



63rd Meeting of the NIH Advisory Committee on Research on Women's Health

Janine Austin Clayton, M.D., FARVO

NIH Associate Director for Research on Women's Health
Director, Office of Research on Women's Health
National Institutes of Health

Director's Report – June 17, 2025



Agenda



1

Opening
Remarks

2

NIH and ORWH
Updates

3

Scientific
Updates

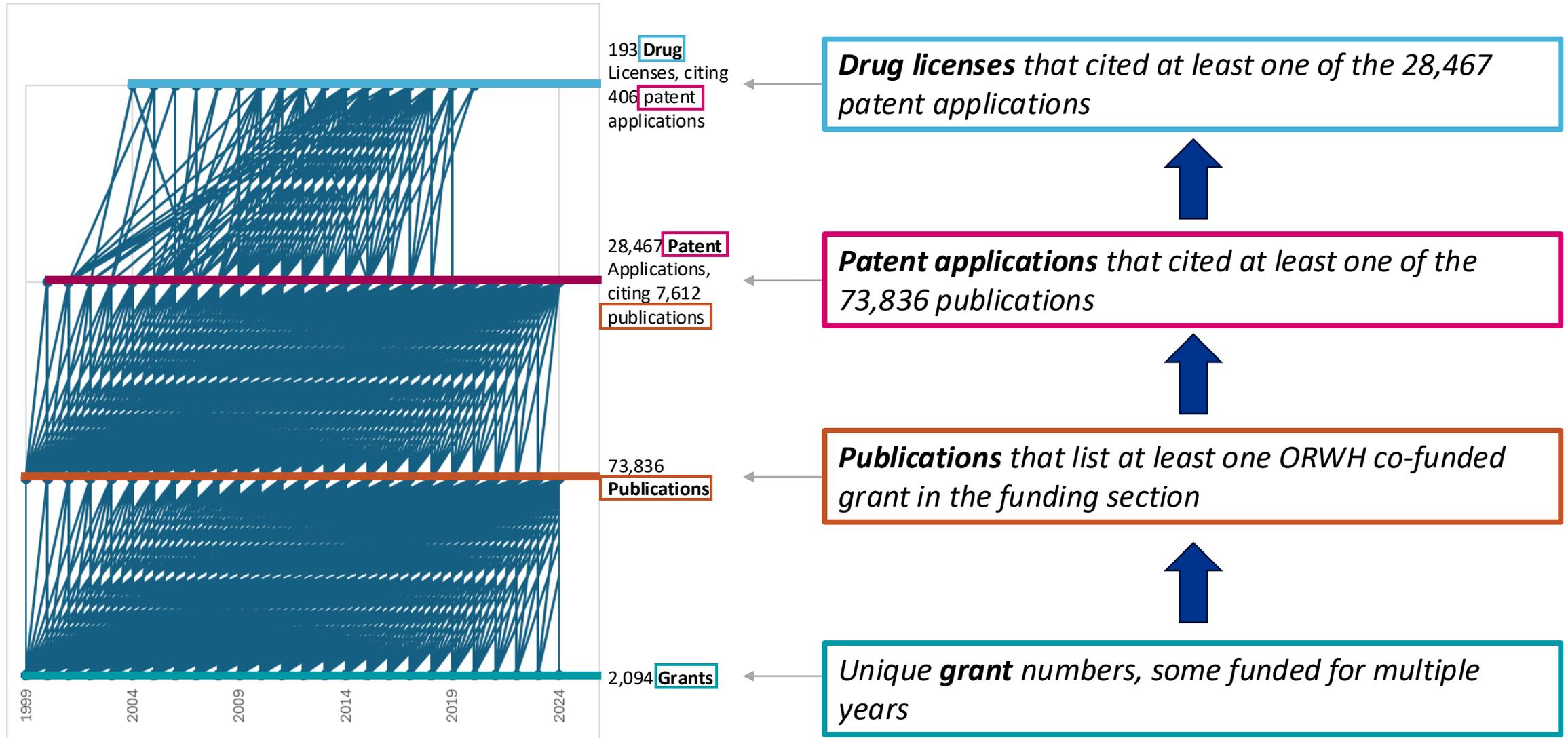
4

ORWH Program
Updates

5

Closing

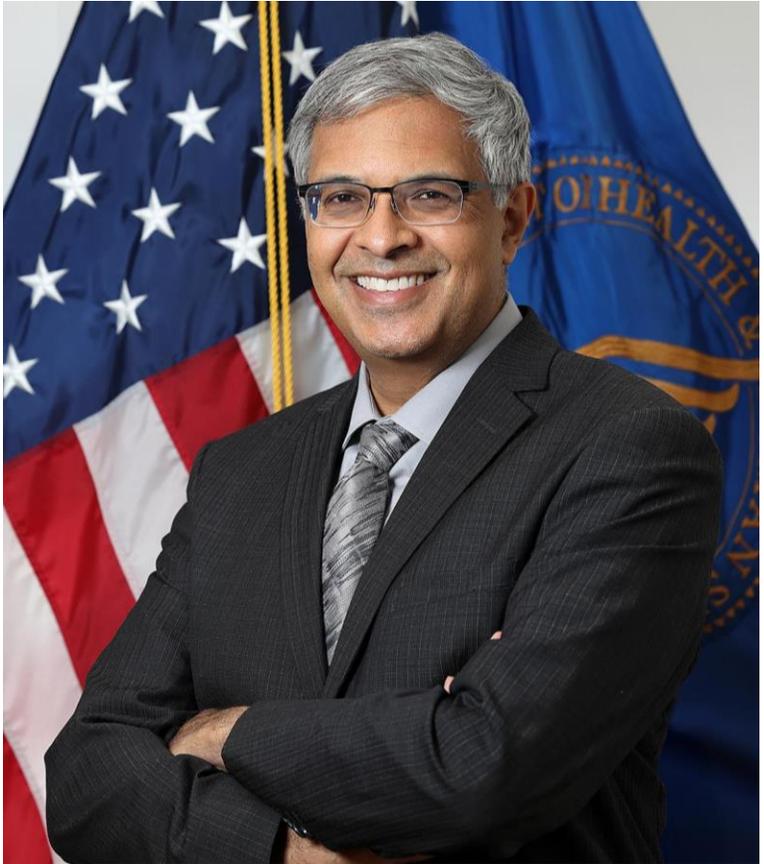
Impact of ORWH Co-funding Research For Over Two Decades





NIH and ORWH Updates

NIH Recently Welcomed the 18th Director



Jay Bhattacharya, M.D., Ph.D.
Director of the National Institutes of Health



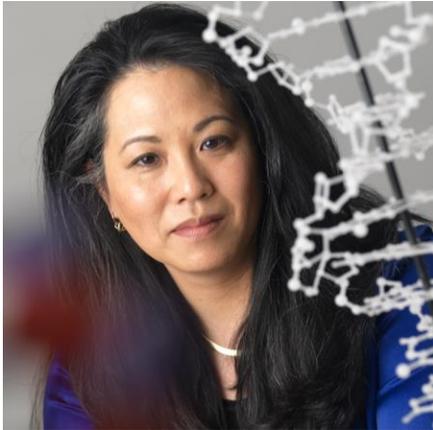
Matthew J. Memoli, M.D., M.S.
Principal Deputy Director of the National Institutes of Health



Nicole Kleinstreuer, Ph.D.
Acting NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives



Carolyn M. Hutter, Ph.D.
Director, Office of Strategic
Coordination is serving as the
Acting Director, National Human
Genome Research Institute



Vivian Ota Wang, Ph.D., FACMG, CGC
Deputy Director, ORWH is serving as the
Acting Director, Office of Strategic
Coordination



Cindy L. Caughman, M.P.H.
Director of Strategic Engagement,
Office of Portfolio Analysis is serving
as the Acting Deputy Director, ORWH



Scientific Updates

ORWH Leads Efforts to Address Trends In Women's Health Research

JAMA | Special Communication | **WOMEN'S HEALTH**

Recent Developments in Women's Health Research at the US National Institutes of Health

