*STILL TIME to register!*

# Higher Education & Healthcare Research Compliance Conference

## June 10–12, 2024 | New Orleans, LA

Get the latest regulatory updates, insights, and strategies for building a stronger compliance program in two distinct but often-related industries at this dual-track learning and networking event.

- More than 50 educational sessions to choose from
- Earn Compliance Certification Board (CCB)® continuing education units (CEUs)
- Connect with peers from other higher education and research institutions
- Sit for an optional CCEP® or CHRC® certification exam offered following the conference


**Learn more and register**
corporatecompliance.org/2024here

SCCE® Society of Corporate Compliance and Ethics

HCCA® Health Care Compliance Association

# ABOUT

Higher education and healthcare research are unique industries with distinct compliance challenges. This dual track, in-person conference is designed to help you learn how to meet those challenges by addressing emerging risks and solutions for both settings and giving you the opportunity to network and exchange ideas with peers from a variety of institutions and organizations. Sessions are led by industry professionals and are organized by knowledge level: basic, intermediate, and advanced—see the section on session levels below for a general description of each level. Attendees will also have the chance to earn live continuing education units (CEUs) and sit for an optional CCB certification exam offered following the conference.

## Session topics

Attendees are invited to explore sessions across both the higher education and healthcare research tracks.

- Name, Image and Likeness (NIL) in College Athletics
- Animal Research
- Patient Rights
- Conflict of Interest
- Data Security
- Minors on Campus
- Investigations
- Title IX
- Risk Assessments
- AI and Machine Learning

## Session levels

- **Basic:** Program knowledge level most beneficial to Compliance Professionals new to a skill or an attribute. These individuals are often at the staff or entry level in organizations, although such programs may also benefit a seasoned professional with limited exposure to the area.
- **Intermediate:** Program knowledge level that builds on a basic program, most appropriate for Compliance Professionals with detailed knowledge in an area. Such people are often at a mid-level within the organization, with operational or supervisory responsibilities, or both.
- **Advanced:** This level focuses on the development of in-depth knowledge, a variety of skills, or a broader range of applications. Advanced level programs are often appropriate for seasoned professionals within organizations, and professionals with specialized knowledge in a subject area.

## Who should attend?

- Compliance officers
- Audit professionals
- Scientists
- Research administrators
- Healthcare executives
- Attorneys
- Academic compliance managers
- Title IX compliance officers
- IT compliance directors and managers
- CFOs, accountants, and others in finance
- Internal auditors
- University privacy officers
- General counsel

## SCCE & HCCA's mission

Society of Corporate Compliance and Ethics® (SCCE®) and Health Care Compliance Association® (HCCA®) exists to champion ethical practice and compliance standards and to provide the necessary resources, education, and networking opportunities for ethics and compliance professionals and others who share these principles.

# PROGRAM AT A GLANCE

*All times listed are in Central Time (CT)*

## Monday, June 10 (Pre-Conference)

| | | |
|---|---|---|
| 7:00 AM–5:30 PM | **Registration Open** | |
| 8:00–9:30 AM Concurrent Sessions | **P1** Small College, Little Resources, Big Compliance: Doing Less with More | **P3** Conducting Research Across Borders: Issues for Human Subject Research Compliance Officials |
| | **P2** Utilizing University Policies to Ensure the Safety of Minors on Campus | **P4** From Zero to Hero: Creating an Effective Program to Reduce and Prevent Error and Non-compliance in Clinical Research |
| 9:30–9:45 AM | **Networking Break** | |
| 9:45–11:15 AM Concurrent Sessions | **P5** Collaborate and Listen: Operationalizing an Effective Compliance Program Through Stakeholder Collaboration | **P7** The Compliance Framework for Animal Research in the US |
| | **P6** Evaluating Your Institution's Conflict of Interest Posture through the Lens of NSPM-33 | **P8** Who Dat? It's the New Research Data Security Requirements Due This Year! |
| 11:15 AM–12:45 PM | **Lunch (on own)** | |
| 12:45–2:15 PM Concurrent Sessions | **P9** Compliance or Legal? Harmonization of the Compliance and Legal Functions | **P11** Good Fences Make Good Neighbors: Scoping Research Security, COI, and Research Misconduct Programs |
| | **P10** Unraveling the Maze for Compliant and Effective Investigative Strategies | **P12** Where Can It Go Wrong: Patient's Rights in Research Studies |
| 2:15–2:30 PM | **Networking Break** | |
| 2:30–4:00 PM Concurrent Sessions | **P13** Compliance Officers Roundtable | **P15** Investigations, Root Cause, and Corrective Actions: An Escape Room Approach to an Investigation |
| | **P14** Let's Talk about Ethics: Engaging Your Institution in Routine Conversations on Ethics | **P16** Stories from the Trenches: An Organization's Cybersecurity Incident and the Critical Impact on Research Operations! |
| 4:00–5:30 PM | **Opening Reception** | |

