WE’VE MOVED
from the autumn to the spring,
so please mark your calendars

RESEARCH
Compliance
Conference

April 21–24, 2010 | Dallas, TX

This is the research conference you cannot miss if you work for a research site, a CRO or SMO, a hospital or hospital system, a sponsor, or for clinicians/investigators who conduct research. Learn about updates to the new CMS Clinical Trials Policy (replacing the Medicare NCD for Clinical Trials), latest trends on compliance with research accounting standards, clinical trial billing and process improvements, 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, and the FDA and from other industry experts who can provide practical perspectives for handling research compliance risks.

Research Compliance Conference registration includes complimentary access to SCCE’s 8th Conference for Effective Compliance Systems in Higher Education (see page 2 for details)

Register at www.hcca-research-conference.org
## Program at a Glance

### Wednesday, April 21: Pre-Conference

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Speakers/Details</th>
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<tbody>
<tr>
<td>12:00 - 6:00 PM</td>
<td>Registration Desk</td>
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<tr>
<td>1:00 - 3:00 PM</td>
<td><strong>Breakout Sessions</strong> Pre-Conference 1</td>
<td><strong>RP1</strong> Research Compliance 101 – Kevin Eskew, MBA, CHC, Managing Director; Sonnenschein, Nath &amp; Rosenthal, LLP; Fred Herman, CHRC, Manager, Research Compliance, University of Maryland Medical System, Department of Finance</td>
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<td></td>
<td><strong>RP2</strong> FDA’s New Enforcement Agenda: What It Means to Clinical Investigators and IRBs – Rachel Nosowsky, Principal Counsel, University of California; Jeffrey Layne, Partner, Fulbright &amp; Jaworski LLP</td>
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<tr>
<td>3:30 - 5:30 PM</td>
<td><strong>Breakout Sessions</strong> Pre-Conference 2</td>
<td><strong>RP3</strong> Faculty Training for Research Compliance Professionals – Angelique Dorsey, JD, CHRC, Research Compliance Director, MedStar Health</td>
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<td><strong>RP4</strong> Raising the Bar on Adequate Human Subject Protection – Cynthia Gates, VP Operations, Western Institutional Review Board; Jeffrey A. Cooper, MD, MMM, Director, Huron Consulting Group</td>
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<tr>
<td>5:30 - 6:30 PM</td>
<td>Welcome Reception</td>
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### Thursday, April 22: Conference

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Speakers/Details</th>
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<tbody>
<tr>
<td>7:00 AM – 6:30 PM</td>
<td>Registration Desk</td>
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<tr>
<td>7:30 – 8:15 AM</td>
<td>Continental Breakfast (provided)</td>
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<tr>
<td>8:15 – 8:30 AM</td>
<td>General Session: Opening Remarks</td>
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<tr>
<td>9:30 – 10:00 AM</td>
<td>Networking Break</td>
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<tr>
<td>10:00 – 11:30 AM</td>
<td><strong>Breakout Sessions</strong></td>
<td><strong>R101</strong> How ARRA HITECH Rule Affects Research Data – Joy Hardee, RHIA, CHPS, CHRC, CPHQ, Administrator, UHS Privacy Officer/Research Compliance Office of Audit &amp; Compliance University Health Systems of Eastern Carolina; Carole A. Klove, RN, JD, CHRC, Special Projects, UCSF Medical Center</td>
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<td></td>
<td><strong>R102</strong> Case Studies in Clinical Research Fraud Enforcement – Jesse Witten, Partner, Drinker Biddle &amp; Reath LLP; Gary W. Eiland, Partner, King &amp; Spalding LLP</td>
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<td><strong>R103</strong> Developing a Research Compliance Program in the Context of Corrective Actions to an OHRP Investigation – Michael Roach, Partner, Meade &amp; Roach, LLP; Ronald R. Sagritalo, JD, MBA, CHC, CPC-A, Chief Compliance Officer, Hospital Group, Spectrum Health</td>
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<tr>
<td>11:45 AM – 12:30 PM</td>
<td>Networking Luncheon (provided)</td>
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<tr>
<td>12:45 – 2:15 PM</td>
<td><strong>Breakout Sessions</strong></td>
<td><strong>R201</strong> Managing Regulatory Compliance for Investigator-Initiated Research – Leah R. Kendall, Senior Associate, Epstein Becker &amp; Green; Thomas Bechert, CHRC, Manager, Huron Consulting Group</td>
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<td><strong>R202</strong> Ensuring a Sound, Compliant Animal Care and Use Program in a Changing (and Challenging) Landscape – Kathy Wadsworth, Director, Office of Animal Research Oversight (OARO), University of California, Los Angeles</td>
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<td><strong>R203</strong> Data Security in Research: Is the IRB Responsible? – Russell Opland, Systemwide Privacy Officer, University of California; Marian Hughlett, CHC, CHRC, Deputy Privacy Officer, University of Louisville</td>
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<td>2:15 – 2:45 PM</td>
<td>Networking Break</td>
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<tr>
<td>2:45 – 4:15 PM</td>
<td><strong>Breakout Sessions</strong></td>
<td><strong>R301</strong> Conflicts of Interest in Research: Ethical, Regulatory, and Practical Considerations – Suzanne M. Rivera, PhD, MSW, Vice President, Research Administration, UT Southwestern Medical Center; Ann N. James, PhD, JD, Senior University Counsel, OGC, Stanford University</td>
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<td><strong>R302</strong> Developing an Effective Anti-Bribery and Corruption Compliance Program in an Environment of Heightened Enforcement – Jay Perlman, Director, Daylight Forensic &amp; Advisory LLC; Joel Rush, Associate, Epstein, Becker &amp; Green</td>
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<td><strong>R303</strong> The Learnings of a Developing Clinical Trials Office Within an Established Teaching Hospital – Eve Sakran, MS, Director, JHS Clinical Trials Office, Jackson Health System; Ljudmila Hadzikadunic, RN, JD, Compliance Manager, Jackson Health System</td>
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<td>General Session: International Research – Dr. Melody Lin, Deputy Director, Office for Human Research Protection, U.S. Department of Health and Human Services</td>
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<td>Networking Reception</td>
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## Program at a Glance

