# 45<sup>th</sup> Meeting of the NIH Advisory Committee on Research on Women's Health

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

April 18, 2018



### Reminder: Special Government Employees

- Subject to the same ethics rules that apply to government employees
- Rules located in "Standards of Ethical Conduct for Employees of the Executive Branch"
- ACRWH members required to disclose any real, potential, or apparent conflict(s) of interest
- ACRWH members may not engage in any lobbying activities while attending committee meetings of ACRWH sponsored events

## Members Retiring from the Advisory Committee Thank you for your service!



Jill B. Becker, PhD
Biopsychology Chair
and Patricia Y. Gurin
Collegiate Professor of
Psychology, Dept. of
Psychology, University
of Michigan



Carmen R. Green, MD
Assoc. Vice President,
Assoc. Dean for Health
Equity & Inclusion, and
Prof. of Anesthesiology,
Obstetrics & Gynecology,
and Health Management &
Policy, Univ. of Michigan
School of Public Health



Mary H. Palmer, PhD
Helen W. & Thomas L.
Umphlet Distinguished
Professor in Aging and
School of Nursing Interim
Co-Director, Institute on
Aging, University of North
Carolina, Chapel Hill



Connie M. Weaver, PhD
Head of the Department of
Nutrition Science and
Distinguished Professor,
Purdue University

### Introducing Our New Advisory Committee Members Welcome aboard!



Wendy Brewster, MD, PhD
Professor and Director,
Center for Women's Health
Research, University of
North Carolina at Chapel
Hill



Kimberly D. Gregory, MD
Associate Professor and
Vice Chair, Women's
Healthcare Quality and
Performance
Improvement, CedarsSinai Medical Center



Rachel Jones, PhD, RN, FAAN Associate Professor, School of Nursing, Bouvé College of Health Sciences, Northeastern University



Marcia Stefanick, PhD
Professor (Research) of
Medicine (Stanford
Prevention Research
Center) and of Obstetrics
and Gynecology, Stanford
University



Susan F. Wood, PhD
Associate Professor and
Executive Director,
Jacobs Institute of
Women's Health,
George Washington U.

# 45<sup>th</sup> Meeting of the NIH Advisory Committee on Research on Women's Health

#### Janine Austin Clayton, MD

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

**Director's Report** 

April 18, 2018



### New Acting NIH IC Director



Jill Heemskerk, PhD

Acting Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB)



National Institute of Biomedical Imaging and Bioengineering

### NIH Office of Research on Women's Health (ORWH) History



Ruth Kirschtein, MD (1926-2009)



**Bernadine Healy, MD** (1944-2011)

Vivian W. Pinn, MD

Sen. Barbara Mikulski D-MD, in office 1977–2017



Janine Clayton, MD



D-NY, in office 1987–2018





### New Team Member



Samia Noursi, PhD
New ORWH Associate Director

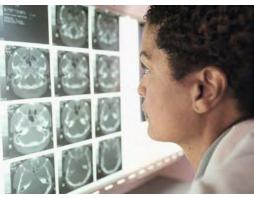


### Outline

- Collaborations with ICOs
- Research Programs
- SABV Update
- Adjusting Our Course
- Women in Biomedical Careers
- Other ORWH Activities









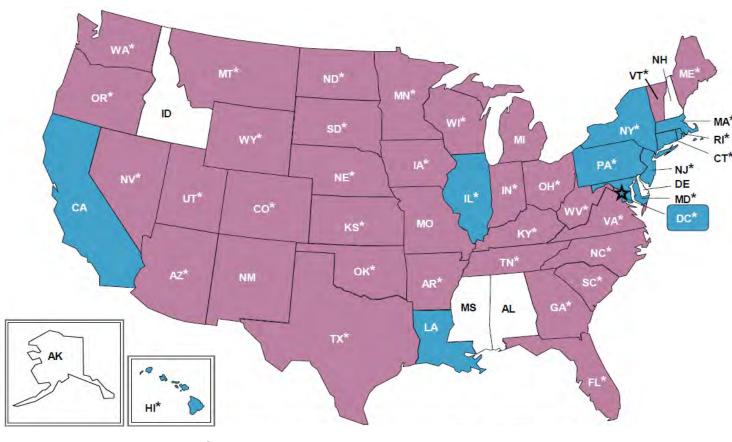
# FY18 omnibus bill provides at least \$500M for NIH-funded research on opioid addiction

- Allows NIH to increase its funding for research on opioid misuse/addiction to \$1.1 Billion in FY18
- On April 4, 2018, Francis Collins, MD, PhD, launched the HEAL Initiative:
  - □ An aggressive, trans-agency effort to speed scientific solutions to stem the opioid crisis

**HEAL: Helping to End Addiction Long-term Therapies** 

### The opioid crisis is a women's health issue

- From 2005 to 2015, opioid-related inpatient hospital stays increased 55% in men and 75% in women.
- In 2014, women had higher rates of opioid-related inpatient hospital stays in most states.
- Between 1999 and 2015, death from Rx opioid overdoses increased 471% in women and 218% in men.



Higher rate of opioid-related inpatient hospital stays in 2014

men

women

no data

Weiss et al. 2017. Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014. HCUP Statistical Brief #224. Rockville, MD: Agency for Healthcare Research & Quality.





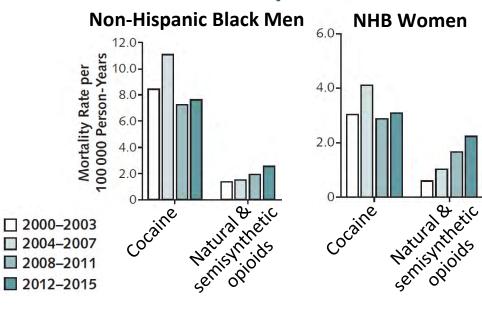
### Rising opioid-related mortality rates in White women & men surpass cocaine-related mortality in non-Hispanic Blacks

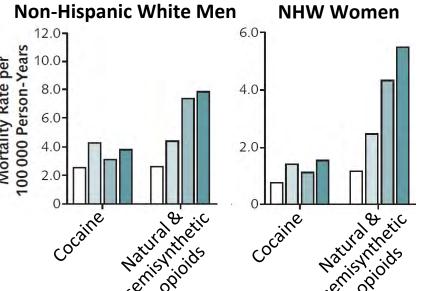
- 2 FOAs posted on April 10, 2018
- "Addressing Challenges of the Opioid Epidemic in Minority Health & Health Disparities Research in the U.S."

