



NIH Office of Research on Women's Health

57th 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

October 18, 2022 – Director's Report



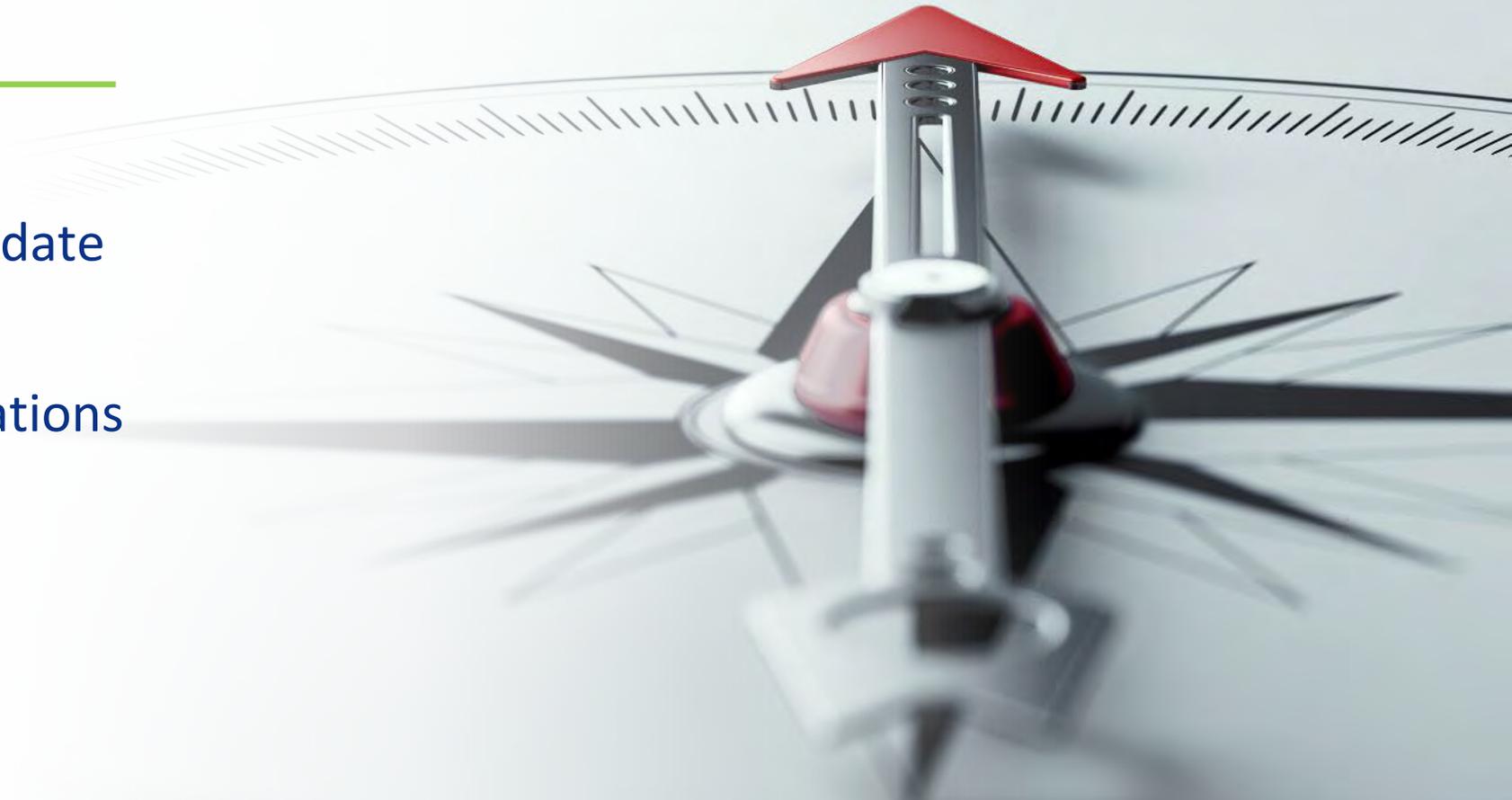
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www.nih.gov/women
#ResearchForWomen



Outline

- I. Opening remarks
- II. ORWH and NIH update
- III. COVID-19 update
- IV. Scientific collaborations
- V. Funding
- VI. Careers
- VII. Closing

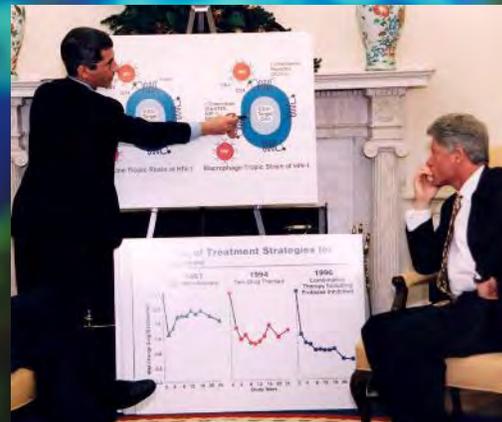


I.

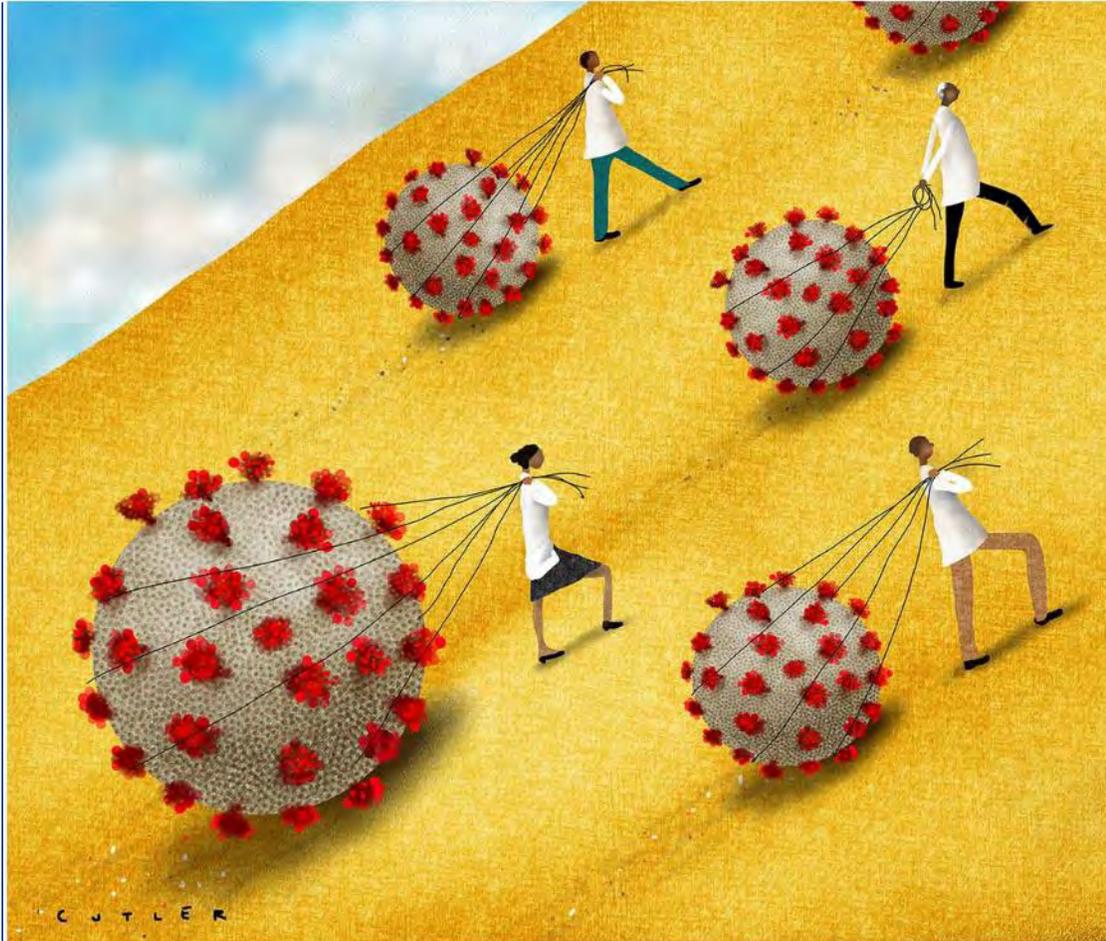


Dr. Anthony M. Fauci retires

Contributions to women's health research



Dr. Fauci advanced women's health research in four key areas



Groundbreaking research on Wegener's granulomatosis

Prevent transmission of HIV from mother to child

Sex differences in immune response to the flu

Inclusion of pregnant people in COVID-19 research

II.



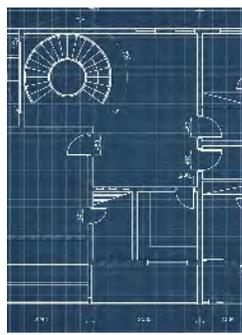
ORWH and NIH Update



Balkissa M. Abdoulaye, M.A.

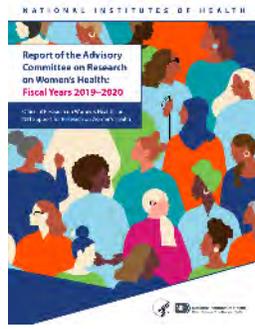
Assistant Director

Management, Reporting, Operations and Communications Section



NIH Strategic Plan for Research on the Health of Women

- RFI solicited input from scientists, advocacy and patient communities, public | NOT-OD-22-186
- Informed by **ACRWH's Women's Health Conference report**
- Submission period closed



NIH-requested changes in Biennial Report

"Report of the Advisory Committee on Research on Women's Health"

- In response to NIH leadership request to reduce length, following changes are being made:
 - Target page count <100 pages (Single-page ICO submissions)
 - Leverage existing digital content
 - Utilize Strategic Plan Tracking and Reporting Tool module
- ACRWH reviews scheduled for early 2023

*<https://orwh.od.nih.gov/research/2021-womens-health-research-conference>

II.

