

# Research Compliance Conference

June 9–12, 2019 • Orlando, FL

Join this conference designed for research compliance professionals and deep-dive into research compliance issues with industry experts.

**Get two conferences for the price of one:** Complimentary access to SCCE's Higher Education Compliance Conference is included with your registration.

[hcca-info.org/research](http://hcca-info.org/research)

Questions? [taci.gregory@corporatecompliance.org](mailto:taci.gregory@corporatecompliance.org)



## About

Research compliance comes with its own unique set of risks and challenges, many of which garner close attention from government regulators and enforcers. Attend this conference to get up-to-date on today's trending topics, learn practical strategies to address risks, and network with your industry peers.

With your registration you will also gain admittance to the SCCE Higher Education Compliance Conference, held at the same time in the same location.

### HCCA's Mission

HCCA exists to champion ethical practice and compliance standards in all organizations and to provide the necessary resources for compliance professionals and others who share these principles.

### Who Should Attend?

This conference is ideal for any compliance professional or person in a related role who works in the clinical research world. Past attendees have included:

- Compliance officers
- Audit professionals
- Scientists
- Research administrators
- Healthcare executives
- Attorneys

### Why You Should Attend?

This yearly conference offers ample opportunities for attendees to:

- Discover ways to increase the effectiveness of your organization's compliance program.
- Discuss emerging risks and issues with your colleagues.
- Share best practices for research compliance.
- Build valuable relationships with other compliance professionals.

### Contact Us

Please visit us online at [hcca-info.org/research](https://hcca-info.org/research) to learn more about the Conference and HCCA's other programs.

## EARN YOUR CERTIFICATION

### Certified in Healthcare Research Compliance (CHRC)<sup>®</sup>

*Learn more about the CHRC certification at [hcca-info.org/certification/become-certified](https://hcca-info.org/certification/become-certified)*

### Take the CHRC Certification Exam on-site after the conference

Wednesday, June 12 | 1:00 PM

\$275 HCCA MEMBERS OR \$375 NON-MEMBERS

To apply, complete the online application or download the CHRC exam application from [hcca-info.org](https://hcca-info.org). Questions? Email [ccb@compliancecertification.org](mailto: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/CEUs.

# Program at a Glance

## Sunday, June 9 / Pre-Conference

12:00 – 5:30 PM	Registration Open	
1:00 – 2:30 PM BREAKOUT SESSIONS PRE-CONFERENCE	P1 Compliance within Your HRPP – <i>Nathalia Henry, Executive Director of the IRB Office, Northwestern University Office for Research; Leyla Erkan, Midwestern Healthcare Lead, Protiviti</i>	P2 Uniform Guidance 101 – <i>Matthew Staman, Managing Director, Huron Consulting Group; Marisa Zuskar, Director, Huron Consulting Group</i>
2:30 – 2:45 PM	Networking Break	
2:45 – 4:15 PM BREAKOUT SESSIONS PRE-CONFERENCE	P3 Sharpening Research Compliance: Heightened Awareness with a Self-Guided Risk Assessment – <i>David Staley, Research Compliance Officer, Children's Hospital Colorado; Hannah Gilbert, Research Compliance Analyst, Children's Hospital Colorado</i>	P4 Identifying and Managing Physician Conflicts of Interest in the Research Context – <i>Amy Joseph, Partner, Hooper, Lundy &amp; Bookman, PC; Rebecca Ryan, Compliance Officer, Yale New Haven Hospital</i>
4:15 – 5:30 PM	Welcome Reception	

## Monday, June 10 / Conference

7:00 AM – 6:00 PM	Registration Open		
7:00 – 8:00 AM	Breakfast		
8:00 – 8:15 AM	Opening Remarks		
8:15 – 9:15 AM	General Session: Research Year in Review – <i>Lisa Murtha, Senior Managing Director, Ankura Consulting Group</i>		
9:15 – 9:45 AM	Networking Break with Exhibitors		
9:45 – 10:45 AM BREAKOUT SESSIONS	101 Demystifying Human Subjects Research Versus Quality Improvement: A Compliance Case Study – <i>David Staley, Research Compliance Officer, Children's Hospital Colorado; Hannah Gilbert, Research Compliance Analyst, Children's Hospital Colorado</i>	102 Tricky Clinical Trial Budget and Research Billing Compliance Issues Inherited from Mergers & Acquisitions – <i>Geoffrey Schick, Senior Consultant, PFS Clinical; Ray Heller, Sr. Director Business Development, PFS Clinical; JoAnne Levy, Vice President, Mercy Research</i>	103 Navigating Federally Sponsored Projects Abroad: Common Compliance Challenges and Solutions – <i>Katherine Morga, Senior Associate, Hogan Lovells US LLP; Adilene Rosales, Associate, Hogan Lovells US LLP</i>
10:45 – 11:00 AM	Networking Break		
11:00 AM – 12:00 PM BREAKOUT SESSIONS	201 The Intersection of Clinical Data Management and HIPAA: How to Assess Privacy and Information Security Compliance of Clinical Data – <i>Andrew Rodriguez, Corporate Privacy and Information Security Officer, Shriners Hospitals for Children</i>	202 Research Privacy and Security Considerations Beyond HIPAA: What are the Compliance Concerns? – <i>Marti Arvin, Vice President, Audit Strategy, CynergisTek, Inc.</i>	203 From Paper to Electronic: Evolution of an IACUC Protocol Management System – <i>Denise Ancharski-Stutler, IACUC Administrative Director, Children's Hospital of Philadelphia</i>
12:00 – 1:00 PM	Lunch		
1:00 – 2:00 PM BREAKOUT SESSIONS	301 Clinical Trials Compliance: Collaboration Builds Effectiveness – <i>Stephanie deRijke, RN, MSN, Director, Clinical Trials Audit and Compliance, Emory University; Anne Adams, JD, MS, Chief Compliance Officer, Emory Healthcare, Inc., Associate Vice President, Clinical Trial Compliance, Emory University</i>	302 Compliance through Collaboration: Partnering with Independent IRBs to Develop and Maintain a Strong Human Research Protection Program (HRPP) – <i>Cynthia Hahn, President, Integrated Research Strategy; Hallie Kassan, Director, HRPP, Northwell Health</i>	<b>DISCUSSION GROUP*</b> AD303 Adapting to New Hazardous Drug Requirements in Research Settings – <i>Anita Austin, MBA, RRT, CCRP, CHRC, Senior Research Compliance Consultant, Intermountain Healthcare; Carrie B. Dunford, PharmD, MBA, BCPS, Clinical Pharmacist–Internal Process Control Director, Intermountain Healthcare</i>
2:00 – 2:30 PM	Networking Break with Exhibitors		
2:30 – 3:30 PM BREAKOUT SESSIONS	401 Exploring Observational Registries and Human Subject Research. Progress Where Ambiguity is the Only Constant – <i>Mark Fox, Privacy and Research Compliance Officer, American College of Cardiology</i>	402 Demystifying Partial Waivers of Consent and Authorization – <i>Andrea Seykora, JD, CIP, Research Compliance Manager, Kaiser Permanente Center for Health Research Northwest; Melinda Allie, CIP, Research Compliance Program Manager, Kaiser Permanente Center for Health Research Northwest; Kaija Maggard, MS, GCNPM, CIP, IRB Manager, Kaiser Permanente Center for Health Research Northwest</i>	<b>DISCUSSION GROUP*</b> AD403 Thorny Clinical Research Billing and Coverage Issues – <i>Kelly Willenberg, Manager, Kelly Willenberg and Associates</i>
3:30 – 3:45 PM	Networking Break		
3:45 – 4:45 PM	General Compliance Session: Reflecting on the Revised Common Rule: Lessons Learned and Deep Thoughts – <i>Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel, HHS; Heather Pierce, JD, MPH, Senior Director, Science Policy, Regulatory Counsel, Scientific Affairs, Association of American Medical Colleges</i>		
4:45 – 6:00 PM	Networking Reception		