#### **ORWH Interests**

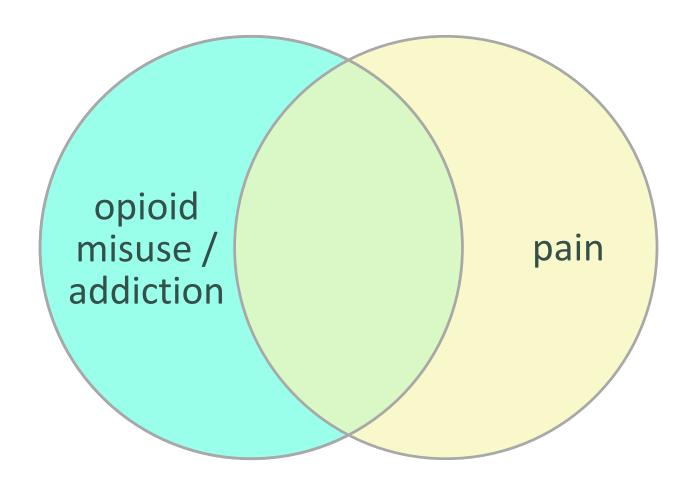
- "Gender-responsive approaches to account for differences associated with OUD"
- "Evidence-based practices (MAT, CBT, etc.) to address gender-specific concerns"
- "Gender-specific approaches to address mental health, reproductive and sexual health, and physical health of women with OUD"

Shiels MS, Freedman ND, Thomas D, Berrington de Gonzalez A. 2018. Trends in U.S. drug overdose deaths in non-Hispanic Black, Hispanic, and non-Hispanic White persons, 2000-2015. *Ann. Intern. Med.* **168**: 453-455.



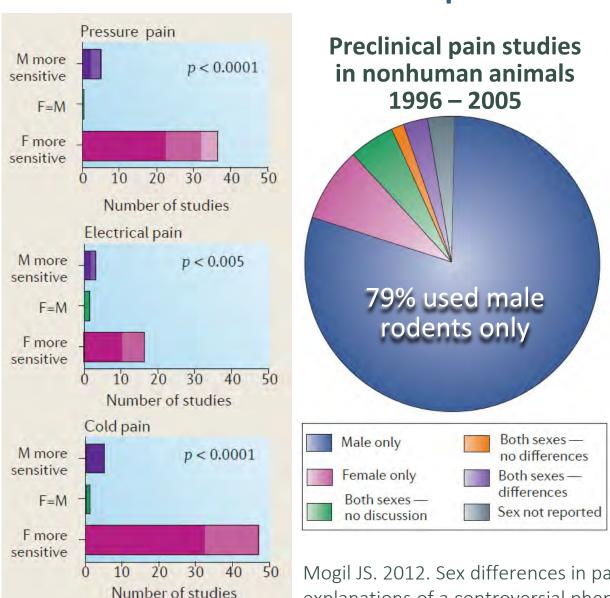


### Opioid abuse and the science of pain are linked





# Females experience greater pain sensitivity than males across all pain modalities



Mogil JS. 2012. Sex differences in pain and pain inhibition: multiple explanations of a controversial phenomenon. *Nat. Rev. Neurosci.* **13**: 859-866.

# NIH Pain Consortium enhances collaboration among NIH Institutes, Centers & Offices that conduct research on pain

Pain Consortium Members:

- NINDS
- NICHD
- NIMHD
- OBSSR

NCCIH

- NIAMS
- NIBIB

• OTT

NINR

• NIMH

- NIDCDNCATS
- ORDR

• ORWH

- NIDCR
- NEI
- NIGMS
- NHLBI

• NCI

NIDA

- NIDDK
- FIC

NIA

- NIAAA
- CC
- Upcoming Pain Consortium Symposium (May 31 June 1, 2018)
   From Science to Society: At the Intersection of Pain Management and the Opioid Crisis
  - Keynote Speaker: Judith Paice, PhD, RN, Northwestern University
  - Info: https://painconsortium.nih.gov/Meetings\_Events/Annual\_Symposium



Judith Paice, PhD, RN

# NIH Pain Consortium enhances collaboration among NIH Institutes, Centers & Offices that conduct research on pain

Centers of Excellence in Pain Education (CoEPEs)

#### **Sponsors**

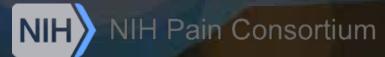
- NIDA
- NICHD
- NCCIH
- NIDCR
- NINR
- NINDS
- OBSSR
- ORWH

#### Recent Awardees

- Johns Hopkins University
- University of Pennsylvania
- University of Pittsburgh
- University of Rochester
- U. Alabama, Birmingham
- Southern Illinois U., Edwardsville
- University of Washington
- University of Connecticut
- U.C. San Francisco
- Harvard University
- University of Iowa







# Interest in the opioid crisis also involves our Federal Partners

Research Impact and Outcomes Framework

Your Research...Your Program...Your Impact







Office of Women's Health

Center for Drug
Evaluation and Research

Center for Tobacco Products



### 7,500+ participants have enrolled for the largest long-term study of brain development and child health in the U.S.

#### **ABCD Study**



Adolescent Brain Cognitive Development

Teen Brains. Today's Science. Brighter Future.

#### 21 Research Sites



#### **Federal Collaborators**

National In



"This comprehensive dataset, which will be disaggregated by sex, racial/ethnic group, and socioeconomic status, will allow researchers to address numerous questions related to adolescent brain development" ... [including] ... "What brain pathways are associated with the onset and progression of mental health disorders and do these pathways differ by sex?"

