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Principal Investigator Education Program Agenda

(rev. August, 2006)

PRINCIPAL INVESTIGATOR EDUCATION PROGRAM

Program Agenda

I. Introductions 9:00am – 9:15am

II. The Drug Development Process 9:15am – 10:00am
1. Types of Research
2. Clinical Research: How Do We Accomplish this Goal?
3. Phases of Clinical Research
4. Common Obstacles

III. Principal Investigator Responsibilities 10:00am – 10:45am
1. What is a Principal Investigator (PI)?
2. FDA Form 1572
3. GCP Guidelines for Investigators

BREAK 10:45am – 11:00am

IV. FDA Regulations in Clinical Research 11:00am – 12:00am
Title 21 CRF – Food and Drug Administration

Reviewed Parts

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

Parts Not Reviewed

1. CFR Part 314: Application for FDA Approval to Market A New Drug
2. CRF Part 320: Bioavailability and Bioequivalence Requirements
3. CFR Part 601: Licensing
4. CFR Part 812: Investigational Device Exemptions
5. CFR Part 814: Premarket Approval of Medical Devices

V. ICH Guidelines for Good Clinical Practice 12:00am – 12:15am
1. What Is GCP and How Do They Differ from FDA Regulations?

VI. Informed Consent 12:15am – 1:00pm
1. What is Informed Consent?
2. FDA Requirements (Sample ICF Review)
3. Developing and Informed Consent Form

LUNCH 1:00pm – 2:00pm

VII. The Clinical Research Protocol 2:00pm – 2:45pm

1. FDA/GCP Requirements
2. Working with the Clinical Research Protocol
3. Protocol Deviations
4. Protocol Compliance

VIII. Understanding Adverse Events 2:45pm – 3:15pm

1. What is an Adverse Event?
2. What is a Serious Adverse Event?
3. Documenting and Reporting Adverse Events

IV. Source Documentation 3:15pm – 3:30pm

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?

BREAK 3:30pm – 3:45pm

IX. Essential Documents 3:45pm – 4:00pm

1. What are Essential Documents?
2. FDA/GCP Regulatory Requirements
3. Maintaining Essential Documents
4. Communicating and Corresponding with the IRB

X. Non-Compliance, Fraud and FDA Suspension 4:00pm – 4:30pm

Questions, Discussion 4:30pm