Register by May 5 and save

Research Compliance Conference

JUNE 14-16 | VIRTUAL

Get updates on today's trending topics, learn practical strategies to address complex regulations, and network with your industry peers.

Topics include:

- Clinical billing research
- Electronic systems in clinical research
- FDA Inspections
- Investigations
- Institutional Review Boards (IRB)
- Research compliance workplans
- Animal research
- AI and research
- Make sure to check out our B Breakouts on Wednesday – these will be Privacy in Research focused!

Receive complimentary access to SCCE's Higher Education Compliance Conference.

Learn more and register
hcca-info.org/2021research

HCCA
Health Care Compliance Association

ABOUT

HCCA's Research Compliance Conference offers attendees the latest insights and guidance on emerging research compliance risks and solutions. Learn best practices and strategies, ask questions of the speakers, and share ideas with other attendees throughout the conference. All virtual sessions are led by industry leaders and are organized by knowledge level: basic, intermediate, and advanced. These levels are a guideline, and you are welcome to attend sessions of any level.

With registration, attendees also gain admittance to the SCCE Higher Education Compliance Conference held at the same time.

Session topics:

- Critical Elements of Animal Research Compliance - Semi-Annual Activities
- Managing Undue Influence in University Research
- Sites Beware: How to Prepare for the Upcoming Changes in Medicaid
- Research Year in Review 2020-2021
- Legal Update: Developments in Clinical Research, EUAs, and IRBs
- AI and Research: Trends to Tackle Bias, Data and Compliance when Using Artificial Intelligence in Clinical Research

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

HCCA's mission

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

CONTINUING EDUCATION

Credits are assessed based on actual attendance and credit type requested. Should the overall number of education hours decrease or increase, the maximum number of CEUs available will be changed accordingly. 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.

Compliance Certification Board (CCB)®: CCB has awarded a maximum of **20.4** 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 6 HR | **7.2** CCB CEUs
Tuesday 5 HR | **6.0** CCB CEUs
Wednesday 6 HR | **7.2** CCB CEUs

*Totals are subject to change.

HCCA is in the process of applying for additional external continuing education units (CEUs). 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.

SCHEDULE AT A GLANCE

ALL TIMES LISTED ARE IN CENTRAL DAYLIGHT TIME (CDT)

MONDAY, JUNE 14

9:00–9:10 AM CDT	**Opening Remarks**	
9:10–10:10 AM CDT	**GENERAL SESSION:** Sites Beware: How to Prepare for the Upcoming Changes in Medicaid	
10:10–10:30 AM CDT	**Coffee Break**	
10:30–11:30 AM CDT	**R1A** If I Knew Then What I Knew Now: Lessons from the Trenches on Building a Physician Practice Clinical Research Compliance Program	**R1B** Electronic Systems in Clinical Research: How to Remain Compliant in the New "Virtual World"
11:30–11:45 AM CDT	**Coffee Break**	
11:45 AM–12:45 PM CDT	**R2A** Bias and Structural Inequity in Research	**R2B** Clinical Trials Research Compliance: Auditing vs Monitoring
12:45–1:45 PM CDT	**Mid-Conference Break**	
1:45–2:45 PM CDT	**R3A** Complicated and Complex: Part C Medicare Advantage Billing for Clinical Trials	**R3B** Considerations in Building a Foreign Influence Compliance Program
2:45–3:00 PM CDT	**Coffee Break**	
3:00–4:00 PM CDT	**R4A** Legal Update: Developments in Clinical Research, EUAs, and IRBs	**R4B** Privacy Considerations and AI in Medicine
4:00–4:15 PM CDT	**Coffee Break**	
4:15–5:15 PM CDT	**R5A** Critical Elements of Animal Research Compliance: Semi-Annual Activities	**R5B** Responsible Conduct of Research (RCR): What It Is and Why It Matters

