Inclusion of Pregnant and Lactating Persons in Clinical Trials - A Workshop

Committee

Ruth R. Faden

Co-Chair

Ruth Faden is the founder of the Johns Hopkins Berman Institute of Bioethics, and its director from 1995 until 2016. She is also the Philip Franklin Wagley Professor of Biomedical Ethics. Her research focuses on structural injustice theory and public policy including national and global challenges in public health, food, agriculture and climate, women’s health, health systems design and priority setting, and advances in science and technology. Currently Dr. Faden is working at the intersection of structural justice and the COVID-19 response, primarily in vaccine allocation and prioritization, pregnancy, and K-12 education. Her latest book, with Madison Powers, is Structural Injustice: Power, Advantage, and Human Rights (September, 2019; Oxford University Press).

Shirley Sylvester

Co-Chair

Dr. Shirley V. Sylvester is a Senior Medical Director for Women's Health with the Office of the Chief Medical Officer (OCMO) at Johnson & Johnson. She works with a team to drive change toward reducing maternal mortality in the United States and globally. As a leader of the Women's Health team, she is responsible for providing strategic and scientific expertise in the development and implementation of programs that support the overall aims of Women's Health at Johnson & Johnson and partnering with external stakeholders to develop a policy agenda which supports women's health. Dr. Sylvester also works across the J&J Enterprise and externally to identify and act on opportunities that leverage J&J's collective assets to positively impact women's health through ethically-based, science- and data-driven approaches; and acts as a subject matter expert in health matters related to women, providing guidance to stakeholders on topics related to women's health.

Dr. Sylvester joined Johnson & Johnson in 2013 where she most recently led the creation of the global medical affairs strategy behind the development of Hepatitis B compounds for the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen). She established external collaborations with key stakeholders, including scientific societies, patient advocacy groups and academic institutions to advance the scientific agenda and to deepen Janssen's commitment to "Make Hepatitis History." She also co-led the clinical development of investigational compounds in partnership with Janssen Research & Development.

In previous roles at Johnson & Johnson, Dr. Sylvester served as Medical Director for compounds in Hepatitis C and Multi-Drug resistant TB in the United States. In these roles, Dr. Sylvester provided brand oversight on all medically related aspects of the compounds, including the design and execution of phase IIIb and IV studies in support of the medical affairs strategy.

Prior to joining Johnson & Johnson, Dr. Sylvester had a long history of working in the public sector, having partnered with NGOs, USAID, Bill and Melinda Gates Foundation, WHO, PAHO, ministries of health and other global constituents. Through these collaborations, she helped to design and implement several public health programs around the world focused on Post-Partum Hemorrhage (PPH) Prevention and other maternal health issues, Immunizations, HIV/TB control, Chagas disease and management of complications from obstetric fistula among others.

Dr. Sylvester holds a MD degree from Universidad de Cartagena with focus on Family Medicine and a Master of Public Health with a specialty in Global Health and Infectious Diseases from the Harvard T.H. Chan School of Public Health.

Kavita Shah Arora

Member

Dr. Kavita Arora is the Division Director for general obstetrics and gynecology and an Associate Professor at the University of North Carolina-Chapel Hill. She is the current Greenwall Fellow in Bioethics at the NAM. She serves as the Chair of the national ethics committee of the American College of Obstetricians and Gynecologists and serves on the Governing Council for the Young Physicians Section of the American Medical Association. She has served on the national ethics committee of the American Medical Association and on the Board of Directors of the American Society for Bioethics and the Humanities. Her clinical, research, and education interests center around reproductive justice and ensuring evidence-based and equitable reproductive health policy, with a focus on sterilization disparities. She completed her BS from the Pennsylvania State University, medical school at Jefferson Medical College, a masters in bioethics at the University of Pennsylvania, a masters of science in clinical research at Case Western Reserve University, and her obstetrics & gynecology residency at Northwestern Memorial Hospital.

