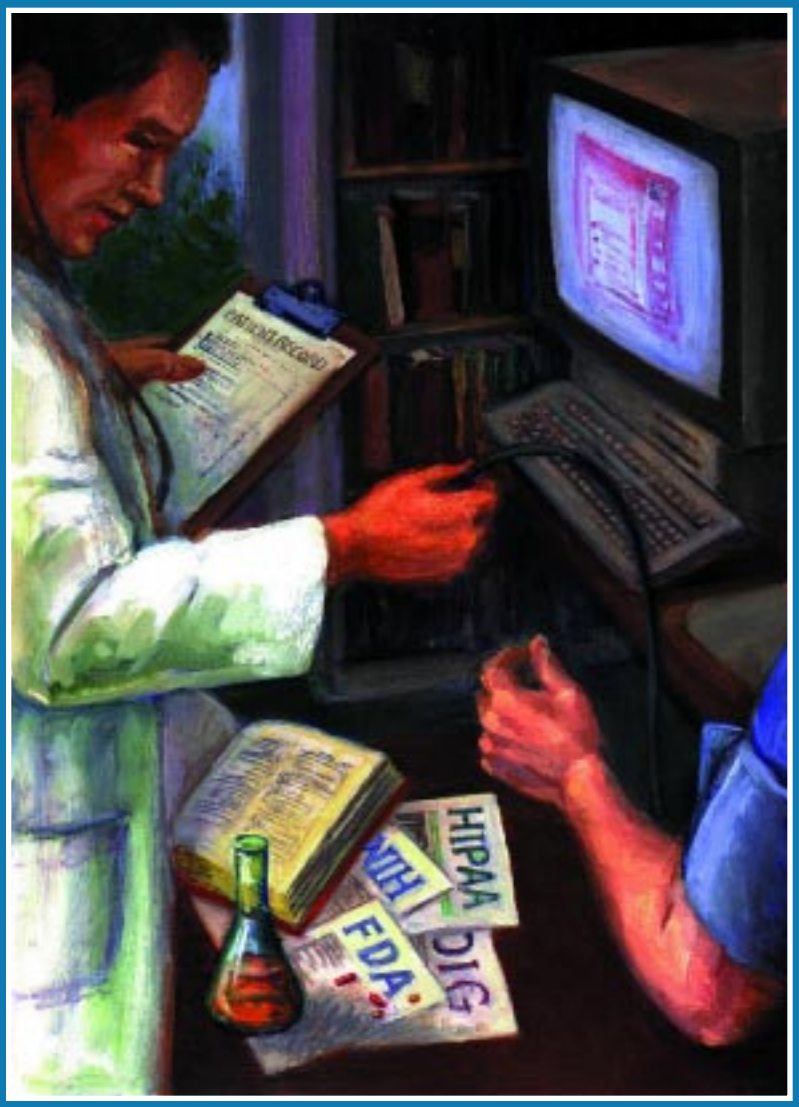
Medical Research Summit

The Leading Forum on the Law, Regulation and Ethics of Medical Research in the United States



March 18-20, 2001

Grand Hyatt Hotel, Washington, DC

www.researchsummit.com

ACCME CREDIT	ACPE CREDIT	CNA CREDIT	ACHE CREDIT	ABA MCLE CREDIT	AHIMA CREDIT	NASBA CREDIT	ACMPE CREDIT	HCCB CREDIT

Featured Speakers

Senator Bill Frist, MD (Invited) (R, Tenn.)
United States Senate, Washington, DC

David Le Pay, MD, Acting Senior Advisor for Clinical Science, Office of the Commissioner, Food and Drug Administration, Rockville, MD

Greg Koski, MD, Director, Office for Human Research Protections, Department of Health and Human Services, Rockville, MD

Julie Kaneshiro, Office of Science Policy and Planning, National Institutes of Health, Washington, DC

Chris Pascal, Director, Office of Research Integrity, Department of Health and Human Services, Washington,DC

Tom Puglisi, PhD, Director, Human Subject Protections Office of Human Research Protections, Germantown, MD

Belinda Seto, PhD, Director, Office of Reports and Analysis, Office of Extramural Research, National Institutes of Health, Bethesda, MD

