56th Meeting of the National Institutes of Health (NIH) Advisory Committee on Research on Women's Health (ACRWH) Office of Research on Women's Health (ORWH) Bethesda, MD April 6, 2022

Members Present
Garnet L. Anderson, Ph.D.
Irene Aninye, Ph.D.
Amanda Bruegl, M.D.
Roger B. Fillingim, Ph.D.
Stacie Geller, Ph.D.
Reshma Jagsi, M.D., D.Phil.
Sabra Klein, Ph.D.
Ana Langer, M.D.
Alyson J. McGregor, M.D.
Judy Regensteiner, Ph.D.
Elena Rios, M.D.
Michelle Robinson, D.M.D.
Yoel Sadovsky, M.D.
Neel Shah, M.D., M.P.P.
Melissa Simon, M.D.
Kimberly J. Templeton, M.D.

ORWH Leadership Present
Janine Clayton, M.D., FARVO, Director
Samia Noursi, Ph.D., Associate Director, Science Policy, Planning, and Analysis
Sarah Temkin, M.D., Associate Director, Clinical Research

Other NIH Leadership Present
Gary H. Gibbons, M.D., Director, National Heart, Lung, and Blood Institute (NHLBI)
Karen Parker, Ph.D., M.S.W., Director, Sexual and Gender Minority Research Office

Call to Order
Samia Noursi, Ph.D., ACRWH Executive Secretary and ORWH Associate Director, Science Policy, Planning and Analysis, called the online meeting to order at 9:30 a.m. She introduced new ACRWH member Garnet L. Anderson, Ph.D., Fred Hutchinson Cancer Research Center; Irene Aninye, Ph.D., Society for Women's Health Research; and Amanda Bruegl, M.D., Oregon Health & Science University. She thanked the following retiring ACRWH members for their service: Roger B. Fillingim, Ph.D., Stacie Geller, Ph.D., Ana Langer, M.D., Margaret McCarthy, Ph.D., and Elena Rios, M.D. Committee members introduced themselves and approved the minutes of the 55th ACRWH meeting held on October 21, 2021.

Dr. Noursi reported on the closure of all five recommendations, as of December 2021, in the Government Accountability Office (GAO) report titled "Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research (GAO 16–13). The final recommendation was addressed in the "National Institutes of Health--Report on the Advisory Committee on Research on Women's Health: Fiscal Years 2019-2020" (Biennial Report).

ORWH Director's Report
Dr. Noursi introduced Janine A. Clayton, M.D., FARVO, Director, ORWH. Dr. Clayton started by announcing with sadness the death of Rebecca DelCarmen-Wiggins, Ph.D., Health Scientist Administrator/Research Program Officer, ORWH, in December 2021.

Dr. Clayton delivered the Director's Report:

Sleep Matters: New Science and New Strategy. Poor sleep is related to many other health issues, including high blood pressure, heart disease, depression, diabetes, and obesity. On average, women report more sleep-related disturbances and take more sleep aids than men. Under the leadership of Marishka K. Brown, Ph.D., Director, National Center on Sleep Disorder Research, NHLBI, there is a new NIH sleep research plan that targets sex differences in sleep and sets high priority research areas, including studying sleep/circadian mechanisms that underlie health and disease; improving treatments; understanding sleep's role in health disparities, including women's; and developing a diverse workforce in sleep research. The plan incorporates crosscutting NIH priorities that address minority health and health disparities, as well as sex as a biological variable (SABV) and inclusion across the lifespan.

NIH and ORWH UPDATES: Leadership changes at NIH include the appointment of Lawrence A. Tabak, D.D.S., Ph.D., as Acting Director; Tara A. Schwetz, Ph.D., as Acting Principal Deputy Director; and Courtney Ferrell Aklin, Ph.D., as Acting NIH Associate Deputy Director. Currently at NIH, there are now 11 women Institute/Center (IC) directors. NIH most recently welcomed Jennifer Webster-Cyriaque, DDS, Ph.D., Deputy Director, National Institute of Dental and Craniofacial Research (NIDCR).

Global Health 5050 Toward Gender Equality in Global Health ranked NIH as one of just 37 high performing organizations, putting it in the top 30 percent of all organizations. GH5050 based its ranking on an assessment of gender-related policies, practices and outcomes of the 200 leading organizations active in global health, examining whether and how organizations are addressing inequality of opportunity in career pathways inside organizations as well as inequality in who benefits from the global health system.

The "Report of the Advisory Committee on Research on Women's Health" for Fiscal Years 2019–2020 (Biennial Report) was available online in January. It describes NIH-wide programs and accomplishments in support of ORWH's core mission over the two-year period. The report includes sections that highlight NIH-supported research on women's health and on the influence of sex and gender on health and disease; detail monitoring of adherence to the NIH policy on inclusion of women and racial and ethnic minorities as subjects in clinical research; and present NIH spending on research on women's health for FY 2019, including data from FY 2017–2018 for comparison purposes. The 2019-2020 edition includes a new section titled "NIH Workforce and Grantees" that has two subsections: The NIH Workforce section provides information on roles, programs, and occupations of women in the NIH workforce for FY 2019–2020; and the NIH Grantees section provides information on NIH grant funding by sex and/or gender, race, and ethnicity for FY 2016–2020. The hope is that these sections help identify areas for improving parity and diversity, and track changes in the demographics of the NIH workforce and grantees.

Among the key findings in the Biennial Report:

- More females than males held scientific occupations within the Extramural Program, while more males than females held such positions in the Intramural Program.
- Among grantees, the percentages of women awardees were consistently below those of men for most award mechanisms between FY 2016-FY 2020; however, women are now receiving more research career awards (e.g., K) than men. Research center grants had the largest increase in the proportion of women awardees, from 23 percent in FY 2016 to 29 percent in FY 2020. There was only a 3-percentage point increase, from 32 percent in FY 2016 to 35 percent in FY 2020, for Research Project Grants (RPGs). Awards to women ranged between 19 percent and 22 percent for Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) awards over the 5 years.

- Success rates among women in R01 equivalent research is lower than among men; success rates among women from underrepresented rates was lower than for women in general. Black female investigators saw the lowest success rates among all females from underrepresented racial and ethnic groups, ranging from 12.0 percent to 18.1 percent in FY 2019 and FY 2020, respectively. Among Asian female investigators, success rates varied, from 19.0 percent in FY 2016 to a peak of 21.3 percent in 2019 and back to 19.2 percent in FY 2020. Hispanic female investigators' success rate was 4.2 percentage points below that of all female investigators in FY 2016 at 15.3 percent and 1 percentage point below that of all female investigators in FY 2020 at 21.1 percent.

