National Institutes of Health
Office of Research on Women's Health



ORWH's Impact on the Health of Women

2013-2025 Report

Office of Research on Women's Health

Introduction

ORWH's Transformative Impact on Women's Health Research Landscape



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Established in 1990, the Office of Research on Women's Health (ORWH)[1] became the **first Public Health Service office dedicated specifically to promoting women's health**. The scientific foundation established by Vivian W. Pinn, M.D., ORWH's first full-time director, created a lasting framework for advancing women's health research that continues to guide and inform ORWH's work today. Under the leadership of Janine Clayton, M.D., FARVO, beginning in 2012, the landscape of women's health research has undergone a profound transformation. ORWH has championed critical advances in understanding sex differences in health and disease, expanded the scientific evidence base for conditions affecting women, and ensured that women are appropriately represented in clinical research. This report highlights the impact of ORWH's leadership through science that works for women's whole lives, turning discoveries into real-world solutions, ensuring that research reflects real experiences and accurate differences between women and men, supporting the scientists behind the science, and leading the charge for women's health research at the National Institutes of Health (NIH).[2]



Figure 1: ORWH Impact Snapshot 2013-2025

Sex as a Biological Variable: Enhancing the Rigor and Reproducibility of Scientific Research

Underpinning many of ORWH's achievements is Sex as a Biological Variable (SABV),[3] a research principle that recognizes that biological sex can influence health, disease, and response to treatment. To ensure appropriate consideration of these influences, ORWH led the implementation of NIH's SABV policy[4] in 2016, requiring researchers to account for sex in the design, analysis, and reporting of NIH-funded studies. Now, a decade later, SABV has become a cornerstone of rigorous biomedical research and a driving force behind discoveries that improve health for women and men alike.

Historically, biomedical research frequently relied on male cells, animals, and research participants, limiting understanding of how sex influences health and disease. The SABV policy established a new standard by requiring scientists to explain how sex will be incorporated throughout their research. The policy covers using cells, tissues, and animals of both sexes in laboratory studies; enrolling sufficient numbers of women in clinical research; and analyzing results to identify potential sex differences.

By championing SABV, ORWH has strengthened the rigor, reproducibility, and relevance of biomedical research. This approach has uncovered important differences in how diseases develop, how medications work, and how treatments can be tailored for women and men, leading to advances ranging from optimized drug dosing to improved recognition of heart attack symptoms to more personalized pain management strategies. The impact extends far beyond NIH, influencing research practices worldwide and helping to build a scientific enterprise that translates discoveries into better health outcomes for everyone.

Figure 2 illustrates ORWH's vision for a sex-specific, whole person framework for precision therapeutics across life stages. The framework addresses a core challenge in biomedical research: that fragmented models often fail to account for how sex, age, and life stage, from puberty through menopause, shape health outcomes, leading to gaps in predicting treatment efficacy and toxicity. By integrating SABV across multiple scales, from the molecular and cellular levels to organs, systems, and the whole person, and accounting for exposures, environment, and life course dynamics, the framework aims to generate more complete and accurate models of women's health. The expected impact includes advances in female-specific health, a better understanding of sex differences, more accurate prediction of treatment responses, and improved prevention and personalized therapeutics.

