



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

2020 MRCT CENTER ANNUAL MEETING
December 3, 2020 | 10am-1:30pm EST

VIRTUAL

SPEAKER BIOGRAPHIES

Zoom Webinar

<https://partners.zoom.us/j/82398645915>

Information and Biographies for MRCT Center Leadership and Staff
are available on our website: <https://mrctcenter.org/about-mrct/people/>



Michelle McMurry-Heath assumed the leadership of the Biotechnology Innovation Organization (BIO) as President and CEO on June 1, 2020. A medical doctor and molecular immunologist by training, Dr. McMurry-Heath became just the third chief executive to steward the world's largest biotechnology advocacy group since BIO's founding in 1993.

BIO represents 1,000 life sciences companies and organizations from 30 countries. The organization's mission is to support companies that discover and deploy scientific breakthroughs that improve human health, environmental stewardship, and sustainable agriculture.

The common thread in McMurry-Heath's work across academia, government and industry has been her focus on broadening access to scientific progress so more patients from diverse backgrounds can benefit from cutting-edge innovation. Driven by her own past family experiences navigating clinical trials and funding uncertainties within the rare disease community, McMurry-Heath calls "the distribution of scientific progress the social justice issue of our age."

She comes to BIO from Johnson & Johnson where she served as Global Head of Evidence Generation for Medical Device Companies and then Vice President of Global External Innovation and Global Leader for Regulatory Sciences. She was also instrumental in bringing J&J's incubator, J Labs, to Washington, DC. She led a global team of 900 with responsibilities in 150 countries around the globe.

Prior to her time at J&J, Dr. McMurry-Heath was also a key science policy leader in government. The Obama-Biden transition team tapped her to conduct a comprehensive analysis of the National Science Foundation's policies, programs and personnel. President Obama then named her associate science director of the FDA's Center for Devices and Radiological Health under Commissioner Peggy Hamburg. In that role, she championed clinical trial evolution, the use of real-world evidence in product evaluation, and an embrace of the patient's voice in health research so new medical products deliver outcomes that matter to them.

McMurry-Heath was the founding director of the Aspen Institute's Health, Biomedical Science, and Society Policy Program, where she promoted personalized medicine and bolstered international preparation for pandemic disease threats. She received her early training in science policy from the Robert Wood Johnson Foundation and later served as Senator Joe Lieberman's top legislative aide for science and health. In that role, she drafted legislation to protect the country from biological attacks.

McMurry-Heath received her MD/PhD from Duke's Medical Scientist Training Program, becoming the first African-American to graduate from the prestigious program. She spent 12 years working at the research bench before taking policy and leadership roles in government and industry.

McMurry-Heath lives in Washington, D.C. with her husband Sebastian Heath, a veterinarian, and their daughter, Isabella. To relax, she enjoys yoga, snorkeling and her daughter's sporting events.



Gianna (Gigi) McMillan, D. Bioethics, is Faculty and Program Administrator for the Bioethics Institute at Loyola Marymount University in Los Angeles, where she manages the graduate and undergraduate curriculum and teaches Research Ethics. She has extensive experience as a Subject/Patient Advocate on local and national IRBs, served on the Subpart A Subcommittee for the Secretary's Advisory Committee on Human Research Protection and is a member of the FDA's Pediatric Advisory Committee. Dr. McMillan is a Board Member for PRIM&R (Public Responsibility in Medicine & Research), has been on their faculty since 2004, and is the Director of Community Engagement for the academic journal, *Narrative Inquiry in Bioethics*. Her primary interests are consent issues in clinical research and the use of narrative as an educational tool in bioethics.



Amy Ohmer is the Director of the International Children's Advisory Network, Inc. (iCAN) and mother and caregiver of two daughters that were diagnosed with Type 1 Diabetes (T1D) at a very young age. After the first diagnosis in 2006, Amy has become the patient/caregiver voice in pediatrics; advocating for better treatment and care, while focusing on a cure for T1D. Amy specializes in creating collaboration through patient-centered care by focusing on the needs of patients/families as a consultant within research and medical communities.

Amy is a passionate advisor for the American Board of Medical Specialties (ABMS) Stakeholder Council, Patient/Parent Advisor Lead for research leading to better T1D outcomes through co-design within T1D Exchange, Patient Family Advisory Council (PFAC) for the University of Michigan, Patient/Family Lead for C.S. Mott Children's Pediatric Endocrinology, Advocate for American Diabetes Association, and member of the State of Michigan Diabetes Partners in Advocacy Coalition (DPAC).

