

51st Meeting of the NIH Advisory Committee on Research on Women's Health

Janine A. Clayton, M.D.

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

October 20, 2020 – Director's Report



**OFFICE OF RESEARCH
ON WOMEN'S HEALTH**

*Advancing the Health of
Women Through Science*

 /NIHORWH

 @NIH_ORWH

 nih.gov/women

#ResearchForWomen



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



Celebrating 30 Years



Amb. Connie Morella on ORWH's founding

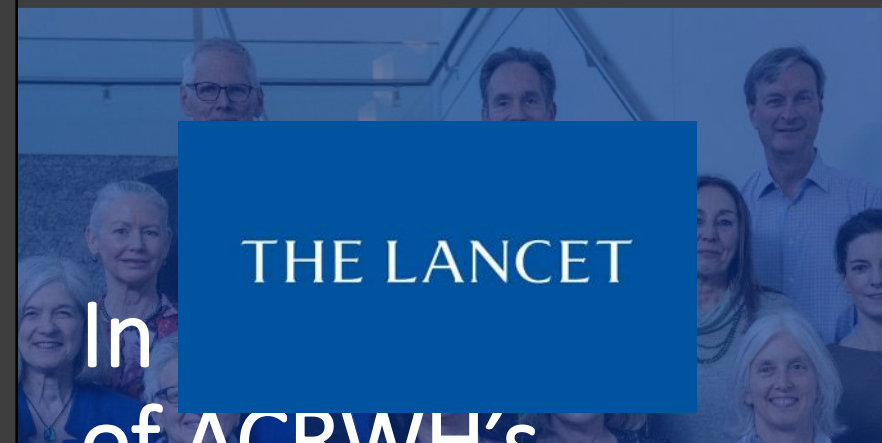
“As we celebrate the 30th anniversary of the NIH ORWH, ‘the gift that keeps on giving,’ we acknowledge that with all its accomplishments we haven’t finished. We will monitor the progress in policies, research, programs, and career development. No longer are we considered ‘little men’; rather, we are proud, healthy women. Onward and upward!”





OFFICE OF RESEARCH
ON WOMEN'S HEALTH

Advancing the Health of
Women Through Science



THE LANCET

In
of ACRWH's
ACRWH Advisors Past and Present

Noel Bairey Merz, Geert J De Vries, C Neill Epperson, Louise D McCullough, Judith G Regensteiner, Kathryn Sandberg et al. Sex and gender: modifiers of health, disease, and medicine. *Lancet*. 2020. 396(10250): 565-582. doi: 10.1016/S0140-6736(20)31561-0.

”

**I could not be prouder of
all the Office of Research on
Women’s Health has done
for women’s health, and I am
honored to be a part of its
foundational history.**

Former Senator Barbara A. Mikulski (D-MD)

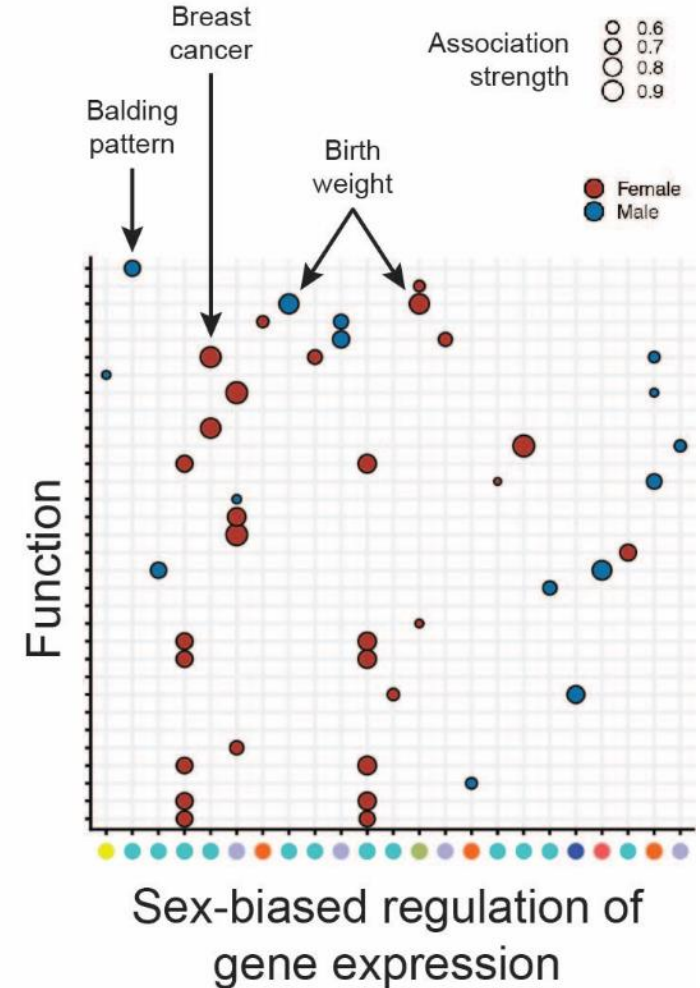
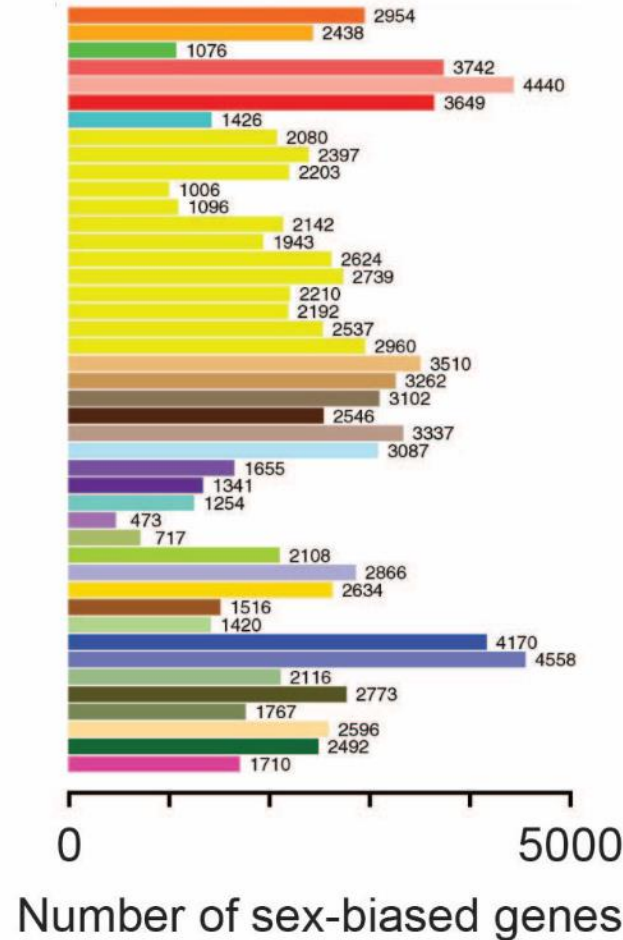
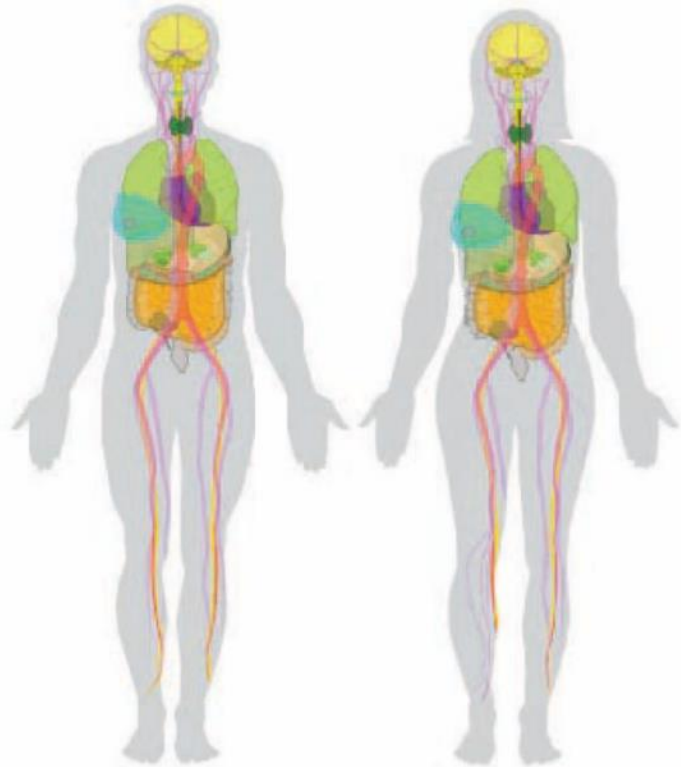


New in Science



SABV in action: Sex differences in gene expression are ubiquitous

44 tissues



COVID-19 is changing academia, research, workplace

- Laid bare gender inequities generally
- But women in academia, especially WOC, face **more severe versions of longstanding gender gaps** that already cause universities to lose women faculty
- Interruption to research can hamper ability to gain tenure
 - Increased gender gap in publication
 - Women first authorship dropped from 35.9% in December to 20.2% in April
 - Last authorship, from 26.1% to 19.3%
- Devastating impact on early-career investigators
- Women's departures will affect direction of research in fundamental ways – and for years

McKinsey report predicts 1 in 3 women will leave workforce





Former BIRCWH scholar leads hospital COVID-19 response

Karen M. Freund, M.D., M.P.H.; Professor of Medicine, Tufts University School of Medicine

CTSA Collaborative Innovation Award

- Breast Cancer Disparities
- Evidence-based strategies to coordinate breast cancer care within and across six Boston hospitals

