

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)[®] exam offered by the Compliance Certification Board (CCB)[®] at the conclusion of the Academy.

Register today
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)[®] 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 the *Research Compliance Professional's Handbook, 3rd 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 to learn more about the Academies and HCCA's other programs.

Our faculty



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



Jeffrey Driver, CHC, CHRC, CCEP-I, JD
Principal & Chief Consultant,
Soteria Risk Works, LLC



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



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[™] 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)[®] 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*)

8:00–8:05 AM

Welcome/Introduction

8:05–9:50 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

9:50–10:15 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

1:45–2:15 PM

Break

2:15–3:45 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

3:45–4:00 PM

Break

4:00–5:15 PM

Conflicts of Interest — *Jeffrey Driver*

- 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

7:30–8:00 AM

Continental Breakfast (*provided*)

8:00–9:15 AM

Scientific Misconduct — *Jeffrey Driver*

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

9:15–9:45 AM

Break

9:45–10:00 AM

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

10:00–11:45 AM

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

11:45 AM–12:45 PM

Lunch (*provided*)

12:45–1:45 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

1:45–2:15 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

7:30–8:00 AM

Continental Breakfast *(provided)*

8:00–9:30 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?

9:30–10:00 AM

Break

10:00–11:15 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

11:15 AM–12:15 PM

Lunch *(provided)*

12:15–1:30 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

1:30–2:00 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

7:30–8:00 AM

Continental Breakfast *(provided)*

8:00–9:30 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)

9:30–10:00 AM

Break

10:00–11:30 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

11:30 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.)

SECTION 1 Attendee Information

☐ Mr ☐ Mrs ☐ Ms ☐ Dr ☐ Other _____ Member/Account ID (if known/applicable) _____

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) _____

SECTION 2 Registration

Healthcare Research Compliance Academies

☐ December 13–16, 2021 • Las Vegas, NV

Options

<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. See "Acknowledgements" below for details.

Group Discount

<input type="checkbox"/> Group Discount for 3–9 Attendees**	(\$200)
<input type="checkbox"/> Group Discount for 10 or More**	(\$400)

**See "Group Discount Policy" under "Acknowledgements" below for details.

TOTAL \$ _____

Dietary Needs Request

☐ Dairy Free ☐ Gluten Free ☐ Kosher ☐ Vegetarian ☐ Vegan ☐ Other _____

On-Site Cell Phone (for emergency on-site use only) _____

HCCA Membership: By selecting the Registration + First-Time Membership Offer, you agree to the full membership Terms and Conditions, including the use of your information, viewable at hcca-info.org/membership/tandc. To see the full use of your information or if you wish to opt-out, visit hcca-info.org/privacy.

Opt-Out: Select if you would like to opt-out of the following:

- ☐ Member Magazine Listing: HCCA lists all new members (first and last name, organization, and state or country) in our monthly magazine, *Compliance Today*.
- ☐ Online Member Directory: HCCA's member directory lists first and last name, organization, title, address, and phone number.

SECTION 3 Payment

Online registration at hcca-info.org/academies

Mail to HCCA, 6462 City West Parkway, Eden Prairie, MN 55344 USA Fax to 952.988.0146

Email to helpteam@hcca-info.org — Due to PCI compliance, do not provide credit card information via email. Email this form without credit card information, then call HCCA at 888.580.8373 or 952.988.0141 with your payment.

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

Credit Card Account Number _____ Expiration Date _____

Cardholder Name _____ Cardholder Signature _____

SECTION 4 Acknowledgements

By submitting this registration, you agree to the full event Terms and Conditions, viewable at hcca-info.org/conference/tandc, including the use of your information that may be shared with conference exhibitors, attendees, speakers, affiliates, and partners for promotional 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 registering for this event, you also agree that you have read and agree to the Personal Accountability Commitment, the Assumption of Risk, and the Liability Waiver and Release viewable at hcca-info.org/conference/tandc.

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.

Photo/Video Release: By registering for this event, you grant HCCA, or anyone authorized by HCCA, the right to use or publish in print or electronic format, any photographs or video containing your image or likeness for educational, news, or promotional purposes, without compensation.

New Members: By selecting the Registration + First-Time Membership Offer, you agree to the full membership Terms and Conditions, including the use of your information, viewable at hcca-info.org/membership/tandc.

Healthcare Research Compliance Academies

Frequently Asked Questions

Where will my Academy take place?

Please see hotel locations on the next page.

What is included in the cost of my attendance?

Access to the sessions, supplemental conference materials, and networking opportunities. You will also enjoy complimentary continental breakfasts, lunches, and snacks with the other attendees.

As an attendee you will also receive 1-year online access to *Research Compliance Professional's Handbook, 3rd Edition* via COSMOS®, available for access on the first day of the Academy.

What COVID-19 safety precautions will be implemented?

HCCA considers the health and safety of all those at in-person programs a top priority. Although participants should recognize that there is risk involved in attending, HCCA will follow the safety recommendations/guidelines provided by the CDC and other state and local government agencies in place at the time of the event. Additionally, HCCA will follow the venue requirements and work with the venue to provide a safe and enjoyable environment for all participants.

