A Legacy of Leadership: ORWH Celebrates 30 Years of Advancing Research on the Health of Women

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### DIRECTOR’S CORNER

Janine Austin Clayton, M.D.,
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With ORWH celebrating its 30th anniversary this year, our feature story in this issue of In Focus acknowledges the accomplishments of the women and men who established and led the office over its three-decade history. This first issue of our third volume introduces a new design to mark this milestone. As we celebrate past achievements, I also want to look forward and consider how we can continue to improve the health of women in the years to come.

ORWH and all other NIH Institutes, Centers, and Offices—as well as many investigators, clinicians, and other stakeholders—remain committed to the idea that health improves when treatment is integrated and addresses the whole person, head to toe. In that vein, the current issue covers a range of topics, from the effects of microbiota on human health to links between pregnancy and later-life cardiovascular disease to connections between sleep habits and women’s risk for obesity. Health improves when researchers and clinicians consider multiple determinants of health such as these in a holistic way, develop treatments consistent with such a consideration, and provide integrated health care to patients.

I hope you enjoy this issue of In Focus and find it informative. Please share it with your colleagues and encourage others to subscribe.

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

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A Legacy of Leadership: ORWH Celebrates 30 Years of Advancing Research on the Health of Women

"Picture a world in which the biomedical research enterprise thoroughly integrates sex and gender influences; every woman receives evidence-based disease prevention and treatment tailored to her own needs, circumstances, and goals; and all women in science careers reach their full potential."

—Janine Austin Clayton, M.D., Director, NIH Office of Research on Women’s Health

Since its establishment in 1990, NIH’s Office of Research on Women’s Health (ORWH) has served as the focal point for women’s health research at NIH. ORWH began with the charge of working in collaboration with other NIH Institutes and Centers (ICs) to:

- Advise the NIH Director and staff on matters relating to research on women’s health
- Strengthen and enhance research related to diseases, disorders, and conditions that affect women
- Ensure that research conducted and supported by NIH adequately addresses issues regarding women’s health
- Ensure that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH
- Develop opportunities for and support the recruitment, retention, reentry, and advancement of women in biomedical careers

Over its 30-year history, ORWH has endeavored to grow the relevance of medical research to the health of all women. ORWH places emphasis on rigorous research (that is also transparent and reproducible) and spotlights the need for researchers to consider the potential influence of sex—being female or male—on health and disease. As such, ORWH has expanded its mission statement to include the following:

- Support and advance rigorous research that is relevant to the health of women
- Ensure NIH-funded research accounts for sex as a biological variable (SABV)

Over the years, ORWH has also emphasized that other demographic factors, such as socioeconomic status, influence health and disease and that “women’s health” encompasses a multidimensional framework of everything that affects the health of a woman—internally (e.g., sex), externally (e.g., gender-related matters), and across the life course. ORWH has strived to advance the understanding that every person should receive unbiased, tailored, sex- and gender-informed, evidence-based care.

On the following pages, we highlight the efforts and achievements of some of the key figures in science, health policy, Government, and advocacy organizations who helped to establish ORWH as an office that could promote the inclusion of women in clinical studies and elevate the study of the health of women as a public funding, policy, and research priority. We also discuss some individuals who have followed in the footsteps of these pioneers.
women's reproductive health and sexuality. This organization, now known as Our Bodies Ourselves, continues to advocate for women's health today. In 1984, health care activist Byllye Avery established the National Black Women’s Health Project, now the Black Women's Health Imperative, to address the reproductive and general health of African-American women within a system that tended to marginalize them. These and other efforts by members of the women's health movement attracted the attention of lawmakers, health officials, and other influential stakeholders.

The Federal Response to the Women’s Health Movement. In the years leading up to the establishment of ORWH, several Federal officials took action to address women’s health concerns. In 1983, then-Assistant Secretary of Health Edward Brandt, Jr., M.D., established the Public Health Service (PHS) Task Force on Women’s Health Issues and appointed Ruth L. Kirschstein, M.D., as its chair. Dr. Kirschstein, the first woman to serve as the Director of an NIH Institute (the National Institute of General Medical Sciences, or NIGMS), was already a respected figure in the biomedical research and health policy communities. (Dr. Kirschstein would later serve as the Deputy Director of NIH, twice as the Acting Director of NIH, and as the first Acting Director of ORWH.) Under Dr. Kirschstein’s leadership, the PHS Task Force on Women’s Health Issues advocated greater inclusion of women in NIH-funded clinical research. The task force also recommended that biomedical and biobehavioral research be expanded to ensure emphasis on conditions and diseases unique to—or more prevalent in—women of all age groups and established evidence-based clinical standards for determining health problems, conditions, and diseases that affect women.

Meanwhile, the Congressional Caucus for Women’s Issues responded to calls from scientific and advocacy organizations to improve women’s health and associated research efforts and joined the PHS Task Force in calling for greater inclusion of women in federally funded clinical research. Four members of the U.S. Congress—Barbara Mikulski, Connie Morella, Olympia Snowe, and Pat Schroeder—pushed for increasing inclusion of women as research subjects. In 1986, in response to (1) encouragement from the Congressional Caucus for Women’s Issues, (2) the recommendations of the PHS Task Force on Women’s Health Issues, and (3) concerns raised by health advocates in the women’s health movement, NIH enacted the Inclusion of Women and Minorities in Clinical Research policy, which urged researchers applying for NIH funding for studies involving human subjects to include women and minorities.

In 1989, the Congressional Caucus for Women’s Issues and the U.S. House of Representatives Energy and Commerce Subcommittee on Health and Environment introduced the Women’s Health Equity Act, which called for the General Accounting Office (now the Government Accountability Office, or GAO) to investigate NIH’s policy and practices regarding the inclusion of women as research subjects in NIH-sponsored studies. In a 1990 report, GAO described its examination of about 50 NIH grant applications, most of which proposed studies on conditions that affect both men and women. Approximately 20% of the proposals provided no information on the sex of the study population, and over a third indicated that both sexes would be included but did not specify in what proportions. Some applications proposed all-male studies without providing a rationale. The findings in the GAO report led the Congressional Caucus for Women’s Issues and other legislators to take action.