TUESDAY, JUNE 15

9:00–10:00 AM CDT	**R6A** Patient Access, 21st Century Cures Act, and Information Blocking	**R6B** What Your Research Investigators and IRB May Not Know: Regulatory and Ethical Implications for Human Subjects Research
10:00–10:15 AM CDT	**Coffee Break**	
10:15–11:15 AM CDT	**R7A** It Takes a Village: Collaborative Solutions for Mitigating Clinical Research Revenue Cycle Risk	**R7B** Grow Up! Maturing a Research Compliance Program
11:15–11:30 AM CDT	**Coffee Break**	
11:30 AM–12:30 PM CDT	**GENERAL SESSION:** Research Year in Review 2020-2021	
12:30–1:30 PM CDT	**Mid-Conference Break**	
1:30–2:30 PM CDT	**R8A** Novel Conflict of Interest Collection Strategies for More Effective Oversight	**R8B** Compliance Reimagined: Making Compliance Intuitive and Accessible while Maximizing the Value Proposition
2:30–2:45 PM CDT	**Coffee Break**	
2:45–3:45 PM CDT	**R9A** FDA Inspections: Always Be Ready and What to Do When They Actually Come Knocking on Your Door!	**R9B** Oops the PI's Gone: What to Do Next!
3:45–4:45 PM CDT	**Conference Social Event**	

WEDNESDAY, JUNE 16

9:00–10:00 AM CDT	**R10A** Compliance Aftermath of COVID Research	**R10B** Data Governance: Unlocking Data to Advance Research While Safeguarding Human Subjects
10:00–10:15 AM CDT	**Coffee Break**	
10:15–11:15 AM CDT	**R11A** Research Compliance Work Plans: Creating a Blueprint for a Successful Research Compliance Program	**R11B** AI and Research: Trends to Tackle Bias, Data, and Compliance when Using Artificial Intelligence in Clinical Research
11:15–11:30 AM CDT	**Coffee Break**	
11:30 AM–12:30 PM CDT	**R12A** The Vital Role of Whistleblower Scientists in Exposing Fraudulent Research During the Pandemic	**R12B** Incorporating Research Compliance into Privacy and Security Risk Management for Healthcare Organizations
12:30–1:30 PM CDT	**Mid-Conference Break**	
1:30–2:30 PM CDT	**R13A** Managing Undue Influence in University Research	**R13B** Clinical Research Privacy: Challenges from Technology, Public Health, and Law Require Both Innovative Solutions and Basic Fundamentals
2:30–2:45 PM CDT	**Coffee Break**	
2:45–3:45 PM CDT	**R14A** Building a New Research Compliance Program: Where Do I Begin?	**R14B** Why Are Organizations Still So Confused about HIPAA and Research?
3:45–4:00 PM CDT	**Coffee Break**	
4:00–5:00 PM CDT	**GENERAL SESSION:** FDA Clinical Research Compliance for Medical Devices: A Primer	

AGENDA ALL TIMES LISTED ARE IN CENTRAL DAYLIGHT TIME (CDT)

Monday, June 15

9:00 – 9:10 AM CDT

Opening Remarks

9:10 – 10:10 AM CDT

General Session: Sites Beware: How to Prepare for the Upcoming Changes in Medicaid

KELLY WILLENBERG, CEO, Kelly Willenberg and Associates

RYAN MEADE, Fellow, University of Oxford

- Analyze potential impact to sites research billing process and coverage analysis
- Discuss how the legislation fits into the federal and state Medicaid legal framework
- Examine possible actions that state needs to take based on the language of the legislation

10:10 – 10:30 AM CDT

Coffee Break

10:30 – 11:30 AM CDT

R1A If I Knew Then What I Knew Now: Lessons from the Trenches on Building a Physician Practice Clinical Research Compliance Program

Level: Basic

JENNIFER SARTOR, Vice President, Compliance, National Spine and Pain Centers

- Challenges and obstacles to developing the research compliance program
- Collaborative solutions that brought it all together
- Continuous improvement: How we are continuing to grow and evolve the research compliance program

R1B Electronic Systems in Clinical Research: How to Remain Compliant in the New "Virtual World"

Level: Intermediate

CANDIDA BARLOW, Clinical Research Informatics Specialist, Bio-Optronics now Advarra