There is a new article, "Research on Women's Health: Ready for the Future" in the *Journal of Women's Health* (DOI: 10.1089/jwh.2022.0014) to mark the 30th anniversary of ORWH. Written by ORWH staff members, the article summarizes ORWH's formation and role within NIH; describes its mission and signature programs; identifies paradigm shifts in the field such as a lifespan focus, multidimensional framework, and NIH's inclusion and Sex as a Biological Variable (SABV) policies; and highlights career programs, progress and barriers relating to women's advancement in biomedical careers.

Dr. Clayton reported on three key inclusion-related reports. As noted previously, the GAO report on inclusion is now closed with the final recommendation addressed in the new Biennial Report. "Measuring Sex, Gender Identity, and Sexual Orientation" is now available from the National Academies of Science, Engineering, and Medicine (NASEM). Requested by Congress and funded by ORWH, this report addresses sex and gender terminology. Finally, NIH's Equator Network study is a review of integration of sex and gender concepts in published research reporting guidelines. Of 407 guidelines, 57.7 percent mentioned at least one sex- and gender-related word; 13.8 percent mentioned "sex" and 11 percent "gender."

Scientific Collaborations. The NIH-wide Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative seeks to prevent maternal deaths, reduce maternal morbidity, and promote health equity before, during, after pregnancy. It focuses on biological, behavioral, sociocultural, and structural factors contributing to maternal mortality and morbidity; cardiovascular disease (CVD), infection, immunity, and contributing health conditions such as COVID-19, mental health, substance use disorders, diabetes, obesity; and geographical disparities and SDoH, including education, racism, and socioeconomic status. Since FY 2020, the NIH Office of Director and 12 ICs contributed more than $20.7 million supporting 58 awards. Recipients include 43 institutions across 21 states. ORWH co-funded Administrative Supplements (NOT-OD-21-071) in FY 2021 for $13.4 million, addressing Inequities in birth outcomes (*Eunice Kennedy Shriver* National Institute of Child Health and Human Development, [NICHD]); opioid use disorder (National Institute on Drug Abuse [NIDA); COVID-19 (NHLBI); and COVID-19 and racial discrimination (National Institute of Mental Health [NIMH]). Twenty-two awards in 20 states were made. It also co-funded Administrative Supplements (NOT-OD-20-104) in FY 2020 for $7.3 million, addressing wellness and prevention services with eight ICOs that made 36 awards in 10 states. Among the initiatives funded under this supplement program is Navigating Wellness, a digital tool for librarians and library patrons that will enhance the accessibility of up-to-date and tailored preventive screening and wellness information to underserved populations.

A new collaboration between ORWH and the National Institute of General Medical Sciences (NIGMS) focused on studying women's health through the Institutional Development Award (IDeA) Program, which supported 13 awards on MMM in FY 2020. The IDeA Program is congressionally mandated and administered by NIGMS, with the goal of building research capacity in states that historically have had low levels of NIH funding (23 states and Puerto Rico). Under a Notice of Special Interest (NOSI),

Supporting Research through the Centers of Biomedical Research Excellence (COBRE) Phase I Program (NOT-GM-21-056), two administrative supplements have funded 34 grants totaling $9 million in 18 IDeA States; ORWH co-funded 8 of these awards. These awards address multiple topics, including maternal obesity. Dr. Clayton highlighted two of these awards, one to Marshall University to study the risk of maternal morbidity in pregnant women with obesity-associated metabolic syndrome and substance use disorder, and one to Louisiana State University to address whether weight loss in early pregnancy can alter genetic programming and attenuate the risk for adult onset cardiometabolic disease in female offspring.

This year marks the fifth anniversary of the Understudied, Underrepresented and Underreported (U3) Program which began in FY 2017. ORWH is celebrating this milestone by expanding content about the U3 program on the ORWH website. The new pages will speak to the concept of U3 as a framework for approaching health disparities research and highlight all past and current U3 projects, as well as featured investigators. The pages will also serve as the home of the U3 webinar recordings, including new installments in the "Diverse Voices: Intersectionality and the Health of Women" series.

Addressing maternal morbidity and mortality (MMM) is an ORWH priority. To that end, the NIH Pathways to Prevention Program is planning an "Identifying Risks and Interventions to Optimize Postpartum Health" Workshop in November 2022. Current U.S. Centers for Disease Control and Prevention (CDC) estimates are that 60 percent of pregnancy-related deaths are preventable, regardless of when they occur. The questions that will guide the Workshop and a systematic evidence review from the Agency for Healthcare Research and Quality (AHRQ) are: 1) At birthing person's entry into prenatal care, what combinations of risk indicators have greatest effect on poor postpartum outcomes? 2) Do these predictors vary by race/ethnicity? And 3) Same questions, but at immediately before or after delivery and before release from care? The outcome of the Workshop will be a report by an independent panel that identifies research gaps and makes recommendations for advancing the field.

New in Sex and Gender. ORWH's Sex and Gender R01 program demonstrates innovation and the advantages of interdisciplinary research approaches. Dr. Clayton highlighted research by early-stage investigator Julia Fridman Simard, Sc.D. at the Stanford University School of Medicine, who is focusing on the problem that over-reliance on the evidence base and potential implicit bias may perpetuate diagnostic delay and poorer management for certain patients.

Hypertension (HTN) has a disproportionate impact on African American women. More than half of Black women over 20 have HTN and nearly 50 percent have heart disease. They are twice as likely to have a stroke as compared to non-Hispanic White women. The COVID-19 pandemic has been linked to increases in blood pressure, especially among women, which may be due to the pandemic's disproportionate impact on women related to childcare, finances, and children's remote learning.

In March 2022, NIH issued a Request for Information (RFI) seeking input on the intersection of the COVID-19 pandemic, long COVID, and women's health. Clinical outcomes of COVID-19 present sex differences in immune response, and sex disparities appear to vary in relation to behaviors, health status, jobs, and other social identifiers. Therefore, the RFI seeks comments on research gaps and opportunities specific to the health consequences of COVID-19 and long COVID at the intersection of women's health concerns, such as sex and gender differences, reproductive health issues, domestic violence or intimate partner violence, and diseases such as cancer, CVD, obesity, mental health conditions, substance use disorders. The response date is May 6, 2022.

In 2019, only about 40 percent U.S. women who gave birth had good heart health prior to pregnancy, with excess weight being the major driver. There were geographic differences in pre-pregnancy heart health across the nation: The South (38.2 percent) and the Midwest (38.8 percent) were less healthy than the West (42.2 percent) and the Northeast (43.6 percent). There was also an inverse correlation between the state-level percentage of favorable cardiometabolic health and the state-level percentage of high school education or less and Medicaid enrollment.

