

Overview of Women's Health Research and Policies Across NIH

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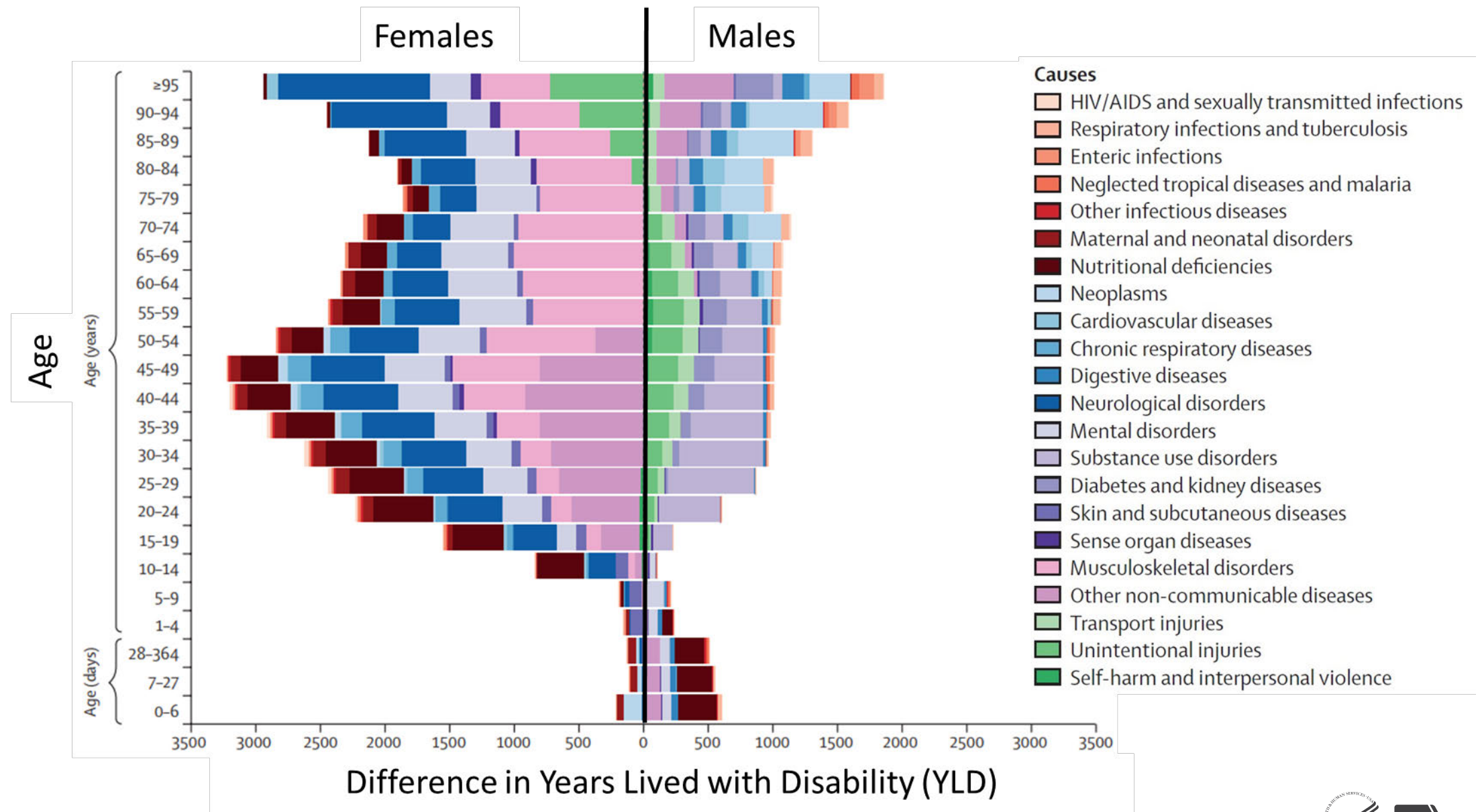


Outline

- I. NIH Office of Research on Women's Health (ORWH) Programs and Activities
- II. Current Women's Health Research Efforts
- III. White House Initiative and Executive Order
- IV. Closing



