

# AGENDA

**8:00 AM - 9:00 AM** Registration

**9:00 AM - 9:15 AM**

**Welcome & Opening Remarks**

**John M. Isidor, JD**

CEO, Schulman Associates IRB, Inc.

**Sandra Degan, PhD**

Vice President for Research,  
University of Cincinnati Academic Health Center

**Ada Sue Selwitz, MA**

Director, Office of Research Integrity  
University of Kentucky

**9:15 AM - 10:15 AM**

**Jeremy Sugarman, MD, MPH, MA**

Harvey M. Myerhoff Professor of Bioethics and  
Medicine  
Johns Hopkins University

**USING DATA TO RATTLE RESEARCH ETHICS**

*Learning Objectives:*

- Explain how obtaining informed consent is a process
- Identify the value and impact of managing conflicts of interests through disclosure
- Describe ways to rigorously evaluate the informed consent process

**10:15 AM - 10:30 AM** Break

**10:30 AM - 11:15 AM**

**Stephen Rhodes, Invited**

Director of IDE and HDE Programs  
Food and Drug Administration

**THE DEVICE REGULATIONS AND GCPS**

*Learning Objectives:*

- Compare and Contrast the Medical Device and Drug Regulations
- Describe the Responsibilities of an IRB reviewing Medical Device Trials
- Identify the FDA Monitoring Program for Medical Device Trials

**11:15 AM - 12:15 PM**

**Steven Walker, MS**

Co-Founder and Chief Advisor  
Abigail Alliance for Better Access to  
Developmental Drugs

**A TERMINAL PATIENT'S PERSPECTIVE:  
A DIFFERENT SET OF CHALLENGES**

*Learning Objectives:*

- Identify the Role of a Patient Advocate
- Describe the problems of the clinical trials system in dealing with the terminally ill
- Discuss lessons to be learned from a research case involving patients seeking access to investigational drugs

**12:15 PM - 1:15 PM** Lunch

**1:15 PM - 2:15 PM**

**B. R. Simon Rosser, PhD, MPH, LP**

Professor, Director of HIPS Program,  
University of Minnesota

**CONDUCTING CONTROVERSIAL HUMAN  
SUBJECT SEX RESEARCH**

*Learning Objectives:*

- Discuss the politics of sex research and the role of the IRB
- Identify strategies to get past "no" when conducting sex research
- Describe a new scale: Whether your IRB is from heaven or hell?
- Explain the importance of the relationship between the researcher and IRB in behavioral science

**2:15 PM - 3:15 PM**

**Don Workman, PhD**

Executive Director, OPRS  
Assistant Professor of Psychiatry and Behavioral  
Sciences, Northwestern University

**BECOMING A GOOD IRB: PROMOTING  
RESPECT FOR AN IRB'S ADVICE AND COUNSEL**

*Learning Objectives:*

- Explain the regulatory requirement that an IRB should earn the respect of the research community
- Explain the impact of two controversial behavioral research studies on the community reputation of the reviewing IRBs
- Describe the application of helpful and harmful group practices to IRBs

**3:15 PM - 3:30 PM** Break

**3:30 - 4:30 PM**

**C. K. Gunsalus, JD**

Special Counsel in the Office of University  
Counsel, Adjunct Professor of Law, Medicine and  
Business, University of Illinois, Urbana-Champaign

**CAN YOU BE ETHICAL WITHOUT BEING  
COMPLIANT AND COMPLIANT WITHOUT BEING  
ETHICAL?**

*Learning Objectives:*

- Describe ethics in a culture of compliance
- Explain "mission creep" and identify its dangers
- Describe the challenges of trying to be both ethical and compliant

**TARGET AUDIENCE** The target audience includes  
physicians and others who conduct human subject  
research, IRB Board members and staff, research  
sponsors and CROs, government regulators and  
members of the clinical research community.