### Friday, April 23: Conference

<table>
<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>7:00 AM – 4:00 PM</td>
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<td>7:30 – 8:30 AM</td>
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</tr>
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<td>8:30 – 8:45 AM</td>
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<td>General Session: Research Compliance: A Year in Review – Lisa Murtha, JD, CHC, CHRC, Partner, Sonnenschein, Nath &amp; Rosenthal, LLP; Kendra Dimond, JD, CHRC, Director, Daylight Forensic &amp; Advisory</td>
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<td>10:15 – 11:15 AM</td>
<td>General Session: An FDA Report: Physician Initiated Device Studies at Academic Medical Centers – Anne T. Hawthorn, JD, Chief, Special Investigations Branch, Division of Bioresearch Monitoring, Office of Compliance, CDRH, FDA</td>
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<td>11:30 – 12:30 PM</td>
<td>Networking Luncheon (provided)</td>
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<tr>
<td>12:30 – 2:00 PM</td>
<td><strong>BREAKOUT SESSIONS</strong>&lt;br&gt;&lt;br&gt;R401 Compliance Challenges in Establishing and Using Clinical Databases – Melissa (Lisa) Thompson, JD, MPH, Sr. Counsel, Adelman, Sheff &amp; Smith, LLC; Betsy Hall, Director of Corporate Compliance, Privacy and Information Security, Jewish Hospital &amp; St. Mary’s HealthCare, Inc. (JHSMH)  &lt;br&gt;&lt;br&gt;R402 Unanticipated Problems in Human Subject Research: Adverse Events and Beyond – Karen Dunn, CIP, Manager, Research Compliance &amp; Quality Improvement, Cedars-Sinai Medical Center; Andra M. Popa, JD, LLM, CHC, CHRC, Consultant, Meade &amp; Roach, LLP  &lt;br&gt;&lt;br&gt;R403 Research Misconduct: Detection and Risk Mitigation Solutions – Susan S. Night, Health Policy and Ethics Fellow, Baylor College of Medicine; Sheryl Tatar Dacso, Partner, Brown McCarroll, LLP</td>
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<td>2:00 – 2:30 PM</td>
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<tr>
<td>2:30 – 4:00 PM</td>
<td><strong>BREAKOUT SESSIONS</strong>&lt;br&gt;&lt;br&gt;R501 Managing Export Control Compliance in Biomedical Research – Don Fischer, Principal, Fischer &amp; Associates, Export Control Consulting  &lt;br&gt;&lt;br&gt;R502 Off-Label Use vs. Clinical Trial Use of Devices: FDA Regulatory Issues – Neil O’Flaherty, Principal Attorney, Olsson Frank Weeda Terman Bode Matz PC  &lt;br&gt;&lt;br&gt;R503 The Ten Steps to an Effective Research Compliance Program: A Practicum for Research Compliance Professionals – Luanna Putney, CHC, CCER, Systemwide Director of Research Compliance, University of California; Juliann Tenney, CHRC, Institutional Research Compliance Officer, Director of the Institutional Research Compliance Program and Privacy Officer, University of North Carolina at Chapel Hill</td>
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### Saturday, April 24: Post-Conference

<table>
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<tr>
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<td>7:00 AM – 12:00 PM</td>
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<tr>
<td>7:30 – 8:30 AM</td>
<td>Networking Break (beverages provided)</td>
</tr>
<tr>
<td>8:30 – 11:30 AM</td>
<td><strong>BREAKOUT SESSIONS</strong>&lt;br&gt;&lt;br&gt;RW1 Research Risks: What’s the Assessment? – Margaret Hambleton, MBA, CPHRM, CHC, Senior Vice President, Ministry Integrity for St. Joseph Health System; Rebecca Scott, Clinical Research Compliance Manager, UK Healthcare  &lt;br&gt;&lt;br&gt;RW2 The Closer: Resolve the Risky Business of Billing Compliance – Kathleen Hurtado, RPh, President and CEO, Health Research Association, Inc., A subsidiary of the University of Southern California; Kelly Willenberg, CHRC, President, Synergism, LLC</td>
</tr>
<tr>
<td>11:30 AM – 12:30 PM</td>
<td>Lunch (on your own)</td>
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<tr>
<td>12:30 – 1:00 PM</td>
<td>CHRC Exam Check-In</td>
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<tr>
<td>1:00 – 3:00 PM</td>
<td>CHRC Exam (optional)</td>
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## Take the CHRC Certification Exam On-Site

