

The Future Face of Protecting Human Subjects:

Legislation & Implementation

National Human Research Protections Workshop

Hosted by

**Lahey Clinic
Harvard Medical School**

Sponsored by

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

At

**Boston Marriott Burlington
One Mall Road
Burlington, Massachusetts**

April 7 & 8, 2003



OHRP/FDA/DVA WORKSHOP

“The Future Face of Protecting Human Subjects: Legislation and Implementation”

Monday and Tuesday April 7 & 8, 2003
Boston Marriott Burlington
One Mall Road
Burlington, Massachusetts 01805

Sponsored by Lahey Clinic and Harvard Medical School

Target Audience: Persons involved in the conduct, sponsorship, and oversight of research involving human subjects protection. Conference participants would include:

- ◆ IRB Members, Chairs, and Administrators
- ◆ Regulatory Administrators
- ◆ Investigators
- ◆ Study Coordinators
- ◆ Students
- ◆ Institutional Officials
- ◆ Biomedical Industry Representatives

Purpose of Conference: To present participants with informational workshops and roundtable discussions on topics including:

- ◆ Current federal regulations for protection of human research subjects
- ◆ Current and proposed legislation for protection of human research subjects

Objectives: Upon completion of this conference, participants will:

- ◆ Become familiar with the ethical principals that form the basis for current Federal Regulations protecting human research subjects
- ◆ Understand conflicts of interest in clinical research
- ◆ Utilize OHRP/FDA/DVA guidance to protect human research subjects and minimize risk
- ◆ Become aware of IRB accreditation advantages
- ◆ Learn how to obtain IRB accreditation
- ◆ Learn how to incorporate HIPAA requirements in human research studies

***Registration Fee:** \$178.00 (before 03/01/03), \$198.00 (after 03/01/03) per attendee for the two day conference.

*Fee includes: two continental breakfasts, two lunches, and workshop materials.

Participants/Questions: For additional information about the workshop, registration, discounted accommodations contact:

Name: Deborah Perry

Phone: 781-744-3714

E-mail: Deborah.K.Perry@lahey.org

Special Needs: If you require special needs please identify these and contact Deborah Perry.

AGENDA

Monday April 7, 2003

| | | |
|-------------------|--|---|
| 7:30AM - 8:30AM | <i>Registration and Continental Breakfast</i> | |
| 8:30AM - 8:45AM | <i>Opening Address</i> | Sarkis H. Soukiasian, MD |
| 8:45AM - 10:45AM | <i>"Latest Federal Updates"</i> | Judith Brooks, MS, RN Richard D'Augusta, RPh, MPA David A. Lepay, MD, PhD |
| | <i><u>"Ask the Feds"</u> Q & A</i> | |
| 10:45AM - 11:00AM | <i>Break</i> | |
| 11:00AM - 11:45AM | <i>"Human Research Protection Accreditation Process"</i> | Marjorie A. Speers, PhD |
| 11:45PM - 12:00PM | <i>Q & A</i> | |
| 12:00PM - 1:00PM | <i>Lunch</i> | |
| 1:00PM - 1:30PM | <i>"Research and Civil Liability"</i> | Dianne J. Bourque, JD |
| 1:30PM - 1:45PM | <i>Q & A</i> | |
| 1:45PM - 2:30PM | <i>"HIPAA Rules and Implementation"</i> | Lora Kutkat, MS |
| 2:30PM - 2:45PM | <i>Q & A</i> | |
| 2:45PM - 3:00PM | <i>Break</i> | |
| 3:00PM - 4:00PM | <i><u>Breakout Discussion</u> "VA Quality Assurance and Accreditation"</i> | Thomas E. Ball, M.Div., CIM |
| | <i>"Certification Process for IRB Professionals"</i> | Richard D'Augusta. RPh, MPA |
| | <i>"HIPAA"</i> | Lora Kutkat, MS Mary E. Oster |

