

Legal, Ethical and Practical Considerations in Protecting Human Research Participants

Thursday, April 10, 2008

8:15-8:30 **Registration and Continental Breakfast**

8:30-9:15 **The Identification and Management of Investigator and IRB Member's Conflict of Interest**
Ernest D. Prentice, PhD, Associate Vice Chancellor for Academic Affairs, University of Nebraska Medical Center

Financial conflict of interest has become a major issue in today's research environment which threatens to compromise the public's trust. Clearly, conflict of interest must be identified and appropriately managed. This presentation will address conflict of interest of investigators as well as IRB members and describe various management techniques.

9:15-10:00 **OHRP: Where We've Been, Where We're Going**

Kevin L. Nellis, MS, MT(ASCP), Public Health Analyst, Division of Education and Development, Office for Human Research Protections, U.S. Department of Health and Human Services

Mr. Nellis will present a brief overview of the Department of Health and Human Services (HHS) human subject protection regulations, with emphasis on challenging issues facing today's clinical research professionals. Mr. Nellis will also provide an update on new and upcoming OHRP guidance and initiatives important to personnel conducting HHS-supported research.

10:00-10:30 **Break**

10:30-11:15 **What is the Value of Pharmacovigilance?**

Jacqueline Edwards, RN, BS, CCRA, Senior CRA, inVentiv Clinical Solutions

The critical role of pharmacovigilance in the world of clinical R&D today will be presented. Several case studies will be provided to illustrate the current industry trends in pharmacovigilance.

11:15-12:00 **Protecting Clinical Trial Subjects: The Role of the Data Monitoring Committee (DMC)**

Ron Kershner, PhD, Vice President, Biometrics, NPS Pharmaceuticals

The DMC plays a critical role in the protection of human subjects during the conduct of the clinical trial. During this session, the key responsibilities of the DMC, the applicable regulations and guidances, and the critical evaluation and decision-making roles played by the members of the DMC team will be reviewed.

12:00-1:00 **Lunch (Provided)**

1:00-1:45 **EDICT: Eliminating Disparities in Clinical Trials**

Dan Bustillos, JD, PhD, Assistant Professor, Center for Healthcare Ethics, St Louis University

The use (and abuse) of certain underprivileged groups in American medical research has had a long and sordid history. This talk will apprise attendees about this history in order to form a foundation upon which to speak about current regulatory and policy environments for the recruitment and retention of certain underrepresented groups. It will give an overview of how abuse of certain groups in our history has paved the way for current FDA and NIH regulations and policies that may have had the inadvertent effect of creating a class that is now underrepresented in possibly beneficial clinical trials.

1:45-2:30 **Ethical Considerations in Pediatric Research**

Victor M. Santana, MD, Associate Director for Clinical Programs, St. Jude Division Director of Solid Tumors, St Jude Children's Research Hospital

Dr. Santana will review the unique regulatory and ethical issues applicable to the conduct of research in children.

2:30-2:45 **Break**

2:45-3:30 **The Shared Responsibility for Safety**

Neila Smith, MD, Advisor: Safety & Pharmacovigilance

During the conduct of clinical trials, there is a shared responsibility for subject safety between the sponsor, study site, monitor, DMC, and regulatory agencies involved. This presentation will cover the responsibilities of each player and present an overview within the context of a global clinical trial project.

3:30-5:00 **IRB Operations: The Role They Serve in the Protection of Human Research Participants**

NCI IRB – Suzanne Pursley-Crotteau, PhD, RN, Director, Protocol Review Office, National Cancer Institute, NIH

Academic Medical Center IRB – Yvonne Higgins, CIP, Director, Human Research Protection, Office of Regulatory Affairs, University of Pennsylvania

Community Medical Center IRB - Harris Stutman, MD, Executive Director of Research, Long Beach Memorial Medical Center

IRBs play a major role in the protection of human research participants. Panel members will discuss the perspective of their IRB on certain topics, including; member selection and training; determining when to bring in a subject matter expert; Investigator training requirements; maximizing communication between the Investigator and the IRB; and electronic systems used in IRB submissions and/or adverse event reporting. The panel will also discuss any major problems they have encountered and how they solved them and will present unique aspects of their system.

Friday, April 11, 2008

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

8:30-10:30 **Informed Consent: Compliance vs. Communication and Perceptions vs. Reality**

Mark Hochhauser, PhD, Readability Consultant

David Perlman, PhD, Senior Lecturer, Penn School of Nursing; Associate, Penn Center for Bioethics

This program will describe informed consent conflicts faced by researchers who must not only comply with federal regulations but also communicate clearly with prospective subjects. In addition to summarizing the history, ethics, and regulatory aspects of informed consent, this presentation will identify challenges associated with successful implementation of informed consent. Incompatibilities between the perception and reality of informed consent will be identified in 1) regulatory writing requirements, 2) communication myths and 3) readability vs comprehension inconsistencies.

10:30-10:45 **Break**

10:45-11:30 **The Role of Study Coordinators in Protection of Human Subjects**

Kathleen B. Quinlan, CCRP, Quality Manager, SNBL Clinical Pharmacology

An overview of the role and responsibilities of the subject coordinator in the conduct of clinical trials will be presented. The speaker will emphasize the value of a knowledgeable coordinator as their role impacts the investigators, the clinical trial and most importantly participants.

11:30-12:15 **The Role of the Patient Advocate in Protecting Clinical Trial Participants**

Fran Visco, President, National Breast Cancer Coalition

Protecting clinical trial participants begins with protocol design and must be the primary focus throughout the process. Knowledgeable patient advocates must participate in decision making at all levels of clinical trials, from trial design, to oversight and implementation. Several training programs have been successfully conducted to enable advocates to fulfill these roles and collaborations with advocates have enhanced both patient protection and the conduct of trials.

12:15-1:15 **Lunch (Provided)**

1:15-2:15 **Legal Issues in Clinical Research**

Jason Kaar, JD, Associate General Counsel / Assistant Professor, Uniformed Services University of the Health Sciences

This presentation will provide an overview of the operation of the legal system in general and its impact on research. Intermixed with law is ethics, even though the two do not always agree with one another. Practical considerations based on actual situations will also be presented.

2:15-3:00 **SOP Considerations: Standardizing Procedures at the Study Site for Effective Delivery of Informed Consent**

Gayla Herschler, MSN, RNC, CCRP, Clinical Research Manager, Scott & White Memorial Hospital

Ensuring the protection of the research participant through carefully planned and conducted trials and adherence to Good Clinical Practice is paramount. Informed consent is one of the first steps for a trial participant. Yet, this informed consent process is a complex one to which each individual brings their own personality and beliefs. Having a standard operating process for obtaining informed consent helps reduce variances in the type and amount of information the potential participant receives.

3:00-3:15 **Break**

3:15-4:45 **Training of Clinical Trial Professionals Regarding HSP Considerations**

Karen Davenport, MS,BSN,CCRC, Sr Clinical Research Coordinator, University of Virginia School of Medicine Clinical Trials Office

Carolyn Rugloski, MS, CCRP, VP, Training and Strategic Development, inVentiv Clinical Solutions

Cheryl Jacobs, BA, CCRP, Director of Clinical Research, Breastlink Medical Group, Inc

The panel will discuss many important training aspects related to HSP and provide key highlights of successful training programs in the field. Covering the viewpoints from a university clinical trial setting, a private study site, and a CRO perspective, the panel members will present several program highlights revealing critical training components related to HSP. Participants will take part in a case study review and discussion at the conclusion of the panel presentation.