

Human Subject Protection

Takin' Care of Business

Covington, Kentucky
Thursday and Friday, October 1 and 2, 2015



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 **Cincinnati
Children's**
Hospital Medical Center

HUMAN SUBJECT PROTECTION: TAKIN' CARE OF BUSINESS

THURSDAY, OCT 1, 2015

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 Associates IRB

Jane E. Strasser, PhD

Associate Vice President, University of Cincinnati

Belinda Smith, MS, RD, CCRC

Research Education Specialist, Office of
Research Integrity, University of Kentucky

Jeremy Corsmo, MPH

Senior Director, Office of Research Compliance and
Regulatory Affairs, Cincinnati Children's Hospital
Medical Center

10:15 am – 11:15 am

The Patient's Perspective: Why Clinical Trials Matter

Charles Sabine, BA

Emmy Award-Winning Television Journalist

Learning Objectives:

- Explain how clinical research as a whole is part of the greater good of aspiring to care for the infirm
- Identify learning opportunities from research that did not result in new treatments to progress clinical trials
- Demonstrate enhanced collaboration with clinical researchers, government and regulatory entities, pharmaceutical companies, and subjects and their families to create a brighter future for clinical research

11:15 am – 12:15 pm

Using Empirical Evidence to Reduce Consent Form Length

Amy Corneli, PhD, MPH

Scientist II, Social and Behavioral Health Sciences, FHI 360

Learning Objectives:

- Describe strategies for reducing the length of informed consent forms
- Discuss barriers to reducing the length of informed consent forms as identified by key stakeholders – research participants and staff, members of institutional review boards, community representatives, institutional officials, and regulatory members – who were interviewed for the EDICT study
- Examine specific strategies for reducing consent form length that were identified and supported by the stakeholders through a consensus-building research process

12:15 pm – 1:15 pm Lunch

1:15 pm – 2:15 pm

Informed Consent in a Mobile Era

John Wilbanks, BA

Chief Commons Officer, Sage Bionetworks

Learning Objectives:

- Discuss emerging informed consent processes tied to a mobile climate
- Describe tiered and hierarchical knowledge structures for consent
- Discuss the role of icons and pictographs for consent
- Explain how the processes presented are working in IRB approved studies

2:15 pm – 3:15 pm

How to Make the IRB Your BFF

Michelle Feige, MSW, LCSW-C

Executive Vice President, Accreditation of Human
Research Protection Programs, Inc. (AAHRPP)

Learning Objectives:

- In this session, faculty will suggest ways to improve the working relationship between the researcher and

the IRB to ensure mutually beneficial interactions resulting in increased efficiency in the IRB process of research review and approval

- Faculty will teach ways for the IRB to assist researchers to more efficiently move research proposals through the IRB process, such as conducting pre-reviews, and ensuring researcher understanding of the regulatory requirements for informed consent and IRB criteria for approval
- Faculty will explain when and how researchers are required to interact with and get approval from the IRB, per the regulations
- Faculty will discuss both investigator and IRB responsibilities, such as reporting and communication requirements

3:15 pm – 3:30 pm Break

3:30 pm – 4:30 pm

Reality vs. Perception: What a Site Really Needs to Do to Be GCP Compliant

Liz Wool, CCRA, CMT

President and CEO, QD-Quality and Training Solutions, Inc.

Learning Objectives:

- Explain how clinical trial execution requirements in 2015 are about the prospective cycle of quality
- Distinguish attributes of patient care - health care standards- clinical care and scope of practice that apply to the execution of clinical trial
- Translate regulatory agency expectations regarding clinical investigator supervision, oversight and control of the clinical investigation

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.

PRIM&R'S SPECIMENS, SERVERS, SETTINGS, AND SITUATIONS: ETHICAL CONSIDERATIONS IN PROTOCOL DESIGN, CONDUCT, AND REVIEW

FRIDAY, OCT 2, 2015

8:00 am – 8:15 am Welcome and Opening Remarks

8:15 am – 9:30 am

Research on Biological Specimens

George Gasparis, CIP

President, The PEER Consulting Group, LLC

Learning Objectives:

- Describe nuances affecting research on biological specimens
- Explore the definition of human subjects research and relevant regulations
- Review categories of HBS collection and appropriate IRB review
- Examine the requirements for consent/authorization and waivers or alterations of consent/authorizations
- Discuss IRB review of tissue banks

9:30 am – 9:45 am Break

9:45 am – 11:00 am

Internet Research

Dean Gallant, AB

Consultant, HRP Consulting Group, Inc.

