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HCCA

Program at a Glance

SUNDAY, JUNE 3 / PRE-CONFERENCE

12:00 – 5:30 PM	**Registration Open**	
1:00 – 2:30 PM BREAKOUT SESSIONS PRE-CONFERENCE	**P1 Operationalizing Government Corrective Action Plans: Aftermath of an OCR Investigation** – *Emmelyn Kim, AVP, Research Compliance & Privacy Officer, Northwell Health; Kathleen McGill, Vice President, Research Administration, The Feinstein Institute for Medical Research, Northwell Health*	**P2 Clinical Research Billing Audits: It's (Almost) All in the Planning!** – *Wendy Portier, Consultant, Kelly Willenberg & Associates; Karen Mottola, Research Compliance Officer, Sutter Health Bay Area; Kelly Willenberg, Manager, Kelly Willenberg & Associates*
2:30 – 2:45 PM	**Networking Break**	
2:45 – 4:15 PM BREAKOUT SESSIONS PRE-CONFERENCE	**P3 Corrective and Preventive Actions (CAPA) Plans that Guide Clinical Research Professionals in Improving Weaknesses, Deficiencies, or in Rectifying Deviation Patterns and Areas of Noncompliance** – *David Staley, Research Compliance Officer, Children's Hospital Colorado; Lita Pereira, Research Compliance Senior Manager, Kaiser Permanente*	**P4 Transforming a Community Health-Based Research Organization: Strategy and Lessons Learned** – *JoAnne Levy, Vice President, Mercy Research, Mercy*
4:15 – 5:30 PM	**Welcome Reception**	

MONDAY, JUNE 4 / CONFERENCE

7:00 AM – 6:00 PM	**Registration Open**		
7:00 – 8:00 AM	**Breakfast (provided)**		
8:00 – 8:15 AM	**Opening Remarks**		
8:15 – 9:15 AM	**General Session 1: Research Year in Review** – *Lisa Murtha, Senior Managing Director, Ankura Consulting Group*		
9:15 – 9:45 AM	**Networking Break in the Exhibit Area**		
9:45 – 10:45 AM BREAKOUT SESSIONS	**101 Turn On, Tune In, Collect Data: Conducting Clinical Investigations with Controlled Substances** – *Kristin West, Chief Compliance Officer, Emory University, Office of Compliance*	**102 PI Compensation: Compliant Methods, Documentation, and Execution** – *Liz Christianson, Client Engagement Manager, PFS Clinical; David Russell, Director Site Strategy, PFS Clinical*	**103 Anatomy of a Research Misconduct Issue** – *Juliann Tenney, Director, Research Compliance Program and Chief Privacy Officer, Retired, UNC-Chapel Hill*
10:45 – 11:00 AM	**Networking Break**		
11:00 AM – 12:00 PM BREAKOUT SESSIONS	**201 Community Hospital Research Programs: A Compliance Officer's Friend or Nightmare** – *Paul Papagni, Executive Director of Research, Holy Cross Hospital CHE; Lisa McCusker, Chief Compliance & Privacy Officer, Holy Cross Hospital, Inc.*	**202 Strategies to Effectively Monitor Researchers' Access to the EMR** – *Dr. Daniel Fabbri, Founder and CEO, Maize Analytics, Assistant Professor, Biomedical Informatics and Computer Science, Vanderbilt University*	**203 An Integrated Model for Building and Maintaining an Effective Research Compliance Program in an Academic Research Center** – *Colleen Sowinski, Clinical Research Auditor, Rush University Medical Center; Mary Keller, Clinical Research Auditor, Rush University Medical Center*
12:00 – 1:00 PM	**Lunch**		
1:00 – 2:00 PM BREAKOUT SESSIONS	**301 Optimizing Research Compliance within the Electronic Health Record (EHR) System** – *Anna Taranova, Executive Research Director, University Health System; Deidre Winnier, Director of Clinical Research, University Health System; Tiffany Mince, Assistant Director, Research Compliance, University Health System*	**302 Conflict of Interest 2.0: Beyond Data Collection** – *Rebecca Scott, Compliance/ Privacy Manager, University of Kentucky; C.J. . Wolf, Senior Compliance Executive, Healthicity; Andrew Hill, Compliance Analyst/ Auditor, UK HealthCare Office of Corporate Compliance*	**ADVANCED DISCUSSION*** **AD303 Thorny Clinical Research Billing and Coverage Issues** – *Kelly Willenberg, Manager, Kelly Willenberg & Associates; Ryan Meade, Director of Regulatory Compliance Studies, Loyola University Chicago School of Law*
2:00 – 2:30 PM	**Networking Break in the Exhibit Area**		
2:30 – 3:30 PM BREAKOUT SESSIONS	**401 Research Compliance Risks and HIPAA Privacy Pitfalls in a Healthcare Academic Setting** – *David Welch, Research Compliance Manager, UT Health San Antonio; Melissa Bazan, Senior Research Compliance Specialist- UT Health San Antonio; Kathy James, Assistant Compliance Officer, UT Health San Antonio*	**402 Integrating Research Integrity with Corporate Compliance** – *Kristen Schwendinger, Senior Managing Consultant, Berkeley Research Group, LLC; Lisa Noller, Chair, Government Enforcement Defense & Investigations Group, Foley & Lardner*	**403 Getting to Compliant: Personal Protective Equipment Use in the Non-Clinical Research Setting** – *Kele Piper, Director, Research Compliance, Beth Israel Deaconess Medical Center*
3:30 – 3:45 PM	**Networking Break**		
3:45 – 4:45 PM	**General Session 2: Whistleblowers in the Research Setting** – *Melissa L. Markey, Attorney, Hall, Render, Killian, Heath & Lyman, PLLC; Drew B. Howk, Attorney, Hall, Render, Killian, Heath & Lyman, PLLC*		
4:45 – 6:00 PM	**Networking Reception**		

