Synergy in Science: Innovations in Autoimmune Disease Research and Care

8TH ANNUAL VIVIANW. PINN SYMPOSIUM

MAY 15, 2024









OVERVIEW

8TH **ANNUAL VIVIAN W. PINN SYMPOSIUM:** Synergy in Science: Innovations in Autoimmune Disease Research and Care

The Vivian W. Pinn Symposium honors the first full-time Director of the National Institutes of Health (NIH) Office of Research on Women's Health (ORWH), Vivian Pinn, M.D., and is held every year during National Women's Health Week. This event serves as a critical forum for experts across sectors to communicate and collaborate for the advancement of women's health.

The title of this year's symposium is "Synergy in Science: Innovations in Autoimmune Disease Research and Care." The symposium is a convergence of cutting-edge insights and collaborative efforts in the realm of autoimmune diseases and will focus on understanding the state of the science on sex-differences in autoimmune diseases, exploring innovations arising from NIH's intramural research programs, and driving progress in autoimmune care, among other topics and insights.

Providing the keynote address, "Understanding the Immunome: Past, Present, and Future," is Jane Buckner, M.D., President, Benaroya Research Institute. A special Fireside Chat by David Fajgenbaum, M.D., M.B.A., M.Sc., co-founder and president of Every Cure, will focus on "Turning Hope into Action—Empowering Communities to Advance Science."

The objectives of the symposium are to:

- Drivers of Autoimmunity: Understand the state of the science on sex differences in autoimmune diseases, and what the future may hold for interventions.
- NIH Research Frontiers: Explore innovations arising from NIH's intramural research programs, driving progress in autoimmune care through rigorous scientific inquiry and technological breakthroughs.
- Advocacy Accelerating Treatments: Examine the synergy between patient advocacy and scientific progress, highlighting how collaborative efforts expedite the development of novel treatments for rare autoimmune diseases.
- Research at the Bedside: Unravel the complexities of autoimmune diseases across the lifespan through patientcentric bedside research insights.



About **Vivian W. Pinn, M.D.**

Founding Director (Retired), ORWH
Senior Scientist Emerita, Fogarty International Center, NIH

Dr. Vivian W. Pinn was the inaugural full-time director of ORWH, from 1991 until her retirement in 2011. Dr. Pinn was also NIH's Associate Director for Research on Women's Health from 1994 until her retirement. Under her leadership, this new office led the implementation of NIH inclusion policies for women and diverse groups in clinical research, developed the first and several subsequent national strategic plans for women's health research, and established many new research funding initiatives and career development programs, including interdisciplinary initiatives, in collaboration with NIH institutes and centers. During that time, she also established and co-chaired the NIH Working Group on Women in Biomedical Careers with the NIH Director. She has since been named a Senior Scientist Emerita at NIH's Fogarty International Center. She has presented her perceptions of women's health and sex and gender research, health disparities, and challenges in biomedical careers for women and people of color to national and international audiences and has served as a mentor to hundreds of young women and men of all races. A special tribute by Senator Olympia Snowe on Dr. Pinn's retirement was published in the Congressional Record in November 2011. Senator Snowe commended Dr. Pinn's contributions during her NIH tenure. At the time of Dr. Pinn's retirement, the Association of American Medical Colleges honored her with a Special Recognition Award for exceptional leadership over a 40-year career.

Dr. Pinn received the Alumna Achievement Award from Wellesley College and was an Alumna Trustee there. She earned her M.D. in 1967 from the University of Virginia School of Medicine, the only woman and only person of color in her class. She completed her postgraduate training in pathology at Harvard University's Massachusetts General Hospital.

She came to NIH from the Howard University College of Medicine, where she had been Professor and Chair of the Department of Pathology since 1982, the third woman in the United States to hold such an appointment and the first African American woman to do so. Dr. Pinn also previously held teaching appointments in pathology at Harvard Medical School and Tufts University, where she was also Assistant Dean for Student Affairs. Her professional area of focus in pathology was immunopathology, specifically renal and autoimmune diseases, and transplant pathology. She now holds the position of Professor at the University of South Florida's Institute for Advanced Discovery & Innovation.

