VIRTUAL CONFERENCE

RESEARCH COMPLIANCE CONFERENCE

JUNE 1-3, 2020

Gain insights into emerging Research compliance risks and develop strategies to address them.

Get complimentary access to SCCE's Virtual Higher Education Compliance Conference.

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HCCA™
Health Care Compliance Association

MONDAY, JUNE 1

8:50–9:00 AM CDT	ROOM 1	Higher Education Compliance Opening Remarks
8:50–9:00 AM CDT	ROOM 3	Research Compliance Opening Remarks
9:00–10:00 AM CDT	ROOM 1	HIGHER EDUCATION COMPLIANCE GENERAL SESSION: Higher Education Compliance: 2019-20 Year in Review – *Marisa Zuskar, Sr. Director, Huron Consulting Group*
9:00–10:00 AM CDT	ROOM 3	RESEARCH COMPLIANCE GENERAL SESSION: Research Year in Review – *Lisa Murtha, Senior Managing Director, Ankura Consulting Group*

	ROOM 1	ROOM 2	ROOM 3	ROOM 4
10:15–11:15 AM CDT	**H2** Imagineering a University-Wide Conflict of Interest/ Commitment Disclosure Process: Make (What Seems Like) the Impossible, Possible	**H3** Compliance Risk Reviews: Developing a Collaborative Compliance Monitoring Process	**R2** OCR Audits: Past, Present, and Future Considerations for Privacy and Security	**R3** Stop! Or Else I'll Say Stop Again! Institutional Responses to COI Noncompliance
11:30 AM– 12:30 PM CDT	**H4** Investigations—The Who, The How, and The What Could Go Wrong? How to Effectively Navigate an Investigation	**H5** Effective Compliance Responses to Covid-19 and Financial Disruption: A Facilitated Discussion	**R4** The Civil Monetary Penalties Law and the Role of HHS-OIG: Self-Disclosure and Enforcement	**R5** Managing Compliance as an NCI National Community Oncology Research Program NCORP Site?
1:15–2:15 PM CDT	**H6** Awareness, Training, and Development: A Scaffold Approach to Compliance Education	**H7** Sports Wagering and Intercollegiate Athletics	**R6** The Pathway of Part 2 Data in Research: Opioids, Covered Entities, and IRBs, Oh My!	**R7** Responsible Conduct: Collaborating on RCR Training
2:30–3:30 PM CDT	**H8** A Journey Down the Road of College and University Cybersecurity Breaches: A Review of Recent University and College Case Studies, Lessons Learned, and How to Mitigate Being a Victim	**H9** Fraud in Higher Education Institutions: It Only Happens at Other Schools	**R8** Compliance and Culture: How Design and Approach Can Help Support Clinical Trial Billing	**R9** How to Overcome the Challenges of Effectively and Legally Implementing Research in a Skilled Nursing Facility
3:45–4:45 PM CDT	**H10** Foreign Influence: Mitigating Risk through Strong Policies and Processes	**H11** Operationalizing Privacy and Data Security Compliance in Higher Education	RESEARCH COMPLIANCE GENERAL SESSION: Preventing Grant Fraud, Waste and Abuse – *Barbara Orlando, Grants Policy Manager, Department of Defense*	

TUESDAY, JUNE 2

7:15–8:15 AM CDT	ShakRa Yoga Flow	
8:50–9:00 AM CDT	ROOM 1	Higher Education Compliance Opening Remarks
8:50–9:00 AM CDT	ROOM 3	Research Compliance Opening Remarks
9:00–10:00 AM CDT	ROOM 1	HIGHER EDUCATION COMPLIANCE GENERAL SESSION: What do Starbucks Coffee, Jimmy Buffet, and a Can of Cheez Whiz Have In Common? A Unique Look at How to Explain Ethics and Compliance and Successfully Embed It Within the Operations – *Beth Colling, Senior Vice President and Chief Compliance Officer, CDM Smith, Inc.*
9:00–10:00 AM CDT	ROOM 3	RESEARCH COMPLIANCE GENERAL SESSION: Difficult Case Scenarios in Clinical Research Billing – *Ryan Meade, University of Oxford*

	ROOM 1	ROOM 2	ROOM 3	ROOM 4
10:15–11:15 AM CDT	**H13** Centralizing University Policy Approval and Management	**H14** Who's Afraid of Internal Controls? Not Me! Using Internal Controls to Make Higher Education Compliance Programs More Effective	**R13** CRRC: Clinical Research Revenue Cycle Management: Avoiding the Pitfalls	**R14** The Benefit of Collaboration between Compliance and Business Units: Enhancing Compliance at Your Institution

Agenda is subject to change.

TUESDAY, JUNE 2

	ROOM 1	ROOM 2	ROOM 3	ROOM 4
11:30 AM–12:30 PM CDT	**H15** High Anxiety—The Drug Free Schools and Communities Act, the Drug Free Workplace Act, and the Legalization of Marijuana	**H16** Investigations Infrastructure and Corrective Actions	**R15** A Compliance Officer's Research Data Nightmare and How to Wake Up From It	**R16** Right to Try Laws vs. FDA Expanded Access: What You Need to Know and What You Need to Do
1:15–2:15 PM CDT	**H17** Dealing with the F Word: Foreign Gifts and Contracts	**H18** Harmonizing the Compliance, Internal Audit, and Enterprise Risk Management Risk Functions	**R17** Protecting Research Participants Financially: Making SENSE of Patient-CENTric Research When Patients Lack CENTS	**R18** In Unity Is Strength: Research Compliance Through Leadership
2:30–3:30 PM CDT	**H19** Building and Sustaining a Culture of Compliance and Ethics: Compliance Training	**H20** Complying with the Shifting Title IX Landscape	**R19** Dealing with Data: Non-technical Thoughts Concerning Data Security and Management	**R20** When is it Research and When is it Not? The Special Cases of Quality Assurance Studies and Medical Device Improvement
3:45–4:45 PM CDT	**HIGHER EDUCATION COMPLIANCE GENERAL SESSION: Foreign Influences on Research Integrity: Tackling the Challenging Issues while Maintaining an Open and Collaborative Global Research Environment** – *Alexander Bustamante, SVP Chief Compliance & Audit Officer, University of CA; Shanda Hunt, UC Systemwide Research Compliance Manager, University of California*		**RESEARCH COMPLIANCE GENERAL SESSION: "Research Compliance During the Pandemic" – A Round Table MODERATORS:** *Lisa Murtha, Senior Managing Director, Ankura Consulting Group; Ryan Meade, University of Oxford* **SPEAKERS:** *Lynn Batholow, Executive Director of Research Compliance, Avera Health; Sarah Duffy-Clinton, Research Compliance Officer, Providence*	
4:50–5:30 PM CDT	Cocktails & Conversations			

