



NIH Office of Research on Women's Health

58th 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

April 12, 2023 – Director's Report



Facebook: /NIHORWH

Twitter: @NIH_ORWH

www.nih.gov/women

#ResearchForWomen

Outline of ACRWH Director's Report

- I. Opening remarks
- II. NIH updates
- III. Funding, Budget, & Legislative updates
- IV. Policy & Scientific updates
- V. ICO Collaborations
- VI. Careers
- VII. Closing



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



In Memoriam

Congresswoman Patricia Schroeder

1940 – 2023

IMPACT

I am the ripple in the pond,
The stone that's thrown into the lake.
I am the wave that crashes on the shore,
The wind that blows through the trees.

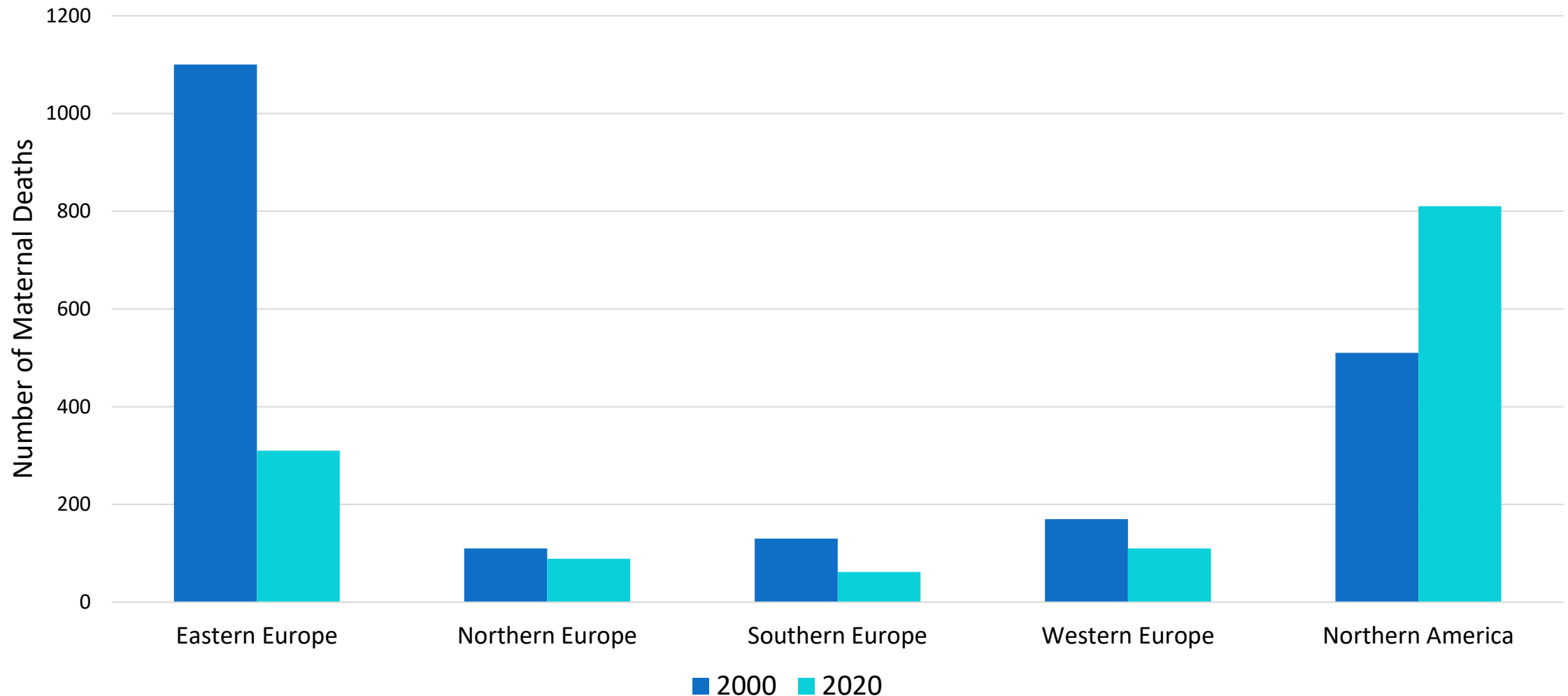
I am the change that you can't see,
The force that makes things happen.
I am the impact that you leave,
The legacy that you create.



"We need to make sure that women have access to quality health care. Women's health is important, and we need to make sure that women have the care they need."



WHO 2023 Report: U.S. Maternal Mortality Worsened from 2000 to 2020 while Peer Nations' Maternal Mortality Improved

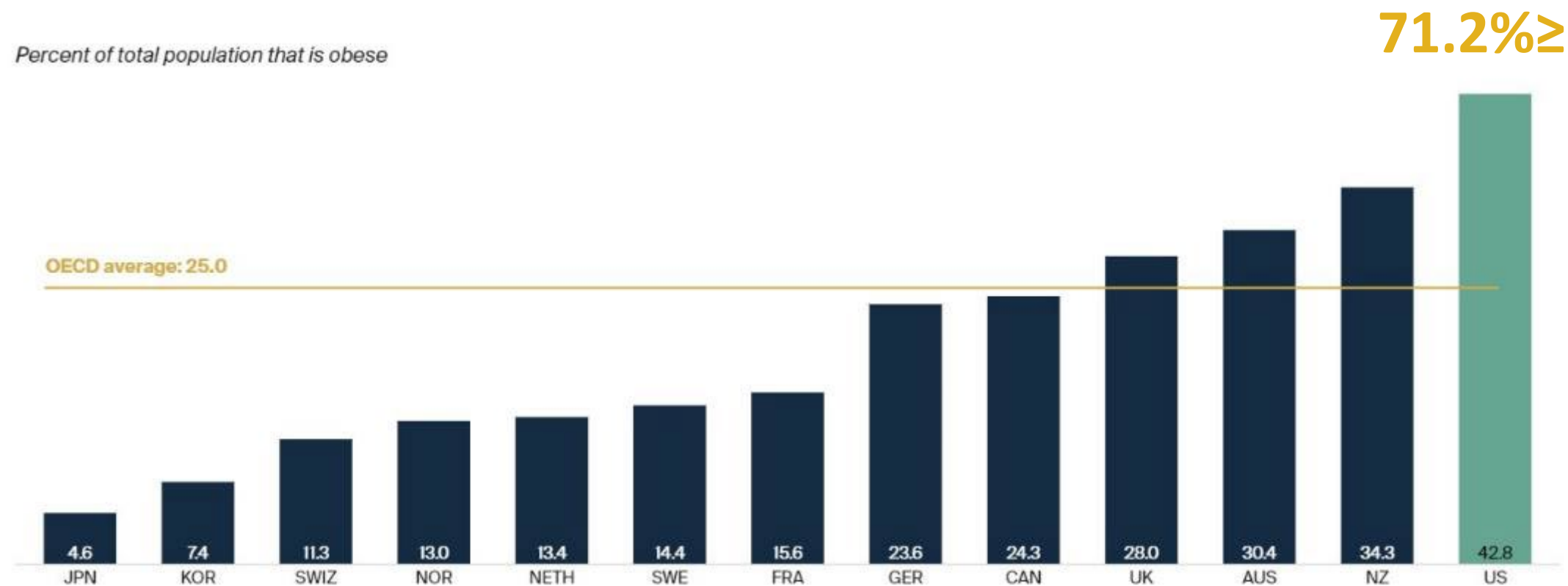


Adapted from Trends in maternal mortality 2000 to 2020: Estimates by WHO, UNICEF, UNFPA, World Bank Group and UNDESA/Population Division. Geneva: World Health Organization; 2023. License: CC BY-NC-SA 3.0 IGO.





The U.S. Obesity Rate Far Exceeds OECD Average

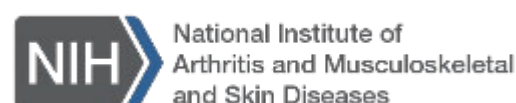
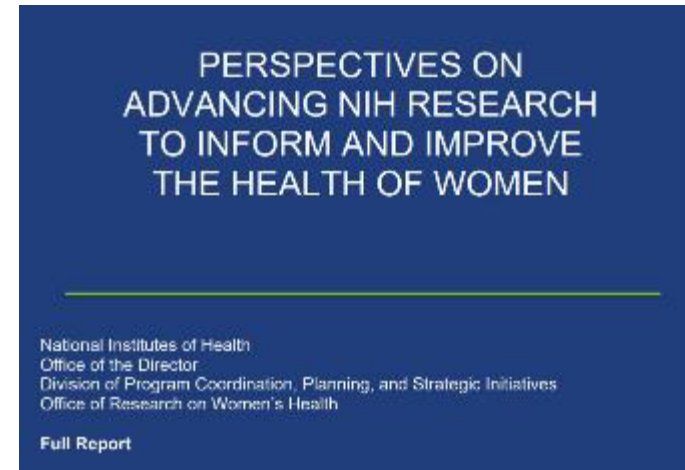


https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top



6 ICOs Partner with ORWH to Issue New Chronic Disease Research Opportunities

- **WHC Report** highlights chronic disease and multimorbidity
- Aligned with Goal 1 of **NIH Strategic Plan for Women's Health Research**:
 - Advance rigorous research relevant to the health of women.
- Understanding Chronic Conditions Understudied Among Women (R21 Clinical Trial Optional) ([RFA-OD-23-013](#))
(R01 Clinical Trial Optional) ([RFA-OD-23-014](#))
- First Due Date: May 19, 2023

