INVESTIGATOR BIOSKETCHES

Jodi B. Segal, MD, MPH, is Principal Investigator of the PCORI Methodology Standards Academic Curriculum project and has developed curricula relating to ***Standards for Data Integrity and Rigorous Analyses*** and ***Standards for Studies of Diagnostic Tests***. She is a professor of medicine at the Johns Hopkins University (JHU) School of Medicine, where she practices general internal medicine (GIM), and has faculty appointments in the Bloomberg School of Public Health in the Departments of Health Policy and Management and Epidemiology. Professor Segal has been involved in the field of evidence generation and synthesis for the past 15 years. She was an associate director of the JHU Evidence-Based Practice Center funded by the Agency for Healthcare Research and Quality and has been involved in large-scale systematic reviews since 1998. She has been a leader in comparative effectiveness research (CER) nationally and developed the first course offered in the United States in the field. She was awarded a PhRMA Foundation award to develop a Center of Excellence in CER at JHU. She is an associate director of the Center for Health Services and Outcomes Research, where she works closely with students and faculty conducting outcomes research using large data sets, including Medicare data and commercial claims data, and serves on the Medicare Evidence Development and Coverage Advisory Committee. As a pharmacoepidemiologist, she co-directs the Center for Drug Safety and Effectiveness at JHU and has undertaken numerous projects on behalf of the US Food and Drug Administration, including developing methodologies to help with its CER and safety evaluations. Professor Segal was an undergraduate student at the Pennsylvania State University, attended medical school at the University of Pittsburgh, and trained in internal medicine at the University of Chicago before joining JHU for public health training and a research fellowship in GIM in 2000.

Zackary Berger, MD, PhD, has developed curricula relating to *Standards for Formulating Research Questions*. Dr. Berger is an assistant professor in the Division of General Internal Medicine at the Johns Hopkins School of Medicine. In addition to his work as an internist and primary care physician, he is an associate faculty member in the Berman Institute of Bioethics (BI), and a core faculty member in the Evidence-Based Practice Center as well as the Center for Health Services and Outcomes Research. He obtained a bachelor of science degree with honors from Caltech and an MD and PhD degree in epidemiology from the joint program at New York University. Thereafter he completed a primary care internal medicine residency at New York University/Bellevue Hospital.

Dr. Berger maintains an active clinical practice in general internal medicine (GIM), with particular clinical expertise in chronic pain, the treatment of depression and anxiety, and coordination of cancer care. His research, clinical, and educational mission is to bridge evidence-based medicine and shared decision making in the context of patient-centered care, to understand how to accomplish this in the common case of uncertainty, to clarify the ethics of decision making, and to describe empirically how shared decision making is and should be done. He has been funded by the Greenwall Foundation for Bioethics and is incoming chair of the Evidence-Based Medicine Task Force of the Society of General Internal Medicine. Dr. Berger is the clinical champion and co-founder of the Comprehensive Unit-Based Safety Practice team in the GIM practice in the Johns Hopkins Outpatient Center, and he teaches with residents and medical students. He created and is teaching a novel course at the BI on the Ethics of Healthcare Decision Making, part of the institute's Masters of Bioethics program.

Eric B. Bass, MD, MPH, has developed curricula relating to ***Standards for Systematic Reviews*** and ***Standards for Formulating Research Questions****.* He is a professor of medicine with joint appointments in health policy and management, epidemiology, and nursing at the Johns Hopkins University (JHU). He is the director of the JHU Evidence-Based Practice Center and previously served as a co-director of the JHU DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Center. Professor Bass was the editor of the *Journal of General Internal Medicine* for five years and was the founding editor-in-chief of *Progress in Community Health Partnerships*. He served as the director of the General Internal Medicine Fellowship at JHU for 15 years. He was the president of the Society of General Internal Medicine in 2013–14. He has extensive research experience in evidence-based medicine, with special interests in assessing the effectiveness, safety, and costs of medical and surgical management strategies. Professor Bass also has expertise in curriculum development, having served as a facilitator for the JHU Faculty Development Program and having co-authored a book on curriculum development. He has published more than 200 peer-reviewed articles as well as numerous evidence reports.