## Tuesday, June 11

| | | |
|---|---|---|
| 7:00–8:00 AM | **Breakfast with Exhibitors** | |
| 8:00–8:15 AM | **Welcome and Opening Remarks** | **Welcome and Opening Remarks** |
| 8:15–9:15 AM | **GS1** University Civil Rights Compliance | **GS1** General Compliance Session TBA |
| 9:15–9:45 AM | **Networking Break (Exhibit Hall)** | |
| 9:45–10:45 AM Concurrent Sessions | **101** Name, Image, and Likeness (NIL) in College Athletics: Current Rules for Educational Institutions and What is Likely to Come Next | **103** Physician Owned Distributorships and Companies: Pitfalls to Watch for and How to Operationalize in Your Organization |
| | **102** Turnover Headaches: They Left—Now What? | **104** Unlocking Research Compliance Excellence: A Symphony of Compliance and Billing Mastery |
| 10:45–11:00 AM | **Networking Break** | |
| 11:00 AM–12:00 PM Concurrent Sessions | **201** Are You Making the Most of Your Anonymous REPORTLINE? | **203** How Academic Research Can Better Integrate with Community and Commercial Research Sites to Reach More Patients |
| | **202** The Adaptable Compliance Office: Crafting a Strategic and Nimble Function | **204** What Is Monitoring Good For? Using Monitor Reports to Strengthen Your Program |
| 12:00–1:00 PM | **Lunch (provided)** | |
| 1:00–2:00 PM Concurrent Sessions | **301** Practice Makes (Better): Developing a Compliance Community of Practice | **303** Considerations in Building and Implementing an Effective Research Security Compliance Program |
| | **302** Skip the Investigation! A Practical Guide for Using Alternative Dispute Practices to Resolve Complaints and Enhance Equity in Higher Education | **304** Overview of Developments in False Claims Act Cases and Research |
| 2:00–2:15 PM | **Networking Break** | |
| 2:15–3:15 PM Concurrent Sessions | **401** Investigation Offices: Convening, Assessing, and Sharing Best Practices | **403** Data Sharing: Ethical and Practical Considerations for Institutions |
| | **402** Visualizing Success: Using Analytics to Communicate Compliance | **404** Financial Toxicity as a Study Risk: Why Not? |
| 3:15–3:30 PM | **Networking Break** | |
| 3:30–4:30 PM Concurrent Sessions | **501** Evaluating the University-Wide Compliance Program | **503** HHS OIG: A Review of the New 2023 Compliance Guidance |
| | **502** SafeGrounds: How UVA Reimagined Its Incident Management System | **504** Research Sponsor Financial Support for KOLs, Trial Sites, and Patient Participants |
| 4:30–5:30 PM | **School Spirit Networking Reception** | |

# PROGRAM AT A GLANCE

*All times listed are in Central Time (CT)*

## Wednesday, June 12

| | | |
|---|---|---|
| 7:00–8:00 AM | **Breakfast with Exhibitors** | |
| 8:00–9:00 AM | **GS2** Updates in Higher Education Compliance | **GS2** Research Compliance 2024 Year In Review |
| 9:00–9:30 AM | **Networking Break (Exhibit Hall)** | |
| 9:30–10:30 AM Concurrent Sessions | **601** The Governing Board Just Does Not Listen to Compliance (or Me) | **603** Managing Modern Research Risk at a Covered Entity |
| | **602** Title IX: The Past, Present, and Future of Campus Investigations, Adjudications, and Litigation | **604** Watch Your Language! Trial Transparency, Study Protocols, and Reporting Results in ClinicalTrials.gov |
| 10:30–10:45 AM | **Networking Break** | |
| 10:45–11:45 AM Concurrent Sessions | **701** Cooperative Investigations and Resolutions: Compliance and Human Resources | **703** Navigating Research Risks & Needed Infrastructure with Emerging GME Programs and Student Research: Essential Insights for Compliance Officers |
| | **702** Getting Your Conflict of Interest Program Off the Ground: A Case Study | **704** Quality Assurance in Clinical Research: Essential Elements, Best Practices & How to Make it Work in Your Organization |
| 11:45 AM–12:45 PM | **Lunch (provided)** | |
| 12:45–1:45 PM Concurrent Sessions | **801** Monitor and Measure: Creating Effective Compliance Risk Assessments | **803** FDA Inspections: Preparedness and Lessons Learned |
| | **802** Maintaining Policies That Are Value-Added | **804** AI and Machine Learning: When Is It Research and What Do IRB Members Need to Know |
| 1:45–2:00 PM | **Networking Break** | |
| 2:00–3:00 PM Concurrent Sessions | **901** Get Out of Your LMS and into the Org! | **903** It's No Fairy Tale: Successful Compliance Initiatives Rest on a Tripod of Neuroscience, Internal Champions, and Storytelling |
| | **902** Welcoming Students into Compliance | **904** Needles in the Haystack: Using Public Data Sources in Conflict of Interest Programs |
| 3:00–3:15 PM | **Networking Break** | |
| 3:15–4:15 PM | **GS3** What Now?! The Role of Compliance in Crisis Management | **GS3** A Refresh on DOJ's Corporate Compliance Polices and Their Intersection with OIG's Recent General Compliance Program Guidance |

## Thursday, June 13

| | | |
|---|---|---|
| 7:45–8:00 AM | **CCEP Exam Check-In** | **CHRC Exam Check-In** |
| 8:00–10:30 AM | **CCEP Exam** | **CHRC Exam** |

# Monday, June 10 (Pre-Conference)

**7:00 AM–5:30 PM**

Registration Open

**8:00–9:30 AM — Higher Education**

## P1 Small College, Little Resources, Big Compliance: Doing Less with More

*Level: Basic*

AMINAH MASSENBURG, Director of Compliance and Privacy Officer, The College of New Jersey

LORI BROWN, Chief Equity, Diversity & Compliance Officer, Seton Hall University

ROBERT ROACH, Senior Advisor, Guidepost Solutions, LLC

- Explore issues affecting small compliance offices at higher education institutions and discuss best practices and tips for how to do more with less
- Learn how to demonstrate your institution's commitment to effective compliance through simplified but thoughtful systems and processes
- Share approaches on how to leverage fewer resources and available existing personnel, while wearing multiple hats

## P2 Utilizing University Policies to Ensure the Safety of Minors on Campus

*Level: Intermediate*

STARR SANDERS, Director, Protection of Minors on Campus, University of North Carolina – Chapel Hill

SANDRA WEAVER, Director, Youth Program Compliance, Penn State University

- Discuss the need for institutional oversight of minors on campus
- Discuss the types of high-risk programs, events, and the related policies
- Discuss operational risks of not having policies in place

**8:00–9:30 AM — Healthcare Research**

## P3 Conducting Research Across Borders: Issues for Human Subject Research Compliance Officials

*Level: Intermediate*

JOHN BAUMANN, Associate Vice President for Research Compliance, Indiana University

- Identify and understand challenges in the oversight of international research collaborations
- Identify best practices - policy and process - for research compliance in the review of inter/trans-national human subjects research
- Understand the regulatory context for inter/trans-national human subjects research

## P4 From Zero to Hero: Creating an Effective Program to Reduce and Prevent Error and Non-compliance in Clinical Research

*Level: Intermediate*

CONNIE MADDEN, Compliance Director & Privacy Officer, LCMCHealth

SIOBHAN TROTTER, DNP, APRN, AGNP-C, Nurse Practitioner and Manager, Research Quality Assurance, University Medical Center New Orleans