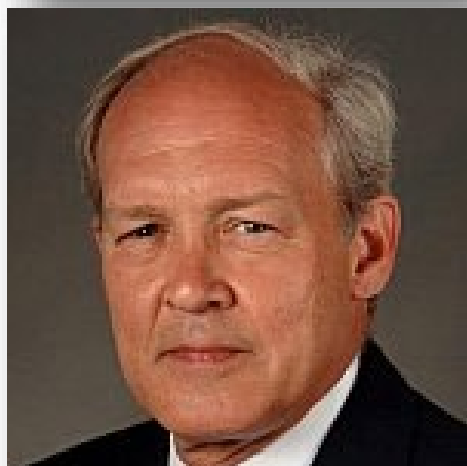


NIH Updates

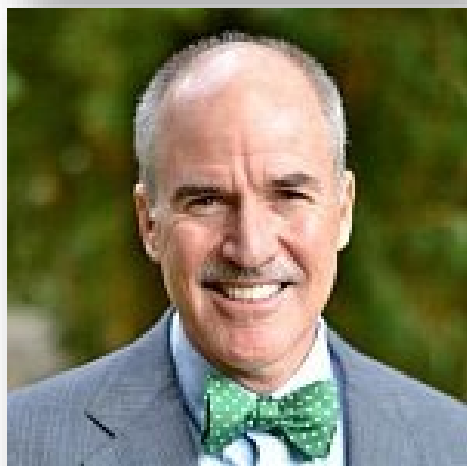




Joni L. Rutter, Ph.D.
Director, NCATS



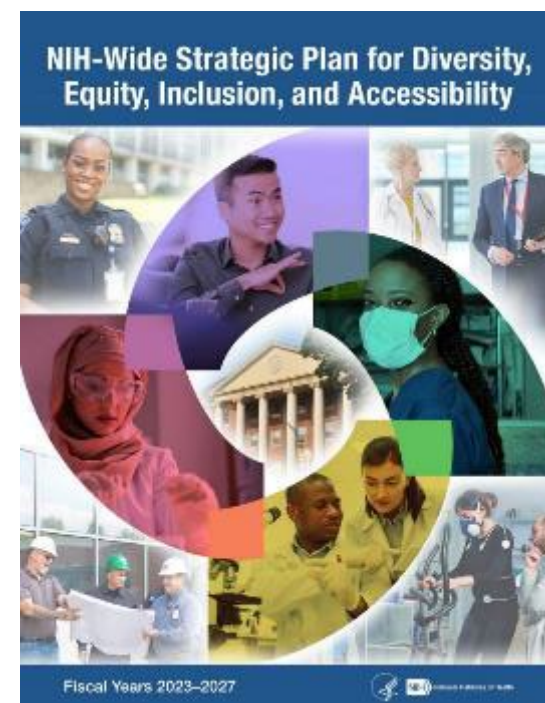
Hugh Auchincloss, M.D.
Acting Director, NIAID



Peter Kilmarx, M.D.
Acting Director, Fogarty International Center

11

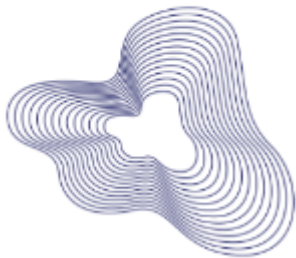
Number of women
IC directors



Advanced Research Projects Agency for Health (ARPA-H)

*Supports transformative research to drive
biomedical and health breakthroughs to provide
transformative health solutions for all*

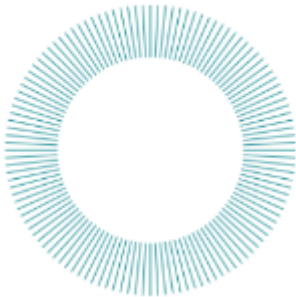
Focus Areas



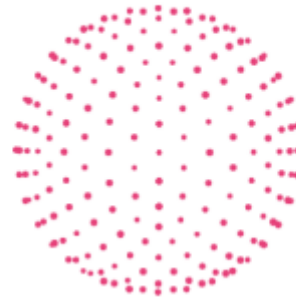
Health Science Futures
Expanding what's technically possible
[Learn More](#)



Scalable Solutions
Reaching everyone quickly
[Learn More](#)



Proactive Health
Keeping people from being patients
[Learn More](#)



Resilient Systems
Building integrated healthcare systems
[Learn More](#)



Renee Wegrzyn, Ph.D.

Director, ARPA-H

Happy 1st Birthday!

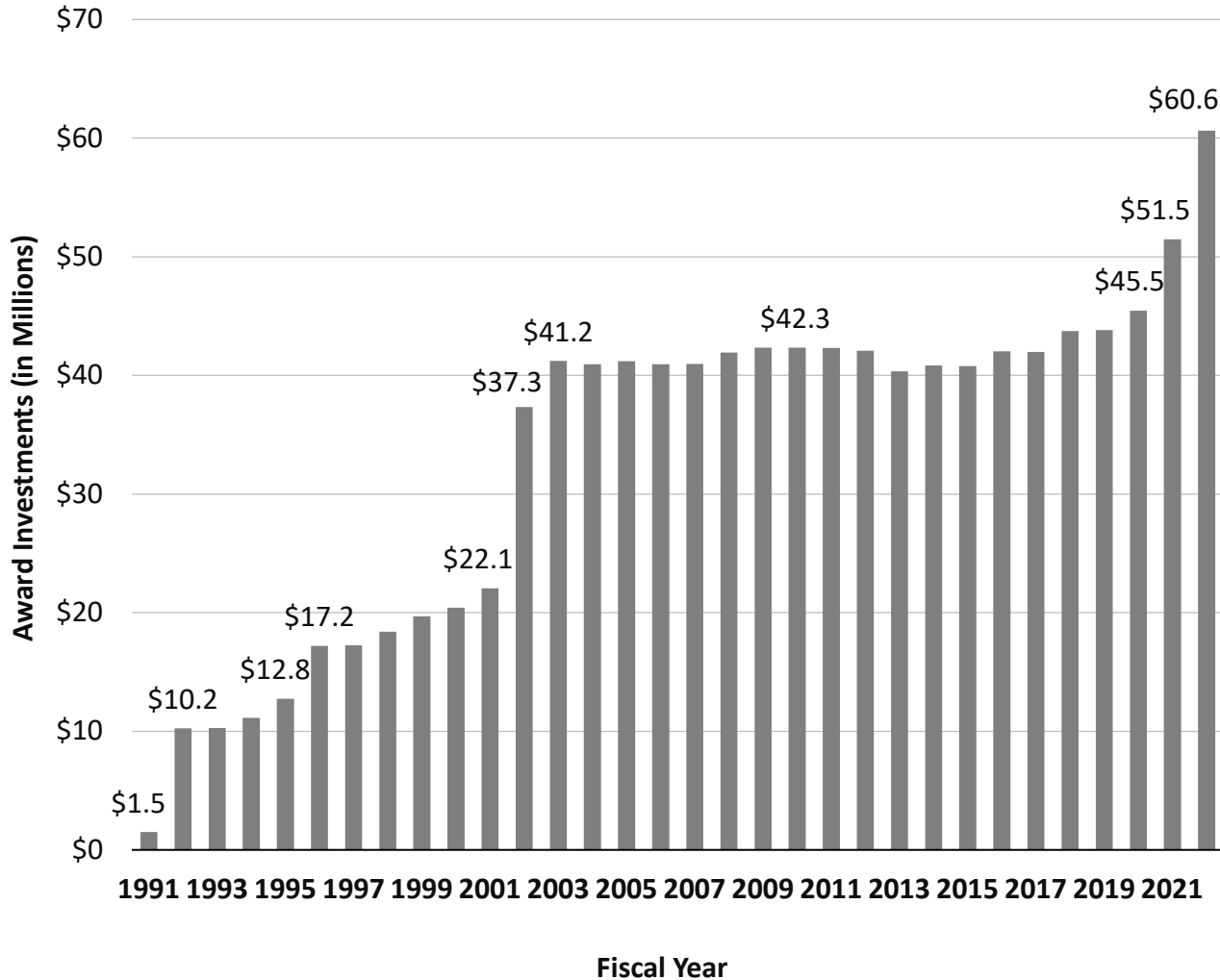


FY22 Funding ORWH Research Programs

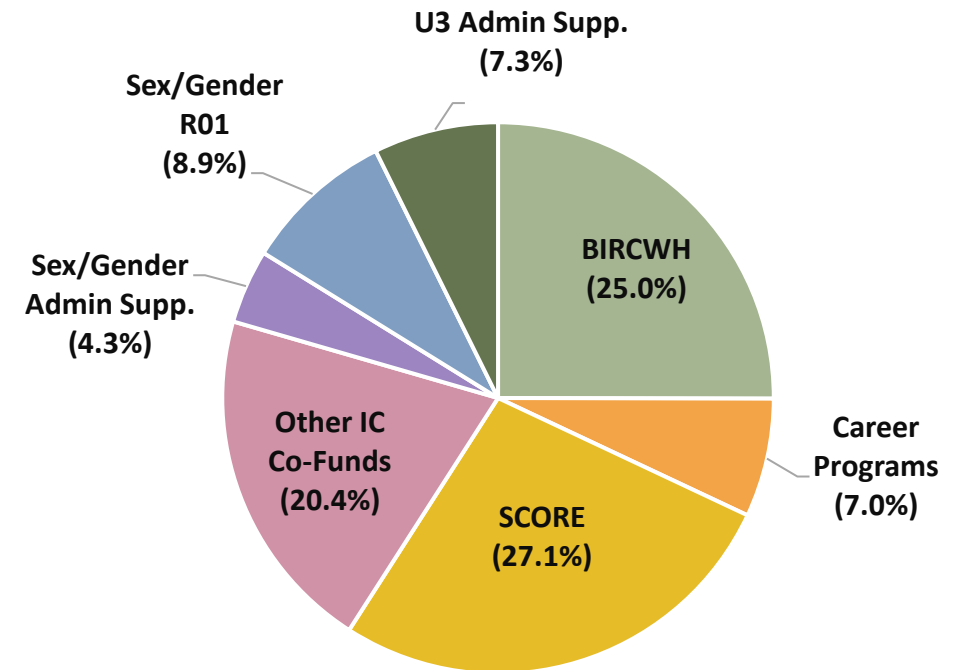


ORWH Budget History & FY2022 Extramural Grant Award Profile

ORWH Budget History



Note: Award investments do not adjust for inflation.



