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, PA 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