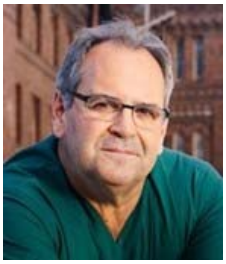
Biomarkers for Traumatic Brain Injury: A Workshop

Biographical Sketches of Speakers and Moderators

Corinne Peek-Asa, PhD MPH (NAM), is the Vice Chancellor for Research and Professor with Distinction of Epidemiology at UC San Diego. She is an elected member of the National Academy of Medicine and served as a member of the National Academies Committee on Accelerating Progress in Traumatic Brain Injury and Care and the Global Violence Forum. Prior to joining UC San Diego, she was the associate dean for research for the University of Iowa College of Public Health and the William G. Battershell Distinguished Professor. Dr. Peek-Asa is a leading epidemiologist in the area of traumatic injury and violence prevention. Dr. Peek-Asa's work has addressed the full spectrum of traumatic brain injuries from surveillance to prevention among a variety of populations. Dr. Peek-Asa has led international traumatic brain injury research, including a role as P.I. on NIH FIC and NINDS projects that have established prospective traumatic brain injury registries in four countries. She has conducted research on data systems to identify TBI; the impact of gender on TBI outcomes; predictors of outcomes based on injury type and severity; the impact of trauma systems on TBI patients reaching definitive care; and, she has evaluated numerous TBI prevention strategies such as motorcycle helmet legislation.

Stuart Hoffman, PhD, is the Scientific Program Manager for the Brain Injury portfolio at the Department of Veterans Affairs, which includes traumatic brain injury (TBI) and stroke. Dr. Hoffman received his doctoral degree in behavioral and molecular neuroscience at Rutgers University in 1995 and completed his postdoctoral training in pharmacology at Virginia Commonwealth University's medical campus in 1997. Prior to accepting this position with VA, he was an assistant professor in the Department of Emergency Medicine at Emory University. Dr. Hoffman was also faculty in both the graduate and undergraduate neuroscience programs at Emory University, where he co-developed and directed a multidisciplinary course on neurotrauma. He was previously the Research Director for the Defense and Veterans Brain Injury Center in Johnstown, Pennsylvania. Dr. Hoffman has more than 24 years of experience and has authored over 45 peer-reviewed publications in translational research on neuroprotection and recovery of function after brain injury. Dr. Hoffman has research experience in the following brain injury areas: in vitro TBI models, animal models of TBI, development of animal rehabilitation models, rodent brain ischemia models, translational drug development for neuroprotection, and clinical neurorehabilitation research.

Geoffrey Manley, MD, PhD, is the Chief of Neurosurgery at Zuckerberg San Francisco General Hospital (ZSFG) and is Professor and Vice Chairman of Neurosurgery at the University of California, San Francisco. Dr. Manley is an internationally recognized expert in neurotrauma. In addition to a robust clinical practice at ZSFG, San Francisco and the Greater Bay Area's level 1 trauma center, he coordinates and leads national and international clinical research efforts in the study of the short- and long-term effects of TBI. With a nationwide team of TBI experts, has recently launched the TRACK-TBI NETWORK, an innovative, precision-medicine driven consortium that will test Phase 2 drugs for TBI. The TRACK-TBI studies have created a modern precision medicine information commons for TBI that integrates clinical, imaging, proteomic, genomic, and outcome biomarkers to drive the development of a new TBI disease classification system, which could revolutionize diagnosis, direct patient-specific treatment, and improve outcomes.