Researchers examining data from the Nurses' Health Study II between 2008-2015 found that sexual assault and harassment is linked with high blood pressure in women. Almost one-quarter (23 percent) of women in the study said they experienced sexual assault, 12 percent reported workplace sexual harassment, and about 6 percent experienced both. Over one in five (21 percent) of the women reported developing high blood pressure over the follow-up period; those who experienced both sexual assault and workplace sexual harassment had the highest risk.

SABV Policy Assessment. Assessment is key to SABV implementation. ORWH has developed SABV resources for NIH staff, award applicants, and editors, such as the SABV Primer. A landscape analysis of NIH R01, R21, and R03 applications and summary statements for vertebrate animal studies between 2011 and 2021, five years before and after the SABV policy went into effect in 2016, was conducted. The analysis considered the use of key terms (e.g., "male," "female," and "sex differences," among other relevant terms) in these documents. It revealed a significant increase in SABV-relevant keyword usage from around 50 percent in 2015 to a plateau of 90 percent through 2021 in the applications and from 14 percent in 2015 to a plateau of around 70 percent through 2021. Thus, SABV represents a seminal change in research and medicine.

ORWH e-Learning Resources*.* ORWH has developed e-learning tools that now have global reach, educating individuals in many roles across 48 countries. These resources include the Bench to Bedside course that offers free continuing medical education (CME) credits, and, more recently, the 6-module SABV Train the Trainer course. Over 1,600 registrants have signed up for these e-learning opportunities; 58 percent are researchers and 32 percent students. Participants include both professors and clinicians.

ORWH has observed growing global interest in sex and gender issues. For example, Dr. Clayton provided testimony to the United Kingdom (UK) House of Commons' Science and Technology Committee on December 1, 2021, about the effects of gender and sex bias on reproducibility. She also participated in a King's Fund podcast on March 7, 2022, about why women struggle to get clinicians to listen to them and the consequent impact on diagnosis, treatment, and mental and physical effects on women. The Medical Research Council, part of the UK government's United Kingdom Research and Innovation, has adopted an SABV policy that will require sex to be specified in design of grant applications involving animals, as well as human and animal tissues and cells. Horizon Europe has also issued guidance on sex gender plans.

Careers. Dr. Clayton co-authored an article in *Nature Communications* titled "Community Voices: NIH Working toward Inclusive Excellence by Promoting and Supporting Women in Science" (March 25, 2022). The article cited American Association of Medical Colleges (AAMC) reports that while women in the United States received nearly half of medical school degrees, they accounted for only 18 percent of key leadership positions, such as department chair or dean. At a recent NASEM workshop, it was noted that women of color, in particular, are dramatically underrepresented across all career stages (13 percent of medical faculty) with little improvement over the past ten years. To achieve inclusive excellence, there is a need for demonstrable leadership, action-oriented accountability, research

interventions/best practices, enhanced flexibility options to meet women's needs, and a culture of inclusion.

The NIH UNITE Initiative is working to end structural racism across the research ecosystem. Dr. Clayton serves on the Transformative Health Disparities Research Working Group of the Common Fund which developed "Transformative Research to Address Health Disparities and Advance Health Equity at Minority Serving Institutions" (RFA-RM-22-001). The Community Partnerships to Advance Science for Society (ComPASS) FY 2023 concept has been cleared by the Council of Councils. The goal of this cross-IC initiative is to catalyze, deploy, and evaluate community-driven health equity structural interventions that leverage multisector partnerships to reduce health disparities.

FY 21 Research Programs Funding. ORWH's total budget increased from $45.46 million in FY 2020 to $51.48 million in FY 2021 (difference = $6.02 million). Of this amount, $35,514,780 is allocated for extramural awards, excluding contract R&D, intra-agency agreements (IAA), and Loan Repayment awards. Funding by program included Specialized Centers of Research Excellence (SCORE), $11,026,106; Building Interdisciplinary Research Careers in Women's Health (BIRCWH), $8,556,235; other IC co-funds, $7,204,278; U3 Administrative Supplements, $2,666,811; career programs (excluding Loan Repayment and Office of Intramural Training and Education), $2,648,041; Sex/Gender R01: $1,830,047; and Sex/Gender Administrative Supplements, $1,583,262.

ORWH's total investment in career programs in FY 2021 was $11,550,610. This included BIRCWH, Administrative Supplement Continuity for K ($430,901), Administrative Supplement Continuity for R ($566,155), K12 Women's Reproductive Health Research (WRHR) ($300,000), Loan Repayment ($346,334), Re-Entry Supplement ($276,320), and other career awards ($1,064,774).

In FY 2021, NICHD received the largest amount of co-funding from ORWH (total=$10,035,393). This included $8,116,235 for BIRCWH awards that NICHD administers. The National Institute on Aging (NIA) ranked second, mostly due to $4,765,779 in SCORE awards. In FY 2021, some ICs contributed their own funds to BIRCWH, including NICHD, $270,001; NIDA, $99,656; the National Cancer Institute (NCI), $100,000; the National Institute on Alcohol Abuse and Alcoholism (NIAAA), $100,000; and the National Institute of Allergy and Infectious Diseases (NIAID), $375,000.

Upcoming Events. The Sixth Annual Vivian W. Pinn Symposium will be held virtually on May 12, 2022. The focus will be 'The Impact of the COVID-19 Pandemic on the Careers of Women Scientists.' ACRWH member Reshma Jagsi, M.D., D.Phil., will deliver the keynote address. Other upcoming events include the 8th Annual Women's Health Awareness (National Institute of Environmental Health Sciences [NIEHS]) on April 9, 2022; Sex Differences in Radiation Research (NIAID) on April 26, 2022; Environmental Impacts on Women's Health Disparities and Reproductive Health (NIEHS) on April 27-28, 2022; Diverse Voices Virtual Talk: COVID-19 in Women, July 28, 2022, and Violence and Women on September 29, 2022, and the 57th ACRWH meeting on October 18, 2022.