- Review quality programs after 1999 Institute of Medicine Report "To Err is Human"; Discuss importance of a just culture & continuous improvement in an organization
- Discuss the role of quality assurance in identifying critical processes, reporting, evaluating, and controlling risks using risk evaluation scale
- Systematic development of educational programs, competency standards & key performance indicators that address issues identified in risk management process

**9:30–9:45 AM**

Networking Break

# Monday, June 10

9:45–11:15 AM — Higher Education

## P5 Collaborate and Listen: Operationalizing an Effective Compliance Program Through Stakeholder Collaboration

*Level: Intermediate*

ASHLEY FOUNTAINE, Director of Ethics & Compliance, George Washington University

DORINDA TUCKER, Associate Vice President for Ethics, Compliance and Risk and Data Privacy Officer, George Washington University

- Identify key program elements that can leverage collaboration
- Understand how to best approach collaboration that yields value to stakeholders and the compliance program
- Discuss strategies for establishing connections and fostering relationships with stakeholders

## P6 Evaluating Your Institution's Conflict of Interest Posture through the Lens of NSPM-33

*Level: Intermediate*

OLGA POLIKARPOVA, Associate Auditor, University of Alaska

MARCY HUEY, Director of Compliance, University of Alabama

KRISTIN ROBERTS, Assistant Director, Institutional Compliance and Privacy, Auburn University

- Evaluate your Conflict of Interest program through the lens of NSPM-33
- Identify gaps and learn of common pitfalls of Conflict of Interest programs
- Learn of some ways to bridge the gaps

9:45–11:15 AM — Healthcare Research

## P7 The Compliance Framework for Animal Research in the US

*Level: Basic*

STACY PRITT, Associate Vice Chancellor & Chief Research Compliance Officer, Texas A&M University System

- Identify and review compliance requirements for animal research from the Public Health Service (PHS) and US Department of Agriculture (USDA)
- Discuss additional requirements for multiple US funding agencies (NSF, NASA, DOD, and the VA) and animal program accreditation by AAALAC International
- Explore IACUC function monitoring and auditing, current trends, and future events that are expected to impact research compliance in the years to come

## P8 Who Dat? It's the New Research Data Security Requirements Due This Year!

*Level: Advanced*

MIKE CULLEN, Principal, Baker Tilly

- Understand why an effective research data security posture can enable researchers
- Gain insights, strategies, and tips on how to address research data security requirements from NSPM-33, NIH DMSP, HIPAA, export controls, and CMMC
- Take away potential solutions and strategies for research data security

11:15 AM–12:45 PM

Lunch (on own)

# Monday, June 10

12:45–2:15 PM — Higher Education

## P9 Compliance or Legal? Harmonization of the Compliance and Legal Functions

*Level: Intermediate*

CHETNA KOSHY, Associate Vice President, Chief Compliance Officer & Risk Management, Rice University

ERUM RAZA, Dep. Chief Global Compliance Officer & Counsel, New York University

ELIZABETH MILLER , Senior Associate General Counsel, University of Arizona

JOSHUA BOSIN, Partner, Holland & Knight LLP

- Understand distinctions in the roles and responsibilities of compliance and legal in higher education and explore different organizational structures
- Learn the about the updated US DOJ Evaluation of Corporate Compliance Programs guidance and other guidance related to compliance program structures
- Develop an understanding of opportunities for compliance and legal function collaboration and the criticality of ensuring a close working relationship

## P10 Unraveling the Maze for Compliant and Effective Investigative Strategies

*Level: Intermediate*

DEEPIKA BHATIA, Associate Vice President Research Compliance, Emory University

LEBRIT NICKERSON, Program Administrator, Emory University

DANISHA BIOSSAT, Compliance Manager, Emory University

- Discuss types of investigations with emphasis on trigger and triage points
- Illustrate the life cycle of an investigation with case studies; discuss roles and responsibilities of investigative teams
- Outline internal reporting, corrective actions, and monitoring considerations as well as external reporting requirements

12:45–2:15 PM — Healthcare Research

## P11 Good Fences Make Good Neighbors: Scoping Research Security, COI, and Research Misconduct Programs

*Level: Intermediate*

AMANDA FERGUSON, Senior Director, Huron Consulting Group

CASSANDRA FARLEY, Director, Research Integrity, Security & Compliance, University of Florida

AMBER MOORE, Associate Director, Research Integrity, University of Florida

- Review existing and potential state, federal, and global regulations governing research security, COI, outside activities, and research misconduct
- Provide strategies for scoping compliance programs and establishing roles and responsibilities among programs
- Discuss tactics to coordinate among programs to minimize burden on and promote clarity for researchers

## P12 Where Can It Go Wrong: Patient's Rights in Research Studies

*Level: Intermediate*

MARTHA ARVIN, Senior Vice President, Chief Compliance and Privacy Officer, Erlanger Health System

ANDREW MAHLER, Vice President, Compliance & Privacy, Clearwater

- Understand the complex regulations that create risks for the subject and the organization if documents and processes are not handled correctly
- Identify requirements related to requests from patient/subjects regarding their rights and the use of their data
- Evaluate issues in research documents that implicate patient rights and best practices to avoid these compliance risks

2:15–2:30 PM

Networking Break

# Monday, June 10

2:30–4:00 PM — Higher Education

## P13 Compliance Officers Roundtable

*Level: Intermediate*

NEDRA ABBRUZZESE-WERLING, Associate Vice President for Compliance Services, Boston University

- The issues and challenges that face other compliance officers
- Strategies for strengthening compliance programs and providing adequate responses to emerging issues
- Adapting your program during unprecedented regulatory, political, and media scrutiny

## P14 Let's Talk about Ethics: Engaging Your Institution in Routine Conversations on Ethics

*Level: Basic*

JASON GARCIA, Senior Deputy Compliance Officer, The University of Texas at Austin

JAIME DAVIS, Deputy Compliance Officer and Training Program Manager, The University of Texas at Austin

- Receive guidance on growing and sustaining a culture of ethical behavior in a university setting
- Evaluate available resources that encourage employees to engage in ethical behavior
- Facilitate easy-to-implement conversations and regular communications at your institution

2:30–4:00 PM — Healthcare Research

## P15 Investigations, Root Cause, and Corrective Actions: An Escape Room Approach to an Investigation

*Level: Intermediate*

KELE PIPER, Director, Research Compliance, Massachusetts General Hospital

ELEANOR KUSZMAR, Director for Research Compliance, Harvard Medical School

- Review of investigation planning, tools, and techniques
- Review root cause analysis methodology and corrective action plan development
- Conduct an interactive investigation from discovery through corrective action

## P16 Stories from the Trenches: An Organization's Cybersecurity Incident and the Critical Impact on Research Operations!