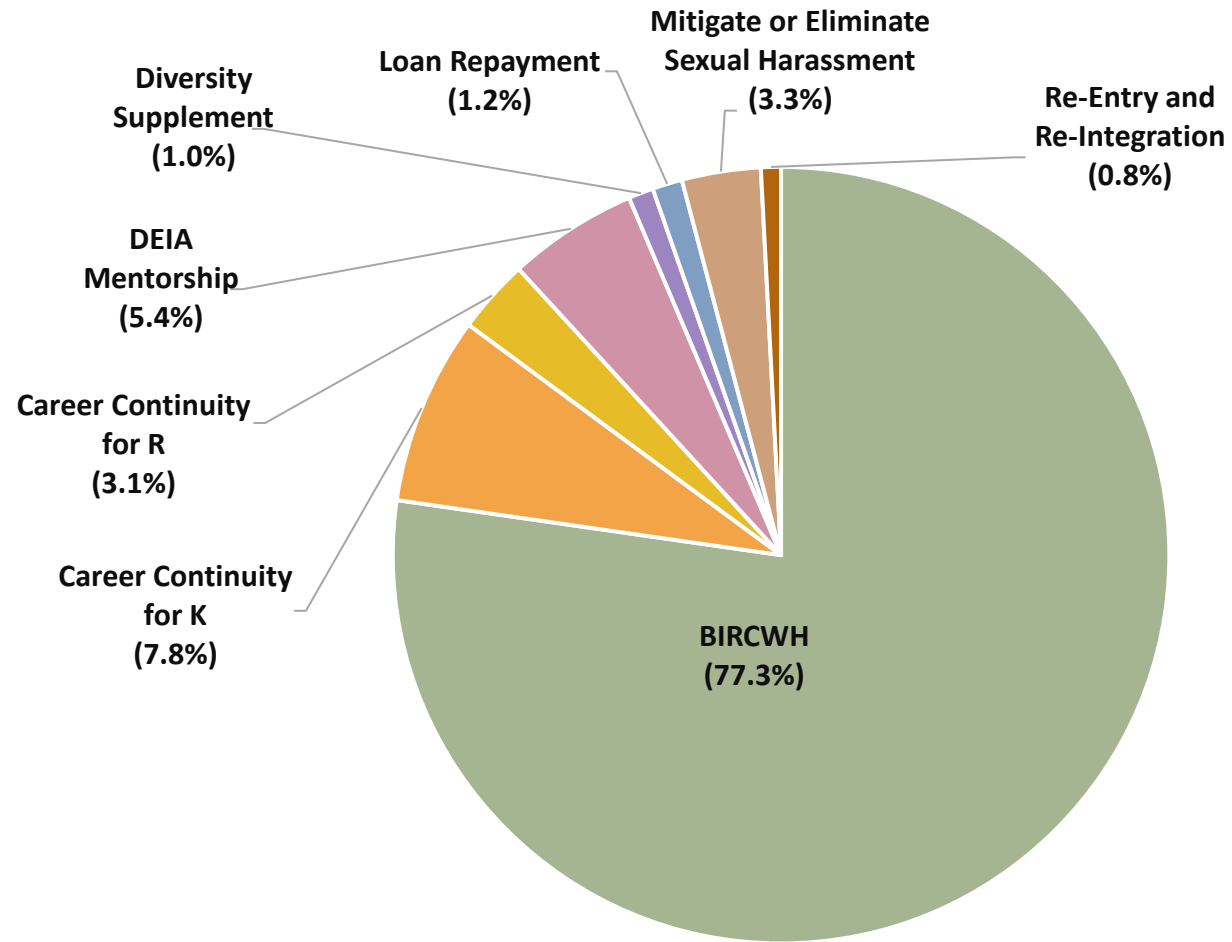
ORWH FY2022 Extramural Grant Awards by Program
(as % of Extramural Budget)

Source: NIH IMPAC II FY2022 frozen data.

Note: ORWH total investments = \$43,222,779. Funding portfolio excludes R&D contracts, IAA, and Loan Repayment awards.

ORWH FY2022 Career Programs

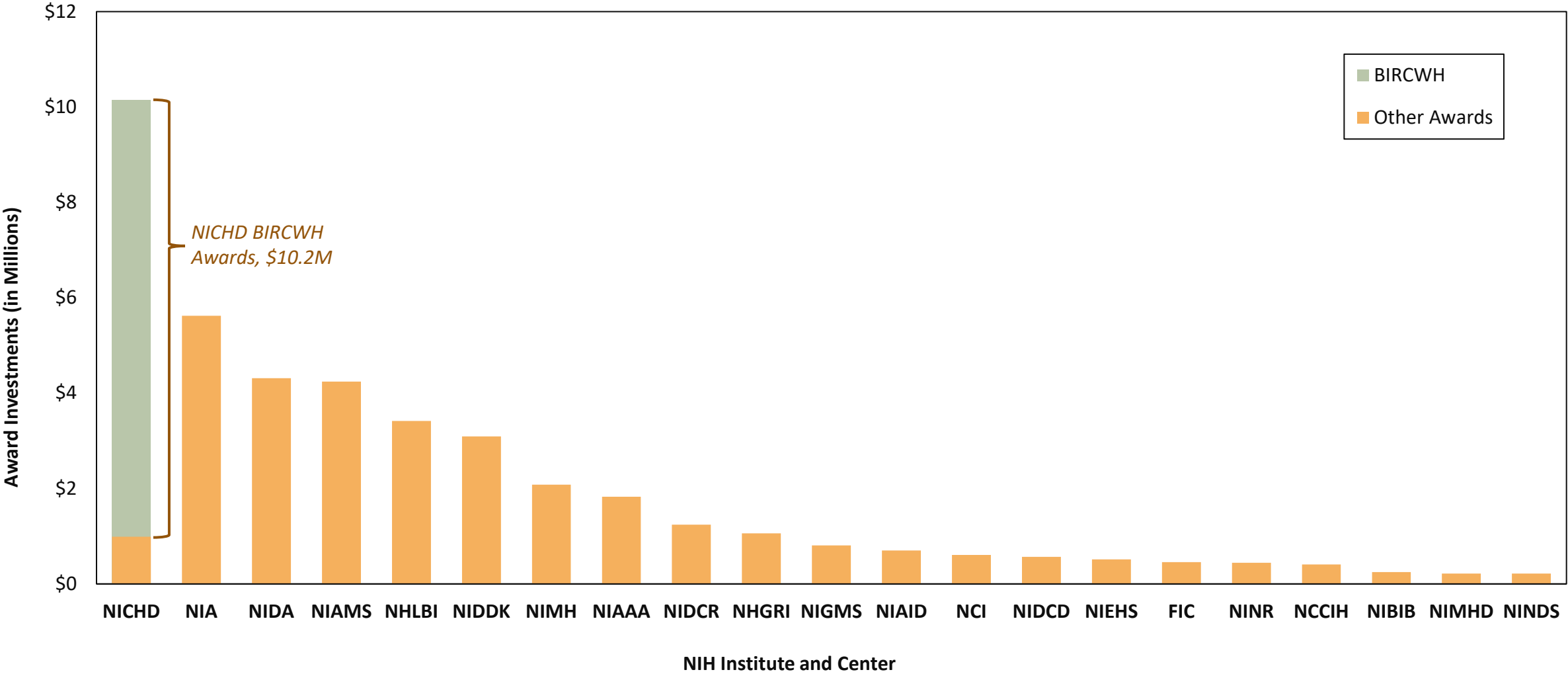
Total = \$14,004,153 Including Loan Repayment Awards



Source: NIH IMPAC II FY2022 frozen data and NIH nVision database (for Loan Repayment

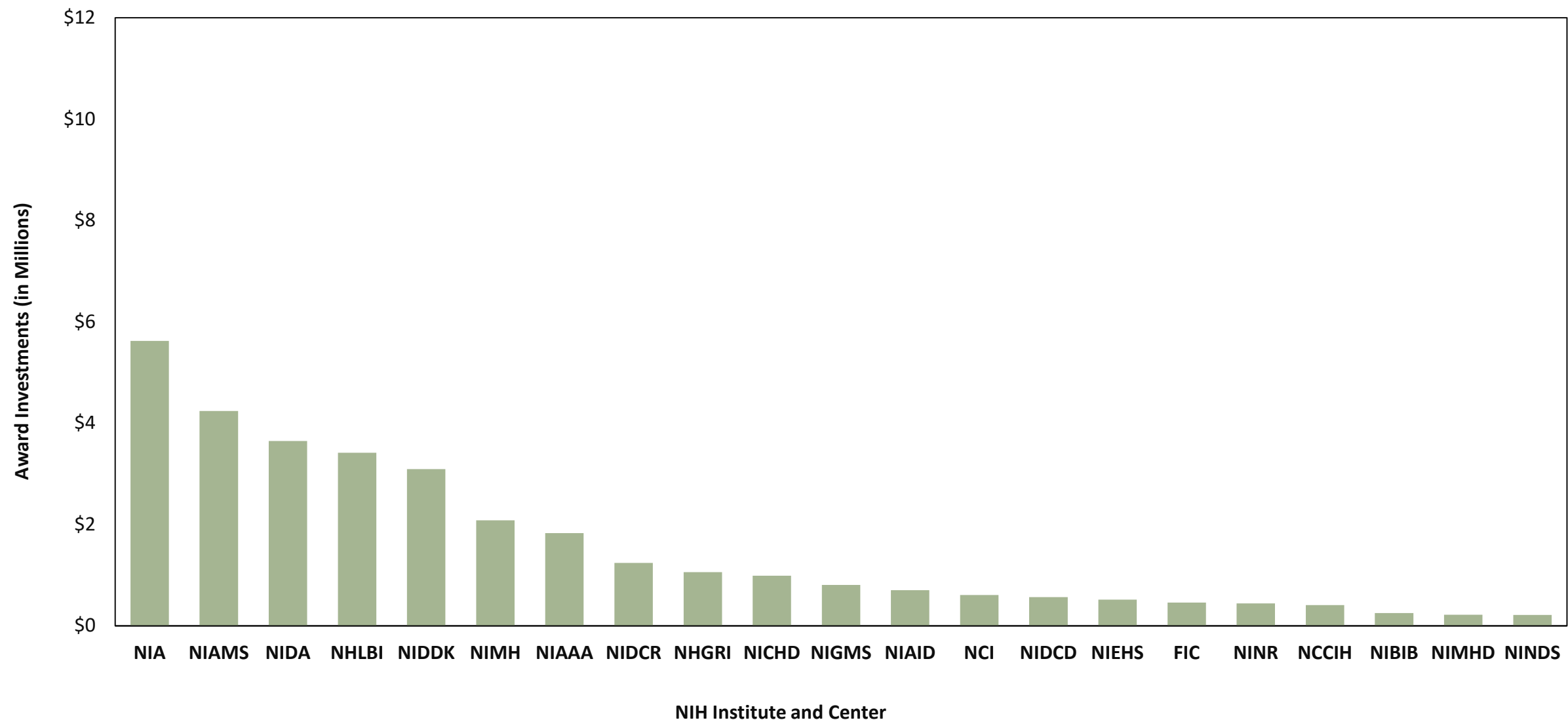


ORWH FY2022 Extramural Award Investments by IC (including BIRCWH funding)



Source: NIH IMPAC II FY2022 frozen data.
Note: ORWH total investments = \$43,222,779. Funding portfolio excludes R&D contracts, IAA, and Loan Repayment awards.

ORWH FY2022 Extramural Award Investments by IC (excluding BIRCWH funding)



Source: NIH IMPAC II FY2022 frozen data.
Note: ORWH total investments = \$32,402,370. Funding portfolio excludes NICHD and NIDA BIRCWH investments, Contract R&D, IAA, and Loan Repayment awards.

