

Principles and Framework to Guide the Development of Protocols and Standard Operating Procedures for Face and Hand Transplants

Committee

Kenneth W. Kizer

Chair

Kenneth W. Kizer, MD, MPH, is an internationally respected physician executive with widely recognized expertise in health system transformation, patient safety and quality improvement, population health management, and veterans and military health issues. He engineered the internationally acclaimed transformation of the Veterans Healthcare System – the nation’s largest and only national healthcare system – in the late 1990s when serving as the VA’s Undersecretary for Health. This transformation implemented numerous systemic changes that produced dramatically improved quality of care, service satisfaction, and operational efficiency. Dr. Kizer was also the founding President and CEO of the National Quality Forum. Early in his career, while serving as Director of the former California Department of Health Services, he orchestrated the state’s response to the then new HIV/AIDS epidemic, established the internationally renowned California Tobacco Control Program, and pioneered Medicaid managed care, among other accomplishments as the state’s top health official. Prior to that, as Director of the California Emergency Medical Services Authority, he was the architect of California’s statewide Emergency Medical Services system. He also was the inaugural Chief Medical Officer for the California Department of Managed Health Care and served as Chairman of The California Wellness Foundation, the nation’s largest philanthropy devoted exclusively to population health improvement. Dr. Kizer is an elected member of both the National Academy of Medicine and the National Academy of Public Administration. He graduated with honors from Stanford University and earned his MD and MPH from the University of California Los Angeles. He is board-certified in six medical specialties and sub-specialties, is a fellow or distinguished fellow of 12 professional societies, has authored more than 500 original articles, book chapters and other reports in the professional literature, and is the recipient of numerous national awards and recognitions. He is currently an Adjunct Professor at the Stanford University School of Medicine and Senior Scholar in the Clinical Excellence Research Center; Distinguished Professor Emeritus, UC Davis School of Medicine; and a member of the Board of Regents of the Uniformed Services University.

Nancy L. Ascher

Member

Nancy L. Ascher MD, PhD, is currently Professor of Surgery at the University of California San Francisco where she is currently active as a transplant surgeon, specializing in liver, kidney transplant and live donor hepatectomy. She was the first woman in the world to perform a liver transplant. She served as Chair of the Department of Surgery at UCSF for 17 years. She has devoted her professional life to transplantation with interests in mechanisms of graft rejection, clinical liver transplant, live donor liver transplant, global transplant issues, and ethical issues in transplant. She has served as President of both the Transplantation Society (largest international association of transplant professionals) and the American Society of Transplant Surgeons. She was awarded the Starzl Prize, the ASTS mentor award, served on the board of the International Liver Transplant Society, and was awarded its Distinguished Service Award. She is a member of the National Academy of Medicine, testified to the committee considering organ distribution, and served on the committee considering xenotransplantation. She established the Liver Transplant Programs at the University of Minnesota and the University of California San Francisco. She headed the Transplant Services at the University of California San Francisco prior to assuming the role of Chair of the Department of Surgery. She received her undergraduate degree and MD at the University of Michigan and completed her residency and transplant fellowship at the University of Minnesota.

Arthur Caplan

Member

Arthur Caplan, PhD, is currently the Drs. William F and Virginia Connolly Mitty Professor and founding head of the Division of Medical Ethics at NYU School of Medicine in New York City. Prior to coming to NYU School of Medicine, Dr. Caplan was the Sidney D. Caplan Professor of Bioethics at the University of Pennsylvania Perelman School of Medicine in Philadelphia, where he created the Center for Bioethics and the Department of Medical Ethics. Dr. Caplan has also taught at the University of Minnesota, where he founded the Center for Biomedical Ethics, the University of Pittsburgh, and Columbia University. Dr. Caplan is the author or editor of thirty-five books and over 860 papers in peer-reviewed journals and has served on a number of national and international committees including as the chair of the National Cancer Institute Biobanking Ethics Working Group, chair of the Advisory Committee to the United Nations on Human Cloning, chair of the Advisory Committee to the Department of Health and Human Services on Blood Safety and Availability. He has also served on the Presidential Advisory Committee on Gulf War Illnesses, the Special Advisory Committee to the International Olympic Committee on Genetics and Gene Therapy, the Special Advisory Panel to the National Institutes of Mental Health on Human Experimentation on Vulnerable Subjects, the Wellcome Trust Advisory Panel on Research in Humanitarian Crises, and is the co-director of the Joint Council of Europe/United Nations Study on Trafficking in Organs and Body Parts. Dr. Caplan has served since 2015 as the chairperson of the Compassionate Use Advisory Committee, an independent group of internationally recognized medical experts, bioethicists, and patient representatives who advise Johnson & Johnson's Janssen Pharmaceuticals about requests for compassionate use of some of its investigational medicines. Dr. Caplan has also consulted with organizations such as MaxCyte (Patient Advisory Board); Boston Scientific Corporation; Merck; Atria Academy of Science and Medicine; and Ferring and iECURE (Data and Safety Monitoring Boards). He also participates in a working group on transplant ethics that receives support from the Applebaum Foundation through the NYU Grossman School of Medicine. Dr. Caplan is the recipient of many awards and honors including the McGovern Medal of the American Medical Writers Association and the Franklin Award from the City of Philadelphia. He was a USA Today 2001 "Person of the Year" and was described as one of the ten most influential people in science by Discover magazine in 2008. He has also been honored as one of the fifty most influential people in American health care by Modern Health Care magazine, one of the ten most influential people in America in biotechnology by the National Journal, one of the ten most influential people in the ethics of biotechnology by the editors of Nature Biotechnology, and one of the 100 most influential people in biotechnology by Scientific American magazine. He received his PhD from Columbia University.

