Return of Individual-Specific Research Results Generated in Research Laboratories

Committee

Bray Patrick-Lake

Member

As the Director of Stakeholder Engagement for Duke Clinical Research Institute, Bray Patrick-Lake supports efforts to actively engage patients, health advocacy organizations, and other stakeholders in local and national research programs. She has led extensive efforts through the Clinical Trials Transformation Initiative to incorporate patient voice into clinical trial design, conduct, oversight, and regulatory frameworks, as well as improvement of the clinical trial enterprise. She co-chaired the Advisory Committee to the NIH Director's Working Group responsible for authoring the vision and roadmap to launch the Precision Medicine Initiative Cohort Program. She served as the Interim Director of Engagement for several months the after program launched and became the All of Research Program, for which she currently serves on the National Advisory Panel. She also leads engagement work at Duke's Coordinating Center for the NIH Environmental Influences on Child Health Outcomes (ECHO) program and serves on the National Academies of Sciences, Engineering, and Medicine Health Sciences Policy Board. Ms. Patrick-Lake founded a nonprofit disease advocacy organization for cardiac patients and served as a patient representative at the FDA on a variety of advisory committees and panels, in workgroups for EMA, IMI, NIH, and NAM/IOM, and as a patient stakeholder or co-investigator for AHRQ and PCORI research projects. She's been a member of the PCORnet Coordinating Center's Executive Leadership Committee where she developed patient engagement strategies. She is member of the America Cancer Society's Clinical Trials Steering Committee and has served on the MDEpiNet's National Medical Device Registry Task Force, the Medical Device Innovation Consortium's Patient-centered Benefit-Risk Steering Committee, American College of Cardiology (ACC) Foundation's Patient-centered Care Shared Decision Making and Patient-generated Health Data working groups, and the ACC Transcatheter Valve Therapy Registry Stakeholder Advisory Committee. She currently also serves as a PCORI reviewer and ambassador.

Brian Zikmund-Fisher

Member

Brian J. Zikmund-Fisher is an Associate Professor in the Department of Health Behavior and Health Education, University of Michigan School of Public Health, as well as a Research Associate Professor in the Division of General Internal Medicine, University of Michigan Medical School and an Associate Director of the UM Center for Bioethics and Social Sciences in Medicine. Dr. Zikmund-Fisher uses his interdisciplinary background in decision psychology and behavioral economics to study factors that affect individual decision making about a variety of health and medical issues. His research in health communications focuses on making risk statistics, test results, and other types of quantitative health information intuitively meaningful and useful for decision making by patients and the public. Dr. Zikmund-Fisher also studies the effects of poor numeracy on people's ability to use numbers to inform their health decisions and the role of narratives in health communications. He serves as an Associate Editor for the journals Medical Decision Making and Medical Decision Making: Policy and Practice.

Jeffrey R. Botkin

Chair

Jeff Botkin is a Professor of Pediatrics at the University of Utah and an Adjunct Professor of Human Genetics. He is Chief of the Division of Medical Ethics and Humanities in the Department of Internal Medicine. He obtained his B.A. from Princeton University, M.D. from the University of Pittsburgh, and M.P.H. from Johns Hopkins. Dr. Botkin is the Associate Vice President for Research Integrity at the University of Utah with oversight responsibilities for the IRB, conflict of interest, responsible conduct of research, biosafety, and research ethics education. His research and publications are focused on the ethical, legal, and social implications of genetic technology with a particular emphasis on research ethics, genetic testing for cancer susceptibility, newborn screening, and prenatal diagnosis. Dr. Botkin was formerly Chair of the Committee on Bioethics for the American Academy of Pediatrics and is a former member of the Secretary’s Advisory Committee on Human Research Protections at DHHS. Dr. Botkin was formerly a member of the Secretary’s Advisory Committee on Heritable Diseases in Newborns and Children. He Chairs the NIH’s Embryonic Stem Cell Working Group and is a member of the FDA’s Pediatric Ethics Advisory Committee. Dr. Botkin is an elected fellow of the Hastings Center.