They rolling thing thing

https://abcdstudy.org/index.html

# ORWH has signed onto recent BRAIN Initiative FOAs to emphasize sex/gender-based reporting



Aims to revolutionize our understanding of accelerating development & application or

#### **FOA Language**

"Applications must ... comply with NIH policy on reporting disaggregated sex-based data and other consideration of sex as a biological variable ..."

"Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?"

- Recent FOAs:
  - RFA-NS-18-008: Exploratory Team-Research BRAIN Circuit Programs— eTeamBCP (U01)
  - RFA-NS-18-009: Targeted BRAIN Circuits Projects TargetedBCP (R01)
  - RFA-NS-18-010: Exploratory Research Opportunities Using Invasive Neural Recording and Stimulating Technologies in the Human Brain (U01)
  - RFA-NS-18-014: Targeted BRAIN Circuits Planning Projects—TargetedBCPP (R34)
- For more info on the BRAIN Initiative® visit www.braininitiative.nih.gov

- Participating ICOs
  - NINDS
- NIDCD
- NEI
- NIDA
- NIA
- NIMH
- NIAAA
- NCCIH
- NIBIB
- OBSSR
- NICHD
- ORWH

### Teenagers exhibit notable sex/gender differences in concussion

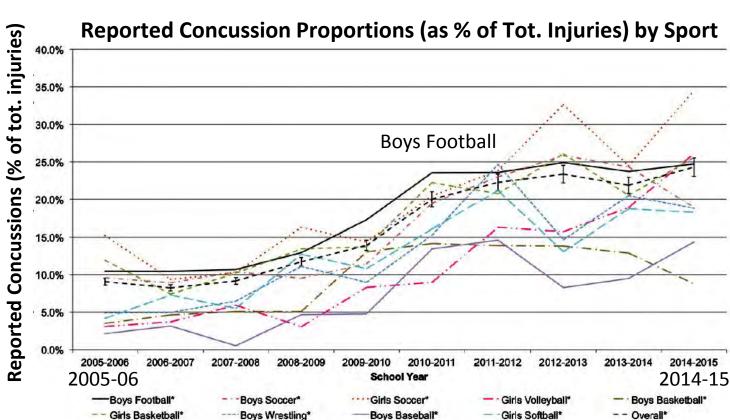
- Incidence of sports-related concussions in high schoolers is increasing.
- Girls soccer shows highest overall proportion of concussions for boys & girls, among all sports.
- Baseline & early postconcussion symptoms are higher in girls.
- Longer-term recovery trends are similar between boys & girls.

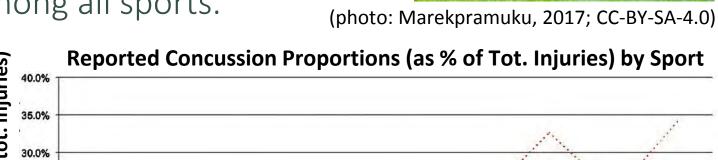


Ono et al. 2016. Am. J. Sports Med. 44: 748-752.

Schallmo et al. 2017. J. Bone Joint Surg. Am. 99: 1314-1320.

Brooks et al. 2018. Am. J. Sports Med. 46: 961-968.





### Understanding TBI in Women Workshop

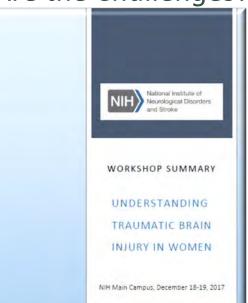
Dec. 18-19, 2017, Natcher Conference Center, NIH Main Campus



 Sponsored by NINDS, in collaboration with NCMRR/NICHD, ORWH, CNRM, and DVBIC

• **Keynote:** *Identifying Sex Differences in Research: What Are the Challenges?* 

- Sex Diffs. in TBI across the Li
- ☐ TBI as a Consequence of Inti
- Lost in Translation: Sex Diffs. Research
- ☐ Sex Diffs. following Sports-Re
- ☐ Sex Diffs. in TBI among Servi
- ☐ Sex Diffs. in Dx, Prognosis &
- ☐ Prioritization of Research Ne



Report available soon



Margaret McCarthy, PhD Chair, Dept. of Pharmacology, U. MD School of Medicine

speakers21 women11 men

### NHLBI, ORWH & NCATS (ORDR) collaboration inspires webinar on sex & gender differences in asthma, COPD & ILD



Female

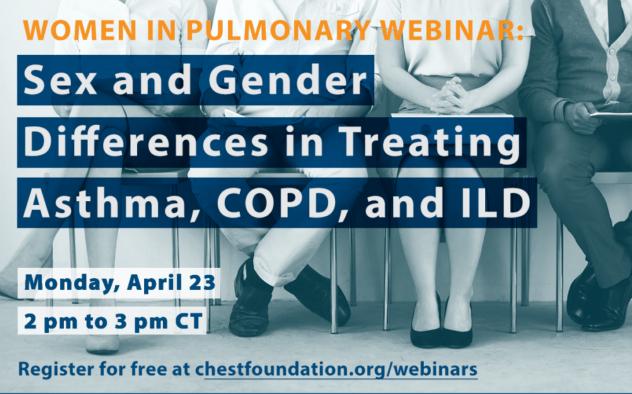
Increased Una Mechanisms I Sep.



Cedai Sep. 1 Sex an in Pre-

Resea

Debo



**PRESENTERS:** Dr. Sonye Danoff | Dr. Dawn Demeo | Dr. Joe Zein

**MODERATOR:** Dr. Ghada Bourjeily

**lational Center** br Advancing ranslational Sciences ffice of Rare Diseases Research

isease:

& Behavioral Lung Disease MD

gato, MD, PhD, FACP Gender-Specific Med.