*Level: Intermediate*

CYNTHIA DUNN, Clinical Research Consultant, Crescent City Research Consulting, LLC

JAKLYN WRIGLEY, JD, Chief Legal and Strategic Affairs Officer, Singing River Health System

- Discuss the critical impact of a health system's organization-wide cybersecurity incident and its effects on clinical research operations
- Outline the steps from a clinical research operations perspective on addressing a cybersecurity incident
- Identify strategies to mitigate cybersecurity incidents and risks from a clinical research operations perspective

4:00–5:30 PM

## Opening Reception

# Tuesday, June 11

## 7:00–8:00 AM

Breakfast with Exhibitors

### 8:00–8:15 AM — Higher Education

Welcome and Opening Remarks

### 8:15–9:15 AM — Higher Education

**GS1** University Civil Rights Compliance

CATHERINE LHAMON, Assistant Secretary for Civil Rights, U.S. Department of Education

- Current civil rights issues on campus
- Overview of federal civil rights obligations for protecting students from discrimination and providing equal access

### 8:00–8:15 AM — Healthcare Research

Welcome and Opening Remarks

### 8:15–9:15 AM — Healthcare Research

**GS1** General Compliance Session TBA

## 9:15–9:45 AM

Networking Break (Exhibit Hall)

### 9:45–10:45 AM — Higher Education

**101** Name, Image, and Likeness (NIL) in College Athletics: Current Rules for Educational Institutions and What is Likely to Come Next

*Level: Intermediate*

CALLAN STEIN, Partner, Troutman Pepper

CHRISTOPHER BROLLEY, Associate, Troutman Pepper

MICHAEL LOWE, Partner, Troutman Pepper

- Identify current NCAA guidance and state laws governing NIL and their impact on educational institutions' NIL compliance risks and responsibilities
- Understand the current state of NCAA and state attorneys general NIL enforcement activity and likely enforcement trends to come in 2024 and beyond
- Evaluate current/future NIL compliance challenges for educational institutions, risk mitigation strategies, and other NIL compliance best practices

**102** Turnover Headaches: They Left—Now What?

*Level: Basic*

NEDRA ABBRUZZESE-WERLING, Associate Vice President for Compliance Services, Boston University

STEPHANIE BARBER, Chief Compliance Officer, Stevens Institute of Technology

TYE WELCH, Director of Compliance, California Institute of Technology

- Attendees will hear how three institutions maintained continuity in the compliance program in the midst of the great resignation
- How to prevent single point of failure situations where one individual is responsible for an important compliance area and that person leaves
- Attendees will learn how to develop reproducible systems that are integrated in the business process and not dependent on a single employee

### 9:45–10:45 AM — Healthcare Research

**103** Physician Owned Distributorships and Companies: Pitfalls to Watch for and How to Operationalize in Your Organization

*Level: Advanced*

RICARDO PABON, Attorney, Ankura Consulting Group

LISA TAYLOR, Managing Director, Ankura Consulting Group

- Identify risks and concerns on these practices by physicians in academy centers
- Discuss the laws and regulations that would apply to this type of arrangement such as Stark Law, Anti-Kickback Statute and False Claims Act
- Discuss policies and procedures that should be in place to reduce risks, and how to prepare and conduct proper auditing and monitoring of the practices

**104** Unlocking Research Compliance Excellence: A Symphony of Compliance and Billing Mastery

*Level: Basic*

CARLY TUCKER, Corporate Compliance Manager, Tufts Medicine

NICOLE HUFF, Chief Compliance & Internal Audit, Tufts Medicine

- Identify important aspects of regulatory requirements that impact clinical research billing processes
- Learn about the importance of a Medicare Coverage Analysis (MCA) to mitigate research billing compliance risks
- Discuss billing & coding obstacles of clinical trials

# Tuesday, June 11

10:45–11:00 AM

Networking Break

11:00 AM–12:00 PM — Higher Education

## 201 Are You Making the Most of Your Anonymous REPORTLINE?

*Level: Intermediate*

KIMBERLY FEARNEY, Chief Compliance Officer, University of Connecticut (UConn)

KIM HILL, Director of University Compliance, University of Connecticut (UConn)

- In this session, you will learn how to spot "red flags" from your Reportline data and how to share these with senior leaders
- How to use data to influence policy development and education
- How to periodically test the effectiveness of your anonymous Reportline

## 202 The Adaptable Compliance Office: Crafting a Strategic and Nimble Function

*Level: Basic*

COLLEEN LEWIS, Manager, Baker Tilly

TERRA DUBOIS, Chief Compliance, Ethics, and Privacy Officer, University of Florida

- Identify, evaluate, and develop a plan to address changing laws, regulations, and institutional priorities
- Understand ways to balance functional compliance responsibilities with overarching strategic objectives
- Learn leading practices and questions to consider when establishing a modern approach to maintaining compliance

11:00 AM–12:00 PM — Healthcare Research

## 203 How Academic Research Can Better Integrate with Community and Commercial Research Sites to Reach More Patients

*Level: Advanced*

EDYE EDENS, Senior Research Compliance Consultant, First Class Solutions

- Why and when partnering with community and commercial research sites makes sense in academic research to expand patient catchment
- Analyze multiple partnership and research site network models integrating academic research sites for hallmarks of success and lack thereof
- Review operational, ethical, compliance, logistical, and downright practical considerations for transitioning to a unique and new model

## 204 What Is Monitoring Good For? Using Monitor Reports to Strengthen Your Program

*Level: Intermediate*

ELIZABETH CARROLL, Research Compliance Officer, Northern Light Health

CHRISTA BALMAS, Clinical Research Supervisor, Cardiology Research, Northern Light Eastern Maine Medical Center