She is a fellow of the American Academy of Arts and Sciences and was elected to the Institute of Medicine (now the National Academy of Medicine) in 1995. She served several terms on the National Academies' Committee on Women in Science, Engineering, and Medicine and was a member of the National Academies committee that prepared the 2020 report titled *Promising Practices for Addressing the Underrepresentation of Women in Science, Engineering, and Medicine: Opening Doors.* She is also a member of the National Academies' Roundtable on Black Men and Black Women in Science, Engineering, and Medicine. Dr. Pinn has written over 200 scientific publications and book chapters, including forewords, and has given more than 500 keynote speeches, lectures, and presentations since 1991.

A native of Lynchburg, Virginia, and educated in segregated public schools, Dr. Pinn has received 17 honorary degrees of science, law, and medicine. The University of Virginia School of Medicine named one of its four advisory medical student colleges the Pinn College in her honor. In 2011, the Tufts University School of Medicine announced the Vivian

W. Pinn Office of Student Affairs, and her former medical students dedicated a scholarship in her name, the Vivian W. Pinn Scholarship Fund, to give needy students an opportunity to study medicine at Tufts. She has held leadership positions in many professional organizations, including as the 88th President of the National Medical Association (NMA), and is currently Chair of the NMA Past Presidents Council. Dr. Pinn serves on the boards of trustees/advisors of Thomas Jefferson University, the Sidney Kimmel Cancer Center at Jefferson Health, the Tufts University School of Medicine, and the Keck Graduate Institute School of Medicine.

Dr. Pinn has received more than 300 honors and awards. She was elected to Modern Healthcare's Hall of Fame, the first African American woman to be so honored, and was also a recipient of the New York Academy of Medicine Medal for Distinguished Contributions in Health Policy. Honors she has received include a special lifetime achievement award from the Drexel University College of Medicine's Institute for Women's Health in 2017, and she also served as the 2017–18 Leader-in-Residence at the Jepson School of Leadership Studies of the University of Richmond. In 2019, she was presented with the John D. Thompson Distinguished Visiting Fellow Award by the Yale University School of Public Health.

She more recently received the 2020 American Medical Association's Distinguished Service Award for her leadership in women's health, as well as the 2020 Alma Dea Morani Award from the Women in Medicine Legacy Foundation and the New York Academy of Medicine. She also was awarded the 2021 Distinguished Service Award from the Association of Pathology Chairs and was elected a 2021 Fellow of the American Association for the Advancement of Science. She was also included in Hearst's "Lift Every Voice" project, a celebration of Black lives.

Research! America awarded her the Outstanding Achievement in Public Health Award as one of its 2022 Advocacy Awards honorees. Tufts University honored her for her efforts as a faculty member at the medical school by selecting her as one of eight influential Black leaders at Tufts for its 2022 project called "Leading While Black: A Legacy of Transformational Black Leadership at Tufts University."

Lectures in women's health named for her have been established at NIH, the National Women's Health Congress, and the National Medical Association. One of her greatest honors has been the announcement by the University of Virginia in the fall of 2016 that the medical research and education building was renamed Pinn Hall for her. And in December 2016, the University of Virginia School of Medicine also announced the inaugural Pinn Scholars program to support and recognize midlevel faculty members for their efforts to take their research in novel directions. Her oral history is included in the National Library of Medicine's exhibit on women physicians, "Changing the Face of Medicine"; in the University of Virginia's project called "Explorations in Black Leadership," conducted by Julian Bond; and in the HistoryMakers collection, which is now housed in the Library of Congress.