Leads Tufts Medical Center COVID-19 response



National Center
for Advancing
Translational Sciences

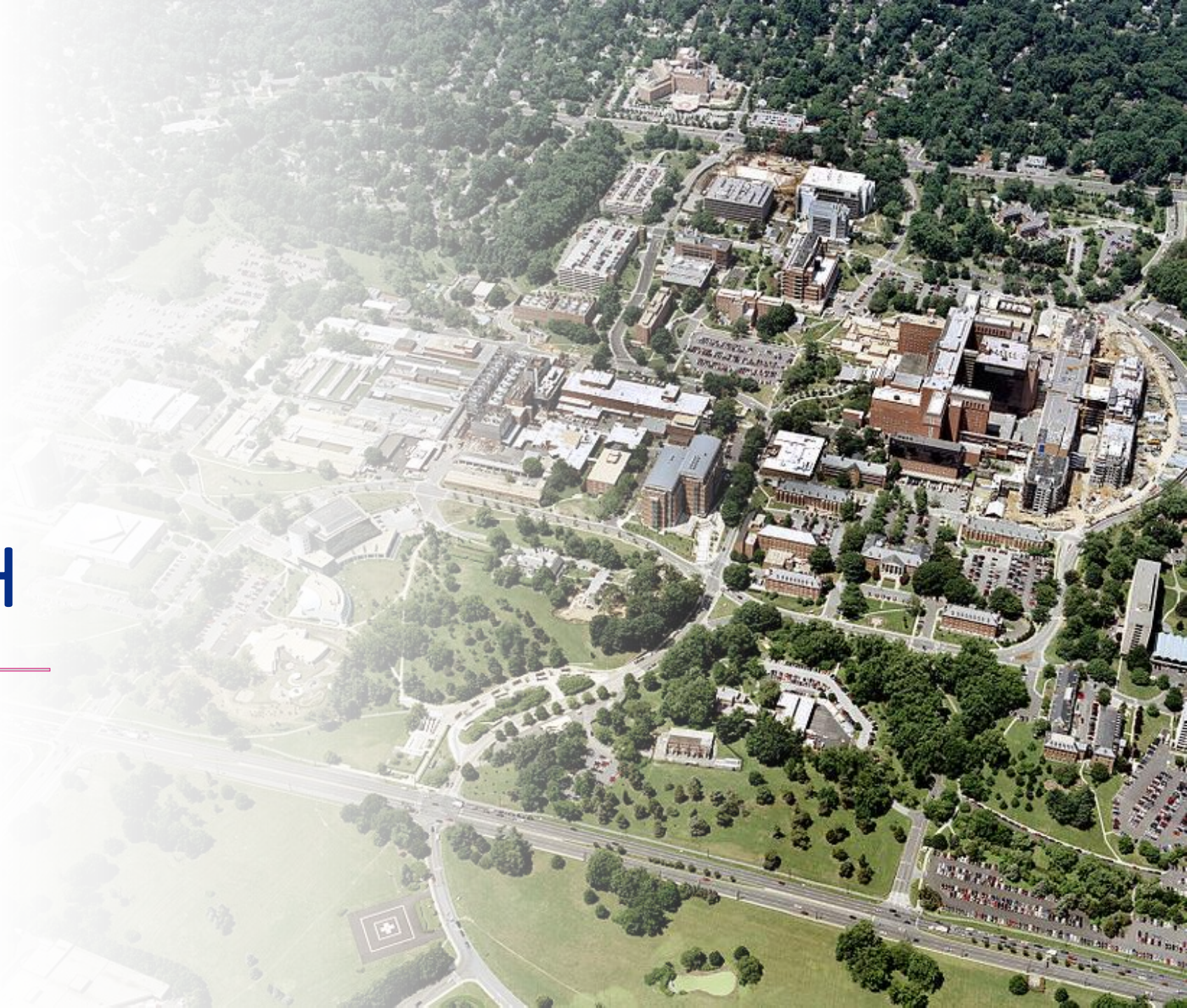
**A watershed moment
that brought gender
equity to medical
science.**

Former Senator Olympia J. Snowe (R-ME)





What's New at NIH and ORWH



Three new women NIH IC directors brings total to 10



Michael Chiang, MD

NEI



Lindsey Criswell, MD, MPH, DSc

NIAMS



Rena D'Souza, DDS, MS, PhD

NIDCR



Rick Woychik, PhD

NIEHS

Nat. Toxicology Program



Shannon Zenk, PhD, MPH, RN, FAAN

NINR

On the move at ORWH

Elizabeth Spencer, B.S.N.



- ORWH Deputy Director
- Named Senior Advisor for Workforce Development in DPCPSI

Samia Noursi, Ph.D.



- Associate Director for Science Policy, Planning, & Analysis
- Appointed ORWH Executive Secretary



NIH survey reveals workplace experiences

Employees, contractors, fellows, and trainees as part of the NIH Anti-Harassment Program – *to end the culture of sexual harassment in science*

- 36,228 surveyed, 44% response rate
- Results for previous 12 months

➤ **1 in 5 experienced sexual harassment**

➤ **Half experienced incivility**

➤ **10%, bullying**

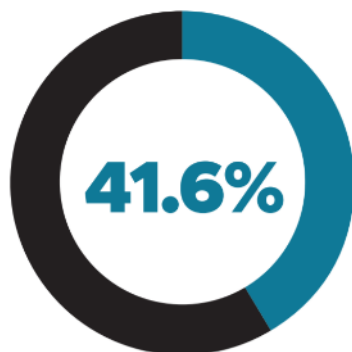




NIH workplace survey chronicles harassment

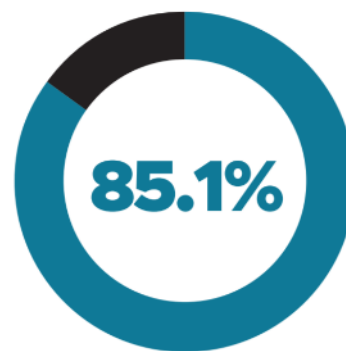
Figure 5. Association Between Sexual Harassment and Incivility in the Past 12 Months

Among respondents not experiencing sexual harassment in the past 12 months...



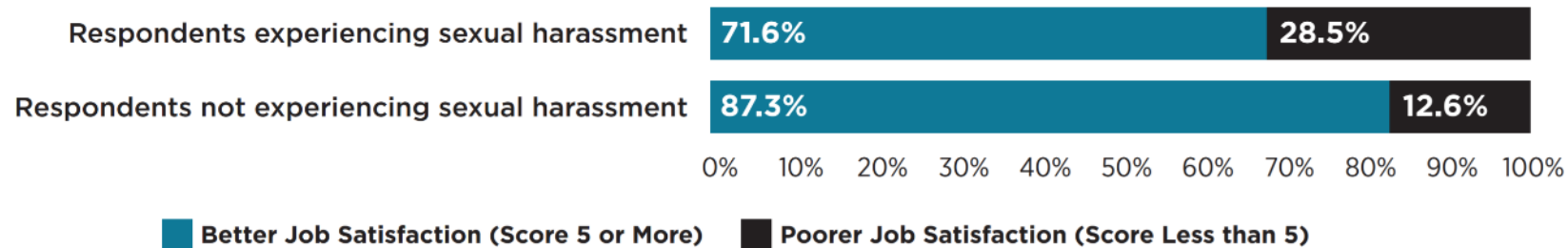
Experienced Any Incivility

Among respondents experiencing sexual harassment in the past 12 months...

