## Issues Involved in Addressing the Drug Development Process

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

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

## ICH Guidelines

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

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.

## Study Development and the Research Budget

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

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.

## Clinical Pharmacology and AE Reporting

**John Kessler, BS Pharm, PharmD, President and Chief Clinical Officer, SecondStory Health**

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.

## Source Documentation and Administration

**George D’Addamio, PhD, President, ParmConsult, Inc.**

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

## IRBs and the Informed Consent Process

**George D’Addamio, PhD, President, ParmConsult, Inc.**

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

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

**George D’Addamio, PhD, President, ParmConsult, Inc.**

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

## Research Ethics

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

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

Cell Biology
Richard Sloane, MS
Understanding cell structure, function, and reproduction.

Genetics and Pharmacogenetics
Richard Sloane, MS
A review of the development and science supporting these interventions.

Anatomy and Physiology
Richard Sloane, MS
Overview of selected body systems and organs and how they function.

FRIDAY

Analysis of Laboratory Values
Kazunori Murata, PhD, Memorial Sloan-Kettering Cancer Center
Samuel McCash, MD, Memorial Sloan-Kettering Cancer Center
A review of basic laboratory values and their importance in the disease process.

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

COURSE INFORMATION:

You may choose to attend Module I (only), Module II (only) or both Module I and II.

Module I (Regulatory/Procedural Module):
Three (3) day course - Monday 8:00 AM - Wednesday 4:30 PM

Module II (Medical/Scientific Module):
Two and one half (2.5) day course - Wednesday 1:00 PM - Friday 4:30 PM

Module I and Module II:
Five (5) day course - Monday 8:00 AM - Friday 4:30 PM

* Module I and Module II combined offers up to 35 CEUs. This course covers all topics listed under Module I and II.