Learning Objectives:

- Describe issues involving internet research
- Outline IRB review requirements for internet research protocols
- Describe issues involving the consent process and privacy and confidentiality
- Analyze data security issues that arise in internet research

11:00 am – 12:15 pm

International Research

Dean Gallant, AB

George Gasparis, CIP

Learning Objectives:

- Identify challenges of conducting research outside the US
- Consider the application of US research ethics standards to research settings in different cultures
- Identify applicable policies, regulations, and laws, and recognize their differences
- Identify and address challenges of conducting research outside of the US
- Provide resources for investigators, staff, and IRB/REC members

12:15 pm – 1:15 pm Lunch

1:15 pm – 2:15 pm

Case Studies in Biomedical Research and Social/Behavioral/Education Research

Dean Gallant, AB

George Gasparis, CIP

In addition to instructor-provided case studies, participants will be asked (in advance of the event) to share redacted copies of cases they'd like to discuss and on which they'd like input or guidance.

Learning Objective:

- Apply case scenario learnings to professional research

2:15 pm – 3:15 pm

Unanticipated Problems and Adverse Events

George Gasparis, CIP

Learning Objectives:

- Describe the regulatory context of unanticipated problems and adverse events
- Develop a useable definition of UPs
- Understand the HHS and FDA reporting requirements
- Gain insight on how to determine relationship of an adverse event to an investigational intervention (i.e., drug, biologic, device, behavioral therapy)

3:15 pm – 3:30 pm Break

3:30 pm – 4:30 pm

Case Studies and Q&A

Dean Gallant, AB

George Gasparis, CIP

In addition to instructor-provided case studies, participants will be asked (in advance of the event) to share redacted copies of cases they'd like to discuss and on which they'd like input or guidance. Presenters will also answer additional questions related to course content.

Learning Objective:

- Apply case scenario concepts to professional research

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

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

DAY 1 Human Subject Protection	\$150 <ul style="list-style-type: none">Includes material, CME and CEU credit, meals and refreshmentsA discounted rate of \$100 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 August 31, 2015
DAY 2 PRIM&R Ethical Considerations	\$150 <ul style="list-style-type: none">Includes material, CME and CE credit, meals and refreshments
DAY 1 and DAY 2 Full Conference	\$250 <ul style="list-style-type: none">Includes above mentioned items

Registration ends Friday, September 18, 2015.

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.

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 Hospital Medical Center and Schulman Associates Institutional Review Board, Inc. 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 (Day 1) and 6.25 (Day 2) 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 (Day 1) and 6.5 (Day 2) contact hours will be awarded to nurses who attend the entire program and complete an evaluation tool. Cincinnati Children's Hospital Medical Center (OH-046/ 9-1-2015) is an approved provider of continuing nursing education by the Ohio Nurses Association (OBN-001-91), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

Psychologists: Cincinnati Children's Hospital Medical Center 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 (Day 1) and 6.5 (Day 2) hours have been approved.

Social Workers: Cincinnati Children's Hospital Medical Center 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 (Day 1) and 6.75 (Day 2) 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. Please note that the session titled "How to Make the IRB Your BFF" is not eligible, but the rest of the sessions are, yielding 4.0 (Day 1) and 6.75 (Day 2) hours of applicable credit to those who attend these sessions.

Conference participants who hold the [CIP® credential](#) who wish to apply the 6.75 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

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 11, 2015, at 12 noon. Call Trish at Victoria Travel at 1.800.626.4932, or email her at [Please reference the Human Subject Protection conference held October 1- 2, 2015.](#)

ABOUT THE JOINT SPONSORS

These programs are jointly sponsored by Schulman Associates IRB, the University of Cincinnati, the University of Kentucky, Cincinnati Children's Hospital Medical Center, and Public Responsibility in Medicine and Research (PRIM&R) as a service to the clinical research community.



Schulman Associates IRB (Schulman) 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 our partner Provision Research Compliance Services. For more information, visit Schulman's website at www.sairb.com.



The University of Cincinnati (UC) along with its Academic Health partners, is the recipient of a prestigious Clinical and Translational Science Award (CTSA) from the NIH (cctst.uc.edu). UC conducts a wide range of clinical and pre-clinical trials to develop new medicines, medical devices, and/or procedures. 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 16 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 1,800+ researchers and staff conduct more than 2,400 research protocols. For more information, visit Cincinnati Children's website at www.cincinnatichildrens.org/research.



Public Responsibility in Medicine and Research (PRIM&R) advances the highest ethical standards in the conduct of biomedical, behavioral, and social science research. We accomplish this mission through education, membership services, professional certification, public policy initiatives, and community building. PRIM&R is a 501 (c) (3) non-profit organization. For more information, visit PRIM&R's website at www.primr.org.