Females Live with Disabilities Disproportionately Across the Life Course



ORWH Mission



Enhance and expand women's health research



Include women and minority groups in clinical research



Promote career advancement for women in biomedical careers

NIH Vision



Sex and gender integrated into biomedical research



Every woman receives evidence-based care

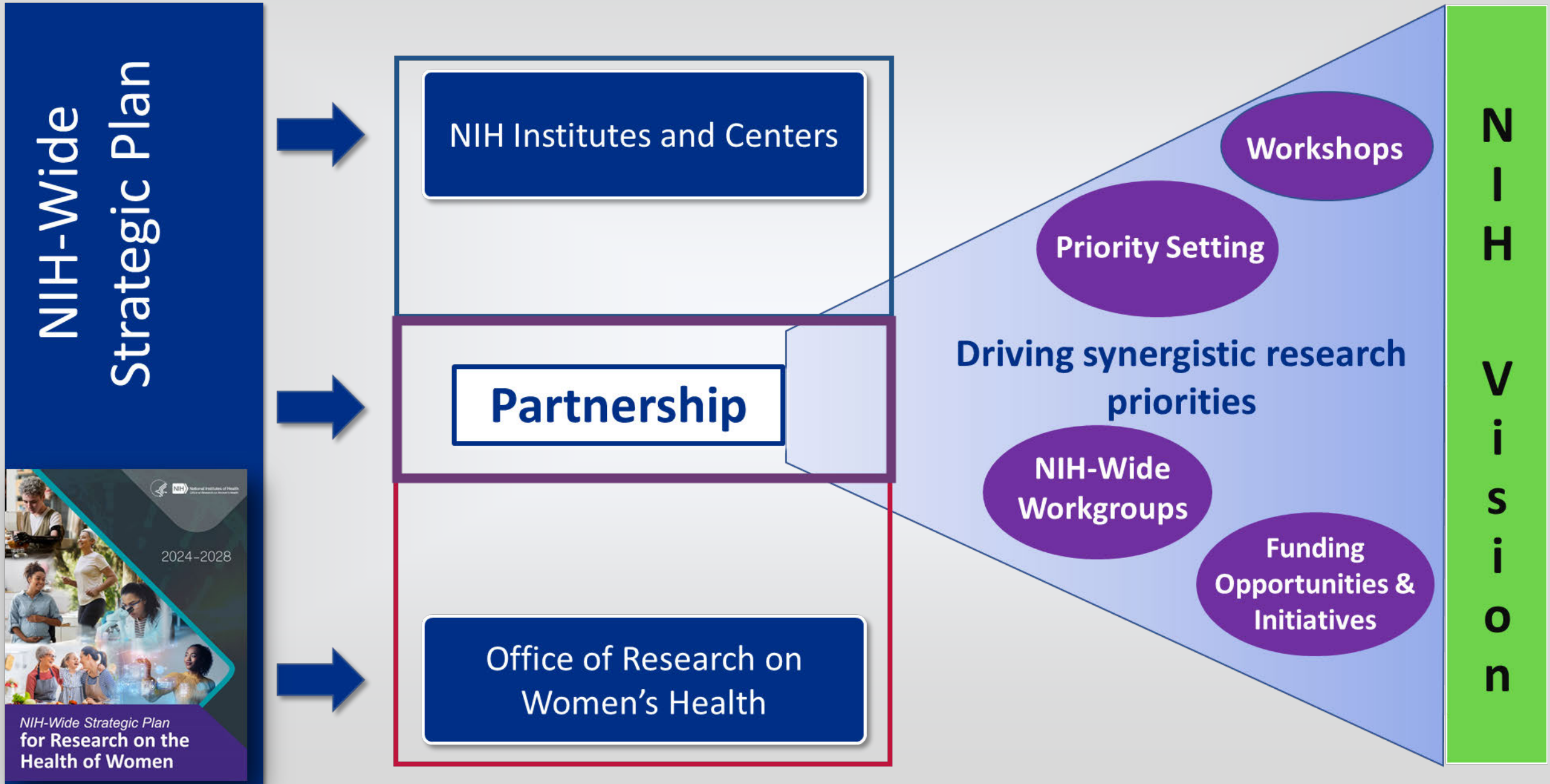


Women in science careers reach their full potential

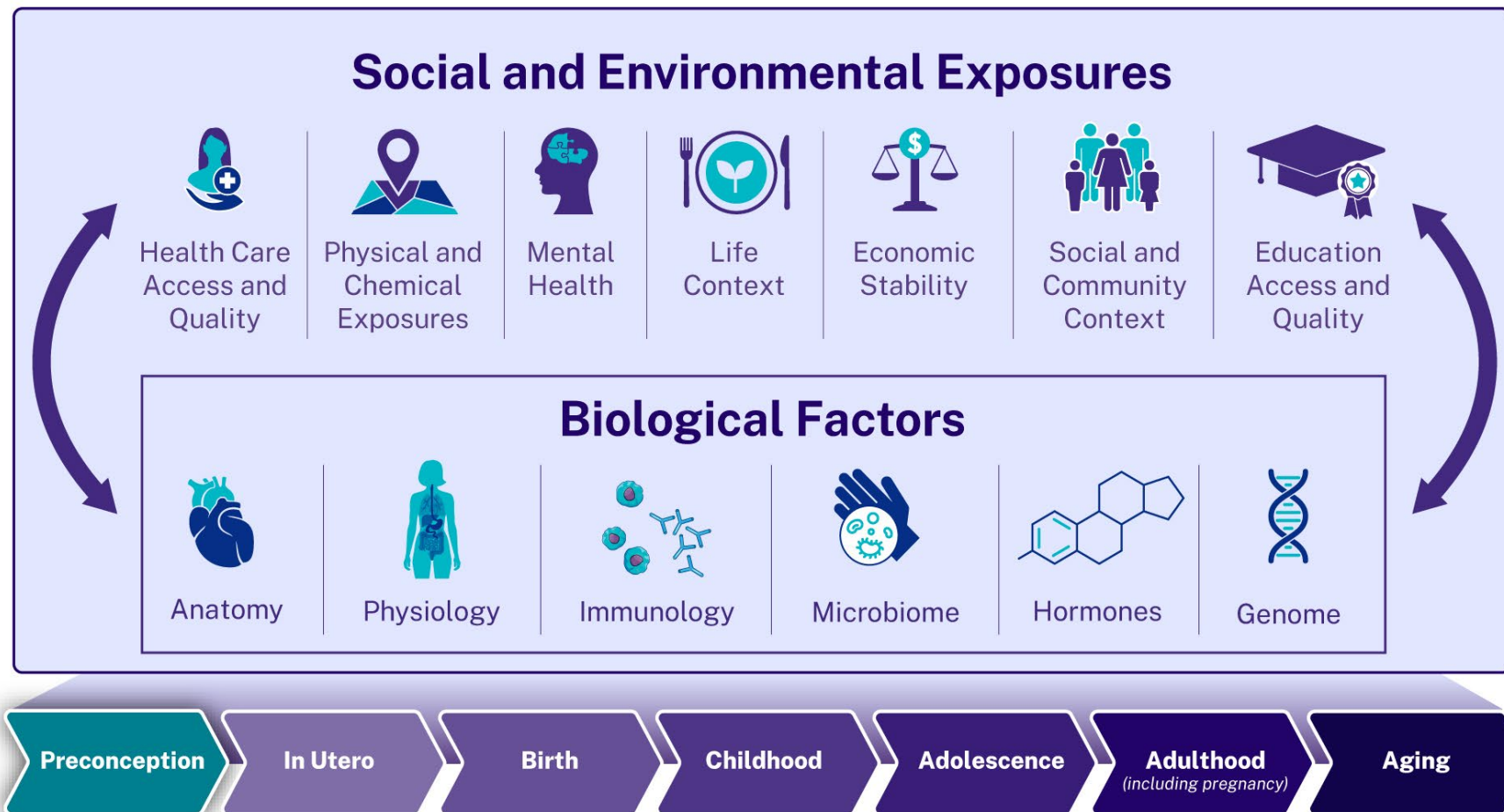


National Institutes of Health
Office of Research on Women's Health

»» Collaboration is Key to Women's Health Research at NIH



Health of Women Across the Life Course



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

»» ORWH Advances Study of Sex and Gender and the Health of Women through Collaborations across NIH

BIRCWH

Building
Interdisciplinary
Research
Careers in
Women's
Health
