



NIH Office of Research on Women's Health

FIVE YEARS OUT: PROGRESS REPORT ON THE NIH SABV POLICY

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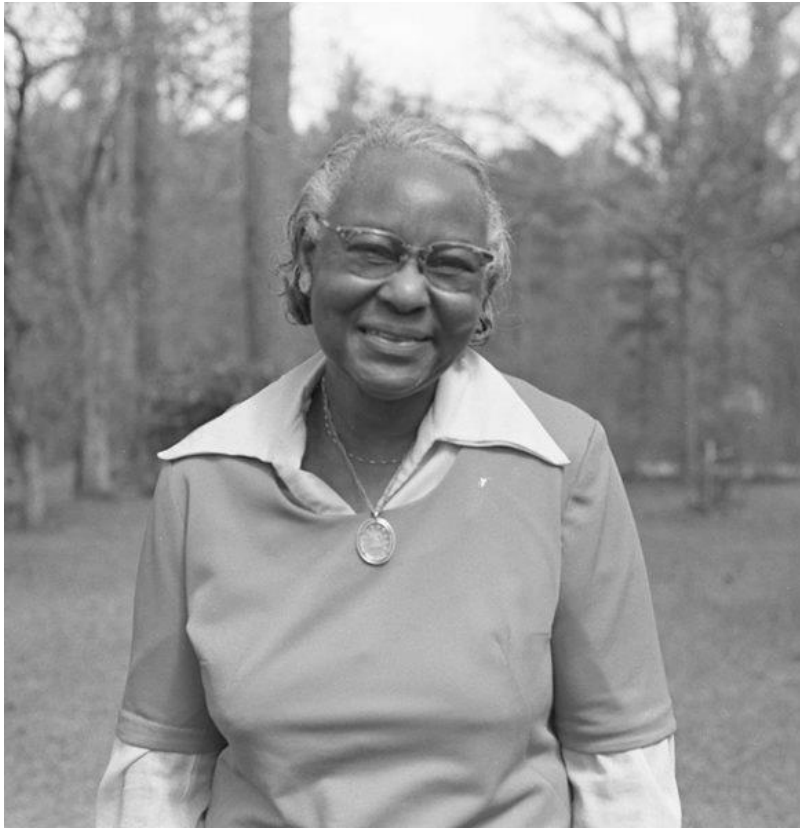




WHI marks its 30th anniversary

- In 1991, Dr. Bernadine Healy, then NIH director-*designate*, announced at her Senate confirmation hearing that NIH would launch a massive research initiative in women's health.
- 2021 also is the 30th anniversary of Dr. Healy's appointment as the first and only woman to lead the NIH.





How did we get here?



ORWH was established to help close a science gap



Default human subject was 154-lb male

- Assumed that fundamental biology included only **shared** molecular, biochemical & physiologic characteristics
- **Other factors** behind exclusion: protectionism, paternalism, women's estrous cycle

Plus **preponderant use of males** in preclinical research

Unisex Research is not unisex fashion >>>

- Unisex research's like trying to hit a bull's eye in the dark
- May hit the target, but not the bull's eye – way too random for medicine

Too little research on diseases and conditions of women



Inclusion – It's in ORWH's DNA

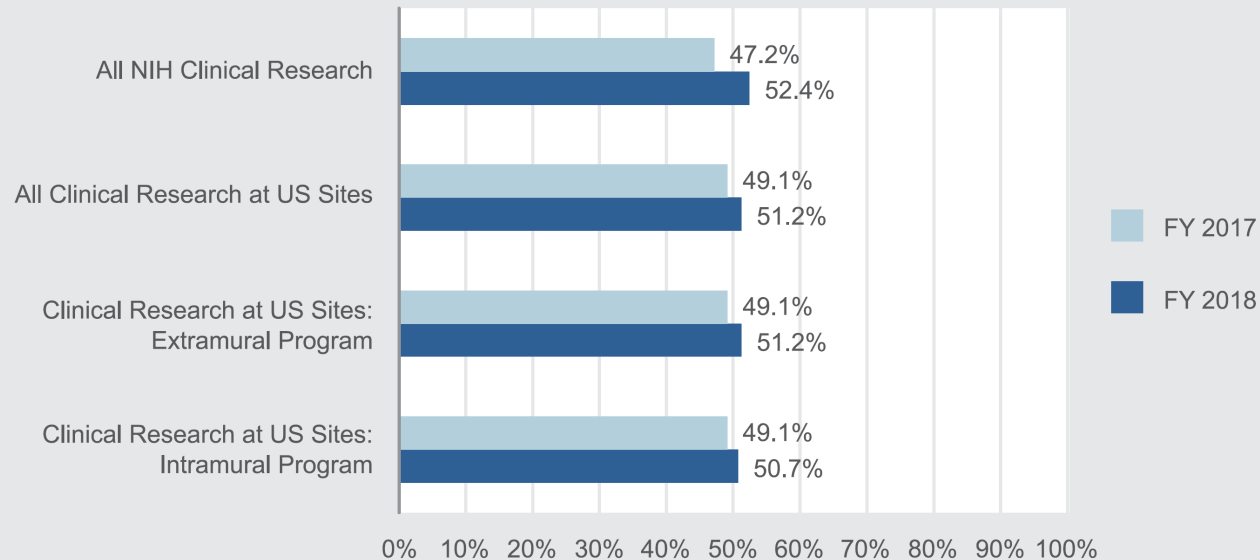
Representative studies and valid analysis make good science



