SPEAKER AND PANELIST BIOGRAPHIES

Linda Coleman, JD, is the Human Research Protection Program (HRPP) Director at Yale University. Ms. Coleman also serves on several committees at Yale University including the Institutional Conflict of Interest, Investigator Conflict of Interest, Institutional Biosafety, Institutional Research Compliance, and Data Safety Monitoring Committees, as well as other committees focused on research policy matters. Before joining Yale, Ms. Coleman held several positions at Quorum Review, an independent IRB and consulting company serving institutional, independent, and international sites (i.e., Vice President of Regulatory & Legal Affairs of Kinetiq, Quorum's consulting division; Director of Regulatory Affairs & General Counsel; and Director of Regulatory Affairs). Prior to working at Quorum Review, Ms. Coleman was an attorney at Bennett, Bigelow & Leedom where her practice focused on general health law matters, Medicare and Medicaid reimbursement, litigation, business/transactional, behavioral health, and employment law. Ms. Coleman received her law degree at the Seattle University School of Law.

Michele Countryman is the Research Compliance Director in the Human Subjects Office at the University of Iowa. In this position, Ms. Countryman oversees the IRB administrative office, as well as matters related to conflict of interest and ClinicalTrials.gov reporting requirements. Ms. Countryman also serves as a member of the University of Iowa's IRB. Ms. Countryman has been involved in various aspects of research compliance for over 13 years, which includes involvement in three Human Research Protection Program (HRPP) reaccreditations and serving as the lead in launching a single IRB program. Ms. Countryman received her bachelor's degree in psychology at the University of Iowa.

Carl D'Angio, MD, is the Chief of the Division of Neonatology at the University of Rochester and the Principal Investigator on the University's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Neonatal Research Network award. Dr. D'Angio has served as a faculty member at the University of Rochester since 1994. As a clinical investigator, Dr. D'Angio holds a particular interest in vaccine immunology and research ethics. Dr. D'Angio received his medical degree from Johns Hopkins School of Medicine and completed a pediatric residency at the Children's Hospital of Philadelphia. He also completed Neonatal-Perinatal Medicine and Clinical Ethics fellowships at the University of Rochester.

Ann Johnson, PhD, is the Director of the University of Utah IRB,, previously serving as the Associate Director and Interim Director. Dr. Johnson leads an IRB that currently hosts more than 6,200 active studies and is an expert in human subject research requirements and regulations. She has been a leader in establishing the central IRB process for the University of Utah, as well as for the National Center for Advancing Translational Sciences (NCATS)-funded Trial Innovation Network.

Martha Jones, MA, is the Executive Director of the Human Research Protection Office (HRPO) at Washington University in St. Louis. Nationally, Ms. Jones serves on the Public Responsibility in Medicine and Research (PRIM&R) Board, the Council on Governmental Relations (COGR) Research and Regulatory Reform Subcommittee, the Association for the Accreditation of Human Research Protection Programs (AAAHRP) Council, the SMART IRB Harmonization Steering Committee, and co-leads the National Comprehensive Cancer Centers (NCCN) IRB Directors' Group. Ms. Jones leads the IT development team for the "myIRB" database and application system at Washington University, a system she co-developed at the University of Iowa. Ms. Jones has additional background in clinical research ethics, epidemiology, biostatistics, speech pathology, audiology, public health and the coordination and implementation of multicenter trials. Ms. Jones received her master's degree in audiology at the University of Iowa.

Lyric A. Jorgenson, PhD, is the Deputy Director for the Office of Science Policy (OSP) at the National Institutes of Health (NIH). In this position, she 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. Prior to joining OSP, Dr. Jorgenson was a Health Science Policy Advisor and Analyst under the Deputy Director for Science, Outreach, and Policy at the NIH, where she served a central role in creating new signature initiatives such as the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the National Center for Advancing Translational Sciences (NCATS). Dr. Jorgenson received her doctorate degree in neuroscience at the University of Minnesota-Twin Cities.

Stuart D. Katz, MD, MS, is the Director of the Heart Failure Program and a Helen L. and Martin S. Kimmel Professor of Advanced Cardiac Therapeutics at New York University (NYU) Langone Health. Dr. Katz is also the Chair of NYU School of Medicine's IRB Board B and Chair of the NYU Clinical and Translational Science Institute's (CTSI's) expanded Scientific Review Committee. Dr. Katz's practice has been devoted solely to clinical care and research in heart failure for over 30 years. He is also Editor-in-Chief for the *Cardiovascular Therapeutics* journal. Dr. Katz received his medical degree from SUNY Downstate Medical Center and his master's degree from Columbia University Mailman School of Public Health.

Jeffrey Krischer, PhD, is the Division Chief of the Health Informatics Institute and a professor of bioinformatics at the University of South Florida Morsani College of Medicine. Dr. Krischer is the principal investigator for several research networks that include more than 100 research sites each. Dr. Krischer's office serves on the National Center for Advancing Translational Sciences (NCATS) SMART IRB harmonization committee and has developed the OneIRB

approach to a simplified reliance agreement and coordination of the implementation of the single IRB model for large networks and consortia. Dr. Krischer received his doctorate degree in applied mathematics at Harvard University.

