

Legacy of Better Science, Better Health for Women

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National Institutes of Health

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Women's Congressional Policy Institute



OFFICE OF RESEARCH ON WOMEN'S HEALTH

Advancing the Health of Women Through Science

 /NIHORWH

 @NIH_ORWH

 nih.gov/women

[#ORWHTurns30](https://twitter.com/ORWHTurns30)



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

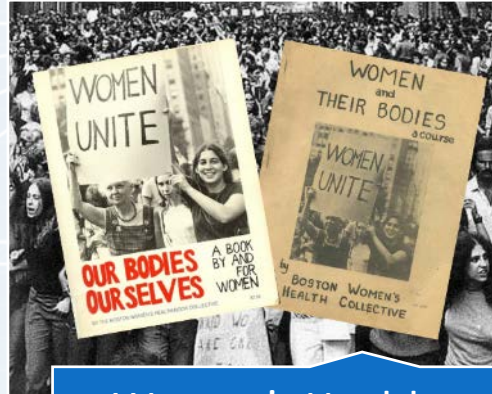
Chapter 1

We Built Women's Health Research Together

MOVEMENTS



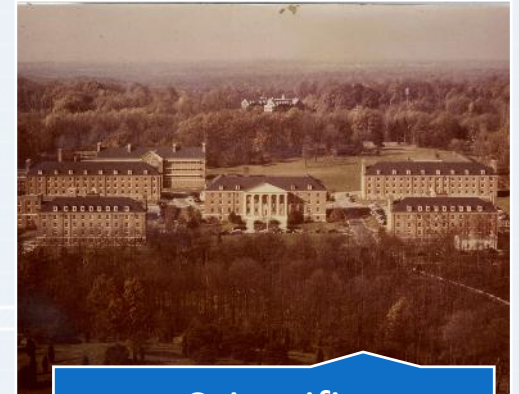
Women's Movement



Women's Health Movement



Congress



Scientific Community

LEADERS



Edward Brandt



Ruth Kirschstein



Bernardine Healy



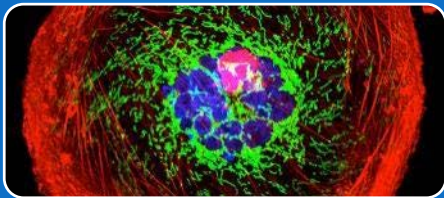
Vivian Pinn

Chapter 2

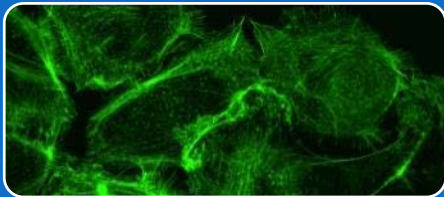
The Past & the Power of Research



Women's Health Initiative



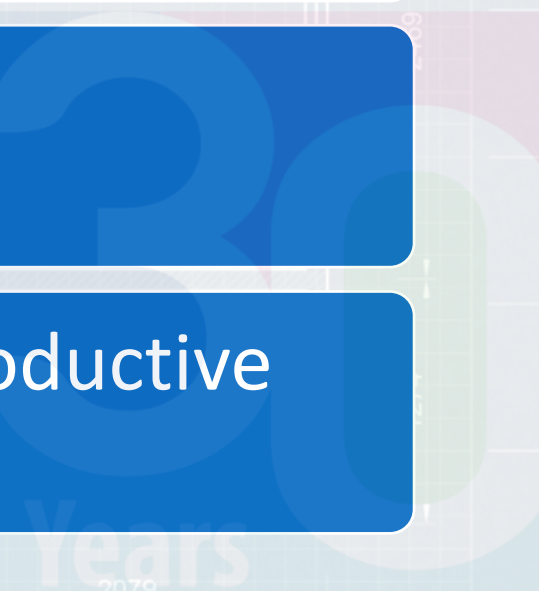
Decline in Breast Cancer Rates



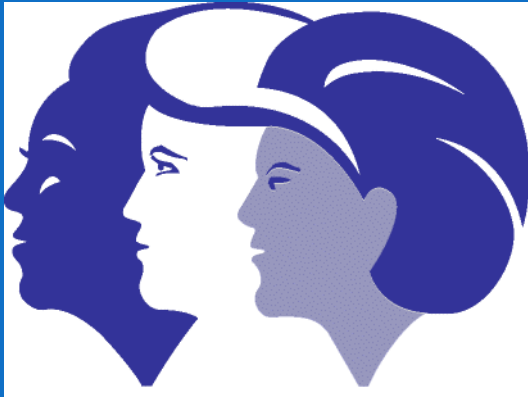
HPV Vaccine



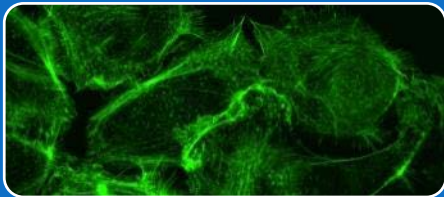
EVATAR™: Modeling the Female Reproductive Tract in 3-D



