



Accountability in Clinical Research

Balancing Risk & Benefit



National Patient Safety Foundation®

Clinical Research Conference
Underwriters

Invites you to attend this special conference

Patron:
Eli Lilly and Company Foundation

April 24-26, 2002

Special Event Sponsors:
AstraZeneca
Amgen, Inc.

**University Place Conference Center
Indiana University - Purdue University
Indianapolis, Indiana**

Educational Grants:
Wyeth-Ayerst

Conference and Registration Information:
www.npsf.org and click on the Accountability
in Clinical Research conference

Conference Description

The field of research with human subjects is attracting much attention and concern. Programs are encountering greater scrutiny, ethical and legal/regulatory issues and unfavorable publicity. Questions are being raised about informed consent as well as oversight by, and accreditation of, IRBs. These concerns are being raised both in the popular press and within the medical literature. This conference examines the funding, management, conduct and accountability of research involving human subjects from the operational, regulatory and ethical perspectives. Representatives from government agencies, industry, academic research centers, the media, patient advocacy and public interest groups will explore the thorny issues of clinical research in human subjects. The meeting is designed to be highly interactive with the audience.

This event was developed for investigators, clinical coordinators, deans/research deans, hospital administrators, IRB members/staff, media, regulators, patients, patient advocacy groups, public interest groups, voluntary health organizations, pharmaceutical/medical device companies, ethicists, risk managers, institutional general counsel, and attorneys.

Conference Objectives

At the conclusion of this conference, participants should be better able to:

1. Define the different groups with a stake in human subjects research
2. Discuss the issues in research with human subjects from different perspectives including that of patients and the public
3. Identify critical components of federal oversight, institutional oversight and ethics
4. Discuss the balance between safety and human subjects research in general and in their individual institutions

Accreditation and Certification

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the Annenberg Center for Health Sciences at Eisenhower and the National Patient Safety Foundation. The Annenberg Center is accredited by the ACCME to provide continuing medical education for physicians. The Annenberg Center designates this educational activity for up to 12.75 hours (1.0 hour for 4/24, 7.25 hours for 4/25, 4.5 hours for 4/26) in category 1 credit 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.

The Annenberg Center for Health Sciences at Eisenhower is approved by the American Council on Pharmaceutical Education



as a provider of continuing pharmaceutical education. This program has been developed according to the ACPE Criteria for Quality and is assigned ACPE Universal Program #797-999-01-010-L01. This program is designated for up to 12.75 contact hours (1.275 CEUs) (1.0 hour for 4/24, 7.25 hours for 4/25, 4.5 hours for 4/26) of continuing pharmaceutical education credit.

Eisenhower Memorial Hospital, Rancho Mirage, California, is approved as a provider of continuing education in nursing by the California Board of Registered Nurses, BRN #00861. This program meets the BRN criteria for 12.75 contact hours (1.0 hour for 4/24, 7.25 hours for 4/25, 4.5 hours for 4/26) (1.275 CEUs). *To receive credit for education contact hours outside of the state of California, please check with your State Board of Registered Nursing for reciprocity.*

American Academy of Physician Assistants (AAPA) accepts Category 1 CME credit for the PRA from organizations accredited by ACCME.

It is the policy of the Annenberg Center to ensure fair balance, independence, objectivity, and scientific rigor in all programming. All faculty participating in sponsored programs are expected to identify and reference off-label product use and disclose any significant relationship with those supporting the activity or any others whose products or services are discussed.

This program is supported by educational grants from Eli Lilly and Company Foundation, AstraZeneca, Amgen, Inc., Wyeth-Ayerst and others.

Hotel Information/Reservations

Two Indianapolis hotels are offering special conference rates through March 25, 2002. After that date, rooms are on a space-available basis, and the special rates may not be honored. Be sure to mention "NPSF Clinical Research Conference" when registering to receive the symposium rates.

Hyatt Regency Indianapolis

(\$139 single occupancy and \$154 double occupancy) – The city's premier business hotel across from the State Capitol and just steps away from Circle Centre mall and downtown entertainment. Call 1-800-233-1234 for reservations.

