



National Hispanic Medical Association

# *All of Us* Research Program Fireside Chat Series

Session 5: Women & the *All of Us* Research Program

May 27, 2021  
7:00 PM – 8:00 PM  
[www.NHMAMD.org](http://www.NHMAMD.org)

# Welcome

**Elena Rios, MD, MSPH, FACP**

*President & CEO*

National Hispanic Medical Association

## Housekeeping

- Presentations to be followed by Q and A discussion
- Type questions in chat box
- Microphones will be muted
- Recording available next week at [www.NHMAmd.org](http://www.NHMAmd.org)

*All of Us* Research Program  
**FIRESIDE CHAT SERIES**

**SESSION 5: Women's Health**

Thursday, May 27, 2021; 7:00 PM - 8:00 PM Eastern Time

**MODERATOR**

**PANELISTS**



**Elena Rios, MD, MSPH, FACP**  
President & CEO  
NHMA



**Sarah M. Temkin, MD**  
Associate Director for Clinical Research  
Office of Research on Women's Health  
National Institutes of Health



**Dr. Michele Crespo-Fierro, PhD, MPH, RN, AACRN**  
Clinical Assistant Professor  
Director of LEAD Honors Program  
NYU Meyers College of Nursing  
President  
NY Chapter- National Association of Hispanic Nurses  
Member, Association of Nurses in AIDS Care



**Nereida Correa, MD, MPH**  
NHMA Chairwoman



**Ana Maria Lopez, MD, MPH, MACP**  
Professor and Vice Chair, Medical Oncology  
Sidney Kimmel Medical College  
Chief of Cancer Services, Jefferson Health New Jersey  
Sidney Kimmel Cancer Center, NCI Designated  
Thomas Jefferson University  
President-Emeritus, American College of Physicians  
NHMA Philadelphia Chapter Leader



**For more information & to register:** <http://bit.ly/NHMAFiresideChats>



Sarah M. Temkin, MD  
Associate Director for Clinical Research  
Office on Research for Women's  
Health  
National Institutes of Health





# Sex<sup>1</sup>

Derived from chromosomal complement

Every cell has a sex (XX or XY)

- Begins *in utero*
- Affects behavior and perception
- Affects health—from disease risk to treatment response



# Gender

Multidimensional psychosocial construct that integrates roles, behaviors, expressions, and identities of girls, women, boys, men, and gender-diverse people

- Influences how people perceive
  - Themselves and others
  - How they act and interact
- Begins after birth
- Affects behavior and health



<sup>3</sup> Nielsen, M, ... Schiebinger, L. Biol Sex Differ. 2021. doi.org/10.1186/s13293-021-00366-3

<sup>1</sup>Exploring the Biological Contributions to Human Health: Does Sex Matter, IOM Report , 2001

<sup>2</sup><https://orwh.od.nih.gov/sex-gender/sexgender-influences-health-and-disease/infographic-how-sexgender-influence-health>

# Inclusion into Clinical Research

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- Seeks distribution of participants by sex/gender, race, ethnicity, and age needed to meet study goals
- Beginning in the 1980s, NIH and later Congress established, formalized, and expanded inclusion to include women and racial and ethnic minorities
- **21<sup>st</sup> Century Cures Act** expanded inclusion
  - Added **individuals of all ages** and eventually **pregnant and lactating women**
  - Requires NIH-defined applicable phase III CTs to report results **disaggregated by sex/gender, race, and ethnicity** into ClinicalTrials.gov

<sup>1</sup> Bernard MA, Clayton JA and Lauer MS. 2018. *JAMA* 320(15):1535-1536. doi:10.1001/jama.2018.12368

# Generalizability of Clinical Trials Results

- Participants should be representative of the patient population for which the intervention is intended
  - Volunteer effect
  - The importance of diversity of sex, gender, race, ethnicity, age, ability among other criteria



# Persistent challenges in clinical research

- Less research of diseases affecting women and lower funding levels
- Male-patterned inclusion criteria and sex-biased outcome measures persist
- Is underrepresentation baked in? Early mouse models for drug discovery use almost exclusively male mice
- Dependent care and time commitment impede participation
- Criteria limiting participation for those with complex needs/multiple chronic conditions

Women and certain racial and ethnic groups have higher prevalence of such comorbidities notwithstanding willingness to participate (comparable to Whites')



