

# BRIDGING GAPS:

## NIH's Approach to Advancing Women's Health Research

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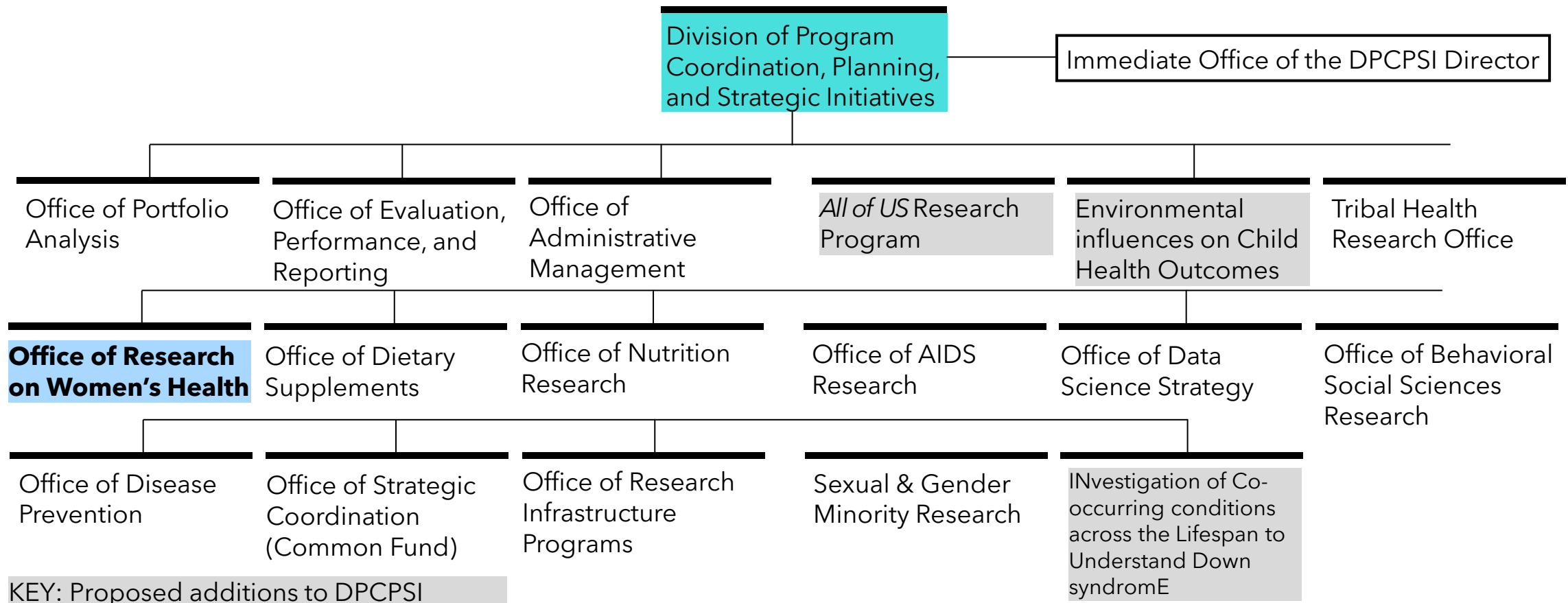
NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives

COMMITTEE ON THE ASSESSMENT OF NIH RESEARCH ON WOMEN'S HEALTH

APRIL 11, 2024

# DPCPSI: Locus of NIH-Wide Science Strategy

**Vision:** To collaboratively advance biomedical and behavioral science through cross-cutting, innovative solutions that improve the health of the Nation.