Address:

Sex Differences in ove Health Care and









### Outline

- Collaborations with ICOs
- Research Programs
- SABV Update
- Adjusting Our Course
- Women in Biomedical Careers
- Other ORWH Activities

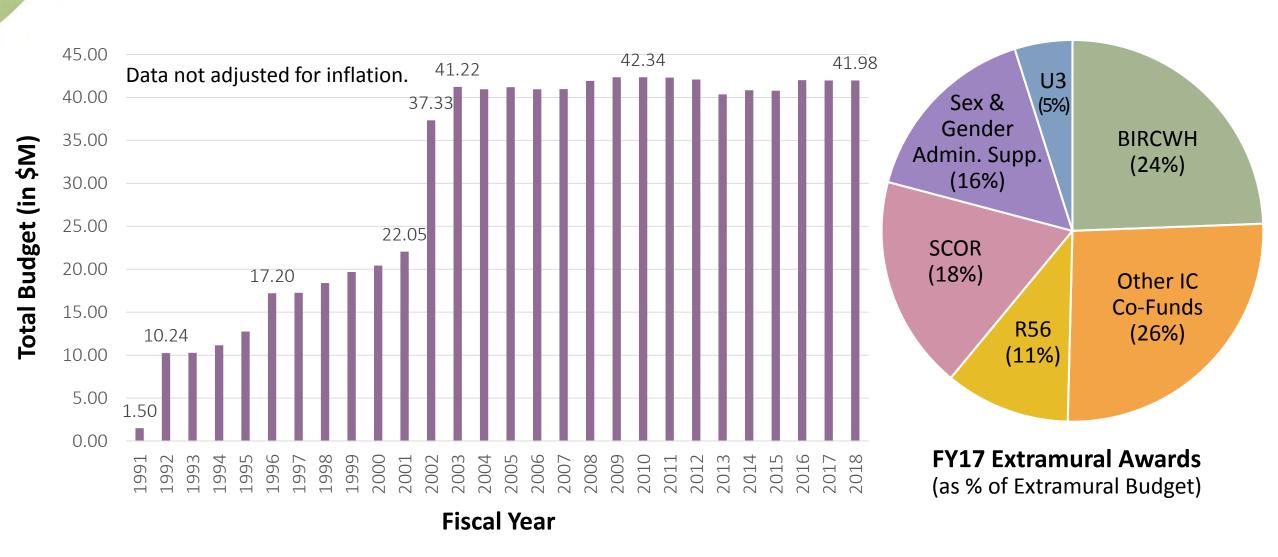




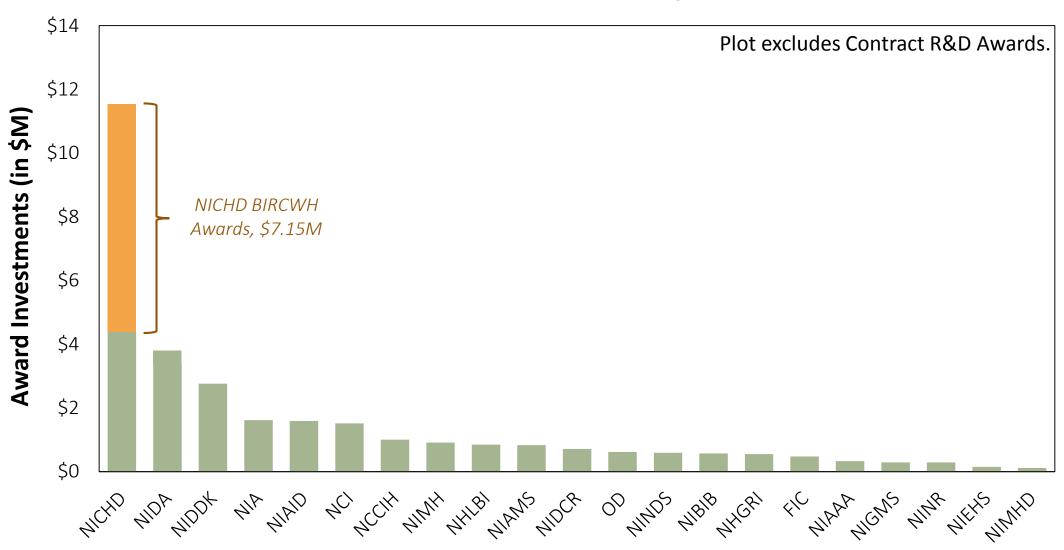




# ORWH Funding History & FY17 Extramural Award Profile

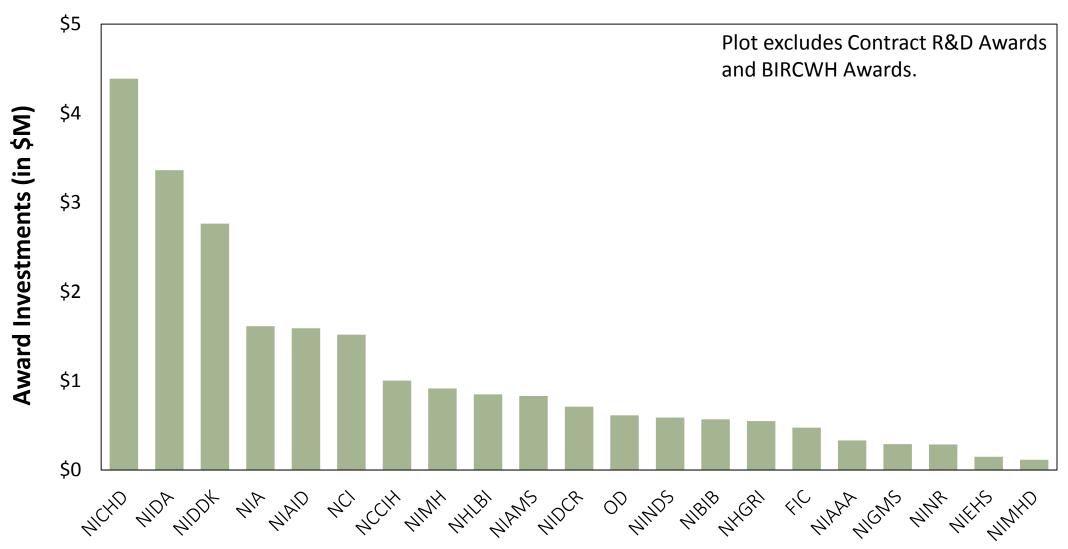


# ORWH FY17 Extramural Award Investments by ICO



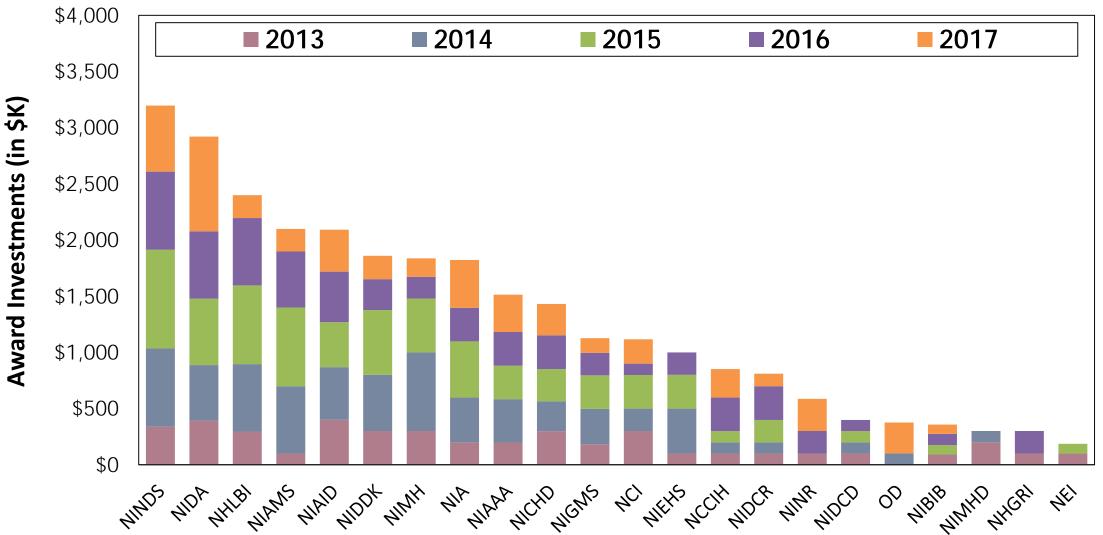
**NIH Institute, Center, or Office** 

# ORWH FY17 Extramural Award Investments by ICO



NIH Institute, Center, or Office

### Sex & Gender Administrative Supplements: Investments by ICO & FY



NIH Institute, Center, or Office

# ORWH FY17 Extramural Award Investments by Program

Program	Number of ICs	List of Collaborating ICs	ORWH Contribution
SCOR	6	NIDA; NICHD; NIDDK; NIA; NIMH; NIAMS	\$5,635,967
Sex/Gender Admin. Supp.	17	List provided on previous slide.	\$4,972,232
R56	5	NCI; NICHD; NIDA; NHLBI; NIDCR	\$3,298,936
U3 Admin. Supp.	8	NICHD; NIA; NIAMS; NIDA; NIAID; NIMHD; NIGMS; NHLBI	\$1,521,821
Other IC Co-funds	16	NIDDK; NICHD; NIAID; NCCIH; NHGRI; NIBIB; FIC; NIA; OD; NIDCR; NIDA; NHLBI; NIMH; NIEHS; NCI; NIGMS	\$8,082,136



# NIH's only center grant on sex differences research gets enhanced

- FY12–FY17: 11 SCOR Awards across 6 ICs
- FY18: Specialized Ctrs. of Research Excellence (SCORE) on Sex Diffs.
- New: P50 → U54