**When:** Saturday, April 24, 2010 / 1:00–3:00 PM  
**Where:** Hyatt Regency Dallas | Dallas, Texas  
**Cost:** $250 (HCCA Members) / $350 (Non-Members)

You must be pre-registered to sit for the exam. To apply, download the CHRC Exam Application <http://www.hcca-research-conference.org/CEU/CHRCexamAp_042410.pdf>. Questions? E-mail ccb@hcca-info.org. Twenty CCB CEUs are required to sit for the exam. For Research Compliance Conference sessions, one clock hour equals 1.2 CCB/CHRC hours. Attending the entire Research Compliance Conference will provide a maximum of 21.9 CEUs to qualify to sit for the exam.
AGENDA

WEDNESDAY, APRIL 21: PRE-CONFERENCE

12:00 – 6:00 PM
Registration Desk

1:00 – 3:00 PM
BREAKOUT SESSIONS: PRE-CONFERENCE 1

RP1 Research Compliance 101

- Provide overview of research compliance (dynamics, accountabilities, regulations)
- Identify the common areas of risk and compliance concerns that health care organizations must face if they choose to nurture research activities
- Summarize what some of the strategic options are for managing research compliance

  Kevin Eskew, MBA, CHC, Managing Director, Sonnenschein, Nath & Rosenthal, LLP; Fred Herman, CHRC, Manager, Research Compliance, University of Maryland Medical System, Department of Finance

RP2 FDA’s New Enforcement Agenda: What It Means to Clinical Investigators and IRBs

- FDA’s enforcement tools and best practices for preparing for and responding to FDA inspections
- Other enforcement options for federal authorities: criminal and civil exposure for investigators and research sites
- Advanced risk evaluation and mitigation strategies for compliance professionals overseeing FDA-regulated activities

  Rachel Nosowsky, Principal Counsel, University of California; Jeffrey Layne, Partner, Fulbright & Jaworski LLP

3:30 – 5:30 PM
BREAKOUT SESSIONS: PRE-CONFERENCE 2

RP3 Faculty Training for Research Compliance Professionals

- Challenges in establishing effective faculty education programs
- Developing a curriculum
- Maximizing utilization and participation

  Angelique Dorsey, JD, CHRC, Research Compliance Director, MedStar Health

RP4 Raising the Bar on Adequate Human Subject Protection

- Principal investigator vs. physician: Avoid therapeutic misconception & ensure proper delegation
- How do we best protect subjects when there’s a conflict of interest?
- Maximize human subject protection while minimizing workload and regulatory oversight

  Cynthia Gates, VP Operations, Western Institutional Review Board; Jeffrey A. Cooper, MD, MMM, Director, Huron Consulting Group

THURSDAY, APRIL 22: CONFERENCE

7:00 AM – 6:30 PM
Registration Desk

7:30 – 8:15 AM
Continental Breakfast (provided)

8:15 – 8:30 AM
Opening Remarks

8:30 – 9:30 AM
General Session: 2010 Update from OHRP and ORI

- Overview of interrelationship between ORI and OHRP compliance oversight jurisdiction
- Update on ORI and OHRP compliance activities
- Discussion of illustrative case studies

  Jo An Rochez, Senior Attorney, Office of the General Counsel, U.S. Department of Health and Human Services; Laura Odwazny, Senior Attorney, Office of the General Counsel, U.S. Department of Health and Human Services

9:30 – 10:00 AM
Networking Break

10:00 – 11:30 AM
BREAKOUT SESSIONS

R101 How ARRA HITECH Rule Affects Research Data

- The importance of HITECH breach notification requirements and how it affects research data
- Education to PIs on encrypting research data and why as it relates to breach notification laws
- Why your research protocol needs to mirror what you do to secure research data

  Joy Hardee, RHIA, CHPS, CHRC, CPHQ, Administrator, UHS Privacy Officer/Research Compliance Office of Audit & Compliance University Health Systems of Eastern Carolina; Carole A. Klove, RN, JD, CHRC, Special Projects, UCSF Medical Center

R102 Case Studies in Clinical Research Fraud Enforcement

- Review leading enforcement theories
- In-depth analysis of selected, representative fraud enforcement matters involving clinical research
- Lessons learned from the government’s enforcement actions

  Jesse Witten, Partner, Drinker Biddle & Reath LLP; Gary W. Eiland, Partner, King & Spalding LLP
AGENDA

THURSDAY, APRIL 22: CONFERENCE (CONT'D)