WEDNESDAY, JUNE 3

7:15–8:15 AM CDT	ShakRa Power Flow
8:15–8:55 AM CDT	Connect over Coffee

	ROOM 1	ROOM 2	ROOM 3	ROOM 4
9:00–10:30 AM CDT	**H22** HIPAA and Hybrid Entity Status: Why Most Universities Get It Wrong	**H23** Free Speech and Protests on Campus: Strategies to Protect Reputation and Safety	**R22** Conflict of Interest 101: Identifying, Managing, and Preventing Research Risk	**R23** Supplementing Traditional Research Compliance Monitoring and Auditing with Anticipatory Surveillance
10:45 AM–12:15 PM CDT	**H24** Export Controls and International Research	**H25** Institution-wide Compliance Assessment: What It Is and Why You Need to Do It	**R24** The Laws of the Jungle: An Introduction to the Regulation of Animal Research	**R25** Research Stepchildren: Humanitarian Use Devices and Expanded Access to Investigational Medical Products
1:00–2:30 PM CDT	**H26** Financial Risk Monitoring in Higher Education: New Compliance Challenges	**H27** Artificial Intelligence and Proactive Compliance	**R26** "Wish I Had Known That a Year Ago": Lessons Learned in the Midst of Conducting a Research Misconduct Inquiry and Investigation	**R27** Let's Talk About It: The Reality of the Impact of the Changes from the Revised Human Subject Rules
2:45–4:15 PM CDT	**H28** Developing and Utilizing a HECA Model Compliance Matrix to Track Compliance Obligations on Your Campus	**H29** Compliance Officers Roundtable	**R28** Noncompliance in Animal Research Oversight	**R29** Demonstrating Good Clinical Practice (GCP) Compliance in Research through the maintenance of Regulatory Documents

Agenda is subject to change.

ABOUT

Research compliance has garnered increased attention from government regulators and enforcers. Learn practical strategies to address regulations at this year's virtual conference. Choose from a variety of sessions organized by knowledge level: Basic, Intermediate, and Advanced.

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 persons 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?

This conference is ideal for any compliance professional or person in a related role who works in the clinical research setting. 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.

HCCA's Mission

The Health Care Compliance Association exists to champion ethical practice and compliance standards and provide resources for healthcare professionals and others who share these principles.

ATTENDEE OPPORTUNITIES

Join us for Virtual Yoga and Virtual Networking!

ShakRa Yoga Flow
Tuesday, June 2 from 7:15 – 8:15 AM CDT

Yoga flow links physical poses (asana) with the breath. This class will start with gentle stretches, breath awareness and move into classic yoga sun salutations. We will build flow sequences, play with balance postures and end with a resting meditation (savasana). This class is for all levels of experience from beginners to more advanced as the focus will be on alignment and breath.

Cocktails & Conversations
Tuesday, June 2 from 4:50 – 5:30 PM CDT

Grab your favorite beverage right after the sessions conclude and join your colleagues for some end of the day dialogues.

ShakRa Power Flow
Wednesday, June 3 from 7:15 – 8:15 AM CDT

This powerful and energetic flow class will combine yoga poses and breath with an element of strength. Slightly longer and faster sun salutations will be performed to build heat in the body. Isometric holds and core work will target strength building the major muscle groups. The class will wind down with a much-deserved stretch and resting meditation (savasana). The poses used in this class are more physically challenging but are not complicated. Modifications will be offered, so persons of any physical ability are welcome to join this class.

Connect over Coffee
Wednesday, June 3 from 8:15 – 8:55 AM CDT

Grab your favorite morning brew or tea and connect with your colleagues to kick off the last day of the conference.

No pre-registration required. A zoom link with password will be sent to you in your conference confirmation email on Friday, May 29.

CONTINUING EDUCATION

NOTE: Only registered attendees are eligible to request CEUs for participation. Attendees must participate in the virtual conference using the online virtual conference format (not just using the dial in) for attendance monitoring purposes.

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. **Only requests from registered attendees will be considered.** 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. To see the most up-to-date CEU information go to HCCA's website, hcca-info.org/all-conferences. Select your conference, and then select the "Continuing Education" option on the left-hand menu.

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)®.

Daily Breakdown:
Monday | **7.2** CCB CEUs
Tuesday | **7.2** CCB CEUs
Wednesday | **7.2** CCB CEUs
Totals subject to change.

If you only need Compliance Certification Board (CCB) CEUs - (CHC, CHPC, CHRC, CHC-F, CCEP, CCEP-I, CCEP-F), it is not required to participate in the active monitoring.