January 6, 2025



As of June 9, 2025 - 8,411 Views | 23 Altmetric

- Historically, women's health research focused on reproductive health and female-specific conditions
 - Now it is expanded to encompass **all aspects of the health of women**
- Novel insights about how diseases and conditions affect women **uniquely, differently, or disproportionately**
- Translation from basic science to **practical benefits**
- Examples of every IC's efforts to **improve the health of women**



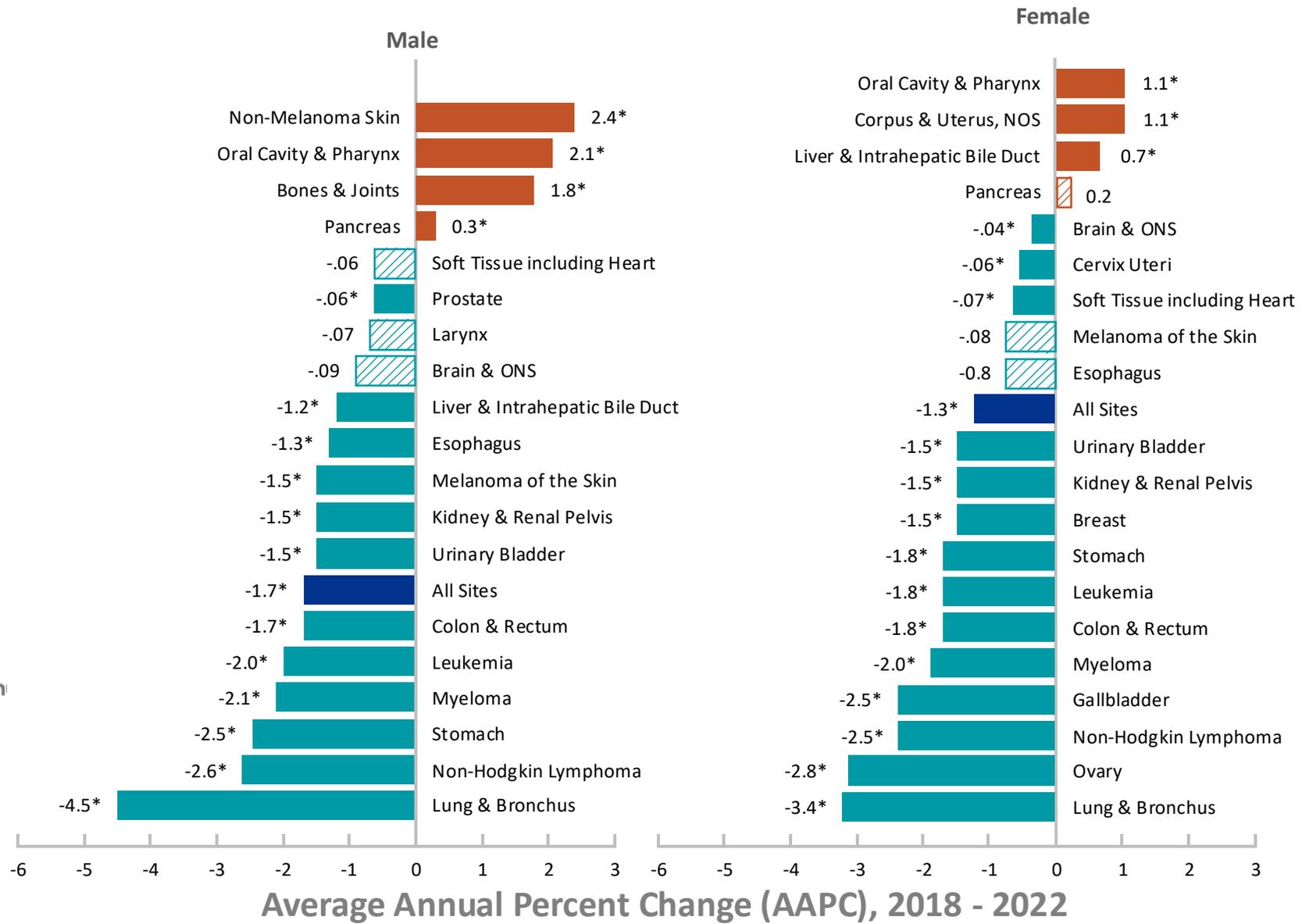
Key NIH programs, policies, and scientific advances discussed on **JAMA Clinical Reviews** podcast with Dr. Kirsten Bibbins-Domingo

2025 Report Shows Cancer Death Rates Decline Steadily

- Falling cancer death rates in both men and women show different patterns
 - **12 of the 19** most common cancers **in men** showed decreases in mortality
 - **14 of the 20** most common cancers **in women** showed decreases in mortality
- Rates of new cancer cases increased at sites associated with excess body weight
 - Including **female breast, uterus, colon and rectum** among adolescents and young adults, **pancreas, kidney, and liver** among women
- Rising rates of estrogen receptor-positive breast cancer
 - Driven by reduction in fertility rates, advancing age at first birth, and rises in obesity and alcohol consumption
- Rates of new cases and deaths from **uterine cancer** increased



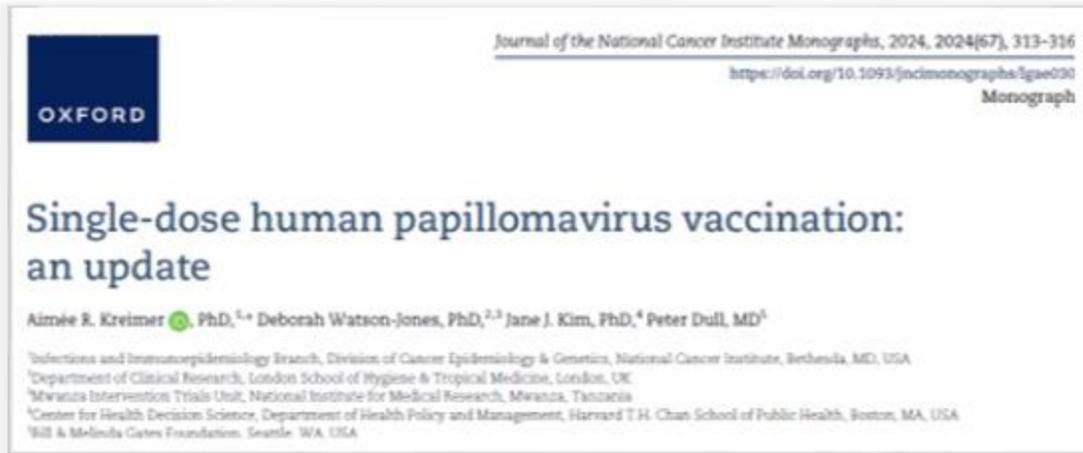
National Trends in Cancer Death Rates



*AAPC is significantly different from zero (p<0.05)

seer.cancer.gov
Source: Annual Report to the Nation

Long Term NIH Investment In Basic Science Related to Virology and Human Disease Pays Off with Effective Single-Dose Intervention



- Leverages long time collaboration
- Demonstrates significant return on investment
- Accelerates cervical cancer prevention by minimizing patient burden while maintaining vaccine effectiveness
- Addresses differences in access to cervical cancer prevention resources

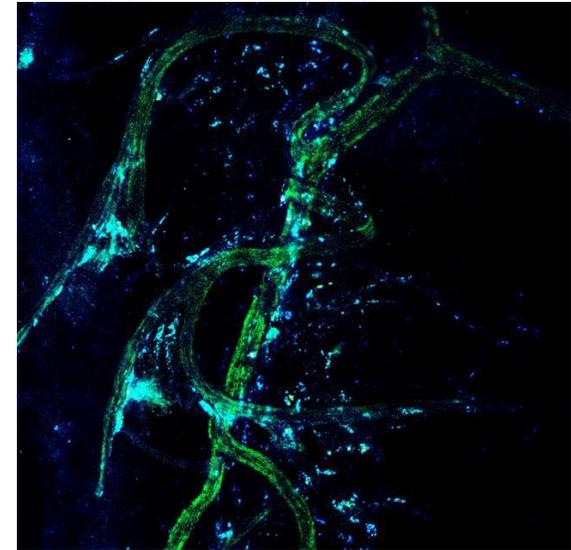
Gene Expression Patterns Differ in Male and Female Placentas

