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**

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

**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