



**Health Care  
Compliance  
Association**

presents

# Research Compliance Conference

June 5 - 7, 2005 | Aladdin Resort & Casino Las Vegas, NV

AND

# Resident Compliance Conference Training for the Resident Trainer

June 8, 2005 | Aladdin Resort & Casino Las Vegas, NV

Register now and receive  
*Guide to Resident Compliance Training*  
**FREE!** (A \$395 value)

REGISTER FOR EITHER  
CONFERENCE BEFORE  
MAY 2

**SAVE \$50**

REGISTER FOR BOTH  
CONFERENCES AND

**SAVE \$200**

Sponsored by:

**PARENTERANDOLPH**

Accountants & Consultants

AIS's Report on Medicare Compliance  
AIS's Report on Research Compliance  
Clinical Trials Compliance



**INFORMATION | REGISTRATION**

## Sunday, June 5, 2005

- 7:30 a.m. - 5:00 p.m. Registration
- 8:00 - 9:00 a.m. Continental Breakfast
- 9:00 - 10:15 a.m. GENERAL SESSION  
**The Big Picture: Key Risk Areas and Compliance Education/Training Topics**  
*Rory Jaffe*, Chief Compliance Officer, UC Davis Health System  
*John Steiner, Jr.*, Esq., Chief Compliance Officer, Cleveland Clinic Foundation
- 10:15 - 10:30 a.m. Break
- 10:30 - 11:45 a.m. GENERAL SESSION  
**From Start to Finish: What Needs to be Done Operationally to Maintain Reimbursement Compliance During Clinical Trials**  
*Swati Ayyargri*, JD, Assistant Director of Compliance, Rush University Medical Center  
*Ryan Meade*, JD, Meade and Roache, LLP
- 12:00 - 1:30 p.m. Lunch Speaker  
**FDA and The Oversight of Device Clinical Trials**  
*Doreen M. Kezer*, MSN, RN, CPC, Special Investigations Branch, Division of Bioresearch Monitoring FDA/CDRH/Office of Compliance
- 1:45 - 3:00 p.m. BREAKOUT SESSIONS
- 101 **Effort Reporting and Compliance**  
*Holley Thames Lutz*, JD, Partner, Sonnenschein, Nath & Rosental LLP  
*Judith Argon*, VP, Research Administration, Children's Hospital of Philadelphia
- 102 **Clinical Trial Billing Process Improvement and Compliance**  
*Jillian Harrington Kuruc*, MHA, CPC, CCS-P, *Ingenix, Inc.*
- 103 **Marketing Compliance for Pharmaceutical Companies**  
*Andy Bender*, President, Polaris Management Partners
- 3:00 - 3:15 p.m. Break
- 3:15 - 4:30 p.m. BREAKOUT SESSIONS
- 104 **Devices and Research Compliance**  
*Robert Wanerman*, Esq., Epstein, Becker & Green, P.C.  
*Kathy Francisco*, MBA, CPC, CEO, The Pinnacle Health Group
- 105 **An Electronic Approach to Handling Operational and Budget Clinical Trial Matters**  
*William Hunt*, President, MedCom Solutions, Inc.  
*Susan O'Connell*, Director, Client Finance, MedCom Solutions, Inc.
- 106 **Privacy Issues for Databases and Repositories and Genetic Research**  
*Thomas Jeffry Jr.*, Esq., Partner, Davis Wright & Tremaine LLP  
*Marti Arvin*, CHC, Privacy Officer, University of Louisville
- 5:00 - 6:30 p.m. Reception

## Monday, June 6, 2005

- 8:00 a.m. - 5:00 p.m. Registration
- 8:00 - 9:15 a.m. Continental Breakfast
- 9:15 - 10:15 a.m. GENERAL SESSION  
**A Sponsor's Perspective on Research Compliance**  
*Karen McDonnell*, Deputy Chief Counsel, Research, Wyeth Pharmaceuticals
- 10:15 - 10:30 a.m. Break
- 10:30 - 11:45 a.m. GENERAL SESSION  
**Off Label Use of Drugs and Devices - Investigative Issues**  
*Bernie Ford*, Managing Director, Navigant Consulting  
*Michael Kendall*, Esq., McDermott, Will & Emery  
*Susan Winkler*, Esq., Assistant United States Attorney, Boston, MA
- 12:00 - 1:30 p.m. Lunch Speaker  
**Research Conduct Update**  
*JoAn Rochez Leonce*, Senior Attorney, Office of the General Counsel, Public Health Division, Dept. of Health and Human Services

