

# Human Subject Protection: **Roll With It**



Covington, KY  
October 4, 2018

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## 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, contract research organizations (CROs), government regulators, and members of the clinical research community about current issues regarding the protection of human subjects participating in clinical research.

### Conference Cost

**\$175**

- Includes material, CME and CEU credits, meals, and refreshments.
- An early-registration discounted rate of \$125 is available to employees of the following co-sponsors: Advarra, Cincinnati Children's, Northern Kentucky University, University of Cincinnati, and University of Kentucky. To receive this rate, select the appropriate employee rate during registration. This early registration discount ends August 31, 2018.
- Registration ends Thursday, September 27, 2018. All payments are non-refundable but transferrable thru 9/27/18.

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

### Conference Location

The conference will take place at the Northern Kentucky Convention Center. Various [parking](#) options are available near the facility. Click for [directions](#).

### Hotel Accommodations

A limited number of discounted hotel rooms are available at the Cincinnati Marriott RiverCenter, which is adjacent to the Northern Kentucky Convention Center via skywalk. Accommodations can be reserved online at a rate of \$169/night through 9/12/2018 at <https://book.passkey.com/go/advarrahsp2018>.

If you have any questions about the conference, please email [hspconference@advarra.com](mailto:hspconference@advarra.com) or call 513.761.4100 and ask to speak with someone about the HSP conference.

## Human Subject Protection: *Roll With It*

### Program Overview (Tentative)

7:30 am – 10:00 am Registration

8:15 am – 8:30 am

#### Welcome and Opening Remarks

Ada Sue Selwitz, MA  
Executive Integrity/Compliance Advisor  
UK CCTS and Office of the Vice President of  
Research University of Kentucky  
Michele Russell-Einhorn, JD  
Chief Compliance Officer and Institutional Official,  
Advarra

8:30 am – 9:30 am

#### Power and Privacy in Data and Biospecimen Research

Nicolle Strand, JD, M.Bioethics  
Temple University

Learning Objective:  
The attendees will be able to discuss why we should reframe how we think about research with data and biospecimens, moving away from a privacy framework toward a new framework focused on power.

9:30 am – 9:45 am **Break**

9:45 am – 10:45 am

#### Social Black Holes: The Ethics of Research on Illicit or Morally Compromising Market Actors

Kimberly Kay Hoang, Ph.D.  
University of Chicago

Learning Objective:  
The attendees will be able to discuss research ethics across different countries and given cultural contexts.

10:45 am – 11:45 am

#### Conducting Trials and Protecting Subjects in the Emergency Setting

Robert Silbergleit, MD  
University of Michigan

Learning Objective:  
The attendees will be able to describe the challenges of clinical research in the emergency setting, and explain ways in which human subject protections can be implemented and regulated in the acute care environment.

11:45 am – 1:15 pm **Lunch**  
Optional: **Ask the IRB Chairs Panel Discussion**

Learning Objective:  
The attendees will be able to discuss issues presented to Institutional Review Boards when reviewing proposed clinical research.

1:15 pm – 2:15 pm

#### mPower: A Case Study in Open Models of Precision Medicine

Megan Doerr, MS, LGC  
Sage Bionetworks

Learning Objective:  
The attendees will be able to discuss the benefits and risks of open models of precision medicine, citing specific examples from the Parkinson mPower study.

2:15 pm – 2:30 pm **Break**

2:30 pm – 3:30 pm

#### What's on Our Plate Now: Current Issues Affecting the Institutional Regulatory Landscape

John Baumann, Ph.D.  
Indiana University

Learning Objective:  
The attendees will be able to describe the impact upon their HRRP and research practices as a result of the current and changing regulations.

3:30 pm – 4:30 pm

#### Beyond the Regulations: Improving the Consenting Process

Susie Hoffman, RN, BSN, CIP  
University of Virginia

Learning Objective:  
The attendees will evaluate practical methods to improve both the consent form and process in order to obtain truly informed consent in their own practices.

4:30 pm – 4:45 pm

#### Final Remarks, Evaluation Information, and Adjourn

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

Please note that the program agenda is subject to change.

## 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 Advarra. 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 7.0 AMA PRA Category 1 Credit(s)<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**Nurses:** 7.25 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)

**Ohio Psychology:** 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. 5.5 hours have been approved – Regular CE.

**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<sup>®</sup> who wish to apply the 6.0 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/](http://www.primr.org/certification/cip/recertification/)

## About the Host Institutions and Sponsors

**Advarra:** [www.advarra.com](http://www.advarra.com)

**Cincinnati Center for Clinical and Translational Science and Training (CCTST):** <https://cctst.uc.edu/>

**Cincinnati Children's:** [www.cincinnatichildrens.org/research](http://www.cincinnatichildrens.org/research)

**Northern Kentucky University:** <https://inside.nku.edu/rgc/research-compliance.html>

**University of Cincinnati:** <http://www.researchcompliance.uc.edu/HSR/Overview.aspx>

**University of Kentucky Office of Research Integrity:** [www.research.uky.edu/ori](http://www.research.uky.edu/ori)

**University of Kentucky Center for Clinical and Translational Science (CCTS):** [www.ccts.uky.edu](http://www.ccts.uky.edu)

**We're looking forward to seeing you on October 4<sup>th</sup>!**