DC CTSA Consortium

Organized by
Sheila Rose Garrity
JD, MPH, MBA
Associate Vice President, Research Integrity, the George Washington University

Julia Slutman
PhD
Director, Research Regulatory Affairs, Children’s National Health System; and Assistant Professor, Department of Pediatrics, the George Washington University

Sheila Cohen Zimmet
BSN, JD
Senior Associate Vice President for Regulatory Affairs, Georgetown University

THE DC CTSA CONSORTIUM PRESENTS

Spring Regulatory Update and Hot Topics in Clinical Research

Monday, May 7, 2018
9:00 AM – 4:00 PM EDT

The George Washington University
Cloyd Heck Marvin Center
800 21st Street, NW | 3rd Floor, Grand Ballroom
Robert Miller, PhD  
Co-Principal Investigator, Clinical and Translational Science Institute at Children’s National, Senior Associate Dean for Research, School of Medicine and Health Sciences, the George Washington University  
Dr. Miller has published more than 200 papers in the area of neural development and disease with a particular interest in the brain and spinal cord. He has served on multiple review groups including as chair of NIH study sections. He is a member of the Scientific Advisory Board of the Shirmera Hospital and has served on the advisory board for the Maryland Stem Cell Foundation. Dr. Miller serves on the editorial board of a number of neurobiological and developmental journals. He has won numerous awards, including the Alfred P. Sloan Fellowship Award, Jacobs Jr Neuroscience Ment Award from the NIH, and the Charles Judson Herrick Award from the American Association of Anatomists.

Debra Paxton, MS  
Director of Office of Human Research, the George Washington University  
Ms. Paxton directs the Office of Human Research (OHR), which supports the George Washington University Institutional Review Boards (IRBs). OHR and the IRBs facilitate ethical and compliant use of human subjects in research. Debra has 20 years of experience in research as a researcher, research investigator, and an IRB director. She is proficient in both biomedical and behavioral research, and serves as consultant to multiple institutions on human subjects and research integrity issues. She earned a master’s of science degree in psychology and is completing her dissertation at North Carolina State University.

Irene Stith-Coleman, PhD  
Director of Grants and Assurances, Office for Human Research Protections, U.S. Department of Health and Human Services  
Dr. Stith-Coleman received her PhD in biochemistry from Meharry Medical College in Nashville, TN and completed postdoctoral training at the National Institutes of Health in National Heart, Lung, and Blood Institute. As director of the Division of Policy and Assurances, she directs development of policy and guidance documents, interpretations of requirements for human subject protections and dissemination of this information to the research community. She also directs the Office for Human Research Protection's Federally Assured of Compliance and registration of institutional review boards program.

Lawrence Tabak, DDS, PhD  
Principal Deputy Director and Deputy Ethics Counselor, National Institutes of Health  
Dr. Tabak has provided leadership for numerous trans-National Institutes of Health (NIH) activities, including the NIH Roadmap effort to support team science, over-the-counter medications, in vitro diagnostics, and associated regulatory policy related to personalized medicine, including the FDA’s recent proposal to begin actively regulating laboratory developed tests. He has been heavily engaged in national efforts to streamline the implementation of sIRB boards programs.

Marianna Bledsoe, MA  
Program Coordinator, Recruitment Unit, Georgetown-Howard Universities Center for Clinical and Translational Science; MedStar Health Research Institute  
Ms. Bledsoe oversees programmatic elements of the Recruitment Unit of the Georgetown-Howard Universities Center for Clinical and Translational Science to ensure all projects are traceable to the objectives. The Recruitment Unit aims to increase clinical trial participation amongst underrepresented populations in the DC-metropolitan region. Prior to this role, Ms. Bledso supported administrative functions of clinical research for the MedStar Georgetown Cancer Network and at Children’s National Health System.

Florencia Gonzalez, MPH  
Community Network Manager, Georgetown-Howard Universities Center for Clinical and Translational Science; Howard University  
Ms. Gonzalez has managed observational cancer studies, clinical trials, and community-based research projects addressing health disparities. She has grassroots field experience conducting case management with Hispanic immigrant women, managing and providing public health projects in cross-cultural settings such as Sub-Saharan Africa and Honduras. In her current role, she provides capacity-building strategies to community organizations for developing infrastructure around research and evaluation and for systematic tracking of client data. Additionally, she provides consultation services to institution faculty, staff, and students on community engaged research practices, and related best practices as well as building sustainable community-academic partnerships.

Katharine Donigan, PhD  
Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, U.S. Food and Drug Administration  
Dr. Donigan has served as an advisory committee member for the FDA’s Center for Devices and Radiological Health. She has a PhD in genetic epidemiology from Yale University, and completed a postdoctoral fellowship in the Laboratory of Genomic Integrity at NIH/NCHD. In her current position, she assists with the development and implementation of regulatory policy related to personalized medicine, including the FDA’s recent proposal to begin actively regulating laboratory developed tests. She has been a Genetic and Public Policy Fellow of the American Society of Human Genetics and the National Human Genome Research Institute.