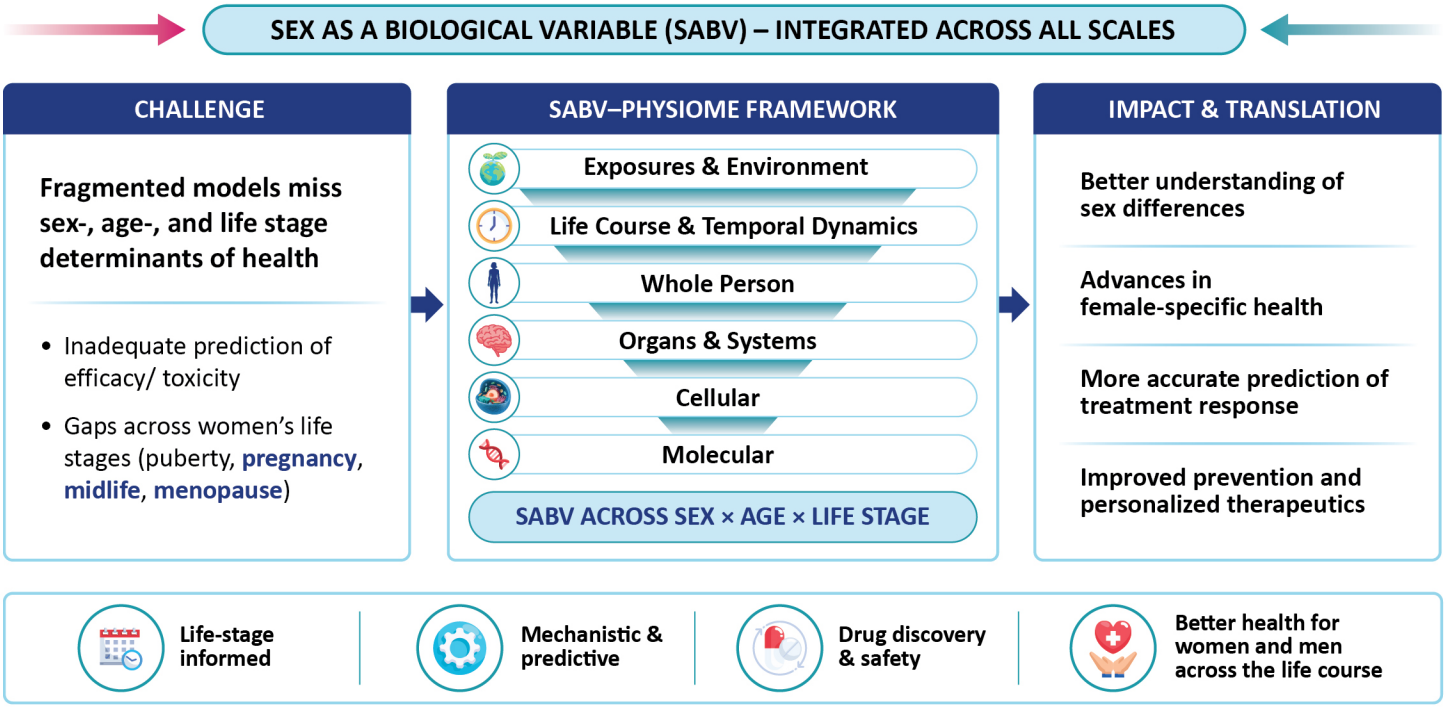


Figure 2: Sex-Specific Whole Person Framework

Science That Works for Women's Whole Lives

The factors that impact a woman's health evolve across life stages, spanning adolescence, the reproductive years, midlife transitions, and older age.

ORWH has championed research that addresses health at every life stage, leading to comprehensive care for the full arc of women's lives. From the earliest life stages, sex shapes health in ways that ripple across generations. ORWH-supported research is revealing how biology, hormones, and environment interact from before birth through older age, and why understanding these influences is essential to improving care for women.

Maternal Health Research and Interventions

Science Spotlight: Understanding How Pregnancy Shapes Lifelong Health: A 45-Year Study Reveals Lasting Brain Effects

Through the Specialized Centers of Research Excellence (SCORE) on Sex Differences[5] program, ORWH-supported researchers are uncovering how maternal health during pregnancy affects both mothers and their children for decades. In a groundbreaking study,[6] researchers at Massachusetts General Hospital and Harvard Medical School followed 80 individuals from prenatal development through age 45, one of the longest-running studies of its kind. They discovered that maternal immune activity during the third trimester of pregnancy had sex-dependent effects on offspring's stress-regulating brain circuitry that persisted 45 years later. For women, higher levels of certain inflammatory markers during their mother's pregnancy were associated with decreased activity in the hippocampus, a brain region essential for regulating stress and mood. These changes may help explain women's higher risks for depression, anxiety, and stress-related disorders across the life course. Pregnancy complications such as preeclampsia and infections, which trigger maternal immune responses, may have long-lasting consequences for offspring brain development in ways that differ between sons and daughters. This research demonstrates SCORE's unique capability to conduct long-term, comprehensive studies that reveal how sex influences health across generations, yielding insights that transform care for both mothers and their children.

