THE DC CTSA CONSORTIUM PRESENTS

2020 Spring Regulatory Update and Hot Topics in Clinical Research

COVID-19: The Virus, Preparedness in the time of Crisis, and Clinical Research

Date: Tuesday, April 21, 2020
Time: 9:00am - 3:30pm
Sponsors: The Georgetown-Howard Universities Center for Clinical and Translational Science and the Clinical and Translational Science Institute at Children’s National (CTSI-CN), a partnership with the George Washington University.

Summary
This annual meeting brings researchers, administrators, and clinical professionals from throughout the local CTSA region together for collaborative discussion and response to regulatory revisions and identified clinical research priorities within the current landscape of clinical trials.

9:00am - 9:15am Welcome
Sheila Garrity, JD, MPH, MBA; Associate Vice President for Research Integrity, the George Washington University

Robert Miller, PhD; Vice President for Research and Associate Dean for Research in the School of Medicine Health Sciences, the George Washington University

- Introduction to the conference, the Clinical and Translational Science Institute, and planning team
- Administrative explanation of the virtual tool and logistics of the conference, timeline, etc.
- Introduce Keynote Speaker

9:15am - 10:15am Keynote Address
Daniel S. Chertow, MD, MPH
The keynote address will cover the emerging infectious disease, the spread and characteristics of COVID-19, and issues related to clinical trials and regulatory efforts.
- Dr. Chertow is a Tenure-Track Investigator in the Critical Care Medicine Department at the National Institutes of Health (NIH) Clinical Center and in the Laboratory of
Immunoregulation, National Institute of Allergy and Infectious Diseases. He is a Fellow in the American College of Critical Care Medicine, and a member of the Infectious Diseases Society of America and the American Public Health Association. He serves as a senior officer in the United States Public Health Service (USPHS). Dr. Chertow's translational research program employs advanced animal models and detailed natural history studies in humans to improve understanding of the pathophysiology and molecular pathogenesis of severe emerging viral infections including Influenza A, Ebola, and Zika viruses to guide improved clinical management of these infections.

10:15am - 11:45am Post-Keynote Panel on COVID-19
Moderator: Julia Slutsman, PhD
The post-keynote panelists will continue the discussion from Dr. Chertow’s keynote address around the impact of the virus on each campus and discuss what each institution is doing on the COVID-19 front: how information has been provided to their campuses; measures implemented to further protect their respective campuses; and what each institution is doing on the clinical front.

- **Roberta L. DeBiasi, MD, MS**
  ○ Dr. DeBiasi is Chief of the Division of Pediatric Infectious Diseases, Co-Director of the Congenital Zika Program and Co-Lead of the Ebola and Highly Contagious Infectious Disease institutional preparedness (including COVID-19) at Children’s National Hospital (CNH) in Washington, DC. She holds appointments as tenured Professor of Pediatrics and Microbiology, Immunology and Tropical Medicine at the George Washington University School of Medicine as well as Principal Investigator in the Center for Translational Research within Children’s Research Institute.

- **Marcia Firmani, PhD, MSPH**
  ○ Dr. Firmani is the current Medical Laboratory Sciences (MLS) Program Director at the George Washington University and has over 10 years of experience in teaching and research. In addition to her program director duties, Dr. Firmani teaches several courses within the MLS program, such as Clinical Microbiology I and Molecular Diagnostics. Prior to her arrival at the George Washington University, Dr. Firmani was a Principal Investigator at the National Biodefense Analysis and Countermeasures Center (NBACC) where she conducted and managed several research projects involving biothreat agent characterization.

- **Seble G. Kassaye, MD, MS**
  ○ Dr. Kassaye is an Associate Professor of Medicine at Georgetown University School of Medicine and an Infectious Diseases clinician at MedStar Georgetown University Hospital. Dr. Kassaye leads a number of observational cohort studies related to HIV/AIDS.