Representative Susan Myrick, United States House of Representatives, Washingon, DC

Susan L. Rose, Health Scientist, Department of Energy, Life Sciences Division, Germantown, MD

Alan Guttmacher, MD, Senior Clinical Advisor, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD

Mary Faith Marshall, PhD, Chairperson, National Human Research Protections Advisory Committee, and Director, Program in Bioethics, University of Kansas Medical Center, Kansas City, KS

David Hoffman, Esq., Assistant United States Attorney, Eastern District of Pennsylvania, Philadelphia, PA

Richard Stern, Esq., Senior Counsel, Office of Inspector General, Department of Health & Human Services, Washington, DC

Diane Dean, Office of Policy on Extramural Research Administration, National Institutes of Health, Bethesda, MD

Sponsored By

Health Care Compliance Association
Inova Institute of Research and Education
Medical Device Manufacturers Association
Department of Energy

Co-Sponsored By

CenterWatch Monthly Newsletter
CW Weekly
Human Research Report
IRB: A Review of Human Subjects Research
The Hastings Center Report
The Research Roundtable

Medical Education Collaborative
A Nonprofit Education Organization

Educational Grantors

PRICEWATERHOUSECOOPERS

ERNST & YOUNG LLP

Medical Research Summit: The Leading Forum

Goals & Objectives:

- To provide an overview of medical research initiatives in the United States
- To establish the legal and regulatory context for medical research
- To analyze the ethical implications of medical research and the appropriate institutional approaches to addressing these ethical issues
- To investigate through case studies strategies to comply with legal, regulatory and ethical constraints on medical research initiatives

Prerequisites: There are no prerequisites for this educational activity.

Who Should Attend:

- Chief Executive Officers
- Chief Operating Officers
- Chief Technology Officers
- Chief Financial Officers
- Compliance Officers
- Health Law Attorneys
- Medical Directors
- Physicians
- Managed Care Professionals
- Medical Group Managers
- Data Managers
- Ethics Officers
- Health Insurance Executives
- Consultants
- Government Agency Employees
- Health Administration Faculty
- Risk Managers
- Pharmacists
- Quality Assurance Professionals
- Registered Nurses
- Long Term Care Professionals
- Billing and Coding Professionals
- Third Party Billing Professionals

The Medical Research Summit invites your organization to participate!

Join us as an Educational Grantor, Sponsor, Exhibitor or Advertiser

Take advantage of this unique opportunity to expand your reach in an audience of highly influential professionals!

For Information Contact:

Joni Lipson
1211 Locust Street • Philadelphia, PA 19107
Phone: 800-546-3750 • Fax: 215-545-8107
Email: joni.lipson@rmpinc.com

Preconference Vendor Show Sunday March 18

Leading software vendors in the area of clinical trials, management and human subjects protection will present the latest developments in software and information technology.

Save the Date!

November 5-7, 2001

2nd Annual Symposium on Compliance in Academic and Research Settings

Sponsored by the Health Care Compliance Association

DoubleTree Hotel · Anaheim, CA

For More Information Call: 888-580-8373

Sunday, March 18, 2001

I. PRECONFERENCE VENDOR SHOW

1:00 – 3:00 Technology and Educational Tools in Medical Research

II. PRECONFERENCE WORKSHOP: Training & Education

3:00 – 4:00 A. Human Subject

Barbara LoDico, *Executive Director, Human Subjects Protections, University of Medicine and Dentistry of New Jersey, Newark, NJ*

John Mather, MD, *Chief Officer, Office of Research Compliance and Assurance, Department of Veterans Affairs, Washington, DC*

4:00 – 5:00 B. Responsible Conduct for Research

Rebecca Landes, Office of Research, Program Analyst, University of California, Los Angeles, CA

Richard E. Rohrbach, Jr., *Manager, Clinical Research Consulting Team, PricewaterhouseCoopers, Philadelphia, PA*

III. PRECONFERENCE WORKSHOP

3:00 – 5:00 Compliance 101

Debbie Troklus, *Immediate Past President, Health Care Compliance Association, Louisville, KY*