# ORWH Works Across NIH to Support Women's Health

## ORWH Mission:



Enhance and expand research to improve the health of women across their lifespan



Promote the inclusion of women and minority groups in clinical research

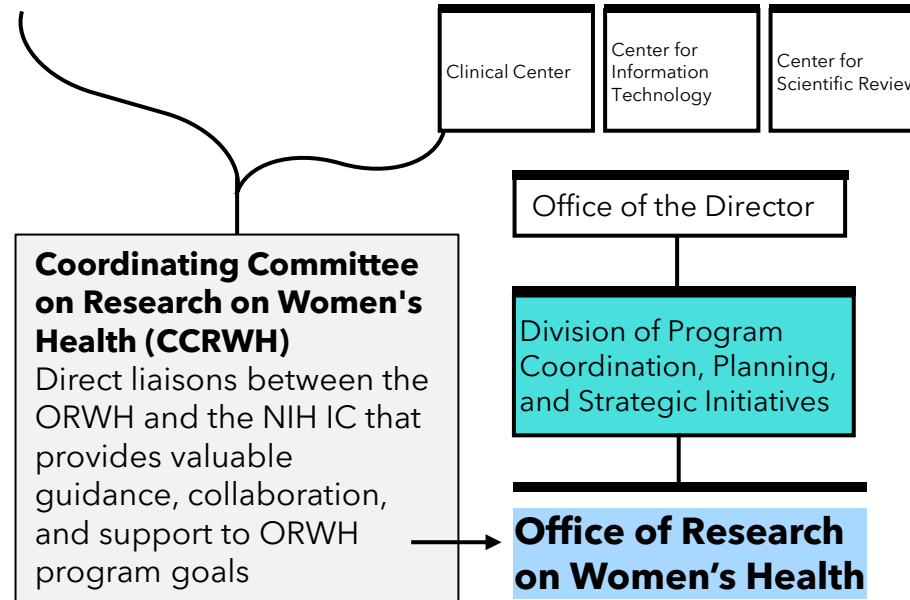


Develop strategies to recruit, retain, and support women in biomedical careers

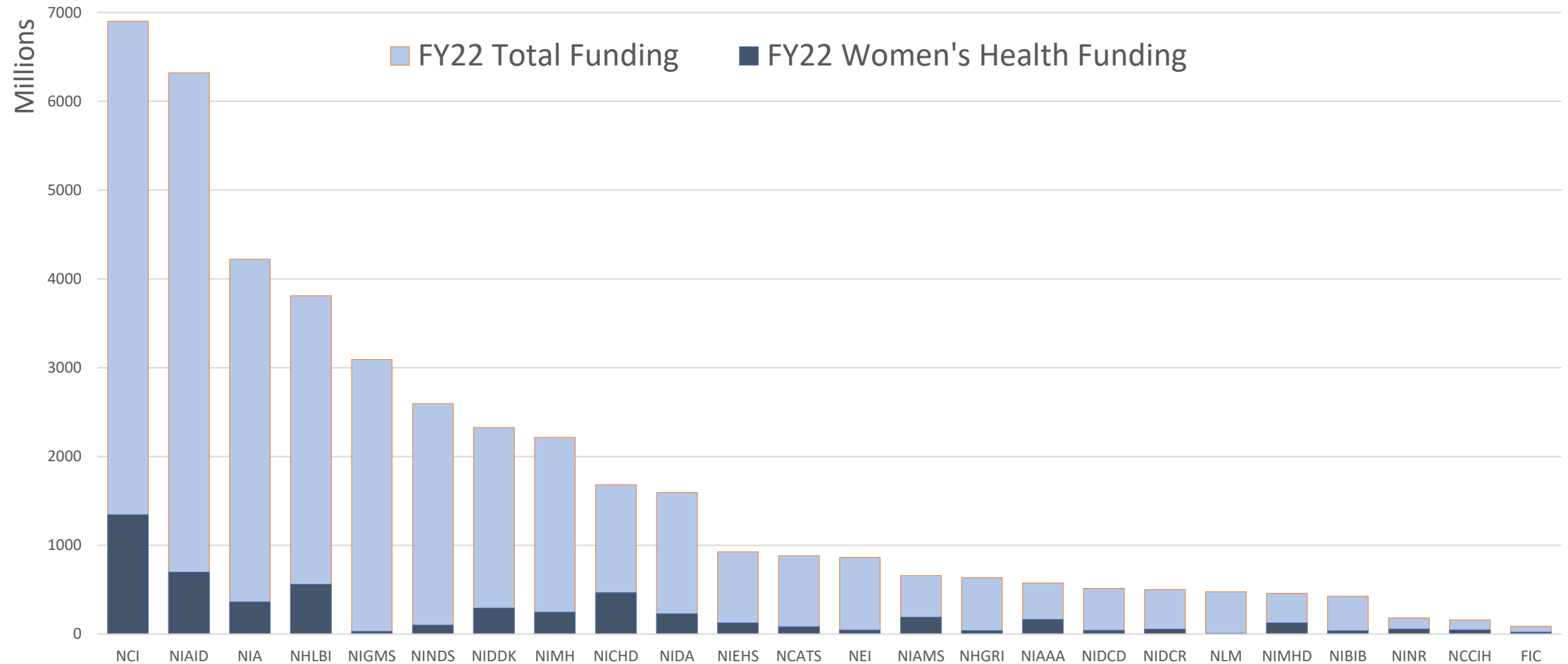


Advance the application of the NIH Sex as a Biological Variable (SABV) Policy and the understanding of sex and gender as critical factors in health and disease.