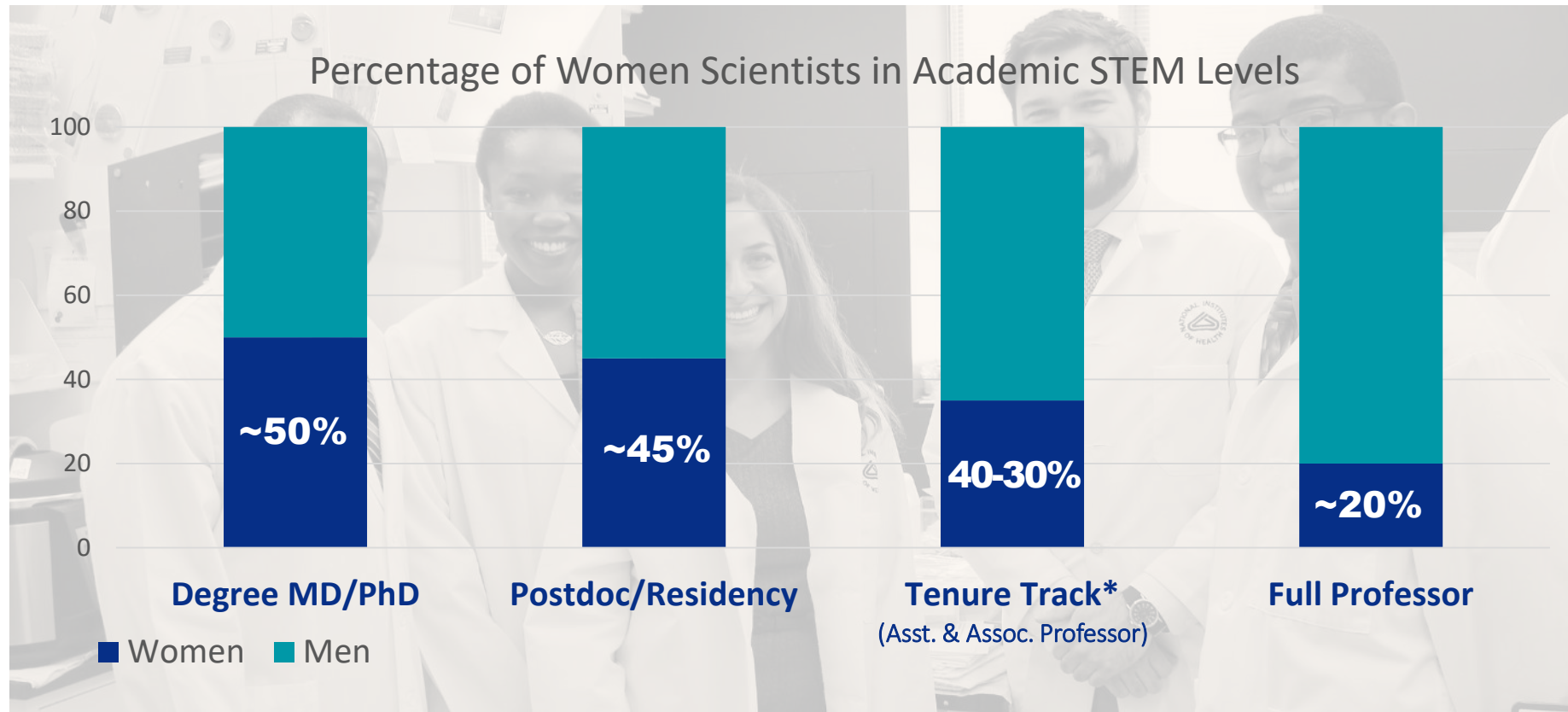


Experienced Any Incivility

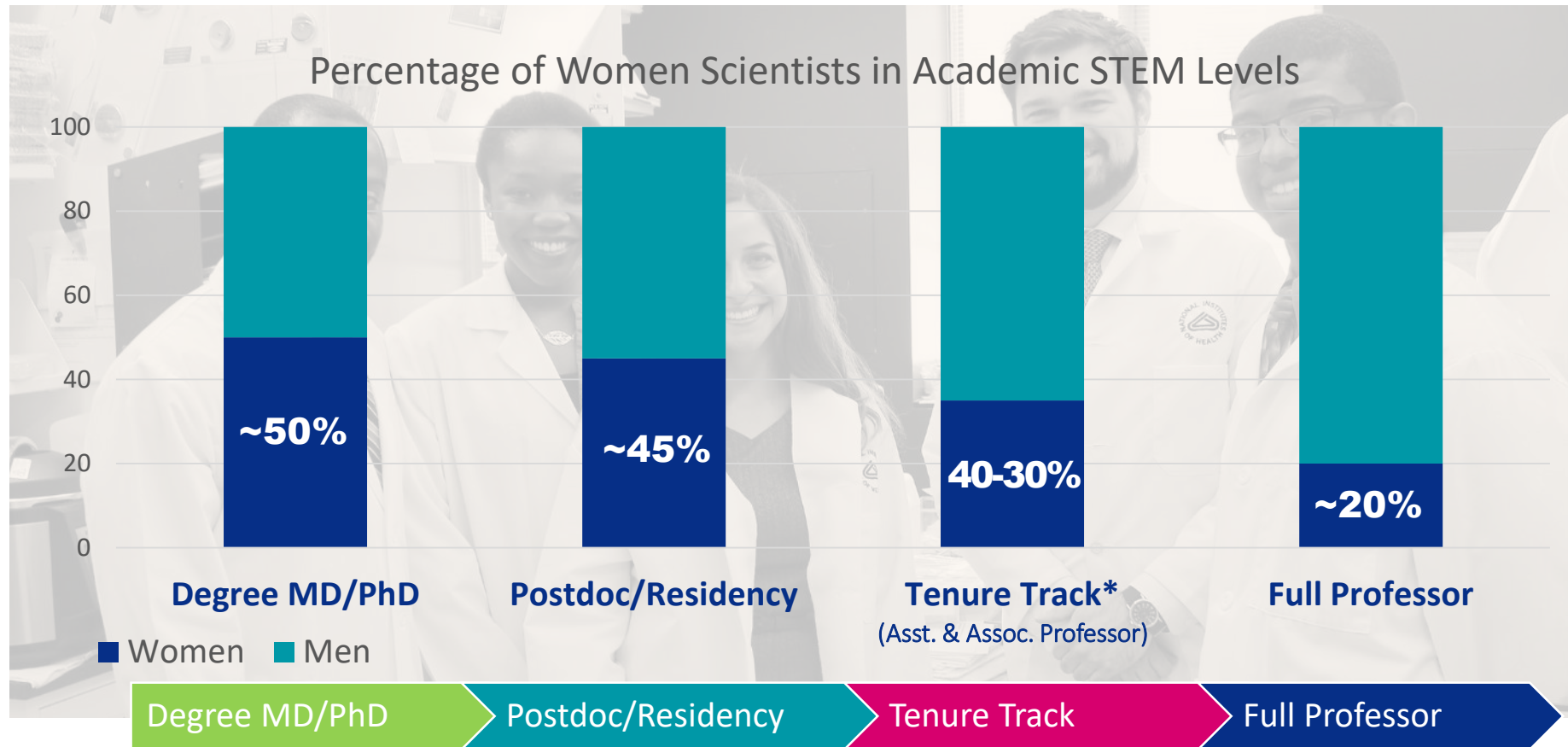
Figure 9. Respondent Job Satisfaction (MOAQ-JSS Average Score, Cutoff of 5)



New programs support women during critical life events

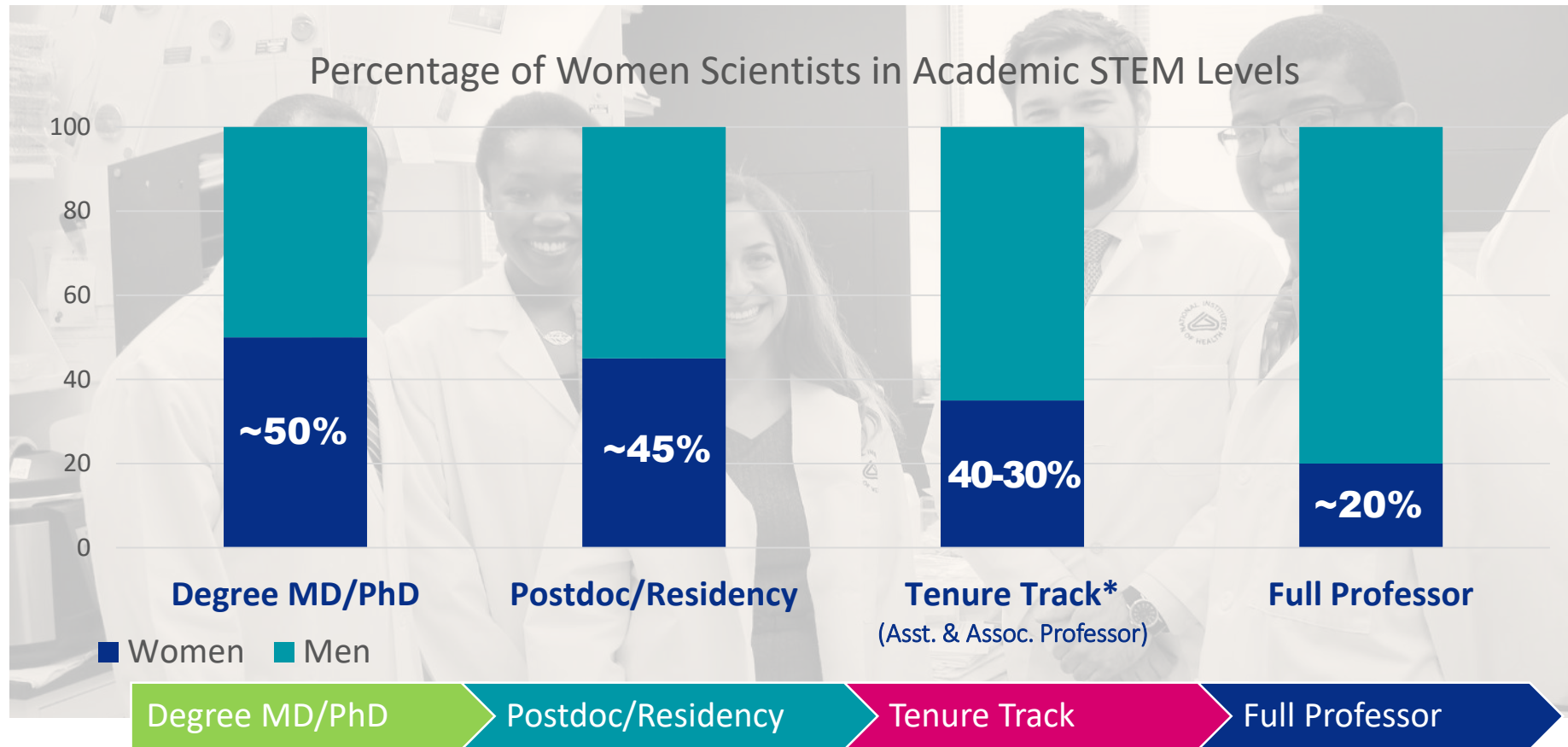


New programs support women during critical life events



Promoting Career Continuity
for K Awardees
[NOT-OD-20-054](#)

New programs support women during critical life events



Promoting Career Continuity
for K Awardees
[NOT-OD-20-054](#)

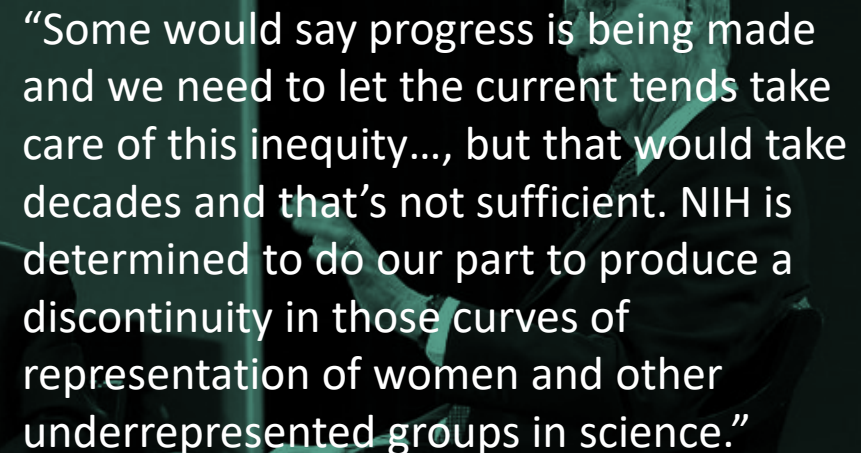
Promoting Career Continuity
for RPG Awardees
NOT-OD-20-055

NIH Challenge Prize to recognize, disseminate transformative institutional approaches

One of 4 concepts developed out of the **Working Group on Women in Biomedical Careers**

Aligns with

- NASEM consensus study
- NIH ACD WG on Changing the Culture to End Sexual Harassment recommendations
- Other NIH policy changes & programs to enhance participation of UR populations



“Some would say progress is being made and we need to let the current trends take care of this inequity..., but that would take decades and that’s not sufficient. NIH is determined to do our part to produce a discontinuity in those curves of representation of women and other underrepresented groups in science.”