CHRISTINE NELSON, Director for Office of Clinical Trials, University of North Carolina at Chapel Hill

LAURA FLUHARTY, Director, Clinical Research Operations, Penn Medicine, University of Pennsylvania Health System

- Educate compliance professionals on FDA guidance for electronic systems
- Explain FDA guidance as it relates to electronic systems used to collect data in clinical research
- Describe steps an organization can take to remain compliant when leveraging technology

11:30 – 11:45 AM CDT

Coffee Break

11:45 AM – 12:45 PM CDT

R2A Bias and Structural Inequity in Research

Level: Basic

MINA KINI, System Director, Diversity and Inclusion, SSM Health

JUDITH BURGAN, Regional Manager, Corporate Responsibility, SSM Health

- Understand the history of bias and structural inequities in healthcare research. Most people know about the Tuskegee Syphilis Study. Explore other examples in the history of research where bias or structural inequity played a role
- Using data, describe the effects of bias and structural inequity on healthcare research today. From basic laboratory research to clinical trials, bias and structural inequities continue to affect research and the healthcare individuals receive
- List four strategies organizations can utilize to advance a culture of inclusion in research. Apply a strategy to improve diversity and inclusion in our workforces and engage with our communities

R2B Clinical Trials Research Compliance: Auditing vs Monitoring

Level: Intermediate

JANA DOCK, Director, Research Business Operations, Mercy Research

GEOFFREY SCHICK, Senior Consultant, PFS Clinical

- Discuss the experience of Mercy's utilization of both auditing and monitoring in research compliance
- Identify the key elements of (external) auditing methodology and discuss pros and cons
- Identify the key elements of (internal) monitoring methodology and discuss pros and cons

12:45 – 1:45 PM CDT

Mid-Conference Break

1:45 – 2:45 PM CDT

R3A Complicated and Complex: Part C Medicare Advantage Billing for Clinical Trials

Level: Intermediate

ELIZABETH RODRIGUEZ, Associate Director, Johns Hopkins Medicine

SCOTT STREIBICH, Director, Clinical Research Revenue Integrity, Moffitt Cancer Center & Research Institute

- Design research workflows supporting charging to Medicare Advantage or conventional Medicare
- Tackle complex research billing scenarios for clinical trials enrolling Medicare Advantage patients
- Clarify regulations related to trial type to include INDs, IDEs, CEDs, and LCDs

R3B Considerations in Building a Foreign Influence Compliance Program

Level: Intermediate

MODERATOR: CALLAN STEIN, Partner, Troutman Pepper Hamilton Sanders

PANELISTS:

JANICE GRACE, Director, Office of Sponsored Projects Administration, Mayo Clinic

KATHLEEN MCNAUGHTON, Administrator, Mayo Clinic

WILL MCINTIRE, Research Counsel, Boston Medical Center

- Understand the Government's (especially NIH, NSF, and DoD) recent focus on increased transparency concerning foreign elements and connections in applications for research grants
- Identify and overcome operational challenges to maintaining foreign influence compliance
- Mitigate legal exposure for investigators/ institutions by implementing an effective foreign influence compliance program

2:45 – 3:00 PM CDT

Coffee Break

3:00 – 4:00 PM CDT

R4A Legal Update: Developments in Clinical Research, EUAs, and IRBs

Level: Intermediate

TRACY FIELD, Partner, Parker Hudson Rainer & Dobbs LLP

SANDRA MILLER, Partner, Womble Bond Dickinson (US) LLP

- Spotting informed consent issues, EUA approvals, and other issues in a pandemic
- Updated review of research subject disparities and practical ways to increase diversity in subjects
- Review recent government enforcement actions for research misconduct with ways to mitigate risk

R4B Privacy Considerations and AI in Medicine

Level: Intermediate

MIRENA TASKOVA, Managing Director-Head of Privacy & Cybersecurity, Armanino

SARAH DUFFY-CLINTON, Research Compliance Officer, Providence Health & Services

- Learn about solutions that will enable the rise of the next generation of AI in medicine
- Address privacy considerations if you use large amounts of data from healthcare machines
- Learn about the role of the stringent global privacy laws GDPR (Europe) and HIPAA (USA) in medicine