- Inclusion of women in CTs was an original goal of ORWH.
- Seeks distribution of participants by sex/gender, race, ethnicity, and age needed to meet study goals
- Beginning in the 1980s, NIH and then Congress established, formalized, and expanded inclusion to include women and racial and ethnic minorities
- **21st Century Cures Act** expanded inclusion
 - To include **individuals of all ages** and eventually pregnant and lactating women
 - Requires NIH-defined applicable phase III clinical trials to report results **disaggregated by sex/gender, race, and ethnicity** into ClinicalTrials.gov
- NIH Research, Condition, and Disease Categorization report publishes selected inclusion data by sex/gender, race, and ethnicity <https://report.nih.gov/riscr/#/>

Today, more than half of CT participants are women

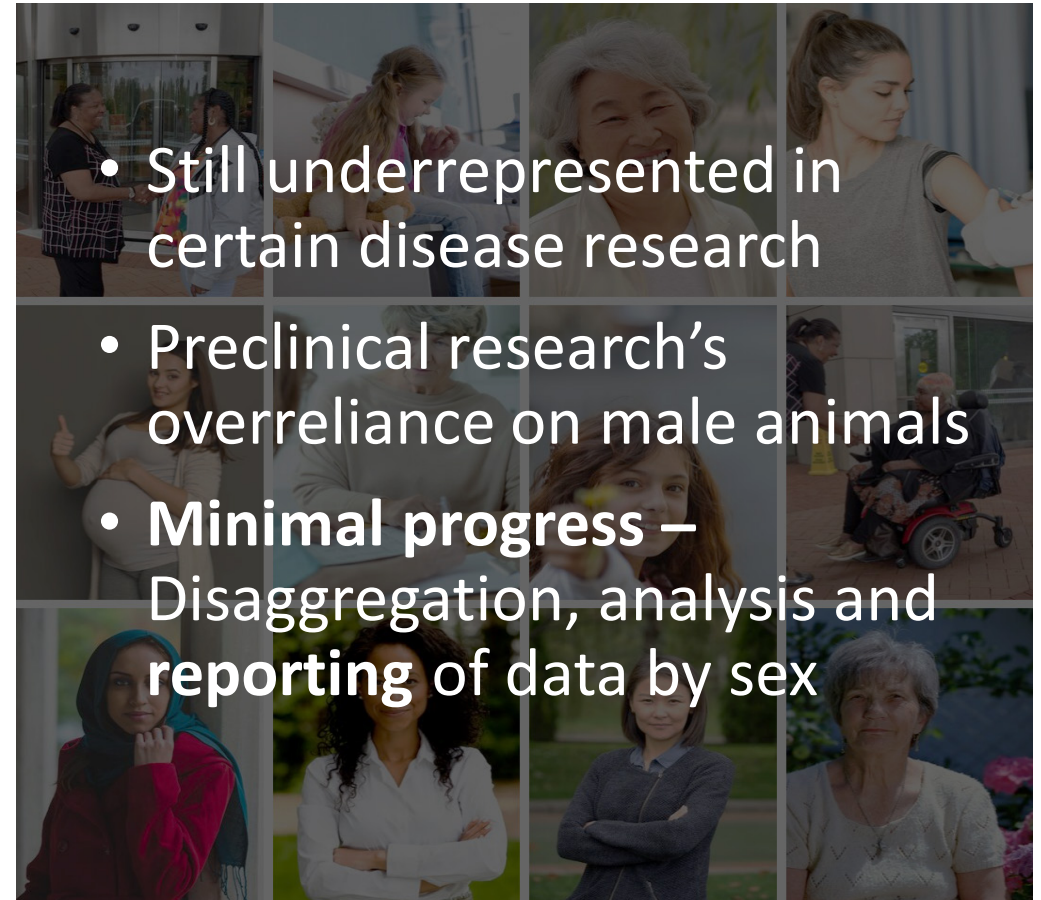
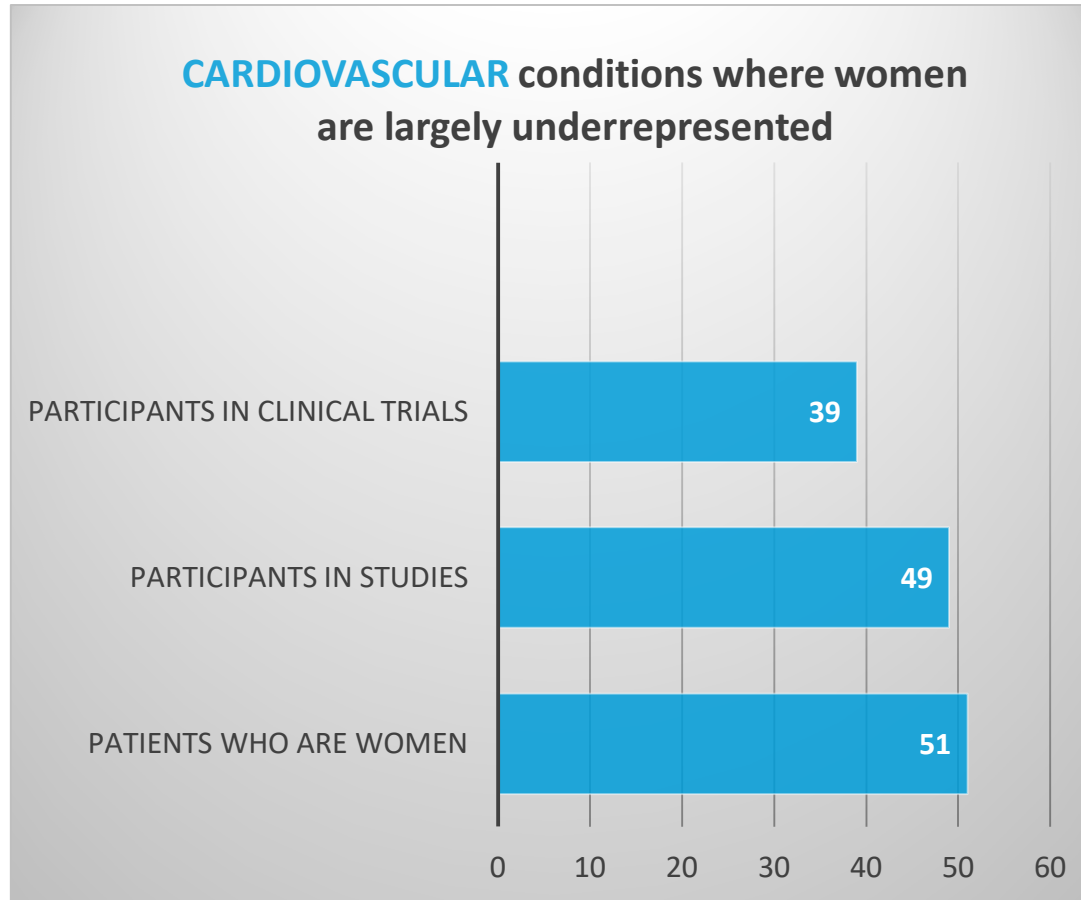
Figure 3: Percentage of Female Participants in NIH-funded Clinical Research for FY 2017 and FY 2018



Note: All NIH clinical research: Includes studies conducted in U.S. and foreign sites.