Francis S. Collins, M.D., Ph.D., Dir., NIH
NASEM Symposium, Addressing the Underrepresentation of
Women in STEMM March 19, 2020

<https://www.herox.com/NIHGenderDiversityPrize>

NIH Challenge Prize to recognize, disseminate transformative institutional approaches

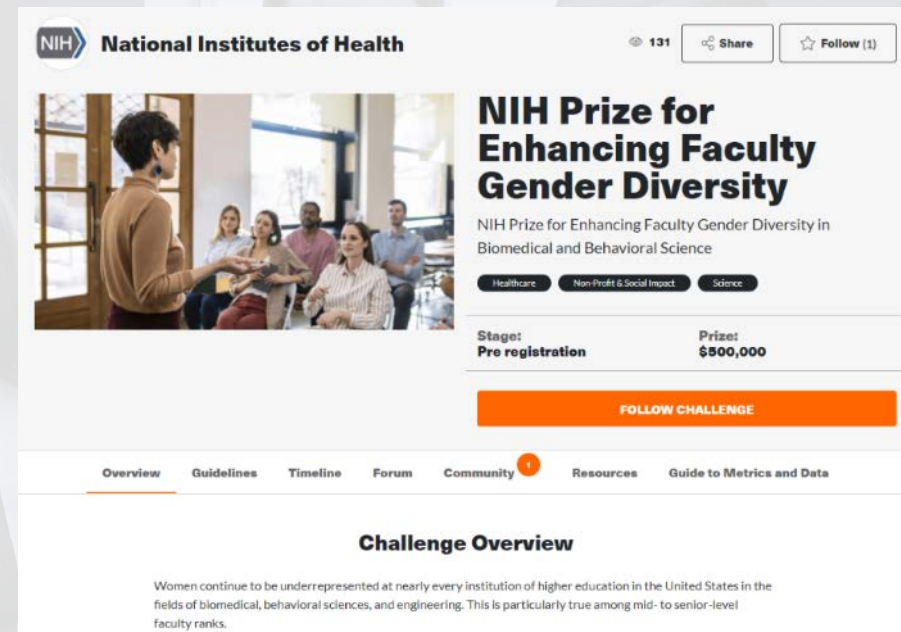
Goal: Recognize structures, systems, projects and processes that have enhanced gender diversity within an institution

- Submission platform is live!
- Announcement on challenge.gov

Prize:

- \$50,000 to up to 10 institutions and possibly honorable mentions
- May include invitation to present approaches at ORWH symposium

Application deadline: April 16, 2021



<https://www.herox.com/NIHGenderDiversityPrize>

ORWH expands e-learning – new courses educate biomedical community on sex & gender

■ Bench to Bedside: Integrating Sex & Gender to Improve Human Health

Immunology | CVD | Pulmonary Disease | Neurology | Endocrinology | Mental Health (Fall 2020)

- Close to 4000 visitors since March
- 445 users in September – more than 500 unique visitors in August
- Immunology is the most popular

■ Coming Soon!

- Sex as a Biological Variable Primer
- Introduction to the Scientific Basis of Sex- and Gender-Related Differences



<https://bit.ly/ORWHonline>



September webinar introduces Neurology module

Farida Sohrabji, Ph.D.

Regents Professor and Interim Department Head,
Department of Neuroscience and Experimental Therapeutics
Director, Women's Health in Neuroscience Program
Texas A&M College of Medicine

- Addressed urgency of considering sex and gender in neurological health and 3 conditions covered in the e-learning module: ischemic stroke, Parkinson's disease, and epilepsy
- 377 participants



ORWH expands e-learning – new courses educate biomedical community on sex & gender

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New!

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<https://bit.ly/ORWHonline>





CoEPEs' new and improved website!

The Centers of Excellence in Pain Education program is an online resource for the development, evaluation, and distribution of pain management curricula material for medical, dental, nursing, pharmacy and other schools

<https://coepes.nih.gov/>

HHS initiatives target hypertension and maternal health



Photo by Amanda Mills, USCDCP



National Women's Blood Pressure Awareness Week, October 11-17

- Increase awareness of blood pressure control for women of reproductive age
- Encourages women to regularly take, track, and share BP numbers with providers
- Incorporate heart healthy behaviors into daily life

Million Hearts® Hypertension Control Challenge

PRGLAC Update: Sec. Azar has acknowledged receipt of Implementation Plan – posted online www.nichd.nih.gov/about/advisory/PRGLAC

**At that time our bipartisan,
bicameral foursome learned of
the omission of women in
clinical trials and protocols. ...
The Office, established in 1990,
has made all the difference!
Let's continue.**

Former Rep. Connie Morella (R-MD)

