Ethical Questions in Implementation Science Workshop

December 10-11, 2020

Program Handout









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Workshop Panelists Biographies

Jenny Blumenthal-Barby, Ph.D., MA



Jenny Blumenthal-Barby, Ph.D., M.A. is the Cullen Professor of Medical Ethics and Associate Director of the Center for Medical Ethics and Health Policy at Baylor College of Medicine. She received her Ph.D. in philosophy, with a specialization in bioethics, from Michigan State University in 2008.

Dr. Blumenthal-Barby's research focuses on medical decision-making and the ethics of the use of behavioral economics and decision psychology to shape people's decisions and behaviors.

Dr. Blumenthal-Barby has been the recipient of a prestigious Greenwall Faculty Scholar Award in Bioethics, a Pfizer Bioethics Fellowship, and served as the Principal Investigator on three awards from the Patient Centered Outcomes Research Institute (PCORI) to study and improve decision making in advanced heart failure. Most recently, she received funding as a

Co-Principal Investigator to study ethics and decision making in pediatric deep brain stimulation through the NIH BRAIN initiative. She has published more than 80 articles in bioethics, philosophy, and medical journals as well as served on several expert panels and committees related to bioethics and medical decision making. She is an Associate Editor for the *Journal of Medical Ethics* and is on the Board of Directors for the American Society for Bioethics and Humanities. She has a book forthcoming with MIT Press: *Good Ethics and Bad Choices: The Relevance of Behavioral Economics for Medical Ethics*.

• Cheryl Anne Boyce, Ph.D.



Cheryl Anne Boyce, Ph.D., is the Chief of the Implementation Science Branch, Center for Translation Research and Implementation Science (CTRIS) within the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), Department of Health and Human Services (DHHS). After doctoral studies at the University of North Carolina at Chapel Hill, and clinical and research fellowships at the Children's National Medical Center and University of Maryland School of Medicine, she began her federal career as a Society for Research in Child Development/American Association for the Advancement of Science (AAAS) Executive Branch Policy Fellow. She has been responsible for research and policy collaborations across agencies on child development, developmental risk, health treatment, evidence-based practice, and implementation research. She has served as federal staff for national studies on children and families and child welfare issues, including the Environmental Children's Health Outcomes (ECHO) Study, Longitudinal Study of Child

Abuse and Neglect (LONGSCAN), and Federal Child Neglect Consortium. Before joining NHLBI, she held scientific leadership positions at the National Institute on Drug Abuse (NIDA) and National Institute of Mental Health (NIMH), focused on neurodevelopment, evidence-based practice, translational research, young children, drug exposures, traumatic stress, health disparities, child maltreatment, and research training. Her commitment to public health science and service has been recognized through awards from the Executive Office of the President, Office of National Drug Control Policy, and NIH Office of the Director. She is an expert on mentoring, career, and research training issues and is dedicated to increasing and diversifying the biomedical research workforce. She co-edited the revised popular eBook on grantsmanship uniquely written by both federal personnel and successful research investigators entitled, "How to write a successful research grant application: A guide for social and behavioral scientists" (2nd edition) (Pequegnat, Stover, & Boyce, 2011).



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• Catherine Burke, MA



Ms. Burke has devoted most of her thirty-three years of government service managing grants in various capacities. From 1988-1991, she was a Program Assistant to the Fulbright Scholars Program at the US Information Agency. During that time, Ms. Burke was responsible for ensuring that the Fulbright scholars had all of the paperwork processed correctly and that they had everything they needed prior to arriving at the foreign institution. Additionally, she managed the foreign grants and supplemental paperwork for the incoming scholars from Eastern Europe. In 1991, Ms. Burke transitioned to the Fogarty International Center at the NIH and continued to manage grants for a new program that enabled US scientists to collaborate with foreign scientists. These small grants provided a stipend to the foreign scientist for their collaborations on US projects. In 1995, Ms. Burke came to the National Heart, Lung, and Blood Institute, where she has assisted program officials with all aspects of extramural grants management and portfolio analysis. In an effort to ensure that all staff are properly trained in

managing extramural grants, Ms. Burke designed an executed a training program for new staff, engaging multiple subject matter experts in the course. In addition to the day to day activities of extramural grants management, Ms. Burke has been involved in several portfolio analysis projects for the Division of Cardiovascular Sciences and sits on two NHLBI portfolio analysis working groups. Ms. Burke has an undergraduate degree in Communications and a Master's degree in Counseling.