ORWH Extramural Award Investments by Research Program in FY2022

Program	ORWH Investments	# of Co-Funding ICs	List of Co-Funding ICs
BIRCWH*	\$10,820,409	2	NICHD; NIDA
Career Programs:			
Without Loan Repayment	\$3,009,110	12	FIC; NCCIH; NHLBI; NIA; NIAAA; NIAMS; NICHD; NIDA; NIDCD; NIDCR; NIDDK; NIGMS
With Loan Repayment**	\$3,183,744		
SCORE	\$11,707,976	5	NIA; NIAAA; NIDA; NIDDK; NIMH
Sex/Gender R01	\$3,830,594	8	NHGRI; NHLBI; NIA; NIAID; NIAMS; NIDA; NIDCR; NIEHS
Sex/Gender Admin Supp.	\$1,877,128	8	NCI; NHLBI; NIA; NIAMS; NICHD; NIDA; NIDDK; NIMH
U3 Admin Supp.	\$3,161,856	11	NCI; NHLBI; NIAAA; NICHD; NIDA; NIDDK; NIGMS; NIMH; NIMHD; NINDS; NINR
Other IC Co-Funds	\$8,815,706	15	FIC; NCCIH; NCI; NHGRI; NHLBI; NIAID; NIAMS; NIBIB; NICHD; NIDA; NIDCR; NIDDK; NIGMS; NIMH; NINR

* In FY2022, NICHD, NIDA, NCI, NIAAA, and NIAID also supported the BIRCWH program with additional funds.





Office of Research on Women's Health Receives **\$76.48 million** FY23

\$5 million

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

\$10 million

Establish the Office of Autoimmune Disease Research (OADR)

\$2 million

Contract with the National Academies of Sciences, Engineering, and Medicine (NASEM) to conduct a study on gaps in NIH women's health research

NASEM study to explore:

- ✓ Proportion of research on conditions that are more common or unique to women
- ✓ Establish how these conditions are defined
- ✓ Evaluate sex differences and racial health disparities
- ✓ Determine the appropriate level of funding to address gaps in women's health research at NIH

Congress to receive a report within 18 months

- ✓ Findings and recommendations to address research gaps in women's health research

P.L. 117-328 Consolidated Appropriations Act of 2023

Division H--Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2023





FY23 Omnibus Language – **NEW**

NIH Office of Autoimmune Disease Research (OADR)

**Many autoimmune diseases predominately affect women-
a 2022 NASEM report recommended the establishment of an
NIH Office of Autoimmune Disease Research**

The agreement 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

ORWH and OADR will brief the Committees within 150 days of enactment of this Act on NIH's efforts to stand up OADR and the status of the directives.

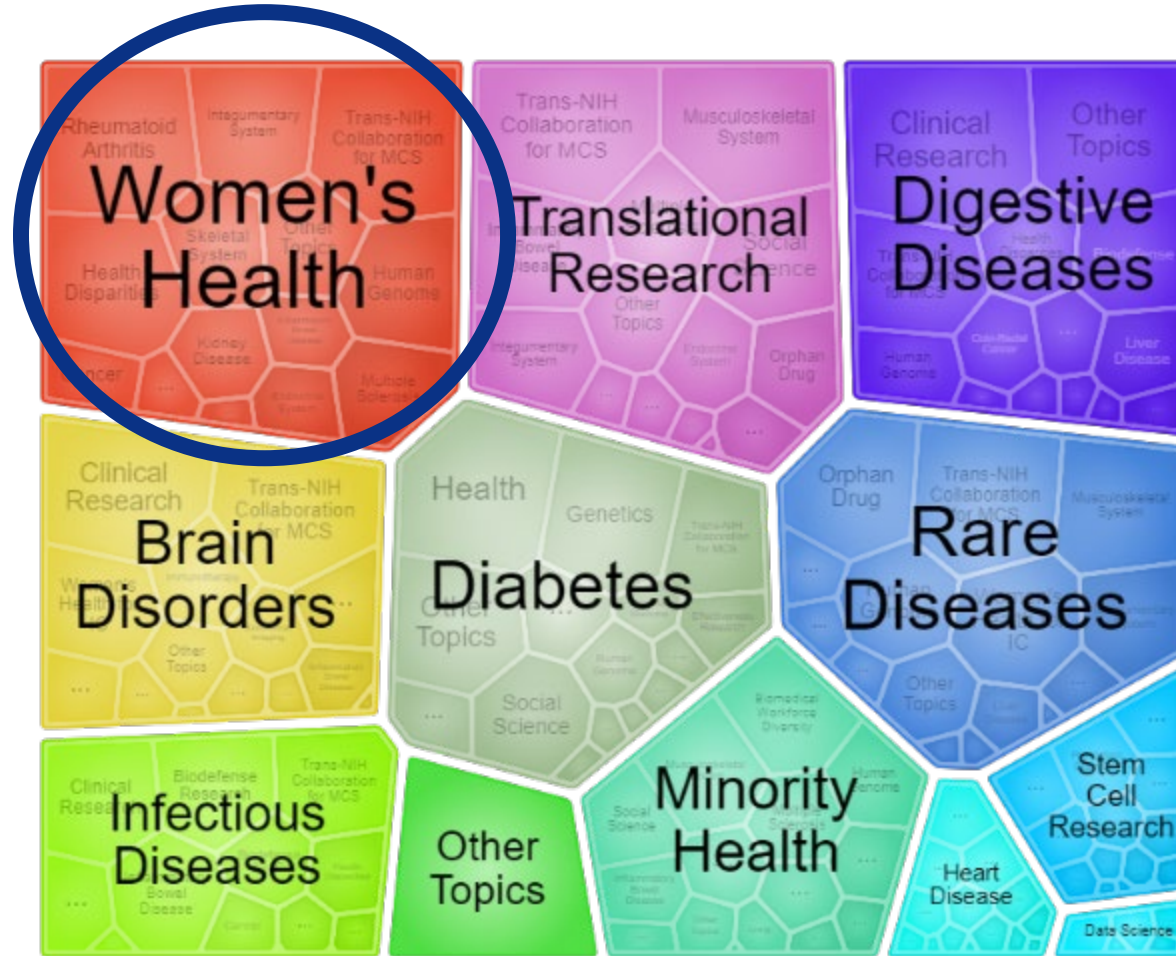


<https://nap.nationalacademies.org/catalog/26554/enhancing-nih-research-on-autoimmune-disease>





NIH Investment in Autoimmune Disease Research



Type 1 and 3 Activities with Autoimmune Disease Spending Category, sorted by additional listed Spending Categories (FY21-22)

NIH investment in Autoimmune Disease Research has increased over the past 5 years, reaching **\$946,356,182** in FY21.

In FY21 and FY22, **1,443** new research and administrative supplement grants listed Autoimmune Disease as the spending category.

Providing pathways to interdisciplinary collaboration across ICOs is key.



OADR-ORWH Current and Future Actions

Infrastructure

- Establish OADR-ORWH Core
- Recruit two FTEs
- Support ADR workforce & trainees
- Identify existing datasets
- Promote Common Data Elements

Scientific Direction

- Conduct environmental scan- e.g. NASEM report
- Establish NIH-wide Coordinating Committee (CCADR)
- Collaborate with ICOs
- Perform portfolio analyses
- Develop strategic plan

Public Engagement

- Meet with patient advocate groups & associations
- Solicit input from the community
- Release Request for Information (RFI)
- Develop communications and stakeholder engagement plans

Funding Opportunities

- FY23 Co-funding ADR from highly meritorious ICO applications
- Collaborative ICO opportunities for FY23 and FY24
- New OADR programs

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- Meet with patient advocate groups & associations
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Funding Opportunities

- FY23 ORWH Strategic Research Program: co-funding ADR from highly meritorious ICO applications
- Collaborative ICO opportunities for FY23 and FY24
- New OADR programs

Autoimmune diseases included in *new* research opportunities

Understanding Chronic Conditions Understudied Among Women (R01 Clinical Trial Optional)

[RFA-OD-23-014](https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-23-014.html)

Understanding Chronic Conditions Understudied Among Women (R21 Clinical Trial Optional)

[RFA-OD-23-013](https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-23-013.html)

Open Date: May 19, 2023*

“This NOFO will support research on chronic conditions that affect all women and individuals assigned female at birth that remain understudied building upon opportunities identified at the ORWH-led [Advancing NIH Research on Women's Health: A 2021 Conference](#) ...

Women have higher prevalence of chronic conditions; often present with different symptoms (e.g., dizziness rather than chest pain with cardiac disease); are affected by different chronic conditions (e.g., female-specific conditions, **autoimmune disease**); and accumulate multi-morbidity at different life course timepoints (e.g., after menopause) compared to men. Additionally, the burden of chronic conditions is not evenly distributed among communities of women, with higher prevalence among populations of women historically understudied and underrepresented in biomedical research (e.g., women from underrepresented racial and ethnic populations, women in economically disadvantaged groups, women who live in underserved rural populations, and women of sexual and gender minority groups).”

<https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-23-014.html>

<https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-23-013.html>



POLICY & SCIENTIFIC UPDATES

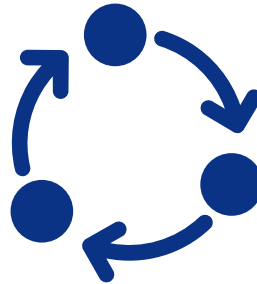
NIH Inclusion Policies Have Evolved Over Time

1993



NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research

2016



Inclusion Across the Lifespan Policy

2019



Expansion of The NIH Inclusion Policy and Guidelines

Dawn Corbett, M.P.H.
NIH's Inclusion Policy Officer



Workshop on Inclusive Participation in Clinical Research

March 30 – March 31, 2023

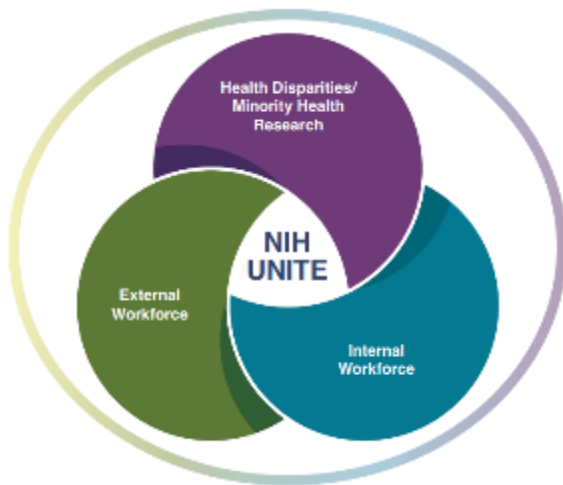




NIH-defined Phase III Clinical Trials Have Clear Instructions

- Per the 1993 NIH Revitalization Act, PL 103-43, enacted June 10, 1993, and the 21st Century Cures Act, PL 114-255, enacted December 13, 2016, NIH requires entities conducting NIH-defined Phase III Clinical Trials to design studies for valid analyses by sex/gender, race, and ethnicity, in addition to submission in [ClinicalTrials.gov](https://clinicaltrials.gov)
- Valid analysis does not need to have high statistical power
- Principal requirements for ensuring a valid analysis of the question of interest:
 - Allocation of study participants by sex/gender and from different racial and/or ethnic groups to the intervention and control groups by an unbiased process such as randomization;
 - Unbiased evaluation of the outcome(s) of study participants; and
 - Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex/gender, race, and/or ethnicity.