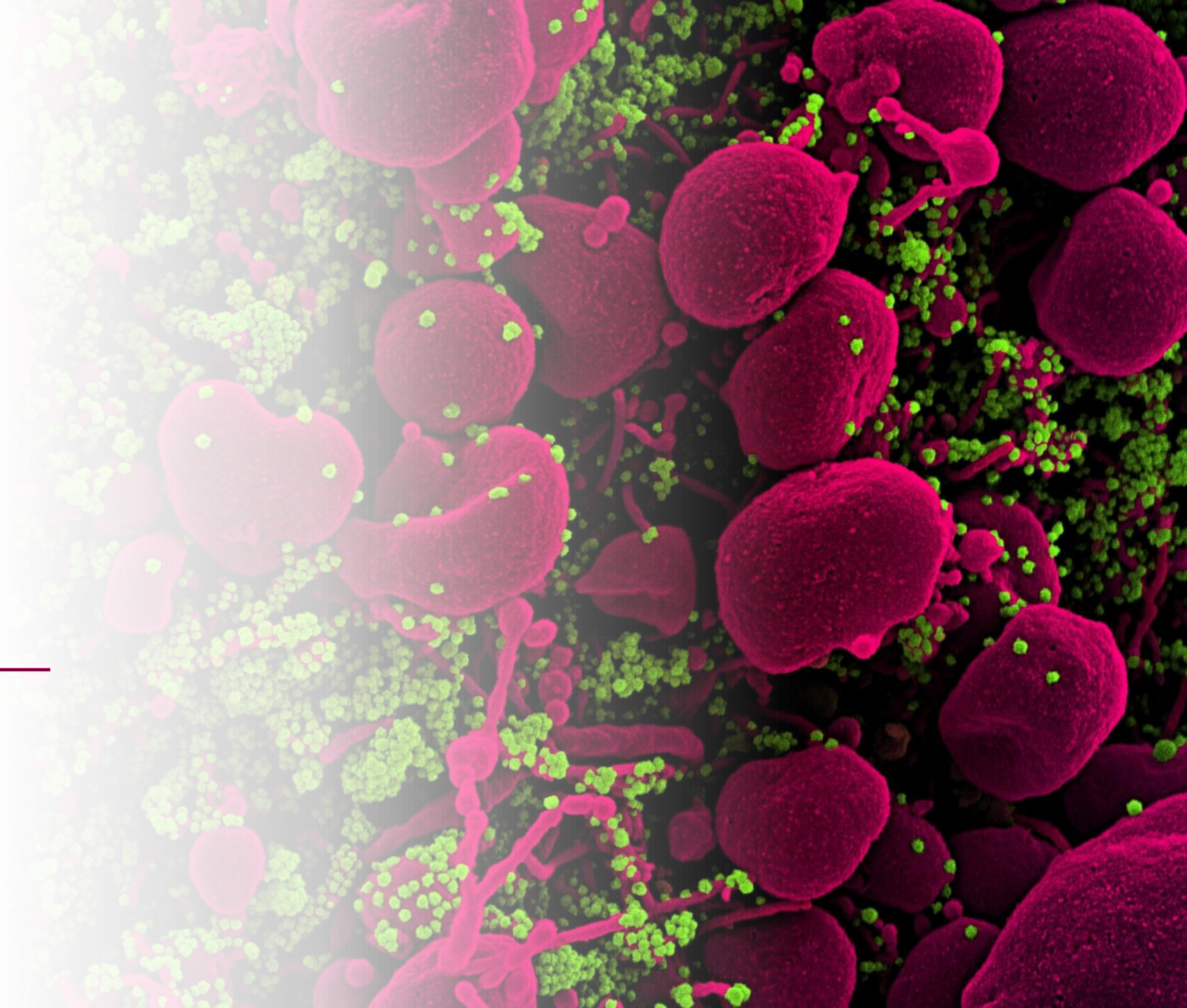


WOMEN'S
CONGRESSIONAL
POLICY
INSTITUTE

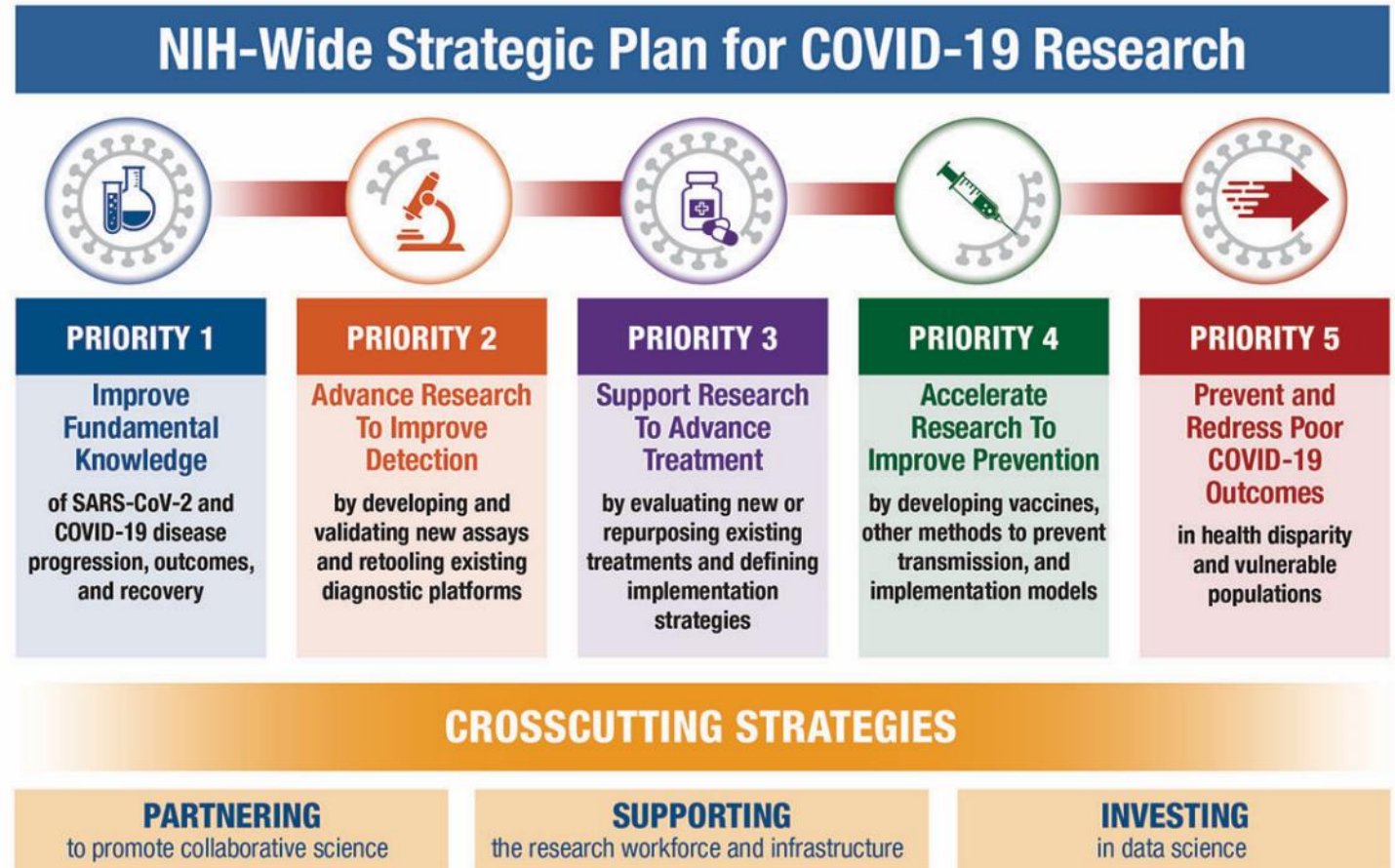




COVID-19 Update



NIH roadmap for COVID-19 research – including pregnancy-related impacts



» ORWH leverages the collective strength of ICOs to accelerate sex and gender research on COVID-19's impacts on women's health

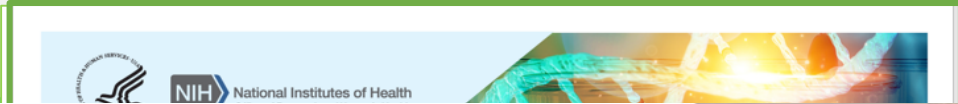
01 Develop and prioritize initiatives for future research

02 Provide strategies for incorporating SABV and NIH inclusion policy into COVID-19

03 Develop COVID-19 women's health research priorities

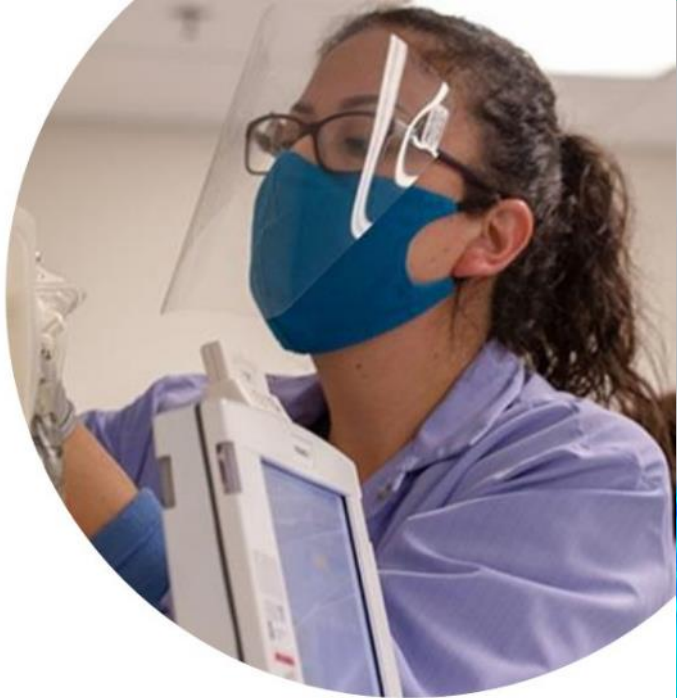
04 Systematically collect and curate relevant information on the current COVID-19 landscape

05 Promote collaboration to accelerate the impacts of research



» ORWH catalyzes scientific synergy across NIH and recently established CCRWH COVID-19 Working Group

- Perform portfolio analysis (e.g., new initiatives, scan of FOAs, etc.)
- Identify gaps in our portfolios
- Setting the priorities
- Accelerating research



CCRWH COVID-19 WG co-chairs
 Nina Schor, NINDS
 Marrah Lachowicz-Scroggins, NHLBI
 Rajeev K. Agarwal, ORWH

Potential research topics	9
Stress, trauma, and mental health resources	9
8. Comorbidities and underlying conditions	9
ORWH Response to the COVID-19 Pandemic: Incorporating a Sex-and-Gender Lens	1
Version date: August 25, 2020	

NIH is moving at an unprecedented rate to develop testing, serology, and technology to combat COVID-19

ACTIV Accelerating COVID-19 Therapeutic Interventions and Vaccines | Public-private collaboration to pursue 4 fast-track areas:

- Forum to identify preclinical treatments
- Accelerate testing of the most promising vaccines and treatments
- Improve clinical trial capacity and effectiveness
- Accelerate the evaluation of vaccine

The Rapid Acceleration of Diagnostics (RADx) Program seeks to improve COVID-19 testing

Tech: Speed development of point-of-care tests; improve laboratory tests (\$500 million).

UP: Identify disparities in Underserved Populations and mitigate factors associated with poor outcomes (\$500 million).

Radical: Support new, non-traditional approaches to testing and non-traditional applications of current methods (\$200 million).

ATP: Scale up existing Advanced Technology Platforms to increase testing capacity with rapid turnaround (\$230 million).

<https://www.nih.gov/research-training/medical-research-initiatives/activ>
<https://www.nih.gov/research-training/medical-research-initiatives/radx>

Tuesday, October 6, 2020

NIH RADx initiative advances six new COVID-19 testing technologies



Ellume/Luminostics

The National Institutes of Health, working in collaboration with the Biomedical Advanced Research and Development Authority (BARDA), today announced a third round of contract awards for scale-up and manufacturing of new COVID-19 testing technologies. The six new **Rapid Acceleration of Diagnostics (RADx) initiative** contracts total \$98.35 million for point-of-care and other novel test approaches that provide new modes of sample collection, processing and return of results. Innovations in these new technologies include integration with smart devices, mobile-lab processing that can be deployed to COVID-19 hot spots, and test results available within minutes.

What's behind men's poorer outcomes?