Ramon Diaz-Arrastia, MD, PhD, is Professor of Neurology at the University of Pennsylvania, where he leads the TBI Clinical Research Initiative. His research interests are focused on understanding the molecular, cellular, and tissue level mechanisms of neuronal injury and neuroregeneration, with the goal of developing neuroprotective and neuroregenerative therapies. Dr. Diaz-Arrastia received his MD and PhD degrees from Baylor College of Medicine, and completed post-graduate training at Harvard and Columbia. Prior to coming to Penn, he served on the faculty at the University of Texas Southwestern, the Uniformed Services University of the Health Sciences, and the National Institute of Neurologic Disorders and Stroke (NINDS). Dr. Diaz-Arrastia has published over 250 primary research papers, as well as over 40 invited reviews and book chapters. He serves on the scientific advisory boards or as a scientific advisor to companies including BrainBox Solutions, NovaSignal, NeurAegis, MesoScale Discoveries, and Ischemix, Inc., and has also served on several national committees related to traumatic brain injury, epilepsy, and dementia, convened by the National Institutes of Health, the Department of Defense, the Veterans Administration, and the National Academy of Medicine.

Rachel Lazarus, PhD, serves as the neuroscientist for Staying Sharp, an AARP program offering content about brain health including articles, recipes, and activities. Dr. Lazarus received her PhD degree at the Uniformed Services University of the Health Sciences (USUHS), where her work investigated blood-based biomarkers and neuroimmunological changes following traumatic brain injury. Following her time at USUHS, she joined the FlyLight Lab at Howard Hughes Medical Institute's Janelia Research Campus, focusing on *Drosophila*-based brain-mapping work and novel methods in immunofluorescent tagging / confocal microscopy. Prior to joining AARP in 2019, Dr. Lazarus served as the Research Portfolio Manager for the Defense Health Agency's Defense and Veterans Brain Injury Center (DVBIC), now called the TBI Center of Excellence. Dr. Lazarus has also volunteered for several years as a Grand Award Judge in Cellular and Molecular Biology for the Regeneron International

Science and Engineering Fair, formerly known as the Intel International Science and Engineering Fair.

Jeffrey J. Bazarian, MD, MPH, is an Emergency Physician with an active concussion clinic and research program at the University of Rochester Medical Center. The goals of the Bazarian TBI lab are to develop neuroimaging and blood-based biomarkers of axonal injury after concussion and repetitive head hits, and to understand the pathophysiologic mechanisms of recovery. He has served on several traumatic brain injury-related task forces and panels for the Centers for Disease Control and Prevention, the National Institutes of Health, the National Science Foundation, and the Institute of Medicine. In 2008, he worked with the Defense and Veterans Brain Injury Center to develop mild traumatic brain injury (concussion) management guidelines for returning troops. He earned his MD and MPH from the University of Rochester School of Medicine/Dentistry.

Alan H.B. Wu, PhD, is Chief of the Clinical Chemistry and Toxicology Laboratories at San Francisco General Hospital. He is also a Professor of Laboratory Medicine and Chief of the Clinical Pharmacogenomics Laboratory at the University of California, San Francisco. Dr. Wu's research focuses on "personalized therapeutics," i.e., the use of biomarkers to determine the proper selection and dosing of drugs to maximize efficacy and minimize adverse reactions. His clinical and research interests also include pharmacogenomics and research on validating novel protein markers for cardiovascular diseases. Dr. Wu earned his PhD from the University of Illinois and performed his post-doctoral fellowship in clinical chemistry and toxicological chemistry at the Hartford Hospital.

Luca Marinelli, PhD, is Senior Principal Scientist at GE Research. Recently, he has led the clinical research study part of the GE/NFL Head Health Initiative, a partnership between GE and National Football League on traumatic brain injury. He is currently co-PI on the GE-MIT performing team for DARPA Measuring Biological Aptitude, a study focused on biological drivers of human performance. Dr. Marinelli also serves on the scientific advisory board of the ALS Finding a Cure foundation. He joined GE Research in 2005 and has had individual contributor, managerial, and business development roles of increasing responsibility. Dr. Marinelli completed a Ph.D in Physics at Harvard University in 2002 where he worked on problems in theoretical condensed matter physics. After leaving Harvard, he joined Bell Laboratories-Lucent Technologies as a postdoctoral member of the technical staff in the theoretical physics group, where he worked on problems in information theory and wireless telecommunications.