- 1:45 - 3:00 p.m. BREAKOUT SESSIONS**
- 201 Privacy Issues for Sponsors**  
*Jessica Blazer*, Esq., Senior Privacy Attorney, Wyeth Pharmaceuticals  
*Jennifer Daniels*, Esq., Blank Rome, LLP
- 202 Scientific Misconduct: The New Face of Fraud**  
*F. Lisa Murtha*, Esq., CHC, Parente Randolph  
*Linda Malek*, Esq., Moses & Singer, LLP
- 203 Investigator Initiated Research - The Perils and the Approach**  
*Kendra Dimond*, Esq., Epstein Becker & Green  
*Stuart Horowitz*, PhD, Director, Miami Children's Hospital Research Institute

**3:00 - 3:15 p.m. Break**

**3:15 - 4:30 p.m. BREAKOUT SESSIONS**

- 204 Developing An Auditing and Monitoring Plan for Clinical Research - Site Perspective**  
*Matthew Staman*, Director, Huron Consulting Group  
*Juliann Tenney*, JD, Assoc. Dean for Compliance School of Medicine, Duke University
- 205 Developing An Auditing and Monitoring Plan for Sponsors**  
*Lynda Hilliard*, Senior Manager, Deloitte & Touche Life Sciences & Healthcare Regulatory Practice  
*Michelle Anderson*, Consultant, Deloitte & Touche Life Sciences & Healthcare Regulatory Practice
- 206 Traffic Problems at the Intersection of Pharmaceutical Companies and Hospital Research**  
*Michael Mustokoff*, Esq., Duane Morris LLP  
*George Bodenger*, Esq., Saul Ewing Law Firm

**Tuesday, June 7, 2005**

**8:00 a.m. - 12:00 p.m. Registration**

**8:00 - 9:00 a.m. Continental Breakfast**

**9:00 - 10:15 a.m. GENERAL SESSION**

**Protecting Human Research Participants: An Enforcement Perspective - Panel**  
**Moderator –**  
*Frank Sheeder*, Esq., Brown Carroll, LLP  
**Panel –**  
*Michael Loucks* (invited), 1st Assistant United States Attorney, Boston, MA  
*David Hoffman*, Assistant United States Attorney, Eastern District of Pennsylvania

**10:15 - 10:30 a.m. Break**

**10:30 a.m. - 12:00 p.m. BREAKOUT SESSIONS**

- 301 Intentional Clinical Trials**  
*Mark Barnes*, JD, LL.M., Ropes Gray LLP
- 302 Partnering with the IRB to Monitor, Audit and Educate**  
*Paul Papagni*, JD, University of Medicine and Dentistry of New Jersey  
*Shelley Carlin*, JD, MPH
- 303 How to Negotiate a Clinical Trial Agreement for Sites and Sponsors**  
*Donna Meyer*, Esq., Cleveland Clinic Foundation  
*Marc Goldstone*, Partner, Hoagland, Longo, Moran, Dunst and Doukas, LLP

**Research Conference  
Continuing Education Credit**

**ACHE**  
 Health Care Compliance Association has forwarded documentation requesting 17 Category II (non-ACHE) continuing education credits for this program toward advancement or recertification in the American College of Healthcare Executives. Participants of this program wishing to have the continuing education hours applied to Category II credit should list their attendance when applying for advancement or recertification in ACHE.

**AHIMA**  
 This program is pending prior approval for 17 CEU Credits for use in fulfilling the continuing

education requirements of the American Health Information Management Association (AHIMA)

**HCCB**  
 This program has been approved for 17 HCCB continuing education credits for Compliance certification.

**NASBA-CPE**  
 Registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor 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 addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Suite 700, Nashville, TN

37219-2417. Phone 615.880.4200. (A maximum of 17 credits based on a 50 minute hour will be granted.) Program Level: Intermediate. Advance preparation: None.

**AAPC**  
 Health Care Compliance Association has submitted this program for continuing education credits from the American Academy of Professional Coders.

**MCLE-CLE**  
 HCCA has applied for CLE credits in the states of AZ, CA, NV and TX - We have requested a total of 17 CLE hours. Please be aware that each state has its own rules and regulations, including its definition of CLE; therefore certain programs may not receive credit in some states.

# Resident Compliance Conference

## Training for the Resident Trainer

June 8, 2005 | Aladdin Resort & Casino Las Vegas, NV

### Agenda

8:30 - 9:00 am	Introduction
9:00 - 10:30 am	Resident Teaching Section
10:30 - 10:45 am	Break
10:45 - 12:00 pm	Resident Teaching Section (continued)
12:00 - 1:00 pm	Lunch
1:00 - 2:30 pm	Teaching Physician Regulations
2:30 - 3:00 pm	Break
3:00 - 4:00 pm	Case Studies and Q&A

### Guest Speakers

<b>Debbie Troklus, CHC</b> Assistant Vice President for Health Affairs/Compliance University of Louisville Louisville, Kentucky
<b>Georgette Gustin, CPC, CCS-P, CHC</b> Director Healthcare Advisory PricewaterhouseCoopers LLP Indianapolis, Indiana

Register now and receive **Guide to Resident Compliance Training FREE!** (A \$395 value)

What education will your residents and/or medical students receive this year? When considering what compliance education is needed for your organization, don't forget the residents and medical students. So many times these individuals are forgotten, and do not receive any compliance related education. This session is geared for the trainer, a how-to, hands-on educational opportunity. Learn how to relate to the physicians and make compliance interesting.