**NIH Inclusion Across the Lifespan II**

<https://grants.nih.gov/sites/default/files/IAL-II-Workshop-Report.pdf>



# All of Us Research Program: Summary of Protocol and Status

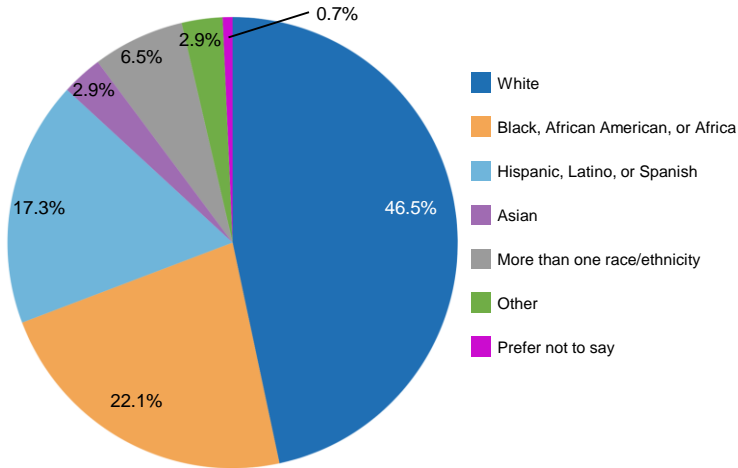
## Key elements:

- **Goal:** 1 million or more diverse participants
- Disease-agnostic, all health stages
- **Focus on diversity:** >50% diverse race/ethnicity, >80% underrepresented in research
- **Focus on engagement:** participants have been partners from the beginning and through all stages
- **Participants get data back** (currently including genetics results)

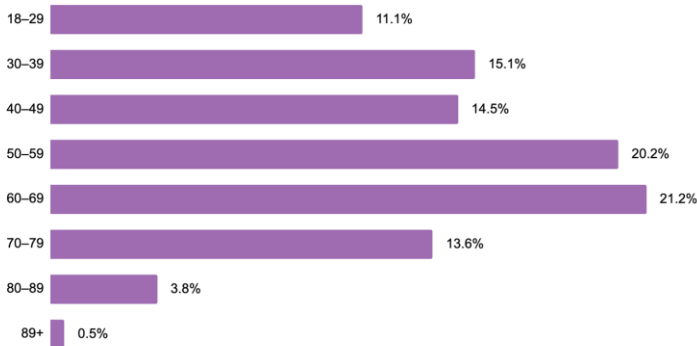


# Status of the *All of Us* Research Program (as of May 4, 2021)

## Race and Ethnicity



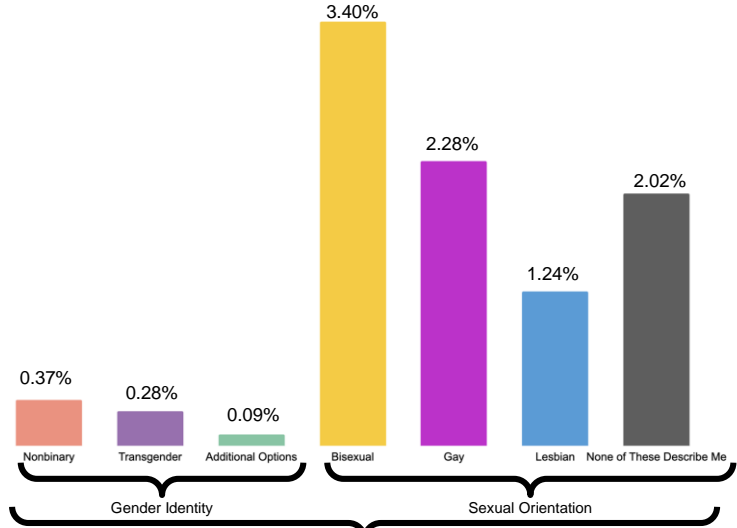
## Age



**Over 80% of *All of Us* participants are underrepresented in biomedical research**

- 39.1% of participants are men
- 59.4% of participants are women
- 1.5% of participants reported other gender identity