  - □ Career Enhancement Core (CEC) now required to meet career enhancement needs of translational science in study of sex diffs.
  - Each SCORE will serve as a vital hub for education & dissemination of sex-based research methods & best practices
  - ☐ Coop. agreement between ORWH & ICs to provide leadership in the dev't. of standards & policies for sex diffs. research
- FY18 IC Participation: NIDDK, NIDA, NIEHS, NIMH, NIAAA, NIA
- New FOA: RFA-OD-18-004 (Applications due April 23, 2018)



Helen I. Stoever Professor of

Helen L. Stoever Professor of Molecular Microbiology, Washington University in St. Louis School of Medicine

Later Today: Urinary Tract
Infection: Complexity
Results from Diversity at
the Bacterial-Host
Interface

# Understudied, Underrepresented, and Underreported Populations of Women

- 1 year of supplemental funding
- FY17
  - ☐ Received 27 applications from 11 ICs
  - \$1.7 M funded for a total of 15 U3 applications
- FY18
  - ☐ 15 ICs signed on
  - ☐ Awards will be made for up to \$200K total costs





(Images: PublicDomainPictures.net & Pixabay, CCO Creative Commons)

### Outline

- Collaborations with ICOs
- Research Programs
- SABV Update
- Adjusting Our Course
- Women in Biomedical Careers
- Other ORWH Activities











### SABV Policy Implementation Roadmap

Clayton & Collins, 2014. NIH to balance sex in cell and animal studies. Nature 509: 282-283.





Rigor & Reproducibility mailbox

NOT-OD-15-103: Rigor NOT-OD-15-102: "SABV"