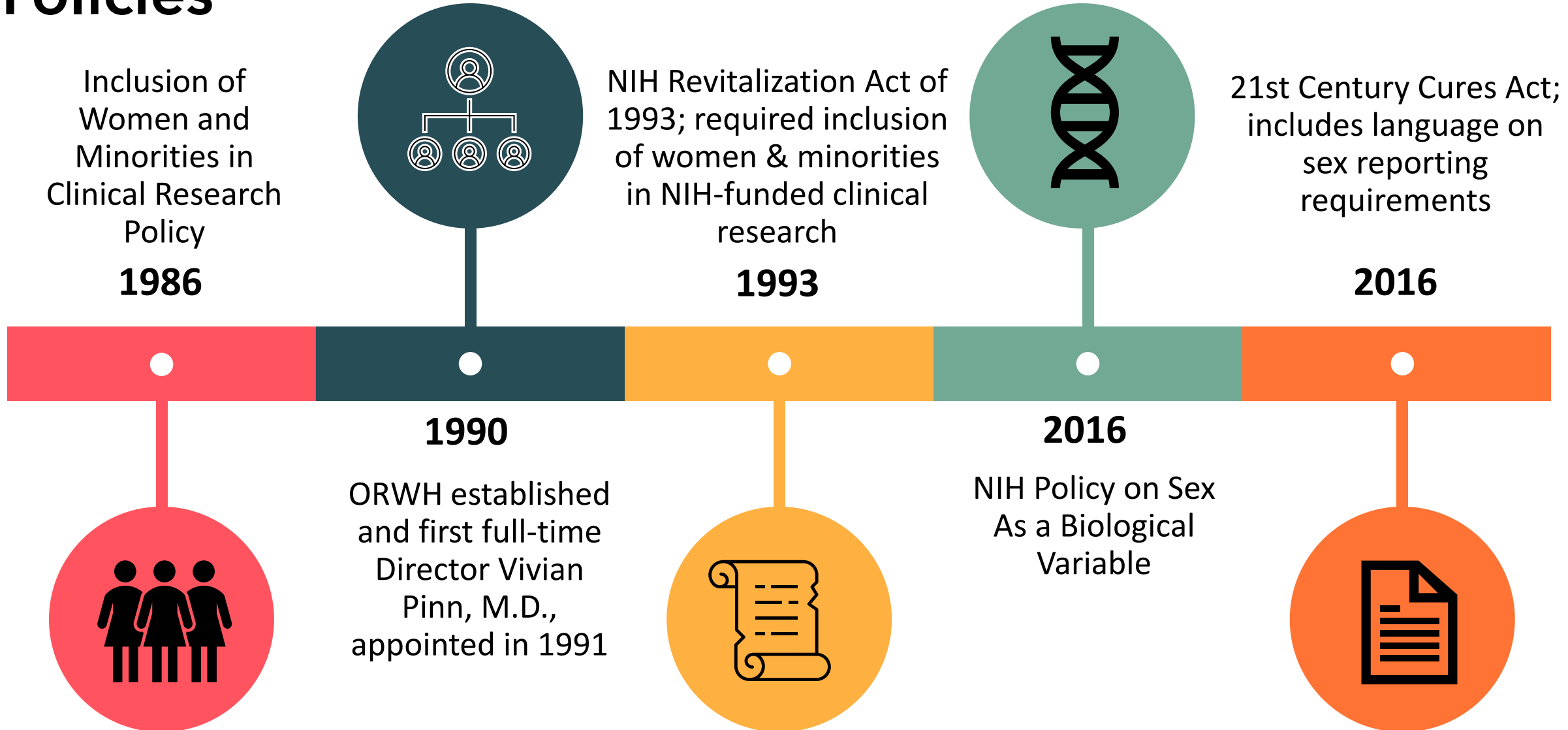
## NIH Institutes and Centers



# NIH-Wide Research Investments in Women's Health (\$4.6 Billion)



# Brief History of Women's Health Research Policies



# NIH Funded Randomized Controlled Trials Reporting Outcomes by Sex Increased Significantly

TABLE 2. INCLUSION AND ANALYSIS BY SEX IN NATIONAL INSTITUTES OF HEALTH-FUNDED CLINICAL TRIALS  
PUBLISHED IN 2004, 2009, 2015, AND 2021