NIH Leadership Update



James M. Anderson, M.D., Ph.D. *Retired*
NIH Deputy Director for Program Coordination, Planning, and Strategic Initiative
Director, Division of Program Coordination, Planning, and Strategic Initiative (DPCPSI)



Robert W. Eisinger, Ph.D.
Acting Director, DPCPSI



Monica Bertagnolli, M.D.
Director of the National Cancer Institute
Beginning Oct. 3, 2022

12 Number of women
IC directors



Andrea Norris *Retiring*
NIH Chief Information Officer
Director, Center for Information Technology



Nina F. Schor, M.D, Ph.D.
Acting Dep. Director for Intramural
Research



Kevin D. Williams, J.D.
Director, Office of Equity, Diversity,
and Inclusion

III.

COVID-19 Update

III.



Literature review found sex differences in COVID-19 sequelae, long COVID syndrome

Of publications reporting original, sex-disaggregated data

COVID-19 sequelae (23 pubs) – **Significantly more likely:**

- **Among women** (vs. men): Psychiatric/ mood, ENT, musculoskeletal, and respiratory sequelae
- **Among males:** Renal sequelae

LCS (12 pubs)

- Women are significantly more likely to have LCS
- **Significantly more likely:**
 - **Among women:** ENT, GI, psychiatric/mood, dermatological, neurological, and other complications
 - **Among men:** endocrine and renal complications



“Few COVID-19 studies report sex-disaggregated data, **underscoring the need** for further sex-based research/reporting”



RECOVER looks for sex differences in COVID-19 infection, Long COVID Syndrome – inc. among pregnant

- 77M+ people with SARS-CoV-2 infection in the US
- Estimated 10%-30% of infected will have PASC
- 200+ researchers at 200+ research clinical sites
- Participants inc. adults, pregnant people, and children

recoverCOVID.org

Acute infection cohort

- Acute SARS-CoV-2 infections
- Prospectively followed for PASC, nested PASC cases vs. controls
 - 9k adults, inc. **200+ pregnant persons**
 - 1k children

Post-acute infection cohort

- PASC patients 4+ weeks after acute SARS-CoV-2 infection
- Matched PASC case-control design
- Prospective and retrospective data capture
 - 9k, inc. **2k pregnant persons**
 - 18k, inc. 800 with MIS-C

Closer look at RECOVER and pregnancy

- Participants pregnant at time of initial infection – inc. in post-acute participant cohort
- Infected and uninfected participants who could be pregnant at the time of RECOVER recruitment and will be included in acute participant cohort
- Protocol designed to collect pregnancy and pregnancy-related outcomes such as effects of COVID on menstruation, menopause symptoms, fertility and sexual function

RECOVER is leveraging 2 pregnancy cohorts:

Maternal-Fetal Medicine Units Network inc. 3,895 diverse pregnant patients with confirmed SARS-CoV-2 who delivered at 35 different hospital sites across US.

PRegnancy Coronavirus Outcomes RegIsTrY (PRIORITY) is nationwide prospective cohort study of women enrolled from Mar-Oct. 2020 with SARS-CoV-2 during or immediately following pregnancy.

III.

CCRWH COVID-19 WG's portfolio analysis to inform IC's research gap analysis



Reviewed grants awarded March '20 – June '20

Used RDC categorization keywords re disorders & conditions that preferentially affect women

Goals

- Accelerate research on effects of sex and gender on COVID-19 and its impact on women's health
- Promote collaboration to accelerate the impact of research

Deliverables

- *Completed* **portfolio analysis**
- *Completed* "**Guiding Principles**: Sex and gender influences in COVID-19 and the health of women"*
- *Issued* **RFI** related to intersection of SARS-CoV-2/COVID-19 pandemic and health of women
- *Contributed* to **NHLBI workshop** "Sex/Gender-Specific COVID-19 Outcomes and Management Relevant for Heart, Lung, Blood, and Sleep Disorders: From Bench to Bedside"**
- Preparing **white paper**

* orwh.od.nih.gov/sites/orwh/files/docs/ORWHGuidingPrinciple.pdf

** www.nhlbi.nih.gov/events/2022/sexgender-specific-covid-19-outcomes-and-management-relevant-heart-lung-blood-and-sleep

irp.nih.gov/catalyst/v30i4/the-sig-beat-sghd-webinar



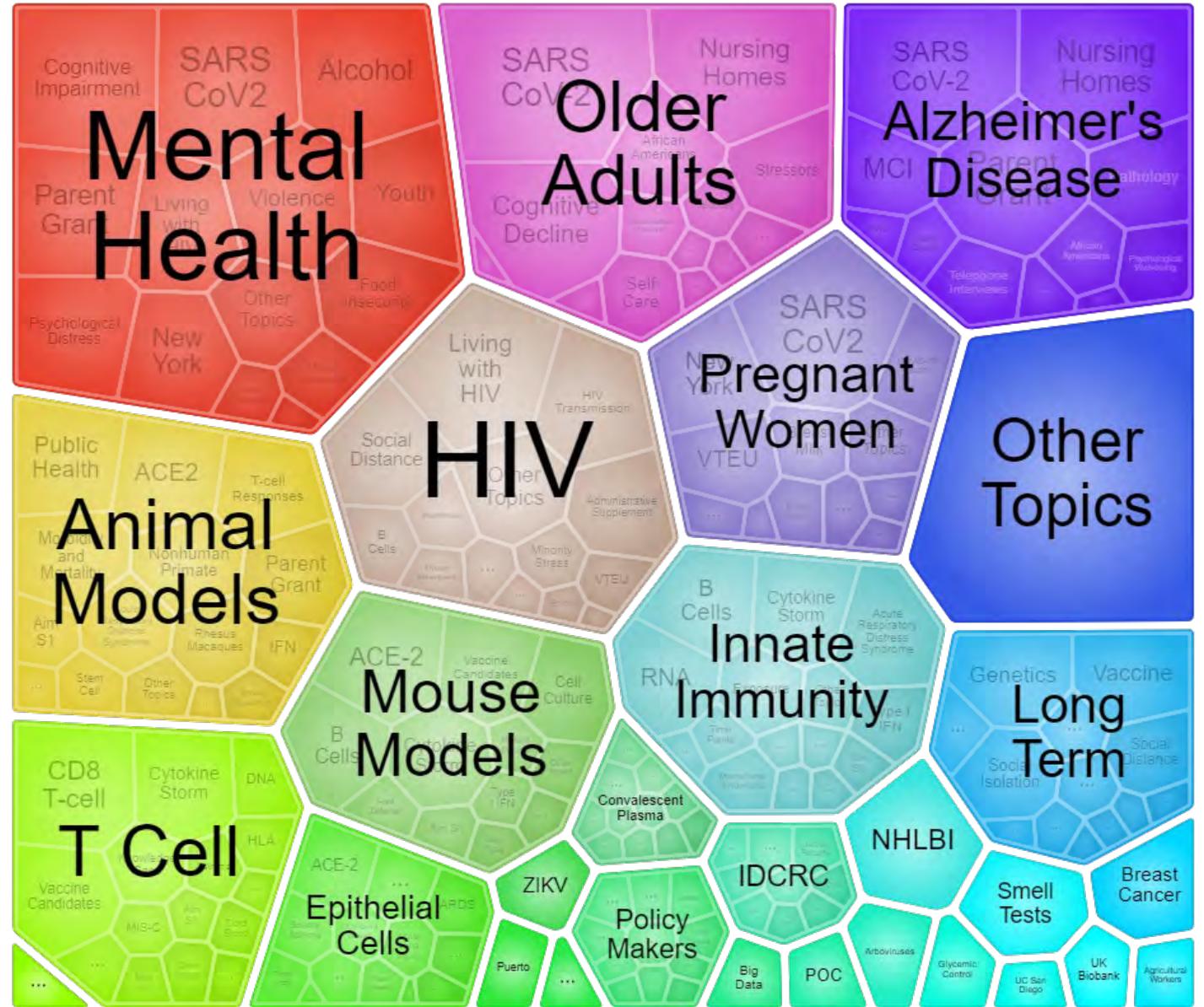
III.

COVID-19/Women's Health Portfolio 2020-22

Funding Distribution by Research Area*



- 523 Grants
- 21 Participating ICOs



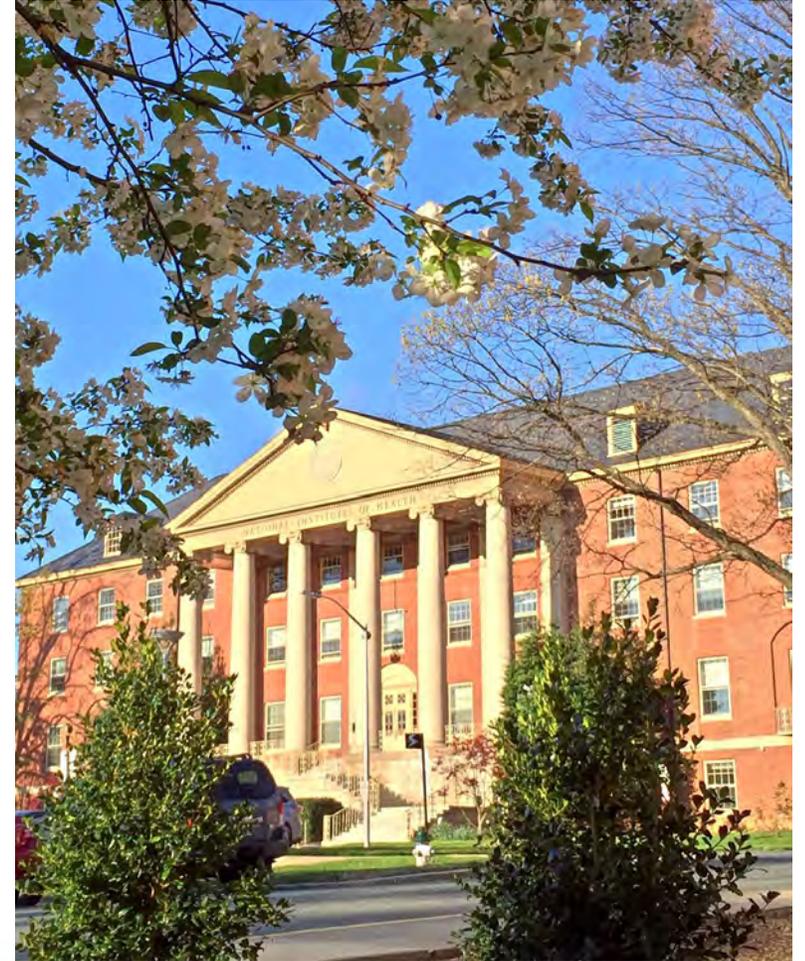
*RCDC terms considered, therefore grants will be counted multiple times across many categories

III.

