



OF SOUTHERN WISCONSIN



**Association of Clinical Research
Professionals of Southern WI**

Fall Symposium

Friday November 18, 2011

Crowne Plaza Milwaukee Airport

6401 South 13th Street

Milwaukee, WI 53221

Come join us for the Fall Symposium sponsored by the:

ACRP of Southern Wisconsin

Bringing together CLINICAL RESEARCH PROFESSIONALS from all over the Midwest. This year we will sponsor the event at the

Crowne Plaza Milwaukee Airport in Milwaukee, Wisconsin.

Target audience: all clinical research professionals.

Attendees will receive educational opportunities regarding: The Impact of U.S. Healthcare Reform and Electronic Health Records on the Clinical Research Industry, SOPs, Basic Oncology Concepts for the Research Professional, Practical Regulatory Compliance in Clinical Trials, and FDA Expectations for the Investigator,

Faculty

David Vulcano, LCSW, MBA, CIP, RAC
AVP & Responsible Executive, Clinical Research
Clinical Services Group @ HCA
Former Chair, Board of Trustees @ ACRP

The Continuing Impact of U.S. Healthcare Reform and Electronic Health Records on the Clinical Research Industry: The 'Next' Practices

Objectives:

- *List sections of the Patient Protection and Affordable Care Act that will likely have an impact on the conduct of clinical research in the United States.*
- *List sections of the Health Care and Education Affordability Reconciliation Act of 2010 that will likely have an impact on the conduct of clinical research in the United States.*
- *Arrange a timeline on when the various impacts of the two major U.S. healthcare reform bills will take place.*

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Gizelle Baker, PhD
Chief operating Officer, OV Clinical Trials

Guidance for Investigators – Got SOPs?

Objectives: *Ensuring that your quality system that is (a) robust and comprehensive (b) easy follow & helps ensure compliance (c) documents.*

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Jennifer May, RN, MSN, CCRA

Clinical Research Consultant, May Research, LLC

Jennifer Herring, RN, CCRA

Clinical Research Consultant, Herring Clinical Consulting, Inc.

Basic Oncology Concepts for the Research Professional

Objectives:

- *Review characteristics of the most prevalent solid tumor and hematologic malignancies*
- *Describe different oncology treatment options, including chemotherapy, radiation therapy and biotherapy and how treatment response is evaluated*
- *Demonstrate knowledge of the most common oncology treatment side effects and how toxicity is assessed in clinical trials*

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Adil E. Shamoo, Ph.D., CIP

President and CEO, Human Research Technologies

Practical Regulatory Compliance in Clinical Trials

Objectives:

- *Learn successful strategies in analyzing the ethics and regulatory compliance of clinical trials.*
- *Identify the areas of risks in clinical trials and offer proper resolution*
- *Better understand how to revise, if necessary, protocols and informed consent to comply with regulation.*

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Liz Wool, CCRA, CMT

President & CEO QD-Quality and Training Solutions, Inc.

Member, Board of Trustees, ACRP

FDA Expectations for Investigator: Are you FDA Compliant?

Objectives:

- *Understand FDA Inspection focus of clinical investigators*
- *Describe data quality attributes in clinical research*
- *Identify two topics defined as protocol violations by the FDA during a clinical investigator/site inspection*

AGENDA
ACRP of Southern Wisconsin Fall Symposium
November 18, 2011

- 7:15-8:00 am** Registration and Breakfast
- 8:00-8:15 am** Business Meeting of ACRP of Southern WI
- 8:15-9:45 am** **David Vulcano:** *The Continuing Impact of U.S. Healthcare Reform and Electronic Health Records on the Clinical Research Industry: The 'Next' Practices*
- 9:45-10:00 am** **BREAK-** BEVERAGES AND SNACKS PROVIDED
- 10:00-11:00 am** **Gizelle Baker:** *Guidance for Investigators – Got SOPs?*
- 11:00am – 12:00 pm** **Jennifer May/Jennifer Herring:** *Basic Oncology Concepts for the Research Professional*
- 12:00 pm-1:00 pm** **LUNCH/networking time**
- 1:00-2:30 pm** **Adil Shamoo:** *Practical Regulatory Compliance in Clinical Trials*
- 2:30-2:45 pm** **BREAK-** BEVERAGES AND SNACKS PROVIDED
- 2:45-3:45 pm** **Liz Wool:** *FDA Expectations for Investigator: Are you FDA Compliant?*

Six (6) Contact Hours have been applied for through ACRP. Fees for contact hours are in addition to the registration fee, \$30 for ACRP members and \$45 for non-ACRP members.

If you have any questions concerning the Fall Symposium please contact:

Laura Wollenweber	414-805-5403	lauraw@mcw.edu
Christine Birchbauer	414-476-2423	fun4birch@wi.rr.com
Jennifer Fink	414-649-5097	jennifer.fink@aurora.org
Nordeana Nimphius	414-805-4763	nordeana@hotmail.com

*Note: There are a limited number of rooms available at the hotel to anyone who needs a room the night of November 17th for **\$89**. These must be reserved by **October 18th**. Just mention that it is for ACRP when making your reservations.*

REGISTRATION for ACRP of Southern Wisconsin Fall Symposium

Registration will be **ONLINE** this year at:

<http://www.acrpnet.org/GetInfoFor/USChapters/SouthernWisconsin.aspx>

There will be choices for just registration and for registration with contact hours.

REGISTRATION FEES (NOT INCLUDING CONTACT HOUR FEE):

\$100 Member of National and Local ACRP of Southern WI

\$125 Member of National ACRP only

\$150 Non-ACRP Member

E-mail acceptance of registration will be sent to all who register.

CONTACT HOURS AND FEES FOR CONTACT HOURS

Six (6) Contact Hours have been applied for through ACRP.
Fees for contact hours are *in addition to the registration fee*:

\$30 ACRP members

\$45 Non-ACRP members.

CANCELLATION AND REFUND POLICY:

No Cancellations or refunds after receipt of registration

The registration fee for this course includes breakfast, lunch and breaks, and all instruction materials. ***Registration and payment is due by November 11, 2011.***

REGISTER EARLY!!!

The California Board of Registered Nursing (Provider Number 11147) approves the Association of Clinical Research Professionals (ACRP) as a provider of continuing nursing education.