

NLM Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization

Chair: Carlos R. Jaén, MD, PhD, University of Texas Health Science Center at San Antonio

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- Gary A. Puckrein, PhD, National Minority Quality Forum

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- Lyric A. Jorgenson, PhD, Office of Science Policy, NIH
- Pamela Reed Kearney, MD, Office of Extramural Research, NIH

External Members:

- Carrie Dykes, PhD, University of Rochester Medical Center
- Alissa Gentile, MSN, RN, The Leukemia and Lymphoma Society
- Sally A. Gore, MS, MS LIS, University of Massachusetts Medical School
- Barbara Kress, BSN, RN, Merck
- Seth A. Morgan, MD, National Multiple Sclerosis Society
- Stephen J. Rosenfeld, MD, MBA, SACHRP
- Joseph S. Ross, MD, MHS, Yale School of Medicine
- Steven Woloshin, MD, The Dartmouth Institute

Biographies

CHAIR: CARLOS R. JAÉN

Carlos R. Jaén, MD, PhD, is the Holly Distinguished Chair, Patient-Centered Medical Home, Professor and Chair of Family and Community Medicine, and Professor of Population Health at the University of Texas Health Science Center at San Antonio. Dr. Jaén's research interests focus on improving preventive care for individuals of all ages and preventing complications from chronic diseases such as diabetes, high blood pressure, and heart disease. He is passionate about building and studying high-performance primary care offices. He served on the panels that published smoking cessation guidelines in 1996 and 2000 and was co-chair of the panel that published an update in 2008. In 2005 he was appointed to the National Advisory Council of the Agency for Healthcare Research and Quality, and he was also an appointed member of the New York State Public Health Council. He was Co-Director of the Center for Research in Family Medicine and Primary Care, which studied more than 500 mostly independent primary-care practices over the last 20 years. He received a Generalist Physician Faculty Scholar Award from the Robert Wood Johnson Foundation and a Cancer Control Career Development Award for Primary Care Physicians from the American Cancer Society. His interests include building a healthier San Antonio through efforts in community wellness.

Dr. Jaén has a PhD in epidemiology and community health and an MD, both from the State University of New York at Buffalo, and an MS in oncology from Niagara University. He completed a residency in Family Medicine and a Primary Care Research Fellowship at Case Western Reserve University. He is a practicing family physician and has been among the Best Doctors in America annually since 2002. He was chair of the Board of Directors of the American Board of Family Medicine in 2014 and was elected to the National Academy of Medicine (formerly the Institute of Medicine) of the National Academies in 2013.

EXECUTIVE SECRETARY: REBECCA (BECKY) J. WILLIAMS

Rebecca (Becky) J. Williams, PharmD, MPH, is Acting Director of ClinicalTrials.gov, an international registry and results database of clinical research, at the National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health. She assumed this role after serving as Assistant Director of ClinicalTrials.gov for more than a decade. Dr. Williams is responsible for technical, scientific, policy, regulatory, and outreach activities related to the operation of ClinicalTrials.gov. Her research interests relate to improving the quality of the reporting of clinical research. Her prior experience includes regulatory affairs consultant and reviewer and supervisory roles at the U.S. Food and Drug Administration in the area of prescription drug advertising and promotion.

Dr. Williams has a PharmD from the University of Wisconsin–Madison and an MPH from the Bloomberg School of Public Health at Johns Hopkins University.

BOARD OF REGENTS MEMBER: LOURDES BAEZCONDE-GARBANATI

Lourdes Baezconde-Garbanati, PhD, MPH, is Associate Dean for Community Initiatives at the Keck School of Medicine and Associate Director for Community Outreach and Engagement at the Norris Comprehensive Cancer Center at the University of Southern California (USC). She is a tenured Professor of Preventive Medicine and the Associate Director for the Center for Health Equity in the Americas.

Dr. Baezconde-Garbanati is an expert in researching cancer disparities in diverse populations, developing effective culturally specific cancer prevention interventions, and engaging at-risk populations in community-based participatory research. She has been a key member of six National Institutes of Health-funded research centers. Currently, she is one of the key investigators at the Tobacco Center for Regulatory Sciences at USC.