**CONTINUING EDUCATION INFORMATION**

Nursing CEU and CME credit hours will be available to  
conference attendees. The application cost for Medical and  
Nursing is \$10.00. (All payments are non-refundable) 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 the University of Cincinnati, Schulman  
Associates Institutional Review Board, Inc. and the University  
of Kentucky. The University of Cincinnati is accredited by the  
Accreditation Council for Continuing Medical Education to  
provide continuing medical education for physicians. The  
University of Cincinnati designates this activity for a  
maximum of 6 AMA PRA Category 1 Credit(s)<sup>TM</sup>. Physicians  
should only claim credit commensurate with the extent of  
their participation.

Approved contact hours: 6.0 continuing education contact  
hours for nurses are approved by the Ohio Board of Nursing  
through the OBN Approver Unit at the University of Cincinnati  
College of Nursing Continuing Education Program, (OBN-011-  
93, Program #080926-1). Please contact Developmental Affairs  
at 513/558-5311 regarding approval status. Contact hours are  
valid in most states.

**REGISTRATION FORM**

Return your completed registration form along with method  
of payment to Belinda Smith, UK Office of Research  
Integrity, 309 Kinkead Hall, Lexington, KY 40506-0057.

**Your UK business manager may pay your registration  
fee by crediting cost center 1013200030-530503 after  
the conference has taken place.**

**(All payments are non-refundable)**

At UK, questions about the conference, may be directed to  
Belinda Smith at (859) 323-2446 or belinda.smith@uky.edu.

## University of Kentucky Registration Form

(for use by UK Researchers and Research Staff)

**HUMAN SUBJECT PROTECTION:  
STILL CHALLENGING AFTER ALL THESE YEARS**

**(conference satisfies UK human research protection  
continuing education requirement)**

FRIDAY, SEPTEMBER 26, 2008  
9:00 AM - 4:30 PM

(Please Type or Print- ALL INFORMATION REQUIRED)

Name: \_\_\_\_\_

Degree: \_\_\_\_\_

Employer: \_\_\_\_\_

Address: \_\_\_\_\_

City: State: Zip: \_\_\_\_\_

Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

For Nursing CEUs or CMEs:

RN Number: \_\_\_\_\_ State: \_\_\_\_\_

\*Social Security Number: \_\_\_\_\_

Birth Date (mm/dd/yyyy): \_\_\_\_\_

**\*Your full social security number is required to receive  
Nursing credit. For CME credits, only the last 4 digits of  
your social security number and birth date are required.**

**ALL PAYMENTS ARE NON-REFUNDABLE.**

- Conference only** Early Bird \$80.00 (limited number)
- Conference only** \$150.00 (after reduced slots are filled)
- Nursing CE** \$10.00 (payable to University of Cincinnati)
- CME credit** \$10.00 (payable to University of Cincinnati)

**Note:** You must apply for credit in advance. Requests for  
credit will not be honored after the day of the conference.

Your registration fee and Nursing/CME credit fee, if  
applicable, are **two separate fees**. PAYMENT for registration  
may be made by check (payable to the University of  
Kentucky) or credited to cost center 1013200030-530503.  
PAYMENT for CME/Nursing credit may be made by  
check only (payable to University of Cincinnati).

**Send registration and applicable payment to:**  
UK Office of Research Integrity, C/O Belinda Smith  
309 Kinkead Hall, Lexington, KY 40506-0057  
belinda.smith@uky.edu FAX: 859-257-8995

## Conference Objectives and Overview

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

### Objectives

At the end of this conference attendees should be able to:

- Describe various challenges in properly obtaining informed consent.
- Explain the differences between the FDA Drug and Device regulations.
- Discuss the issues regarding allowing terminally ill patients to have access to investigational drugs.
- Identify the politics involved in the review of sex research.
- Explain how the IRB can gain community respect
- Describe the differences between ethics and compliance

### Overview

The first speaker will use empirical data to describe things that are effective in obtaining informed consent. Our next speaker will compare and contrast the FDA Drug and Device regulations. Our third speaker will describe whether the terminally ill should be given access to investigational drugs. Following lunch, our speaker will explain the politics of conducting and reviewing sex research. Our next speaker will discuss how IRB review interacts with the obligation to earn community respect. The conference will conclude with a provocative presentation regarding the challenges in being both ethical and compliant.

