101 Federal Street, Suite 1900 #10
Boston, Massachusetts 02110-1821
508-865-8907
info@eclinicalresearchconsulting.com
http://www.eclinicalresearchconsulting.com

Clinical Research Education Program
Online Course Agenda

(rev. August, 2006)

CLINICAL RESEARCH EDUCATION PROGRAM

Online Course Agenda

Module 1

The Drug Development Process

1. The Goal of Clinical Research
2. Preclinical and Clinical Research
3. Phases of Clinical Research
4. The Process of Developing a Drug through Clinical Research
5. Common Obstacles

Module 2

The Role of the Principal Investigator

1. What is a Principal Investigator (PI)?
2. FDA Form 1572
3. Principal Investigator Responsibilities
4. GCP Guidelines for Investigators

Module 3

Informed Consent

1. What is Informed Consent?
2. FDA Requirements (Sample ICF Review)
3. Developing and Informed Consent Form

Module 4

The Clinical Research Protocol

1. FDA/GCP Requirements
2. Working with the Clinical Research Protocol
3. Protocol Deviations
4. Protocol Compliance
5. Creating Tools that Aid in Protocol Adherence

Module 5

Understanding Adverse Events

1. What is an Adverse Event
2. What is a Serious Adverse Event
3. Documenting and Reporting Adverse Events
4. IND Safety Reports

Module 6

Source Documentation

1. What are Source Documents?
2. Examples of Source Documents Used in Clinical Research
3. How to Maintain Adequate Source Documentation

4. What are Sponsor Companies Looking For?

Module 7

Essential Documents

1. What are Essential Documents?
2. GCP Guidelines for Essential Documents
3. Maintaining Essential Documents
4. Communicating and Corresponding with the IRB

Module 8

Audits

1. Audits in General
2. Quality Assurance (QA)/Sponsor Audits
3. History of FDA Auditing Program
4. FDA Audits
5. Surviving QA/Sponsor and FDA Audits

Module 9

Non-Compliance, Fraud and FDA Suspension

1. What is Noncompliance?
2. What is Fraud?
3. Why the FDA may Disqualify an Investigator
4. FDA Disqualification Process
5. An Example of an FDA Warning Letter
6. Clinical Investigator Inspection List, FDA Investigator Disqualification List, List of Assurances Accepted for Future Performance of Studies with Investigational Product

Module 10

Completing the Case Report Form/Data Collection

1. What is a Case Report Form?
2. Case Report Form Guidelines
3. How to Complete a Case Report Form
4. Checks and Balances

Appendix 1:

FDA Regulations in Clinical Research
Title 21 CRF – Food and Drug Administration

1. CFR Part 11: Electronic Records; Electronic Signatures
2. CFR Part 50: Protection of Human Subjects
3. CFR Part 54: Financial Disclosure by Clinical Investigators
4. CFR Part 56: Institutional Review Boards
5. CFR Part 312: Investigational New Drug Application
6. CFR Part 314: Application for FDA Approval to Market a New Drug
7. CFR Part 320: Bioavailability and Bioequivalence Requirements
8. CFR Part 601: Licensing

9. CFR Part 812: Investigational Device Exemptions
10. CFR Part 814: Premarket Approval of Medical Devices

Appendix 2:

Guidance for Industry E6
Good Clinical Practice Consolidated Guidance
ICH 1996

1. Introduction
2. Glossary
3. The Principles of ICH GCP
4. IRB/IEC
5. Investigator
6. Sponsor
7. Clinical Trial Protocol
8. Investigator's Brochure
9. Essential Documents

Appendix 3:

Sample Informed Consent Form