Elisabeth Wilde, PhD, is an Associate Professor in the Department of Neurology at the University of Utah. She also holds an appointment as a Health Research Scientist at the VA Salt Lake City Healthcare System. Dr. Wilde is currently the Director of the Neuroimaging Core for the Department of Defense and Veterans Affairs co-funded Long-term Impact of Military-relevant Brain Injury Consortium (LIMBIC)/Chronic Effects of Neurotrauma Consortium (CENC) Neuroimaging Core and has been actively involved in the International Common Data Elements (CDE) initiative and co-leads the Enhancing Neuroimaging Genetics Meta-analysis (ENIGMA) Working Group for TBI. Her research interests include the use of advanced forms of neuroimaging to enhance diagnosis and prognosis, monitor recovery and neurodegeneration, evaluate the efficacy of therapeutic intervention, and elucidate aspects of neuroplasticity in traumatic brain injury. She has participated in over 40 federally-funded clinical projects in TBI, and has authored over 140 peer-reviewed publications. She earned her PhD from Brigham Young University Clinical Psychology.

Jessica Gill, PhD, RN, is the Bloomberg Distinguished Professor of Trauma Recovery Biomarkers at Johns Hopkins School of Nursing. Gill has spent decades investigating differential responses in military personnel, athletes, and other patients that have experienced TBIs and the mechanisms underlying these divergent responses. Specifically, Dr. Gill looks for ways to use biomarkers to identify which patients are at high risk for poor recovery and long-term effects including post-traumatic stress disorder, depression, and post-concussive syndrome, and to develop treatments. After earning her PhD at Johns Hopkins University School of Nursing, she went to the National Institutes of Health (NIH) to complete a postdoctoral fellowship at the National Institute of Nursing Research that focused on the biological mechanisms of PTSD and depression. At NIH, she also served as a senior investigator and acting deputy scientific director of the National Institute of Nursing Research and deputy director of the Center for Neuroscience and Regenerative Medicine. Dr. Gill was the first nurse to receive the Lasker Clinical Research Scholar Award.

Paul Rapp, PhD, is a Professor of Military and Emergency Medicine at the Uniformed Services University and Director of the Traumatic Injury Research Program. He also holds a secondary appointment as a Professor of Medical and Clinical Psychology. Previously, Dr. Rapp was a Professor of Pharmacology and Physiology at Drexel University College of Medicine and Director of Research at the Clinical Research Center at Norristown State Psychiatric Hospital. While in Philadelphia, he was a Candidate at the Philadelphia School of Psychoanalysis and practiced under supervision as a psychotherapist/psychoanalyst at the Philadelphia Consultation Center. He was also a service provider for the City of Philadelphia under the Center's Community Based Health Contract. Dr. Rapp has held visiting faculty appointments in the Department of Mathematics at the University of Western Australia and has been a Visiting Professor at the University of California Irvine since 2018. He is a past editor of Physica, and has served on the editorial boards of the

International Journal of Bifurcation and Chaos, Chaos and Complexity Letters, and Cognitive Neurodynamics. Past honors include a Certificate of Commendation from the Central Intelligence Agency for “significant contributions to the mission of the Office of Research and Development.”

Christina Master, MD, FAAP, CAQSM, FACSM, is a Professor of Clinical Pediatrics at the

