

National Library of Medicine (NLM) Board of Regents Public Service Working Group on ClinicalTrials.gov Modernization

Chair: Lourdes Baezconde-Garbanati, PhD, MPH, University of Southern California

Executive Secretary: Anna M. Fine, PharmD, MS, NLM, NIH

Board of Regents Members:

- Kent J. DeZee, MD, MPH, MACP, COL, MC, Defense Health Agency
- Jennifer (Jennie) S. Lucca, MSW, The Children's Inn at NIH
- Omolola (Lola) Ogunyemi, PhD, FACMI, Charles R. Drew University of Medicine and Science
- Nancy Smider, PhD, Epic

Ex Officio NIH Members:

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

External Members:

- Carrie Dykes, PhD, University of Rochester Clinical and Translational Science Institute
- Alissa T. Gentile, MSN, RN, Dana-Farber Cancer Institute
- 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, North Star Review Board and Freeport Research Systems
- Joseph S. Ross, MD, MHS, Yale School of Medicine
- Steven Woloshin, MD, The Dartmouth Institute for Health Policy and Clinical Practice

Biographies

Chair: 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 tenured Professor of Population and Public Health Sciences and 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 NIH-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.

Executive Secretary: Anna M. Fine

Anna M. Fine, PharmD, MS, 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, NIH. As Acting Director, she is responsible for technical, scientific, policy, regulatory, and outreach activities related to the operation of ClinicalTrials.gov. Dr. Fine assumed this role in 2021, after having served as deputy director since 2018. Her previous experience includes over a decade of service in stakeholder engagement, adverse drug event reporting, and supervisory roles at the U.S. Food and Drug Administration. Prior to that, she was Chief of Pharmacy Services at Hanscom Air Force Base in Massachusetts.

Dr. Fine has a PharmD from Northeastern University and an MS in psychopharmacology from William James College. She completed a postgraduate year two drug information residency at Stanford Hospital.

Board of Regents Member: Kent J. DeZee

Kent J. DeZee, MD, MPH, MACP, COL, MC, is Director for Graduate Medical Education at the Defense Health Agency. He previously served as Director of the Army Medical Education Directorate for the Office of the Surgeon General Defense Health Headquarters.

Col. DeZee earned his medical degree from The Ohio State University College of Medicine. He completed his residency at the Tripler Army Medical Center and a fellowship in general medicine at the Uniformed Services University of the Health Sciences, where he earned an MPH.

Board of Regents Member: Jennifer S. Lucca

Jennifer (Jennie) S. Lucca, MSW, is Chief Executive Officer of The Children's Inn at NIH. A seasoned human service professional, Ms. Lucca has more than 20 years of experience in the nonprofit sector. She previously served as The Inn's Chief Program and Services Officer, overseeing the daily management of resident services, family programs, and facility operations.

Ms. Lucca's career began in Anchorage, Alaska, where she worked for The Arc of Anchorage, an organization dedicated to serving individuals with disabilities. Since that time, she has focused primarily on developing and managing family support programs in community and health care settings. Passionate about supporting families during times of significant stress, Ms. Lucca has been acknowledged for her compassion, dedication, and strategic leadership.

Ms. Lucca has a bachelor's degree in child psychology from the University of Minnesota and an MSW with a focus on policy, planning, and administration from The Catholic University of America.

Board of Regents Member: Omolola Ogunyemi

Omolola (Lola) Ogunyemi, PhD, FACMI, is Director of the Center for Biomedical Informatics (CBI) and a professor in the Department of Preventive and Social Medicine at Charles R. Drew University of Medicine and Science. She is also a co-chair of the UCLA Clinical and Translational Science Institute's biomedical informatics program and adjunct Professor of Radiological Sciences at the David Geffen School of Medicine at UCLA, with the Medical and Imaging Informatics group. Her research at CBI focuses on novel biomedical informatics solutions for problems that affect medically underserved communities, and her research interests include computerized medical-decision support, reasoning under uncertainty, 3D graphics and visualization, and machine learning. Before becoming Director of CBI, Dr. Ogunyemi was a biomedical informatics faculty member in the Department of Radiology at Brigham and Women's Hospital and Harvard Medical School, among other teaching positions.

