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

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

Executive Secretary: Rebecca (Becky) J. Williams, PharmD, MPH, NLM, NIH

Board of Regents Members:

- Jennifer (Jennie) S. Lucca, MSW, The Children’s Inn at NIH
- Lauren A. Maggio, PhD, Uniformed Services University of the Health Sciences
- Omolola (Lola) Ogunyemi, PhD, FACMI, Charles R. Drew University of Medicine and Science

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 Gentile, MSN, RN, Dana-Farber Cancer Institute
- Sally A. Gore, MS, MS LIS, University of Massachusetts Medical School
- Carlos R. Jaén, MD, PhD, University of Texas Health Science Center at San Antonio
- Barbara Kress, BSN, RN, Merck
- Seth A. Morgan, MD, National Multiple Sclerosis Society
- Stephen J. Rosenfeld, MD, MBA, Freeport Research Systems, LLC and North Star Review Board
- 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 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 (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 (UCLA), 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: Rebecca 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 (NCBI), National Library of Medicine (NLM), NIH. 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, and her research interests relate to improving the quality of the reporting of clinical research. Her prior experience includes serving as a regulatory affairs consultant and reviewer and in 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: 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 working in the nonprofit sector. She previously served as The Inn’s Chief Program and Services Officer, where she oversaw 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: Lauren A. Maggio

Lauren A. Maggio, PhD, is Professor of Medicine at the Uniformed Services University of the Health Sciences (USU) and Associate Director of Scholarly Communications at USU’s Center for Health Professions Education. In addition, she is Programs Scholar at the Association of Academic Health Centers. Dr. Maggio’s research explores how to effectively connect physicians, learners, and patients with biomedical information through the design of educational interventions and technical solutions and by facilitating access to knowledge for public and professional use. Her research interests include evidence-based practice, meta-research and responsible conduct of research, knowledge syntheses, and scholarly communication. She is a coauthor of Clinician’s Guide to Evidence-Based Practices: Behavioral Health and Addictions (2nd ed.).

Dr. Maggio has been an editor for Perspectives on Medical Education since 2017 and is currently Acting Editor-in-Chief. She is also a member of the editorial board for Academic Medicine and has served as Associate Editor for BMC Medical Education and as an editorial board member for the Journal of the Medical Library Association and for Evidence Based Librarianship and Practice.

Dr. Maggio has a PhD in medical education from the University of Utrecht/University of California, San Francisco, and an MS from Simmons Graduate School of Library and Information Science.

Board of Regents Member: Omolola Ogunyemi

Omolola (Lola) Ogunyemi, PhD, FACMI, is a computer scientist and biomedical informatics researcher. She is Director of the Center for Biomedical Informatics (CBI) and Professor in the Department of Preventive and Social Medicine at Charles R. Drew University of Medicine and Science, as well as a co-chair of the UCLA Clinical and Translational Science Institute’s biomedical informatics program and an Adjunct Professor of Radiological Sciences in the David Geffen School of Medicine at UCLA, with the Medical Imaging and 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 until 2013. She served on NLM’s 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 as both a member and as chair. She was member of the Agency for Healthcare Research and Quality (AHRQ) 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 holds an undergraduate degree in computer science from Barnard College, Columbia University and an MSE and a PhD in computer and information science from the University of Pennsylvania. She was elected a Fellow of the American College of Medical Informatics in 2019.

**Ex Officio NIH Member: Lyric A. Jorgenson**

**Lyric A. Jorgenson, PhD,** is Deputy Director for the NIH Office of Science Policy (OSP). 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 and played 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 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 NIH 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 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 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 also 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 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 she 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 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 an NLM grant-funded informationist at the Lamar Soutter Library, a reference and instruction librarian, and a consumer health librarian.
External Member: 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 AHRQ National Advisory Council, 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 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 named one of 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.

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 percent of her time: ClinicalTrials.gov. Fourteen years and over two dozen 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 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.

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 membership on 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 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 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, Maine, and as Chief Executive Officer of the Western Institutional Review Board in Olympia, Washington. Dr. Rosenfeld served for seven years as the executive chair of Quorum Review IRB. Dr. Rosenfield is currently the President of Freeport Research Systems LLC, a consulting firm focused on the people and systems of biomedical research. He also co-leads the North Star Review Board, a Research Ethics Review Board established in 2020.

Dr. Rosenfeld earned his medical degree from Cornell University, trained in internal medicine at Dartmouth College, and completed his hematology fellowship at NHLBI. In addition, he holds 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 Department of Health and Human Services, and he served as chair of that 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, where he is currently vice-chair.

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 400 articles in peer-reviewed biomedical journals and is currently an Associate Editor at *JAMA Internal Medicine*.

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, 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 NCBI’s 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 also has an MS from the Geisel School of Medicine at Dartmouth.