Linda C. Cendales

Member

Linda Cendales, MD, is a Professor of Surgery and Director of the VCA Program at Duke University. Dr. Cendales helped organize the first VCA team in the U.S. and participated in the country's first two hand transplants. She organized the first international consensus on VCA histopathology at the International Banff Conferences on Allograft Pathology leading to the published classification system now used as a standard for clinical reporting of rejection worldwide. She established the VCA programs at Emory University and subsequently at Duke University leading the multi-disciplinary teams that performed Georgia's first hand transplant in 2011 and North Carolina's first hand transplant in 2016. Dr. Cendales is the Principal Investigator of clinical and translational studies in VCA including hand transplantation (NCT 02310867) and abdominal wall transplantation (NCT 03310905). Dr. Cendales is the only person in the United States to have completed formal fellowship training in both Hand and Microsurgery and Transplant Surgery. Dr. Cendales is the Past President of the International Society of Vascularized Composite Allotransplantation Society (ISVCA), and the Past Chair of the Organ Procurement and Transplantation Network VCA Committee. She is also the Past-Chair of the American Transplant Congress, and the Past-Chair of the American Society of Transplantation VCA Advisory Board. Dr. Cendales is an Associate Editor of the American Journal of Transplantation and of Clinical Transplantation. She is the Councilor at Large of the American Society of Transplant Surgeons (2022-2024), the Councilor at Large on the Board of the American Society of Transplant Surgeons (2022-2024), the past Secretary of the Organ Procurement and Transplant Network (2022-2024), and of the United Network for Organ Sharing (2022-2024), and an associate editor of the American Journal of Transplantation and of Clinical Transplantation. She is also the VCA organ transplant lead of the Banff International Consensus Working Group on Allograft Pathology and a Past-Chair of the American Society of Transplantation VCA Advisory Board. She received her MD at the Universidad Autonoma Metropolitana-Xochimilco.

David Crandell

Member

David Crandell, MD, is an Assistant Professor in the Department of Physical Medicine and Rehabilitation (PM&R) at the Harvard Medical School and a physiatrist at Spaulding Rehabilitation Hospital (SRH) Boston. He is the Medical Director of the Amputee Program and directs the Amputee Rehabilitation Fellowship. He is an Attending Physician in the Comprehensive Rehabilitation Program at Spaulding and a member of the Interdisciplinary Care for Amputees Clinic at the Massachusetts General Hospital. He has broad clinical background in working with patients with limb loss and a variety of musculoskeletal trauma and research interests in product design, innovative technology, and training. His research is focused on therapeutic approaches for limb loss and interdisciplinary approaches to amputee care. He has collaborated with other researchers to find optimized treatments for amputees with phantom limb pain and using novel 3-D printing for prosthetic fabrication. Dr. Crandell participates in an active IRB protocol for leg transplants, though there have been no enrollees so far. He received his undergraduate BS degree at Cornell University and completed an internship in Internal Medicine at the Millard Fillmore Hospital in Buffalo, NY. He completed his residency in PM&R at the Tufts University School of Medicine, followed by NIH NRSA Institutional Training Grant Fellowship at Tufts in Sports Medicine.