The Establishment of ORWH. In September 1990, Senator Mikulski and Representatives Morella, Schroeder, and Snowe requested a meeting with NIH leadership and held a news conference
on the NIH campus to express concerns about the lack of inclusion of women in clinical research. Acting under the aegis of U.S. Department of Health and Human Services (HHS) Secretary Louis Wade Sullivan, M.D., then-Acting NIH Director William F. Raub, Ph.D., used the occasion to give assurance that efforts would be made to include more women in clinical studies and announced the establishment of ORWH. The new office would strive to increase women’s participation in NIH-funded clinical research; enhance NIH’s efforts to improve the prevention, diagnosis, and treatment of illness in women; and enhance research related to diseases, disorders, and conditions that affect women.1

Dr. Raub appointed Dr. Kirschstein to serve as the new office’s Acting Director, and she insisted that research remain central to the mission of ORWH and that the new office should also focus on increasing the number of women in biomedical careers. At the time, women in biomedical research and health care faced numerous barriers to career success, including unequal pay, lack of opportunities for promotion, sexual and gender harassment, and unfriendly workplace policies. Despite considerable progress, some of these exclusionary workplace barriers persist to this day.

Over the next year, Dr. Kirschstein organized, staffed, and set the priorities of the new office, with strong support from the newly appointed Director of NIH, Bernadine Healy, M.D., the first—and, to date, only—woman to hold the position. Dr. Healy was a strong advocate for women’s health research and the architect of NIH’s Women’s Health Initiative (WHI), a 15-year research program addressing the health of postmenopausal women. Drs. Kirschstein and Healy organized the “Hunt Valley Conference” for scientists, clinicians, and other stakeholders to share their ideas for ORWH over several days of meetings and working group sessions. A formal report of the conference’s proceedings, often referred to as the “Hunt Valley Report,” set NIH’s first women’s health research agenda. The Hunt Valley Report summarized the topics discussed at the conference and articulated some of the goals that would become central to ORWH’s mission, such as ensuring the inclusion of women in clinical research, addressing gaps in scientific knowledge about women’s health across the lifespan, and increasing the number of scientific investigations designed to reveal sex and gender differences in health outcomes.

Dr. Kirschstein also recruited key personnel to the ORWH staff, including Judith H. LaRosa, Ph.D., who served as ORWH’s first Deputy Director for several years; Wendy Wertheimer, a legislative and health policy specialist and later a Senior Advisor in the Office of AIDS Research (OAR); and Vivian Pinn, M.D., a pathologist from Howard University, who, in 1991, became the first full-time Director of ORWH, a position she would hold until she retired in 2011. Additional individuals who made substantial contributions to the establishment of the office and/or were general supporters of women’s health research around that time include U.S. Representatives Louise Slaughter and Henry Waxman; former U.S. Congressional staffers Cindy Hall, Ruth Katz, J.D., M.P.H., and Susan F. Wood, Ph.D.; and health advocates Cynthia A. Pearson and Diana Zuckerman, Ph.D.*

**Dr. Pinn’s Tenure: Setting Priorities and Initiating Changes in Women’s Health Research.** Prior to taking the helm of ORWH, Dr. Pinn had broken many barriers over a successful and trailblazing career. In 1967, she earned her medical degree as the only woman and only person of color in her class at the University of Virginia School of Medicine. She received her postgraduate training as a Research Fellow in pathology at the Massachusetts General Hospital, with a focus on immunopathology. She was a Teaching Fellow at Harvard University and, later, an Assistant Professor of Pathology and Assistant Dean of Student Affairs at Tufts University. In 1982, Dr. Pinn became a Professor and the Chair of the Pathology Department at Howard University Hospital—only the third woman and the first African-American woman to lead a pathology department in the United States.

ORWH accomplished much during Dr. Pinn’s early tenure. ORWH initiated the Re-Entry into Biomedical Research Careers program, which assists researchers with high potential to re-enter active research careers after a qualifying interruption, such as childbirth, and the Research Enhancement Award Program (REAP), which supported universities that trained research scientists but that had not yet received major NIH support. ORWH also cosponsored the Women’s Reproductive Health Research (WRHR) Career Development Program, an initiative created by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) to promote the physician-scientist workforce with a focus on women’s reproductive health. In 1993, the U.S. Congress statutorily established ORWH as a provision of the NIH Revitalization Act. This legislation also mandated that ORWH establish the Coordinating Committee on Research on Women’s Health (CCRWH), a group of NIH Directors or their senior-level designees that

* Early advocates, including government officials, who had a role in the origins of ORWH remained supportive through the years, and in different roles in their careers.
makes recommendations to advance NIH goals regarding women’s health research, and the Advisory Committee on Research on Women’s Health (ACRWH), a group of non-Federal experts who make similar recommendations from an external perspective.7

In 1999, ORWH launched the Building Interdisciplinary Research Careers in Women’s Health (BIRCWH) program, a mentorship program aimed at career development within fields related to the health of women.9 Since its establishment, BIRCWH has connected junior and senior faculty with shared research interests in women’s health and sex differences. In 2002, the Office of Women’s Health (OWH) of the U.S. Food and Drug Administration (FDA) and ORWH started the Specialized Centers of Research (SCOR) on Sex and Gender Factors Affecting Women’s Health program (now known as SCORE), supporting research centers that integrate sex and gender factors and differences into their interdisciplinary studies of major medical conditions.9

Under Dr. Pinn’s direction, ORWH published or supported the publication of several seminal texts on women’s health and research. Women and Health Research, an ORWH-supported report from the Institute of Medicine (IOM), describes the facts behind perceptions of women as subjects in biomedical research as well as principles for ethical conduct of research on women.10 Women’s Health in the Medical School Curriculum details results from surveys of medical schools and provides a rationale for the development of a women’s health curriculum.11 The Women of Color Health Data Book provides clinicians and researchers comprehensive information on the unique health features of women of color.12 Beyond Bias and Barriers: Fulfilling the Potential of Women in Academic Science and Engineering, an ORWH-supported publication of the National Academies of Sciences, Engineering, and Medicine (NASEM), made recommendations for supporting women working in scientific and academic fields.13

