

# Research Basic Compliance Academies

**Orlando, FL**  
November 3–6, 2014

**ACADEMIES  
FILL FAST**

**Don't Miss Your  
Last Chance  
to Attend  
in 2014**

Questions: [jennie.nguyen@hcca-info.org](mailto:jennie.nguyen@hcca-info.org)

With a wide range of research-related issues becoming hot topics with enforcement agencies, HCCA's Research Basic Compliance Academy® provides the opportunity to get information on many areas that affect research compliance officers and their staff on a day-to-day basis. A small audience encourages hands-on educational techniques, small group interaction, and networking.

Learn more & register at  
[www.hcca-info.org/academies](http://www.hcca-info.org/academies)

**HCCA®**



HEALTH CARE  
COMPLIANCE  
ASSOCIATION

### MONDAY

8:00 – 8:30 AM

#### Registration and Continental Breakfast (provided)

8:30 – 9:45 AM

#### Health Care Compliance 101



*Debbie Troklus, CHC-F, CCEP-F, CCEP-I, CHRC, CHPC, Managing Director, Aegis Compliance & Ethics Center*

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

10:00 – 11:45 AM

#### Research Compliance 101



*F. Lisa Murtha, JD, CHC, CHRC, Senior Managing Director, FTI Consulting*

- 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

11:45 AM – 12:45 PM

#### Lunch (provided)

12:45 – 2:00 PM

#### Conflicts of Interest



*Juliann Tenney, JD, CHRC, Institutional Research Compliance & Privacy Officer; Director, Institutional Research Compliance Program, The University of North Carolina at Chapel Hill*

- 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
- Discussing action that can be taken to decrease the possibility of conflict of interest situations arising in the conduct of research

2:15 – 5:00 PM (15-MIN. BREAK INCLUDED)

#### Research Billing



*Ryan D. Meade, CHRC, CHC-F, Director of Regulatory Compliance Studies, Loyola University Chicago School of Law*

- 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

### TUESDAY

7:30 – 8:00 AM

#### Continental Breakfast (provided)

8:00 – 9:30 AM

#### Human Research Protections



*Ryan D. Meade, CHRC, CHC-F, Director of Regulatory Compliance Studies, Loyola University Chicago School of Law*

- 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

9:45 – 11:00 AM

#### FDA-Regulated Research



*Kristin H. West, JD, M.S. Pharm., CHRC, Associate Vice President and Director of the Office of Research Compliance, Emory University*

- 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

11:15 – 12:30 PM

#### Research Records Management



*F. Lisa Murtha, JD, CHC, CHRC, Senior Managing Director, FTI Consulting*

- To understand what is the research record
- To differentiate the research record from the medical record
- To define methods for managing the research record for regulatory compliance

12:30 – 1:30 PM

#### Lunch (provided)

1:30 – 3:00 PM

#### Auditing and Monitoring



*Ryan D. Meade, CHRC, CHC-F, Director of Regulatory Compliance Studies, Loyola University Chicago School of Law*

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

3:15 – 4:30 PM

#### Scientific Misconduct



*Juliann Tenney, JD, CHRC, Institutional Research Compliance & Privacy Officer; Director, Institutional Research Compliance Program, The University of North Carolina at Chapel Hill*

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

5:30 PM

#### Networking Event (optional)

### WEDNESDAY

8:00 – 8:30 AM

#### Continental Breakfast (provided)

8:30 – 9:45 AM

#### Data and Safety Monitoring Issues



*Kelly Willenberg, MBA, BSN, RN, CHC, CHRC, President, Kelly Willenberg, LLC*

- 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

10:00 – 11:30 AM

#### Integrating Research Compliance into the Corporate Compliance Program



*John Falcetano, CHC-F, CIA, CCEP-F, CHRC, CHPC, Chief Audit & Compliance Officer, Vidant Health*

- Integrating a research compliance program with an institutional compliance program
- Understanding how the federal sentencing guidelines are appropriately applied to the research compliance program
- Applying risk assessments, specialized training, monitoring and assurance functions, and reporting to your research compliance programs

11:30 AM – 12:30 PM

#### Lunch (provided)

12:30 – 1:45 PM

#### Conducting a Research Risk Assessment



*Dwight Claustre, CHC-F, CHRC, Director, Aegis Compliance & Ethics Center*

- 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?

