HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

LAST CHANCE: REGISTER NOW

NEW LOCATION IN 2016

Research Compliance Conference

June 5–8, 2016 | Baltimore, MD

Join your peers at the primary networking and educational event for compliance professionals working in research compliance.

TWO CONFERENCES FOR THE PRICE OF ONE

Complimentary access to SCCE's Higher Education Compliance Conference is included with your registration. Build your own schedule and attend sessions at both conferences!

hcca-info.org/research

QUESTIONS? catherine.stollenwerk@corporatecompliance.org

SUNDAY, JUNE 5: PRE-CONFERENCE

12:00 – 6:00 PM	**Registration Open**	
1:00 – 2:30 PM BREAKOUT SESSIONS PRE-CONFERENCE	**P1 The Life Cycle of an FDA Review** – *Margaret M. Groves, Dir, HSRC, Duke Univ Office of Audit, Risk and Compliance; Tina R. Tyson, Chief Ethics & Compliance Officer, Duke Univ Office of Audit, Risk and Compliance*	**P2 Research Billing Compliance and Human Research Protections: How to Create and Sustain a Happy Marriage** – *Dawn Pedinelli, Director of Research at Trinity Health; Joyce Samet, Research Compliance Officer, Boston Medical Center*
2:30 – 3:00 PM	**Networking Break**	
3:00 – 5:00 PM BREAKOUT SESSIONS PRE-CONFERENCE	**P3 Preclinical Compliance Audit Program 101** – *Emmelyn Kim, Director, Research Compliance, Northwell Health; Stephen Frattini, DVM, Manager, PreClinical Research Compliance, Northwell Health*	**P4 Three Lines of Defense against Conflict of Interest: Research COI Risk Management** – *Rebecca M. Scott, Research & COI Compliance Manager, UK HealthCare; Andrew H. Hill, Compliance Analyst/Auditor, UK HealthCare; William Sacks, VP Product Mgmt, HCCS–A HealthStream Company*
5:00 – 6:00 PM	**Welcome Reception**	

MONDAY, JUNE 6: CONFERENCE

7:00 AM – 6:00 PM	**Registration Open**		
7:00 – 8:15 AM	**Breakfast (provided)**		
8:15 – 8:30 AM	**Opening Remarks**		
8:30 – 9:30 AM	**General Session 1: Research Year In Review** – *Lisa Murtha, Senior Managing Director, FTI Consulting*		
9:30 – 10:00 AM	**Networking Break**		
10:00 – 11:30 AM BREAKOUT SESSIONS	**101 Starting at Ground Zero: Assessment of Research Compliance at a Large, Community-Based Healthcare System** – *Dawn Pedinelli, Director of Research, Trinity Health; Harriet E. Kinney, Director, Research Integrity & Compliance, Trinity Health*	**102 The Buck Stops Here…Or Does It? Medicare Secondary Payer and Beneficiary Inducement** – *Rachel Delaney, Corporate Counsel Research, Aurora Health Care; Diane M. Austin, Compliance Officer-Research, Aurora Health Care; Anne M. Ruff, Attorney, Hall, Render, Killian, Health & Lyman, P.C.*	**103 Risk and Animal Research Compliance** – *Kimberley Peterson, IACUC Liaison, UT Southwestern Medical Center*
11:30 AM – 12:30 PM	**Networking Lunch (provided)**		
12:30 – 2:00 PM BREAKOUT SESSIONS	**201 Most Challenging Clauses in Clinical Trial Agreements** – *Michael C. Roach, Partner, Meade, Roach & Annulis, LLP*	**202 Enforcing Your Conflict of Interest Policy and Sunshine on Industry Payments** – *CJ Wolf, Senior Compliance Executive, Healthicity*	**203 External IRB Review: What Does It Mean for Your Institution?** – *Wesley G. Byerly, Associate Vice President for Research Compliance, UCONN Health*
2:00 – 2:30 PM	**Networking Break**		
2:30 – 4:00 PM BREAKOUT SESSIONS	**301 SMIIT: Support & Monitoring for Investigator-Initiated Trials—Analysis of a New Internal Collaborative** – *Leah Silbert, Sr Research Compliance Analyst, Cedars-Sinai Medical Center; Annie Yi, IDS Pharmacist, Cedars-Sinai Medical Center*	**302 Research-Related Subject Injury: Findings and Lessons Learned from Implementation of a New Policy** – *Keren Dunn, Manager, Research Compliance & QI, Cedars-Sinai Medical Ctr; Ambereen Burhanuddin, Research Compliance Analyst III, Cedars-Sinai Medical Center*	**303 Research and Compliance Challenges Between Academic Medical Centers and HIPAA Covered Entities** – *Andrew Mahler, Research Integrity and Privacy Officer, The University of Arizona; Mariette Marsh, Director, Human Subjects Protection Program, The University of Arizona*
4:00 – 4:15 PM	**Networking Break**		
4:15 – 5:15 PM	**General Session 2: Common Rule NPRM** – *Laura Odwazny, Senior Attorney, Public Health Division, Office of the General Counsel, U.S. Department of Health and Human Services*		
5:15 – 6:30 PM	**Networking Reception**		