• Neal Dickert, M.D., Ph.D.



Dr. Dickert is an Associate Professor of Medicine in the Division of Cardiology. He also holds a secondary appointment in the Department of Epidemiology at the Rollins School of Public Health, is a Senior Faculty Fellow at the Emory Center for Ethics, and is a member of the Emory Clinical Cardiovascular Research Institute and the Emory Health Services Research Center (https://med.emory.edu/departments/medicine/research/centersinstitutes/health-services-research/index.html). Dr. Dickert is a board-certified cardiologist whose clinical work is primarily in cardiac critical care and echocardiography. He completed medical school at the Johns Hopkins University School of Medicine and a PhD in health policy and bioethics and the Johns Hopkins Bloomberg School of Public Health. He completed an internal medicine residency at Johns Hopkins and a cardiology fellowship at Emory. Dr. Dickert joined the faculty at Emory in 2012 as part of the Emory Clinical Cardiovascular Research Institute.

Dr. Dickert's research focuses on ethical issues relevant to cardiology practice and clinical research. In particular, he is actively engaged in research projects addressing the conduct of clinical research in acute care contexts where informed consent is either impossible or very difficult. Dr. Dickert is also interested in and has published work regarding investigators' responsibilities to provide ancillary care to research participants, the process of shared decision-making for clinical care and research participation, and the role of incentives for research recruitment.



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Kathleen Fenton, M.D., MS



As a pediatric heart surgeon, Dr. Fenton was already working with colleagues to help broaden their understanding and appreciation of surgical ethics. Then, after completing Master of Science in Bioethics, she wanted to make a more profound contribution to domestic and international health care policy, combining her unique background in medicine, global health and bioethics. With this in mind, she started working in the Global Health branch of the Center for Translation Research and Implementation Science (CTRIS) at NHLBI in mid-2019. A year and a half later, she accepted the position of deputy chief of the Advanced Technologies and Surgery Branch of NHLBI's Division of Cardiovascular Sciences, where she currently works. This followed two previous exciting turning points in her career.

The first was in 2006. Having had two academic positions as a surgeon in the U.S., she moved to Managua to help establish a pediatric heart surgery program. Her intention was

to return home after two or three years, but the work was immensely rewarding. She quickly realized that she was not only giving life back to children who otherwise would have no access to surgery, but that by mentoring the local surgeon and medical team she was allowing them to develop their careers in a way that would not have otherwise been possible.

Meanwhile, when she was appointed to serve on the Standards and Ethics Committee for the Society of Thoracic Surgeons in 2010, it did not occur to her that it would be anything other than a short-term act of service to her colleagues. However, Dr. Fenton soon realized just how great a need there is for surgeons to be actively involved in bioethics! This motivated her to obtain formal training in bioethics, and she now applies this both at NHLBI and as an Affiliate Scholar in NIH's Department of Bioethics.

• Garth Graham, M.D., MPH, FACP, FACC



Dr. Garth Graham, M.D., MPH, FACP, FACC, is a leading authority on social determinants of health and health equity. As the Vice President of Community Health for CVS Health, Dr. Graham leads the enterprise-wide community and social determinants of health (SDoH) strategy, working closely with CVS Health's many businesses, to ensure differentiated, measurable and scalable approaches to addressing community health in communities across the country. Additionally, he leads public health partnerships and cardiovascular initiatives for CVS Health. Dr. Graham joined CVS Health through the Aetna acquisition, where he was President of the Aetna Foundation since 2014.

A cardiologist and professor of medicine, Dr. Graham is passionate about the opportunity to improve local health through cross-sector collaboration. Dr. Graham previously served as Deputy Assistant Secretary at the U.S. Department of Health and Human Services

under both the Obama and Bush Administrations, where he also ran the Office of Minority Health. He directed the development of the federal government's first National Health Disparities Plan released under the Obama administration. Dr. Graham was also the assistant dean for health policy at the University of Florida School of Medicine, where he led several research initiatives looking at how to improve outcomes and readmission rates in cardiac patients in underserved populations.