The Common Fund Moves the NIH Mission Forward-Faster

- Supporting bold scientific programs that catalyze discovery **across all biomedical and behavioral research**
- Advances areas of biomedical and behavioral research important to the missions of **multiple NIH Institutes and Centers**
- Spurs subsequent biomedical and behavioral advances that **otherwise would not be possible** without initial strategic investment

commonfund.nih.gov



III. ComPASS's triple aim: advance health equity, improve outcomes, reduce disparities

What is ComPASS?

- Community Partnerships to Advance Science for Society
- NIH Common Fund supported

Innovative

- Fund community organizations (CO) **directly**
- **Health equity** (HE) focus
- Encourage **multi-sector partnerships** among COs, researchers, other sectors
- Design **structural interventions** that address SDOHs



Program Goals

- Catalyze, deploy, evaluate community-led HE structural interventions that employ multi-sector partnerships to reduce disparities
- Develop HE research model for community-led, multisectoral structural intervention research across NIH, other federal agencies

III.

Two funding opportunities kick off ComPASS

ComPASS Program: Community-Led, Health Equity Structural Interventions Initiative

- OTA-22-007
- **Letter of Intent Due: Nov. 18, 2022**

Community Partnerships to Advance Science for Society: Coordination Center (U24 - Clinical Trial Optional)

- RFA-RM-23-001:
- **Application Due: Jan. 27, 2023**

Resources

- <https://commonfund.nih.gov/compass>
- Register for Pre-Application ComPASS Coordination Center [Webinar](#)
- Register for Community-Led HE Structural Intervention Initiatives Office Hours: <https://commonfund.nih.gov/compass/meetings>
- FAQs: <https://commonfund.nih.gov/compass/faqs>



IV.

Scientific Collaborations

IV.



Project outcomes instructions specify that valid analyses for sex or gender, race and ethnicity for Phase III CTs must be reported

INCLUSION



NIH and Other PHS Agency Research Performance Progress Report (RPPR) Instructional Guide

May 13, 2022

IV.

May 4th NASEM Report Presentation to NIH Inclusion Governance Committee

Study Statement

Examine long-term medical and economic impacts of lack of inclusion of women and underrepresented minority groups in clinical research and subsequent translational work.

External guests included representatives from:

- Executive Office of the President
- HHS Office of the Secretary
- HHS Office of the Assistant Secretary for Planning and Evaluation
- Veterans Affairs
- FDA



INCLUSION

Dr. Kirsten Bibbins-Domingo

*University of California, San Francisco;
NASEM Committee Chair*

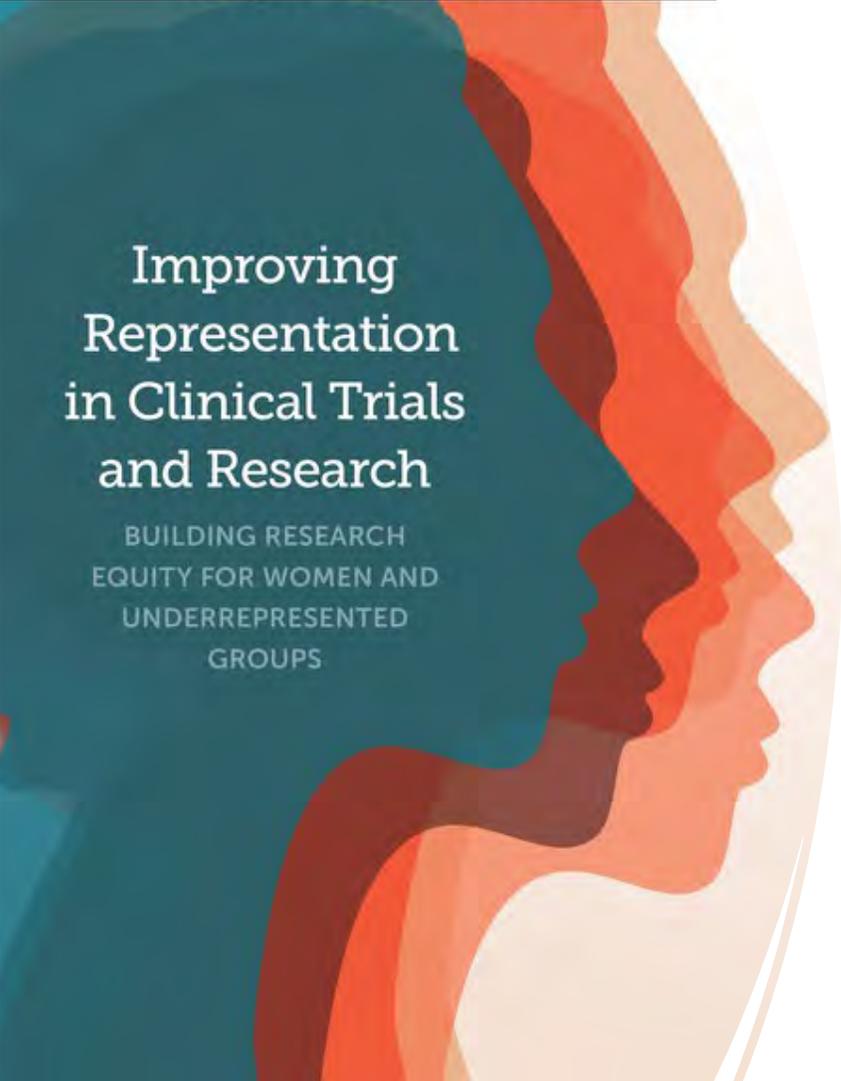
Economic cost of health disparities

If all life expectancy disparities were eliminated for diabetes, heart disease, and hypertension, the value would be approximately **\$11 trillion**.

Value for even a modest reduction in health disparities would be worth **billions of dollars**.

For example, if **1%** of health disparities were alleviated by better representation in clinical research, it would result in more than **\$40 billion** in gains for diabetes and **\$60 billion** for heart disease alone.





Improving Representation in Clinical Trials and Research

BUILDING RESEARCH
EQUITY FOR WOMEN AND
UNDERREPRESENTED
GROUPS

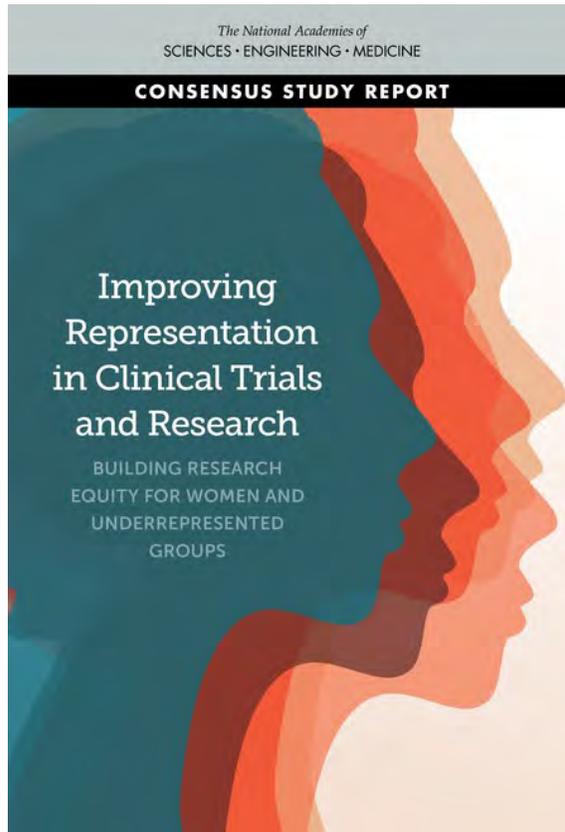
- “Large swaths of population,” inc. those who face greatest health challenges, not adequately represented in clinical research
- Little progress in last three decades to increase participation of racial and ethnic minority population groups
- Also underrepresented: older adults, pregnant & lactating individuals, LGBTQIA+ populations, persons with disabilities
- Underrepresentation compounds health disparities and compromises generalizability of research

Benefits of Improved Representation

- Reducing health disparities would **save billions of dollars**
- Exploring heterogeneity of treatment effects would **lead to more innovation**
- Would **expand access** to a specific therapeutic agent
- Would **increase trust** in science and new therapies

INCLUSION

NASEM Consensus Study Report recommendations



- **RECOMMENDATION #1: Development of DHHS Task Force**
- **RECOMMENDATION #3: Standardization of Clinicaltrials.gov Demographic and Other Data Elements**
- **RECOMMENDATION #4: Incorporate representativeness in score-driving review criteria and assess enrollment goals at time of progress report**
- **RECOMMENDATION #12: Develop guidance on equitable participant and caregiver compensation**
- **RECOMMENDATION #17: HHS should invest in funding community research infrastructure**

IV.



Application of NIH SABV policy



“Findings that men and women differ in risk cut-offs “was actually a real ‘eureka moment’”, Cheng says. “I was like, ‘how did we not see this before?’.” She attributes the results to the NIH’s challenge. “They made it all happen.”

