



Jill Abell, M.P.H., Ph.D., is senior director of clinical effectiveness and safety at GlaxoSmithKline and adjunct assistant professor in clinical epidemiology and evaluative sciences research at Weill Cornell Graduate School of Medical Sciences. Dr. Abell received a master's degree in epidemiology from Emory University and a doctoral degree in epidemiology from the Medical University of South Carolina, where she was supported by an American Heart Association Pre-Doctoral Fellowship.

Her current work focuses on methodological strategies and pragmatic approaches to research implementation that advance clinical effectiveness evaluations in populations and individuals. She maintains a strong passion for innovation, rigor, and relevance, with a special focus on the promotion, collection, and incorporation of patient-centered information into clinical trials and observational studies. Dr. Abell also leads a TransCelerate BioPharma Workstream to increase diversity in clinical trials.



Vanessa Arnedo, M.P.H., is associate director of research partnerships at the Michael J. Fox Foundation for Parkinson's Research, the largest nonprofit funder of Parkinson's disease research. In this role, Vanessa is responsible for the development of recruitment and retention strategies for the Foundation's observational cohort studies portfolio, including the Parkinson's

Progression Markers Initiative (PPMI), a landmark clinical biomarker study. Prior to joining the Michael J. Fox Foundation, she served as project manager for the NeuroNEXT and NETT clinical trials networks at the State University of New York at Downstate Medical Center, where she managed recruitment and clinical trial operations for several multi-center studies. Vanessa holds an M.P.H. in epidemiology from the Mailman School of Public Health of Columbia University and a B.A. from the New York University College of Arts and Sciences.



Cynthia Bower, M.S., RN, serves as an administrative director for the Michigan Institute of Clinical & Health Research (MICHHR) Clinical Research Support Services Program and the University of Michigan School of Dentistry's Clinical Trials Program. In these roles, she partners with the senior associate dean for research in the School of Dentistry and the faculty director for the Clinical Research Services Program in MICHHR, advocating for the investigative teams and research participants as part of supporting the research mission of the

University of Michigan Health System and School of Dentistry. As the business and administrative lead for the research mission, Ms. Bower is responsible for the

operational and fiscal management of these programs and their reporting units. She assists with devising and deploying strategic research initiatives; managing projects; and advising on policy, procedural, and operational issues for the research enterprise associated with these programs. She also serves as the lead administrative liaison and the primary staff interfacing and represents her programs interests to the NIH/CTSA consortium. She has directed her own research in the areas of participant experience in research and the variables affecting retention, satisfaction, and regret. She has published on a business model using mobile research support teams to enhance investigators' ability to include vulnerable populations in research. Ms. Bower is an active member of committees at both the local and national level and is an adjunct instructor for the University of Michigan School of Nursing Leadership and Management/Transition Program and preceptor for the IOE students from the College of Engineering.



Moon S. Chen, Jr., Ph.D., M.P.H., is a nationally renowned expert in cancer health disparities, particularly as they affect Asian-American populations. He is UC Davis Comprehensive Cancer Center's associate director for cancer control, leading a portfolio of research that addresses determinants of cancer risk and their mitigation in human populations. Determinants include access to care, behaviors (e.g., tobacco use, screening), socio-cultural factors, and the interactions of individuals with their environment and the health care system.

In addition, Dr. Chen oversees shared resources for cancer epidemiology, including leveraging the California Cancer Registry, the world's largest registry of cancer data in a single geographical entity with the richest diversity of data on cancer in diverse racial/ethnic populations.

Dr. Chen also oversees shared resources for the cancer biorepository, an increasingly important source of biospecimens for investigating cancer causes. He serves as a liaison with the California Department of Public Health, Kaiser Permanente Division of Health, and other external agencies.



Mildred Cho, Ph.D., is a professor in the Division of Medical Genetics of the Department of Pediatrics at Stanford University, associate director of the Stanford Center for Biomedical Ethics, and director of the Center for Integration of Research on Genetics and Ethics (an NIH-supported Center for Excellence in Ethical, Legal and Social Implications Research). She received her B.S. in biology in 1984 from the Massachusetts Institute of Technology and her Ph.D. in 1992 from the Stanford University Department of Pharmacology. Her postdoctoral training was in health policy as a Pew Fellow at the Institute for Health Policy Studies at the University of California, San

Francisco, and at the Palo Alto VA Center for Health Care Evaluation. She is a member of several international and national advisory boards, including Genome Canada, the March of Dimes, and the Board of Reviewing Editors of *Science* magazine.