8 ICOs
Mentored
Career
Development



SCORE

Specialized
Centers of
Research
Excellence on
Sex Differences
6 ICOs
Disease-
Agnostic
Research
Centers

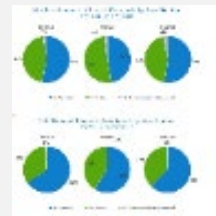


RFA-OD-22-014

Administrative Supplements

Sex and Gender
22 ICOs

Understudied,
Underrepresented, &
Underreported (U3)
16 ICOs
Funding Program to
Expand Sex &
Gender Data



R01

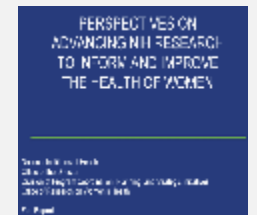
Intersection of
sex & gender
influences on
health &
disease
11 ICOs
Sex & Gender
Influences on
Health &
Disease



RFA-OD-22-028

R21 & R01

Understanding
Chronic Conditions
Understudied
Among Women
6 ICOs
A 2021 Women's
Health Conference
Report



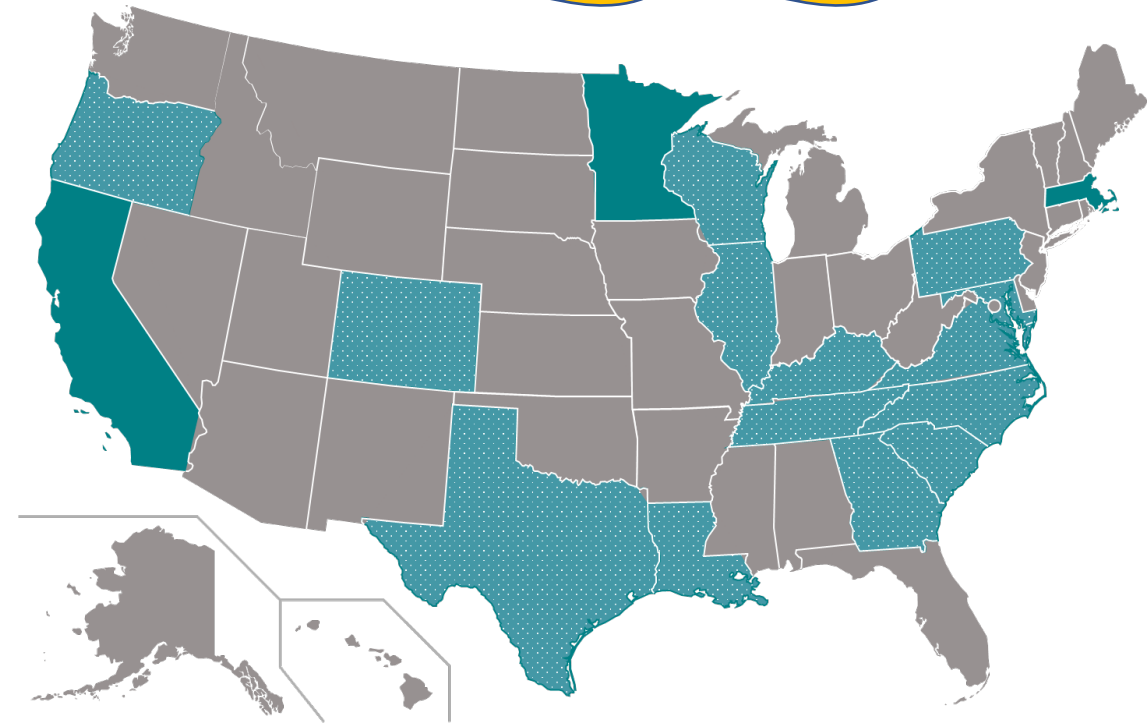
RFA-OD-23-103
RFA-OD-23-014

ORWH created the **Building Interdisciplinary Research Careers in Women's Health (BIRCWH)**, a successful mentored research career development program for junior faculty.

