



Ethics, Regulations and Study Implementation For Research Involving Human Subjects

Co-Sponsored by GHUCCTS

Friday, March 23, 2018

MedStar Health Research Institute

6525 Belcrest Road

Suite 700

Hyattsville, MD 20782

AGENDA

Time	Content	Faculty
8:00 am – 8:30 am	Registration and Breakfast	
8:30 am – 8:45 am	Welcome to MedStar Health Research Institute	Mary Anne Hinkson, MBA (MHRI)
8:45 am – 9:00 am	Overview: Georgetown-Howard Universities Center for Clinical and Translational Sciences	Introduction to the CTSA and Welcome by Jason Umans, MD, PhD (MHRI)
9:00 am – 10:00 am	Ethics: Informed Consent and Participant Capacity	Sarah Vittone, RN, MSN, MA (GU)
10:00 am – 10:45 am	Investigational Drug, Device and Biologic Development	Mary Anne Hinkson, MBA (MHRI)
10:45 am – 11:00 am	BREAK	
11:00 am – 11:30 am	Investigational Drug, Device and Biologic Development (continued)	Mary Anne Hinkson, MBA (MHRI)
11:30 am – 12:30 pm	Good Clinical Practice (GCP) Documentation and Regulatory Binder	Maureen McNulty, RN, MS (MHRI)
12:30 pm – 1:00 pm	LUNCH	
1:00 pm – 1:30 pm	Investigational Test Articles: Accountability, Handling and Storage	Tamaro Hudson, PhD (HU)
1:30 pm – 2:15 pm	Study Initiation, Implementation and Termination	Shaunagh Browning MSN, RN, FNP-BC (GU)
2:15 pm – 2:45 pm	Internal and External Audits	Maureen McNulty, RN, MS (MHRI)
2:45 pm – 3:15 pm	Clinical Trial Budgeting, Coverage Analysis and Billing Compliance	Tina Stanger, MA, CRA (MHRI) Mary Anne Hinkson, MBA (MHRI)
3:15 pm – 3:30 pm	BREAK	
3:30 pm – 4:00 pm	Recent Updates: Common Rule and GCP	Kate Cohen, JD, CHRC, CIP (MHRI)
4:00 pm – 4:30 pm	Research Integrity: COI, HIPAA, GINA, Scientific Misconduct	Kate Cohen, JD, CHRC, CIP (MHRI)
4:30 pm	WRAP-UP and FEEDBACK	

Visit www.WePartner4Research.org/ethics to view the slides. (Password = ethics)