\*Discussion Groups are limited to 50 attendees and open on a first-come, first-served basis. No pre-registration is available.

# Program at a Glance

## Tuesday, June 11 / Conference

7:00 AM – 4:30 PM	Registration Open		
7:00 – 8:00 AM	Breakfast		
8:00 – 8:15 AM	Opening Remarks		
8:15 – 9:15 AM	General Session: HHS OIG and Research Compliance – <i>Gregory Demske, Chief Counsel to the Inspector General, HHS-OIG</i>		
9:15 – 9:45 AM	Networking Break with Exhibitors		
9:45 – 10:45 AM BREAKOUT SESSIONS	501 ClinicalTrials.gov: Oversight and Compliance at a Diverse Academic Research Center – <i>Melanie Chladny, Research Compliance Specialist, University of Michigan Medical School; Linda Mendelson, Research Compliance Specialist, University of Michigan Rogel Cancer Center</i>	502 Research PHI in the Cloud: Human Subjects Protection Transformed – <i>Rebecca Scott, Privacy Manager, UK Healthcare, University of Kentucky; Darin Poynter, Enterprise Data Architect, UK HealthCare Information Technology</i>	503 Mining the Sunshine Data: Finding Potential Conflicts of Interest – <i>C.J. Wolf, Senior Compliance Executive, Healthicity; Paul Papagni, Executive Director of Research, Holy Cross Hospital, Trinity Health</i>
10:45 – 11:00 AM	Networking Break		
11:00 AM – 12:00 PM	601 Research Billing Compliance Program – From Zero to 100 in 60 seconds! – <i>Isai Senthil, Esq., CHRC, VP/Associate General Counsel, Summit Medical Group, P.A./Summit Health Management, LLC; Kelly Ritter, LPN, CCRC, Manager of Clinical Research, Summit Medical Group, P.A.</i>	602 GDP – What? How the European Union General Data Protection Regulations Impact Research – <i>Karen Hartman, MS, CRHC, Administrator - Research Compliance, Mayo Clinic; Robyn Shapiro, JD, Founder - Health Sciences Law Group LLC</i>	603 Export Controls in Medical Research: Compliance Considerations for International Collaborations – <i>Scott Long, Chief Compliance Officer, St. Jude Children's Research Hospital; Wendy Epley, Export Control Analyst, University of Arizona</i>
12:00 – 1:00 PM	Lunch		
1:00 – 2:00 PM BREAKOUT SESSIONS	701 Relying on Someone Else's IRB: Why, When, and How for Hospitals and Academic Medical Centers – <i>Amy Waltz, JD, CIP, Associate Director, Human Subjects Office, Indiana University; Bethany Johnson J.D., CIP, University Director, HRPP, Indiana University</i>	702 Investigator Initiated Trials (IITs): Addressing the Challenges of Auditing IITs for Compliance and GCP – <i>Wendy Portier, Independent Consultant, Kelly Willenberg and Associates; Gabriella Neff, Research Compliance Officer, Moffitt Cancer Center</i>	703 The Dos and Don'ts of Investigating Research Misconduct Cases – <i>Sarah Archibald, Research Integrity Officer, University of Maryland-Baltimore</i>
2:00 – 2:15 PM	Networking Break		
2:15 – 3:15 PM BREAKOUT SESSIONS	801 Importance of Ensuring Blockchain Compliance for Your Institution – <i>Wendy Charles, PhD, CIP, Research Compliance Manager, Denver Health</i>	802 Dealing with Data: Non-technical Thoughts Concerning Data Security and Management – <i>John Baumann Ph.D., Associate Vice President for Research Compliance, Indiana University; Bethany Johnson J.D., CIP, University Director, HRPP, Indiana University</i>	803 Radioactive Drug Research Committees- Do you have one? Do you need one? Do you want one? – <i>Katherine Cohen, Research Compliance Director, MedStar Health</i>
3:15 – 3:30 PM	Networking Break		
3:30 – 4:30 PM	General Session: Case Studies in Clinical Research Billing Risk – <i>Ryan Meade, JD, CHC, CHRC, Director of Regulatory Compliance Studies, Loyola University Chicago School of LawD</i>		