But underrepresentation and underreporting still exist





Moving focus beyond reproductive health to entire life course

“Women’s health” traditionally/historically focused on reproductive health

Today, **“health of women”** encompasses the whole women, head to toe and **over the life course**

- All diseases and conditions that affect women
- Recognizes that disease mechanisms, diagnoses, and treatment might differ for women



Multidimensional Framework represents intersection of factors affecting the health of all women



HEALTH OF WOMEN ACROSS THE LIFE

Women in Context – **External** Factors

Such as *social determinants of health* including **gender**, environment, & policies

Preconception

In
Utero

Childhood

Adolescence

Adulthood

Biological Perspective – **Internal** Factors

such as **sex** influences at genetic, molecular, cellular, & physiological levels

Interaction

Interaction



2019-2023 Trans-NIH Strategic Plan for Women's Health Research



Strategic Goals



Advance rigorous research that is relevant to the health of women



Develop methods and leverage data sources that consider sex and gender



Enhance dissemination and implementation of evidence to improve the health of women



Promote training and careers to advance science for the health of women



Improve evaluation of research that is relevant to the health of women

Signature programs advance research of women's health

Strategic Goal 1

Research

Advance rigorous research that is relevant to the health of women.

BIRCWH

Building
Interdisciplinary
Research
Careers in
Women's Health

7 ICOs

Mentored Career
Development
Program



SCORE

Specialized
Centers of
Research
Excellence on
Sex Differences

8 ICOs

Disease-Agnostic
Research Centers

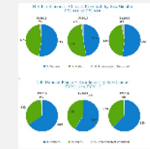


Sex & Gender

Studies that are
preclinical, clinical,
or both preclinical
and clinical

26 ICOs

Expand Sex &
Gender Data



R01

Intersection of
sex & gender
influences on
health & disease

11 ICOs

Sex & Gender
Influences on Health
& Disease



RFA-OD-19-029

Bringing rigor to the study of sex effects

- Expand and develop advanced approaches for study design, data collection, and analysis
- Develop measures that can be used to evaluate conditions or diseases relevant to women
- **Expand and refine methodologies to improve the recruitment and retention of women underrepresented in clinical research**



Strategic Goal 2

Methods

Develop methods and leverage data sources to consider sex and gender influences that enhance research for the health of women.

Strategic Goal 4

Training and Careers

Promote training and careers to develop a well-trained, diverse, and robust workforce to advance science for the health of women.

Pivotal steps in advancing careers of women in biomedical research

- **BIRCWH's** 20 years (2000-2020) of research and careers development
- National Academies of Sciences, Engineering and Medicine (NASEM) *Beyond Bias and Barriers* (2006)
- NIH Working Group on Women in Biomedical Careers
- Family-friendly policies
- *Causal Factors and Interventions* RFA
- Women of Color Research Network
- NASEM *Promising Practices for Addressing the Underrepresentation of Women in Science, Engineering, and Medicine* (2020)
- *No More Manels*



NIH Challenge Prize to recognize, disseminate transformative institutional approaches

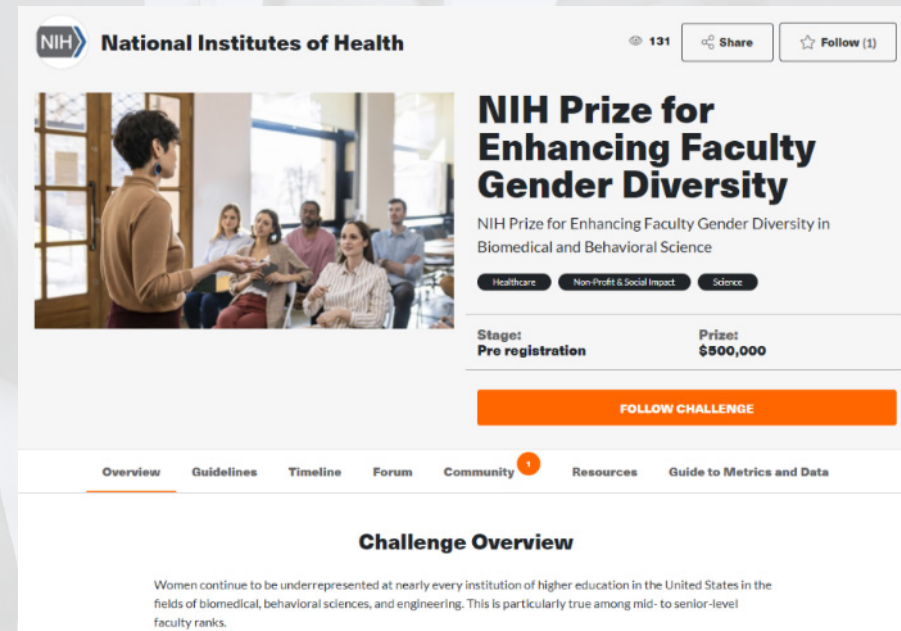
Goal: Recognize structures, systems, projects and processes that have enhanced gender diversity within an institution

- 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>

In response to WHI research in 2002 indicating that postmenopausal women taking combination hormone therapy for menopause symptoms had an increased risk for breast cancer, many women stopped taking hormone therapy, producing a sharp decline in breast cancer.