5:00 p.m. ADJOURNMENT

Monday, March 19, 2001

8:00 a.m. Welcome and Introduction

Odell Guyton, Esq., *Corporate Compliance Officer, University of Pennsylvania, Philadelphia, PA*

Michele Russell-Einhorn, *Director, Clinical Research Consulting Team, PricewaterhouseCoopers, and Former Director of Regulatory Affairs for the Office for Human Research Protection, Department of Health Human Services, Washington, DC*

Conference Co-chairs

8:15 a.m. Human Subject Protections: The View from Congress

Senator Bill Frist, MD *(R, Tenn.), United States Senate, Washington, DC (invited)*

8:45 a.m. Human Subject Protections: Food and Drug Administration Policies

David Le Pay, MD, *Acting Senior Advisor for Clinical Science, Food and Drug Administration, Office of the Commissioner, Rockville, MD*

9:30 a.m. Office for Human Research Protections Initiatives

Greg Koski, MD, *Director, Office for Human Research Protections, Department of Health and Human Services, Rockville, MD*

10:15 a.m. BREAK

10:45 a.m. CONCURRENT SESSIONS 1

101. Enforcement & Response: Investigator Misconduct in Your Organization

Sheila Zimmet, JD, *Georgetown University, Washington, DC*

Kathleen McDermott, *Blank Rome Comisky & McCauly, Baltimore, MD*

102. IRB Operations: ABC's of Establishing an IRB

Stephanie J. Taylor, *Manager, Research Compliance, Greenville Hospital System, Greenville, SC*

Adam Kohn, Esq., *Shaw Pittman, Washington, DC*

103. Reimbursement and Finance: Medicare Billing and Reimbursement Essentials for Research

Soo Bang, *Senior Associate, Clinical Research Consulting Team, PricewaterhouseCoopers, Washington, DC*

Jorge Lopez, Esq., *Akin Gump Strauss Hauer & Feld, Washington, DC*

104. Research Compliance A: The Effect of HIPAA on Research, Part I

Richard Marks, Esq., *Partner, Davis Wright Tremaine LLP, Washington, DC*

Carol Pratt, JD, PhD, *Davis Wright Tremaine, Portland, OR*

105. Research Compliance B: Fraud and Abuse, Stark and Business Issues in Contracting With Research Sites and Investigators

Ron Wisor, Esq., *Arent Fox Kintner Plotkin & Kahn , Washington, DC*

Elizabeth A. Lewis, Esq., *Epstein Becker & Green, Washington, DC*

11:45 a.m. LUNCHEON AND PRESENTATIONS

12:15 p.m. The Impact of Information Technology on Clinical Research

John Cline, *CEO, ETRIALS, Morrisville, NC*

1:00 p.m. Emerging Governmental Initiatives in Medical Research

Julie Kaneshiro, *National Institutes of Health, Office of Science Policy and Planning, Washington, DC*

Chris Pascal, *Director, Office of Research Integrity, Department of Health & Human Services, Washington, DC*

Tom Puglisi, PhD, *Director, Human Subject Protections, Office for Human Research Protections, Rockville, MD*

Belinda Seto, PhD, *Director, Office of Reports & Analysis, Office of Extramural Research, National Institutes of Health, Bethesda, MD*

Michele Russell-Einhorn, *Director, Clinical Research Consulting Team, PricewaterhouseCoopers LLP, Washington, DC (Moderator)*

2:15 p.m. TRANSITION BREAK

2:30 p.m. CONCURRENT SESSIONS 2

201. Enforcement and Response: Whistleblowers in Research: The Role of the False Claims Act
Christopher A. Myers, Esq., *Partner, Holland & Knight, Washington, DC*

Edwin Rauzi, Esq., *Partner, Davis Wright Tremaine LLP, Seattle, WA*

202. Financing Research Compliance Operations
David Hudson, PhD, *Associate Vice President for Research & Public Service, University of Virginia, Charlottesville, VA*

Anthony M. Boccanfuso, PhD, *Manager, Clinical Research Consulting Team, PricewaterhouseCoopers LLP, Charlotte, NC*