In response to the NASEM report, NIH established the Working Group on Women in Biomedical Careers in 2007. Since its inception, the working group has sponsored workshops on mentoring and sustaining career success, changed NIH grant and conference applications to accommodate working women, improved family leave policies, and established the Women of Color Research Network, a social networking platform for women of color and their supporters in the biomedical workforce. In 2008, the working group, in concert with ORWH and numerous participating ICs, developed a Request for Applications (RFA) titled “Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering.” This RFA resulted in 14 grants supporting research into the factors determining the career patterns of women in scientific fields and into the efficacy of programs designed to support the careers of women in these disciplines. This research improved our understanding of how individuals make career choices and how workplaces might inadvertently impede the professional advancement of women in the sciences. A summary of the research on these causal factors is available on the ORWH website. Additional discussion of the working group’s accomplishments is available on its website, and a summary of the working group’s initiatives responding to the recommendations of Beyond Bias and Barriers was published in Academic Medicine.14

Throughout her tenure as ORWH Director, Dr. Pinn developed innovative practices for soliciting stakeholder input, gathering information and ideas, and synthesizing them into effective policies and plans. Following the example of the Hunt Valley Conference in 1991, ORWH regularly reached out to experts from across NIH, other agencies in the Federal Government, academic institutions, the health care industry, the corporate world, and other sectors as well as to members of the general public—particularly the women who could benefit most from NIH research—to gather data and ideas to inform actionable plans. “Dr. Pinn set new standards for broad and inclusive stakeholder engagement,” said current ORWH Director Janine A. Clayton, M.D. “Through her conferences, working groups, and town hall meetings, she established a solid methodology for gleaning information from across disciplines to set this office’s agenda and inform its strategic planning.”

Dr. Pinn, Dr. Clayton, and colleagues outlined the ORWH model of leveraging an “interactive scientific and public partnership . . . in its research agenda setting efforts” in an article published in the Journal of Women’s Health.15 The article articulates how ORWH used Federal Register notices to request public testimony and other input from audiences other than those normally addressed through scientific channels.15 Doing so “helps to ensure that ORWH continues to meet its original mandate and reflects the research needs expressed by both public and scientific communities to strengthen the scientific foundation for improved health and healthcare.”15 These types of outreach efforts contributed to the development of the Agenda for Research on Women’s Health for the 21st Century16 and Moving into the Future with New Dimensions and Strategies for Women’s Health Research: A Vision for 2020 for Women’s Health Research. Published in 2010, A Vision for 2020 set
NIH’s scientific agenda for research on the health of women for the next decade and incorporated input from scientists, advocates, health care providers, Government officials, and the public.

Dr. Pinn retired in 2011, and her tenure saw many changes in the field of women’s health research. Studies of data from this time showed women and men participating equally in many NIH-funded clinical trials. Dr. Pinn’s legacy includes enduring mentoring programs, funding mechanisms, seminal scientific and health policy literature, best-practice guidelines for scientists and health administrators, and a successful office guided by a well-defined mission and priorities to promote research on the health of women and advance women in scientific careers.

2012 to the Present: The Tenure of ORWH Director Janine A. Clayton, M.D.

In 2012, ORWH’s Deputy Director, Dr. Janine A. Clayton, was appointed Director of ORWH and the NIH Associate Director for Research on Women’s Health. Over the past 8 years, Dr. Clayton, a board-certified ophthalmologist and former Deputy Clinical Director of the National Eye Institute (NEI), has continued to build on the foundation laid by Dr. Pinn and others, leading to important advancements for research on the health of women, including the following.

- ORWH established a new funding mechanism for Administrative Supplements for Research on Sex/Gender Influences, enabling NIH grantees opportunities to explore sex and gender more thoroughly within the scope of their original NIH research grants.
- ORWH also developed How Sex/Gender Influence Health & Disease (A-Z), a webpage linking to plain-language scientific resources on the influence of sex and gender on health and disease.
- In 2014, Dr. Clayton and NIH Director Francis Collins, M.D., Ph.D., published an article in Nature calling for greater consideration of SABV in animal and cell studies. The article also announced NIH’s intentions to develop a policy concerning this, which was realized with the publication of Consideration of Sex as a Biological Variable in NIH-funded Research (NOT-OD-15-102). This policy, spearheaded by Dr. Clayton and ORWH, requires NIH-supported investigators to address SABV in preclinical research design and analysis in animal and human studies.
- ORWH established the Research on the Health of Understudied, Underrepresented, and Underreported (U3) Populations program to support interdisciplinary, transdisciplinary, and multidisciplinary research focused on the health effects of sex and gender influences at the intersection of social determinants, such as race, ethnicity, and socioeconomic status. ORWH offers administrative supplement grants for NIH-funded research focusing on NIH-designated populations with health disparities, and it sponsors a webinar series featuring the work of researchers of U3 populations and U3 issues.
- In 2015, Congress passed the 21st Century Cures Act, re-emphasizing ORWH as the focal point in promoting women’s health research across NIH; increasing funding for interdisciplinary, transdisciplinary, and multidisciplinary research; and requiring ICs to explicitly address women’s health and health disparities across the NIH.
- ORWH led a trans-NIH effort with broad stakeholder input to develop and, in early 2019, publish Advancing Science for the Health of Women: The Trans-NIH Strategic Plan for Women’s Health Research. This document articulates NIH’s 5-year (2019–2023) plan to advance women’s health research, improve research methodology, disseminate evidence on women’s health, promote training and develop a robust scientific workforce relevant to the health of women, and improve the evaluation of research on the health of women.
- In May 2019, NIH launched a new Research, Condition, and Disease Categorization (RCDC) Inclusion Statistics Report on the RCDC website, which publicly reports inclusion data by sex and gender, RCDC category, and IC, helping to ensure that women are appropriately included in research across an array of diseases and conditions.

