IRBMED SEMINAR SERIES

Common Rule Preparedness: An Eleventh Hour Look at the Common Rule Changes

IRBMED
MEDICAL SCHOOL OFFICE OF RESEARCH

Ford Auditorium
December 18, 2018
2:00 pm – 4:00 pm

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
Additional Federal and Institutional Updates	Corey Zolondek, PhD, CIP	2:35 PM
Recent sIRB requirements, FDA harmonization with the Common Rule & a discussion on the state of available guidance for implementation of new regulatory requirements.		
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

Seminar Series