



Discover emerging
research compliance risks
and solutions to increase
the effectiveness of your
institution's compliance program

Healthcare Research Compliance Academies

Only 1 Academy Remaining in 2020

Nashville, TN • Nov 2–5

Sit for the CHRC exam! Demonstrate your expertise and enhance your career—take the optional Certified in Healthcare Research Compliance (CHRC)[®] exam offered by the Compliance Certification Board (CCB)[®] at the conclusion of the Academy.

Academies are limited to 75 participants.
Register early to secure your spot.

Register today
hcca-info.org/academies



About our Academies

Increase the effectiveness of your institution's research compliance program by focusing on the basics. Whether you're getting started in the compliance field or need a refresher course, our Healthcare Research Compliance Academy can expand your knowledge of compliance and shape your organization's program. Join us to learn from industry experts, and meet other professionals with real-world experiences to share.

Who should attend?

Our Academies are designed for participants with basic knowledge of and professional experience in healthcare research compliance.

This includes:

- Chief compliance officers
- Compliance specialists
- Research auditors
- Clinical research compliance officers
- Research and compliance directors
- Compliance analysts
- Research coordinators

Why should you attend?

Kick-start your compliance program and head back to work with a wealth of new information and resources.

- Gain core healthcare research compliance knowledge
- Learn from faculty hand-selected for their expertise
- Network with other compliance professionals
- Earn live continuing education units (CEUs)
- Take the optional Certified in Healthcare Research Compliance (CHRC)[®] exam

Enrollment for each Academy is limited to 75 participants, ensuring personal interaction with our experts.

Course materials and takeaways

In addition to the knowledge you gain by attending, you also receive:

- All course materials (A binder will be provided on the first day of the Academy.)
- One-year online access to *Research Compliance Professional's Handbook, 3rd Edition* (A link will be sent to the email address in your HCCA account.)

HCCA's mission

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

Contact Us

Please visit hcca-info.org to learn more about the Academies and HCCA's other programs.

Our faculty



Dwight Claustre, CHC-F, CHRC, CHPC
Retired Compliance Professional



Sheila Limmroth, CIA, CHC
HIPAA Privacy Officer/Legal Services Specialist,
DCH Health System



Ryan Meade, JD, CHC, CHRC
Fellow in Law and Ethics,
University of Oxford



Lisa Murtha, JD, CHC, CHRC
Senior Managing Director,
Ankura Consulting Group



Joan M. Podleski, CHC, CHPC, CHRC, CCEP
Chief Privacy Officer,
Children's Health



Juliann Tenney, JD, CHRC
Former Associate Dean, Duke University
School of Medicine; Chief Privacy and
Director, Research Compliance Program,
University of North Carolina (retired)



Debbie Troklus, CHC-F, CCEP-F, CCEP-I, CHRC, CHPC
President, Troklus Compliance Consulting;
SCCE & HCCA Board Member



Kristin H. West, JD, M.S. Pharm, CHRC
Director of Research Ethics and
Compliance Committee, Council on
Governmental Relations (COGR)



Kelly Willenberg, DBA, RN, CCRP, CHC, CHRC
Manager/CEO,
Kelly Willenberg and Associates

(Faculty subject to change.)

CHRC[™] Do you qualify? Become certified!

Certification can enhance your career and give you credibility with your organization and peers. Immediately following each Academy, we offer an optional Certified in Healthcare Research Compliance (CHRC)[®] exam. A separate application and fee submitted in advance directly to the Compliance Certification Board (CCB)[®] is required.

PLEASE NOTE: Although the Academies can provide the CEUs you need to qualify, they are not a preparation class for the exam itself.