Today, ORWH maintains its support of programs, policies, funding mechanisms,
The 2018 meeting of BIRCWH Scholars and Mentors. Katherine Hartmann, M.D., Ph.D., is pictured third from the left, second row from the back.

training, and events related to sex- and gender-appropriate research. Support of successful programs such as SCORE continues, as does ORWH cofunding through the Administrative Supplements for Research on Sex/Gender Influences mechanism. Informational efforts, programs, and training and outreach resources support NIH’s inclusion and SABV policies, and ORWH has released a series of online training modules on sex and gender and SABV, more of which will soon be available. Led by ORWH, NIH recently announced its first Research Project Grant (R01) that will fund investigator-initiated, disease-agnostic research across scientific disciplines to understand how sex and gender influence health and disease.

ORWH and NIH as a whole continue to support the advancement of women in scientific careers through numerous initiatives, including the Re-Entry into Biomedical Careers Program; the Working Group on Women in Biomedical Careers and its Women of Color (WOC) Committee, which provides online resources and networking through the WOC Research Network (WoCRN) and nominates speakers for the prestigious NIH Director’s Wednesday Afternoon Lecture Series (WALS); anti-harassment initiatives; and the ORWH Pearls of Wisdom series, a collection of video clips featuring scientific dignitaries offering advice on STEMM education and professional development. Dr. Collins and Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) Director Jim Anderson, M.D., Ph.D., have announced their unwillingness to participate in “manels” (i.e., male-dominated panels at professional conferences) and have issued formal public statements to this effect to encourage others to follow their example. (Read Dr. Collins’ statement here.) Currently, 9 Directors of ICs and 13 Deputy Directors are women. Later this year, NASWEM will publish Promising Practices for Addressing the Underrepresentation of Women in Science, Engineering, and Medicine. (See “STEMM Diversity Is Not an Option,” page 9, for more information.) ORWH and the Office of Extramural Research (OER) recently collaborated to develop two notices of special interest (NOT-OD-20-054 and NOT-OD-20-055) to provide early-career researchers with funds and time to address qualifying life events, such as childbirth, thereby promoting career continuity for junior investigators.

Through the BIRCWH program and other efforts, ORWH continues its commitment to support the career development of women’s health researchers in line with the goal of the Trans-NIH Strategic Plan for Women’s Health Research to promote “training and careers to develop a well-trained, diverse, and robust workforce to advance science for the health of women.” Since 2000, BIRCWH has provided funding to over 700 BIRCWH Scholars, men and women who plan to conduct interdisciplinary basic, translational, behavioral, clinical, or health services research relevant to women’s health. The career of Katherine Hartmann, M.D., Ph.D., provides a telling example of the success of the BIRCWH program. As a junior investigator, Dr. Hartmann was accepted as a BIRCWH Scholar. Now an Associate Dean, Professor, and Program Director at Vanderbilt University Medical Center, Dr. Hartmann serves as a BIRCWH Principal Investigator and mentor to junior faculty in the BIRCWH program.

The Future of ORWH. Although progress has been made, ORWH’s mission will remain relevant and necessary for years to come. Expert recommendations made decades ago are still in the process of being fully realized, and the long history of biomedical research focusing on men as the norm has resulted in wide gaps in our knowledge of women’s health that are still being addressed. While women now represent approximately half of the participants in NIH-supported clinical trials, they remain underrepresented in studies of some diseases. Also, Stacie Geller, Ph.D., of the Center for Research on Women and Gender and colleagues recently reported troubling findings that fewer than one-third of NIH-supported Phase III clinical trials publish sex-specific results.20 Inclusion is not enough; only when results are analyzed for sex differences and this analysis is published in the scientific literature can the benefit of inclusion of women in clinical research be fully realized.

Women now outnumber men in U.S. medical schools and many life science graduate programs but continue to be underrepresented in leadership positions in the biomedical professional community. By supporting the next generation of researchers through BIRCWH and other programs, ORWH will help usher in a new generation of women to assume leadership roles and to pursue careers that engender new ideas, new research questions, and new methodologies and fully realize interdisciplinary, transdisciplinary, and multidisciplinary approaches to advance the health of women—and everyone. ORWH will also help women in biomedical fields to have greater opportunities and fewer barriers to career success. This will help to better ensure that women, as well as their families and communities, will receive the full benefit of our national investment in health research and that scientists will be able to reach their full potential to do their best work for the good of all.

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ORWH Deputy Director

Elizabeth Spencer, BSN

A MESSAGE FROM THE ORWH DEPUTY DIRECTOR

STEMM Diversity Is Not an Option:
Promising Practices for Addressing the Underrepresentation of Women in Science, Engineering, and Medicine

ORWH and the National Academies of Sciences, Engineering, and Medicine (NASEM) have enjoyed a long and fruitful partnership. NASEM’s 2007 publication of Beyond Bias and Barriers: Fulfilling the Potential of Women in Academic Science and Engineering, supported by ORWH, made an appreciable contribution toward mitigating gender bias in science, technology, engineering, mathematics, and medicine (STEMM). Preparation of Beyond Bias and Barriers prompted the formation of the NIH Working Group on Women in Biomedical Careers, an influential committee that identifies obstacles hindering women’s successful careers in the sciences and develops strategies to promote the entry, retention, and advancement of women in STEMM fields.

In 2015, ORWH and NASEM sponsored a workshop, “Raising the Bar: Improving the Health of Women in the United States,” examining why American women experience poorer health than women in other high-income countries. A follow-up workshop summary, published in 2016, characterized the national trends affecting American women’s health and identified ways to reverse these health disparities.

In March of last year, NASEM held a Symposium Highlighting Evidence-Based Interventions for Addressing the Underrepresentation of Women in Science, Engineering, and Medicine in Washington, DC. The symposium explored how, though progress has been made, women, particularly women of color, remain underrepresented in STEMM. Building on concepts and findings from Beyond Bias and Barriers and other NASEM publications—as well as NIH’s Causal Factors and Interventions program, NIH’s Women in Biomedical Research: Best Practices for Sustaining Career Success, and other sources—participants identified remaining institutional barriers and discussed evidence-based practices for improving the representation of women in STEMM.