TUESDAY, JUNE 7: CONFERENCE

7:30 AM – 4:00 PM	**Registration Open**		
7:30 – 8:30 AM	**Breakfast (provided)**		
8:15 – 8:30 AM	**Opening Remarks**		
8:30 – 10:00 AM	**General Session 3: A Panel Discussion on the CMS Perspective of Clinical Research Billing** – *Rosemarie Hakim, PhD, Senior Research Technical Advisor, Coverage and Analysis Group Centers for Medicare & Medicaid Services; Frederick Herman, Dir Corp Research Compliance, Univ of MD Medical System; Ryan Meade, Dir Regulatory Compliance Studies, Loyola Law School; Kelly Willenberg, Owner, Kelly Willenberg & Associates*		
10:00 – 10:30 AM	**Networking Break**		
10:30 AM – 12:00 PM BREAKOUT SESSIONS	**401 Risk It, Fix-It, Re-Mix It: Comply for What?** – *Marsha C. Wallace, Asst Dir Res QA & Monitoring, Children's Hospital of Philadelphia; Denise Ancharski-Stutler, Assistant Director, Post-Approval Monitoring, Children's Hospital of Philadelphia*	**402 Expanded Access INDs** – *Karen A. Hartman, Research Compliance Officer, Mayo Clinic; Peggy Beat, Senior Director, Cleveland Clinic; Jennifer McCafferty, Director of Research, Nicklaus Children's Hospital*	**403 Keys to Implementing an Export Controls Compliance Program** – *Jeff Seo, Executive Dir for Research Integrity and Compliance, Harvard Medical School*
12:00 – 1:00 PM	**Networking Lunch (provided)**		
1:00 – 2:30 PM BREAKOUT SESSIONS	**501 A Call for Action: Examining Why IRB Review so Frequently Fails to Protect the Privacy of Human Subject Data and How IRBs and Researchers Can Build Meaningful Privacy and Security Controls Into Human Subject Research** – *David Behinfar, HIPAA Privacy Officer, University of Wisconsin-Madison; Katherine Georger, Privacy Officer, WPS Health Insurance*	**502 Considerations for Incorporating Research into the Electronic Medical Record (EMR)** – *Kelé Piper, Director, Research Compliance, Beth Israel Deaconess Medical Center*	**503 One Rule, Two Rule, Red Rule, Blue Rule: Taking Advantage of Flexibility in the Uniform Guidance** – *Marisa Zuskar, Director, Huron Consulting Group; Matthew W. Staman, Managing Director, Huron Consulting Group*
2:30 – 2:45 PM	**Networking Break**		
2:45 – 4:00 PM	**General Session 4: Staying on the Grid: A Matrix Approach to Ensuring Compliance with NIH Grant/Contract Requirements** – *Kristin H. West, Chief Compliance Officer, Emory University, Office of Compliance*		

WEDNESDAY, JUNE 8: POST-CONFERENCE

7:30 – 11:30 AM	**Registration Open**	
8:30 – 11:30 AM BREAKOUT SESSIONS POST-CONFERENCE (INCLUDES 15-MIN BREAK)	**W1 A Research Compliance Program: Build It To Comply!** – *Dwight Claustre, Director, AegisCompliance & Ethics Center, LLP; Karen Mottola, Research Compliance Officer, Sutter Health*	**W2 Indiana University ClinicalTrials.gov Compliance Program** – *Casandra J. Greene, Quality Improvement Consultant, Indiana University; Christine S. Caldwell, Regulatory Knowledge and Support Program Manager, Indiana Clinical and Translational Sciences Institute*
11:30 AM – 12:30 PM	**Lunch (on your own)**	
12:30 PM	**CHRC Exam Check-in**	
1:00 – 3:30 PM	**Certified in Healthcare Research Compliance (CHRC)® exam *(optional)***	

EARN YOUR CERTIFICATION

Certified in Healthcare Research Compliance (CHRC)®

Learn more about the CHRC certification at compliancecertification.org/chrc

Take the CHRC Certification Exam on-site after the conference

Wednesday, June 8 | 1:00–3:30 PM

$250 HCCA MEMBERS OR $350 NON-MEMBERS

You must be pre-registered to sit for the exam. To apply, download the CHRC exam application from hcca-info.org. Questions? Email ccb@compliancecertification.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 sufficient CEUs to qualify to sit for the exam.

