

# Ethics, Regulations and Study Implementation for Research Involving Human Subjects: An Advance face-to-face Course

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## Meet the Presenters

### Sarah Vittone

Assistant Professor, Clinical Ethics Consultant, Georgetown University

Research Subject Advocate, GHUCCTS

Dr. Vittone has over 25 years of experience in clinical ethics consultation and is a primary consultant with the Ethics Consultation Service of the Pellegrino Center for Clinical Bioethics at GUMC and MGUH. Her clinical ethics interests are in decision making. She completed her Doctor of Bioethics (DBe) from Loyola University Chicago. Her research ethics interests are in decisional capacity and informed consent. Sarah has been with GHUCCTS as a Research Participant Advocate since 2010.

### Shannon Gopaul

Administrative Director, GHUCCTS, Howard University

Shannon joined Howard University in 2011 as the Research Administrator for the Department of Psychiatry, where she provided fiscal oversight of the department's clinical research studies and directly coordinated several studies. As a clinical research coordinator, she prepared budgets, coordinated contract execution, managed the regulatory aspects of the studies, oversaw participant recruitment, and coordinated the day to day activities of clinical research. Shannon now serves as the Administrative Director of GHUCCTS at Howard University where she not only manages the fiscal and administrative aspects of the center but provides direct research start-up guidance to new investigators. She is also an investigator on a current GHUCCTS pilot award.

### Yejide Obisesan

GHUCCTS Program Coordinator, Pilot Translational & Clinical Studies Program

Administration Coordinator, GHUCCTS, Howard University

Yejide joined the Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS) in 2014 to serve as the Program Coordinator for Pilot Translational and Clinical Studies Program (PTCS) and administrative coordinator for GHUCCTS at Howard University. In this role, she manages the funding mechanism that supports researchers across the GHUCCTS consortium to advance translational science and promote interdisciplinary research as well as assist with the administrative happenings in the GHUCCTS. In addition, she works on projects to aid in the effective start up and activation of multi-site trials.

### Candice Vance

Director, Clinical Research Revenue Cycle

MedStar Health Research Institute

Candice oversees clinical research billing compliance, coverage analysis, budget negotiation, and revenue recognition. Candice has a background in auditing health systems for billing and coding compliance and moved into the research realm over ten years ago. Candice has an MBA and is certified in healthcare research compliance.

### Emily Paku

Program manager, Trial Innovation Network, Georgetown-Howard Universities, CTSA

Viral Hepatitis Research, MedStar Medical & Surgical Research Network

Emily Paku oversees all programmatic elements of the Recruitment Unit and Multisite Study Support Unit of Georgetown-Howard Universities Center for Clinical and Translational Science, which include contractual and regulatory obligations, clinical research recruitment support, data management and analysis support, coordination and completion of project within timeline, budget and scope.

**Allie Moses**

Clinical Trial Management System (CTMS), MedConnect Integration

MedStar Health Research Institute and GHUCCTS

Ms. Moses joined MHRI in 2016 to support the OnCore Clinical Trial Management System (CTMS) implementation. She currently manages the OnCore for MHRI and Georgetown, leading end user support and training, continual process improvement, and MedConnect integration. She also oversees the new centralized MHRI Recruitment Center. With a background in electronic medical record and CTMS implementation, Allie seeks strategic and technical solutions to optimize clinical research and study recruitment. Allie received her BS from the University of Notre Dame.

**Petros Okubagzi**

Assistant Vice President, Research Operations

MedStar Health Research Institute

Petros has more than fifteen years of experience in managing large research undertakings and is the AVP, Research Operations. Prior to this role, he served as the Executive Director of Cardiovascular Research and before that as Director of Cardiovascular Research Programs for Medstar Cardiovascular Research Network. Petros was awarded his medical degree from Gondar College of Medical Sciences in Gondar, Ethiopia. He completed a certificate in Internal Medicine at Addis Ababa University in Addis Ababa, Ethiopia, followed by training in research at Nottingham City Hospital, Nottingham, UK.

**Florencia Gonzalez**

Co-Director, Including Diverse Populations (IDP) core, GHUCCTS

Ms. Gonzalez is a public health professional specialized in building community-academic partnerships for inclusion of under-represented groups in research. Ms. Gonzalez has experience in managing clinical trials and overseeing disparity health research within community settings. She has a history of grassroots field experience conducting case management with immigrant populations or managing public health projects in cross-cultural settings such as Sub-Saharan Africa and Honduras. She has proven capacity in program design, planning, monitoring and evaluation. In the last seven years, she has served as Community Networks Manager under Community Engagement of the Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS). In this role, Ms. Gonzalez provides capacity building strategies to community organizations for developing research and evaluation infrastructure to measure program outcomes and to systematically track client data. In addition, she provides consultation services to GHUCCTS member institutions faculty, staff, and students on community & patient engaged research on best practices. She currently serves as Co-director of the Including Diverse Populations core for GHUCCTS.

**Amy Loveland**

Associate Director, Clinical Research

MedStar Health Research Institute

Amy started her career with MedStar Health in 2003 as a Research Assistant with the Women's Health Initiative. She is currently the Associate Director, Clinical Research, and coordinates and manages all phases and types of clinical trials, mostly in endocrinology and metabolic disorders. Amy is a Certified Clinical Research Coordinator (CCRC) and received her MA in Psychology and English.

**Mary Anne Hinkson**

Vice President, Research Operations,

MedStar Health Research Institute

Mary Anne is responsible for all operational facets and management of clinical research being conducted at MedStar Health. She provides oversight of clinical research services based on an integrated professional approach for key services lines with an emphasis on professionalism and quality of support to investigators and the research community. She has regulatory and clinical research experience in both the pharmaceutical and medical device industries, domestic and global. Mary Anne received her MBA and received her BS in Health Care Management. She began her career as a cardiovascular technologist.

**Shaunagh Browning**

Director, Office of Research Quality Assurance

Georgetown University Medical Center

Shaunagh oversees the Office of Research Quality Assurance (ORQA) at GUMC. She is responsible for quality assurance and quality improvement initiatives necessary to improve compliance with research regulatory requirements, including but not limited to, the Institutional Review Board (IRB), federal/state regulations and guidance, and University policies and procedures. Shaunagh is eager to collaborate with study teams to achieve the goals of the office. She received her BS in Nursing from George Mason University and her MS as a Family Nurse Practitioner at Georgetown University. Shaunagh completed her Doctorate in Nursing Practice from Georgetown University in December 2019. Her doctoral work focuses on roles and responsibilities of Clinical Research Coordinators to better enhance the research care delivery model.