AGENDA – VIRTUAL EVENT

Virtual Event Page

| TIME | AGENDA | SPEAKER | |
|----------------|---|---|--|
| 1:00–1:15 p.m. | Opening Remarks | Janine Austin Clayton, M.D., FARVO | |
| | | Director, Office of Research on Women's Health, NIH | |
| | | Associate Director for Research on Women's Health, NIH | |
| 1:15–2:00 p.m. | Keynote Address: | Jane Buckner, M.D. | |
| | "Understanding the Immunome: Past, Present, and Future" | President of the Benaroya Research Institute | |
| | | Affiliate Professor, Department of Medicine, Division of Rheumatology, University of Washington, Seattle, WA | |
| 2:00–2:45 p.m. | Inside Innovation: Intramural Impact at NIH | | |
| | "Understanding the Genetics of Childhood-onset Systemic Lupus Erythematosus in Global Populations" | Laura Lewandowski, M.D., M.S. | |
| | | Head, Lupus Genomics and Global Health Disparities Unit, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH | |
| | "Anticytokine Autoantibodies: Who Knew?" | Steven Holland, M.D. | |
| | | Director of the Division of Intramural Research, National Institute of Allergy and Infectious Diseases, NIH | |
| | "Genetic and Environmental Risk Factors of Autoimmune Diseases" | Alison Motsinger-Reif, Ph.D. | |
| | | Chief, Biostatistics & Computational Biology Branch and Principal Investigator, National Institute of Environmental Health Sciences, NIH | |
| 2:45-3:00 p.m. | Break | | |

AGENDA (CONTINUED)

| TIME | AGENDA | SPEAKER |
|----------------|--|--|
| 3:00–3:45 p.m. | Fireside Chat: | David Fajgenbaum, M.D., M.B.A., M.Sc. |
| | "Turning Hope into Action – Empowering Communities to Advance Science" | Co-Founder and President, Every Cure |
| | | Director, Center for Cytokine Storm Treatment & Laboratory at the University of Pennsylvania |
| | | Co-Founder & President, Castleman Disease Collaborative Network |
| | | Victoria Shanmugam, MBBS, MRCP, FACR, CCD |
| | | Director, Office of Autoimmune Disease Research in the Office of Research on Women's Health, NIH |
| 3:45-4:30 p.m. | Capstone Speaker: "Making a Difference" | Gail Kerr, M.D., FRCP (Edin), FACR, MACR |
| | | Washington, D.C. Veterans Affairs Medical Center; MedStar Georgetown University Hospital; Howard University Hospital |
| 4:30–5:00 p.m. | Closing Remarks | Vivian W. Pinn, M.D. |
| | | Senior Scientist Emerita, Fogarty International Center, NIH |
| | | Founding Director (Retired), Office of Research on Women's Health, NIH |

OPENING REMARKS



Janine Austin Clayton, M.D., FARVO

Associate Director for Research on Women's Health Director, ORWH, NIH

Dr. Janine Clayton was appointed Associate Director for Research on Women's Health and director of the ORWH at NIH in 2012. Dr. Clayton has strengthened NIH support for research on diseases, disorders, and conditions that affect women. She is the architect of the NIH policy requiring scientists to consider sex as a biological variable across the research spectrum, a part of NIH's initiative to enhance reproducibility, rigor, and transparency. As co-chair of the NIH Working Group on Women in Biomedical Careers with NIH Director Dr. Monica Bertagnolli, Dr. Clayton also leads NIH's efforts to advance women in scientific careers. In 2021, Dr. Clayton was elected to the Board of Directors of the American Association for the Advancement of Science. Dr. Clayton was previously the Deputy Clinical Director of the National Eye Institute (NEI). As a board-certified ophthalmologist, Dr. Clayton has interest in research on autoimmune ocular diseases and the role of sex and gender in health and disease. Dr. Clayton has a particular interest in ocular surface disease and discovered a novel form of disease associated with premature ovarian insufficiency that affects young women, setting the stage for her commitment to rigorous, thoughtful exploration of the role of sex and gender in health and disease. She is the author of more than 120 scientific publications, journal articles, and book chapters. Her clinical research has ranged from randomized controlled trials of novel therapies for immune-mediated ocular diseases to studies on the development of digital imaging techniques for the anterior segment.

