49th Meeting of the NIH Advisory Committee on Research on Women’s Health

Elizabeth Spencer
Deputy Director
Office of Research on Women's Health
National Institutes of Health
October 23, 2019
Reminder: Special Government Employees (SGE)

• 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 are 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
New SGE Procedures

- Electronic submission of Confidential Financial Disclosure Report (OGE form 450) via NIH Ethics Enterprise System (NEES)
- ACRWH 2019 slate is first to use new system
- Conflict of Interest (COI) updates will be pre-populated with data from previously filed forms
Saluting Retiring Member

Rachel Jones, Ph.D., R.N.
Associate Professor
School of Nursing
Northeastern University
Welcome New Members

Scott Hultgren, PhD
Helen L. Stoever Prof. of Molecular Microbiology; Dir., Center for Women’s Infectious Disease Research, Washington Univ. School of Medicine in St. Louis

Sabra Klein, PhD
Assoc. Prof. Dept. of Molecular Microbiology and Immunology, Dept. of Biochemistry and Molecular Biology, Bloomberg School of Public Health, Johns Hopkins University

Judy Regensteiner, PhD
Director, Center for Women’s Health Research, School of Medicine, Univ. of Colorado, Anschutz Medical Campus

Michelle Robinson, DMD, MA
Interim Dean
School of Dentistry, University of Alabama at Birmingham

Alyson McGregor, MD, MA
Assoc. Prof. of Emergency Medicine, Director, Division of Sex and Gender in Emergency Medicine, Alpert Medical School, Brown University

Neel Shah, MD, MPP
Asst. Prof., Obstetrics, Gynecology, and Reproductive Biology, Harvard Medical School; Dir., Delivery Decisions Initiative, Ariadne Labs, Harvard University
49th Meeting of the NIH Advisory Committee on Research on Women’s Health

Janine Austin Clayton, M.D.
NIH Associate Director for Research on Women’s Health
Director, Office of Research on Women's Health
National Institutes of Health

Director’s Report
October 23, 2019
Elijah Cummings
United States House of Representatives | Maryland
1951 - 2019
NIH leadership update

Retiring

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.
Director
National Institute of Environmental Health Sciences
Your Environment. Your Health.

Ann Cashion, PhD, RN, FAAN
Acting Director
National Institute of Nursing Research
Congratulations!

Debara L. Tucci, M.D., M.S., M.B.A.
Director
NIH National Institute on Deafness and Other Communication Disorders

Santa Tumminia, Ph.D.
Acting Director
NIH National Eye Institute Research Today...Vision Tomorrow
Meet the new Director of Office of Data Science Strategy

Mission

To catalyze new capabilities in biomedical data science by providing trans-NIH leadership and coordination for modernization of the NIH data resource ecosystem, development of a diverse and talented data science workforce, and building strategic partnerships to develop and disseminate advanced technologies and methods.

Susan K. Gregurick, Ph.D.
LEADING THE WAY

NORA D. VOLKOW, M.D.
National Institute on Drug Abuse

PATRICIA FLATLEY BRENNA, R.N., PH.D.
National Library of Medicine

HELENE LANGEVIN, M.D.
National Center for Complementary and Integrative Health

ANDREA T. NORRIS
Center for Information Technology

SANTA TUMMINIA, PH.D
National Eye Institute

MARTHA J. SOMERMAN, D.D.S., PH.D.
National Institute of Dental and Craniofacial Research

DEBARA L. TUCCI, M.D., M.S., M.B.A.
National Institute on Deafness and Other Communication Disorders

DIANA W. BIANCHI, M.D.
Eunice Kennedy Shriver National Institute of Child Health and Human Development

NONI BYRNE, PH.D.
Center for Scientific Review

*Acting
13 of 27 ICs have woman deputy directors!

LEADING THE WAY
ORWH’s Mission

- Enhance and expand women’s health research
- Include women and minority groups in clinical research
- Promote career advancement for women in biomedical careers
Another way to improve health outcomes is to develop objective point-of-care diagnostic tools.