SUNDAY, JUNE 5

PRE-CONFERENCE

1:00–2:30 PM

BREAKOUT SESSIONS

P1 The Life Cycle of an FDA Review

Margaret M. Groves, Dir, HSRC, Duke Univ Office of Audit, Risk and Compliance

Tina R. Tyson, Chief Ethics & Compliance Officer, Duke Univ Office of Audit, Risk and Compliance

- This session will walk attendees through the investigator's response to a phone call from the FDA that a routine or for cause review is being scheduled at your institution
- What to do immediately following the phone call; actions during the inspection itself
- What to do after the inspection in the event a 483 is issued; closeout and follow up after the inspection

P2 Research Billing Compliance and Human Research Protections: How to Create and Sustain a Happy Marriage

Dawn Pedinelli, Director of Research at Trinity Health

Joyce Samet, Research Compliance Officer, Boston Medical Center

- Examine the implications of the CMS research billing requirements as they apply to the ethical review of research
- Illustrate best practices to integrate Medicare Coverage Analysis with IRB review of research
- Provide actionable tips to operationalize processes to synchronize review of the coverage analysis, clinical trial agreement, and IRB approved informed consent document

2:30 – 3:00 PM

Networking Break

3:00–5:00 PM

BREAKOUT SESSIONS

P3 Preclinical Compliance Audit Program 101

Emmelyn Kim, Director, Research Compliance, Northwell Health

Stephen Frattini, DVM, Manager, PreClinical Research Compliance, Northwell Health

- Essentials for developing a risk based preclinical compliance audit program
- Key elements for an effective escalation and reporting policy and process
- Lessons learned dealing with Researchers, IACUCs, IBCs, Vets, IOs and more

P4 Three Lines of Defense against Conflict of Interest: Research COI Risk Management

Rebecca M. Scott, Research & COI Compliance Manager, UK HealthCare

Andrew H. Hill, Compliance Analyst/ Auditor, UK HealthCare

William Sacks, VP Product Mgmt, HCCS-A HealthStream Company

- Review NIH Conflict of Interest regulations pertaining to publicly funded research, and discuss recent enforcement actions
- Provide an overview of the "Three Lines of Defense" risk management model, and discuss how such a model can be used to manage research COI risk
- Learn how one AMC utilizes technology in the "Three Lines of Defense" model to provide tools, processes, and information to risk managers at all levels of the organization

5:00 – 6:00 PM

Welcome Reception

MONDAY, JUNE 6

7:00 AM – 6:00 PM

Registration Open

7:00 – 8:15 AM

Breakfast (provided)

8:15 – 8:30 AM

Opening Remarks

8:30–9:30 AM

General Session 1: Research Year In Review

Lisa Murtha, Senior Managing Director, FTI Consulting

9:30 – 10:00 AM

Networking Break

10:00–11:30 AM

BREAKOUT SESSIONS

101 Starting at Ground Zero: Assessment of Research Compliance at a Large, Community-Based Healthcare System

Dawn Pedinelli, Director of Research, Trinity Health

Harriet E. Kinney, Director, Research Integrity & Compliance, Trinity Health

- Sharing the story of how a newly integrated, multi-state, community based healthcare system has made the commitment to support research compliance system wide
- Development and implementation of a research compliance assessment strategy that includes both corporate and community hospital based research compliance components
- Implementation challenges for a comprehensive research compliance program in an ever changing, complex healthcare environment

102 The Buck Stops Here…Or Does It? Medicare Secondary Payer and Beneficiary Inducement

Rachel Delaney, Corporate Counsel Research, Aurora Health Care

Diane M. Austin, Compliance Officer-Research, Aurora Health Care

Anne M. Ruff, Attorney, Hall, Render, Killian, Health & Lyman, P.C.