With a BA from Michigan State University in Advertising, Communications Arts and Science, Amy brings a passion for engaging audiences by offering open patient/family communication by utilizing social networks, technology and marketing to strengthen the overall medical community.



Jennifer (Jenny) Preston currently has a full-time position at the University of Liverpool, based at the Institute in the Park at Alder Hey Children's Hospital in Liverpool. Her role is to deliver a strategy for the involvement and engagement of children and young people and families in pediatrics health research. Current projects include coordinating and facilitates a National Group called GenerationR Alliance (www.generationr.org.uk), which is made up of Young Person's Advisory Groups across the UK, enabling 100s of young people to have a voice in research design and delivery both in the UK and across the globe. Jenny is also senior patient involvement lead on a six-year multidisciplinary public-private initiative conect4children (c4c), which is a large collaborative pediatric network that will facilitate the development of new drugs and other therapies for the entire pediatric population in Europe; co-founder of a European Young Person's Advisory Group Network (eYPAGnet) to empower young people and families across Europe to contribute to pediatric health research; patient involvement and engagement Executive Lead for the NIHR Children and Young People MedTech Co-operative (CYPMedTech) to advance medical technologies for children and young people.

Jenny has written and co-authored over 30 peer-reviewed articles about patient and public involvement including lead author of three book chapters.

Jenny has delivered numerous training sessions, workshops and conference presentations over the years for a variety of audiences including patients and families, health care professionals, and health researchers about the importance and impact of patient involvement in health research. She has just obtained a fellowship to undertake a PhD looking at the impact of young people's involvement in the design and delivery of pediatric research.



Jasmine (Jaz) Gray is a researcher, patient advocate, and transformational speaker from Memphis, TN. She speaks and leads workshops on a range of topics including the power of stories, healthy self-image, patient-centered care, health equity, and resilience. She has had over forty-six surgeries in thirty-two years for a rare condition called Arteriovenous Malformation. Her nonprofit Jaz's Jammies Inc. has donated over 6,000 pairs of new pajamas to sick and homeless children and created opportunities for over 2,000 donors and volunteers.

Jaz has been featured on affiliate networks for NBC, CBS, ABC, and Fox. She has worked for media publications including the *Nashville Tennessean* and the *Louisville Courier-Journal* and entertainment corporations including Cartoon Network, BET, and Paramount Pictures where she co-founded an ad-hoc committee to address health-related diversity.

In addition to a B.S. from Middle Tennessee State University and an M.A. from Syracuse University, she is currently pursuing a Ph.D. in Communication at the University of North Carolina at Chapel Hill where she is an instructor.



Richard (Rich) Moscicki, M.D. is the Executive Vice President for Science and Regulatory Advocacy and the Chief Medical Officer at Pharmaceutical Research and Manufacturers of America (PhRMA).

Dr. Moscicki (Mo-shis-ke) came to PhRMA in 2017 after serving as the Deputy Center Director for Science Operations for the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) since 2013. While at FDA, Dr. Moscicki brought executive direction of Center operations and leadership in overseeing the development, implementation, and direction of CDER's programs. Previous positions include serving as Chief Medical Officer at Genzyme Corporation from 1992 to 2011, where he was responsible for worldwide global regulatory and pharmacovigilance matters, as well as all aspects of clinical research and medical affairs for the company. He served as the senior vice president and head of Clinical Development at Sanofi-Genzyme from 2011-2013.

Dr. Moscicki received his medical degree from Northwestern University Medical School. He is board certified in internal medicine, diagnostic and laboratory immunology, and allergy and immunology. He completed his residency in internal medicine, followed by a fellowship at Massachusetts General Hospital (MGH) in clinical immunology and immunopathology. He remained on staff at MGH and on the faculty of Harvard Medical School from 1979 until 2013.



Dr. Monica Webb Hooper is Deputy Director of the National Institute on Minority Health and Health Disparities (NIMHD). She works closely with the Director, Dr. Pérez-Stable, and the leadership, to oversee all aspects of the institute and to support the implementation of the science visioning recommendations to improve minority health, reduce health disparities, and promote health equity.