Susan Cheng, cardiologist,
Cedars-Sinai Medical Center,
Los Angeles

nature

IV.



FOA reissued for Specialized Centers of Research Excellence on Sex Differences

RFA-OD-22-014 | Reissue of RFA-OD-19-013

- Support interdisciplinary approaches to advance translational research on sex differences
- Develop research agenda bridging basic & clinical research underlying health issues pertinent to women
- Promote and train diverse scientific workforce and address health disparities
- 8 participating ICs: NHLBI, NIA, NIAAA, NIAMS, NIDA, NIDDK, NIEHS, NIMH
- Next app. receipt date – July 15, 2024

Sex/Gender R01 Reissued

“The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional)”

- RFA-OD-22-028
- 10 ICs, one OD office signed on
- First receipt date: Dec. 19, 2022

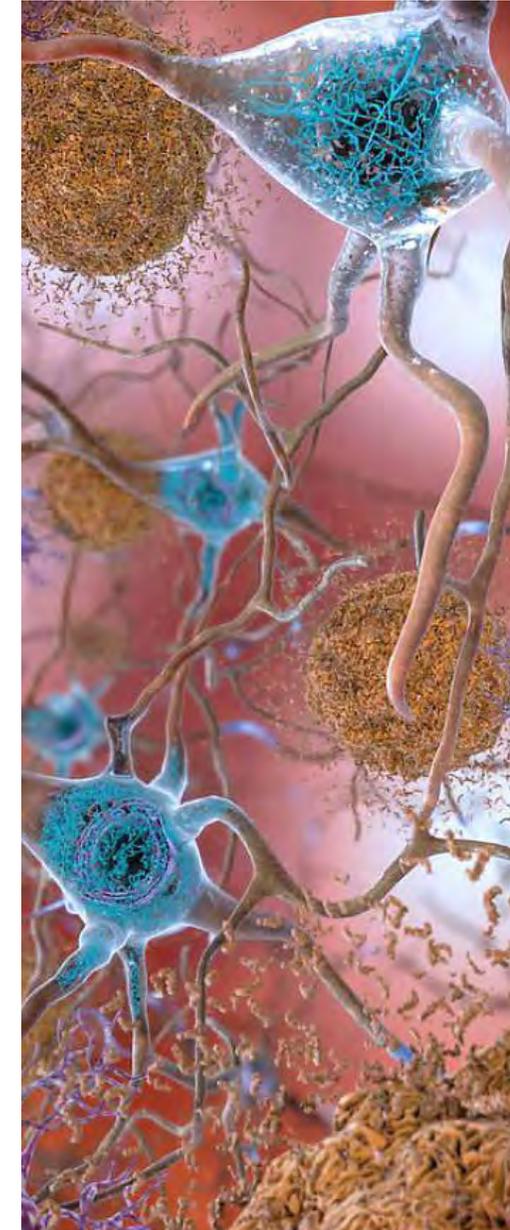
SCORE UPDATE

IV.

NIA FOA investigates sex differences on molecular determinants of Alzheimer's disease risk

Integrative Research to Understand the Impact of Sex Differences on the Molecular Determinants of AD Risk and Responsiveness to Treatment

- **PAR-22-228** | Reissue of RFA-AG-21-029
- Invites applications that apply **cross-disciplinary and team science approach** to gain comprehensive mechanistic understanding of **impact of sex differences on molecular trajectories of brain aging on the**
 - Phenotypes of risk and resilience to Alzheimer's disease (AD) and AD-related dementias (ARD), and
 - Molecular determinants underlying responsiveness to pharmacologic and non-pharmacologic interventions
- Earliest submission date: Nov. 11, 2022



SABV IN ACTION

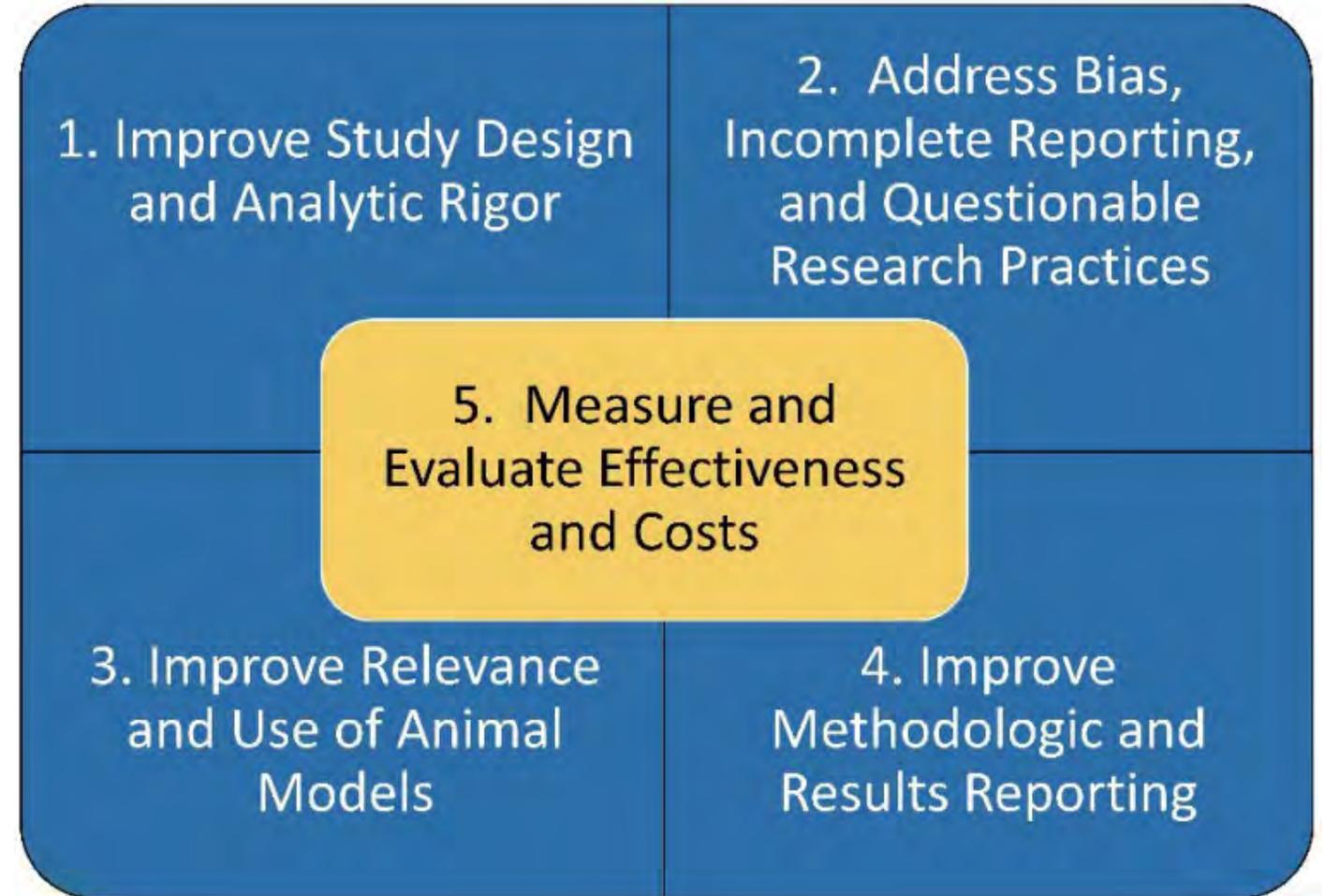
IV.

Improving the translatability of animal models

ACD Working Group on Enhancing Rigor, Transparency and Translatability in Animal Research Report, 2021

- Advised how NIH can help researchers **improve rigor, transparency, and reproducibility of animal research**
- Overarching goals
 - **Increase confidence** in quality and applicability of research
 - Ensure animal subjects used with **consideration of ethics and harm-benefit analysis**

REPORT RECOMMENDATION'S FIVE THEMES





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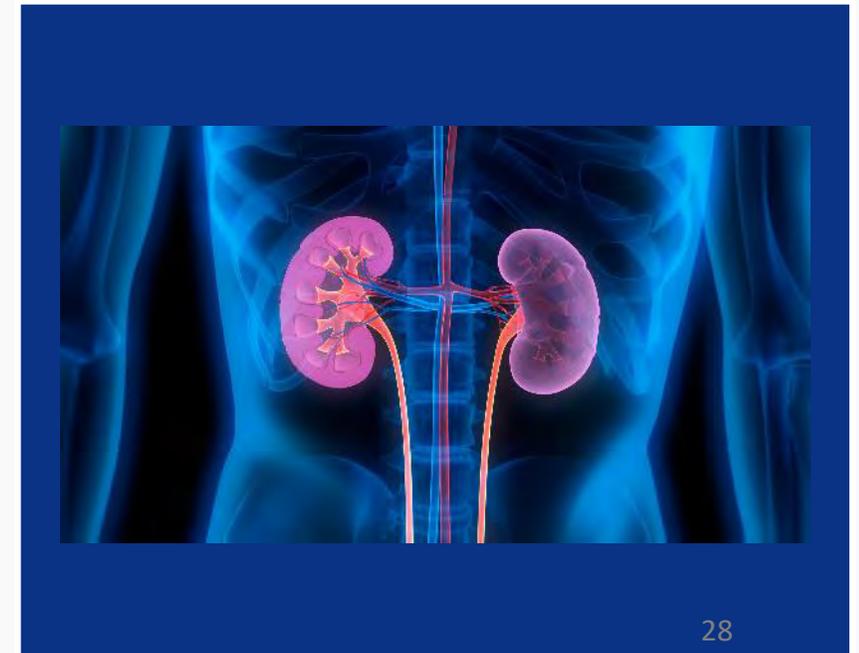
New study shows for first time that neurons in women's spinal cord process pain differently than men's

- Women experience pain differently, BUT most pain research uses male rodents
- Study **used female and male spinal cord tissue from both rats and humans**
- Found neuronal growth factor (BDNF) plays major role in amplifying spinal cord pain signaling in male humans and male rats, **but not in female humans or female rats**
- When **female rats had ovaries removed, difference disappeared**
- Foundational step toward treating pain

IV.