203. Enforcement & Response: Assuring Scientific Integrity
Pat Kuochar, *Deputy General Counsel, National Institutes of Health, Bethesda, MD*

204. Research Compliance A: The Effect of HIPAA on Research, Part II
Richard Marks, Esq., *Partner, Davis Wright Tremaine LLP, Washington, DC*

Carol Pratt, JD, PhD, *Davis Wright Tremaine LLP, Portland, OR*

205. Research Compliance B: Old and New Issues in Recruiting Subjects for Clinical Trials
Karen McDonnell Suddath, Esq., *Pepper Hamilton LLP, Philadelphia, PA*

3:30 p.m. TRANSITION BREAK

3:45 p.m. CONCURRENT SESSIONS 3

301. Enforcement & Response: Responding to Government Investigation
Harvey Yampolsky, Esq., *Partner, Arent Fox Kintner Plotkin & Kahn, Former, Chief Counsel to the Inspector General, Department of Health & Human Services, Washington, DC*

302. Maintaining Compliance in a Growing Research Environment
Patrick Mauldin, PhD, *Medical University of South Carolina Charleston, Charleston, SC*

Leslie Platt, JD, *Principal & Leader, Health Sciences Research Compliance Group, Ernst & Young LLP, McLean, VA*

303. Reimbursement and Finance: Implementing the National Coverage Decision for Clinical Trials
Diane Lee, Esq., *Partner, Davis Wright Tremaine LLP, San Francisco, CA*

Karen Dunlop, Esq., *Sidley & Austin, Chicago, IL*

304. Research Compliance A: Special Issues in International Research
Shirley Hicks, *National Institutes of Health, Bethesda, MD*

305. Research Compliance B: Investigator and Institutional Conflicts of Interest
Guy Collier, Esq., *Shaw Pittman, Washington, DC*

Susan K. Burgess, Esq., *CCO, MCV Physicians, Richmond, VA*

4:45 p.m. TRANSITION BREAK

5:00 p.m. The Government's Role in Supporting Biomedical Research
Representative Susan Myrick, *United States House of Representatives, Washingon, DC*

6:00 p.m. ADJOURNMENT

6:30 p.m. NETWORKING RECEPTION

Tuesday, March 20, 2001

8:00 a.m. Welcome

Greg Warner, *President, Health Care Compliance Association, and Director for Compliance, Mayo Foundation, Rochester, MN*

Leslie Platt, JD, *Principal & Leader, Health Sciences Research Compliance Group, Ernst & Young, LLP, McLean, VA*

The New National Human Research Protections Advisory Committee's Role in Protecting Human Subjects
Mary Faith Marshall, PhD, *Chairperson, National Human Research Protections Advisory Committee, and Director of Programs in Bioethics, University of Kansas Medical Center, Kansas City, KS*

8:45 a.m. Human Genome Project
Alan Guttmacher, MD, *Senior Clinical Advisor, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD*

9:30 a.m. Managing Research in Changing World of Healthcare
Myron Genel, MD, *Associate Dean for Governmental Affairs, Yale University, New Haven, CT*

Susan Philip, Esq., *Powers, Pyles, Sutter & Verville, P.C., Washington, DC*

Jeffrey M. Sconyers, Esq., *General Counsel, Children's Hospital & Regional Medical Center, Seattle, WA*

Kenneth Dretchen, *Dean of Research and Graduate Education, Georgetown University Medical Center, Washington, DC*

Anthony M. Boccanfuso, PhD, *PricewaterhouseCoopers LLP (Moderator)*

10:45 a.m. BREAK

11:00 a.m. CONCURRENT SESSIONS 4

401. Enforcement & Response: Establishing Research Compliance Program
Kendra Dimond, Esq., *Partner, Arent Fox Kintner Plotkin & Kahn, Washington, DC*

402. IRB Operations: The Changing Roles of IRBs
Dan K. Nelson, M.S., *Director, Office of Human Research Studies, University of North Carolina, Chapel Hill, NC*

Eugene DiMagno, MD, *Chair IRB, Mayo Foundation, Rochester, MN*

403. Reimbursement and Finance: Using the National Coverage Decisionmaking Process for Investigational Products/Uses
Ron Milhorn, *Ron Milhorn LLC, Finksburg, MD*