- Learn how to evaluate monitor reports, self-monitors, and FDA Warning Letters
- Explore ways to get away from processing paperwork and move to finding value in reports
- Demonstrate ways to use these reports as tools for strengthening a research program

12:00–1:00 PM

Lunch (provided)

# Tuesday, June 11

1:00–2:00 PM — Higher Education

## 301 Practice Makes (Better): Developing a Compliance Community of Practice

*Level: Intermediate*

LUCAS CHRISTAIN, Associate Director, University Compliance, Northwestern University

KATHLEEN BOOTH, Assistant Vice President, Risk & Compliance, Northwestern University

- Identify challenges of working collaboratively within a federated HE compliance environment
- Learn to foster collaboration amongst compliance subject matter experts and execute projects using a compliance community of practice
- Understand frameworks for reviewing and escalating reported concerns when material conflicts may exist

## 302 Skip the Investigation! A Practical Guide for Using Alternative Dispute Practices to Resolve Complaints and Enhance Equity in Higher Education

*Level: Intermediate*

JENNIFER SMITH, Assistant Vice President of Compliance & Title IX Coordinator, Texas A&M University

JOSEPH ALFE, Informal Resolution Facilitator & Mediator, Texas A&M University

- Understand why resolving complaints through mediation is a WIN-WIN for all and how skipping the investigation is quick and reduces legal and reputational exposure
- Learn best practices for setting up a legally compliant mediation program, selecting a mediator, and promoting mediation as the preferred option
- Explore pros and cons of "mediating the dispute" vs. "mediating the outcome" and receive practical advice for facilitating the preferred approach

1:00–2:00 PM — Healthcare Research

## 303 Considerations in Building and Implementing an Effective Research Security Compliance Program

*Level: Intermediate*

KATHLEEN MCNAUGHTON, Research Compliance Officer, Mayo Clinic

CALLAN STEIN, Partner, Troutman Pepper

- Understanding current guidance on NSPM-33 and OSTP Research Security Standards
- Identifying and addressing operational challenges to maintaining Research Security Standards compliance
- Mitigating legal exposure for investigators/institutions by implementing an effective Research Security compliance program

## 304 Overview of Developments in False Claims Act Cases and Research

*Level: Intermediate*

KELLY WILLENBERG, CEO, Kelly Willenberg and Associates

MARTA THOMPSON, Counsel, Akin Gump Strauss Hauer & Feld

KRISTIN WEST, Director, Research Ethics & Compliance, Council on Governmental Relations (COGR)

- False Claims Act updates in the areas of research billing, research security, research misconduct, and cybersecurity
- Tips for self-disclosure and reporting
- Mitigating FCA risk in your compliance program

2:00–2:15 PM

## Networking Break

# Tuesday, June 11

2:15–3:15 PM — Higher Education

## 401 Investigation Offices: Convening, Assessing, and Sharing Best Practices

*Level: Intermediate*

SUSAN FRECCIA, Deputy Chief Executive of Compliance and Ethics, Oregon State University

- Recognize the common threads, rather than the differences, among specialized investigation areas
- Use an informal self-assessment to spark awareness of local and systemic improvement opportunities
- Foster collegiality and build a community of practice across decentralized compliance units

## 402 Visualizing Success: Using Analytics to Communicate Compliance

*Level: Basic*

STEPHANIE SUERTH, Director, University of Maryland, Baltimore

SUSAN BUSKIRK, Vice President, Chief Accountability Officer, Institutional Official Human and Animal Research, University of Maryland, Baltimore

- Identifying Meaningful Data Analytics: Inventorying and assessing your data to identify analytics that are meaningful to you and your stakeholders
- Visualizing Performance: Creating dashboards, general and tailored, to share relevant information in an understandable way
- Publish or Protect: Reviewing and working with data (de-identifying) to create dashboards for public or protected access

2:15–3:15 PM — Healthcare Research

## 403 Data Sharing: Ethical and Practical Considerations for Institutions

*Level: Intermediate*

CHERI PETTEY, Senior Consultant, Research Compliance & Site Operations, Advarra

VANESSA HILL, Director of Clinical Research, Duke Cancer Network, Duke University Health System

- Define and discuss the practical and ethical issues related to data sharing and secondary research use of existing research and non-research data
- Understand data ownership and institutional responsibility with emphasis on participant trust, especially in a community setting
- Identify the institutional resources needed to successfully manage the use, creation, transfer, and receipt of data to be used for research

## 404 Financial Toxicity as a Study Risk: Why Not?

*Level: Intermediate*

KATHERINE COHEN, Chief Compliance Officer, SIU Medicine

DAWN PITTINGER, Research Financial Compliance Officer, Moffitt Cancer Center

- Explore why financial toxicity is not commonly considered a risk by study teams, sponsors, or IRBs
- Discuss regulatory impact of failing to identify financial toxicity as a risk
- Brainstorm ways to minimize risk of financial toxicity to research participants

3:15–3:30 PM

## Networking Break

# Tuesday, June 11

## 3:30–4:30 PM — Higher Education

### 501 Evaluating the University-Wide Compliance Program

*Level: Basic*

JANELLE DYJASEK, Senior Consultant, Protiviti

KAYLA HUISENGA, Compliance Manager, Protiviti

- Discuss how DOJ compliance guidance relates to the 7 elements compliance guidance from the USSG, and how the elements are used to design the program
- Determine the government's expectation of an adequately resourced and empowered compliance program
- Assess the functionality of the compliance program to ensure the program is operating as designed

### 502 SafeGrounds: How UVA Reimagined Its Incident Management System

*Level: Intermediate*

GARY NIMAX, Assistant Vice President for Compliance, University of Virginia

STEVE SHERMAN, Manager, University Compliance Program, University of Virginia

- Implement a university-wide incident management system for multiple areas and reporting portals
- Explore new ways to collaborate in a decentralized environment with a centrally funded platform
- Review lessons learned from the implementation and continuous improvement of the system