Conference Sponsors

8:50–9:00 AM CDT

ROOM 1

Higher Education Compliance Opening Remarks

ROOM 3

Research Compliance Opening Remarks

9:00–10:00 AM CDT

ROOM 1

HIGHER EDUCATION COMPLIANCE GENERAL SESSION: Higher Education Compliance: 2019-20 Year in Review

MARISA ZUSKAR, Sr. Director, Huron Consulting Group

- Provide a Year-In-Review perspective of higher education compliance, as well as what the current environment and the past year suggest for the changes to come in 2020 and beyond
- Recap significant current events impacting higher education and major changes in the regulations impacting higher education, with a focus on the response of the impacted institution, the industry, and the community at large
- Cover the broad spectrum of higher education compliance areas including student administration, research and federal contracting, Title IX, NCAA, etc., as well as compliance program models for higher education

ROOM 3

RESEARCH COMPLIANCE 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

10:15–11:15 AM CDT Breakouts

ROOM 1

H2 Imagineering a University-Wide Conflict of Interest/ Commitment Disclosure Process: Make (What Seems Like) the Impossible, Possible

Level: Intermediate

ROBERT W. GOTTESMAN, Executive Director, Institutional Compliance & Privacy, Auburn University

KEVIN ROBINSON, AVP Audit, Compliance & Privacy, Auburn University

- Readiness: We discuss the legal impetus, campus culture, and administrative will, leading to creation of our disclosure procedure. We will share considerations on drafting policy, crafting a questionnaire, and selecting delivery method
- Roll-out: How we prepared for the disclosure process including beta testing, messaging/ marketing to employees, and developing resources. Hear our lessons learned, surprising response rates, and how we dealt with the unexpected
- Review: Learn how we devised an efficient and consistent approach to review thousands of responses. Having template management plans available and determining when they are needed. How and when to communicate with respondents and other campus partners

ROOM 2

H3 Compliance Risk Reviews: Developing a Collaborative Compliance Monitoring Process

Level: Advanced

BOYD KUMHER, Chief Compliance Officer, University of Minnesota

- How confident are you that compliance risks are being well managed? Knowing if and how these risk areas are being monitored, the measures that are taken when gaps or failures are found, and how this is communicated within the organization
- Jump start your own compliance risk review program by using tools and templates that we've developed or compare our approach to what you may already have in place at your institution
- Enhance synergies and reduce redundancy between your compliance program and internal audit program by defining the purpose and the roles and responsibilities for these two functions

ROOM 3

R2 OCR Audits: Past, Present, and Future Considerations for Privacy and Security

Level: Intermediate

DEANNA PETERSON, Vice President, Health Consulting Services, First Class Solution

EDYE EDENS, Senior Research Compliance Consultant, First Class Solutions, Inc.

- This session will provide an overview of the current state of audits performed by the Office of Civil Rights to enforce the requirements of HIPAA, especially as related to the current state of COVID.
- After capturing the current picture, session presenters will offer an informed discussion on predictions for future enforcement trends and audits based on progress by OCR thus far
- Finally, one of the most readily overlooked components of your privacy program in healthcare includes HIPAA implications and protections in human subject research. This session aims to close the gap between clinical and research considerations

ROOM 4

R3 Stop! Or Else I'll Say Stop Again! Institutional Responses to COI Noncompliance

Level: Intermediate

CRAIG CONWAY, JD, LLM, Associate Vice President, Office of Institutional Compliance, University of Texas Medical Branch (UTMB)

- An interactive session designed to share ideas and best practices
- How do institutions respond when faculty members or employees intentionally or unintentionally fail to adhere to federal, state, or institutional COI requirements?
- This session will seek to identify common COI noncompliance areas We will provide strategies and recommendations for handling COI noncompliance that participants may take back to their respective institutions

11:30 AM–12:30 PM CDT BREAKOUTS

ROOM 1

H4 Investigations—The Who, The How, and The What Could Go Wrong? How to Effectively Navigate an Investigation

Level: Intermediate

VINCENT A. LACOVARA, Chief Ethics and Compliance Officer, Catholic University

COREY PARKER, Senior Manager, Baker Tilly

VICKI DUGGAN, Chief Compliance, Risk and Ethics Officer, Montgomery College

- Engage with a panel of experienced compliance professionals on the role of the compliance function in an investigation. What is an investigation? What must be investigated? How is it documented? Who performs the investigation? How is information shared?
- Discuss how institutions can create standards for conducting different types of compliance and workplace investigations to ensure the process is consistently performed in a way that adds value for all stakeholders and protects the institution
- Present opportunities to leverage existing communication channels, internal controls, data analytics, key performance indicators, and other leading practices to enhance the investigations process and monitor trending activities across the institution

ROOM 2

H5 Effective Compliance Responses to Covid-19 and Financial Disruption: A Facilitated Discussion

Level: Basic

GATES GARRITY-ROKOUS, Vice President and Chief Compliance Officer, The Ohio State University

- Analyze the major Covid-19 related regulatory changes, and their expected impact on compliance for universities;
- Supply an analytical framework for approaching mid-cycle, urgent changes to compliance priorities, due to operational and fiscal pressures; and
- Provide points of discussion for participants on successful approaches for compliance leaders to maintain relevance and effectiveness during a protracted crisis

ROOM 3

R4 The Civil Monetary Penalties Law and the Role of HHS-OIG: Self-Disclosure and Enforcement

Level: Basic

MICHAEL TORRISI, Senior Counsel, Office of Counsel to the Inspector General, U.S. Department of Health and Human Services

GEETA TAYLOR, Senior Counsel, Office of Counsel to the Inspector General, U.S. Department of Health and Human Services

- Have you identified potential fraud or non-compliance impacting your award? This presentation will help institutions and recipients of HHS awards understand their responsibilities to report potential misconduct
- Review BASICs of grant self-disclosures including mandatory disclosures of Federal criminal law violations, voluntary disclosures of conduct violating civil or administrative law, as well as the benefits of self-disclosure
- Overview of HHS-OIG sanctions for improper conduct related to federal awards under the Civil Monetary Penalties Law

ROOM 4

R5 Managing Compliance as an NCI National Community Oncology Research Program NCORP Site?