**Advanced Discussions are interactive sessions geared toward more experienced compliance and ethics professionals. They are limited to 50 attendees and open on a first-come, first-served basis. No pre-registration is available.*

Program at a Glance

TUESDAY, JUNE 5 / CONFERENCE

7:00 AM – 4:30 PM	**Registration Open**		
7:00 – 8:00 AM	**Breakfast (provided)**		
8:00 – 8:15 AM	**Opening Remarks**		
8:15 – 9:15 AM	**General Session 3: The Revised Common Rule: What Should We Do Now** – *Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel, HHS*		
9:15 – 9:45 AM	**Networking Break in the Exhibit Area**		
9:45 – 10:45 AM BREAKOUT SESSIONS	**501 It All Starts in a Lab! Laboratory Issues and the Research Regulatory Environment** – *Juliann Tenney, (Moderator), Director, Research Compliance Program, UNC-Chapel Hill, and Chief Privacy Officer, Ret.; Kristin West, Chief Compliance Officer, Emory University; Deborah Howard, Regional Biosafety Manager NA, Bayer Crop Science Division Research*	**502 Implementing a Research Compliance Program in a Large National Healthcare System** – *Sheila Wrobel, Corporate Responsibility Officer, CHI Health*	**503 503 The Tissue Issue: Perspectives on Protection and Privacy Issues in Data/ Tissue Repositories** – *Bethany Johnson, JD, CIP, University Director, HRPP, Indiana University; John R. Baumann, PhD, Associate Vice President for Research Compliance, Indiana University*
10:45 – 11:00 AM	**Networking Break**		
11:00 AM – 12:00 PM	**601 Conflict of Interest: Is it My Problem or Yours?** – *Katherine Cohen, Research Compliance Director, MedStar Health*	**602 Self-Imposed Regulatory Burden in Animal Research Oversight** – *Stacy Pritt, Director, IACUC, UT Southwestern Medical Center*	**ADVANCED DISCUSSION*** **AD603 FDA Compliance at-a-Glance** – *Neil O'Flaherty, Partner, Baker & McKenzie, LLP*
12:00 – 1:00 PM	**Lunch**		
1:00 – 2:00 PM BREAKOUT SESSIONS	**701 Strategies to Promote Physician Investigator GCP Compliance** – *Scott Lipkin, Managing Director, Ankura Consulting*	**702 Does the Thought of International Research Keep You Up at Night?** – *Kele Piper, Director, Research Compliance, Beth Israel Deaconess Medical Center; Eleanor Greene, Sr. Research Compliance Specialist, Beth Israel Deaconess Medical Center*	**ADVANCED DISCUSSION*** **AD703 The IRB and Research Compliance: A Crucial Partnership** – *Dwight Claustre, CHC-F, CHRC, CHPC, Managing Director, Ankura Consulting Group; Karen Mottola, Research Compliance Officer, Sutter Health Bay Area*
2:00 – 2:15 PM	**Networking Break**		
2:15 – 3:15 PM BREAKOUT SESSIONS	**801 Auditing in a Post–Common Rule World** – *Scott Lipkin, Managing Director, Ankura Consulting; Emmelyn Kim, AVP, Research Compliance & Privacy Officer, Northwell Health; John R. Baumann, PhD, Associate Vice President for Research Compliance, Indiana University*	**802 Outcome Unknown: The Ethics and Mechanics of Informed Consent in Research Involving Genomics, Questionable Pre-clinical Results, and the Risk of Death** – *Carrie Hanger, Partner, Nelson Mullins Riley Scarborough; Jennifer Mallory, Partner, Nelson Mullins Riley & Scarborough; David Hoffman, Chief Compliance Officer, The Floating Hospital*	**803 Facilitating Compliance with 21 CFR Part 11** – *Michael Hurley, Director of Product Management, Complion, Inc.*
3:15 – 3:30 PM	**Networking Break**		
3:30 – 4:30 PM	**General Session 4: Clinical Trial Agreements and Unintended Compliance Issues** –*Ryan Meade, Director of Regulatory Compliance Studies, Loyola University Chicago School of Law*		