Ebony B. Carter

Member

Dr. Ebony Carter is a tenured Associate Professor and Chief of the Division of Clinical Research in the Department of Obstetrics and Gynecology at Washington University School of Medicine. She practices Maternal Fetal Medicine and serves as Associate Editor for Equity at Obstetrics & Gynecology (the Green Journal). Her research focuses on group prenatal care, as a tool to promote health equity, and is funded by the Robert Wood Johnson Foundation, National Institutes of Health, and the American Diabetes Association.

Dr. Carter earned her undergraduate degree in human biology with honors from Stanford University, Master of Public Health in health policy from the University of Michigan, and medical degree from Duke University. She completed residency in Obstetrics and Gynecology at the Harvard integrated program at Brigham and Women’s/Massachusetts General Hospitals and fellowship training in Maternal Fetal Medicine at Washington University School of Medicine.

Nahida Chakhtoura

Member

Nahida Chakhtoura is an Obstetrician/Gynecologist who joined the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) in October of 2014 as a medical officer in the Maternal and Pediatric Infectious Disease Branch. As a medical officer, she overseas various mother to child transmission (PMTCT) research including congenital CMV, Zika, as well as HIV/AIDS related clinical trials involving women, adolescents, and infants within the International Maternal Pediatric Adolescent AIDS Clinical Trial (IMPAACT) network and overseas grants and clinical trials related to prevention of HIV transmission and Multipurpose Prevention Technologies (MPTs). Her grant portfolio includes PMTCT of HIV, TB, CMV, Hepatitis, as well HIV and contraception.

William Cooper

Member

William O. Cooper, MD, MPH is a practicing physician, researcher, teacher, and administrator. He has led School of Medicine programs, including the Center for Patient and Professional Advocacy, the Master of Public Health Program and the Pediatrics Office for Faculty Development. He is an internationally recognized expert in medication safety in children and has published over 140 scholarly articles to date. In his role as Associate Dean for Faculty Affairs for Vanderbilt University School of Medicine and Vice President for Patient and Professional Advocacy, Vanderbilt University Medical Center, Dr. Cooper oversees the Medical Center’s professional programs and provides leadership and direction for the Center for Patient and Professional Advocacy.

Brownsyne T. Edmonds

Member

Dr. Brownsyne Tucker Edmonds is an associate professor of obstetrics and gynecology and clinical pediatrics at Indiana University’s School of Medicine with fellowship training in both health services and health policy research, as well as clinical ethics. She serves as the inaugural VP and Chief Health Equity Officer for IU Health (IUH) and Associate Dean for Health Equity Research for IU School of Medicine (IUSM), holding an endowed chair for health equity research. Dr. Tucker Edmonds holds faculty appointments in the Department of Obstetrics and Gynecology and the Center for Pediatric and Adolescent Comparative Effectiveness Research (PACER), and serves as an affiliate scientist in the Regenstrief Institute and faculty of the Research in Palliative and End-of-Life Communication and Training (RESPECT) Center. She completed her fellowship in Clinical Ethics through the Fairbanks Center for Medical Ethnic at IU Health and was a Greenwall Faculty Scholar from 2016-2019. Her research program has been supported by mentored career development awards including a KL2, awarded through the Indiana CTSI; then the Robert Wood Johnson Foundations’ Harold Amos Medical Faculty Development Program. Her work on periviable parental decision-making has subsequently been funded by the Greenwall Foundation, NICHD, and AHRQ.