Level: Intermediate

SARAH DUFFY-CLINTON, Research Compliance Officer, Providence St. Joseph Health System

STACEY MEDEIROS, Research Director, Providence Anchorage Medical Center

- Examine the NCORP program's structure from both a main site and a sub-site perspective
- Overview of the various research compliance items that need to be managed: grants, research billing, IRB review, data integrity, document management
- Provide tips on managing cooperative group research compliance from both a main site and sub-site perspective

1:15–2:15 PM CDT BREAKOUTS

ROOM 1

H6 Awareness, Training, and Development: A Scaffold Approach to Compliance Education

Level: Basic

OMAR ANDUJAR, Associate Compliance Officer, Univ of CT

KIMBERLY HILL, Associate Compliance Officer, Univ of CT Health Center

- Based on the Department of Justice guidance and research-based adult-learning concepts, presenters will provide innovative strategies for developing a comprehensive multi-modality education program
- Presenters will share their experiences and explore tools for designing and developing engaging and effective compliance learning environments
- Presenters will discuss the value of leveraging metrics to assess education efforts and drive creative solutions and initiatives to enhance a culture of compliance

ROOM 2

H7 Sports Wagering and Intercollegiate Athletics

Level: Basic

JESSICA TEETS, Policy Office Coordinator, Purdue University

DEBORAH B. TRICE, Director of Compliance & Associate Counsel, Student Affairs, Purdue University

ALYSA C. ROLLOCK, VP for Ethics and Compliance, Purdue University

- The Supreme Court lifted the federal ban on sports betting in May 2018. Several states have legalized sports betting, including wagering on intercollegiate athletics
- What factors should colleges and universities consider in adopting policies to regulate sports betting on teams, student-athletes, coaches, or events?
- Who should be covered by such policies? How should the policies be enforced?

ROOM 3

R6 The Pathway of Part 2 Data in Research: Opioids, Covered Entities, and IRBs, Oh My!

Level: Advanced

MARTI ARVIN, Executive Advisor, CynergisTek, Inc.

- Basic overview of Part 2 and the implications of recent proposed changes to the regulations
- The complexity of protecting Part 2 data and ensuring appropriate availability and use in research
- Educating the research team and the IRB on the requirements of Part 2

ROOM 4

R7 Responsible Conduct: Collaborating on RCR Training

Level: Intermediate

SARAH ARCHIBALD, Research Integrity Officer, University of Maryland, Baltimore

STEPHANIE SUERTH, Education & Outreach Program Director, University of Maryland, Baltimore

- Tapping into institutional expertise to improve quality and encourage participation
- Customizing sessions so speakers and case studies are consistent and reinforce key concepts
- Keeping what works about the RCR training design while constantly improving to keep it fresh

2:30–3:30 PM CDT BREAKOUTS

ROOM 1

H8 A Journey Down the Road of College and University Cybersecurity Breaches: A Review of Recent University and College Case Studies, Lessons Learned, and How to Mitigate Being a Victim

Level: Advanced

CHARLES SHUGG, Partner, Chief Operating Officer, Sylint Group Inc.

- Gain awareness and understanding of today's potential unauthorized actors that could put your network at risk to include their intent, tactics, and outward appearance
- Review real case examples of higher education attacks that highlights the avenues of attack and recommend mitigation actions to minimize the risk of compromise
- Examine a prioritized list of recommended cybersecurity measures to reduce risk, maintain security awareness, and determine your organization's cybersecurity maturity level

ROOM 2

H9 Fraud in Higher Education Institutions: It Only Happens at Other Schools

Level: Intermediate

JOSEPH AGINS, Compliance Officer, Sam Houston State University

- Case studies—Can it really happen here? The answer is yes. Discuss and learn from countless recent examples as we cover several, entirely preventable, frauds at institutions of higher education just like yours
- There are a multitude of factors that contribute to educational institutions being repeat victims of fraud. Understanding these factors can help you detect, deter and minimize occupational fraud from occurring at your institution
- Why do they do it? Delve into the mind of a fraudster to understand how they commit the fraud, and more importantly, how they rationalize and justify crossing the line to well-liked and good employees from your institution

ROOM 3

R8 Compliance and Culture: How Design and Approach Can Help Support Clinical Trial Billing

Level: Advanced

KELLY WILLENBERG, Manager, Kelly Willenberg and Associates

TRACY POPP, Senior Director, Clinical Research, Tampa General Hospital

- Elevate your billing compliance program while building morale of stakeholders with ROI through research related billing reviews
- Describe how to gain buy-in for an understanding of the ADVANCED risks related to research billing such as payer issues, off-label drugs, CART-T, etc
- Discuss approach of self-monitoring and auditing of billing compliance that is authentic to the culture you have built

ROOM 4

R9 How to Overcome the Challenges of Effectively and Legally Implementing Research in a Skilled Nursing Facility

LEVEL: Basic

JOSEPH ZIELINSKI, Senior Counsel, Wooden McLaughlin LLP

- Discussion and analysis of the regulatory requirements of research in a skilled nursing facility and how a compliance program can effectively monitor them
- Attendees will learn about the unique challenges of doing research in a skilled nursing facility and how to assess and overcome those challenges, using a data driven approach, so research can be performed in a compliant manner
- Discussion of best practices for effectively implementing research in your organization and how to illustrate compliance with the regulatory requirements. Attendees will see and receive a tool they can use to apply a data driven approach to research

3:45–4:45 PM CDT BREAKOUTS

ROOM 1

H10 Foreign Influence: Mitigating Risk through Strong Policies and Processes

Level: Basic

MARY D. MILLSAPS, Director, Research Information Assurance, Purdue University

DEBORAH B. TRICE, Director of Compliance & Associate Counsel, Student Affairs, Purdue University

- Since February 2018, the federal government has expressed increasing concern regarding foreign influence in academia. This topic has been the subject of multiple congressional hearings, federal advisory groups, and proposed and enacted legislation
- What policies and processes should be reviewed and adopted to address the potential for foreign influence?
- One university's approach to identify and address compliance issues related to foreign influence will be presented