MONDAY

7:30–8:00 AM

Registration and Continental Breakfast (*provided*)

8:00–8:15 AM

Welcome / Introduction

8:15–10:00 AM

Research Compliance 101 — *Kelly Willenberg*

- A high level overview of key research compliance issues
- Human research protections, scientific misconduct, conflicts of interest, research billing, effort reporting, and more
- Integration of research compliance into the corporate compliance program

10:00–10:15 AM

Break

10:15–11:15 AM

Healthcare Compliance 101 — *Debbie Troklus*

- An overview of general compliance topics focusing on the elements of an effective compliance program
- The infrastructure of a research compliance program
- The Board's role in compliance

11:15 AM–12:15 PM

Lunch (*provided*)

12:15–1:45 PM

Human Research Protections — *Ryan Meade*

- Overview of Federal Regulations governing investigators, institutions, IRBs
- Discussion of frequent trouble spots identified in Determination Letters and Warnings, and how they can be managed
- Interactive dissection of hypothetical scenarios and practical approaches managing thorny issues

1:45–2:00 PM

Break

2:00–3:30 PM

FDA-Regulated Research — *Kristin H. West*

- Guidelines for determining whether research is regulated by FDA and, if so, by which component
- Institutional and investigator responsibilities in FDA-regulated research: FDA and industry expectations for compliance
- FDA inspections: What to expect and how to respond

3:30–3:45 PM

Break

3:45–5:00 PM

Conflicts of Interest — *Juliann Tenney*

- Identifying a potential conflict of interest that may introduce bias into the design, conduct, or reporting of research
- Determining when action needs to be taken, and what actions are necessary and appropriate for reduction, management, or elimination of the potential or actual conflict
- Action that can be taken to decrease the possibility of conflict of interest situations arising in the conduct of research

TUESDAY

8:00–8:30 AM

Continental Breakfast (*provided*)

8:30–9:45 AM

Scientific Misconduct — *Juliann Tenney*

- Introduction to concepts of Research Misconduct: What it is and what it isn't
- Governing regulations
- Remedies and consequences

9:45–10:00 AM

Break

10:00–10:15 AM

Certified in Healthcare Research Compliance (CHRC)[®] Exam Information

10:15 AM–12:00 PM

Research Billing — *Ryan Meade*

- In-depth review of rules for billing payors for clinical research services
- Review a methodology for determining coverage of clinical research services
- Overview of a clinical research Medicare coverage analysis

12:00–1:00 PM

Lunch (*provided*)

1:00–2:00 PM

Research Billing (Continued) — *Ryan Meade*

- Review the impact of budgets and clinical trial agreements on billing compliance
- Examine language in informed consent forms that impact billing
- Discuss research billing coding

2:00–2:15 PM

Break

2:15–3:30 PM

Animal Research — *Kristin H. West*

- Overview of the main regulators/regulations in the animal research arena
- Working with institutional animal care and use committees, institutional officials, attending veterinarians, and other important players in animal research oversight
- Case analysis: Issuing, spotting, and applying pertinent regulations in animal research settings

3:30–3:45 PM

Break

3:45–5:00 PM

Research Documentation and GCP — *Joan M. Podleski*

- Understand what is the research record
- Differentiate the research record from the medical record
- Understand the basics of GCP and documentation standards/guidelines

5:30 PM

Networking Event (*optional*)

WEDNESDAY

8:00–8:30 AM

Continental Breakfast *(provided)*

8:30–10:00 AM

Conducting a Research Risk Assessment — *Dwight Claustre*

- What is a risk and what does it mean to assess it?
- Who needs to be involved in the process and why?
- Identifying the risk and conducting the assessment
- What do we do with the results?