2:00 – 3:00 PM

#### Animal Research



*Kristin H. West, JD, M.S. Pharm., CHRC, Associate Vice President and Director of the Office of Research Compliance, Emory University*

- 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

3:15 – 4:45 PM

#### Operationalizing Research Compliance



*Kelly Willenberg, MBA, BSN, RN, CHC, CHRC, President, Kelly Willenberg, LLC*

- Strategy to assess state of the “operational engine” of research compliance at your Institution
- Realizing compliance business risk when there is a lack thereof
- Improving inter-disciplinary collaboration with the Hospital/Institution infrastructure
- Increasing the visibility of expert compliance decision-making to hospital/institution hierarchy

### THURSDAY

7:30 – 8:00 AM

#### Continental Breakfast (provided)

8:00 – 10:00 AM

#### Privacy and Security Issues in Research



*Kelly Willenberg, MBA, BSN, RN, CHC, CHRC, President, Kelly Willenberg, LLC*

- 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

10:15 – 11:45 AM

#### Grants Management



*John Falcetano, CHC-F, CIA, CCEP-F, CHRC, CHPC, Chief Audit & Compliance Officer, Vidant Health*

- 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

2:00 PM EXAM CHECK-IN

2:30 – 5:30 PM EXAM TIME

#### Certified in Healthcare Research Compliance (CHRC)<sup>®</sup> Exam

*The CHRC exam is optional. You must be preregistered to sit for the exam. The cost of the exam is not included in the Academy registration fee. To register for the exam, complete the date specific exam application mail or fax as directed on the application. For a link to the exam application, visit [www.hcca-info.org/academies](http://www.hcca-info.org/academies) and look for information on the Academy you are attending.*

*PLEASE NOTE: If you are not present at the specified “Exam 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. Time range above includes mandatory exam procedures and proctor instructions.*

*Please note: agenda and speakers are subject to change.*

### REGISTRATION TERMS

**Payment:** Make your check payable to HCCA. Enclose payment with registration form and return 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. For information on group discounts, please see the box on the registration form. The cost of exams and hotel accommodations are not included in the registration fee. Breakfast and lunch are included in the tuition amount.

**Cancellations/Substitutions:** You may send a substitute in your place or request a conference credit. Conference credits are issued in the full amount of the registration fees paid and are good for 12 months from the date of the cancelled event. Conference credits may be used towards any HCCA service. If you need to cancel your participation, notify us prior to the start date of the event by email at [helpteam@hcca-info.org](mailto:helpteam@hcca-info.org) or by fax at 952-988-0146. Please note that if you are sending a substitute, an additional fee may apply.

### CERTIFIED IN HEALTHCARE RESEARCH COMPLIANCE (CHRC)<sup>®</sup> EXAMS

The cost of the CHRC exam is not included in the Academy registration fee. To register for the exam, complete the date-specific exam application and send directly to AMP, the testing agency. For a link to the exam application, visit [www.hcca-info.org](http://www.hcca-info.org) and look for information on the Academy you are attending. All CHRC exams will be held at 3:00 PM on the final Thursday of the Academy, and will be held in the same hotel as the Academy.

### HOTEL & CONFERENCE LOCATION Orlando, FL | November 3–6, 2014

**Walt Disney World Swan and Dolphin  
1500 Epcot Resorts Boulevard  
Lake Buena Vista, FL 32830**

A special rate of \$199.00 single/double per night has been arranged. In addition there is a Mandatory Resort Services Package fee of \$17.00 per day (exclusive of tax). This fee includes unlimited domestic long distance and local calls, complimentary bottled water replenished daily, high-speed internet access, and unlimited admission to fitness centers featuring the WestinWORKOUT. Make reservations directly with the hotel at 1-800-227-1500 and reference HCCA14. This rate is valid until Friday, October 10, 2014 at 5:00 PM Eastern, or until the group room block is full, whichever comes first.