WEDNESDAY, JUNE 6 / POST-CONFERENCE

8:00 – 11:45 AM	**Registration Open**	
8:30 – 10:00 AM BREAKOUT SESSIONS POST-CONFERENCE	**W1 A Case Study of the Implementation Process** – *Anne Daly, Corporate Compliance Officer, Children's Hospital of Chicago Medical Center; Cassandra Lucas, Chief Operating Officer, Stanley Manne Children's Research Institute; Kimberly Zajczenko, Director of Audits and Investigations, Children's Hospital of Chicago Medical Center*	**W2 Grant Compliance for Dummies** – *Matthew Staman, Managing Director, Huron Consulting Group; Marisa Zuskar, Director, Huron Consulting Group*
10:00 – 10:15 AM	**Networking Break**	
10:15 – 11:45 AM BREAKOUT SESSIONS POST-CONFERENCE	**W3 Patient Privacy In Research Under HIPAA and the Additional HIPAA and Privacy Issues Related to Big Data Sets** – *Marti Arvin, Vice President, Audit Strategy, CynergisTek, Inc; Shannon Hoffert, Attorney, Butler Snow LLP*	**W4 Dissecting the Clinical Trial Agreement: Avoiding Compliance Pitfall in Clinical Trial Agreements** – *Michael Roach, Partner, Meade Roach & Annulis, LLP*
12:30 PM	**CHRC Exam Check-in**	
12:45 – 3:15 PM	**Certified in Healthcare Research Compliance (CHRC)® exam** ***(optional)***	

**Advanced Discussions are interactive sessions geared toward more experienced compliance and ethics professionals. They are limited to 50 attendees and open on a first-come, first-served basis. No pre-registration is available.*

Agenda

SUNDAY, JUNE 3
PRE-CONFERENCE

12:30 – 5:30 PM
Registration

1:00 – 2:30 PM
BREAKOUT SESSIONS

P1 Operationalizing Government Corrective Action Plans: Aftermath of an OCR Investigation


Emmelyn Kim, AVP, Research Compliance & Privacy Officer, Northwell Health


Kathleen McGill, Vice President, Research Administration, The Feinstein Institute for Medical Research, Northwell Health

- Discuss key components of carrying out a CAP: People, Planning and Process
- Consider unanticipated government challenges, external resources and cost
- Discover what complex organizations should consider in their training programs

P2 Clinical Research Billing Audits: It's (Almost) All in the Planning!


Wendy Portier, Consultant, Kelly Willenberg & Associates


Karen Mottola, Research Compliance Officer, Sutter Health Bay Area


Kelly Willenberg, Manager, Kelly Willenberg & Associates

- Understand how to plan and prepare to perform a research billing audit including document concordance review processes
- Review claims against the coverage analysis and the billing rules including Medicare Advantage and coding
- Identify useful data to capture during a clinical research billing audit for analysis, calculating error rates, overpayments, and underpayments

2:30 – 2:45 PM
Networking Break

2:45 – 4:15 PM
BREAKOUT SESSIONS

P3 Corrective and Preventive Actions (CAPA) Plans that Guide Clinical Research Professionals in Improving Weaknesses, Deficiencies, or in Rectifying Deviation Patterns and Areas of Noncompliance


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


Lita Pereira, Research Compliance Senior Manager, Kaiser Permanente

- Specify the elements that structure effective corrective and preventative action plans
- Demonstrate writing and developing effective corrective and preventative action plans
- Distinguish between a corrective action and preventative action

P4 Transforming a Community Health-Based Research Organization: Strategy and Lessons Learned

JoAnne Levy, Vice President, Mercy Research, Mercy

- Learn about Mercy Research's strategy in becoming a dedicated, centralized, fully integrated research organization within Mercy, a top five, large community health system headquartered in St. Louis, MO with operations in four states
- Gain insight into Mercy Research's Supersite™ strategy and its value to clinical researchers and sponsors
- In the context of those strategies, hear about real-life challenges and lessons learned regarding (1) IRBs, (2) centralized regulatory and business operations, (3) standard start-up, business and clinical processes, and (4) change management

4:15 – 5:30 PM
Welcome Reception

MONDAY, JUNE 4
CONFERENCE

7:00 AM – 6:00 PM
Registration Open

7:00 – 8:00 AM
Breakfast

8:00 – 8:15 AM
Opening Remarks

8:15 – 9:15 AM
GENERAL SESSION 1: Research Year in Review


Lisa Murtha, Senior Managing Director, Ankura Consulting Group

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

9:15 – 9:45 AM
Networking Break

Agenda

9:45 – 10:45 AM
BREAKOUT SESSIONS

101 Turn On, Tune In, Collect Data: Conducting Clinical Investigations with Controlled Substances

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

- Schedule I Controlled Substances such as marijuana and Ecstasy show promise in treating certain conditions like epilepsy and PTSD, but, by law, these substances are considered to have no medicinal use. How can they be used in clinical trials?
- This session will help attendees understand how to legally conduct these trials, including working with regulators, obtaining controlled substances for research, establishing security protocols, and properly disposing of test articles
- Human subjects research considerations, planning for adverse events, and communications strategies regarding these controversial studies also will be discussed

