

Meet the Presenters

“Sickle Cell Disease and Gene Therapies: A Two-Part Webinar Series”

Part 1—Trust, Clinical Trials, and Transformative Therapies: Ethical Pathways in Gene Therapy and Sickle Cell Disease

Thursday, September 18, 2025, 1-2:30 PM ET

Jonathan M. Green, MD, MBA (Moderator)

Director, Office of Human Subjects Research Protections

National Institutes of Health

Bethesda, MD



Jonathan M. Green, MD, MBA, is Director, Office of Human Subjects Research Protections and Institutional Official for Human Subjects at the National Institutes of Health (NIH). Prior to joining the NIH, Dr Green was professor of medicine, pathology, and immunology, as well as Associate Dean for Human Studies, and Executive Chair of the institutional review board at Washington University School of Medicine in St. Louis, MO. At Washington University, Dr Green conducted research on the molecular mechanisms of T cell activation, focusing on the CD28 costimulatory family of receptors. He received his medical degree from Wayne State University in Detroit followed by residency training in internal medicine at Boston City Hospital. He then completed a fellowship in pulmonary and critical care medicine at the

University of Michigan Medical Center, and additional post-doctoral training at the University of Chicago. He received an MBA from Washington University Olin School of Business in 2017. He is board certified in internal medicine, pulmonary diseases, and critical care medicine. Dr. Green continues to serve as an attending physician in the Medical Intensive Care Unit and Pulmonary Consult Service at the NIH Clinical Center and has conducted both basic science and clinical research on the regulation of the immune response.

Dr Green has had a long-standing interest in biomedical ethics. He had been a member of the Barnes Jewish Hospital Ethics Committee since 2000, leading the clinical ethics consultation service from 2001-2005 and serving as Chair of the Ethics Committee from 2005-2009. After joining the Washington University Institutional Review Board in 2008, he assumed the role of committee co-chair in 2009. In 2010, he was appointed Associate Dean of Human Studies and Executive Chair of the IRB at Washington University in St Louis. Dr Green served on the Secretary's Advisory Committee on Human Research Protections (SACHRP) from 2015-2018, also serving on the Subpart A subcommittee.

Areas of Expertise: Biomedical ethics, human research protections, institutional review boards, pulmonary-critical care medicine

Antuan Sartin

Sickle Cell Disease Advocate

Louisville, KY



My name is Antuan Sartin, and I am the father of Kali Sartin. I was born in Louisville, Kentucky, and attended Ballard High School in 2001. I subsequently enrolled at Western Kentucky University to pursue higher education. A few years later, I became an employee of the United States Postal Service (USPS) as a city carrier.

Throughout my life, I have been aware of sickle cell anemia, but it did not fully resonate with me until after discovering my daughter's diagnosis. During my childhood, my aunt and uncle were afflicted with sickle cell anemia, and I frequently observed them visiting the hospital. When my mother would mention, "That's your auntie or uncle returning from the hospital," I perceived it as a routine occurrence. However, it was not until November 2008 that I comprehended the severity of the condition. That same year, I tragically lost my aunt due to complications associated with sickle cell anemia, at the age of 36. My uncle subsequently succumbed to sickle cell complications in March 2019, at the age of 51.

In 2014, my family and I were introduced to the Sickle Cell Association of Kentuckiana. This organization provided us with valuable information and support regarding our daughter's condition. We actively participated in some of the events they organized.

Presently, as a full-time parent and caregiver for my 12-year-old daughter, I am committed to making numerous sacrifices to ensure her well-being. Together, we have forged a strong bond and are determined to navigate the challenges of sickle cell anemia.

Areas of Expertise: Advocacy, lived experience as a caregiver of a child with SCD, navigating SCD clinical care and treatment options

Wally R. Smith, MD

Florence Neal Cooper Smith Professor of Sickle Cell Disease

University Distinguished Professor

Vice-Chair for Research

Division of General Internal Medicine

Virginia Commonwealth University School of Medicine

Richmond, VA



Wally R. Smith, MD, is the Florence Neal Cooper Smith Professor of Sickle Cell Disease and Vice Chair for Research of the Division of General Medicine at Virginia Commonwealth University (VCU). Dr. Smith is Executive Editor of the *Journal of Sickle Cell Disease*, sponsored by the Foundation for Sickle Cell Disease Research and published by Oxford University Press. He is active in the American Society of Hematology. He has held over 50 grants, but is best known for his NIH-funded Pain in Sickle Cell Epidemiology Study (PiSCES), which led to the first NIH Request for Proposals on the Neurobiology of Pain in SCD, and supported national consensus

research definitions of acute and chronic pain in SCD. He was a member of the Interagency Pain Research Coordinating Committee for DHHS, which published the National Pain Strategy.