ROOM 2

H11 Operationalizing Privacy and Data Security Compliance in Higher Education

Level: Intermediate

STARR DRUM, Maynard Cooper & Gale

TRES CLEVELAND, Maynard Cooper & Gale

- This session covers the predominant privacy and data security regulations affecting the education sector, including CCPA, GDPR, FERPA, and state data breach laws. Participants will learn the key requirements of these laws and when they apply
- Participants will also learn how to prioritize privacy and data security risks by assessing their geographic footprint, the types of personal information they are processing, and the platforms they are using to interface with individuals
- Specific actions to operationalize privacy and data security compliance will be covered, including notice and consent, information governance policies, individual rights, vendor management, employee training, and incident response procedures

3:45–4:45 PM CDT

ROOM 3

RESEARCH COMPLIANCE GENERAL SESSION: Preventing Grant Fraud, Waste and Abuse

BARBARA ORLANDO, Grants Policy Manager, Department of Defense

- DoD Terms and Conditions
- Identifying possible grant fraud
- Sub-recipient monitoring

8:50–9:00 AM CDT

ROOM 1

Higher Education Compliance Opening Remarks

ROOM 3

Research Compliance Opening Remarks

9:00–10:00 AM CDT

ROOM 1

HIGHER EDUCATION COMPLIANCE GENERAL SESSION: What do Starbucks Coffee, Jimmy Buffet and a Can of Cheez Whiz Have in Common? A Unique Look at How to Explain Ethics and Compliance and Successfully Embed It Within the Operations

BETH COLLING, Senior Vice President and Chief Compliance Officer, CDM Smith, Inc.

- Learn how to introduce or refresh a compliance and ethics program into your organization, especially where buy-in seems lacking
- Develop methods to market your program to internal stakeholders using real-life examples
- Take away practical tips for establishing and defining the program and embedding it within your organization using the operational leaders as your Compliance Ambassadors

ROOM 3

RESEARCH COMPLIANCE GENERAL SESSION: Difficult Case Scenarios in Clinical Research Billing

RYAN MEADE, University of Oxford

10:15–11:15 AM CDT BREAKOUTS

ROOM 1

H13 Centralizing University Policy Approval and Management

Level: Basic

JOHN D. LAWLEY, Deputy Chief Compliance Officer, Emory University

SCOTTY JENKINS, Assistant Director Compliance and Ethics Programs, Emory University

- This session will describe a new policy approval process developed at Emory as we move from a decentralized approach to a centralized process
- The presentation will detail the methods by which centralized review can bring about greater transparency and standardization
- The presenters will also share key challenges faced when overhauling the policy approval process

ROOM 2

H14 Who's Afraid of Internal Controls? Not Me! Using Internal Controls to Make Higher Education Compliance Programs More Effective

Level: Basic

MARISA ZUSKAR, Sr. Director, Huron Consulting Group

DEENA KING, Chief Compliance Officer, The University of Texas at Tyler

- Internal controls (ICs) are not as scary or technical as you may think. You are likely using them in your institutional compliance program already. We will uncover the true definition and intent of ICs so they are easier to understand, design, and apply
- We will discuss and share examples of how to balance different types of internal controls--including compliance activities you may not have considered to be controls, such as technology, procedures, and training–to build a strong compliance structure
- We will review how you can use commonly available tools and reference guides, such as the federal "Green Book," the HCCA-OIG Resource Guide, and the Internal Control Integrated Framework to establish an effective, controls-based compliance program

ROOM 3

R13 CRRC: Clinical Research Revenue Cycle Management: Avoiding the Pitfalls

Level: Advanced

MARY VEAZIE, Exec Dir Clinical Research Finance, UT MD Anderson Cancer Center

ERIKA STEVENS, Principal, Recherche Transformation Rapide

- This session describes leading practices for establishing a clinical research revenue cycle CCRC, explores the regulatory landscape, identifies processes for implementing appropriate safeguards for risk mitigation, and applies methods for CCRC management
- Apply proven methods, such as data analytics and tracking trial performance trends, to improve CCRC program success and promote accountability
- Analyze lessons learned, leading practices, proven tools and implementation methods from a recent case study

ROOM 4

R14 The Benefit of Collaboration between Compliance and Business Units: Enhancing Compliance at Your Institution

Level: Intermediate

KELE PIPER, Director, Research Compliance, Massachusetts General Hospital

ELEANOR KUSZMAR, Associate Director for Research Compliance, Harvard Medical School

- Define collaborative research compliance initiatives and discuss when they can be effective for your institution
- Evaluate the role research compliance can play in a collaborative initiative, including recognizing scope creep into operations
- Using case studies, work in small groups to discuss and map possible collaborative initiative scenarios from a compliance perspective

11:30 AM–12:30 PM CDT BREAKOUTS

ROOM 1

H15 High Anxiety—The Drug Free Schools and Communities Act, the Drug Free Workplace Act, and the Legalization of Marijuana

Level: Basic

SARAH E. MCPHEE, Senior Coordinator of Compliance, University of Illinois

DAVID E. GROGAN, Associate Director of University Compliance, University of Illinois

- Understanding the Drug Free Schools and Communities Act and the Drug Free Workplace Act before trying to comply with them
- New recreational and medical use marijuana laws are sweeping across the states – exploring Illinois and other examples
- Rolling it all together – how to address the conflicting federal and state marijuana mandates in your Clery compliance program

ROOM 2

H16 Investigations Infrastructure and Corrective Actions

Level: Intermediate

JESSICA L. TOBIAS, Ethics Director and Compliance Investigator, The Ohio State University

CHRIS GLAROS, Assistant VP for Compliance Operations & Investigations, The Ohio State University

- Explore how colleges and universities can investigate and centrally track increasingly wide-ranging and complex allegations of legal and policy violations
- Practice using materiality ratings and clear protocols for effective stakeholder coordination and efficient leadership reporting
- Discuss how to formalize corrective actions and incorporate the development and assessment of corrective actions into a compliance program