102 PI Compensation: Compliant Methods, Documentation, and Execution

Liz Christianson, Client Engagement Manager, PFS Clinical

David Russell, Director Site Strategy, PFS Clinical

- Assuring compliant payments to investigators with regard to Fair Market Value (FMV), Stark Laws and Anti-Kickback Statute
- Different PI Payment Model Pros and Cons
- Compliant Investigator agreement considerations
- Appropriate budget development
- Tactics for Execution: CTMS utilization and compliant documentation

103 Anatomy of a Research Misconduct Issue

Juliann Tenney, Director, Research Compliance Program and Chief Privacy Officer, Retired, UNC-Chapel Hill

- The governing statutes and policies
- What is the research compliance officer's role in managing the process?
- Where the rubber has met the road: case studies and examples

10:45 – 11:00 AM
Networking Break

11:00 AM – 12:00 PM
BREAKOUT SESSIONS

201 Community Hospital Research Programs: A Compliance Officer's Friend or Nightmare

Paul Papagni, Executive Director of Research, Holy Cross Hospital CHE

Lisa McCusker, Chief Compliance & Privacy Officer, Holy Cross Hospital, Inc.

- Building a successful research program in a community hospital setting can be a disaster or a delight for a compliance officer depending on the level of collaboration in building/perfecting the model
- Often research was not on the Compliance Officer's radar until processes were already in place. But a collaborative approach to FDA/OHRP Regulations, Research Billing, COI, Quality Controls, FMV, Stark and Sunshine Act Concerns will yield best practices
- Operational models centralized vs decentralized: when to consider operationalizing operations and regulatory oversight. Reporting metrics to assist Compliance Oversight

202 Strategies to Effectively Monitor Researchers' Access to the EMR

Dr. Daniel Fabbri, Founder and CEO, Maize Analytics, Assistant Professor, Biomedical Informatics and Computer Science, Vanderbilt University

- Identify steps to initiate a data exchange between the Internal Review Board (IRB) submission process and HIPAA Privacy Officers that expands IRB forms to collect structured patient characteristics (e.g., ICD-10 codes) to define research cohorts
- Discuss ways to adjust existing HIPAA access monitoring processes to incorporate IRB-approved patient cohorts to detect accesses outside of research protocols
- Learn methods to approach research staff to facilitate a culture of compliance within your organization

203 An Integrated Model for Building and Maintaining an Effective Research Compliance Program in an Academic Research Center

Colleen Sowinski, Clinical Research Auditor, Rush University Medical Center

Mary Keller, Clinical Research Auditor, Rush University Medical Center

- Research Compliance as a Shared Responsibility: Research Compliance, Research Affairs and Corporate Compliance
- Integrated Approach to Shared Goals and Diversified Implementation Practices
- Strategies for Addressing the Challenges of Research Compliance in a Small Research Program

12:00 – 1:00 PM
Lunch

Agenda

1:00–2:00 PM
BREAKOUT SESSIONS

301 Optimizing Research Compliance within the Electronic Health Record (EHR) System


Anna Taranova, Executive Research Director, University Health System


Deidre Winnier, Director of Clinical Research, University Health System


Tiffany Mince, Assistant Director, Research Compliance, University Health System

- Incorporating Research Within the Electronic Health Record (EHR) System
- Standardization of documentation and billing processes
- Mining of EHR for research

302 Conflict of Interest 2.0: Beyond Data Collection


Rebecca Scott, Compliance/Privacy Manager, University of Kentucky


C.J. Wolf, Senior Compliance Executive, Healthicity


Andrew Hill, Compliance Analyst/ Auditor, UK HealthCare Office of Corporate Compliance

- Join us while we review the intricacies of COI policy evolution
- We'll discuss updates and advancements in CMS' Open Payments Database
- We'll provide useful skills and tools to help you conduct investigations and implement conflict management plans

ADVANCED DISCUSSION

These interactive sessions are geared toward more experienced compliance and ethics professionals. Limited to 50 attendees and open on a first-come, first-served basis. No pre-registration is available.

AD303 Thorny Clinical Research Billing and Coverage Issues


Kelly Willenberg, Manager, Kelly Willenberg & Associates


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

- Discuss challenges with Medicare Advantage Patients
- Review billing for screening tests
- Explore what happens when insurance rules conflict with medical necessity

2:00–2:30 PM
Networking Break

2:30–3:30 PM
BREAKOUT SESSIONS

401 Research Compliance Risks and HIPAA Privacy Pitfalls in a Healthcare Academic Setting


David Welch, Research Compliance Manager, UT Health San Antonio


Melissa Bazan, Senior Research Compliance Specialist-UT Health San Antonio


Kathy James, Assistant Compliance Officer, UT Health San Antonio

- Investigator Initiated studies increase the risk for Compliance issues
- Collaboration with IRB and other affiliated groups to achieve compliance objectives
- HIPAA privacy/security pitfalls