4:00 – 4:15 PM CDT

Coffee Break

4:15 – 5:15 PM CDT

R5A Critical Elements of Animal Research Compliance: Semi-Annual Activities

Level: Intermediate

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

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

- Present the regulatory obligations for semi-annual program reviews, reports, and inspections
- Examine various strategies and practices for conducting these semi-annual activities
- Assess regulatory agency allowances for these activities during the COVID-19 pandemic and beyond

R5B Responsible Conduct of Research (RCR): What It Is and Why It Matters

Level: Intermediate

NANCY RHEA, Senior Research Compliance Analyst, MS, CHRC, CCRP, University of Arkansas for Medical Sciences

DARRI SCALZO, Research Compliance Officer, CHRC, CCRP, University of Arkansas for Medical Science

- Discuss the definition of RCR, why it is important, and who should receive RCR training
- Explore the role of the compliance officer in RCR training and best practices for providing training
- Demonstrate how embedding RCR concepts in daily work can help avoid ethical issues in research

Tuesday, June 15

9:00 – 10:00 AM CDT

R6A Patient Access, 21st Century Cures Act, and Information Blocking

Level: Intermediate

DEBI PRIMEAU, President, Primeau Consulting Group

JAIME JAMES, MHA, RHIA, Senior HIM Consultant, Legislative Policy and Compliance, MMRA

- Explore the Cures Act as it relates to the Information Blocking Rule and the research environment
- Discuss components of the Information Blocking Rule, including definitions, timelines, and exception
- Examine key areas where research compliance professionals can focus efforts to prepare for change

R6B What Your Research Investigators and IRB May Not Know: Regulatory and Ethical Implications for Human Subjects Research

Level: Intermediate

BARBARA VIMONT JD, MPH, RHIA, CHC, Director, Compliance and Privacy , Akron Children's Hospital

PATRICIA BLOUNT MD, MSL, CIP, CHRC, Managing Director, ProtocolsByDesign, LLC

- Understand the fundamental difference between the practice of medicine and clinical research: The confusing roles of physician and clinical investigator
- Understand the FDA regulatory landscape of sponsor-investigator INDs, nutraceuticals, and devices
- Understand the fundamental difference between an interventional and observational study: Misperceptions concerning research interventions considered "standard of care" procedures

10:00 – 10:15 AM CDT

Coffee Break

10:15 – 11:15 AM CDT

R7A It Takes a Village: Collaborative Solutions for Mitigating Clinical Research Revenue Cycle Risk

Level: Basic

CYNTHIE LAWSON, Consultant, Self-Employed

KATHERINE COHEN, Chief Compliance Officer, Southern Illinois University Medicine

- Understanding clinical research revenue cycle basics and risks,
- Common challenges in managing the Clinical Research Revenue Cycle
- Best practices in efficient and compliant Clinical Research Revenue Cycle management

R7B Grow Up! Maturing a Research Compliance Program

Level: Intermediate

JORDAN MUHLESTEIN, Compliance & Ethics Director, Intermountain Healthcare

NEIL NOKES, Compliance Partner, Intermountain Healthcare

- Defining research compliance program maturity to obtain stakeholder buy-in
- Applying compliance program maturity principles to a research compliance program
- Measuring the research compliance program's maturity and effectiveness through KPIs

11:15 – 11:30 AM CDT

Coffee Break

11:30 AM – 12:30 PM CDT

General Session: Research Year in Review 2020-2021

F. LISA MURTHA, Partner, Moses & Singer, LLP

- Understand new research-related laws, regulations, agency guidance, enforcement cases, and other updates in research over the last year
- Review OIG and DOJ cases as well as enforcement at the agency level: OHRP, ORI, FDA, ETC.
- How should we shift our research compliance focus in light of the new laws, regs, and guidance?