- **Celia J. Maxwell, MD, FACP, FIDSA**
  ○ Dr. Maxwell serves as the Associate Dean for Research at Howard University College of Medicine and is an Associate Professor of Medicine in the Department of Medicine, Division of Infectious Diseases. She is board certified in Internal Medicine and Infectious Diseases and is a Fellow of the American College of Physicians and the Infectious Diseases Society of America. She is currently the Principal Investigator of several prestigious projects, including The Center for Infectious Disease Management and
Research, Ryan White EIS program, The DC DOH Routine HIV Testing Program and as Co-PI for the PEPFAR funded HBCU Clinical Practice Transformation Project in Zambia.

11:45am - 12:30pm Panel 1: Research Data Management and Sharing
Moderator: Megan Potterbusch, MLIS

This session serves to inform the community about the significance and complexity in the sharing of data from human subjects and clinical research, including data from genetic and genomic research and social/behavioral research. Panel members will discuss policies from their respective agencies, best practices for responsible data maintenance, and what investigators should consider before the research begins, from data collection to data curation, based on the FAIR (findable, accessible, interoperable, and reproducible) data principles.

- **Lyric Jorgenson, PhD**
  - Dr. Jorgenson is Deputy Director, Office of Science Policy, NIH. Dr. Jorgenson provides senior leadership in the development and oversight of policies and programs associated with emerging, high-impact issues of importance to the biomedical research enterprise and the United States Government. Most recently, Dr. Jorgenson was also the Deputy Executive Director of the White House Cancer Moonshot Task Force in the Office of the Vice President, where she directed and coordinated cancer-related activities across the Federal government and worked to leverage investments across sectors to dramatically accelerate progress in cancer prevention, diagnosis, and treatment.

- **Nawar M. Shara, PhD**
  - Dr. Shara is the Director of the Department of Biostatistics and Bioinformatics at MedStar Health Research Institute (MHRI); Director of the Biostatistics Core in the Georgetown-Howard Universities Center for Clinical and Translational Science; and Associate Professor of Medicine, Division of Endocrinology, at Georgetown University. Dr. Shara’s expertise is in the design and analysis of large-scale epidemiological trials, specifically in the development of novel statistical methodologies, such as adaptive dosage-finding techniques, imputation methods and predictive analytics for big data. In addition, she has been developing tools to extract electronic health records data for use in research to improve patient outcomes.

- **Raja Mazumder, PhD**
  - Dr. Mazumder is a Professor of Biochemistry and Molecular Medicine and Co-Director of The McCormick Genomic Proteomic Center at the George Washington University. Dr. Mazumder’s background is in evolutionary biology and bioinformatics. While working at the National Center for Biotechnology Information (NCBI) at NIH and Georgetown University, Dr. Mazumder worked closely with colleagues in developing international molecular biology resources and using these resources to identify therapeutics, diagnostics and vaccines targets. Through federal and industry funding he is involved in genomic and bioinformatics research in cancer biology, glycobiology, metagenomics and bioinformatics standards development.

12:30pm - 1:30pm Lunch Break
1:30pm - 2:15pm  Panel 2: Does this Relationship Need to be Managed:
Conflicted Over Conflict of Interest
Moderator: Hiromi Sanders, JD, PhD
This session will provide a brief overview of the heightened U.S. Government scrutiny on
conflict of interest due to concerns about safeguarding research against undue foreign
influence. The panelists will discuss how to navigate disclosures when the university/health
systems and the Government requirements are not yet in sync. Panelists will then explore some
of the conflicts that arise in the conduct of clinical research and best practices for mitigating bias
and coercion. The session will conclude with a discussion about the significance of balancing
compliance and flexibility to facilitate a swift response to COVID-19 research.

- Katherine (Kate) B. Cohen, JD, CHC, CHRC
  - Ms. Cohen is the Chief Compliance Officer of Southern Illinois University (SIU) Medicine.
    In that role, she leads the compliance program for the SIU School of Medicine, the SIU
    Physicians and Surgeons, and the SIU federally qualified health center. Focusing on
    collaborative, proactive compliance support for the organization, the compliance office is
    responsible for physician billing auditing and compliance, referral issues, conflict of
    interest, research compliance, research integrity, and privacy. Prior to her work with SIU
    Medicine, Ms. Cohen was the Research Compliance Director for MedStar Health.