	2004	2009	2015	2021	
Enrollment by sex					
Median % of women enrolled (interquartile range)	43% (25–61%)	38% (28–54%)	46% (34–56%)	44% (24–56%)	
	n (%)	n (%)	n (%)	n (%)	Fisher's exact p-value
Analysis and reporting by sex					
Analysis by sex provided or sex included in statistical analysis	6 (13.0)	14 (25.0)	28 (26.2)	34 (43.0)	<0.01
Did not analyze by sex, but provided explanation	9 (19.6)	6 (10.7)	2 (1.9)	5 (6.3)	
Did not include sex in analysis or provide an explanation	31 (67.4)	36 (64.3)	77 (72.0)	40 (50.6)	
Total	46 (100.0)	56 (100.0)	107 (100.0)	79 (100.0)	

Among studies enrolling male and female participants.

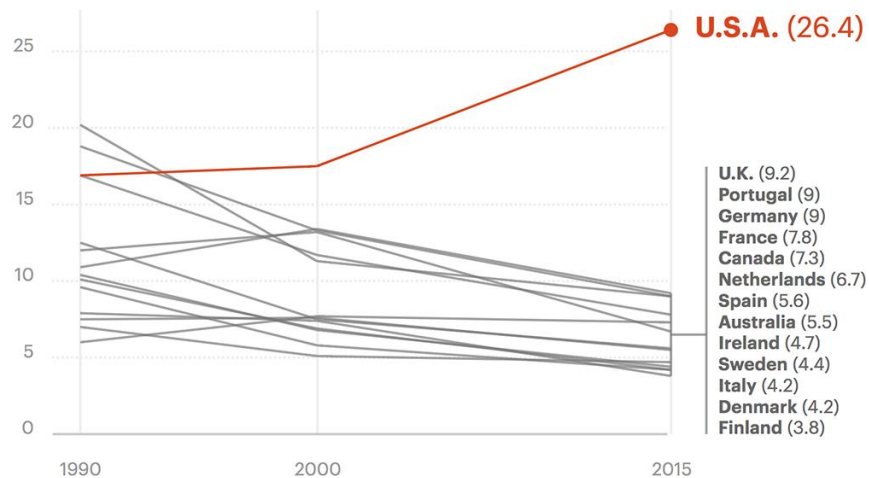
**Analysis and reporting by sex, race, and ethnicity significantly increased despite no corresponding increase in enrollment.**

# FY21 Congressional Request for NIH to Review Women's Health Research Portfolios

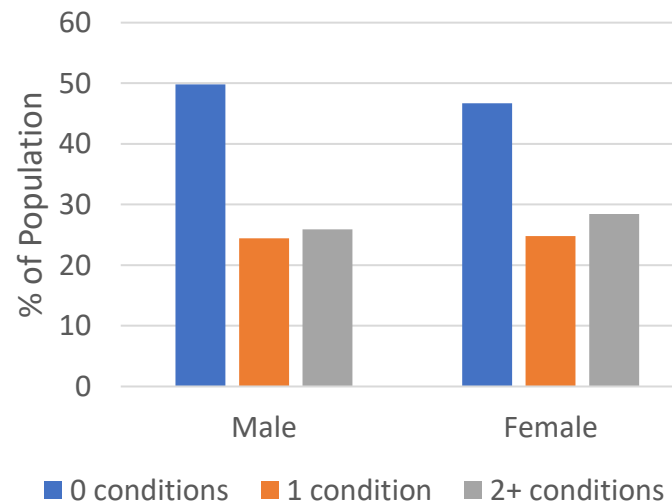
The ORWH held the **Advancing NIH Research on the Health of Women: A 2021 Conference** on October 20, 2021, as part of the Advisory Committee on Research on Women's Health (ACRWH) Meeting

House: <https://www.congress.gov/116/crpt/hrpt450/CRPT-116hrpt450.pdf> (page 149), Senate: <https://www.appropriations.senate.gov/imo/media/doc/LHHSRept.pdf> (page 123)

