Clinical Research Coordinator Training

A 16-topic Certificate Program Based in FDA and ICH Requirements

1. Introduction to Clinical Research and the Product Development Process
2. History of U.S. Research Ethics Part 1
3. History of U.S. Research Ethics Part 2
4. Understanding a Protocol and the Importance of Protocol Compliance
5. Clinical Research Versus Routine Medical Care
6. An Overview of the Role and Operation of the IRB/EC
7. The Informed Consent Process
8. Obligations of the Investigator and Clinical Research Professional
9. The Recruitment and Retention of Study Subjects
10. Identification, Reporting, and Management of Adverse Events
11. The Regulations and Practices Regarding Drug and Device Accountability
12. Expectations for the Site in Collections, Handling, and Management of Clinical Lab Data
13. Data Collection: Generating Quality Source Documents and Accurate Case Report Forms
14. Essential Documents: Maintaining the Site's Regulatory Binder
15. What to Expect During Site Monitoring of a Protocol
16. Audits and Inspections

Case Studies, Handouts, and Exercises Included!

New in 2011, this program offers unmatched quality with practical day-to-day training for the research coordinator or study nurse. We illustrate key regulatory principles and industry best practices in a format that allows re-training of experienced coordinators and other research professionals. Developed and taught by industry experts, this course combines audio and visual delivery methods and includes an extensive glossary of terms, as well as, handouts and hyperlinks to applicable regulations and guidance documents. The entire program covers 16 topics with case studies and exercises to reinforce what's presented.

This program focuses on "must know" key topics for coordinators and research nurses, all in a self-paced delivery format. It is based upon ICH/GCP requirements and each of the modules utilizes case studies, exercises, and actual FDA Warning letters to reinforce specific FDA regulations and ICH principles. The program establishes a comprehensive knowledge-base preparing individuals for conducting clinical research in human subjects.

The program will assist in the preparation of any research professional pursuing industry-certification and also serve as documentation of Good Clinical Practice (GCP) training required by many regulatory agencies, institutions, or ethics committees.

Activity is a series of 16 videos averaging 60 minutes per video. Participant has 90 days to complete the course from the initial date of log-on to the system. Participants will be awarded 17.0 contact hours of continuing nursing education upon completion of the learning activity, participant evaluation (quiz) and feedback. Contact hours expire May 31, 2013.

Disclosures: This learning activity is provided by LSUHSC School of Nursing and co-provided by Aureus Research Consultants. There is no conflict of interest or relevant financial interest by the faculty or planners of this activity. There is no commercial support of this activity. There is no endorsement of any product by LSUHSC School of Nursing and Aureus Research Consultants for this activity.

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For more information about course content and pricing, contact Aureus Research Consultants, LLC, 2237 N. Hullen Street, Suite 301, Metairie, LA 70001, USA at www.AureusResearch.com or toll free in the US at 1-877-284-1815, ext. 101.

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