He contributes to several boards including the National Heart, Lung, and Blood Institute Advisory Council, the Institute of Medicine Board on Population Health, Board of the National Quality Forum, the American Heart Association/American Stroke Associational National Quality Oversight Committee, the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards, the Harvard Medical School Diversity Fund (chair) and was named by the President to the U.S. Federal Coordinating Council on Comparative Effectiveness Research many others.



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Dr. Graham has been featured in media outlets including Fortune, USA Today, The Hill, The Chicago Tribune, Essence, U.S. News & World Report, Quartz and Ebony. Dr. Graham holds a medical degree from Yale School of Medicine, an MPH from Yale School of Public Health and a bachelor of science in biology from Florida International University. He completed clinical training at Massachusetts General Hospital and Johns Hopkins where he trained in cardiology and interventional cardiology. He holds three board certifications including internal medicine, cardiology and interventional cardiology.

Steven Joffe, M.D., MPH



Dr. Joffe is the Founders Professor of Medical Ethics and Health Policy at the University of Pennsylvania Perelman School of Medicine, Acting Chair of the Department of Medical Ethics and Health Policy, Chief of the Division of Medical Ethics, and Director of the Penn Postdoctoral Training Program in the Ethical, Legal and Social Implications of Genomics. He is also Professor of Pediatrics at the Children's Hospital of Philadelphia.

Dr. Joffe attended Harvard College, received his MD from the University of California San Francisco (UCSF), and received his public health degree from UC Berkeley. He trained in pediatrics at UCSF and in pediatric hematology/oncology at the Dana-Farber Cancer Institute and Boston Children's Hospital. His research addresses the ethical challenges that arise in the conduct of biomedical investigation and in genomic medicine and science. He is a member of the FDA's Pediatrics Ethics Subcommittee and the National Human Genome Research Institute's Genomics and Society Working Group.

Jeremy M. Kahn, M.D. MSc



Dr. Kahn is Professor of Critical Care Medicine and Health Policy & Management at the University of Pittsburgh School of Medicine and Graduate School of Public Health. Dr. Kahn's research program focuses on the organization, management, and financing of critical care services in the United States. Specific areas of interest include ICU workforce and staffing, quality measurement, benchmarking, telemedicine, and regionalization of critical and emergency care. His work integrates approaches from the fields of epidemiology, health services research, health economics and organizational science to investigate novel strategies for increasing the quality and efficiency of care for critically ill patients. In addition to his research activities, he provides patient care in the ICU at Magee Women's Hospital of UPMC in Pittsburgh.

• Nancy Kass, ScD



Nancy Kass, ScD is Vice Provost for Graduate and Professional Education, Johns Hopkins University and Phoebe R. Berman Professor of Bioethics and Public Health in the JHU Berman Institute of Bioethics and Bloomberg School of Public Health, and Professor of Health Policy and Management. In 2009-2010, Dr. Kass was based in Geneva, Switzerland, working with the World Health Organization (WHO). Dr. Kass received her B.A. from Stanford University, completed doctoral training in health policy from the Johns Hopkins School of Public Health and post-doctoral training at the Kennedy Institute of Ethics, Georgetown University. As Vice-Provost, Dr. Kass focuses on the quality of PhD education and postdoctoral training, including promoting transparency about programs, diversity of the student body, professional development, and mentoring. In her faculty role, Dr. Kass conducts empirical work in bioethics, public health, and human research with publications on global and U.S. research ethics, public health ethics, and the learning healthcare system.

Dr. Kass chairs the NIH All of Us Research Program Central IRB; she previously served as consultant to the President's



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Advisory Committee on Human Radiation Experiments, the National Bioethics Advisory Commission, and the National Academy of Sciences. Dr. Kass is an elected member of the National Academy of Medicine (formerly Institute of Medicine) and an elected Fellow of the Hastings Center.

Meeta Prasad Kerlin, M.D., MSCE



Dr. Kerlin is Assistant Professor of Medicine and core faculty member of the Palliative and Advanced Illness Research (PAIR) Center of the Perelman School of Medicine at the University of Pennsylvania. Her primary research interests include studying and optimizing the contribution of the ICU organization to outcomes of critical illness, with a focus on implementation science related to critical care interventions and interprofessional care. She has led multiple secondary data analyses, randomized trials, experimental implementation studies, systematic reviews, survey studies, and qualitative studies. She has held ongoing NIH funding since 2013, including two current R01s, one of which funds a currently active trial of nudges to increase utilization of evidence-based mechanical ventilation strategies.