The Past & the Power of Research



- Funded by NHLBI and launched in 1993
- One of the largest disease prevention and clinical studies ever conducted for women's health
- Ongoing, still contributing knowledge about CVD and aging
- Inspired rapid changes in medical practice, offering benefits 143 times the cost of the original research



HPV Vaccine

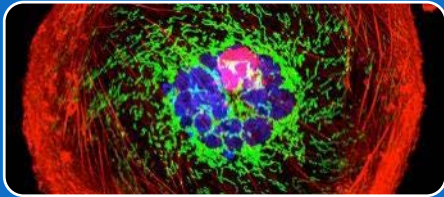


EVATAR™: Modeling the Female Reproductive Tract in 3-D

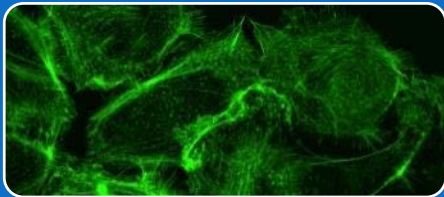
The Past & the Power of Research



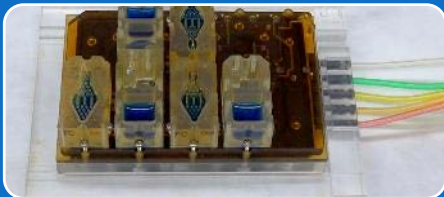
Women's Health Initiative



Decline in Breast Cancer Rates



HPV Vaccine

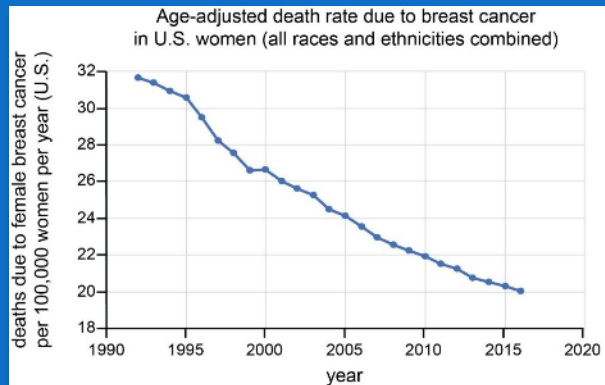


EVATAR™: Modeling the Female Reproductive Tract in 3-D

The Past & the Power of Research



Women's Health Initiative



- Continuous progress on reducing death rates since 1990
- 1994 discovery by NIH-funded researchers of the first gene shown to be responsible for some inherited breast (and ovarian) cancer
- Discoveries in breast cancer genetics have informed screening, genetic testing, risk assessment models, and clinical management decisions
- Evidence informed menopausal hormone therapy implications