“We were expecting to find small or no disparities in how men and women were managed, because guidelines do not make distinctions by sex. **Instead, we observed profound differences** in the detection work up and management of chronic kidney disease **suggesting suboptimal care among women.**”¹



¹ Press release: Co-author Juan J. Carrero, Pharm, PhD.
Swartling O et al. 2022. *JASN* DOI: <https://doi.org/10.1681/ASN.2022030373>

IV.

Disparities in MI care for women and underrepresented populations persist

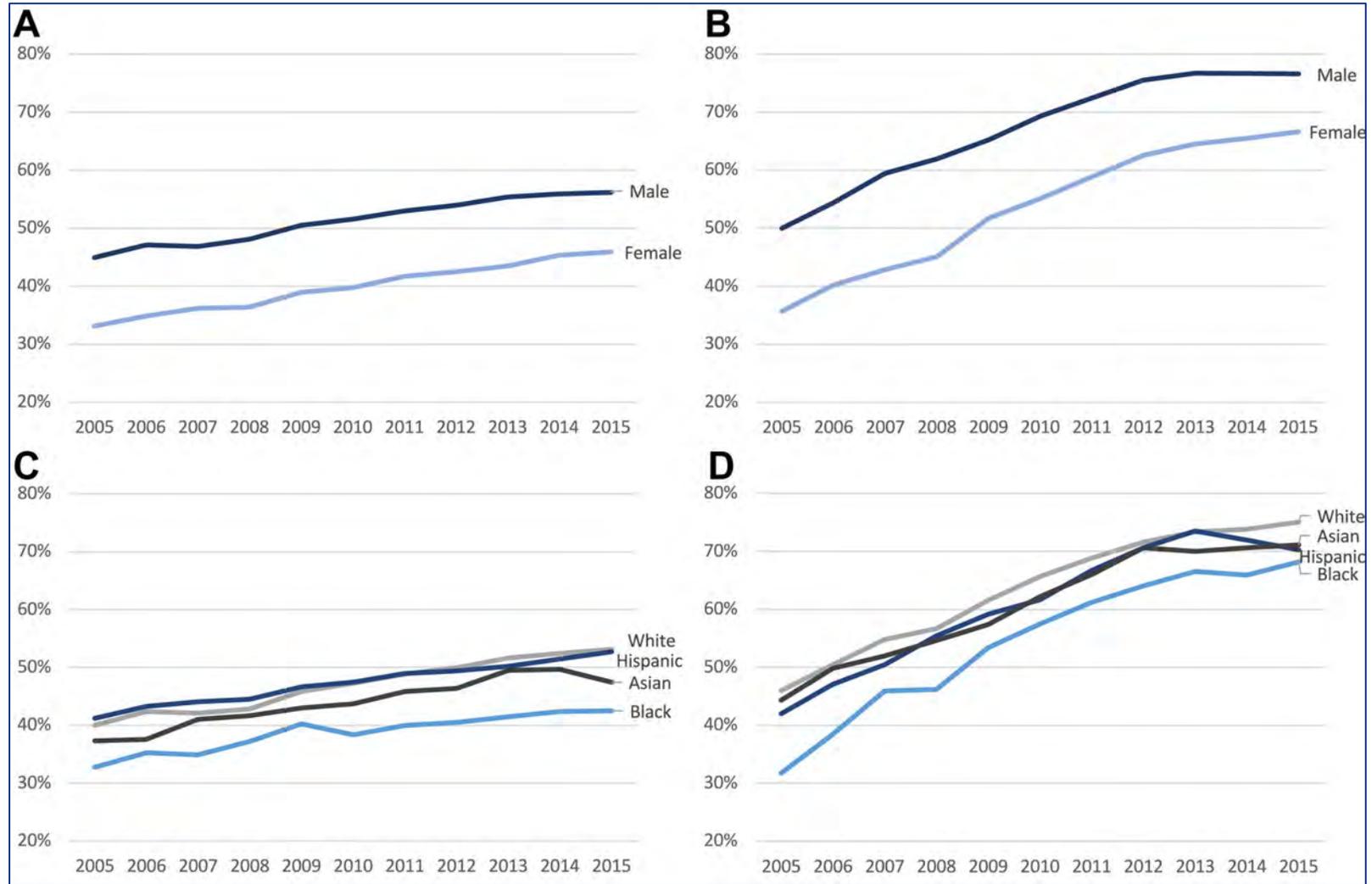
Patients with:

ST-segment elevation myocardial infarction (STEMI)

Non-ST-segment elevation myocardial infarction (NSTEMI)

NSTEMI acc. to SEX

STEMI acc. to SEX



Charts show probability of **timely angiography** during index admission

NSTEMI acc. to RACE/ETHNICITY

STEMI acc. to RACE/ETHNICITY

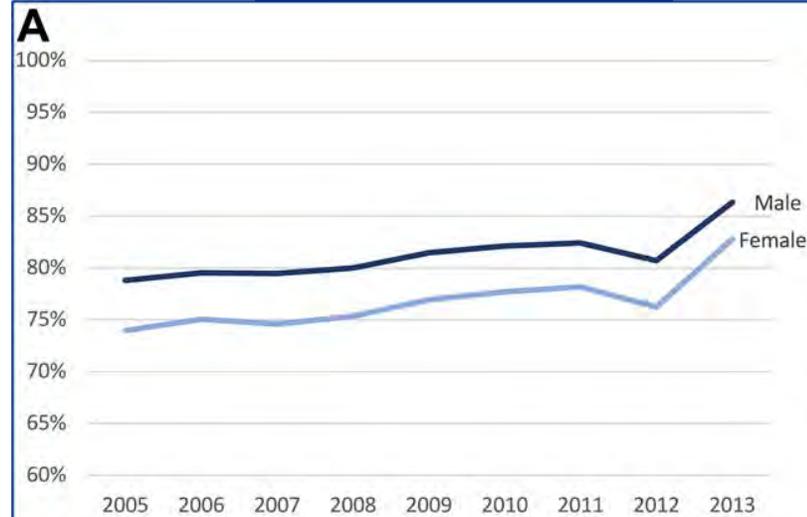
IV.

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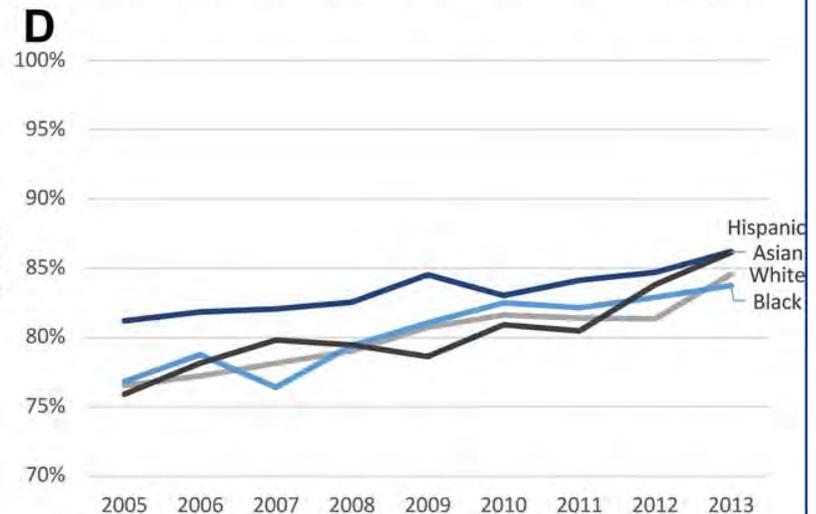
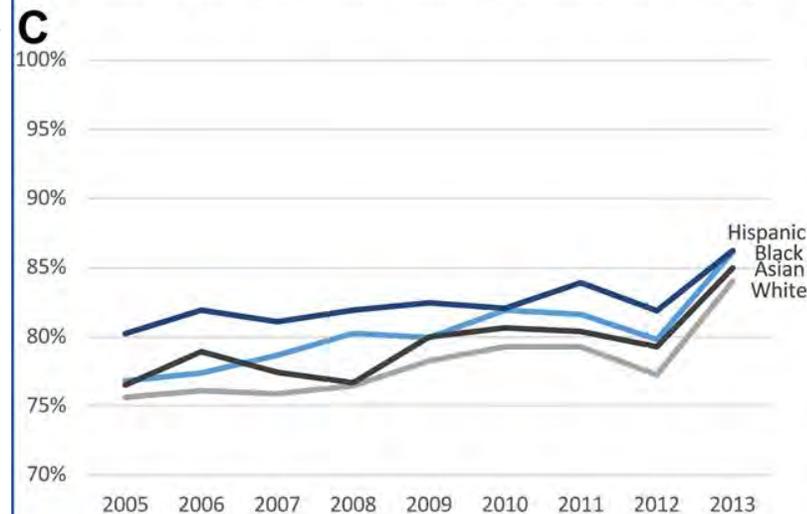
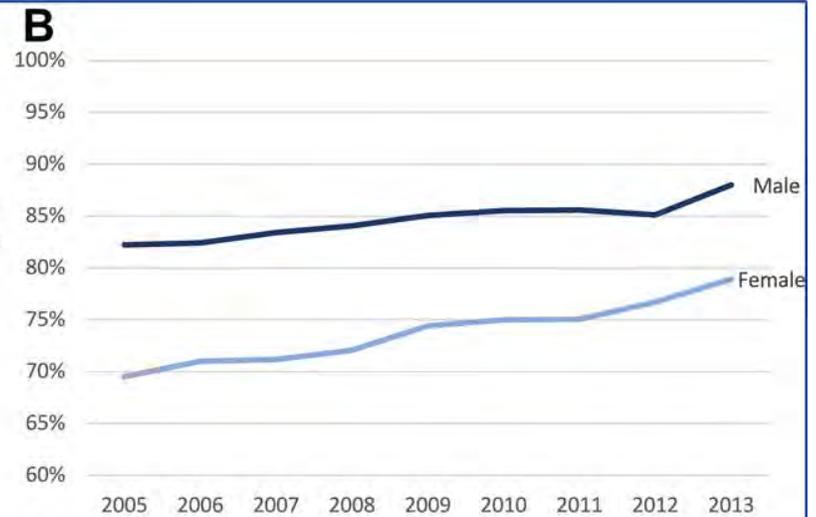
Charts show survival at 1 year after STEMI or NSTEMI