### CONTINUING EDUCATION UNITS

**HCCA is in the process of applying for additional credits. If you do not see information on your specific accreditation, please contact us at 952-988-0141 or 888-580-8373 as we would like the opportunity to offer it. Visit [www.hcca-info.org](http://www.hcca-info.org) for up-to-date information.**

**ACHE:** The Health Care Compliance Association is authorized to award 23 hours of pre-approved ACHE Qualified Education credit (non-ACHE) for this program toward advancement, or recertification in the American College of Healthcare Executives. Participants in this program wishing to have the continuing education hours applied toward ACHCE Qualified Education credit should indicate their attendance when submitting application to the American College of Healthcare Executives for advancement or recertification.

**AHIMA:** This program has been approved for 23 continuing education unit(s) 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.

**Compliance Certification Board (CCB):** Certified in Healthcare Compliance (CHC)<sup>®</sup>, Certified in Healthcare Compliance-Fellow (CHC-F), 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), Certified Compliance & Ethics Professional-International (CCEP-I): CCB has awarded a maximum of 28.2 CEUs for these accreditations in the following subject areas: Application of Management Practices for the Compliance Professional; Application of Personal and Business Ethics in Compliance; Written Compliance Policies and Procedures; Designation of Compliance Officers and Committees; Compliance Training and Education; Communication and Reporting Mechanisms in Compliance Enforcement of Compliance Standards and Discipline; Auditing and Monitoring for Compliance; Response to Compliance Violations and Corrective Actions; HIPAA Privacy Implementation and/or Complying with Government Regulations.

**CLE:** The Health Care Compliance Association is a State Bar of California Approved MCLE provider, a Pennsylvania Accredited Provider, a Rhode Island Accredited Provider, and a Texas Accredited Sponsor. An approximate maximum of 23.5 clock hours of CLE credit will be available to attendees of this conference. All CLE credits will be awarded based on individual attendance. Please visit [www.hcca-info.org/academies](http://www.hcca-info.org/academies) for CLE details.

**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 and may not accept one-half credits. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Suite 700, Nashville, TN 37219-2417. Website: [www.nasba.org](http://www.nasba.org). A recommended maximum of 28.0 credits based on a 50-minute hour will be granted for the entire learning activity. This program addresses topics that are of a current concern in the compliance environment. This is an update, group-live activity.

For more information regarding administrative policies such as complaints or refunds, call HCCA at 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 12990, for a maximum of 28.2 contact hour(s). The following states will not accept CA Board of Nursing contact hours: Delaware, Florida, New Jersey and Utah. Massachusetts and Mississippi nurses may submit CA Board of Nursing contact hours to their state board, but approval will depend on review by the board. Please contact the Accreditation Department at [ccb@hcca-info.org](mailto:ccb@hcca-info.org) with any questions you may have. Oncology Nurses who are certified by ONCC may request CA Nursing Credit (check box or indicate "Nursing" on the CEU form).

**RACC:** Attendees seeking CRA credits through the Research Administrators Certification Council (RACC) may request a certificate of attendance from HCCA by completing an Application for Continuing Education and indicating RACC/CRA on the form. A certificate of attendance along with a complete brochure should be submitted to RACC at the end of each individual's RACC renewal period. The Research Administrators Certification Council (RACC) promotes the concept of voluntary certification by examination for all research and sponsored programs administrators. Certification in research and sponsored programs administration is highly valued and provides formal recognition of basic knowledge in the field.