R103 Developing a Research Compliance Program in the Context of Corrective Actions to an OHRP Investigation

- An experience with a recent OHRP for-cause audit
- Lessons learned from using an external IRB
- Revising aspects of the human subjects protection program during the audit

Michael Roach, Partner, Meade & Roach, LLP; Ronald R. Sagritalo, JD, MBA, CHC, CPC-A, Chief Compliance Officer, Hospital Group, Spectrum Health

11:45 AM – 12:30 PM
Networking Luncheon (provided)

12:45 – 2:15 PM
BREAKOUT SESSIONS

R201 Managing Regulatory Compliance for Investigator-Initiated Research

- Key regulatory compliance responsibilities related to investigator-held IND or IDE research
- Risk-management strategies for institutions whose investigators hold INDs/IDEs
- Internal processes and written agreements for managing investigator-initiated research

Leah R. Kendall, Senior Associate, Epstein Becker & Green; Thomas Bechert, CHRC, Manager, Huron Consulting Group

R202 Ensuring a Sound, Compliant Animal Care and Use Program in a Changing (and Challenging) Landscape

- Overview of animal research compliance
- Hot topics & updates in regulatory oversight, compliance and risk assessment
- Anticipating challenges from animal rights extremists

Kathy Wadsworth, Director, Office of Animal Research Oversight (OARO), University of California, Los Angeles

R203 Data Security in Research: Is the IRB Responsible?

- Review data breach trends and drivers
- Discuss IRB and investigator obligations to safeguard data
- Present solutions, strategies, and tools for data security in research

Russell Opland, Systemwide Privacy Officer, University of California; Marian Hughlett, CHC, CHRC, Deputy Privacy Officer, University of Louisville

2:45 – 4:15 PM
BREAKOUT SESSIONS

R301 Conflicts of Interest in Research: Ethical, Regulatory, and Practical Considerations

- What is an “interest” and why interests can create real or apparent conflicts
- What kinds of measures are required by regulation to protect research subjects from potential conflicts and to maintain scientific integrity
- What steps your institution can take to prevent, identify and manage conflicts of interest in research

Suzanne M. Rivera, PhD, MSW, Vice President, Research Administration, UT Southwestern Medical Center; Ann N. James, PhD, JD, Senior University Counsel, OGC, Stanford University

R302 Developing an Effective Anti-Bribery and Corruption Compliance Program in an Environment of Heightened Enforcement

- The Elements of an Effective FCPA Compliance Program
- Using Technology to Address Third-Party Risk
- Responding to Investigative Findings

Jay Perlman, Director, Daylight Forensic & Advisory LLC; Joel Rush, Associate, Epstein, Becker & Green

R303 The Learnings of a Developing Clinical Trials Office Within an Established Teaching Hospital

- The hospital established a requirement for 3-party agreements
- Working with financial systems to create a bill hold and audit process
- Creating collaborative relationships with the University’s PIs and research administration

Eve Sakran, MS, Director, JHS Clinical Trials Office, Jackson Health System; Ljudmila Hadzikadunic, RN, JD, Compliance Manager, Jackson Health System

4:15 – 4:30 PM
Networking Break

4:30 – 5:30 PM
General Session: International Research

Dr. Melody Lin, Deputy Director, Office for Human Research Protection, U.S. Department of Health and Human Services

5:30 – 6:30 PM
Networking Reception
AGENDA

FRIDAY, APRIL 23: CONFERENCE

7:00 AM – 4:00 PM
Registration Desk

7:30 – 8:30 AM
Continental Breakfast (provided)

8:30 – 8:45 AM
General Session: Opening Remarks

8:45 – 9:45 AM
General Session: Research Compliance: A Year in Review
• Updates in laws, regulations, and settlements in research compliance
  Lisa Murtha, JD, CHC, CHRC, Partner, Sonnenschein, Nath & Rosenthal, LLP; Kendra Dimond, JD, CHRC, Director, Daylight Forensic & Advisory

9:45 – 10:15 AM
Networking Break

10:15 – 11:15 AM
General Session: An FDA Report: Physician Initiated Device Studies at Academic Medical Centers
• Overview of FDA Device Research Inspection Program
• Review of Device Physician Initiated studies
• Case study
  Anne T. Hawthorn, JD, Chief, Special Investigations Branch, Division of Bioresearch Monitoring, Office of Compliance, CDRH, FDA

11:30 – 12:30 PM
Networking Luncheon (provided)

12:30 – 2:00 PM
BREAKOUT SESSIONS

R401 Compliance Challenges in Establishing and Using Clinical Databases
• Understanding the regulatory requirements for clinical research databases
• Overcoming compliance challenges when linking clinical information and research databases
• Avoiding pitfalls when setting up databases
  Melissa (Lisa) Thompson, JD, MPH, Sr. Counsel, Adelman, Sheff & Smith, LLC; Betsy Hall, Director of Corporate Compliance, Privacy and Information Security, Jewish Hospital & St. Mary’s HealthCare, Inc. (JHSMH)