Dr. Cho's major areas of interest are the ethical and social impacts of genetic research and its applications and how conflicts of interest affect the conduct of academic biomedical research. Her current research projects examine ethical and social issues in research on prenatal genetic testing, genetics of behavior, the human microbiome, and synthetic biology. In addition, she established the Benchside Ethics Consultation Service at Stanford University in 2005 and is chair of a working group to develop a national collaborative research ethics consultation service.



Emil Chiauzzi, Ph.D., is research director at PatientsLikeMe, a patient network that improves lives and a real-time research platform that advances medicine. He leads a multidisciplinary research team focused on analyzing patient-reported data to help academic partners, pharmaceutical companies and other organizations gain clinical and business insights into patient conditions, symptoms, treatments, and disease journeys. A clinical research psychologist, Dr. Chiauzzi has served as the Principal Investigator on numerous NIH grants and as a reviewer and chair on a variety of NIH grant review committees. Dr. Chiauzzi was previously the VP of Research and Innovation at Inflexion, where he conducted and supervised a range of interactive health research projects with technology-based clinical interventions. He led the development and testing of patient-centered programs that address a range of behavioral health disorders, opioid abuse and chronic pain. The latter programs have been integrated into pharmaceutical opioid risk evaluation and mitigation strategies (REMS) programs for training physicians and educating chronic pain patients.



Jonathan Davis, M.D., is vice-chair of pediatrics and chief of newborn medicine at the Floating Hospital for Children at Tufts Medical Center and professor of pediatrics at Tufts University School of Medicine. His research has focused on breathing problems in newborn infants, causes of newborn brain injury, and neonatal drug development. He has authored over 150 manuscripts and book chapters and received numerous grant awards from the National Institutes of Health, the FDA, the March of Dimes, the American Lung Association, and many others. Dr. Davis has lectured worldwide, including at the Vatican Children's Hospital in Rome, the Pasteur Research Institute in Paris, and the National Academy of Sciences in Washington.

Dr. Davis has conducted the basic science and animal studies to support human trials of exogenous surfactant, human recombinant antioxidants, human recombinant anti-inflammatory agents (rhCC10), and many other drugs and devices in newborn infants,

and he has been intimately involved in trial design, data collection, data analyses, and peer-reviewed publications. He is currently funded by the NIH and the FDA to develop better biomarkers and outcome measures for clinical trials in preterm infants and new and existing therapeutics to improve neonatal outcome. Dr. Davis is chair of the Neonatal Advisory Committee in the Office of the Commissioner at the FDA and was recently elected to the Leadership Council of the American Pediatric Society. He has been actively involved in the Clinical and Translational Science Award Program and the BPCA Prioritization Committee at the NIH. These positions permit him to work closely with the NIH, the FDA, academic leaders, and industry to promote the development of important pediatric therapeutics.



Dana Dornsife received her undergraduate degree in business from Drexel University, Philadelphia, her interior design certification from John F. Kennedy University, San Francisco, and her lighting design certification through the Illuminating Engineering Society of North America. In 1991, she co-founded Axiom Design, Inc., a lighting design and architectural electronics consulting firm.

In 2003, Dana's focus turned to cancer as she watched a family member succumb to pancreatic cancer at age 42. In 2006, she founded Lazarex Cancer Foundation, and she currently serves as its president. Lazarex is a nonprofit that exists to help fill the gap in resources for cancer patients seeking life through FDA clinical trials. Lazarex Cancer Foundation gives hope, dignity, and life to end-stage cancer patients and the medically underserved by providing assistance with costs for FDA clinical trial participation, navigation through clinical trial options, community outreach, and education.

Dana serves on several boards: those of Epeius Biotechnologies, developing genetic medicines for the treatment of cancer; the USC Brain and Creativity Institute; the USC Center for Civic Engagement; and the Yosemite Conservancy.

Dana and her husband, Dave Dornsife, a USC trustee, support a WASH (Water, Sanitation, and Hygiene) initiative in 22 countries throughout Africa through World Vision, an international humanitarian agency. They are council members of the Yosemite Conservancy and support ground-breaking research in imaging and cerebral spinal fluid analysis for early detection of Alzheimer's disease.