Nature: Sex differences in immune responses explain disease outcomes

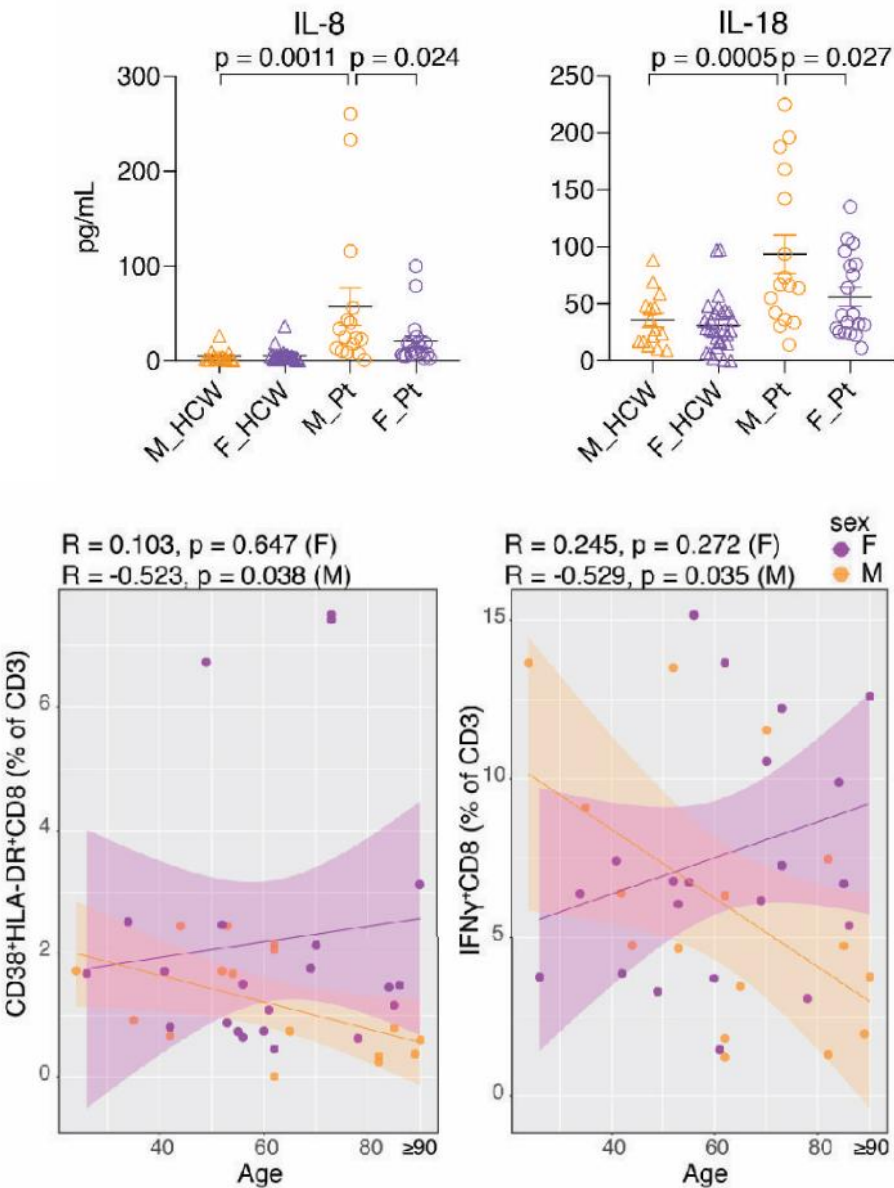
- Men had **higher levels of proinflammatory innate immune chemokines and cytokines** (IL-8, IL-18, and CCL5) – which correlated with higher non-classical monocytes
- In contrast, **women mounted more robust T cell activation** during infection – including older women
- Conversely, elevated levels of innate immune cytokines in women associated with worse disease progression, but **not** in men
- Suggests **potential immunological underpinning** of the distinct mechanisms of disease progression between sexes
- Provides potential basis for **sex-dependent approaches** to prognosis, prevention, care, and therapy

Takahashi, T. et al. 2020. *Nature* doi.org/10.1038/s41586-020-2700-3



Akiko Iwasaki, Ph.D.

Distinct immune responses predict symptom severity in men and women



Males and females with moderate COVID-19 symptoms have different immune profiles:

- Males
 - Higher plasma levels of innate immune cytokines IL-8 and IL-18
 - Robust induction of non-classical monocytes
- Females
 - Robust T cell activation is sustained in old age

Case deterioration is associated with distinct immune processes between sexes

- Males: Decreases in proportions of T cells that are activated (CD38+HLA-DR+), differentiated (PD-1+TIM-3+)
- Females: Increases in cytokines/chemokines (TNFSF10, CCL5, IL-15)



Scientific Collaborations

- Maternal Health
- Inclusion
- Sex and gender

NIH's robust response to maternal health disparities



IMPROVE

• NIH Maternal Mortality Task Force

- *NICHD-OD-ORWH**
 - CVD
- Infection/immunity
- Mental health
- **~\$7 Million**



IDEA States

• Institutional Development Award States program

- Administrative supplements to expand research and research capability
- **~\$4.8 Million**



R01 | NIHMD

• Addressing Racial Disparities in MMM

- Intersection of domains and levels of influence
- **NIHMD-ORWH**
 - SMM disparities



U3

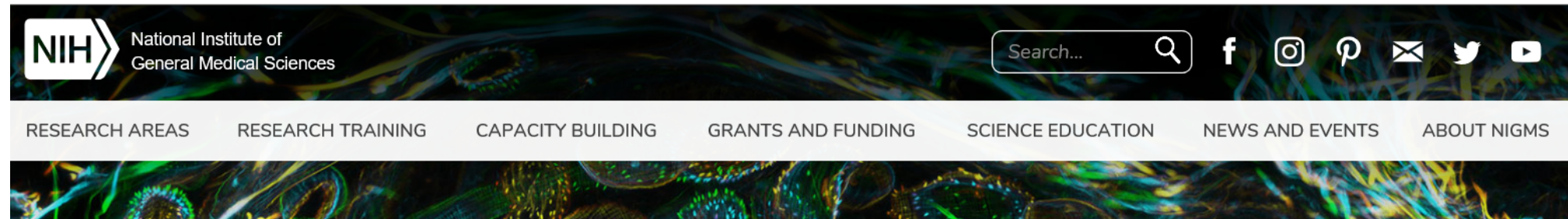
• FY2017–20 | >50 awards

- Sickle cell disease
- Fibroid growth
- Biologic & social determinants of severe maternal morbidity



IMPROVE | <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-104.html>

NIH's robust response to maternal health disparities



[News and Events](#) > [News](#) > Supporting Women's Health Research in Underserved States: NIGMS Collaborates with ORWH to Facilitate Trans-NIH Effort Through the Institutional Development Award (IDeA) Program

NIGMS Home	
Research Areas	+
Research Training	+
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Supporting Women's Health Research in Underserved States: NIGMS Collaborates with ORWH to Facilitate Trans-NIH Effort Through the Institutional Development Award (IDeA) Program

Release Date:
10/9/2020

Contact:
[NIGMS Communications and Public Liaison Branch](#)
301-496-7301

The National Institute of General Medical Sciences (NIGMS), together with the Office of Research on Women's Health (ORWH) and seven other institutes of the National Institutes of Health (NIH), provided funding to scientists across the country to expand their research on women's health. This initiative, which supports trans-NIH efforts to address high rates of maternal mortality and morbidity, funded 19 administrative supplements in response to [NOT-GM-20-017](#), Notice of Special Interest (NOSI): Administrative Supplements for Research on Women's Health in the IDeA States.

NIH's robust response to maternal health disparities



IMPROVE

• NIH Maternal Mortality Task Force

- *NICHD-OD-ORWH**
 - CVD
- Infection/immunity
- Mental health
- **~\$7 Million**



IDeA States

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U3

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-
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- Fibroid growth
- Biologic & social determinants of severe maternal morbidity

IMPROVE | <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-104.html>

ORWH's robust response includes education and resources

Maternal health workshops

- NICHD/ORWH Pregnancy and Maternal Conditions That Increase Risk of Morbidity and Mortality Workshop, May 19 | <https://orwh.od.nih.gov/about/newsroom/events/nichdorwh-pregnancy-and-maternal-conditions-increase-risk-morbidity-and>
- NINR–NICHD–NIMHD–ORWH–THRO Workshop on Models of Care for Reducing Disparities in Maternal Health, Sep. 29, 2020.

MMM Portal <https://orwh.od.nih.gov/research/maternal-morbidity-and-mortality>

MMM Brochure — *Update for 2020*

https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH_MMM_Booklet_93020_508c.pdf