Trans-NIH SABV Working Group

21st Century Cures Act

STAKE-

HOLDER

ON RAMP

**SABV RFI** 

FASEB

Preclinical Methods Workshop



NIH SABV Workshop

SABV goes into effect Jan. 25, 2016

SABV Roadshows at ICOs

**NIH Governance Committees** 



RPC, EAWG

EPMC, PLC



Resource Development

FASEBJOURN



New FAQs

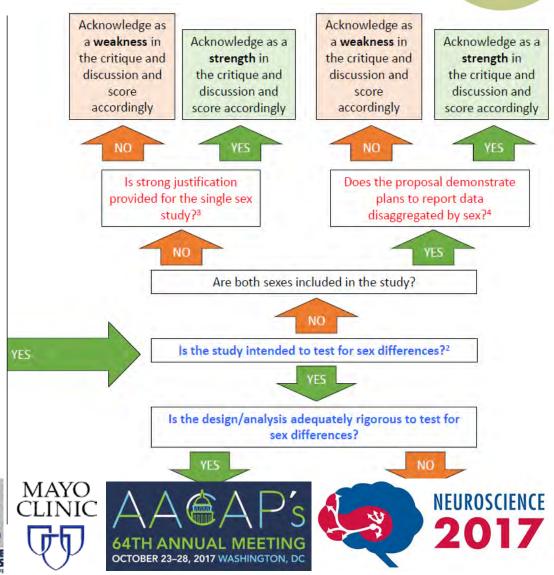
More to come

# ORWH leads the development of SABV resources & activities

- ORWH develops SABV application tools:
  - SABV Decision Tree (for reviewers)
    https://bit.ly/2EGQIRN
  - ☐ SABV Checklist (for researchers)
- ORWH advances SABV dissemination:
  - ☐ Re-launched the Women's Health Research Seminar Series
  - Founded the NIH Sex & Gender in Health & Disease SIG
  - ☐ Gave several scientific presentations

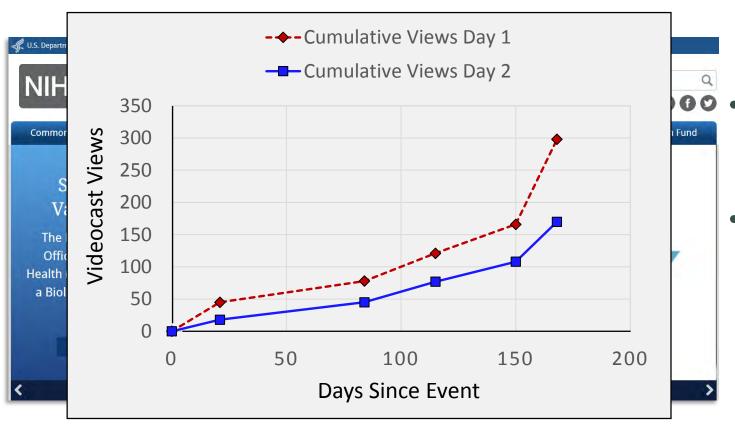






ORWH partners with Common Fund to host the first SABV Workshop

October 26 - 27, 2017



• Keynote speaker—Dr. Virginia Miller: Sex-Specific Risk for Cardiovascular Dysfunction and Cognitive Decline

#### Sessions:

- ☐ Poster Session
- Sex Diffs. in Brain Function & Behavior
- How Sex Impacts Our Interactions with External Influences
- ☐ Sex Differences in Animal Models
- ☐ Sex Differences in Gene Expression
- Panel Discussion on Applying SABV

Videocasts available at:

- □ Day 1: https://videocast.nih.gov/summary.asp?Live=26050&bhcp=1
- ☐ Day 2: https://videocast.nih.gov/summary.asp?Live=26054&bhcp=1





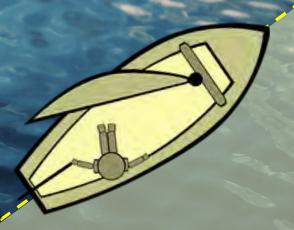
MAYO CLINIC

# Adjusting Our Course into the Future



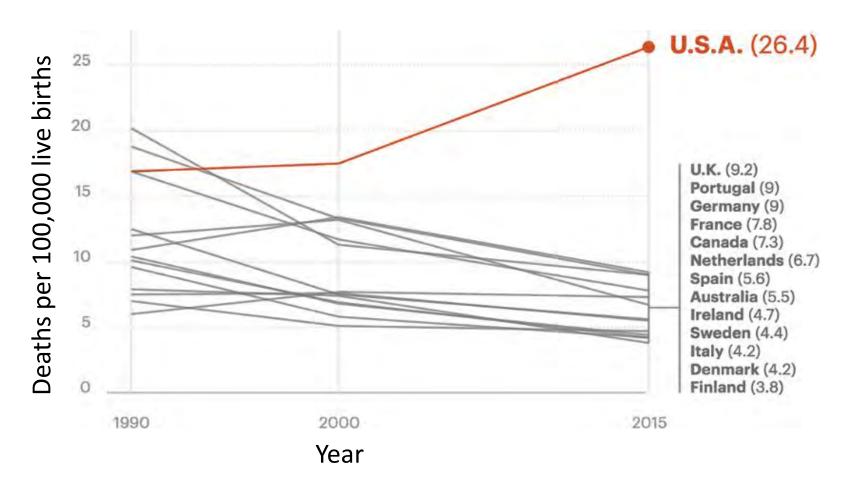


Legislative & 21<sup>st</sup> Century Cures Act Update



- 21st Century Cures Act
- Advances in science & tech.
- Evolving public health needs

# Maternal mortality is rising in the U.S. as it declines in our peer countries



GBD 2015 Maternal Mortality Collaborators. 2016. Global, regional, and national levels of maternal mortality, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *The Lancet* **388** (10053): 1775-1812.



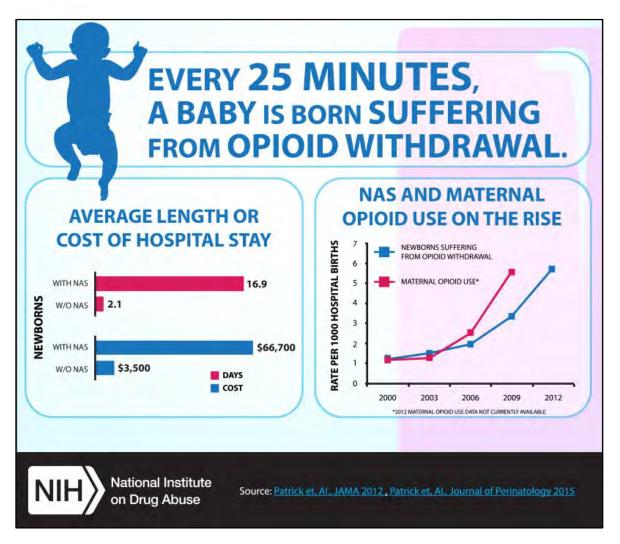
## An Officer's Story



- Dr. Shalon Irving, CDC Epidemiologist
- Lieutenant commander
- Commissioned Corps of the U.S.
   Public Health Service
- Two master's degrees
- Dual-subject Ph.D.