Albert W. Wu, MD, MPH, has developed curricula relating to *Standards Associated with Patient-Centeredness*. He is a practicing internist and professor of health policy and management at the Johns Hopkins Bloomberg School of Public Health, with joint appointments in epidemiology, international health, medicine and surgery, and the Carey Business School. Professor Wu has been at Johns Hopkins since 1990, and his research and teaching focus is on patient outcomes and quality of care. He was president of the International Society for Quality of Life and has authored over 380 peer-review publications. He was the first to study patient-reported outcomes (PROs) in HIV/AIDS clinical trials, including the original Burroughs Wellcome clinical trial of AZT. He founded the Outcomes Committee within the National Institutes of Health's AIDS Clinical Trials Group, which designed and implemented measures of health-related quality of life, symptoms, adherence, and cost. He led PRO assessments for other national trials networks (SOCA, CCTG, CPCRA, SMART) and cohort studies (HCSUS, ALIVE, ICONA), and helped develop the leading measurement instruments in the field, including the MOS-HIV Health Survey, the ACTG HIV Symptom Index, and the ACTG Adherence questionnaires. Professor Wu was responsible for assessing PROs in the Robert Wood Johnson–funded SUPPORT study of seriously ill hospitalized adults, and he developed the first clinical models to predict future functional status. He developed PRO measures for the Agency for Healthcare Research and Quality–funded PORT study of kidney dialysis (CHOICE). Professor Wu has been a thought leader on the incorporation of PRO data into the electronic health record and was co-developer of PatientViewpoint, an early web tool that allowed providers to routinely order PRO questionnaires as lab tests.

Clifton O. Bingham III, MD, has developed curricula relating to *Standards Associated with Patient-Centeredness*. Dr. Bingham is a rheumatologist and associate professor of medicine at Johns Hopkins, where he serves as director of research for the Division of Rheumatology, director of the Center for Patient Centered Outcomes Research in Rheumatology, and director of the Johns Hopkins Arthritis Center. After medical school and an internal medicine residency at Columbia University College of Physicians and Surgeons in New York, he completed fellowships in rheumatology and in allergy and clinical immunology at the Brigham and Women's Hospital in Boston. He was recruited to New York University Hospital for Joint Diseases, where he established and directed the Seligman Center for Advanced Therapeutics for clinical trials and translational research in rheumatology. He was recruited to Johns Hopkins in 2005 as a member of the rheumatology faculty and has directed the Johns Hopkins Arthritis Center since 2010. He has been an investigator and leader of numerous clinical trials for rheumatoid arthritis, psoriatic arthritis, and osteoarthritis, with expertise in clinical trial study design, patient population selection, and outcome measure development and selection.

Dr. Bingham is a member of the Executive Leadership Committee for the international group Outcome Measures in Rheumatology, which has developed a standardized outcome to define "flare" of rheumatoid arthritis. He is the recipient of a Pilot Project Award from PCORI and a subsequent PCORI Methodology Award to evaluate the feasibility, validity, and impact of improved patient-reported outcome assessments in rheumatology clinical practice using the National Institutes of Health's Patient Reported Outcome Measurement Information System. He founded and directs the Center for Patient Centered Outcomes Research in Rheumatology to facilitate innovative, collaborative, and transformative patient-centered research that will enable more complete integration of patients' voices in rheumatology research, education, and clinical care.

Scott L. Zeger, PhD, has developed curricula relating to ***Standards for Data Integrity and Rigorous Analyses*** and ***Standards for Causal Inference Methods****.* He is a professor of biostatistics at the Johns Hopkins Bloomberg School of Public Health and is the director of the Johns Hopkins Individualized Health Initiative. From 2008 to 2013, he was vice provost for research to represent the university in all matters related to the research and scholarship of its faculty and students. Professor Zeger is author or co-author of three books and more than 200 scientific articles and book chapters. *Science Watch* identified him as one the top 25 most cited mathematical scientists.

Professor Zeger has led Hopkins *in*Health, a signature initiative of the Rising to the Challenge Campaign to bring modern biological and data sciences to the practice of American medicine and public health. He has been awarded an honorary doctorate from Lancaster University (United Kingdom), elected as a member of the National Academy of Sciences' Institute of Medicine, and named a fellow of the American Association for the Advancement of Science and of the American Statistical Association (ASA). He has served as expert witness to the US Department of Justice in their civil suits against the tobacco industry and as a member of the Board of Scientific Advisors for the Merck Research Laboratory. He is a member of the Springer-Verlag editorial board for statistics and was the founding co-editor of the Oxford University Press journal *Biostatistics*. He was jointly awarded the 2015 Karl Pearson Prize by the International Statistical Institute. Professor Zeger received the 2008 Wilks Award from the ASA for contributions to statistical science, the 2007 Bradford Hill Medal from the Royal Statistical Society for outstanding contributions to medical statistics, and the 2007 Marvin Zelen Award from Harvard University for leadership in the field of biostatistics.