Menopause and Midlife Health

For decades, menopause and midlife health were overlooked and undertreated, leaving more than one million U.S. women navigating symptoms that affect sleep, mood, cardiovascular health, bone strength, and overall quality of life without adequate evidence to guide care. This lack of evidence has hampered clinicians' ability to provide effective, personalized treatment and has slowed scientific progress on understanding a critical life inflection point that influences long-term health trajectories. In 2025, ORWH, ODP,[7] and other NIH partners initiated work to address this gap by launching a Pathways to Prevention (P2P) program[8] on the menopausal transition to bring clarity and direction to this underdeveloped research field. Beginning with the "Advancing Research to Improve Health During the Menopausal Transition"[9] workshop, ORWH and its partners catalyzed progress by convening federal agencies, researchers, and community members to synthesize the best available information and identify the most consequential scientific gaps.

To accelerate progress in the areas identified through these efforts, ORWH also invested directly in innovative research to generate new evidence and advance care for women during midlife. Building on more than $5 million in successful research collaborations with NIH's in-house research program, ORWH launched the Women's Health Intramural Innovation Awards[10] program with OIR[11] and OBSSR[12] to catalyze breakthrough interdisciplinary research on midlife women's health. The program supports one-year collaborative awards that leverage expertise across NIH Institutes and Centers (ICs) while integrating mentorship to develop the next generation of women's health researchers. Reflecting strong scientific momentum in this field, ORWH funded five awards in Fiscal Year 2025 spanning eight ICs to investigate critical questions related to menopause, brain aging, gut microbiome, hot flashes, immune and metabolic health, and sleep quality.

For example, a recent NIH intramural study[13] examined how genes in the brain work differently in women and men and found thousands of genes that are switched on or off differently depending on sex. Many of these differences were linked to brain conditions that affect women more often, including Alzheimer's disease (AD), depression, and multiple sclerosis, and may help to explain why women are more vulnerable to these conditions, particularly during and after menopause. Together, these projects demonstrate how coordinated intramural science accelerates advances beyond the capacity of individual laboratories or ICs.

Long Term Health Trajectories

As women age, chronic diseases become increasingly important determinants of health, quality of life, and longevity. Recognizing that women experience many chronic conditions differently than men, ORWH has advanced an approach to examining how biological, hormonal, environmental, and social factors interact across the life course to influence disease risk and outcomes.

The ORWH-supported National Academy of Sciences, Engineering, and Medicine (NASEM)[14] report titled *Advancing Research on Chronic Conditions in Women*[15] identified critical evidence gaps and called for coordinated, large-scale, scientific investment to improve prevention, diagnosis, and treatment of chronic conditions in women. In response, ORWH launched targeted funding opportunities for both comprehensive research projects[16] and exploratory studies.[17] Recent awards are already advancing practical insights: for example, community-engaged approaches to improve cardiovascular health in rural regions, neuroendocrine research on menopausal symptoms such as hot flashes and sleep disruption, and data-science studies to better predict hypertensive disorders of pregnancy. By supporting interdisciplinary teams aligned with the missions of multiple NIH ICs, ORWH is expanding the evidence base upon which clinicians rely and is accelerating discoveries that improve health outcomes and quality of life for women across life stages. Building on this momentum, a new round of Women's Health Intramural Innovation Awards focused on chronic conditions is anticipated within NIH's Intramural Research Program[18] in 2026.

A National Office for Autoimmune Disease

Autoimmune diseases represent a major chronic health challenge across the life course, often emerging during women's reproductive and midlife years and contributing to long-term illness, disability, and reduced quality of life. Affecting up to 50 million Americans, these conditions disproportionately burden women, who account for nearly 80% of affected individuals. Recognizing both the magnitude of this burden and the need for coordinated scientific leadership, NIH established the Office of Autoimmune Disease Research (OADR-ORWH)[19] in 2023 under Congressional direction to coordinate and elevate autoimmune research across ICs.