### Mothers & newborns are suffering from the opioid crisis



Patrick SW et al. 2012. Neonatal abstinence syndrome & associated health care expenditures: US, 2000-2009. *JAMA* **307**: 1934-1240.

Desai RJ et al. 2014. Increase in prescription opioid use during pregnancy among Medicaid-enrolled women. *Obstet. Gynecol.* **123**: 997-1002.



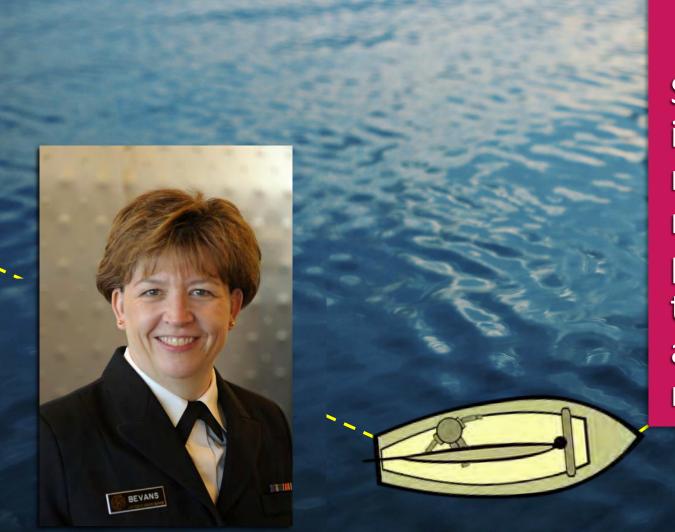


Diana W. Bianchi, MD

Director, Eunice Kennedy Shriver
National Institute of Child Health and
Human Development (NICHD)

## Later Today: Inclusion of Pregnant and Lactating Women in Research

Patrick SW et al. 2015. Increasing incidence and geographic distribution of NAS: US 2009-2012. *J. Perinatol.* **35**: 650-655.



### **New ORWH Vision**

Sex and gender influences are integrated into the biomedical research enterprise; every woman receives evidence-based disease prevention and treatment tailored to her own needs, circumstances, and goals; and women in science reach their full potential.

Margaret Bevans, PhD, RN

Assoc. Director, Clinical Research, ORWH

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

### Outline

- Collaborations with ICOs
- Research Programs
- SABV Update
- Adjusting Our Course
- Women in Biomedical Careers
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### NIH Working Group on Women in Biomedical Careers

- Co-chairs: Francis Collins, MD, PhD and Janine Clayton, MD
- Funded the Causal Factors & Interventions RFA
  - 14 research grants investigating a range of obstacles facing women at all stages of the career pipeline
  - \$16.8M over 4 yrs., with support from 11 ICs & 4 OD Offices
  - Well over 100 papers published
- Work-life integration policies
- Women of Color Research Network (WoCRn)
  - 4 regional chapters: DC, IN, MD, NC
  - Over 500 members and growing
  - https://womeninscience.nih.gov/women-of-color/





Shirley Malcom, PhD, Director of the Science, Technology, Engineering, and Mathematics Equity Achievement (SEA) Change Program, addressed the NIH Working Group on Women in Biomedical Careers on Jan. 17, 2018.





# Women in science offer career advice in a growing video series



**Yvonne C. Collins, MD**, is a Gynecologic Oncologist with AIM Specialty Health, where she serves as a Physician Team Lead.



**Eve Higginbotham, MD**, is the inaugural Vice Dean for Inclusion and Diversity at the University of Pennsylvania.



Janine Austin Clayton, MD, Assoc. Director for Research on Women's Health and Director of ORWH at the NIH, is the architect of the NIH policy requiring scientists to consider sex as a biological variable across the research spectrum.







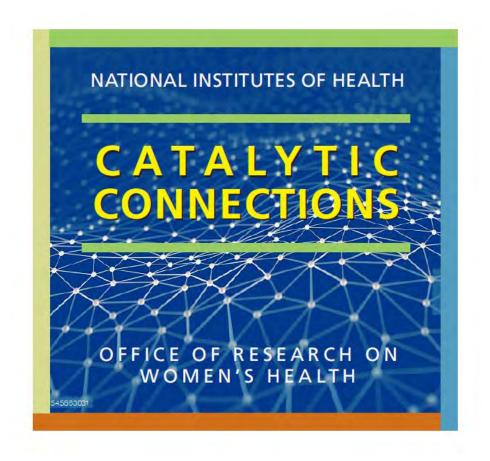
**Keri F. Allen, MD**, is a 3rd-year ophthalmology resident at Palmetto Health University of South Carolina.

Available at https://womeninscience.nih.gov/resources/pearls\_of\_wisdom.asp

## 3<sup>rd</sup> Annual NIH Vivian Pinn Symposium will emphasize "Leveraging the Network to Advance Women in Science"

#### Wed., May 16, 2018, 1:00-4:00 pm NIH Main Campus, Lister Hill Auditorium

- Vivian W. Pinn, MD
- Kay Lund, PhD, Director, NIH Division of Biomedical Research Workforce Programs: Advancing Women in the NIH Biomedical Research Workforce through Mentoring
- Daniel Ford, MD, PhD, Director, Johns Hopkins Institute for Clinical & Translational Research: Achieving Advanced Leadership Positions for Women in an Academic Setting
- Rachelle Heller, PhD, Assoc. Provost, GWU School of Engineering & Applied Science: Achieving Success for Women in STEM
- Janet Bandows Koster, MBA, CEO, AWIS: Moderated Panel
   Discussion
  - Catalytic Connections: "speed" networking





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## ORWH staff publish three new papers



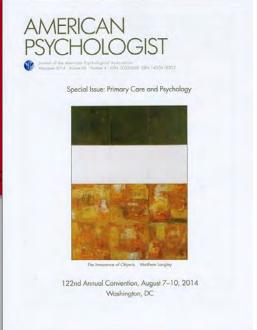
ioid profile and incidence of atrial fibrittatio

Clayton JA, **Arnegard ME**. 2018. Taking cardiology clinical trials to the next level: a call to action. *Clin. Cardiol.* **41**: 179-184.