Elevating Standards of Care via Objective Diagnostic Tools

<table>
<thead>
<tr>
<th>Potential Biomarkers for Preeclampsia</th>
<th>Pretest probability for preeclampsia</th>
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<tbody>
<tr>
<td></td>
<td>5%</td>
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<td>25%</td>
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<table>
<thead>
<tr>
<th>Test</th>
<th>Cutoff</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Positive predictive value (%)</th>
<th>Negative predictive value (%)</th>
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<tr>
<td>sFLT-1*</td>
<td>7463 pg/mL</td>
<td>83</td>
<td>58</td>
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<td>98.5</td>
</tr>
<tr>
<td></td>
<td>9795 pg/mL</td>
<td>71</td>
<td>68</td>
<td>10.5</td>
<td>97.8</td>
</tr>
<tr>
<td>Endoglin*</td>
<td>21.3 ng/mL</td>
<td>94</td>
<td>58</td>
<td>10.5</td>
<td>98.5</td>
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<tr>
<td></td>
<td>24.6 ng/mL</td>
<td>86</td>
<td>63</td>
<td>10.9</td>
<td>98.6</td>
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<tr>
<td>Serum PI GF*</td>
<td>84.9 pg/mL</td>
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<td>58</td>
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<tr>
<td>Urine PI GF*</td>
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<td>47</td>
<td>7.9</td>
<td>98.5</td>
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<tr>
<td>Podocin*</td>
<td>0.85 cells/^2</td>
<td>100</td>
<td>100</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Nephrin*</td>
<td>0.75 cells/^2</td>
<td>93</td>
<td>75</td>
<td>16.4</td>
<td>99.5</td>
</tr>
<tr>
<td>Podocardin*</td>
<td>0.83 cells/^2</td>
<td>93</td>
<td>75</td>
<td>16.4</td>
<td>99.5</td>
</tr>
<tr>
<td>Synaptopin*</td>
<td>1.11 cells/^2</td>
<td>93</td>
<td>81</td>
<td>20.5</td>
<td>99.5</td>
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</tbody>
</table>


Goal:
Development of a peptide-modified bead POC device to unambiguously diagnose preeclampsia in the 2nd trimester before women are symptomatic

(SBIR-R44)

Point-of-care device to identify patients at risk for preeclampsia

https://projectreporter.nih.gov/project_info_history.cfm?aid=9789872&icde=0
I. Scientific Collaborations
II. Research Programs
III. SABV Update
IV. Women in Biomedical Careers
V. Building Connections
NIH Institute & Center Mission Areas

**ORWH Mission**
- To enhance research related to diseases, disorders, and conditions affecting women
- To help ensure that women are appropriately represented in biomedical research supported by the NIH
- To improve the advancement of women in biomedical careers

**NIH 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
- Women in science careers reach their full potential

**Trans-NIH Strategic Plan for Women’s Health Research**
ORWH contributes $1M to planning grants to study effects of pre/postnatal opioid exposure on brain development

R34 planning grants for 3 of 6 sites for the HEALthy Early Development Study

- Emory, Case Western, OSU Ctr. for Health Sci.
- To refine design of this large-scale, 6-site study of maternal substance use effects on children’s brain, cognitive & emotional development (prenatal → mid-childhood)

R34 feasibility study of technology to minimize motion-induced biases in MRI of young, opioid-affected cohorts

- University of Pennsylvania
- Addresses in-scanner motion by children, which is exacerbated by the association between prenatal opioid exposure & ADHD

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Study finds endometriosis research underfunded¹

Highly prevalent (10% of women of reproductive age), painful, costly

- Yet, research is underfunded and disease, under-researched
- Slow advance in much-needed diagnostic and treatment options

Lack of awareness among patients, providers and public

- Societal normalization of women’s pain
- Stigma around menstrual issues


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Botox relieves endometriosis-associated pain, spasms, disability²

