Current Human Research Issues and Solutions

Regulatory Overview & Hot Topics

MUSC
MEDICAL UNIVERSITY OF SOUTH CAROLINA

FDA

Department of Veterans Affairs

STATE

Trident HEALTH SYSTEM

Ralph H. Johnson VA Medical Center

College of Charleston

Office for Human Research Protections
U.S. Food and Drug Administration
Department of Veterans Affairs
National Human Subject Protections Workshop

June 21 - 22, 2001

This workshop is jointly sponsored by the Medical University of South Carolina and the Office for Human Research Protections in collaboration with the U.S. Food and Drug Administration, the Department of Veterans Affairs, South Carolina State University, Trident Health System, the Ralph H. Johnson VAMC, and the College of Charleston.

Audience

This workshop is part of a national series of programs being designed for anyone involved in the conduct or oversight of research involving human participants.

Workshop Overview

This workshop is a two-day session designed to give participants an overview of federal regulations with special emphasis on hot topics and solutions to problems.

Day one - Representatives from the Office for Human Research Protections, the U.S. Food and Drug Administration and the Veterans Health Administration will provide regulatory updates and interpretation of federal regulations. Participants will have the opportunity to ask for clarification and additional interpretation in the “Ask the Feds” session.

Day two – Institutional compliance will be addressed in the plenary session. Colleagues from academia and medical institutions will present breakout sessions on the use of placebos, recruiting minorities, behavioral research, and IRB basics. Representatives from the federal government will present breakout sessions on the HIPAA regulations and vulnerable populations. The conference will end with a panel of federal representatives and workshop faculty in the “Ask the Experts” session.

Objectives

After completing this workshop, you should be able to:

- discuss the fundamentals of 45 CFR 46
- identify the principles of The Belmont Report
- identify special research issues pertaining to vulnerable populations
- discuss the fundamentals of 21 CFR 50 & 38 CFR 16
- identify areas of institutional non-compliance
- describe appropriate & inappropriate use of placebos
- discuss strategies to enhance recruitment of minorities
- identify special issues in behavioral research
- apply strategies to solve IRB administrative issues
- discuss the fundamentals of HIPAA regulations

Accreditation

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 Medical University of South Carolina and the Office for Human Research Protections. The Medical University of South Carolina is accredited by the ACCME to provide continuing medical education for physicians.

Continuing Medical Education Credit

The Medical University of South Carolina designates this continuing medical education activity for a maximum of 12 credit hours in category 1 towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Continuing Education Credit

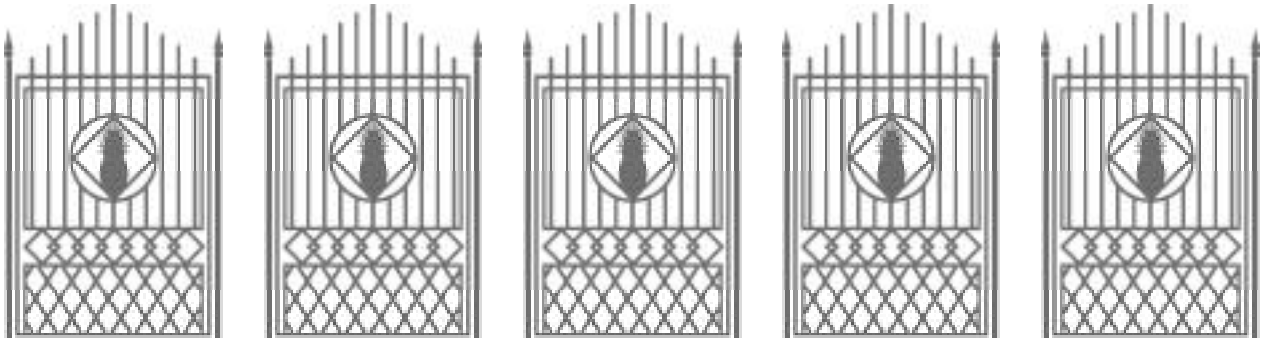
The Medical University of South Carolina will award 1.2 CEUs (12 contact hours) for full time attendance.

Disclosure Statement

The Medical University of South Carolina adheres to ACCME Standards regarding industry support of continuing medical education, and disclosure of faculty and commercial support relationships, if any, will be made known at the conference.

Americans with Disabilities Act

It is the policy of the Medical University of South Carolina not to discriminate against any person on the basis of disabilities. If you feel you need services or the auxiliary aids mentioned in this act in order to fully participate in this continuing medical education activity, please call the Office of CME at (843) 876-1925 before June 7, 2001.