NASEM will soon publish a report on a consensus study associated with last year’s symposium. The forthcoming report, Promising Practices for Addressing the Underrepresentation of Women in Science, Engineering, and Medicine, will explore how women’s participation varies in different STEMM disciplines; identify practices that improve women’s recruitment, retention, and advancement to leadership positions in STEMM; analyze why STEMM organizations have not widely adopted effective interventions; consider the effects of the intersection of racial and gender biases on women of color in STEMM; demonstrate that diversity in the STEMM workforce makes for better science; and recommend actionable solutions to improve the representation of women in specific STEMM fields, particularly in leadership roles.

We look forward to what promises to be a landmark report and ask that you stay tuned to the ORWH and NASEM websites for more details.

References

IN THE JOURNALS

Sleeping with Artificial Light Might Lead to Obesity in Women


Women who sleep while exposed to artificial light at night (ALAN) might be at a significantly higher risk of obesity than women who do not, a recent study by Yong-Moon Park, M.D., Ph.D.; Dale P. Sandler, Ph.D.; and colleagues at the National Institute of Environmental Health Sciences (NIEHS) finds. Their analysis of data from the Sister Study, a longitudinal study of approximately 50,000 women whose sisters had breast cancer, shows that regularly sleeping in the presence of ALAN was associated with weight gain and obesity, even after the researchers adjusted for other factors such as diet and physical activity.

Although previous studies have connected short sleep duration to obesity, the NIEHS study is the first to associate ALAN with weight gain. Study participants reported whether they slept with no ALAN, with a small night-light, with light outside the room, or in a room with a lamp or television on. Researchers compared several measures of obesity (e.g., body mass index and waist-to-hip ratio) at baseline and at follow-up, which occurred 5.7 years (mean) after baseline. Exposure to any ALAN increased the risk of weight gain. In particular, sleeping in a room with a television or light on was positively associated with a weight gain of 5 kilograms (11 pounds) or more.

The mechanism connecting ALAN, sleep disruption, and weight gain remains unclear. Speculations suggest that ALAN and lower sleep duration might cause daytime fatigue resulting in less physical activity, might encourage increased energy intake and decreased energy expenditure, might affect hormone levels associated with appetite regulation, or might initiate other physiological changes that could affect metabolism. ALAN exposure during sleep is associated with multiple related factors, including socioeconomic disadvantage and unhealthy lifestyle behaviors such as unhealthy diet, little physical activity, and poor sleep hygiene.

Given the findings of this research, as well as those from studies of the effects of electronic devices such as smartphones and tablets on sleep, the researchers recommend additional consideration of the health effects of ALAN and “blue light” from screen-based electronics. Limiting exposure to sources of artificial light before bedtime and while sleeping might constitute an effective, no-cost preventive health measure.

NIH Initiatives Expand Our Understanding of Microbiomes and Their Effects on Human Health


Two recent publications highlight NIH’s efforts to deepen the current understanding of human microbiota—the trillions of bacteria, viruses, and fungi that live in close association with the body—and their effects on health and disease.

In a recent issue of Science, Stephan P. Rosshart, M.D., and Barbara Rehermann, M.D., of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and colleagues describe experiments with a mouse model that combines the microbes and pathogens of wild mice with the genetics of lab mice and makes them suitable for research. Compared with traditional lab mice, the new mouse strain provides a better approximation of human responses to drugs targeting innate and adaptive immune responses. In an earlier study, the same researchers transplanted gut microbiota from wild mice into lab mice, a process that improved the animals’ survival rates when challenged with flu virus or colorectal cancer. Building on this research, the investigators transplanted lab-mouse embryos into wild-mouse mothers that gave birth to the new mouse strain, what the researchers call “wildling” mice.
A comparison of wild mice, lab mice, and wildlings showed that wildlings had microbiota comparable to those of wild mice. These microbiota were stable across five generations of wildlings, even after disruptive diet changes and antibiotic treatments. Most importantly, the wildlings, compared with lab mice, better predicted human immune responses to pharmaceutical treatment, indicating that they might offer better translatability from preclinical studies to first-in-human trials. The researchers posit that wildlings or similar mouse strains could improve the safety, reproducibility, and overall success of future immunological studies.

Another NIH microbiome initiative, the Human Microbiome Project (HMP), has supported multiple investigations characterizing human microbiota and provides data to researchers to inform study of human health and disease. A recent article in *Nature* reports on the completion of the second phase of HMP and refers readers to several studies detailing the interactions between host and microbiome that occur with inflammatory bowel diseases, during pregnancy, and in prediabetic states. The article reviews the Inflammatory Bowel Disease Multi’omics Database project, which collected microbiome data related to Crohn’s disease and ulcerative colitis; the Multi-Omic Microbiome Study–Pregnancy Initiative, which characterized the relationship between the maternal microbiome and preterm birth; and the Integrated Personal Omics Profile, which collected microbiome data from prediabetic individuals and healthy controls. Throughout the two phases of the project, HMP studies have generated 42 terabytes of data on human microbiomes, all of which are available to researchers to inform future investigations.

These and other investigations have demonstrated the crucial roles that microbiomes play in human health. These fundamental research studies will most likely serve as the foundation of future biomedical advancements that are especially relevant to women’s health, given the critical process of microbiome transmission from mother to child and the pervasive effects of host sex on microbiome structure and function. You can read more about the effects of the microbiome on women’s health in the feature story of the *Summer 2018 Issue of In Focus*.

**Studies Link Pregnancy Outcomes to Risk of Future Cardiovascular Disease**


Two recent articles refine the current understanding of the connection between adverse pregnancy outcomes (APOs), such as preeclampsia and preterm birth, and later-life cardiovascular disease (CVD), the most common cause of death in women worldwide.