Jonathan Ellen, M.D., is a pediatrician and professor of pediatrics who specializes in adolescent medicine and public health. At All Children's Hospital Johns Hopkins Medicine (ACH JHM), Dr. Ellen is leading academic transformation through the development of new education and research programs, including an innovative ACH JHM pediatric residency training program, new fellowship programs, and the Clinical

and Translational Research Organization dedicated to new understanding, treatment, and prevention of pediatric disease and pediatric-onset chronic disease in adults.

After graduating from the University of Pennsylvania, he received his medical degree from Temple University and completed an internship and residency in pediatrics at Children's Hospital of Philadelphia. Dr. Ellen completed a fellowship in adolescent medicine at the University of California, San Francisco (UCSF), followed by fellowships in sexually transmitted diseases at UCSF, the San Francisco Department of Public Health, and the Centers for Disease Control and Prevention (CDC).

Dr. Ellen's research focuses on prevention of sexually transmitted infections, including HIV, in adolescents and on the structural and environmental factors associated with disease transmission. He has authored more than 166 peer-reviewed scientific articles and 30 reviews, editorials, and book chapters and has trained more than 40 pre- and post-doctoral fellows in the fields of adolescent medicine and public health. He has received numerous research awards from the CDC, the National Institutes of Health, and other agencies.

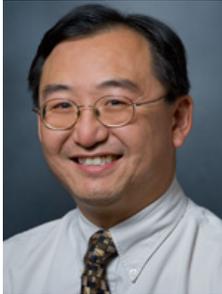
Raised in Philadelphia, Dr. Ellen now resides in St. Petersburg. He and his wife, attorney Margaret de Lisser, have two teenage children.



Maria C. Freire, Ph.D., is the president and executive director and member of the Board of Directors of the Foundation for the National Institutes of Health (FNIH). Prior to this appointment, Dr. Freire was the president of the Albert and Mary Lasker Foundation from 2008 to 2012, where she established novel programmatic initiatives that expanded the brand and reach of the foundation. From 2001 to 2008, she served as president and chief executive officer of the Global Alliance for TB Drug Development (TB Alliance), a not-for-profit organization that develops drugs to fight tuberculosis. She directed the Office of Technology Transfer at the NIH from 1995 to 2001.

Dr. Freire obtained her B.S. at the Universidad Peruana Cayetano Heredia in Lima, Peru, and her Ph.D. in biophysics from the University of Virginia; she completed post-graduate work in immunology and virology at the University of Virginia and the University of Tennessee, respectively. She is active on national and international boards and committees, including the Board of the GAVI Alliance and Alexandria Real Estate Equities, Inc. She is co-chair of the Science Board of the U.S. Food and Drug Administration (FDA), which advises the Commissioner. Dr. Freire was selected as one of ten Commissioners of the World Health Organization's Commission on Intellectual Property Rights, Innovation and Public Health, and she is a member of the Executive Committee of the United Nations' Sustainable Development Solutions Network. She is the recipient of numerous awards, including the DHHS Secretary's Award for

Distinguished Service, the Arthur S. Flemming Award, and The Bayh-Dole Award. Dr. Freire is a member of the Institute of Medicine of the National Academy of Sciences and of the Council on Foreign Relations.



Alan S. Go, M.D., has a background that includes training in general internal medicine, followed by a clinical research fellowship focused on epidemiologic methods and applied outcomes research at UCSF and the VA. During his past 16-plus years at the Kaiser Permanente Northern California Division of Research, he has developed an internationally recognized research program in the areas of cardiovascular disease (atrial fibrillation, ischemic heart disease, and heart failure) and renal disease. His projects include clinical trials, comparative effectiveness research, pharmacoepidemiology, clinical epidemiology, and health services research studies within large, diverse, “real-world” populations. He is a regional medical director of clinical trials for Kaiser Permanente Northern California and is responsible for the operational support of trials at 22 Medical Centers and the regional Division of Research. He is also director for the Cardiovascular Research Network (CVRN), a multi–health plan research consortium conducting epidemiology, outcomes, health services, and clinical trial research that was sponsored by NHLBI and involves a broad spectrum of health care delivery systems throughout the United States.



