



## CONFIRMED SPEAKERS AND PANELISTS

# PCORI Workshop on Methodologic Challenges in Intellectual and Developmental Disabilities Research

**March 15, 2021 via GoToWebinar**

### Opening Remarks

#### **Kara Ayers, PhD**

Assistant Professor

Associate Director

University of Cincinnati Center for Excellence in Developmental Disabilities

Cincinnati Children's Hospital Medical Center

Division of Developmental and Behavioral Pediatrics

Board of Governors Member, PCORI

Kara Ayers, PhD, is the Associate Director and an Assistant Professor at the University of Cincinnati Center for Excellence in Developmental Disabilities. She is Director of the Center for Dignity in Healthcare for People with Disabilities and a cofounder of the Disabled Parenting Project. Her interests include disability identity/culture, bioethics, community inclusion, and the use of media to teach, empower, and reduce stigma. She serves on multiple task forces and national and state coalitions related to improving outcomes for people with disabilities and infuses the mantra, "Nothing about us without us," into all her scholarly and community-based pursuits. Follow Kara Ayers on Twitter @drkaraayers.

#### **Steven Goodman, MD, MHS, PhD**

Associate Dean for Clinical and Translational Research

Professor of Epidemiology & Population Health and of Medicine

Stanford University School of Medicine

Steven Goodman, MD, MHS, PhD, is Associate Dean for Clinical and Translational Research and Professor of Medicine and of Health Research & Policy (HRP) at the Stanford University School of Medicine. He directs Stanford's CTSA/Spectrum training programs in medical research methods and serves as Chief of the Division of Epidemiology in HRP. He is cofounder and codirector of the Meta-research Innovation Center at Stanford (METRICS), a group dedicated to examining and improving the reproducibility and efficiency of biomedical research.

He has been a Senior Statistical Editor of *Annals of Internal Medicine* since 1987 and has served on numerous Institute of Medicine committees since the mid-1990s, including committees on drug safety and sharing clinical trial data. He was awarded the 2016 Spinoza Chair in Medicine from the University of

Amsterdam. From 1989 to 2011, Goodman served on the faculties of the Johns Hopkins Schools of Medicine and Public Health, where he was codirector of the doctoral program in epidemiology and Director of the Johns Hopkins Cancer Center's Division of Biostatistics and Bioinformatics. He served as Editor of *Clinical Trials: Journal of the Society for Clinical Trials* from 2004 to 2013. Goodman received a bachelor of arts from Harvard University, a medical degree from New York University School of Medicine, and a master of health sciences in biostatistics and doctorate degree in epidemiology from Johns Hopkins Bloomberg School of Public Health.

## Topic 1: Measurement Issues

### Speakers

#### **Maureen Durkin, PhD, DrPH**

Evan and Marion Helfaer Professor of Public Health and Chair, Department of Population Health Sciences

University of Wisconsin School of Medicine and Public Health

Maureen Durkin, PhD, DrPH, is an epidemiologist at the University of Wisconsin-Madison, where she is Professor and Chair of the Department of Population Health Sciences and a Waisman Center investigator. Durkin received her doctorate in anthropology from UW-Madison, and master and doctor of public health degrees in epidemiology from Columbia University. Her research focuses on the epidemiology and prevention of neurodevelopmental disabilities and childhood injuries, both globally and within the United States. She has collaborated on the development of cross-culturally comparable tools for identifying children with developmental disabilities in diverse populations and has served as principal investigator and collaborator on numerous public health surveillance programs and epidemiologic studies related to intellectual and developmental disabilities including autism, cerebral palsy, and others.