ROOM 3

R15 Compliance Officer's Research Data Nightmare and How to Wake Up From It

Level: Intermediate

ASHLEY HUNTINGTON, Privacy Officer, Cook County Health

LEYLA ERKAN, Global Healthcare Compliance Lead, Protiviti

MELISSA MITCHELL, Chief Compliance Officer, Shirley Ryan Ability Lab

- Compliance officers in the research sphere play a significant role in protecting PHI and other forms of health data as it flows into from organizations to research and beyond, which often raises significant privacy issues
- We will discuss the privacy issues that arise in this cycle; including using data to recruit patients; communicating on and triaging issues when deviations in research occur and how, when, and why data is shared beyond the scope of research
- We will focus specifically on trends in how data are handled, potentially manipulated and shared, and how compliance can best partner with other departments across the organization to support this function while still safeguarding patient information

ROOM 4

R16 Right to Try Laws vs. FDA Expanded Access: What You Need to Know and What You Need to Do

Level: Intermediate

PAUL PAPAGNI, Executive Director of Research, Holy Cross Hospital Trinity Health

- Many states are passing laws allowing terminally ill patients access to experimental therapies that have not been approved by the Food and Drug Administration. The FDA already allows access to such drugs through Expanded Access Programs
- Do you your doctors, IRB, pharmacists, compliance staff know the differences in these laws/regulations and the different processes for seeking permission to use unapproved therapies?
- Know which is best for your patient, which is best for your institution, and which is more likely to be approved

1:15–2:15 PM CDT BREAKOUTS

ROOM 1

H17 Dealing with the F Word: Foreign Gifts and Contracts

Level: Basic

KATY GALLOWAY, Compliance Coordinator, The University of Alabama

MARCY R. HUEY, Executive Director of Institutional Compliance, The University of Alabama

- Recently, the Department of Education has increased their scrutiny of Foreign Gifts and Contracts reporting from colleges and universities
- The challenge? What to report, how to report it, and how to streamline the process to make it effective
- Changes and proposed changes call for collaboration, continued vigilance, and process modifications

ROOM 2

H18 Harmonizing the Compliance, Internal Audit, and Enterprise Risk Management Risk Functions

Level: Intermediate

JOHN POWERS, Director, PwC

- How colleges and universities are coordinating second and third lines of defense to increase risk coverage in a cost-effective efficient manner
- How are compliance professionals leveraging developments in technology to enhance both the compliance program as well as coordination efforts between ERM and internal audit
- Plus, relevant updates from PwC's 2020 Global State of Compliance Survey

ROOM 3

R17 Protecting Research Participants Financially: Making SENSE of Patient-CENTric Research When Patients Lack CENTS

Level: Intermediate

GEOFFREY SCHICK, Senior Consultant, Site Strategy, WCG-PFS Clinical

- Explore challenges for participants in clinical trials when the patient is indigent or has high out-of-pocket expenses due to their commercial healthcare insurance policy. Explore effects from Medicare secondary payer, anti-kickback statutes, etc.
- Investigate the challenges of participating in sponsor-provided "Financial Hardship Programs" designed to help research participants with financial obligations
- Discuss opportunities to create a vehicle for the research entity to assist clinical trial participants through relationships with foundations. What are the benefits/risks of a program running side by side with existing charity care programs?

ROOM 4

R18 In Unity Is Strength: Research Compliance Through Leadership

Level: Intermediate

DAVID STALEY, Research Compliance Officer, Children's Hospital Colorado

- Identify your bundle of sticks as a leader in research compliance
- Frame a culture of research compliance by engaging with others, making commitments, and being present
- Construct tools that empower compliance leaders in bringing what matters to a collaborative space

2:30–3:30 PM CDT BREAKOUTS

ROOM 1

H19 Building and Sustaining a Culture of Compliance and Ethics: Compliance Training

Level: Basic

ROBERT ROACH, Vice President, Chief Global Compliance Officer, New York University

ERUM RAZA, Deputy Global Compliance Officer, New York University

- Whether your institution has a long established compliance training program or has recently started to focus on this area, compliance training is a critical element of every university compliance program and should be routinely reviewed and updated
- This session will focus on ways in which compliance officers can enhance compliance training and awareness programs across their institution in order to ensure a sustained and strong culture of compliance
- We will explore various topics and answer fundamental questions, such as: What are the basic training elements every university compliance training and awareness program should have? and How can institutions scale up their current training efforts?

ROOM 2

H20 Complying with the Shifting Title IX Landscape

Level: Intermediate

WENDI DELMENDO, Chief Compliance Officer, University of California, Davis

- Responding to allegations of sexual misconduct remains a hot button issue for higher education
- At the same time, the Department of Education is poised to release Title IX regulations in early 2020 that could significantly change how colleges and universities investigate and adjudicate Title IX matters. These regulations may conflict with state laws and will likely result in litigation
- This session will discuss the shifting Title IX landscape and review how a large university system is approaching these compliance challenges in its handling of complaints involving students, employees, and patients

ROOM 3

R19 Dealing with Data: Non-technical Thoughts Concerning Data Security and Management

Level: Intermediate

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

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

ROOM 4

R20 When is it Research and When is it Not? The Special Cases of Quality Assurance Studies and Medical Device Improvement

Level: Advanced

DAVID HOFFMAN, Chief Compliance Officer, Carthage Area Hospital

- When Johns Hopkins launched its quality assurance study of central line infection control practices, they exposed a fault line in the medical research community that continues to generate strong opinions about when IRB approval is appropriate
- In addition to the ongoing debate about whether their intervention required IRB approval due to human exposure to harm, the OHRP reaction to the Hopkins study triggered a debate about the need for IRB review as a condition of scholarly publication
- This presentation will explore the lingering impact of the OHRP-Johns Hopkins confrontation. We will discuss how to evaluate application of the common rule to non-patient focused research and medical device improvement efforts

