

Healthcare Research Compliance Academies

ONLY 1
ACADEMY
REMAINING
in 2019



Las Vegas

November 18–21 LIMITED SEATS

Increase the effectiveness of your institution's research compliance program during this three-and-a-half-day academy. You'll learn the basics about emerging risks in scientific misconduct, human research protection, grant management, and more — plus, strategies to mitigate risk. Best of all, you'll gain insight from industry experts and have the opportunity to network with other professionals in the industry. The Academy is limited to 75 participants to create a hands-on learning experience.

hcca-info.org/academies

Questions? taci.gregory@corporatecompliance.org



About the Healthcare Research Compliance Academies

How effective is your institution's research compliance program? With help from our Healthcare Research Compliance Academies, you can learn vital insights to help you effectively manage your compliance program and mitigate risk at your organization.

Who Should Attend?

Our academies are designed for participants with basic knowledge of and professional experience in research compliance. This includes chief compliance officers, compliance specialists, research auditors, clinical research compliance officers, research and compliance directors, compliance analysts, and research coordinators.

Why Should You Attend?

More than 1,000 compliance professionals have turned to our Healthcare Research Compliance Academies to gain extensive knowledge of industry topics. Our Academies are not conferences. Instead, they provide in-depth, classroom-style training in healthcare research compliance along with great networking opportunities.

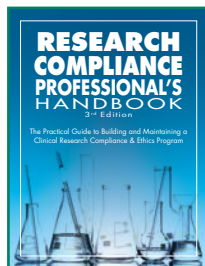
The HCCA Healthcare Research Compliance Academies also:

- Cover the basic healthcare compliance training you need, including scientific misconduct, research billing, auditing and monitoring, research records management, data and safety monitoring, grants management, risk assessments, and research investigations
- Are taught by compliance professionals, hand-selected for their experience and teaching skills
- Limit enrollment to 75 participants per academy, ensuring personal interaction with our expert faculty
- Provide opportunities to network with both faculty and peers at a networking event and during training breaks.

What Will You Receive?

Course materials are provided onsite on the first day of the Academy. This includes a binder that contains all course materials.

2019 attendees will also receive a free copy of the *Research Compliance Professional's Handbook* (normally \$200).



Faculty



Janis Anfossi, JD, MPH, CHC, CHPC
Senior Fellow in Residence – Center for Compliance Studies,
Loyola University Chicago School of Law



Dwight Claustre, CHC-F, CHRC, CHPC
President/CEO, Healthcare Compliance Professional, LLC



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



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
Senior Managing Director, Ankura Consulting Group



Kristin H. West, JD, M.S. Pharm, CHRC
Chief Compliance Officer, Emory University



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

PLEASE NOTE: Faculty is subject to change.

Becoming Certified

Why do people add JD, MBA, or CPA after their name? Because they know those initials add credibility. Become Certified in Healthcare Research Compliance (CHRC)[®] by taking the optional exam on the last day of the Academy.

More than 500 compliance professionals around the world have earned a CHRC designation. By taking and passing the certification exam, you will not only join this distinguished group, but also help to further the development of the healthcare compliance profession.

Learn More

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

To receive CHRC certification, you will need:

- At least one year of full-time experience in the profession or 1,500 hours within the past two years
- 20 hours of continuing education units (CEUs) in compliance within the 12 months prior to your exam date; the Healthcare Research Compliance Academy can provide all the credits you need, although it is not a preparation class for the exam itself
- A passing score on the CHRC certification exam.

The exam is optional and a separate application and fee is required. For more information, visit compliancecertification.org and click on the "CHRC" tab.

Academy Questions?

taci.gregory@corporatecompliance.org

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. 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.

Visit HCCA's website, hcca-info.org, for up-to-date information.

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

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, and the State Bar of Texas. An approximate maximum of 23.25 clock hours of Continuing Legal Education (CLE) credit will be available to attendees of this conference licensed in these states, along with Alabama, Florida, Georgia, Illinois, Ohio, and Rhode Island. 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, Sponsor Identification No: 105638. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be submitted to the National Registry of CPE Sponsors through its website: www.nasbaregistry.org. 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 and Application. For more information regarding administrative policies such as complaints or refunds, call 888.580.8373 or 952.988.0141.

Nursing Credit: The Health Care Compliance Association is preapproved by the California Board of Registered Nursing, Provider Number CEP 14593, for a maximum of 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).

CEU Questions?

Contact us at 888.580.8373 or ccb@compliancecertification.org.

HCCAnet Study Groups

Join one of HCCAnet's study groups to help prepare yourself for a certification exam. Post questions, share your insights, and network with other compliance professionals who have taken—or are preparing to take—the CHRC exam.