Sybil Hosek, Ph.D., is a clinical psychologist and HIV researcher in the Department of Psychiatry at John Stroger Hospital of Cook County in Chicago. Dr. Hosek has more than 15 years of clinical and research experience working with HIV-infected and uninfected adolescents and young adults. Dr. Hosek’s research efforts focus on the development and implementation of primary and secondary HIV prevention interventions. Through strong working relationships with community leaders, Dr. Hosek has successfully led two HIV intervention trials for black men: an NIMH-funded intervention targeting young men who have sex with men (MSM) and a CDC-funded trial testing an Internet-based HIV prevention intervention for bisexual men. Dr. Hosek has broad experience with research networks, starting with her involvement in the NICHD-funded Adolescent Trials Network for HIV/AIDS Interventions (ATN). Dr. Hosek has led three PrEP trials through the ATN (082/110/113) that have been the only domestic PrEP trials to enroll a high proportion of youth, particularly racial and ethnic minority youth. Dr. Hosek currently co-chairs the Behavioral Leadership Group of the ATN and is a member of the Executive Committee. Due to her experience with youth, Dr. Hosek was recently chosen as vice-chair of the IMPAACT HIV Prevention Scientific Committee. Dr. Hosek is also a member of the HPTN Adolescents-At-Risk Science Committee and co-chair of the cross-network Youth Prevention Research Working Group facilitated by HANC.



Virginia J. Howard, Ph.D., FAHA, FSCT, is a stroke epidemiologist with over 30 years of experience in multicenter, multidisciplinary clinical trials and longitudinal cohort studies with a focus on stroke, stroke risk factors, and health disparities. She is a professor of epidemiology at the School of Public Health, University of Alabama at Birmingham. She is currently co-principal investigator of a national stroke

epidemiologic study, the NINDS-funded Reasons for Geographic and Racial Differences in Stroke (REGARDS) that successfully enrolled, conducted in-home visits, and is following over 30,000 black and white adults over age 45 from across the United States for stroke, cognitive decline, and related risk factors. In addition, Dr. Howard is PI of the Statistical and Data Management Center of the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST) (1999–present), funded by NINDS. She has also been co-investigator/project director in two other completed NIH stroke prevention trials. Dr. Howard’s other experience includes being chairperson of the subcommittee on Bridges to Community: Assuring Ethical Conduct of Studies and Data Integrity for the 2002 NINDS Advisory Panel on Stroke Disparities, a member of relevant American Heart Association/American Stroke Association (AHA/ASA) committees such as the Minority Affairs Committee (Stroke Council) and the Cardiovascular Disease and Stroke in Older Populations Committee. She has been active in the international Society for Clinical Trials (SCT), including the Education Committee for two terms, program committee, and Board of Directors. Most recently, she participated in the SCT workshop on Best Practices and Innovations in Patient and Community Engagement in Clinical Trials.



Nancy M. P. King, J.D., is a professor at the Department of Social Sciences and Health Policy and Wake Forest Institute for Regenerative Medicine at Wake Forest School of Medicine, and the co-director of the Center for Bioethics, Health, and Society and the Graduate Program in Bioethics at Wake Forest University. Her

scholarship addresses a range of bioethics issues, including informed consent in health care and research; medical decisions at the beginning and end of life; the development and use of experimental technologies; preclinical and animal research; international and cross-cultural questions in human subjects research; benefit and uncertainty in human subjects research; ethical issues in large-scale genetic research and biobanking, gene transfer research, and regenerative medicine; and connections between science, ethics, design, and policy in biotechnology research. She has published over 100 scholarly articles and book chapters and is co-editor of *The Social Medicine Reader* (2nd ed., Duke University Press, 2005), *Beyond Regulations: Ethics in Human Subjects Research* (UNC Press, 1999), and *Bioethics, Public Moral Argument, and Social Responsibility* (Routledge, 2012). She has served on hospital ethics committees, IRBs, DSMBs and the NIH Recombinant DNA Advisory Committee and has taught research ethics in national and international settings.