Paul S. Appelbaum

Member

Paul S. Appelbaum is the Elizabeth K. Dollard Professor of Psychiatry, Medicine, and Law, and Director, Division of Psychiatry, Law, and Ethics, Department of Psychiatry, College of Physicians and Surgeons of Columbia University; a Research Psychiatrist at the NY State Psychiatric Institute; and an affiliated faculty member, Columbia Law School. He directs Columbia's Center for Research on Ethical, Legal, and Social Implications of Psychiatric, Neurologic, and Behavioral Genetics, and heads the Clinical Research Ethics Core for Columbia's Clinical and Translational Science Award program. Dr. Appelbaum is the author of many articles and books on law and ethics in clinical practice. His current research focuses on the implications of new genetic technologies. Dr. Appelbaum is Past President of the American Psychiatric Association and the American Academy of Psychiatry and the Law, and has twice served as Chair of the Council on Psychiatry and Law and of the Committee on Judicial Action for the American Psychiatric Association (APA). Dr. Appelbaum is currently Chair of the DSM Steering Committee for APA, and of the Standing Committee on Ethics of the World Psychiatric Association. He has received the Isaac Ray Award of the American Psychiatric Association for "outstanding contributions to forensic psychiatry and the psychiatric aspects of jurisprudence," was the Fritz Redlich Fellow at the Center for Advanced Study in the Behavioral Sciences, and has been elected to the National Academy of Medicine.

Suzanne Bakken

Member

Suzanne Bakken, R.N., Ph.D., FAAN, FACMI, is the Alumni Professor of Nursing and Professor of Biomedical Informatics at Columbia University. Following doctoral study in nursing at the University of California, San Francisco, she completed a National Library of Medicine postdoctoral fellowship in Medical Informatics at Stanford University. The goal of Dr. Bakken's program of research is to promote health and reduce health disparities in underserved populations through application of innovative informatics and data science methods. A major focus of her current grant portfolio is visualization of healthcare data for community members, patients, clinicians, and community-based organizations. Dr. Bakken currently directs the Precision in Symptom Self-Management (PriSSM) Center and the Reducing Health Disparities Through Informatics (RHeaDI) pre-doctoral and postdoctoral training program; both funded by the National Institute of Nursing Research (NINR). She also served as Principal Investigator of the AHRQ-funded Washington Heights Inwood Informatics Infrastructure for Comparative Effectiveness Research (WICER) and its follow-up study, WICER 4 U, which is focused on promoting the use of WICER infrastructure through stakeholder engagement including return of individual research results. She has also received funding from the National Cancer Institute, National Library of Medicine, National Institute of Mental Health, and the Health Resources and Services Administration. Dr. Bakken has published more than 200 peer-reviewed papers. In 2010, she received the Pathfinder Award from the Friends of the National Institute of Nursing Research. In 2015-16, Dr. Bakken served as the AAN/ANA/ANF Distinguished Nurse Scholar-in-Residence at the National Academy of Medicine and is a member of the Roundtable on Health Literacy. She is a fellow of the New York Academy of Medicine, American Academy of Nursing, and American College of Medical Informatics, and a member of the National Academy of Medicine.

Chester W. Brown

Member

Dr. Brown is the St. Jude Chair of Excellence in Genetics, and Professor and Division Chief of Genetics at the University of Tennessee Health Science Center, Le Bonheur Children's Hospital and St. Jude Children's Research Hospital where he was recruited to help develop precision medicine initiatives in Memphis, TN, including the development of DNA and tissue repositories and large-scale –omics technologies to aid in population-based genomic research, considering also the ethical, legal and social implications of such efforts in underserved communities. His clinical interests include a variety of rare genetic syndromes in children and adults with a research emphasis on rare genetic disorders that have severe, early onset obesity as a feature. He completed his undergraduate degree at Howard University followed by MD/PhD training at the University of Cincinnati College of Medicine. His postdoctoral and subsequent faculty roles were in Pediatrics and Medical Genetics at Baylor College of Medicine. He has more than 20 years' clinical experience with Medical Genetics patients representing a broad spectrum of conditions. He is an active member of the Society for Pediatric Research, a member of an NIH study section, and recently completed service as a committee member for the National Academies of Sciences, Engineering and Medicine to develop a framework to inform decision-making related to genetic testing. He also directs a basic science research laboratory supported by grants from the NICHD, NIDDK, industry and a variety of foundations. He works collaboratively to better understand the host genomic factors that contribute to HIV and TB progression in African children, funded by the NIH/NIAID H3Africa initiative. He has continued clinical practice throughout his career and has never lost sight of the fundamental importance of careful observation and listening carefully to patients.

Wylie Burke

Member

Wylie Burke, M.D., Ph.D. is Professor Emeritus and former Chair of the Department of Bioethics and Humanities at the University of Washington. Her work focuses on the ethical and policy implications of genetic information in research, public health and clinical care. She founded the University of Washington Center for Genomics and Healthcare Equality, an NHGRI-funded center of excellence in ethical, legal and social implications research addressing the implications of genomic research for underserved communities; and co-directs the Northwest-Alaska Pharmacogenomics Research Network, a research partnership involving universities and tribal communities in Alaska, Montana and Washington. Dr. Burke received a Ph.D. in Genetics and an M.D. from the University of Washington, and completed Internal Medicine residency training at the University of Washington, where she was also a Medical Genetics fellow. She is a member of the National Academy of Medicine and past President of the American Society of Human Genetics.