Dr. Clayton, a native Washingtonian, received her undergraduate degree with honors from Johns Hopkins University and her medical degree from the Howard University College of Medicine. She completed a residency in ophthalmology at the Medical College of Virginia. Dr. Clayton completed fellowship training in cornea and external disease at the Wilmer Eye Institute at Johns Hopkins Hospital and in uveitis and ocular immunology at NEI.

Dr. Clayton has received several awards and has been recognized as a leader by her peers. She received the Senior Achievement Award from the Board of Trustees of the American Academy of Ophthalmology in 2008, was selected as a 2010 Silver Fellow by the Association for Research in Vision and Ophthalmology, and won the European Uveitis Patient Interest Association Clinical Uveitis Research Award in 2010. In 2015, she was awarded the American Medical Women's Association's Lila A. Wallis Women's Health Award and the Wenger Award for Excellence in Public Service. Dr. Clayton was granted the Bernadine Healy Award for Visionary Leadership in Women's Health in 2016. She was also selected as an honoree for the Woman's Day Red Dress Awards and the American Medical Association's Dr. Nathan Davis Awards for Outstanding Government Service in 2017.

KEYNOTE ADDRESS



Jane Buckner, M.D.

President of the Benaroya Research Institute

Affiliate Professor, Department of Medicine, Division of Rheumatology, University of Washington (UW), Seattle Affiliate Professor, Department of Immunology, University of Washington, Seattle Affiliate Faculty, UW Medicine Diabetes Institute, Seattle Partner, Allen Institute of Immunology

Rheumatologist, Virginia Mason Medical Center, Seattle

Dr. Jane Buckner is the president of the Benaroya Research Institute (BRI), an affiliate professor at the University of Washington, and practicing rheumatologist. She is known for her research in translational immunology, combining genetics, immunology, and clinical medicine to advance the understanding of the causes of autoimmune diseases.

At the Benaroya Research Institute, Dr. Buckner was instrumental in developing the translational immunology research program and establishing the BRI biorepository, which currently includes more than 350,000 samples from 14,000 participants. Dr. Buckner has made significant contributions to our understanding of how human T cells are dysregulated in type 1 diabetes and rheumatoid arthritis and has been a pioneer in the development of antigenspecific Treg therapies.

Dr. Buckner is the inaugural holder of the Gerald Nepom Endowed chair at BRI. She also leads the Coordinating Center of the Immune Tolerance Network, an NIH funded collaborative network for clinical research, and is a scientific advisor for Type 1 Diabetes TrialNet, an NIH-funded clinical trial network for type 1 diabetes prevention and early treatment. She is the current Chair of the NIH/NIAMS Board of Scientific Counselors and served as the Chair of the NIH/NIAID Cooperative Study Group for Autoimmune Disease Prevention.

Dr. Buckner received her bachelor's degree in chemistry from Carleton College, her M.D. from Johns Hopkins School of Medicine, her residency in Internal Medicine at University of Minnesota, and a rheumatology fellowship at the University of Washington. Dr. Buckner has received multiple awards including the American College of Rheumatology Arthritis Investigator Award and is the 2024 recipient of the American Association of Immunologists Steinman Award for Human Immunology Research.

BIOGRAPHIES



David Fajgenbaum, M.D., M.B.A., M.Sc.

Co-Founder and President, Every Cure
Director, Center for Cytokine Storm Treatment & Laboratory at the
University of Pennsylvania
Co-Founder & President, Castleman Disease Collaborative Network

Dr. David Fajgenbaum is a physician-scientist at the University of Pennsylvania (Penn) and one of the youngest ever Penn Medicine professors to receive tenure, co-founder of Every Cure, and the national bestselling author of *Chasing My Cure: A Doctor's Race to Turn Hope Into Action*. Dr. Fajgenbaum is also a patient battling a deadly disease which he discovered a treatment for that is saving his life and others. Through his work at Penn, he has also identified and advanced 16 other repurposed treatments for diseases. He recently co-founded Every Cure to unlock the full potential of FDA-approved medicines to treat every disease possible and serves on the Board of Directors for the Reagan-Udall Foundation for the FDA.