- Brief summary of requirements related to Medicare billing for clinical trials, including a general discussion of what Medicare will and will not pay for
- Legal and ethical implications of conditional insurance language in subject injury and non-subject injury situations. Discussion of the application of Medicare Secondary Payer rules and false claim risks
- Legal and ethical implications of offers to waive copays and deductibles in clinical trial agreements and informed consent forms

103 Risk and Animal Research Compliance

Kimberley Peterson, IACUC Liaison, UT Southwestern Medical Center

- Review animal research oversight requirements and mechanisms of institutional oversight
- Evaluate a risk based approach to animal research compliance and discuss how risk identification and assessment for animal research can direct strategy and areas of emphasis for animal research compliance oversight, including decreasing self-imposed regul
- Review the process of post-approval monitoring for animal research compliance in the context of risk identification and assessment

11:30 AM – 12:30 PM

Networking Lunch (provided)

12:30–2:00 PM

BREAKOUT SESSIONS

201 Most Challenging Clauses in Clinical Trial Agreements

Michael C. Roach, Partner, Meade, Roach & Annulis, LLP

- Speakers will discuss clauses of CTAs that seem to generate the most negotiation
- Attendees will have opportunities to pitch in to the discussion
- Attendees should come away with more appreciation for CTA sticking points and perhaps some suggested approaches to deal with these problem clauses

202 Enforcing Your Conflict of Interest Policy and Sunshine on Industry Payments

CJ Wolf, Senior Compliance Executive, Healthicity

- Explain Industry's approach to "Sunshine" reporting
- Explore potential researcher conflicts of interest with reported Industry payments
- Learn when, why and how to dispute transfers of value reported in the name of a hospital or physician

203 External IRB Review: What Does It Mean for Your Institution?

Wesley G. Byerly, Associate Vice President for Research Compliance, UCONN Health

- What are considerations when developing an agreement with an external IRB?
- What are instituitional issues to consider beyond the agreement?
- What does use of an external IRB mean for compliance?

2:00 – 2:30 PM

Networking Break

2:30–4:00 PM

BREAKOUT SESSIONS

301 SMIIT: Support & Monitoring for Investigator-Initiated Trials—Analysis of a New Internal Collaborative

Leah Silbert, Sr Research Compliance Analyst, Cedars-Sinai Medical Center

Annie Yi, IDS Pharmacist, Cedars-Sinai Medical Center

- History & overview of the SMIIT program, which was initiated in 2010 and is aimed at encouraging and supporting investigator-initiated research conducted at Cedars-Sinai Medical Center Services currently include SIVs, QA monitoring, & REDCap
- Review metrics from first two years of monitoring: Highlights, evolution, lessons learned & what's next
- Investigative drug service (IDS) pharmacy role: key components to managing investigator-initiated drug trials

302 Research-Related Subject Injury: Findings and Lessons Learned from Implementation of a New Policy

Keren Dunn, Manager, Research Compliance & QI, Cedars-Sinai Medical Ctr

Ambereen Burhanuddin, Research Compliance Analyst III, Cedars-Sinai Medical Center

- Provide an overview of current regulatory climate pertaining to research-related subject injury (RRSI)
- Present experience with implementation of a revised policy on RRSI at Cedars-Sinai, including intersection between research billing compliance and human subject protection
- Discuss successes and challenges since implementation of new RRSI policy and management plan

303 Research and Compliance Challenges Between Academic Medical Centers and HIPAA Covered Entities

Andrew Mahler, Research Integrity and Privacy Officer, The University of Arizona

Mariette Marsh, Director, Human Subjects Protection Program, The University of Arizona

- A discussion of challenges between academic medical center environments and affiliated hospitals and possible solutions
- Understand implications for human subject research conducted "outside" of HIPAA covered entities
- Understand compliance challenges when issues arise that impact two separate legal entities

4:00 – 4:15 PM

Networking Break

4:15–5:15 PM

General Session 2: Common Rule NPRM

Laura Odwazny, Senior Attorney, Public Health Division, Office of the General Counsel, U.S. Department of Health and Human Services

5:15 – 6:30 PM

Networking Reception

TUESDAY, JUNE 7

7:30 – 4:00 PM
Registration Open

7:30 – 8:30 AM
Breakfast (provided)

8:15 – 8:30 AM
Opening Remarks

8:30–10:00 AM
General Session 3: A Panel Discussion on the CMS Perspective of Clinical Research Billing

Rosemarie Hakim, PhD, Senior Research Technical Advisor, Coverage and Analysis Group Centers for Medicare & Medicaid Services


Frederick Herman, Dir Corp Research Compliance, Univ of MD Medical System


Ryan Meade, Dir Regulatory Compliance Studies, Loyola Law School


Kelly Willenberg, Owner, Kelly Willenberg & Associates

10:00 – 10:30 AM
Networking Break

10:30 AM–12:00 PM
BREAKOUT SESSIONS

401 Risk It, Fix-It, Re-Mix It: Comply for What?


Marsha C. Wallace, Asst Dir Res QA & Monitoring, Children's Hospital of Philadelphia