Open-label proof-of-concept case series.
Participants: women with endometriosis³ and chronic pelvic pain persisting despite surgical and hormonal treatments

³Surgically diagnosed
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Botox relieves endometriosis-associated pain, spasms, disability²

<table>
<thead>
<tr>
<th>Pain</th>
<th>Prior to</th>
<th>4-6 weeks after</th>
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<tbody>
<tr>
<td>Moderate (median VAS score 5/10) varied widely (VAS score range: 2–7)</td>
<td>•All reported reduction in pain (median VAS=2, range 0–5/10, p&lt;0.0001) •11 of 13 rated pain as absent or mild</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Spasms</th>
<th>Prior to</th>
<th>Follow-up</th>
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</thead>
<tbody>
<tr>
<td>11 of 13 had palpable spasm in at least 4 pelvic floor muscles</td>
<td>Not detectable or less widespread</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disability</th>
<th>Prior to</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>•5, moderately disabled; 2, severely disabled; 1, crippled</td>
<td>•6 of 8 experienced improvement</td>
<td></td>
</tr>
</tbody>
</table>

Women’s Health Issues partnered with VA to highlight importance of sex & gender differences in veterans affairs research

- June 25th issue supported by VA Cooperative Studies Program
- Features research reports & commentaries on growing number of women vets and their unique health needs
- Commentary by Bevans & Clayton: Integrating the Influence of Sex and Gender in Research: Keeping Women Veterans in Focus*
  - Quality medical care stems from integrated consideration of military-related health needs and influence of sex & gender on health
  - Combat stress & exposure affect women differently than men
  - How do combat exposures in a woman’s 20s affect her health decades later?
  - Are sex differences among veterans related to their service or to the same sex differences civilians have, or to a complex combination of factors?

*doi.org/10.1016/j.whi.2019.05.001
#WomensHealth is trending
Announcing CDRH’s Health of Women Program Strategic Plan: Why It Matters for All Women and Their Access to Safe and Effective Medical Devices

The FDA’s Center for Devices and Radiological Health (CDRH) Health of Women Program recognizes the importance of addressing sex- and gender-specific issues in medical technology design, development, and implementation. Our program extends beyond reproductive and gynecologic health. Our approach is comprehensive – it considers a woman’s entire body.

CDRH’s Health of Women Program:

- **Explores** unique issues related to the performance of medical devices in women
- **Improves** analysis and communication of sex- and gender-specific data to better assure the safe and effective use of medical devices
- **Develops** and implements health science programs, strategies and initiatives focused on women’s health issues across CDRH

The FDA seeks public feedback on CDRH’s Health of Women Program’s new Strategic Plan through a public docket in the Federal Register under docket number FDA-2019-N-3804. The last day to submit comments to the docket is December 23, 2019. Your input will help shape how CDRH implements the program.

**Questions?**
If you have questions about CDRH’s Health of Women Program contact: CDRHHealthofWomeninfo@fda.hhs.gov

Read the Strategic Plan

Submit Comments
21st Century Cures Act advances research on the health of women

• Inclusion policy updates
• IC strategic plans must take into account women and minorities and include details on reduction of health disparities for women and minorities
• CCRWH reconstituted to be composed of IC Directors or their senior-level designees

Public Law 114-255, Sec. 2031 & 2038
NIH-defined phase III clinical trials and applicable clinical trials* must report results –
• stratified by sex/gender, race and ethnicity in ClinicalTrials.gov
Clinical research studies should include individuals of all ages
• unless there are sci. or ethical reasons not to

*Subset of clinical trials subject to FDA Amendments Act
NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases

STRATEGIC PLAN FISCAL YEARS 2020-2024
Turning Discovery Into Health

- "Health and Disease in Diverse Populations" theme
- "Advancing and Accelerating Systemic Rheumatic and Autoimmune Diseases Research" goal -- a women’s health research priority
Working across NIH to advance the health of women

NIH Institutes and Centers

Implementation and Evaluation

Office of Research on Women’s Health
Working across NIH to advance the health of women

