



“Fear No Yellow Stickies Training Institute”

**Important Topics for Clinical Research Professionals
in these *CHANGING TIMES!***

Tuesday, July 14, 2009

Learning Objectives Include:

Protocol Feasibility

- List the critical categories of research that can affect protocol feasibility.
- Define the protocol characteristics that affect study operations.
- Identify the extraneous protocol factors that change coordinator workloads and study conduct.
- Identify Facility Logistics as it applies to protocol feasibility.

Maximizing Investigator Involvement: Don't Practice Medicine without a License!

- Identify the four topics of research that maximize investigator involvement.
- Describe methods the nurse coordinator can institute to maximize investigator involvement.

The Informed Consent Process in Special Populations

- Identify special populations that trigger unique regulations and procedures during the informed consent process.
- Describe regulations and best-practices regarding informed consent in populations such as pediatrics, prisoners, and the cognitively-impaired.
- List the difference between informed consent in the emergency-medicine setting versus emergency use of a test-article.
- Identify techniques to improve the design of the ICF Template.
- Define basic components of a standard operating procedure for informed consent that complies with FDA/ICH/GCP standards.

Improving Data Quality to Avoid Data Queries

- Define necessary components of source documents that meet FDA/ICH requirements.
- Identify source document review techniques that nurse coordinators can use to enhance a site's internal quality assurance program.
- Identify data inconsistencies that jeopardize protocol compliance.
- List the integral parts of an internal audit plan.

**This Event is
sponsored by the
Norton Healthcare
Research
Department.**

Register On-Line at
www.AureusResearch.com

For additional information:
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Contact Hours Earned: This Presenter-Paced Activity is approved for 5.95 contact hours of continuing nursing education. “This continuing nursing education activity was approved by the Louisiana State Nurses Association (LSNA), an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation.

Price: \$199.00

Location: Norton Healthcare Pavilion, Interactive Conference Room, 4th Floor
315 East Broadway, Louisville, KY 40202

Time: 8:00 am to 8:30 am Registration
8:30 am to 3:30 pm Class