### Conference Cost

The conference is jointly sponsored by the University of Cincinnati, Schulman Associates IRB, Inc., and the University of Kentucky as a service to the clinical research community. The cost to attend the conference is \$150.00. This fee includes conference materials, lunch and refreshments.

Please register early, as seating is limited.

(All payments are non-refundable.)

## About the Sponsors

**SCHULMAN ASSOCIATES IRB** Schulman Associates Institutional Review Board, Inc. (SAIRB) is a national, accredited independent IRB established in 1983. For more information, visit SAIRB's web site at [www.sairb.com](http://www.sairb.com).

**UNIVERSITY OF CINCINNATI** The University of Cincinnati (UC) conducts a wide range of clinical trials to develop new medicines, devices or procedures so physicians will learn more about the treatment of medical diseases and conditions. For more information, visit UC's web site at [www.research.uc.edu](http://www.research.uc.edu).

**UK UNIVERSITY OF KENTUCKY** The University of Kentucky (UK) has a nationally recognized program for the protection of subjects involved in both human and animal research. UK has been consistently recognized for providing national leadership in the development of protections for human subjects in clinical research. The UK human research program is fully accredited by AAHRPP. For more information, visit UK's web site at [www.research.uky.edu/ori](http://www.research.uky.edu/ori).

### Conference Location

The conference will take place at the Northern Kentucky Convention Center, located just across the Ohio River from downtown Cincinnati at One W. RiverCenter Boulevard, Covington, Kentucky 41011.

For information about local events happening in the area September 22-26, 2008 please visit [www.cincinnatiusa.com/VisitorInfo/index.asp](http://www.cincinnatiusa.com/VisitorInfo/index.asp).

### Directions

**From Cincinnati/Northern Kentucky International Airport:** Take I-275 East to I-71/75 North. Exit 192/Covington-Fifth Street. On Fifth Street, go six blocks; turn left on Madison to RiverCenter Blvd. The Convention Center is on the left.

**From Lexington, KY:** Take I-75 North to Exit 192/Covington-Fifth Street... same as above. **From Cincinnati, OH:** Take I-75 South to Exit 192/Covington-Fifth Street... same as above.

### Travel & Hotel Accommodations

Airfare and hotel discounts may be available if booked through Victoria Travel. For cheaper airfares, consider the Dayton, Ohio airport which is about an hour's drive from the convention hotel. A limited number of discounted hotel rooms are available at the Embassy Suites. To obtain the discounted hotel price, you must reserve a room by no later than August 29, 2008.

Call Victoria Travel at 800-626-4932 and ask for Trish or email her at [Trish@victoriatravel.biz](mailto:Trish@victoriatravel.biz), and please reference the Human Subject Protection conference on September 26, 2008.

**Suggested Hotel:** (Across from the Northern Kentucky Convention Center) Embassy Suites - 10 E. RiverCenter Blvd., Covington, KY.

309 Kinkhead Hall  
Lexington, KY 40506-0057

**UK UNIVERSITY OF KENTUCKY**  
Office of Research Integrity

# Human Subject Protection:

*Still Challenging  
After All These Years*



**Friday, September 26, 2008**  
**9:00 AM - 4:30 PM**

Northern Kentucky Convention Center  
Covington, Kentucky

**SCHULMAN ASSOCIATES IRB**

**UNIVERSITY OF CINCINNATI**

**UK UNIVERSITY OF KENTUCKY**

**Attendance at this conference will satisfy the University of Kentucky mandatory human research protection continuing education requirement.**