This session will :

1. Provide the trainer with practical tips and suggestions on structuring an effective resident education program.
2. Provide tools, templates and presentations to be used by the trainer in conducting compliance training programs for residents and/or medical students.
3. Provide an overview of the teaching regulations and give advice on what a resident needs to know regarding these regulations.

#### HOTEL ACCOMMODATIONS:

*The conferences will be held at the:  
Aladdin Resort & Casino  
Las Vegas, NV*

Hotel accommodations are not included in the registration fee. Call the **Aladdin Resort & Casino** at (877) 244-9474. Indicate that you are with the HCCA Research Compliance Conference to be eligible for the special group rate of \$159 single/double. The room rate expires Friday, May 13th, 2005. Reservations received after this date will be accepted on a space and rate availability.

#### CANCELLATIONS/SUBSTITUTIONS

No refunds will be given for "no-shows" or cancellations. You may send a substitute; please call the HCCA at (888) 580-8373.

#### Resident Training Conference Continuing 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 addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Nashville, TN 37219-2417 [www.nasba.org](http://www.nasba.org). A maximum of 8 credits based on a 50-minute hour will be granted. Recommended experience level for this course is intermediate to advanced. No prerequisites or advance requirements exist for this activity. This is a live-group activity. For more information regarding administrative policies such as complaint or refund, call the

HCCA at (888) 580-8373.

##### ACHE

The Healthcare Compliance Association is authorized to award 5.75 hours of preapproved Category II (non-ACHE) continuing education credit 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 Category II credit should indicate their attendance when submitting application to the American College of Healthcare Executives for advancement or recertification.

##### HCCB

This program has been approved for 6.9 HCCB continuing education credits for compliance certification.

##### Tax Deductibility

Expenses of training including tuition, travel, lodging and meals incurred to maintain or improve skills in your profession may be tax deductible. Consult your tax advisor.

Federal tax ID: 23-2882664

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# Resident Compliance Conference

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### Registration Information

First name: \_\_\_\_\_ Last Name: \_\_\_\_\_ HCCA Member ID# \_\_\_\_\_

Title: \_\_\_\_\_

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Email: \_\_\_\_\_

Telephone: (\_\_\_\_) \_\_\_\_\_ Fax: (\_\_\_\_) \_\_\_\_\_

*Email & Telephone are required for conference correspondence.*

### Registration Fees: Register by May 2nd and **SAVE \$50**

#### Research Compliance

HCCA Members:  \$595 before May 2  \$645 after May 2  
Non-Members:  \$695 before May 2  \$745 after May 2

#### Sunday, June 5, 2005

1:45 - 3:00 pm SESSIONS

101

102

103

3:15 - 4:30 pm SESSIONS

104

105

106

#### Monday, June 6

1:45 - 3:00 pm SESSIONS

201

202

203

3:15 - 4:30 pm SESSIONS

204

205

206

#### Tuesday, June 7

10:30 am - 12:00 pm SESSIONS

301

302

303

#### Resident Compliance Conference, Training for the Resident Trainer

HCCA Members  \$495 before May 2  \$545 after May 2  
Non-Members  \$545 before May 2  \$595 after May 2

#### Both Conferences: Research Compliance AND Resident Compliance Conference. **SAVE \$200**

HCCA Members  \$890 before May 2  \$990 after May 2  
Non-Members  \$1040 before May 2  \$1140 after May 2

I want to become an HCCA member. Please add \$200 to the member conference registration fee.

### Payment Information

Total Enclosed: \$ \_\_\_\_\_  Check enclosed (make payable to Health Care Compliance Association)

P.O. Number: \_\_\_\_\_  Invoice Me Bill my credit card:  Visa  MasterCard  American Express

Card Number: \_\_\_\_\_ Exp Date \_\_\_\_\_

Name of Cardholder: \_\_\_\_\_ Signature of Cardholder: \_\_\_\_\_

Please note: Should your credit card total be miscalculated HCCA will charge the correct amount due.

**To register: Remit payment and completed registration form via:**



WEB  
www.hcca-info.org



FAX  
(952) 988-0146



QUESTIONS?  
info@hcca-info.org  
1-888-580-8373



MAIL  
Send form with registration fee to:  
HCCA  
5780 Lincoln Dr., Suite 120  
Minneapolis, MN 55436

**HCCA**



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