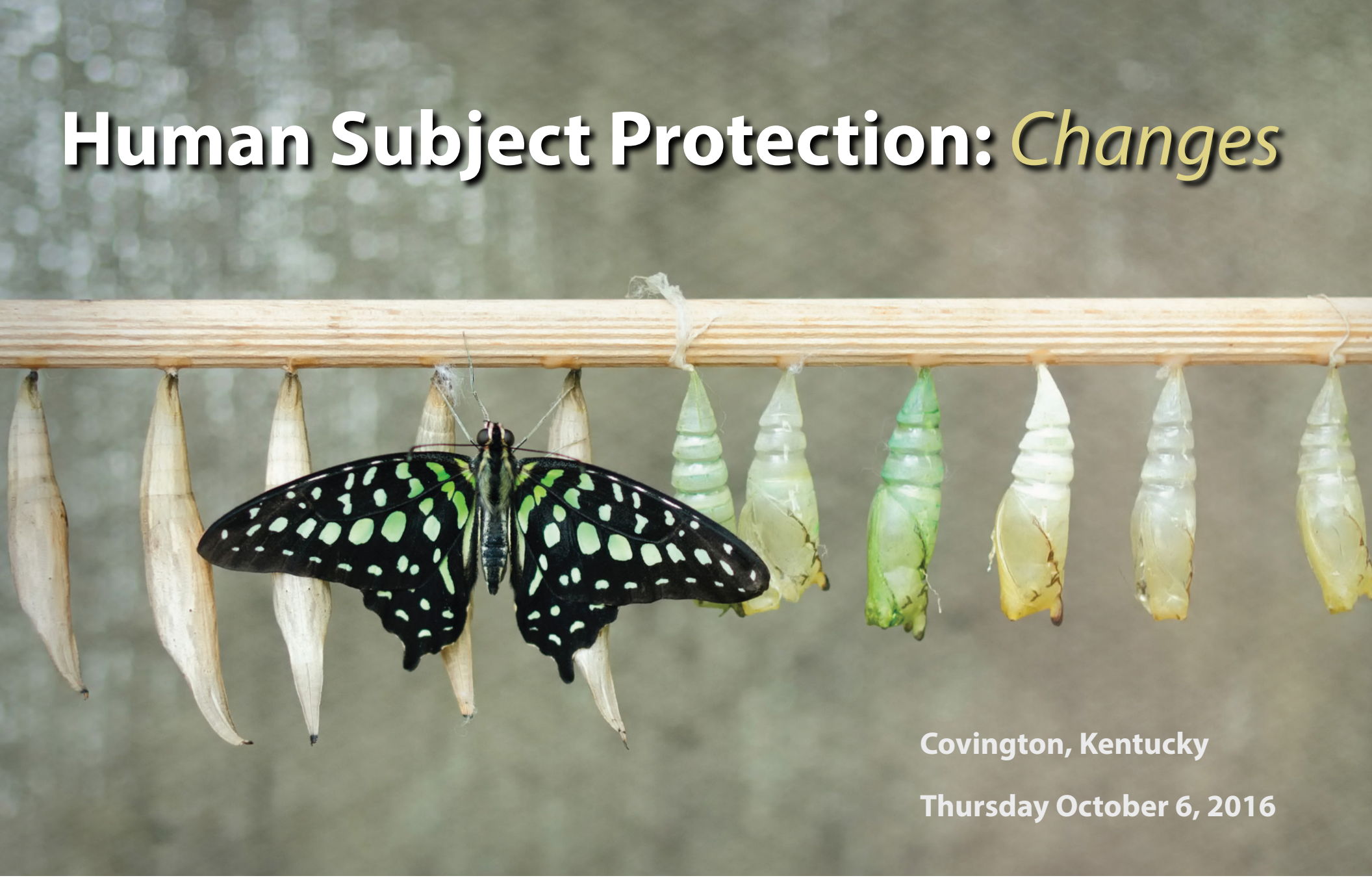
Human Subject Protection: *Changes*



Covington, Kentucky

Thursday October 6, 2016

JOINTLY SPONSORED BY

Schulman IRB

UK University of Kentucky

University of Cincinnati

Cincinnati Children's

HUMAN SUBJECT PROTECTION: CHANGES

THURSDAY, OCT 6, 2016

9:00 am – 10:00 am Registration

10:00 am – 10:15 am Welcome and Opening Remarks

Michael J. Woods, MS
President and CEO, Schulman IRB

Jane E. Strasser, PhD
Associate Vice President, University of Cincinnati

Ada Sue Selwitz, MA
Executive Integrity/Compliance Advisor, Office of Research Integrity, University of Kentucky