Workshop Schedule

Thursday, June 21, 2001

7:00 – 8:00 a.m. **Registration and Continental Breakfast**

8:00 – 8:15 **Welcome and Introductions**

Raymond Greenberg, MD, PhD
President
Medical University of South Carolina
Charleston, SC

Jeffrey M. Cohen, PhD
Director, Division of Education
Office for Human Research Protections
Department of Health and Human Services
Rockville, MD

8:15 – 8:30 **Human Research Skills Assessment**

Jan Z. Temple, PhD
Director, Professional Development
Office of Continuing Medical and Public Education
Medical University of South Carolina
Charleston, SC

8:30 – 10:00 **Federal Update**

David A. Lepay, MD, PhD
Acting Senior Advisor on Clinical Science and Acting Director
Office of Clinical Science
Office of the Commissioner
U.S. Food and Drug Administration
Rockville, MD

Jeffrey M. Cohen, PhD
Director, Division of Education
Office for Human Research Protections
Department of Health and Human Services
Rockville, MD

John H. Mather, MD, Chief Officer
Office of Research Compliance and Assurance
Veterans Health Administration
Department of Veterans Affairs
Washington, DC

10:00 - 10:15 **Networking Break**

10:15 – 12:00 **Four Breakout Sessions**

1. **Overview of "Common Rule"**
   Jeffrey M. Cohen, PhD
   Director, Division of Education
   Office for Human Research Protections
   Department of Health and Human Services
   Rockville, MD

2. Overview of FDA Regulations
Bonnie Lee
Health Issues Analyst, Office the Commissioner
U.S. Food and Drug Administration
Rockville, MD

3. Overview of VA Regulations
Beth Gibbs, RN
Research Assurance Compliance Officer
VISN 7
Charleston, SC

David Miller, PhD
Regional Office Director
Office of Research Compliance and Assurance
Washington, DC

4. Advanced IRB Review Issues
Becky Roberts, RDH, MS
IRB Program Manager
Medical University of South Carolina
Charleston, SC

George E. Lindenmayer, MD, PhD
Chairman, IRB
Medical University of South Carolina
Charleston, South Carolina

12:00 – 1:30 Lunch

1:30 – 2:15 Compliance Oversight and Investigations

Jeffrey M. Cohen, PhD
Director, Division of Education
Office for Human Research Protections
Department of Health and Human Services
Rockville, MD

David Miller, PhD
Regional Office Director
Office of Research Compliance and Assurance
Washington, DC

2:15 – 3:00 IRB/Investigator Education

Jeffrey M. Cohen, PhD
Director, Division of Education
Office for Human Research Protections
Department of Health and Human Services
Rockville, MD

David Miller, PhD
Regional Office Director
Office of Research Compliance and Assurance
Washington, DC

Bonnie Lee
Health Issues Analyst, Office the Commissioner
U.S. Food and Drug Administration
Rockville, MD

3:00 – 3:30 **Networking Break**

3:30 – 4:30 **Ask the Feds**

Jeffrey M. Cohen, PhD
Director, Division of Education
Office for Human Research Protections
Department of Health and Human Services
Rockville, MD

Bonnie Lee
Health Issues Analyst, Office the Commissioner
U.S. Food and Drug Administration
Rockville, MD

David Miller, PhD
Regional Office Director
Office of Research Compliance and Assurance
Washington, DC

4:30 **Adjourn**

5:00 **Wine and Cheese Reception**

Friday, June 22, 2001

7:30 – 8:30 a.m. **Registration and Continental Breakfast**

8:30 – 8:45 **Welcome and Opening Remarks**
Introductions

8:45 – 9:30 **How Do You Know If Your Institution is in Trouble?**
David Clark, PhD
Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois

9:30 – 10:30 **Breakout Sessions**
(Workshop participants will have the opportunity to attend two breakout sessions)

Placebo Controlled Trials
Brent Egan, MD / Medical University of South Carolina
Paul Gold, PhD / Medical University of South Carolina

Recruiting Minorities
Deanna Cheek, MD / Medical University of South Carolina
Donna Zimmerman, MSW / South Carolina State University

Behavioral Research
Candace Gauthier, PhD / University of North Carolina at Wilmington
Kathleen Lowney, PhD / Valdosta State University

IRB Basics
Patricia Arford, PhD, RN / Medical University of South Carolina
Alison Faulk, BS / McGuire Veterans Administration Medical Center
Becky Roberts, RDH, MS / Medical University of South Carolina

HIPAA Regulations
Julie Kaneshiro, MA / NIH

Vulnerable Populations
Jeffrey M. Cohen, PhD / OHRP

10:30 – 10:45	**Break**
10:45 – 11:45	**Repeat Breakout Sessions**
12:00 – 1:15	**Lunch**
1:15 – 2:45	**Ask the Experts** Federal representatives and workshop faculty
2:45 – 3:00	**Closing Remarks**
3:00	**Adjourn**

Contact Person

For more information please contact Pam Benjamin, Office of CME, Medical University of South Carolina, 843-876-1925; fax – 843-876-1931.