Susan S. Ellenberg

Member

Susan S. Ellenberg, MAT, PhD, is Professor Emerita of Biostatistics, Department of Biostatistics and Epidemiology with a secondary appointment in the Department of Medical Ethics and Health Policy, Medicine at the University of Pennsylvania School of Medicine. Prior to her current appointment at Penn, Dr. Ellenberg was previously at the National Institutes of Health and the U.S. Food and Drug Administration. Her research has focused on practical problems and ethical issues in designing, conducting, and analyzing data from clinical trials. At Penn, she has taught the primary course on clinical trials, led the statistical design and analysis of many major collaborative studies, chaired the organizing committee for the annual Penn conference on statistical issues in clinical trials, and mentored many students and junior faculty. She is a Fellow of the American Statistical Association, the Society for Clinical Trials, and the American Association for the Advancement of Science, and is an elected member of the International Statistical Institute. Her many awards include the F.N. David Award and Lectureship, given biannually by the Committee of Presidents of Statistical Societies to an outstanding woman in the statistical profession, and the American Statistical Association Karl E. Peace Award for Outstanding Statistical Contributions for the Betterment of Society. Dr. Ellenberg has past consultancies with organizations such as Takeda, Janssen, Mallinkrodt, and Merck. She is currently on data monitoring committees for Lilly and Novartis for studies related to prevention of adverse cardiovascular outcomes in people at elevated risk, and will participate in an upcoming data monitoring committee for Gritstone Pharmaceuticals for COVID-19 vaccine development. She received her PhD from the George Washington University.

Michele B. Goodwin

Member

Michele B. Goodwin, SJD, LL.M., JD, is the Linda D. & Timothy J. O'Neill Professor of Constitutional Law and Global Health Policy at Georgetown University. She is also Co-Faculty Director of the O'Neill Institute for National and Global Health Law. Her expertise spans law, bioethics, biotechnology, and sociology. Her books include *Black Markets: The Supply and Demand of Human Body Parts* as well as *Altruism's Limits* and *Policing The Womb: Invisible Women and the Criminalization of Motherhood* among others. She is the 2022 recipient of the American Bar Association's Margaret Brent Award as well as the 2022 Trailblazer Award from the Black Women Lawyers Association of Los Angeles. In 2020-21, she received the Distinguished Senior Faculty Award for Research, the highest honor bestowed by the University of California. Goodwin was named the 2022 Provost's Distinguished Visiting Faculty Fellow at the University of Pennsylvania. She is an elected member of the American Law Institute as well as an elected Fellow of the American Bar Foundation and the Hastings Center. She has participated in National Academies Committees focused on organ transplantation, access to technologies, and reproductive health. She received her SJD from the University of Wisconsin.

L. Scott Levin

Member

Lawrence Scott Levin, MC, FACS, is the Vice President and Associate Dean of Resource Development, Paul B. Magnuson Professor of Bone and Joint Surgery, Chairman of the Department of Orthopedic Surgery and Professor of Surgery (Plastic Surgery) at the University of Pennsylvania School of Medicine. Previously Dr. Levin served as the Chief of Plastic Surgery in the Department of Surgery and Professor of Orthopedic Surgery at Duke University Medical Center. Dr. Levin directs the Penn Hand and Upper Extremity VCA Program at the University of Pennsylvania and the Pediatric Hand Transplant Program at the Children's Hospital of Philadelphia. He has performed VCA research in the past at Duke University in addition to his current work at the University of Pennsylvania. He is the Past President of the American Society of Reconstructive Microsurgery and Past Chair of the VCA Committee of the United Network for Organ Sharing. Dr. Levin has had funding for basic science and clinical research from the Department of Defense, Wyss Foundation, Gift of Life, and the Mendez National Institute of Transplantation Foundation. Dr. Levin has received the Weiland Medal from the American Society of Surgery of the Hand and the Kappa Delta Elizabeth Winston Lanier Award from the American Academy of Orthopedic Surgery. He is a member of multiple societies including the American Society of Transplantation, the American Society of Transplant Surgeons, and the American Surgical Association. Dr. Levin is a Trustee of the American Association of Plastic Surgeons, on an advisory committee for the American Society of Transplant Surgeons, and was the past President of the American Society for Surgery of the Hand. He is President-elect of the American Foundation of Surgery of the Hand and has leadership roles at the American Academy of Plastic Surgeons. He was also a paid participant as a subject expert for VCA patient scenario reviews as part of a Temple University grant funded by the Department of Defense. Dr. Levin completed residencies in general and thoracic surgery, orthopedic surgery, and plastic surgery at Duke University and a hand fellowship in Louisville Kentucky.