To join the CHRC Candidate Group for healthcare compliance and ethics, go to hcca-info.org/hccanet to get started. Login to your account via the "Login" button on the upper right corner of the page. Click on "Communities", select "All Communities", then scroll down to locate the "CHRC Candidate Group" and click the "Join" button.

With more than 16,000 members, HCCAnet is the official social network of the Health Care Compliance Association, and is free to join.

HCCAnet[®]
hcca-info.org/hccanet



Get CHRC Certified — Be recognized ...for your experience and knowledge in healthcare compliance

Take advantage of the opportunity to sit for the CHRC exam on the last day of the Academy. The CHRC exam requires advance application and payment separate from the Academy. To learn more, visit compliancecertification.org and click on "CHRC".

CHRC[™]
CERTIFIED IN HEALTHCARE
RESEARCH COMPLIANCE

MONDAY

8:00 – 8:30 AM	Registration and Continental Breakfast <i>(provided)</i>
8:30 – 10:15 AM	Research Compliance 101 <ul style="list-style-type: none"> • 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
10:15 – 10:30 AM	Break
10:30 – 11:30 AM	Health Care Compliance 101 <ul style="list-style-type: none"> • 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
11:30 AM – 12:30 PM	Lunch <i>(provided)</i>
12:30 – 2:00 PM	Human Research Protections <ul style="list-style-type: none"> • 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
2:00 – 2:15 PM	Break
2:15 – 3:45 PM	FDA-Regulated Research <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <i>(provided)</i>
8:30 – 9:45 AM	Scientific Misconduct <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <i>(provided)</i>
1:00 – 2:00 PM	Research Billing (Continued) <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <i>(optional)</i>

WEDNESDAY

8:00 – 8:30 AM	Continental Breakfast <i>(provided)</i>
8:30 – 10:00 AM	Conducting a Research Risk Assessment <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Key elements of a successful health care research auditing and monitoring plan • How at least 2 key risk areas in health care research could be developed into auditing and monitoring tools • How to optimize health care research tools provided to apply to their individual organizations
11:30 AM – 12:30 PM	Lunch <i>(provided)</i>
12:30 – 1:45 PM	Grants Management <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <i>(provided)</i>
8:30 – 10:00 AM	Conducting an Internal Research Investigation <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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
1:00 PM	CHRC Exam Check-In Time
1:15 – 4:15 PM	Exam Time – Certified in Healthcare Research Compliance (CHRC)[®] <i>(optional)</i> 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.

PLEASE NOTE: Agenda is subject to change.

Healthcare Research Compliance Academies and optional CHRC exams are held at the locations listed at right. 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 it is affiliated with will ever contact you to make a hotel reservation. If you receive a call soliciting reservations on behalf of HCCA or the event, it is likely from a room poacher and may be fraudulent. We recommend you make reservations directly with the hotel using the phone number or web link in this brochure. If you have concerns or questions, please contact 888.580.8373.

Chicago, IL • March 11–14

Hyatt Centric Chicago Magnificent Mile
633 North Saint Clair Street, Chicago, IL 60611

A reduced rate of \$129 per night (plus applicable taxes; currently 17.4%; subject to change) for single/double occupancy has been arranged. Basic guest room Internet and access to the fitness center and pool are included. To make reservations, visit bit.ly/bca031119 or call **888.591.1234** and ask for the Healthcare Compliance or HCCA group rate. All reservations must be accompanied by a first night room deposit or guaranteed with a major credit card. Cancellation must be received 72 hours prior to arrival or one night room plus applicable fees will be assessed. The cutoff date to receive the group rate is Sunday, February 17, 2019 or when the room block is full, whichever comes first.

Las Vegas, NV • November 18–21

The Cosmopolitan of Las Vegas
3708 Las Vegas Blvd S, Las Vegas, NV 89109

A reduced rate of \$209 per night (plus applicable taxes; currently 13.38%; subject to change) for single/double occupancy has been arranged. To make reservations, visit bit.ly/bca111819 or call **855.435.0005** and reference the group code SHCCA9. All reservations must be accompanied by a first night room deposit or guaranteed with a major credit card. The cutoff date to receive the group rate is Monday, October 28, 2019 or when the room block is full, whichever comes first.

LEARN. NETWORK. INSPIRE.



Maximize and grow your compliance program.

Stay informed on privacy issues, Stark compliance, conflicts of interest, False Claims Act, risk management, HIPAA, regulatory changes and patient rights, and more. Learn proactive compliance strategies from industry leaders and network with peers.