404. Research Compliance A: Allocating Compliance Responsibilities among CROs, SMOs, Investigators and Institutions
Richard P. Anthony, PhD, *President & CEO, AxisMed LLC, Pasadena, CA*

405. Research Compliance B: Managing Multi-Site Research Projects
Leslie Bevan, PhD, *Director, Research Support, Oregon Health Sciences University, Portland, OR*

William Alexander, PhD, *Manager, Health Sciences Research Compliance Group, Ernst & Young LLP, McLean, VA*

Noon **LUNCHEON AND PRESENTATIONS**

Susan L. Rose, *Health Scientist, Deptartment of Energy, Life Sciences Division, Germantown, MD (Moderator)*

12:30 p.m. **When Things Go Wrong in the Conduct of Clinical Research: Lessons Learned**

Stephen Hanlon, Esq., *Partner, Holland & Knight*

1:15 p.m. **Investigation and Prosecution of Medical Research Civil and Criminal Wrongs**

David Hoffman, Esq., *Assistant United States Attorney for the Eastern District of Pennsylvania, Philadelphia, PA*

Richard Stern, Esq., *Senior Counsel, Office of Inspector General, Department of Health & Human Services, Washington, DC*

Diane Dean, *Office of Policy on Extramural Research Administration, National Institutes of Health, Bethesda, MD*

Paul Kalb, MD, JD, *Partner, Sidley & Austin, Washington, DC (Moderator)*

2:15 p.m. **TRANSITION BREAK**

2:30 p.m. **CONCURRENT SESSIONS 5**

501. Academic Medical Center: Position on Human Subjects Research Protection
Stephen Heining, *Division of Biomedical & Health Sciences Research Association of American Medical Colleges, Washington, DC*

Viki Saito, *Associate Vice Chancellor, Health Affairs and Communication, Duke University, Durham, NC*

Soo Bang, MHSA, *PricewaterhouseCoopers LLP, Washington, DC (Moderator)*

502. IRB Operations: Using Central and Commercial IRBs
Philip Cyr, *Manager, Health Sciences Research Compliance Group, Ernst & Young LLP, Boston, MA*

503. Reimbursement and Finance: Costing Protocols Appropriately
Victor Lampafona, Pharm.D, *Clinical Pharmaceutical Research Program, Emory University, Atlanta, GA*

504. Research Compliance A: Adverse Event Reporting
George Kasparis, *Office for Human Research Protections, Department of Health and Human Services, Rockville, MD*

505. Research Compliance B: Managing Multiple IRBs
Don Workman, PhD, *St. Jude Children's Research Hospital, Memphis, TN*

3:30 p.m. **ADJOURNMENT**

General Information

TAX DEDUCIBILITY

Expenses of training including tuition, travel, lodging and meals, incurred to maintain or improve skills in your profession may be tax deductible. Consult your tax advisor.

Federal Tax ID: 91-1892021

CANCELLATIONS/SUBSTITUTIONS

No refunds will be given for "no-shows" or for cancellations. You may send a substitute; please call the Conference Office at 1-800-546-3750.

HOTEL ACCOMMODATIONS

Special rates of $209 (plus tax) per single per night, and $234 (plus tax) per double per night, have been arranged for the Medical Research Summit. There are a limited number of rooms available at the special rate. Please make your reservations directly with the Grand Hyatt Hotel and mention the Summit to receive the reduced rate. Reservations will be accepted until Feb. 23, 2001. After that cut-off date, reservations will be accepted on a space-available basis only.

Grand Hyatt Hotel, 1000H Street NW, Washington, DC 20001

Reservations: (202) 582-1234

AIRLINE TRAVEL

Get there for less! The Medical Research Summit has selected Stellar Access, Inc. (SAI; formerly Conventions in America) as the official travel agency for this meeting.
Call 800-929-4242 and ask for Group #551 to receive the following discounts or the lowest available fares on any other carrier:

American Airlines and US Airways: Save 5-10% on the lowest applicable fares. Ask about applicable zone fares and discounts. All rules and restrictions apply. Travel between March 13 thru 25, 2001.