Dr. Baezconde-Garbanati speaks multiple languages and holds five academic degrees. She has a PhD and an MPH in public health from the University of California, Los Angeles, where she focused on community health sciences and social epidemiology. She has a master's degree from the Université catholique de Louvain in Belgium and received dual degrees in industrial and clinical psychology from the Universidad Nacional Pedro Henríquez Ureña in the Dominican Republic.

BOARD OF REGENTS MEMBER: GARY A. PUCKREIN

Gary A. Puckrein, PhD, is President and Chief Executive Officer of the National Minority Quality Forum (NMQF). NMQF strengthens efforts to use evidence-based, data-driven initiatives to eliminate premature death and preventable illness for racial and ethnic minorities and other special populations.

Under Dr. Puckrein's leadership, and with support from the Department of Health and Human Services, the Health Resources and Services Administration, and the Robert Wood Johnson Foundation, NMQF launched the ZIP Code Analysis Project (ZCAP) in 1998. ZCAP is the predecessor database of the National Health Index (NHI).

NHI is a comprehensive database that links vital statistics, demographic, environmental, claims, prescription drug, clinical laboratory values, health care access points (e.g., hospitals, physicians' offices), and other data elements in one centralized data warehouse, organized around ZIP Code. NHI measures and forecasts health status in small geographic areas, evaluates the impact of scientific interventions, monitors changes in health outcomes, and undertakes risk assessments (i.e., health care utilization and its financial implications). NMQF uses NHI to provide a common set of indicators—geographic and health status referents—to stratify communities by health status.

In addition to his work for NMQF, Dr. Puckrein possesses a unique business and academic background. He has a PhD and a master's degree from Brown University, where he graduated Phi Beta Kappa.

EX OFFICIO MEMBER: LYRIC A. JORGENSON

Lyric A. Jorgenson, PhD, is Deputy Director for the Office of Science Policy (OSP) at the National Institutes of Health (NIH). 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 federal government. She also served as Deputy Executive Director of the White House Cancer Moonshot Task Force in the Office of the Vice President during the Obama administration, directing and coordinating cancer-related activities across the federal government and working 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 NIH, playing a central role in creating new signature initiatives such as the Brain Research through Advancing Innovative Neurotechnologies Initiative and the National Center for Advancing Translational Sciences. She was also a Science and Technology Fellow for the American Association

for the Advancement of Science and has received numerous awards in recognition of her accomplishments and service.

Dr. Jorgenson has a PhD from the Graduate Program for Neuroscience at the University of Minnesota Twin Cities, where she conducted research in neurodevelopment with a focus on learning and memory systems.

EX OFFICIO MEMBER: PAMELA REED KEARNEY

Pamela Reed Kearney, MD, is Director of the Division of Human Subjects Research within the Office of Extramural Research (OER) at the National Institutes of Health (NIH). Prior to joining OER, she was the deputy chair of the Combined NeuroScience Institutional Review Board (CNS IRB) in the NIH Intramural Program for approximately a decade. In this capacity, she sat on three to four duly constituted IRBs, chairing one and serving as the vice chair of the others.

Dr. Kearney graduated with distinction from The George Washington University School of Medicine and completed an otolaryngology residency at The George Washington University. She was a Neurology Clinical Fellow for the National Institute of Neurological Disorders and Stroke in the Medical Neurology Branch's Laryngeal and Speech Section, and she later served as the Staff Clinician of the section. She has done clinical work at The George Washington University, Walter Reed Army Medical Hospital, and the NIH Clinical Center.

EXTERNAL MEMBER: CARRIE DYKES

Carrie Dykes, PhD, serves as Director of Research Services at the University of Rochester Clinical and Translational Science Institute (UR CTSI). Her primary role is to strategically plan, develop, implement, and evaluate the research resources and services of UR CTSI, and she provides leadership for the management and oversight of the Research Help Desk, Recruitment Unit, Clinical Research Center, Pilot and Incubator award programs, and Office of Regulatory Support. Dr. Dykes develops and assesses research education materials for a variety of constituencies across the University of Rochester Medical Center. She serves as the University of Rochester's ClinicalTrials.gov Protocol Registration and Results System administrator and is on the leadership board of the Clinical Trials Registration and Results Reporting Taskforce.

Dr. Dykes has a PhD from the University of Rochester and worked in the field of HIV drug resistance research for 20 years before joining UR CTSI.