University Place DoubleTree Hotel

(\$110 single occupancy and \$125 double occupancy) – This Four-Diamond hotel has been awarded the 2001 Pinnacle Award for excellence by *Successful Meetings* and will be the host site for our conference. Call 1-800-627-2700 for reservations.



NPSF ANNENBERG IV

Patient Safety: Let's Get Practical

Come to Indy early and invite your colleagues to attend the back-to-back nationally acclaimed NPSF Annenberg IV conference ~~Patient Safety: Let's Get Practical~~, April 22-24, 2002. For conference and registration information visit the conference website at www.npsf.org and click on NPSF Annenberg IV conference.



presented by
National Patient Safety Foundation®



Conference Agenda in Brief

Wednesday April 24

- 6:00 - 7:00 pm Reception – *Supported by AstraZeneca*
 7:00 - 8:00 pm Dinner – *Supported by AstraZeneca*
 Meeting Introduction and Recognition of Conference Underwriters by the Conference Chair: *William R. Hendee, PhD*, Sr. Associate Dean and Vice President, Medical College of Wisconsin

Ensuring Clinical Research Accountability: A View From the Catbird Seat

Dr. Koski addresses how assessing the safety and accountability of clinical research programs across the nation has changed over his two year directorship.

Keynote Speaker: Greg Koski, MD, PhD, Director, Office for Human Research Protections

Thursday April 25

- 7:00 - 8:00 am Registration and Continental Breakfast
 8:00 - 8:45 am Meeting Opening & Welcome
Craig Brater, MD, Dean, Indiana University School of Medicine
Past as Prelude: Learning from the History of Clinical Research
 This session reviews the history of the development of the ethical codes and regulations for the protection of human subjects of research since the promulgation of the Nuremberg Code in 1947.

Keynote Speaker: Robert J. Levine, MD, Professor of Medicine, Yale University

8:45 - 10:15 am Communicating Risks of Clinical Trials: You Bet Your Life

This session describes the conceptual issues around risk discussions including the notion of informed consent, discusses common practical barriers, provides a framework, and suggests strategies and tools that may aid risk communications between investigators and human subjects.

Moderator: Carol A. Ley, MD, MPH, Director Occupational Medicine, 3M

Speakers: Gerald B. Hickson, MD, Professor and Vice Chairman (Pediatrics), Vanderbilt University
James W. Pichert, PhD, Associate Professor, Vanderbilt University

- 10:15 - 10:45 am Break
 10:45 - 12:15 pm **Views from the Ivory Tower: Accountability and Responsibility in Clinical Investigation**
 This session will focus on three hot issues:

adverse event reporting, training investigators, and conflict of interest.

Moderator: Peter K. Honig, MD, MPH, Director, Center for Drug Evaluation and Research, United States Food and Drug Administration

Topic I: Reacting to Shutdown of Clinical Research: Lessons Learned from the Duke Experience

Speaker: Jeremy Sugarman, MD, MPH, MA, Professor of Medicine and Philosophy, Duke University

Topic II: Filling in the Gaps: Cleaning up the Ivory Towers through Training

Speaker: Alan C. Moses, MD, Associate Professor, Harvard Medical School

Topic III: Too Many Masters? Ethics and Conflicts of Interest in Clinical Research

Speaker: Jeffrey P. Kahn, PhD, MPH, Director, Center for Bioethics, University of Minnesota

12:15 - 1:15 pm Lunch

1:15 - 2:45 pm

Sponsorship or Partnership?

This session explores sponsorship/partnership considerations from industry, government and institutional perspectives, especially relating to safety matters.

Moderator: Hugh Tilson, MD, DrPH, Sr. Advisor to the Dean, University of North Carolina

Panelists: Carolyn M. Clancy, MD, Center Director, Agency for Healthcare Research and Quality
James Gavin III, MD, PhD, Sr. Scientific Officer and Director, Howard Hughes Medical Institute

Jennifer L. Stotka, MD, Executive Director US Regulatory Affairs, Eli Lilly and Company

2:45 - 3:15 pm Break

3:15 - 4:15 pm

Doing It Right: Shared Responsibility in Clinical Research

This session focuses on a description of agency jurisdictions and functions by illustrating both “good” and “bad” approaches for promotion of patient safety with the use of case studies drawn from actual clinical trials.