Through a centralized framework that aligns NIH-wide priorities, integrates SABV, and fosters collaboration across diseases, OADR-ORWH is building the scientific infrastructure needed to accelerate discovery and transform the prevention, diagnosis, and treatment of autoimmune diseases, which disproportionately affect women. A landmark achievement of this effort is OADR-ORWH's leadership in developing and implementing the *NIH-Wide Strategic Plan for Autoimmune Disease Research (Fiscal Years 2026-2030)*,[20] creating a unified roadmap for advancing autoimmune research across NIH. OADR-ORWH has mobilized resources to strengthen critical research infrastructure, including defining Common data elements (CDEs)[21] that enable researchers across institutions to collect and compare data consistently. In partnership with NLM[22] and NIEHS,[23] OADR-ORWH supported development of CDEs for myositis core set activity measures, helping to accelerate research on this muscle-weakening autoimmune disease.

Turning Discoveries into Real-World Solutions for Women, Their Clinicians, and Their Families

ORWH has strategically invested in translating scientific discoveries into practical solutions that reach communities, overcome limitations of traditional research methods, and provide accessible information to those who need it most.

Women's Health Research in Institutional Development Award (IDeA) Program

The Women's Health Research Institutional Development Award (IDeA) Program,[24] created by ORWH in collaboration with NIGMS,[25] is expanding biomedical research capacity across America by strengthening research infrastructure in states that historically received lower levels of NIH funding. Many of these states include rural communities where women often face greater barriers to health care access and experience poorer health outcomes. ORWH, NIGMS, and 14 other NIH Institutes, Centers, and Offices (ICOs) have invested $35 million over the past six years, funding 21 of 23 IDeA States and Puerto Rico. This strategic investment is increasing access to clinical trials, supporting locally based researchers studying community-specific health challenges, generating STEM jobs, and creating new opportunities for aspiring scientists to pursue biomedical research careers in the regions they call home.

Science Spotlight: Building Centers of Excellence to Advance Women's Health

At the University of Kansas, Lawrence, ORWH-supported research through the Centers of Biomedical Research Excellence (COBRE) program is harnessing the power of big data to improve women's health. The Leveraging Big Data to Improve Women's Health[26] COBRE brings together experts from biomedical, behavioral, and social sciences to integrate health records, environmental data, and other large datasets to better understand the factors that shape women's health across the life course. A recent study[27] from this center illustrates the importance of this approach: researchers examining large-scale brain imaging in older adults at risk for AD found that the biological pathways driving early brain changes differ meaningfully between women and men. Because two-thirds of AD patients are women, these findings carry significant implications for prevention. Specifically, the study found that modifiable risk factors, including abdominal fat distribution, blood pressure, and blood glucose levels, were most strongly linked to brain changes in women, suggesting that these factors may be important targets for reducing postmenopausal AD risk. These results reinforce a core principle of COBRE's work: that sex must be treated as a critical variable in research, not just a background factor, to develop more effective prevention, diagnosis, and treatment strategies for women across the life course and across communities nationwide.



New Approach Methodologies and Artificial Intelligence

New Approach Methodologies (NAMs) are urgently needed to fill critical gaps in providing human-relevant models that accelerate discovery on conditions that remain difficult to understand, diagnose, and treat. NAMs use advanced technologies such as organ-on-chip systems, computational modeling, artificial intelligence (AI), machine learning, and human-derived cell cultures to reduce animal testing while providing human-relevant models that enhance our understanding of reproductive biology, hormonal systems, and other complex aspects of women's health. ORWH and DPCPSI[28] recently launched an innovative initiative[29] leveraging computational approaches and AI-enhanced multi-scale models to better understand how sex-specific hormone balance shapes health outcomes, including how drugs work in the body and why certain diseases affect women differently than men.

Science Spotlight: Building "Mini Organs" to Accelerate Treatments for Women's Health Conditions

Researchers at the Massachusetts Institute of Technology are leading the NAMs Technology Development Center for Women's Health,[30] bringing together experts from science, medicine, engineering, and industry to develop better ways to study conditions such as endometriosis, adenomyosis, heavy menstrual bleeding, and polyendocrine metabolic ovary syndrome (PMOS). Using advanced human-based models and computer tools, including miniature "organs in a dish" and connected organ system models, the center is creating more accurate ways to predict pain, treatment responses, drug safety, and metabolism while reducing reliance on animal testing. By advancing these innovative approaches toward broader clinical and commercial use, the initiative aims to accelerate the development of safer, more effective treatments for women's health conditions.