#### **Tracy M. King, MD, MPH**

Medical Officer, Intellectual and Developmental Disabilities Branch

*Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)*

National Institutes of Health

Tracy King, MD, MPH, is a Medical Officer in NICHD's Intellectual and Developmental Disabilities Branch. She is a board-certified pediatrician with extensive research, clinical, and teaching experience in providing pediatric care for diverse populations. King currently oversees the NICHD portfolio on Fragile X syndrome and chairs the NIH Fragile X working group. Her portfolio also includes research on self-injurious behaviors in individuals with intellectual and developmental disabilities (IDD); the ethical, legal, and social implications of IDD research; and dissemination and implementation research relevant to IDD conditions. She also has a specific interest in research methods relevant to clinical preventive services for children. She serves as NICHD's liaison to the US Preventive Services Task Force.

King earned a bachelor's degree in biological sciences from Stanford University and a medical degree from Baylor College of Medicine. She completed her pediatric residency training at the Boston Medical Center and Boston Children's Hospital. She also completed a research fellowship in general academic

pediatrics at the Johns Hopkins School of Medicine, during which time she earned a master's degree in public health from the Johns Hopkins Bloomberg School of Public Health. Prior to joining NICHD in 2015, she served on the leadership team of the Harriet Lane Clinic, the pediatric primary care clinic for the Johns Hopkins Children's Center, and conducted research focused on improving early identification of children with developmental delays.

#### Panelists

##### **Marc J. Tassé, PhD**

Director, Nisonger Center - UCEDD  
Professor, Departments of Psychology and Psychiatry  
Ohio State University

Marc J. Tassé, PhD, is a Professor in the Department of Psychology and in the Department of Psychiatry and Behavioral Health at The Ohio State University. He is also the Director of the Ohio State Nisonger Center, a University Center for Excellence in Developmental Disabilities. Tassé has more than 30 years of experience in conducting research and providing clinical services in the field of intellectual disability (ID), autism spectrum disorder (ASD), and other related neurodevelopmental disorders (ND). He has been involved in the development of a number of standardized assessment tests for people with ID/ASD, including: Diagnostic Adaptive Behavior Scale, Supports Intensity Scale for Children, Supports Intensity Scale for Adults, Nisonger Child Behavior Rating Form, and the Quebec Adaptive Behavior Scale. His publications include more than 160 articles in peer-reviewed journals, book chapters, and books. He has given more than 285 scientific and professional presentations.

Tassé is a Fellow of the American Association on Intellectual and Developmental Disabilities, American Psychological Association, and International Association for the Scientific Study of Intellectual and Developmental Disabilities. His work has been recognized by the American Association on Intellectual and Developmental Disabilities (Exceptional Service Award: 2011, 2009 & 2007) and the American Psychological Association (Division 33 2017 John W. Jacobson Award for "meritorious contributions to the field of intellectual and developmental disabilities in an area related to behavioral psychology, evidence-based practice, dual diagnosis or public policy"), and he was recognized in 2020 for his significant national contributions to the field of IDD in the United States. (National Historic Recognition Project: 2000-2020). He is a past president of the American Association on Intellectual and Developmental Disabilities (2012-2013). Tassé is also actively involved in conducting evaluations and giving expert testimony in capital cases where intellectual disability is an issue.

##### **Ruth Luckasson, JD**

Distinguished Professor  
Chair, Department of Special Education  
University of New Mexico

Ruth Luckasson, JD, is a Distinguished Professor and Chair of the Department of Special Education at the University of New Mexico. As an educator and lawyer, Luckasson focuses on supporting people with disabilities and their families to build satisfying lives in the community, including their school communities, across the lifespan. Her work includes the definition, diagnosis, classification, and planning of supports for people with intellectual disability, clinical judgment, and the professional preparation of special education teachers and disability leaders. Luckasson has served in many leadership positions including as president of the American Association on Intellectual and Developmental Disabilities, two

terms on the President's Committee for People with Intellectual Disabilities, and as Chair of The Arc-US Legal Advocacy Committee. Recognition of her work includes the National Historic Recognition Project, AAIDD Distinguished Career Award, and the Gunnar Dybwad Humanitarian Award. She is the author or coauthor of many publications, including the 9th, 10th, 11th, and 12th editions of *Intellectual Disability: Definition, Diagnosis, Classification, and Systems of Supports*.