## Wednesday, June 12 / Post-Conference

8:00 – 11:45 AM	Registration Open		
8:30 – 10:00 AM BREAKOUT SESSIONS POST-CONFERENCE	W1 Two Offices Divided by a Common Goal: Col and IRB Review – <i>John Baumann, Ph.D., Associate Vice President for Research Compliance, Indiana University</i>	W2 Mindful Cross Training: Framing an Effective Approach in the Present to Assist Your Institution's Research Compliance Risks for the Future – <i>Ianthe Bryant-Gawthrop, Director RRA and HRPP, Purdue University; Ryan P. Fayhee, Partner, Hughes, Hubbard &amp; Reed LLP</i>	
10:00 – 10:15 AM	Networking Break		
10:15 – 11:45 AM BREAKOUT SESSIONS POST-CONFERENCE	W3 Integrating Community Hospital Based Research in a System Wide Network: Just Mix in Compliance, Collaboration, Billing, HIPAA, Central IRB then Stir Until Done – <i>Paul Papagni, Executive Director of Research, Holy Cross Hospital, Trinity Health; Harriet Kinney, Director, Research Integrity &amp; Compliance, Trinity Health</i>	W4 Stage Two! – Applying Concepts Learned at the HCCA Research Academy over Consecutive Years – <i>Anne Daly, Chief Compliance and Integrity Officer, Children's Hospital of Chicago Medical Center; Kimberly Zajczenko, Senior Director of Audit, Children's Hospital of Chicago Medical Center; Liz Hernandez, Sr. Privacy Analyst, Children's Hospital of Chicago Medical Center</i>	
12:30 PM	CHRC Exam Check-in		
12:45 – 3:15 PM	Certified in Healthcare Research Compliance (CHRC) <sup>®</sup> exam (optional)		

## Sunday, June 9

Pre-Conference

**12:00 – 5:30 PM**

Registration Open

**1:00 – 2:30 PM**

Breakout Sessions

### P1 Compliance within Your HRPP



**Nathalia Henry,**  
Executive Director of the IRB  
Office, Northwestern University  
Office for Research



**Leyla Erkan,**  
Midwestern Healthcare Lead,  
Protiviti

- What is a HRPP and what do you have to comply with?
- Key HRPP components and structures.
- What mechanisms can you put in place to monitor compliance?

### P2 Uniform Guidance 101



**Matthew Staman,**  
Managing Director,  
Huron Consulting Group



**Marisa Zuskar,**  
Director,  
Huron Consulting Group

- Provide a (brief) background and introduction the Uniform Guidance, including the purpose and impact of these federal sponsored project regulations.
- Review critical changes within the UG (from previous circulars) and cover major topical areas of the guidance, including: Cost Principles, Effort Reporting, Procurement, and Subrecipient Monitoring.
- Discuss the shift of the regulations towards Internal controls and institutional responsibility for ensuring compliance.

**2:45 – 4:15 PM**

Breakout Sessions

### P3 Sharpening Research Compliance: Heightened Awareness with a Self-Guided Risk Assessment



**David Staley,**  
Research Compliance Officer,  
Children's Hospital Colorado



**Hannah Gilbert,**  
Research Compliance Analyst,  
Children's Hospital Colorado

- Employ risk assessment philosophies and principles to heighten awareness of risks in clinical research.
- Empower research teams to weigh and prioritize self-identified risks in order to create meaningful action plans.
- Form a self-guided risk assessment tool to encourage risk preparedness and sharpen research compliance.

### P4 Identifying and Managing Physician Conflicts of Interest in the Research Context



**Amy Joseph,**  
Partner,  
Hooper, Lundy & Bookman, PC

**Rebecca Ryan,**  
Compliance Officer, Yale New  
Haven Hospital

- Review potential compliance issues related to physician relationships in the research context, including under anti-kickback and physician self-referral laws.
- Identify factors that could increase compliance risk for such relationships based on OIG guidance and recent enforcement actions.
- Discuss best practices for how a compliance program can effectively identify and address physician conflicts of interest, including approaches to policies and screening measures.

**4:15 – 5:30 PM**

Welcome Reception

## Monday, June 10

Conference

**7:00 AM – 6:00 PM**

Registration Open

**7:00 – 8:00 AM**

Breakfast

**8:00 – 8:15 AM**

Opening Remarks

**8:15 – 9:15 AM**

General Session:  
Research Year in Review



**Lisa Murtha,**  
Senior Managing Director,  
Ankura Consulting Group

- This session is designed to cover all new laws, regulations and guidance promulgated by the government in the area of research.
- The session will outline new research related enforcement initiatives and settlements by the Department of Justice and the Office of Inspector General.
- The speaker will describe the implications of these laws, regulations and guidance on research programs and will suggest affirmative actions to be considered to strengthen research compliance programs for universities, academic medical centers, hospitals, CROs and other research organizations.

**9:15 – 9:45 AM**

Networking Break with Exhibitors

**9:45 – 10:45 AM**

Breakout Sessions

### 101 Demystifying Human Subjects Research Versus Quality Improvement: A Compliance Case Study



**David Staley,**  
Research Compliance Officer,  
Children's Hospital Colorado



**Hannah Gilbert,**  
Research Compliance Analyst,  
Children's Hospital Colorado

- Review related laws and regulations which help define human subjects research.
- Examine real regulatory cases to distinguish quality improvement activities from human subjects research.
- Describe a governance structure that reviews quality improvement activities which aim to evaluate and enhance programs, processes, or systems.



## 102 Tricky Clinical Trial Budget and Research Billing Compliance Issues Inherited from Mergers & Acquisitions



Geoffrey Schick,  
Senior Consultant,  
PFS Clinical

Ray Heller,  
Sr. Director Business  
Development,  
PFS Clinical



JoAnne Levy,  
Vice President,  
Mercy Research

- Session will use a “mock debate” format to present arguments on both sides of clinical trials research billing compliance challenges that arise from “inherited” studies.
- What happens when a Site “inherits” a Study – through merger, acquisition, PI relocation – that has questionable terms that have been in place from the start?
- Attendees will utilize real time voting tools to weigh in on the “winner” of each scenario.

## 103 Navigating Federally Sponsored Projects Abroad: Common Compliance Challenges and Solutions

Katherine Morga,  
Senior Associate,  
Hogan Lovells US LLP

Adilene Rosales,  
Associate,  
Hogan Lovells US LLP

- Identify key award terms and regulations that affect federally sponsored research abroad compliance.
- Discuss financial and administrative challenges, including engaging foreign personnel, managing foreign sub recipients, complying with U.S. and foreign human subjects research and ethical requirements, and applying cost accounting rules.
- Share practical experience and tips on how to manage risks and resolve challenges.