Call SAI: 800-929-4242, ask for Group #551
Website: www.stellaraccess.com

NOTE: First time users must register and refer to Group # 551

- Lowest available fares on any airline
- Free flight insurance of $100,000
- Save 50% on transaction fees – only $10

Outside US & Canada, call 619-232-4298/fax 619-232-6497

Reservation Hours: M-F 6:30am – 5:00pm Pacific Time

If you call direct or use your own agency, refer to these codes:

American Airlines (#13761) - 800-433-1790

US Airways (#56651791) - 877-874-7687

Continuing Education Credits Maximum credit hours include 2 hours for Preconference.

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 Medical Education Collaborative and Health Care Conference Administrators, LLC. Medical Education Collaborative (MEC), a nonprofit education organization, is accredited by the ACCME to provide continuing medical education for physicians and takes responsibility for the content, quality and scientific integrity of this CME activity.

Medical Education Collaborative designates this educational activity for a maximum of 16 hours 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.

Medical Education Collaborative, Inc. is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. Medical Education Collaborative, Inc. has assigned 16 contact hours/1.6 CEUs of continuing pharmaceutical education credit. ACPE provider number: 815-999-01-002-L03

Participants will be required to sign in daily and complete an evaluation form for credit. Registration fee includes certificate, which will be mailed within six weeks after the meeting.

CNA (Nursing Credit) - This educational activity for 19.5 contact hours is provided by Medical Education Collaborative. Medical Education Collaborative is approved as a provider of continuing education in nursing by the Colorado Nurses Association, which is accredited as an approver of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. Provider approved by the California Board of Registered Nursing. Provider number: CEP-12990 for 19.5 contact hours. Florida BN provider number: FBN-2773.

ACHE - Medical Education Collaborative is authorized to award 16 hours of pre-approved Category II (non-ACHE) continuing education credit for this program toward advancement or re-certification in the American College of Healthcare Executives. Participants in this program wishing to have the continuing education hours applied toward Category II credit should list their attendance when applying for advancement or re-certification in ACHE.

ABA MCLE - Required sponsor documentation has been forwarded to and credit requested from most MCLE states with general requirements for all lawyers. We have requested a total of 16 CLE hours from most MCLE states. Lawyers seeking credit in Pennsylvania must pay fees of $1.50 per credit hour directly to the PA CLE Board. Medical Education Collaborative pays applicable fees in other states where the sponsor is required to do so, and in states where a late fee may become applicable. Please be aware that each state has its own rules regulations, including its definition of CLE; therefore, certain programs may not receive credit in some states. For information on approved credit hours for your state, please contact Medical Education Collaborative at (303) 278-1900 ext. 151 starting two to three weeks prior to the program date.

AHIMA - This program is pending approval of 16 CE Credits for use in fulfilling the continuing education requirements of the American Health Information Management Association (AHIMA).

NASBA - Registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Nashville, TN, 37219-2417. Telephone: 615-880-4200.

A maximum of 19 credits based on a 50-minute hour will be granted. Recommended experience level for this course is intermediate to advanced.

ACMPE – This program may qualify for continuing education credit in the American College of Medical Practice Executives (ACMPE). To apply for ACMPE credit, submit a generic credit hour form with a copy of the brochure. Forms will be available on-site.

HCCB - This program has been approved for a maximum of 18 HCCB continuing education credits for compliance certification.

Save the Date!

April 22 – 24, 2001

4th Annual National Congress on Health Care Compliance

Grand Hyatt Hotel · Washington, DC

For Information Call 1-888-580-8373

Conference Fee

PRECONFERENCE	$ 295
CONFERENCE	
❑ Before Feb. 23, 2001	$ 995
❑ After Feb. 23, 2001	$1095
❑ Yes, add $50 to my conference registration fee — I want to become an HCCA member:	
❑ Before Feb. 23, 2001	$1045
❑ After Feb. 23, 2001	$1145

NON-MEMBERS
To join HCCA for one full year, just add $50 to your registration fee. You will receive benefits at all upcoming conferences and events.