Dr. Ogunyemi is currently an editorial board member for the *Journal of Biomedical Informatics* and was an editorial board member for *Computers in Biology and Medicine* from 2007 to 2013. She served on the National Library of Medicine's (NLM) Biomedical Library and Informatics Review Committee study section from 2003 to 2007 and on NLM's Literature Selection and Technical Review Committee from 2010 to 2014, both as a member and as chair. She was a member of the Agency for Healthcare Research and Quality Health Information Technology Research study section from 2016 to 2019 and a member of the American Medical Informatics Association's Doctoral Dissertation Award Committee from 2017 to 2020.

Dr. Ogunyemi has an undergraduate degree in computer science from Barnard College and an MSE and a PhD in computer and information science from the University of Pennsylvania. She is an elected Fellow of the American College of Medical Informatics.

Board of Regents Member: Nancy Smider

Nancy Smider, PhD, is Director of Research Informatics at Epic, where she focuses on Epic's electronic health record system as an enabling and accelerating technology to support the clinical research mission

of health care organizations, including the execution of clinical trials. Dr. Smider joined Epic in 2001 and has led Epic's Research Advisory Council for more than 15 years. In addition to her extensive engagement with research leadership and stakeholders across the Epic community, Dr. Smider has been involved in numerous industrywide research work groups, conferences, and initiatives. She currently serves on the Vulcan HL7 FHIR Accelerator Advisory Council, which advocates for standards-based interoperability to facilitate a range of research activities.

Dr. Smider has a PhD in psychology from the University of Wisconsin–Madison. After completing a postdoctorate in health services research, she accepted a position as a research scientist at the University of Wisconsin School of Medicine, where she continued her work as part of a multidisciplinary team examining biopsychosocial models of health and disease.

Ex Officio NIH Member: Lyric A. Jorgenson

Lyric A. Jorgenson, PhD, is Acting Associate Director for Science Policy and Acting Director of the Office of Science Policy at NIH. In this role she provides senior leadership in the development and oversight of cross-cutting biomedical research policies and programs considered to be of high priority to NIH and the U.S. government. Previously she served in many roles across the agency, including Deputy Director of the Office of Science Policy, and she has led the development of numerous high-impact science and policy initiatives, such as the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the National Center for Advancing Translational Sciences. Dr. Jorgenson 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, 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.

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, and a bachelor's degree in psychology from Denison University.

Ex Officio NIH Member: Pamela Reed Kearney

Pamela Reed Kearney, MD, is Director of the Division of Human Subjects Research in the Office of Extramural Research (OER) at NIH. Prior to joining OER, she was the deputy chair of the Combined NeuroScience Institutional Review Board (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 Neurolaryngology 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 conducted clinical work at The George Washington University, Walter Reed Army Medical Hospital, and the NIH Clinical Center.

External Member: Carrie Dykes

Carrie Dykes, PhD, is 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. She also develops and assesses research education materials for a variety of constituencies across the University of Rochester Medical Center. Dr. Dykes 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 T. Gentile

Alissa T. Gentile, MSN, RN, serves as the Dana-Farber Cancer Institute Research Nursing Manager for the Satellites and Collaborative. In this role she leads the design, implementation, and evaluation of clinical oncology research and services conducted at Dana-Farber satellite and Collaborative locations and is a key facilitator for the oncologists in the growth and development of the clinical research program across all Dana-Farber sites. Her responsibilities include providing nursing input for the review of prospective clinical trials and for retrospective review protocols; collaborating with study teams and network nurse leaders on hiring, training, and supervising satellite research nurses; and training and supporting Collaborative research nursing staff. She serves as the primary research nursing liaison between the satellite and Collaborative sites and Dana-Farber's main Longwood campus.