University of Pennsylvania Perelman School of Medicine and a pediatric and adolescent primary care sports medicine specialist, as well as an academic general pediatrician, at the Children’s Hospital of Philadelphia (CHOP). She completed her undergraduate studies at Princeton University with an A.B. in Molecular Biology and graduated summa cum laude from the University at Buffalo School of Medicine and Biomedical Sciences. She completed pediatric residency training with an additional year as chief resident at CHOP where she subsequently served for 14 years as the Associate and Vice Program Director for the Pediatric Residency Program prior to completing a sabbatical year of sports medicine fellowship training at the Hospital of the University of Pennsylvania in 2010. She is board-certified in pediatrics, sports medicine, and brain injury medicine, and is also an elected fellow of the American College of Sports Medicine. She treats over 800 children, youth and young adults with concussion annually in her clinical sports medicine practice while also continuing in her 28th year of general academic pediatric practice. She is the cofounding director of the Minds Matter Concussion Program, a CHOP Frontier Program which provides comprehensive cutting edge multi-disciplinary clinical care and rehabilitation for concussion, community advocacy and outreach, while advancing the field of concussion and mild traumatic brain injury in children, youth and young adults through translational clinical research. Her particular research emphasis focuses on furthering our understanding of visual deficits following concussion, their role in those with persistent post-concussive symptoms, and as a target for active intervention and treatment, as well as developing objective physiological measures as quantitative biomarkers of injury and recovery.

Patrick M. Kochanek, MD, is Distinguished Professor of Critical Care Medicine, the Ake N.

Grenvik Professor and Vice Chair of Critical Care Medicine; Director of the Safar Center for Resuscitation Research; and Professor of Pediatrics, Anesthesiology, Bioengineering and Clinical and Translational Science at the University of Pittsburgh School of Medicine. As the Safar Center Director for 25 years, he has a record of leading a translational and multi-departmental team studying traumatic and ischemic brain injury and neurointensive care, funded by the NIH, US Department of Defense, andthe Laerdal Foundation. He is PI of Operation Brain Trauma Therapy for the U.S. Department of Defense and has been PI for 19 years of a T-32 titled “Training in Pediatric Neurointensive Care and Resuscitation Research” funded by the NICHD. He has mentored numerous trainees, many of whom have gone on to receive independent funding and careers of national prominence. He has been Editor-in-Chief of Pediatric Critical Care Medicine for the past 20 years and is on the editorial board of numerous journals on acute brain injury. He received the Distinguished Investigator Award from the American College of

Critical Care Medicine in 2007, was named one of the inaugural Masters of Critical Care Medicine, and received the Lifetime Achievement Award from the Society of Critical Care Medicine in 2017.

David Okonkwo, MD, PhD, is professor of neurological surgery and director of the

Neurotrauma Clinical Trials Center at the University of Pittsburgh. He is also director of Neurotrauma and the Scoliosis and Spinal Deformity Program at UPMC Presbyterian. Dr. Okonkwo is past chair of the AANS/CNS Section on Neurotrauma and Critical Care. In addition, Dr. Okonkwo is team neurosurgeon for the Pittsburgh Steelers. He completed his medical and doctoral education through the MD/PhD program of the Medical College of Virginia of Virginia Commonwealth University. He joined the University of Pittsburgh Department of Neurological Surgery in 2006, following completion of neurosurgical residency at the University of Virginia and a fellowship at Auckland Public Hospital in Auckland, New Zealand. He has additional specialized training in scoliosis surgery. Dr. Okonkwo's clinical interests are traumatic injuries to the brain and spine as well as scoliosis and spinal deformity. His research endeavors involve developing biomarkers, advanced neuroimaging modalities and novel therapeutic interventions for brain and spinal cord injury. Dr. Okonkwo is a principal investigator of a national clinical research network (TRACK-TBI) to advance our understanding and treatment of traumatic brain injury and a principal investigator of ongoing clinical studies in neurotrauma in Pittsburgh. He is a member of the American Association of Neurological Surgeons, the Congress of Neurological Surgeons and the National and International Neurotrauma Societies.