Dr. Smith sits on the Multi-disciplinary Working Group advising the NIH's \$500 million/year Helping to End Addiction Long-term (HEAL) Initiative. He was a principal investigator in the Cooperative Study of Sickle Cell Disease, the Multicenter Study of Hydroxyurea in Sickle Cell Disease, the Sickle Cell Disease Clinical Research Network, the Sickle Cell Disease Outcomes Research Network, the Health Resources and Services Administration Sickle Cell Disease Treatment Demonstration Program, and the NIH Basic and Translational Research Program in SCD. Dr. Smith has been associated with the development of two potential remittive agents for SCD at VCU and has been a major contributor to several trials of SCD remittive agents either just approved or nearing FDA approval. His latest multicenter NIH-funded trial was SHIP HU, which is now complete with several publications.

Areas of expertise: SCD clinical trials, pain research and management, epidemiology, emerging therapies, institutional research oversight

Lakshmanan Krishnamurti, MD

Professor of Pediatrics

Chief, Section of Pediatric Hematology/Oncology/Bone Marrow Transplantation

Yale School of Medicine

Yale New Haven Hospital

New Haven, CT



Dr. Krishnamurti is a pediatric hematologist oncologist with a primary focus interest in clinical and patient reported outcomes research, and clinical trials in SCD. He currently serves as Professor of Pediatrics and the Chief of Pediatric Hematology, Oncology, and Bone Marrow Transplantation at Yale University Hospital. Dr. Krishnamurti's research contributions in SCD span acute and chronic pain, newborn screening, community and international outreach, bone marrow transplantation and gene therapy. His research has been funded by the NIH, CDC, HRSA, PCORI, and several philanthropic foundations. Dr. Krishnamurti's experience in curative therapies for SCD also extends to patient

education, patient decision making, implementation of these therapies program and evaluation of short-term and long-term outcomes. Dr. Krishnamurti has been active as a site principal investigator (PI) in multiple clinical trials of gene therapy for SCD and is an author in several peer reviewed publications relevant to the subject.

Areas of expertise: SCD clinical trials, bone marrow transplantation, gene therapies, patient education and decision making

Megha Kaushal, MD, MSc

Branch Chief, Division of Clinical Evaluation Hematology

Office of Therapeutic Products

Center for Biologics Evaluation and Research

Food and Drug Administration

White Oak, MD



Megha Kaushal, MD, MSc. is a pediatric hematologist/oncologist who serves as the Branch Chief for Benign Hematology in the Division of Clinical Evaluation Hematology within the Office of Therapeutic Products in the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA).

Dr. Kaushal received her M.D. from Rush University, Chicago and completed her medical training in Pediatrics at Medical College of Georgia and her fellowship in Pediatric Hematology Oncology at Children's National in DC. Her clinical interests include SCD, hemophilia, bone marrow failure syndromes, and hemostasis and thrombosis.

Following fellowship, she joined the Division of Bone Marrow Transplant at Children's National prior to joining the FDA in 2014 as a clinical reviewer. In her role, she has been responsible for the review and regulatory oversight of several benign and malignant hematology Investigational New Drug (IND) and Biologic Licensing Applications (BLAs).

Areas of expertise: Sickle cell disease, clinical review and regulatory oversight of gene therapies and other biologics

Natalie Klein, PhD

Acting Director

Office for Human Research Protections

U.S. Department of Health and Human Services

Rockville, MD



Natalie Klein, PhD, is the Acting Director of the U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), which provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by HHS.

Dr. Klein joined OHRP as the Director of the Division of Policy and Assurances in 2021 from the U.S. Army Medical Research and Development Command (USAMRDC), where she served as a liaison to the Command's intramural research institutes for human research protections policy and helped provide regulatory oversight for USAMRDC-supported research conducted at over 1600 institutions in 67 countries. She holds a doctorate in Brain and Cognitive Sciences.

Areas of expertise: Human research protections, regulatory oversight, policy development