David M. Haas, M.D., and colleagues of the *nuMoM2b* (Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-Be) Heart Health Study analyzed data from 4,484 women during their first pregnancy and 2–7 years thereafter. The analysis showed that 22.7% of study participants experienced APOs, including preterm births, stillbirths, small-for-gestational-age births, and hypertensive disorders of pregnancy. Among study participants without baseline hypertension, women with APOs had almost twice the incidence of hypertension at follow-up than women without APOs (31% and 17%, respectively). Women with multiple APOs were at even greater risk, particularly women who both experienced hypertension during pregnancy and delivered preterm. Some study participants experiencing APOs developed high blood pressure within 3 years of giving birth. Although the association of preeclampsia and later-life CVD has been well-established, this 3-year period before onset of APO-related hypertension is shorter than previously expected. [The nuMoM2b Heart Health Study is funded by the National Heart, Lung, and Blood Institute (NHLBI) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), with additional support provided by ORWH.]

A review of scientific literature by Pensee Wu, M.D., and colleagues further illuminates the relationship between APOs and increased risk of future CVD. The authors summarize evidence that preeclampsia is linked to a 2-fold increased risk of stroke, coronary heart disease (CHD), and mortality caused by CHD or CVD, as well as a 4-fold increased risk of heart failure. Preterm births are associated with a 1.4- to 1.7-fold increase in the future risk of many cardiovascular events (including cardiovascular death), CHD, death from CHD, and stroke. Gestational diabetes mellitus is associated with an increased (as high as 1.9-fold in some studies) risk of future hypertension and other CVDs. Women who delivered small-for-gestational-age infants are at a 1.6- to 3-fold higher risk for CVD and a 2-fold higher risk for CHD. Women with a history of miscarriage have a 45% higher risk of CHD, and this risk increases in women who have had multiple miscarriages.

Both teams of investigators emphasize the need for health care providers to understand fully the medical histories of women, including any APOs, to assess more accurately patients’ risks of CVD and other health complications later in life in order to recommend preventive interventions and facilitate early diagnosis of those complications.
Gender Bias Continues to Affect Women in the Sciences


In a recent article in *Microbiology and Molecular Biology Reviews*, NIH-supported researcher Rachel L. Roper, Ph.D., provides an overview of current research on the impact of gender bias on women in professional scientific positions. She reports that some progress has occurred: The percentage of women in such positions has increased, and universities, corporations, and organizations such as NIH and the National Science Foundation (NSF) have implemented effective programs and policies to increase diversity, equity, and the recruitment and retention of women in the sciences. However, since 2005, though more women have graduated with Ph.D.s in life sciences than men, women continue to represent a minority of the scientific workforce and to receive fewer grants from leading funding organizations.

Recent studies demonstrate that gender biases persist in the sciences and pervade all stages of the scientific career track, from early, secondary, and higher education to hiring, promotion, publication, and professional prestige. Dr. Roper also describes research on the continuing problem of sexual harassment in the scientific workplace, a leading cause of women leaving scientific careers, and outlines initiatives by NIH, NSF, the National Academy of Sciences, and the American Association for the Advancement of Science aimed at mitigating the problem.

The article concludes with evidence-based recommendations for countering gender bias in the sciences. As studies show that effective instructional programs can promote gender equity, Dr. Roper advocates for the implementation of formal training courses and other awareness initiatives to counter unconscious or implicit biases pertaining to evaluation of student and professional performance, mentoring, hiring, funding, and other areas of professional development.

Dr. Roper calls for additional research to monitor progress in this area and to initiate new inquiries into gender bias in institutional review boards. She posits that collection and analysis of departmental data against national faculty gender data could improve equity by identifying those institutions that lag behind the national average in terms of the proportion of women on their faculties and that should address inequities in their practices and culture. The article also recommends equitable practices for scoring candidates for jobs and promotions, setting up faculty search and review committees, writing job announcements and letters of recommendation, allocating start-up funds, and mentoring.

Study Links Gender of Medical School Research Leadership to Research Grant Portfolios


Women remain underrepresented in research leadership roles in medical schools, and the relatively few leadership positions held by women tend to involve education- and community-based research rather than basic and clinical research. A recent study by Nina F. Schor, M.D., Ph.D., Deputy Director of the National Institute of Neurological Disorders and Stroke (NINDS), found that the grant portfolios of medical schools with women serving as deans of research were heavily weighted toward areas of inquiry traditionally associated with women researchers.

Dr. Schor analyzed the funding portfolios of 15 comparably ranked medical schools—five with women research deans, five with men research deans, and five that did not list a research dean on their websites. Funding for training, community-based research, and core facilities dominated the portfolios of schools with research deans who were women.
(60 ± 10% of the portfolio), whereas basic and clinical research grants dominated the portfolios of other schools (76 ± 8% of the portfolio).

Limiting analysis to funding for neuroscience research—currently a predominantly male field—Dr. Schor found that percentages of neuroscience funding did not differ between men-led research programs and women-led research programs. However, within the neuroscience category, portfolios of research programs led by women had a higher percentage of grants related to education, mentoring, community-based research, and facilities projects than those of programs led by men (26 ± 11% versus 4 ± 2%, respectively). Consistent with these results, Dr. Schor found that when turnover resulted in a transition from a man to a woman research dean, a corresponding shift in the research funding portfolio occurred, with increased emphasis on education, mentoring, community-based research, and facilities and a decreased percentage of funding for basic and clinical research. Transitions involving deans of medical schools, as opposed to deans of research, resulted in similar but subtler changes in research portfolio distribution.

As medical school research programs led by women—both overall and within the field of neuroscience—continue to have disproportionately high percentages of funding for education, mentoring, community-based research, and facilities projects, forthcoming findings from ongoing studies on this topic might inform future equity-based initiatives to effect change in research funding.

**Scientist Spotlight**

Karen Berman, M.D., of the National Institute of Mental Health (NIMH) conducts translational investigations, using multimodal neuroimaging to bridge the gap between neurogenetic, molecular, cellular, and system-level mechanisms in neurodevelopment and in neuropsychiatric disorders. She earned her M.D. from St. Louis University; did residencies at Washington University in St. Louis and at the University of California, San Diego; and is board-certified in both psychiatry and nuclear medicine. She is an elected member of the National Academy of Medicine. Dr. Berman recently talked about her research on the genetic underpinnings of Williams syndrome in the Anita B. Roberts Lecture Series, “Distinguished Women Scientists” at NIH.