Dr. Tucker Edomnds' areas of research expertise are in shared decision-making, reproductive justice, and health equity. Methodologically, her expertise is in mixed qualitative and quantitative methods. Tucker Edomnds' current research examines the manner in which social and cultural factors influence patient-provider communication and decision-making when faced with ethically complex and uncertain outcomes in the setting of extreme prematurity. The overarching goal of the program of research is to facilitate patient-centered care and shared decision-making between providers, patients, and families making end-of-life decisions at the very beginning of life for periviable (extremely premature) infants. She is particularly interested in tailoring decision support to the needs of minoritized and marginalized populations. Early on, she utilized a variety of qualitative and quantitative methodologies to elucidate factors affecting the quality and consistency of obstetricians’ and neonatologists communication and decision-making. These studies have identified substantial deficits in risk communication, value clarification, goals of care discussions and preference elicitation in periviable counseling sessions. Tucker Edmonds then turned her attention to qualitatively examining patient perspectives and measuring mental health measures in relationship to their decision-quality. In doing so, she found that better decision quality was associated with better postpartum mental health outcomes. She also identified critical gaps in current models of care which preclude full engagement of partners and support persons; and inadequately attend to the potential for parental conflict. Subsequent qualitative studies of women facing the treat of periviable delivery helped develop values clarification exercises to support resuscitation decision-making; identify racial differences to help tailor tool content; and found that improving decision quality could improve postpartum parental mental health outcomes. Ultimately, these findings informed the development of Periviable GOALS (Getting Optimal Alignment around Life Support decisions), a mobile health application decision support intervention for resuscitation decision-making co-designed with families using human-centered design techniques and stakeholder engagement. The tool is currently being tested in a multisite RCT for effect on decision quality and parental mental health outcome.

Darcie Everett

Member

Darcie Everett, MD, MPH is a Medical Officer for the FDA's Division of Vaccines and Related Product Applications (DVRPA) in the Office of Vaccine Research and Review, Center for Biologics Evaluation and Research. As a clinical reviewer for DVRPA since 2014, she evaluates a variety of investigational vaccines and other biologics in all phases of clinical development. Her professional interests include maternal immunization. Dr. Everett is board-certified in Internal Medicine, Pediatrics and Preventive Medicine. She received her medical degree and a Master of Public Health in International Health and Development from Tulane University in New Orleans. She completed residencies at The Mount Sinai School of Medicine in New York (combined Internal Medicine and Pediatrics), where she also worked as a hospitalist, and at Emory University in Atlanta (Preventive Medicine), where she focused on maternal and infant health.

Leslie Meltzer Henry

Member

Leslie Meltzer Henry, J.D., Ph.D., M.Sc., is a lawyer and bioethicist with expertise in assessing, navigating, and advising on a range of ethical and legal issues that arise at the intersection of medicine, public health, and public policy. She is a Professor of Law at the University of Maryland Carey School of Law, and a faculty member at the Johns Hopkins Berman Institute of Bioethics. Her scholarly work primarily focuses on aspects of biomedical research regulation and practice that have implications for, and are implicated by, social justice and public health. Her recent scholarship has addressed barriers as well as potential facilitators to including pregnant people in research, compensation schemes for research-related injuries, challenges associated with including adolescents in research, and the complexities of conducting research during pandemics. She has been an investigator on both NIH and internationally funded grants aimed at developing ethically and legally acceptable strategies for conducting research during pregnancy. Professor Henry's research has been published in the nation's leading law reviews and medical journals. She has served in an advisory capacity to a variety of federal and local agencies and commissions—including the U.S. Department of Defense, Trans-NIH Bioethics Advisory Committee, NIAID, NICHD, NIMH, NIH Office of Research on Women's Health, and FDA—to identify limits, as well as areas of flexibility, in regulations related to the inclusion of special populations in research. Professor Henry received her J.D. from Yale Law School, Ph.D. from the University of Virginia, and M.Sc. from the University of Oxford, where she was a Wellcome Trust Fellow in the History of Medicine. She completed post-doctoral work at Johns Hopkins University as a Greenwall Fellow in Bioethics and Health Policy.

Steven E. Kern

Member

Steven E. Kern, Ph.D., is Deputy Director of Quantitative Sciences at the Bill and Melinda Gates Foundation. The Quantitative Sciences group is focused on quantitative analysis to support program strategies for therapeutic projects that the foundation funds across multiple disease domains.