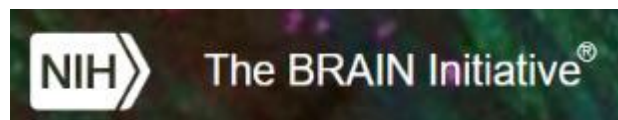
Progress Reports: For projects involving NIH-defined Phase III Clinical Trials, annual [Research Performance Progress Reports \(RPPRs\)](#) should include a statement indicating the status of analyses of the primary outcome by sex or gender, race, and ethnicity. The results of these analyses should be included in the “Project Outcomes” section of the RPPR.



Understanding and Addressing the Impact of Structural Racism and Discrimination on Minority Health and Health Disparities ([RFA-MD-21-004](#))



[Plan for Enhancing Diverse Perspectives](#)



[Common Fund's Transformative Research to Address Health Disparities and Advance Health Equity initiative](#)



Updated [eRA Commons](#) to include racial discrimination as a specific concern grantee institutions can report



[Community Partnerships to Advance Science for Society \(ComPASS\)](#)



[Data Dashboard](#)



[The Power of an Inclusive Workspace Recognition Project](#)

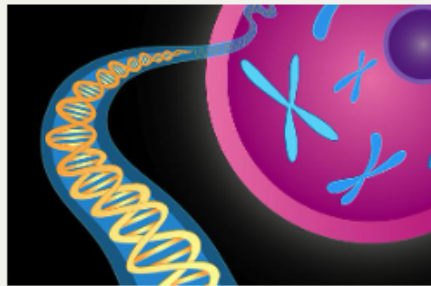




Take A Look At What's **NEW!**

SABV Impact Page

Sex as a Biological Variable



NIH established the Sex as a Biological Variable (SABV) Policy requiring that all eligible funding applicants consider the influence of sex in their research to better understand health and disease for all. Since this policy, other funding agencies adopted similar policies reflecting the importance of sex as a biological variable.

Image credit: National Institute of Mental Health, NIH

Flip

- SABV applies to funding applications proposing studies with vertebrate animals and humans, of which NIH receives tens of thousands of applications annually.
- A historical focus on the biology of men, including use of male cells and animal models, contributed to the development of medications and treatments that are less effective or potentially harmful for women.
- SABV set a standard for the scientific community, paving the way for discoveries of important sex influences in many diseases and conditions.

Back

Sex & Gender Webpage

Dimensions of Sex (Biological Variable) & Gender (Social and Cultural Variable)



Interactive options to learn about sex and gender





ICO COLLABORATIONS

Nearly Half of New HIV Infections Among Women

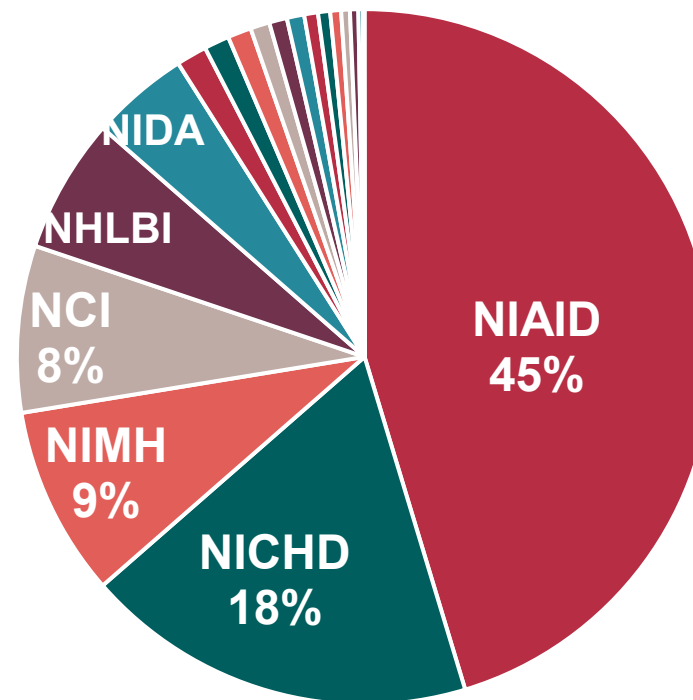
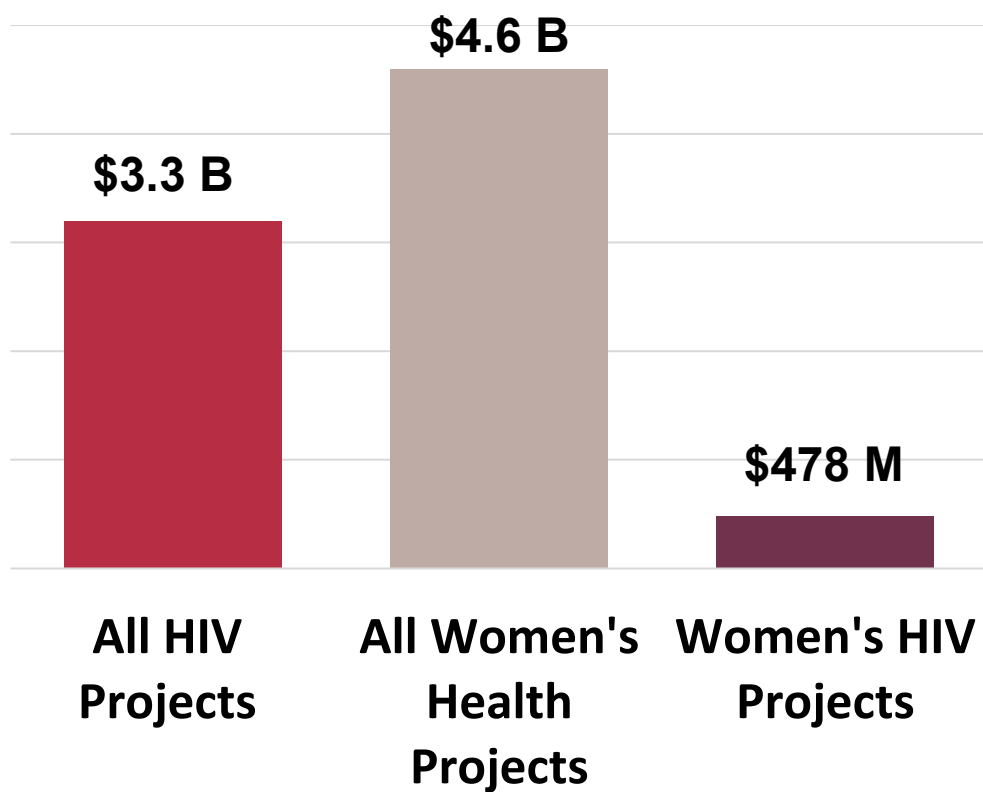
- **20 million** women and girls are HIV-positive (54% global prevalence)
- **2X** greater prevalence among adolescent girls and young women in sub-Saharan Africa
- **14X** risk of HIV acquisition among transgender vs. cisgender women





19 NIH ICOs Support Research on HIV & Women

Interdisciplinary cross-cutting strategies



FY 2022 Funding



OAR-ORWH Program: HIV & Women

Program Objectives

- Promote health for all women living with or at risk for HIV acquisition
- Support career development for women in HIV research

Strategies

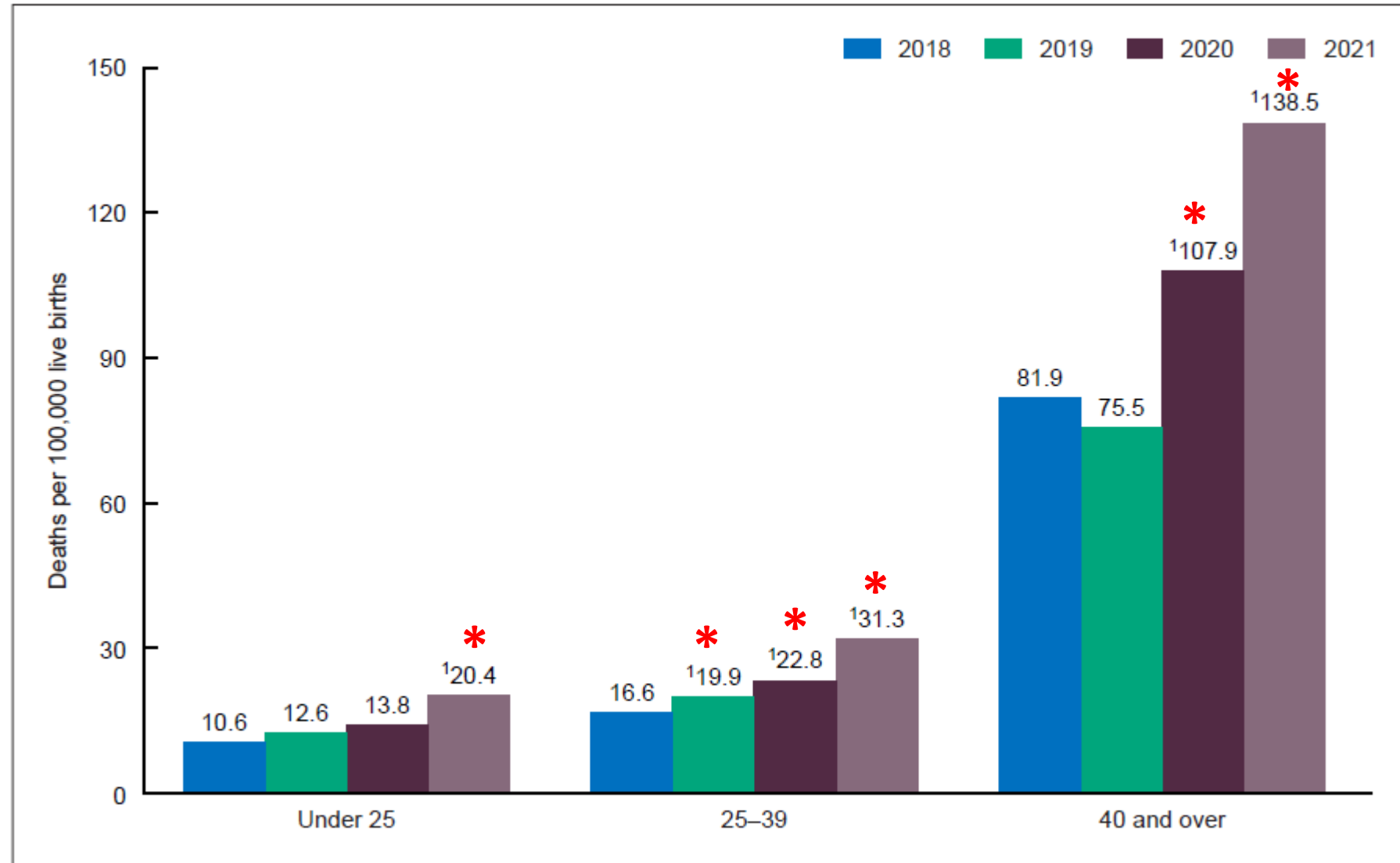
- HIV & Women Working Group
- *OAR-ORWH Symposium: Considerations from Across the Lifespan* at 13th International Workshop on Women and HIV
- Held on February 18, 2023