Denise Ancharski-Stutler, Assistant Director, Post-Approval Monitoring, Children's Hospital of Philadelphia

- Identify research risks affecting human subject and animal research and discuss strategies to implement corrective and preventative actions
- Describe trends and challenges of internal audit and monitoring programs for human and animal research
- Discuss strategies for development of education and training for minimizing and mitigating risks

402 Expanded Access INDs


Karen A. Hartman, Research Compliance Officer, Mayo Clinic


Peggy Beat, Senior Director, Cleveland Clinic


Jennifer McCafferty, Director of Research, Nicklaus Children's Hospital

- Describe the differences between traditional, single patient and intermediate (treatment) INDs
- Understand how to navigate the expanded access IND submission process through FDA
- Share best practices and lessons learned

403 Keys to Implementing an Export Controls Compliance Program


Jeff Seo, Executive Dir for Research Integrity and Compliance, Harvard Medical School

- Federal export controls regulations limit the export of goods, technology, data, and services without first procuring the necessary license. Multiple federal agencies have issued rules, regulations and policies that span across a broad spectrum of issues
- This session is intended to help stakeholders identify potential export controls issues and to adopt strategies to mitigate liability and exposure without necessarily investing in additional resources
- If your researchers regularly collaborate internationally, travel abroad, ship biologicals or transfer technology or data abroad, or routinely hire foreign nationals to engage in research, then join us for an informative session highlighting best practice

12:00 – 1:00 PM
Networking Lunch (provided)

1:00–2:30 PM
BREAKOUT SESSIONS

501 A Call for Action: Examining Why IRB Review so Frequently Fails to Protect the Privacy of Human Subject Data and How IRBs and Researchers Can Build Meaningful Privacy and Security Controls Into Human Subject Research


David Behinfar, HIPAA Privacy Officer, University of Wisconsin-Madison


Katherine Georger, Privacy Officer, WPS Health Insurance

- Philosophical underpinnings of privacy in human subjects research
- Why IRB review all too often fails to adequately protect the privacy of human subjects and why IRBs at academic medical centers are some of the worst offenders
- Proposed models for building privacy and security controls into your IRB review

502 Considerations for Incorporating Research into the Electronic Medical Record (EMR)


Kelé Piper, Director, Research Compliance, Beth Israel Deaconess Medical Center

- Discussion on how to determine what information goes into the EMR. Things to think about and ask organizational leaders
- Looking at how data will be used and extracted as well as who needs to have access to the data. Thinking about consent and HIPAA, do they play a role in how you store your data?
- Considerations for multiple electronic systems. How do they communicate? Do they need to communicate?

503 One Rule, Two Rule, Red Rule, Blue Rule: Taking Advantage of Flexibility in the Uniform Guidance


Marisa Zuskar, Director, Huron Consulting Group


Matthew W. Staman, Managing Director, Huron Consulting Group

- Red rules are mandatory, driven by regulations. Blue rules involve self-imposed policies and procedures
- The existence of both, institutional flexibility, and the element of choice defines an institution's research compliance environment
- We will explore how the red, blue and choice come to play in interpreting and implementing the federal regulations within the Uniform Guidance

2:30 – 2:45 PM
Networking Break

2:45–4:00 PM
General Session 4: Staying on the Grid: A Matrix Approach to Ensuring Compliance with NIH Grant/Contract Requirements


Kristin H. West, Chief Compliance Officer, Emory University, Office of Compliance

WEDNESDAY, JUNE 8

POST-CONFERENCE
(Sessions include one 15-minute break)

7:30 – 11:30 AM
Registration Open

8:30–11:30 AM
BREAKOUT SESSIONS

W1 A Research Compliance Program: Build It To Comply!


Dwight Claustre, Director, AegisCompliance & Ethics Center, LLP


Karen Mottola, Research Compliance Officer, Sutter Health

- Survey the land, pour the foundation: gather organizational resources and champions; identify risks and prioritize needs
- Draft the blueprints, mount the scaffolding: plan the program, using the seven elements as outline pillars Test the foundation: identify risks and prioritize needs
- Commence construction, inspect resulting structure: realize the plan, monitoring results and detailing as needed

W2 Indiana University ClinicalTrials.gov Compliance Program

Casandra J. Greene, Quality Improvement Consultant, Indiana University

Christine S. Caldwell, Regulatory Knowledge and Support Program Manager, Indiana Clinical and Translational Sciences Institute