Prior to this, he was Global Head of Pharmacology Modeling at Novartis Pharma AG based in Basel Switzerland where he lead a team focused on providing model based drug development support to therapeutics in many disease conditions across all stages of drug development. He joined Novartis in 2010 from the University of Utah in Salt Lake City, Utah where he was Associate Professor of Pharmaceutics, Anesthesiology, and Bioengineering, and served as co-investigator for their NIH funded Pediatric Pharmacology Research Unit. He has designed, conducted, and served as a principal investigator for clinical pharmacology studies in adults and children that spanned the population from preterm infants to elderly adults.

He has a bachelor’s degree in Mechanical Engineering from Cornell University, a Master’s degree in Bioengineering from Penn State University, and a doctoral degree in Bioengineering from the University of Utah. Dr. Kern has published over 70 papers in areas of pharmacokinetic and pharmacodynamic modeling, applying principles of control systems engineering to drug delivery, and clinical pharmacology.

Leyla Sahin

Member

Leyla Sahin, M.D., is an obstetrician-gynecologist who joined the FDA’s Division of Pediatrics and Maternal Health (DPMH) in the Office of New Drugs, Center for Drug Evaluation and Research in 2008 following clinical practice for twelve years. She is currently serving as Acting Deputy Director for Safety, Maternal Health, for DPMH, and over the years has led various maternal health related scientific and regulatory/policy initiatives. She was a working group member on the HHS Task Force for Research Specific to Pregnant Women and Lactating Women (PRGLAC). The focus of her work involves advancing FDA’s scientific and regulatory policies related to pregnancy and lactation, through all phases of drug development. Her principal area of interest is promoting the public health of pregnant and breastfeeding individuals through improved data collection.

Diane Spatz

Member

Diane L. Spatz, Ph.D., R.N.-BC, FAAN, is a Professor of Perinatal Nursing & the Helen M. Shearer Professor of Nutrition at the University of Pennsylvania School of Nursing sharing a joint appointment as a nurse scientist in lactation the Children's Hospital of Philadelphia (CHOP) in the Center for Pediatric Nursing Research and Evidence Based Practice. Dr. Spatz is the Founder of the CHOP Lactation Program & Mothers' Milk Bank.

Dr. Spatz is an active researcher, clinician, and educator who is internationally recognized for her work surrounding the use of human milk and breastfeeding particularly in vulnerable populations. Dr. Spatz has been PI or co-investigator on over 60 research grants, included several from the NIH. She has authored and co-authored over 210 peer-reviewed publications and written numerous book chapters related to human milk and breastfeeding. Dr. Spatz has authored or co-authored position statements for the International Lactation Consultant Association, the Association of Women's Health Obstetric & Neonatal Nursing (AWHONN), the Society of Pediatric Nurses (SPN) and the National Association of Neonatal Nurses. She has also written the clinical practice guidelines on human milk and breastfeeding for AHWONN and SPN as well as a technical brief for the USAID on human milk and breastfeeding in developing countries.

In 2004, Dr. Spatz develop her 10-step model for human milk and breastfeeding in vulnerable infants. This model has been implemented in NICUs throughout the United States and other countries worldwide (Thailand, India, China, Mexico, Japan, Chile). Dr. Spatz has been named a prestigious "Edge Runner" for the American Academy of Nursing related to the outcomes of her model. Her nurse driven models of care are critical in improving human milk & breastfeeding outcomes and thus the health of women and children globally. Dr. Spatz is the only PhD prepared nurse appointed to the Congressional Task Force on Research Specific to Pregnant Women and Lactating Women. Dr. Spatz has also been appointed to a World Health Organization Task Force on human milk and milk banking globally. Dr. Spatz was elected to the Executive Committee of International Society of Research in Human Milk and Lactation in April 2020.

Dr. Spatz is also the recipient of numerous awards including: the Lifetime Achievement Award from the National Association of Neonatal Nurses, the Research Utilization Award from Sigma Theta Tau International and from the University of Pennsylvania: the Dean's Award for Exemplary Professional Practice, the Expert Alumni Award and the Family and Community Department's Academic Practice Award She is also the recipient of the Lindback Award for Distinguished Teaching. Dr. Spatz received the Distinguished Lang Award for her impact on scholarship, policy & practice. In 2019, Dr. Spatz received AWHONN's Distinguished Researcher Award and was named Nurse of the Year by the Philadelphia Inquirer.