R402 Unanticipated Problems in Human Subject Research: Adverse Events and Beyond
• Overview of OHRP and FDA regulations and guidance on reporting adverse events and unanticipated problems
• Discussion of events that may occur in clinical research and how to determine whether they are reportable
• Learn how one institution streamlined adverse event reporting to maximize value
  Keren Dunn, CIP, Manager, Research Compliance & Quality Improvement, Cedars-Sinai Medical Center; Andra M. Popa, JD, LLM, CHC, CHRC, Consultant, Meade & Roach, LLP

R403 Research Misconduct: Detection and Risk Mitigation Solutions
• Decisions made by each investigator is the “front line” of research compliance.
• Training investigators in responsible conduct of research is not enough for compliance.
• Creating a culture of research integrity is the road to successful compliance in research
  Susan S. Night, Health Policy and Ethics Fellow, Baylor College of Medicine; Sheryl Tatar Dacso, Partner, Brown McCarroll, LLP

2:00 – 2:30 PM
Networking Break

TAKE ADVANTAGE OF ADDITIONAL SAVINGS

Register for the 2010 HCCA Compliance Institute simultaneously and receive $100 off each registration fee—another $200 SAVINGS!
FRIDAY, APRIL 23: CONFERENCE (CONT’D)

2:30 – 4:00 PM
BREAKOUT SESSIONS

R501 Managing Export Control Compliance in Biomedical Research
- Identifying compliance risks in U.S.-based research and international collaborations
- Current U.S. government enforcement efforts in biomedical research involving sensitive materials and equipment
- Pragmatic tools and solutions for remaining compliant: minimizing individual and institutional risk

Don Fischer, Principal, Fischer & Associates, Export Control Consulting

R502 Off-Label Use vs. Clinical Trial Use of Devices: FDA Regulatory Issues
- What are the legal criteria and requirements for appropriate off-label use of devices?
- How does such off-label use differ from clinical trial use of devices?
- How does one avoid confusing the concepts and minimize enforcement risks?

Neil O’Flaherty, Principal Attorney, Olsson Frank Weeda Terman Bode Matz PC

R503 The Ten Steps to an Effective Research Compliance Program: A Practicum for Research Compliance Professionals
- Key steps necessary to foster an effective compliance program
- Understanding importance of prioritizing steps for different research compliance areas
- Recognizing and leveraging opportunities to build an effective compliance program

Luanna Putney, CHC, CC eP, Systemwide director of Research Compliance, University of California; Juliann Tenney, CHRC, Institutional Research Compliance Officer, Director of the Institutional Research Compliance Program and Privacy Officer, University of North Carolina at Chapel Hill

SATURDAY, APRIL 24: POST-CONFERENCE

7:00 AM – 12:00 PM
Registration Desk

7:30 – 8:30 AM
Networking Break (beverages provided)

8:30 – 11:30 AM
BREAKOUT SESSIONS

RW1 Research Risks....What’s the Assessment?
- Why should you be concerned?
- How to identify the risk
- Is a risk assessment the answer?

Margaret Hambleton, MBA, CPHRM, CHC, Senior Vice President, Ministry Integrity for St. Joseph Health System; Rebecca Scott, Clinical Research Compliance Manager, UK Healthcare

RW2 The Closer: Resolve the Risky Business of Billing Compliance
- Provide attendees with an understanding of current key billing compliance areas including device studies and how to find solutions to challenges
- Highlight common success strategies for bill holds, expand the compliance billing network
- Make an affordable investment and provide ways to link performance improvement into the billing compliance model

Kathleen Hurtado, RPh, President and CEO, Health Research Association, Inc., A subsidiary of the University of Southern California; Kelly Willenberg, CHRC, President, Synergism, LLC

11:30 – 12:30 PM
Lunch (on own)

12:30 – 1:00 PM
CHRC Exam Check-In

1:00 – 3:00 PM
CHRC Exam (optional)
SPEAKERS

THOMAS BECHERT, CHRC, Manager, Huron Consulting Group

JEFFREY A. COOPER, MD, MMM, Director, Huron Consulting Group

KENDRA DIMOND, JD, CHRC, Director, Daylight Forensic & Advisory

ANGELIQUE DORSEY, JD, CHRC, Research Compliance Director, MedStar Health

KEREN DUNN, CIP, Manager, Research Compliance & Quality Improvement, Cedars-Sinai Medical Center

GARY W. EILAND, Partner, King & Spalding LLP

KEVIN ESKEW, MBA, CHC, Managing Director, Sonnenschein, Nath & Rosenthal, LLP

DON FISCHER, Principal, Fischer & Associates, Export Control Consulting

CYNTHIA GATES, VP Operations, Western Institutional Review Board

LUJODMILA HADZIKADUNIC, RN, JD, Compliance Manager, Jackson Health System

BETSY HALL, Director of Corporate Compliance, Privacy and Information Security, Jewish Hospital & St. Mary’s HealthCare, Inc. (JHSMH)

MARGARET HAMBLETON, MBA, CPHRM, CHC, Senior Vice President, Ministry Integrity for St. Joseph Health System