**U.S. Maternal
Mortality
Rates Are
Trending In
The Wrong
Direction**

Figure 2. Maternal mortality rates, by age: United States, 2018–2021



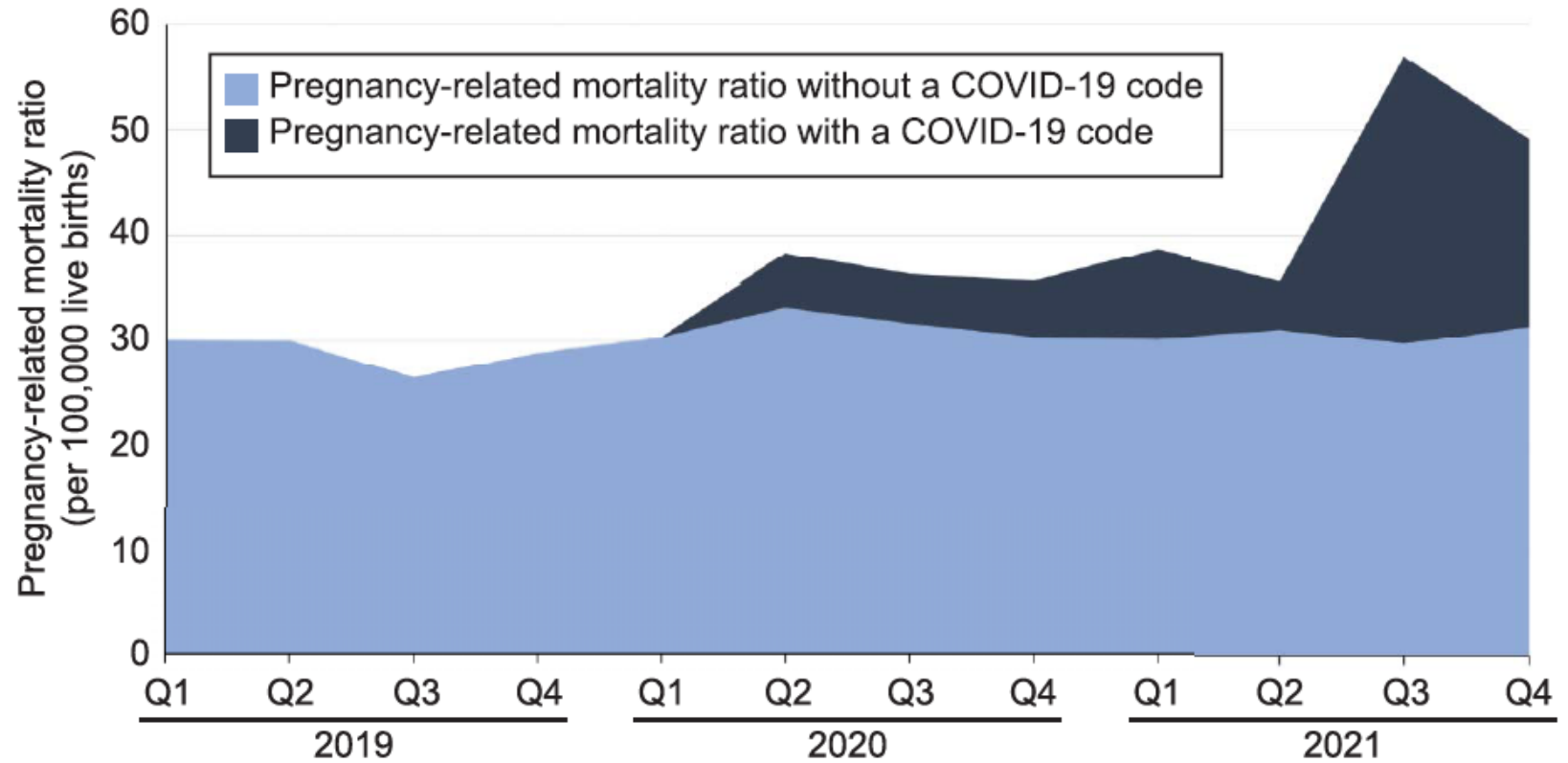
¹Statistically significant increase from previous year ($p < 0.05$).

SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality.



Pregnancy-Related Mortality Ratio Increased Significantly More in 2021 than in 2020

Total Pregnancy-Related Mortality Ratio 2019-2021





NIH & HHS Have COVID-19 Resources Available

The NIH-led research response to COVID-19
Investment, collaboration, and coordination have been key

FRANCIS COLLINS, STACEY ADAM, CHRISTINE COLVIS, ELIZABETH DESROSIER, RUXANDRA DRAGHIA-ARL, ANTHONY FAUCI, MARIA FREIRE, GARY GIBBONS, MATTHEW HALL, [...] AND JOHN YOUNG **+22 authors** [Authors Info & Affiliations](#)

SCIENCE • 2 Feb 2023 • Vol 379, Issue 6631 • pp. 441-444 • DOI:10.1126/science.abb5167



NIH Research COVID to Enhance Recovery (RECOVER)

NIH Community Engagement Alliance-Long COVID resources

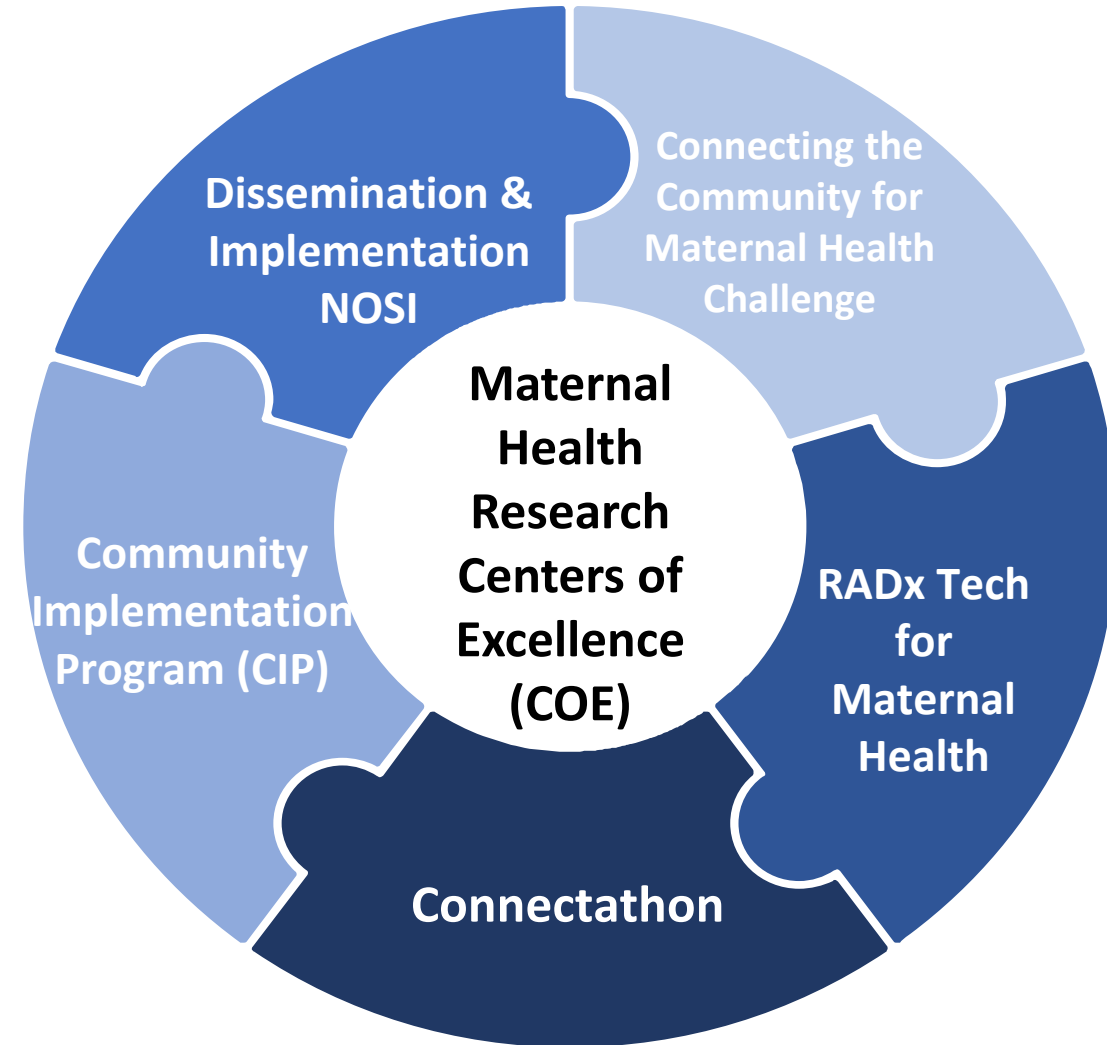
HHS We Can Do This

Bivalent boosters provide better protection against severe COVID-19

NIMHD Health Disparities Research Institute: August 7-11, 2023



NIH Joins Forces to Tackle Critical Public Health Crisis: IMPROVE Initiative





IMPROVE Initiative Updates



<https://videocast.nih.gov/watch=49018>

- Shared results & lessons learned from IMPROVE projects
- Identified common themes, shared research gaps & opportunities for ongoing collaboration
- Further defined needs of pregnant & postpartum individuals to reduce preventable deaths



Congressional briefing held
March 28, 2023



NIH Leadership updated
March 31, 2023



**Innovative
Approaches
to Improve
Maternal
Health**

HYBRID WORKSHOP

May 8-9, 2023





Maternal Health Diagnostic Challenge Winners



1st Place:

Dr. Bethany Hedt-Gauthier, Harvard University, Boston
mHealth tools for community health worker-led home-based diagnosis of surgical site infections and anemia post-caesarean delivery



2nd Place:

University of California, Irvine
Maternal obstetrics monitoring sock (MOMS)



3rd Place tie:

Raydiant Oximetry, Inc., San Francisco
LUMERAH™ near infrared spectroscopy platform to diagnose maternal hemorrhage and fetal distress during pregnancy



Raydiant Oximetry, Inc.