10:00–10:15 AM

Break

10:15–11:30 AM

Auditing and Monitoring — *Kelly Willenberg*

- Key elements of a successful healthcare research auditing and monitoring plan
- How at least 2 key risk areas in healthcare research could be developed into auditing and monitoring tools
- How to optimize healthcare research tools provided to apply to their individual organizations

11:30 AM–12:30 PM

Lunch *(provided)*

12:30–1:45 PM

Grants Management — *Lisa Murtha*

- Discuss the basic requirements for grants management
- Determine how to identify compliance risks related to grants management
- Discuss the significant risk areas related to grants management
- Understand effective management practices for managing externally funded research programs

1:45–2:00 PM

Break

2:00–3:15 PM

Data and Safety Monitoring Issues — *Joan M. Podleski*

- Understand the criteria for establishment of a Data Monitoring Committee (aka DSMB)
- Writing an operational charter for the Data Monitoring Committee
- Key requirements for operating a functioning DMC

3:15–3:30 PM

Break

3:30–5:00 PM

Research Compliance Hot Topics & Watch List — *Lisa Murtha*

- Important research compliance issues and trends not otherwise covered in the Academy
- Overview of the Foreign Corrupt Practices Act and UK Bribery Act as they impact international research and technology
- Detailed overview of Good Clinical Practice regulations and Good Manufacturing Practices as they relate to research
- Applicable new laws, regulations, and enforcement trends related to the conduct of research

THURSDAY

8:00–8:30 AM

Continental Breakfast *(provided)*

8:30–10:00 AM

Conducting an Internal Research Investigation — *Dwight Claustre*

- Being prepared is a key to conducting a good investigation
- Where to look, what to look for, and how to find it
- Interviews (and guidelines for conducting them)

10:00–10:15 AM

Break

10:15–11:45 AM

Privacy and Security Issues in Research — *Sheila Limmroth*

- Overview of the basics of privacy and security in research
- Discussion of HIPAA privacy and security in research
- Discussion of FDA and other regulations that impact privacy and security in research

11:45 AM

Academy Ends

12:45 PM

CHRC Exam Check-In Time

1:00–4:00 PM

Exam Time — Certified in Healthcare Research Compliance (CHRC)[®] *(optional)*

The CHRC exam is optional. You must apply and pay for the exam separately from the Academy.

To apply online, visit: hcca-info.org/Certification/ApplyforCCBCertification.aspx.

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

(Agenda subject to change.)

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

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

Upon request, if there is sufficient time and we are able to meet their requirements, HCCA may submit this course to additional states or entities for consideration. If you would like to make a request, please contact us at 952.988.0141 or 888.580.8373 or email ccb@compliancecertification.org.

To see the most up-to-date CEU information, visit hcca-info.org/all-conferences-home-page; select your conference; then select the "Continuing Education" option from the left-hand menu.

ACHE: The Health Care Compliance Association is authorized to award 23.0 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 23.0 continuing education units (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.

CCB: The Compliance Certification Board (CCB)[®] has awarded a maximum of 27.9 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)[®], and Certified Compliance & Ethics Professional–International (CCEP-I)[®].

CLE: The Health Care Compliance Association is a provider/sponsor, approved/accredited by the State Bar of California, the Pennsylvania Bar Association, the Rhode Island MCLE Commission, and the State Bar of Texas. An approximate maximum of 21.0 clock hours of Continuing Legal Education (CLE) credit will be available to attendees of this conference licensed in these states. HCCA's practice is to apply for CLE credits to the state in which the event is being held, if that state has a CLE approval process for sponsors. Upon request, if there is sufficient time and if we are able to meet their CLE requirements, HCCA may submit this course to additional states for consideration. Only requests from registered attendees will be considered. All CLE credits will be assessed based on actual attendance and in accordance with each state's requirements.

NASBA/CPE: The Health Care Compliance Association is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE sponsors. 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: www.nasbaregistry.org. Sponsor Identification No: 105638. The education level for this activity is considered basic. No prerequisites are required for this education. Delivery Method: Group Live. Advanced Preparation: None. A recommended maximum of 27.5 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. 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 27.9 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).