EXTERNAL MEMBER: ALISSA GENTILE

Alissa Gentile, MSN, RN, serves as Director of The Leukemia and Lymphoma Society (LLS) Clinical Trial Support Center, leading LLS's efforts to educate and assist patients and caregivers affected by blood cancers regarding the treatment option of clinical trials. Through education, advocacy, coaching, and decision-support services, she and her team of nurse navigators help patients weigh their unique concerns related to receiving care through standard treatment or a clinical trial. LLS is the world's largest voluntary health agency dedicated to blood cancer. Its mission is to cure leukemia, lymphoma, and myeloma and to improve the quality of life of patients and their families. In addition to her work for LLS, Ms. Gentile is an active member of the American Cancer Society Cancer Action Network Barriers to Clinical Trial Enrollment work group.

Prior to joining LLS, Ms. Gentile held the position of nurse educator for the Emergency Department and Cardiac Interim Care Unit at St. Elizabeth's Medical Center in Boston, MA, and early in her career, she worked as a Certified Emergency Department Nurse. She has a bachelor's degree in nursing from the University of New Hampshire and an MSN in nursing management and education from Capella University.

EXTERNAL MEMBER: SALLY A. GORE

Sally A. Gore, MS, MS LIS, is Manager of Research and Scholarly Communication Services for the Lamar Soutter Library at the University of Massachusetts Medical School. She oversees the library's collaborative efforts with basic science and clinical researchers on campus, including expanded support and instruction in data services. Her department leads all scholarly communication endeavors for the library, including providing bibliometric analysis; tracking research impacts; ensuring funder-based public-access compliance; promoting open science initiatives; and managing eScholarship@UMMS, the university's open access institutional repository. Ms. Gore also serves on the Board of Directors of the Medical Library Association and is Associate Editor of the *Journal of eScience Librarianship*.

Prior to assuming her current position, Ms. Gore was the Research Evaluation Analyst for the University of Massachusetts Center for Clinical and Translational Science. She was also a National Library of Medicine grant-funded informationist at the Lamar Soutter Library, a reference and instruction librarian, and a consumer health librarian.

EXTERNAL MEMBER: BARBARA KRESS

Barbara Kress, BSN, RN, is Executive Director of Clinical Data Disclosure and Transparency at Merck. She is responsible for registry and results disclosure, redaction operations, data sharing, and the return of plain language summaries to patients. She joined Merck 23 years ago as a clinical scientist working on the successful development and submission of several compounds. In 2007 Ms. Kress was asked to assume an additional responsibility that she was told would take up only 5 percent of her time: ClinicalTrials.gov. Twelve years and 28 staff members later, disclosure requires 100 percent of her time.

Ms. Kress began her career as a critical care and emergency room nurse. She currently participates in various Pharmaceutical Research and Manufacturers of America, European Federation of Pharmaceutical Industries and Associations, and TransCelerate disclosure work streams. Ms. Kress is a member of the Executive Committee of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, participating in the Data Sharing and Return of Results (aggregate and individual) working groups.

EXTERNAL MEMBER: SETH A. MORGAN

Seth A. Morgan, MD, was a clinical neurologist for more than 20 years before becoming an advocate for people living with multiple sclerosis (MS), following his own MS diagnosis in 2004. As an activist, Dr. Morgan has been involved in a number of efforts to support people with MS and other types of disabilities. He has been an advocate/activist for the National Multiple Sclerosis Society Greater DC-Maryland Chapter, serving on the Governmental Relations Committee and as a District Activist Leader since 2014. He has been a commissioner on the Montgomery County, Maryland, Commission on People with Disabilities since 2009 and has chaired the commission since 2015; he has also been a member of the Maryland Alliance of Disability Commissions and

Committees since 2012 and has served as vice-chair since 2015. Dr. Morgan's other public service activities have included being a member of the iConquerMS Research Committee since 2016, the Patient-Centered Outcomes Research Institute's Clinical Trials Advisory Panel from 2016 to 2019, and the National Multiple Sclerosis Society Activism Advisory Committee since 2018. He was also a reviewer for the Congressionally Directed Medical Research Programs from 2014 to 2016.

Dr. Morgan received his medical degree from The George Washington University School of Medicine and Health Sciences, and he completed a residency in neurology at The George Washington University Medical Center. He is a Fellow of the American Academy of Neurology, a Fellow of the Stroke Council of the American Heart Association, and a Diplomate of the American Academy of Pain Medicine. Dr. Morgan was inducted into the National Multiple Sclerosis Society Advocacy Hall of Fame in 2015.