Moderator: Peter Abbrecht, MD, PhD, Office of Research Integrity, Department of Health and Human Services

Panelists: David LePay, MD, PhD, Director, Office of Good Clinical Practice, United States Food and Drug Administration

Greg Koski, MD, PhD, Director, Office for Human Research Protections

John H. Mather, MD, Chief Officer, Office of Research Compliance & Assurance, Veterans Administration

4:15 - 5:15 pm

When Reporters Call: Handling the News Media Following a Sentinel Event

This session features a staged interview of a mock sentinel event followed by panel analysis.

Moderator: Gina Barton, Reporter, *Indianapolis Star*

Interviewer: Barbara Lewis West, Sound Medicine – WFYI-FM, Indianapolis

Interviewee: David W. Crabb, MD, Professor of Medicine, Indiana University

Panelists: Dennis DeRosia, Vice President, Paragon Biomedical
Sharon Alseth, WIBC Radio/Network Indiana
Bruce B. Dan, MD, President, MedNet Communications

5:15 - 6:30 pm Reception - Supported by Amgen, Inc.

Friday April 26

7:00 - 8:00 am Continental Breakfast

8:00 - 9:00 am Welcome

John Lechleiter, MD, Executive Vice President, Eli Lilly and Company

Accreditation of Human Subjects Research Programs: Objectives and Implications

The objectives and implications of accreditation programs for research involving human subjects are examined in this presentation and roundtable discussion.

Moderator: William R. Hendee, PhD, Sr. Associate Dean and Vice President, Medical College of Wisconsin

Keynote: Mryl Weinberg, CAE, President, National Health Council

Panelists: Marjorie A. Speers, PhD, Executive Director, Association for the Accreditation of Human Research Protection Programs

Jessica Briefer French, MHSA, Assistant Vice President, National Committee for Quality Assurance

Bert Spilker, MD, PhD, Sr. Vice President, Pharmaceutical Research and Manufacturers of America

9:00 - 11:00 am **Compliance or Conscience: The Role of Oversight in Assuring Safety in Clinical Research**

Part I: Balancing Safety and Benefits in Research Protocols

This session focuses on discussion of the appropriate balance of safety and benefits in research, the evolution of policies in this area, the role of institutional oversight, and first-hand experiences in these areas.

Moderator: Sharon M. Moe, MD, Assistant Dean, Indiana University

Panelists: Ernest Kraybill, MD, Research Subject Advocate, University of North Carolina

Robert M. Califf, MD, Associate Vice Chancellor, Duke University

Anna C. Mastroianni, JD, MPH, Professor, University of Washington

Elizabeth A. Bankert, MA, IRB Director, Dartmouth College

Part II: How Informative is Informed Consent?

This session uses audience participation as either mock IRB members or potential subjects

to evaluate the quality and understandability of the information in sample informed consents.

Moderators: Eric M. Meslin, PhD, Director, Center for Bioethics, Indiana University

Jeffrey P. Kahn, PhD, MPH, Director, Center for Bioethics, University of Minnesota

11:00 - 11:45 am **What I am Taking Home From This Conference:**

A Panel of Conference Participants

Lessons learned and how they will be applied in the participants' organizations.

Moderator: Mark S. Frankel, PhD, Program Director, American Association for the Advancement of Science

Panelists: Timothy R. Franson, MD, Vice President, Eli Lilly and Company

Gordon West, PhD, Continuing Education Specialist, Annenberg Center for Health Sciences
Nancye Buelow, Vice President of Consumers, Genetic Alliance

William H. Beeson, President Elect, Federated Ambulatory Surgery Association

Kate-Louise Gottfried, JD, MSPH, Executive Director, National Human Research Protections Advisory Committee

11:45 - 12:30 pm **Safety in Clinical Research: Restoring Public Trust**

At the fundamental level, safety in clinical research is an ethical responsibility of investigators, institutions, and research sponsors. When safety is compromised, the ethical framework of the research environment is brought into question. It is only through strengthening this ethical framework that the public's trust in clinical research can be restored.