Second and other registrations from the same organization receive $100 discount off regular registration fee — deduct from your total payment.

TOTAL PAYMENT
Please type or print

First Name Last Name

Name as you would like it to appear on your badge

ACHE Credentials: ❑ CHE ❑ FACHE

Degrees

Place of Employment

Title

❑ Work Address or ❑ Home Address
(List only preferred mailing address)

Address

City State Zip

Daytime Phone ( )

Fax ( )

E-mail

Areas of Most Interest/Compliance Focus

Years in Compliance

Job Function

Register today!

215-545-8107

800-546-3750 or
215-545-3894

conference.office@hcca-info.org

Or mail this form with correct tuition fee (U.S. funds) to: Conference Office, 1211 Locust Street, Philadelphia, PA 19107

Federal Tax ID: 91-1892021

Payment Terms

Please enclose payment with your registration and return it to the conference registrar at the above address, or fax your credit card payment to 215-545-8107.

❑ Check/money order enclosed (checks payable to Health Care Conference Administrators)

❑ American Express ❑ Visa ❑ MasterCard

Account No.

Name of Cardholder

Signature Exp. Date /

Please indicate your choices below:

Preconference

❑ PRECONFERENCE 1: Vendor Show
❑ PRECONFERENCE 2: Training & Education
❑ PRECONFERENCE 3: Compliance 101

Concurrent Sessions

Check one for each time slot:

Mon. 10:45 – 11:45
❑ 101 ❑ 102 ❑ 103 ❑ 104 ❑ 105

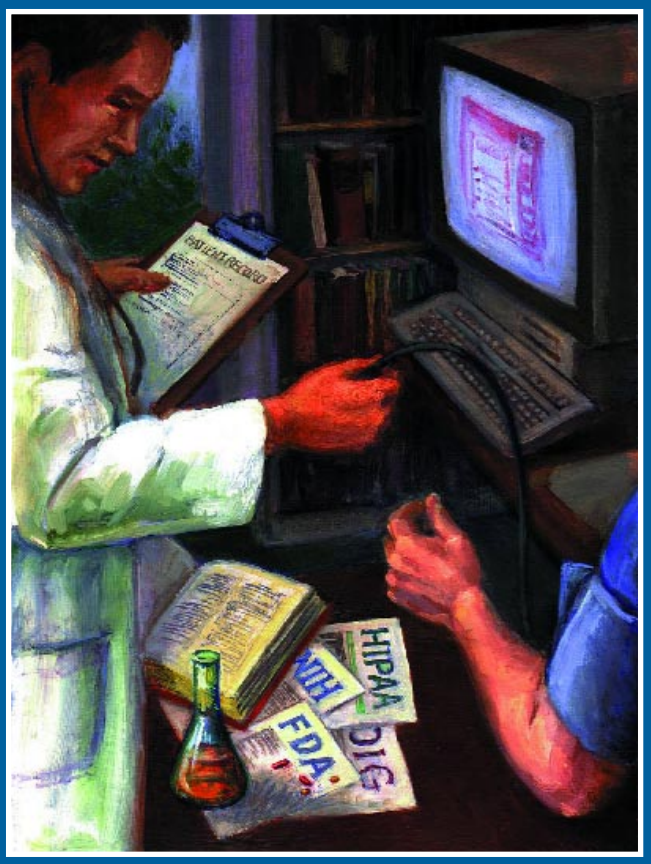
2:30 – 3:30
❑ 201 ❑ 202 ❑ 203 ❑ 204 ❑ 205

3:45 – 4:45
❑ 301 ❑ 302 ❑ 303 ❑ 304 ❑ 305

Tues. 11:00 – 12:00
❑ 401 ❑ 402 ❑ 403 ❑ 404 ❑ 405

2:30 - 3:30
❑ 501 ❑ 502 ❑ 503 ❑ 504 ❑ 505

Conference Office
1211 Locust Street
Philadelphia, PA 19107



Medical Research Summit

The Leading Forum on the Law, Regulation and Ethics of Medical Research in the United States

March 18–20, 2001

Grand Hyatt Hotel · Washington, DC