AGENDA

Tuesday April 8, 2003

| | | |
|-------------------|--|---|
| 7:30AM - 8:30AM | Continental Breakfast | |
| 8:30AM - 8:45AM | <i>Welcome Address from Lahey's CEO</i> | David M. Barrett, MD |
| 8:45AM - 9:45AM | <i>"Trust in the American Healthcare Enterprise"</i> | David A. Shore, PhD |
| 9:45AM - 10:00AM | Q & A | |
| 10:00AM - 10:15PM | Break | |
| 10:15AM - 11:00AM | <i>"The IOM Report on Protection of Human Research Participants"</i> | Daniel D. Federman, MD |
| 11:00AM - 11:15AM | Q & A | |
| 11:15AM - 12:00PM | <u>Panel Discussion</u> <i>"Trust in a Time of Turbulence"</i> | Deborah L. Barnard Richard D'Augusta, RPh, MPA Daniel D. Federman, MD Margaret Jurgan, MS, ED David A. Shore, PhD Elyse I. Summers, JD |
| 12:00PM - 12:15PM | Q & A | |
| 12:15PM - 1:15PM | Lunch | |
| 1:15PM - 2:30PM | <u>Breakout Discussion</u> <i>"Grants for Education From Funding to Implementation"</i> | Deborah L. Barnard |
| | <i>"Informed Consent: Elements and Ethics"</i> | Michael Cantor, MD, JD |
| | <i>"Evaluation and Management of Adverse Events"</i> | Elizabeth Bankert, MA, CIP Craig Donahue, RPh |
| 2:30PM - 2:45PM | Closing Comments | Sarkis H. Soukiasian, MD |

Workshop Faculty

Thomas E. Ball, M.Div., CIM

Medical Director, Certified IRB Manager
Program Director, National Association of IRB Managers
Washington, DC

Elizabeth Bankert, MA, CIP

Director, Dartmouth IRB
Dartmouth College
Hanover, New Hampshire

Deborah L. Barnard

Director, IRB and Animal Offices
Dana Farber/Harvard Cancer Center
Boston, Massachusetts

David M. Barrett, MD

Chief Executive Officer
Lahey Clinic
Burlington, Massachusetts

Dianne J. Bourque, JD

Legal Department
Lahey Clinic
Burlington, Massachusetts

Judith Brooks, MS, RN

Health Policy Analyst, Division of Education and Development
Office for Human Research Protections
Rockville, Maryland

David J. Bryan, MD

Vice Chairman, IRB
Lahey Clinic
Burlington, Massachusetts

Michael Cantor, MD, JD

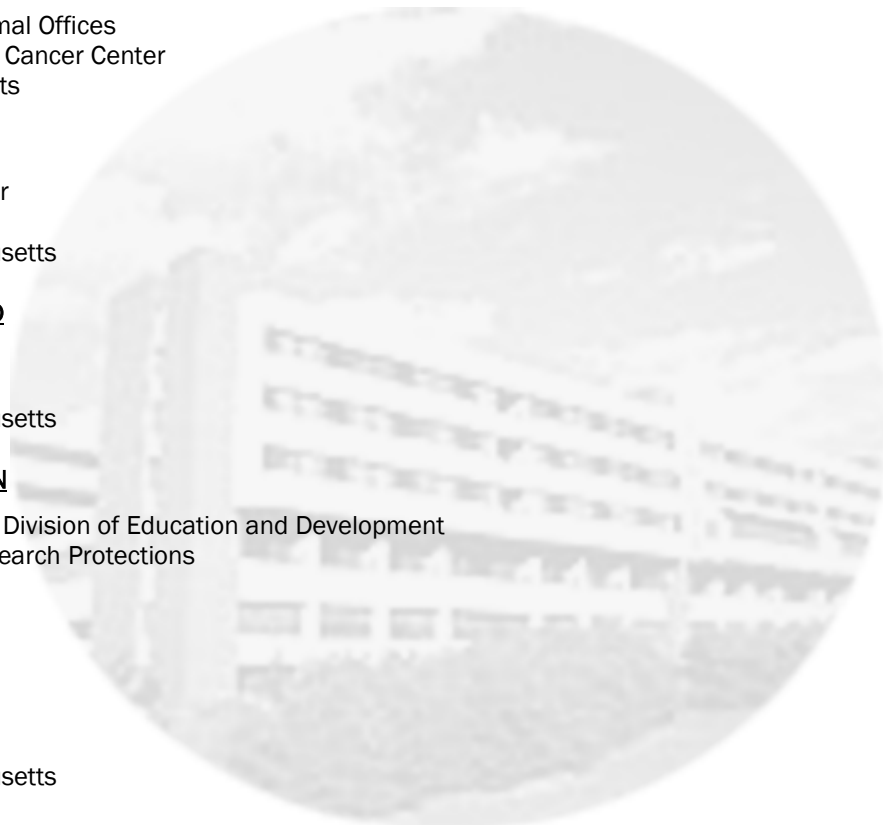
Clinical Director, New England VA Geriatric Research, Educational and Clinical Center
Boston Division
Boston, Massachusetts

Richard D'Augusta, RPh, MPA

Northeast Director, Office of Research Compliance and Assurance
Edith Norse Rogers Memorial Veterans Hospital
Bedford, Massachusetts