- DNA methylation patterns of male and female placentas **vary markedly** in how they are expressed
- 2,497 previously unreported DNA sites with different methylation patterns
- Increases in methylation associated with
 - Male placentas: greater neonatal size
 - Female placentas: greater placental size
- Differences in placental function underlie pregnancy complications and set the stage for differences in male and female health later in life
- Conducted by NICHD in collaboration with other institutions



Novel Role for Regulatory T Cells in Sex-Specific Pain Suppression

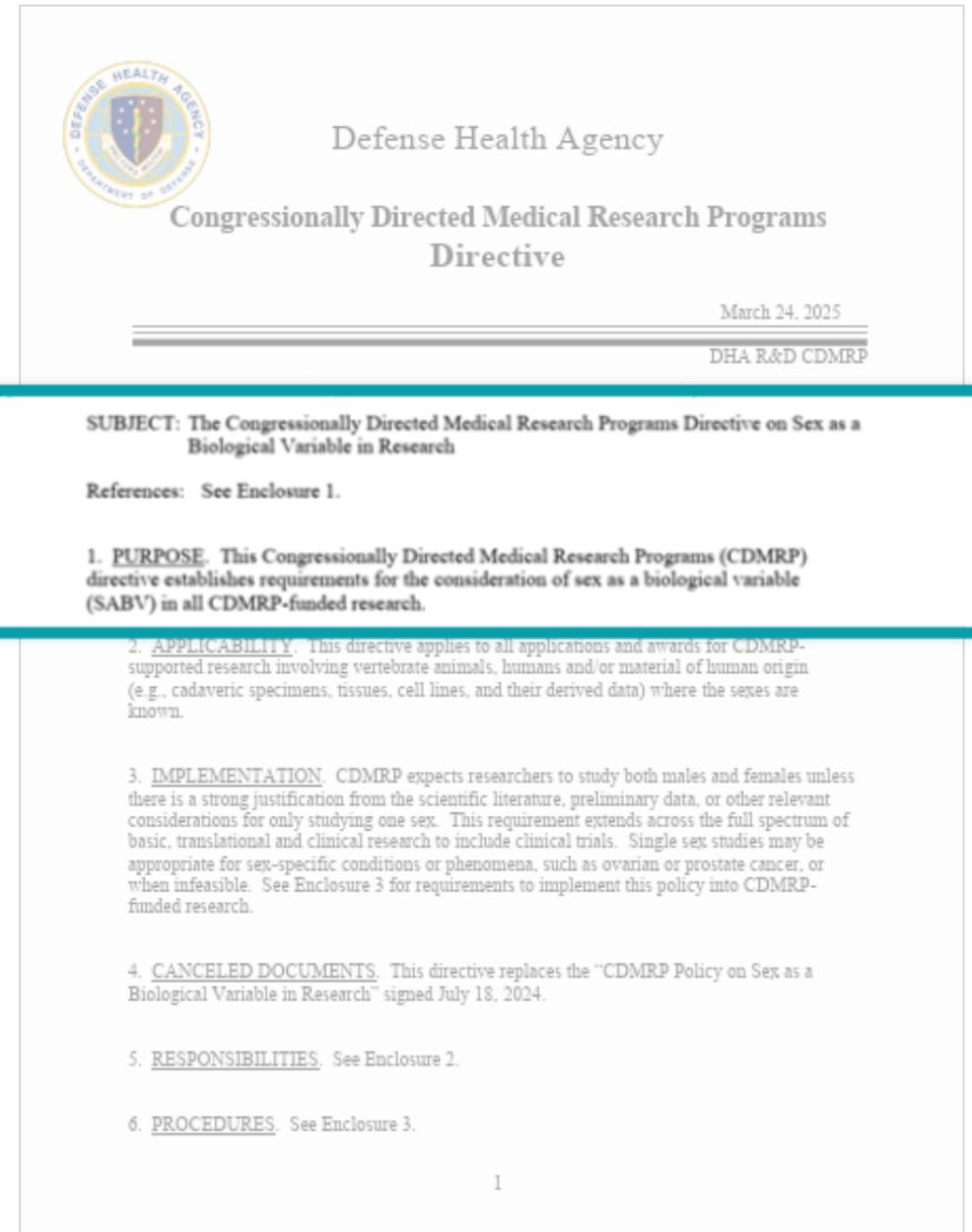
- Evidence suggests that **T cells** may contribute to pain processing **differences between women and men**
- Regulatory T (T_{reg}) cells are controlled by a gene located on the **X chromosome**
- Primary scientific results
 - T_{reg} cells inhibit nociception in a sex-specific way
 - Depleting meningeal T_{reg} (mT_{reg}) cells increased sensitivity to a specific type of pain in female mice, but not male mice
 - Some mT_{reg} cells produced an analgesic compound with anti-nociceptive action called **enkephalin**. Female mice had more enkephalin-producing mT_{reg} cells than male mice
 - Injection of interleukin-2 increased mT_{reg} levels and decreased pain sensing in female mice
- T_{reg} cells may be key regulators of sex-specific nociceptive mechanical pain sensation and explain why men and women **differ in their sensitivity to pain**



Funded in part by NIH's: National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Congressionally Directed Medical Research Programs Released Directive on Sex as A Biological Variable

- This Congressionally Directed Medical Research Programs (CDMRP) Directive establishes requirements for the consideration of **Sex as a Biological Variable** in all CDMRP-funded research
- Extends across the full spectrum of basic, translational, and clinical research to include clinical trials



Adoption of SABV to Advance Women's Health Research Worldwide

SCIENCE ADVANCES | FOCUS

WOMEN'S HEALTH

The power—and complexity—of policy to drive advances in women's health

Bronwyn M. Graham^{1,2*}, Cara Tannenbaum³, Alice Witt⁴, Keziah Bennett-Brook¹, Sue Haupt¹, Kate Womersley⁴, Séverine Lamon⁵, Robyn Norton^{1,4}

March 5, 2025

- Sex characteristics may include:
 - Chromosomes, hormones, or sex organs
- North American sex research policies have seen an almost 3X increase in the proportion of mixed-sex studies compared to single-sex studies
- Inclusion is not synonymous with consideration
- SABV policies exist in:
 - Canadian Institutes for Health Research (2006)
 - Horizon Europe (2014)
 - US National Institutes of Health (2016)
 - United Kingdom (coming soon)

Regenerative Medicine Enhances Women's Health

The Intersection of Regenerative Medicine and Women's Health: Proceedings of a Workshop— in Brief (2025)

CONTRIBUTORS

Michelle Drewry, Theresa M. Wizemann, and Sarah H. Beachy, Rapporteurs; Forum on Regenerative Medicine; Forum on Temporomandibular Disorders; Board on Health Sciences Policy; Health and Medicine Division; National Academies of Sciences, Engineering, and Medicine



Photo Credit: <https://nap.nationalacademies.org/resource/29088/interactive/>

- Regenerative medicine: bridge gaps to better understand role of sex in health and disease, translate knowledge into improved clinical care
 - Clinical trials
 - Women in the biomedical workforce
 - Reporting of data by sex
 - Research on women
 - Sex as a Biological Variable
- Collaboration with Department of Defense

Regenerative Medicine Enhances Women's Health

Ideas to Advance the Development of Regenerative Medicine Therapies for Women's Health

- Better understanding of underlying biology
- Impact of sex and hormones on regenerative medicine
- Model systems (i.e., cellular, microphysiologic systems)
- Multidisciplinary approaches
- Emerging therapies to target the causes of disorders that affect women



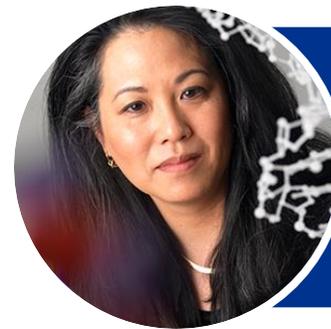
"Now that patients with diseases such as sickle cell are living longer, more attention is needed beyond survival to quality of life concerns, like reproductive and maternal health."

Teonna Woolford
Co-founder and Chief Executive Officer
Sickle Cell Reproductive Health Education Directive
<https://sicklecellred.org>



"Increased research on the female hormonal milieu across the lifespan and on hormonal conditions in cell cultures and their influence on cellular responses is needed."