402 Integrating Research Integrity with Corporate Compliance


Kristen Schwendinger, Senior Managing Consultant, Berkeley Research Group, LLC


Lisa Noller, Chair, Government Enforcement Defense & Investigations Group, Foley & Lardner

- Consider how research integrity fits within enterprise risk management for academic medical institutions. Acknowledge the risk profile of colleges, universities, and other recipients of public funds that conduct biomedical and behavioral research. Confirm current expectations from government stakeholders
- Identify the basic elements of a compliance program—and affiliated research integrity offices
- Share the value proposition of integrating research integrity compliance within the culture's broader values and code of conduct to encourage reporting and corrective action. Understand the elements of a mature, integrated, effective program—suggest approaches to measure effectiveness

403 Getting to Compliant: Personal Protective Equipment Use in the Non-Clinical Research Setting


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

- To understand the compliance concerns around personal protective equipment use in the non-clinical research lab setting
- To identify PPE compliance challenges faced by research compliance professionals in the academic medical center setting based on organizational structure and physical space
- To learn strategies for PPE compliance program and policy development

3:30–3:45 PM
Networking Break

Agenda

3:45 – 4:45 PM

GENERAL SESSION 2: Whistleblowers in the Research Setting

Melissa L. Markey, Attorney, Hall, Render, Killian, Heath & Lyman, PLLC

Drew B. Howk, Attorney, Hall, Render, Killian, Heath & Lyman, PLLC

- Provide an overview of the False Claims Act and its impact in the research setting
- Review recent guidance from the OIG that OHRP should inform potential complainants on how they can seek whistleblower protections
- Discuss proactive steps and best practices for your institution to take regarding whistleblowing issues

4:45 – 6:00 PM

Networking Reception

TUESDAY, JUNE 5

CONFERENCE

7:00 AM – 4:30 PM

Registration Open

7:00 – 8:00 AM

Breakfast

8:00 – 8:15 AM

Opening Remarks

8:15 – 9:15 AM

GENERAL SESSION 3: The Revised Common Rule: What Should We Do Now

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

The past few years have seen a previously-unprecedented level of change to Federal statutes, regulations, and policies applicable to human subjects research. These include the substantial changes to the "Common Rule," the Federal regulations that protect human subjects in research. The session will:

- Describe significant recent developments in the Federal regulation of human subjects research, focusing on the revised Common Rule
- Address the challenges involved with integrating the revised Common Rule's new mandates and flexibilities within the existing system of Federal law and policy
- Identify decision points for regulated entities working toward implementation of the revised Common Rule

9:15 – 9:45 AM

Networking Break

9:45 – 10:45 AM

BREAKOUT SESSIONS

501 It All Starts in a Lab! Laboratory Issues and the Research Regulatory Environment

Juliann Tenney, (Moderator), Director, Research Compliance Program, UNC-Chapel Hill, and Chief Privacy Officer, Ret.

Kristin West, Chief Compliance Officer, Emory University

Deborah Howard, Regional Biosafety Manager NA, Bayer Crop Science Division Research

- What kinds of research are covered by research laboratory regulations: does size matter?
- What the heck is "Dual Use" and are fertilizers included?
- Tales from the crypt: you never know who might be "interested" in your institution

502 Implementing a Research Compliance Program in a Large National Healthcare System

Sheila Wrobel, Corporate Responsibility Officer, CHI Health

- Applying research compliance policies in many different community hospital and academic medical center environments
- Importance of communicating and collaborating with national and local division research management and compliance team members
- Oversight and monitoring of clinical trial billing, conflict of interest and research privacy and information security

Agenda

503 The Tissue Issue: Perspectives on Protection and Privacy Issues in Data/Tissue Repositories

Bethany Johnson, JD, CIP, University Director, HRPP, Indiana University

John R. Baumann, PhD, Associate Vice President for Research Compliance, Indiana University

- Discuss recent regulatory changes impacting use of biospecimens for research, including new Common Rule requirements
- Discuss the potential regulatory pitfalls of allowing broad consent for storage and use of biospecimens
- Identify best practices for protection of data and confidentiality while encouraging sharing in repositories

10:45 – 11:00 AM

Networking Break

11:00 AM – 12:00 PM

BREAKOUT SESSIONS

601 Conflict of Interest: Is it My Problem or Yours?

Katherine Cohen, Research Compliance Director, MedStar Health

- Where does your COI for research sit? The session will examine the pros and cons of your research COI sitting with research vs. an integrated approach with the general hospital process
- Session will look at how to integrate COI review into your IRB processes when the IRB isn't the responsible body for the review
- Logistics for managing conflicts and setting internal guidelines, including institutional conflicts of interest outside of an academic setting

602 Self-Imposed Regulatory Burden in Animal Research Oversight

Stacy Pritt, Director, IACUC, UT Southwestern Medical Center

- Review why self-Imposed regulatory burden is pervasive in animal research oversight
- Identify self-imposed regulatory burden in animal research oversight policies and procedures
- Determine how to decrease or eliminate self-imposed regulatory burden by incorporating appropriate risk mitigation strategies in animal research oversight

ADVANCED DISCUSSION

These interactive sessions are geared toward more experienced compliance and ethics professionals. Limited to 50 attendees and open on a first-come, first-served basis. No pre-registration is available.

