

## **DAY ONE:**

### **8:00 – 8:15 - Registration and Continental Breakfast**

### **8:15 – 9:00 - Welcome and Introduction to the Drug Development Process**

**Carole Sampson-Landers, MD**, Program Chairperson, Former Director, Global Clinical Development, General Medicine, Bayer HealthCare Pharmaceuticals

Dr. Sampson-Landers will review the product development process and discuss how clinical trials are integrated into that process.

### **9:00 – 9:45 - Investigator / Investigational Site Responsibilities**

**Mike M. Rashti, BS**, Consultant, BIMO Auditor & Trainer, LLC; Former FDA Investigator

Mr. Rashti will highlight the importance of investigator and investigational site responsibilities, and relate Good Clinical Practice compliance to successful completion of clinical studies in support of New Drug Applications. He will describe how to prepare for an audit by FDA staff, how to address deficiencies, and will share past audit experiences.

### **9:45 – 10:30 - Protocol Development**

**Janelle Allen, MS, BS, CCRP**, Consultant, Trainer, Faculty, Miami University / Director, Clinical Research Operations, Quality & Education, Institute for Advanced Clinical Trials for Children

Ms. Allen will discuss the fundamental guidelines for development of a clinical research protocol. This presentation will discuss the structure of a protocol including considerations related to research methodology, plans for analysis, budget preparation, and study timelines.

### **10:30 – 10:45 - Break (with opportunity for discussion)**

### **10:45 – 11:30 - Developing Grants for Clinical Research**

**Janelle Allen, MS, BS, CCRP**, Consultant, Trainer, Faculty, Miami University / Director, Clinical Research Operations, Quality & Education, Institute for Advanced Clinical Trials for Children

This talk will focus on types of grants, structure and requirements of grants. It will include discussion on identifying key personnel involved in the development. The talk will discuss format and required components of a writing plan. The talk will include techniques and tips on writing for the reviewers and insight into the grant review process.

### **11:30 – 12:15 - The Informed Consent Process**

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

Mr. D'Addamio will explain the informed consent process, including discussion of various aspects involved in administration and documentation based on established FDA Guidelines. He will also review special considerations that may impact the process and offer suggestions for issues resolution.

### **12:15 – 1:15 - Lunch (Provided) and opportunity for discussion**

### **1:15 – 2:00 - Informed Consent Forms: Compliance? Communication? Confusion?**

**Nancy Wintering, LCSW, CRC, CCRP**, Assistant Director of Research, Brind Center at Thomas Jefferson University

The consent process reflects basic conflicts between compliance with federal regulations vs effective subject communications. This presentation will suggest readability and plain language strategies that can help resolve that conflict. Plus, a case study will describe possible liability issues from two confusing consent forms from a single study.

### **2:00 – 2:45 - Clinical Trial Budgets and Finance**

**Sandra Sarafin, BA, CCRP**, Director, Research Finance Office, Ohio State University

This session will address issues involved in developing a comprehensive clinical trial budget and tracking and managing finances. The speaker will address financial considerations and risk areas.

### **2:45 – 3:00 - Break (with opportunity for discussion)**

### **3:00 – 5:00 - Breakout Sessions**

#### **BREAKOUT #1 Investigator-Initiated Research: Key Steps of Study Conduct**

**Nancy Wintering, LCSW, CRC, CCRP**, Assistant Director of Research, Brind Center at Thomas Jefferson University

Ms. Wintering will provide an overview of the key steps involved in Investigator-initiated research. The roles and responsibilities of a Sponsor-Investigator will be discussed. Ms. Wintering will present critical steps designed to ensure regulatory compliance, to collect high quality data and to assure the protection of human subjects.

**BREAKOUT #2 - "The FDA is here"... Are you ready?**

**Kimberly M. Kiner, BSc, CCRA, President, 2K Clinical Consulting, Inc.**

This session will involve a Mock Audit which will simulate an actual FDA GCP audit, including the introduction, review of documents, interview process, the identification of deficiencies and the debriefing portion of the audit. This session is designed to help effectively prepare for and implement a proactive approach to upcoming/future audits.

**BREAKOUT #3 - Clinical Trial Budget and Finance Workshop**

**Sandra Sarafin, BA, CCRP, Director, Research Finance Office, Ohio State University**

This workshop session will provide hands on, interactive discussion of clinical trial budgeting and financial best practices.

## **DAY TWO:**

**8:15 – 8:30 - Continental Breakfast**

**8:30 - 9:30 - Standard Operating Procedures for the Research Site**

**Leann Speering, MS, CCRP, Senior Clinical Study Manager, MicroPort Orthopedics**

Current GCP guidelines recommend that research sites develop and follow Standard Operating procedures.

This session will review the philosophy and rationale of SOPs, discuss various SOP templates and evaluate a sample SOP.

**9:30 – 10:30 - Source Documentation and Record Retention**

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

This session will discuss source documentation required for clinical research. Topics of discussion will include the regulatory requirements, examples of source documents, and some of the challenges associated with ensuring compliance with the regulations. Practical considerations for managing the research efforts will be offered.

**10:30 – 10:45 - Break (with opportunity for discussion)**

**10:45 - 11:45 - The Clinical Research Environment - An Overview of Research Activities: Roles, Rules & Regulators**

**Marie Falvo, CCRP, Program Chairperson, Senior Clinical Quality Specialist, D&R Operations, Bausch & Lomb, Inc**

This presentation will provide an overview of different types of research, research roles, regulatory bodies and accompanying regulations/standards. The goal of this presentation is to provide investigators and site staff with an understanding of today's clinical research environment and to provide suggestions that can help foster communication and ensure a GCP-compliant research program.

**11:45 – 12:45 - Lunch (Provided) and opportunity for discussion**

**12:45 – 1:45 - Safety Reporting (Adverse Events / Serious Adverse Events)**

**Kimberly M. Kiner, BSc, CCRA, President, 2K Clinical Consulting, Inc.**

This session will review the definitions of adverse events and serious adverse events and adverse drug reactions. We will discuss the reporting requirements and evaluate scenarios related to safety reporting.

**1:45 – 2:45 - Monitoring Visits and Audits: Different Perspectives to Ensure High Quality Research**

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

This session will discuss differences and similarities of monitoring visits and audits, two activities performed by sponsors to ensure high quality research. The relationships between laws, regulations, guidelines, and standard operating procedures will be discussed. The purposes of various types of monitoring visits will be described, as will the objectives and activities associated with a sponsor audit or FDA inspection.

**2:45 - 3:00 Break (with opportunity for discussion)**

**3:00 - 4:00 Clinical Study Agreements**

**Melissa L. Markey JD, CISSP, Attorney, Hall, Render, Killian, Heath & Lyman, P.C.**

This presentation will discuss the most common and problematic terminology inherent in agreements with research sponsors that study personnel need to be aware of in order to assure that the interests of their site and researchers are protected. The speaker will consider negotiating terms and tools that will inform and educate the attendee so that they may be better prepared to negotiate contracts. The speaker will present replacement terminology that will assure better understanding and long-term compatibility among sponsors, contract research organizations, and clinical research sites.

**4:00 Closing / Adjournment**