Kelley O'Donoghue, MPH, is the Associate Vice President for Human Subject Protection and the Director of the Office for Human Subject Protection (OHSP) at the University of Rochester. Ms. O'Donoghue is responsible for directing and managing the University of Rochester's Human Research Protection Program (HRPP), which includes oversight for the Research Subject Review Board (RSRB), as well the Research Education and Training, Research Quality Improvement, and Regulatory Systems Divisions. She has held various positions in research for 19 years, which includes serving as a clinical research coordinator, human subjects protection specialist, clinical research associate, project manager, and the RSRB Director. Ms. O'Donoghue received her master's degree in public health from the University of Rochester and has received certification as an IRB professional.

Heather H. Pierce, JD, MPH, is the Senior Director for Science Policy and Regulatory Counsel at the Association of American Medical Colleges (AAMC). Ms. Pierce serves as AAMC's leader for scientific regulatory issues including human subjects protections, clinical research, conflicts of interest, research data sharing, evidence-based regulation, and collaborations between industry, government, and academia in biomedical research. She provides subject matter expertise for AAMC's Forum on Conflict of Interest in Academe and for Convey (AAMC's global financial interest disclosure system). Ms. Pierce also serves as Chair of the Board of Directors for Public Responsibility in Medicine and Research (PRIM&R). Ms. Pierce received her law degree from New York University School of Law and her master's degree in public health from Boston University.

Emily Serdoz, MPA, is the Manager of Translational Research for the Vanderbilt Institute for Clinical and Translational Research (VICTR) at Vanderbilt University Medical Center. Ms. Serdoz has also served as the project manager for VICTR's national single IRB infrastructure initiatives, which first started as IRBshare, which became IRBchoice, and is now the IRB Reliance Exchange (IREx). With the support of the IREx team and consultants, Ms. Serdoz currently oversees system development, testing and training; marketing and outreach; user education and support; evaluation; and strategic planning of the IREx platform. Ms. Serdoz began her career at Vanderbilt University as a Research Coordinator at the Center for Evaluation and Program Improvement, coordinating the evaluation of several mental health programs, and later then went on to manage the software development of a clinical feedback system for mental health clinicians. Ms. Serdoz received her master's degree in public administration at Tennessee State University.

Susan C. Sonne, PharmD, is an Associate Professor of Psychiatry at the Medical University of South Carolina (MUSC) and serves as one of the Chairs of the MUSC IRB. She is also the

Associate Director of the Regulatory Knowledge and Support Program of MUSC's Clinical and Translational Science Award (CTSA) (South Carolina and Translational Research (SCTR) Institute) and has served as one of the primary regulatory educators throughout the MUSC campus. Dr. Sonne was an integral part of the team that developed MUSC's single IRB solution through the Click Commerce eIRB system as well as the policies and procedures needed to review and approve single IRB studies. Dr. Sonne provides trainings to the research community in good clinical practice, informed consent, IRB submission and review process, human subjects protections, vulnerable populations, engagement in research, and quality improvement versus research. Dr. Sonne received her pharmacy degree at MUSC.

Elyse Summers, JD, is the President and CEO of the Association for the Accreditation of Human Research Protection Programs (AAHRPP). She provides strategic and substantive leadership and oversight on all aspects of AAHRPP's operations. Prior to AAHRPP, Ms. Summers spent almost 15 years at the US Department of Health and Human Services' (HHS') Office for Human Research Protections (OHRP) and its predecessor, the Office for Protection Research Risks (OPRR). Prior to joining OPRR/OHRP, Ms. Summers practiced law pertaining to food, drugs, and other medical products (Buc & Beardsley) and served in the Office of the Commissioner at the US Food and Drug Administration (FDA). She has also practiced law pertaining to tax-exempt organizations (Baker and Hostetler/Steptoe and Johnson). Ms. Summers received her law degree at the George Washington University National Law Center.

Pamela Wernett, PhD, is a Health Science Policy Analyst in the Clinical and Healthcare Research Policy (CHRP) Division of the Office of Science Policy (OSP) at the National Institutes of Health (NIH). In this position, Dr. Wernett leads OSP's efforts to advance the bioethics research and policy agenda at NIH, which includes facilitating coordination between all of NIH's institutes and centers and identifying high priority areas for NIH funding. In this role, she also leads efforts related to fulfilling certain legislative clinical trials reporting requirements and analyzes science policy issues associated with clinical research, human subjects protections, and international research. Prior to joining OSP, Dr. Wernett was a Health Program Specialist at the National Institute of Neurological Disorders and Stroke (NINDS), where she served a central role in analyzing NINDS' and NIH's various neurodegenerative research portfolios and facilitating NINDS' programmatic efforts associated with neurodegenerative research. Dr. Wernett received her doctorate degree in neuroscience at the University of Iowa.

John Wilbanks is the Chief Commons Officer at Sage Bionetworks. He leads efforts in legal, technical, policy designs for informed consent; governance design, development, and implementation; communications, outreach, and partnering within various communities; and strategy. Mr. Wilbanks also serves as a co-principal investigator on various research awards that Sage Bionetworks has received from the National Institutes of Health (NIH), including ones associated with the All of Us Research Program, the Center for Data to Health, and ethical, legal, and social implications (ELSI) issues in unregulated mobile research. Mr. Wilbanks received his bachelor's degree in philosophy from Tulane University.