



# *The Buck Starts & Stops Here: Investigator Responsibilities for the Ethical Conduct of Research*

**San Diego Convention Center • San Diego, CA  
December 5, 2010 • 8:30 AM-4:30 PM**

This full-day program is designed for researchers whose studies involve human subjects. The goal is to provide them with the practical knowledge needed to ensure they design high-quality, ethical clinical trials that are in compliance with federal regulations. Topics will include what every researcher needs to know about designing and running safe, ethical, and effective studies; working with an IRB; the informed consent process, conference, and form; ethical and practical issues of recruitment and retention; financial and non-financial conflicts of interest; and communicating with an IRB, the FDA, patients, and subjects.

## Agenda\*

7:00 AM	<i>Registration</i>
7:00-8:30 AM	<i>Continental Breakfast</i>
8:30-8:45 AM	<b>Welcome and introduction</b>
8:45-9:45 AM	<b>What Every Researcher Needs to Know About Their Responsibilities to Subjects In Order to Design and Run Safe, Ethical, and Effective Studies</b> <i>Bruce Gordon, MD; University of Nebraska Medical Center</i>
9:45-10:30 AM	<b>What Every Researcher Needs to Know About Financial and Non-Financial Conflicts of Interest and How to Avoid Compromise or Loss of Objectivity</b> <i>Mark Barnes, JD; Harvard University</i>
10:30-10:45 AM	<i>Break</i>
11:00 AM-12:00 PM	<b>What Every Researcher Needs to Know About Ethical and Practical Issues in the Recruitment and Retention of Research Subjects</b> <i>Joseph Brown, PhD; University of Nebraska Omaha</i>
11:45-12:15 PM	<b>Boxed Lunch</b>

## Agenda

---

- 12:15-1:15 PM **What Every Researcher Needs to Know About the Informed Consent Process, Conference, and Form**  
*Sue Fish, PharmD, MPH; Boston University School of Public Health*
- 1:15-2:15 PM **What Every Researcher Needs to Know About Research Competence, Communications & Partnerships: Are the Right People on the Job, Partnering With Your IRB and Communications with Your Research Partners – subjects, IRB, OHRP, FDA & Your Team**  
*Greg Koski, MD; Harvard Medical School*
- 2:15-3:15 PM **Case Studies, OHRP Compliance Findings, Warning Letters**  
At this time, attendees will break into small groups to discuss their case and prepare a summary of findings and lessons to the group
- 3:15-3:30 PM *Break*
- 3:30-4:30 PM **View Movie Clips from various films that illustrate the concepts presented in this workshop, followed by discussion of these concepts**  
*Charlotte Coley, MACT, CIP; Duke University*
- 4:30-5:00 PM **Questions, answers, and discussion**
- 5:00 PM *Adjournment*

\* Please note the agenda is subject to change.

# Agenda

---

➤ **What Every Researcher Needs to Know About their Responsibilities to Subjects In Order to Design and Run Safe, Ethical, and Effective Studies**

This presentation will include a summary of the background information for researchers, including the history of research ethics and the current state of the federal regulations governing human subjects research. It will also cover the researcher's responsibility over the entire study staff, will outline the top findings from the reports of auditors who have reviewed research protocols, and will describe best practices for handling complaints.

➤ **What Every Researcher Needs to Know About Financial and Non-Financial Conflicts of Interest and How To Avoid Compromise or Loss of Objectivity**

This presentation will review the definition of conflicts of interest (COI) and why it matters to the researcher, the IRB, and the study as a whole. Addressing and managing COI issues before starting a study will avoid serious problems that could derail the study, divert attention from the study results, and cause potential research subjects to avoid clinical trials.

➤ **What Every Researcher Needs to Know About Ethical and Practical Issues in the Recruitment and Retention of Research Subjects**

This presentation will examine the third Belmont Principle, justice, in the identification and recruitment of subjects. Subjects recruitment has implications for the retention of subjects until the end of a study, and the diversity of subjects not only shares the burdens and benefits of research, but contributes to whether the study results can be applied to a broader population.

➤ **What Every Researcher Needs to Know About the Informed Consent Process, Conference, & Form**

This presentation will provide a hands-on lesson on how to craft consent forms and educate prospective subjects in a manner that strengthens the study. The informed consent conference should be approached as a partnership with the subject and, when handled in an ethical and sensitive manner, can help ensure subject comprehension and better data, a win/win for everyone. The session will also introduce attendees to the current thinking regarding the need for simplified consent forms, as per the AAMC's recent initiative. Finally, the importance of revisiting the consent during the research will also be addressed.

➤ **What Every Researcher Needs to Know About Research Competence, Communications & Partnerships: Are the Right People on the Job, Partnering With Your IRB and Communications with Your Research Partners – subjects, IRB, OHRP, FDA & Your Team**

This presentation will examine essential elements needed to effectively communicate with the IRB, regulatory agencies, and your subjects. We will explore what you should report to your IRB, and how to do so in the most productive manner. The speaker will further discuss what to tell sponsors and the FDA (and give a glimpse of what IRBs have to communicate to other agencies and regulators). Finally, we will cover communication with subjects beyond the consent form, such as conveying new information and current thoughts on the responsibility of investigators to transmit study results, sometimes well after the subject's participation ends.