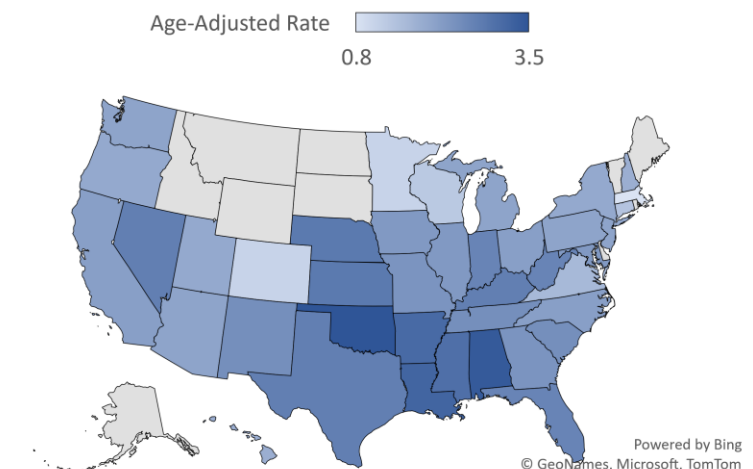
## Rising Rates of Maternal Morbidity and Mortality



## Rising Rates of Chronic Debilitating Conditions in Women

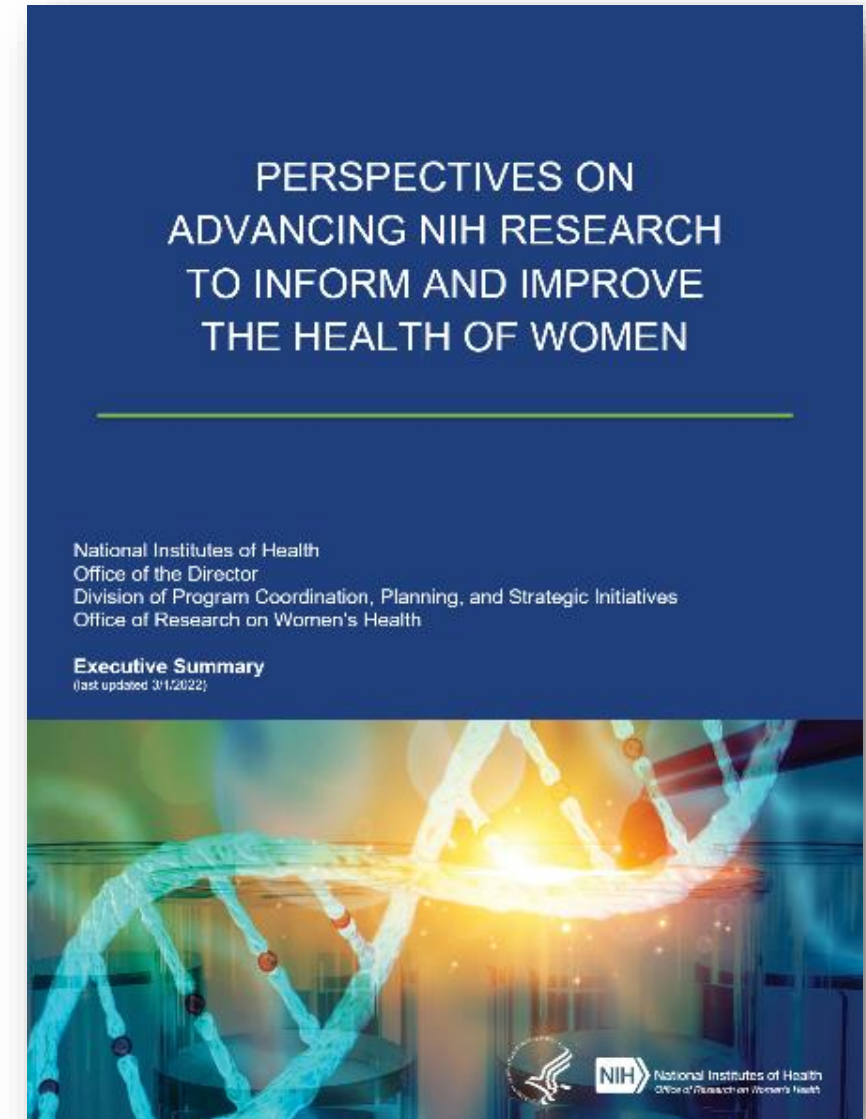


## Stagnant Survival Rates among Cervical Cancer Patients



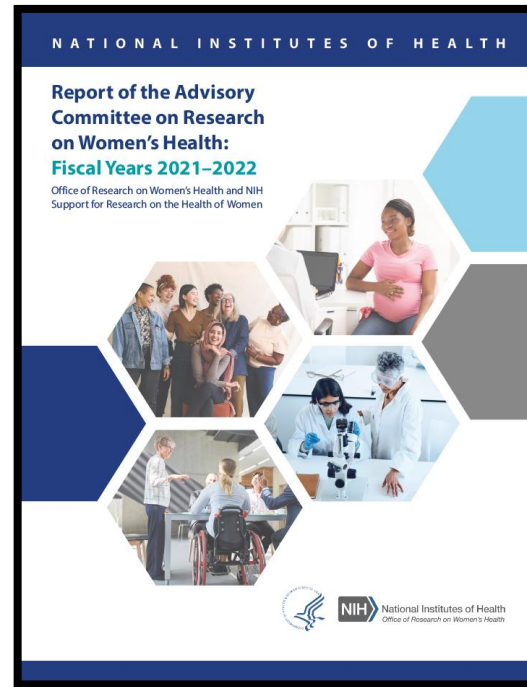
# Crosscutting Themes Identified: Where Research is “Urgently Needed”

- **Implementing best practices** – evidence-based and more holistic, patient-centered care
- **Addressing care inequities** – especially among populations with overlapping identities
- **Intentional research** – two components:
  - Historic overreliance on male clinical research participants left significant gaps regarding female-specific disorders and diseases more common in women
  - Despite Sex As a Biological Variable (SABV) policy, gaps remain in basic and translational understanding of sex differences





# Report of the Advisory Committee on Research on Women's Health: Fiscal Years 2021- 2022



## Noteworthy Developments in:



Women's Health Research conducted by  
ICO's



Inclusion of Women & Minorities in Clinical  
Research



Careers & Workforce Demographics

## NEW Crosscutting Integrative Topics in Research

Aging

Autoimmune Diseases

Mental Health & Substance Use (Opioids/Pain)

Maternal Morbidity & Mortality (MMM)

Social Determinants of Health (SDOH)

Violence

# Executive Order on Advancing Women's Health Research and Innovation



MARCH 18, 2024

THE WHITE HOUSE

Executive Order 14120

A handwritten signature in black ink, appearing to read "J. R. Biden Jr.", written over a light blue background.



# Executive Order 14120: Advancing Women's Health Research and Innovation

President Biden's Executive Order directs the most comprehensive set of executive actions ever taken to expand and improve research on women's health.



- **Integrates Women's Health Across the Federal Research Portfolio** | to develop and strengthen research and data standards on women's health across all relevant research and funding opportunities.