Creating and Maintaining Trusted Sources for Women's Health Information

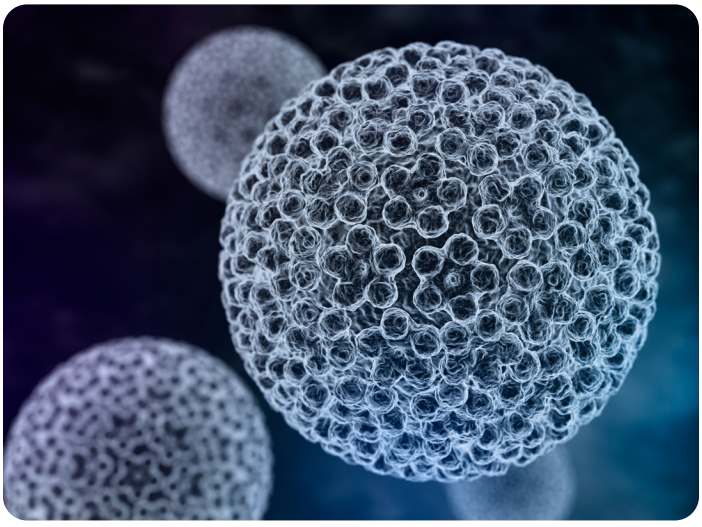


Access to accurate, evidence-based health information is critical. ORWH collaborated with NLM to launch Discover Women's Health Research (DiscoverWHR),[31] a centralized resource designed to increase visibility, accessibility, and public understanding of NIH-supported research on the health of women. The platform spans dozens of women's health research areas and brings together the latest scientific advances, funding opportunities, awarded research projects, clinical trials seeking participants, research literature, and evidence-based health information.

Beyond improving access to information, ORWH is also helping to strengthen the research infrastructure that supports scientific discovery. Recent enhancements to DiscoverWHR include expanded search functionality for chronic conditions and integration of CDEs, supporting NIH-wide efforts to improve data standardization, interoperability, and cross-study comparison.

To further translate research knowledge into practical learning opportunities, ORWH recently launched an E-Learning course on chronic conditions[32] in women to help researchers, clinicians, and the public better understand the complex and often interconnected health challenges women face across the life course. By connecting patients, clinicians, researchers, and the public to evidence-based information, these resources demonstrate the real-world impact and public health value of women's health research while supporting informed decision-making, collaboration, and scientific discovery.

Simplifying Cervical Cancer Prevention for Resource-Constrained Settings



Cervical cancer disproportionately affects women in resource-constrained settings where prevention programs are more difficult to implement. ORWH-supported research, funded through NIH's in-house research program and led by Aimée Kreimer, Ph.D., at NCI,[33] led to a game-changing discovery[34]: a single dose of the human papillomavirus (HPV) vaccine was as effective as two doses in providing protection against cervical cancer. One immunization can help prevent cervical cancer while reducing costs and simplifying delivery in communities with limited health care infrastructure. This breakthrough exemplifies how rigorous research can transform barriers to care into opportunities for prevention, giving more women access to protection against a leading cancer threat.

Ensuring That Research Reflects Real Experiences and Differences Between Women and Men

ORWH has helped to strengthen biomedical research by advancing approaches that incorporate sex differences and reflect the real-world complexity of women's health.

Advancing Pain Research for Women

Pain affects women and men differently, yet much of what we know about pain mechanisms and treatments comes from limited understanding of sex differences. Women experience higher rates of chronic pain conditions, respond differently to pain medications, and face unique challenges in pain management.

Through the NIH-wide Helping End Addiction Long-term® (HEAL) Initiative,[35] ORWH partnered with NIDA[36] and NINDS[37] on research that is already transforming pain management for women. Within the Pain Management Effectiveness Research Network,[38] researchers tested an intervention enabling women to personalize their pain relief strategy following cesarean section surgery, resulting in fewer opioid prescriptions without sacrificing pain control. This finding offers a practical pathway to reduce opioid exposure for new mothers without compromising their comfort during recovery. Additionally, HEAL researchers developed and tested an adapted behavioral pain coping skills intervention for people with end-stage kidney disease undergoing long-term dialysis, reducing the extent to which pain affected daily activities, mood, and relationships. Together, these studies demonstrate how understanding sex-specific pathways can lead to more effective, personalized pain management strategies without impacting quality of life.