3rd Place tie:

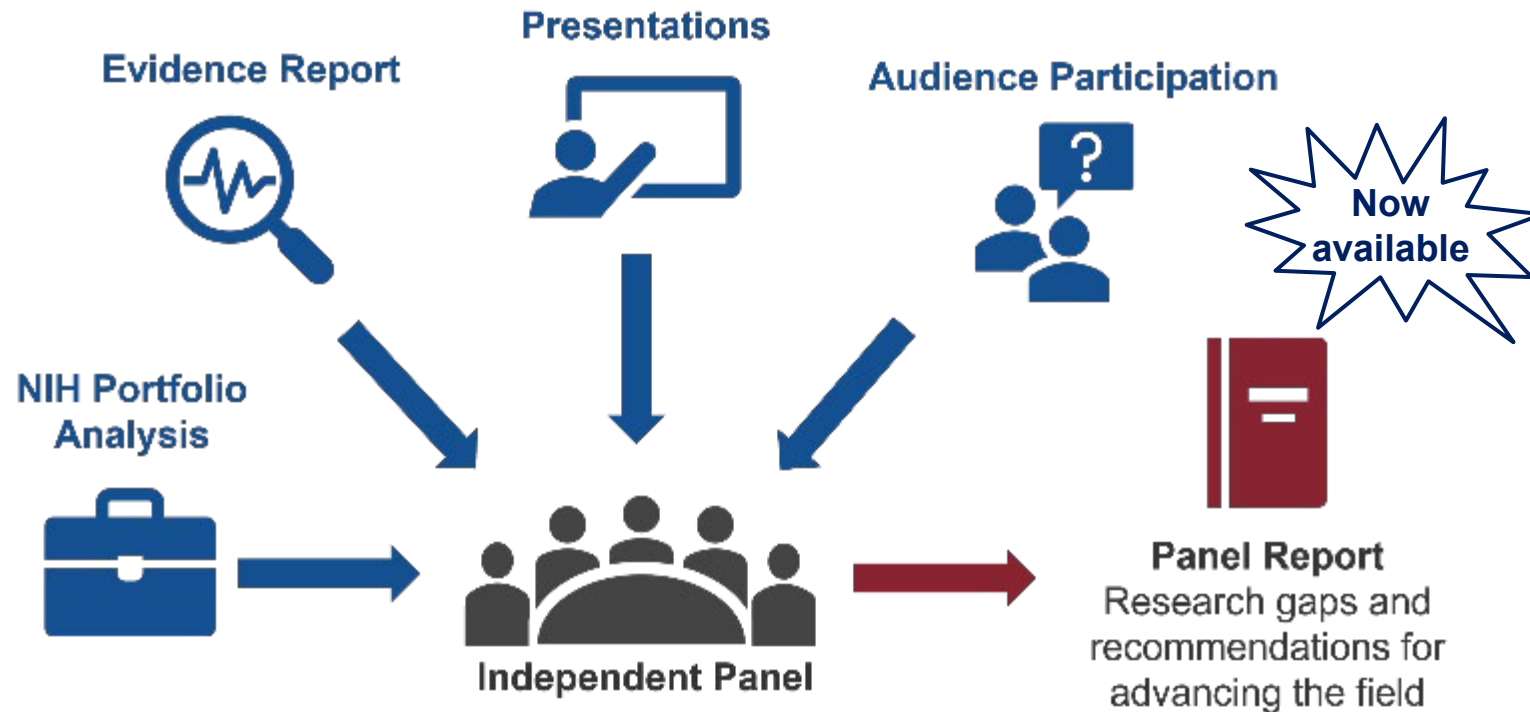
Softsonics, LLC, San Diego
A wearable ultrasound/electrochemical sensor for maternal health surveillance

Softsonics



Office of Disease Prevention: Pathways to Prevention Program (P2P)

Identifying Risks and Interventions to Optimize Postpartum Health



Workshop Components

Workshop Takeaways

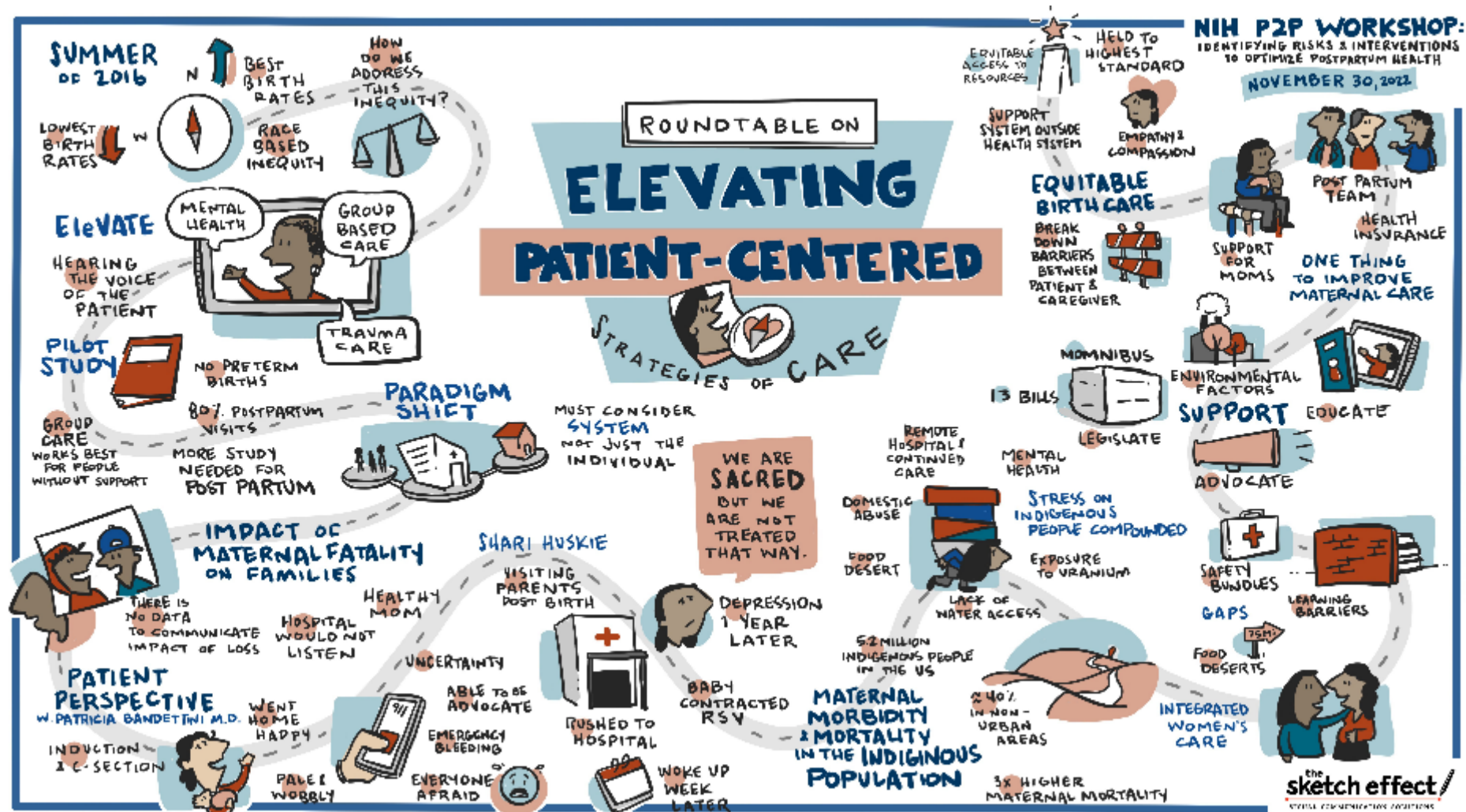
- The “stress test” of pregnancy continues postpartum
- We need to bridge the chasm
- Take a life course perspective
- And importantly, listen to the patient and their families...
- Panel Report available and open for comment*

Conference Recordings are available on the ODP website

*<https://prevention.nih.gov/sites/default/files/P2P/P2P-PostpartumHealth-DraftReport-FINAL-508.pdf>



Pathways to Prevention: Identifying Risks and Interventions to Optimize Postpartum Health



<https://prevention.nih.gov/research-priorities/research-needs-and-gaps/pathways-prevention/identifying-risks-and-interventions-optimize-postpartum-health/graphic-recording-roundtable-elevating-patient-centered-strategies-care>

Intimate Partner Violence during Pandemic is Associated with Adverse Mental Health Outcomes Among Women

3 prospective, population-based, longitudinal U.S. cohort studies:

- Nurses' Health Study II
- Growing Up Today Study
- Nurses' Health Study 3

IPV experiences at the start of the pandemic associated with higher endorsement of:

- Depression
- Anxiety
- Posttraumatic stress symptoms

IPV also associated with:

- Poorer sleep quality
- Shorter sleep duration
- Increased use of alcohol
- Use of alcohol or other substances to cope with stress



JAMA
Network | **Open**™

**New RFI: Future Directions
in Violence Against Women
Research ([NOT-NR-23-008](#))**

**Issued by: NINR, NICHD,
NIMHD, SGMRO, ODP,
OBSSR, ORWH**

CAREERS





- **Develop and implement inclusive plans, promote an accessible culture, and address bias.**
- **Collect data on demographics and educational outcomes, and fund research on best practices.**
- **Redress bias and discrimination in organizational processes.**


Summary of 8 Recommendations from NASEM Report to Advance ADEI in STEMM



<https://nap.nationalacademies.org/catalog/26803/advancing-antiracism-diversity-equity-and-inclusion-in-stemm-organizations-beyond>

RFI: Re-envisioning U.S. Postdoctoral Research Training & Career Progression within the Biomedical Research Enterprise

- Understand perspectives, experiences of recent/current postdoc trainees, postdoc office leaders & graduate students considering becoming postdoc trainees in academic sector
- Hearing the voices of postdoc trainees along with others impacted by this unique & skilled training position to explore ways to address fundamental challenges faced by the postdoc trainee community
- **Response due date: April 14, 2023**
- <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-084.html>



**Advisory Committee
to the NIH Director
Working Group
facilitated 4 listening
sessions in March**

Galvanizing Health Equity Through Novel and Diverse Educational Resources = *GENDER*



- GENDER R25 (RFA-OD-22-015)
- Help meet the need for gender-specific training in science, medicine, and allied health professions
- Supports development of gender-focused courses, curricula, and methods for extramural community
- **Application due date: June 27, 2023**
- Partner ICOs: NIA, NIAMS, NIDA, NIMHD, NLM, NIDCR, OBSSR, OAR, SGMRO
- <https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-22-015.html>

Braided River: A New Metaphor for Career Paths



- People take many paths through school and weave careers around an assortment of circumstances such as:
 - Rearing families
 - Serving in the military or volunteer corps
 - Fulfilling caregiving responsibilities
 - Reengaging with formal education
- Individuals move in and out of roles and positions in which they consult, start businesses, and hold jobs across disciplines and sectors.