**What are some of the challenges you have faced as a woman in science?**

When I was going through undergraduate school, people said, “You’re a woman. You shouldn’t be a doctor.” That made me want to do it more. There were very few women in my class at medical school. When I came to NIH, there were very few senior women here and not that many junior women either. The climate is different now. More than 50% of the students in medical school are women, which is very inspiring.

**Please explain your research on Williams syndrome, the topic of your Anita B. Roberts Lecture.**

I was extremely honored to do the Anita B. Roberts Lecture. Dr. Roberts was one of the first women to serve as a role model and leader at NIH, and she inspired many young women. Williams syndrome stems from a known genetic problem in which several genes are hemi-deleted on chromosome 7, which means there is only one copy of these genes instead of the expected two. These genes have a clear effect on complex human behavior, particularly social function. People with Williams syndrome tend to be hypersocial, with outgoing personalities driving them to interact with others. Those with Williams syndrome also have difficulties with visual-spatial tasks and might have cardiovascular problems and other symptoms. For me as a brain imager, this rare developmental disorder presented an amazing opportunity to use our armamentarium of neuroimaging methods to study how genes work through the brain to produce complex human behavior.

**What are some challenges that women scientists continue to face today?**

A lot of it is subtle. For example, there’s considerable literature that shows that the words used in professional settings can convey biases. Letters of recommendation, for instance, might praise a woman for being a “team player” rather than a “leader” or a “discoverer.” In meetings, women often need to make their points more than once. Some of it is not so subtle. Also, while some men contribute to child-rearing and household chores—and my husband was particularly wonderful and did at least half—a lot of this work still falls to women, which can create professional challenges. Now, there are mechanisms for parental leave and for women in tenure-track positions to “stop the clock” for childbirth and other family responsibilities. These programs are excellent. However, science is a harsh task mistress, and difficulties balancing work and home life continue to present challenges for many women.
AAMC Explores Why Many Women Physicians Leave Medicine

A recent article published by the Association of American Medical Colleges (AAMC) explores why nearly 40% of women physicians either leave medicine or switch to part-time practice within 6 years of completing their residencies. Research shows that although salary inequity, gender bias, and harassment play roles, family responsibilities and child care are the primary reasons for this mass departure. Other findings within the medical field show that women take home more work than men, that married men with children work 7 hours a week more than women with children but spend 12 fewer hours a week on parenting and domestic tasks, and that one in three physician-mothers has experienced discrimination related to pregnancy or breastfeeding. Other issues leading to women’s departure from medicine include limited opportunities for advancement and restrictive parental leave policies, as well as the difficult, lengthy, and expensive process of recredentialing and re-entering medical practice after taking years off to raise young children. Some medical centers have begun to address these problems by increasing family leave, providing on-site child care, offering monetary awards for dependent care, and creating more opportunities for tenure and promotion.

Forbes’ List of Best Employers for Women Includes Organizations Recognized by NIH and NSF

On July 2, 2019, Forbes magazine and its market research partner Statista released a list of U.S. companies and organizations liked most by women employees. This list is the result of a survey of 40,000 American women and 20,000 American men working for companies with at least 1,000 employees. Estée Lauder, Ulta Beauty, and the University of Utah earned the top three spots. Several of the academic institutions on the list have received grants through the NIH Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering, including Cornell and Harvard universities. Other academic institutions on the list have received National Science Foundation (NSF) ADVANCE Awards, including Virginia Commonwealth University, Ohio State University, and Cornell.

ORWH Director Speaks at National Health Research Forum

On September 5, 2019, ORWH Director Janine A. Clayton, M.D.—along with an all-woman lineup of leaders from Government, academic, patient advocacy, industrial, and nonprofit organizations—participated in a panel discussion titled “Women Researchers Leading Discovery” at the 2019 National Health Research Forum. This annual meeting, convened by the Research!America organization, explores trends in health initiatives, research, policy, and related issues. Dr. Clayton and her fellow panelists discussed work–life integration, the value of networking for women researchers, “team science,” and the development of validated measures of workplace culture. You can read more about this meeting and watch a video of the closing remarks by then–Acting U.S. Food and Drug Administration Commissioner Norman “Ned” Sharpless, M.D., here.

GAO Report Encourages Colleges to Inform Student-Parents About Financial Aid

A report from the Government Accountability Office (GAO) shows that U.S. colleges and universities could provide more information on Federal financial assistance programs to the 22% of undergraduate students who are struggling to raise children while pursuing their studies. The report and a National Public Radio (NPR) story on its findings explain that, of these undergraduate student-parents, a disproportionate number of whom are women and people of color, fewer than half will complete their degrees. Many student-parents remain unaware of Federal programs that could help pay for child care, and the GAO report encourages colleges to do more to inform student-parents of these financial aid programs. Students can take the initiative by applying for a “dependent care allowance” through their college’s financial aid office or bursar.

South African Scientists Honored

South African Minister of Higher Education, Science, and Technology Blade Nzimande, Ph.D., hosted the 15th annual South African Women in Science Awards (SAWiSA) on August 15, 2019. These awards recognize noteworthy research by South African women scientists and profile them as role models for aspiring students and young women. The theme of this year’s awards presentation was “Making the Fourth Industrial Revolution Work for Women.” Among this year’s honorees were Michèle Ramsay, Ph.D., of the University of Witwatersrand, and Lunic Base Khoza, Ph.D., of the University of Venda. A complete list of the winners is available here.
ORWH Begins Release of E-Learning Courses on Sex and Gender

A new section of the ORWH website features free online courses designed to give users a thorough and up-to-date understanding of sex and gender influences on health and disease and NIH requirements on factoring sex as a biological variable (SABV) into research design. Learners will be able to apply this knowledge of sex and gender influences when designing and conducting research or interpreting evidence for clinical practice. Course material showcases examples from basic science through clinical trials and translation into practice to ensure learners understand the importance of considering the influence of sex and gender throughout the research spectrum and beyond. The first course, *Bench to Bedside: Integrating Sex and Gender to Improve Human Health*, was developed in partnership with the U.S. Food and Drug Administration (FDA) Office of Women’s Health (OWH) and is now available. A second course, *Sex as a Biological Variable: A Primer*, will be added soon. The courses are open to the public, and registration is free. Read more [here](#).