• Scott Kim, M.D., Ph.D.



Scott Kim is a Senior Investigator in the Department of Bioethics, National Institutes of Health. Prior to joining NIH, he was Professor of Psychiatry and Co-Director of the Center for Bioethics and Social Sciences in Medicine at the University of Michigan.

Dr. Kim received his MD from Harvard and PhD in moral philosophy (on Kantian ethics) from the University of Chicago, and trained in adult psychiatry at the Massachusetts General Hospital.

Dr. Kim combines philosophical, clinical, and empirical research approaches to his work, using a variety of methods to address several bioethical topics, including: ethical issues in pragmatic clinical trials, assessment of decision-making capacity, surrogate consent for incapacitated patients, theory of informed consent, end of life issues (especially euthanasia

and physician-assisted suicide), and a variety of topics in research ethics. Dr. Kim's work has been supported by the NIMH, NINDS, NIA, NHGRI, Michael J. Fox Foundation, American Association for Geriatric Psychiatry, and the Greenwall Foundation. His work has appeared in *New England Journal of Medicine*, *Nature*, *JAMA*, and other key journals. His book *Evaluation of Capacity to Consent to Treatment and Research* (Oxford, 2010) is available in English and Japanese.

• Aisha Langford, Ph.D., MPH



Aisha Langford, PhD, MPH, is an Assistant Professor in the Department of Population Health, Division of Comparative Effectiveness and Decision Science within NYU's Grossman School of Medicine. She is also an affiliate faculty member of the Division of Medical Ethics within Population Health. Under NYU Langone Health's Clinical and Translational Science Institute, she co-directs the Recruitment and Retention Core. Broadly, Dr. Langford's research explores how health communication can improve individual decision making and reduce population health disparities for conditions or behaviors that lead to preventable mortality and morbidity. Historically, she has done work in cancer prevention and minority clinical trial participation in community-based settings. Her current work has expanded to include cardiovascular disease broadly, with a particular interest in hypertension-related decision making and patient-physician communication. Dr. Langford earned her BA in English from the University of Virginia,



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MPH in Behavioral Science from Saint Louis University, and PhD in Health Behavior and Health Education from the University of Michigan. Prior to transitioning to a career in academic research, Dr. Langford held professional roles in public relations, adult literacy, and community outreach. She is an active member of the Society for Medical Decision Making, Society of Behavioral Medicine, and Academy of Communication in Healthcare. She serves as an associate editor for two journals: (1) *Clinical Trials* and (2) *Patient Education and Counseling*.

• Jim Lavery, Ph.D., MSc



Jim Lavery is the inaugural Conrad N. Hilton Chair in Global Health Ethics, Professor in the Hubert Department of Global Health in the Rollins School of Public Health, and Faculty of the Center for Ethics, Emory University, Atlanta, Georgia. Prior to joining the Emory faculty, he was a Research Scientist and Managing Director of the Centre for Ethical, Social & Cultural Risk at the Li Ka Shing Knowledge Institute of St. Michael's Hospital, and an Associate Professor in the Dalla Lana School of Public Health, Institute of Medical Science, and Joint Centre for Bioethics at the University of Toronto.

Jim received M.Sc. and Ph.D. degrees from the Institute of Medical Science and Centre for Bioethics at the University of Toronto and held a post-doctoral fellowship in applied ethics and health policy at the Queen's University Health Policy Research Unit, funded jointly by the Social Sciences and Humanities Research Council and the Canadian

Foundation for Health Services Research. He then spent 3 years at the Fogarty International Center, and Warren G. Magnuson Clinical Center Department of Clinical Bioethics, at the National Institutes of Health in Bethesda, Maryland, where he worked on U.S. federal government policy on the regulation of federally-funded research outside the United States.

