

Subject: General Announcement: UK Human Research Protection Conference Registration Form and Agenda

Attachments: 2007 Schulman Brochure for UK

To All University of Kentucky Research Investigators, Research Staff, and Study Personnel:

Attached is the registration form and agenda for the UK Human Research Protection Conference to be held at Covington on October 19, 2007. We sincerely hope that all of you can attend this important conference.

Note that PAYMENT for registration may be made by check (payable to the University of Kentucky) or credited to cost center 1013200030. PAYMENT for CME/Nursing credit may be made by check only (payable to the University of Cincinnati).

Please excuse any duplicate mailings.

Cheers,

Scott A. McIntosh, MHP
University of Kentucky
Office of Research Integrity
309 Kinkead Hall
Lexington, KY 40506-0057
(859)257-6072

8/30/2007

Human Subject Protection: The Long and Winding Road
Friday, October 19, 2007
9:00 am - 4:30 pm
Northern Kentucky Convention Center
Covington, Kentucky

Registration Form for UK Researchers and Research Staff

(Please Type or Print- ALL INFORMATION IS REQUIRED)

Name: _____
Degree: _____
*Last Four Digits of Social Security Number: _____
*Birth Date (mm/dd/yyyy) _____
Employer: _____
Address: _____
City: State: Zip: _____

Phone: _____
Fax: _____
E-mail: _____
RN Number: _____ State: _____

Payment is required with registration. ALL PAYMENTS ARE NON-REFUNDABLE. Your registration fee and Nursing/CME credit fee (if applicable) are two separate fees and must be paid separately.

- Conference only—Early Bird \$75.00 (until reserved slots are filled)
- Conference only \$150.00 (after reserved slots are filled)
- Nursing credit \$10.00
- CME credit \$10.00

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

PAYMENT for registration may be made by check (payable to the University of Kentucky) or credited to cost center 1013200030. PAYMENT for CME/Nursing credit may be made by check only (payable to the University of Cincinnati). For further information, see page 4.

Send registration and, if applicable, Nursing/CME credit payment to:

**Office of Research Integrity
C/O Scott McIntosh
309 Kinkead Hall
Lexington, KY 40506-0057
scottm@uky.edu**

CONFERENCE AGENDA

8:00 am - 9:00 am *Registration*

9:00 am - 9:15 am

Welcome & Opening Remarks

9:15 am - 10:15 am

David H. Strauss, M.D

Director of Human Subjects Research,
Associate Clinical Professor of Psychiatry,
Columbia University

Research Challenges With The Decisionally Impaired

Learning Objectives:

- Identify the complex nature of doing research with the decisionally impaired.
- Explain the regulatory framework that governs research with the decisionally impaired
- Describe barriers to improving research with the decisionally impaired

10:15 am - 10:30 am - *BREAK*

10:30 am – 11:15 am

Susan Kornetsky, M.P.H., C.I.P.,

Director Of Clinical Research Compliance,
Boston Children's Hospital

Children In Research: Interpreting and Applying The Pediatric Regulations

Learning Objectives:

- Describe the History of Subpart D -
- Identify the Terms and Definitions used in Pediatric Research
- Discuss the application of the regulations to different types of pediatric research

11:15-12:15 pm

E. Haavi Morreim, Ph.D

Professor, Department of Human Values and Ethics,
University of Tennessee, College of Medicine

Caught in the Cross-Hairs: Litigation in Clinical Research

Learning Objectives:

- Describe the history of litigation involving clinical research

- Identify why courts misunderstand clinical research
- Discuss lessons to be learned from a highly publicized research case

12:15 pm - 1:15 pm - LUNCH

1:15 pm -2:30 pm

Elizabeth Moench,
President & CEO, MediciGroup, Inc.
June Smith Tyler, J.D., Counsel,
Schulman Associates IRB

Ethical Approaches to Subject Recruitment

Learning Objectives:

- *Discuss how market pressures affect the ethics of subject recruitment strategies*
- *Explain how the regulations and research guidances interact with subjects' expectations*
- *Describe ethical concerns with some recruitment methods*
- Identify several case studies and how ethical recruitment strategies were applied

2:30 pm - 3:15 pm

Ivor Pritchard, Ph.D.,
Senior Fellow, Office for Human Research Protections

Exempt Research and Expedited Research: What The (*@!&?) Are They?

Learning Objectives:

- Identify how to apply the categories of exempt Research
- Describe the ethical concerns with exempt research
- Identify how to determine whether research can be reviewed by expedited review
- Describe what is and what is not minimal risk research

3:15 pm - 3:30 Break

3:30- 4:30 pm

Ernest D. Prentice, Ph.D.,
Associate Vice Chancellor for Academic Affairs,
University of Nebraska Medical Center

Investigator and IRB Member Conflicts of Interest

Learning Objectives:

- *Describe the genesis of concerns about conflicts of interest*
- Define a conflict of interest
- Describe the different types of conflicts of interest

- Identify different approaches in managing conflicts of interest

Target Audience

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

CONTINUING EDUCATION INFORMATION

Nursing CEUs & CMEs

The University of Cincinnati designates this educational activity for a maximum of 6 AMA PRA Category 1 Credit(s)[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity. This activity has been planned and implemented in accordance with the Essentials and Policies of the Accreditation Council for Continuing Medical Education (ACCME). The University of Cincinnati is accredited by the ACCME to provide continuing medical education for physicians.

Approved contact hours: 7 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). 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 check made payment to **The University of Cincinnati** if you are requesting Nursing/CME credit) to: Scott McIntosh, Office of Research Integrity, 309 Kinkead Hall, Lexington, KY 40506-0057. Your UK business manager can pay your registration fee by creating a parked document within SAP using screen FV50 crediting cost center 1013200030. When applying for Nursing CEU or CME credit hours, ***you must provide your social security number and indicate the type of credit for which you are applying. Registered Nurses must provide license number and state of issue.***

(All payments are non-refundable)

If you have any questions about the conference, please contact Scott McIntosh at (859) 257-6072 or samcin1@uky.edu

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 challenges in conducting research with the decisionally impaired.
- Identify current policies and regulations regarding research with children.
- Discuss the history of litigation involving clinical research.
- Identify ethical approaches to subject recruitment.
- Explain how to apply the categories of exempt research and expedited review.
- Describe how to identify and manage conflicts of interest with investigators and IRB members.

Overview

The first speaker will describe the ethical challenges in conducting research with the decisionally impaired. Our next speaker will clarify the application of the pediatric regulations. Our third speaker will describe different court cases involving clinical research. Following lunch, our speakers will use case studies to identify ethical and effective recruitment strategies. Our next speaker will clarify the morass surrounding the application of exempt research and expedited review. The conference will conclude with a provocative presentation regarding investigator and IRB member conflicts of interest.

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. A limited number of seats are available at a reduced rate of \$75.00 on a first-come, first-served basis. UK Business managers may create a parked document within SAP using screen FV50. Please credit cost center 1013200030 for the registration fees. Please register early, as seating is limited. Registration fees include conference materials, lunch and refreshments.

(All payments are non-refundable)

ABOUT THE SPONSORS

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.

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.

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. For more information, visit UK's web site at www.rgs.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 October 14–21, 2007 please visit <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 to the right.

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 September 27, 2007. Call Victoria Travel at 800-626-4932 and ask for Trish or email her at Trish@victoriatravel.biz, and please reference the Human Subject Protection conference on October 19, 2007.

Suggested Hotel:

(Across from the NK Convention Center) Embassy Suites -10 E. RiverCenter Blvd., Covington, KY.