CLINICAL RESEARCH/ CLINICAL SCIENCE COURSE AGENDA

SOCRA FOR CLINICAL RESEARCH EXCELLENCE

MODULE I - MONDAY - WEDNESDAY

MODULE II - WEDNESDAY AFTERNOON - FRIDAY

MONDAY
MODULE I
8:00 AM - 4:30

Issues Involved in Addressing the Drug Development Process
Patricia Beers Block, MDEd, 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, MDEd, 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.

TUESDAY
MODULE I
8:00 AM - 4:30

Clinical Pharmacology and AE Reporting
John Kessler, PharmD, *President and Chief Clinical Officer, SecondStory Health; Chairman, Duke University Health System IRB*
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 dispostion of source doucments.

IRBs and the Informed Consent Process
George D'Addamio, PhD, *President, ParmConsult, Inc.*
Discussion of regulations, generall accepted policies and procedures, and audit practices associated with IRBs and the informed consent process.

WEDNESDAY
MODULE I
8:00 AM - 4:30

MODULE II
1:00 - 4:30

Good Clinical Practices (GCP) and Preparing for a GCP Audit
George D'Addamio, PhD, *President, PharmConsult, 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.

CLINICAL RESEARCH/ CLINICAL SCIENCE COURSE AGENDA

SOCRA® FOR CLINICAL RESEARCH EXCELLENCE

MODULE I - REGULATORY/ PROCEDURE MODULE - (3 DAY COURSE: MONDAY - WEDNESDAY)
MODULE II - MEDICAL/ SCIENTIFIC MODULE - (2.5 DAY COURSE: WEDNESDAY AFTERNOON - FRIDAY)

THURSDAY MODULE II 8:00 AM - 4:30

Cell Biology
Richard Sloane, MS, *Durham Technical Community College*
Understanding cell structure, function, and reproduction.

Genetics and Pharmacogenetics
Richard Sloane, MS, *Durham Technical Community College*
A review of the development and science supporting these interventions.

Anatomy and Physiology
Richard Sloane, MS, *Durham Technical Community College*
Overview of selected body systems and organs and how they function.

FRIDAY MODULE II 8:00 AM - 4:30

Analysis of Laboratory Values
Kazunori Murata, PhD, *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.