Daniel O. Scharfstein, ScD, has developed curricula relating to *Standards for Preventing and Handling Missing Data.* He is a professor of biostatistics at the Johns Hopkins Bloomberg School of Public Health. He received undergraduate degrees in applied science and economics from the University of Pennsylvania, a master's degree in operations research from the Georgia Institute of Technology, and master's, doctoral, and post-doctoral training in biostatistics at the Harvard School of Public Health. He joined the faculty at Johns Hopkins University in 1997. His research is focused on how to draw inferences about treatment effects in the presence of selection bias. Specifically, he is interested in how to report results in randomized trials with informative missing or censored data and in observational studies with nonrandom treatment assignment. He recently served on the National Academy panel, which issued the report "The Prevention and Treatment of Missing Data in Clinical Trials." He has received funding from the Food and Drug Administration and PCORI to develop and disseminate methods and software for conducting global sensitivity analysis of randomized trials with missing outcome data. Professor Scharfstein is the principal statistician of the METRIC consortium, which is funded by the Department of Defense to conduct multicenter clinical research relevant to the treatment and outcomes of orthopedic trauma sustained in the military. He has also served as the lead statistician on a number of large evaluation studies, including the National Study of the Costs and Outcomes of Trauma, Guided Care for Chronically Ill Older Adults, and Healthy Steps for Young Children. He is a fellow of the American Statistical Association, received the 1999 George W. Snedecor Award for best paper in biometry, and, in 2010, was recognized with the Distinguish Alumni Award from the Department of Biostatistics at Harvard.

Tianjing Li, MD, PhD, has developed curricula relating to *Standards for Preventing and Handling Missing Data* and *Standards for Systematic Reviews*. Dr. Li is an assistant professor in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. She holds advanced degrees in medicine, epidemiology, and biostatistics. Dr. Li's research interests include the methodology of meta-analysis, network meta-analysis, systematic review, clinical trial, missing data, reporting bias, and methods for patient-centered outcomes research and comparative effectiveness research. Dr. Li has served as the Principal Investigator or co-investigator on multiple PCORI-funded projects.

Ravi Varadhan, PhD, has developed curricula relating to *Standards for Heterogeneity of Treatment Effects*. Dr. Varadhan is an associate professor in the Division of Biostatistics and Bioinformatics, Department of Oncology, at the Johns Hopkins University. He is a statistical methodologist with a wealth of clinical and epidemiological research experience. His major areas of research expertise include the development and translation of statistical methodology for patient-centered outcomes research, including novel study designs and analysis methods for the assessment of heterogeneous treatment effects and for competing risks, and the development of efficient computational algorithms and software for solving high-dimensional problems in statistical modeling. He has authored or co-authored over 80 peer-reviewed publications. He has developed numerous software packages for computational statistics written in the R language. He has been funded by the Agency for Healthcare Research and Quality (AHRQ) and the Food and Drug Administration (FDA) to develop statistical methods for developing novel framework and statistical methods to address heterogeneity of treatment effects (HTE); cross-design synthesis for estimating treatment effects in target groups not represented in trials; benefit-harm assessment in systematic reviews; and evaluating the impact of interventions in the presence of competing risks. Dr. Varadhan has written a chapter on how to address HTE for AHRQ's best practice manual for statistical methods in comparative effectiveness research. He prepared the draft standards for the analysis of HTE for PCORI. He is currently funded by PCORI to develop guidance and software tools for the analysis of HTE. He is also funded by the FDA to develop causal inference methods for comparing generic with branded drugs.
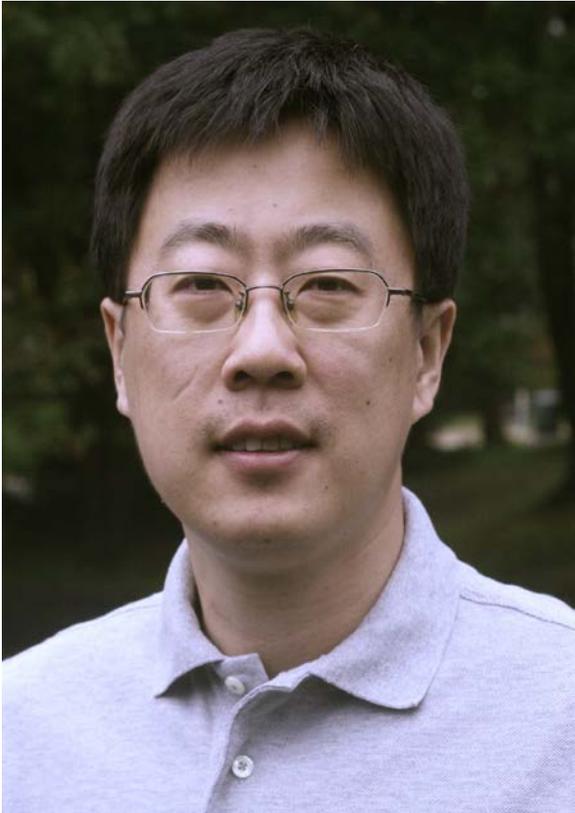
Chenguang Wang, PhD, has developed curricula relating to *Standards for Heterogeneity of Treatment Effects*. Dr. Wang is an assistant professor in the Department of Oncology at Johns Hopkins University (JHU) School of Medicine and a member of the Biostatistics Core for the Sidney Kimmel Comprehensive Cancer Center at JHU. Dr. Wang has a strong background in the field of computer science. He worked for many years within the Children's Oncology Group on children's acute lymphoblastic leukemia trials and as a Food and Drug Administration mathematical statistical reviewer. Dr. Wang has worked on developing and applying a broad array of biostatistical methodologies to the design and analysis of a wide range of research studies, including clinical trials and observational studies pertaining to various cancers. Dr. Wang's statistical methodology interests involve applying Bayesian parametric and nonparametric methods for missing data analysis, causal inference, and comparative effectiveness research; he is particularly interested in extending existing Bayesian methodologies to meet new statistical challenges that arise from medical research.