Richard Fabsitz

Member

Dr. Richard Fabsitz joined the Department of Global and Community Health as Adjunct Faculty teaching Applied Health Statistics after a long-term career with the National Institutes of Health. His NIH career began with the National Institute of Mental Health but was primarily spent at the National Heart, Lung and Blood Institute where he last served in the position of Deputy Chief, Epidemiology Branch. He has extensive experience in research team management, program administration, and the conduct of cardiovascular epidemiology research in large population-based studies focused on longitudinal cohort studies, Native Americans, families, twins, and genetics. Additional research interests include the use of metrics in the management of scientific research, methods to promote collaboration and innovation in research projects, research translation, and the ethical and practical issues surrounding the return of genetic research results to study participants. He has authored or co-authored a wide range of journal articles related to cardiovascular epidemiology.

Vanessa N. Gamble

Member

Vanessa Northington Gamble, a physician and medical historian, is University Professor of Medical Humanities and Professor of Health Policy and American Studies at the George Washington University. Before coming to GWU, she was director of Tuskegee University’s National Center for Bioethics and Health Care. She is an internationally recognized expert on the history of race and American medicine, racial and ethnic inequities in health and health care, and bioethics. Dr. Gamble is a member of the National Academy of Medicine and Fellow of the Hastings Center.

Gregg Gonsalves

Member

Gregg Gonsalves is an Assistant Professor of Epidemiology of Microbial Diseases at Yale School of Public Health. His research focuses on the use of quantitative models for improving the response to epidemic diseases. Gonsalves is also an Associate Professor (Adjunct) and Research Scholar in Law at Yale Law School, a co-director of the Yale Collaboration for Research Integrity and Transparency, and a leading HIV/AIDS activist. For more than 20 years, he worked on HIV/AIDS and other global health issues with several organizations, including the AIDS Coalition to Unleash Power, the Treatment Action Group, Gay Men’s Health Crisis, and the AIDS and Rights Alliance for Southern Africa. He was also a fellow at the Open Society Foundations and in the Department of Global Health and Social Medicine at Harvard Medical School from 2011-2012. He is a 2011 graduate of Yale College and received his PhD from Yale Graduate School of Arts and Sciences/School of Public Health in 2017.

Rhonda G. Kost

Member

Dr. Kost has expertise in several content areas relevant to Return of Individual-Specific Research Results. First, and perhaps most importantly, as the Clinical Research Officer for The Rockefeller University Center for Clinical Translational Science, she has spent more than a decade studying participant-centered research outcomes, specifically developing validated tools and using them to assess what research participants think of, and want from, their research experiences. She has been a member of The Rockefeller University Institutional Review Board since 1997, and has directed the Clinical Research Support office as the lead in human subject protections, research ethics, regulatory compliance, engaging stakeholders, and participant advocacy, for more than a decade. In another role, as Co-Director of the Community Engagement Core, she is experienced and attuned to addressing the priorities of communities and patients. Trained in Internal Medicine and Infectious Diseases, Dr. Kost served as a Medical Staff Fellow at the National Institutes of Health, NIAID, and as an HIV Clinical Trialist at the Aaron Diamond AIDS Research Center prior to her current position at Rockefeller. She has served on and led national CTSA committees, and is respected as an active and innovative contributor to the national CTSA Consortium.

Debra Leonard

Member

Debra Leonard, M.D., Ph.D., received her M.D. and Ph.D. from the New York University School of Medicine, and is currently Professor and Chair of the Department of Pathology and Laboratory Medicine at the Robert Larner, M.D. College of Medicine at the University of Vermont and at the University of Vermont Health Network. She was previously Vice Chair for Laboratory Medicine in the Department of Pathology and Laboratory Medicine, and Director of the Clinical Laboratories for New York-Presbyterian Hospital’s Cornell campus (NYPH-WCMC), where she also served as Director of the Pathology Residency Training Program. Dr. Leonard is a nationally recognized expert in Molecular Pathology. She has served on several national committees that develop policy for the use of genetic and genomic technologies and information, including most recently the Secretary’s Advisory Committee on Genetics, Health and Society that advised the Secretary of Health and Human Services. Dr. Leonard is editor of two molecular pathology textbooks and has spoken widely on various molecular pathology test services, the future of molecular pathology, and the impact of gene patents on molecular pathology practice. Dr. Leonard is interested in the use of genomic technologies in the practice of medicine to improve patient outcomes.

