

Course Description

This two-day course is designed to provide a brief overview of clinical research, terminology, and acronyms followed by a comprehensive review of FDA GCP and ICH GCP (E6). It also reviews the fundamental elements involved in coordinating a clinical trial from the investigator's perspective and reviews key FAQs on the FDA form "1572." It includes practical tips and suggestions that can be applied to promote a GCP and HIPAA compliant clinical trial, including preventative measures and problem solving techniques of some of the most common GCP non-compliance issues. MRM provides each participant with a credit card size CD-ROM Regulatory Reference.

Course Objectives

1. Discuss the drug development process and the roles of the clinical research team.
2. Describe FDA / GCP and ICH GCP E6
3. List and discuss the key elements of a clinical trial.
4. Discuss the consent process, source documentation and IMP accountability requirements.
5. Recognize the differences between adverse and serious adverse events.
6. List the key documentation of adverse and serious adverse events.

Contact Hours

Florida State Provider #50-11408, Provider approved by the California Board of Registered Nursing, Provider #CEP 13617 for 11 contact hours. Credits can be applied to ACRP certification.

Daily Agenda / Course Topics

Day 1

I. Overview of Clinical Research

- IDE Studies & IND Studies (Phases & Data Focus)
- Acronym, Terminology, & Forms
- Roles and Responsibilities of the Clinical Research Team

II. FDA GCP & ICH GCP-The Investigator's Perspective

- FDA Guidance: Investigator Supervisory Role, October 2009
- ICH GCP (E6) Section 4: Investigator
- FDA GCP: Investigator Obligations Drug / Biologic / Device Studies
- FDA Form 1572 "Statement of the Investigator"
 - Key FAQs on the FDA Form 1572
 - FDA Form 1572 Completion and Review Activity
- Financial Disclosure by Clinical Investigators
- IRB Role and Responsibility
- Informed Consent Requirements & Documentation
 - Exceptions, Assent, and use of Legal Authorized Representatives
- ICH GCP (E6) Consent Similarities and Differences
- HIPAA: Research Authorization Requirements
- Informed Consent Compliance Drill

Day 2

III. Clinical Trial Fundamentals

- Recommended Standard Operating Procedures (SOPs)
- Study Start up Preparation, Subject Recruitment/Retention, and Source Documentation Strategies.
- Investigational Medicinal Product storage, Documentation, and Potential Issues & Prevention
- GCP compliance using the 8 R's of Consent and Documenting using a TAPC note
- Source Documentation Strategies Developed after Performing a Source Document Gap Analysis
- Budget Analysis and Protocol Feasibility Assessments
- Adverse Event definitions (ICH GCP E2A, and ISO 14155-1:2003)
 - Adverse Device Effects & Serious Adverse Device Effects
 - Serious Adverse Events
- Unanticipated Adverse Device Effects
- AE Drill Exercise

Who Should Take This Course

Clinical research professionals with limited experience or experienced CRCs interested in obtaining a greater understanding of the GCP and HIPAA requirements, or anyone interested in the field of clinical research.

- Course hours are from 9 AM - 4 PM
- Continental breakfast (8:30 AM) and lunch are provided

Fees / Registration

Location: *MRM Headquarters, Coral Springs, FL*

Select a date:

- | | |
|--|---|
| <input type="checkbox"/> September 1-2, 2011 | <input type="checkbox"/> December 1-2, 2011 |
| <input type="checkbox"/> February 23-24, 2012 | <input type="checkbox"/> May 3-4, 2012 |
| <input type="checkbox"/> September 27-28, 2012 | <input type="checkbox"/> December 6-7, 2012 |

Fees: \$995.00 (15% discount for 3 or more)

Register by phone at 1-877-633-3322, online, or complete the information below and fax to 954-346-2791

Name: _____

Address: _____

Tel: _____ Fax: _____

Email: _____

Company Name: _____

Method of Payment:

Company Check MasterCard VISA Amex Discover

Name on card _____

Credit Card # _____

Security Code: _____ Expiration Date: _____

Signature _____

Make checks payable to **Medical Research Management.**

Mail to: **Medical Research Management; PO Box 8629; Coral Springs, FL 33075**

Cancellations and Substitutions

Cancellations by registrants must be provided in writing prior to the start date of the seminar, such registrants shall receive a credit voucher toward a future MRM seminar. Companies may substitute someone registered with another participant at any time. MRM reserves the right to cancel a seminar due to poor enrollment or acts of nature and shall not be responsible for any airfare, hotel, or other costs. MRM shall offer a credit voucher to a future seminar or a complete refund for MRM Seminar cancellations. Seminar topics and speakers may be subject to change without any prior notice.