Martin Makary, MD, MPH, has contributed to ***Standards for Data Registries.*** He is a professor of surgery and health policy and management at Johns Hopkins, the *New York Times* best-selling author of *Unaccountable*, and a leading voice for physicians as a writer for the *Wall Street Journal* and *Time* magazine. Makary is a surgical oncologist and is the creator of "The Surgery Checklist" described in the book *The Checklist Manifesto*. He led the World Health Organization workgroup to measure surgical quality worldwide.

At Johns Hopkins, Professor Makary is chief of islet transplantation surgery. He pioneered two laparoscopic pancreas operations and received the national Nobility in Science Award from the National Pancreas Foundation. In 2006, Professor Makary was named the Mark Ravitch Endowed Chair of Gastrointestinal Surgery at Johns Hopkins, and in 2010 was appointed the director of surgical quality and safety at Johns Hopkins. He has published over 200 scientific publications and is an advocate for greater physician input in the redesign of health care. His most recent articles have focused on the hazards of corporate medicine, the issue of appropriateness in medical care, and price transparency. Last year, Professor Makary was named as one of America's 40 Smartest People in Healthcare by *Becker's Hospital Review*. Currently, he serves as the national director for Improving Wisely, a Robert Wood Johnson Foundation project that aims to empower physicians to define and endorse quality metrics in health care.

Alison Klein, PhD, MHS, has developed curricula relating to ***Standards for Data Registries***. Dr. Klein is an associate professor of oncology, pathology, and epidemiology and a trained genetic epidemiologist/statistical geneticist specializing in pancreatic cancer. She has studied the genetic epidemiology of pancreatic cancer for over 15 years. She is the director of the National Familial Pancreas Tumor Registry, the largest registry of familial pancreatic cancer in the world. Currently, over 5,600 families have enrolled in this registry, including over 1,700 with familial pancreatic cancer. Her long-term interests include understanding the genetic and environmental risk factors that cause pancreatic disorders, and developing risk prediction models to identify individuals at high risk of developing pancreatic cancer.

Dr. Klein led the efforts that identified *PALB2* and *ATM* as causes of familial pancreatic cancer. Her work quantifying these causes of pancreatic cancer helped lay the foundation for many of the ongoing pancreatic cancer early detection trials. Currently, she is a co-leader of the Familial Pancreatic Cancer Genome Sequencing Project, where she has recently completed whole genome sequencing analysis of 638 patients with familial pancreatic cancer. She is the director of the Gastrointestinal SPORE at Johns Hopkins. She is also the Principal Investigator of a NCI/CIDR–supported multicenter GWAS for pancreatic cancer. In addition to her gene discovery work, she holds a Research Investigator award from the Lustgarten Foundation for Pancreatic Cancer Research to develop risk models of pancreatic cancer.