Jim was the co-principal investigator of the Ethical, Social and Cultural (ESC) Program for the Bill & Melinda Gates Foundation's Global Health and Global Development programs from 2005-2015. He is currently leading the development of the Human Engagement Learning Platform (HELP) for Global Health at Emory University, to support funders and implementation partners to improve community and stakeholder engagement and organizational learning in global health and global development programs. He is the 2017 recipient of the Global Forum for Bioethics in Research Award for Contributions to Progress in International Research. He is a member of the Board of Directors of the Council for Health Research for Development (COHRED) USA, a member of the Scientific and Technical Advisory Committee of the Health Campaign Effectiveness Coalition at the Task Force for Global Health, and a member of the Bioethics Advisory Panel of Pfizer, Inc.

• Daniel D. Matlock, M.D., MPH



Dr. Matlock is an Associate Professor of Medicine, Division of Geriatrics at University of Colorado, and the Director of the Colorado Program for Patient Centered Decisions at ACCORDS (The Adult and Child Consortium for Outcomes Research and Delivery Science). He is board certified in Internal Medicine, Geriatrics, and Palliative care. His research is aimed at fundamentally changing and improving how patients make decisions around invasive cardiovascular technologies. He is currently the PI for a PCORI project implementation a decision aid for left ventricular assist devices to all programs in the United States.



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• George Mensah, M.D., FACC



Dr. George Mensah is a clinician-scientist who currently serves as the Director of the Center for Translation Research and Implementation Science at the National Heart, Lung, and Blood Institute (NHLBI), a part of the National Institutes of Health (NIH). In this role, Dr. Mensah leads a trans-NHLBI effort to advance late-stage translational research and implementation science to address gaps in the detection, prevention, treatment, and control of heart, lung, and blood diseases and sleep disorders, and the elimination of related health inequities. His goal is to maximize the health impact of advances made in fundamental discoveries, clinical and translational research, and population science research. Dr. Mensah is an honors graduate of Harvard University. He obtained his medical degree from Washington University and trained in Internal Medicine and Cardiology at Cornell. His professional experience includes more than 20 years of public health service at the U.S. Department of Veterans Affairs, the Centers for

Disease Control and Prevention (CDC), and the NIH. In addition to his public service, Dr. Mensah had 15 years of experience in direct patient care, teaching, and research at Cornell, Vanderbilt, and the Medical College of Georgia (MCG). He was a full professor with tenure at MCG and is currently a Visiting Full Professor at the University of Cape Town, South Africa. Dr. Mensah has been admitted to fellowships in several national and international societies including the American Heart Association, American College of Cardiology, and the European Society of Cardiology. He is an Honorary Fellow of the College of Physicians of South Africa and a Life Member of the Association of Black Cardiologists. He maintains active collaboration with several international groups to advance research on the global burden of diseases and risk factors.

• Joseph Millum, Ph.D.



Joseph Millum is a bioethicist with the Clinical Center Department of Bioethics and the Fogarty International Center at the US National Institutes of Health. He studied philosophy at Edinburgh University and the University of Toronto, where he received his doctorate, and economics at Johns Hopkins University. His research focuses on the rights and responsibilities of parents, the ethics of international research, informed consent, and priority setting for health care and research. He is author of the monograph *The Moral Foundations of Parenthood* (2018), and co-editor of *Global Justice and Bioethics* (2012) and *Global Health Priority-Setting: Beyond Cost-Effectiveness* (2019).

Mollie Minear, Ph.D.



Dr, Minear is a Program Officer in the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute (NHLBI) of the NIH. She has a Ph.D. in genetics and genomics, and postdoctoral training in the ethical, legal, and social implications (ELSI) of genetics. Mollie came to the NIH as an American Association for the Advancement of Science (AAAS) Science & Technology Policy Fellow, where she worked in the NHLBI's Epidemiology Branch to address questions about the return of genetic results to participants in longitudinal cohort studies. She works with the NHLBI's Trans-Omics for Precision Medicine (TOPMed) program, where she is the staff lead for ELSI topics like informed consent and genomic data sharing. Mollie is interested in facilitating the ethical translation of genomics into clinical practice and developing a better understanding of the personal use and clinical utility of genomic information.



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Lora Reineck, M.D., MS



Dr. Lora Reineck joined NHLBI in 2014 and is the Acute Lung Injury/Critical Care Program Director in the Division of Lung Diseases. She is a pulmonary and critical care physician with expertise in health services and clinical research. Dr. Reineck completed medical school at Johns Hopkins University, internal medicine residency at the University of Michigan, and pulmonary and critical care fellowship at the University of Pittsburgh.