3:45–4:45 PM CDT

ROOM 1

HIGHER EDUCATION COMPLIANCE GENERAL SESSION: Foreign Influences on Research Integrity: Tackling the Challenging Issues while Maintaining an Open and Collaborative Global Research Environment

ALEXANDER BUSTAMANTE, SVP Chief Compliance & Audit Officer, University of CA

SHANDA HUNT, UC Systemwide Research Compliance Manager, University of California

- A brief overview of the landscape (including new federal policies and federal law enforcement's shift toward criminal prosecution)
- UC Office of Ethics, Compliance, and Audit Services Strategy for Foreign Influence Compliance - Training and Awareness Campaign - Compliance Assessments - Systemwide Audits - Investigative Protocols Tracking and Monitoring
- Lessons learned and next steps - Communicating with Academics - Expanding awareness engagements with federal law enforcement and federal funding agencies

ROOM 3

RESEARCH COMPLIANCE GENERAL SESSION: "Research Compliance During the Pandemic" – A Round Table

MODERATORS:

LISA MURTHA, Senior Managing Director, Ankura Consulting Group

RYAN MEADE, University of Oxford

SPEAKERS:

LYNN BATHOLOW, Executive Director of Research Compliance, Avera Health

SARAH DUFFY-CLINTON, Research Compliance Officer, Providence

- Examine rapid study start-up
- Discuss human subject protection safeguards during a crisis
- Review emergency use FDA rules

9:00–10:30 AM CDT BREAKOUTS

ROOM 1

H22 HIPAA and Hybrid Entity Status: Why Most Universities Get It Wrong

Level: Advanced

MARTI ARVIN, Executive Advisor, CynergisTek, Inc.

- Brief overview of the regulations on hybrid entity status
- Top 10 mistakes universities make in designating hybrid status
- Understanding the compliance implications of getting this wrong

ROOM 2

H23 Free Speech and Protests on Campus: Strategies to Protect Reputation and Safety

Level: Intermediate

KATHRYN BEAUMONT MURPHY, Saul Ewing Arnstein & Lehr LLP

ALEXANDER R. BILUS, Partner, Saul Ewing Arnstein & Lehr LLP

- Foster awareness of the legal and policy related implications of student protest and counter-protest activities on campus, as well as reputational implications in a crisis management situation
- Develop an understanding of techniques to prepare for student free speech activities, and the importance of having a strategic response plan in place both during and after a protest
- Explore best practices for before, during, and after incidents related to protests on campus

ROOM 3

R22 Conflict of Interest 101: Identifying, Managing, and Preventing Research Risk

Level: Basic

REBECCA SCOTT, Compliance/Privacy Manager, UK HealthCare Office of Corporate Compliance

ANDREW HILL, Compliance Analyst/Auditor, UK HealthCare Office of Corporate Compliance

CJ WOLF, Director, Conflict of Interest Program, Intermountain Healthcare

- Understanding the Sunshine Act, including recent changes and how they impact your research organization
- Gain useful insight and tools for managing COI research risk at your institution
- Learn to identify risks using the Open Payments database

ROOM 4

R23 Supplementing Traditional Research Compliance Monitoring and Auditing with Anticipatory Surveillance

Level: Advanced

ROBERT BIENKOWSKI, Director, Office of Research Compliance, Central Michigan University

LYNN SMITH, Director, Research Compliance, Tampa General Hospital

- Undetected research noncompliance presents risks to subjects, institutions, researchers, and entire fields of research
- Formal systems of monitoring and auditing have inherent blind spots to some types of research noncompliance
- Anticipatory surveillance is a proactive, predictive compliance activity that assists in the early detection of potential noncompliance and mitigation of noncompliance before it becomes serious

10:45 AM–12:15 PM CDT BREAKOUTS

ROOM 1

H24 Export Controls and International Research

Level: Basic

ROBERT ROACH, Vice President, Chief Global Compliance Officer, New York University

JULIE MYERS WOOD, CEO, Guidepost Solutions

- This session will provide a broad overview of key US export control and trade sanction laws which may impact international research, whether your institution has a significant overseas presence or limited international research activities
- The session will cover multiple ways in which university compliance officers working with other university departments can work towards mitigating risks in this area. We will explore various monitoring techniques, and touch on some actual cases. We will also briefly discuss potential penalties for noncompliance with relevant federal laws
- Finally, we will touch on the importance of conducting periodic program assessments (including, self-assessments and third-party assessments)

ROOM 2

H25 Institution-wide Compliance Assessment: What It Is and Why You Need to Do It

Level: Intermediate

MEGHAN ST. GEORGE, Manager, Baker Tilly

BRIAN DANIELS, Chief Audit and Compliance Officer, University of Tennessee

- Understand the key elements (e.g., structures, processes, key activities) and benefits of performing an institution-wide compliance program assessment
- Discuss the role of the compliance function, as well as other stakeholders, in executing an institution-wide compliance program assessment
- Learn how to leverage the results of a compliance program assessment within the organization's risk management framework to provide value to institutional stakeholders

ROOM 3

R24 The Laws of the Jungle: An Introduction to the Regulation of Animal Research

Level: Basic

KRISTIN WEST, Chief Compliance Officer, Emory University

- Overview of the major federal agencies involved in the regulation of animal research and their roles and responsibilities
- Discussion of major laws and regulations in this area of research including the Animal Welfare Act, Public Health Service Policy on Human Care and Use of Laboratory Animals, and the Guide for the Care and Use of Laboratory Animals
- How to effectively work with Institutional Animal Care and Use Committees IACUCs and other institutional players to ensure a compliant research animal care and use program, including issue spotting and common program pitfalls

ROOM 4

R25 Research Stepchildren: Humanitarian Use Devices and Expanded Access to Investigational Medical Products