Hadi Kharrazi, MD, PhD, has developed curricula relating to *Standards for Data Networks as Research-Facilitating Structures*. Dr. Kharrazi is the assistant director of the Johns Hopkins Center for Population Health IT. His expertise includes assessing the needs and impact of health IT on care delivery, designing interoperable platforms for population health, developing and evaluating advanced predictive models for risk stratification, and testing the feasibility of new quality metrics across various denominators and healthcare workflows.

Dr. Kharrazi has an extensive record on education. He has developed more than a dozen courses in health informatics. He is the co–Principal Investigator (co-PI) of an ONC award to develop a national curriculum for population health informatics and train more than 6,000 healthcare professionals nationally. He has been part of the NLM training programs and has participated in curriculum development for two certificate programs (funded by ONC). He is currently the director of the DrPH Informatics track program at the Johns Hopkins School of Public Health and the co-director of the PhD program in health informatics at the Johns Hopkins School of Medicine. Dr. Kharrazi has also been the PI of several federal grants and contracts with a special focus on population health informatics.

Dan Ford, MD, MPH, has developed curricula relating to *Standards for Data Networks as Research-Facilitating Structures*. Dr. Ford has been the vice dean for clinical investigation at Johns Hopkins School of Medicine and Principal Investigator (PI) of the Clinical and Translational Science Award Program for the past eight years. In this role he acts as the institutional official, director of the Johns Hopkins Medicine Institutional Review Board, and director of contracting for clinical research protocols. Dr. Ford is on the board of directors for the Clinical Research Forum and the Society for Clinical and Translational Science and is co-chair of the Clinical Research Forum IT Roundtable. During his career, Dr. Ford has been broadly focused on understanding the biological interrelations of mental disorders and cardiovascular disease as well as on improving the care of patients with addictive and mental disorder conditions in general medical settings.

Dr. Ford has been the PI of grants from the NIMH, NIDA, and NCI and is currently the PI for the PCORI Clinical Data Research Network site at Johns Hopkins. He has been the PI, and now co-PI, for the HRSA Primary Care Health Services Research Training Grant supporting five post-docs in the Division of General Internal Medicine since 1992. In addition to mentoring over 20 junior faculty members, he has been the primary mentor for five individuals who started with awards and have gone on to become professors, division directors, and MacArthur Award winners. His academic career has been as a core faculty member of the Welch Center for Prevention, Epidemiology, and Clinical Research—an academic unit known for a culture that promotes interdisciplinary research and support for young investigators across specialties.

Elizabeth Stuart, PhD, has developed curricula relating to *Standards for Causal Inference Methods*. She is a professor in the Department of Mental Health (primary), Department of Biostatistics (joint), and Department of Health Policy and Management (joint) at Johns Hopkins Bloomberg School of Public Health (JHSPH). She received her PhD in statistics from Harvard University. Before joining JHSPH she was a researcher at Mathematica Policy Research. Professor Stuart's primary research interests are in the development and use of methodology to better design and analyze the causal effects of public health and educational interventions. Her two primary research areas include the use of propensity score methods for estimating causal effects in nonexperimental studies and methods to assess and enhance the external validity (generalizability) of randomized trial results to enable policy makers to determine how applicable the results of a particular randomized study are to their own target population. The applied areas she focuses on include autism, the long-term consequences of adolescent substance abuse, education, mental health services and systems, and the effects of healthcare reform models on mental health service use. Professor Stuart has been a member of the American Statistical Association since 2001 and was named a fellow in 2014. She is the inaugural chair of the PCORI Clinical Trials Advisory Panel, an associate director of the Wendy Klag Center for Autism and Developmental Disabilities at JHSPH, core faculty in the JHSPH Center for Drug Safety and Effectiveness, and co-director of the JHSPH Center for Mental Health and Addiction Policy Research.

Gary Rosner, ScD, has developed curricula relating to ***Standards for Adaptive and Bayesian Trial Designs***. He is the Eli Kennerly Marshall Jr. Professor of Oncology at the Johns Hopkins University (JHU) School of Medicine and a professor of biostatistics at the Bloomberg School of Public Health, JHU. He directs the Division of Biostatistics and Bioinformatics in the Department of Oncology and heads the Research Program in Quantitative Sciences at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins.

Professor Rosner received his ScD in biostatistics from the Harvard School of Public Health in 1985. He was a member of the faculties of Yale University, Duke University, and The University of Texas M. D. Anderson Cancer Center. His collaborations include the design and analysis of clinical studies in cancer and population modeling in pharmacokinetics and pharmacodynamics. Professor Rosner carries out research on Bayesian statistical methods to improve the design and analysis of complex cancer research studies. He is a fellow of the American Statistical Association and an associate editor for the journals *Biometrics* and *Clinical Trials*.

