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April 15, 2019

The Honorable Rosa DeLauro
Chair
House Labor-HHS Appropriations
Subcommittee
U.S. House of Representatives
Washington, DC 20515

The Honorable Tom Cole
Ranking Member
House Labor-HHS Appropriations
Subcommittee
U.S. House of Representatives
Washington, DC 20515

Dear Chairman DeLauro and Ranking Member Cole,

I am writing on behalf of the Society for Women's Health Research (SWHR) to urge the U.S. House of Representatives Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (herein referred to as "House LHHS Subcommittee") to provide renewed investment in scientific and medical research within the National Institutes of Health (NIH) as part of its fiscal year (FY) 2020 federal budget appropriations process.

For nearly 30 years, SWHR has been widely considered the thought leader in promoting research on biological sex differences in disease and improving women's health through science, policy, and education. As women comprise 50.8% of the U.S. population¹, it is clearly in our nation's best interests for Congress to appropriately fund a federal research agenda inclusive of women's health and sex differences research.

To accomplish this goal, we respectfully ask the House LHHS Subcommittee to maintain its commitment to increasing funding for the NIH and ensure essential funding is allocated to the following NIH Institutes and Offices so that vital research initiatives to improve women's health can continue:

- *Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)*
- *Office of Research on Women's Health (ORWH)*
- *National Institute on Minority Health and Health Disparities (NIMHD)*

NATIONAL INSTITUTES OF HEALTH

NIH is America's premier medical research agency and the largest source of funding for biomedical and behavioral research in the world. As such, its public health mission is vital to promote the overall health and well-being of Americans by fostering creative discoveries and innovative research, training and supporting researchers to ensure continued scientific progress, and expanding the scientific and medical knowledge base. To sustain and bolster its funding through competitive grants to researchers across the United States and around the world as well as support the work of researchers within the NIH, **SWHR requests that Congress set, at a minimum, a budget of \$41.6 billion in FY2020, a \$2.5 billion increase over FY2019.**

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

NICHD has achieved extraordinary feats in research on women's health throughout the lifecycle; reproductive sciences; maternal, child, and family health; and population health. It is only with adequate resources that NICHD can build upon new and existing initiatives, several of which we highlight below, to address knowledge gaps and identify solutions to benefit women, children, and families throughout the U.S.

Reproductive Sciences: NICHD conducts research on reproductive biology to foster medical innovation that can improve treatment options for serious gynecologic conditions that are often overlooked and/or underfunded, despite their significant burden on millions of women. For example, an estimated 10% of reproductive-aged women are living with endometriosis and an astounding 80% of African American women and 70% of white women will develop uterine fibroids at some point in their lifetime.^{2,3} Despite the prevalence of these diseases and their potentially severe effects on women, their families, and society, a clear understanding of the basic biology behind these conditions is lacking, resulting in delayed diagnosis (7-12 years on average for endometriosis^{4,5}) and limited treatment options.

Task Force Specific to Research in Pregnant Women and Lactating Women: NICHD is leading the field in supporting inclusion of pregnant women in clinical trials. Pregnant women historically have been excluded from research — even in studies that would advance knowledge of medical conditions and treatments in pregnancy. On March 25, 2019, NIH announced that the NICHD Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), established in 2016 by the 21st Century Cures Act, has been renewed for an additional two years by the Secretary of Health and Human Services (HHS). NICHD must have sufficient resources for PRGLAC to continue its work and act on the 15 recommendations outlined in its mandated report⁶ to Congress and HHS.

PregSource®: NICHD's PregSource initiative allows pregnant women to track their health data from gestation to early infancy and access evidence-based information about healthy pregnancies. This program encourages researchers to use aggregated data and recruit pregnant and postpartum women in clinical trials and is making important headway in eliminating knowledge gaps and imbalances in care for these understudied patient populations.

Maternal Mortality: NICHD's Pregnancy and Perinatology Branch plays a pivotal role in supporting research to improve the health of women before, during, and after pregnancy. More women die of pregnancy-related complications in the United States than in any other developed country, and the U.S. maternal mortality rate is increasing.^{7,8} In addition, pregnancy-related complications have been associated with increased risk for diseases such as cardiovascular disease, obesity, and diabetes for women and their children later in life.^{9,10} Adequate resources are needed for NICHD to realize its goal to improve pregnancy outcomes to maximize the *lifelong* health of women and their children, and to assist women and their health care providers in managing downstream health risks related to these complications.