A Broad Scientific Ecosystem Advancing Sex-Informed Biomedical Research

One of ORWH's flagship achievements is the establishment and expansion of the SCORE program, a unique national resource dedicated to sex differences research. Since its inception, the SCORE program, along with 10 IC partners and the FDA,[39] is reshaping biomedical research by revealing how sex differences influence health and disease and why a one-size-fits-all approach to medicine is insufficient, across conditions ranging from cardiovascular disease to neurological disorders and cancer.

Science Spotlight: Redefining "Normal" Blood Pressure: Clinical Implications for Women's Cardiovascular Risk

In a landmark study[40] of more than 27,000 participants, SCORE researchers at Cedars-Sinai Medical Center demonstrated that women's cardiovascular risk begins at systolic blood pressure levels as low as 100–109 mm Hg, more than 20 mm Hg lower than in men. Notably, women with readings of 110–119 mm Hg faced similar heart attack risk to men with readings above 160 mm Hg, challenging the long-standing threshold of 120 mm Hg. These findings suggest that uniform blood pressure thresholds may delay treatment for women and underscore the need for sex-specific clinical guidelines to improve prevention and risk assessment in both sexes.

Supporting the Scientists Behind the Science

Great science requires great scientists. ORWH's strategic investments in developing the next generation of women's health researchers recognize that building research capacity means investing in people, their training, their career development, and their sustained success.



Investing in the Next Generation of Women's Health Researchers

Created by ORWH in 2000 in partnership with 11 ICOs, the Building Interdisciplinary Research Careers in Women's Health (BIRCWH)[41] program is a mentored career-development program designed to expand the cadre of women's health researchers across the country. It connects junior faculty, known as BIRCWH Scholars, with senior investigators who share interests in women's health and sex differences research. Since its creation, 894 early-career BIRCWH Scholars have been funded at 47 institutions in 28 states, with ORWH and its NIH partners contributing more than $15 million per year to support this program. A 2026 NIH-VA BIRCWH partnership[42] further expanded the program's reach by integrating VA researchers and extending its impact to the military veteran population.

Science Spotlight: BIRCWH Scholar Identifies the Critical Week After Childbirth When Blood Pressure Peaks

ORWH's BIRCWH program is producing research that is helping to save mothers' lives. BIRCWH Scholar, Alisse Hauspurg, M.D., discovered[43] that greater than 80% of women who develop high blood pressure during pregnancy continue to experience unsafe levels after leaving the hospital, with blood pressure peaking three to seven days after delivery, precisely when women are home and most vulnerable. This research is transforming postpartum care nationwide by strengthening the evidence for remote monitoring programs, earlier medication initiation, and more intensive follow-up during this critical window.



Training the Next Generation of Leaders in Autoimmune Diseases: The Leadership Scholars Program

While BIRCWH supports early-career scientists, the Team Science Leadership Scholars Program (LSP),[44] supported by ORWH, helps mid-career scientists who study autoimmune and immune-related diseases by providing salary support and protected time to focus on their research.

As part of the Accelerating Medicines Partnership® Autoimmune and Immune-Mediated Diseases (AMP® AIM)[45] initiative, the LSP trains scientists to lead large, collaborative research teams within one to two years. To date, 10 AMP AIM LSP projects have been funded in collaboration with ODSS.[46] Current scholars are tackling some of the most pressing questions in autoimmune disease research, including developing novel computational AI methods to decipher the sex-biased biological factors that account for the striking imbalance in autoimmune disease rates between women and men. Other scholars are working to identify biomarkers that can predict patient responses to treatment before therapy begins, ending the frustrating trial-and-error cycle many women with rheumatoid arthritis and lupus endure. This program plays an important role in advancing AMP AIM's mission to better understand complex immune-mediated conditions and improve patient care.

Supporting Innovation Through Small Business: SBIR/STTR Programs

Small businesses are essential partners in advancing women's health, bringing innovative solutions from concept to clinical reality. ORWH participated in a funding announcement for small businesses, strategically prioritizing women's health research through a collaborative funding opportunity with the FDA, CDC,[47] and America's Seed Fund at NIH. Through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR)[48] programs, ORWH supports small businesses developing breakthrough technologies for women's health challenges, helping promising discoveries reach the market and ultimately patients.