Frederick Korley, MD, PhD, is an Associate Professor of Emergency Medicine and the Associate

Chair for Research at the University of Michigan Emergency Department. He is the Scientific Director of Massey TBI Grand Challenge at the Weill Institute, University of Michigan. He received his medical and emergency medicine education at Northwestern University School of Medicine, and doctoral training in clinical investigation at the Johns Hopkins University School of Public Health with election into Phi Beta Kappa. His research work is focused on the development of diagnostics and therapeutics for traumatic brain injury (TBI). Dr. Korley holds two patents for biofluid-based biomarkers for diagnosing traumatic brain injury and prognosticating TBI outcomes. He is a co-investigator of the largest observational study of TBI in the US (the Transforming Research and Clinical Knowledge in TBI, TRACK-TBI). In collaboration with colleagues in engineering, Dr. Korley is developing a DoD-funded credit card-sized microfluidic device for point-of-care measurement of TBI biofluid biomarkers. He is also a national principal investigator of two federally funded multi-center studies run by the Strategies to Innovate Emergency Clinical Care Trials (SIREN) network, that are investigating the use of biofluid-based biomarkers for 1) subject selection in clinical trials; 2) monitoring individual patient response to promising neuroprotective agents. In addition, he is a national principal investigator of an NINDS funded phase II adaptive design multi-center clinical trial that is investigating the optimal treatment parameters of hyperbaric oxygen for treating severe TBI.

Martin Schreiber, M.D., is a Professor of Surgery; Chief of the Division of Trauma, Critical Care, and Acute Care Surgery; and Director of the Donald D. Trunkey Center for Civilian and Combat Casualty Care at Oregon Health and Science University. He is adjunct professor of surgery at the Uniformed Services University of the Health Sciences. He is also a colonel in the U.S. Army Reserve. Dr. Schreiber's training includes significant military instruction and practice, including direct clinical experience as a military surgeon in Afghanistan. Dr. Schreiber has served as director of the Joint Theater Trauma System for Iraq and Afghanistan. He also serves as a subject matter expert on several Department of Defense committees, including the Committee on Surgical Combat Casualty Care (since 2016); the Tactical Combat Casualty Care Subject Matter Expert Panel (since 2018); and, as chairman, the Committee on Surgical Combat Casualty Care (since 2019). Dr. Schreiber is head of the Trauma Research Laboratory. He has been awarded the lifetime achievement award in trauma resuscitation science by the American Heart Association, and the Asmund S. Laerdal Memorial Award for extensive involvement in resuscitation research and publishing from the Society of Critical Care Medicine.

Beth McQuiston, MD, RD, is a neurologist, registered dietitian, and medical director for Abbott's neuroscience diagnostics business. She completed her medical training at University of Chicago, Rush University Medical Center and Harbor UCLA. She actively participates in the evaluation of several neuroscience related biomarkers and technologies to be used in the diagnosis, treatment and monitoring of disease. One of her current areas of focus includes research and development of blood based biomarkers for use in traumatic brain injury. A licensed physician, Dr. McQuiston has participated in the Alzheimer's Disease Neuroimaging Initiative and served on the executive board for the Center for Nutrition Learning and Memory. In 2014, Abbott and the Department of Defense announced a collaboration on blood based biomarker development. She has a number of traumatic brain injury related patents, publications and invited presentations. Dr. McQuiston leads a global neuroscience team at Abbott focused on blood tests to help evaluate and treat brain injury.

Allison Kumar, founded Arina Consulting in 2018 after working 10 years at FDA's Center for Devices and Radiological Health (CDRH). During her time at FDA, she spent five years as a Senior Program Manager in the Center Director's Office and five years as a Senior Pre-market Reviewer in the Office of Device Evaluation. In her Senior Program Manager role, Ms. Kumar developed collaborations and worked as a liaison between medical device developers working in government agencies, DoD, academia, and industry and the CDRH review divisions to reduce the regulatory hurdles that often accompany bringing novel, high-risk, high-benefit innovative technology to market. Kumar holds a bachelor's degree in Biomedical Engineering from Virginia Tech, a graduate certificate in Biohazardous Threat Agents and Emerging Infectious Diseases from Georgetown University, and is a graduate of the Harvard T.H. Chan School of Public Health's National Preparedness Leadership Institute.

