

# MODULE 1 – REGULATORY / PROCEDURAL

Three (3) day course

**MONDAY 8:00 AM to WEDNESDAY 4:30 PM**

## Module 1 Regulatory / Procedural Module Session Descriptions

### MONDAY

8:00 am to 4:30 pm

#### Issues Involved in Addressing the Drug Development Process

Review and discussion regarding the definitions, regulations and processes from IND to NDA.

**Patricia Beers Block, BS, CCRP**, Assistant Professor, Rutgers University, School of Health Professions

#### ICH Guidelines

Discussion regarding the development and implementation of the International Committee on Harmonisation, the clinical research guidelines resulting from that collaboration, and how the ICH Guidelines affect the clinical researcher.

**Patricia Beers Block, BS, CCRP**, Assistant Professor, Rutgers University, School of Health Professions

#### Study Development and the Research Budget

Review of the (drug, device, biologics) development program, including protocol development, data collection, project and program management, and assessing costs and building budgets. How to develop budgets and strategies for managing costs (at the investigational site). Clinical Research billing compliance from the perspective of a study coordinator will be briefly discussed.

**Bryan Soronson, BS, MPA**, Senior Administrator, Department of Neurology, University of Maryland Medical Center

### TUESDAY

8:00 am to 4:30 pm

#### Clinical Pharmacology and AE Reporting

Understanding the presentation and detection of adverse drug events, the pharmacodynamic and pharmacokinetic mechanisms of reactions, methods of causality assessment, safe medication practices in clinical research, and a review of FDA and OHRP guidance on adverse event reporting.

**John Kessler, PharmD**, President and Chief Clinical Officer, SecondStory Health;  
Chairman, Duke University Health System IRB

#### Good Clinical Practices (GCP) and Preparing for a GCP Audit

Perspectives and regulations regarding adherence to protocol, patient rights, informed consents, and regulatory issues related to an FDA audit.

**George D'Addamio, PhD**, President, PharmConsult, Inc.

### WEDNESDAY

8:00 am to 4:30 pm

#### Source Documentation and Administration

Review of procedural and management issues regarding utilization and disposition of source documents.

**George D'Addamio, PhD**, President, PharmConsult, Inc.

#### IRBs and the Informed Consent Process

Discussion of regulations, generally accepted policies and procedures, and audit practices associated with IRBs and the informed consent process.

**George D'Addamio, PhD**, President, PharmConsult, Inc.

#### Research Ethics

The importance of the informed consent and the principles of medical research ethics are discussed as well as therapeutic misconceptions, randomizations, and placebos.

**Victor Santana, MD**, Vice President of Clinical Trials Administration, St. Jude Children's Research Hospital

**Module 1 offers 21 CE (Continuing Education) credit hours.**

**Module 1 will begin at 8:00 AM Monday (Registration 7:30 AM) and will end at 4:30 PM Wednesday**

*Continental Breakfast will be available beginning at 7:45 daily and a buffet luncheon will be provided daily.*

# MODULE 2 – MEDICAL / SCIENTIFIC

Two and one half (2 ½) day course

**WEDNESDAY 1:00 PM to FRIDAY 4:30 PM**

## Module 2 Medical / Scientific Module Session Descriptions

### WEDNESDAY

1:00 pm to 4:30 pm

#### Research Ethics

The importance of the informed consent and the principles of medical research ethics are discussed as well as therapeutic misconceptions, randomizations, and placebos.

**Victor Santana, MD**, Vice President of Clinical Trials Administration, St. Jude Children's Hospital

### THURSDAY

8:00 am to 4:30 pm

#### Cell Biology

Understanding cell structure, function, and reproduction.

**Richard Sloane, MS**, Durham Technical Community College

#### Genetics and Pharmacogenetics

A review of the development and science supporting these interventions.

**Richard Sloane, MS**, Durham Technical Community College

#### Anatomy and Physiology

Overview of selected body systems and organs and how they function.

**Richard Sloane, MS**, Durham Technical Community College

### FRIDAY

8:00 am to 4:30 pm

#### Analysis of Laboratory Values

A review of basic laboratory values and their importance in the disease process.

**Dean C. Carlow, MD, PhD, FCAP** Section Chief, Clinical Consultation, Memorial Sloan Kettering Cancer Center

#### Epidemiology and Statistical Issues

The study of the distribution and determinants of health related events in certain populations.

**Brad Pollock, PhD**, Professor and Chairman, Department of Epidemiology and Biostatistics, School of Medicine, University of Texas Health Science Center at San Antonio; Associate Director for Cancer Prevention, San Antonio Cancer Institute

**Module 2 offers 17.2 CE (Continuing Education) credit hours.**

**Module 2 will begin at 1:00 PM Wednesday (Registration 12:30 PM) and will conclude at 4:30 PM Friday**

*Continental Breakfast will be available beginning at 7:45 AM and a buffet luncheon will be provided on Thursday and Friday*

## MODULE 1 and MODULE 2

**Five (5) day course**

**MONDAY 8:00 AM to FRIDAY 4:30 PM**

**Module 1 AND Module 2 (combined) offers up to 35 CE (Continuing Education) credit hours**

**This course covers all topics listed under Module 1 and Module 2.**