## 10:45 – 11:00 AM Networking Break

## 11:00 – 12:00 PM Breakout Sessions

### 201 The Intersection of Clinical Data Management and HIPAA: How to Assess Privacy and Information Security Compliance of Clinical Data

Andrew Rodriguez,  
Corporate Privacy and  
Information Security Officer,  
Shriners Hospitals for Children

- Conducting a Privacy Assessment on Clinical Research Data
- Conducting a Security Assessment on Clinical Research Data
- “De-identification, you keep using that word. I do not think it means what you think it means.”

### 202 Research Privacy and Security Considerations Beyond HIPAA: What are the Compliance Concerns?



Marti Arvin,  
Vice President,  
Audit Strategy, CynergisTek, Inc.

- Privacy and security concerns that are unrelated to HIPAA such as a GDPR, FERPA, GLBA, and contractual.
- What education may be necessary for the IRB and others to understand these obligations.
- Practical ways to incorporate this into the process for study preparation, approval and execution.

### 203 From Paper to Electronic: Evolution of an IACUC Protocol Management System



Denise Ancharski-Stutler,  
IACUC Administrative Director,  
Children’s Hospital of  
Philadelphia

- Provide an overview of IACUC and protocols.
- Discuss methods to transition from paper to an electronic system.
- Identify opportunities within the electronic protocol form to reduce burden.

## 12:00 – 1:00 PM Lunch

## 1:00- 2:00 PM Breakout Sessions

### 301 Clinical Trials Compliance: Collaboration Builds Effectiveness

Stephanie deRijke, RN, MSN,  
Director, Clinical Trials Audit and  
Compliance, Emory University

Anne Adams, JD, MS,  
Chief Compliance Officer,  
Emory Healthcare, Inc.,  
Associate Vice President,  
Clinical Trial Compliance,  
Emory University

- Outline steps to implement an independent clinical trial compliance program in a large academic medical center. Discuss reporting structure, function, responsibilities, and goals.
- Discuss strategies to connect researchers with the compliance team to develop proactive, collaborative, and reciprocal methods to achieve compliance through continuous quality assurance and improvement.
- Share Emory Clinical Trials Compliance tools: electronic audit tool in REDCap, data analytics tool to show trends, and clinical trial tools for researchers.

### 302 Compliance through Collaboration: Partnering with Independent IRBs to Develop and Maintain a Strong Human Research Protection Program (HRPP)



Cynthia Hahn,  
President,  
Integrated Research Strategy

Hallie Kassin,  
Director, HRPP,  
Northwell Health

- Provide an overview of the current regulatory and business climate for sIRB review, including the NIH Policy on sIRB review and changes to the Common Rule at 46CFR46.
- Discuss models for sIRB review and partnership with academic and commercial IRBs, differentiating and outlining the responsibilities of the institution versus the responsibilities of the reviewing sIRB.
- Demonstrate through case studies how differing business models can both achieve and improve compliance with the new federally mandated requirements for the use of sIRB in multi center clinical research studies.

## DISCUSSION GROUP

Discussion Groups are limited to 50 attendees and open on a first-come, first-served basis.

### AD303 Adapting to New Hazardous Drug Requirements in Research Settings



Anita Austin, MBA, RRT, CCRP, CHRC, Senior Research Compliance Consultant, Intermountain Healthcare



Carrie B. Dunford, PharmD, MBA, BCPS, Clinical Pharmacist—Internal Process Control Director, Intermountain Healthcare

- New safe handling and storage requirements for research hazardous drugs.
- Key components of a research hazardous drug risk assessment.
- Cost considerations for research centers to achieve compliance with new USP <800> regulations.

### 2:00 – 2:30 PM

#### Networking Break with Exhibitors

### 2:30 – 3:30 PM

#### Breakout Sessions

### 401 Exploring Observational Registries and Human Subject Research. Progress Where Ambiguity is the Only Constant



Mark Fox, Privacy and Research Compliance Officer, American College of Cardiology

- Identify compliance considerations for secondary use of data in an observational registry.
- Navigate the applicability of the revised Common Rule to observational registries.
- Explore transparency of data use in the world of big data.

### 402 Demystifying Partial Waivers of Consent and Authorization



Andrea Seykora, JD, CIP, Research Compliance Manager, Kaiser Permanente Center for Health Research Northwest

Melinda Allie, CIP, Research Compliance Program Manager, Kaiser Permanente Center for Health Research Northwest



Kaija Maggard, MS, GCNPM, CIP, IRB Manager, Kaiser Permanente Center for Health Research Northwest

- The concept of a “partial” waiver of consent or authorization is common in IRB review, despite not appearing in the HHS, FDA, or HIPAA regulations.
- Examine the regulatory criteria for waiver and alteration of consent and authorization and learn how they may apply to different portions of a study.
- Explore strategies for collecting information from researchers to facilitate clear and compliant waiver determinations by the IRB.

## DISCUSSION GROUP

Discussion Groups are limited to 50 attendees and open on a first-come, first-served basis. .

### AD403 Thorny Clinical Research Billing and Coverage Issues



Kelly Willenberg, Manager, Kelly Willenberg and Associates

- Medicare Advantage issues.
- Sham Procedures.
- Contingency Budgets.

### 3:30 – 3:45 PM

#### Networking Break

### 3:45 – 4:45 PM

#### General Session: Reflecting on the Revised Common Rule: Lessons Learned and Deep Thoughts



Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel, HHS



Heather Pierce, JD, MPH, Senior Director, Science Policy, Regulatory Counsel, Scientific Affairs, Association of American Medical Colleges

- The rollout of the revised Common Rule and interpretative agency guidance.
- Challenges involved with integrating the revised Common rule’s new mandates and flexibilities within the existing system of human subjects research law and policy.
- Key decision points for regulated institutions responsible for implementing the revised Common Rule’s requirements.