## Gender Identity and Sexual Orientation



**Collectively, 13% of participants identify as a Sexual/Gender Minority**

# ORWH Mission



Enhance and expand women's health research



Include women and minority groups in clinical research

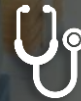


Promote career advancement for women in biomedical careers

# NIH Vision



Sex and gender integrated into biomedical research



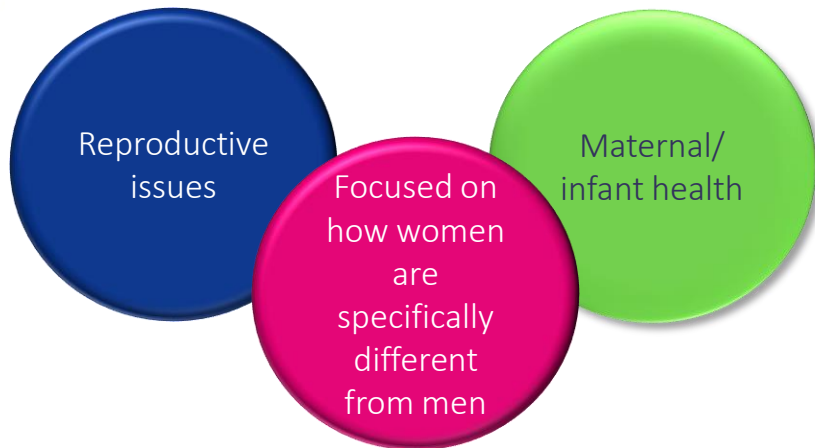
Every woman receives evidence-based care



Women in science careers reach their full potential

# The Future of Women's Health

## Previous Framework: Women's Health



## Current Framework: Health of Women



The US Department of Health and Human Services defines the health of women as “diseases and conditions that affect women...all health concerns experienced by women across the lifespan and in the social context of their lives”





Multidimensional Framework represents intersection of factors affecting the health of 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

# ORWH advances study of sex/gender and the health of women through collaborations across NIH | FY 2020

## BIRCWH

Building Interdisciplinary Research Careers in Women's Health

**8 ICOs**

Mentored Career Development



## SCORE

Specialized Centers of Research Excellence on Sex Differences

**5 ICOs**

Disease-Agnostic Research Centers



## Administrative Supplements

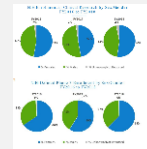
Sex and Gender

**22 ICOs**

Understudied, Underrepresented, & Underreported (U3)

**15 ICOs**

Funding Program to Expand Sex & Gender Data



## R01

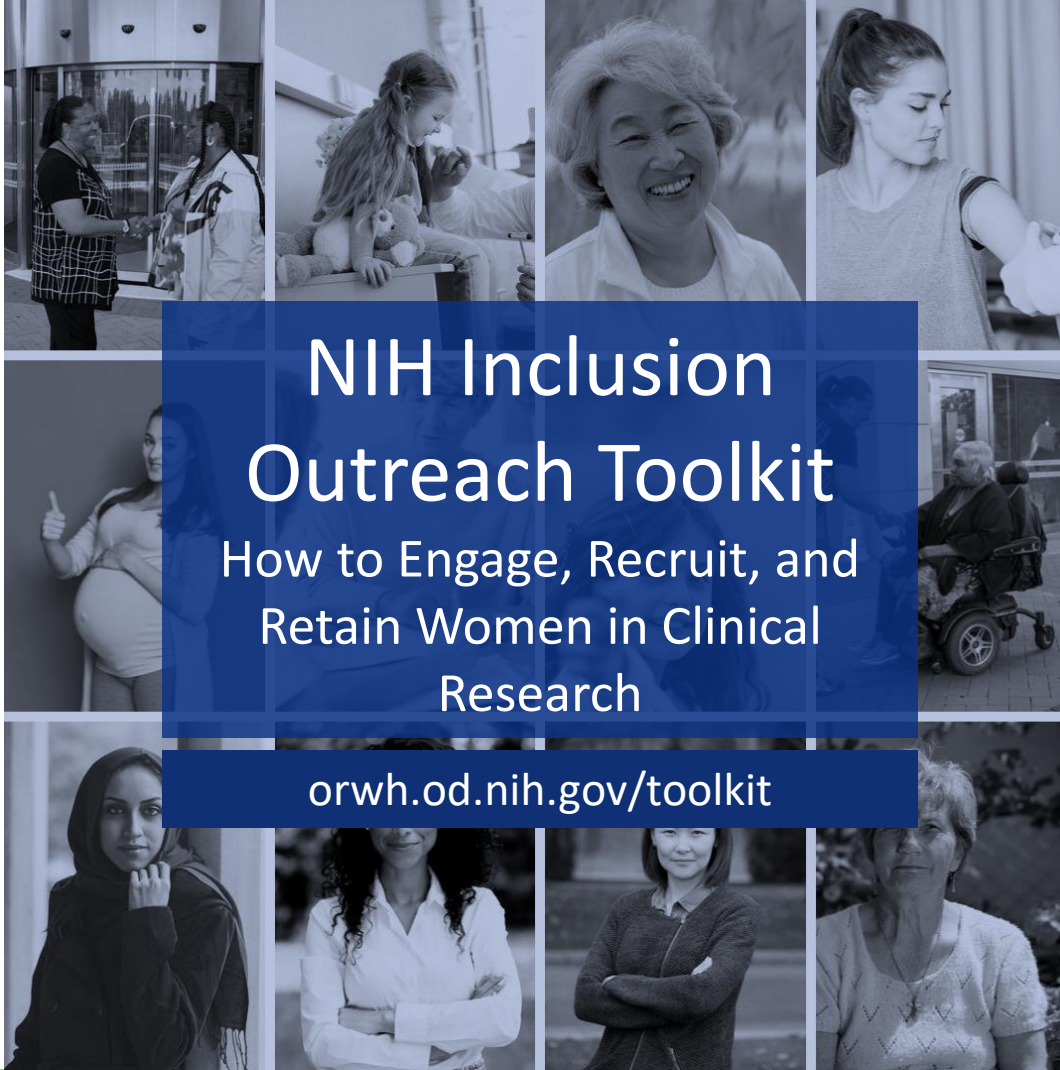
Intersection of sex & gender influences on health & disease