**SoCRA:** The Society of Clinical Research Associates (SoCRA—[www.SoCRA.org](http://www.SoCRA.org)) accepts documentation of candidate participation in continuing education programs for recertification if the program is applicable to clinical research regulations, operations or management, or to the candidate's clinical research therapeutic area. This program offers 23.5 hours of CE credit. SoCRA's requirements for recertification Continuing Education credit are quite general, as they pertain to clinical research regulations, operations and management, and to the therapeutic area of the clinical research in which the candidate participates. We therefore leave it to the candidate to determine whether a course or program would be acceptable for SoCRA's CE requirement. SoCRA does not "validate" individual training courses/workshops. Some portions of this program may meet the requirements for CPIA continuing education. The CPIA Council accepts documentation of continuing education hours when the topics fall within the CPIA Body of Knowledge. If you are unsure about whether a specific session meets these requirements you should consult with PRIM&R. Some portions of this program may meet the requirements for CIP continuing education. CCIP accepts documentation of continuing education hours when the topics fall within the CIP Body of Knowledge and the education is intended to be beyond initial, basic or fundamental level education. If you are unsure about whether a specific session meets these requirements you should consult with PRIM&R.

### CONTACT INFORMATION (please type or print)

Mr.  Mrs.  Ms.  Dr.

Member ID \_\_\_\_\_

First \_\_\_\_\_ MI \_\_\_\_\_ Last \_\_\_\_\_

Credentials \_\_\_\_\_

Job Title \_\_\_\_\_

Name of Employer \_\_\_\_\_

Street Address \_\_\_\_\_

City/Town \_\_\_\_\_

State/Province \_\_\_\_\_ Zip/Postal Code \_\_\_\_\_

Phone \_\_\_\_\_

Fax \_\_\_\_\_

Email (required for registration confirmation) \_\_\_\_\_

### GROUP DISCOUNTS

**5 or more:** \$200 discount for each registrant

**10 or more:** \$400 discount for each registrant

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. 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.

### RESOURCES INCLUDED WITH REGISTRATION

*Research Compliance Professional's Handbook: The Practical Guide to Building and Maintaining a Clinical Research Compliance & Ethics Program*

Conference materials binder

**Materials will be given to participants on-site.**



### CHOOSE YOUR ACADEMY

Orlando, FL | November 3–6, 2014

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### REGISTRATION OPTIONS

- HCCA Member .....\$2,500
- Non-Member .....\$3,000
- Registration plus HCCA membership .....\$2,700  
*Save by joining HCCA today (new members only; dues regularly \$295 annually)*
- Registration and membership renewal .....\$2,795  
*Current members, register and renew your membership today*
- Group Discount: subtract \$\_\_\_\_\_ from my registration fee (see details in box at left)

**TOTAL** \_\_\_\_\_

Please note that payment must be sent in at least two weeks prior to the start date or your space may be released. The cost of the hotel accommodations are not included in the registration fee. Breakfast and lunch are included in the tuition amount where indicated on the agenda.

### PAYMENT OPTIONS

#### Mail check to:

HCCA | 6500 Barrie Road, Suite 250 | Minneapolis, MN 55435

**Fax to:** 952-988-0146

- Invoice me
- Check enclosed
- I authorize HCCA to charge my credit card (choose below)

CREDIT CARD:  American Express  MasterCard  Visa

Due to PCI compliance, **please do not provide any credit card information via email.** You may email this application (without credit card information) and call HCCA at 888-580-8373 or 952-988-0141 with your credit card information.

Credit Card Account Number \_\_\_\_\_

Credit Card Expiration Date \_\_\_\_\_

Cardholder's Name \_\_\_\_\_

Cardholder's Signature \_\_\_\_\_

Please make your check payable to HCCA, enclose payment with your registration, and return it to the HCCA office, or fax your credit card payment to 952-988-0146. If your total is miscalculated, HCCA will charge your card the correct amount.

RCA1114

### Health Care Compliance Association

6500 Barrie Road, Suite 250, Minneapolis, MN 55435

[www.hcca-info.org](http://www.hcca-info.org) | [helpteam@hcca-info.org](mailto:helpteam@hcca-info.org)

888-580-8373 (p) | 952-988-0146 (f)



**HCCA**<sup>®</sup>



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