# 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

<table>
<thead>
<tr>
<th>Time</th>
<th>Content</th>
<th>Faculty</th>
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<tbody>
<tr>
<td>8:00 am</td>
<td>Registration and Breakfast</td>
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<tr>
<td>8:30 am</td>
<td>Welcome to MedStar Health Research Institute</td>
<td>Mary Anne Hinkson, MBA (MHRI)</td>
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<tr>
<td>8:45 am</td>
<td>Overview: Georgetown-Howard Universities Center for Clinical and Translational Sciences</td>
<td>Introduction to the CTSA and Welcome by Jason Umans, MD, PhD (MHRI)</td>
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<tr>
<td>9:00 am</td>
<td>Ethics: Informed Consent and Participant Capacity</td>
<td>Sarah Vittone, RN, MSN, MA (GU)</td>
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<tr>
<td>10:00 am</td>
<td>Investigational Drug, Device and Biologic Development</td>
<td>Mary Anne Hinkson, MBA (MHRI)</td>
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<td>10:45 am</td>
<td>BREAK</td>
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<tr>
<td>11:00 am</td>
<td>Investigational Drug, Device and Biologic Development (continued)</td>
<td>Mary Anne Hinkson, MBA (MHRI)</td>
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<td>11:30 am</td>
<td>Good Clinical Practice (GCP) Documentation and Regulatory Binder</td>
<td>Maureen McNulty, RN, MS (MHRI)</td>
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<td>12:30 pm</td>
<td>LUNCH</td>
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<tr>
<td>1:00 pm</td>
<td>Investigational Test Articles: Accountability, Handling and Storage</td>
<td>Tamaro Hudson, PhD (HU)</td>
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<td>1:30 pm</td>
<td>Study Initiation, Implementation and Termination</td>
<td>Shaunagh Browning MSN, RN, FNP-BC (GU)</td>
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<td>2:15 pm</td>
<td>Internal and External Audits</td>
<td>Maureen McNulty, RN, MS (MHRI)</td>
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<td>2:45 pm</td>
<td>Clinical Trial Budgeting, Coverage Analysis and Billing Compliance</td>
<td>Tina Stanger, MA, CRA (MHRI)</td>
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<td>3:15 pm</td>
<td>BREAK</td>
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<td>3:30 pm</td>
<td>Recent Updates: Common Rule and GCP</td>
<td>Kate Cohen, JD, CHRC, CIP (MHRI)</td>
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<td>4:00 pm</td>
<td>Research Integrity: COI, HIPAA, GINA, Scientific Misconduct</td>
<td>Kate Cohen, JD, CHRC, CIP (MHRI)</td>
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<td>4:30 pm</td>
<td>WRAP-UP and FEEDBACK</td>
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Visit [www.WePartner4Research.org/ethics](http://www.WePartner4Research.org/ethics) to view the slides. (Password = ethics)