Pamela M. McInnes, D.D.S., is the deputy director for the National Center for Advancing Translational Sciences (NCATS). She has more than 25 years of NIH experience, including knowledge and expertise in clinical and translational research, extramural research management, and trans-NIH collaborations and public-private partnerships. Before joining NCATS, Dr. McInnes served as director of the Division of Extramural Research at the National Institute of Dental and Craniofacial Research (NIDCR). There, she was responsible for all of the Institute's extramural research, including large and complex clinical and population-based trials. Her work in translational sciences has led to several product development and clinical evaluation programs, and she actively collaborates with the broader extramural research community on efforts to improve health.

Prior to her time at NIDCR, Dr. McInnes spent 16 years at the National Institute of Allergy and Infectious Diseases (NIAID), where she served in many capacities, including as deputy director for the Division of Microbiology and Infectious Diseases. In addition, she led the reorganization and oversight of NIAID's complex and diverse Divisional Clinical Research Program, as well as the scientific design and programmatic implementation of a Challenge Grant Program promoting joint ventures among NIH and biotechnology, pharmaceutical, and medical device companies.



Edith Peterson Mitchell, M.D., is board certified in internal medicine and medical oncology and is clinical professor, Department of Medicine and Medical Oncology, and Program Leader, Gastrointestinal Oncology at Jefferson Medical College of Thomas Jefferson University, and Associate Director for Diversity Programs and Director of the Center to Eliminate Cancer Disparities for the Kimmel Cancer Center at Jefferson.

Dr. Mitchell has spent her medical career helping individuals in medically underserved areas realize that simple changes in lifestyle can have a dramatic impact on cancer care. Through her work, Dr. Mitchell has demonstrated the importance of community service and outreach especially to those individuals who may not have the means to seek out more conventional medical advice.

Dr. Mitchell's research in breast, colorectal, and pancreatic cancers and other GI malignancies involves new drug evaluation and chemotherapy, development of new therapeutic regimens, chemoradiation strategies for combined modality therapy, patient selection criteria, and supportive care for patients with gastrointestinal cancer. She travels nationally and internationally teaching and lecturing on the treatment of gastrointestinal malignancies.

In addition to her medical achievements, Dr. Mitchell is a retired Brigadier General, the first female physician to attain this rank in the history of the U.S. Air Force, having served as the Air National Guard Assistant to the Command Surgeon for U.S. Transportation command and Headquarters Air Mobility Command (AMC) based at the Scott Air Force Base in Illinois. In this capacity, she served as the senior medical Air National Guard advisor to the command surgeon and was the medical liaison between the active Air Force and the Air National Guard. Her responsibilities in this role included ensuring maximum wartime readiness and combat support capability of the worldwide patient movement and aeromedical evacuation system, the Global Patient Movement Requirements Center, and AMC's 52 Air National Guard medical squadrons.

General Mitchell has been awarded more than 15 military service medals and ribbons, including the Legion of Merit, Meritorious Service Medal, Air Force Achievement and Commendation Medals, National Defense Service Medal, and Humanitarian Service Medal. Dr. Mitchell was selected for inclusion in America's Top Oncologists. She is a Fellow of the American College of Physicians and a member of the American Society of Clinical Oncology, the European Society of Medical Oncology, the American Medical Association, the National Medical Association, the Aerospace Medical Association, the Association of Military Surgeons, the Medical Society of Eastern Pennsylvania, the Eastern Cooperative Oncology Group, the Radiation Therapy Oncology Group, and the National Surgical Adjuvant Breast and Bowel Project.



Ann Partridge, M.D., M.P.H., is a medical oncologist and clinical researcher focused on improving the care and outcomes of patients with cancer, with a particular focus on breast cancer. She is the former clinical director of the Breast Oncology Program, founded and directs the Program for Young Women with Breast Cancer, and was recently named the director of the Adult Survivorship Program at Dana-Farber/Brigham and Women's Cancer Center. Dr. Partridge has published numerous manuscripts and lectures both nationally and internationally on issues of cancer survivorship and young women with breast cancer in particular. She has received several awards and grants, including an American Society of Clinical Oncology (ASCO) Improving Cancer Care Grant, a Lance Armstrong Foundation Survivorship Award, and a Tracy Starr Breast Cancer Research Fund Award, and she serves as a Susan G. Komen for the Cure Scholar. She serves on several committees, including as chair for the Federal Advisory Committee on Breast Cancer in Young Women. Dr. Partridge graduated from Georgetown University, earned her M.D. at Cornell University, trained in internal medicine at the Hospital of the University of Pennsylvania, and completed hematology and medical oncology fellowships at DFCI. She received a master's degree in public health at the Harvard School of Public Health.