AD603 FDA Compliance at-a-Glance

Neil O'Flaherty, Partner, Baker & McKenzie, LLP

- Enforcement trends and hot issues in the Agency's bioresearch monitoring efforts
- Recent Agency initiatives in the regulation of clinical trials
- Best practices and tips for achieving compliance and avoiding enforcement issues

12:00 – 1:00 PM

Lunch

1:00 – 2:00 PM

BREAKOUT SESSIONS

701 Strategies to Promote Physician Investigator GCP Compliance

Scott Lipkin, Managing Director, Ankura Consulting

- Examine common GCP compliance errors made by physician investigators
- Explore underlying causes of GCP compliance errors
- Discuss strategies to promote physician investigator GCP compliance

702 Does the Thought of International Research Keep You Up at Night?

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

Eleanor Greene, Sr. Research Compliance Specialist, Beth Israel Deaconess Medical Center

- Identify areas of risk for your organization such as research activities, foreign nationals, shipping, travel, etc
- Discuss institutional strategies for assessment of risk for international research activities
- Describe strategies to identify, manage, and monitor international research activities

Agenda

ADVANCED DISCUSSION

These interactive sessions are geared toward more experienced compliance and ethics professionals. Limited to 50 attendees and open on a first-come, first-served basis. No pre-registration is available.

AD703 The IRB and Research Compliance: A Crucial Partnership

Dwight Claustre, CHC-F, CHRC, CHPC, Managing Director, Ankura Consulting Group

Karen Mottola, Research Compliance Officer, Sutter Health Bay Area

- To what extent does the: IRB have a compliance function, does the larger organization have oversight over the IRB
- What is the relationship between your IRB and your research compliance program
- What is the ideal partnership between the IRB and Compliance

2:00 – 2:15 PM

Networking Break

2:15 – 3:15 PM

BREAKOUT SESSIONS

801 Auditing in a Post–Common Rule World

Scott Lipkin, Managing Director, Ankura Consulting

Emmelyn Kim, AVP, Research Compliance & Privacy Officer, Northwell Health

John R. Baumann, PhD, Associate Vice President for Research Compliance, Indiana University

- Understanding the retroactive application of the revised Common Rule
- Highlighting key areas where pre and post rules will make a difference when auditing study and IRB committee files
- Top three areas to focus audit activity in post–Common Rule world

802 Outcome Unknown: The Ethics and Mechanics of Informed Consent in Research Involving Genomics, Questionable Pre-clinical Results, and the Risk of Death

Carrie Hanger, Partner, Nelson Mullins Riley Scarborough

Jennifer Mallory, Partner, Nelson Mullins Riley & Scarborough

David Hoffman, Chief Compliance Officer, The Floating Hospital

- The Current and Revised Common Rule framework for obtaining Informed Consent
- Ethics of obtaining Informed Consent for research that involves the unknown and currently unknowable, including genomic research, future undefined research, significant risk studies involving death as a risk
- Case study: When a healthy volunteer died in a European clinical trial for a new FAAH Inhibitor pain and mood disorder medication, the Temporary Specialist Scientific Committee's call for further clarification regarding use of healthy volunteers in light of troubling animal study results

803 Facilitating Compliance with 21 CFR Part 11

Michael Hurley, Director of Product Management, Complion, Inc.

- Identify purpose and scope of 21 CFR Part 11, including who must comply and risks of non-compliance
- Best practices for expanding organizational awareness and facilitating compliance
- Understand steps and elements of auditing a site for 21 CFR Part 11 compliance, including inspection readiness

3:15 – 3:30 PM

Networking Break

3:30 – 4:30 PM

GENERAL SESSION 4: Clinical Trial Agreements and Unintended Compliance Issues

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

- Review pitfalls in CTA language that can cause unintended consequences
- Discuss fair market value and research rates
- Explore strategies for efficient CTA negotiations

Agenda

WEDNESDAY, JUNE 6
POST-CONFERENCE

8:00 – 11:45 AM
Registration Open

8:30 – 10:00 AM
BREAKOUT SESSIONS

W1 A Case Study of the Implementation Process

Anne Daly, Corporate Compliance Officer, Children's Hospital of Chicago Medical Center

Cassandra Lucas, Chief Operating Officer, Stanley Manne Children's Research Institute

Kimberly Zajczenko, Director of Audits and Investigations, Children's Hospital of Chicago Medical Center

- Presenters will review the infrastructure and activities presented and recommended at the HCCA Research Conference and describe how the conference program recommendations were assessed for applicability in their entity's environment
- Presenters will describe how program recommendations were prioritized for implementation and staged for rollout
- The presenters will describe obstacles encountered and solutions deployed to overcome prioritize activities and overcome challenges to enhancing research compliance program activities