Signature Program

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

- Created by the Office of Research on Women's Health (ORWH) and established by the various institutes and centers of the National Institutes of Health (NIH) in 1999.
- The BIRCWH program supports junior faculty by 1) providing them with funds to ensure 75% of their time is protected to engage in research and 2) pairing them with senior faculty with shared interests in women's health and sex differences research who can give career, research, and grantsmanship advice.
- The BIRCWH program has supported 42 institutions since it was established.
 - There are currently 19 active programs
 - More than 830 scholars have been funded.



Map showing locations of active BIRCWH programs. Darker color indicates multiple programs located in a particular state.

Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54 Clinical Trial Optional)



BRIGHAM AND
WOMEN'S HOSPITAL

Stress and neural regulation
of reproductive aging health
outcomes

NIH > NIA



Cedars
Sinai

Microvascular aging and
eicosanoids – Women's
evaluation of systemic aging
tenacity

NIH > NIA



EMORY
UNIVERSITY

Influence of sex on
microbial-host-pathogen
interactions

NIH > NIA



JOHNS HOPKINS
UNIVERSITY

Sex and age differences in
immunity to influenza

NIH > NIA



MASSACHUSETTS
GENERAL HOSPITAL

Sex differences in major
depression: Impact of
prenatal stress-immune and
autonomic dysregulation

NIH > NIMH



MAYO CLINIC

Sex-specific effects of
endocrine disruption on
aging and Alzheimer's
disease

NIH > NIA



MUSC Health
Medical University of South Carolina

Sex and gender impacts on
addiction and stress-related
disorders

NIH > NIDA



UCLA

Sex differences in the
cardiometabolic health and
disease

NIH > NHLBI



UCLA

Sex-related differences in
brain-gut microbiome
interactions in irritable bowel
syndrome

NIH > NIDDK



University of Colorado
Denver

Bioenergetic and
cardiometabolic
consequences of loss of
gonadal function

NIH > NIA



Yale University

Sex differences in alcohol use
disorder

NIH > NIAAA



AUGUSTA
UNIVERSITY

Hypertension across health
span through community
outreach

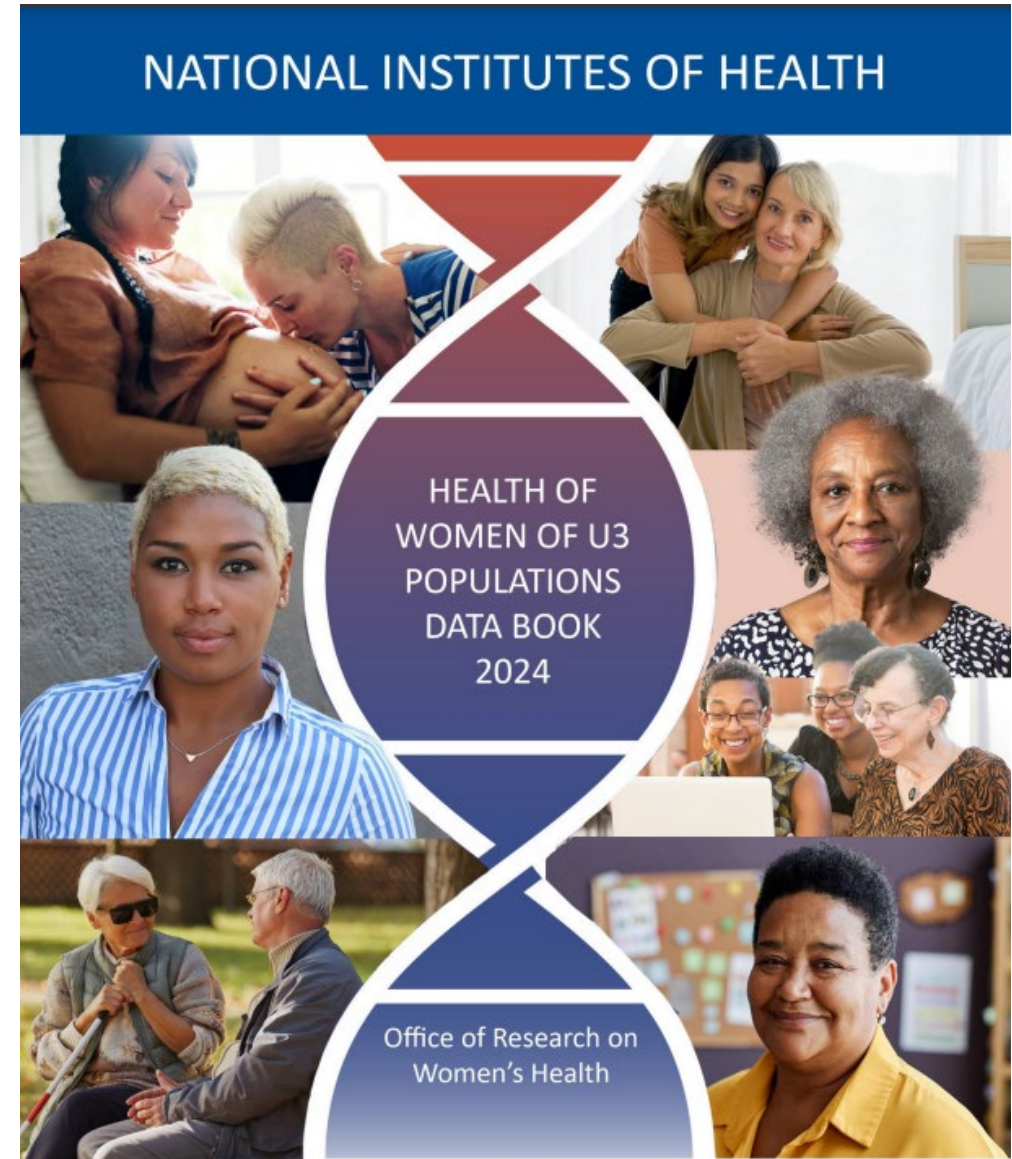
NIH > NHLBI



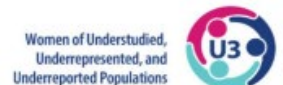
U3 Interdisciplinary Research

Bringing Women of **U**nderstudied, **U**nderrepresented, and **U**nderreported Populations into Focus