**11 ICOs**

Sex & Gender Influences on Health & Disease



RFA-OD-19-029



# NIH Inclusion Outreach Toolkit

How to Engage, Recruit, and  
Retain Women in Clinical  
Research

[orwh.od.nih.gov/toolkit](https://orwh.od.nih.gov/toolkit)

**NIH** National Institutes of Health  
*Turning Discovery Into Health*

NIH Clinical  
Center  
Introductory  
Principles of  
Clinical  
Research

Module Two

\*<https://ocr.od.nih.gov/courses/ippcr.html>

# ORWH's e-learning educates biomedical community on sex & gender

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

Immunology | CVD | Pulmonary Disease | Neurology | Endocrinology | Mental Health

## ■ Sex as a Biological Variable Primer

- With support from  National Institute of General Medical Sciences and the NIH Office of the Director

## ■ Introduction to the Scientific Basis of Sex- and Gender-Related Differences | Including facilitator's guide





# Connect with ORWH



**30TH ANNIVERSARY ISSUES**

**quarterly newsletter**  
[bit.ly/ORWHInFocus](http://bit.ly/ORWHInFocus)

WOMEN'S HEALTH *In Focus* AT NIH  
A QUARTERLY PUBLICATION OF THE NIH OFFICE OF RESEARCH ON WOMEN'S HEALTH  
National Institutes of Health - Office of the Director | Volume 4, Issue 1, 2021

**Technological Innovations  
in Breast Cancer Screening  
and Treatment**

**IN THIS ISSUE**

- 3. Technological Innovations in Breast Cancer Screening and Treatment
- 8. COVID-19 and the ORWH Mission
- 14. NIH Director Interviews Nohel Laouate-Jamouil Douadia, Ph.D.

Visit the [sub-02.020101.nih.gov](http://sub-02.020101.nih.gov) to sign up to receive future issues of *Women's Health in Focus at NIH*.

**Volume 4, Issue 1  
2021**

WOMEN'S HEALTH *In Focus* AT NIH  
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**The Pulse**

**monthly email**  
[bit.ly/ORWHpulse](http://bit.ly/ORWHpulse)



# Women's Health Research and Nursing Practice

Michele Crespo-Fierro, PhD, MPH, RN, AACRN

NHMA Fireside Chat: May 27, 2021



# Historical Context of Clinical Research and Women's Health

- Belief that the male body was the ideal and the only differences between males and females were specific to the sex organs and reproductive functions.
- Findings of research on other body systems conducted with male participants was sufficient to determine care for females
- Female experiences of the menstrual cycle and any other reproductive related physical and emotional presentations seen as disordered
- Black and brown women's bodies manipulated to discover medical care practices for use on white women's bodies