#### Moderator

##### **Naomi Aronson, PhD**

Executive Director

Clinical Evaluation, Innovation and Policy

Office of Clinical Affairs

Blue Cross Blue Shield Association

Naomi Aronson, PhD, leads Blue Cross Blue Shield Association's clinical effectiveness and policy engagement with government, regulatory agencies, and policy consortia. Her areas of leadership include comparative effectiveness, patient-centered research, safety surveillance, regulatory science, and methodological standards. She is a member of PCORI's Methodology Committee, the Health Technology Assessment International Health Policy Forum, the New Drug Development Paradigms initiative of the MIT Center for Biomedical Innovation, and the Medical Device Innovation Consortium National Evaluation System for Health Technology Governing Committee.

#### Topic 2: Issues in Observational and Interventional Designs

#### Speakers

##### **David Mandell, ScD**

Professor and Director, Penn Center for Mental Health; Vice Chair for Faculty Development, Department of Psychiatry

University of Pennsylvania School of Medicine

David Mandell, ScD, is the Kenneth E. Appel Professor of Psychiatry at the University of Pennsylvania Perelman School of Medicine. He is trained as a psychiatric epidemiologist and mental health services researcher. The goal of his research is to improve the quality of care individuals with psychiatric and developmental disabilities receive in their communities, with a particular focus on people with autism. This research is of two types. The first examines, at the state and national level, the effects of different strategies to organize, finance, and deliver services on service use patterns and outcomes. The second consists of experimental studies designed to determine the best strategies to successfully implement proven-efficacious practices in community settings. Mandell holds a bachelor of arts in psychology from Columbia University and a doctorate of science from the Johns Hopkins School of Hygiene and Public Health.

##### **Luther G Kalb, PhD**

Director of Informatics, Center for Autism and Related Disorders, Department of Neuropsychology

Kennedy Krieger Institute  
Assistant Professor, Department of Mental Health  
Johns Hopkins Bloomberg School of Public Health

Luther Kalb, PhD, received his master of health science and doctorate degrees from the Department of Mental Health at Johns Hopkins Bloomberg School of Public Health. Today, he is Director of Informatics at the Center for Autism and Related Disorders at the Kennedy Krieger Institute and Assistant Professor in the Department of Mental Health at the Johns Hopkins Bloomberg School of Public Health. Kalb serves as core faculty in the Wendy Klag Center for Autism at Johns Hopkins and within the Clinical Translational Arm of the Intellectual and Developmental Disabilities Research Center at Kennedy Krieger. He also chairs the National Research Consortium on Mental Health in Intellectual and Developmental Disabilities. Kalb's substantive area of research focuses on improving the measurement and treatment of mental health problems among youth with a developmental disability. Most of his research leverages data from the electronic medical record.

### Panelists

#### **Daniele Fallin, PhD**

Sylvia and Harold Halpert Professor and Chair, Department of Mental Health, Johns Hopkins Bloomberg School of Public Health  
Director, Wendy Klag Center for Autism & Developmental Disabilities  
Co-Director, Genetics Core, Claude D. Pepper Older Americans Independence Center

M. Daniele Fallin, PhD, holds a joint appointment in medicine at the Johns Hopkins University School of Medicine. She is the Sylvia and Harold Halpert Professor and Chair of the Department of Mental Health at the Johns Hopkins Bloomberg School of Public Health, where she holds joint appointments in biostatistics and genetic epidemiology. An internationally recognized expert in aging and neuropsychiatric disorders, Fallin is the Director of the Wendy Klag Center for Autism & Developmental Disabilities. She serves on the faculty of the Center for Global Health, Center for Mental Health Initiatives, and Center for Epigenetics. She earned her doctorate in genetic epidemiology from Case Western Reserve University. She also holds a bachelor of science from the University of Florida, Gainesville. Fallin joined the Johns Hopkins faculty in 2000.