Jeremy Corsmo, MPH
Senior Director, Office of Research Compliance and Regulatory Affairs, Cincinnati Children's

10:15 am – 11:15 am

The Twins Study: NASA's First Foray into 21st Century Omics Research and Ethics

Craig Kundrot, PhD
Life Science Lead, Office of the Chief Scientist, NASA

Learning Objectives:

- Discuss the unusual ethical issues associated with astronauts participating as research subjects in genomic studies.
- Describe the protections NASA provided the research subjects in the Twins Study to address the ethical issues associated with astronauts participating as research subjects in genomic studies.
- Extrapolate how ethical issues of concern to astronaut research subjects might apply to other special populations.
- Summarize the comprehensive nature of the NASA Twins Study, ranging from genomics to cognition.

11:15 am – 12:15 pm

Privacy Risk and Big Data: The Promise and Peril of Re-Identification Research

Michelle N. Meyer
Assistant Professor and Associate Director for Research Ethics, Geisinger Health System

Learning Objectives:

- State the purpose and value of re-identification research.
- Identify the ethical and regulatory issues involved in re-identification research.
- Assess re-identification research protocols.
- Determine if a research protocol may create data sets vulnerable to re-identification attack.

12:15 pm – 1:15 pm Lunch

You Are A Hero: How Your Role In The Critical Trial Industry Impacts Real Research Subjects' Lives

Michael Noss, MD

Do you ever wonder if your job in the clinical research industry makes a difference or why your work is important? Dr. Noss, a principal investigator for over 20 years, answers these questions in a **video presentation.** Enjoy this opportunity to see and hear how clinical trials have affected a few of his hundreds of study participants.

1:15 pm – 2:15 pm

Digital Health Research: Ethical, Regulatory, and Technological Challenges and Opportunities for Researchers and IRBs - And What to Do About It

Jeremy Block, PhD
Managing Partner, Venture Catalyst

Learning Objectives:

- Identify strategies for conducting and reviewing digital/mHealth research protocols.
- Discuss privacy, security, and compliance issues in mobile/digital health research.
- Discover the range of digital and mHealth technologies and their potential application in research.

2:15 pm – 3:15 pm

An Update on Efforts to Modernize FDA's Clinical Trials and BIMO Programs

Janet Donnelly, RAC, CIP
Policy Analyst, FDA's Office of Good Clinical Practice

Learning Objectives:

- Discuss FDA's recent initiatives and accomplishments to address challenges in clinical trials and the FDA Bioresearch Monitoring Program (BIMO).
- Describe motivators for change that are driving FDA's efforts to modernize clinical trials and the BIMO program.
- Identify emerging program activities affecting future BIMO inspections.

3:15 pm – 3:30 pm Break

3:30 pm – 4:30 pm

Participant-Centered Research: If We Are Not at the Table, We Are on the Menu

Sharon Terry
President and CEO, Genetic Alliance

Learning Objectives:

- Explain the need to integrate participants into all phases of research.
- Summarize multiple ways of engaging patients and participants in a meaningful way.

4:30 pm – 4:40 pm Final Remarks, Evaluation, and Adjourn

Each session will include time for questions and answers with the panelists to allow for active learning opportunities.

PLEASE NOTE THAT THE PROGRAM AGENDA IS SUBJECT TO CHANGE

Program Overview

The purpose of this program is to provide information to institutional review board (IRB) members, IRB administrators, clinical investigators, research support staff, research sponsors and CROs, contract research organizations, government regulators, and members of the clinical research community about current issues regarding the protection of human subjects.

Conference Cost

$175

- Includes material, CME and CEU credit, meals and refreshments.
- An early-registration discounted rate of $125 is available to employees of the following co-sponsors: UC, UK, and Cincinnati Children's. To receive this rate, select the appropriate employee rate during registration. This early registration discount ends September 8, 2016.
- Registration ends Thursday, September 29, 2016. All payments are non-refundable.

To register online, visit www.**cincinnatichildrens**.org/cme and click the "Continuing Education Portal" link on the right for event registration. Seating is limited; please register early.

If you have questions about the conference, please email hspconference@sairb.com or contact Angela Kovatch at 513.761.4100.