Monica Laronda, Ph.D.
Assistant Professor
Department of Pediatrics
Ann and Robert H. Lurie Children's Hospital of Chicago and
Northwestern University



"Sex influences the care and treatment that women receive and how they experience health and disease."

Vivian Ota Wang, Ph.D.
Deputy Director
NIH Office of Research on Women's Health



ORWH Program Updates

2025 Vivian W. Pinn Symposium Highlights Data-Driven Innovation

Advancing Data-Driven Innovation for the Health of Women

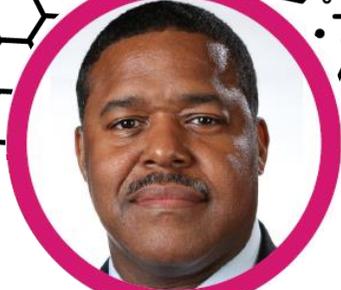
9TH ANNUAL
VIVIAN W. PINN
SYMPOSIUM

MAY 15, 2025

Panel Speakers



Melissa Buffalo, M.S.
CEO, American Indian
Cancer Foundation



Alex Carlisle, Ph.D.
Founder, Chairman, and CEO,
National Accelerator for Discovery
in Precision Health



Pilar Ossorio, Ph.D., J.D.
Professor of Law and
Bioethics, University of
Wisconsin-Madison



Rochelle Prosser, R.N., CLNC
Founder,
Orchid Healthcare Solutions

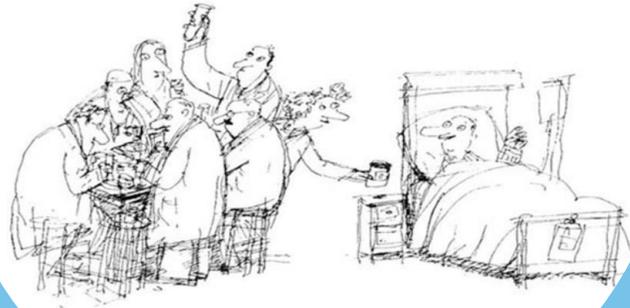


Liat Shenhav, Ph.D.
Assistant Professor,
NYU Grossman School of
Medicine

Videocast URL: <https://orwh.od.nih.gov/events/9th-annual-vivian-w-pinn-symposium#event--videocast>



NIH Promotes Intramural and Extramural Collaborations: Bench-to-Bedside and Back Program (BtB)



- Established in 1999 to seed new partnerships between basic science and clinical investigators; in 2006, added extramural collaborations
- Allows investigators to move into new fields and broaden scientific approaches, especially for trans-NIH projects and external collaborations
- **Since 2006, ORWH co-funded 19 BtB projects at \$4.95M**
 - Co-funding with NIH Director, Deputy Director for Intramural Research, other ICOs
- Improving women's health through biomedical and behavioral research aligned with the NIH-Wide Strategic Plan for Research on the Health of Women

2023

Novel Gut Microbiome Factors in Pregnancy & Early Childhood: ETCHED Study

NIDDK: Madhumita Sinha
NIAID: Suchitra Hourigan

ORWH Leads NIH Women's Health Research (WHR) Scientific Interest Group (SIG) to Share Research Insights

Panel Discussion

2025
June 10

Convenes the NIH community around updates and developments in women's health research

SPEAKERS



Madhumita Sinha, M.D.

Assistant Clinical Investigator, Head of the Diabetes Epidemiology & Clinical Research Section, Phoenix Epidemiology & Clinical Research Branch Intramural Research Program, NIDDK

Presentation

"Impact of obesity and diabetes in pregnancy on the gut microbiome & long-term maternal/offspring metabolic health"



Suchitra Hourigan, M.D.

Chief, Clinical Microbiome Unit (CMU), Lasker Clinical Research Scholar, NIAID

Presentation

"Shaping The Early Life Microbiome To Improve Future Health"

MODERATOR



Balkissa Ouattara, M.D., Ph.D., MPH

Medical Officer, Office of Research on Women's Health (ORWH), DPCPSI

THE NIH OFFICE OF RESEARCH ON WOMEN'S HEALTH AND THE
USU MILITARY WOMEN'S HEALTH RESEARCH PROGRAM
PRESENT:

The Military Women's Health Webinar Series

Menopause and Midlife Health



2025
JUNE
12

PM
3-4



For More Information:

<https://orwh.od.nih.gov/events/menopause-and-midlife-health-webinar#event--event-information>



Miranda Janvrin, MPH

Research Associate & Doctoral Student
The Henry M. Jackson Foundation for
the Advancement of Military Medicine
& Uniformed Services University of
the Health Sciences

*The Experiences of Mid-Life Active
Duty Service Women Accessing
Treatment for Menopausal Symptoms:
A Pilot Study*



Hadine Joffe, MD, MSc

Executive Director
Mary Horrigan Connors Center for
Women's Health and Gender
Biology
Brigham and Women's Hospital

*Centrality of sleep and mood in
optimizing health and function for
midlife women across menopause*

ORWH Efforts Promoted Across NIH Institutes, Centers, and Offices

May 14, 2024

**National Library of
Medicine Board of Regents**

May 15, 2024

**National Institute of
Biomedical Imaging and
Bioengineering
Advisory Council**

June 13-14, 2024

**128th NIH Advisory
Committee to the
Director**

September 18-19, 2024

**National Advisory Council
on Aging**

October 30, 2024

**National, Heart, Lung, and
Blood Institute Advisory
Council**

NIH Pain Consortium Meeting Highlights Sex Differences

The annual NIH Pain Consortium Symposium highlights recent and important advances in pain research by NIH and other Federal Agencies

- Sex differences in pain
- Differences in access to pain management and care
- Pain across the lifespan

Videocast URL: <https://videocast.nih.gov/watch=54765>

2024
May 30-31



New Approach Methodologies (NAMs) Generate Scientific Advances to Improve Human Health



The Molecular Transducers of Physical Activity Consortium

This ten-year program is the largest targeted NIH investment of funds into the mechanisms of how physical activity improves health and prevents disease



National Center for Advancing Translational Sciences

A Translational Center for Microphysiological Systems-Based Drug Development Tools for Pregnancy and Women's Health

Texas A&M, College Station & University of Texas Medical Branch Galveston



National Institute of Mental Health

Explainable **artificial intelligence** research, including for the design and testing of **computational models** to imitate sex differences in clinical phenotypes

NOT-MH-23-110



National Institute of Dental and Craniofacial Research

In September 2024, NIDCR Advisory Council cleared a concept titled **Digital Twins** for Advancing Innovation and Optimizing Clinical Outcomes in Dental, Oral, and Craniofacial (DOC) Medicine

Accelerating Women's Health Through Strategic Partnerships

DiscoverWHR

- ORWH & NLM resource
- Centralized breakthroughs and funding opportunities
- Additional topics coming soon
- Reached over 40 countries

National Health Interview Survey Menopause Questions

- ORWH & CDC collaboration
- Reaches over 35K households in the US

Menopause Pathways to Prevention (P2P)

- Focus on midlife health and menopause
- Prioritization of future research areas based on open scientific discourse

Small Business (SBIR/STTR) Funding Opportunity Extended

- NIH, CDC, FDA collaboration
- September 6, 2025

SABV Simplified Review Framework

- Supports SABV policy implementation
- Rigor and reproducibility

NIH Shared Instruments Play Significant Roles in Supporting Research on Women's Health

- NIH funds the S10 Shared Instrumentation Program
- Collaboration with The Office of Research Infrastructure Programs (ORIP)
- Pivotal role in enabling basic, translational, and clinical research on women's health
- **1,032 publications relevant to women's health from FY22-FY24**
- S10 Program overview video available at <https://www.youtube.com/watch?v=5DmxfqqmB38>