• Rebecca Roper, M.S., M.P.H.



Rebecca Roper, M.S., M.P.H., serves as a Project Officer in the Implementation Science Branch in the NHLBI's Center for Implementation Science (CTRIS). Prior to joining CTRIS in 2017, Ms. Roper Directed the Primary Care Practice-Based Research Network (PBRN) Initiative at the Agency for Healthcare Policy and Research (AHRQ). The registered PBRN community burgeoned in numbers and types of PBRNs, both domestically and internationally, during her tenure. Areas of technical expertise include the use of health information technology (Health IT) for quality measurement and quality improvement; implementation research for the enhanced prevention and treatment of chronic conditions; development and assessment of practice-setting-informed implementation research; community engagement for health improvement; epidemiology; development of professional society-approved training materials (e.g., maintenance of certification and clinical medical education) for clinician-researchers; and, the production of award-winning videos showcasing impact of late-stage

implementation research. Ms. Roper received a B.S. in Health Services Administration from Providence College, a dual M.S. in Biostatistics and Epidemiology from Georgetown University, and an M.P.H. in Health Policy and Administration from the University of North Carolina at Chapel Hill---during their respective March-Madness glory days.

• Donna Spiegelman, ScD



Dr. Spiegelman is an expert in statistical methods in epidemiology, clinical, and public health research. Dr. Spiegelman has nearly 30 years of experience in the design and conduct of randomized trials and large longitudinal cohort studies, in both domestic and international settings. She has nearly 750 peer-reviewed publications and has received numerous NIH sponsored awards which have supported her research. She was recently the recipient of the NIH Director's Pioneer Award (DP1), a prestigious five-year, \$2.5 million direct cost award given to a very small number of individual scientists "of exceptional creativity, who propose pioneering, and possibly transforming, approaches to major challenges in biomedical and behavioral research". The DP1 supported work by herself and colleagues to advance the emerging field of implementation science to promote today's global and domestic health agenda, through methodologic innovation that paves the way for widespread evaluation and adoption of evidence-based programs and interventions, resulting in scores of original

scientific publications. She is the inaugural Director of the Yale Center for Methods in Implementation and Prevention Science (CMIPS); Professor of Biostatistics, Statistics and Data Science; Director, Interdisciplinary Methods Core, Center for Interdisciplinary Research on AIDS'; and Assistant Director of the Global Oncology Department at the Yale Cancer Center. Her regular columns in the *American Journal of Public Health*, on evaluating public health interventions, are widely read. She recently launched a Pathways in Implementation Science Methods within Yale's Department of Biostatistics, for



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MS and PhD students, and is expecting to receive a 5-year T32 training grant from NHLBI to support, in part, students enrolling in this program, in the coming year.

• Catherine M. Stoney, Ph.D.



Catherine M Stoney is a health psychologist and psychophysiologist with specialization in behavioral cardiology. She is Deputy Director, Center for Translation Research and Implementation Science (CTRIS) at the National Institutes of Health's National Heart, Lung, and Blood Institute where she works across the institute to promote the translation of effective interventions into real-world care.

Dr. Stoney has wide-ranging expertise in the area of stress and cardiovascular disease with a special interest in studying the behavioral, physiological, environmental, and psychological pathways by which stress and diseases of the heart and cardiovascular system are linked and modified, as well as understanding disparities in such responses. She is a faculty member for the NIH course on the Principles and Practice of Clinical Research at the NIH Clinical Center and served as Director of the annual OBSSR/NHLBI Summer Institute on Randomized Behavioral Clinical Trials for many years, and where she remains a faculty member.

Immediately prior to joining NIH, Dr. Stoney was Professor of Psychology at the Ohio State University, where she conducted laboratory and clinical investigations of phenotypes associated with patterns of coping with psychosocial stress and health, examinations of how psychological and social factors impact metabolic and inflammatory processes, clinical interventions to reduce physiological stress responses, and the biologic and cognitive mechanisms by which negative affect and depression may affect the progression of cardiovascular risk. She publishes widely in these areas as well as in implementation approaches to address health disparities. She is a fellow of the Academy of Behavioral Medicine Research, the American Psychological Association, and the Society of Behavioral Medicine.