Conference Location

The conference will take place at the Northern Kentucky Convention Center. Various parking options are available near the facility.

Travel & Hotel Accommodations

Airfare and hotel discounts may be available if booked through Victoria Travel. A limited number of discounted hotel rooms are available. To obtain the discounted hotel price, you must reserve a room by no later than September 8, 2016, at 12 noon. Call Trish at Victoria Travel at 1.800.626.4932, or email her at trish@victoriatravel.biz. Please reference the Human Subject Protection conference held October 6, 2016.

Continuing Education Information

Physicians: This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Cincinnati Children's and Schulman IRB. Cincinnati Children's is accredited by the ACCME to provide continuing medical education for physicians.

Cincinnati Children's designates this live activity for a maximum of 5.0 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nurses: 5.1 contact hours will be awarded to nurses who attend the entire program and complete an evaluation tool. Cincinnati Children's Hospital Medical Center is an approved provider of continuing nursing education by the Ohio Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation. (OBN-001-91) (OH-046, 9/1/2018

Psychologists: Cincinnati Children's is approved by the Ohio Psychological Association-MCE Program to offer continuing education for psychologists. Cincinnati Children's (provider #310833936) maintains responsibility for the program. 5.0 hours have been approved.

Social Workers: Cincinnati Children's Social Service is an approved provider of social work clock hours by the State of Ohio Counselor, Social Worker, and Marriage and Family Therapist Board (provider number RSX069302). This conference is approved for 5.0 social work continued education clock hours. The Social Work Program Area: Social Work Research

CIP: Conference sessions that meet the criteria in the Certified IRB Professional (CIP) recertification guidelines are eligible as accredited continuing education units.

Conference participants who hold the CIP® credential who wish to apply the 5.0 credits from this program toward CIP recertification may submit their Certificate of Attendance as documentation of their participation. This program has received advance recognition from the CIP Council. Additional information about CIP recertification can be found here: www.primr.org/certification/cip/recertification/

ABOUT THE JOINT SPONSORS

These programs are jointly sponsored by Schulman IRB, the University of Cincinnati, the University of Kentucky, and Cincinnati Children's as a service to the clinical research community.

Schulman IRB provides high quality, rigorous IRB reviews for all therapeutic areas and research phases in North America via streamlined processes, customized technology, and responsive customer service. We provide dedicated, AAHRPP-accredited IRB services for sponsors, CROs, research institutions, and sites and have an unparalleled clean audit history with FDA. We also offer CQA and HRP consulting via Provision Research Compliance Services and Falcon Consulting Group. For more information, visit Schulman's website at www.schulmanirb.com.

The University of Cincinnati (UC) serves as the Central IRB for StrokeNet, the largest NIH-funded extramural CIRB. UC is actively engaged in building local and regional collaborations aimed at protecting participants and facilitating research. Along with its Academic Health partners, UC is the recipient of a prestigious Clinical and Translational Science Award (CTSA) from the NIH (hhtp://cctst.uc.edu). In addition to conducting a wide range of clinical and pre-clinical trials to develop new medicines, medical devices and/or procedures UC researchers are also actively engaged in social, behavioral, and educational research. For more information, visit UC's Human Research Protection Program website at www.researchcompliance.uc.edu/HSR/Overview.aspx.

The University of Kentucky (UK) has nationally recognized and accredited programs for the protection of subjects involved in both human and animal research. In addition to 17 academic and professional colleges, UK possesses the states only NCI-Designated Cancer Center and NIH funded Center for Clinical and Translational Science (CCTS). The CCTS Regulatory Support & Research Ethics Core integrates faculty, staff, and community expertise in bioethics, regulatory knowledge, and research integrity. For more information, visit UK's website at www.research.uky.edu/ori or www.ccts.uky.edu.

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) houses the largest pediatric research program in the Midwest, conducting both basic and clinical research. Through its Cincinnati Children's Research Foundation, Cincinnati Children's is recognized for many research breakthroughs, including the Sabin oral polio vaccine, the rotavirus vaccine, the first practical heart-lung machine, and the surfactant preparation used worldwide to prevent premature infant deaths. Cincinnati Children's has been accredited by AAHRPP since 2007. Annually, its 2,000+ researchers and staff conduct more than 2,500 research protocols. For more information, visit Cincinnati Children's website at: www.cincinnatichildrens.org/research.