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
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
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."

The U.S. Obesity Rate Far Exceeds OECD Average

Percent of total population that is obese

OECD average: 25.0

71.2%≥

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](https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH-WHC-Report-508C.pdf))
  - (R01 Clinical Trial Optional) ([RFA-OD-23-014](https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH-WHC-Report-508C.pdf))
- 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
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

Award Investments (in Millions)

Fiscal Year


$0 $10 $20 $30 $40 $50 $60 $70

$1.5 $10.2 $12.8 $37.3 $41.2 $42.3 $45.5 $51.5 $60.6

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

- BIRCWH (77.3%)
- Career Continuity for K (7.8%)
- Career Continuity for R (3.1%)
- DEIA Mentorship (5.4%)
- Diversity Supplement (1.0%)
- Loan Repayment (1.2%)
- Mitigate or Eliminate Sexual Harassment (3.3%)
- Re-Entry and Re-Integration (0.8%)
- Mitigate or Eliminate Sexual Harassment (3.3%)

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

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

* 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*
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.**

**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.
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
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 public and community constituents
- Develop communications and stakeholder engagement plans

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

Understanding Chronic Conditions Understudied Among Women (R21 Clinical Trial Optional)
RFA-OD-23-013

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).”

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

https://orwh.od.nih.gov/womens-health-research/clinical-research-trials/nih-inclusion-policies
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.

• Valid analysis does not need to have high statistical power.

• Principal requirements for ensuring a valid analysis of the question of interest:
  o 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;
  o Unbiased evaluation of the outcome(s) of study participants; and
  o 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

Updated eRA Commons to include racial discrimination as a specific concern grantee institutions can report

Common Fund’s Transformative Research to Address Health Disparities and Advance Health Equity initiative

Community Partnerships to Advance Science for Society (ComPASS)

Data Dashboard

The Power of an Inclusive Workspace Recognition Project

https://www.nih.gov/ending-structural-racism/unite
Take A Look At What’s NEW!

SABV Impact Page

- 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.

Image credit: National Institute of Mental Health, NIH

Sex & Gender Webpage

Interactive options to learn about sex and gender

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

- Sex
  - Anatomy
  - Physiology
  - Genetics
  - Hormones
- Gender
  - Identity
  - Roles & Norms
  - Relations
  - Power

Mental Health

One example of how sex influences mental health is that the sex hormones estrogen and progesterone play a role in increasing the activity of key neurotransmitters including dopamine and serotonin, which affect mood. Variations in these sex hormones likely contribute to differences observed between male and female incidence rates of depression, as well as responses to treatment.

Leclaire et al., 2019. PMID: 30932992

Mental Health

There are many ways in which gender influences mental health. For example, gender norms of masculinity—such as self-reliance and toughness—have been shown to negatively influence boys’ and men’s willingness to seek mental health treatment. Gender-based violence (power relations) is associated with an increase in post-traumatic stress, anxiety, and depressive symptoms in women.

Recher-Frieler, 2017. PMID: 27364257
Nino et al., 2015. PMID: 26402943

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

- All HIV Projects: $3.3 B
- All Women's Health Projects: $4.6 B
- Women's HIV Projects: $478 M

FY 2022 Funding:
- NIAID: 45%
- NICHD: 18%
- NIMH: 9%
- NIDA: 8%
- NHLBI: 8%
- NCI: 8%

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
Pregnancy-Related Mortality Ratio Increased Significantly More in 2021 than in 2020
NIH & HHS Have COVID-19 Resources Available

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

Implementing a Maternal health and PResponse Outcomes Vision for Everyone (IMPROVE) Initiative

[Image of puzzle pieces with logos of NIH, NICHD, and NICI]

Connecting the Community for Maternal Health Challenge

Maternal Health Research Centers of Excellence (COE)

Dissemination & Implementation NOSI

Community Implementation Program (CIP)

Connectathon

RADx Tech for Maternal Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development

NIH National Institutes of Health

NIH National Institute of Nursing Research

NIH Office of Research on Women’s Health

https://www.nichd.nih.gov/research/supported/IMPROVE
IMPROVE Initiative Updates

• 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

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

https://www.eventbrite.com/e/innovative-approaches-to-improve-maternal-health-hybrid-workshop-tickets-530984899127
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:
Softsonics, LLC, San Diego
A wearable ultrasound/electrochemical sensor for maternal health surveillance

3rd Place tie:
Raydiant Oximetry, Inc., San Francisco
LUMERAH™ near infrared spectroscopy platform to diagnose maternal hemorrhage and fetal distress during pregnancy
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

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

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

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

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**

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

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.


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

ODSS Director’s Blog
Women’s History Month: Celebrating NIH’s Women in Data Science

https://orwh.od.nih.gov/sites/orwh/files/docs/Partnership_Summit_Executive_Summary_2022_508c.pdf
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.
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

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

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
The Pulse
Monthly Email
bit.ly/ORWHpulse *

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

*All Bitly addresses are case-sensitive