Ethics, Regulations and Study Implementation for Research Involving Human Subjects

Co-Sponsored by
Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS)

Meeting Agenda
March 31, 2017

Location: Howard University - Louis Stokes Health Sciences Library

Time	Session
8:00am - 8:30am	Program Overview and Introduction
8:30am - 10:00am	Ethics Module • The Ethics of Research Involving Human Subjects • Institutional Review Board • Informed Consent and Participant Capacity • Research with Vulnerable and Minority Populations
10:00am - 10:15am	Break
10:15am - 12:00pm	Regulatory Module • US Government and Federal Regulations • Reporting Requirements • Investigational Drug/Biologic Development • Investigational Device Development • Conflict of Interest • Good Clinical Practice • Research Integrity and Compliance • Health Insurance Portability and Accountability (Act/HIPAA)
12:00pm - 1:00pm	Lunch
1:00pm - 4:00pm	Study Implementation • Industry-Sponsored Site Selection • Study Feasibility and Medicare Coverage Analysis • Site Initiation/Study Start-Up • Protocol Essentials • Data Collection and Record Keeping for the Study Coordinator • Recruitment and Retention • Investigational Drugs- Accountability, Handling, and Storage • Monitoring of Clinical Trials, Study Termination, and Close-Out Procedures • Internal./External Audits • Financials for the Study Coordinator
4:00pm - 4:30pm	Closing Remarks