Amy McGuire

Member

Amy McGuire, J.D., Ph.D., is the Leon Jaworski Professor of Biomedical Ethics and Director of the Center for Medical Ethics and Health Policy at Baylor College of Medicine. Dr. McGuire's research focuses on clinical integration of emerging technologies, with a particular focus on ethical and policy issues in human genetics and genomic research. Her research is funded by the National Institutes of Health. Dr. McGuire served as a member of the National Advisory Council for Human Genome Research from 2011-2015. Currently, she on the program committee for the Greenwall Foundation Faculty Scholars Program in Bioethics and is president of the Association of Bioethics Program Directors.

James H. Nichols

Member

James H. Nichols, PhD, DABCC, FACB, is a Professor of Pathology, Microbiology, and Immunology; Medical Director of Clinical Chemistry and Point-of-Care Testing at Vanderbilt University School of Medicine in Nashville, Tennessee. Dr. Nichols received his BA in General Biology/Premedicine from Revelle College, University of California at San Diego. He went on to complete an MS and a PhD in Biochemistry from the University of Illinois, Urbana-Champaign. Dr. Nichols was a fellow in the Postdoctoral Training Program in Clinical Chemistry at the Mayo Clinic, Rochester, Minnesota. He is board certified in both Clinical Chemistry and Toxicological Chemistry by the American Board of Clinical Chemistry. Dr. Nichols spent several years as Associate Director of Clinical Chemistry, Director of Point-of-Care Testing, and an Associate Professor of Pathology at Johns Hopkins Medical Institutions. He later served as Medical Director of Clinical Chemistry for Baystate Health in Springfield, Massachusetts, and was a Professor of Pathology at Tufts University School of Medicine. Dr. Nichols' research interests span evidence-based medicine, information management, laboratory automation, point-of-care testing, and toxicology. Dr. Nichols has served on CLIAC – The Clinical Laboratory Improvement Amendments Advisory Committee and has been involved with CLSI in a number of roles. He was a member of the Subcommittee on Point-of-Care Testing, as well as Vice-Chairholder and Chairholder of the Consensus Committee on Point-of-Care Testing. Dr. Nichols served on the Chairholders Council; participated as a member of the Consensus Committee on Evaluation Protocols; and was an advisor, member, Chairholder, and Co-Chairholder of several document development committees.

Consuelo Wilkins

Member

Consuelo H. Wilkins, MD, MSCI is the Executive Director of the Meharry-Vanderbilt Alliance and Associate Professor of Medicine at both Vanderbilt University Medical Center and Meharry Medical College. As Associate Director of the Vanderbilt Institute for Clinical and Translational Science, she oversees programs in team science and community engagement. Dr. Wilkins is currently a Principal Investigator of the Vanderbilt-Miami-Meharry Center of Excellence in Precision Medicine and Population Health, which focuses on decreasing disparities among African Americans and Latinos using precision medicine, and the Vanderbilt Recruitment Innovation Center, national center dedicated to enhancing recruitment and retention in clinical trials. She has pioneered methods of stakeholder engagement that involve community members and patients in research across the translational spectrum. One approach, the Community Engagement Studio, was recently scaled to engage more than 650 community members across 12 states in 77 face-to-face consultations for the Precision Medicine Initiative Pilot. This work included eliciting perspectives from diverse communities on returning individual research results. With colleagues at Vanderbilt, Dr. Wilkins has developed a framework that extends the concept of return of results to “return of value”, which integrates influencers of participants’ perspectives of value and considers clinical and personal utility. Prior to joining the faculty at Vanderbilt University Medical Center in 2012, Dr. Wilkins was an Associate Professor in the Department of Medicine, Division of Geriatrics, with secondary appointments in Psychiatry and Surgery (Public Health Sciences) at Washington University School of Medicine in St. Louis. She served as Founding Director of the Center for Community Health and Partnerships in the Institute for Public Health, co-director of the Center for Community Engaged Research in the CTSA, and director of "Our Community, Our Health"- a collaborative program with Saint Louis University to disseminate culturally relevant health information and facilitate community-academic partnerships to address health disparities. Dr. Wilkins earned a Bachelor of Science in microbiology (magna cum laude, Phi Beta Kappa) and a Doctor of Medicine from Howard University. She completed residency training in Internal Medicine at Duke University Medical Center and a Geriatric Medicine fellowship at Washington University School of Medicine/Barnes-Jewish Hospital. Following her medical training, Dr. Wilkins earned a Master of Science in Clinical Investigation from Washington University School of Medicine.