# Instances of harmful research on Women of Color

- 1840s J. Marion Simms – forced enslaved women to endure gynecological procedures without sedation to develop techniques to treat vesicovaginal fistulas
- 1950s Oral contraceptive testing in Puerto Rico – first large-scale use of early and higher dosages of the pill. Puerto Rico selected as “close” to the mainland and without the restrictions on birth control in the US. Reports of side effects and the 3 deaths of women in the study not investigated. Study continued after use in the US, complaints of American women and lawsuits until 1964

# Benefits of Research Findings for Nursing Practice

- Nursing is the protection, promotion, and optimization of health and abilities; prevention of illness and injury; facilitation of healing; alleviation of suffering through the diagnosis and treatment of human response; and advocacy in the care of individuals, families, groups, communities, and populations. <https://www.nursingworld.org/practice-policy/scope-of-practice/>
- Emphasis on research findings and evidence-based practice to guide nursing care.
- Nurses' proximity to patients and being the most trusted profession allows them to learn of individual presentations of disease that may not be shared with other providers. <https://news.gallup.com/poll/328136/ethics-ratings-rise-medical-workers-teachers.aspx>
- Nurses' role as patient educators and supporters of self-care activities to manage disease and other health conditions requires current findings.



# Variations in Presentation of Health Conditions for Biological Females

- Heart Disease – differing symptoms of a heart attack
- HIV/AIDS – 1993 addition of cervical dysplasia and cancer to AIDS defining diagnoses

# Nurses as Researchers

- National Institute of Nursing Research <https://www.ninr.nih.gov/researchandfunding/spotlights-on-nursing-research/womens-health-and-nursing-science>
- Recent Research Highlights
  - Alterations in the placental microbiome were observed in women with spontaneous pre-term birth, with additional differences noted in women who developed chorioamnionitis (an infection of the membranes surrounding the fetus).
  - An inexpensive, internet-based intervention for adolescent mothers was effective at changing attitudes, perceived control, and seeking treatment for depressive symptoms.
  - Researchers identified two distinct and dynamic symptom clusters in women undergoing chemotherapy for breast cancer.
  - Several problem-focused and emotion-focused coping strategies were found to be effective at managing pain and other symptoms among women with a history of ovarian cancer.
  - A study of caregivers of stroke victims revealed that women caregivers experience more difficulty with life tasks and suffer higher rates of depressive symptoms than their male counterparts.
  - A culturally tailored physical activity intervention for Latinas led by laywomen significantly increased aerobic fitness, muscle strength and flexibility, and daily physical activity levels.
  - The majority of female graduate students interviewed reported systemic gender inequities and/or instances of unequal treatment during their PhD training.
  - Researchers discovered 12 genes that were expressed differently in women with fibromyalgia compared to healthy controls, an important step towards the development of better testing and therapeutic advances.
  - Seven bacteria were found to significantly increase the risk of preterm births, with a stronger effect seen in African American women. The researchers also found that higher levels of an antimicrobial produced by the immune system lowered the risk of preterm birth, with a greater effect in African American women.

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**Nereida Correa, MD**

*Chairwoman*

NHMA



# *All of Us* Research Program Fireside Chat Series Session 5: Women & the *All of Us* Research Program

**Ana Maria Lopez, MD, MPH**

*Professor & Vice Chair*

Medical Oncology

Sidney Kimmel Medical College

Jefferson University

*Philadelphia Chapter Leader*

NHMA



# Q and A

# How to contact NHMA & NHHF

- Join NHMA as a member and get involved with the *All of Us* Research Program by going to [nhmamd.org/nih-all-of-us](https://nhmamd.org/nih-all-of-us) or contacting Vito Gearity at [vgearity@nhmamd.org](mailto:vgearity@nhmamd.org).
- Physicians and researchers can apply for the Researcher Workbench by visiting <https://www.researchallofus.org/> and enroll themselves or patients by visiting [joinallofus.org/together](https://joinallofus.org/together).
- NHMA - [www.nhmamd.org](http://www.nhmamd.org)
- NHHF - [www.nhmafoundation.org](http://www.nhmafoundation.org)
- **NHMA 25th Annual Hispanic Health Conference –WDC, March 2022  
#NHMA2022**
- NHHF Giving Campaign tax deductible



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