**Plank-Bazinet JL**, **Sampson A**, Kornstein SG, Germino GG, Robert-Guroff M, Gilman SE, Wetherington CL, Cook N, **Cornelison TL**, **Begg L**, Clayton JA. 2018. A report of the 24th Annual Congress on Women's Health—workshop on transforming women's health: from research to practice. *J. Women's Health* **27**: 115-120.

EDITOR-IN-CHIEF
Susan G. Kornstein, M.D.
DEPUTY EDITOR
Robert W. Downs, Jr., M.D.

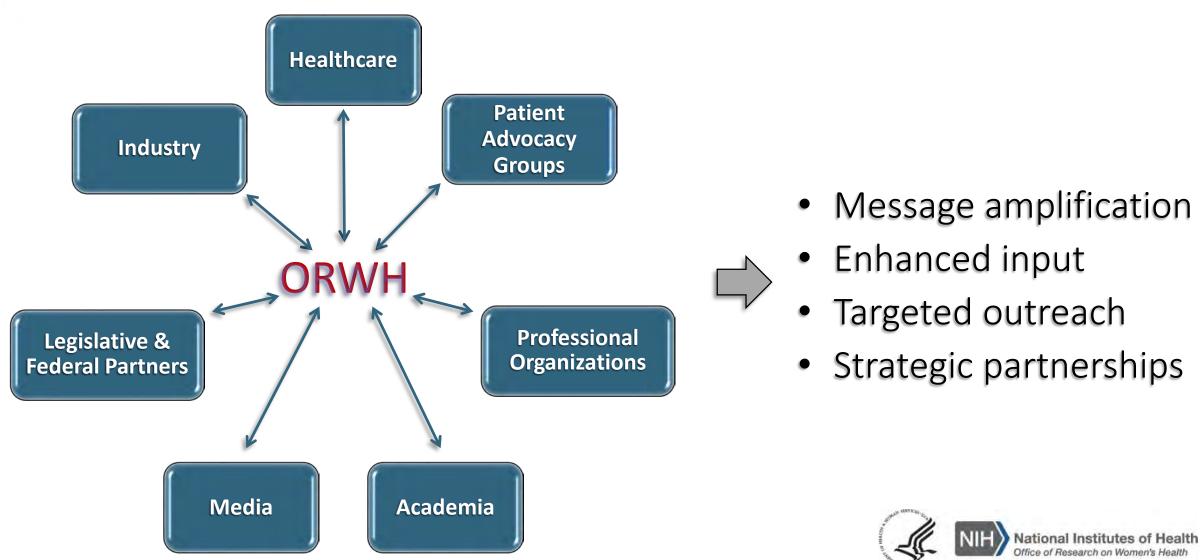
**₩**SWHR



Hall KL, Vogel AL, Huang GC, **Serrano KJ**, Rice EL, Tsakraklides S, Fiore SM. *In Press (accepted)*. The science of team science: a review of the empirical evidence and research gaps on collaboration in science. *Am. Psychol.* 



## Investment in stakeholder engagement has yielded significant returns



## ORWH launches its newsletter, "Women's Health In Focus at NIH"



Feature Story for July, 2018: Microbiome & Women's Health Science Direct Feati SAB\ portunities In th (Montage: Jonathan Bailey, NHGRI. Photo credits [clockwise from top-left]: Tom Schmidt; A. Earl, Broad Institute/MIT; Tom Schmidt; J.H. Carr, CDC)

To subscribe, send an email to <a href="https://orwind.com/ORWHINFO@mail.nih.gov">ORWHINFO@mail.nih.gov</a> with the subject line "Subscribe me to ORWH newsletter"

## ORWH re-designs its website

#### Redesigned ORWH Website

The Office of Research on Women's Health is relaunching its website at https://nih.gov/women.

#### The new site features:

- New research reports, such as Improving the Health of Women in the United States;
- Videos on hot topics such as Progress on the Inclusion of Women in Clinical Research;
- · The Women of Color Health Data Book;
- · The A to Z Guide on Sex and Gender Influences on Health; and
- Online courses on sex and gender in health disease that are free and open to the public.

The website places the latest information on women's health and women's health research at the fingertips of consumers, health providers, researchers, and media. Access includes multiple points of entry across all platforms, including desktops, tablets, and mobile devices.



## ORWH amplifies its messaging via social media



#### Twitter Overview: March, 2017 – March, 2018

2,555 net followers gained

	Follower Increase	Tweets Sent	Organic Impressions	Engagements	Retweets
16,179	18.8%	925	2,336,252	23,920	4,665



#### Facebook Overview: March, 2017 – March, 2018

712 net likes gained

Total Fans	Fan Increase	Posts sent	Impressions	Engagements	Link Clicks
30,471	1.55%	806	570,937	3,927	1,498



- 610 LinkedIn followers for Clayton; 583 members for WoCRn as of April 2, 2018
- 26 Mainstream media mentions between March, 2017 and March,
   2018
- ORWH tweet about NIH Vivian W. Pinn Symposium retweeted by Barbra Streisand



NIH Women's Health

#### **ORWH Pre-Conference Symposium:**

Addressing Health Challenges of Women Across the Life Course: Novel & Emerging Research

May 3, 2018, 1:00-5:00 pm Crystal Gateway Marriott, Arlington, VA



best practices for better outcomes

#### Connect With Us!

NIH.gov/women



@NIH\_ORWH



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#### It's not too late to register!

To register, visit us at www.nih.gov/women & follow the May 3<sup>rd</sup> link under "Upcoming Events"

#### 2018 Women's Health Conference begins May 4th



## **THANK YOU**