- **Prioritizes Investments in Women's Health Research** | towards funding and encouraging high-impact research and innovation.
- **Galvanizes New Research on Women's Midlife Health** | to narrow research gaps that are more likely to occur after menopause and diseases and conditions associated with women's midlife health.
- **Assesses Unmet Needs to Support Women's Health Research** | to determine gaps in federal funding for women's health research and identify changes—whether statutory, regulatory, or budgetary—that are needed to maximally support the broad scope of women's health research.

# NIH Actions and Efforts Aligned with EO Requirements

## Create a Dedicated, Front Door to NIH Funding Opportunities on Women's Health

NIH issued a **new NIH-wide Women's Health Research NOSI** linking to NIH parent funding opportunities across Institutes, Centers, and Offices. **ORWH** will create a **dedicated front door to NIH funding opportunities & resources** related to women's health research.

## Help Standardize Data to Support Research on Women's Health

NIH is launching an effort **to identify and develop new common data elements** related to women's health that **will help researchers share and combine datasets, promote interoperability, and improve the accuracy of datasets.**

## Support Private Sector Innovation Through Additional Federal Investments in Women's Health Research.

The NIH's competitive **Small Business Innovation Research Program** and the **Small Business Technology Transfer Program** is committing to **further increasing—by 50 percent—its investments in research and development on women's health.**

## Create a Comprehensive Research Agenda on Menopause

NIH is **launching its first-ever Pathways to Prevention series on menopause and the management of menopause related issues.**

## Use Biomarkers to Improve the Health of Women Through Early Detection and Treatment of Conditions, such as Endometriosis