Learn more and join HCCA's community today!



hcca-info.org/join

MEMBERSHIP BENEFITS

- 12 issues of *Compliance Today* magazine, exclusively for HCCA members
- Join a community of 12,000+ compliance professionals
- Members-only discounts on conferences, publications, and newsletters
- Network and learn at 50+ conferences a year
- Save on weekly Web conferences for live learning at your desk
- Receive a discount on Compliance Certification Board (CCB)[®] exam pricing for CHC, CHRC, and CHPC

ADDITIONAL RESOURCES

- HCCAnet[®] provides access to an online Resource Library and networking
- Weekly newsletters and blog posts from industry experts

Contact Information (please type or print)

Mr. Mrs. Ms. Dr.

Member/Account Number (if applicable/known)

First Name MI

Last Name

Credentials

Job Title

Organization (name of employer)

Street Address (post office boxes not acceptable)

City/Town

State/Province Zip/Postal Code

Country

Phone Number Fax Number

Email Address (required for registration confirmation)

Academy Options (choose one below)

Chicago, IL • March 11–14

Las Vegas, NV • November 18–21 — **LIMITED SEATS**

Registration Options (Registration fees listed below are considered net of any local withholding taxes applicable in your country of residence.)

HCCA Member \$2,750

Non-Member \$3,250

Registration plus HCCA membership \$2,970
Save by joining HCCA today (first-time members only; annual dues \$325)

Group Discount subtract \$_____ from my registration fee (see details at left)

TOTAL _____

Dietary Accommodations

Kosher (Hechsher certified) Kosher-Style (no shellfish, pork, or meat/dairy mixed)

Gluten Free Vegetarian Vegan Other _____

Payment Options

Invoice me Check enclosed

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

Credit Card: American Express MasterCard Visa Discover

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

Terms & Conditions

Registration Payment Terms: Checks are payable to HCCA. Credit cards accepted: American Express, MasterCard, Visa, or Discover. Enclose check with your registration form and return it to the HCCA office, or fax your credit card payment to 952.988.0146. Payment must be sent in at least two weeks prior to the start date or your space may be released. If your total is miscalculated, HCCA will charge your card the correct amount. If you wish to pay using wire transfer funds, please email helpteam@hcca-info.org for instructions. **The cost of any exams and the hotel accommodations are not included in the registration fee. Breakfast and lunch are included in the tuition amount where indicated in the agenda. The CHRC exam application form must be faxed or mailed as indicated on the form.**

Cancellations/Substitutions: No refunds will be given for cancellations. If you need to cancel your participation, your request must be submitted by email to helpteam@hcca-info.org. Cancellation requests received within 7 days of the event start date will be assessed a \$250 cancellation fee. A conference credit will be issued for all registration fees paid (minus any cancellation fee) 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. Conference credit may be applied toward any HCCA event, service, or product. If a conference credit is applied toward an event, the event must take place prior to the credit's expiration date. Alternatively, you may choose to send a substitute attendee in your place. An additional fee may apply depending upon the membership status of the substitute. Substitution requests must be submitted by email to helpteam@hcca-info.org.

Group Discounts: Discounts take effect the day a group reaches the discount number of registrants. Please send registration forms together to ensure that the discount is applied. A separate registration form is required for each registrant. The group discount is NOT available through online registration. Note that discounts will NOT be applied retroactively if more registrants are added at a later date, but new registrants will receive the group discount. **5 or more:** \$200 discount for each registrant / **10 or more:** \$400 discount for each registrant

Recording: Unauthorized audio or video recording of HCCA events is not allowed.

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

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

By submitting this registration, you agree to the **Terms & Conditions**, including the **Use of Information** as stated (above), and our Privacy Statement located at hcca-info.org/privacy.aspx.

Credit Card Account Number

Credit Card Expiration Date

Cardholder Name

Cardholder Signature

Registration Methods

MAIL HCCA, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435-2358

ONLINE hcca-info.org/academies

FAX 952.988.0146 (include completed registration form with payment information)

EMAIL helpteam@hcca-info.org (do not include credit card information)

**ONLY 1
ACADEMY
REMAINING**
in 2019

Healthcare Research Compliance Academies

Plan to attend HCCA's three-and-a-half day in-depth program focusing on subject areas at the heart of healthcare research compliance practice.

Healthcare Research Compliance Academies

Las Vegas

November 18–21 LIMITED SEATS

“The material presented was valuable in and of itself, but the ***added value of the fabulous instructors*** made it invaluable!”

“Faculty was very good, ***informative, and experts in their topics***. Fantastic group of people!”

“At least one part of every presentation was applicable to my job, and ***I learned something new at each one***. All of the faculty were very knowledgeable.”

“***Integration of topics*** throughout the conference ***aided in learning the material***.”