## 3:30–4:30 PM — Healthcare Research

### 503 HHS OIG: A Review of the New 2023 Compliance Guidance

*Level: Intermediate*

ROBERT ROACH, Senior Advisor, Guidepost Solutions, LLC

MARCY HUEY, Director of Compliance, University of Alabama System

ELIZABETH RODD, Partner, McDermott Will & Emery LLP

- Gain insight into how OIG's new guidance should be factored into a healthcare entity's compliance program
- Understand the OIG's new Interpretation of Fraud, Waste and Abuse Laws
- Hear about the OIG's latest views on Common Compliance Risk Areas, and how these might be leveraged for areas outside of healthcare

### 504 Research Sponsor Financial Support for KOLs, Trial Sites, and Patient Participants

*Level: Intermediate*

ROBERT WADE, Partner, Nelson Mullins

- Types of financial support that sponsors can offer (and sites can accept) for research trials, including DEI engagement
- Compliant financial support for patient participants
- Compliance issues under the Anti-Kickback Statute and Civil Monetary Penalty Act, including Personal Services Safe Harbor

## 4:30–5:30 PM

### School Spirit Networking Reception

# Wednesday, June 12

## 7:00–8:00 AM

Breakfast with Exhibitors

## 8:00–9:00 AM — Higher Education

### GS2 Updates in Higher Education Compliance

REBECCA KIMURA, Member, Bond Schoeneck & King

AMY PICCOLA, Partner, Saul Ewing Arnstein & Lehr LLP

- Update on new Title IX regulations and Gainful Employment regulations
- Primer on artificial intelligence in higher education, data privacy, and cybersecurity
- Refresher on avoiding discrimination claims in scholarships, pay, and web accessibility
- Preparing for student organizing on your campus

## 8:00–9:00 AM — Healthcare Research

### GS2 Research Compliance 2024 Year In Review

*Level: Advanced*

F. LISA MURTHA, Vice President and US Compliance Officer, Walgreens

- Provide an overview of new laws, regulations, and enforcement updates in clinical research from 6/2023-2024 from FDA, NIH, OHRP, ORI, OMB, DOJ and OIG
- Outline the DOJ and OIG's enforcement agenda for research compliance for 2024
- Provide practical updates for training auditing and monitoring research compliance for 2024 and beyond

## 9:00–9:30 AM

Networking Break (Exhibit Hall)

## 9:30–10:30 AM — Higher Education

### 601 The Governing Board Just Does Not Listen to Compliance (or Me)

*Level: Intermediate*

JUDY SPAIN, President, Higher Education Compliance Consulting

- Identify various methods to present concepts and issues to board members with limited time and possibly limited interest
- Learn how to build a sustainable compliance program that will engage your board and your institution
- Discuss how to encourage long-term relationships with the board and throughout the institution that will sustain the compliance efforts

### 602 Title IX: The Past, Present, and Future of Campus Investigations, Adjudications, and Litigation

*Level: Intermediate*

PATRICK SMITH, Attorney, Montgomery, McCracken, Walker & Rhoads LLP

ASHLEY LYNAM, Attorney, Montgomery, McCracken, Walker & Rhoads LLP

- Understand the current status of the Title IX regulations and what changes we expect to see with the new proposed regulations
- Discuss current regulations, compliance requirements, major policy changes required, Department of Education Guidance, and implementation concerns
- Provide recommendations and advice to avoid litigation and promote safe, compliant campus community

## 9:30–10:30 AM — Healthcare Research

### 603 Managing Modern Research Risk at a Covered Entity

*Level: Advanced*

MOLLY HUBBARD, Privacy & Info Security Officer, Sutter Health

- Overview of the unique risks of research at HIPAA Covered Entity (CE)
- Tips for ways to engage the specific stakeholders
- Strategies for maximizing your risk mitigation efforts in your CE, while enabling a robust research portfolio

### 604 Watch Your Language! Trial Transparency, Study Protocols, and Reporting Results in ClinicalTrials.gov

*Level: Intermediate*

MICHAEL CALLAHAN, Senior Regulatory Specialist, University of Michigan

JESSICA HOULIHAN, Associate Director, Research Operations, Duke University School of Medicine

- Understand requirements for protocols and results reporting in ClinicalTrials.gov and learn strategies for addressing associated regulatory issues
- Explore solutions, applicable across different institutions, for resolving common issues with study protocols and ClinicalTrials.gov requirements
- Explore the evolution of research transparency, the regulatory changes facilitating that evolution, and the increasing role ClinicalTrials.gov plays

# Wednesday, June 12

10:30–10:45 AM

Networking Break

10:45–11:45 AM — Higher Education

## 701 Cooperative Investigations and Resolutions: Compliance and Human Resources

*Level: Intermediate*

STEPHANIE SUERTH, Director, University of Maryland, Baltimore

- Building Trust for Collaboration: Working together requires trust to identify and work together on issues that fall within the scope of both units
- Engage in Customer-Centric Responses: Cooperative investigations reduce the burden on participants and create efficiency in addressing concerns
- Consistency in Outcomes: Collaboration allows for more consistent, transparent communication of outcomes to implicated parties

## 702 Getting Your Conflict of Interest Program Off the Ground: A Case Study

*Level: Basic*

KELLY TORNOW, Associate General Counsel / Chief Compliance Officer, Western Carolina University

MALLORY BALL, Director, Research Compliance & Integrity, Western Carolina University

- How to break down the COI process into smaller tasks for big impact
- Helpful Dos and Don'ts for streamlining your COI process and transitioning to an electronic process
- How to utilize project management strategies to identify gaps in current COI processes and address those associated risks for greater compliance

10:45–11:45 AM — Healthcare Research

## 703 Navigating Research Risks & Needed Infrastructure with Emerging GME Programs and Student Research: Essential Insights for Compliance Officers

*Level: Intermediate*

WENDY PORTIER, Consultant, Portier and Associates, LLC

GABRIELLA NEFF, Research Compliance Officer, H. Lee Moffitt Cancer Center and Research Institute, Inc.