NIH will **launch a new initiative** dedicated to research on **biomarker discovery and validation** to help improve our ability to **prevent, diagnose, and treat conditions that affect women uniquely.**



**NEW**

## Notice of Special Interest: Women's Health Research

First available due date: May 6, 2024

Expiration date: November 5, 2027

NIH has issued this NOSI to highlight interest in receiving research applications focused on diseases and health conditions that are:



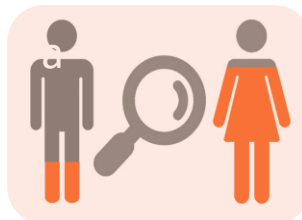
### **Female specific**

Endometriosis; Cervical Cancer;  
Menopause



### **Disproportionately impact women**

Autoimmune Disease; Mental Health;  
Pain Conditions



### **Present and progress differently in women**

Cardiovascular Disease; Stroke;  
Metabolic Disorders

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# Pathways to Prevention Workshop: Management of Menopausal Symptoms

- Menopause is a normal phase of life. However, the experience is different for everyone.
- More research is needed to help women and their health care providers navigate the menopausal transition and promote well-being through midlife and beyond.
- Office of Disease Prevention will hold a P2P workshop to identify research gaps in this area.

## Sponsoring ICOs

- Office of Research on Women's Health
- National Cancer Institute
- National Heart, Lung, and Blood Institute
- National Institute on Aging
- *Eunice Kennedy Shriver* National Institute of Child Health and Human Development
- National Institute of Mental Health
- Office of Disease Prevention

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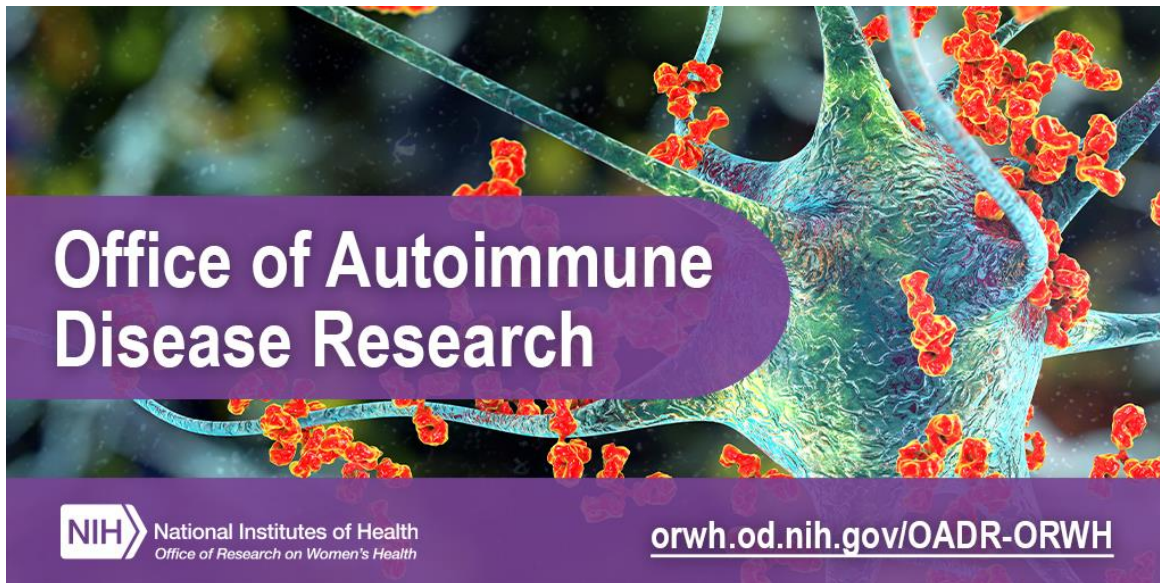
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# Establishment of the Office of Autoimmune Disease Research (OADR) within ORWH



## FY23 Omnibus language directs OADR to:

1. Coordinate development of multi-IC strategic research plan
2. Identify emerging areas of innovation and research opportunity
3. Coordinate and foster collaborative research across ICs
4. Annually evaluate NIH Autoimmune Disease Research (ADR) portfolio
5. Provide resources to support planning, collaboration, and innovation
6. Develop publicly accessible central repository for ADR