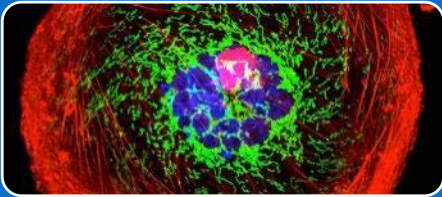


EVATAR™: Modeling the Female Reproductive Tract in 3-D

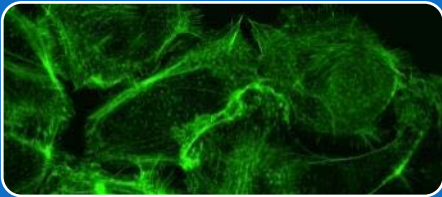
The Past & the Power of Research



Women's Health Initiative



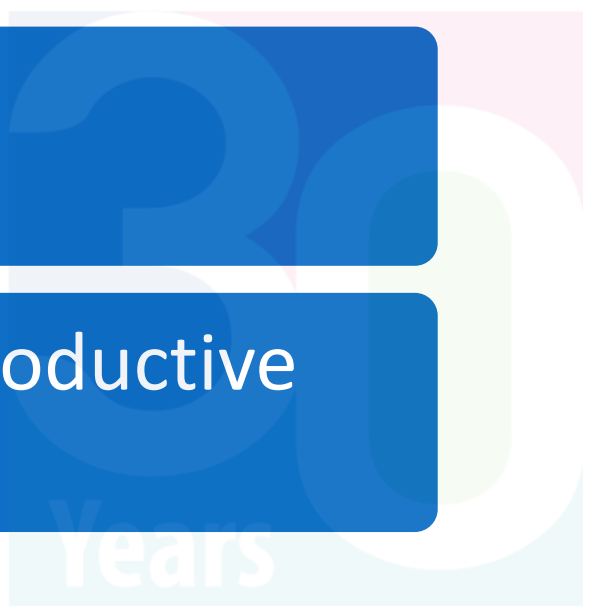
Decline in Breast Cancer Rates



HPV Vaccine



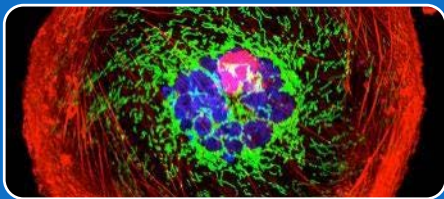
EVATAR™: Modeling the Female Reproductive Tract in 3-D



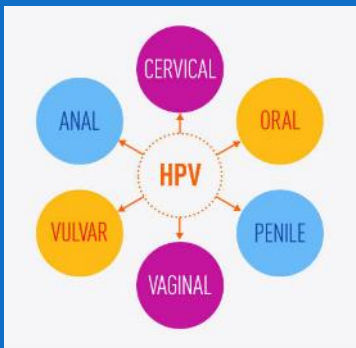
The Past & the Power of Research



Women's Health Initiative



Decline in Breast Cancer Rates

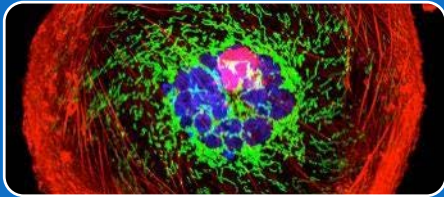


- 70% of cervical cancers are caused by HPV types 16 & 18
- More than 1/3 of HPV-associated cancers are diagnosed in males (e.g., oropharyngeal) – more than half of oropharynx cancers are type 16
- NCI-funded, ORWH-supported clinical trial is testing efficacy of single-dose vaccine against cervical cancer; interim results indicate long-lasting protection

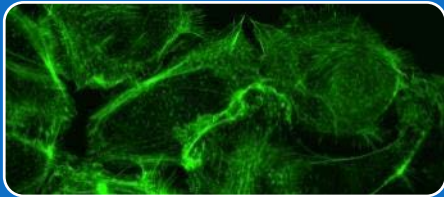
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Women's Health Initiative



Decline in Breast Cancer Rates

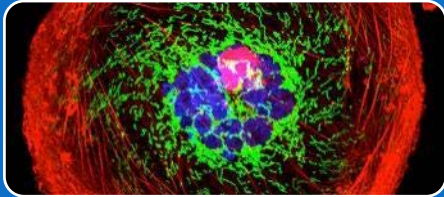


HPV Vaccine

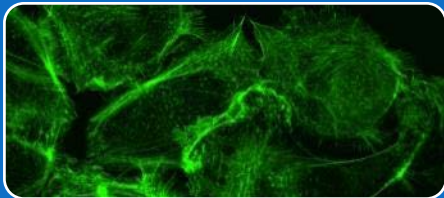


EVATAR™: Modeling the Female Reproductive Tract in 3-D

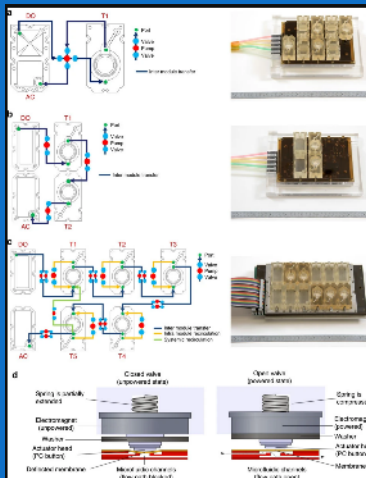
The Past & the Power of Research



Decline in Breast Cancer Rates



HPV Vaccine



- NIH–DOD–FDA collaboration to address high rates of failure of candidate medications due to toxicity or lack of efficacy
- EVATAR™ is a miniaturized 3-D model of the female reproductive tract & liver
 - Could pave way for improved testing for infertility, endometriosis, uterine fibroids, cancer, etc.
 - Current use includes modeling PCOS and testing candidate meds

