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RESEARCH Compliance Conference

October 31—November 2, 2007 | Chicago, IL
Chicago Marriott Downtown Magnificent Mile

CONFERENCE SPONSORS



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Date _____

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Date _____

Agenda

Wednesday, October 31, 2007

8:00 AM – 5:00 PM

Registration

9:00 – 11:45 AM

PRE-CONFERENCE CONCURRENT BREAKOUT SESSIONS

P1 Clinical Research Billing 101

- ✘ How to work with researchers to develop a plan for appropriate billing of clinical services provided to research participants during a research study
- ✘ Manage the compliance risks associated with clinical research
- ✘ Protect research participants from unexpected financial responsibilities

ANN MATHIAS, Director, Ethics & Compliance, UPMC/University of Pittsburgh Medical Center

ANN E. MITCH-RESIGNALO, Manager, Ethics and Compliance, UPMC/University of Pittsburgh Medical Center

P2 Research Compliance Basics

- ✘ Overview of legal and regulatory issues in research compliance
- ✘ Key topics to address in an institutional research compliance program
- ✘ Which topics should you worry about most...and how to respond if those worries become real

DAVID CLARK, Assistant Dean for Patient Services, University of Illinois at Chicago

PAUL DEMAURO, Partner, Latham & Watkins LLP

JOHN STEINER, Chief Compliance Officer, UK HealthCare

P3 Auditing & Monitoring for Research Sites

- ✘ Review and clarify the definitions/differences between auditing and monitoring
- ✘ Discuss at least 2 techniques for conducting an enterprise wide compliance risk inventory for research
- ✘ “Shock and (Not Quite) Awe”—discuss some techniques to use in an environment of contrarians

SHERYL VACCA, Director, Health Care and Life Science-Regulatory Practice, Deloitte & Touche LLP

JULIANN TENNEY, Institutional Research Compliance Officer, University of North Carolina at Chapel Hill

11:45 AM – 1:00 PM

Lunch (on your own)

1:00 – 4:00 PM

PRE-CONFERENCE CONCURRENT BREAKOUT SESSIONS

P4 Clinical Research Billing 202

- ✘ What are the rules? An outline of the rules for clinical research billing, when to apply which rules, and a discussion of the issues presented when applying the various rules
- ✘ How do I comply? An approach to the operational issues and options available for large to small research institutions (e.g., work group configuration, manual and technological solutions).
- ✘ What about non-compliance? A discussion of the issues surrounding suspected or known non-compliance (e.g., attorney/client privilege issues, voluntary disclosures, etc.)

JILL ALVAREZ, Nixon Peabody LLP

LEAH GUIDRY, Manager, Huron Consulting Group

P5 Human Subject Protections 101

- ✘ Identify essential elements for informed consent in research involving human subjects
- ✘ Discuss issues commonly encountered by researchers in their effort to obtain and document informed consent
- ✘ Describe a “best practice” framework for obtaining and documenting informed consent

JOHN MILLS, Legal Counsel, Mayo Clinic

MARIANNE OLSON, Education Specialist, Mayo Clinic

P6 Research Privacy & Security: Myths, Facts & Practical Approaches

- ✘ Briefly review the primary federal regulations (HIPAA, Common Rule, and FDA)
- ✘ Review of some state privacy laws and security breach notification laws
- ✘ Discussion of latest developments including OHRP draft engagement guidance myths and facts about the requirements and restrictions of applicable laws and regulations
- ✘ Open forum for discussion of issues identified by the audience

MARTI ARVIN, Privacy Officer, University of Louisville

RACHEL NOSOWSKY, Assistant General Counsel, University of Michigan

Thursday, November 1, 2007

7:30 AM – 5:00 PM

Registration

7:30 AM – 9:00 AM

Continental Breakfast

9:00 AM – 10:15 AM

General Session: Sponsor-Investigator Roles and Responsibilities in Device Trials and the FDA

- ✘ What is good clinical practice
- ✘ Role and responsibilities of a sponsor-investigator
- ✘ FDA Inspections; how to prepare for one

DOREEN KEZER, Senior Compliance Officer, FDA/Office of Compliance

10:15 – 10:30 AM

Break

10:30 – 11:45 AM

General Session: CMS Clinical Research Policy: How to Avoid a Fraud Case

- ✘ Detailed overview of the history of the NCD and CRP
- ✘ Detailed summary of the CRP and updates from the draft CRP issued in April
- ✘ Review of recent enforcement actions and settlements on research billing
- ✘ What should research organizations do to avoid a research billing fraud case