Craig Donahue, RPh

Investigational Pharmacist
Lahey Clinic
Burlington, Massachusetts



Workshop Faculty

Daniel D. Federman, MD

Senior Dean, Alumni Relations and Clinical Teaching
Carl W. Walter Distinguished Professor of Medicine and Medical Education
Harvard Medical School
Boston, Massachusetts

Margaret Jurgen, MS, ED

Lay Member, IRB
Lahey Clinic
Burlington, Massachusetts

Lora Kutkat, MS

Health Science Policy Analyst
National Institutes of Health
Office of Science Policy
Bethesda, Maryland

David A. Lepay, MD, PhD

Senior Advisor, Clinical Science
Director, Good Clinical Practice Programs
OSHC, Office of the Commissioner, U.S. Food and Drug Administration
Rockville, Maryland

Mary E. Oster

Director, Research Administration
Lahey Clinic
Burlington, Massachusetts

David A. Shore, PhD

Associate Dean and Executive Director, Center for Continuing Professional Education
Harvard University School of Public Health
Boston, Massachusetts

Sarkis H. Soukiasian, MD

Chairman, IRB
Lahey Clinic
Burlington, Massachusetts

Marjorie A. Speers, PhD

Executive Director
Association for the Accreditation of Human Research Protection Programs
Washington, DC

Elyse I. Summers, JD

Education Coordinator, Division of Education and Development
Office for Human Research Protections
Rockville, Maryland

Planning Committee

Nancy E. Arbeene, MT

Research Department
Lahey Clinic
Burlington, Massachusetts

Judith Brooks, MS, RN

Education Specialist, Division of Education and Development
Office for Human Research Protections, DHHS
Rockville, Maryland

David J. Bryan, MD

Vice Chairman, IRB
Lahey Clinic
Burlington, Massachusetts

Jessica A. Hayes

Research Department
Lahey Clinic
Burlington, Massachusetts

Margaret Jurgen MS, ED

Lay Member, IRB
Lahey Clinic
Burlington, Massachusetts

David A. Lepay, MD, PhD

Senior Advisor, Clinical Science
Director, Good Clinical Practice Programs
OSHC, Office of the Commissioner, U.S. Food and Drug Administration
Rockville, Maryland

Mary E. Oster

Director, Research Administration
Research Department
Lahey Clinic
Burlington, Massachusetts

Deborah K. Perry, LPN, CIM

Research Department
Lahey Clinic
Burlington, Massachusetts

Joan Porter, DPA, MPH

Associate Director, Office of Research Compliances and Assurance - 10R
Veterans Health Administration, Department of Veterans Administration
Washington, DC

Darlene M. Ross, BS

Education Coordinator, Division of Education and Development
Office for Human Research Protections, DHHS
Rockville, Maryland

Planning Committee

Sarkis H. Soukiasian, MD

Chairman, IRB
Lahey Clinic
Burlington, Massachusetts



Attendance Confirmation

Name of Attendee(s):

Institution:

Address:

Phone:

E-Mail Address:

Please remit this section with \$178.00 payment (before 03/01/2003), \$198.00 (after 03/01/2003) per attendee to:

**Lahey Clinic
Research Administration
OHRP Conference Registration
31 Mall Road
Burlington, Massachusetts 01805**

Registration:

***Special Needs:* If you require special needs, please identify these.
MasterCard, American Express, or Visa may be used.**

Contact Name: Deborah Perry
Phone: 781-744-3714
E-mail: Deborah.K.Perry@lahey.org

Accreditation

CME: This activity has been approved for AMA PRA credit.
CEU's have been approved.



For further information:

Contact Name: Deborah Perry
Phone: 781-744-3714
E-mail: Deborah.K.Perry@lahey.org

Hotel/Workshop Site Information



One Mall Road
Burlington, Massachusetts 01805

Phone: 781-229-6565

Fax: 781-229-7973



To make hotel reservations by phone, call 1-800-228-9290 in the United States and Canada (or any of Marriott's worldwide reservation numbers), contact a local travel agency, or visit on-line: www.marriott.com/bosbu

*Group discount code: **Icilia**

Local Directions



Boston (points North) - Take I-93 North to I-95 South.
Take Exit 33B (Burlington) straight through the lights.
Hotel is on the left.

Needham (points South) - Take I-95 North to exit 33B.
Left on to Mall Rd.
Hotel is on the left.

Nashua NH area - Take Route 3 South. Take Middlesex Turnpike exit
towards Burlington/Arlington staying on right ramp.
Right on Mall Road.
Hotel is on the right.

*** Group Discount Rate ends March 17, 2003**