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GHUCCTS
Georgetown-Howard Universities Center for Clinical and Translational Science

CTSI Clinical and Translational Science Institute at Children's National
A PARTNERSHIP WITH THE GEORGE WASHINGTON UNIVERSITY

The DC CTSA Consortium Presents:

DC CTSA Spring Regulatory Update & Hot Topics in Clinical and Translational Research

Dates: Friday, April 23, 2021 & Friday, April 30, 2021

Time: 9:30am - 12:30pm EST

Click here to register

Subtitle: An Annual Meeting Sponsored by Georgetown-Howard Universities Center for Clinical and Translational Science and Clinical and Translational Science Institute at Children's National (CTSI-CN) in 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.

This conference will focus on:

Day 1 - Moving Swiftly to Combat the COVID-19 Global Health Crisis
Day 2 - Beyond Covid-19: Challenges & Lessons Learned during a Pandemic

Day 1 - Moving Swiftly to Combat the COVID-19 Global Health Crisis

9:30am - 9:35am Welcome

Joseph Verbalis, MD, Professor of Medicine, Chief of Endocrinology and Metabolism. Georgetown University Principal Investigator of GHUCCTS

9:35am - 9:45am Introduction

Sheila Garrity, JD, MPH, MBA. Associate Vice President for Research Integrity. Office of the Vice President for Research. George Washington University

9:45am - 10:30am Keynote Address

Dr. David Diemert, MD, FRCP(C). Professor, Departments of Medicine and Microbiology, Immunology & Tropical Medicine. George Washington University School of Medicine & Health Sciences

Moderator: Rebecca Eberle, MSHS, CIP. Interim Director, Office of Human Research. George Washington University

Dr. Diemert will provide an overview of the different vaccines, how the science ramped up in the development of the various vaccines, the differences in manufacturing the vaccines, the effectiveness of the vaccines before they were rolled out, and whether these same approaches would be replicated in other diseases or conditions.

10:35am - 11:35am Panel 1: COVID-19 Vaccine Research, Recruitment, and Testing

Moderator: A. Mariel Jais, PharmD, RBP. Manager of the Office of Laboratory Safety. Office of the Vice President for Research. George Washington University

As COVID-19 vaccines reach more people all over the country, different efforts to ensure equity are being utilized. This panel of local experts will highlight the ethical lessons learned from the COVID-19 vaccine research and rollout, diverse participant recruitment efforts, testing, and the regulatory issues related to human subject research.

- Molly Klote, M.D. | Director, Office of Research Protections, Policy, and Education. VA Office of Research and Development. U.S. Department of Veterans Affairs
- Florencia Gonzalez, MPH | Director, Including Diverse Population (IDP), GHUCCTS; Community Engagement, GHUCCTS, Howard University
- Megan Ware | Study Coordinator/Peer Support Coordinator, Howard University Vaccine Trials

11:40am - 12:25pm Panel 2: Regulatory Issues Related to Human Subject COVID Research

Moderator: Mary Schmiedel, J.D. Senior Director, Office of Research Oversight. Georgetown University

This panel will discuss how the research community had to swiftly pivot to combat Covid-19, leveraging regulatory flexibilities under the Common Rule to manage the challenges in conducting and reviewing research, and to move research more swiftly during the pandemic.

- Heidi Maloni, Ph.D. ANP-BC, CNRN, MSCN | National Clinical Director of the Multiple Sclerosis Centers of Excellence - East, Washington DC VA Medical Center, U.S. Department of Veterans Affairs
- James (Jim) Boscoe, MA, CIP | Director, Office of Research Integrity. MedStar Health Research Institute
- Yvonne Lau, MBBS, MBHL, Ph.D. | Director, Division of Education and Development, Office for Human Research Protections. Department of Health and Human Services

12:25 - 12:30pm Day 1, Close: Sheila Garrity

Day 2 - Beyond COVID-19: Challenges & Lessons Learned during a Pandemic

9:35am - 9:45am Introduction

Sheila Garrity, JD, MPH, MBA. Associate Vice President for Research Integrity. Office of the Vice President for Research. George Washington University

9:45am - 10:45am Keynote Address

Dr. Stephen Hansen, Ph.D. Supervisory Investigator, Office of Bioresearch Monitoring Operations. U.S. Food & Drug Administration

Moderator: Jane Otado, Ph.D., Interim Director, GHUCCTS Regulatory, Ethics, Knowledge and Support (REKS), Howard University

Dr. Hansen will discuss Emergency Use Authorizations (EUA) from the FDA perspective. Dr. Hansen will discuss what it means, the process for EAU review specifically for vaccines, circumstances that justify their authorization, and how it may Impact future approvals.

10:45am - 11:30am Panel 1: Challenges for Researchers During the Pandemic

Moderator: Hiromi Sanders, J.D., Ph.D. Director, Research Integrity and Compliance. Office of the Vice President for Research. George Washington University

This panel will provide insight into the many challenges faced by researchers during the COVID pandemic. Researchers will discuss their projects, specific challenges experienced, and whether project goals were reconfigured due to the inability to conduct the original research.

- Federico M. Asch, M.D., FASE, FACC | Director, Cardiovascular Core Labs. Director, Cardiac Imaging Research. MedStar Health Research Institute at Washington Hospital Center
- Sharon Dowell, M.D. | Associate Professor of Medicine, Department of Internal Medicine, Division of Rheumatology, Howard University Hospital
- Jill Smith, M.D. | Professor of Medicine, Department of Medicine and Lombardi Comprehensive Cancer Center. Georgetown University Medical Center

11:30am - 12:25pm Panel 2: Dissemination of Research During the Pandemic

Moderator: Sarah Vittone, DBe, MA, MSN, RN. Doctor of Bioethics. Assistant Professor, School of Nursing and Health Studies. Georgetown University

This panel will provide perspectives on the dissemination of research during the pandemic. Impact on the changing publishing landscape, editorial and review process, costs, retractions, case study reports, and MedRxiv will be discussed. Balancing the pace of science as well as keeping with standard and ethics will be addressed.

- Lars Berglund, M.D., Ph.D. | Editor, Journal of Clinical and Translational Science
- Theodora Bloom, Ph.D. | Executive Editor, The BMJ

12:25pm - 12:30pm Day 2, Close: Sheila Garrity