- Outline the unique challenges and risks associated with research in emerging Graduate Medical Education (GME) programs and student research projects
- Discuss the needed infrastructure elements crucial for supporting successful and compliant faculty, resident, and student research projects
- Discuss lessons learned and proactive strategies to foster a compliant and supportive environment for successful research project completion

## 704 Quality Assurance in Clinical Research: Essential Elements, Best Practices & How to Make it Work in Your Organization

*Level: Intermediate*

DRACO FORTE, Director, Research Operations & Quality Assurance, Baptist Health South Florida

NICHOLAS REPUCCI, Director, Research Administration, Lahey Hospital and Medical Center

TOMAS PEREIRA, Associate Vice President, Research Administration, Tulane University

ERIC TOMASINI, Managing Director, Huron Consulting Group

- Understand the importance of quality assurance & quality control (QA/QC) to clinical research and why it matters
- Discover the essential elements of effective QA/QC programming
- Share industry best practices and discuss challenges to implementation & maintenance of your QA/QC program

# Wednesday, June 12

**11:45 AM–12:45 PM**

Lunch (provided)

**12:45–1:45 PM — Higher Education**

## 801 Monitor and Measure: Creating Effective Compliance Risk Assessments

*Level: Basic*

KENNETH LIDDLE, Consultant, Liddle Consulting

ROBERT ROACH, Senior Advisor, Guidepost Solutions, LLC

GREER GRIFFITH, Partner, McDermott Will & Emery LLP

- Practical tips for evaluating the effectiveness of a university compliance program
- Measure and communicate using maturity models
- Creating an ongoing monitoring program for compliance partners across the university

## 802 Maintaining Policies That Are Value-Added

*Level: Intermediate*

JESSICA TEETS, Policy Office Director, Purdue University

- Determine who should be involved in the review process based on the institution's policy management structure
- Consider what questions to ask when reviewing policies to ensure a thorough review
- Assess when it is appropriate to eliminate a policy

**12:45–1:45 PM — Healthcare Research**

## 803 FDA Inspections: Preparedness and Lessons Learned

*Level: Intermediate*

JINAH CHANG, Research Compliance Principal Analyst, UC Irvine Health

BEVERLY ALGER, Director of Clinical Research, Administration and Finance, UC Irvine Center for Clinical Research

JESSICA SHELDON, Director, Human Research Protections, University of California, Irvine

- Examples of routine application-based FDA inspections of clinical investigators under BIMO
- Understand how our institution prepares for, facilitates, and conducts FDA inspections
- Acquire and analyze information from our experiences to apply to your institution

## 804 AI and Machine Learning: When Is It Research and What Do IRB Members Need to Know

*Level: Intermediate*

PAUL PAPAGNI, Assistant Vice President, Corporate Research, Baptist Health

- Determining what protections are needed when sharing data for AI/ML development (ICD, DUA, CTA, IP agreement)
- How to recognize when AI/ML development moves from Non-Human Subject Research to Exempt Research, and to an AI device requiring FDA oversight/approval
- Is your IRB equipped to perform an assessment of harm to individuals and groups and the potential for bias in the algorithms used for learning?

**1:45–2:00 PM**

Networking Break

# Wednesday, June 12

2:00–3:00 PM — Higher Education

## 901 Get Out of Your LMS and into the Org!

*Level: Intermediate*

JAYCEE DEMPSEY, Director of Customer Success, Broadcat

JENNIFER MAY, Director of Compliance Advisory, Broadcat

- Learn how to think strategically about your communications as a tool to make training stick
- Explore ways to start measuring behavior changes instead of chasing completion rates
- Review examples and start building a roadmap to use for your own program

## 902 Welcoming Students into Compliance

*Level: Basic*

SARAH BRINTON, Chief Compliance Officer, Brigham Young University

JAYMON ROAN, Brigham Young University

ADRIANNE BARTON, Senior Compliance Law Clerk, Brigham Young University Integrity & Compliance Office

- Enable attendees to recognize the benefits of involving students in compliance
- Engage attendees with examples of successful student involvement in compliance
- Empower attendees to create a student-driven culture of compliance on campus

2:00–3:00 PM — Healthcare Research

## 903 It's No Fairy Tale: Successful Compliance Initiatives Rest on a Tripod of Neuroscience, Internal Champions, and Storytelling

*Level: Intermediate*

CHARLIE BARTON, President, Barton Consulting, LLC

- Successful change initiatives emerge from stories people tell about the events; stories also shroud the failures
- People require stories to understand their circumstances; different areas of the brain engage when someone hears or shares a story
- Internal champions are trusted story/memory keepers; internal champions are present whenever there is a successful change initiative

## 904 Needles in the Haystack: Using Public Data Sources in Conflict of Interest Programs

*Level: Intermediate*

C.J. WOLF, Faculty, BYUI

- Explore sources of public data for conflict of interest professionals
- Observe and share basic ways to mine public data for conflict of interest purposes
- Identify characteristics of data that might need deeper investigation for potential conflicts of interest

3:00–3:15 PM

## Networking Break

# Wednesday, June 12

3:15–4:15 PM — Higher Education

## GS3 What Now?! The Role of Compliance in Crisis Management

*Level: Intermediate*

KATHLEEN BOOTH, Assistant Vice President, Risk & Compliance, Northwestern University

LAWRENCE LOKMAN, Vice President, University Marketing & Communications, Santa Clara University

- Define what a crisis is for your institution and how to identify and distinguish a crisis from issues or incidents
- Explore development of a crisis management framework from stakeholder identification, assessing current gaps, drafting, and pressure-testing your plan
- Discuss the role a compliance officer might play in developing and/or executing an institution's crisis response framework

3:15–4:15 PM — Healthcare Research

## GS3 A Refresh on DOJ's Corporate Compliance Polices and Their Intersection with OIG's Recent General Compliance Program Guidance

*Level: Intermediate*

TERANCE GONSALVES, Partner, Alston & Bird LLP

DEBORAH SOLMOR, General Counsel, Gateway Foundation, Inc.

KELLY WILLENBERG, CEO, Kelly Willenberg and Associates

- An overview of DOJ's Evaluation of Corporate Compliance Programs and their application to healthcare settings
- An overview of OIG's November 2023 General Compliance Program Guidelines (GCPG) and any to-be released Industry Segment Specific CPGs
- Best practice guidance to create and update your healthcare compliance program to align with these recent guidelines

# Thursday, June 13

## Optional Compliance Certification Board (CCB)® exams; separate fee and application required.

7:45–8:00 AM — Higher Education

### CCEP Exam Check-In

7:45–8:00 AM — Healthcare Research

### CHRC Exam Check-In

8:00–10:30 AM — Higher Education

### CCEP Exam

The exam is optional. You must apply and be approved to sit for the CCEP exam by CCB, separately from your conference registration. To apply online, go to: bit.ly/CCEP-reg.