Dr. Webb Hooper is an internationally recognized translational behavioral scientist and clinical health psychologist. She has dedicated her career to the scientific study of minority health and racial/ethnic disparities, focusing on chronic illness prevention and health behavior change. Her program of community engaged research focuses on understanding multilevel factors and biopsychosocial mechanisms underlying modifiable risk factors, such as tobacco use and stress processes, and the development of community responsive and culturally specific interventions. Her goal is to contribute to the body of scientific knowledge and disseminate findings into communities with high need.

Before joining NIMHD, Dr. Webb Hooper was a Professor of Oncology, Family Medicine & Community Health and Psychological Sciences at Case Western Reserve University. She was also Associate Director for Cancer Disparities Research and Director of the Office of Cancer Disparities Research in the Case Comprehensive Cancer Center. During her time as a professor, Dr. Webb Hooper was principal investigator of federal and foundation grants, totaling over \$15 million. To date, she has published over 90 peer-reviewed articles and book chapters.

Dr. Webb Hooper completed her doctorate in clinical psychology from the University of South Florida, internship in medical psychology from the University of Florida Health Sciences Center, and her Bachelor of Science from the University of Miami.



Roberto Lewis-Fernández M.D. is a Professor of Clinical Psychiatry at Columbia University and the Director of the New York State Center of Excellence for Cultural Competence and the Hispanic Treatment Program, and the Co-Director of the Anxiety Disorder Clinic, at New York State Psychiatric Institute. His research focuses on developing culturally valid interventions and instruments to enhance patient engagement, reduce misdiagnosis, and help overcome disparities in the care of underserved cultural groups, especially Latinxs. He also studies the way culture affects individuals' experience of mental disorder and their help-seeking expectations, including how to explore this cultural variation during the psychiatric evaluation.

He led the development of the DSM-5 Cultural Formulation Interview, a standardized method for cultural assessment for use in mental health practice, and was the Principal Investigator of its international field trial. He is Chair of the Cultural Committee of the Group for the Advancement of Psychiatry, President of the World Association of Cultural Psychiatry, Immediate Past President of the Society for the Study of Psychiatry and Culture, and Past President of the American Society of Hispanic Psychiatry. He was a member of the NIMH National Advisory Mental Health Council and Chair of the Cross-Cultural Issues Subgroup of DSM-5. Currently, he is Co-Chair of the ICD-11 Working Group on Culture-Related Issues and a member of the Working Group on Somatic Distress and Dissociative Disorders. He is also Chair of the DSM Review Committee for Internalizing Disorders and Chair of the Cultural Issues Review Committee of DSM-5-TR. His awards include the 2014 Simón Bolívar Award and the 2018 Health Services Senior Scholar Research Award of the American Psychiatric Association, the 2014 Creative Scholarship Award of the Society for the Study of Psychiatry and Culture, and the 2015 Multicultural Excellence Award of the New York State Chapter of the National Alliance on Mental Illness.

Dr. Lewis-Fernández received a B.A. from Harvard College, an M.T.S. from Harvard Divinity School, and an M.D. from Yale Medical School.



David Peloquin is a Partner at Ropes & Gray and Senior Advisor of the MRCT Center.

David Peloquin practices law at Ropes & Gray LLP where he is a member of the firm's health care group. He focuses his practice on advising academic medical centers, life sciences companies, and information technology companies on issues related to human subject's research and data privacy. He frequently writes and speaks on topics related to each of these areas and is a regular presenter at conferences and webinars of the American Health Lawyers Association, the Association for the Accreditation of Human Research Protection Programs, the International Association of Privacy Professionals, and central and institution-specific institutional review boards. Outside of his law practice, David serves as a community member of the Institutional Review Board at Partners Healthcare in Boston. In recent months, David has spent considerable time advising clients on their response to the COVID-19 pandemic, including with respect to modifications to clinical research, implementation of telehealth technologies, and development and implementation of clinical diagnostic testing programs.

David has worked with MRCT Center since 2013. He has contributed to projects on data sharing, the return of research results to clinical trial subjects, and the impact of the European Union's General Data Protection Regulation (GDPR) on research. He has presented at the MRCT Center's Research, Regulatory, and Development Roundtable (R3) on topics including GDPR, secondary uses of health data for clinical trial recruitment purposes, legal and ethical issues that arise when a company or institution uses its own employees or students as research participants and decentralized clinical trials.

David received his undergraduate degree from Carleton College, his law degree from the Yale Law School and clerked for Judge Diana E. Murphy of the United States Court of Appeals for the Eighth Circuit. Before attending law school, David worked as a project manager for Epic Systems, a manufacturer of electronic medical records.