Member Vote: Establishment of the ACRWH Working Group on the 2024-2028 NIH-Wide Strategic Plan on Research on Women's Health

ORWH seeks ACRWH approval to convene a Working Group to support development of the 2024-2028 NIH-wide Strategic Plan on Research on the Health of Women. To provide a context for discussion, Dr. Noursi summarized relevant background information about the implementation of the 2019-2023 Trans-NIH Plan for Women's Research, including development of "A Guide for Implementing and Evaluating the 2010-2023 Trans-NIH Strategic Plan for Women's Health Research Across Institutes, Centers, and

Offices" (March 2021) to help ICOs with their implementation and evaluation plans for inclusion of women's health research activities; a paper "Developing the Process and Tracking the Implementation and Evaluation of the National Institutes of Health Strategic Plan for Women's Health Research" in *Global Advances in Health and Medicine* (August 2021); development of a data call webform and module on the START platform in collaboration with the Office of Evaluation, Performance, and Reporting (OEPR) that ICO staff populated with information about their FY 2019 and FY 2020 women's health research activities. Evaluation of the FY 2019 – 2023 plan will contribute to the creation of the FY 2024 – 2028 Plan.

The Working Group will include members of ACRWH, members of the NIH scientific community and HHS with expertise on the health of women. Information on how to volunteer for the Working Group will be forthcoming.

Action: The ACRWH approved creation of the ACRWH Working Group on the 2024-2028 NIH-wide Strategic Plan on Research on Women's Health via an online poll with 12 in favor.

Discussion. Dr. Clayton opened the floor for questions about the Director's Report or the Working Group. Discussion topics included:

- What research about the career trajectory of women in the biomedical workforce reveals and how ORWH has designed its administrative supplements in response to address key transition points when women typically drop out due to caregiving demands;
- The current status of ORWH's focus on gender, e.g., it is hyperlinked in the SABV policy that outlines the importance of both sex and gender, and the expectation that its work will reflect a greater emphasis on gender as more research, e.g., validated instruments to assess gender, become available.

National Heart, Lung, and Blood Institute (NHLBI) Director's Report

Dr. Clayton introduced Gary H. Gibbons, M.D., Director, NHLBI, who addressed "Advancing Shared Priorities for Eliminating Health Inequities and Improving Women's Health." Dr. Gibbons introduced NHLBI's mission of "discovery science that enhances human health." NHLBI is focusing on women's health research to advance health equity.

Commitment to Inclusive Excellence. Dr. Gibbons noted that there have been successes and persistent challenges in achieving equity in the biomedical workforce. Women comprise only 27 percent of the science, technology, engineering, and medicine (STEM) workforce and there are leaky spots in the research career pipeline, especially at key transition points where there are difficulties in resolving work/life balance issues. In response, NHLBI is tracking its portfolio to identify trends in its award data by sex and gender. Between FY 2018-2021, there was a substantial increase in moving toward parity in R01s among early-stage investigators and in achieving parity among K and F awardees. NHLBI has established programs from high school through the established investigator career phase to recruit and support a diverse talent pool and to help women remain in the workforce. To address early career transition points where women often drop out, these programs include re-entry supplements, continuity awards, and participation in the Common Fund's Faculty Institutional Recruitment for Sustainable Transformation (FIRST)**.**

NHLBI shares ORWH's commitment to women's health research and inclusive participation in research. Dr. Gibbons illustrated this commitment by citing the 1948 Framingham Heart Study in which each of six cohorts were majority women and that reported sex differences in treatment and outcomes. This study

put NHLBI on a strong path as a good strategic partner to ORWH when the Women's Health Initiative (WHI) was established in 1990, first housed in the Office of the Director and then transferred to NHLBI where it continues today with a combination of observational and interventional studies across women's lifespans. For example, the WHI Objective Physical Activity and Cardiovascular Health Study (OPACH) was an observational study that explored associations of accelerometer-assessed physical activity and sedentary behavior with cardiovascular events; it found a positive relationship between light physical activity and reduced risk of coronary heart disease (CHD) or cardiovascular disease (CVD). It was followed by the WHI Strong and Healthy Study (WHISH), an ongoing physical activity intervention trial for CVD prevention in approximately 50,000 older women.

The Impact of COVID on Women. In NHLBI's portfolio, there is evidence of COVID-19's impact on heart, lung, and sleep disorders, e.g., blood pressure generally increased during the pandemic and more so for women than for men. NHLBI is currently collecting evidence of sex differences that might influence exposure to COVID and its sequelae, i.e., "long" COVID. For example, some COVID effects appear to affect auto-immune diseases which disproportionately affect women: Women comprise 80 percent of all autoimmune disease cases. Long COVID overlaps with other multisystem syndromes, including Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), more common in women than men, and Multi-System Inflammatory Syndrome in Children (MIS-C). NHLBI is one of the lead ICs involved in the Researching Covid to Enhance Recovery (RECOVER) Initiative that seeks to characterize Post-Acute Sequelae of SARS-COV-2 (PASC) infection, including identification of sex differences in incidence, severity, underlying mechanisms, and clinical features. This inclusive "big data" study will overcome the shortcomings of many of the current studies which are skewed to hospitalized patients or predominantly male populations.

Advancing Maternal Health. The rise in maternal mortality during the pandemic exacerbated existing health disparities which are influenced by social determinants of health (SDoH). MMM is a priority for NHLBI, as well as for ORWH. Within the NHLBI portfolio is research on the leading risk factors for MMM, including gestational diabetes mellitus related to obesity, hypertension, bleeding disorders, and cardiomyopathy, and on addressing related health disparities.

NHLBI has adopted a lifespan lens to women's health. Thus, pregnancy during the reproductive years is not only a critical event but also a stress test that identifies women with long-term risk for CVD. The common risk factors for adverse outcomes in pregnancy overlap with obstructive sleep apnea, unhealthy diets, smoking, alcohol use, and obesity. Secular trends, e.g., women becoming pregnant at older ages with increased prevalence of risk factors such as hypertension and obesity have been observed. Preeclampsia, even if it resolves post-partum, identifies women who are likely to develop CV risk later in life; the child in utero is at higher risk for developing hypertension. Thus, it's important to identify the trajectory of disease in women's lives and to find ways to intervene to help both the woman and her child. Therefore, NHLBI is pleased to be a partner in the IMPROVE initiative. NHLBI is developing a portfolio of programs that support IMPROVE, including the Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-Be (nuMOM2b) study that established that blood pressure category and trajectory in early pregnancy is independently associated with risk of preeclampsia and gestational HTN. Stage 1 HTN is associated with poorer outcomes for both mother and child.

Interventions that address HTN and gestational diabetes are likely to have an impact on preventing MMM if they occur prior to a clinical catastrophe. For example, NHLBI's Clinical Hypertension and Pregnancy (CHAP) initiative was a randomized trial to evaluate benefits and risks of pharmacologic treatment of mild chronic HTN (CHTN) during pregnancy. It reported that treatment of mild CHTN during

pregnancy to achieve BP below 140/90 reduced adverse pregnancy outcomes without compromising fetal growth. Previously, obstetricians had considered blood pressure greater than 140/90 as mild. NHLBI believes this finding will change obstetrical practice across the nation and thus advance women's health during pregnancy and across the lifespan.

