



Protecting Human Research Participants - Legal, Ethical and Practical Considerations

Agenda for April 26 and 27, 2012 (Thursday and Friday) in Boston, MA

Day One - Thursday, April 26, 2012

- 8:15 - 8:30 Registration and Continental Breakfast
- 8:30 -12:00 **Informed Consent: Compliance vs. Communication and Perceptions vs. Reality**
Mark Hochhauser, PhD, Readability Consultant / IRB Member
David Perlman, PhD, President and Founder,
E-4 – Eclipse Ethics Education Enterprises, LLC
This presentation will focus on: 1) Knowing the fundamental history, ethics and regulatory aspects of informed consent and 2) Understanding the myriad challenges associated with successfully implementing informed consent. An example of confusing law, ethics and practice will be included, and several ethical case studies will be discussed.
- 10:00 -10:30 Break
- 12:00 -1:00 Lunch (Provided)
- 1:00 -2:00 **The Role of the Data Monitoring Committee**
Ronald Kershner, PhD, VP Biostatistics and Data Operations,
Premier Research Group
The responsibilities of the Data Monitoring Committee (DMC) will be discussed from the perspective of protecting patient safety and providing critical, independent oversight to key study objectives. Operational considerations, such as meeting frequency and content, control of information, data cleaning issues and scope and format of data tabulations will be discussed when DMCs are used. Examples from clinical trials will be used to illustrate key points.
- 2:00 -2:30 **Case Study in Research Ethics - Device**
Carolyn Rugloski, MS, CCRP, Senior Project Manager, Paragon Biomedical, Inc.
In this interactive session, workshop participants will identify and discuss human research protection issues through case study examples.
- 2:30 - 2:45 Break
- 2:45 - 3:45 **Ethical Considerations in Pediatric Research**
Victor Santana, MD, VP Clinical Trials Administration,
St. Jude Children's Research Hospital
Advances in pediatric medicine over the past 50 years have led to dramatic improvements and important benefits in the health care of children. Special ethical and regulatory considerations have been central to this progress and new initiatives currently under way have stimulated further research efforts. We will review specific pediatric regulatory and ethical considerations including recent national and international efforts that impact the conduct of research in children.
- 3:45 – 4:30 **State Regulations Protecting Research Participants**
Cheryl Jacobs, CCRP, Vice President Research Operations,
Translational Research Management
A number of states have regulations governing clinical research. Most of these regulations are intended to provide additional protections for trial participants. We will examine a number of these regulations and their impact on subject participation and study conduct.



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Day Two - Friday, April 27, 2012

8:15 - 8:30 Continental Breakfast

8:30 -10:00 **Legal Issues in Clinical Research**

**Jason Kaar, JD, Deputy General Counsel,
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.

10:00 -10:15 Break

10:15 -11:15 **Educating Medical Professionals in the Conduct of Human Research**

**Victor Santana, MD, VP Clinical Trials Administration,
St. Jude Children's Research Hospital**

Dr. Santana will focus on providing insights into the training and education of medical health care professionals in the ethical conduct of human research. These activities should be part of a continuum in health care education that may begin in the formative years of medical school, residency training and carried forward into a life-long professional career.

11:15 -12:15 **Continuing Education for IRB Members and IRB Staff: Why is That Important?**

**Felix Khin-Maung-Gyi, PharmD, MBA, CIP, RAC, Chief Executive Officer,
Chesapeake IRB**

While the responsibility of protecting the safety, rights and welfare of research participants is shared among all involved in the research enterprise, the IRB plays a central role in this process. The efficiency and effectiveness of the IRB members are maximized to the extent they have adequate support by the staff. In the current environment of evolving technology, changing regulatory and legislative climates, and increased business competition, IRB members and staff must have access to ongoing training and education in order to fulfill their duties.

12:15 -1:15 Lunch (Provided)

1:15 -2:15 **Human Research Protection - Shared Responsibility for Safety**

**George Demos, MD, Senior Medical Director, Global Safety and Epidemiology,
Allergan, Inc.**

Dr. Demos will review the relationship between study subjects, investigators, sponsors, institutional review boards, contract research organizations and regulators and how to manage those relationships for successful outcomes.

2:15 - 2:30 Break

2:30 - 3:30 **FDA Inspections and Human Subject Protection**

**M. Patricia Murphy, Bioresearch Monitoring Specialist,
U.S. Food and Drug Administration**

Discuss FDA inspection procedures, informed consent documentation, case studies, and the impact significant deviations may have on human subject protection.

3:30 - 4:15 **Case Study in Research Ethics - Drug**

Carolyn Rugloski, MS, CCRP, Senior Project Manager, Paragon Biomedical, Inc.

In this interactive session, workshop participants will identify and discuss human research protection issues through case study examples.