A “chronic debilitating condition” addressed in Women’s Health Conference report*

NSTEMI acc. to SEX



STEMI acc. to SEX



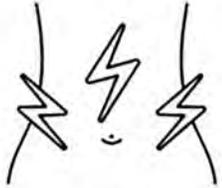
NSTEMI acc. to RACE/ETHNICITY

STEMI acc. to RACE/ETHNICITY

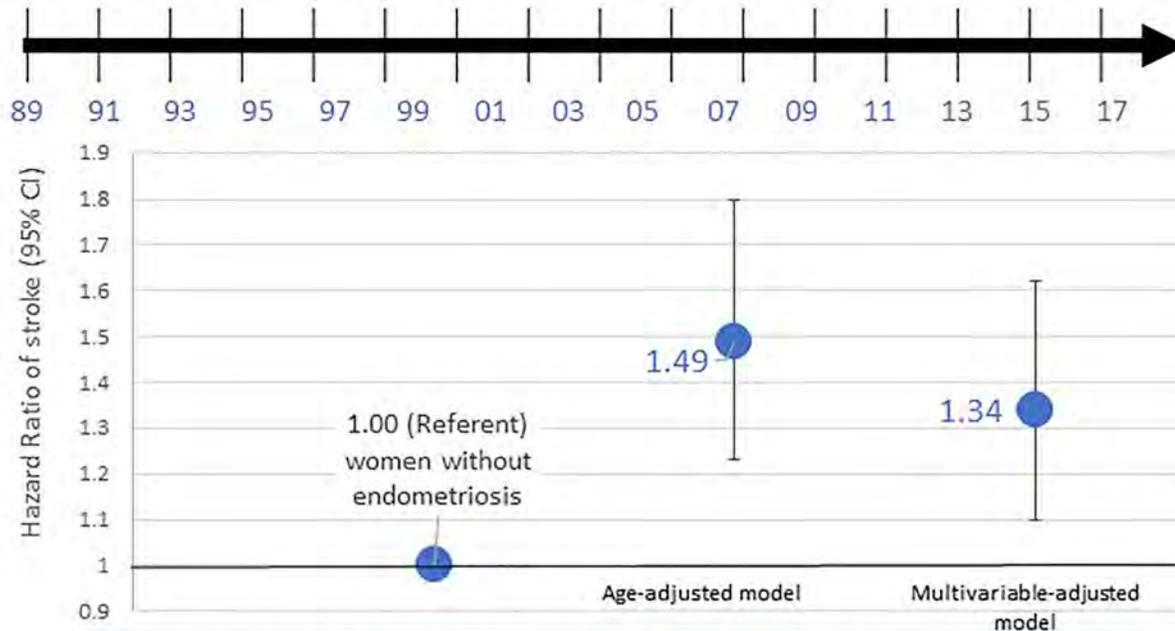
IV.



Laparoscopically confirmed endometriosis and risk of incident stroke: a prospective cohort study



Women with and without endometriosis in the Nurses' Health Study II (n=116,429) were followed for over 28 years to see who developed incident stroke



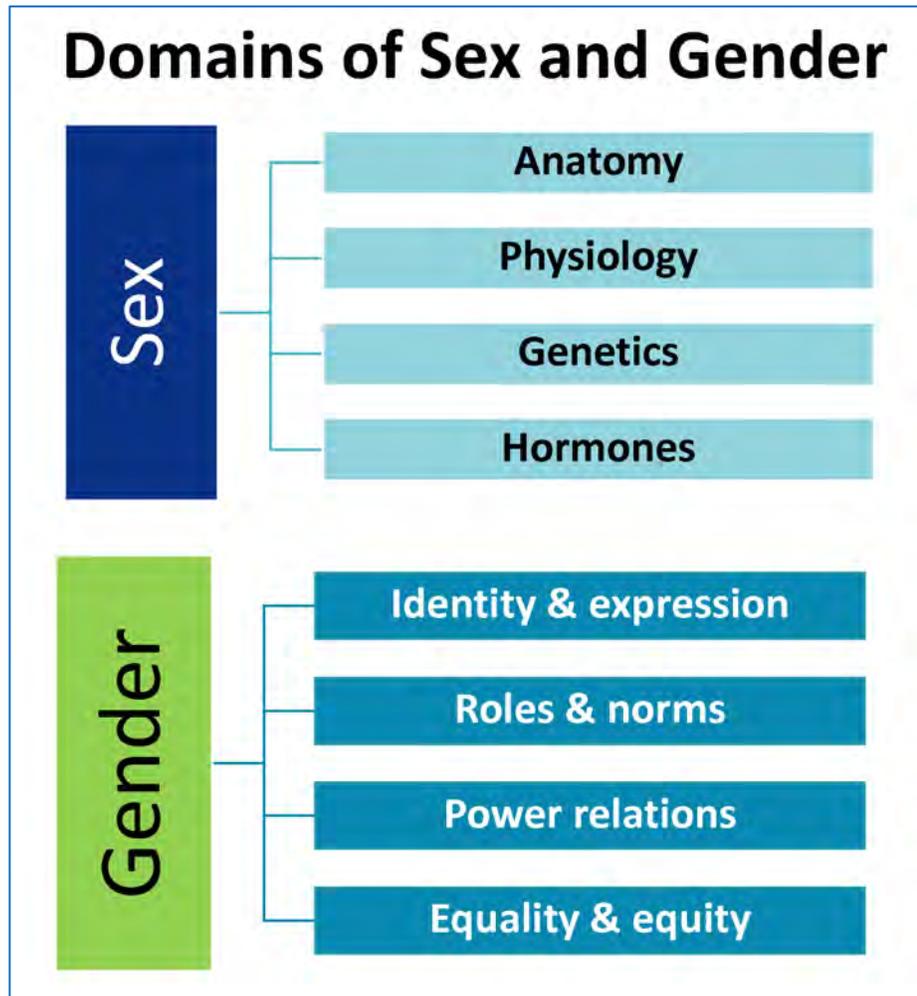
Women with laparoscopically confirmed endometriosis had a 34% greater risk of incident stroke (HR:1.34, 95% CI:1.10-1.62)



Eunice Kennedy Shriver National Institute of Child Health and Human Development

- **Endometriosis** may influence risk through alterations in endogenous inflammatory, immunologic, hormonal milieu
- Clinicians should **consider both reproductive and gynecologic health history** when counseling patients regarding CVD risk

ORWH's new way to galvanize health equity through education



GENDER 25 | Galvanizing Health Equity through Novel and Diverse Educational Resources

Purpose

Support **sex and/or gender-related** educational activities that complement and/or enhance **training of diverse workforce** to meet nation's health research needs

Educational activities

- Courses for skills development
- Curriculum or methods development

Participating ICOs | NIA, NIAMS, NIDA, NIMHD, NLM, NIDCR, OBSSR, OAR, & SGMRO

Round 1 application due dates

- Non-AIDS -- Oct. 27, 2022
- AIDS and AIDS-related -- Jan. 7, 2023

IV.

Bench to Bedside: Integrating Sex and Gender to Improve Human Health Course

Earn up to 6 CME credits – free!

- Developed by ORWH in partnership with FDA Office of Women's Health
- Provides thorough, up-to-date understanding of sex and gender influences on health and disease
- For staff, researchers, clinicians, students, faculty
- Offered **FREE** in acc. with Accreditation Council for Continuing Medical Education through joint provision of Johns Hopkins University School of Medicine and NIH



Share with colleagues!
<https://bit.ly/ORWHonline>

A graphic for the ORWH E-Learning Course Guide. It features a blue background with a white DNA double helix on the left and a chemical structure on the right. The text "ORWH E-Learning" is at the top, followed by the subtitle "Bridging the Learning Gap on Sex & Gender Differences in Health and Disease". Below this is a dark blue button that says "COURSE GUIDE". Underneath are three icons: a DNA helix, a caduceus, and a female figure. At the bottom, there are images of a laptop, a tablet, and a smartphone displaying the course content. A pink arrow points from the left towards the URL "bit.ly/ORWH_ELearning".

Get Copy Here

bit.ly/ORWH_ELearning

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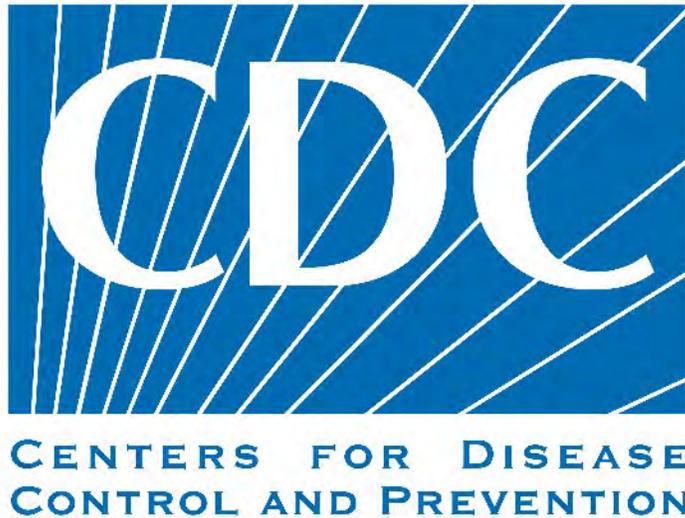
FDA Office of Women's Health

DEVELOPED IN COLLABORATION WITH MULTIPLE FEDERAL AGENCIES AND OVER 25 EXPERTS FROM LEADING INSTITUTIONS WORLDWIDE



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

IV.