LISA MURTHA, Managing Director, Huron Consulting Group

RYAN MEADE, Meade & Roach

12:00 – 1:30 PM

Lunch Speaker: How to Manage Billions of Dollars in Research in a Compliant Manner

- ✦ As a decentralized university system with 15 institutions, research is only one of a dozen significant risks
- ✦ With each institution having IRBs, IACUCs, sponsored project offices, and organizations, organizing research compliance has been a challenge
- ✦ By leveraging the collective knowledge through the organization and HCCA, the University of Texas System has developed a highly successful research compliance program

CHARLES G. CHAFFIN, System-Wide Compliance Officer and Chief Audit Executive, The University of Texas System

1:45 – 3:00 PM

CONCURRENT BREAKOUT SESSIONS

101 Combining Research Quality and Compliance in a Community

NANCY MOSER, Regional Director, Compliance, Quality & Risk Management, Community Healthcare System

102 Effort Reporting, the Good, the Bad and the Very Ugly

- ✦ Participate in discussion of good, bad, and ugly scenarios related to effort reporting
- ✦ See examples of good and bad effort reporting policies
- ✦ Understand the effort reporting process to identify the ugly results of process breakdown

TERRY REEVES, Institutional Compliance Officer, University of Texas Medical Branch

103 Protecting Research Information: Privacy and Security in Research

- ✦ Is it—research? Research with human subjects? Exempt? Expeditable?
- ✦ De-identifying data
- ✦ Honest broker systems
- ✦ Managing large clinical and research databases when research meets QI
- ✦ Re-evaluating HIPAA-related policies with four years of experience

JUDITH ARGON, Chief Administrative Officer, Research, Geisinger Health System

LINDA MALEK, Partner, Moses & Singer LLP

104 Federal Grant Accounting: Compliance and Enforcement

- ✦ Overview of relevant rules and regulations, as well as highlighting NIHGPS provisions necessary for proper grant accounting
- ✦ Recent enforcement activities and FCA settlements
- ✦ Practical tips for compliance

HOLLEY THAMES LUTZ, Sonnenschein Nath & Rosenthal

3:30 – 4:45 PM

CONCURRENT BREAKOUT SESSIONS

201 Scientific Misconduct and Research Fraud

- ✦ Falsification, fabrication, plagiarism, and ghost authorship
- ✦ Overview of federal research misconduct investigations requirements
- ✦ After the investigation: What comes next?

ANGELIQUE DORSEY, University Research Compliance Officer, Tulane University

RORY JAFFE, Executive Director- Medical Services, University of California–Office of the President

202 Getting Your Arms Around Research Medical Records

- ✦ Understanding laws and regulations that affect the research record
- ✦ Compatibility of patients' legal medical records and the research record
- ✦ Training strategies for PIs and research coordinators to ensure ongoing compliance

CAROLE KLOVE, Chief Compliance and Privacy Officer, UCLA Medical Sciences

203 The Tissue Issue: Challenging Problems in Biorepository Research

- ✦ Determining when the use of stored specimens becomes “research”
- ✦ Seeking informed consent and responding to requests to withdraw consent
- ✦ Protecting the privacy of donors

KRISTEN ROSATI, Coppersmith Gordon Schermer & Brockelman PLC

204 How to Create Whistleblowers and What to Do When You Have Them

- ✦ Characteristics of whistleblowers
- ✦ How we create them
- ✦ How to deal with them

FRANK SHEEDER, Partner, Jones Day

4:45-6:30 PM

Networking Reception

Friday, November 2

8:00 AM – 4:30 PM

Registration

8:00 – 9:00 AM

Continental Breakfast

9:00 – 10:15 AM

General Session: Updates in Human Subject Protections

- ✦ Human Research Protection Programs need to evolve in to more robust operations for Research Volunteers Safety
- ✦ Accreditation and certification programs can significantly enhance institutional compliance with regulatory requirements
- ✦ Progress and developments for improved, flexible and harmonized regulations and guidances

JOHN H. MATHER, Director, Huron Consulting Group

Agenda

Friday, November 2 (continued)

10:15 – 10:30 AM

Break

10:30 – 11:45 AM

General Session: The Enforcement Agenda for Research

FRANK SHEEDER, Partner, Jones Day (moderator)