# NIH-Wide Strategic Plan

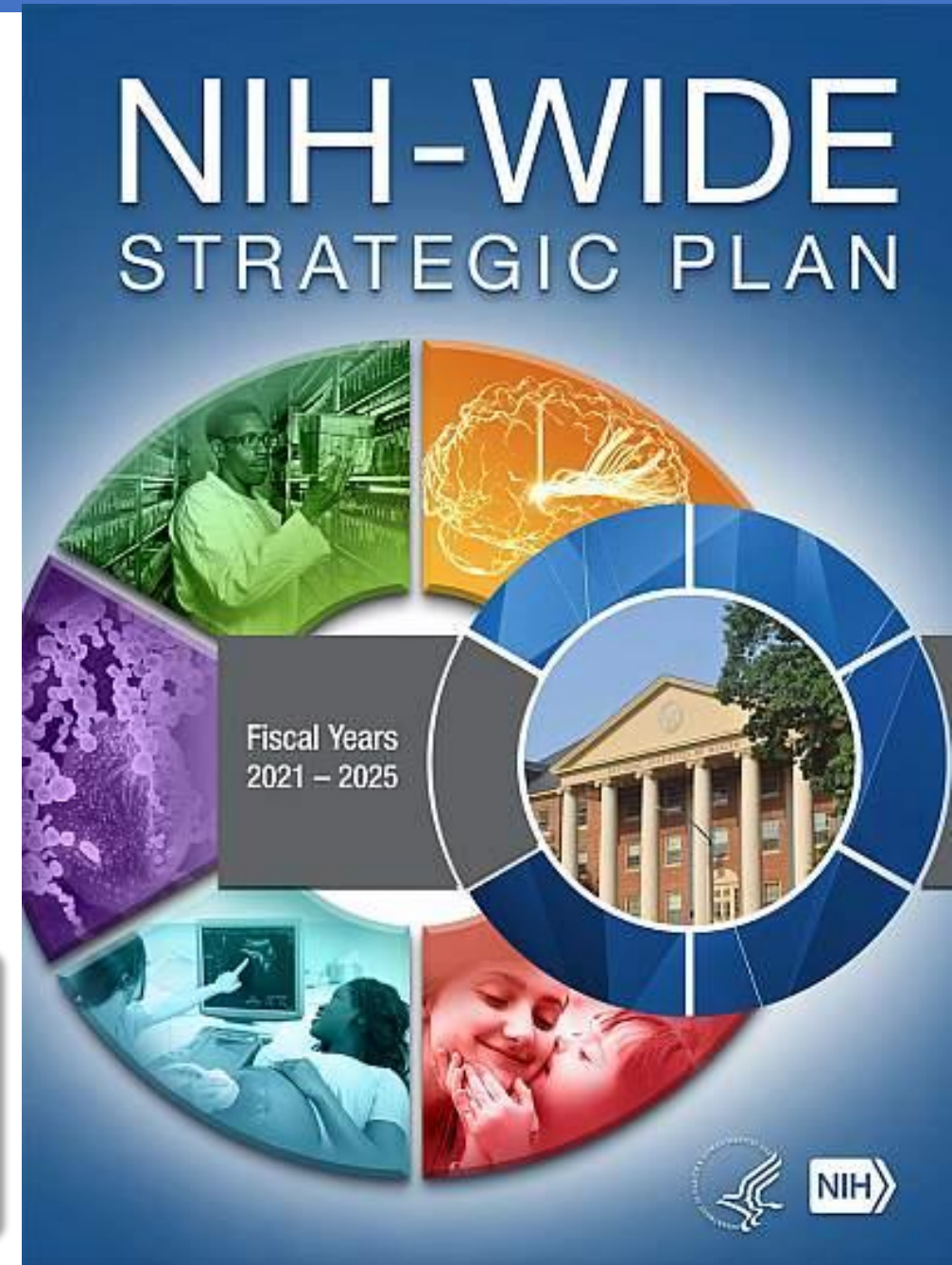
Enhancing women's health is a central crosscutting theme

- Emphasized importance of interdisciplinary partnerships
- Expand reporting requirements
- Promote the recruitment, retention, and advancement of women scientists

Coming soon...

**NIH-wide strategic plan on women's health**

Interdisciplinary Approaches | Community Involvement | Innovative Data Science







National Institutes of Health

*Division of Program Coordination, Planning, and Strategic Initiatives*

# THANK YOU!



**Have Questions, Ideas, Feedback?**

Email us at:

[DPCPSIDirectorsOffice@nih.gov](mailto:DPCPSIDirectorsOffice@nih.gov)