12:30 – 1:30 PM CDT

Mid-Conference Break

1:30 – 2:30 PM CDT

R8A Novel Conflict of Interest Collection Strategies for More Effective Oversight

Level: Intermediate

CATHARINE FORTNEY, Chief Compliance and Audit Officer, Denver Health and Hospital Authority

WENDY CHARLES, Chief Scientific Officer, BurstIQ

- Identify hidden gaps between conflicts of interest reported (and not reported) with other sources
- Describe risks to institutions, individuals, and the public, of failure to identify and manage COI
- Design an efficient COI collection process that promotes broader integrity and public trust

R8B Compliance Reimagined: Making Compliance Intuitive and Accessible while Maximizing the Value Proposition

Level: Basic

ANDREW MACAN , Senior Vice President, General Counsel, Chief Compliance Officer & Corporate Secretary, Neuronetics, Inc.

- Reimagining Compliance: Transitioning from rules to principles
- - Policy simplification and consolidation
- - Placing tools where they can be used
- Making training memorable
- Proving the value proposition

2:30 – 2:45 PM CDT

Coffee Break

2:45 – 3:45 PM CDT

R9A FDA Inspections: Always Be Ready and What to Do When They Actually Come Knocking on Your Door!

Level: Advanced

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

- Learn from other people's mistakes: Common findings from 483s, FDA warning letters, and trends
- Learn from the Compliance Program Guidance Manual: Instructions for conducting FDA inspections
- Before, during and after inspection: What you need to know and what you need to do to prepare

R9B Oops the PI's Gone: What to Do Next!

Level: Intermediate

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

WENDY PORTIER, Independent Consultant, Portier & Associates, LLC

JOHN BAUMANN, Ph.D., Associate Vice President for Research Compliance, Office of Research Compliance, Office of Vice President for Research, Indiana University

- Discuss common oversight gaps that occur when the PI changes or leaves an organization
- Outline areas to consider when a PI changes, including: IRB review/approval, contract changes, sponsor notification, the Form FDA 1572, delegation of authority, training, and more
- Review key processes to address when a PI changes

3:45 – 4:45 PM CDT

Conference Social Event

Wednesday, June 16

9:00 – 10:00 AM CDT

R10A Compliance Aftermath of COVID Research

Level: Intermediate

R10B Data Governance: Unlocking Data to Advance Research While Safeguarding Human Subjects

Level: Intermediate

DEB MARKO KOEBERER, Privacy Officer & Manager Compliance Operations, University Hospitals (Cleveland)

THORA JOHNSON, Partner, Venable LLP

MARK FOX, Privacy and Research Compliance Officer, American College of Cardiology

- Review the commentary from the Office of Human Subjects on Reasonable and Appropriate Safeguards
- Discuss the balance between protecting patient privacy and driving research discoveries
- Explore practical examples of effective data governance that promotes successful research while safeguarding data

10:00 – 10:15 AM CDT

Coffee Break

10:15 – 11:15 AM CDT

R11A Research Compliance Work Plans: Creating a Blueprint for a Successful Research Compliance Program

Level: Intermediate

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

KELE PIPER, Director, Research Compliance, Massachusetts General Hospital

- Discuss how to use research compliance work plans to transform your program from reactive to proactive
- Use the work plan to motivate and incentivize your research compliance staff and build confidence with your research community
- Learn to build a flexible work plan that maximizes resources while adapting to a changing compliance environment

R11B AI and Research: Trends to Tackle Bias, Data, and Compliance when Using Artificial Intelligence in Clinical Research

Level: Advanced

NAMANDJÉ N. BUMPUS, PhD, Professor and Director, Department of Pharmacology and Molecular Sciences, Johns Hopkins School of Medicine

RICHARD KORMAN, Chief Legal Officer & General Counsel, Avera Health

SARAH SWANK, Counsel, Nixon Peabody LLP

- Defining AI and current trends in clinical research
- AI FDA regulations, virtual and home trials, data security, intellectual property, and COVID guidance
- Addressing AI ethics, bias, and compliance

11:15 – 11:30 AM CDT

Coffee Break

AGENDA

ALL TIMES LISTED ARE IN CENTRAL DAYLIGHT TIME (CDT)

11:30 AM – 12:30 PM CDT

R12A The Vital Role of Whistleblower Scientists in Exposing Fraudulent Research During the Pandemic