Conference Location and Accommodations

Mills House Hotel • 115 Meeting Street • Charleston, South Carolina 29401 • 843/577-2400
A visit to The Mills House is like a delightful trip in time to a fine antebellum home. Each guest room is individually decorated with fine period furnishings, including demi-canopied beds. From your window you can enjoy a spectacular view of Charleston's Historic District … or of the hotel's pool and sundeck. You'll also appreciate many exquisite details, such as nightly turndown service, along with such conveniences, as color television, climate control, data ports and in-room hair dryers. The web site for Mills House Hotel is www.millshouse.com. Their phone number is 843-577-2400.

Please make your reservations directly with the hotel. Identify yourself as a participant in this conference to receive the conference rate of $154.00 for a single/double room for the dates of June 20-21, 2001 and a conference rate of $169.00 for the dates of June 22-23, 2001 for a single/double. A block of rooms will be held until May 20 or until the block is full. Reserve your room as soon as possible as June is a very popular time to visit Charleston.

Registration Fee

The workshop fee is $175.00. This fee includes all educational sessions, continental breakfast and lunch both days, breaks, a wine and cheese reception, a syllabus and continuing education credit processing.

Cancellations

A refund will be made upon written request prior to June 1st, 2001; however, $50.00 will be retained to cover administrative fees. We reserve the right to cancel this program if necessary. Full registration fees will be refunded for cancelled programs. The University cannot be responsible for reimbursement of airline or other transportation fares or hotel charges, including penalties.

Charleston International Airport

The airport is approximately 11 miles from downtown Charleston. Several shuttle and taxi companies service the airport. The following car rental agency's desks are located at the airport:

Avis • Budget • Hertz • National

Faculty

Patricia H. Arford, PhD, RN
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College of Nursing
Chair, IRB
Medical University of South Carolina
Charleston, SC

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Assistant Professor of Nephrology
Medical University of South Carolina
Charleston, SC

David Charles Clark, PhD
Office of Research Affairs
Rush Presbyterian - St. Luke's Medical Ctr.
Chicago, IL

Jeffrey M. Cohen, PhD
Associate Director, Office of Education
Office for Human Research Protections
Rockville, MD

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Charleston, SC

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IRB Coordinator
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Veteran's Affairs Medical Center
Richmond, VA

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Associate Professor of Philosophy & Religion
The University of North Carolina
Wilmington, North Carolina

Beth Gibbs, RN
Research Assurance Compliance Officer
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Assistant Professor of Psychiatry
Medical University of South Carolina
Charleston, SC

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Medical University of South Carolina
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NIH, Office of the Director
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Bethesda, MD

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Health Issues Analyst
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Rockville, MD

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Office of the Commissioner
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Medical University of South Carolina
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Janet Z. Temple, PhD
Director of Professional Development
Office of Continuing Medical and Public Education
Medical University of South Carolina
Charleston, SC

Donnis K. Zimmerman, MSW
Department of Social Work
South Carolina State University
Orangeburg, SC

Registration Form

Current Human Research Issues and Solutions
June 21 - 22, 2001 • Mills House Hotel • Charleston, SC
(Please print or type all information on this form)

Last Name (please print clearly) First Name Middle Initial

❑ MD ❑ DO ❑ Other (specify) _____

Social Security Number

Address

City State Zip

(_____)_____-_____ (_____)_____-_____

Office Telephone Office Fax E-mail Address

Do you require vegetarian meals ❑ Yes ❑ No

Breakout Sessions

Thursday, June 21, 2001

10:00 - 11: 45 a.m.
(Check one)

- ❑ **Overview of "Common Rule"**
- ❑ **Overview of FDA Regulations**
- ❑ **Overview of VA Regulations**
- ❑ **Advanced IRB Review Issues**

Friday, June 22, 2001

9:30 - 10:30 a.m.
(Check one)

- ❑ **HIPAA Regulations**
- ❑ **Placebo Controlled Trials**
- ❑ **Recruiting Minorities**
- ❑ **Behavioral Research**
- ❑ **IRB Basics for the IRB Administrator**
- ❑ **Vunerable Populations**

10:45 - 11:45 a.m.
(Check one)

- ❑ **HIPAA Regulations**
- ❑ **Placebo Controlled Trials**
- ❑ **Recruiting Minorities**
- ❑ **Behavioral Research**
- ❑ **IRB Basics for the IRB Administrator**
- ❑ **Vunerable Populations**

Payment Received:

❑ $175

Payment must accompany registration

❑ Check Payable to
Medical University of South Carolina

❑ MasterCard

❑ Visa

_____
Cardholder's Name

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Card Number Expiration Date

Please use ONE of these methods to register (do not mail if previously faxed or telephoned):

Mail registration form with check or credit card information to:

Pamela Benjamin, Office of CME
Medical University of South Carolina,
261 Calhoun Street, Suite 301
P.O. Box 250189
Charleston, SC, 29425

Telephone: (843) 876-1925
Registration by credit card only

Fax: (843) 876-1931
Registration by credit card only