

Ethics, Regulations and Study Implementation for Research Involving Human Subjects

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



Things to Know

Time:	8:00 am to 4:00 pm
Date:	Wednesday, May 8, 2019
Place:	MedStar Health Research Institute 6525 Belcrest Road Suite 700 Hyattsville, MD 20782
Contact:	301-560-7300
Parking:	Garage A (validated ticket)

*dress and atmosphere
is business casual*



Course Goal

To provide advanced training in the methods and conduct of clinical research in a blended-learning approach with case study discussion and research staff participation.




Course Objectives

At the completion of the training, you will be able to:

- Describe the primary roles and responsibilities of the research team in a research study.
- Identify relevant content and tools needed to facilitate the implementation and conduct of a clinical research study.
- Recognize the critical elements of clinical trials, including best practice related to safety, monitoring, and human subject protection.



Agenda-at-a-Glance

7:30 am	Light Breakfast and Coffee
8:00 am	Welcome Mary Anne Hinkson
8:15 am	Drug/Biologic Development Tamaro Hudson
9:00 am	Device Development Mary Anne Hinkson
9:45 am	Study Feasibility Shaunagh Browning
10:30 am	BREAK 
10:45 am	Coverage Analysis Sarah Null
11:15 am	Site Initiation Petros Okubagzi
12:00 pm	LUNCH and LEARN  Behavioral Health Q & A
1:15 pm	Informed Consent Process Sarah Vittone
2:00 pm	Risk-Based Monitoring Approach Amy Loveland
2:45 pm	BREAK 
3:00 pm	Billing Compliance Candice Vance
3:30 pm	Common Rule Update Kate Cohen
4:00 pm	Get Out Your Phones! Wrap- Up with Game-Based Learning