Gary A. Puckrein, Ph.D., is president and chief executive officer of the National Minority Quality Forum. The Forum is dedicated to improving the quality of health care through the use of evidence-based, data-driven initiatives. The Forum maintains a centralized data warehouse of vital statistics, demographics, environmental information, provider claims, prescription drug use, clinical laboratory values, health-care access points, and other data. The Forum employs these data resources to build web-based indexes and atlases that enable users to measure and forecast health status and disease prevalence in small geographic areas, evaluate the impact of specific interventions, and monitor changes in health outcomes. The Forum has also recently launched the Clinical Trial Engagement Network, the health care industry resource addressing a critical need in drug research: improving the representation of diverse populations, including African Americans, Asian Americans, and Hispanics, in clinical trials. Dr. Puckrein is considered a preeminent authority on health information products and was the publisher of *American Visions* and *Minority Health Today*. Dr. Puckrein has served on numerous health care advisory boards, including the National Advisory Board on Health Disparities for the Health Research and Educational Trust (American Hospital Association), the CLAS/Health Disparities Expert Panel (National Committee for Quality Assurance), and the Pharmacy Education Advisory Council (American Association of Colleges of Pharmacy). Between 1974 and 1992, Dr. Puckrein taught and lectured at Brown University, Rutgers University, Connecticut College, and Roger Williams College. Dr. Puckrein has received many awards and honors, including being named a visiting scholar and fellow at the Smithsonian's National Museum of American History and a visiting fellow at Princeton University. He was awarded doctoral and master's degrees in history from Brown University and a bachelor's degree from California State University at Los Angeles.



Joseph Ravenell, M.D., is assistant professor of population health and medicine at the NYU School of Medicine. He is a core member of the NYU Center for Healthful Behavior and a board-certified internist and clinical hypertension specialist with a strong track record of NIH funding to improve hypertension in diverse populations. He is PI of a NHLBI R01 (1R01HL096946) project to test community-based strategies to improve blood pressure control and colon cancer screening among 720 black men in churches throughout New York City. He is also PI of a recently completed NIMHD-funded project that examines barbershop-based interventions to address hypertension and colorectal cancer in older black men. This work, collectively called the NYU Men's Health Initiative (MHI), has resulted in a community-based research network of over 200 community-based sites, including churches, barbershops, mosques, and soup kitchens throughout New York City. Through MHI, over 7,000 black men age 50 and older have been screened for hypertension and educated about cardiovascular risk and colon cancer prevention, and over 1,100 have been enrolled in community-based trials. The MHI network is home to two new projects that recently received funding

from NIDDK to examine a barbershop-based video intervention to improve organ donation registration among black and Latino men. Dr. Ravenell is also PI of an NIA-funded RC4 grant to examine the impact of a behavioral economics intervention to improve adherence to clinical lipid-lowering guidelines among physicians in a community-based primary care practice in New York City.



Joe V. Selby, M.D., M.P.H., executive director of PCORI, is a family physician, clinical epidemiologist, and health services researcher with more than 35 years of experience in patient care, research, and administration. He is responsible for identifying strategic issues and opportunities for PCORI and implementing and administering programs authorized by the PCORI Board of Governors.

Dr. Selby joined PCORI from Kaiser Permanente, Northern California, where he was director of the Division of Research for 13 years and oversaw a department of more than 50 investigators and 500 research staff members working on more than 250 ongoing studies. He was with Kaiser Permanente for 27 years. An accomplished researcher, Dr. Selby has authored more than 200 peer-reviewed articles and continues to conduct research, primarily in the areas of diabetes outcomes and quality improvement. His publications cover a spectrum of topics, including effectiveness studies of colorectal cancer screening strategies; treatment effectiveness, population management, and disparities in diabetes mellitus; primary care delivery; and quality measurement.

Dr. Selby was elected to membership in the Institute of Medicine in 2009 and was a member of the Agency for Healthcare Research and Quality study section for Health Care Quality and Effectiveness from 1999 to 2003. A native of Fulton, Missouri, Dr. Selby received his M.D. from Northwestern University and his M.P.H. from the University of California, Berkeley. He was a commissioned officer in the Public Health Service Corps from 1976 to 1983 and received the Commissioned Officer's Award in 1981.