LINDA WAWZENSKI, U.S. Attorney's Office, Deputy Chief, Civil Division

12:00 – 1:15 PM

Lunch Speaker: On the Road Ahead

- ✦ Regulatory trends
- ✦ Medical science and ethics
- ✦ Future roles and responsibilities

RORY JAFFE, Executive Medical Director–Medical Services, University of California–Office of the President

JOHN STEINER, Chief Compliance Officer, UK HealthCare

1:15 – 2:30 PM

CONCURRENT BREAKOUT SESSIONS

301 Contracts: What Every Research Compliance Officer Needs to Know

- ✦ Key provisions of clinical trial sponsorship agreements
- ✦ Financial relationships with sponsors and investigators
- ✦ Ensuring consistency between agreements and consents

DAVID VUKADINOVICH, Senior Counsel, Catholic Healthcare West

302 Practical Perspectives on IRB Compliance

- ✦ Measuring the adequacy of IRB protocol review
- ✦ Developing quality indicators for institutional review boards
- ✦ Developing outcome measures for institutional review boards

MARIA PEKAR, Chief Compliance Officer, Loyola University Health System

URSULA BROZEK, Compliance and Privacy Officer, University of Illinois, College of Nursing

303 The Inside Story on Clinical Research Billing

- ✦ The ins & outs of a compliant research billing operation: practical strategies to making it work
- ✦ Integrating current research billing compliance programs with revised CMS policy
- ✦ Centralizing research compliance for a successful research billing program

BEAU GOSTOMSKY, Director, NYU School of Medicine, Office of Clinical Trials

KELLY WILLENBERG, Director, Health Sciences Research, Spartanburg Regional Healthcare System

304 Designing a Dynamic Research Compliance Program: Can It Be Done?

- ✦ Assessing the research risk: What's going on at my institution?
- ✦ Thinking outside the box for education & training
- ✦ Developing a post-monitoring review plan
- ✦ Aligning policies with institutional mission

SHERRY BREWER, Compliance Officer, University of Tennessee Graduate School of Medicine–Knoxville, TN

SYLVIA FRIEDL, Research Compliance Officer, UT College of Medicine–Chattanooga

2:30 – 2:45 PM

Break

2:45 – 4:00 PM

CONCURRENT BREAKOUT SESSIONS

401 Clinical Trials: Budgets, Billing and Procedure

- ✦ Clinical trial billing issues start with a budget
- ✦ Billing procedures and training on how to bill Clinical Trials claims in the patient accounting system
- ✦ Clinical trials support staff: preparation, communication, training

SUSAN KOENIG, Director of Compliance, University of Missouri–Columbia School of Medicine

LISA DILLION, Assistant Manager, Hospital Patient Accounts, University of Missouri

402 Auditing & Monitoring Clinical Research for Sponsors

- ✦ Describe the regulatory basis for establishing an audit and monitoring program
- ✦ Outline a business case for a viable audit and monitoring program
- ✦ Describe the necessary elements for an effective audit and monitoring program, including audit content considerations for sponsor organizations; and scope development, sampling techniques, and reporting

MICHELLE ANDERSON, Senior Consultant, Deloitte & Touche, LLP

LYNDA HILLIARD, Senior Manager, Deloitte & Touche, LLP

403 Conflicts of Interest in Research

- ✦ How do different research institutions define financial conflicts of interest?
- ✦ What are the benefits and risks of promoting academia/biomedical industry collaborations?
- ✦ How can financial conflicts of interest in research be effectively managed and monitored by compliance officers?
- ✦ What is the best way to disclose financial conflicts of interest to research participants, and how are participants likely to react?

JOAN CARON, Director, Office of Research Compliance, University of Connecticut Health Center

MARK HALL, Professor of Law & Public Health, Wake Forrest University Medical School

Speakers

Jill Alvarez

Nixon Peabody LLP
Washington, DC

Michelle Anderson

Senior Consultant
Deloitte & Touche, LLP
Costa Mesa, CA

Judith Argon

Chief Administrative Officer
Geisinger Health System
Danville, PA

Marti Arvin, CHC, CIPP/G, CCEP, CPC

Privacy Officer
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Sylvia Friedl

Research Compliance Officer
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Carole Klove

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Linda Wawzenski

U.S. Attorney's Office, Deputy Chief, Civil Division
Chicago, IL

Kelly Willenberg

Director, Health Sciences Research
Spartanburg Regional Healthcare System
Spartanburg, SC

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SESSION SELECTION: Please indicate below which sessions you would like to attend. This information will be used for planning. You are not obligated to attend selected sessions.