W2 Grant Compliance for Dummies

Matthew Staman, Managing Director, Huron Consulting Group

Marisa Zuskar, Director, Huron Consulting Group

- Of course there are no dummies in compliance. This session is aimed at those (fairly) new to sponsored research compliance
- The session will start with the basics and review the Uniform Guidance and the cost principles and how these regulations shape sponsored research administration
- We will talk about how these, and other, regulations drive requirements for grant funded activity and how you can apply them in your day-to-day responsibilities

10:00 – 10:15 AM
Networking Break

10:15 – 11:45 AM
BREAKOUT SESSIONS

W3 Patient Privacy In Research Under HIPAA and the Additional HIPAA and Privacy Issues Related to Big Data Sets

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

Shannon Hoffert, Attorney, Butler Snow LLP

- Discussion of the relative risks under HIPAA among research stakeholders including the PI, IRB, grants and contracts, sponsors and more
- The additional issues when discussing HIPAA, privacy and big data
- Other considerations when thinking about creating and maintaining big data sets

W4 Dissecting the Clinical Trial Agreement: Avoiding Compliance Pitfall in Clinical Trial Agreements

Michael Roach, Partner, Meade Roach & Annulis, LLP

- Briefly review the Medicare research billing rules, the Federal False Claims Act, and other Federal laws
- Discuss how those laws and regulations can impact the CTA negotiations
- Analyze some real cases to learn what they teach us about CTA drafting and structure

12:30 PM
CHRC Exam Check-in

12:45 – 3:15 PM
Certified in Healthcare Research Compliance (CHRC)® exam *(optional)*

Continuing Education Units

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, HCCA may submit this course to additional states or entities for consideration. If you would like to make a request, please contact us at 952.988.0141 or 888.580.8373 or email CCB@compliancecertification.org. Visit HCCA's website, hcca-info.org, for up-to-date information.

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

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

Compliance Certification Board (CCB)®: CCB has awarded a maximum of **21.6** CEUs for these certifications: Certified in Healthcare Compliance (CHC)®, Certified in Healthcare Compliance-Fellow (CHC-F)®, Certified in Healthcare Privacy Compliance (CHPC®), Certified in Healthcare Research Compliance (CHRC)®, Certified Compliance & Ethics Professional (CCEP)®, Certified Compliance & Ethics Professional-Fellow (CCEP-F)®, Certified Compliance & Ethics Professional-International (CCEP-I)®.

Continuing Legal Education (CLE): The Health Care Compliance Association is a provider/sponsor, approved/accredited by the State Bar of California, the Pennsylvania Bar Association, and the State Bar of Texas. An approximate maximum of **18.0** clock hours of CLE credit will be available to attendees of this conference from these states. Upon request HCCA may submit this course to additional states for consideration. All CLE credits will be assessed based on actual attendance and in accordance with each state's requirements.

NASBA/CPE: The Health Care Compliance Association is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE sponsors, Sponsor Identification No: 105638. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be submitted to the National Registry of CPE Sponsors through its website: learningmarket.org. A recommended maximum of **21.5** credits based on a 50-minute hour will be granted for this activity. This program addresses topics that are of a current concern in the compliance environment and is a group-live activity in the recommended field of study of Specialized Knowledge and Application. For more information regarding administrative policies such as complaints or refunds, call 888.580.8373 or 952.988.0141.

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

Become Certified

A few letters after your name can make a big difference.

Why do people add JD, MBA, or CPA after their name? They know those initials add credibility.

Showcase your healthcare compliance knowledge and experience: Become Certified in Healthcare Compliance (CHC)®, Certified in Healthcare Privacy Compliance (CHPC®), Certified in Healthcare Research Compliance (CHRC)®, or a Certified in Healthcare Compliance-Fellow (CHC-F)®.

Applying to become certified is easy.

To learn what it takes to earn the CHC, CHPC, CHRC, or CHC-F designation, visit **compliancecertification.org**.

CHC™ CERTIFIED IN HEALTHCARE COMPLIANCE

CHPC™ CERTIFIED IN HEALTHCARE PRIVACY COMPLIANCE

CHRC™ CERTIFIED IN HEALTHCARE RESEARCH COMPLIANCE

CHC-F™ CERTIFIED IN HEALTHCARE COMPLIANCE FELLOW

CCB™ COMPLIANCE CERTIFICATION BOARD

Full name _____

please type or print

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

1 Demographic Information

What is your functional job title? Please select one.

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

List others not listed here:

_____

_____

_____

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

☐ YES ☐ NO

REGISTRATION CONTINUES ON NEXT PAGE (OVER)

What is your primary health care entity?

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

List others not listed here:

_____

_____

_____

What credentials do you hold? Select all that apply.

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

List others not listed here:

_____

_____

_____

Registration

Contact Information

○ Mr ○ Mrs ○ Ms ○ Dr

Member ID (if applicable)

First Name MI

Last Name

Credentials (CHC, CCEP, etc.)