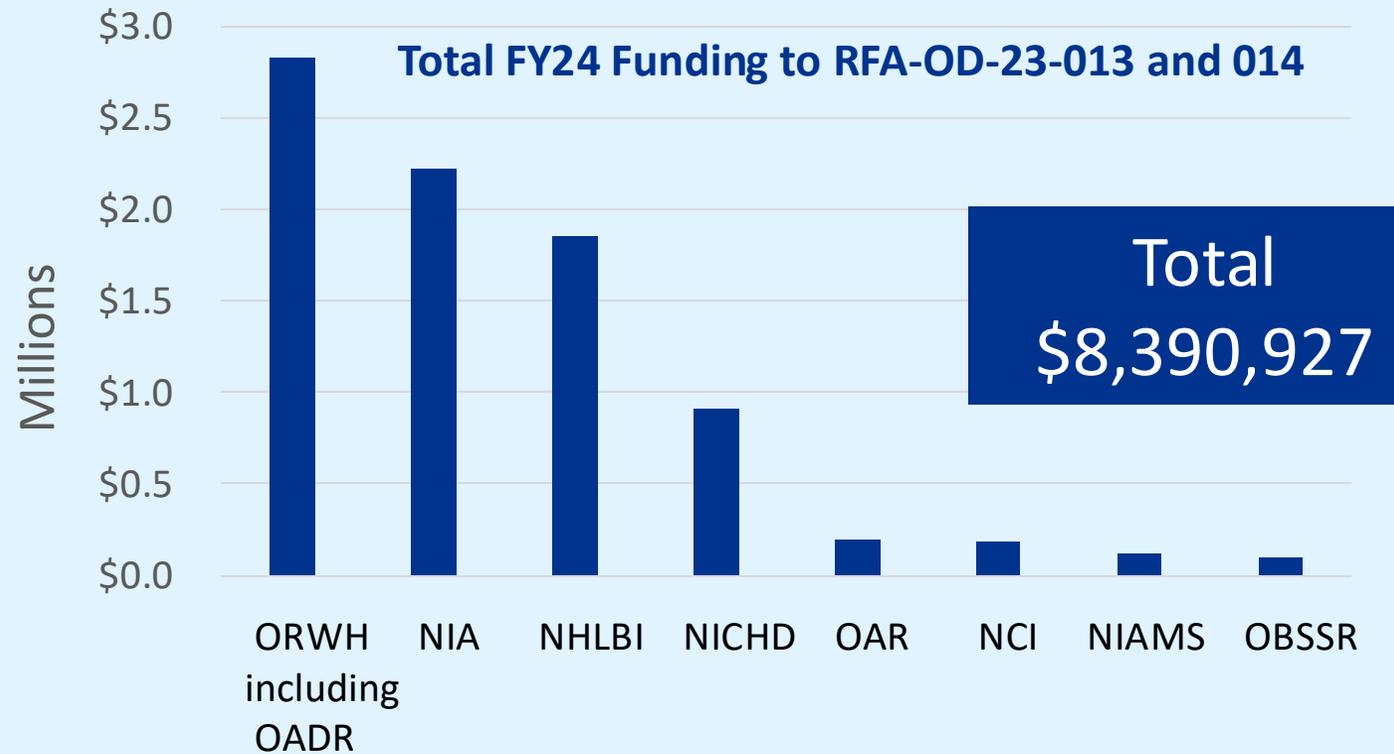




Chronic Disease Research Efforts

ORWH and ICO Partners Collaborate to Fund Studies of Chronic Diseases in Women

- Funding opportunities for Understanding Chronic Conditions Understudied Among Women (R01, R21)
- ORWH (including OADR-ORWH) and 7 other ICOs funded 21 awards
 - NCI, NHLBI, NIA, NICHD, NIDDK, NIAMS, OD
 - 9 R01 awards; 12 R21 awards



Addressing the Gaps in Understudied Chronic Disease Research



Dajiang Liu, Ph.D., M.A.
Pennsylvania State University

Multi-omic Characterization of Chronic Obstructive Pulmonary Disease in Females (NHLBI- and ORWH-funded)



William Krause, Ph.D.
University of California, San Francisco

Targeting Estrogen-Sensitive Hypothalamic Neurons to Reverse Frailty in Aging Females (NIA- and ORWH-funded)



Karen Reue, Ph.D.
University of California, Los Angeles

A Sex-Biased Obesity Gene on the X Chromosome (NIDDK- and ORWH-funded)

NHLBI

- Aortic Stenosis
- Cardiovascular Disease Prevention
- Chronic Obstructive Pulmonary Disease
- Heart Failure with Preserved Ejection Fraction (HF-PEF)
- **Menstrual Disorders***
- **Polycystic ovarian syndrome***

NICHD

- **Adenomyosis***
- **Endometriosis (2)***
- *HIV infection*
- *Intimate partner violence*
- **Pelvic floor disorders***

* Female-specific conditions

NIA

- Cardiovascular Disease
- Depression
- Eating Disorders
- Frailty and Aging
- **Genitourinary syndrome of menopause***

NCI

- HPV infection
- **Radiotherapy-induced vaginal toxicity***

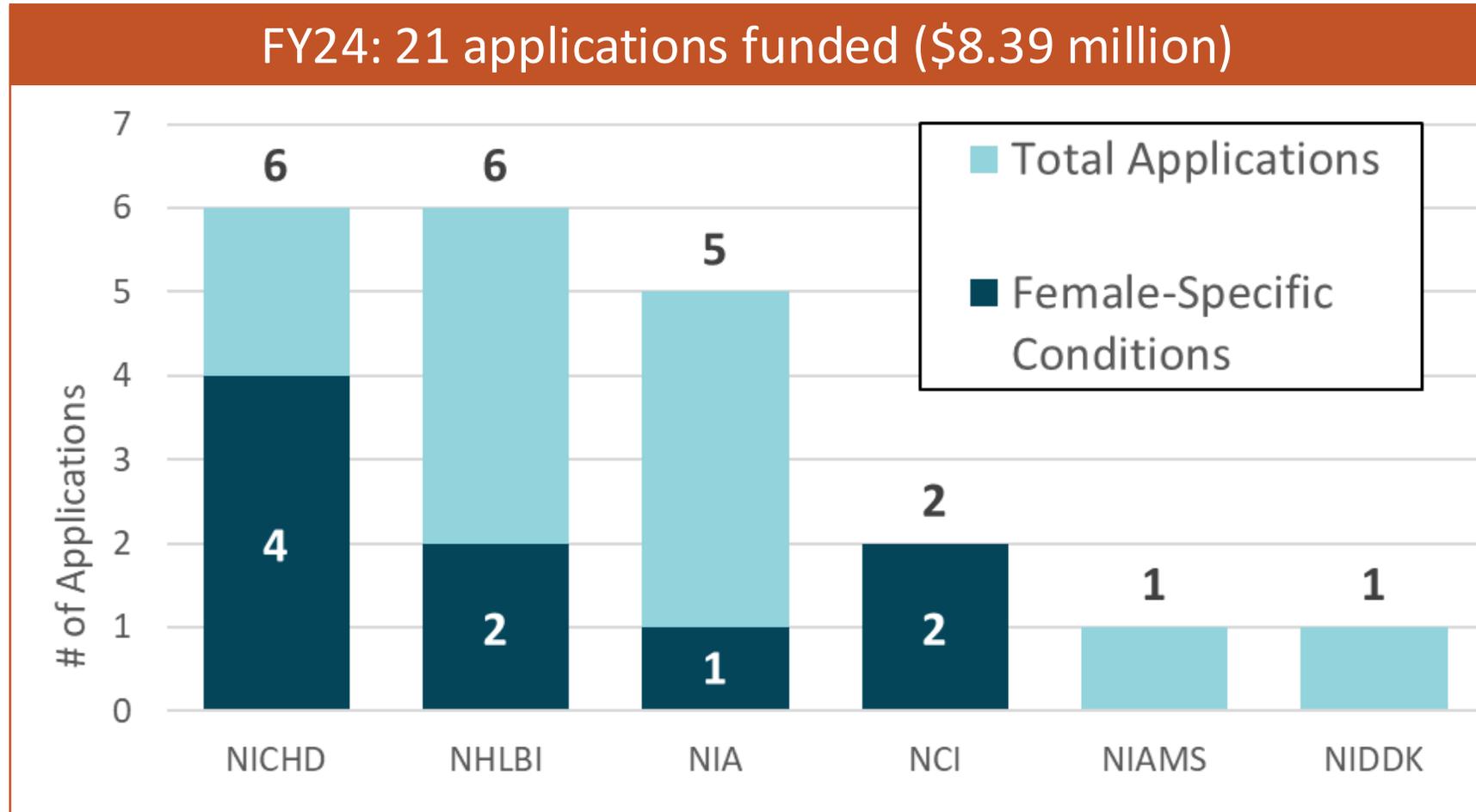
NIDDK

- Obesity

NIAMS

- Systemic lupus erythematosus

Addressing the Gaps in Understudied Chronic Disease Research



ORWH, including OADR funding: 10 applications, \$2.8M total

OSSD 19th Annual Meeting Features SCORE Program Research Insights

Association between Social Determinants of Health and Disease Outcomes and Symptoms in Women