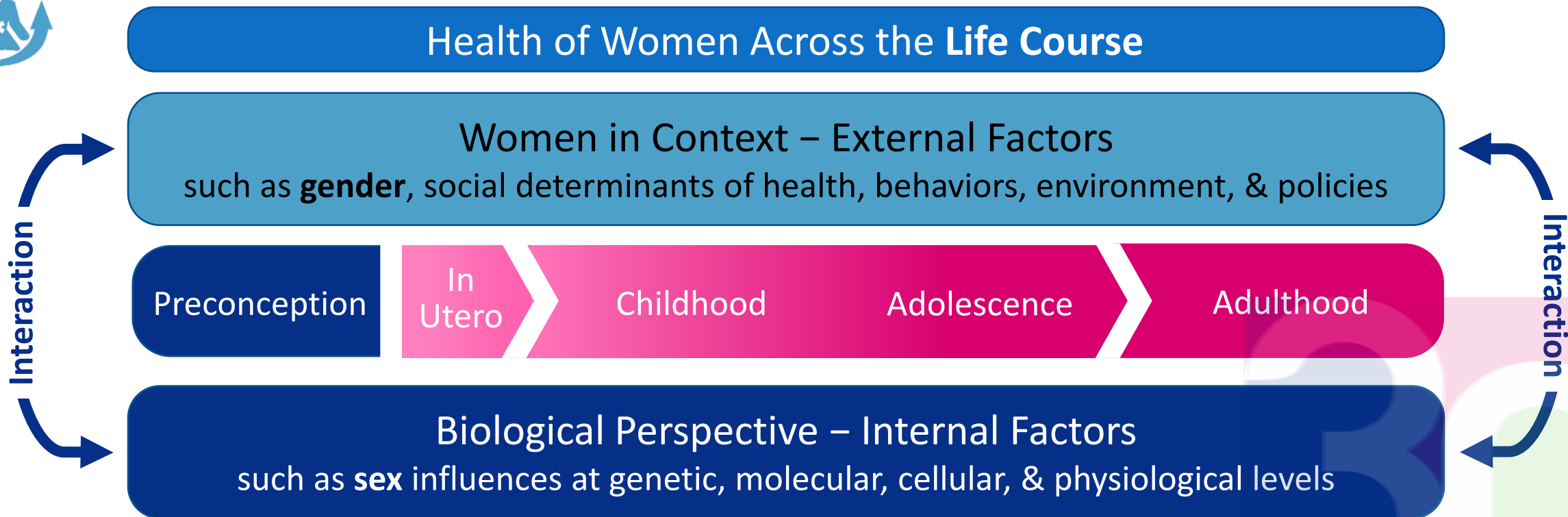
Inclusion – it's in our DNA



- 42 USC 289a-2 and the 1993 NIH Revitalization Act require researchers to include women and men
- Seeks distribution of participants by sex/gender, race, ethnicity, and age to reflect populations needed to meet study goals
- In response to the **21st Century Cures Act**, NIH issued the **Inclusion Across the Lifespan** policy
 - Requires inclusion of **all ages** – unless there's scientific or ethical rationale for exclusion
- Requires NIH-defined applicable phase III clinical trials to report results **disaggregated by sex/gender, race, and ethnicity** into ClinicalTrials.gov

INCLUSION >>> **MULTIDIMENSIONAL & LIFE COURSE PERSPECTIVE**

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



NIH to balance sex in cell and animal studies

Janine A. Clayton and Francis S. Collins unveil policies to ensure that preclinical research funded by the US National Institutes of Health considers females and males.

More than two decades ago, the US National Institutes of Health (NIH) established the Office of Research on Women's Health (ORWH). At that time, the Congressional Caucus for Women's Issues, women's health advocacy groups and NIH scientists and leaders agreed that excluding women from clinical research was bad for women and bad for science. In 1993, the NIH Revitalization Act required the inclusion of women in NIH-funded clinical research.