One of the youngest ever awardees of multiple top NIH and FDA grants, Dr. Fajgenbaum has published scientific papers in high-impact journals such as the New England Journal of Medicine, The Lancet, and the Journal of Clinical Investigation, including a paper selected as one of the top innovations in science and medicine of 2020. He has been profiled by *The New York Times*, TODAY, Good Morning America, *USA Today*, and others and received numerous awards, including the 2016 Atlas Award along with then Vice President Joe Biden and Forbes 30 Under 30. Dr. Fajgenbaum earned a M.Sc. from the University of Oxford, M.D. from the University of Pennsylvania, and M.B.A. from The Wharton School.



Steven M. Holland, M.D.

Director of the Division of Intramural Research, National Institute of Allergy and Infectious Diseases, NIH

Dr. Steven Holland, serves as director of the Division of Intramural Research (DIR) at the National Institute of Allergy and Infectious Diseases (NIAID). Dr. Holland provides overall executive direction and scientific leadership for the division's basic and clinical research activities, which cover a wide range of biomedical disciplines related to infectious diseases, immunology, and allergy. Dr. Holland also serves as the chief of the Immunopathogenesis Section within the Laboratory of Clinical Immunology and Microbiology (LCIM).

DIR researchers currently conduct more than 180 clinical trials at the NIH Clinical Center and at collaborating domestic and international sites. The ultimate goal of the division's research is to contribute to the development of therapies, diagnostics, and vaccines that improve human health. Toward this goal, DIR does the following:

- Expand knowledge of normal immune system components and functions.
- Define mechanisms responsible for abnormal immune function (e.g., primary and acquired immunodeficiencies, allergy, and autoimmunity).
- Understand the biology of infectious agents (e.g., viruses, bacteria, fungi, and parasites) and the host response to them.
- Develop strategies to prevent, diagnose, and treat immunologic, allergic, and infectious diseases.

Dr. Holland received his M.D. from the Johns Hopkins University School of Medicine. He remained at Johns Hopkins for his internal medicine residency, chief residency, and fellowship in infectious diseases. His research areas of special interest have included Chronic Granulomatous Disease, Job's syndrome (autosomal dominant STAT3 deficiency) and the genetic conditions predisposing people to mycobacterial infections, including GATA2 deficiency. More recently, he has been interested in genetic conditions associated with severe coccidioidomycosis and acquired forms of anticytokine autoimmunity predisposing to opportunistic infections.

Dr. Holland came to NIAID in 1989 as a National Research Council fellow in Dr. Sundararajan Venkatesan's section in the Laboratory of Molecular Microbiology, working on *rev*-mediated transcriptional regulation of HIV. In 1991, he joined Dr. John Gallin's section in the Laboratory of Host Defenses (LHD), shifting his research to the host side, with a focus on phagocyte defects and their associated infections. His work in the LHD centered on the pathogenesis and management of Chronic Granulomatous Disease, as well as other congenital immune defects affecting phagocytes. He was tenured in 2000 and became chief of the Immunopathogenesis Section, which now resides within LCIM. In 2004, Dr. Holland became chief of the newly created Laboratory of Clinical Infectious Diseases, a position he held until becoming director, DIR in 2016.

Dr. Holland is the author of more than 700 publications and has been named an NIH Distinguished Investigator. He is a member of the National Academy of Medicine and has received the American College of Physicians Award for Science, the Boyle Scientific Achievement Award of the Immune Deficiency Foundation, the American Society for Microbiology Abbott Award, the Erwin Neter Award of the Association of Medical Laboratory Immunologists, the NIH Distinguished Clinical Teacher Award, and the Walter E. Stamm Mentoring Award of the Infectious Diseases Society of America, among other awards.



