AGENDA

Refreshments
Ford Auditorium Lobby

Welcome & Introduction
Judith Birk, JD
2:00 pm
A brief history and overview of the Common Rule Changes.

Impact on Current and Future Research
Ray-Nitra Reynolds, MLIS, CIP
2:15 PM
Recent sIRB requirements, FDA harmonization with the Common Rule & a discussion on the state of available guidance for implementation of new regulatory requirements.

Additional Federal and Institutional Updates
Corey Zolondek, PhD, CIP
2:35 PM

Updated Informed Consent Requirements
Joseph Austin, JD LL.M
2:55 PM

Mock IRB
3:30 pm
The mock IRB will review an amendment to an Oncology study to demonstrate review of the new Common Rule requirements for Informed Consent. This will be followed by a Q&A session with IRBMED Board Members comprising the mock IRB:

Robert Davenport, MD, Chair
Judith Avery, MA
Pam Brown, MD, PhD

Robert Eber, DDS, MS
Duke Morrow, MDiv, DMin
Amy Skyles, PharmD

Wendy Ulmer, BBA – Senior Associate Regulatory Analyst

Q&A
3:55 PM