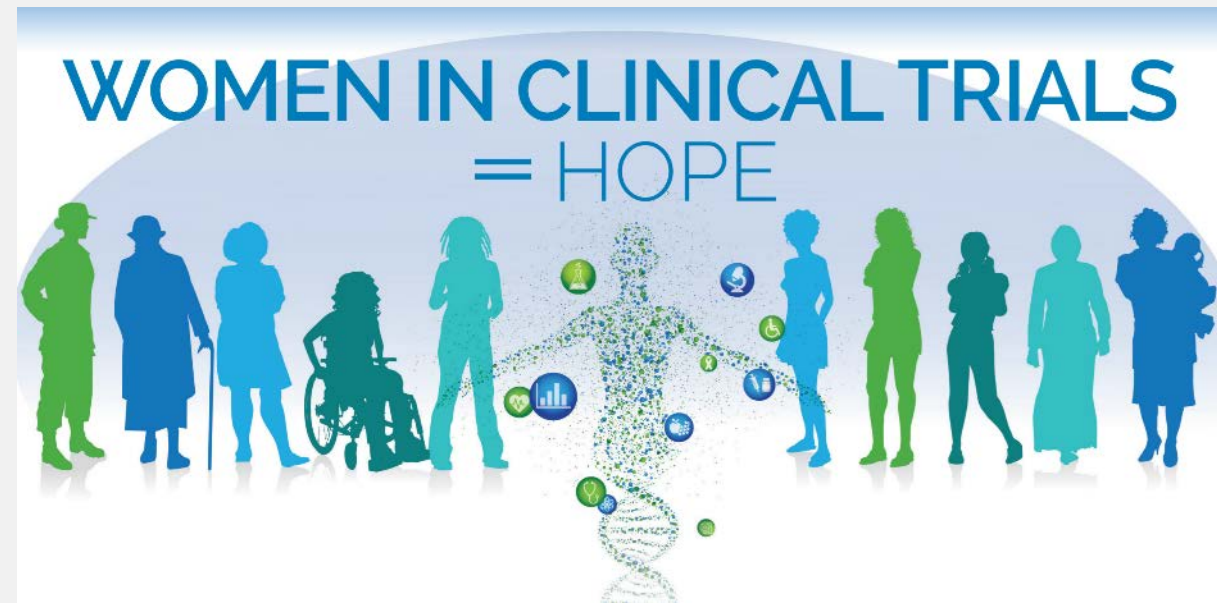


ORWH inclusion initiatives produce better science

- Community Engagement Alliance (CEAL) Against COVID-19 Disparities | <https://covid19community.nih.gov/assets/documents/about-ceal508.pdf>
- Monica Webb Hooper, PhD | Deputy Director, National Institute on Minority Health and Health Disparities
- Research!America: “Is there an area of science that deserves more attention than it receives?” <https://raforum.vfairs.com/>
 - Answer? “Inclusion and study of SABV”
- NIH Inclusion Across the Lifespan-II Workshop, Sep. 2 – over 1000 registrants!
- 2020-21 NIH Introduction to the Principles and Practice of Clinical Research (IPPCR) course | <https://ocr.od.nih.gov/courses/ippcr.html>
 - Dr. Noursi and I presented on NIH inclusion policy
 - Reached ~8000 around the world
 - Free, self-paced, online – runs through Aug. 1, 2021
- NIH Inclusion Outreach Toolkit: How to Engage, Recruit, and Retain Women in Clinical Research | <https://orwh.od.nih.gov/toolkit>
- Diverse Women in Clinical Trials collaboration with FDA OWH | <https://www.fda.gov/consumers/womens-health-topics/women-clinical-trials>



Monica Webb Hooper, PhD



Thirty years later, the goal of knowing as much about women's health as men's gets closer every year. Power on!

Former Rep. Pat Schroeder (D-CO)

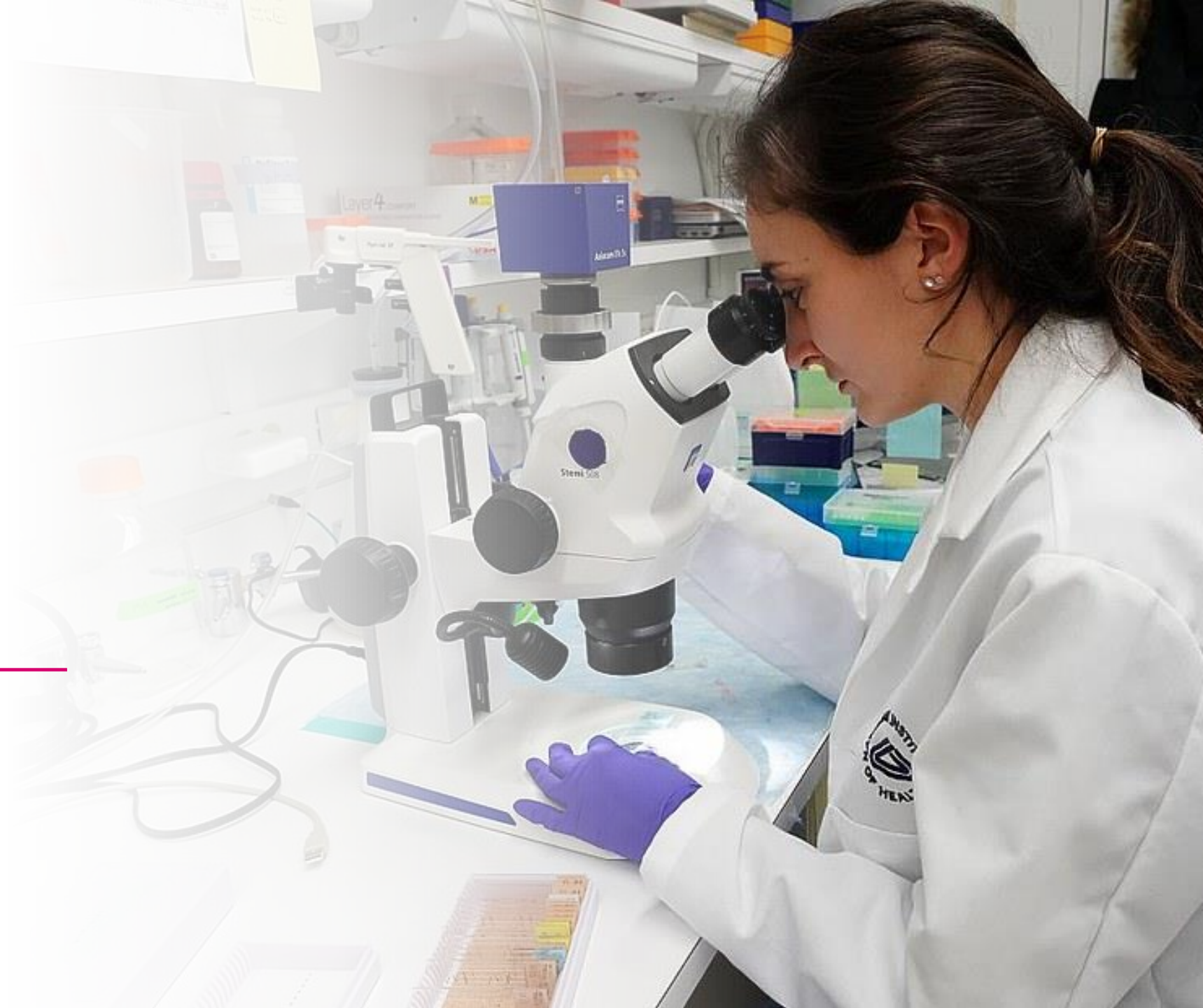


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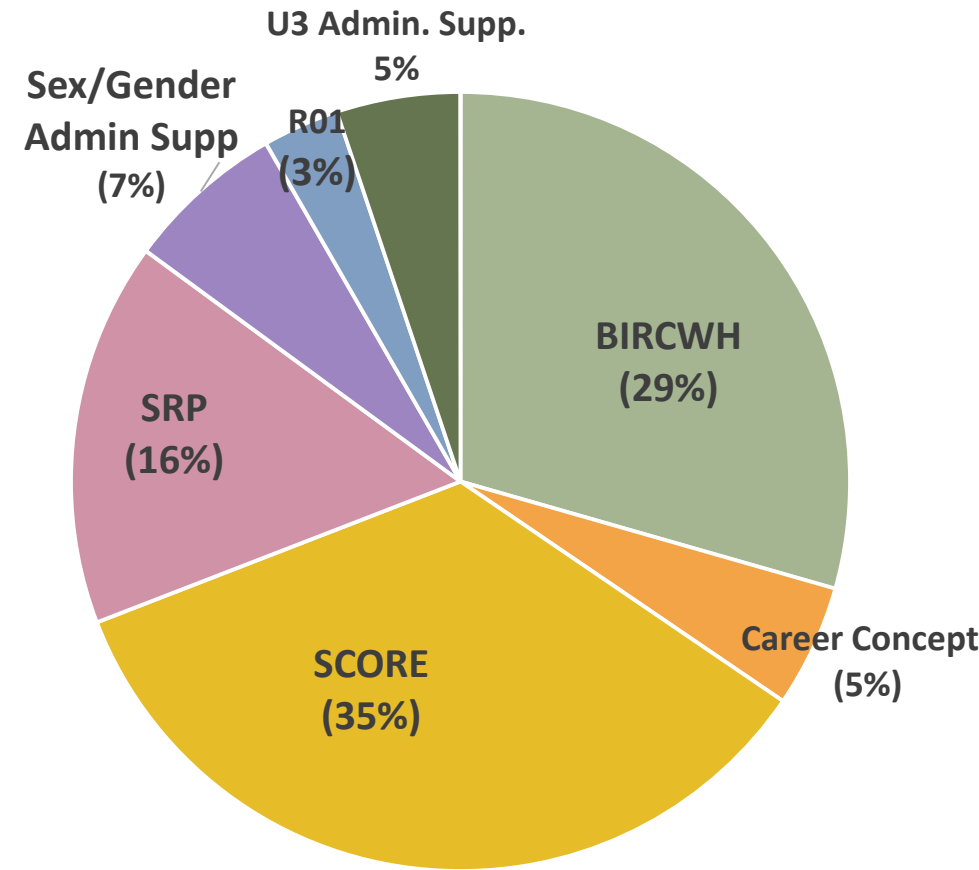
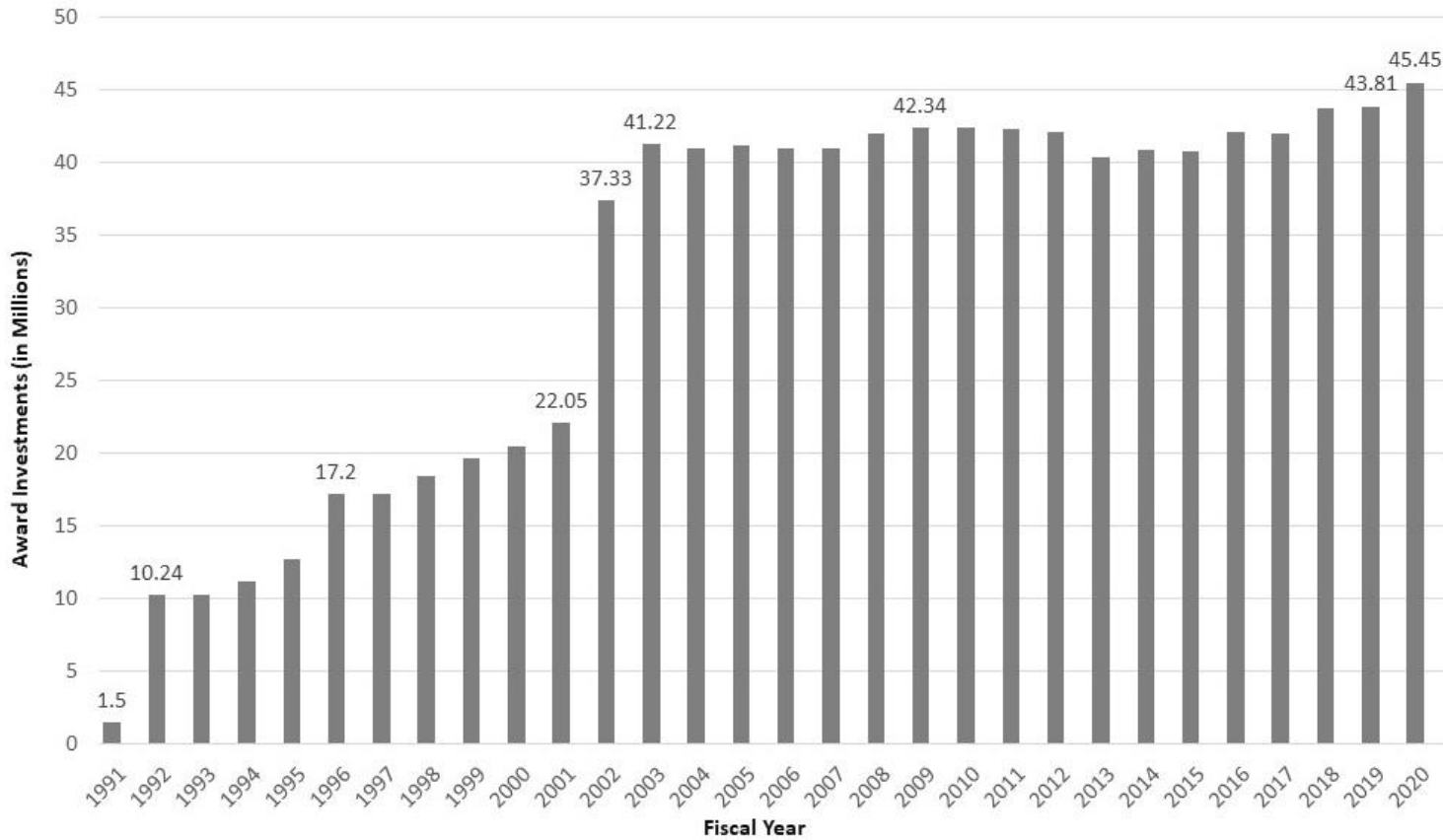