- Indiana University identified a need to develop a ClinicalTrials.gov Compliance program capable of monitoring, auditing and training. In January 2015, the compliance program replaced the previous structure of staff serving as PRS administrators only
- The compliance program leverages different data sources to identify actions needed to meet the requirements outlined in FDAAA 801. The research community is engaged through notifications, face-to-face interactions and training opportunities
- The institution collaborates with the Indiana Clinical and Translational Sciences Institute to address results reporting issues by offering guided assistance and training to mitigate risks to the institution

11:30 AM – 12:30 PM
Lunch (on your own)

12:30 PM
CHRC Exam Check-in

1:00 – 3:30 PM
Certified in Healthcare Research Compliance (CHRC)® exam *(optional)*

CONTINUING EDUCATION UNITS

HCCA is in the process of applying for additional credits. If you do not see information on your specific accreditation and would like to make a request, please contact us at 952-988-0141 or 888-580-8373 or email ccb@compliancecertification.org. Visit HCCA's website, www.hcca-info.org, for up-to-date information.

ACHE: The Health Care Compliance Association is authorized to award 18 hours of pre-approved ACHE Qualified Education credit (non-ACHE) for this program toward advancement, or recertification in the American College of Healthcare Executives. Participants in this program wishing to have the continuing education hours applied toward ACHE Qualified Education credit should indicate their attendance when submitting and application to the American College of Healthcare Executives for advancement or recertification.

Compliance Certification Board (CCB): CCB has awarded a maximum of 22.2 CEUs for these certifications: Certified in Healthcare Compliance (CHC)®, Certified in Healthcare Compliance–Fellow (CHC-F)®, Certified in Healthcare Privacy Compliance (CHPC)®, Certified in Healthcare Research Compliance (CHRC)®, Certified Compliance & Ethics Professional (CCEP)®, Certified Compliance & Ethics Professional–Fellow (CCEP-F)®, Certified Compliance & Ethics Professional–International (CCEP-I)®.

CLE: The Health Care Compliance Association is a State Bar of California Approved MCLE provider, a Pennsylvania Accredited Provider, and is an accredited sponsor, approved by the State Bar of Texas, Committee on MCLE. An approximate maximum of 18.5 clock hours of CLE credit will be available to attendees of this conference. All CLE credits will be awarded based on individual attendance.

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 Identification No: 105638. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be submitted to the National Registry of CPE Sponsors through its website: www.learningmarket.org. A recommended maximum of 22.0 credits based on a 50-minute hour will be granted for this activity. This program addresses topics that are of a current concern in the compliance environment and is a group-live activity in the recommended field of study of Specialized Knowledge and Application. For more information regarding administrative policies such as complaints or refunds, call (888) 580-8373 or (952) 988-0141.

Nursing Credit: The Health Care Compliance Association is preapproved by the California Board of Registered Nursing, Provider Number CEP 14593, for a maximum of 22.2 contact hour(s). The following states will not accept CA Board of Nursing contact hours: Delaware, Florida, New Jersey and 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 ccb@compliancecertification.org with any questions you may have. Oncology Nurses who are certified by ONCC may request CA Nursing Credit (check box or indicate "Nursing" on the CEU form).

PRIM&R: Some portions of this program may meet the requirements for CPIA continuing education. The CPIA Council accepts documentation of continuing education hours when the topics fall within the CPIA Body of Knowledge. If you are unsure about whether a specific session meets these requirements you should consult with PRIM&R. Some portions of this program may meet the requirements for CIP continuing education. CCIP accepts documentation of continuing education hours when the topics fall within the CIP Body of Knowledge and the education is intended to be beyond initial, basic or fundamental level education. If you are unsure about whether a specific session meets these requirements you should consult with PRIM&R.

RACC: Attendees 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 as the credit type sought. HCCA will issue a certificate of attendance that details your completed continuing education hours. Those sections of the conference which match sections of the CRA Body of Knowledge will be able to count toward contact hours for recertification of your CRA. If proof of participation is requested by RACC, your certificate will serve as proof that you completed the coursework as described. 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 18 hours of CE credit.

SoCRA's requirements for recertification Continuing Education credit are quite general, as they pertain to clinical research regulations, operations and management, and to the therapeutic area of the clinical research in which the candidate participates. We therefore leave it to the candidate to determine whether a course or program would be acceptable for SoCRA's CE requirement. SoCRA does not "validate" individual training courses/workshops.

Full name _____

please type or print

Sharing your demographic information with HCCA will help us create better networking opportunities for you. Thank you for taking a moment to fill out the following information.

DEMOGRAPHIC INFORMATION

What is your functional job title? Please select one.