Najlla Nassery, MD, MPH, has developed curricula relating to *Standards for Studies of Diagnostic Tests*. Dr. Nassery is a practicing internal medicine physician with experience in medical education and health services research. She completed a three-year academic general internal medicine (GIM) fellowship at the Johns Hopkins University School of Medicine and fulfilled training requirements in both the clinician-educator and clinician-investigator tracks. She joined the Division of General Internal Medicine as assistant professor of medicine in 2013. Presently, she is a core facilitator of the Longitudinal Curriculum Development Seminar and the Semi-Annual Curriculum Development Workshops at Johns Hopkins that target medical faculty. As a GIM fellow, Dr. Nassery obtained a master's degree in public health from the Johns Hopkins School of Public Health; her academic focus was in heath policy and management. She was involved in a number of research projects during fellowship and also completed a consultancy at the National Committee for Quality Assurance. During this time, she also developed an interest in healthcare quality/patient safety and studying the efficiency of healthcare resource use. She is presently working with mentors to prepare an application for a career development award (K08). The aim of the K08 is to develop predictive models/metrics using billing and administrative data that will estimate the incidence of diagnostic delay in ambulatory care settings—a patient safety, healthcare quality, and cost problem. This data will expand our limited epidemiological knowledge on diagnostic delay and diagnostic error, and could lead to the development of point-of-care metrics that can be used in the future to improve care delivery.

Rohini Vanchiswaran, MS, is an instructional designer at the Center for Teaching and Learning and is involved in the design, management, and evaluation of courses, project management, and online program development in the area of public health. With over 12 years of professional experience in the field of digital learning and technology integration, Ms. Vanchiswaran has managed projects that span online programs, trainings, virtual science labs, and electronic portfolios. She has a background in science and education with graduate degrees in applied chemistry and curriculum and instructional technology. Recent topics of interest include interdisciplinary programs, STEM education, educational gaming/simulations, and competency-based credentialing.

Nancy Kass, ScD, provided ethical oversight for the PCORI MSC project. She is the Phoebe R. Berman Professor of Bioethics and Public Health in the Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, and deputy director for public health in the Berman Institute of Bioethics. Professor Kass conducts empirical work in bioethics and health policy. Her publications are primarily in the field of US and international research ethics, ethics and learning healthcare systems, HIV/AIDS ethics policy, public health ethics, and ethics of public health preparedness. Current research projects examine ethics for a learning healthcare system including quality improvement and comparative effectiveness, informed consent in randomized trials, ethics issues that arise in international health research, and ethics and public health preparedness. Professor Kass teaches the Bloomberg School of Public Health's course on US and International Research Ethics and Integrity, is the director of the School's PhD program in bioethics and health policy, and is the director of the Johns Hopkins Fogarty African Bioethics Training Program. Professor Kass is an elected member of the Institute of Medicine and a fellow of the Hastings Center.

Thomas Lynch, PhD, MA, is project manager of the PCORI Methodology Standards Academic Curriculum project. Dr. Lynch is an international leader on the development of global palliative care provision. His studies have been widely used by policy makers and public and private funders in the global palliative care community to guide investment, set strategy, and monitor progress. Based on the World Health Organization public health model, he has assisted in the development of sustainable social policy for disadvantaged and underserved groups in many resource-poor countries. His methodological expertise is primarily in qualitative research on behavioral projects (depression and demoralization in patients with advanced cancer); quality-of-life projects (narratives written by patients about the experiences of knowingly facing death); and communication projects (communication, clarification, and facilitation of patients' preferences for care at the end of life). He has taught widely at universities in the United Kingdom in the areas of hospice and palliative care, public health, and qualitative research and has lectured internationally on these subjects in many resource-poor countries.

Dr. Lynch has been involved in the development of medical curricula through his work with the European Association for Palliative Care Task Force for the Mapping of Medical Education in Europe, and has also developed international health studies/palliative care curricula for the Centre for Strategic Health Studies in Damascus, Syria, and at the Kazakhstan School of Public Health in Almaty. He has mentored many international PhD students in his roles at Lancaster University and as a visiting professor at the Kazakhstan School of Public Health. Since coming to Johns Hopkins, he has been the project manager or a co-investigator on three projects funded by PCORI. He is deeply committed to patient-centered research.