Between 2003 and 2012

76,000

fewer cases of cardiovascular disease

126,000

fewer breast cancer cases

143 times

**multiple of economic benefits over
original cost**

National Heart, Lung, and
Blood Institute

<https://www.ncbi.nlm.nih.gov/pubmed/24798522>

WOMEN'S HEALTH INITIATIVE

WHI is the gift that keeps on giving

Link between sickle cell trait (SCT) and risk of heart attack in African Americans? **NO!**

- Study examined whether SCT was associated with a higher risk of heart attack (myocardial infarction) and coronary heart disease (CHD)
- Evaluated 23,197 African Americans from 5 studies, **including 5,904 women from the WHI study**
- African American individuals with SCT did not have a higher incidence of heart attack or CHD

Link between vision impairment and dementia? **Possibly YES!**

- Analysis of data on 1,061 community-dwelling older women enrolled in the WHI Sight Examination and WHI Memory Study
- Risk of dementia and mild cognitive impairment (MCI) was **greater among women with vision impairment** than those without
- **More severe visual impairment** was associated with **higher risk of cognitive impairment**
- Greatest risk for dementia or MCI? Vision impairment of 20/100 or worse at baseline

Hyacinth HI, et al. 2021. JAMA Netw Open. doi: 10.1001/jamanetworkopen.2020.30435.

16 Tran EM, et al. 2020. JAMA Ophthalmology. doi: 10.1001/jamaophthalmol.2020.0959.



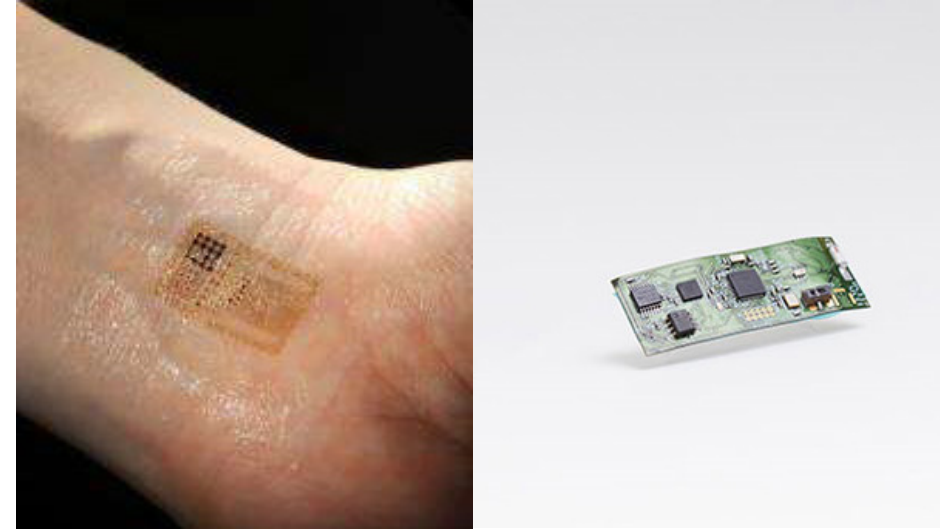


THANK YOU

*For your courage and your contributions to science,
medicine, and the health of all*

THE FUTURE OF CLINICAL TRIALS

- Built-in sensors in clothing, phones and household devices that collect data from patients 24/7
- Small, wireless, self-powered, passive sensors placed in parts of the body that comfortably capture high-quality data
- Temporary digital tattoos that capture ECG measurement, fall detection, and even drug release
- Clinical trials aren't just for the sick!



Credit: UC San Diego



WOMEN'S HEALTH *In Focus* AT NIH



30TH ANNIVERSARY ISSUES



**Volume 4, Issue 1
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The Pulse

monthly email | bit.ly/ORWHpulse

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