HCCAnet

SOCIAL NETWORK

- Join other compliance professionals in discussion and get answers to your most difficult compliance questions.
- Participate in study groups for certification exams.
- Discuss best practices, get advice, learn the newest trends, etc.



hcca-info.org/hccanet



Healthcare Research Compliance Academies and optional CHRC exams are held at the locations listed below. The costs of hotel accommodations are not included in your conference registration fee. The hotel room rate listed for each Academy is good until the cutoff date indicated or until the room block is full, whichever comes first. Reservations received after the cutoff date or after the room block is full will be accepted based on space and rate availability. Please note that parking and Internet service charges are set by the hotel and may be subject to change.

NOTICE: Neither HCCA—nor any hotel with which it is affiliated—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.

San Diego, CA • March 9–12

The US Grant
326 Broadway, San Diego, CA 92101

A reduced rate of \$239 per night (plus applicable taxes; currently 12.77%; subject to change) for single/double occupancy has been arranged. To make a reservation, visit bit.ly/academy030220 or call 888.236.2427 and ask for the “HCCA Compliance Academy” group rate. All reservations must be guaranteed by a first night’s room deposit or a valid credit card. The cutoff date to receive the discounted rate is Friday, February 7, 2020 or when the group block is full, whichever comes first.

Nashville, TN • November 2–5

Hilton Nashville Downtown
121 Fourth Avenue South, Nashville, TN 37201

A reduced rate of \$254 per night (plus applicable taxes—currently 15.25%; subject to change—and fees) for single/double occupancy has been arranged. To make a reservation, visit bit.ly/academy110220 or call 615.620.1000 and ask for the “HCCA Compliance Academy” group rate. All reservations require a first night’s room (plus tax) deposit in the form of check or credit card. Any room cancellations 48 hours (or less) prior to the arrival date or a no-show will forfeit this deposit. The cutoff date to receive the discounted rate is Monday, October 12, 2020 or when the group block is full, whichever comes first.



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2020 Healthcare Research Compliance Academies

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

City/Town State/Province

Zip/Postal Code Country

Work Phone

Email (required)

Dietary Needs Request

Dairy Free Gluten Free Kosher Vegetarian Vegan
 Other _____

Acknowledgements

By submitting this registration, you agree to the full Terms and Conditions, including the use of your information, viewable at hcca-info.org/academies.

Your information (postal address) may be shared with conference exhibitors, attendees, speakers, affiliates, and partners for marketing and/or networking purposes. To see the full use of your information or if you wish to opt-out, visit hcca-info.org/privacy.

By participating in an HCCA conference, you grant HCCA, or anyone authorized by HCCA, the right to use or publish in print or electronic medium any photograph or video containing your image or likeness for educational, news, or promotional purposes without compensation.

Cancellation fee: A \$250 fee will be charged for any registration changed within seven days of the start of an Academy.

Academies

| | |
|--------------------------|--------------------------------------------|
| <input type="checkbox"/> | March 9–12 • San Diego, CA SOLD OUT |
| <input type="checkbox"/> | November 2–5 • Nashville, TN |

Registration Fees

| | | |
|--------------------------|---------------------------------------|---------|
| <input type="checkbox"/> | Member | \$2,750 |
| <input type="checkbox"/> | Non-Member | \$3,250 |
| <input type="checkbox"/> | Registration + First-Time Membership* | \$2,970 |
| <input type="checkbox"/> | Group Discount for 5–9 Attendees | (\$200) |
| <input type="checkbox"/> | Group Discount for 10 or More | (\$400) |

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

TOTAL \$ _____

Payment

Online registration at hcca-info.org/academies

Mail this form to HCCA, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435-2358

Fax this form to 952.988.0146

Email this form to helpteam@hcca-info.org — Due to PCI compliance, do not provide credit card information via email. You may email this form (without credit card information), then call HCCA at 888.580.8373 with payment information.

- Invoice me
 Check enclosed (payable to HCCA)
 Wire transfer requested
 Credit card: I authorize HCCA to charge my:
 Visa MasterCard Discover American Express

Credit Card Account Number

Credit Card Expiration Date

Cardholder Name

Cardholder Signature