- The U3 framework and administrative supplement program seeks to draw attention to and support research that addresses this gap, with the aim of advancing health equity
- **U3 Populations** (NIH-designated health disparity populations)
 - Black or African American
 - Hispanic or Latina
 - American Indian or Alaska Native
 - Asian
 - Native Hawaiian/other Pacific Islander
 - Socioeconomically disadvantaged
 - Underserved rural
 - Sexual and gender minority



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



Women of Understudied,
Underrepresented, and
Underreported Populations



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NIH Policy on

Consideration of Sex as a Biological Variable (SABV) in NIH-funded Research

“NIH expects that [SABV] will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.”



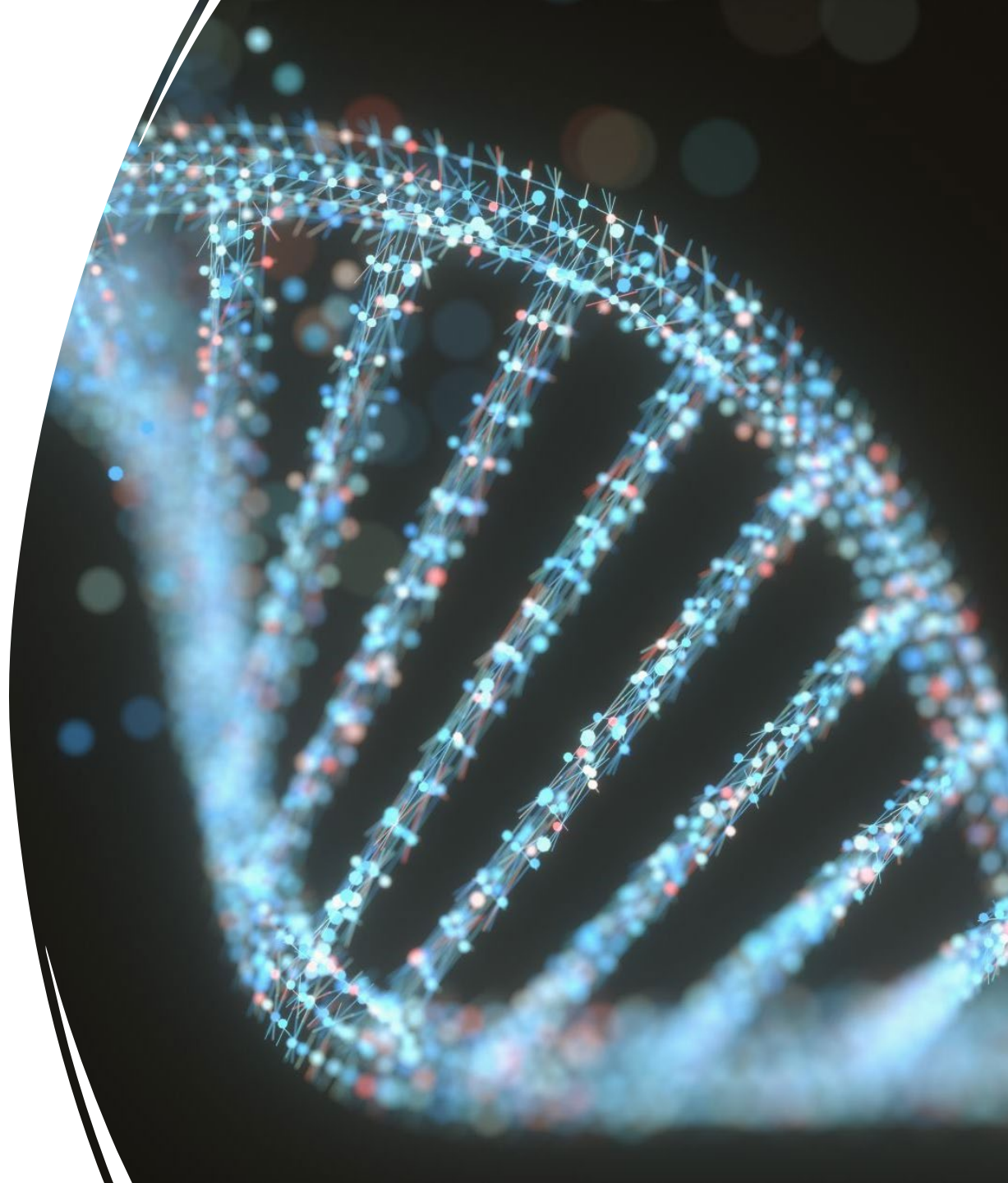
Effective 01/25/2016

SABV Policy Notice: NOT-OD-15-102



The Intersection of Sex and Gender Influences on Health and Disease R01

- The Role of Menopause-Driven DNA Damage and Epigenetic Dysregulation in Alzheimer's Disease
- Sexually dimorphic pain signaling mechanisms
- Sex, Gender and the Immunopathogenesis of HIV
- Substance use and DNA methylation at the intersection of sex and gender
- Stress, inflammation and coronary endothelial injury in preeclampsia