In the university portion of her job, she teaches an entire semester course on breastfeeding and human lactation to undergraduate nursing students and in the hospital portion of her job, she developed the Breastfeeding Resource Nurse program. Dr. Spatz is Past Chair of the American Academy of Nursing's Expert Panel on Breastfeeding and their representative to the United States Breastfeeding Committee.

Raman Venkataramanan

Member

Raman Venkataramanan, Ph.D., is currently a Professor of Pharmaceutical Sciences and Pathology in the University of Pittsburgh. He is the director of Clinical Pharmacokinetics Laboratory and the Therapeutic Drug Monitoring program at the University of Pittsburgh. Venkataramanan received his B.Pharm degree from the University of Madras, India; Master of Pharmacy degree from the Birla Institute of Technology and Science, India; and doctorate in Pharmaceutical Sciences from the University of British Columbia, Canada. After a postdoctoral fellowship at the University of Washington, he joined the University of Pittsburgh in July 1980. He has been appointed as a Food and Drug Administration special government employee by Center for Drug Evaluation and Research. Venkataramanan serves as a scientific reviewer for several journals. He is an editorial board member for Therapeutic Drug Monitoring, and four online journals. He is the editor for the American Journal of Analytical Chemistry. He is the recipient of the Distinguished Service Award from AAPS (2021), HiREC Endowed visiting chair at the University of Puerto Rico (Oct 2021), Distinguished Scientists award from American Association of Indian Pharmaceutical Scientists (AAiPS) in 2016, Graduate faculty of the year award from the School of Pharmacy in 2015, 2021, Tyler Prize for Stimulation of Research from the American Pharmacists Association (APhA), in 2011, the Bristol-Meyers Squibb Mentorship in Clinical Pharmacology from the American College of Clinical Pharmacy [ACCP], in 2009; the Provost’s Award for Excellence in Graduate Education from the University of Pittsburgh, in 2009; the Innovations in Teaching award the Rho Chi Society at the University of Pittsburgh, in 2009; the Scholarly Contributions award from the Rho Chi Society at the University of Pittsburgh, in 2007, Ranbaxy Research Award in Pharmaceutical Sciences in 1998, and the Distinguished Research scientists award from KDRI in Ahmadabad, India in 1996. The research in his laboratory revolves around “LIFE”. One half addresses the first chance in life – Optimizing the use of medications in pregnant women based on pharmacokinetics and pharmacodynamics data; the second half addresses optimization of the use of medications in organ transplant patients—a second chance in life. His current research is funded by NICHD (OPRC-Co-PI), NCI and United Therapeutics. He has presented more than 200 lectures / seminars at national/international meetings and published over 450 scientific articles. He has been an active member in various professional organizations such as American Association of Pharmaceutical Scientists, American Association of Indian Pharmaceutical Scientists, American College of Clinical Pharmacology, American Association of Colleges of Pharmacy, and American Society of Transplantation.

Michelle Vichnin

Member

Michelle Vichnin, M.D., is the Executive Director and Global Lead, Patient Advocacy and Strategic Alliances at Merck, where she and her team are strengthening the company’s patient engagement and advocacy presence around the world. She works on several initiatives to address healthcare disparities, increase health literacy, and explore innovative ways to meet the needs of patients during and beyond the COVID-19 pandemic.

Michelle joined as a US Medical Director for adolescent vaccines in 2007, and became a Global Medical Director in 2009. With her experience in cervical cancer prevention, she served as the medical lead for Merck’s public health initiatives to bring vaccines to low income countries. She then served as the Executive Director for Oncology in the Office of the Chief Medical Officer and worked to bring patient perspectives into the company. She is an expert advisor for Merck for Mothers, the company’s global initiative to help create a world where no woman has to die while giving life. She also is a member of the Diversity and Inclusion in Clinical Trials team, and recently published a paper in JCO Oncology Practice on strategies for increased inclusion of racial and ethnic minorities in clinical trials.