Chair and Moderator:

Rajeev Kumar Agarwal, Ph.D., ORWH

“SCORE program on sex differences to promote discoveries of women’s health research and their translation to the human population”



The Organization for the Study of Sex Differences (OSSD)

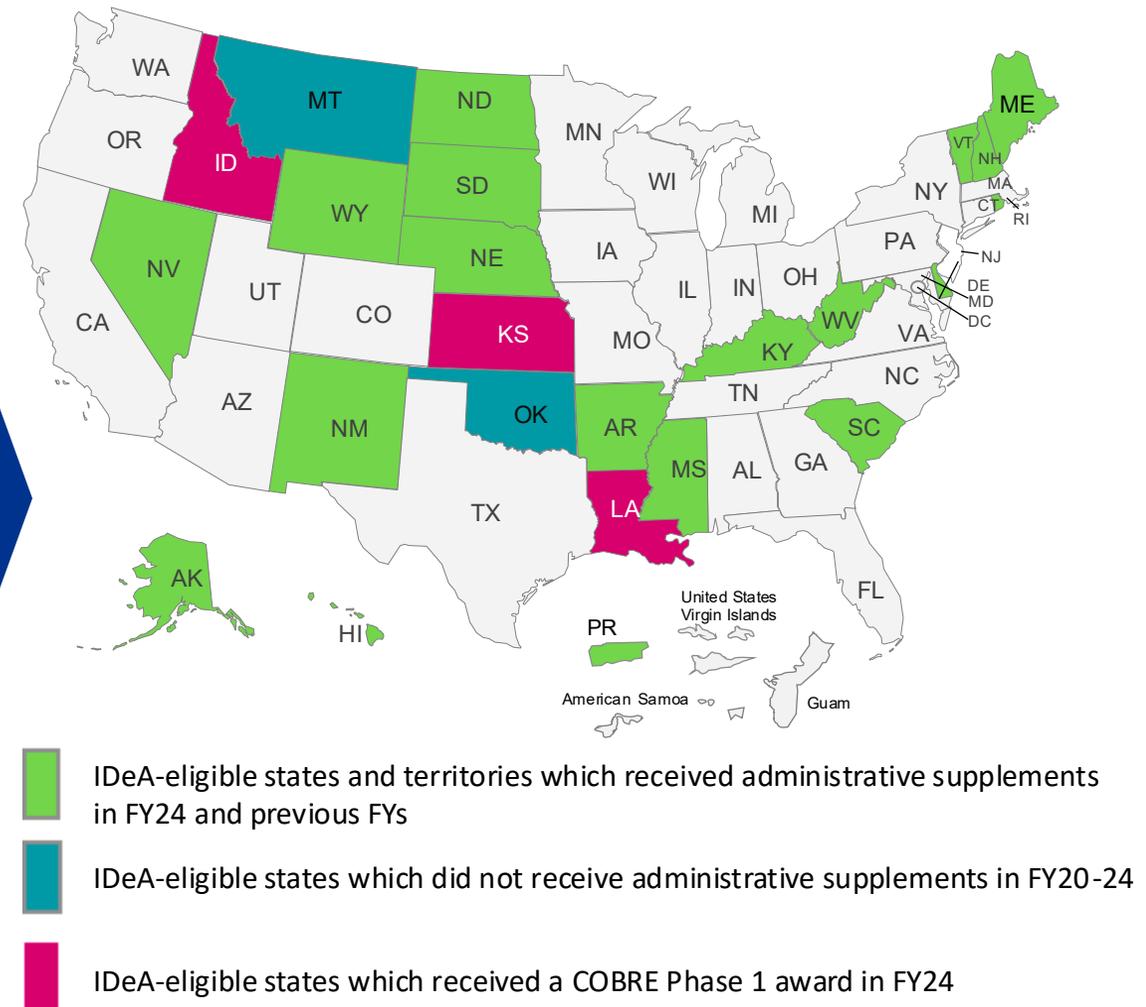
Specialized Centers of Research Excellence (SCORE) on Sex Differences

Presenters:

- **Arpana Church, Ph.D., UCLA SCORE**
“Sex commonalities and differences in associations between neighborhood disadvantage in patients with irritable bowel syndrome: Insights from brain-gut microbiome interactions”
- **Izzuddin Aris, Ph.D., Harvard ROSA SCORE**
“Neighborhood Vulnerability and Women’s Health – Insights from the Project Viva Cohort”
- **MacKenzie Peltier, Ph.D., Yale SCORE**
“Alcohol Use During Pregnancy: The Impact of Social Determinants of Health”

ORWH Expands the Reach of Women's Health Research Across the US: Institutional Development Award States (IDeA States)

- **IDeA Program:** enhance biomedical research in states with historically low NIH grant funding success rates
- ORWH, NIGMS and 14 other ICOs
- **83 Administrative supplements** for research on women's health (**\$23.4M, FY20-24**)
- Now funded awards in 21 of 23 states plus Puerto Rico
- **FY24- 3 Centers of Biomedical Research Excellence (COBRES)** on Women's Health
 - Nutrition and Women's Health (University of Idaho)
 - Leveraging Big Data to Improve Women's Health (University of Kansas Lawrence)
 - Sex-Based Precision Medicine (Tulane University of Louisiana)
- June 2024: Inaugural Symposium on Women's Health Research in IDeA States. September 2025: 2nd Symposium



ORWH Advances Innovation in Women's Health Research with the SBIR/STTR Program



APPLICANT WEBINAR

SERIES: Small Business Opportunities for Innovative Women's Health Research

- Overview of SBIR/STTR Program and ICO-specific women's health research interests
- Opportunity for applicant Q&A
- Unified interest in small business research on women's health

2024

June 26

543 registrants and 291 attendees

Participating ICOs: ORWH, SEED Office, NIMHD, NINDS, NIBIB, NHLBI, NIDA, NICHD

2024

Oct 30

634 registrants and 312 attendees

Participating ICOs: ORWH, SEED Office, NCCIH, NEI, NIDDK, NIDCR, NIAID, NIEHS, NIGMS