Level: Intermediate

ELISABETH BIK, PhD, Science Integrity Consultant, Harbers-Bik LLC and Founder and Editor of the Science Integrity Digest

MARY INMAN, partner and Head of International Whistleblower practice at Constantine Cannon LLP in San Francisco and London offices

- Understand the compliance risks posed by scientists' ability to bypass the peer-review process and expedite publishing of COVID-19-related research
- Identify types of COVID-19 research fraud from real-world examples presented by whistleblower and scientific sleuth, Dr. Bik.
- Learn techniques for how to handle internal whistleblower complaints of research fraud and obviate need for WB employee to proceed externally by contacting government authorities

R12B Incorporating Research Compliance into Privacy and Security Risk Management for Healthcare Organizations

Level: Intermediate

HAMANGI PATEL, Research Compliance Director, Northwell Health

EMMELYN KIM, AVP, Research Compliance & Privacy Officer, Northwell Health

- Implement effective ways to integrate research compliance into the healthcare compliance framework
- Identify and manage unique areas locally and globally in research pertaining to privacy and security
- Work with other stakeholders in research to better monitor and manage risk at healthcare organizations

12:30 – 1:30 PM CDT

Mid-Conference Break

1:30 – 2:30 PM CDT

R13A Managing Undue Influence in University Research

Level: Intermediate

DANIEL SHAPIRO, Assistant Vice President for Research Compliance, University of Southern California

KENNETH LIDDLE, Chief Compliance Officer, Rice University

ROBERT ROACH, Senior Advisor, Guidepost Solutions LLC, Guidepost Solutions LLC

- Understand the Biden Administration's approach to "undesirable" foreign influence in university research
- Learn 5 steps universities can take to manage effective international research collaborations
- Develop monitoring techniques to meet ongoing federal expectations and avoid federal agency review

R13B Clinical Research Privacy: Challenges from Technology, Public Health, and Law Require Both Innovative Solutions and Basic Fundamentals

Level: Intermediate

MARY ALEXANDER, Research Compliance Officer, UC Irvine

NICHOLAS WEIL, Senior Director, Ankura Consulting Group

- See how industry and public demands clash with data laws and risks, catching researchers in between
- Respond with an innovative compliance program to engage colleagues and show commitment to ethics
- Review the basics of a research privacy investigation: How to assess, respond, and mitigate breaches

2:30 – 2:45 PM CDT

Coffee Break

2:45 – 3:45 PM CDT

R14A Building a New Research Compliance Program: Where Do I Begin?

Level: Intermediate

TRACY POPP, Sr. Director, Clinical Research, Tampa General Hospital

LYNN SMITH, Dir, Research Compliance Officer, Tampa General Hospital

- Understanding the importance of a research compliance program
- Define the elements of a research compliance program and what should be implemented first
- Address the impact of research compliance on research operations

R14B Why Are Organizations Still So Confused about HIPAA and Research?

Level: Intermediate

MARTI ARVIN, Executive Advisor, CynergisTek, Inc.

LINDA MALEK, Partner, Moses & Singer LLP.

- Overview of the ways in which PHI can be used and disclosed for research
- Why the structure and nature of the organization can result different obligations under the rules
- Common errors and implications of information blocking for research

3:45 – 4:00 PM CDT

Coffee Break

4:00 – 5:00 PM CDT

General Session: FDA Clinical Research Compliance for Medical Devices: A Primer

NEIL O'FLAHERTY, Partner, Amin Talati, Wasserman

- When does research of a medical device become subject to FDA oversight?
- What are the key considerations for running a medical device clinical study in compliance with FDA requirements?
- Strategies for avoiding non-compliant clinical research and running FDA-compliant studies

Research Compliance Conference

JUNE 14-16, 2021 | VIRTUAL

Contact Information

◯ Mr ◯ Mrs ◯ Ms ◯ Dr

Member/Account ID (if known)

First Name | MI | Last Name

Credentials (CHC, CCEP, etc.)

Job Title

Organization (Name of Employer)

Street Address

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Work Phone

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