

SoCRA and FDA Jointly Sponsored Program
FDA Clinical Trial Requirements, Regulations, Compliance and GCP
Agenda for November 4 and 5, 2010 (Thursday and Friday) in Jersey City, NJ

Day One- Thursday, November 4, 2010

- 8:00 - 8:30 **Registration and Continental Breakfast**
- 8:30- 8:45 **Welcome and Opening Comments**
Diana Amador Toro, District Director, New Jersey District Office, FDA
The speaker will address the role of the FDA District Office relative to the Bioresearch Monitoring Program.
- 8:45 – 9:45 **Are We There Yet?**
David Lepay, MD, PhD, Senior Advisor for Clinical Science, Office of the Commissioner, FDA
This presentation will provide an overview of the good clinical practice program through a discussion of achievements in the regulation of FDA regulated clinical trials, the challenges facing Clinical Investigators, Sponsors, and IRBs in clinical research, and the various initiatives underway within FDA.
- 9:45 - 10:15 **Break (with opportunity for conversation and discussion)**
- 10:15 - 11:30 **What FDA Expects in a Pharmaceutical Clinical Trial**
Susan Leibenhaut, MD, Medical Officer, Division of Scientific Investigations, Office of Compliance, Center for Drug Evaluation and Research, FDA
The regulations regarding clinical trials are clear and published. FDA guidance, policies, and requirements abound. This presentation will offer a discussion of the FDA's oversight of the conduct of pharmaceutical clinical research, including trends FDA has found when comparing research with FDA standards for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials.
- 11:30 – 12:30 **Medical Device Aspects of Clinical Research**
Jonathan Helfgott, MS, Consumer Safety Officer, Division of Bioresearch Monitoring, Center for Devices and Radiological Health, FDA
Mr. Helfgott will discuss how studies with investigational devices differ from those with drugs and biologics. These differences can create issues, especially for companies that may have dealt only with pharmaceuticals in the past. There are some similarities between devices and drugs and biologics. Device differences include the nature of firms and studies, statutory distinctions, and regulatory distinctions.
- 12:30 – 1:30 **Lunch (Provided)**
- 1:30 - 2:30 **Adverse Event Reporting – Science, Regulation, Error and Safety**
John Kessler, PharmD, BCPS, Co-Founder and Chief Clinical Officer of SecondStory Health; Clinical Associate Professor in the University of North Carolina School of Pharmacy Chairman of the Duke University Health System Institutional Review Board
The science, regulation and assessment of adverse events will be discussed in a context that brings forth the motivations and ethics of human research protections. The role of systems errors and safe medication practices will be discussed.
- 2:30-3:30 **Working with FDA's Center for Biologics Evaluation and Research**
Patricia Holobaugh, MS, Branch Chief, Division of Inspections and Surveillance Center for Biologics Evaluation and Research, FDA
The Center for Biologics Evaluation and Research regulates research, development, production, and marketing of biologic drug products. This session will consider the organization, mission, and activities of the Center as well as the Center's inspection program.
- 3:30- 3:45 **Break (with opportunity for conversation and discussion)**
- 3:45 - 4:30 **Ethical Issues in Subject Enrollment**
Joal Hill, JD, MPH, PhD, Senior Ethics Consultant; Director of Research Ethics; Chairman, Advocate Health Care IRB
As applied to human subject studies, the ethical principles of respect for persons and justice underlie responsible participant selection requiring fair distribution in the burdens and benefits of research. Although some groups have been specifically identified in federal regulations as particularly vulnerable to exploitation in research, subjects who are not members of those groups may also require special consideration because of cognitive, medical, or other deficits. This session will address how the current research climate (e.g., increased industry investment in research, online research, etc.) affects the ethics of subject enrollment and will suggest ways of recognizing and safeguarding susceptibilities of research subjects.
- 4:30 - 5:00 **Question and Answer Session / Panel Discussion**

Day Two - Friday, November 5, 2010

8:00 - 8:30 **Registration and Continental Breakfast**

8:30 – 9:00 **Keeping Informed and Working Together**

Joan Lytle, *Public Affairs Specialist, New Jersey District Office, FDA*

The speaker will explain how the FDA can assist members of the research community in their efforts to find information and understand FDA regulations.

9:00 - 9:45 **FDA Conduct of Clinical Investigator Inspections**

Deborah Nixon, *Investigator, New Jersey District Office, FDA*

The speaker will explain the responsibilities of the Clinical Investigator including the regulations and guidelines to which the FDA expects the Clinical Investigator to adhere in their participation, review and oversight of clinical investigations.

9:45 - 10:00 **Break (with opportunity for conversation and discussion)**

10:00 - 10:45 **Investigator Initiated Research**

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

The Sponsor/Investigator takes on numerous additional responsibilities including Protocol Development, assurance of Peer Review, development and quality assurance related to Data Capture Procedures. They must secure Financial and Clinical Resources, and they have the opportunity for Publication. All of these activities fall under the regulations and are subject to FDA oversight. This session will offer details about the Sponsor/ Investigator's legal responsibilities and insight into the additional activities the Sponsor/Investigator must provide.

10:45-11:30 **Meetings with the FDA - Why, When and How**

June Germain, MS, *Regulatory Health Project Manager, Division of Special Pathogen and Transplant Products, Office of Antimicrobial Products, Center for Drug Evaluation and Research, FDA*

It is of utmost importance to the research project to assure good communication and timely interactions with the FDA. This speaker will discuss the regulatory tools available to sponsors/investigators to enhance the communication process with the FDA and offer some practical tips that can greatly facilitate the review process.

11:30 - 12:15 **Part 11 Compliance - Electronic Signatures**

Jonathan Helfgott, MS, *Consumer Safety Officer, Division of Bioresearch Monitoring, Center for Devices and Radiological Health, FDA*

This session offers discussion of Part 11 compliance, including scope, implementation, and definitions. The regulations in Part 11 establish the criteria under which the agency considers electronic records, handwritten and electronic signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

12:15 – 1:15 **Lunch (Provided)**

1:15 - 2:00 **IRB Regulations and FDA Inspections**

Dawn Wydner, *Investigator, New Jersey District Office, FDA*

During this session, the speaker will discuss FDA regulations covering the operations of Institutional Review Boards, the procedures used by FDA investigators during inspections of IRBs, and FDA enforcement options.

2:00-2:45 **Informed Consent Regulations**

Peter Lenahan, *Investigator, New Jersey District Office, FDA*

This discussion considers regulations addressing the Informed Consent process and documentation from the inspector's point of view.

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

3:00 - 3:15 **The Inspection is Over - What Happens Next? Possible FDA Compliance Actions**

Patricia Holobaugh, MS, *Branch Chief, Division of Inspections and Surveillance Center for Biologics Evaluation and Research, FDA*

Ms. Holobaugh will discuss the array of actions taken when research fails to meet standards enforced by the FDA.

3:15 - 4:35 **Question and Answer Session / Panel Discussion**

4:35 **Closing Remarks and Adjournment**