Sam Simha, M.D., was born in Israel and as a young child moved with his family to Chile. After graduating from the University of Chile Medical School in 1978, he completed an OB/GYN residency at the University of Toronto, Ontario, Canada. He practiced for 9 years in Ontario until moving to Memphis, Tennessee, 21 years ago, where he worked as an OB/GYN consultant, first for a multidisciplinary group and then in a private practice.

About 13 years ago, he expanded his practice to include clinical trials in the area of women's health. He has acted as a PI for over 40 pharmaceutical trials involving a wide array of indications, such as STDs, vaginitis, uterine fibroids, heavy menstrual bleeding,

and endometriosis. He has also been involved in obstetrical trials and trials involving birth control.

He was a clinical instructor for the University of Tennessee, Memphis, for 18 years and has held privileges at the Baptist and Methodist hospital systems in Memphis. During the last two years, his practice has focused mainly on clinical research.

Over the years, Dr. Simha has been involved in the Memphis Hispanic community. He has volunteered his help to Latino Memphis, a local nonprofit, with their health programs, and has been invited as a guest speaker on a local Spanish radio station on programs covering women's health.

Dr. Simha is board-certified in obstetrics and gynecology and is certified as a Principal Investigator (CPI) by the Association of Clinical Research Professionals (ACRP). He has been a member of the ACRP and the Academy of Physicians in Clinical Research (APCR) for the past 10 years and has held several leadership roles within both organizations. Currently, he is the president of APCR and a board member for ACRP.



Veronica (Ronnie) Todaro, M.P.H., is vice president of national programs for the Parkinson's Disease Foundation (PDF), where she is responsible for strategic initiatives that further patient involvement in clinical research, medical care, and support services. Ms. Todaro created and leads Parkinson's Advocates in Research (PAIR), a national research advocacy initiative that advances the role of people with Parkinson's in the clinical research process. The PAIR program features a three-day Learning Institute that prepares people with Parkinson's and care partners for collaborating with the research community. Ms. Todaro has led multi-stakeholder roundtables that focus on barriers to clinical research participation, including topics on building patient trust in clinical research and engaging community physicians, and has written and speaks on the authentic engagement of patients along the clinical research continuum. Prior to her work with PDF, Ms. Todaro was a partner with the Carol-Trevelyan Strategy Group, a Washington, D.C.-based public policy and grassroots organizing consulting practice, and she served in a number of staff leadership roles within Planned Parenthood Federation of America.

Ms. Todaro is chair of the Patient Leadership Council of the Clinical Trials Transformation Initiative and an Editorial Board member for the *Global Forum*, the journal of the Drug Information Association, and she serves on the Institutional Review Board at the North Shore-Long Island Jewish Health System. She holds a bachelor of science degree in policy and planning from Cornell University and a master of public health degree in planning and administration from the University of Michigan.



Jocelyn B. Ulrich, M.P.H., has over 10 years of diverse experience in the pharmaceutical and biotech industries. She is currently director of scientific and regulatory affairs at PhRMA, where she supports PhRMA's advocacy strategies on clinical trials and innovative biologics and biosimilars. Prior to joining PhRMA, Jocelyn held positions of increasing responsibility at Pfizer and Human Genome Sciences in SOP development and implementation, clinical research management, and medical affairs. She is a recognized expert in managing public-private research collaborations, and from 2011 to 2013 she led the Investigator-Initiated and Sponsored Research Association's (IISRA) Collaboration Forum, a cross-functional group that aims to establish best practices for research conducted in partnership with industry and the NCI-funded Cooperative Groups. Jocelyn is an active member of the Healthcare Businesswomen's Association (HBA) Mid-Atlantic Chapter and has served as chair of the Membership and Outreach sub-committee of the Mid-Atlantic Women in Science Committee since 2012. She received her M.P.H. in global health policy and management from NYU in 2009.