Wednesday, October 31

PRE-CONFERENCES

9:00–11:45 AM

P1

P2

P3

1:00–4:00 PM

P4

P5

P6

Thursday, November 1

1:45–3:00 PM

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104

3:30–4:45 PM

201

202

203

204

Friday, November 2

1:15–2:30 PM

301

302

303

304

2:45–4:00 PM

401

402

403

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Special rates of \$239 (plus tax) per night have been arranged for the Health Care Compliance Association's Research Compliance Conference at Chicago Marriott Downtown Magnificent Mile. Call the hotel directly at 1-800-228-9290 to make a reservation (a deposit of the first night's stay is required). This rate is good until Friday, October 13, 2007, or until the group block is sold out, whichever comes first. Reservations received after this date or after the group block is filled will be accepted on space and rate availability.

Group Discounts: Five or more individuals from the same company receive a \$100 conference registration discount per person, based on membership status. Please complete a registration form for each attendee and fax or mail in simultaneously.

Tax Deductibility: All expenses incurred during training to maintain or improve skills in your profession (including tuition, travel, lodging, and meals) may be tax deductible. Please consult your tax advisor.

Cancellations/Substitution: No refunds will be given for "no-shows" or cancellations. You may send a substitute or receive a conference credit. Cancellation by telephone is NOT valid. Please fax written cancellations to 952-988-0146 or e-mail Patti Hoskin at patti.hoskin@hcca-info.org.

Dress Code: Business casual dress is appropriate.

Conference Objective

This is the research conference you cannot miss if you work for a sponsor, a research site, or for clinicians who conduct research. Learn about updates to the new CMS Clinical Research Policy (replacing the Medicare NCD for Clinical Trials), latest trends on compliance with research accounting standards, clinical trial billing and process improvement, effort reporting, scientific misconduct, conflicts of interest, off-label use issues, FDA compliance, and government enforcement trends. Hear directly from representatives from NIH, OHRP, ORI, the FDA, the OIG, and the DOJ, and from other industry experts who can provide practical perspectives for handling research compliance risks.

Continuing Education Credits

AAPC: This program/publication/subscription/etc. has prior approval of the American Academy of Professional Coders for 5.5 per day Continuing Education Units. Granting of this approval in no way constitutes endorsement by the Academy of the program, content or the program sponsor.

ACHE: The Health Care Compliance Association is authorized to award 17.5 hours of preapproved Category II (non-ACHE) continuing education credit for this program toward advancement or recertification in the American College of Healthcare Executives. Participants of this program wishing to have the continuing education hours applied to Category II credit should list their attendance when applying for advancement or recertification in ACHE.

AHIMA: This program has been approved for 18 continuing education units for use in fulfilling the continuing education requirements of the American Health Information Management Association (AHIMA).

HCCB: This program has been approved for 21.3 HCCB continuing education credits for compliance certification.

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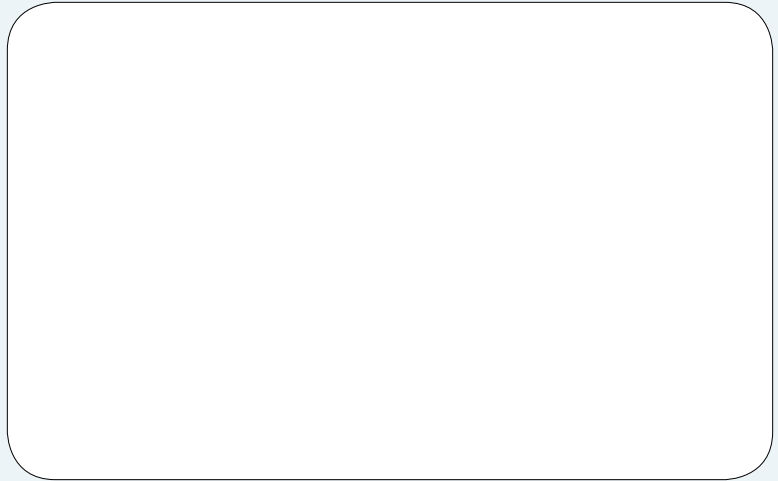
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