### 4:45 – 6:00 PM

#### Networking Reception

## Tuesday, June 11

### Conference

### 7:00 AM – 4:30 PM

#### Registration Open

### 7:00 – 8:00 AM

#### Breakfast

### 8:00 – 8:15 AM

#### Opening Remarks

### 8:15 – 9:15 AM

#### General Session: HHS OIG and Research Compliance



Gregory Demske, Chief Counsel to the Inspector General, HHS-OIG

### 9:15 – 9:45 AM

#### Networking Break with Exhibitors

## 9:45 – 10:45 AM

### Breakout Sessions

#### 501 ClinicalTrials.gov: Oversight and Compliance at a Diverse Academic Research Center



Melanie Chladny,  
Research Compliance Specialist,  
University of Michigan  
Medical School



Linda Mendelson,  
Research Compliance Specialist,  
University of Michigan Rogel  
Cancer Center

- Speakers will describe the oversight processes, management tools, and structural challenges of a diverse university and large cancer research center. We'll explain how different administrative roles intersect to achieve effective oversight and compliance.
- Presenters will share lessons learned, best practices, and tips to pro-actively manage ClinicalTrials.gov records at a large institution.
- We'll demonstrate how institutions can adapt to ongoing regulatory and policy change using ClinicalTrials.gov: uploading informed consent documents for the Common Rule, meeting the ICMJE's new data sharing policy, and monitoring NIH-funded clinical trials.

#### 502 Research PHI in the Cloud: Human Subjects Protection Transformed



Rebecca Scott,  
Privacy Manager,  
UK Healthcare,  
University of Kentucky

Darin Poynter,  
Enterprise Data Architect,  
UK HealthCare Information  
Technology

- Discuss the need for a secure cloud-based environment in which to manage PHI from research studies.
- Outline a process to create a secure cloud environment in which to facilitate large PHI data set sharing and manipulation.
- Ponder questions regarding research PHI data governance and data ownership in an academic medical center environment.

#### 503 Mining the Sunshine Data: Finding Potential Conflicts of Interest



C.J. Wolf,  
Senior Compliance Executive,  
Healthicity



Paul Papagni,  
Executive Director of Research,  
Holy Cross Hospital,  
Trinity Health

- Get the most out of mining publicly available sunshine data.
- What nuances exist in the data that might raise red flags for COI or other compliance risks.
- Discuss scenarios and case studies of industry influences gone badly.

## 10:45 – 11:00 AM Networking Break

## 11:00 – 12:00 PM Breakout Sessions

#### 601 Research Billing Compliance Program — From Zero to 100 in 60 seconds!

Isai Senthil, Esq., CHRC,  
VP/Associate General Counsel,  
Summit Medical Group, P.A./  
Summit Health Management, LLC

Kelly Ritter, LPN, CCRC,  
Manager of Clinical Research,  
Summit Medical Group, P.A.

- This presentation will focus on how to develop a research billing compliance program and how to select the key stakeholders who need to be involved along the way.
- Research billing compliance encompasses several functional areas - all of which must come together in order to develop and successfully implement a research billing compliance program.
- The presenters will speak to their experiences in the development of a research billing compliance program at a large, multi-specialty private physician practice which tripled its participation in clinical trials in just two short years.

#### 602 GDP – What? How the European Union General Data Protection Regulations Impact Research



Karen Hartman, MS, CRHC,  
Administrator – Research  
Compliance, Mayo Clinic



Robyn Shapiro, JD,  
Founder – Health Sciences  
Law Group LLC

- Review the scope of the EU GDPR and impact to clinical research.
- Identify best practices for implementation, including gap analyses and working with teams external to research.
- Share practical considerations for compliance with GDPR through case studies.

#### 603 Export Controls in Medical Research: Compliance Considerations for International Collaborations



Scott Long,  
Chief Compliance Officer,  
St. Jude Children's  
Research Hospital



Wendy Epley,  
Export Control Analyst,  
University of Arizona

- Gain an understanding of export control regulations and their impact to medical research.
- Explore risks of export controls in medical research through case-study examples (including interactions with sanctioned countries).
- Discuss mitigation techniques and best practices for managing risk.

## 12:00 – 1:00 PM Lunch

## 1:00 – 2:00 PM Breakout Sessions



## 701 Relying on Someone Else's IRB: Why, When, and How for Hospitals and Academic Medical Centers



Amy Waltz, JD, CIP,  
Associate Director,  
Human Subjects Office,  
Indiana University



Bethany Johnson J.D., CIP,  
University Director, HRPP,  
Indiana University

- Why IRB reliance is valuable: the landscape of IRB reliance including the NIH single IRB policy, why it matters, and what it means for hospitals and academic medical centers.
- When you should rely: defining your institutional risk tolerance and when you should accept an external IRB's review, drafting your institutional policy for reliance, and identifying the information you need to rely.
- How to rely: understanding the responsibilities of your institution, investigators, and IRB and implementing processes to fulfill them; drafting reliance agreements based on your risk tolerance; collecting and providing local context information.

## 702 Investigator Initiated Trials (IITs): Addressing the Challenges of Auditing IITs for Compliance and GCP



Wendy Portier,  
Independent Consultant,  
Kelly Willenberg and Associates



Gabriella Neff,  
Research Compliance Officer,  
Moffitt Cancer Center

- Identify the unique regulatory and operational challenges of IITs, as well as, the associated risks.
- Discuss suggestions for risk-based audit plans, sampling and testing techniques for IITs.
- Share success stories and lessons learned conducting IIT audits at a designated cancer center.

## 703 The Dos and Don'ts of Investigating Research Misconduct Cases

Sarah Archibald,  
Research Integrity Officer,  
University of Maryland-Baltimore

- What is required for a research misconduct investigation.
- Some of the pitfalls at each stage of a research misconduct investigation.
- Dos and don'ts when conducting a research misconduct investigation.

### 2:00 – 2:15 PM Networking Break

### 2:15 – 3:15 PM Breakout Sessions

#### 801 Importance of Ensuring Blockchain Compliance for Your Institution

Wendy Charles, PhD, CIP,  
Research Compliance Manager,  
Denver Health

- Blockchain technology is coming to your institution soon. It is important to learn the common research use cases of blockchain and understand why this technology will create advances in clinical research.
- The blockchain itself is secure, but there are still legal and security risks to your institution, such as uses of smart contracts.
- This presentation will teach how to oversee blockchain technology with regard to IRB submissions, FDA and HIPAA Security Rule regulations and considerations for state statutes.