Today, just over half of NIH-funded clinical research participants are women. We know much more about the role of sex and gender in medicine, such as that testosterone has different preventive effects in women and men, and that drugs such as zolpidem, used to treat insomnia, require different dosing in women and men.

There has not been a corresponding revolution in experimental design and analysis in

cell-to-cell. Publications often continue to neglect sex-based considerations and analyses in preclinical studies³³. Reviewers, for the most part, are not attuned to this failure. The over-reliance on male animals and cells in preclinical research obscures key sex differences that could guide clinical studies. And it might be harmful: women experience higher rates of adverse drug reactions than men³⁴. For the most part, inadequate inclusion of female cells and animals in experiments and inadequate analysis of data by sex may well contribute to the troubling rise of reproductive health in preclinical biomedical research, which the NIH is now actively working to address³⁴.

The NIH plans to address the issue of sex and gender inclusion across biomedical research multi-dimensionally — through programme oversight, [NIH's new](#) [reproducibility](#) review and policy, as well as through [NIH's](#)

stakeholders including publishers. This more is essential, potentially very powerful and need not be difficult or costly.

BETTER WITH BOTH
Certain rigorous studies evaluating the effects of sex differences have been effective in bridging the divide between animal and human work. One example concerns multiple sclerosis (MS). Women are more susceptible to MS than men, but develop less severe forms of the disease. The most widely accepted MS animal model — rodent experimental autoimmune encephalomyelitis (EAE) — has revealed that sex differences in MS are related to both reproductive and non-reproductive factors. Findings that oestrogen therapy provided benefits in women EAE supported use of an oestrogenic ligand as a candidate neuroprotective agent for MS that is now being studied.

Moreover, differences between the sexes in



Chapter 3

Putting Science to Work for the Health of Women



SABV

More
Complete
Knowledge
Base

Est. Jan. 25, 2016

NIH's policy to consider sex as a biological variable

Informs and improves **design** of clinical research and human trials

Informs development of sex- and gender-appropriate medical care

Enables **individualized** care for women and men

Fosters **system-based understanding** of influences of sex and gender on health & disease



ORWH advances science through focused NIH-wide research collaborations

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

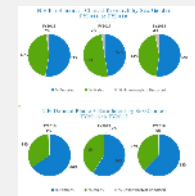


Sex & Gender

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

26 ICOs

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's robust response to maternal health disparities



IMPROVE

• Trans-NIH Maternal Mortality Task Force

- *NICHD-OD-ORWH*
 - CVD
- Infection/immunity
- Mental health



IDEA States

- Institutional Development Award States program
 - Administrative supplements to expand research and research capability



R01 | NIHMD

- Addressing Racial Disparities in Maternal Mortality & Morbidity
- Intersection of domains and levels of influence



U3

- FY2017–20 | >50 awards
- Insulin resistance, neonatal adiposity
- Sickle cell disease
- Fibroid growth

ORWH is producing E-Learning modules on sex and gender for the biomedical and research community