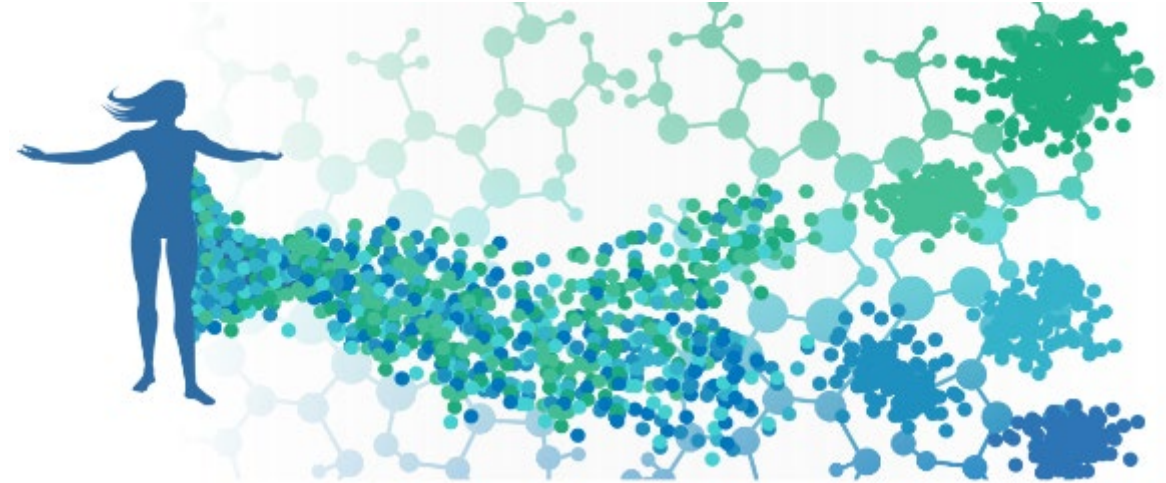
Batchelor, R. L. et al (2021), Reimagining STEM workforce development as a braided river, *Eos*, 102, <https://doi.org/10.1029/2021EO157277>.

These experiences bring new ideas that are more creative and practical to offer interdisciplinary solutions to science.

Team Science Leadership Scholar Program (LSP) in Women's Health, Autoimmune and Immune-Mediated Diseases

A pilot program to support and train women's health scholars by helping them acquire and hone team science leadership and mentoring skills

An immersive, cross-sectoral, collaborative experience that will enable women's health scholars to become large consortium team leaders





RFA: Advancing Gender Inclusive Excellence (AGIE)

- Women remain underrepresented at faculty levels in STEMM
- AGIE will address and intervene on systemic gender-based inequities impacting the STEMM academic and research workforce
- **Open date: May 1, 2023**
- <https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-23-004.html>



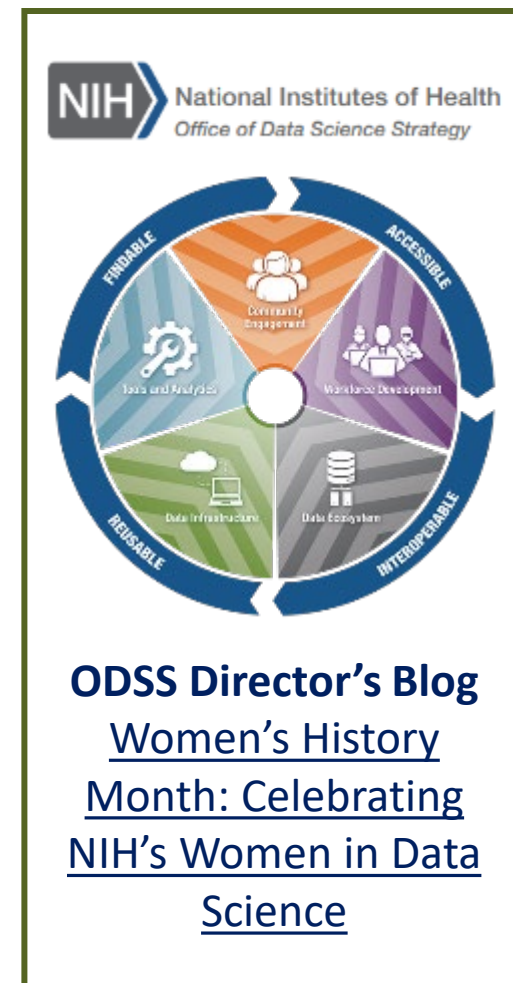
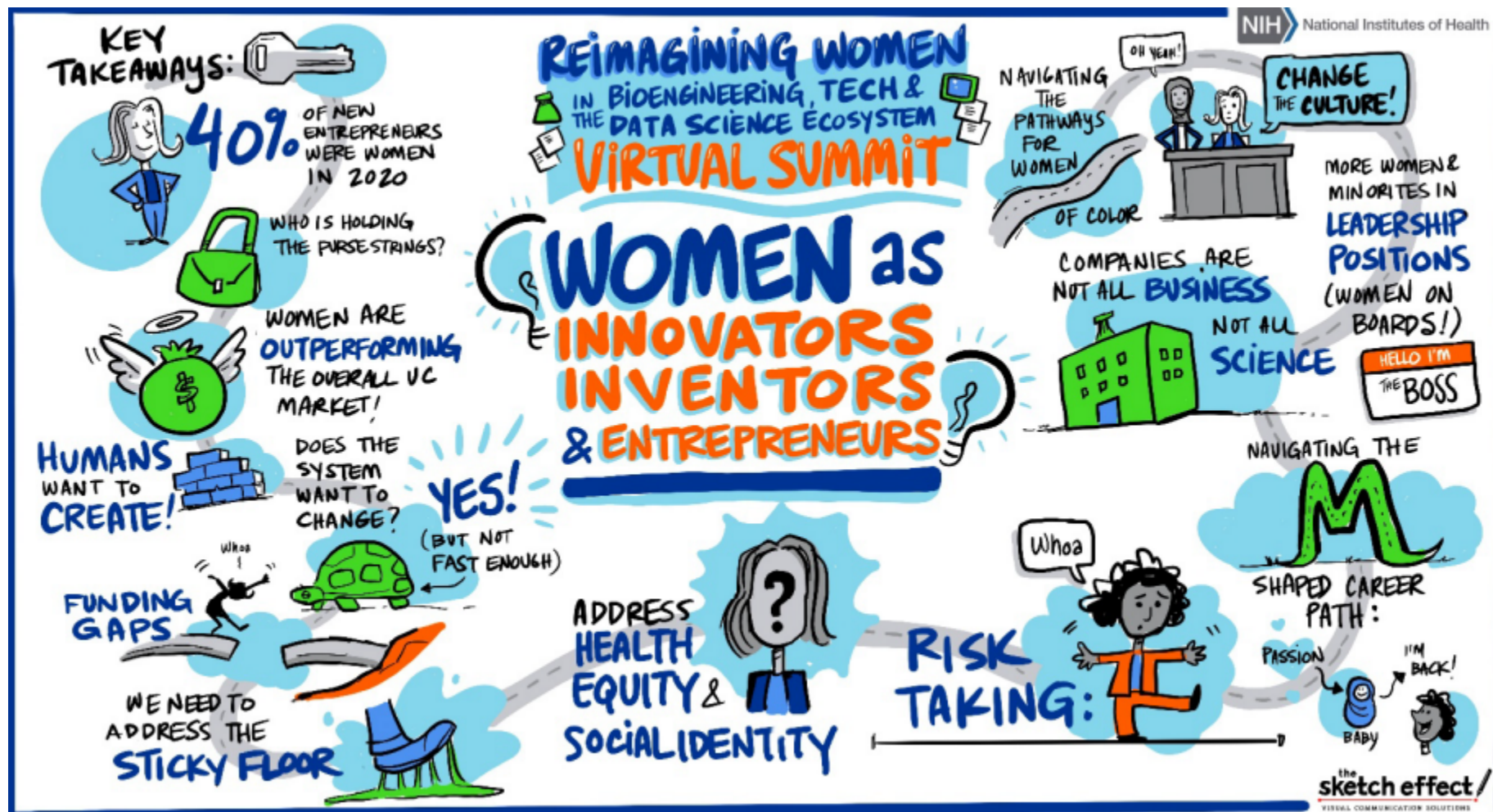
Office of Research
on Women's Health



National Institute of
Diabetes and Digestive
and Kidney Diseases



NIH Partnership Summit: Reimagining Women in the Bioengineering, Technology, and Data Science Ecosystem



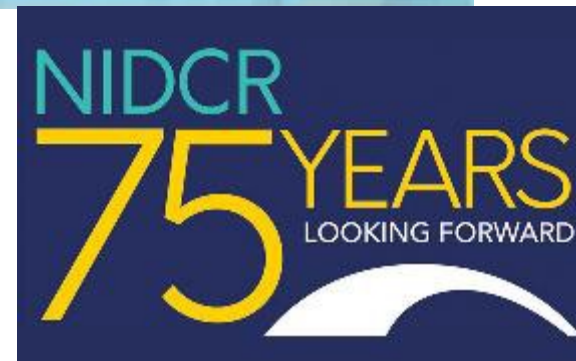
EVENTS





NIDCR Hosted A Fireside Chat With A Legend Dr. Jeanne Sinkford

- Jeanne Sinkford, D.D.S., Ph.D., a legend at the forefront of equity in oral health, human subject research, career development, and in many other spaces.
- Black History Month, 2023
- NIDCR and the ORWH co-sponsored the fireside chat.



SAVE THE DATE!



Seventh Annual Vivian W. Pinn Symposium | May 16, 2023

Honoring the first full-time director of ORWH | Held annually during National Women's Health Week

Menopause and Optimizing Midlife Health of Women

May 16, 2023 | Virtual Meeting



Vivian W. Pinn, M.D.

ORWH Quarterly Lecture Series: DIVERSE VOICES

January 23:

**Cancer Disparities: Methods and Measurement
of Racial and Ethnic Diversity**



Laura Fejerman, Ph.D., M.Sc.,
University of California Davis
Scarlett Lin Gomez, Ph.D., M.P.H.,
University of California San
Francisco

March 23: Intersectional Stigma and Mental Health



Melissa DuPont-Reyes, Ph.D.,
M.P.H., Columbia University



Janet M. Turan, Ph.D., M.P.H.,
University of Alabama
Birmingham



July 27:

**Intersectional Approaches to Substance
Use and Misuse**

September 28:

**Social Determinants and Uptake of Infectious
Disease Control Measures**

Videocast: <https://www.youtube.com/watch?v=AoaasHlzHCM>

CONNECT WITH ORWH

The Pulse

Monthly Email

bit.ly/ORWHpulse *

EVENTS

bit.ly/ORWHevents

Women, Science, and the Impact of COVID-19

bit.ly/ORWHcovid

WOMEN'S HEALTH *In Focus* AT NIH
A QUARTERLY PUBLICATION OF THE NIH OFFICE OF RESEARCH ON WOMEN'S HEALTH



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
- SABV Primer Instructor Guide
- Intro. to Scientific Basis of Sex- & Gender-Related Differences

bit.ly/ORWHeLearning

www.nih.gov/women



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