Level: Intermediate

DENEICE KRAMER, Compliance Manager, Essentia Health, MA, MBA, CCRP

CATHY MURRAY, Compliance Specialist, Essentia Health, MBA, CHC, CHRC

KIM WOLD, Compliance Specialist, Essentia Health, MSPH, CCRC

- Review related laws and regulations which help define HUDs and Expanded Access
- Describe IRB and institutional challenges when reviewing and monitoring HUDs and Expanded Access projects
- Essentia Health's approach, lessons learned and yet to be learned

1:00–2:30 PM CDT BREAKOUTS

ROOM 1

H26 Financial Risk Monitoring in Higher Education: New Compliance Challenges

Level: Advanced

JAMES G. SHEEHAN, Chief, Charities Bureau, NY Attorney General

JONATHAN C. GREEN, Assist Attorney General & Deputy Chief, Massachusetts Office of the Attorney General

- Colleges and universities are facing significant financial constraints and a declining college-age population. These conditions require compliance and governance measures to protect the mission of the institution and the interests of students
- Two state nonprofit regulators review available data and reporting about trends and identification of at-risk institutions, and what compliance programs are needed and plans to address risks
- The speakers will discuss specific case examples: including the College of New Rochelle, Mount Ida College, Wheelock College, and Dowling College; and what regulators now expect, including requirements of the new Massachusetts statute on Risk Monitoring

ROOM 2

H27 Artificial Intelligence and Proactive Compliance

Level: Intermediate

ALEJANDRA VALLEJOS, Co Founder, Seal Legal Forensics

SANDER VAN DER VOORDE, Seal Legal Forensics

- Using AI and deciding what to investigate. Handling the difference between what you want and need to review. What are the strategic decisions to be taken? How are these decisions taken?
- Effective communication on internal investigations that have used AI. How to keep the company engaged and involved with a sound corporate environment for the employees
- AI and privacy. What are the consequences, the risks and the measures to be taken before, during and after an investigation?

ROOM 3

R26 "Wish I Had Known That a Year Ago": Lessons Learned in the Midst of Conducting a Research Misconduct Inquiry and Investigation

Level: Intermediate

DARRI SCALZO, Research Compliance Officer, University of Arkansas for Medical Sciences

NANCY RHEA, Compliance Analyst, University of Arkansas for Medical Sciences

- This session will include a discussion of regulatory guidance on misconduct proceedings, as well as detailed information related to conducting inquiries and investigations of research misconduct
- Additional discussion points include mistakes to avoid and best practices to help the audience members become more prepared to take on a research misconduct inquiry and investigation
- Steps to help the audience members be prepared before getting the dreaded "I think we have a problem" call and tips for encouraging a culture of integrity and compliance at your institution

ROOM 4

R27 Let's Talk About It: The Reality of the Impact of the Changes from the Revised Human Subject Rules

Level: Intermediate

MARIETTE MARSH, Director, Human Subjects Protection & Privacy Program, University of Arizona

- Identify gaps and problems areas after implementation of the new rule
- Learn various innovative methods for handling research activity revised under the rule
- Hear from peer organizations on best implementation practices to maintain compliance under the new rule

2:45–4:15 PM CDT BREAKOUTS

ROOM 1

H28 Developing and Utilizing a HECA Model Compliance Matrix to Track Compliance Obligations on Your Campus

Level: Intermediate

KATIE IGNATOWSKI, Director of Compliance, University of Wisconsin System

KIMBERLY LANGOLF, Director of Sponsored Programs and Risk and Safety, University of Wisconsin-Oshkosh

GRACE CRICKETTE, Vice Chancellor for Administrative Affairs, University of Wisconsin-Whitewater

- This session will discuss how the University of Wisconsin System developed a compliance matrix database to inventory, track, and organize compliance obligations from federal law, state law, and Board of Regents policy across the entire system
- We'll cover the approach we used to create the platform, the research strategies we used to populate the relevant compliance information, and the methods we deployed to identify accountability for each obligation at three levels within each of our 13 institutions
- We'll walk through how this tool integrates with our HR system to ensure that reporting and disclosure obligations don't "fall through the cracks" when an employee leaves and that new employees receive information regarding relevant compliance obligations in the onboarding process

ROOM 2

H29 Compliance Officers Roundtable

JACQUELINE KNISKA, Univ Integrity/Compliance Ofcr, Virginia Commonwealth University

NEDRA ABBRUZZESE-WERLING, Assoc VP for Compliance Services, Boston University

- This session will feature an in-depth discussion of real-time and emerging challenges faced by compliance and ethics officers on campuses of varied sizes and within compliance programs at every stage of maturity, and specifically: The opportunity to understand the issues and challenges that face other Compliance Officers;
- Strategies for strengthening compliance programs and providing adequate responses to emerging issues and trends; and
- Program success in a shifting landscape, and maintaining focus and integrity in the face of truly unprecedented regulatory, political, and media scrutiny

ROOM 3

R28 Noncompliance in Animal Research Oversight

Level: Intermediate

STACY PRITT, Assistant Vice President COI/IACUC, UT Southwestern Medical Center

ELIZABETH TRUMPOWER, IACUC Manager, University of Texas Southwestern Medical Center

- Attendees will be given an overview of requirements relating to noncompliance in animal research, including federal laws and regulations along with accreditation guidelines, which the Institutional Animal Care and Use Committee is charged with managing
- Attendees will learn about options available in identifying, investigating, correcting, and documenting animal research noncompliance
- Attendees will be given different models for examining institutional risk when it comes to animal research oversight

ROOM 4

R29 Demonstrating Good Clinical Practice (GCP) Compliance in Research through the maintenance of Regulatory Documents

Level: Basic

CHRISTINA JACKSON, Director, Research Integrity, AdventHealth Research Institute

- Discussion of the 13 Principles of ICH GCP Guidelines Identify Regulatory Documents to Maintain
- Recognizing the Most Common Deficiencies in Regulatory Documentation
- Moving from Paper to a Digital Environment

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First Name | MI | Last Name

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