Gail Kerr, M.D., FRCP (Edin), FACR, MACR

Washington, D.C. Veterans Affairs Medical Center; MedStar Georgetown University Hospital; Howard University Hospital

Dr. Gail Kerr completed her medical training at the University of the West Indies, Kingston, Jamaica, where she received honors in Biochemistry, Physiology, and Pharmacology. She was the recipient of the Allenbury Prize and the Clinical Gold Medal in Internal Medicine for the most outstanding performance in the written and clinical examinations, respectively. She received her Rheumatology Fellowship training at the National Institutes of Allergy and Infectious Diseases at Georgetown University. At the NIH, she received a Special Recognition Award for contributions to the studies on the treatment and pathogenesis of systemic vasculitis.

She then joined the Georgetown/Veterans Affairs Rheumatology Training Program as an Attending at the Washington D.C. Veterans Affairs (VA) Medical Center in 1994, where she continues to be involved in trainee education, patient care, and clinical research. In 2002, she spearheaded a revival of the Rheumatology Division at Howard University Hospital (HUH), which evolved to have an established presence in the resident training program and in the D.C. academic community. Dr. Kerr has trained and mentored several residents and fellows over the past 30 years. At Howard University, she guided many residents that were members of diverse groups into the specialty of rheumatology, more than any other single academic institution or Historically Black Colleges and Universities. She received the Dedication & Service Award from the HUH Department of Medicine in 2010 and along with the HUH Rheumatology faculty, the Leadership Graduate Medical Education Award from the Department of Medicine in 2015. In 2014, she received support from the American College of Rheumatology for one-on-one preceptorship and real-world experience of Howard University medical students.

In 2002, Dr. Kerr brought community to VA Rheumatologists with the formation of a Consortium, which spawned the development of observational chronic disease registries, all dedicated to improving care and outcomes of U.S. veterans. Her clinical research activities have been based on observational and administrative data analyses of chronic disease registries from institutions—both academic and government, related to veterans and civilians, and inclusive of community practices—all reflecting routine, real world care. Her scholarly achievements have demonstrated her expertise and commitment in addressing and seeking solutions to barriers that hinder equity in the care and outcomes of vulnerable patients, particularly in underserved racial and ethnic groups. Dr. Kerr also collaborates with the Association of Women in Rheumatology to promote membership participation in clinical research and educate trainees in advocacy and leadership. In 2019, Dr. Kerr was the first rheumatologist to receive the Johns Hopkins University's 16th Myron L. Weisfeldt Distinguished Visiting Professorship in Diversity. She is also the 2023 recipient of the American College of Physicians, D.C. Chapter Sol Katz Excellence in Teaching Award. In 2023, Dr. Kerr was also designated as Master of the American College in Rheumatology, the first black woman to receive its highest honor.



Laura Lewandowski, M.D., M.S.

Head, Lupus Genomics and Global Health Disparities Unit, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH

Dr. Laura Lewandowski completed pediatric residency training at the University of Massachusetts Medical Center and went on to serve as a chief resident in pediatrics. During her chief resident year, she developed a specialty track for pediatric residents in Global Health, including curriculum design and coordination of international rotations. She completed a combined four-year pediatric rheumatology/global health fellowship at Duke University Medical Center, during which she characterized a pediatric lupus patient cohort in South Africa. She holds a Masters in Global Health from Duke University. During her fellowship, she collaborated with Dr. Chris Scott to establish a registry of pediatric lupus patients that continues to grow and is now the largest cohort in sub-Saharan Africa. She was awarded a Fogarty Global Health Fellowship and a Lupus Foundation Early Career award for her work with pediatric lupus patients in South Africa.

In 2015, she joined the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) under Dr. Mariana Kaplan as a Lawrence Shulman Scholar in Translational Medicine. She currently holds the position of Assistant Clinical Investigator and Head of the Lupus Genomics and Global Health Disparities Unit at NIAMS. Her current research interests include clinical and translational research in pediatric systemic lupus erythematosus, with a focus on genetic drivers of severe disease and inflammation in varied cohorts around the world.

