IRBMED SEMINAR SERIES

Phase I Clinical Trials and Safety: Consideration of a Subject's Death in France

IRBMED
MEDICAL SCHOOL OFFICE OF RESEARCH

Danto Auditorium
October 4, 2016
2:00pm – 4:30pm

AGENDA

Welcome & Introduction	Judith Birk, JD	**2:00pm**
Video/Definition of Phase 1 Trials		2:10pm
Mock IRB		2:20pm

This installment in our series of mock IRB meetings provides insight into IRB review of a serious adverse event involving the death of a subject on a Phase I clinical trial. This will be followed by a Q&A session with IRBMED Board Members comprising the mock IRB:

Robertson Davenport, MD
Michael Geisser, PhD
Duke Morrow, MDiv, DMin
Michael Paschke, MA
Robin Sedman, AM, MSN
Amy Skyles, PharmD
Alan Sugar, MD

Institutional evaluation of the event	Judith Birk, JD Lois Brako, PhD (UMOR)	2:50pm
Break and snacks	----------	3:30pm
Regulatory reporting and outcomes	Pat Ward, MPA (Regulatory Affairs)	3:40pm
Summary and questions	Presenters	4:20pm
End	----------	**4:30pm**

Seminar Series