Marie-Christine Nizzi

Member

Marie-Christine Nizzi, PhD, PhD, is a licensed clinical neuropsychologist. She is the CEO of Precision Psychologie PLLC and a Clinical Faculty in the Department of Psychiatry at the UCLA David Geffen School of Medicine; Jane & Terry Semel Institute for Neuroscience; and Stewart & Lynda Resnick Neuropsychiatric Hospital at UCLA. Her research focuses on developing new patient-reported outcome measures (PROMs) to inform treatments and better support the resilience, quality of life, and sense of self of patients with a history of trauma or surgery. She was named 2018 Harvard Horizons Scholar for her work with U.S. Veterans and recipients of a face transplant. As the immediate Past President and the current Chair of the Board of Trustees at Harvard Alumni for Mental Health, she received the Outstanding Community Impact award from Harvard in 2023. An international specialist, Dr. Nizzi completed two PhDs: one from Harvard University and one from Paris I Pantheon-Sorbonne.

Justin Sacks

Member

Justin M. Sacks, MD, MBA, FACS, is the Shoenberg Professor and Chief of the Division of Plastic and Reconstructive Surgery at Washington University in St. Louis School of Medicine. His previous tenure at Johns Hopkins School of Medicine included roles as Vice-Chair of Clinical Operations and Director of Oncological Reconstruction. He is an expert in vascularized composite allotransplantation (VCA), tissue engineering, and the assessment of vascular perfusion. Dr. Sacks was the Past chair of the Plastic Surgery Research Council and was a founding member of the American Society of Reconstructive Transplantation. Dr. Sacks specializes in the reconstructive surgery of a range of acquired, oncological, and traumatic defects. He was a member of the hand, face, and genital transplant team at Johns Hopkins and has performed basic science research in VCA throughout his career. While he does not currently have funding for VCA, a VCA program is forthcoming at Washington University in St. Louis. He has a grant from the Department of Defense for microsurgery. Dr. Sacks has lectured extensively both nationally and internationally and is an active member of multiple surgical societies, including the American College of Surgeons and the American Society of Plastic Surgeons. He co-founded and serves on the clinical advisory board of the Johns Hopkins Biotech Startup LifeSprout and has been instrumental in developing innovative medical devices. He was also on the advisory board for 3M from 2021-2023. He serves as the finance chair for the American Society of Plastic Surgeons and is the co-chair for the annual meeting of the American Academy of Plastic Surgeons. Dr. Sacks has published over 184 original articles and 29 textbook chapters. He completed his medical education at Mount Sinai School of Medicine, followed by a general and plastic surgery residency, a research fellowship at the University of Pittsburgh, and a microvascular reconstructive surgery fellowship at the University of Texas M.D. Anderson Cancer Center. He also has an MBA in medical service management from the Carey Business Center at Johns Hopkins University.

Laura A. Siminoff

Member

Laura A. Siminoff, PhD, MA, is the Laura H. Carnell Professor of Public Health at Temple University and was the founding dean of its College of Public Health from 2014 -2022. She was the founding chair of the Department of Social and Behavioral Health at Virginia Commonwealth University School of Medicine and professor of bioethics and medicine at Case Western Reserve University. Dr. Siminoff is an internationally renowned public health scientist, an expert in health communication with a focus on empirical bioethics using qualitative and multi-method research methods. Dr. Siminoff has spent 30 years conducting groundbreaking work in the field of organ and tissue donation for both transplantation and research, including face and hand transplantation. She has a current grant from a consortium of organ procurement organizations to study communication strategies with Black American families for solid organ donation. She is the author of over 200 scientific articles, book chapters, and a book on applying empirical methods in bioethics and has been awarded funding from the National Institutes of Health, the Health Resources and Services Administration, the Department of Defense, and private foundations. Dr. Siminoff has been recognized as one of the world's top research scientists (e.g., AD Scientific Index of Word's Top Research Scientists), has held three named professorships, and has been appointed as a visiting international scholar. Dr. Siminoff originally trained as an anthropologist and holds a doctorate in public health from the Johns Hopkins Bloomberg School of Public Health.

John E. Ware, Jr.

Member

John E. Ware, PhD, MA, is a research psychologist specializing in psychometrics. His career began with developing patient-reported outcome (PRO) measures in the 5-year randomized RAND Health Insurance Experiment and 4-year quasi-experimental Medical Outcomes Study (MOS), leading to the development of the MOS 36-item Health Survey (SF-36), and industry-sponsored International Quality of Life Assessment (IQOLA) Project translations of SF-36 used in multinational population surveys and clinical trials worldwide. He is an elected member of the National Academy of Medicine and one of the most frequently cited scientists in his field. His current emphasis is on more practical and more useful applications of disease-specific and generic PRO measures and results. He received his MA from Pepperdine University and his PhD from Southern Illinois University.