Dr. Lewandowski has held several leadership positions including serving as co-chair of the Childhood Arthritis and Rheumatic Diseases Research Alliance (CARRA) Lupus Nephritis workgroup, co-chair of the CARRA Lupus Genetics Workgroup, chair of the CARRA Translation Research and Technology Committee Data Management, and chair of the CARRA Annual Meeting Planning Committee. She is a member of Early Career Investigator Committee within the American College of Rheumatology, whose aim is to develop the next generation of researchers in the rheumatology field. In addition, she has mentored students and trainees in North America and South Africa in rheumatology research. She is a U.S. representative on the Pediatric Musculoskeletal Task Force. She has published many articles on lupus in Africa and the challenges to rheumatology clinical care, education, and practice in less resourced countries. She has lectured nationally and internationally on the genetics of pediatric lupus in global populations and global rheumatology clinical care and research.



Alison Motsinger-Reif, Ph.D.

Chief, Biostatistics & Computational Biology Branch and Principal Investigator, National Institute of Environmental Health Sciences, NIH

Dr. Alison Motsinger-Reif is chief of and a principal investigator in the Biostatistics and Computational Biology Branch. Overall, her group focuses on the development and application of modern statistical approaches for understanding the etiology of common, complex diseases. As the field of human genetics increasingly accepts a complex model of phenotypic development involving many genetic and environment factors, it is increasingly important to develop analytical strategies that incorporate this complexity. Data collected from different physiological compartments that represent biological flux across time and space, such as genetic, metabolomics, and environmental data, will need to be incorporated to gain a fuller understanding of the biological mechanism underlying complex phenotypes.

As chief of the National Institute of Environmental Health Sciences (NIEHS) Biostatistics & Computational Biology Branch, Dr. Motsinger-Reif oversees a dynamic and diverse staff that is involved in biostatistical and computational methods development, software development, study design, and collaborative real data applications.

Dr. Motsinger-Reif obtained her Ph.D. in human genetics and an M.S. in applied statistics from Vanderbilt University. She was a faculty member at North Carolina State University from 2007 to 2018. In December 2018, she joined NIEHS as chief of the Biostatistics & Computational Biology Branch.



Victoria Shanmugam, MBBS, MRCP, FACR, CCD

Director, Office of Autoimmune Disease Research in the Office of Research on Women's Health, NIH

Dr. Victoria Shanmugam currently serves as the director of the <u>Office of Autoimmune Disease Research in the Office of Research on Women's Health (OADR-ORWH)</u>.

Dr. Shanmugam is an experienced physician-scientist, rheumatologist, and academic leader. She graduated from Oxford University with a B.A. in physiology and completed her medical degree at Imperial College School of Medicine in London, graduating with honors in medicine. She is a member of the Royal College of Physicians in London. Dr. Shanmugam completed the Internal Medicine Residency and Rheumatology Fellowship at Georgetown University and joined the faculty of Georgetown University School of Medicine in 2007.

Dr. Shanmugam received master's-level clinical and translational research training through the K30 program and was a KL2 scholar at the Georgetown-Howard Universities Center for Clinical and Translational Science. Her research focused on scleroderma and wound healing, as well as the interplay of the host immune system with the microbiome in patients with chronic wounds. While on faculty at Georgetown, she served as the chair of the Institutional Review Board and as director of the Orthopedics, Rheumatology, and Dermatology module for Georgetown University School of Medicine.

A talented academic leader, Dr. Shanmugam subsequently served as chief of rheumatology at the George Washington University School of Medicine and Health Sciences from 2014 to 2021. She was the inaugural chair of the Clara Bliss Hinds Society for Women in Medicine and Health Sciences and served as chair of the Research Committee for the School of Medicine and Health Sciences. Dr. Shanmugam is widely respected in the field of autoimmune diseases, having served in multiple leadership roles for the American College of Rheumatology.

ABOUT

NIH Office of Research on Women's Health (ORWH)

ORWH was established in September 1990 in response to congressional, scientific, and advocacy concerns that a lack of systemic and consistent inclusion of women in NIH-supported clinical research could result in clinical decisions being made about health care for women based solely on findings from studies of men—without any evidence that they were applicable to women. ORWH is part of the Office of the Director of NIH, and works in partnership with the 27 NIH institutes and centers to ensure that women's health research is part of the scientific framework at the NIH—and throughout the scientific community.