Can I see what sessions will be presented before I arrive on-site?

Yes, program information is posted on the conference website.

Will I receive a recording of this conference?

No. Registered attendees must participate in this event in real time as recordings are not available for any missed sessions. No audio or video recording by attendees is allowed.

Is there a group discount—if so, what is it?

Yes, we offer discounts for groups of three or more from the same organization for all our live in-person and virtual events (excluding webinars). Please send all group registration forms together to helpteam@hcca-info.org for processing. 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. For groups of 10 or more, please call +1 952.988.0141 or 888.580.8373 or email helpteam@hcca-info.org.

What do I get with "Registration + First Time Membership?"

If you've never been an HCCA member, you can register as a First-Time Member. This gives you HCCA membership at a discounted rate for your first year. You also receive the member rate for the conference. As a member you receive all HCCA member benefits (discounts, *Compliance Today*® monthly magazine, *Ethikos*® digital quarterly newsletter, member-exclusive webinars, and more). A full list of benefits can be viewed at hcca-info.org/membership. Your membership will begin once payment is received.

How do I use the credit on my account for this event?

You can complete the registration online and select the "Invoice Me" payment option at checkout. Once you receive your confirmation, email helpteam@hcca-info.org or call 952.988.0141 or 888.580.8373 to request your credit be applied toward the registration fee.

Can I get the member rate if I am an SCCE member instead of HCCA or vice versa?

Yes. As a member of SCCE or HCCA, you can receive the membership discount for both organizations' conferences; however, this cannot be done online. Please send your registration form via email to helpteam@hcca-info.org to complete your registration.

How can I cancel my registration?

If you need to cancel your participation (or send a substitute), your request must be submitted by email to helpteam@hcca-info.org. A conference credit will be issued for all registration fees paid (minus a \$250 cancellation fee if cancelled within 7 days of the start of the Academy) and will expire 12 months from the date of the original canceled event. Conference credits will not be issued if you do not attend the event and have not requested cancellation prior to the event start date. If sending a substitute, an additional fee may apply depending upon the membership status of the substitute.

Who can I notify of special needs or concerns prior to the conference?

Please call HCCA at +1 952.988.0141 or 888.580.8373 or email helpteam@hcca-info.org if you have a special need and/or require an accommodation to participate.

Continuing Education

Can I earn continuing education units (CEUs) for attending this Academy?

Yes. This Academy offers live Compliance Certification Board (CCB)® continuing education units (CEUs) for participation as well as other external credit types.

To see the most up-to-date CEU approval information, go to HCCA's website, hcca-info.org/conferences/academies. Select your Academy and choose the Continuing Education option on the left-hand menu.

How many CEUs will I earn from attending?

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

How do I request CEUs following this Academy?

While on-site at this Academy, you will be provided the Application for Continuing Education Units (CEUs). To receive CEUs, you must submit this completed application following the Academy to ccb@compliancecertification.org. Only registered attendees are eligible to request CEUs for participation.

When will I receive my CEU certificate for participation?

Once your completed Application for Continuing Education Units (CEUs) has been received by our staff, your CEU account will be updated within 2–4 weeks. To view your CCB CEUs and access your certificate, you can log in to your hcca-info.org account, go to your Account Dashboard, and scroll down to View My CEUs.

I would like to sit for one of the Compliance Certification Board (CCB)® exams offered on the last day of this Academy; will I qualify?

While this Academy, if attended in full, can provide you with all the CEUs you need to meet the continuing education requirement, you will also need to review the applicable Candidate Handbook found at hcca-info.org/candidate-handbooks to ensure you meet the work experience requirement.

I have reviewed the Candidate Handbook and want to apply for the exam; what's next?

If you want to sit for the exam offered on the last day of the Academy and have reviewed your Candidate Handbook, you can go ahead and apply online for your exam at hcca-info.org/apply-exam. You must be registered for the Academy first before you can apply to sit for the exam offered on-site.

I would like to sit for the exam, but not on-site at the Academy. Can I take my exam remotely at another time?

Yes, CCB offers the flexibility for candidates to take their exam remotely, at a local testing site, or following certain HCCA conferences. To learn more about our various testing options, visit HCCA's website, hcca-info.org/exam-information.

I have more questions about exams and seeking certification; who can help me?

For more questions about CCB certifications, call to speak to a Certification Specialist at 952.988.0141 or 888.580.8373 or email ccb@compliancecertification.org.

Healthcare Research Compliance Academies

Hotel and Academy Locations

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.

PLEASE NOTE: 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 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 HCCA at 952.988.0141 or 888.580.8373.

December 13–16, 2021 • Las Vegas, NV

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 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.

Become a member of HCCA to enhance and stay current on best practices in compliance

Member-exclusive benefits include:

- Four free webinars each year
- *Compliance Today*® Magazine
- *Ethikos*® quarterly newsletter
- Discounts on:
 - Educational conferences
 - Publications and products
 - CCB certification

Learn more
hcca-info.org/membership