Science Spotlight: Simple Blood Test Replaces Invasive Biopsies: Faster Diagnosis for Disease Affecting Women

Through investment in small business innovation, ORWH supported Kephera Diagnostics, LLC[49] in developing a new blood test for sarcoidosis,[50] a complex inflammatory disease that impacts women at higher rates. Until now, many patients required invasive biopsies and lengthy testing, delaying treatment while the disease causes lasting organ damage. This new test uses a simple blood draw to enable earlier detection, benefiting an estimated 200,000 Americans living with sarcoidosis, many of whom have waited years for an accurate diagnosis and appropriate care.

Continuing a Legacy of Advancing Research on the Health of Women at NIH



Impact and Leadership

True leadership in women's health requires both vision and sustained investment.

Since its establishment in 1990, ORWH has directed resources to areas where they will have the most significant impact, driving groundbreaking discoveries that are fundamentally changing how we prevent and treat disease in women. Under the successive leadership of Dr. Vivian Pinn and Dr. Janine Clayton, ORWH has built a legacy of scientific excellence, policy influence, and program innovation that has reshaped the landscape of women's health research at NIH and beyond. The impact of this legacy is now showcased in "Women at the Helm,"[51] a new exhibit at the NIH Office of NIH History & Stetten Museum[52] that chronicles ORWH's history and its pivotal role in advancing women's health research.

Under Dr. Clayton's leadership, ORWH has expanded its scientific reach, forged new partnerships across federal agencies, and championed fundamental changes in how biomedical research is conducted. Over more than three decades, ORWH has not only advanced scientific knowledge but has reshaped the research environment itself, strengthening how studies are designed and translated so that discoveries lead to better health outcomes for all women. ORWH's reach extends beyond NIH through strategic partnerships that bring together researchers, clinicians, policymakers, and other stakeholders. In partnership with the Uniformed Services University,[53] ORWH supported the Military Women's Health Webinar Series, a national forum advancing research on the unique health needs and medical readiness of female service members across areas including brain health, mental health, cardiovascular disease, and reproductive health.

As ORWH looks to the future, its mission remains clear: to advance rigorous, evidence-based research that improves health outcomes for women across the life course. ORWH will continue to integrate SABV throughout biomedical research, advance innovative technologies and interdisciplinary science, and ensure that scientific discovery reflects the full breadth of human biology and experience.

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Abbreviations

AI	artificial intelligence
AD	Alzheimer's disease
AMP® AIM	Accelerating Medicines Partnership® Autoimmune and Immune-Mediated Diseases
BIRCWH	Building Interdisciplinary Research Careers in Women's Health
CDC	U.S. Centers for Disease Control and Prevention
CDEs	common data elements
COBRE	Centers of Biomedical Research Excellence
DiscoverWHR	Discover Women's Health Research
DPCPSI	NIH Division of Program Coordination, Planning, and Strategic Initiatives
FDA	U.S. Food and Drug Administration
HEAL	Helping End Addiction Long-term® Initiative
HPV	human papillomavirus
ICs	NIH Institutes and Centers
ICO	NIH Institutes, Centers, and Offices
IDeA	Institutional Development Award
LSP	Team Science Leadership Scholars Program
NAM	New Approach Methodologies
NASEM	National Academies of Sciences, Engineering, and Medicine
NCI	National Cancer Institute
NIDA	National Institute on Drug Abuse
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
NLM	National Library of Medicine
OADR-ORWH	Office of Autoimmune Disease Research
OBSSR	Office of Behavioral and Social Sciences Research
ODP	Office of Disease Prevention
ODSS	Office of Data Science Strategy
OIR	Office of Intramural Research
ORWH	Office of Research on Women's Health
PMOS	polyendocrine metabolic ovarian syndrome
P2P	Pathways to Prevention
SABV	Sex as a Biological Variable
SBIR	Small Business Innovation Research
SCORE	Specialized Centers of Research Excellence on Sex Differences
STTR	Small Business Technology Transfer
VA	U.S. Department of Veterans Affairs

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