As NHLBI pursues efficacy trials, there is an opportunity to assure findings such as these are translated to the "real world" via translational studies designed with a lens of health equity to reach populations at greatest risk. Currently, NHLBI is partnering with ORWH, the Health Resources & Services Administration (HRSA), Administration for Children and Families (ACF) and other ICs to launch the Early Intervention to Promote Cardiovascular Health of Mothers and Children **(**ENRICH) program to address maternal health and disparities. ENRICH provides wraparound support during home visits by nurses to implement evidence-based interventions that address lifestyle, SDoH, and health care access.

There are racial and ethnic disparities in sleep among pregnant women. There is a large body of evidence that sleep affects every part of health, e.g., it plays a role in diabetes, cardiovascular disease, and obesity, among other conditions. The nuMOM2b study found that elevation in measures of sleep-disordered breathing in pregnancy and 2–7 years after delivery is associated with a greater than three times increased risk for incident high blood pressure and a greater than two times increased risk for metabolic syndrome. The study also documented sleep disordered breathing and obstructive sleep apnea (OSA) during pregnancy. NHLBI has subsequently moved beyond observational studies to test novel interventions in high-risk pregnant women to reduce adverse pregnancy outcomes and potentially influence the long-term trajectory of CVD risk. For example, CPAP (continuous positive airway pressure) for Sleep Apnea in Pregnancy (SLEEP) is a randomized trial of 2,700 women testing the efficacy of sleep advice counseling + CPAP versus sleep advice counseling alone. It seeks to answer the question*:* Does CPAP for OSA reduce pregnancy-related high blood pressure?

Finally, NHLBI is committed to a holistic approach to women in their reproductive years to embrace a socio-ecological framework to address women as individuals and to support clinicians in seeing women embedded within their family and community. Such an approach would take into account the interactions of SDoH and the built environment as they impact women. The goal is to help women and their children, especially those on a risk trajectory, to build resilience and thrive, even in a community facing significant adversity. To that end, NHLBI is building a community-engaged research platform to improve maternal health and narrow the health equity gap. The Maternal Health Community Implementation Project (CIP), currently operating in four locations, adopts a lifespan lens and community care approach. It provides intervention strategies to implement pre-pregnancy counseling for women and/or partner/father, diabetes prevention programs, and prenatal nutrition counseling. It combines maternal lifestyle education and counseling with community health workers. The evidence base that emerges from this research will help NHLBI fulfill its mission of moving from discovery science to health for all.

Discussion. Issues discussed among ACRWH members and Dr. Gibbons included:

- The relationship between rural communities and environmental health, including asthma, maternal health, and health disparities;
- The need for more research on estrogen at NHLBI, particularly within its lifespan approach to women's health research; and
- The ways in which NHLBI is integrating intervention science and a holistic view of women's health into its research portfolio.

NIH Inclusion Update

Dr. Noursi introduced Ching-yi Shieh, Ph.D., ORWH, who introduced Dawn Corbett, M.P.H., NIH Inclusion Officer, Office of Extramural Research. Ms. Corbett reviewed NIH policies for the inclusion of women and minorities in clinical research studies, as well as its inclusion across the lifespan policy. She also reviewed the recurrent themes that emerged from an NIH "Across the Lifespan II" workshop (September 2, 2020), including selecting trial outcomes that reflect participant concerns; limiting use of unnecessary inclusion/exclusion criteria; adequately weighing risks of excluding groups—like pregnant women and children—with that of their participation; minimizing participant and caregiver burden; considering the diversity of individuals within a given group (e.g. size, comorbidities, diet, cognitive status); and regularly assessing recruitment and retention and making modifications as needed. NIH has issued communications to researchers about the lifespan inclusion policy and conducts an annual virtual workshop; the most recent one had over 24,000 registrants.

Ms. Corbett then reviewed data from the ICs' triennial reports covering FY 2019-2021. Key findings include:

- The proportion of participants in clinical research who identified as female increased from 52.1 percent in FY 2019 to 58.5 percent in FY 2021.
- For US-only clinical research between FY 2019 to 2021, enrollment of American Indian/Alaska Native participants remained stable at approximately 1 percent; Asian enrollment increased
- from 3.2 percent to 5.0 percent; Black/African American participants decreased over time from 15.7 percent to 13.0 percent; Native Hawaiian/Other Pacific Islander increased from 0.2 percent to 0.8 percent; and White participants were 65.9 percent in FY 2019, decreased to 61.2 percent in FY 2020, and increased to 64.2 percent in FY 2021.
- Adults comprised 58 percent of clinical research enrollees, followed by children (20 percent) and older adults (19 percent).

Current efforts to inform NIH's next steps include a soon-to-be-released NASEM report on "Improving Representation of Women and Underrepresented Minorities in Clinical Trials and Research"; a multi-stakeholder diversity project from the Food & Drug Administration (FDA)'s Clinical Trials Transformation Initiative that identifies strategies for inclusion; and the NIH Community Engagement Alliance (CEAL) that is reaching out to communities about COVID-19 research.

Discussion. Discussion following Ms. Corbett's presentation included:

- The impact of NIH's inclusion policies on industry partners, e.g., through the FDA's Clinical Trials Transformation Initiative; and
- The need to report on sex and gender, race/ethnicity, and age in journal articles and other dissemination outlets, e.g., clinicaltrials.gov, and efforts to educate authors, reviewers, and journal editors about this topic.

2021 Women's Health Conference—Updates and Next Steps

Dr. Noursi introduce Sarah Temkin, M.D. and Judy Regensteiner, Ph.D. Together, they and Dr. Noursi provided an update on the Women's Health Conference held in October 2021. Dr. Noursi began by reviewing the three topics addressed by the Conference in response to a request from Congress--rising MMM rates, rising chronic debilitating conditions in women, and stagnant cervical cancer rates—and the ACRWH/NIH working group process to prepare for the conference, including reviews of relevant research and NIH portfolios. The Executive Summary of the conference report, "Perspectives on Advancing NIH Research to Inform and Improve the Women," was cleared on April 5, 2022, and is posted on the ORWH website.

Dr. Temkin reported on NIH activities in the three content areas, noting that 10.8 percent of the NIH budget supports women's health research. In FY 2020, the total NIH investment in women's health research was $4.466 million. The wealthier ICs, including NCI, NIAID, NHLBI, and NIA, allocated the greatest amount of fundings to women's health research.