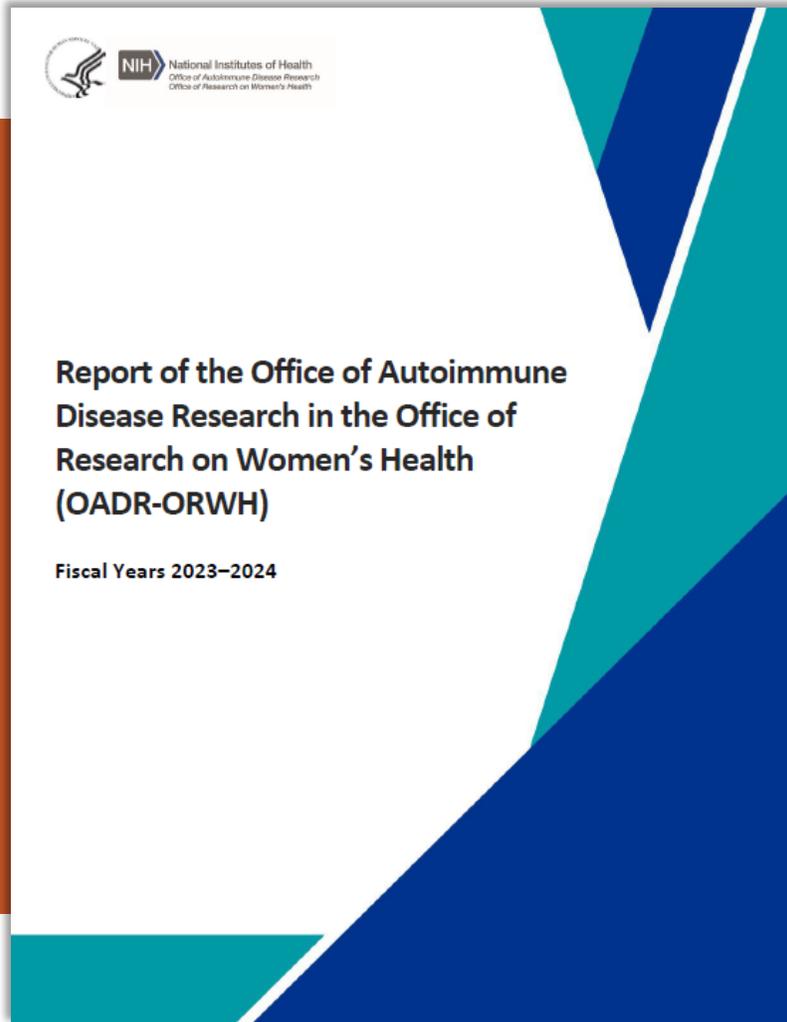
2025

June 25

384 registrants as of 6/5/2025

Participating ICOs: ORWH, SEED Office, NCATS, NCI, NHLBI, NIAAA, NIAMS, NIMH, NLM, NHGRI, ORIP

Office of Autoimmune Disease Research in the Office of Research on Women's Health Shares FY23-24 Achievements



This report encapsulates the achievements of OADR-ORWH in Fiscal Year (FY) 2023 and 2024, highlighting progress made toward fulfilling the congressional directives set forth with its establishment.

Available on OADR-ORWH webpage:
<https://orwh.od.nih.gov/OADR-ORWH>

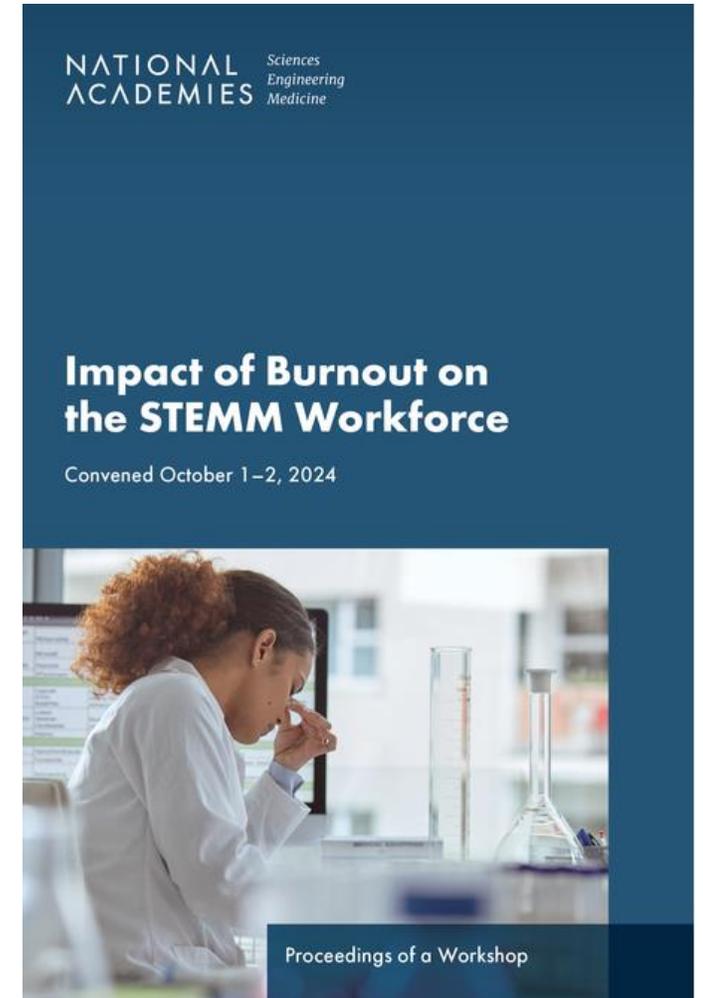
NASEM Releases Report on the Impact of Burnout of the STEMM Workforce

A thriving Science, Technology, Engineering, Math, and Medicine (STEMM) ecosystem relies on

- Healthy workplaces
- Healthy individuals
- Physical health
- Mental health

Burnout diminishes creativity and innovation Workshop in 2024 co-sponsored by ORWH

- Examine current knowledge
- Share lessons learned
- Consider ways to address burnout



2025 NIH ORWH Science Policy Travel Award Recipients Present at OSSD Annual Meeting

June 1st-5th, 2025 Albuquerque, New Mexico



**Amanda
Koire,
M.D., Ph.D.**



Brigham and Women's Hospital

Sex differences in clinical trial enrollment in the United States across psychiatric disorders

**Nefia
Chacko**



**New York Institute of Technology College of
Osteopathic Medicine**

Vascular dysfunction is associated with elevated asprosin levels in postmenopausal mice

ORWH Provides Junior Investigators Travel Awards for The Menopause Society Annual Meeting

October 21st-25th, 2025 Orlando, FL



**Madeline
Wood
Alexander**



University of Toronto

Inflammation and APOE ε4 genotype modify the link between earlier menopause and memory decline

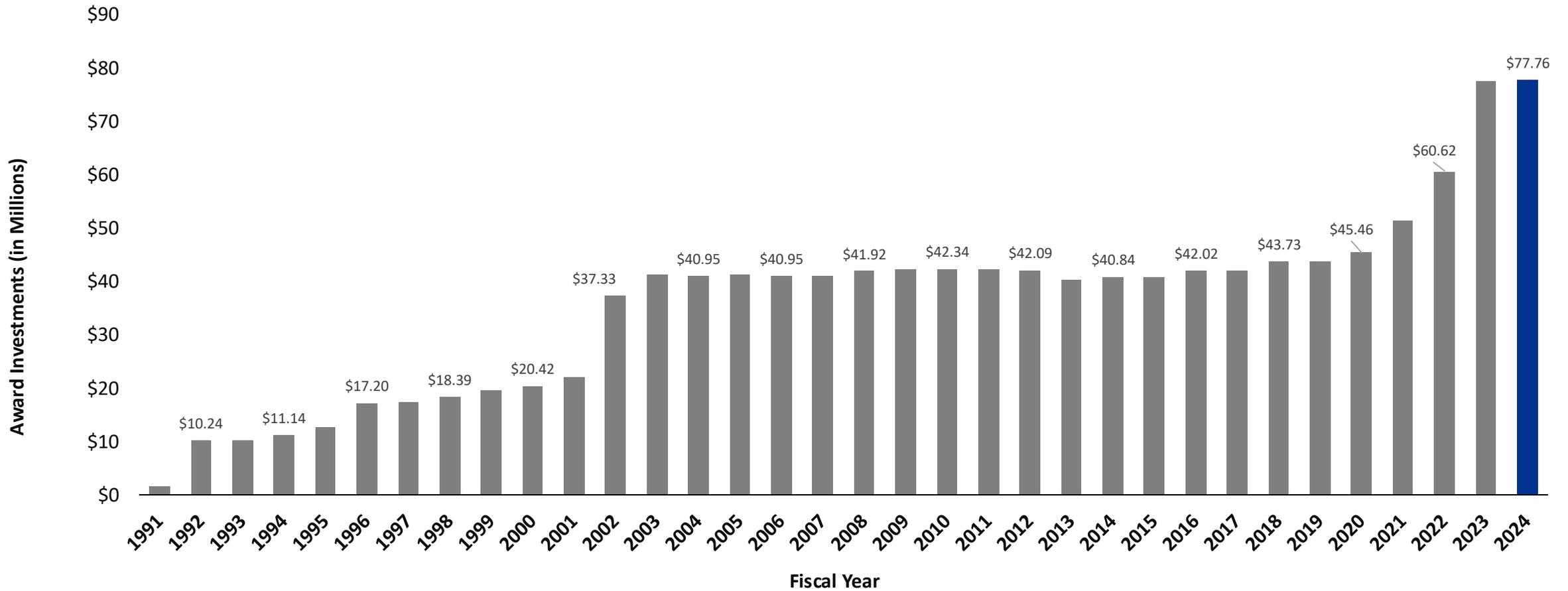
**Sonia
Raghuram**



University of California Los Angeles

Advancing Person-Centered Menopause Care: Development and Implementation of a Novel Facilitated Group Care Model

ORWH Budget History 1991-2024



Note: Award investments do not adjust for inflation.

