Human Subject Protection:
I WILL SURVIVE!

2019 Conference Brochure

September 5, 2019 | Covington, KY

ADVARRA | Cincinnati Children's changing the outcome together | University of Cincinnati | Office of Research Integrity | NKU Northern Kentucky University | CCTST Center for Clinical & Translational Science & Training | Center for Clinical and Translational Science

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.

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.

Conference Cost

Full Day: **$175**

New This Year:
Morning-Only/PI-Focused Option: **$125**

- Includes material, CME and CEU credits, meals, and refreshments (Morning-Only registration excludes lunch).
- An early registration $50 discount is available to employees of the host institutions shown above. To receive the discount, select the appropriate employee rate during registration. This early registration discount ends July 31, 2019.
- Registration ends Friday, August 30, 2019. All payments are non-refundable but transferrable through August 30.

Conference location

The conference will take place at the Northern Kentucky Convention Center. Various parking options are available near the facility. Click here 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 August 14, 2019.

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

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Please note: Program agenda is subject to change

Program Overview (Tentative)

7:30am–8:30am **Registration**

8:15am–8:30am **Welcome & Opening Remarks**
Sara Harnish, JD | Executive IRB Chair, Advarra
Ada Sue Selwitz, MA | Executive Integrity & Compliance Advisor, University of Kentucky

8:30am – 9:30am **What Are the Research Risks of Pragmatic Randomized Control Trials (RCTs) Comparing "Standard of Care" Treatments?**
Scott Kim, MD, PHD | National Institutes of Health
Learning Objective:
The attendees will be able to identify the ethical issues regarding research risks and informed consent in pragmatic "standard of care" RCTs and identify/evaluate key research risks of such RCTs.

9:30am–9:45am **Break**

9:45am–10:45am **Biorepositories...New Regulations: Old Headaches & Evolving Challenges**
Pearl O'Rourke, MD | Partners Healthcare
Learning Objective:
The attendees will be able to discuss how to plan for changing expectations of data and tissue donors and how regulations impact data and tissue repositories.

10:45am–11:45am **When Human Rights, Big Tech, and Research Ethics Collide!**
Mary Gray, PhD | Senior Researcher, Microsoft Research New England; Associate Professor, School of Informatics, Computing, and Engineering – Indiana University; Fellow, Harvard University Berkman Klein Center for Internet and Society
Learning Objective:
The attendees will be able to assess the benefits of a predictive system and identify the stakeholders impacted by them; maximize the inclusion and diversity of AI systems; and demonstrate respect for the rights and freedoms of individuals and society when interacting with them through large-scale, online systems that, for the average person, are not just data-rich but deeply social environments.

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

11:45am–1:15pm **Lunch**

12:00pm-1:00pm **Ask the IRB Chairs Panel Discussion** *(optional)*
Learning Objective:
The attendees will be able to submit and discuss issues presented to Institutional Review Boards when reviewing proposed clinical research. ***Please submit questions in advance to ORCRAEducation@cchmc.org.***

1:15pm - 2:15 pm **Surviving Stage IV and The Hurdles of Clinical Research Participation**
T.J. Sharpe
Learning Objective:
The attendees will be able to identify the importance of trial and treatment option awareness between physicians and patients. Attendees will also be able to navigate roadblocks in trial access and discuss survivorship effect of patient access to trial medicines.

2:15pm–2:30pm **Break**

2:30pm–3:30pm **Reviewing Serious & Continuing Noncompliance – Can We Harmonize?**
Nichelle Cobb, PhD | University of Wisconsin-Madison
Learning Objective:
The attendees will be able to identify ways institutions vary in their definitions and processes for the reporting and review of serious and continuing noncompliance as well as the challenges in these approaches, especially in light of single IRB review. Through case studies, attendees will examine key components of the process for assessing and developing corrective action plans and identify areas where approaches to serious and continuing noncompliance can be harmonized.

3:30pm–4:30pm **The 7 Habits of Highly Effective Clinical Research Teams**
Jennifer Goldfarb, MSN, RN, CCRP | ACI Clinical
Learning Objective:
The attendees will be able to implement strategies to lead effective and efficient high-performing study teams and provide insight into various communication styles and techniques for successful communication, including giving and receiving feedback and conflict management skills.

4:30pm–4:45pm **Final Remarks, Evaluation Information, and Adjourn**

Continuing Education Information

In support of improving patient care, this activity has been planned and implemented by Cincinnati Children's, Northern Kentucky University, and Advarra. Cincinnati Children's is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

CME: Cincinnati Children's designates this live activity for a maximum of 6.0 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nursing: This activity is approved for a maximum 6.0 continuing nursing education (CNE) contact hours.

IPCE: This activity was planned by and for the healthcare team, and learners will receive 6.0 Interprofessional Continuing Education (IPCE) credits for learning and change.

Social Work: 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 6.0 social work continued education clock hours. The Social Work Program Area: Social Work Research

Psychology: 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. 6.0 hours have been approved – Ethics Credit.

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

Credits for Optional Ask the IRB Chairs Panel Discussion

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CME: Cincinnati Children's designates this live activity for a maximum of 1.0 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nursing: This activity is approved for a maximum 1.0 continuing nursing education (CNE) contact hours.

IPCE: This activity was planned by and for the healthcare team, and learners will receive 1.0 Interprofessional Continuing Education (IPCE) credits for learning and change.

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 1.0 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.

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We're looking forward to seeing you on September 5th!