EXTERNAL MEMBER: STEPHEN J. ROSENFELD

Stephen J. Rosenfeld, MD, MBA, is a hematologist. He spent 19 years at the National Institutes of Health (NIH), holding positions at the National Heart, Lung, and Blood Institute (NHLBI) and the NIH Clinical Center related to both basic and clinical research and, later, working in medical informatics and administration. He ended his career at NIH as Chief Information Officer of the NIH Clinical Center. He subsequently served as Chief Information Officer of MaineHealth, a large independent delivery network based in Portland, ME, and as Chief Executive Officer of the Western Institutional Review Board in Olympia, WA. Most recently, Dr. Rosenfeld served for 7 years as the executive chair of Quorum Review IRB.

Dr. Rosenfeld earned his medical degree from Cornell University. He trained in internal medicine at Dartmouth College and completed his hematology fellowship at NHLBI. Dr. Rosenfeld also has an MBA from Georgetown University. He received the honor of Distinguished Professor of Medicine from Daegu Catholic University Medical Center in Korea in 2013. Also in 2013, he was appointed to the Secretary's Advisory Committee on Human Research Protections (SACHRP) at the Department of Health and Human Services, and in 2016 he was appointed chair of SACHRP. In 2018 he was elected to the Board of Directors of Public Responsibility in Medicine and Research, and in 2019 he joined the Board of Directors of the Association for the Accreditation of Human Research Protection Programs.

EXTERNAL MEMBER: JOSEPH S. ROSS

Joseph S. Ross, MD, MHS, is Professor of Medicine (General Medicine) and of Public Health (Health Policy and Management) at the Yale School of Medicine, a member of the Center for Outcomes Research and Evaluation at Yale-New Haven Health System, and Co-Director of the National Clinician Scholars Program at Yale School of Medicine. With expertise in the development of performance measures and the translation of clinical research into practice, Dr. Ross examines the use and delivery of higher-quality care and issues related to pharmaceutical and medical device regulation, evidence development, postmarket surveillance, and clinical adoption. Dr. Ross codirects the Yale University-Mayo Clinic Center of Excellence in Regulatory Science and Innovation, the Yale University Open Data Access Project, and the Collaboration for Research Integrity and Transparency at Yale Law School. He has published more than 400 articles in peer-reviewed biomedical journals and is currently U.S. Outreach and Research Editor for the *British Medical Journal* (BMJ).

Dr. Ross earned his medical degree from the Albert Einstein College of Medicine and an MHS from the Yale School of Medicine.

EXTERNAL MEMBER: STEVEN WOLOSHIN

Steven Woloshin, MD, is a general internist, Professor of Medicine and Community and Family Medicine, and Director of the Center for Medicine and the Media at The Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth. His research addresses the excessive fear and hope created by exaggerations and selective reporting in medical journals, advertising, and the health news. He has worked to improve the communication of medical evidence to physicians, journalists, policy makers, and the public, so they can make wiser decisions.

With Lisa Schwartz, Dr. Woloshin developed the National Institutes of Health's Medicine in the Media workshop and ran it for more than a decade. He is coauthor of the books *Know Your Chances* (selected for the National Library of Medicine bookshelf) and *Overdiagnosed* (winner of the Prescrire Prize). His essays have appeared in *The New York Times*, *The Washington Post*, and *Los Angeles Times*. Dr. Woloshin is a founding organizer of the international Preventing Overdiagnosis meetings sponsored by *The BMJ*, The Dartmouth Institute, Consumers Union, and Oxford and Bond University (Australia). He collaborates frequently with the National Cancer Institute, serves on the editorial board of *JAMA Internal Medicine*, is a series consultant for *The BMJ*, and is a strategic advisor to Cochrane Sustainable Healthcare. He and Dr. Schwartz were co-winners of the American Medical Writers Association John P. McGovern Award for preeminent contributions in research and enhancing the communication of medical evidence. He is also the founder and director of the Lisa Schwartz Foundation for Truth in Medicine.

Dr. Woloshin received his medical degree from the Boston University School of Medicine, completed internal medicine training at NYU/Bellevue Hospital, and completed a research fellowship at the White River Junction VA Medical Center in Vermont. He has an MS from the Geisel School of Medicine at Dartmouth.