JOY HARDEE, RHIA, CHPS, CHRC, CPHQ, Administrator, UHS Privacy Officer/Research Compliance Office of Audit & Compliance University Health Systems of Eastern Carolina

ANNE T. HAWTHORN, JD, Chief, Special Investigations Branch, Division of Bioresearch Monitoring, Office of Compliance, CDRH, FDA

FRED HERMAN, CHRC, Manager, Research Compliance, University of Maryland Medical System, Department of Finance

MARIAN HUGHLETT, CHC, CHRC, Deputy Privacy Officer, University of Louisville

KATHLEEN HURTADO, RPh, President and CEO, Health Research Association, Inc., A subsidiary of the University of Southern California

ANN N. JAMES, PhD, JD, Senior University Counsel, OGC, Stanford University

LEAH R. KENDALL, Senior Associate, Epstein Becker & Green

CAROLE A. KLOVE, RN, JD, CHRC, Special Projects, UCSF Medical Center

JEFFREY LAYNE, Partner, Fulbright & Jaworski LLP

DR. MELODY LIN, Deputy Director, Office for Human Research Protection, U.S. Department of Health and Human Services

LISA MURTHA, JD, CHC, CHRC, Partner, Sonnenschein, Nath & Rosenthal LLP

SUSAN S. NIGHT, Health Policy and Ethics Fellow, Baylor College of Medicine

RACHEL NOSOWSKY, Principal Counsel, University of California

NEIL O’FLAHERTY, Principal Attorney, Olsson Frank Weeda Terman Bode Matz PC

LAURA ODWAZNY, Senior Attorney, Office of the General Counsel, U.S. Department of Health and Human Services

RUSSELL OPLAND, Systemwide Privacy Officer, University of California

JAY PERLMAN, Director, Daylight Forensic & Advisory LLC

ANDRA M. POPA, JD, LLM, CHC, CHRC, Consultant, Meade & Roach, LLP

LUANNA K. PUTNEY, CHC, CCEP, Director of Research Compliance, University of California

SUZANNE M. RIVERA, PhD, MSW, Vice President, Research Administration, UT Southwestern Medical Center

MICHAEL ROACH, Partner, Meade & Roach, LLP

JO AN ROCHEZ, Senior Attorney, Office of the General Counsel, U.S. Department of Health and Human Services

JOEL RUSH, Associate, Epstein, Becker & Green

RONALD R. SAGRITALO, JD, MBA, CHC, CPC-A, Chief Compliance Officer, Hospital Group, Spectrum Health

EVE SAKRAN, MS, Director, JHS Clinical Trials Office, Jackson Health System, Miami, FL

REBECCA SCOTT, Clinical Research Compliance Manager, UK Healthcare

SHERYL TATAR DACSO, Partner, Brown McCarroll, LLP

JULIANN TENNEY, CHRC, Institutional Research Compliance Officer, Director of the Institutional Research Compliance Program and Privacy Officer, University of North Carolina at Chapel Hill

MELISSA (LISA) THOMPSON, JD, MPH, Sr. Counsel, Adelman, Sheff & Smith, LLC

KATHY WADSWORTH, Director, Office of Animal Research Oversight (OARO), University of California, Los Angeles

KELLY WILLENBERG, CHRC, President, Synergism, LLC

JESSE WITTEN, Partner, Drinker Biddle & Reath LLP
WHAT TO DO IN DALLAS

**DID YOU KNOW...**

The Dallas metropolitan area is the #1 visitor and leisure destination in Texas.

Dallas has the largest contiguous arts district in the United States.

The City of Dallas has over 300 public art works in its collection.

The Dallas area has more than 200 area golf courses.

**THE WOMEN’S MUSEUM**, located in historic Fair Park, is a Smithsonian affiliate and the nation’s only comprehensive women’s history museum.

**THE MEADOWS MUSEUM**, located on the campus of Southern Methodist University, houses one of the most comprehensive collections of Spanish art outside of Spain.

**THE AFRICAN AMERICAN MUSEUM** in Dallas’ Fair Park has one of the largest collections on African-American folk art in the nation and is a Smithsonian affiliate.

**THE NASHER SCULPTURE CENTER**, designed by Renzo Piano, features more than 300 works of modern and contemporary sculpture from the Raymond and Patsy Nasher collection.

**DALLAS’ FARMERS MARKET** is one of the largest working farmer’s markets in the country, with over a million visitors annually.

**THE DALLAS ARBORETUM** holds the Southwest’s largest annual outdoor floral festival.

The historic **MCKINNEY AVENUE TROLLEY** operates a free service daily and is one of the largest volunteer-run systems in the world.

**THE DALLAS AREA RAPID TRANSIT** (DART) light rail system is one of the fastest growing rail lines in the nation.

**THE DALLAS WORLD AQUARIUM** is home to a 255,000 gallon freshwater aquarium tank.

FOR ADDITIONAL INFORMATION ABOUT DALLAS ATTRACTIONS, PLEASE VISIT WWW.VISITDALLAS.COM
Step 1: Contact Information (please type or print)

- MR.  - MRS.  - MS.  - DR.