Research Investments



ORWH Budget History & FY20 Extramural Award Profile

FY20: \$45,458,253



**ORWH FY2020 Extramural Award by Program
(as % of Extramural Budget)**

Source: NIH IMPAC II FY2020 frozen data.
Note: ORWH total investments = \$31,867,666. Funding portfolio excludes Contract R&D and IAA awards.

Connecting



FALL 2020 SABV-RELATED SYMPOSIA



ORWH Interprofessional Education: Courses and Resources on Sex and Gender and Women's Health

Sex and Gender Health Education 2020 Summit

Presenter

Chyren Hunter, Ph.D.
Basic and Translational Programs
ORWH



Advancing Sex and Gender-Based Research: Transitions over the Life Course for Understanding Young Women's Risk for Affective Psychopathology

2020 American Academy of Child and Adolescent
Psychiatry (AACAP) 2020 Annual Meeting

Presenter

Rebecca DelCarmen-Wiggins, Ph.D.
Basic and Translational Programs
ORWH

ORWH's stress message reaches >300,000

General public newsletter distributed to community health clinics, senior centers, libraries, schools, and individuals across the country



Health Capsule

Manage Stress and Build Resilience

Send us your comments

It's hard to avoid stress. Work, money, current events, and the hassles of everyday life are just a few of the things that can cause stress. Long-term, or chronic, stress is linked to several health conditions like heart disease, high blood pressure, diabetes, depression, and anxiety.



fizkes / iStock / Getty Images Plus

It's important to learn how to manage stress so it doesn't overwhelm you. The first step is to recognize your body's signals. These could include headaches, poor concentration, or feeling on edge. Once you identify these signs, work to counter their effects. Some people benefit from deep breathing, going for a walk, or writing down their thoughts.

Whatever works for you, make taking care of yourself part of your daily routine. Work in time to exercise, eat healthy foods, and get good quality sleep. This will help make you more resilient to life's stresses.

Experts also recommend staying socially connected. Being in touch with family and friends can combat stress and depression. Video chats and other technology make staying in touch easier than ever.

If you can, also try to see problems a different way. Experts call this "reframing." Stuck in traffic? It may be an opportunity to enjoy some music or catch up on a podcast. Practice reframing the situation and you'll likely get better at it over time.

Finally, if stress is affecting your well-being, talk to a health professional. They can help guide you through times of severe stress. Find [more tips](#).



OFFICE OF RESEARCH
ON WOMEN'S HEALTH

Advancing the Health of
Women Through Science

ORWH Staff Publications

Regensteiner JG, Libby AM, **Begg L, Ghim M, and Clayton JA**. Sex As a Biological Variable: The Importance of Curriculum Development in the 21st Century. *Journal of Women's Health*. 2020. DOI.org/10.1089/jwh.2019.8114

Clayton JA and Stratton P. The role of gynecologists in screening older women for ocular surface disease symptoms. *Menopause*. 2020. DOI: 10.1097/GME.0000000000001627

Noursi S, Clayton JA et al. The Intersection of Maternal Morbidity and Mortality and Intimate Partner Violence in the United States. 2020. *Current Women's Health Reviews*. DOI: 10.2174/1573404816999200502024742

Noursi S et al. Using the Ecological Systems Theory to Understand Black/White Disparities in Maternal Morbidity and Mortality in the United States. 2020. *Journal of Racial and Ethnic Health Disparities*. DOI:10.1007/s40615-020-00825-4

Parisi X, ... **Stratton P**, and Freeman AF. Obstetric and Gynecological Care in Patients with STAT3 Deficient Hyper IgE Syndrome. *J. Clin Immunol*, 2020. doi: 10.1007/s10875-020-00827-1.

Ortiz R, ... **Stratton P**. Hypothalamic-Pituitary-Adrenal Axis Responses in Women with Endometriosis-related Chronic Pelvic Pain. *Reproductive Sciences*. 2020. doi: 10.1007/s43032-020-00201-x.

Schultz KA, ... **Stratton P** et al. DICER1 Tumor Predisposition. 2014 Apr 24 [Updated 2020 Apr 30]. In Adam MP et al., editors. GeneReviews®. University of Washington. <https://www.ncbi.nlm.nih.gov/books/NBK196157/>

Shiels MS, ... **Thomas DA** et al. Trends in Mortality From Drug Poisonings, Suicide, and Alcohol-Induced Deaths in the United States From 2000 to 2017. *JAMA Netw Open*. 2020. doi: 10.1001/jamanetworkopen.2020.16217



Facebook Lives on careers reach tens of thousands

ORWH's Four Programs

Sadhanna Jackson, MD | Feb 2019

Faustine Williams, MD | Aug 2019

Panel | March 4, 2020

Panel | August 5, 2020

<https://www.facebook.com/NIHORWH/videos/656271685007682>

More than 30,000 Reached!

FACEBOOK LIVE Q&A
A discussion about leadership among women in STEM fields

Wednesday, August 5, 2020 • 2:00 to 3:00 p.m. EDT

Host: Janine Austin Clayton, M.D.
 Director, NIH Office of Research on Women's Health (ORWH)

Moderator: Xenia Tigno, Ph.D.
 Associate Director for Careers, ORWH

Kizzmekia Corbett, Ph.D.
 Senior Research Fellow, NIH Vaccine Research Center
 Scientific Lead, Coronavirus Vaccines & Immunopathogenesis (coVip) Team, National Institute of Allergy and Infectious Diseases (NIAID)

Rosemarie Ramos, Ph.D., M.P.H.
 Biostatistician for the Defense Health Agency

Kandice Tanner, Ph.D.
 Senior Investigator, Center for Cancer Research, National Cancer Institute (NCI)

The event will be hosted on Facebook Live and Zoom. Live closed-captioning available. **Register Today!**



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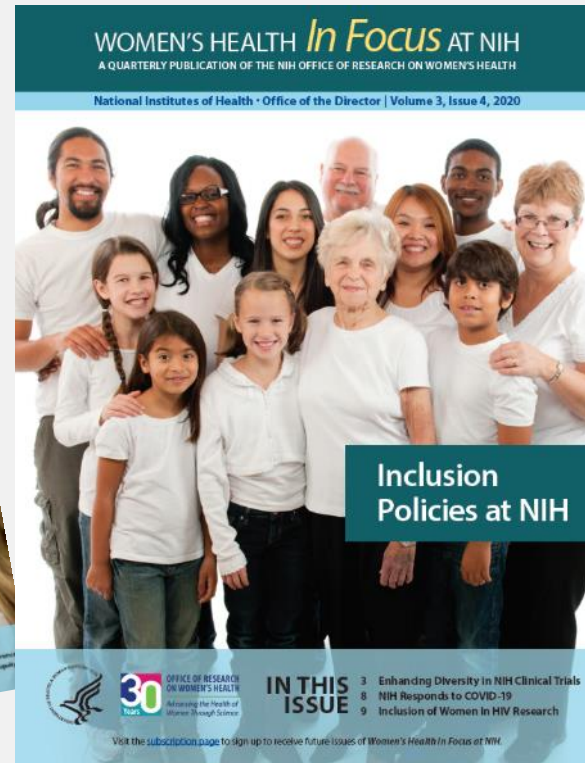
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