

AGENDA

8:00 AM - 9:00 AM

Registration & Continental Breakfast

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

Stephen B. Thomas, PhD

Director, Center for Minority Health

University of Pittsburgh

BEYOND THE LEGACY OF TUSKEGEE: ENGAGING AFRICAN AMERICAN COMMUNITIES IN RESEARCH

Learning Objectives:

- Describe the historical and social context that enabled the Tuskegee study to begin and to go on for 40 years.
- Describe the most common misconceptions about the Tuskegee Study.
- Describe how the aftermath of the Tuskegee Study strengthened protection of human subjects guidelines in the Belmont Report.
- Identify the impact of Tuskegee on minority recruitment into research.
- Describe new and innovative models for building trust needed to engage African Americans and other minority populations in research.

10:15 AM - 10:30 AM Break

10:30 AM - 11:30 AM

Neal W. Dickert, MD, PhD

Fellow, Cardiovascular Disease Fellowship Training

Program, Emory University School of Medicine

TWO CHALLENGES TO INFORMED CONSENT: PAYMENT FOR PARTICIPATION AND RESEARCH IN MEDICAL EMERGENCIES

Learning Objectives:

- Define the concepts of coercion and undue inducement.
- Demonstrate that payment is not coercive but that it can lead to undue inducement that warrants concern in protocols near the limits of approvability.
- Identify the challenges of obtaining informed consent in clinical trials involving medical emergencies.
- Define a new set of goals for obtaining consent in emergency situations.

11:30 AM - 12:30 PM

Don Rosenstein, MD

Professor of Psychiatry and Director of the UNC

Comprehensive Cancer Support Program at the UNC

Lineberger Comprehensive Cancer Center

ENROLLING DECISIONALLY IMPAIRED ADULTS IN RESEARCH

Learning Objectives:

- Identify the Regulatory and IRB considerations for research involving decisionally impaired adults.
- Evaluate research for this population with more than minimal risk and no prospect of direct benefit.
- Identify considerations in reviewing a Fragile X PET Protocol.
- Describe concerns of a father raising a son with autism and mental retardation.

12:30 PM - 1:30 PM Lunch

1:30 PM - 2:30 PM

P. Pearl O' Rourke, MD

Director of Human Research Affairs at Partners HealthCare

Systems in Boston and an Associate Professor of Pediatrics at

Harvard Medical School

PERSONALIZED MEDICINE: PROBLEMS AND PERPLEXITIES FOR THE IRB

Learning Objectives:

- Define personalized medicine.
- Describe research needed to develop personalized medicine.
- Identify IRB issues involving tissue and data banks and risk assessment of genetic issues.
- Discuss Direct to Consumer genetic testing in personalized medicine.

2:30 PM - 3:15 PM

Carol Fedor, RN, ND, CCRP

Clinical Research Manager for The Center for Clinical

Research at University Hospitals Case Medical Center (UHCCM)

THE ROLE OF THE STUDY COORDINATOR IN RESEARCH

Learning Objectives:

- Describe the current role of the Clinical Research Coordinator (CRC).
- Identify the professionalization of the role of the CRC.
- Discuss the ethical challenges of the CRC.

3:15 PM - 3:30 PM Break

3:30 - 4:30 PM

Ivor Pritchard, PhD

Senior Advisor to the Director in the Office for Human

Research Protections (OHRP) in the Department of Health

and Human Services

HOW DO IRB MEMBERS MAKE DECISIONS? RESEARCH SPECULATIONS?

Learning Objectives:

- Identify potential problems from flawed IRB decisions.
- Discuss possible causes for poor IRB decisions.
- Describe a model for rational decision-making.
- Identify how existing psychological research can illustrate patterns in deviations from rational decisions.
- Describe how IRB decision-making can be improved.

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 CEUs & CMEs

Nursing CEU and CME credit hours will be available to conference attendees.

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, University of Cincinnati, Schulman Associates Institutional Review Board, Inc., the University of Kentucky. Cincinnati Children's is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Cincinnati Children's designates this educational activity for a maximum of 5.75 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Approved contact hours: 5.75 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). Contact hours are valid in most states. Program #091008-1.

