

# Healthcare Research Compliance Academies

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

## Upcoming 2021 Academy

Las Vegas, NV • Dec 13–16

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

Register today  
[hcca-info.org/academies](https://hcca-info.org/academies)



# About our Academies

HCCA's Healthcare Research Compliance Academy is a three-and-a-half-day intensive training program designed to help attendees increase their ability to manage effective research compliance programs. Our faculty of experts provide guidance and insights on many areas that affect research compliance professionals on a day-to-day basis, including emerging risks and solutions. Unlike larger conferences, the Healthcare Research Compliance Academy offers attendees a classroom-style, hands-on approach to learning that encourages small-group interactions and networking opportunities.

## 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)<sup>®</sup> exam

Enrollment for each Academy is limited, 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, 3<sup>rd</sup> Edition* (\$200 value) (A link will be sent on the first day of the Academy 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](http://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  
Fellow in Law and Ethics,  
University of Oxford



**Lisa Murtha**, JD, CHC, CHRC  
Partner,  
Moses & Singer LLP



**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  
SCCE & HCCA Board Member

(Faculty subject to change.)

# CHRC<sup>™</sup> Do you qualify? Become certified!

Certification can enhance your career and give you credibility with your organization and peers. Immediately following the Academy, we offer an optional Certified in Healthcare Research Compliance (CHRC)<sup>®</sup> exam. A separate application and fee submitted in advance directly to the Compliance Certification Board (CCB)<sup>®</sup> 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)<sup>®</sup> 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 two 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)<sup>®</sup> *(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](https://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.)*

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

**CCB:** The Compliance Certification Board (CCB)\* has awarded a maximum of 27.9 CEUs for these certifications: Certified in Healthcare Compliance (CHC)<sup>®</sup>, Certified in Healthcare Compliance–Fellow (CHC-F)<sup>®</sup>, Certified in Healthcare Privacy Compliance (CHPC)<sup>®</sup>, Certified in Healthcare Research Compliance (CHRC)<sup>®</sup>, Certified Compliance & Ethics Professional (CCEP)<sup>®</sup>, Certified Compliance & Ethics Professional–Fellow (CCEP-F)<sup>®</sup>, and Certified Compliance & Ethics Professional–International (CCEP-I)<sup>®</sup>.

Daily Breakdown:

Monday = 7.0 hours / 8.4 credits

Tuesday = 6.5 hours / 7.8 credits

Wednesday = 6.75 hours / 8.1 credits

Thursday = 3.0 hours / 3.6 credits

\*Hours are subject to change

**ACHE:** The Health Care Compliance Association is authorized to award 23.25 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.

**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](http://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 27.9 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](mailto: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).

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 952.988.0141 or 888.580.8373 or email [ccb@compliancecertification.org](mailto:ccb@compliancecertification.org).

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

# 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](http://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.

## Las Vegas, NV • December 13–16

**MGM Grand**  
3799 South Las Vegas Boulevard, Las Vegas, NV 89109

A reduced rate of \$48 per night per night plus applicable taxes (currently 13.38%, subject to change) for single/double occupancy has been arranged. A \$37 Daily Resort Fee plus applicable Clark County room tax at the time of stay (currently 13.38%, subject to change) is applied to each hotel room reservation and includes property-wide high-speed wireless internet access, unlimited local and toll-free calls, airline boarding pass printing, and cardio room access for guests 18+. The Daily Resort Fee is separate and distinct from the room rate and taxes. To make a reservation, visit [bit.ly/121321lasvegas](http://bit.ly/121321lasvegas) or call 855.788.6775 and ask for the HCCA Academy group rate. To secure a reservation, submit a valid credit card with the name as it appears on the card, billing address, and credit card expiration date—or a deposit equal to the first night's room rate plus tax as a guarantee—at the time the reservation is made. The credit card will be charged the first night's room rate plus tax at that time. Refunds will be issued on individual attendee's reservation only if canceled at least seventy-two (72) hours in advance of the confirmed arrival date. All guaranteed reservations will only be held until 6:00AM on the day after confirmed arrival date. The balance of the room, resort fee, tax, and incidental charges must be paid at check-out. The cutoff date to receive this discounted rate is November 12, 2021 or when the group block is full, whichever comes first. After the cutoff date, it is at Hotel's discretion whether to accept additional reservations, which will be subject to prevailing rates and availability.



**GROW YOUR HEALTHCARE  
COMPLIANCE CAREER WITH**

**HCCA MEMBERSHIP**

**EDUCATION | PROFESSIONAL GROWTH  
CCB CERTIFICATION | NETWORKING**

# 2021 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 \_\_\_\_\_

## Acknowledgments

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

**Group Discount Policy:** Registration forms must be sent together to ensure that the discount is applied. 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.

## Academies

December 13–16 • Las Vegas, NV

## Registration Fees

<input type="checkbox"/> Member	\$2,750
<input type="checkbox"/> Non-Member	\$3,250
<input type="checkbox"/> Registration + First-Time Membership Offer*	\$2,970

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

## Group Discounts

<input type="checkbox"/> Group Discount for 5–9 Attendees**	(\$200)
<input type="checkbox"/> Group Discount for 10 or More**	(\$400)

\*\*See "Group Discount Policy" under "Acknowledgments" for details

TOTAL \$ \_\_\_\_\_

## Payment

Online registration at [hcca-info.org/academies](http://hcca-info.org/academies)

Mail this form to Health Care Compliance Association, 6462 City West Parkway, Eden Prairie, MN 55344 USA

Fax this form to 952.988.0146

Email this form to [helpteam@hcca-info.org](mailto: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