

webinar

Expanded Access: Ethical & Regulatory Issues for Investigational Drugs & Devices

Wednesday, Sept. 15, 2010 | 1:00 – 2:30 PM ET



PRIM&R PUBLIC RESPONSIBILITY IN
MEDICINE AND RESEARCH

Join **Public Responsibility in Medicine and Research (PRIM&R)** for a webinar titled ***Expanded Access: Ethical and Regulatory Issues for Investigational Drugs and Devices***, to be held **Wednesday, September 15, 2010, from 1:00 to 2:30 PM ET**.

Two esteemed faculty members will share their expertise, explain their unique regulatory and institutional perspectives, and present a comprehensive view of expanded access. During this program, you'll learn more about:

- Ethical and regulatory implications of expanded access programs for institutional review boards (IRBs), patients, healthcare providers, and researchers;
- Distinctions between expanded access programs and clinical research;
- Interpretations and applications of investigational drug and device regulations; and
- Strategies for managing these complex issues successfully.

Faculty

Richard Klein is the HIV/AIDS program director with the FDA Office of Special Health Issues, serving as the primary interface between the agency and the HIV/AIDS patient and advocacy communities. He works extensively with HIV and other patient communities and within the agency's scientific offices to address issues including drug access, product safety, and clinical trial design. Mr. Klein has worked at the FDA in various capacities for more than 30 years, and is a member of the FDA IRB, participating in the ethical review of research conducted by the agency.

George Gasparis is the assistant vice president and senior assistant dean for research ethics at Columbia University Medical Center. He also serves as the executive director, human subjects protection program for both Columbia University and Columbia University Medical Center. Before his arrival at Columbia University in June 2003, Mr. Gasparis was the director for the division of assurances and quality improvement at the Office for Human Research Protections (OHRP). He received his CIP[®] in 2003.

Who should attend?

The target audience for this webinar includes institutional officials, investigators, physicians, research staff, human research protections program (HRPP) professionals, and IRB members and administrators.

For more information, please visit www.primr.org.

Questions?

Call Alexandra Shlimovich at 617.423.4112, ext. 18, or e-mail ashlimovich@primr.org

webinar

Conflicting Interest and Conflicting Expectations: Challenges Presented by NIH's New Rule

Wednesday, October 6, 2010 | 1:00 - 2:30 PM ET



PRIM&R PUBLIC RESPONSIBILITY IN
MEDICINE AND RESEARCH

Public Responsibility in Medicine and Research PRIM&R is pleased to offer a webinar titled *Conflicting Interest and Conflicting Expectations: Challenges Presented by NIH's New Rule*, on **Wednesday, October 6, from 1:00 to 2:30 PM ET**.

This webinar will provide an array of concrete tools to assist those who will be charged with developing strategies to manage the transitions required once the NIH rule is finalized. More specifically, this webinar will:

- Broaden your understanding of the laws, ethics, and recommended standard operating procedures (SOPs) for identifying and managing financial conflicts of interest;
- Explain the expected areas of focus in the forthcoming NIH rule;
- Discuss the procedures that will likely be necessary to comply with the new rule;
- Offer strategies for integrating those procedures into your institutional culture;
- Review some of the unique challenges involved in educating institutional leadership and faculty, including possible approaches for effective educational programs; and
- Compare the roles and responsibilities of institutional review boards (IRBs) and institutional conflicts committees in identifying, responding to, and/or managing conflicts.

Faculty

David Korn is the vice provost for research at Harvard University, as well as professor of pathology at Harvard Medical School, since 2008. Before Harvard, Dr. Korn served as the chief scientific officer and senior vice president for biomedical and health sciences research at the Association of American Medical Colleges (AAMC). Dr. Korn served as Carl and Elizabeth Naumann Professor and dean of the Stanford University School of Medicine from 1984 to 1995, and as vice president of Stanford University from 1986 to 1995. From 1984 to 1991 he served as chairman of the National Cancer Advisory Board, a position to which he was appointed by former President Ronald Reagan. Previously, he had served as professor and chairman of the department of pathology at Stanford, and chief of the pathology service at the Stanford University Hospital, since 1968.

Patrick Taylor is currently a mid-career fellow at the Petrie-Flom Center at Harvard Law School and assistant clinical professor at Harvard Medical School. Until recently, he was the deputy general counsel and chief counsel for research affairs at Children's Hospital Boston. Starting on Wall Street, he has successively worked in government, and the nonprofit world, on diverse aspects of health care law and policy and biotechnology. His current work focuses primarily on legal, ethical and policy issues in biomedical research, biotechnology, and compliance, including privacy.

Who should attend?

The target audience for this webinar includes institutional officials, deans, provosts, and department chairs, federal agency representatives, sponsors, ethicists and policy analysts, and anyone working with or for a human research protections program (HRPP) or IRB.

For more information, please visit www.primr.org.

Questions?

Call Alexandra Shlimovich at 617.423.4112, ext. 18, or e-mail ashlimovich@primr.org