HCCA MEMBER ID

FIRST  MI  LAST

CREDENTIALS (CHRC, CHC, ETC.)

TITLE

PLACE OF EMPLOYMENT

ADDRESS

CITY  STATE  ZIP

PHONE

FAX

E-MAIL (REQUIRED FOR CONFIRMATION NOTIFICATION & CONFERENCE INFORMATION)

Step 2: Choose Your Sessions

Please select sessions to assist in room planning. Select ONE session per time slot.

Wednesday, April 21

Pre-Conference 1: 1:00 – 3:00 PM
  □ Rp1  □ Rp2

Pre-Conference 2: 3:30 – 5:30 PM
  □ Rp3  □ Rp4

Thursday, April 22

Breakout Sessions 10:00 – 11:30 AM
  □ R101  □ R102  □ R103

Breakout Sessions 12:45 – 2:15 PM
  □ R201  □ R202  □ R203

Breakout Sessions 2:45 – 4:15 PM
  □ R301  □ R302  □ R303

Friday, April 23

Breakout Sessions 12:30 – 2:00 PM
  □ R401  □ R402  □ R403

Breakout Sessions 2:30 – 4:00 PM
  □ R501  □ R502  □ R503

Saturday, April 24

Post-Conference: 8:30 – 11:30 AM
  □ Rw1  □ Rw2

☐ Yes, I’m interested in selecting sessions from SCCE’s Conference for Effective Compliance Systems in Higher Education. Please send me more information.

Step 3: Choose Your Registration

☐ HCCA Members .......................................................... $599
☐ Membership Renewal & Registration .................................. $894
☐ Non-Members ............................................................. $699
☐ New Membership & Registration ...................................... $799
  NEW MEMBERS ONLY. DUES REGULARLY $295 ANNUALLY.
☐ Pre-Conference Registration 1 ..................................... $100
  FREE ONLY WITH PURCHASE OF EARLY BIRD REGISTRATION.
☐ Pre-Conference Registration 2 ..................................... $100
  FREE ONLY WITH PURCHASE OF EARLY BIRD REGISTRATION.
☐ Post-Conference Registration .............................................
  FREE WITH FULL CONFERENCE REGISTRATION ONLY. PLEASE CHECK IF YOU PLAN TO ATTEND.
☐ Discount for Attending HCCA’s 2010 Compliance Institute in Dallas, Texas ........................................ (100)
☐ Research Conference Binder ........................................ $45

Total:

Step 4: Payment

☐ Check enclosed (payable to HCCA)  ☐ Invoice me  ☐ Purchase Order #

Charge my:  ☐ AmericanExpress  ☐ Diners Club  ☐ MasterCard  ☐ Visa

Credit Card Account Number

Credit Card Expiration Date

Cardholder’s Name

Cardholder’s Signature  RC0410

Yes, I’m interested in selecting sessions from SCCE’s Conference for Effective Compliance Systems in Higher Education. Please send me more information.
**Hotel & Conference Location**

Hotel information will be announced. Please visit www.hcca-info.org for updates.

**Registration Terms & Conditions**

Checks are payable to HCCA. Credit cards accepted: American Express, MasterCard, or Visa. HCCA will charge your credit card the correct amount should your total be miscalculated.

**Group:** $100 per person for five or more from the same company, based on membership status; only if each attendee completes a registration and they are faxed or mailed in simultaneously.

**Compliance Institute Special:** Attend HCCA's 2010 Compliance Institute preceding this conference and save $100 off the Institute and $100 off the Higher Education or Research Conference. That's an additional savings of $200!

**Tax Deductibility:** All expenses incurred to maintain or improve skills in your profession may be tax deductible; including tuition, travel, lodging and meals. Please consult your tax advisor (Federal Tax ID # 23-2882664).

**Cancellations/Substitutions:** No refunds will be given for “no-shows” or cancellations. You may send a substitute, or receive a credit for other conferences to be used within one year. Please call Patti Hoskin at 888-580-8373 or e-mail patti.hoskin@hcca-info.org.

**Dress Code:** Business casual dress is appropriate.

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**HCCA Is Going Green:** Attendees will receive electronic access to the course materials prior to the program as well as an electronic version of the materials at the program. Attendees will not automatically receive the binders. If you would like to purchase the binders for $45, please check “Conference Binders” on the registration form.

**Prerequisites:** None.

**Special Needs/Concerns:** Prior to your arrival, please call HCCA at 888-580-8373 if you have a special need and require accommodation to participate in the Research Compliance Conference.

**Agreements & Acknowledgements:**

I agree and acknowledge that I am undertaking participation in HCCA events and activities as my own free and intentional act, and I am fully aware that possible physical injury might occur to me as a result of my participation in these events. I give this acknowledgement freely and knowingly and assert that I am, as a result, able to participate in HCCA events, and I do hereby assume responsibility for my own well-being. I agree and acknowledge that HCCA plans to take photographs at the HCCA Research Compliance Conference and reproduce them in HCCA educational, news, or promotional material, whether in print, electronic, or other media, including the HCCA website. By participating in the HCCA Research Compliance Conference, I grant HCCA the right to use my name, photograph, and biography for such purposes.