#### 802 Dealing with Data: Non-technical Thoughts Concerning Data Security and Management



John Baumann Ph.D.,  
Associate Vice President for  
Research Compliance,  
Indiana University



Bethany Johnson J.D., CIP,  
University Director, HRPP,  
Indiana University

- Review and identify challenges and obstacles for data security and protection of confidentiality.
- Identify best practices for IRBs in the review of researchers' plans for protection of data and confidentiality.
- Identify strategies for institutions to work with researchers and IRBs to develop and implement data management/ security strategies.

## 803 Radioactive Drug Research Committees- Do you have one? Do you need one? Do you want one?



Katherine Cohen,  
Research Compliance Director,  
MedStar Health

- Understand what a Radioactive Drug Research Committee (RDRC) is and what types of studies need RDRC review.
- It's not just radiation safety! Overview of the requirements of an RDRC, including membership, committee operations, committee documentation and record keeping.
- If you don't have an RDRC and decide you don't want one, there are alternatives! Understand what those alternatives are to help you evaluate whether you can support an RDRC.

### 3:15 – 3:30 PM Networking Break

### 3:30 – 4:30 PM General Session: Case Studies in Clinical Research Billing Risk



Ryan Meade, JD, CHC, CHRC,  
Director of Regulatory  
Compliance Studies,  
Loyola University Chicago  
School of Law

- Review "hard cases" in clinical research billing.
- Discuss guiding principles when stuck in the "gray area".
- Explore what to do when the rule do not seem to fit.

## Wednesday, June 12

### Post-Conference

### 8:00 – 11:45 AM Registration Open

## 8:30 – 10:00 AM Breakout Sessions

### W1 Two Offices Divided by a Common Goal: Col and IRB Review



John Baumann, Ph.D.,  
Associate Vice President for  
Research Compliance,  
Indiana University

- Identify points of overlap and divergence in the Col and IRB processes.
- Identify best practices for Col and IRB review of outside financial interests related to human subjects research.
- Assess the integrity of your institution's Col-IRB processes.

### W2 Mindful Cross Training: Framing an Effective Approach in the Present to Assist Your Institution's Research Compliance Risks for the Future



Ianthe Bryant-Gawthrop,  
Director RRA and HRPP,  
Purdue University



Ryan P. Fayhee,  
Partner,  
Hughes, Hubbard & Reed LLP

- Learn how research regulations can be interconnected. Presenters will develop strategies with workshop participants to engage in interactive examples using export controls and collaboration risks in non-traditional settings as a model.
- The group will develop framework to spark research compliance cross-training ideas appropriate for their institution and move past silos in research compliance efforts.
- The constantly changing landscape of research compliance demands awareness in many topics to identify when subtle signs can lead to larger concerns. Teach staff to identify bigger picture concerns early, including how and when to request a subject matter expert.

## 10:00 – 10:15 AM Networking Break

## 10:15 – 11:45 AM Breakout Sessions

### W3 Integrating Community Hospital Based Research in a System Wide Network: Just Mix in Compliance, Collaboration, Billing, HIPAA, Central IRB then Stir Until Done



Paul Papagni,  
Executive Director of Research,  
Holy Cross Hospital,  
Trinity Health



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

- Clinical Research on a multi-site/multi-state scale is not a Compliance Officer's favorite undertaking, irrespective of financial and staffing resources available. Build an expert team with collaboration and communication as central themes.
- Integrating a successful Community Hospital Model across an entire healthcare network creates a whole new set of workflows and challenges to overcome.
- Operational models centralized vs decentralized: when to consider centralizing operations and regulatory oversight and what needs to remain decentralized? Establishing compliance oversight and metrics.

## W4 Stage Two! — Applying Concepts Learned at the HCCA Research Academy over Consecutive Years



Anne Daly,  
Chief Compliance and Integrity  
Officer, Children's Hospital of  
Chicago Medical Center



Kimberly Zajczenko,  
Senior Director of Audit,  
Children's Hospital of Chicago  
Medical Center

Liz Hernandez,  
Sr. Privacy Analyst,  
Children's Hospital of Chicago  
Medical Center

- After presenting last year on using the HCCA Research Academy as a starting point, presenters will share the experience of assessing and building new infrastructure and connection between Research and Corporate Compliance.
- Presenters will engage with attendees to identify and categorize obstacles and opportunities that present in building a cooperative model of Research Compliance between clinical and research entities.
- Presenters will encourage discussion and assessment of tools and activities that enable effective collaboration and help avoid or mitigate risk of research noncompliance.

## 12:30 PM CHRC Exam Check-in

## 12:45 – 3:15 PM Certified in Healthcare Research Compliance (CHRC)<sup>®</sup> exam (optional)

# Continuing Education

HCCA is in the process of applying for additional external continuing education units (CEUs). Should overall number of education hours decrease or increase, the maximum number of CEUs available will be changed accordingly. Credits are assessed based on actual attendance and credit type requested.

Approval quantities and types vary by state or certifying body. For entities that have granted prior approval for this event, credits will be awarded in accordance with their requirements. CEU totals are subject to change.

Upon request, if there is sufficient time and we are able to meet their requirements, HCCA may submit this course to additional states or entities for consideration. If you would like to make a request, please contact us at +1 952.988.0141 or 888.580.8373 or email [CCB@compliancecertification.org](mailto:CCB@compliancecertification.org). Visit HCCA's website, [hcca-info.org](http://hcca-info.org), for up-to-date information.

**ACHE:** The Health Care Compliance Association is authorized to award **18.0** clock hours of pre-approved ACHE Qualified Education credit for this program toward advancement, or recertification, in the American College of Healthcare Executives. Participants in this program who wish to have the continuing education hours applied toward ACHE Qualified Education credit must self-report their participation. To self-report, participants must log into their MyACHE account and select ACHE Qualified Education Credit.

**Compliance Certification Board (CCB)®:** CCB has awarded a maximum of **21.6** 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)®.