Understanding Chronic Conditions Understudied Among Women R01 & R21

Partnering ICOs:

NHLBI, NIA, NIAMS,
NICHD, NCI, ORWH

[RFA-OD-23-014](#)

[RFA-OD-23-013](#)

Special Areas of Research Interest

- Female-specific conditions
- Conditions more common in women and/or morbidity is great in women, (e.g., autoimmune diseases)
- Conditions that are potentially understudied in women
- Conditions that cause high morbidity in women



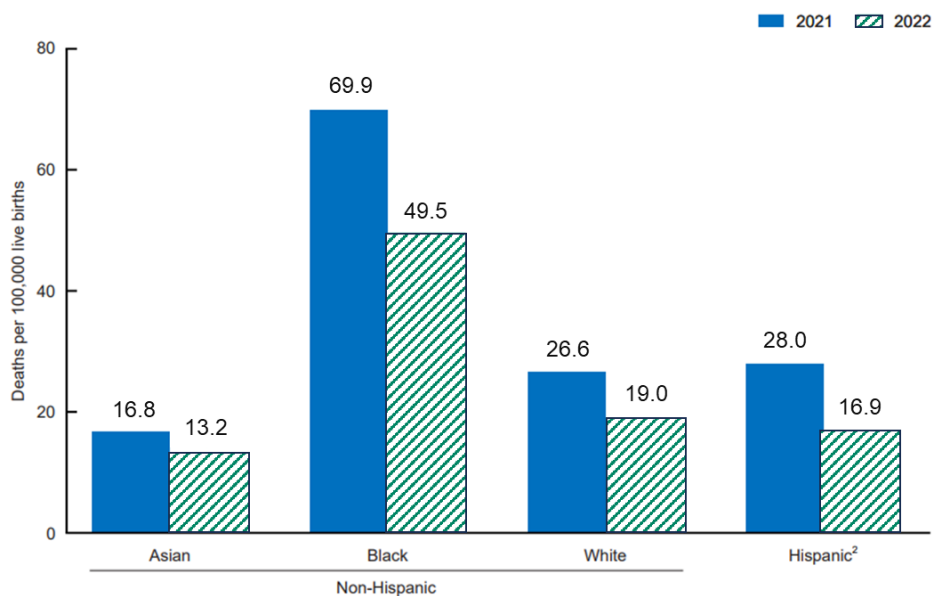
Applications close June 20, 2024





Implementing a **M**aternal Health and **P**regnancy **O**utcomes **V**ision for **E**veryone (IMPROVE) Initiative

Maternal mortality rate, by race and Hispanic origin: United States, 2021 and 2022



<https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2022/maternal-mortality-rates-2022.pdf>



Women of Understudied, Underrepresented, and Underreported Populations



**NIH
Maternal Morbidity & Mortality Web Portal**

Presented by the Office of Research on Women's Health

Fact Sheet:

<https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH22 MMM Info Factsheet 508.pdf>





Pathways to Prevention (P2P) Program: Identifying Risks and Interventions to Optimize Postpartum Health



Independent Panel Report: Maternal Mortality- A National Institutes of Health Pathways to Prevention Panel Report



Independent Panel Summary



Systematic Evidence Review: An Evidence Map for Social and Structural Determinants for Maternal Morbidity and Mortality