NIH Institutes and Centers

Engines of mission-focused research relevant to the health of women

Reconstituted CCRWH: Coordinating Committee on Research on Women's Health

Nexus for driving synergistic research priorities

Office of Research on Women's Health

Focal point for coordinating women’s health research via policies & signature programs
BOLD

Readiness

Significant

Innovative

Synergy

Impact
“real public health need”

“more efficient and cost-effective if we do it together”

“an idea that hasn’t gotten our focus”

“benefit from increased, focused trans-NIH effort”

“think beyond what’s right in front of us”
The NIH CCRWH generates **bold ideas** on women’s health.
ANNOUNCING

NIHAPPLE & HARVARD

WOMEN’S HEALTH STUDY

Collaboration will permit researchers to study conditions, including:
- Pregnancy
- Infertility
- Polycystic ovary syndrome (PCOS)
- Menopausal transition
- Osteoporosis.
Apple’s new Research App will help users participate in the study. NIEHS will provide expert advice and data analysis.

Addressing a Compelling Challenge for the Health of Women -- MMM

Tara Schwetz, Ph.D.
Dorothy Fink, M.D.
Sarah Foster, M.P.H.
Johannie Escarne, M.P.H.

PREGNANCY & MATERNAL CONDITIONS THAT INCREASE RISK OF MORBIDITY AND MORTALITY

Meeting, May 19-20, 2020

NICHID - ORWH - ICs
ORWH-cofunded study finds life course impact of pregnancy complications

Women who experience complications (such as preterm births & preeclampsia) during 1st pregnancy are developing hypertension soon after – some within 3 years

• They’re nearly 2X more likely than women without complications to develop hypertension later
• 31% with at least one adverse outcome experienced chronic hypertension (v. 17% for those without)

Study underscores need for
• Greater focus on pregnancy histories
• Possibly, closer health monitoring & more lifestyle counseling to prevent hypertension

doi.org/10.1161/JAHA.119.013092
FY19 Sex/Gender Admin. Supp. explores role of fetal sex in maternal health

Cardiometabolic complications, including hypertensive disorders and GDM –
- Contribute to US’s excessive rates of maternal mortality (MM) and racial disparity in MM
- Increases mothers’ increased lifetime risk of CV and metabolic disease
- Risk factors & biomarkers can’t adequately identify at-risk women
- Research will investigate whether:
  - Distinct lipidomic profiles in early and/or later pregnancy associate with cardiometabolic complications
  - Differences in lipidomic profile occur according to fetal sex
- Participants will be pregnant Black women 18-40
NICHD
Strategic Plan 2020

- Understanding the Molecular, Cellular, and Structural Basis of Development
- Promoting Gynecologic, Andrologic, and Reproductive Health
- Setting the Foundation for Healthy Pregnancies and Lifelong Wellness
- Improving Child and Adolescent Health and the Transition to Adulthood
- Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities
ORWH coordinating resources to drive impact in maternal health
ORWH coordinating resources to drive impact in maternal health

4th Annual NIH Vivian W. Pinn Symposium
Improving Maternal Health: Behind the Numbers
Celebrating 20 Years of National Women’s Health Week

Symposium*
>680 people reached
• 113 in person
• 567 via videocast

Federal Representation:
HRSA | CDC | FDA

Web Portal**
2236 Total
1520 Unique
Sources
ICOs – HHS - CDC - ACOG
HRSA - Others

MMM Booklet**
600 Disseminated
Trans-HHS resource summarizes >50 publications and resources

*As of 10/01/19
**As of 10/01/19
Outline

I. Scientific Collaborations
II. Research Programs
III. SABV Update
IV. Women in Biomedical Careers
V. Building Connections
2019 - 2023
ADVANCING SCIENCE FOR THE HEALTH OF WOMEN
Trans-NIH Strategic Plan for Women's Health Research

Goal 1
Advance rigorous research that is relevant to the health of women.