CDC: 4 in 5 U.S. pregnancy-related deaths are preventable

93% of deaths among American Indian or Alaska Native

- Maternal Mortality Review Committees | 2017-2019 data | 36 states
- Reviewed deaths **during pregnancy** (22%), **day of or week after delivery** (25%), and from **day 7 to one year out** (53%)
- **Leading underlying causes**
 - Mental health conditions, inc. OD (23%)
 - Hemorrhage (14%)
 - Cardiac and coronary conditions (13%)
 - Infection (9%); Thrombotic embolism (9%); Cardiomyopathy (9%)
- **Underlying causes varied by racial group**
 - Mental health conditions – leading cause for Hispanic & non-Hispanic White
 - Hemorrhage – non-Hispanic Asian
 - Heart conditions – non-Hispanic Black

<https://www.cdc.gov/media/releases/2022/p0919-pregnancy-related-deaths.html>



IV.

ORWH & ICOs collaborate on *Pathways to Prevention of poor postpartum health outcomes*

Identifying Risks and Interventions to Optimize Postpartum Health

Open to Public:

Registration Opens in August 2022

Workshop to be held virtually
November 29-December 1



- Speakers will discuss scientific evidence on predicting and preventing poor postpartum outcomes
- Opportunities for attendees to submit questions and comments
- After workshop, independent panel will draft report outlining evidence gaps and priorities for future research
- Draft agenda: prevention.nih.gov/P2P-PostpartumHealth

More than 500 registrants

[Register for the workshop](https://prevention.nih.gov/P2P-PostpartumHealth)

P2P

IV.

P2P workshop will address two questions

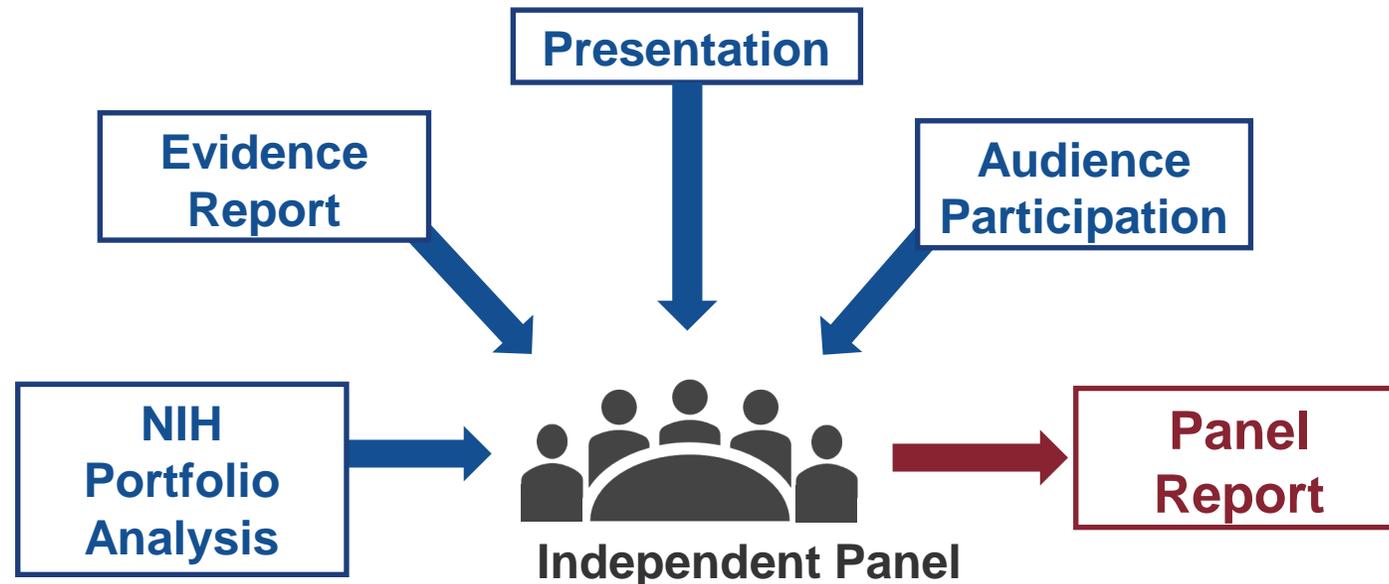
1. At a birthing person's entry into prenatal care, what combinations of risk indicators have greatest effect on **poor postpartum health outcomes**?

– To what extent do these patterns **vary by the race/ethnicity**?

2. Immediately before or after delivery and before release from care, what combinations of risk indicators have the greatest effect on poor post-partum health outcomes?

– To what extent do these patterns of predictors **vary by the race/ ethnicity**?

P2P



FY 2022 initiatives lay groundwork for COEs

Included \$30 M for NIH to expand IMPROVE

IMPROVE

- Dissemination and Implementation NOSI (FY22 awards; Reissue NOSI FY23)
 - Evidence-based findings with emphasis on strategies for populations with health disparities
- Community Partnerships Challenge (Launched)
 - Build research infrastructure that helps address structural barriers for community & advocacy organizations conducting maternal health research
- RADx-Tech for Maternal Health Challenge (Launch 9/15)
 - Innovate POC and home-based diagnostics that predict/diagnose risk of SMM/MM for postpartum individuals
- Connectathon (IAA estimated 8/12)
 - Identify, create, standardize maternal health-related data elements to advance care delivery and prenatal, birth & postpartum research
- IMPROVE Community Implementation Program (ROA issued 10/12)
 - Community-engaged implementation projects for evidence-based interventions in disproportionately impacted populations & maternity care deserts



IV.



Diverse Voices: Intersectionality and the Health of Women

Lecture Series address COVID-19 and violence

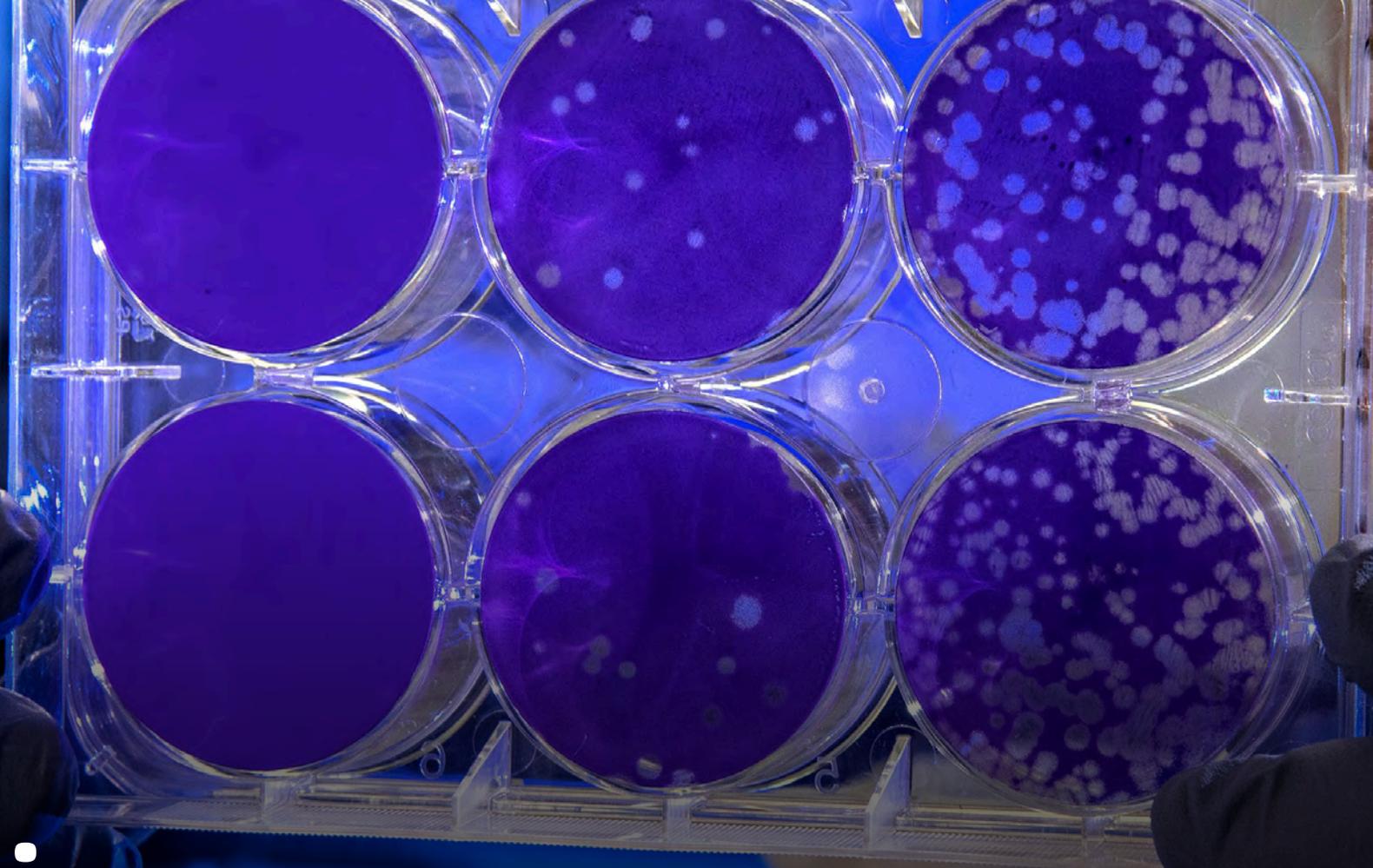
COVID-19 and Women | July 28

Speakers

- **Heather Shattuck-Heidorn, Ph.D.,**
University of Southern Maine
- **Stephaun Wallace, Ph.D., M.S.,
M.O.L.,** of the Fred Hutchinson
Cancer Research Center.