#### **Danny van Leeuwen, MPH, RN, CPHQ**

Founder, Health Hats  
Board of Governors Member, PCORI

Danny van Leeuwen, MPH, RN, is the founder and principal of Health Hats, where he advocates for patients and caregivers, focusing on health equity, healthcare decision making, and communicating health information, and is also a member of the PCORI Board of Governors. He previously served as the Vice President for Quality Management at Advocates, Inc., providing support services to individuals and families with mental illness and developmental and cognitive challenges, and led Boston Children's Hospital's Patient-Family Experience Initiative. A patient-caregiver activist, person with disabilities from multiple sclerosis, care partner to several family members' end-of-life journeys, registered nurse for over 45 years, informaticist, and podcaster, he serves widely as a technical expert. For example, he is a National Quality Forum Patient and Caregiver Engagement advisor and serves as a member of their Standing Committee for Cost and Efficiency Measures. He serves on the Centers for Medicare &

Medicaid Services-funded panel for Physician Cost Measures and Patient Relationship Codes and the Agency for Healthcare Research and Quality's Digital Healthcare Research Strategy Plan. He served on the steering committee of the agency's Patient-Centered Clinical Decision Support Learning Network. van Leeuwen earned his master of public health from the University of Minnesota, his bachelor of arts from Glenville State College, and his registered nurse degree from Wayne County Community College.

#### Moderator

##### **Brian Mittman, PhD**

Director

Research Scientist, Health Services Research and Implementation Science, Kaiser Permanente Southern California, Dept. of Research & Evaluation

Brian S. Mittman, PhD, is a research scientist at the Kaiser Permanente Department of Research and Evaluation, Division of Health Services Research and Implementation Science. He co-leads the UCLA Clinical and Translational Science Institute's Implementation and Improvement Science Initiative, and has additional affiliations with the US Department of Veterans Affairs (voluntary position) and RAND Health Program. Mittman chaired the planning committee that launched the journal *Implementation Science*, and is currently coeditor in chief emeritus. He was a founding member of the Institute of Medicine Forum on the Science of Health Care Quality Improvement and Implementation, and past Chair of the NIH Special Emphasis Panel on Dissemination and Implementation Research in Health. He serves on the Association of American Medical Colleges Advisory Panel on Research and on additional advisory committees for research programs, projects, and training institutes in the United States and internationally. Mittman received a bachelor of science in engineering from Princeton University, master of arts in sociology from Stanford University, and a doctorate in organizational behavior and management from the Stanford University Graduate School of Business.

#### Topic 3: Heterogeneity

#### Speakers

##### **Sarabeth Broder-Fingert, MD, MPH**

Associate Professor

Boston University School of Medicine

Sarabeth Broder-Fingert, MD, MPH, is a pediatrician, health services research, and implementation scientist working to develop and test novel interventions to improve the lives of vulnerable children with autism spectrum disorder (ASD). She has a successful track record of developing, testing, implementing, and disseminating interventions to improve care for ASD. She is principal investigator (PI) of multiple National Institute of Mental Health-funded R01-awards to study novel interventions to improve early diagnosis and treatment of ASD. She serves as the implementation PI for a multisite randomized controlled trial of a community-based intervention for ASD in which she is working to advance methodology for measuring and analyzing fidelity and adaptations to autism interventions in the "real world." She is a Fellow of the Implementation Research Institute; has over 50 publications in the field; and codirects the Innovation in Autism Disparities, Inclusion, Outreach, and Transition Services Lab at

Boston University. In her spare time, she enjoys swimming, gardening, and tumbling down the mountain while her young children ski circles around her.