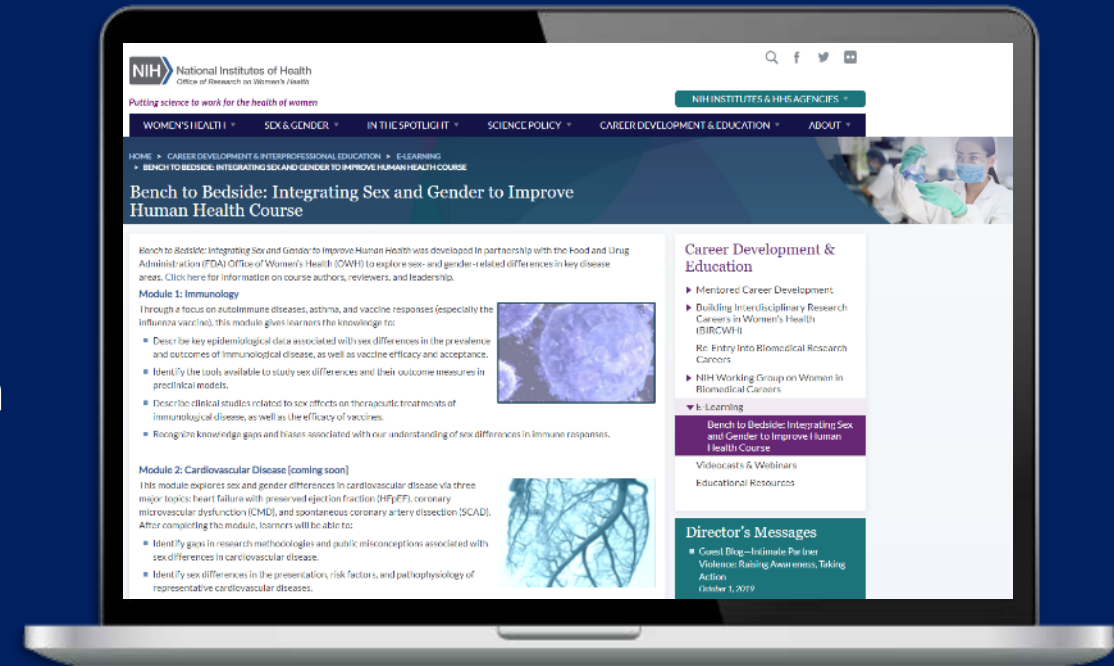
SABV Primer

Introduction to the scientific basis of sex- and gender-related differences

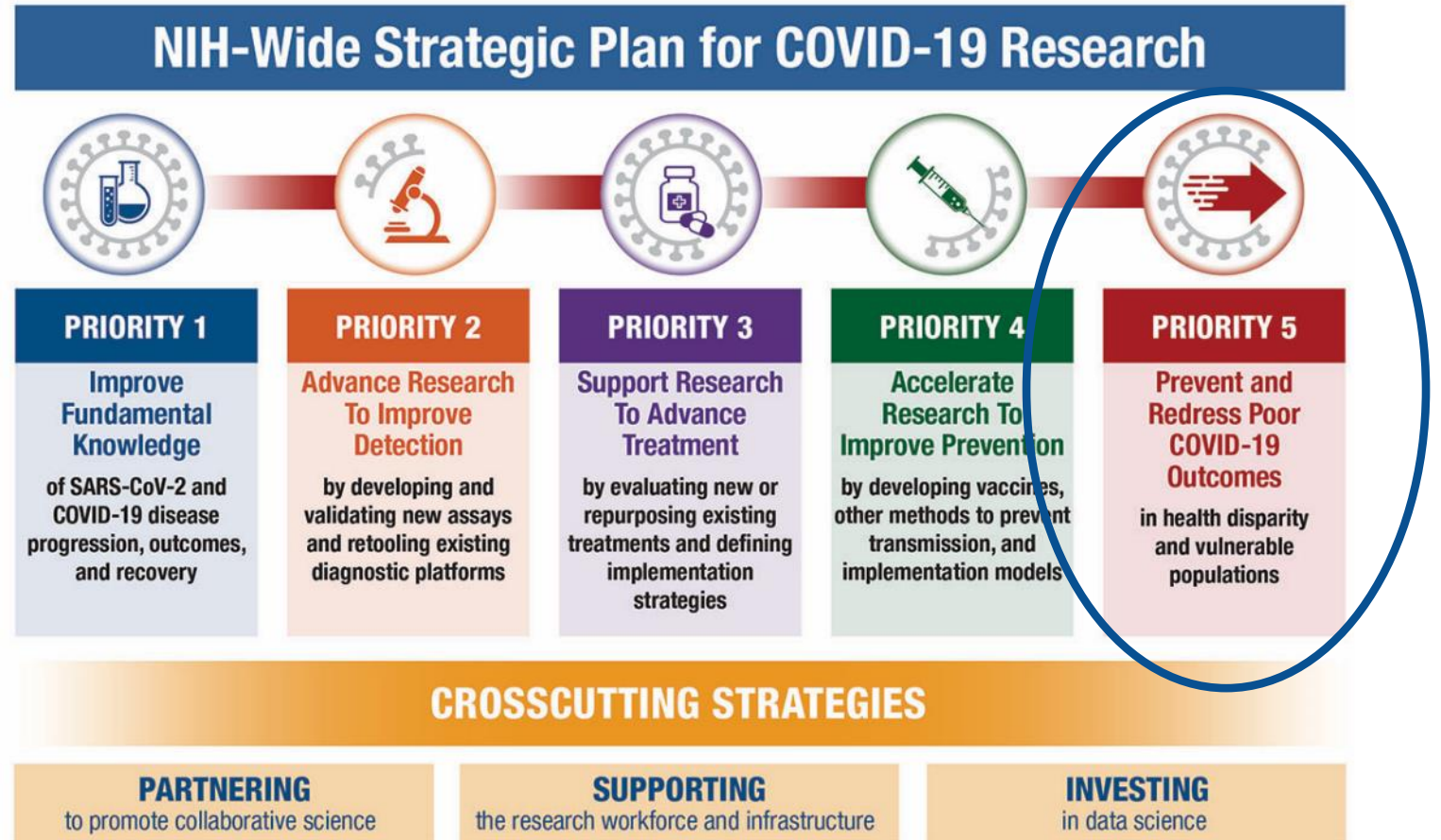
Bench to Bedside

Integrating sex & gender to improve human health

- 1 – Immunology
- 2 – Cardiovascular Disease
- 3 – Pulmonary Disease
- 4 – Neurology



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



Chapter 4