MMM. The maternal morbidity rate continues to rise. For 2020, it was 23.8 deaths per 100,000 live births compared with a rate of 20.1 in 2019. Minority women are disproportionately affected; they face a three times higher rate compared to non-Hispanic White women. In response to this crisis, NIH invested $406,679,474 on maternal health research In FY 2020, including $223,522,448 on MMM topics such as diagnosing, treating, and preventing pregnancy complications, and epidemiological studies of pregnancy-associated mortality. In addition to multiple IC MMM initiatives, trans-NIH efforts include a Maternal Mortality Task Force; the IMPROV) Initiative; and the IDeA program.

Chronic Debilitating Conditions in Women (CDCW). Although chronic conditions and multiple chronic conditions are more common among women and rates are increasing, several challenges emerged as NIH began addressing CDCW. For example, there is no definition of chronic conditions that is specific to women. Further, it's difficult to quantitatively assess multiple conditions. Therefore, the CDCW working group created a framework with inclusion criteria such as female-specific conditions, those conditions more common in women and those with higher mortality in women, and those that occur in both sexes but are likely to be neglected in women. A survey of ICs revealed multiple IC-supported research on chronic debilitating conditions in women, but few studies on multimorbidity. Spending on CDCW as measured by Disability Adjusted Life Years (DALYs) varied widely across ICs.

Stagnant Cervical Cancer Survival Rates. Despite the availability of the human papillomavirus (HPV) vaccine, the age-adjusted death rate for cervical cancer (CC) fell only slightly between 2000-2018 and at a lower rate than that of other cancers that affect women. Further, significant racial/ethnic disparities in survival rates remained with Blacks more likely than other racial/ethnic groups to develop CC and to die from it. There has even been an increase in CC rates in the lowest income areas since 2010. NIH total spending on CC in FY 2020 was $113,490,444, with most of it coming from NCI. The scope of the funded research is broad and includes basic science, translational, clinical and health services research; pre-malignant and malignant HPV disease; and screening, prevention (primary and secondary), and treatment.

Public Comment. Beyond reviewing NIH portfolios, input from the public was a requirement. In July 2021, a Request for Information (RFI) was issued; 247 comments were received from researchers, members of the public, awareness and advocacy groups, patients, and healthcare professionals. The ten most frequently identified keywords were: (1) MMM, (2) racial disparities, (3) access to care, (4) healthcare professional training, (5) mental health, (6) Black or African American women, (7) screening, (8) quality of care, (9) time to diagnosis, and (10) SDoH. Of the 247 comments received, 182 addressed CDCW.

Dr. Regensteiner reported on cross-cutting themes where research is urgently needed that emerged from the Conference. These included 1) Implementing best practices, e.g., safety bundles to prevent MMM; 2) Addressing care inequities, especially among populations of women with overlapping identities; and 3) Intentional research, i.e., studies that provide detailed sex-disaggregated clinical outcomes data—tied to critical life course windows, such as menarche and menopause—from a diverse population of women, as well as application and enforcement of SABV policy.

Discussion. Dr. Noursi moderated a discussion about the Conference and its report:

- The need to include infectious disease considerations into approaches to MMM;
- How the lessons learned from COVID-19 influenced discussions of all three topics; and
- The process by which the Executive Summary and full Conference report will be distributed to Congress, and the urgency to do so.

Concept Clearance: Reissuance of Administrative Supplements to Promote Research Continuity and Retention for Mentored Career Development (K) Award Recipients and Continuity of Biomedical and Behavioral Research Among First-Time Recipients of NIH Research Project Grants

Dr. Clayton introduced Xenia Tigno, Ph.D., ORWH Associate Director for Careers, who presented ORWH's proposal for the reissuance of "Administrative Supplements to Promote Research Continuity and Retention for Mentored Career Development (K) Award Recipients" (NOT-OD-20-054) and "Continuity of Biomedical and Behavioral Research Among First-Time Recipients of NIH Research Project Grants (RPG)" (NOT-OD-20-055).

The purpose of these Funding Opportunity Announcements (FOAs) is to support the retention of well-trained biomedical scientists at two critical transition periods: from the K award to an independent research award and when the researcher tries to get a renewal of the first RPG or a second R01 or equivalent. A study of the careers of more than 6,000 scientists identified these two periods as the "leaky points" for women, which lead to women becoming Principal Investigators (PIs) at a much lower rate than their male peers. Both supplements are open to both sexes, but they are tied to life events such as childbirth or adoption. By defining these events, the supplements were intended to address the needs of women because these are the reasons that women say they drop out of the academic pipeline. Both concepts were developed by the trans-NIH Working Group on Women in Biomedical Careers.

In the last two years in which these funding opportunities were available, 24 ICOs participated. Supplement budget requests cannot exceed $50,000/ year direct costs plus facilities and administrative (F&A) costs. Supplements may be requested by any of the PDs/PI' s in parent awards that include multiple Program Directors (PDs)/PIs. Total awards in 2020 and 2021 amounted to $10,438,820. Of the 192 supplements awarded over this period, 29 were funded by ORWH. Women accounted for 87 percent of awardees.

Success Rates. Applications for the supplements are reviewed by individual ICs according to their own criteria, so the success rate varies across ICs. Despite these restrictions, the success rates were high at 64 percent for RPG awards and 57 percent for K awards. Among the latter, most of the successful K applications were for K23 (clinician) awards, followed by K01s and K08s. NIDDK, NHLBI, and NIMH were leaders among the ICs in terms of funds invested in these supplements for K awardees. For the RPG continuity supplements, NIGMS and NIDA led in continuity supplement funding.

Sixty percent of supplement awardees were White, followed by Asians (23 percent). Black and mixed-race awardees represented 6 percent and 5 percent of total awardees respectively. This demographic pattern is consistent with NIH demographic patterns for both research and training grants.

The largest single category of proposed spending for the supplements, 71 percent, was for additional staff to sustain the researcher's work.

The most commonly reported qualifying event for funding reported by applicants was childbirth (73 percent). Parental leave was cited by 11 percent of applicants, particularly men. Caregiving for family members during the pandemic was also cited.

Based on ORWH's ongoing evaluation, these programs have had wide support among ICs and sustain investigators during sensitive periods in their lives so they can continue their careers. There is a compelling need for these programs in light of the COVID-19 pandemic and its impact on women scientists. Thus, ORWH is seeking approval to reissue these FOAs which are set to expire this year. The reissuance of these FOAs for administrative supplements will cover FY 2023-2026. Based on IC input, other eligible grant types and qualifying life events will be added to the existing announcements.