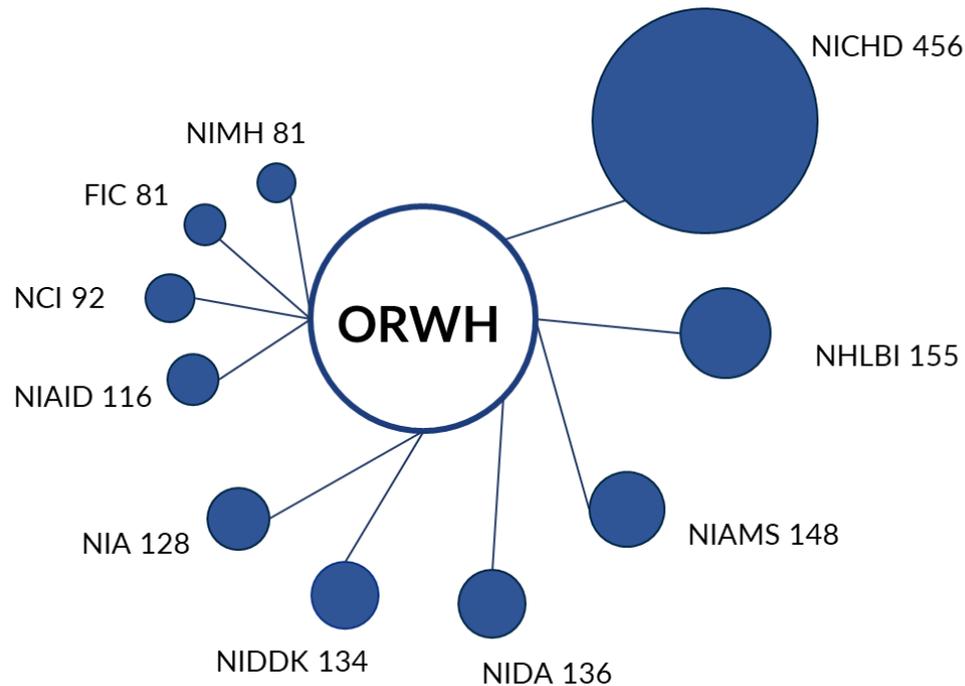
ORWH Extramural Grant Award Investments by Research Program in FY 2024

| Program | Percentages | # of Co-Funding ICs | List of Co-Funding ICs |
|---------------------|-------------|---------------------|---|
| BIRCWH* | 26.4% | 7 | NIAAA, NIAID, NIAMS, NCI, NIDA, NICHD, NIMH |
| Career Programs | 11.1% | 12 | NIA, NIAMS, NCI, NIDA, NIDCR, NIDDK, NIGMS, NICHD, NHLBI, NLM, NINDS, FIC |
| Chronic Diseases + | 7.9% | 7 | NIAAA, NIA, NIAMS, NCI, NIDDK, NICHD, NHLBI |
| OADR-ORWH | 12.7% | 12 | NIA, NIAID, NIAMS, NCCIH, NCI, NIDCR, NIEHS, NEI, NICHD, NHLBI, NIMHD, NINDS |
| Sex Differences R01 | 8.2% | 5 | NIA, NIDA, NIDCR, NHGRI, NHLBI |
| SCORE | 18.8% | 6 | NIAAA, NIA, NIDA, NIDDK, NHLBI, NIMH |
| Other IC Co-Funds | 14.8% | 21 | NIAAA, NIA, NIAID, NCCIH, NCI, NIDCD, NIDCR, NIDDK, NIBIB, NIGMS, NICHD, NHGRI, NHLBI, NLM, NIMHD, NIMH, NINR, NINDS, OD, NCATS |

* In FY2024, BIRCWH awards were administered by NIAMS with additional funds provided by NIAAA, NIAID, NCI, NIDA, NICHD, & NIMH

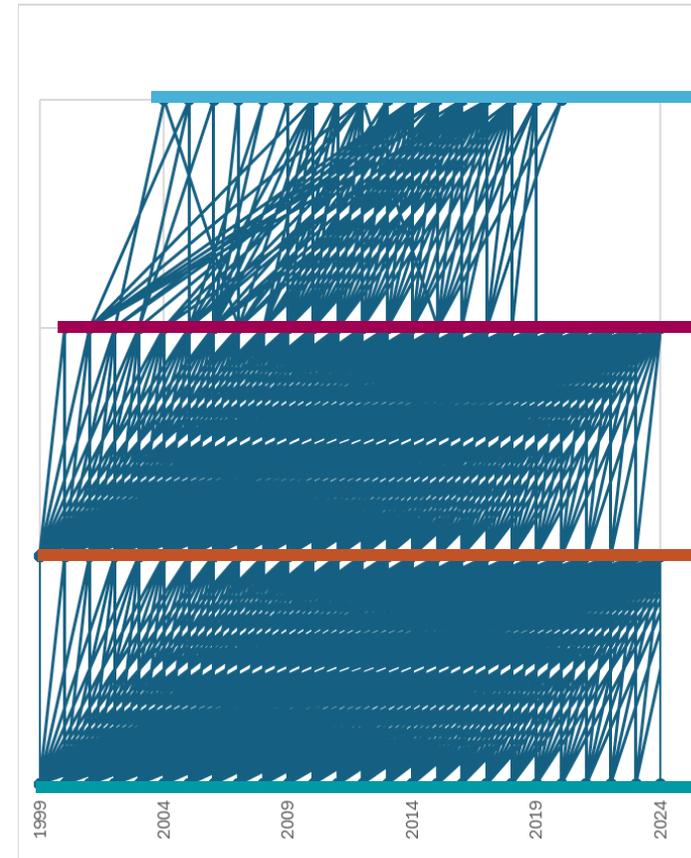
Small Office, Big Impact

Top 10 ICs That Co-invested With ORWH



From 2013-2024, ORWH supported over 2,000 biomedical research projects

Impact of ORWH Co-funding Research For Over Two Decades



193 **Drug** Licenses, citing
406 **patent** applications

28,467 **Patent**
Applications, citing
7,612 **publications**

73,836 **Publications**

2,094 **Grants**

“Our endeavors are often marked by the challenge of stretching every dollar to its fullest.”

Fiscal Years
2026
—through—
2030

NIH-Wide Strategic Plan for Autoimmune Disease Research

Save the Date
Strategic Plan Launch
1 p.m. on July 21, 2025



Access the full strategic plan online:
[https://orwh.od.nih.gov/OADR-ORWH/
Strategic-Planning-for-ADR](https://orwh.od.nih.gov/OADR-ORWH/Strategic-Planning-for-ADR)



Mark Your Calendar

June 25, 2025

11:00 a.m. – 1:00 p.m. EDT

Small Business Opportunities for Innovative Women's Health Research Webinar

July 17, 2025

3:00 p.m. – 4:00 p.m. EDT

NIH Women's Health Research Roundtable: Vaginal Microbiome and Implications for Women's Health

October 7, 2025

9:00 a.m. – 4:00 p.m. EDT

64th Meeting of the Advisory Committee on Research on Women's Health (ACRWH) – with a 35th Anniversary Session

November 3, 2025

8:00 a.m. – 5:00 p.m. EST

Specialized Centers of Research Excellence (SCORE) on Sex Differences 2025 Annual Meeting Keynote and Capstone Addresses

November 4, 2025

8:00 a.m. – 5:00 p.m. EST

Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Annual Meeting

Coming Soon

Late 2025

P2P Menopause Workshop: A workshop on management of menopausal symptoms



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

*Advancing the Health of Women
through Research and Innovation*



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



THANK YOU!