Advancing careers and diversity for better science

MISSION

“develop opportunities and support for recruitment, retention, re-entry, and advancement of women in biomedical careers”

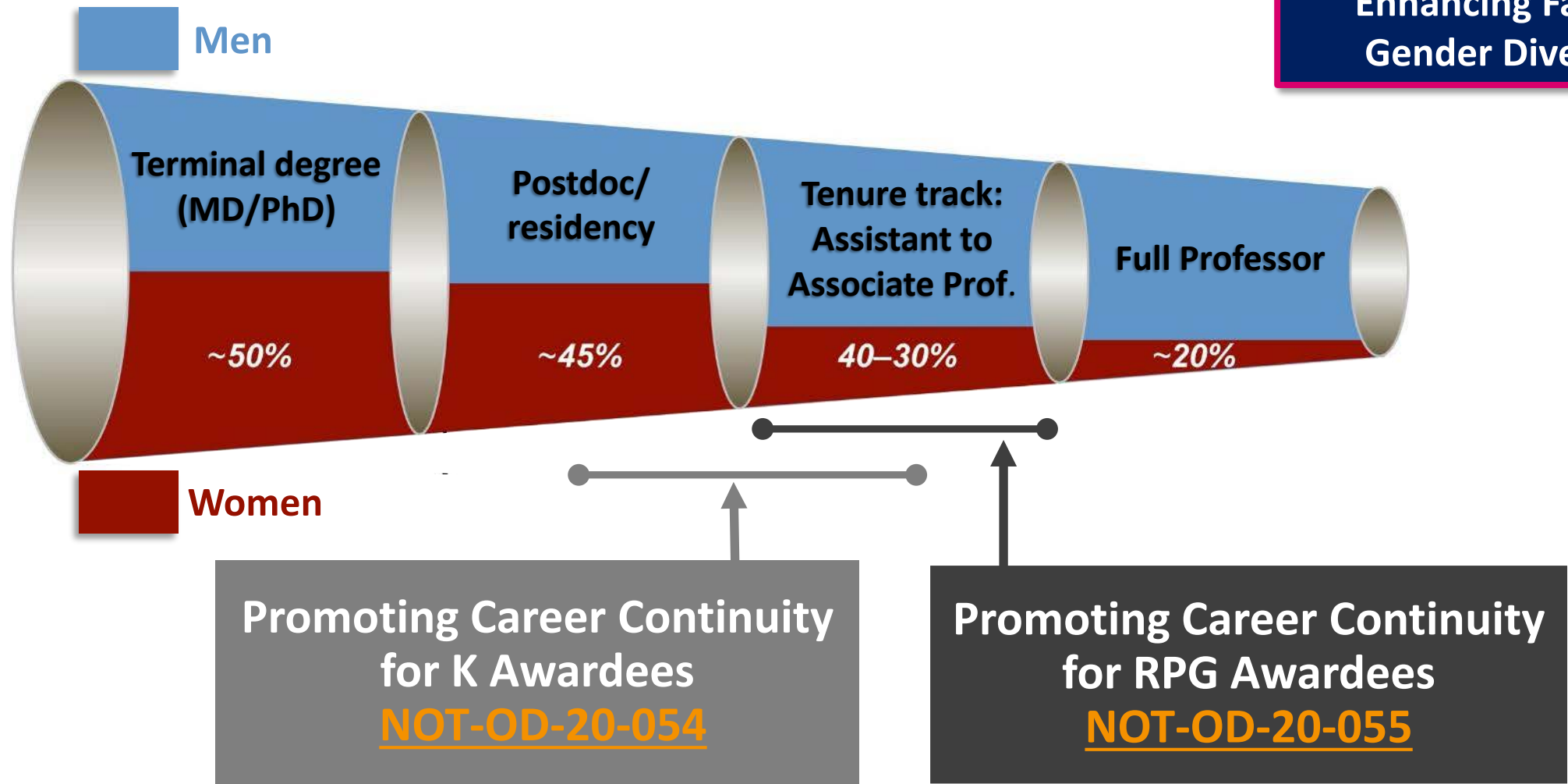
PIVOTAL EVENTS

- **BIRCWH’s** 20 years of research and careers development
- NASEM *Beyond Bias and Barriers* (2006)
- WG 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*