Federal Partners Report Released April 2, 2024

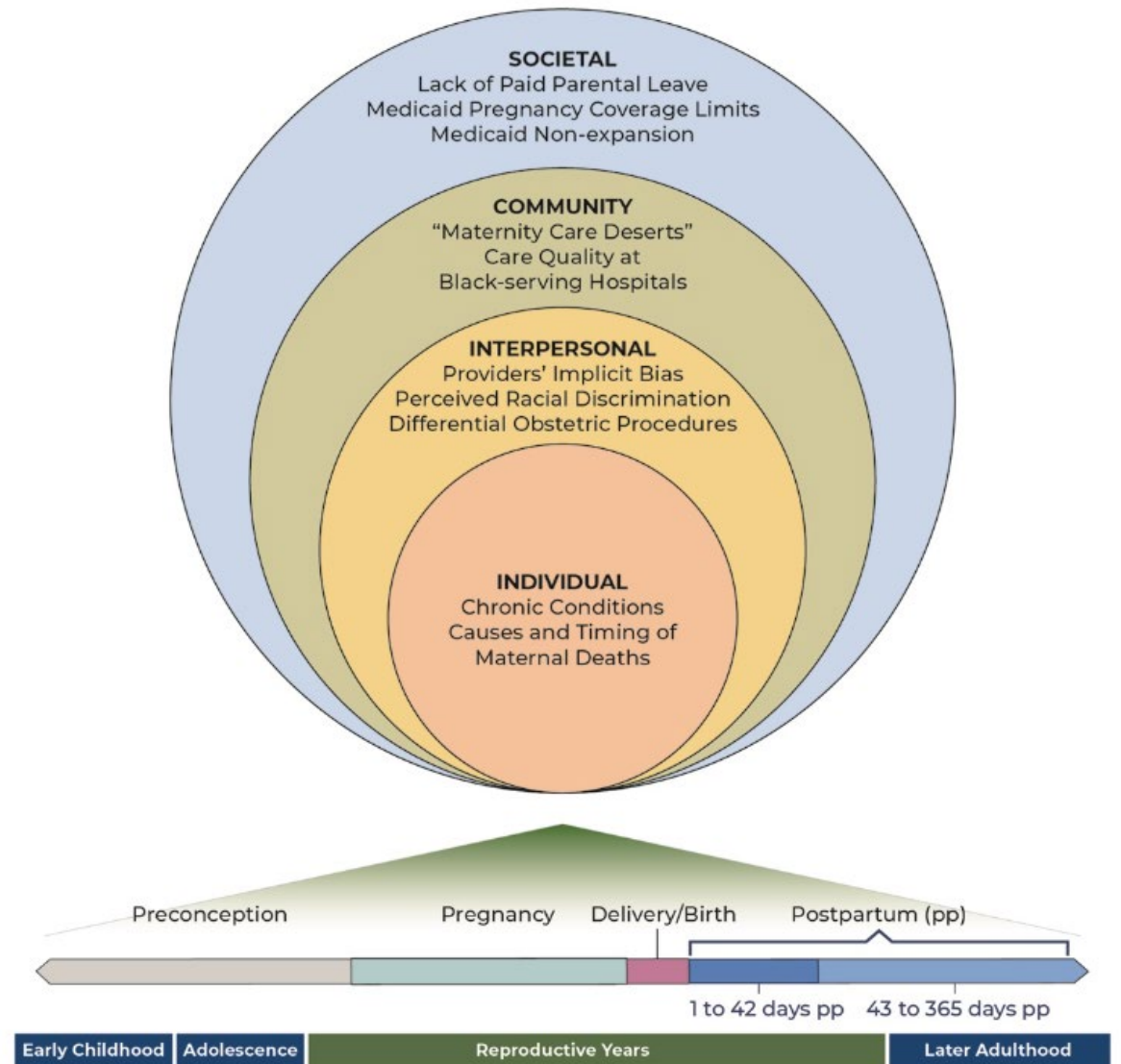
<https://prevention.nih.gov/sites/default/files/2024-04/P2P-PostpartumFPMReport-FINAL.pdf>

<https://prevention.nih.gov/research-priorities/research-needs-and-gaps/pathways-prevention/identifying-risks-and-interventions-optimize-postpartum-health>

https://journals.lww.com/greenjournal/fulltext/2024/03000/maternal_mortality_a_national_institutes_of_25.aspx

<https://prevention.nih.gov/sites/default/files/2023-12/P2P-PostpartumHealth-PanelSummary-FINAL-508.pdf>

https://journals.lww.com/greenjournal/fulltext/2024/03000/an_evidence_map_for_social_and_structural_10.aspx



The Opportunity Map lays out 50 equitable, high-return opportunities to advance global innovation for women's health



Women's Health Innovation Opportunity Map 2023

50 High-Return Opportunities
to Advance Global Women's Health R&D

A report of the Innovation Equity Forum, sponsored by the Bill & Melinda Gates Foundation and US National Institutes of Health



<https://bit.ly/3PEcl20>

Co-chaired by the Bill & Melinda Gates Foundation and the National Institutes of Health

By prioritizing resources and efforts along five criteria...

Potential for impact Readiness Innovation Matters to women Equity

...With four lenses in mind...

Serving the underserved Sex and gender influences Life course perspective Quality of life and well-being

...We can advance opportunities to lay stronger foundations for equitable innovation...

Data and modeling

Research design and methodologies

Regulatory and science policy

Innovation introduction

Social and structural determinants

Training and careers

...To benefit women across the spectrum of conditions that affect them uniquely, differently, or disproportionately...

Communicable diseases

Non-communicable and chronic conditions

Female-specific conditions

⚙️ ...Powered by global collaboration, knowledge sharing, and mutual commitment. ⚙️



Partnerships for Women's Health R&D

»»» OAR and ORWH Collaborate On Signature Program on Women and HIV

Objectives

- Foster interdisciplinary, intersectional, community-centered knowledge exchange on topics of relevance to HIV and cisgender and transgender women, girls, and gender-diverse people
- Review the state of the science in HIV and women, with attention to prevention, treatment, cure, and social and structural determinants of health
- Highlight modifiable factors, interventions, methods, and challenges to advance health equity for women with, or affected by, HIV
- Identify opportunities to advance health research and foster interdisciplinary collaborations on HIV and women



NEW publication



The Lancet HIV
Volume 11, Issue 3, March 2024, Pages e186-e194

Position Paper

Centring the health of women across the HIV research continuum

Elizabeth Barr PhD^a  , Leslie J Marshall PhD^b, Lauren F Collins MD^d, Catherine Godfrey MD^e, Noelle St Vil PhD^f, Prof Jamila K Stockman PhD^g, Dvora L Joseph Davey MD^{h i}, Krista Dong MD^{j k}, Sarah M Temkin MD^a, Mary T Glenshaw PhD^b, Corette Byrd RN^b, Janine A Clayton MD^a, Maureen M Goodenow PhD^c

<https://www.sciencedirect.com/science/article/pii/S2352301824000043?via%3Dihub>

Lifespan approach
(e.g., adolescent girls, young women, and ageing)

Population-specific
(e.g., pregnant and lactating people)

Structural determinants of health
(e.g., intimate partner violence)

Social determinants of health
(e.g., substance use treatment access)

Context-specific
(e.g., multimorbidity)