The proposed supplements support the 2019-2023 Trans-NIH Strategic Plan for Women's Health Research's Strategic Goal 4: to promote training and careers to develop a well-trained, diverse, and robust workforce to advance science for the health of women (objectives 4.1, 4.2, 4.3, 4.4, 4.5); the NIH –wide Strategic Plan (FY 2021-2025): Objective 2: Developing, Maintaining and Renewing Scientific Research Capacity/Enhancing the Biomedical and Behavioral Research Workforce and Enhancing Women's Health; and the National Strategy on Gender Equity and Equality.

Discussion: Key discussion points included:

- Ongoing evaluation strategies to determine if supplement awardees remain in the biomedical workforce, considering that tracking the movement of training grantees into K awardees and then follow-up of K awardees needs to be conducted at the IC level; ORWH can follow up more easily with the RPG continuity grantees;
- The importance of a diverse biomedical research workforce and ORWH's ongoing efforts to seek representation from all communities, including the underserved; and
- Expanding the evaluation of supplement awardees to understand their experiences more fully (beyond how they intend to spend the funds), as well as to gain a better understanding of resources provided by their institutional employers (e.g., on-site childcare), and to characterize which segments of the workforce are most deeply impacted.

Vote: Dr. Noursi called for a vote to approve the reissuance of "Administrative Supplements to Promote Research Continuity and Retention for Mentored Career Development (K) Award Recipients" (NOT-OD-20-054) and "Continuity of Biomedical and Behavioral Research Among First-Time Recipients of NIH Research Project Grants (RPG)" (NOT-OD-20-055). ACRWH members approved the motion via an online poll with 12 in favor.

Concept Clearance: Reissuance of the Intersection of Sex and Gender Influences on Health and Disease R01

Dr. Clayton introduced Chyren Hunter, Ph.D.., Associate Director for Basic and Translational Research, ORWH, who presented a concept clearance for the reissuance of the "Intersection of Sex and Gender Influences on Health and Disease" R01 (R01 OD-19-029), that was originally published in September 2019. The late Dr. DelCarmen-Wiggins was a tireless advocate on its behalf.

When the concept was first introduced in 2018, it was the only NIH-wide funding opportunity that focuses broadly on the health of women. It encouraged new research on the differential effects of sex and gender and their intersection on women's health; increase collaborative partnerships across NIH institutes, Centers and Offices to support disease - agnostic topics to advance women's health; provide

an opportunity to conduct transdisciplinary research that is ordinarily beyond the scope of one NIH IC or Center; and satisfy evolving public health needs and legislative mandates as identified in the 21st Century Cures Act, and the 2019-2023 Trans-NIH Strategic Plan for Women's Health Research.

The proposed new initiative is designed to stimulate research that incorporates and/or enhances understanding of the influence of sex and gender and their intersectionality in health outcomes across a broad array of scientific disciplines. FOA applications must address both sex- and gender-related variables; the intersection of sex and gender in health and disease, and Goal #1 of the 2019-2023 Trans-NIH Strategic Plan for Women's Health Research, advancing rigorous research that is relevant to the health of women. Consistent with other ORWH programs this initiative is disease agnostic, supporting basic, preclinical, translational and clinical research investigations across a range of disciplines
Based on the intersectionality of the initiative, Interdisciplinary or transdisciplinary research and research teams who share expertise, knowledge, and skills across a range of disciplines are encouraged. Such teams are well-suited to conduct research from a multi-disciplinary perspective to address research gaps and the underlying common root causes of poorer health outcomes in the lives of women. Studies that leverage existing funded cohorts and datasets for analyses of hypotheses related to sex and gender influences in health and disease, as well as comparative analyses of existing samples/datasets/databases and/or data mining and data curation to investigate the role of sex/gender are also encouraged. Applications are encouraged to consider health disparities, a lifespan perspective, IC-specific priorities, and COVID-19.

There were three "receive dates for the initial FOA; each had a robust response. Of 48 applications received in 2020, 8 were funded; of 46 in 2021, 9 received funding. Another 46 applications were received in 2022; no funding decisions have been announced to date. The NIH investment has been $9 million with an overall success rate of 17 percent. Eleven ICOs participated in the R01; NHLBI was the biggest recipient applications, despite not participating until the second receive date.

New and early career stage investigators represented an increasing percentage of the applicant pool from 12 to 24 new investigators between FY 2020 and FY 2020. They experienced a success rate of 30 percent success rate, exceeding NIH's overall success rate. They represent over one-half of the awardees of this R01.

There was broad scientific diversity among the funded grants and a number of the investigators have been tapped to participate on Center for Scientific Review (CSR) panels.

Thus, the Sex and Gender R01 has met its objectives to stimulate research that incorporates and/or enhances understanding of the influence of sex and gender and its intersectionality in health outcomes across a broad array of scientific disciplines; includes one or more sex-based variables, including but not limited to: evaluation of sex as a biological variable; sex-based comparisons on conditions in females and males; biologically based variables such as hormones, physical features, anatomy, or biomarkers; and includes one or more gender-based variables, including but not limited to: assessment of psychosocial variables relevant to health conditions; measures of socially constructed roles, experiences, identities, or behaviors of girls, women, boys, men, or gender diverse people.

Further, the Sex and Gender R01 program has provided unexpected dividends to the scientific community to advance women's health by recruiting new and early-stage investigators into biomedical research investigations on sex and gender; identifying a cadre of reviewers with broad expertise in sex and gender and the intersection of sex and gender research; stimulating cross-cutting

research on understudied populations; and advancing research on the consideration of sex and gender research and its intersectionality in SARS CoV-2.

Future directions for the Sex and Gender R01 program include reissuance of The Intersection of Sex and Gender Influences on Health and Disease Research (R01); encouragement of additional ICs to partner with ORWH on the FOA; expansion of scientific areas of interest, including COVID-19; leveraging and curation of large sex and gender datasets; and a new investigators forum.

Discussion. Dr. Anderson expressed support for the concept and asked if application can address both sexes or be sex-specific. Dr. Hunter replied that either approach works, provided the application addresses both sex and gender**.**

Vote. A motion to approve the reissuance of the Intersection of Sex and Gender Influences on Health and Disease R01 was approved with 13 votes in favor.