Job Title

Name of Employer

Street Address

City/Town

State/Province Zip/Postal Code

Country

Phone Fax

Email *(required for registration confirmation and conference info)*

Payment Options

○ Check enclosed (payable to HCCA)

○ Invoice me

○ I authorize HCCA to charge my credit card (choose card below):

CREDIT CARD: ○ American Express ○ Discover ○ MasterCard ○ Visa

Due to PCI Compliance, please **do not provide any credit card information via email**. You may email this form to helpteam@hcca-info.org (without credit card information) and call HCCA at 888.580.8373 or 952.988.0141 with your credit card information.

Credit Card Account Number

Credit Card Expiration Date

Cardholder's Name

Cardholder's Signature

RC0618

Use of your information. To find out how we may use your information please read our Privacy Statement at hcca-info.org/privacy.aspx. By submitting this registration form you agree to the terms and conditions, including the use of your information as stated in our Privacy Statement and Terms & Conditions.

Registration Options

☐ HCCA Members: MONDAY & TUESDAY $799

☐ Non-Members: MONDAY & TUESDAY $949

☐ New Membership & Registration: MON/TUE $999
NEW MEMBERS ONLY. DUES REGULARLY $295 ANNUALLY.

☐ Pre-Conference: SUNDAY $125

☐ Post-Conference: WEDNESDAY $125

☐ Discount for 5 or more from same org ..... ($50)

☐ Discount for 10 or more from same org ..... ($100)

All registration fees are as listed and considered net of any local withholding taxes applicable in your country of residence.

TOTAL $ _____

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

Special Request: Dietary Needs

○ Gluten Free

○ Kosher-Style *(NO SHELLFISH, PORK, OR MEAT/DAIRY MIXED)*

○ Kosher *(HECHSHER CERTIFIED)*

○ Vegetarian

○ Vegan

○ Other *(WRITE BELOW):*

_____

REGISTER ONLINE
hcca-info.org/research

EMAIL your completed form (do not include credit card) to helpteam@hcca-info.org

MAIL your registration form with check enclosed:

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

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

QUESTIONS? Call 888.580.8373 or email helpteam@hcca-info.org

Terms & Conditions

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

Tax deductibility. All expenses incurred to maintain or improve skills in your profession may be tax deductible, including tuition, travel, lodging, and meals. Please consult your tax advisor.

Cancellations/substitutions. You may send a substitute in your place or request a conference credit. Refunds will not be issued. Conference credits are issued in the full amount of the registration fees paid, and will expire 12 months from the date of the original cancelled event. Conference credits may be used towards any HCCA service or product, except *The Health Care Compliance Professional's Manual*. If a credit is applied towards an event, the event must take place prior to the credit's expiration date. If you need to cancel your participation, notification is required by email at helpteam@hcca-info.org, prior to the start date of the event. Please note that if you are sending a substitute, an additional fee may apply.

Group discounts.

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

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

Agreements & acknowledgments. I agree and acknowledge that I am undertaking participation in Health Care Compliance Association events and activities as my own free and intentional act, and I am fully aware that possible physical injury might occur to me as a result of my participation in these events. I give this acknowledgment freely and knowingly, and I assert that I am, as a result, able to participate in HCCA events, and I do hereby assume responsibility for my own well-being. I agree and acknowledge that HCCA plans to take photographs and/or video at this conference and reproduce them in HCCA educational, news, or promotional material, whether in print, electronic, or other media, including the HCCA website. By participating in this HCCA conference, I grant HCCA the right to use my name, photograph, video, and biography for such purposes. As a participant of this event, I understand that my name, job title, organization, city, state, and country will be listed on the attendee list that will be distributed to attendees and speakers at this event.

Use of Information. Your information may be received by exhibitors at our conference as well as our affiliates and partners, who we may share it with for marketing purposes. Please note that only postal address information is shared. If you wish to opt out please follow the process described in our Privacy Statement. The full terms as to how we may use your information are also found in our Privacy Statement. Visit hcca-info.org/privacy.aspx.

Prerequisites/advanced preparation. None.

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

Special needs/concerns. Prior to your arrival, please call HCCA at 888.580.8373 if you have a special need and require accommodation to participate in the Research Compliance Conference. See the registration form to indicate any special requests for dietary accommodations you may require.

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

Continuing education units.
See page 10 for more information.

Hotel & conference location.

Hilton Austin
500 East 4th Street
Austin, TX 78701

PHONE RESERVATIONS: Call the hotel directly at 512.482.8000 and ask for the HCCA Research Compliance Conference rate.

ONLINE RESERVATIONS:
https://aws.passkey.com/go/HCCASCCE

A reduced rate of $239 per night for single/double occupancy plus applicable state and local taxes has been arranged for this conference. This rate is good through May 11, 2018, or until the group room block is full, whichever comes first. All reservations must be secured with a valid credit card, along with a first night's deposit, refundable up to three days in advance of your arrival date.

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

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Health Care Compliance Association®
6500 Barrie Road, Suite 250
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PHONE 888.580.8373 | FAX 952.988.0146
EMAIL helpteam@hcca-info.org | WEB hcca-info.org

HCCA
Health Care Compliance Association
6500 Barrie Road, Suite 250
Minneapolis, MN 55435
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