Executive Order 14120 to Advance Women's Health Research & Innovation Key Points

- ❖ Prioritize Investments in Women's Health Research
- ❖ Integrate Women's Health Across the Federal Research Portfolio
- ❖ Galvanize New Research on Women's Midlife Health
- ❖ Assess Unmet Needs to Support Women's Health Research

<https://www.whitehouse.gov/briefing-room/statements-releases/2024/03/18/fact-sheet-president-biden-issues-executive-order-and-announces-new-actions-to-advance-womens-health-research-and-innovation/#:~:text=The%20Executive%20Order%20also%20directs,to%20Support%20Women's%20Health%20Research>

Executive Order Extends Across U.S. Government Partners

Department of Veterans Affairs



Office of Management and Budget



Department of Defense



Agency for Healthcare Research and Quality



Center for Medicare & Medicaid Services



National Institutes of Health



Department of Health and Human Services



Environmental Protection Agency



U.S. Department of Agriculture



National Science Foundation



U.S. Food and Drug Administration

Collaborative, Multi-agency, Cross-cut Program
Among 11 Federal agencies

Fund to advance new, interdisciplinary women's health research towards transformative research and development in women's health.

NIH Revisioning Women's Health Research Funding and Data

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

- **Increase SBIR/STTR investments by 50%** to bridge the gap between performance of basic science and commercialization of resulting innovations

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

- **One location** to find all Women's Health Research funding

Create a Comprehensive Research Agenda on Menopause

- Launch a Pathways to Prevention **series on menopause**





First NIH Wide Women's Health Research Notice of Special Interest Linked to All NIH Parent Funding Opportunities (NOT-OD-24-079)

Participating ICOs:

ORWH, OAR, NEI, NHLBI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIDA, NIEHS, NIGMS, NIMH, NINDS, NINR, NIMHD, NLM, FIC, NCCIH, NCATS, NCI, ODP, OBSSR, ODS, SGMRO, ODSS



Expiration date: November 5, 2027

In alignment with the **White House Initiative on Women's Health Research**, NIH is issuing this NOSI to highlight interest in receiving research applications focused on diseases and health conditions that:

- ❖ Predominantly affect women (e.g., autoimmune diseases; depressive disorders, Alzheimer's disease and Alzheimer's disease-related dementias, gender-based-violence)
- ❖ Present and progress differently in women (e.g., cardiovascular disease; HIV; reproductive aging and its implications)
- ❖ Are female-specific (e.g., uterine fibroids; endometriosis; menopause)



Menopause and Midlife Health



More than **1 million** women in the United States experience menopause each year

Review | Women's Health

May 1, 2024

The Women's Health Initiative Randomized Trials and Clinical Practice A Review

JoAnn E. Manson, MD, DrPH¹; Carolyn J. Crandall, MD, MS²; Jacques E. Rossouw, MD³; et al

» [Author Affiliations](#)

JAMA. Published online May 1, 2024. doi:10.1001/jama.2024.6542

<https://pubmed.ncbi.nlm.nih.gov/38691368/>

During menopausal transition, more than **80%** of women experience vasomotor symptoms

Only **15%** of women receive evidence-based interventions for menopause symptoms

Menopause is associated with risk for development of **chronic conditions, e.g., heart disease and osteoporosis**

NIH is committed to improving the lives and health of women across **the life span.**



Putting science to work for the health of women

OUR WORK RESOURCES & TRAINING SEX & GENDER WOMEN'S HEALTH EQUITY & INCLUSION CAREER SUPPORT ABOUT ORWH

HOME > WOMEN'S HEALTH EQUITY & INCLUSION > RESEARCH ON MENOPAUSE & MIDLIFE HEALTH

Research on Menopause & Midlife Health



<https://orwh.od.nih.gov/womens-health-equity-inclusion/research-on-menopause-midlife-health>

NIH Revisioning Women's Health Research

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

- **Biomarker discovery to prevent, diagnose, and treat conditions that affect women uniquely, such as endometriosis**

Help Standardize Data to Support Research on Women's Health

- **New common data elements help researchers share and combine datasets, promote interoperability, and improve the accuracy of datasets related to women's health**

NOT-HD-24-016

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) will develop, advance, and/or validate new devices, biomarkers, and/or methods for non-invasive diagnosis of endometriosis

The initiative requires research to improve our understanding of endometriosis initiation, progression, and pathophysiology



Eunice Kennedy Shriver National Institute
of Child Health and Human Development



NIH Fact Sheets on Women's Health Research

NIH FACT SHEETS ON Women's Health Research



- Highlights key topics related to morbidity and mortality in women in the US
- The fact sheets outline the state of the science for women's health on:
 - Autoimmune diseases
 - Cancer
 - **Cardiovascular disease**
 - **Dementia**
 - HIV
 - Maternal morbidity and mortality
 - Menopause
 - Mental health
 - Substance use disorder
 - **Violence against women**
- More than 60 million women (45%) in the U.S. living with CVD, including hypertension
- Over two-thirds of the 6 million people aged 65 and older with Alzheimer's Disease are women
- About 41% of women have experienced sexual violence, physical violence, and/or stalking by an intimate partner





CONNECT WITH ORWH

The Pulse
Monthly Email

bit.ly/ORWHpulse *



bit.ly/ORWHevents



bit.ly/ORWHInFocus

**All Bitly addresses are case-sensitive*

✕ @JanineClaytonMD
✕ @NIH_ORWH
f NIHORWH
NIH.gov/women

E-LEARNING



- Bench to Bedside: Integrating Sex & Gender to Improve Human Health
- SABV Primer
- And more!

bit.ly/ORWHeLearning

www.nih.gov/women