A board-certified obstetrician/gynecologist, she is a graduate of the Pennsylvania State University/Jefferson Medical College accelerated six-year medical program and performed her residency in Obstetrics and Gynecology at the New York-Presbyterian Weill Cornell Medical Center.

Prior to joining Merck, Michelle was an Assistant Clinical Professor in the department of Obstetrics and Gynecology at the University of Pennsylvania School of Medicine. She practiced at Penn Health for Women, a nationally recognized program for excellence in women's health, and was the Director of the Colposcopy Clinic at the Hospital of the University of Pennsylvania, where she received awards for her research. For several years she served on ACOG’s Committee on Adolescent Health.

She supports numerous nonprofit organizations, has volunteered as an attending physician at a clinic in the Andes Mountains in Peru, and most recently volunteered at a COVID-19 vaccine clinic.

Carmen D. Zorrilla

Member

Dr. Carmen D. Zorrilla is a Professor of Obstetrics and Gynecology at the UPR School of Medicine, certified by the American Board of Obstetrics and Gynecology and the American Academy of HIV Medicine. Dr. Zorrilla has experience in Obstetrics and Gynecology and HIV related research that includes behavioral interventions and clinical trials with HIV infected and at-risk populations, as well as with pregnant and non-pregnant women. She was part of the group of examiners for the American Oral Board of Ob-Gyn (ABOG) for 22 years and Past Residency Program Director for the UPR Ob-Gyn program. She established an infrastructure for the care of pregnant and nonpregnant women living with HIV. The transmission rate of HIV infection among the more than 500 infants born to pregnant women living with HIV during the past 20 years at her clinic has been zero. And Dr. Zorrilla worked with the PR health Department in the elimination of HIV transmission for which she published the experience and stating that PR was in fact the first country to eliminate transmission. For almost 2 decades, she has been the PI of the Integrated UPR Clinical Trials Unit (IUPR-CTU), including the Pediatric AIDS Clinical Trials Unit (IMPAACT), the Adult Clinical Trials Unit (ACTG) until last year when funding was modified to protocol-specific. She has been a consultant for diverse national and international organizations including the National Institutes of Health (NIH), the Maternal and Child Health Bureau (MCHB), the Centers for Disease Control (CDC), the Agency for Health Research Quality (AHRQ) and others, and a former member of the Office of Women's Health Advisory Committee and the CDC/HRSA AIDS and STD Advisory Committee (CHAC). Dr. Zorrilla is a member of the National Institute of Health Disparities and Minority Health Advisory Council (NACMHD).

Dr. Zorrilla established the first group prenatal care program in PR (Centering Pregnancy) with funds from the Innovation Center of the Centers for Medicare & Medicaid Services (CMS). This is the first Spanish Centering Program outside of the Mainland US. One of the outcomes of the program has been the reduction in preterm births and low birth weight among infants born of women enrolled in group prenatal care at the University Hospital. Expanding the program to impact and improve the health of mothers and infants is also one of her professional goals. She is part of the group of leaders who spearheaded the research response to the emerging Zika epidemic among pregnant women in PR. She also established a multidisciplinary clinic for pregnant women with Zika. Dr. Zorrilla is the site PI for the Zika in Infants and Pregnancy (ZIP Study) in San Juan. She is a member of the Scientific Coalition named by PR Governor Hon. Pedro Pierluisi to advise on issues related to the COVID pandemic response and to further incorporate the input of Science into public policy. During the COVID-19 pandemic she spearheaded the development of a Molecular testing program at the RCM, a COVID vaccine center and a Phase III vaccine trial at the UPR-MSC. Her team was responsible for the immunization of 97% of the faculty, students, and staff at the UPR Medical Sciences Campus early in 2021.