Office of Research on Women's Health (ORWH)

As the NIH focal point for coordinating women's health research, ORWH strengthens research related to diseases, disorders, and conditions that affect women's health and ensures that women are appropriately represented in biomedical and behavioral research supported by NIH.

In 2015, NIH announced a policy (NOT-OD-15-102) to factor sex as a biological variable (SABV) into research designs, analyses, and reporting for NIH-funded vertebrate animal and human studies. ORWH is leading collaborations across NIH Institutes and Centers in implementing this policy and providing critical leadership to develop research programs like Building Interdisciplinary Research Careers in Women's Health (BIRCWH), an initiative that aims to increase the number and skills of investigators who conduct research on sex and gender influences on health and disease. The Specialized Centers of Research Excellence (SCORE), another signature ORWH program, is designed to expedite the development and application of new knowledge to human diseases that affect women, to learn more about the etiology of these diseases, and to foster improved approaches to treatment and/or prevention. ORWH needs adequate funding to continue these initiatives and to support established scientists across the country who are conducting groundbreaking research that integrates basic, clinical, and behavioral research approaches to incorporate sex differences.

National Institute on Minority Health and Health Disparities (NIMHD)

NIMHD serves as the leader of scientific research initiatives dedicated to improving minority health and reducing health disparities — differences in the incidence and outcome of health conditions among specific populations defined by race or ethnicity, *gender*, disability status, geographic location, or other sociodemographic classifications. Delays in referral of female patients in comparison to male patients for certain conditions like rheumatoid arthritis must be better understood. Circumstances in which women receive different therapeutic regimens despite having higher disease risk than men must also be addressed.

NIMHD invests in critical research that supports the study of many aspects of minority health and health disparities — from genetic, molecular, and biologic science to clinical behavioral and translational research. By fostering collaborations and partnerships to promote and support evidence-based science, their work also informs practice and policy to increase the scientific community's focus on equally important non-biological factors such as socioeconomic, politics, discrimination, culture, and environment in relation to health disparities.

Thank you in advance for consideration of this NIH FY2020 funding request and the rationale behind it. If you have questions, please contact Sarah Wells Kocsis, Vice President of Public Policy, at 202.496.5003 or swellskocsis@swhr.org.

Sincerely,



Amy M. Miller, PhD
President and Chief Executive Officer
Society for Women's Health Research

¹ United States Census Bureau. QuickFacts: United States. <https://www.census.gov/quickfacts/fact/table/US/SEX255217>. Published June 2018. Accessed April 9, 2019.

² Baird DD, Dunson DB, Hill MC, Cousins D, Schectman JM. High cumulative incidence of uterine leiomyoma in black and white women: Ultrasound evidence. *Am J Obstet Gynecol*. 2003;188(1):100-107.

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- ³ Shafir AL, Farland LV, Shah DK, et al. Risk for and consequences of endometriosis: A critical epidemiologic review. *Best Pract Res Clin Obstet & Gynaecol.* 2018;51:1-15.
- ⁴ Nnoaham KE, Hummelshoj L, Webster P, et al. Impact of endometriosis on quality of life and work productivity: A multicenter study across ten countries. *Fertil Steril.* 2011;96(2):366-373.e8.
- ⁵ Hudelist G, Fritzer N, Thomas A, et al. Diagnostic delay for endometriosis in Austria and Germany: Causes and possible consequences. *Hum Reprod.* 2012;27(12):3412-3416.
- ⁶ Task Force on Research Specific to Pregnant Women and Lactating Women. Report to Secretary, Health and Human Services, and Congress. https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf. Published September 2018. Accessed April 10, 2019.
- ⁷ Kassebaum NJ, Barber RM, Bhutta ZA, et al. Global, regional, and national levels of maternal mortality, 1990–2015: A systematic analysis for the Global Burden of Disease Study 2015. *Lancet.* 2016;388(10053):1775-1812.
- ⁸ MacDorman MF, Declercq E, Cabral H, Morton C. Is the United States maternal mortality rate increasing? Disentangling trends from measurement issues. *Obstet Gynecol.* 2016;128(3):447-455.
- ⁹ Cirillo PM, Cohn BA. Pregnancy complications and cardiovascular disease death: 50-year follow-up of the child health and development studies pregnancy cohort. *Circulation.* 2015;132(13):1234-1242.
- ¹⁰ Cheng SB, Sharma S. Preeclampsia and health risks later in life: An immunological link. *Semin Immunopathol.* 2016;38(6):699-708.