Concept Clearance: Galvanizing Health Equity through Novel and Diverse Educational Resources (GENDER)

Dr. Noursi introduced Elizabeth Barr, Ph.D., Social and Behavioral Scientist Administrator, ORWH, who sought ACRWH input on a new concept, Galvanizing Health Equity through Novel and Diverse Educational Resources (GENDER). Dr. Barr began by citing Objective 4.1 of the 2019-2023 Trans-NIH Strategic Plan for Women's Health Research: "Knowledge of sex and gender influences should be integrated with the skills that nurture effective researchers…development and implementation of educational training programs will be needed to update the knowledge and skills of current biomedical researchers as well as those returning to or entering the workforce." However, training on gender and sex is lacking. For example, existing data on sex and gender-based medicine in medical schools' curricula suggests that concepts of sex and gender are underexplored. A 2016 study found that medical students have a strong desire for sex- and gender-specific training; less than half feel prepared to apply sex- and gender-specific knowledge clinically. Ameliorating these training gaps is critical for moving the needle forward on sex and gender research.

Current ORWH interprofessional efforts, such as SABV Primer and train-the-trainer program and the PowerPoint training program "Sex- and Gender-Related Differences in Health" (currently under revision) have had broad reach and appeal; however, opportunities for expansion remain. One in five public commenters identified provider training as a priority in the RFI published prior to the 2021 women's health conference.

Therefore, ORWH is seeking approval of the GENDER concept. Its objective is to support the development of courses for skills development and curricula/methods related to sex and/or gender for a broad array of audiences at any career stage, including: researchers, health care providers, students (undergraduate, graduate, medical, dental, veterinary, nursing, public health, and other health professions), postdocs, community advocates, public health workforce, and more. Courses and curricula developed under this program will be made available to the extramural and academic communities through a redesigned ORWH Interprofessional Education Portal.

Two rounds of applications are proposed: Round 1 will be open December 2022 – January 2023, and Round 2 from December 2023 - January 2024. Areas of interest include multidimensional and life course

approaches, innovative methodologies, advocacy and community-based education, and other topics relevant to the 2019-2023 Trans-NIH Strategic Plan for Women's Health Research.

NIH will conduct a scientific workshop on October 26, 2022, on "Gender and Health," addressing the health impacts of structural sexism, gender norms, relational power dynamics, and gender inequity health impacts. The planning committee includes ORWH and ten ICs, chaired by NCI.

Discussion. Key discussion points about the GENDER concept clearance included:

- The complex nature of gender, the increasing number of younger persons identifying as a sexual or gender minority, and the challenges in measuring sex and gender, including the absence of research/evidence. The Sexual & Gender Minority Research Office (SMRO) at NIH is working to help NIH and other agencies to address these issues.
- The challenges in communicating about sex and gender, and the importance of clear and inclusive language about it; and
- Course audience, design, and certification.

Vote. A motion to approve the concept clearance of Galvanizing Health Equity through Novel and Diverse Educational Resources (GENDER) was approved with 13 in favor.

Concept Clearance: ORWH U3 Research Program Expansion to Emphasize Understudied Conditions Relevant to the Health of Women

Dr. Noursi welcomed Dr. Temkin back to present a concept clearance on expanding the ORWH U3 research program to emphasize understudied conditions relevant to the health of women. Established in 2017, the U3 supplement program is an ORWH Signature Program. The proposed concept expands ORWH support for conditions that affect women that remain Understudied. It aligns with the Trans-NIH Strategic Plan for Women's Health Research Goal 1: Advancing rigorous research that is relevant to the health of women.

The U3 framework was developed by ORWH to draw attention to the lack of research on persistent disparities in women's health and healthcare and to support research and evidenced-based programs to address this gap. The U3 supplement program highlights the intersectional experiences of women, exploring the ways in which socially determined categories – like race and gender – overlap and interact to create different outcomes for individuals and communities. To date, it has supported research on many understudied conditions. Between FY 2017-FY 2021, the program has supported 71 projects co-funded by 16 ICs.

"Advancing NIH Research on the Health of Women: A 2021 Conference" addressed the complexities of CDCW, including multimorbidity which is more common among women, especially among Black women. Unfortunately, data disaggregated by race, ethnicity and gender is infrequently reported and the influences of social factors is understudied. Based on recommendations from the 2021 women's health conference, including public comments in response to the RFI, ORWH has identified opportunities in CDCW research, including developing definitions and a framework specific to chronic debilitating diseases in women; aligning clinical research with the needs of women (e.g., study objectives and endpoints); increasing research activity on female-specific diseases, menopause and aging; creating clinical research networks, specific to research on chronic diseases in women; and encouraging research through the development of funding opportunities around multimorbidity in women. Some U3 research projects have addressed understudied chronic conditions in women, including menopause, trauma and

mental health, musculoskeletal disease, multimorbidity, female-specific conditions, and inflammation and immunity.

Proposed expansion of the U3 program to emphasize research on understudied conditions that affect women's health will entail developing a new funding opportunity to support research on Understudied conditions that affect women. Specific conditions of interest include menopause, musculoskeletal disease, inflammation and immunity, mental health and trauma, and female-specific conditions. Participation of diverse patients (including U3 populations) will be encouraged, and research in the populations with the highest burdens of Understudied conditions will be supported. ORWH plans to partner with interested ICs on this funding opportunity.

Discussion. Discussion focused primarily on the clarification of topics covered by the program, e.g., worsened inflammation and immunity during pregnancy might not qualify because CDCW are defined as conditions lasting for more than one year. A counter-argument from a life course perspective, however, is that everything that affects a health condition before and afterwards is important to consider. Clarification of such issues should be specified in the FOA language.

Vote. To motion to approve ORWH U3 Research Program Expansion to Emphasize Understudied Conditions Relevant to the Health of Women was approved with 12 votes in favor.

Open Discussion

During the open discussion, the following topics were considered:

- How the highly valuable BIRCWH program can gain support from additional ICs, particularly in light of what is defined as women's health research and which funding mechanisms are supported by various ICs, as some do not support K12 career development awards while others have their own large K12 programs, and how visibility of BIRCWH can be expanded within institutions;
- Whether reporting results by sex in and of itself constitutes women's health research;
- Appreciation for including sleep, an area in which there are sex differences, in the Director's report;
- A re-cap of the anticipated activities of the ACRWH Working Group on the 2024-2028 NIH-Wide Strategic Plan on Research on Women's Health; and
- A request for suggested topics for the October ACRWH meeting.

Closing Statement

Dr. Clayton thanked ACRWH members and ORWH staff and contractors for their contributions and expressed appreciation. She adjourned the meeting at 3:46 p.m.

Certification

We certify that the contents above are accurate and complete.

Janine Clayton, MD

Janine Austin Clayton, M.D., Director
Office of Research on Women's Health

Date 05/31/2022

Samia D. Noursi

Samia Noursi, Ph.D., Executive Secretary
Advisory Committee on Research on Women's Health

Date 5/17/2022