Joseph Unger, Ph.D., is a faculty member at the Fred Hutchinson Cancer Research Center. He received his Ph.D. in health services research and his M.S. in biostatistics from the University of Washington. Dr. Unger is the coordinating statistician for the Southwest Oncology Group (SWOG) Cancer Control and Prevention Program, overseeing the design, implementation, analysis, and reporting activities within the program. Dr. Unger's focus is on health disparities and comparative effectiveness research in cancer. He has particular expertise utilizing the SWOG database, in conjunction with large registry and administrative databases (e.g., SEER, Census, SEER-Medicare), to conduct innovative analyses on racial, ethnic, gender, and income-based disparities in trial access and treatment outcomes, on the generalizability of trial outcomes, and on patterns of diffusion of trial results into the cancer treatment community.



Jeff Vigne has served as president of the FOCC Board (now known as The Friends of Patients at the NIH) since 2011. Founded in 1984 by NIH employees, The Friends provides financial assistance for patients participating in research protocols at the National Institutes of Health. The Friends mission is to enhance the lives of Clinical Center patients and their family members by relieving them of emergency financial burdens related to their participation in clinical trials. Financial support from The Friends ultimately provides shelter, support systems, and improved quality of life for patients and their families. The Friends work closely with Clinical Center social workers to identify patients with financial and other needs that

present obstacles to their participation in research. The Friends has recently expanded its role in providing off-campus housing to select patients and their families.

Mr. Vigne is the executive vice president of Exeter Government Services, which is located in Gaithersburg, Maryland. He possesses a degree in journalism from the University of Southern California and is also a member of the Board of Directors of Archbishop Spalding High School in Severn, Maryland.



John Walsh is the co-founder, president, and CEO of the Alpha-1 Foundation in Miami, Florida. Under his leadership, the organization has become internationally recognized and has invested more than \$52 million to support Alpha-1 research and research-related projects, including funding grant awards to 97 academic institutions in North America, Europe, Australia, and the Middle East. Mr. Walsh is also co-founder and president of AlphaNet, Inc., a not-for-profit health disease management services company providing comprehensive care exclusively for individuals with Alpha-1 antitrypsin deficiency. Mr. Walsh is co-founder, president, and board member of the U.S. COPD Foundation and past chair of the International COPD Coalition (2006–2008). He is a former member of the NIH Director’s Council of Public Representatives and Council of Councils and is a member of the National Institute of Diabetes and Digestive and Kidney Diseases Advisory Council. Mr. Walsh has also served as chair of the National Health Council Board of Directors (2005–2006). His appointment as emeritus member of the American Thoracic Society (ATS) Public Advisory Roundtable stemmed from his involvement as former chair and member, serving as Presidential Appointee (2004–2005) of the ATS Board of Directors and Trustee of the Foundation of the American Thoracic Society (2006–2008). In 2002, Mr. Walsh’s contribution to pioneering collaboration in orphan drug development was recognized by the FDA with the Commissioner’s Special Citation. He was also recognized for his efforts with the COPD Foundation and was inducted into the COPD Hall of Fame in 2012. In 2014, the National Organization of Rare Disorders presented Mr. Walsh with a Lifetime Achievement Award in recognition of his continued dedication to the Alpha-1 and COPD communities.

Mr. Walsh was diagnosed with Alpha-1 genetic-related COPD in 1989. Since then, he has participated in numerous clinical trials and has cultivated a commitment for clinical participation in his work with the Foundation. He regularly testifies before Congress and advisory groups as a patient advocate.



Mary Woolley is the president of Research!America, the nation's largest not-for-profit alliance working to make research to improve health a higher national priority. Ms. Woolley is an elected member of the Institute of Medicine and serves on its Governing Council. She is a Fellow of the American Association for the Advancement of Science and serves on the National Academy of Sciences Board on Life Sciences. She is a founding member of the Board of Associates of the Whitehead Institute for Biomedical Research and is a member of the visiting committee of the University of Chicago Medical Center. Ms. Woolley is also a member of the National Council for Johns Hopkins Nursing. She holds an honorary doctoral degree from the Northeast Ohio Medical University (NEOMED). Ms. Woolley has served as president of the Association of Independent Research Institutes, as editor of the Journal of the Society of Research Administrators, as a reviewer for the National Institutes of Health and the National Science Foundation, and as a consultant to several research organizations. She has a 30-year publication history on science advocacy and research related topics and is a sought-after speaker, often interviewed by science, news, and policy journalists.