**Tawara D. Goode**

Director, Georgetown University Center for Excellence in Developmental Disabilities

Director, Georgetown University National Center for Cultural Competence

Georgetown University Center for Child & Human Development

Assistant Professor, Department of Pediatrics

Georgetown University Medical Center

Tawara Goode is an Assistant Professor in the Department of Pediatrics, Georgetown University Medical Center in Washington, DC. She has been on the faculty of the Georgetown University Center for Child and Human Development for more than 30 years and has served in many capacities. She has degrees in early childhood education and education and human development. Goode has extensive experience as a principal investigator for federal and private sector grants and contracts. She is the Director of the National Center for Cultural Competence (NCCC) at Georgetown University Center for Child & Human Development. The NCCC has been in existence for the past 25 years during which Goode was the director for 24 years. She is also the Director of the Georgetown University Center for Excellence in Developmental Disabilities and is responsible for short-term and ongoing programs for individuals at risk for and with developmental and other disabilities and their families.

A primary area of focus for Goode is national-level efforts to advance and sustain cultural and linguistic competence within an array of settings including but not limited to institutions of higher education, health, mental health, and other human service systems. She continues to conduct research on cultural and linguistic competence and its role in addressing health and healthcare disparities. Selected examples of studies include: 1) a collaborative effort to create validated instruments to measure cultural and linguistic competence in healthcare settings; 2) a multisite project to examine health disparities for populations at the intersection of race, ethnicity, and disability; and 3) a community-engaged study to examine if barriers to participation in research by racial and ethnic groups (other than non-Hispanic White) can be reduced by “truth and reconciliation” community forums designed to acknowledge past injustices and exploitation committed by researchers and research institutions and to foster reconciliation.

Goode is currently a co-principal investigator for a PCORI study entitled Reconciling the Past and Changing the Future: Engaging Young Adults with Intellectual and Developmental Disabilities and Researchers in Comparative Effectiveness Research, and is an investigator for a PCORI supplement entitled Understanding the Impact of COVID-19 on Young Adults with IDD-MH and their Families: An Analytical Framework and Database to Identify Service Experiences and Outcomes Across Diverse Populations in Real Time.

**Panelists**

**Elizabeth Stuart, PhD**

Associate Dean for Education, Professor; Department of Mental Health, Department of Biostatistics, Department of Health Policy and Management  
Johns Hopkins Bloomberg School of Public Health

Elizabeth A. Stuart, PhD, is Bloomberg Professor of American Health in the Department of Mental Health at the Johns Hopkins Bloomberg School of Public Health, with joint appointments in the Department of Biostatistics and the Department of Health Policy and Management. She received her doctorate in statistics in 2004 from Harvard University and is a Fellow of the American Statistical Association (ASA) and the American Association for the Advancement of Science. Stuart has extensive experience in methods for estimating causal effects and dealing with the complications of missing data in experimental and nonexperimental studies, particularly as applied to mental health, public policy, and education. Her primary research interests include designs for estimating causal effects in nonexperimental settings (such as propensity scores) and methods to assess and enhance the generalizability of randomized trials to target populations. She has received research funding for her work from the National Science Foundation, the Institute of Education Sciences, the WT Grant Foundation, and the National Institutes of Health and has served on advisory panels for the National Academy of Sciences, the US Department of Education, and PCORI.

She received the mid-career award from the Health Policy Statistics Section of the ASA, the Gertrude Cox Award for applied statistics, Harvard University's Myrto Lefkopoulos Award for excellence in biostatistics, and the inaugural Society for Epidemiologic Research Marshall Joffe Epidemiologic Methods Award. She was also the inaugural Chair of the PCORI Clinical Trials Advisory Panel.

### **Bradley L Schlaggar, MD, PhD**

President & CEO, Zanvyl Krieger Endowed Chair  
Kennedy Krieger Institute

Bradley L. Schlaggar, MD, PhD, is the President and CEO of Kennedy Krieger Institute in Baltimore, Maryland, where he holds the Zanvyl Krieger Faculty Endowed Chair. He is also a Professor of Neurology and Pediatrics at Johns Hopkins University School of Medicine. Schlaggar directs the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development-funded Intellectual & Developmental Disabilities Research Center at Kennedy Krieger Institute. He also directs the National Institute of Neurological Disorders and Stroke-funded Child Neurologist Career Development Program, supporting the early career development of aspiring physician-scientists.