Certificates of Attendance

Continuing medical and nursing education credit certificates as well as certificates of attendance for this event will be provided upon request. When you sign in the day of the event please indicate which type of certificate you are requesting. A link to the evaluation form will be emailed to you. When your completed form is received, the certificate will be emailed to you.

Conference satisfies UK human research protection continuing education requirement

University of Kentucky Registration Form

(for use by UK Researchers and Research Staff)

HUMAN SUBJECT PROTECTION:

IT'S A BRAND NEW DAY

THURSDAY, OCTOBER 8, 2009

9:00 AM - 4:30 PM

(Please Type or Print- COMPLETE ALL APPLICABLE INFORMATION)

Name: _____

Degree: _____

*License #: _____ State _____

Title: _____

Department: _____

Employer: University of Kentucky

Address: _____

City: State: Zip: _____

Phone: _____

Fax: _____

E-mail: _____

ALL PAYMENTS ARE NON-REFUNDABLE.

Conference Early Bird \$80.00 (limited number)

Conference \$150.00 (after reduced slots are filled)

**Please note there is no additional fee for CME or Nursing credits. If applying for nursing credits, please provide the RN number and the state.*

**Note: You must apply for credit in advance. Requests for credit will not be honored after the day of the conference. If you are applying for Nursing credits, we must have your RN # and state*

Method of Payment

Check (payable to the University of Kentucky)

Department Voucher (credit cost center 1013200030 and gl 408610 and debit gl 530503 and the cost center you wish to charge after the conference has taken place)

Provide contact information for department official or business manager responsible for payment:

Name: _____

Phone: _____

Email: _____

Send registration and applicable payment to:

UK Office of Research Integrity, C/O Stephanie Morris,

314a Kinkead Hall, Lexington, KY 40506-0057

Email: samo222@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 the challenges in enrolling minority populations in research.
- Identify the ethical concerns with paying research subjects.
- Discuss the challenges in enrolling decisionally impaired subjects.
- Identify the complexities of reviewing research involving personalized medicine.
- Explain the ethical concerns facing a clinical research coordinator.
- Describe how to improve IRB decision-making.

Overview

The first speaker will discuss the things that have stifled the enrollment of minorities in research and identify some solutions. Our next speaker will identify concerns about paying subjects and will also discuss consent in an emergency setting. Our third speaker will describe challenges for IRBs in reviewing research involving the decisionally impaired. Following lunch, our next speaker will define personalized medicine and describe what type of research is needed for its development. Our next speaker will discuss the importance of and challenges for the clinical research coordinator. The conference will conclude with a provocative presentation regarding the strengths and weaknesses of IRB decision making and our speaker will suggest ways to improve it.

Conference Cost

The conference is jointly sponsored by the University of Cincinnati, Schulman Associates IRB, Inc., the University of Kentucky and Cincinnati Children's Hospital Medical Center as a service to the clinical research community. The cost to attend the conference is \$150.00. This fee includes conference materials, CME and CEU credit, lunch and refreshments. *Please register early, as seating is limited.* (All payments are non-refundable.)

If you have any questions about the conference, please contact Belinda Smith at (859) 323-2446 or belinda.smith@uky.edu.

About the Joint Sponsors

Schulman Associates Institutional Review Board, Inc. (Schulman) is a national, accredited independent IRB established in 1983. For more information, visit Schulman'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. The UK human research program is fully accredited by AAHRPP. For more information, visit UK's web site at www.research.uky.edu/ori. **The Research Foundation at Cincinnati Children's Hospital Medical Center** encompasses basic, translational, clinical, and quality research aimed at answering the questions behind childhood disease with the intent of being a leader in improving child health. For more information, visit Cincinnati Children's web site at www.cincinnatichildrens.org/research.

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 5-9th, 2009 please visit www.cincinnatiusa.com/itinerary/itinerary.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 September 9, 2009. 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 8, 2009.

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

314a Kinkhead Hall
Lexington, KY 40506-0057

UK UNIVERSITY OF KENTUCKY
Office of Research Integrity

Human Subject Protection:

It's a Brand New Day

Thursday, October 8, 2009
9:00 AM - 4:30 PM

Northern Kentucky Convention Center
Covington, Kentucky

SCHULMAN
ASSOCIATES IRB

UNIVERSITY OF
Cincinnati

UK
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