The establishment of the Office heralded earnest efforts by NIH to develop a research agenda addressing gaps in scientific knowledge about women's health across the lifespan and to increase the number of scientists pursuing investigations with a scientific design that would reveal sex and gender differences in outcomes. These aims were articulated in the first ORWH agenda-setting report, Report of the National Institutes of Health: Opportunities for Research on Women's Health (commonly referred to as the Hunt Valley report).

In 1997, ORWH undertook a second systematic program of collaborative planning and convened a series of public hearings and scientific workshops that culminated in the publication of the Agenda for Research on Women's Health for the 21st Century. That agenda expanded the vision for NIH, going "beyond Hunt Valley" to highlight the importance of promoting interdisciplinary, collaborative research; studying and addressing the health differences and needs of all populations of women; and increasing the diversity of the biomedical workforce.

ACCOMPLISHMENTS

Thirty years after the establishment of ORWH, significant progress has been achieved in four benchmark areas: (1) policies have been developed and implemented to ensure the inclusion of women in NIH clinical research; (2) women's health and sex differences research has increased; (3) new programs have been implemented to prepare researchers to conduct women's health research; and (4) there has been new focus on interdisciplinary career development and sex and gender differences research across the research continuum. Consequently, reports on sex- and gender-related factors in health and disease and analysis of clinical trials by sex of participants have steadily increased in the scientific literature.

Over the years, the biennial reports of the Advisory Committee on Research on Women's Health, in collaboration with the NIH Coordinating Committee on Research on Women's Health, attest to the attention and greater appreciation that has developed for women's health and sex and gender differences research in the design of studies and the translation of findings into clinical practice. The growth of NIH-funded women's health research addressing the expanded concept of women's health across the lifespan—including more than just the reproductive years while continuing to explore understudied areas of reproductive health and the menopausal transition—has been impressive. Additionally, increasing numbers of investigator-initiated women's health research in areas such as cardiovascular disease and stroke, musculoskeletal and immune disorders, and mental health and substance abuse, among many others, reflect enormous progress.

As a result of the increased attention to women's health research funded by the NIH institutes and centers, women's health scientists, providers, and advocates have gained a strong sense of their capacity to effect change. Research on women's health has become a tangible reality.

ABOUT

NIH Office of Autoimmune Disease Research (OADR)

Approximately 8% of the United States population is living with an autoimmune disease, and nearly 80% of those with an autoimmune disease are women. Autoimmune diseases can affect almost every organ in the body, occur at any point across the lifespan, and may be chronic with no known cure. To accelerate progress in autoimmune disease research (ADR), the U.S. Congress directed NIH to establish an Office of Autoimmune Disease Research in the Office of Research on Women's Health (OADR-ORWH).

As described in the Consolidated Appropriations Act, 2023 (Public Law 117-328) for the departments of Labor, Health and Human Services, and Education, and related agencies, the OADR-ORWH will:

- Coordinate development of a multi-institute and center (IC) strategic research plan;
- · Identify emerging areas of innovation and research opportunity;
- Coordinate and foster collaborative research across ICs;
- Annually evaluate the NIH ADR portfolio;
- · Provide resources to support planning, collaboration, and innovation; and
- Develop a publicly accessible central repository for ADR.

ADR expertise is housed across various NIH institutes, centers, and offices (ICOs) in alignment with their mission areas. Thus, establishing OADR-ORWH within the NIH Office of the Director positions the office well to amplify and synergize individual ICO efforts and create opportunities for collective innovation.

The mission of OADR-ORWH is to support high priority ADR, identify emerging areas of innovation, and foster collaboration across NIH ICOs. In addition to co-funding research with the ICOs, OADR-ORWH is advancing several initiatives that will lay the foundation for high-priority ADR across NIH, including evaluating NIH's ADR portfolio, which includes more than 140 diseases, and developing the inaugural NIH-wide strategic plan for ADR, which will guide future OADR-ORWH activities, amplify ICO efforts, and advance opportunities for innovation.

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