- ☐ Academic/Professor
- ☐ Administration
- ☐ Asst Compliance Officer
- ☐ Attorney (In-House Counsel)
- ☐ Attorney (Outside Counsel)
- ☐ Audit Analyst
- ☐ Audit Manager/Officer
- ☐ Billing Manager/Officer
- ☐ Charger Master
- ☐ Chief Compliance Officer
- ☐ CEO/President
- ☐ Chief Financial Officer
- ☐ Chief Information Officer
- ☐ Chief Medical Officer
- ☐ Chief Operating Officer
- ☐ Clinical
- ☐ Coder
- ☐ Compliance Analyst
- ☐ Compliance Coordinator
- ☐ Compliance Director
- ☐ Compliance Fraud Examiner
- ☐ Compliance Officer
- ☐ Compliance Specialist
- ☐ Consultant
- ☐ Controller
- ☐ Ethics Officer
- ☐ Executive Director
- ☐ General Counsel
- ☐ HIM Professional
- ☐ HIPAA/Privacy Officer
- ☐ Human Resources
- ☐ Medical Director
- ☐ Nurse
- ☐ Nurse Manager
- ☐ Patient Safety Officer
- ☐ Pharmacy Director
- ☐ Physician
- ☐ Quality Assurance/ Quality of Care
- ☐ Regulatory Officer
- ☐ Reimbursement Coordinator
- ☐ Research Analyst
- ☐ Risk Manager
- ☐ Trainer/Educator
- ☐ Vice President
- ☐ Other (please list below)

List others not listed here:

_____

_____

_____

Please tell us if you are a first-time attendee of the Research Compliance Conference:

- ☐ This is my first Research Compliance Conference

REGISTRATION CONTINUES ON NEXT PAGE (OVER)

What is your primary health care entity?

- ☐ Academic
- ☐ Ambulance/Transportation
- ☐ Behavioral Health
- ☐ Consulting Firm
- ☐ Durable Medical Equipment
- ☐ Government Provider
- ☐ Health System
- ☐ Health System/Teaching
- ☐ Home Care/Hospice
- ☐ Hospital
- ☐ Hospital/Teaching
- ☐ Integrated Delivery System
- ☐ Integrated Health System
- ☐ Laboratory
- ☐ Law Firm
- ☐ Long-Term Care
- ☐ Managed Care
- ☐ Medical Device Manufacturer
- ☐ Medical/Clinical Research
- ☐ Nursing
- ☐ Other Provider of Services/ Products to Health Care Entities
- ☐ Payor/Insurance
- ☐ Pharmaceutical Manufacturer
- ☐ Physician Practice
- ☐ Rehabilitation
- ☐ Retail Pharmacy
- ☐ Third-Party Billing
- ☐ Other (please list below)

List others not listed here:

_____

_____

_____

What credentials do you hold? Select all that apply.

- ☐ BA
- ☐ BBA
- ☐ BS
- ☐ BSN
- ☐ CCEP
- ☐ CEM
- ☐ CCS
- ☐ CCS-P
- ☐ CFE
- ☐ CHC
- ☐ CHE
- ☐ CHP
- ☐ CHPC
- ☐ CHRC
- ☐ CIA
- ☐ CPA
- ☐ CPC
- ☐ CPHQ
- ☐ DDS
- ☐ ESQ
- ☐ FHFMA
- ☐ JD
- ☐ LLM
- ☐ MA
- ☐ MBA
- ☐ MHA
- ☐ MPA
- ☐ MPH
- ☐ MS
- ☐ MSHA
- ☐ MSN
- ☐ MT
- ☐ NHA
- ☐ PhD
- ☐ RHIA
- ☐ RHIT
- ☐ RN

List others not listed here:

_____

_____

_____

CONTACT INFORMATION

◯ Mr ◯ Mrs ◯ Ms ◯ Dr

HCCA Member ID (if applicable)

First Name MI

Last Name

Credentials (CHC, CCEP, etc.)

Job Title

Name of Employer

Street Address

City/Town State/Province

Country Zip/Postal Code

Phone

Email (required for registration confirmation & conference information)

SESSION SELECTION

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

SUN, JUNE 5
PRE-CONFERENCE

1:00–2:30 PM
◯ P1
◯ P2

3:00–5:00 PM
◯ P3
◯ P4

MON, JUNE 6
BREAKOUTS

10:00–11:30 AM
◯ 101
◯ 102
◯ 103

12:30–2:00 PM
◯ 201
◯ 202
◯ 203

2:30–4:00 PM
◯ 301
◯ 302
◯ 303

TUE, JUNE 7
BREAKOUTS

10:30 AM–12 PM
◯ 401
◯ 402
◯ 403

1:00–2:30 PM
◯ 501
◯ 502
◯ 503

WED, JUNE 8
POST-CONFERENCE

8:30–11:30 AM
◯ W1
◯ W2

☐ *I'm interested in selecting sessions from SCCE's Higher Education Compliance Conference. Please send me more information.*