Science Journalist Angela Saini Lectures on How Race and Gender Influence Science

On October 31, 2019, Angela Saini gave a lecture titled “Gender, Race, and Power in Science” on the NIH main campus. Saini is an award-winning science journalist, a presenter on BBC Radio, and the author of three books—*Geek Nation: How Indian Science Is Taking Over the World*, *Inferior: How Science Got Women Wrong and the New Research That’s Rewriting the Story,* and *Superior: The Return of Race Science*. Ms. Saini spoke about how prejudice has affected science research and writing and how researchers must be careful not to conflate social, gender, and racial disparities with biological differences. She stated that scientists “have an immense amount of power in terms of, not just medicine and how we’re treated, but also how we think about ourselves and how we structure our ideas about who we are ... political agendas, funding agendas, personal bias, and prejudice can affect what scientists tell us and can sometimes collide with their desire to get to the truth.” A video of her lecture is available [here](#).

Kuwaiti Scientists and Educators Meet with NASEM and NIH to Improve Women’s Representation in the Sciences

On October 28 and 29, 2019, scientists and educators from Kuwait and other nations visited the National Academies of Sciences, Engineering, and Medicine (NASEM) in Washington, DC, for a workshop titled “Promising Practices for Improving the Inclusion of Women in Science, Engineering, and Medicine: Lessons from Kuwait and the United States.” Some of the visitors also attended the public release event for *The Science of Effective Mentorship in STEMM*, a report from NASEM. On October 29, workshop attendees convened at the ORWH office with NIH staff to discuss strategies for successful career development in the sciences, the BIRCWH program, the NIH Re-Entry into Biomedical Research Careers program, SEA Change, the NIH Maximizing Opportunities for Scientific and Academic Independent Careers (MOASIC) award, and other topics related to women’s health research and careers in biomedicine. The visitors represented the Kuwait Foundation for the Advancement of Sciences, Kuwait University, the Kuwait Institute for Scientific Research, the Kuwait Oil Company, the Public Authority for Applied Education and Training (Kuwait), the FAWSEC Educational Company (Kuwait), the King Abdulaziz City for Science and Technology (Saudi Arabia), the Zewail City of Science and Technology (Egypt), and the American University of Beirut. ORWH Deputy Director Elizabeth Spencer said, “Participants left the meeting feeling energized. Many stated that it was an invaluable opportunity for a scientific, intellectual, and cultural exchange.”

WOC Committee Nominates Speakers for NIH WALS Lecture Series

The Women of Color (WOC) Committee, part of the NIH Working Group on Women in Biomedical Careers, regularly nominates and hosts scientists for the NIH Director’s Wednesday Afternoon Lecture Series (WALS), a high-profile program showcasing distinguished leading scientists. On December 18, 2019, the WOC Committee hosted WALS lecturer Melody Goodman, Ph.D., who spoke on the social risk factors that contribute to health disparities in urban areas. On January 9, Gilda Barabino, Ph.D., spoke on the character of cells and the role of biomechanics. A full list of recent and upcoming WALS lectures is available [here](#).

ORWH Hosts Webinar on Incarceration, HIV, and Women

Kim Blankenship, Ph.D., Professor of Sociology at American University, delivered a presentation and ORWH-sponsored webinar titled “Mass Incarceration, Housing, and HIV/STI Risk: Focusing Attention on Women” on September 12, 2019. This presentation, part of the Understudied, Underrepresented, and Underreported (U3) Women Lecture Series, focused on how mass incarceration produces and maintains racial, class, and gender inequalities and, as such, represents an important social determinant of health, particularly in increasing women’s risk of acquiring sexually transmitted infections (STIs) such as HIV. More information on the webinar is available [here](#).
ORWH Website Features a Reading Room for Articles on Sex and Gender

To promote understanding and awareness of the NIH Policy on Sex as a Biological Variable, the ORWH website features a reading room webpage with links to news and journal articles on the study of sex and gender in the sciences. Visit the reading room here.

FUNDING OPPORTUNITIES

NIH Updates Extension Policy for Eligibility Window for Pathway to Independence Awards (K99/R00)

The NIH Pathway to Independence Awards (K99/R00) help outstanding postdoctoral researchers complete mentored training and transition in a timely manner to independent, tenure-track, or equivalent faculty positions. NIH recently announced NOT-OD-20-011, an update to the extension policy on the eligibility window in which Principal Investigators may apply for a K99/R00 Pathway to Independence Award. Applicants for the K99 awards that fall under this new extension policy must have no more than 4 years of postdoctoral research experience at the time of the initial (new) or subsequent resubmission application. NIH considers requests for extension of the K99 eligibility window for various reasons, including medical concerns, disability, family care, extended periods of clinical training, natural disasters, and active-duty military service. These requests are reviewed on a case-by-case basis. Consistent with the NIH Extension Policy for Early Stage Investigator Status (ESI), NIH will approve an extension of 1 year for childbirth within the 4-year K99 eligibility window. More information, including instructions for submitting a request, is available here.

NIH Offers Its First Investigator-Initiated R01 on Sex and Gender

NIH has released a funding opportunity announcement (FOA) titled The Intersection of Sex and Gender Influences on Health and Disease for Research Project Grant (R01) applications. The FOA encourages research across many scientific disciplines. Proposed investigations must include both sex- and gender-related variables and also address at least one of the five objectives from Strategic Goal 1 of the 2019–2023 Trans-NIH Strategic Plan for Women’s Health Research, which is to advance rigorous research that is relevant to the health of women. As NIH’s first investigator-initiated R01 on sex and gender, this FOA represents a milestone achievement and reaffirms NIH’s commitment to considering sex and gender influences in research and to the mission of ORWH. Future application due dates for this R01 are November 25, 2020, and November 26, 2021. Additional information on this important funding opportunity is available here.