- Mary E. Schmiedel, JD, CPCM
  - Ms. Schmiedel is the inaugural Senior Director, Office of Research Oversight, at
    Georgetown University. She serves as the chief Conflict of Interest Officer for the Main
    Campus and Medical Center and carries University-wide responsibility for export controls
    and research integrity. Ms. Schmiedel previously served as the Associate Dean for
    Research Administration and Director, Office of Sponsored Programs. She is a frequent
    presenter on research administration and compliance topics.

- James (Jim) H. Boscoe, MA, CIP
  - Mr. Boscoe is the Director of the MedStar Health Research Institute Office of Research
    Integrity (ORI). The ORI is primarily responsible for the regulatory oversight of clinical
    and pre-clinical research for MedStar Health. The office coordinates the research
    process with other components of the Human Research Protections Program and
    Research Operations throughout the MedStar system. Mr. Boscoe previously worked as
    an IRB Manager in the Johns Hopkins School of Medicine IRB office. Prior to his work in
    research ethics and regulations, Mr. Boscoe worked as a Behavior Analyst and has
    worked with children with feeding disorders, children and adults with developmental
    disabilities, and adults with substance use disorders. He is the MedStar Health
    representative to the Regulatory, Ethics, Knowledge & Support (REKS) component of
    GHUCCTS.

2:15pm - 3:15pm  Panel 3: Accelerated Clinical Trials - Adapting to the Pace
Moderator: Debra Paxton, MS, CIP
This panel will address the emerging challenges and mitigation for accelerated clinical trials
specifically issues around safety and protection for vulnerable populations, Data and Safety
Monitoring Plans or Boards in real time, research quality, and ethical considerations in accelerated clinical trials.

- **Debra Paxton, MS, CIP**
  - Ms. Paxton directs the Office of Human Research (OHR) at the George Washington University (GW), which houses and supports the GW Institutional Review Boards (IRBs). OHR and the IRBs facilitate the ethical and compliant use of human subjects in research. Ms. Paxton has 20 years of experience in research as a researcher, research integrity officer, and 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.

- **David Diemert, MD, FRCP(C)**
  - Dr. Diemert is a Professor in the Departments of Medicine and Microbiology, Immunology, and Tropical Medicine at the George Washington University. Prior to joining GW, he worked for four years at the Malaria Vaccine Development Branch of the US National Institute of Allergy and Infectious Diseases, where he was responsible for conducting clinical trials of novel malaria vaccines in the United States and Mali. Dr. Diemert’s research is focused on conducting clinical trials in the United States, Brazil, and Africa to develop new vaccines particularly for neglected tropical diseases. He has served as the Principal Investigator on multiple clinical trials of hookworm, schistosomiasis and malaria vaccines, and more recently those for Zika and HIV.

- **Shaunagh Browning, DNP, RN, FNP-BC**
  - Dr. Browning serves as the Director for the Office of Research Quality Assurance (ORQA) at Georgetown University. She joined ORQA as the inaugural director in 2018 and directs activities related to the mission and purpose of ORQA at Georgetown University. As a Family Nurse Practitioner, Dr. Browning provided clinical care to research patients in addition to coordinating research and clinical projects. Dr. Browning’s work centers around the role of the Clinical Research Coordinator, with emphasis on the Clinical Research Nurse and education of staff and scientists with the goal of research quality and efficiency.

- **Sarah Vittone, DBE, MSN, RN**
  - Dr. Vittone is faculty with Georgetown University; a Clinical Bioethicist with the Pellegrino Center for Clinical Bioethics and a Research Participant Advocate with the Georgetown-Howard University CTSA. Dr. Vittone has over 20 years of experience in clinical bioethics and 10 years in Research Ethics. She provides consultation, safety and human subjects review, and education in research ethics. Dr. Vittone’s specific interests are in decision making relating to consent. She serves as an independent reviewer of consent in high risk studies.

3:15pm - 3:30pm  Closing Remarks
Sheila Garrity, JD, MPH, MBA