REGISTRATION OPTIONS *(Registration fees are as listed and considered net of any local withholding taxes applicable in your country of residence.)*

☐ HCCA/SCCE Members.....$799
☐ Non-Members.....$899
☐ HCCA/SCCE Membership & Registration.....$999
NEW MEMBERS ONLY / DUES REGULARLY $295 ANNUALLY
☐ Pre-Conference Registration.....$125
☐ Post-Conference Registration.....$125
☐ Group Discount: subtract $_____ from my total (SEE DETAILS AT LEFT)

TOTAL $_____

Registering for HCCA's Research Compliance Conference automatically registers you for SCCE's Higher Education Compliance Conference at no additional cost.

SPECIAL REQUEST FOR DIETARY ACCOMMODATION

◯ Gluten Free ◯ Kosher ◯ Vegetarian ◯ Vegan ◯ Other _____

PAYMENT OPTIONS

◯ Invoice me
◯ Check enclosed *(payable to HCCA)*
◯ I authorize HCCA to charge my credit card *(choose below)*

Credit Card: ◯ American Express ◯ Discover ◯ MasterCard ◯ Visa

Due to PCI Compliance, please **do not provide any credit card information via email**. You may email this form to helpteam@hcca-info.org (without credit card information) and call HCCA at 888-580-8373 or 952-988-0141 with your credit card information.

Credit Card Account Number

Credit Card Expiration Date

Cardholder's Name

Cardholder's Signature

RC0616

WAYS TO REGISTER

MAIL to HCCA, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435

ONLINE at hcca-info.org/research

FAX to 952-988-0146 (include completed registration form with payment)

EMAIL helpteam@hcca-info.org (without credit card information)

Hotel & conference location:

Marriott Baltimore Waterfront
700 Aliceanna Street
Baltimore, MD 21202
410-385-3000
baltimoremarriottwaterfront.com

Book online: https://resweb.passkey.com/go/HECCRRB

Book via phone: Call 410-385-3000 and ask for the HCCA Research Compliance Conference rate

A reduced rate of $242 per night for single/double occupancy plus applicable taxes has been arranged for this conference. This rate is good through May 16, 2016, or once the group room block is full, whichever comes first. Hotel accommodations are not included in your conference registration fee. The group rate includes complimentary Internet in guestrooms.

Registration Terms & Conditions:
Please make your check payable to HCCA, enclose payment with your registration, and return it to the HCCA office, or fax your credit card payment to 952-988-0146. If your total is miscalculated, HCCA will charge your card the correct amount. 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.

Cancellations/Substitutions: You may send a substitute in your place or request a conference credit. Conference credits are issued in the full amount of the registration fees paid and are good for 12 months from the date of the cancelled event. Conference credits may be used toward any HCCA service. If you need to cancel your participation, notify us prior to the start date of the event by email at helpteam@hcca-info.org or by fax at 952-988-0146. Please note that if you are sending a substitute, an additional fee may apply.

Group Discounts: Discounts take effect the day a group reaches the discount number of registrants. Please send registration forms together to ensure that the discount is applied. A separate registration form is required for each registrant. Note that discounts will NOT be applied retroactively if more registrants are added at a later date, but new registrants will receive the group discount.

5 or more: $50 discount for each registrant

10 or more: $100 discount for each registrant

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.

Dress Code: Business casual dress is appropriate.

Recording: No unauthorized audio or video recording of HCCA Conferences is allowed.

Continuing Education Units: HCCA is in the process of applying for credits. See page 8 of this brochure for details, or visit HCCA's website, hcca-info.org, for up-to-date information.

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.

HEALTH CARE COMPLIANCE ASSOCIATION
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P 888-580-8373 OR 952-988-0141 | F 952-988-0146
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NEW LOCATION IN 2016

Research Compliance Conference

June 5–8, 2016 | Baltimore, MD

Research Compliance Conference

June 5–8, 2016 | Baltimore, MD

LAST CHANCE: REGISTER NOW

Join your peers at the primary networking and educational event for compliance professionals working in research compliance

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Register today and enjoy the flexibility of two conferences for the price of one!

Complimentary access to SCCE's Higher Education Compliance Conference is included with your registration. The parallel schedule gives you the freedom to attend sessions at either conference—two for the price of one.