Prior to moving to Baltimore in August 2018, Schlaggar was the A. Ernest and Jane G. Stein Professor of Developmental Neurology and Professor of Neurology, Radiology, Neuroscience, Psychiatry, and Pediatrics at Washington University in St. Louis School of Medicine. From 2005 to 2013, he served as the Pediatric Neurology Residency Director. From 2014 to 2018, he served as the Head of Pediatric & Developmental Neurology, Codirector of the Intellectual & Developmental Disabilities Research Center, and Neurologist-in-Chief at St. Louis Children's Hospital.

He has received numerous awards for research, mentorship, clinical care, and community service, including the Philip R. Dodge Young Investigator Award from the Child Neurology Society, the Humanitarian Award from the Tourette Association of America, the Norman Geschwind Award for Behavioral Neurology from the American Academy of Neurology, the E. Mead Johnson Award from the

Society for Pediatric Research, and the Frank Hatch Award for Outstanding Community Service from the John Merck Foundation. In 2021, he was elected to the Association of American Physicians.

Schlaggar's research efforts are directed at understanding the development of the brain's functional network architecture in typically and atypically developing children. He received a bachelor of science from Brown University in 1986 and a medical degree/doctorate from Washington University in 1994.

**Melissa A. Parisi, MD, PhD**

Chief, Intellectual & Developmental Disabilities Branch, DS-Connect® Registry Coordinator  
*Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)*  
National Institutes of Health (NIH)

Melissa A. Parisi, MD, PhD, Chief of NICHD's Intellectual and Developmental Disabilities Branch, joined NICHD in October 2008 and currently oversees NICHD's Eunice Kennedy Shriver Intellectual and Developmental Disabilities Research Centers. She is interested in advancing basic, clinical, and translational research that will improve the lives of individuals with developmental disabilities. Parisi earned her medical and doctorate degrees in developmental biology from Stanford University, where her research focused on mitochondrial transcription. She completed a pediatric residency at the University of Washington, followed by fellowship training in medical genetics.

Prior to joining NIH, she was an Assistant Professor in the Department of Pediatrics at the University of Washington and Seattle Children's Hospital, where she was active as a clinical geneticist and as a researcher in the field of congenital malformations of the human hindbrain, specifically Joubert syndrome and related disorders. In her clinical practice in Washington and Alaska, Parisi was involved in the evaluation, diagnosis, and management of children and adults with genetic syndromes, chromosomal disorders, and developmental disabilities. She also served as Chair of the scientific advisory board of the Joubert Syndrome and Related Disorders Foundation.

**Moderator**

**Cindy Girman, DrPH**

President and Sole proprietor  
CERobs Consulting LLC

Cynthia Girman, DrPH, FISPE, is president and sole proprietor of CERobs Consulting, LLC, which provides consulting on study design and methodology for comparative effectiveness research and real-world randomized pragmatic clinical trials as well as the development and validation of patient-reported outcomes. Previously, Girman was Executive Director and Head of Data Analytics & Observational Methods in the Center for Observational & Real World Evidence at Merck Research Laboratories, from which she retired after 33 years. She founded the Merck Center of Excellence on the development and validation of endpoints for clinical trials, including patient-reported outcomes, and her work has focused on incorporating patient input into clinical trials endpoint identification. With experience in biostatistics, epidemiology and observational research methods, Girman has been involved in a range of collaborative methodology research activities with universities in the United States and Europe.

She is Adjunct Professor in Epidemiology at the University of North Carolina Gillings School of Public Health and a Fellow of the International Society for Pharmacoepidemiology. Girman received a master of science in applied statistics and computer science from Villanova University and a doctor of public health in biostatistics/epidemiology from the School of Public Health at the University of North Carolina.