New programs support women during critical life events

**NIH Challenge Prize for
Enhancing Faculty
Gender Diversity**





Impact of COVID-19 on Biomedical Careers

Women are >70% of health care workers

Eroding progress that's been made toward gender equity

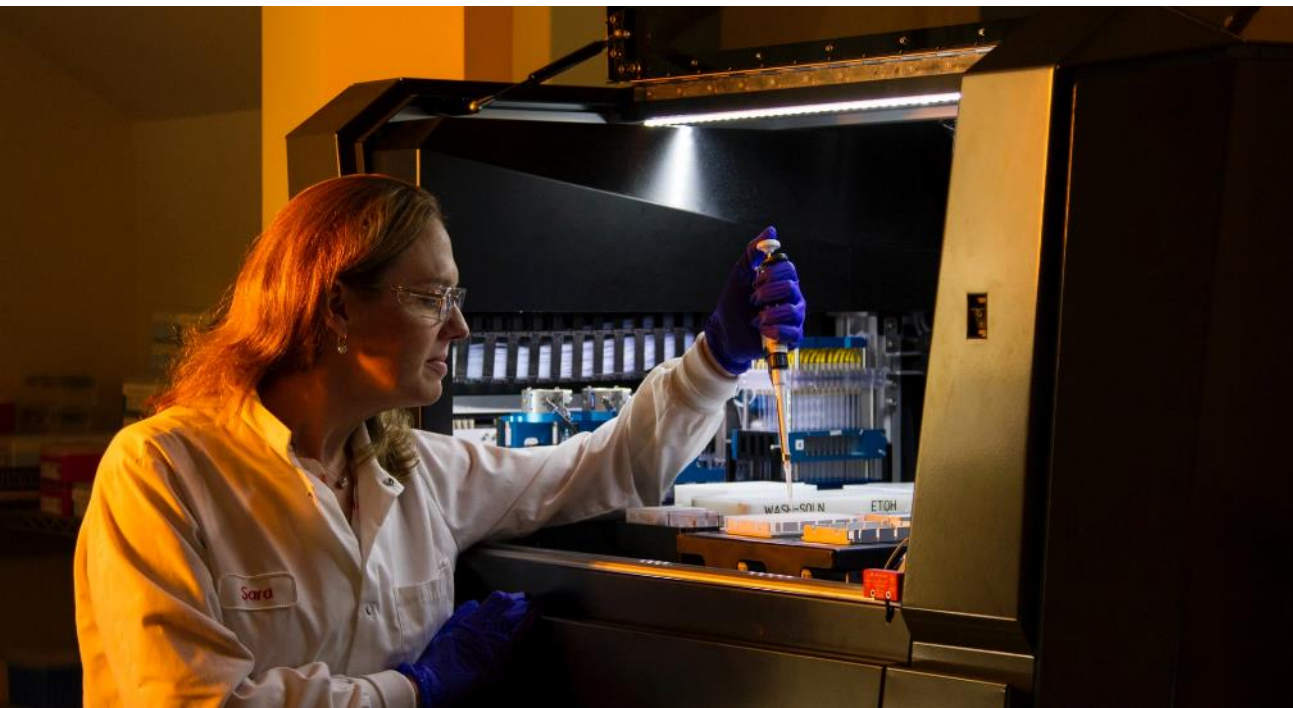
Exacerbating challenges many women scientists already face – especially among principal caregivers

Navigating work from home, homeschooling and caregiving

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%

Even more devastating impact on early-career investigators and women of color



WOMEN'S HEALTH *In Focus* AT NIH



30TH ANNIVERSARY ISSUES

bit.ly/ORWHInFocus

30 Years
OFFICE OF RESEARCH ON WOMEN'S HEALTH
Advancing the Health of Women Through Science

The Pulse

ORWH's monthly email | bit.ly/ORWHpulse

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Thank you!