





# THE DC CTSA CONSORTIUM PRESENTS THE FIFTH ANNUAL

## Spring Regulatory Update on Hot Topics in Clinical and Translational Research

Date Thursday, April 28, 2022

Thursday, May 5, 2022

**Time** 12:00pm – 4:00pm EDT

### **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 – Lasting Impacts of the COVID-19 Pandemic DC CTSA Consortium Day One | GHUCCTS (georgetownhowardctsa.org)

Day 2 – Artificial Intelligence in Research and Healthcare DC CTSA Consortium Day Two | GHUCCTS (georgetownhowardctsa.org)

Webinar Registration - Zoom

#### DAY 1 – LASTING IMPACTS OF THE COVID-19 PANDEMIC

12:00pm – 12:05pm

#### Introduction

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

12:05pm – 12:15pm

#### **Conference Welcome**

Pamela M. Norris, PhD. Vice Provost for Research. Office of the Vice Provost for Research, The George Washington University

#### 12:15pm – 1:15pm

## Keynote Address – Transcriptome profiling of human blood as a platform for diagnostic biomarker development: Measure broadly, listen carefully.

Session Description. The human genome project ignited DNA-based research into heritable biomarkers of disease. However, RNA-based diagnostics and therapeutics are only now being fully realized. In this keynote, Dr. McCaffrey we'll explore a true 'Bench to Bedside' adventure from sequencing of the RNA transcriptome to identify clinically relevant biomarkers of cardiovascular and infectious diseases.

 Timothy McCaffrey, PhD – Professor of Medicine, Professor of Microbiology, Immunology, and Tropical Medicine. The George Washington University School of Medicine & Health Sciences

**Moderator**: Hiromi Sanders, JD, PhD. Director, Research Integrity & Compliance, The George Washington University

1:20pm - 2:35pm

#### Panel 1: Long-term COVID-19 Impacts on the Body

Session Description. As COVID-19 infects people all over the country and world, the long-term effects on the body and the mind become clearer. This panel of local experts will present on the findings from their observational studies.

- Hassan Ashktorab, PhD Professor, Department of Pathology & Human Genetics. Director of Microarray Facility. Howard University
- Hassan Brim, MS, PhD Associate Professor of Pathology, College of Medicine. Director of Research. Howard University
- Sabyasachi Sen, MD, PhD, FRCP Professor, Department of Medicine. Professor of Biochemistry & Molecular Medicine, The George Washington University School of Medicine and Health Science. Associate Chief Endocrinology, Veterans Affairs Medical Center

**Moderator**: Jane Otado, PhD. Interim Director, Regulatory, Ethics, Knowledge & Support (REKS). Georgetown-Howard Universities for Clinical & Translational Science (GHUCCTS) College of Medicine, Family Medicine & Community Health. Howard University

2:40pm - 3:55pm

Panel 2: Vaccines Mandates, Distribution, and the Structure of Herd Immunity
Session Description. The US COVID-19 vaccination landscape has shaped the population
health impacts of SARS-CoV-2, structured the potential for local elimination alongside natural
immunity and behavioral containment, and will drive the transition out of the pandemic to
endemic circulation of SARS-CoV-2. However, the tracking of vaccination progress at a fine
geographical scale and through time has not been a US public health priority. Here we discuss
the tracking of COVID-19 vaccination progress in the United States, characterize the spatiotemporal heterogeneity in these patterns, and discuss the epidemiological consequences of this
distribution.

- Shweta Bansal, PhD Provost's Distinguished Associate Professor, Department of Biology, Georgetown University
- Daniel P. Sulmasy, MD, PhD, MACP Andre Hellegers Professor of Biomedical Ethics. Director, Kennedy Institute of Ethics

**Moderator:** Nabeel Qureshi, MBBS, MPH. Deputy Conflict of Interest Officer and Senior Research Compliance Officer, Georgetown University

3:55pm – 4:00pm Day 1 Close. Sheila Garrity

#### DAY 2 - ARTICIAL INTELLIGENCE IN RESEARCH AND HEALTHCARE

12:00pm - 12:05pm

#### Introduction

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

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12:05pm - 12:15pm

#### **Conference Welcome**

Thomas Mellman, MD – Professor of Psychiatry. Director, Stress/Sleep Studies Program at Howard University. Principal Investigator for the Georgetown-Howard Universities Center for Clinical and Translational Science (GHUCCTS), Howard University

12:15pm – 1:15pm

#### **Keynote Address – Al Across Borders: The Need for a Cosmopolitan Ethic.**

Session Description. As AI and data systems become more multinational enterprises, cultural ethico-legal issues, problems - and solutions - relevant to safety, and biosecurity become increasingly important. Dr. Giordano will address these emerging trends, and propose possible paths toward ethically sound global engagement.

 Dr. James Giordano, PhD, MPhil – Professor of Neurology and Biochemistry. Chief of Neuroethics Studies Program at the Pelligrino Center for Clinical Bioethics. Director, REKS Ethics Subcomponent (GHUCCTS), Georgetown University

**Moderator**: Assya Pascalev, PhD. Associate Professor of Philosophy, Co-Director, REKS Ethics Subcomponent (GHUCCTS), Howard University. Executive Director, Bulgarian Center for Bioethics

1:20pm – 2:35pm

### Panel 1: Al Across Borders: Staying Between the Ethical Lines in Biomedical and Translational Research.

Session Description. The panelists will discuss the influence and use of artificial intelligence in the health-tech industry, incorporating risk assessment frameworks on the front end of biotechnology development and ultimately how artificial models of moral reasoning can be trained and augmented in both experimental and clinical contexts.

- William Casebeer, PhD Riverside Research Director of Artificial Intelligence and Machine Learning (AI/ML), Open Innovation Center (OIC)
- Diane DiEulis, PhD Senior Research Fellow, National Defense University
- Ophir Frieder, MS, PhD Professor, Department of Computer Science. Professor, Department of Biostatistics, Bioinformatics & Biomathematics. Georgetown University Medical Center

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

2:40pm – 3:55pm

#### Panel 2: IRB in Technology Industry

Session Description. The panelists will discuss the basics of machine learning, how it introduces ethical risks, and potential ways to minimize these ethical risks and will present a deeper dive into specific case studies including the Axon ethics panel, Google, and Microsoft and whether or not ethics committees work at scale.

- Reid Blackman, PhD CEO/Founder of Virtue
- Tracy Kosa, PhD Privacy Researcher, Stanford University. Adjunct Professor, Seattle University Faculty of Law

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

3:55pm - 4:00pm

Day 2, Close. Sheila Garrity