Introduction: William R. Hendee, PhD, Sr. Associate Dean and Vice President, Medical College of Wisconsin

Keynote: Ruth R. Faden, PhD, MPH, Professor of Biomedical Ethics, Johns Hopkins University

Complete detailed program information is available by visiting the conference website at www.npsf.org and click on the Accountability in Clinical Research conference.

A DISTINGUISHED HONORARY COMMITTEE has joined together to call attention to the crucial issue of patient safety and clinical research across our great nation:

Dr. Steven Beering

President Emeritus, Purdue University; Professor of Medicine, Indiana University; Professor of Pharmacology, Purdue University

Dr. Otis Bowen

Lester B. Bibler Professor Emeritus of Family Medicine, Indiana University; U.S. Secretary of Health & Human Services (1985-89); Governor, State of Indiana (1973-81)

The Honorable Frank O'Bannon

Governor, State of Indiana

Convening Organizations

- National Patient Safety Foundation
- American Association for the Advancement of Science
- American Society for Bioethics and Humanities
- American Society of Law, Medicine, and Ethics
- Annenberg Center for Health Sciences
- Association for Clinical Research Professionals
- Food and Drug Law Institute
- Genetic Alliance
- Indiana University School of Medicine
- National Consumers League
- National Health Council
- National Institutes of Health, U.S. Department of Health and Human Services
- Office for Human Research Protections
U.S. Department of Health and Human Services
- Office of Research Integrity, U.S. Department of Health and Human Services
- U.S. Food and Drug Administration
U.S. Department of Health and Human Services
- U.S. Department of Veterans Affairs
Veterans Health Administration

Exhibitors Welcome

For information about exhibiting at the conference, please contact:

Carol Lieser

National Patient Safety Foundation
760-323-6955 or clieser@npsf.org

Be recognized as a partner and leader in patient safety. Information regarding sponsorship of this conference is available by contacting Lynda Williams, NPSF (202) 437-5053 or Lwilliams@npsf.org

Accountability in Clinical Research Registration Form

SPACE IS LIMITED! Early registrations must be postmarked by March 27, 2002.

Visit our website www.npsf.org and click on the Accountability in Clinical Research conference for convenient online registration. Or complete this form and fax to (760) 773-4550, or mail to Annenberg Center, Accountability in Clinical Research, 39000 Bob Hope Dr., Rancho Mirage, CA 92270.

Make checks or purchase orders payable to the Annenberg Center for Health Sciences, Tax ID 95-3382683. A confirmation letter will be mailed within 10 working days for receipt.

PLEASE PRINT CLEARLY

Name _____

Degree _____

Social Security Number _____

(used for attendance tracking only)

Mailing Address (Home Work)

City _____ State ____ Zip _____

Daytime Phone (_____) _____

Fax (_____) _____

E-mail Address _____

Special Needs (dietary, hearing/sight impaired, etc.)

Name Badge Information

Affiliation _____ City _____

	By 3/27	After 3/27, but Before 4/24	On-Site
Registration	\$350.00	\$400.00	\$475.00

Special Two-Conference Discount

If you are registering for the NPSF Annenberg IV conference – **Patient Safety: Let's Get Practical**, you will receive a \$50 discount on each of the conference registration fees.

Method of Payment Check Mastercard Visa
(U.S. Funds Only) American Express Discover

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Your primary profession/field of practice:

- | | |
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| <input type="checkbox"/> News Media | <input type="checkbox"/> Public Interest Group |
| <input type="checkbox"/> Other: _____ | |

Cancellation requests must be in writing. A \$50 fee will be charged for cancellations. No refunds will be issued after April 12, 2002. For registration inquiries, call Helen Cox at 1-800-321-3690.

ACHS Proj #1595 20M