Carol Taylor-Burds, PhD, is a Program Director in the NINDS Division of Translational Research

for the NINDS Biomarker Program and a Scientific Project Manager for the Blueprint Neurotherapeutics Program. She obtained her PhD in Biology from the University of Vermont and completed her postdoctoral fellowship at NIH in the NINDS intramural program. From there, she joined the extramural division of NINDS as a Health Program Specialist supporting the neurotrauma portfolios, before becoming a Program Officer in the Division of Translational Research. While at NINDS she has been involved in a variety of efforts for TBI including a preclinical biomarker consortium and programmatic oversight of the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System.

Narayan Iyer, PhD, is a Chief for Burn Medical Countermeasures at the Biomedical Advanced Research and Development Authority (NARDA) in the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services. Dr. Iyer has professional experience in both the biotechnology industry and the U.S. government, including providing strategic direction to the Burn Program toward development and deployment of medical countermeasures (MCMs) for burns and blast injuries. His program focuses on aligning development of new products toward market sustainability and adopting new products into routine clinical care to generate immediate impact. Products under development in the Burn Program specifically address the challenges in current routine burn- and blast-injury care and increase in overall long-term national preparedness for mitigating consequences from mass casualty incidents with large cases of burn and blast injuries. Dr. Iyer works closely with other ASPR offices, the Strategic National Stockpile, the CDC, and the FDA that are focused on MCMs to support integration and decisions related to burn and trauma products for use and deployment. He also works with the end-user community of surgeons to ensure that the products under development have a meaningful impact. Prior to joining the U.S. government, Dr. Iyer worked as a senior development scientist at Corning, Inc. and in technical operations in the biotech industry. Dr. Iyer received his doctoral degree in molecular microbiology, working as a United Nations Educational, Scientific and Cultural Organization fellow at Biological Research Center in Szeged, Hungary, from the Indian Institute of Science in Bangalore, India.

CDR Travis Polk, MD, FACS*, (invited)* is Director of the Combat Casualty Care Research

Program, Department of Defense and an Assistant Professor of Surgery at the Uniformed Services University. He is board certified in general surgery with an added qualification in surgical critical care. He is the Navy State Chair for the American College of Surgeons Committee on Trauma, Chair of the Navy Trauma Clinical Community and represents the Navy on the Defense Committee on Surgical Combat Casualty Care. His academic and research interests include mentoring, surgical simulation and alternative devices for the treatment of tension pneumothorax. CDR Polk's personal awards include the Meritorious Service Medal (four awards), the Navy Commendation Medal (two awards), and Surface Warfare Medical Department Officer

qualification device. CDR Travis Polk graduated from Norwich University with a Bachelor of Science in Nursing and was commissioned through the Naval Reserve Officer Training Corps Scholarship program in 1997. He attended the Uniformed Services University of the Health Sciences on active duty and graduated with a Doctor of Medicine in 2001.

Leslie Prichep, PhD, is the Chief Scientific Officer of BrainScope, a medical device

neurotechnology company, where she directs research and algorithm development efforts using machine learning to identify scientifically validated biomarkers of traumatic brain injury and concussion. Dr. Prichep came to BrainScope from a significant academic tenure as a neuroscientist at NYU School of Medicine where she was the Director of the Brain Research Laboratories (BRL) and Professor of Psychiatry. The BrainScope platform has at its core, technology she co-developed while at BRL and which they licensed from NYU. Throughout her career her focus on quantitative electrophysiology and translational research has been applied to a number of brain-related disease states including, traumatic brain injury, dementia, addiction, depression, pain, and schizophrenia. Dr. Prichep has successfully led the path for integrating objective measures of brain function into commercially available medical devices from concept through FDA clearance for several applications. She has published extensively in peer-reviewed journals (totaling >130); has led the BrainScope team to 8 FDA clearances and 8 Department of Defense research contracts in development of the products and has added substantially to the company's patent portfolio. In 2019 she was elected as a Fellow to the National Academy of Inventors, having been nominated by NYU School of Medicine.