Goal 2
Develop methods to leverage data so as to consider sex/gender influence in enhancing research.

Goal 3
Enhance dissemination and implementation of evidence to improve the health of women.

Goal 4
Promote careers in women's health research to advance health equity.

Goal 5
...
Advance rigorous research that is relevant to the health of women.
ORWH Funding History & FY18 Extramural Award Profile

Extramural Award Profile (as % of Extramural Budget)

- BIRCWH: 30%
- Score: 17%
- Other IC Co-Funds: 23%
- R56: 6%
- U3 Admin. Supp.: 10%
- Sex/Gender Admin. Supp.: 14%

*Data not adjusted for inflation
What's the SCORE?

- UCLA'S SCORE SEEKS TO UNDERSTAND SEX DIFFERENCES IN CARDIO-METABOLIC DISEASE
SCORE research on sex differences in MetSyn could improve diagnosis & treatment

Investigating sex differences in risk factors & treatments for Metabolic Syndrome, incl. obesity, insulin resistance/diabetes, dyslipidemia
- Differences in susceptibility are known
- But underlying mechanisms, genetic and physiological, are poorly defined

Investigating from multiple perspectives, such as effects of
- Estrogen
- XX vs. XY sex chromosome
- Genetic variation

Identifying factors that determine sex-specific risk may lead to better diagnosis & treatment for both sexes
**R01**

**Intersection of Sex & Gender Influences on Health & Disease**

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**ORWH FIRST!**

ORWH's first R01 is a major milestone. On the eve of our 30th Anniversary, with a $1M contribution, ORWH is taking research on sex and gender influences to the next level.

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**INTERSECTION**

R01 supports disease-agnostic research across scientific disciplines to understand how sex and gender factors intersect with health and disease.

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**NIH FIRST!**

NIH’s first R01 on sex and gender. It reaffirms its commitment to advancing research of sex and gender influences and advancing ORWH’s mission.

---

**TRANS-NIH & STRATEGIC**

A collaboration with 11 ICs, R01 supports research that addresses Strategic Goal 1 of the Trans-NIH Strategic Plan for Women's Health Research.
Outline

I. Scientific Collaborations
II. Research Programs
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IV. Women in Biomedical Careers
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Young women’s cancer death rate is higher than young men’s – incidence rate, substantially so

*NIH Annual Report to the Nation on the Status of Cancer*

- Overall, men fared worse – their average annual incidence¹ and death² rates were higher
- **But among young women**, ages 20 to 49...
  - Death rate was 27.1 v. 22.8 among young men
  - Incidence rate was 203.3 v. 115.3 among young men
- Overall death rates in this age group are declining
  - But declining at faster rate among men: 2.3% v. 1.7%

¹ Per 100K people, 2011-2015
² Per 100K people, 2012-2016

ORWH is developing courses to educate biomedical community on sex and gender

- Bench to Bedside: Integrating Sex & Gender to Improve Human Health (Updated)
  FDA Office of Women’s Health

- Sex as a Biological Variable Primer* (New)
ORWH is developing comprehensive SABV evaluation tools

- Development of statistically reliable evaluation tools:
  - To assess SABV in grant applications
  - To identify relevant reviewer comments in summary statements
- Pilot testing of the analysis tools on select applications and corresponding summary statements
- Assessment of the inter-rater reliability of the tools
- Evaluation of the tools’ utility, validity, and limitations
- Refine tools for large scale analysis
At ORWH’s urging, ICs are increasingly highlighting studies that identify sex influences or differences

- NIMH press release promoted recently published *Neurolmage* article
  - Co-author: Armin Raznahan, inaugural speaker for Sex & Gender in Health & Disease Scientific Interest Group (SGHD SIG)
  - NIMH and Director Joshua Gordon’s Twitter accounts highlighted article

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Outline

- Scientific Collaborations
- Research Programs
- SABV Update
- **Women in Biomedical Careers**
- Building Connections
EXAMINE