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**Continuing Education Credits**

HCCA is in the process of applying for additional credits. If you do not see information on your specific accreditation, please contact us at 855-989-0141 or 888-580-8373 as we would like the opportunity to offer it. Visit HCCA's Research Compliance Conference website, www.hcca-research-conference.org, for up-to-date information.

**ACHE:** This program has prior approval from the American College of Healthcare Executives (ACHE) for a recommended maximum of 18 category II continuing education credits.

**AHIMA:** This program has been approved for 18.0 continuing education units (CEUs) for use in fulfilling the continuing education requirements of the American Health Information Management Association (AHIMA). Granting prior approval from AHIMA does not constitute endorsement of the program content or its program sponsor.

**CA NURSING CE:** The Health Care Compliance Association is pre-approved by the California Board of Registered Nursing; Provider Number CEP 12990, for a maximum of 21.9 contact hours. The following states will accept CA Board of Nursing Contact Hours: Alabama, Alaska, Arkansas, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Texas, West Virginia, Wyoming. The following states do not have continuing education requirements: Arizona, Colorado, Connecticut, Georgia, Hawaii, Indiana, Maine, Missouri, Montana, New York, Oklahoma, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, Wisconsin. The following states will NOT accept CA Board of Nursing contact hours: Delaware, Florida, New Jersey, Utah, Massachusetts and Mississippi nurses may submit CA Board of Nursing contact hours to their state board; but approval will depend on review by the board. Please contact the Accreditation department at cbca@hcca-info.org with any questions you may have.

**CHRC:** You must be pre-registered to sit for the CHRC exam. To apply, download the CHRC Exam Application http://www.hcca-research-conference.org/CEU/CHRCexamAp_042410.pdf. Questions? Email cbcl@hcca-info.org. Twenty CBCE CEUs are required to sit for the exam. For Research Compliance Conference sessions, one clock hour equals 1.2 CBEC/CHRC hours. Attending the entire Research Compliance Conference will provide a maximum of 21.9 CEUs to qualify to sit for the exam.

**CLE:** The Health Care Compliance Association/Society of Corporate Compliance and Ethics is a State Bar of California Approved MCLE provider, a Rhode Island Accredited Provider, and a Texas Accredited Sponsor. All CLE credits will be awarded based on individual attendance.

**Compliance Certification Board (CCB):** Certified in Healthcare Compliance (CHC), Certified Compliance & Ethics Professional (CCEP), Certified in Healthcare Research Compliance (CHRC). For Research Compliance Conference sessions, one clock hour equals 1.2 CCE credit hours. CCB has awarded a maximum of 21.9 CCE Credits for these credentials in the following subject areas: Application of Management Practices for the Compliance Professional; Application of Personal and Business Ethics in Compliance; Written Compliance Policies and Procedures; Designation of Compliance Officers and Committees; Compliance Training and Education; Communication and Reporting Mechanisms in Compliance; Enforcement of Compliance Standards and Discipline; Auditing and Monitoring for Compliance; Response to Compliance Violations and Corrective Actions; HIPAA Privacy Implementation and/or Complying with Government Regulations.

**CRA:** Attendee seeking CRA credits through the Research Administrators Certification Council (RACC) may request a certificate of attendance from HCCA by completing an Application for Continuing Education and indicating RACC/CRA on the form. A certificate of attendance along with a complete brochure should be submitted to RACC at the end of each individual’s RACC renewal period.

**NASBA/CPE:** The Health Care Compliance Association is 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. Sponsor Registration No: 105638. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit and may not accept one-half credits. To verify if your state board of accountancy has accepted one-half credits, please visit our website at www.hcca-info.org/accountancycredits. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Suite 700, Nashville, TN 37219-2417. Website: www.nasba.org. A recommended maximum of 21.5 credits based on a 50-minute hour will be granted for the entire learning activity. This program addresses topics that are of a current concern in the compliance environment. This is an update, group-live activity. For more information regarding administrative policies such as complaints or refunds, call the HCCA at 888-580-8373 or 952-988-0141.

**RACC:** The Research Administrators Certification Council (RACC) promotes the concept of voluntary certification by examination for all research and sponsored programs administrators. Certification in research and sponsored programs administration is highly valued and provides formal recognition of basic knowledge in the field.

**SoCRA:** The Society of Clinical Research Associates (SoCRA) www.Socra.org accepts documentation of candidate participation in continuing education programs for recertification if the program is applicable to clinical research regulations, operations, or management, or to the candidate’s clinical research therapeutic area. This program offers approximately 18.25 hours of CE credit.

Please note that the maximum number of CEU hours awarded may be subject to change if a change in the final program presented occurs.
We’ve moved from the autumn to the spring, so please mark your calendars.

REGISTER ONLINE AT WWW.HCCA-RESEARCH-CONFERENCE.ORG