Prior to joining Dana-Farber, Ms. Gentile was the director of The Leukemia and Lymphoma Society's Clinical Trial Support Center, leading the efforts of a team of nurse navigators to educate people affected by blood cancers about the treatment option of clinical trials and to assist them in navigating the process of clinical trial enrollment. Previously she held the position of nurse educator at St. Elizabeth's Medical Center in Boston, Massachusetts, and early in her career she worked for many years as a Certified Emergency Department Nurse. Ms. Gentile has a bachelor's degree in nursing from the University of New Hampshire as well as an MSN focused on nursing management and education.

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. Ms. Gore has an MS LIS from Syracuse University.

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. Ms. Kress joined Merck in 1997 as a clinical scientist working on the successful development and submission of several compounds. In 2007 she was asked to assume an additional responsibility that she was told would take up only 5% of her time: ClinicalTrials.gov. Fifteen years and more than 30 staff members later, disclosure requires 100% of her time.

Ms. Kress currently participates in various Pharmaceutical Research and Manufacturers of America, European Federation of Pharmaceutical Industries and Associations, and TransCelerate disclosure work streams. She is also 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. Ms. Kress began her career as a critical care and emergency room nurse. She has a bachelor's degree in nursing science from Rutgers University.

External Member: Seth A. Morgan

Seth A. Morgan, MD, is a Fellow of the American Academy of Neurology who served as 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. An activist for people with MS and other types of disabilities, Dr. Morgan is a member and the current chair of the National Multiple Sclerosis Society's (NMSS) Maryland Governmental Relations Committee and an NMSS District Activist Leader. He is a commissioner on and the current chair of the Montgomery County, Maryland, Commission on People with Disabilities, the vice chair of the Maryland Alliance of Disability Commissions and Committees, and a commissioner on the Maryland State Disability Commission. Dr. Morgan's other public service activities include serving as a member of the iConquerMS Research Committee, a reviewer for the Patient-Centered Outcomes Research Institute's Clinical Trials Advisory Panel, and a member of the NMSS Activism Advisory Committee. He was also a reviewer for the Congressionally Directed Medical Research Programs from 2014 to 2016.

Dr. Morgan earned 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 Stroke Council of the American Heart Association and a Diplomate of the American Academy of Pain Medicine. Dr. Morgan was inducted into the NMSS Advocacy Hall of Fame in 2015.

External Member: Stephen J. Rosenfeld

Stephen J. Rosenfeld, MD, MBA, trained as a hematologist. He spent 19 years at 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, and he ended his time 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, Maine, and as Chief Executive Officer of the Western Institutional Review Board (IRB) in Olympia, Washington. He was also the executive chair of Quorum Review IRB for seven years. Dr. Rosenfeld is a founder of North Star Review Board, the first nonprofit 501(c)(3) independent IRB, and is the president of Freeport Research Systems, a consulting firm focused on the people and systems of biomedical research.

Dr. Rosenfeld earned his medical degree from Cornell University, trained in internal medicine at Dartmouth College, and completed his hematology fellowship at NHLBI. He has an MBA from Georgetown University. Dr. Rosenfeld 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 at the U.S. Department of Health and Human Services, and he served as chair of the committee from 2017 to 2021. 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, which he currently chairs.

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 addresses issues related to pharmaceutical and medical device regulation, evidence development, post-market surveillance, and clinical adoption. Dr. Ross co-directs 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 500 articles in peer-reviewed biomedical journals and is currently the U.S. Outreach and Research Editor at *The BMJ*.

Dr. Ross earned his medical degree from Albert Einstein College of Medicine and an MHS from 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, policymakers, and the public, so they can make wiser decisions.

With Lisa Schwartz, Dr. Woloshin developed NIH'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 Center for Biotechnology Information's Bookshelf) and *Overdiagnosed* (winner of the Prescrire Prize). His essays have appeared in *The New York Times*, *The Washington Post*, and the *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 boards of *JAMA Internal Medicine* and the Cochrane Library, 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 to research and enhancing the communication of medical evidence. Dr. Woloshin is also the founder and director of the Lisa Schwartz Foundation for Truth in Medicine.

Dr. Woloshin earned 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.