• How women’s participation varies across disciplines
• How intersection of race & gender impacts WOC
• What interventions have produced sustained improvements in representation and leadership
• Why effective interventions haven’t been scaled up or adopted

DEVELOP

• Actionable recommendations to improve representation and leadership

Stay tuned for NASEM report!
ACD Working Group
on Changing the Culture to End Sexual Harassment

Working Group’s Charge

Assess current state of sexual harassment allegation investigation, reporting, remediation, and disciplinary procedures at NIH-funded organizations;

Advise on oversight, accountability, and reporting measures for awardee institutions that will encourage a reduction in, and prevention of, sexual harassment in biomedical research laboratories;

Propose actions and policies that would promote a safe and inclusive culture at NIH-supported research conferences;

Suggest system-wide changes to culture and climate to prevent harassment and gender discrimination through diffusion of hierarchical environments by mentoring networks and committee-based advisement + strong and diverse leadership;

Develop strategies for encouraging research on anti-harassment policies, procedures, and training, as well as measures and evaluations of their effectiveness.

https://acd.od.nih.gov/working-groups/sexual-harassment.html
No More Manels

"When I consider speaking invitations, I will expect a level playing field, where scientists of all backgrounds are evaluated fairly for speaking opportunities. If that attention to inclusiveness is not evident in the agenda, I will decline to take part."

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
06.12.19
No More Manels

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Media Response

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<tr>
<th>Media</th>
<th>NBC, 6/13</th>
<th>ORWH</th>
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<tbody>
<tr>
<td>Twitter*</td>
<td>Engagements 22K</td>
<td>Impressions 4,961</td>
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<tr>
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</tr>
<tr>
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<td>14M</td>
<td>1.69M</td>
</tr>
</tbody>
</table>

*@NIHDirector

LinkedIn
Views 3,340
Outline

- Scientific Collaborations
- Research Programs
- SABV Update
- Women in Biomedical Careers
- Building Connections
Media coverage advances case for women’s health research

German Public Radio, July 23, 2019
“Neuroscience: Do too many male experimental animals distort the results?” Interview with Chyren Hunter, Ph.D. reached 2M listeners.

Lasker Foundation, June 17, 2019
“Stopping the leaks.” About the Action Collaborative on Preventing Sexual Harassment in Higher Education.

Research!America’s National Health Research Forum, Sep. 5, 2019
“Women Researchers Leading Discovery” panel discussion.

The Washington Post, Oct. 19, 2019
“Women are more than twice as likely as men to suffer from PTSD. Studies are underway to find out why”
VICTORIA CARGILL, M.D. & JANINE A. CLAYTON, M.D.

MARGARET BEVANS, PH.D., RN, FAAN & JANINE A. CLAYTON, M.D.
Integrating the Influence of Sex and Gender in Research: Keeping Women Veterans in Focus. *Women’s Health Issues* 29: 59-11. doi.org/10.1016/j.whi.2019.05.001

ELENA GORODETSKY, M.D., PH.D.

DAVID A. THOMAS, PH.D.
Fall Issue’s Top Story: Stress, Its Effects on the Health of Women, and Stress Mitigation

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>Dec. 11, 2019</td>
<td>BIRCWH Meeting</td>
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<tr>
<td>2020</td>
<td>NASEM Symposium on Consensus Study, NIH</td>
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<td>March 19</td>
<td>OSSD Keynote and ORWH Travel Awards</td>
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<td>May 4-7</td>
<td>Annual Vivian W. Pinn Symposium</td>
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<td>May 12</td>
<td>Pregnancy &amp; Maternal Conditions that Increase Risk of Morbidity &amp; Mortality Symposium</td>
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<td>May 19-20</td>
<td>50th ACRWH Meeting</td>
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<td>Sep. 2-3</td>
<td>NIH Inclusion Across the Lifespan Workshop</td>
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<td>Oct. 13</td>
<td>BIRCWH 20th Anniversary</td>
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<td>Oct. 21</td>
<td>30th Anniversary Scientific Symposium</td>
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1990 – 2020