**Continuing Legal Education (CLE):** The Health Care Compliance Association is a provider/sponsor, approved/ accredited by the State Bar of California, the Pennsylvania Bar Association, and the State Bar of Texas. An approximate maximum of **18.0** clock hours of CLE credit will be available to attendees of this conference licensed in these states. HCCA's practice is to apply for CLE credits to the state in which the event is being held, if that state has a CLE approval process for sponsors. Upon request, if there is sufficient time and if we are able to meet their CLE requirements, HCCA may submit this course to additional states for consideration. Only requests from registered attendees will be considered. All CLE credits will be assessed based on actual attendance and in accordance with each state's requirements.

**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:

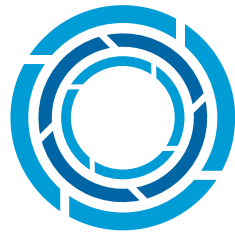
105638. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be submitted to the National Registry of CPE Sponsors through its website: [nasbregistry.org](http://nasbregistry.org). The education level for this activity is considered basic. No prerequisites are required for this education. Delivery Method: Group Live. Advanced Preparation: None. A recommended maximum of **21.5** 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 +1 952.988.0141w.

**Nursing Credit:** The Health Care Compliance Association is preapproved by the California Board of Registered Nursing, Provider Number CEP 14593, for a maximum of **21.6** contact hour(s). The following states will not accept California Board of Registered Nursing contact hours: Delaware, Florida, New Jersey and Utah. Massachusetts and Mississippi nurses may submit California Board of Registered 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](mailto:ccb@compliancecertification.org) with any questions you may have. Oncology nurses who are certified by ONCC may request California nursing credit (check box or indicate "Nursing" on the CEU form).

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& ASSOCIATES**  
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**HCCA**<sup>TM</sup>  
Health Care Compliance  
Association

LEARN. NETWORK. INSPIRE.



Maximize and grow your compliance program.

Stay informed on privacy issues, Stark compliance, conflicts of interest, False Claims Act, risk management, HIPAA, regulatory changes and patient rights, and more. Learn proactive compliance strategies from industry leaders and network with peers.

### **MEMBERSHIP BENEFITS**

- *Compliance Today* magazine, 12 issues exclusively for HCCA members plus full access to the magazine archives
- Join a community of 12,000+ compliance professionals
- Members-only discounts on conferences, publications, and newsletters
- Network and learn at 50+ conferences a year
- Save on weekly web conferences for live learning at your desk
- Receive a discount on Compliance Certification Board (CCB)<sup>®</sup> exam pricing and renewal for CHC, CHRC, and CHPC

### ***Additional resources***

- HCCAnet<sup>®</sup> provides access to an online Resource Library and networking
- Weekly newsletters and blog posts from industry experts

**Learn more and join HCCA's community today.**  
**[hcca-info.org/join](http://hcca-info.org/join)**

# Registration

**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.

## 1 Demographic Information

What is your functional job title? Please select one.

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

List others not listed here:

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Are you a first-time attendee of the Research Compliance Conference?

YES  NO

**REGISTRATION CONTINUES ON NEXT PAGE (OVER)**

What is your primary health care entity?

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

List others not listed here:

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What credentials do you hold? Select all that apply.

- |                                |                               |                                |                               |
|--------------------------------|-------------------------------|--------------------------------|-------------------------------|
| <input type="checkbox"/> BA    | <input type="checkbox"/> CHE  | <input type="checkbox"/> FHFMA | <input type="checkbox"/> MSN  |
| <input type="checkbox"/> BBA   | <input type="checkbox"/> CHP  | <input type="checkbox"/> JD    | <input type="checkbox"/> MT   |
| <input type="checkbox"/> BS    | <input type="checkbox"/> CHPC | <input type="checkbox"/> LLM   | <input type="checkbox"/> NHA  |
| <input type="checkbox"/> BSN   | <input type="checkbox"/> CHRC | <input type="checkbox"/> MA    | <input type="checkbox"/> PhD  |
| <input type="checkbox"/> CCEP  | <input type="checkbox"/> CIA  | <input type="checkbox"/> MBA   | <input type="checkbox"/> RHIA |
| <input type="checkbox"/> CEM   | <input type="checkbox"/> CPA  | <input type="checkbox"/> MHA   | <input type="checkbox"/> RHIT |
| <input type="checkbox"/> CCS   | <input type="checkbox"/> CPC  | <input type="checkbox"/> MPA   | <input type="checkbox"/> RN   |
| <input type="checkbox"/> CCS-P | <input type="checkbox"/> CPHQ | <input type="checkbox"/> MPH   |                               |
| <input type="checkbox"/> CFE   | <input type="checkbox"/> DDS  | <input type="checkbox"/> MS    |                               |
| <input type="checkbox"/> CHC   | <input type="checkbox"/> ESQ  | <input type="checkbox"/> MSHA  |                               |

List others not listed here:

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## Contact Information

Mr  Mrs  Ms  Dr

Member ID/Account Number

First Name MI

Last Name

Credentials (CHC, CCEP, etc.)

Job Title

Organization (Name of Employer)

Street Address

City/Town

State/Province Zip/Postal Code

Country

Phone Fax

Email (Required for registration confirmation and conference information)

## Payment Options

Check enclosed (payable to HCCA)

Invoice me

I authorize HCCA to charge my credit card (choose card 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](mailto: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

RC0619

## Registration Options

	On or before 4.11.19	After 4.11.19
<input type="checkbox"/> HCCA/SCCE Members: MONDAY & TUESDAY.....	\$825	\$875
<input type="checkbox"/> Non-Members: MONDAY & TUESDAY .....	\$995	\$1045
<input type="checkbox"/> New Membership & Registration: MON/TUE.....	\$1025	\$1095
<i>First time members only. Dues regularly \$325 annually.</i>		
<input type="checkbox"/> Pre-Conference: SUNDAY .....	FREE*	\$140
<input type="checkbox"/> Post-Conference: WEDNESDAY .....	FREE*	\$140
<input type="checkbox"/> Discount for 5 or more from same org.....	(\$50)	(\$50)
<input type="checkbox"/> Discount for 10 or more from same org.....	(\$100)	(\$100)

\*Free only with paid Monday & Tuesday conference registration by 4/11/19. All registration fees are as listed and considered net of any local withholding taxes applicable in your country of residence.