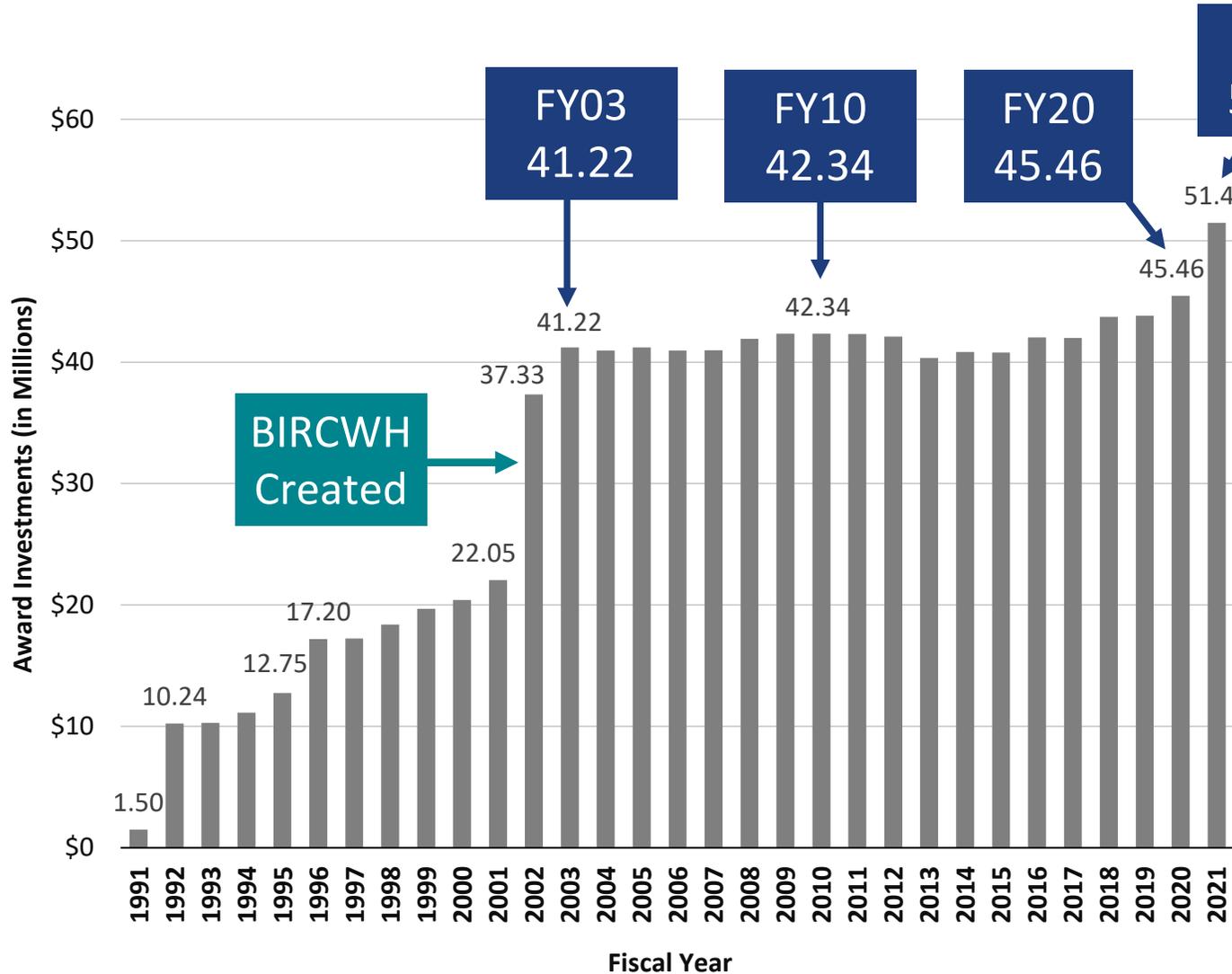
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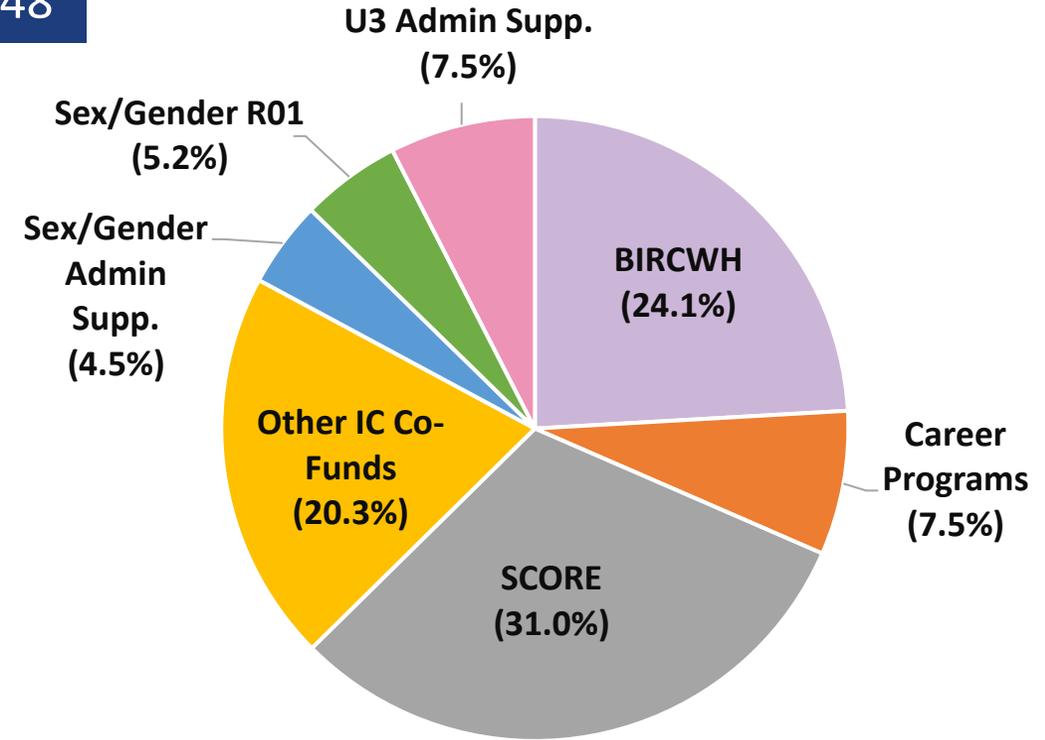
Funding

V.

ORWH Budget History & FY21 Extramural Grant Award Profile



Note: Award investments do not adjust for inflation



ORWH FY2021 Extramural Grant Awards by Program (as % of Extramural Budget)

Source: NIH IMPAC II FY2021 frozen data.
 Note: ORWH total investments = \$35,514,780. Funding portfolio excludes Contract R&D, IAA, and Loan Repayment awards.

VI.



Careers

NIH expands anti-harassment enforcement, requires reporting

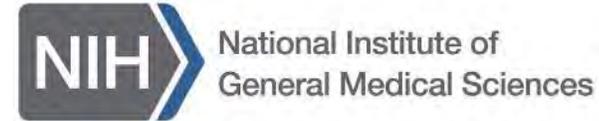
- NIH previously lacked clear authority to require institutions to report personnel changes (on a grant) related to harassment
- **Sec. 239 of Consolidated Appropriations Act for FY 2022:**

“[NIH director] shall hereafter require institutions that receive funds through a grant or cooperative agreement ... to notify the Director when individuals identified as a principal investigator or as key personnel in an NIH notice of award **are removed from their position** or are **otherwise disciplined** due to concerns about harassment, bullying, retaliation, or hostile working conditions.”
- **Under NOT-OD-22-129** | As of July 9, 2022
 - Institutions **must report within 30 days**
 - When PI or key personnel “in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions”
- Additional steps include changing personnel, restricting funds, or suspending or terminating grant per NIH Grants Policy Stmt.

VI.

»» **NASEM: research needed on correcting & preventing sexual harassment (SH)**

- 38% of women grad students experience SH from faculty/staff
- Challenges include lack of –
 - Coordination in documenting SH
 - Transparency in responding
 - Consistency in responding
 - Accountability
- There's no readily available guide for administrators on sanctioning and intervening
- Call for research on coordination, transparency, and consistency in sanctioning and early intervention
 - To hold faculty accountable
 - To support those harmed



Two new ORWH-funded grants

NIGMS R01 awards on SH research in response to FOA “Research on Interventions that Promote the Careers of Individuals in the Biomedical Research Enterprise” PAR-21-269

- **PI: Salles, Institution: Stanford** | ORWH funded full cost (\$404K) for 5 year¹
- **PI: Stockdale, Institution: Indiana/Purdue**. | ORWH funded 10% total cost (\$43K) for 5 years²

¹1R01GM147063-01

²1R01GM147151-01



Women's Health Research Events 2022

Gender and Health: Impacts of Structural Sexism, Gender Norms, Relational Power Dynamics, and Gender Inequities | October 26

Plenary Speakers

- Nancy Krieger, Ph.D. Harvard T.H. Chan School of Public Health
- Patricia Homan, Ph.D., M.A., Florida State University
- Typhanye Vielka Dyer, Ph.D., M.P.H. Univ. of Maryland School of Public Health

Afternoon Concurrent Sessions | Videolinks <https://bit.ly/3BV4dyf>.

- Methods and Measurement
- Modifiable Factors & Clinical Interventions
- Modifiable Factors & Social Determinants of Health

In partnership with

- NICHD, NIA, NIAID, NCI, NHLBI, NIDDK, NINDS, NIMH, NIDA, OBSSR



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



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E-LEARNING

- Bench to Bedside: Integrating Sex & Gender to Improve Human Health
- SABV Primer
- SABV Train the Trainer Course
- Intro. to Scientific Basis of Sex- & Gender-Related Differences

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