PLEASE NOTE: If you are not present at the specified "Exam Time" as listed above, and as determined by the exam proctor, you will not be allowed to sit for the exam. Actual exam duration is 120 minutes per the Candidate Handbook. Time range above includes mandatory exam procedures and proctor instructions.

8:00–10:30 AM — Healthcare Research

### CHRC Exam

The exam is optional. You must apply and be approved to sit for the CHRC exam by CCB, separately from your conference registration. To apply online, go to: hcca-info.org/apply-exam.

PLEASE NOTE: If you are not present at the specified "Exam Time" as listed above, and as determined by the exam proctor, you will not be allowed to sit for the exam. Actual exam duration is 120 minutes per the Candidate Handbook. Time range above includes mandatory exam procedures and proctor instructions.

# Higher Education & Healthcare Research Compliance Conference

June 10–12, 2024 • New Orleans, LA

## SECTION 1 Attendee Information

○ Mr ○ Mrs ○ Ms ○ Dr ○ Other _____

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 _____

Work Phone _____ Email (required) _____

## SECTION 2 Registration

### In-Person Options

| | | |
|---|---|---|
| **Full Conference (Monday–Wednesday)** | | |
| ☐ | Member | $1,299 |
| ☐ | Non-Member | $1,549 |
| ☐ | Registration + First-Time Membership* – SCCE | $1,524 |
| ☐ | Registration + First-Time Membership* – HCCA | $1,524 |
| **Main Conference (Tuesday—Wednesday only)** | | |
| ☐ | Member | $1,049 |
| ☐ | Non-Member | $1,299 |
| ☐ | Registration + First-Time Membership* – SCCE | $1,274 |
| ☐ | Registration + First-Time Membership* – HCCA | $1,274 |

*Save by joining today (first-time members only). Dues renew at $325.

### Group Discount

| | | |
|---|---|---|
| ☐ | Group Discount for 3–9** | ($50) |
| ☐ | Group Discount for 10 or More** | ($100) |

**Subtract the discount amount from your registration price.

**TOTAL** (BEFORE ANY APPLICABLE TAXES) $ _____

**Group Discount:** Registration for group discounts should be submitted online in one transaction. If your registrations include a Registration + First-Time Membership, please contact Member Services for assistance. 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. If submitting via email or mail, registration forms (one for each participant) must be sent together to ensure the discount is applied.

**Dietary Needs Request** (for in-person attendees only)

☐ Gluten Free ☐ Kosher Certified ☐ Lactose Intolerant ☐ No Red Meat/Pork ☐ Nut Allergy
☐ Shellfish/Seafood Allergy ☐ Vegan ☐ Vegetarian ☐ Other _____

**On-site Attendee Mobile Phone** (for emergency on-site use only) _____

**Emergency Contact** (name & phone) _____

**SCCE or HCCA Membership:** By selecting Registration + First-Time Membership, you agree to the full membership terms and conditions, including the use of your information, viewable at corporatecompliance.org/membership-terms-and-conditions or hcca-info.org/membership-terms-and-conditions. Visit corporatecompliance.org/privacy or hcca-info.org/privacy to see the full use of your information or to opt out.

**Opt Out:** Select if you would like to opt out of the following:

☐ Online Member Directory: SCCE & HCCA's member directory lists first and last name, organization, title, address, and phone number.

**Registration FAQs:** Visit corporatecompliance.org/faqs-national-person or hcca-info.org/faqs-national-person for answers to frequently asked questions (FAQs) about your registration.

## SECTION 3 Payment

**Register online** with credit card payment at corporatecompliance.org/2024here

**Mail a check** to SCCE & HCCA, 6462 City West Parkway, Eden Prairie, MN 55344 USA (contact SCCE & HCCA for applicable tax and total)

☐ Invoice me Purchase Order Number (attach PO) _____

☐ Wire transfer requested

To register with a check, wire transfer, or purchase order, or to pay with a credit card over the phone, please contact SCCE & HCCA for an invoice with applicable taxes. Due to PCI compliance, do not provide credit card information via email.

**Registration is not complete until full payment is received. Tax may apply. Access to the event will not be allowed until all fees have been paid. SCCE & HCCA reserves the right to cancel your registration if we do not receive payment by the start date of the event. Payments received with incorrect amounts will be returned.**

Email helpteam@corporatecompliance.org or helpteam@hcca-info.org; or call SCCE at +1 952.933.4977 or 888.277.4977; or call HCCA at 952.988.0141 or 888.580.8373.

## SECTION 4 Acknowledgements

By submitting this registration, you agree to the full event Terms and Conditions, viewable at corporatecompliance.org/event-terms-and-conditions or hcca-info.org/event-terms-and-conditions, including the use of your information that may be shared with conference exhibitors, attendees, speakers, affiliates, and partners for promotional and/or networking purposes. Visit corporatecompliance.org/privacy or hcca-info.org/privacy to see the full use of your information or to opt out.

By registering for this event, you grant SCCE & HCCA, or anyone authorized by SCCE & HCCA, the right to use or publish, in print or electronic format, any photographs or video containing your image or likeness for educational, news, or promotional purposes, without compensation.

## Conference Location

**Hyatt Regency New Orleans**
**601 Loyola Avenue**
**New Orleans, LA 70113**

Make hotel reservations online or call 1.504.561.1234 and reference Group Code: G-SCCE, or the 2024 SCCE Higher Education and HCCA Healthcare Research Compliance Conference. The group rate is $249 per night for single/double occupancy plus tax. The cutoff date to receive the group rates is Friday, May 17, 2024, or once the group block is full, which may be prior to this date. Please cancel your reservation 72 hours prior to arrival to avoid penalty. There is no deposit required at the time of booking.

PLEASE NOTE: Neither SCCE 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 SCCE or the event, it 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 SCCE at +1 952.933.4977 or 888.277.4977.