**TOTAL \$** \_\_\_\_\_

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

## Special Request: Dietary Needs

- Gluten Free  Vegetarian
- Kosher-Style  
(NO SHELLFISH, PORK,  
OR MEAT/DAIRY MIXED)  Vegan
- Kosher  
(HECHSHER CERTIFIED)  Other (WRITE BELOW): \_\_\_\_\_

**Use of your information** – To find out how we may use your information please read our Privacy Statement at [hcca-info.org/privacy.aspx](http://hcca-info.org/privacy.aspx).  
**By submitting this registration form you agree to the terms and conditions,** including the use of your information as stated in our Privacy Statement located at [hcca-info.org/privacy.aspx](http://hcca-info.org/privacy.aspx).

## REGISTER ONLINE

[hcca-info.org/research](http://hcca-info.org/research)

**EMAIL** your completed form (do not include credit card) to [helpteam@hcca-info.org](mailto:helpteam@hcca-info.org)

**MAIL** your registration form with check enclosed:

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

**FAX** your completed form to 952.988.0146  
(include all billing information)

**QUESTIONS?** Call 888.580.8373  
or email [helpteam@hcca-info.org](mailto:helpteam@hcca-info.org)

### Health Care Compliance Association®

6500 Barrie Road, Suite 250  
Minneapolis, MN 55435-2358  
PHONE 888.580.8373 | FAX 952.988.0146  
EMAIL [helpteam@hcca-info.org](mailto:helpteam@hcca-info.org) | WEB [hcca-info.org](http://hcca-info.org)

# Terms & Conditions

## Registration payment terms

Checks are payable to HCCA. Credit cards accepted include American Express, Discover, MasterCard, or Visa. HCCA will charge your credit card the correct amount should your total be miscalculated. If you wish to pay using wire transfer funds, please email [helpteam@corporatecompliance.org](mailto:helpteam@corporatecompliance.org) for instructions.

## 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.

## Cancellations/substitutions

You may send a substitute in your place or request a conference credit. Refunds will not be issued. Conference credits are issued in the full amount of the registration fees paid, and will expire 12 months from the date of the original, cancelled event. Conference credits may be used toward any HCCA service or product. If a credit is applied toward an event, the event must take place prior to the credit's expiration date. If you need to cancel your participation, notification is required by email, sent to [helpteam@corporatecompliance.org](mailto:helpteam@corporatecompliance.org), prior to the start date of the event. Please note that if you are sending a substitute, an additional fee may apply.

## Group discounts

**5 or more.** \$50 discount for each registrant  
**10 or more.** \$100 discount for each registrant

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. The group discount is NOT available through online registration. 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.

## Agreements & acknowledgments

I agree and acknowledge that I am undertaking participation in Health Care Compliance Association 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 acknowledgment freely and knowingly, and I 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 and/or video at this 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 this HCCA conference, I grant HCCA the right to use my name, photograph, video, and biography for such purposes. As a participant of this event, I understand that my name, job title, organization, city, state, and country will be listed on the attendee list that will be distributed to attendees and speakers of this event.

By submitting this registration form, I agree to the Terms & Conditions—including the Use of Information—as well as HCCA's Privacy Statement, located at [hcca-info.org/privacy.aspx](http://hcca-info.org/privacy.aspx).

## Prerequisites/advanced preparation.

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 Higher Education Compliance Conference. See the registration form to indicate any special requests for dietary accommodations you may require.

**Dress code.** Business casual dress is appropriate for conference attendees.

**Recording.** No unauthorized audio or video recording of HCCA conferences is allowed.

## Continuing education units

See page 10 for more information.

## Hotel & conference location

Loews Royal Pacific  
6300 Hollywood Way  
Orlando, FL 32819  
[loewshotels.com/royal-pacific-resort](http://loewshotels.com/royal-pacific-resort)

A reduced rate of \$235 per night for single/double occupancy plus applicable state and local taxes has been arranged for this conference. This rate is good through Monday, May 20, 2019 or until the group room block is full, whichever comes first. Reservation must be accompanied by a first night room deposit which is refundable five days prior to arrival.

Online Reservations:  
[bit.ly/Loews-Royal](http://bit.ly/Loews-Royal)

Telephone reservations: 866-360-7395  
*(Indicate that you are affiliated with the HCCA Research Compliance Conference)*

Group Rate includes complimentary internet in sleeping room and complimentary fitness access. Guests receive exclusive theme park benefits including: Universal Express Unlimited™ ride access, Early Park Admission (valid theme park admission required), complimentary water taxis, shuttle buses or walking paths to the theme parks and Universal CityWalk™.

## Additional Room Block:

Loews Sapphire Falls  
6601 Adventure Way  
Orlando, FL 32819  
[loewshotels.com/sapphire-falls-resort](http://loewshotels.com/sapphire-falls-resort)

An additional block of rooms have been arranged at a reduced rate of \$219 for single/double occupancy plus applicable state and local taxes. This rate is good through Monday, May 20, 2019 or until the group room block is full, whichever comes first. Reservation must be accompanied by a first night room deposit which is refundable five days prior to arrival.

Online Reservations:  
[bit.ly/Loews-Sapphire](http://bit.ly/Loews-Sapphire)

Telephone reservations: 866-360-7395  
*(Indicate that you are affiliated with the HCCA Research Compliance Conference)*

Group Rate includes complimentary internet in sleeping room and complimentary fitness access. Guests receive exclusive theme park benefits including: Universal Express Unlimited™ ride access, Early Park Admission (valid theme park admission required), complimentary water taxis, shuttle buses or walking paths to the theme parks and Universal CityWalk™.

**PLEASE NOTE:** Neither HCCA nor any hotel it is affiliated with will ever contact you to make a hotel reservation. If you receive a call soliciting reservations on behalf of HCCA or the event, it is likely from a room poacher and may be fraudulent. We recommend you make reservations directly with the hotel using the phone number or web link in this brochure. If you have concerns or questions, please contact 888.580.8373.

## Agenda Inside

# Research Compliance Conference

June 9–12, 2019 • Orlando, FL

# Research Compliance Conference

June 9–12, 2019 • Orlando, FL

**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. Build your own schedule and attend sessions at both conferences!

[hcca-info.org/research](http://hcca-info.org/research)

Questions? [taci.gregory@corporatecompliance.org](mailto:taci.gregory@corporatecompliance.org)