

Women First Research Coalition

WFRC First Quarter 2024 Activities Update

Legislative Activities

Update on Fiscal Year 2024 Appropriations

On March 23, Congress passed the final Labor, Health and Human Services (Labor-HHS) funding bill for Fiscal Year 2024 on March 22. The bill includes \$47.081 billion for the National Institutes of Health (NIH), \$1.759 billion for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), \$7.224 billion for the National Cancer Institute, \$4.507 billion for the National Institute on Aging, and \$1.5 billion for ARPA-H.

The bill includes \$76.480 million for the Office of Research on Women's Health (ORWH), as well as \$7 million for the Building Interdisciplinary Research Centers in Women's Health (BIRCWH) program. This is a \$2 million increase for BIRCWH over FY 2023.

The Senate <u>report</u>, which includes both the BIRCWH program and the Reproductive Medicine Network (RMN) language requested by the WFRC, as well as similar language for the WRHR program, will be deemed in effect. Here is the language that was included:

Congress recognizes ORWH's critical leadership in promoting women's health research and spearheading research programs like the Building Interdisciplinary Research Careers in Women's Health [BIRCWH] program, which aims to increase the number and skills of investigators who conduct research on sex and gender influences on health and disease, and the Specialized Centers of Research Excellence on Sex Differences, a program 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. The Committee recognizes persistent gaps remain in the knowledge of women's health. Within the total for ORWH, the Committee provides \$7,000,000, an increase of \$2,000,000 above the fiscal year 2023 enacted level, to expand the BIRCWH program. ORWH is encouraged to support additional researchers focused on women's health and sex differences, including research focused on cancer and maternal health.

Women's Reproductive Health Research [WRHR] Program.—The Committee encourages NICHD to fund additional scholars, with the goal of increasing the diversity of the scholars, sites, and research supported by the program. The Committee recognizes the effectiveness of the WRHR program, which provides an opportunity for obstetrician/gynecologists who recently completed postgraduate clinical training to further their training in basic, translational and clinical research.

Reproductive Medicine Network [RMN].—Infertility, defined as the inability to conceive within 1 year of unprotected intercourse, affects an estimated 19 percent of reproductive aged couples. In addition, about 26 percent of women have difficulty getting pregnant or carrying a pregnancy to term. The RMN, which has since been replaced by the Consortia for Infertility and Reproductive Medicine [ConFIRM] Clinical Trial Program of linked R01s, had a proven track record of supporting infertility research by providing a single hub that supported multiple substudies and secondary analyses. Most importantly, it informed major changes to clinical practice and supported the training of young investigators in the field. While the Committee understands that NICHD has moved away from the U01/U10 mechanism the RMN utilized, it is noted that the ConFIRM Clinical Trial Program may not be supporting coordination or a pipeline of young

SUPPORTING ORGANIZATIONS

AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS • AMERICAN GYNECOLOGICAL & OBSTETRICAL SOCIETY • AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE • AMERICAN UROGYNECOLOGIC SOCIETY • COUNCIL OF UNIVERSITY CHAIRS IN OBSTETRICS AND GYNECOLOGY • INFECTIOUS DISEASE SOCIETY FOR OBSTETRICS & GYNECOLOGY • NORTH AMERICAN SOCIETY FOR PEDIATRIC AND ADOLESCENT GYNECOLOGY • SOCIETY FOR ASSISTED REPRODUCTIVE TECHNOLOGY • SOCIETY FOR ACADEMIC SPECIALISTS IN GENERAL OBSTETRICS AND GYNECOLOGY • SOCIETY FOR REPRODUCTIVE ENDOCRINOLOGY OF GYNECOLOGIC ONCOLOGY • SOCIETY FOR MATERNAL-FETAL MEDICINE • SOCIETY FOR REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY • SOCIETY FOR REPRODUCTIVE INVESTIGATION • SOCIETY FOR WOMEN'S HEALTH RESEARCH investigators in this field in the same manner as the RMN. The Committee urges NICHD to report on its plans to support clinical trials on infertility within 180 days of enactment.

2024 Virtual Hill Day

The WFRC held a successful virtual hill day on March 19. Staff scheduled 15 meetings with Hill staff which were attended by 11 representatives of the WFRC member organizations. WFRC's goals for the virtual hill day were to ask Congress to support WFRC's federal funding priorities, educate members of Congress about WFRC and the need for increased funding for women's health research; and develop relationships with Members of Congress and their staff. Specifically, the WFRC asked Congress to –

- Include WFRC's report language on "BIRCWH Fellows Program", "WRHR Career Development Program", and "Maternal Morbidity & Mortality Research at NICHD"; and
- Include increased funding for the NIH and ORWH in the Labor HHS bill for FY 2025.

WFRC Report Language Requests for Fiscal Year 2025

WFRC developed three report language requests for Fiscal Year 2025. The first request is for the committee to include \$7 million for the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program. The second request is for the committee to include \$3 million for the Women Reproductive Health Research (WRHR) career development program. The third request is for the NICHD to support research on the impact of OB/GYN closures on maternal morbidity and mortality, as well as women's health more broadly. Due to the final funding increase for the BIRCWH program in FY 2024, which was finalized after our Hill Day, we are going to increase our ask to \$8 million for BIRCWH for FY 2025 in our advocacy efforts going forward.

Agency Outreach

NICHD - WFRC Meeting

On March 26, WFRC members met with Dr. Bianchi and other NICHD staff to discuss shared areas of interest. Dr. Bianchi discussed NICHD's role in the White House Initiative on Women's Health Research, as well as the need for additional funding to implement the initiative and the recent Executive Order. We also discussed our concerns with changes to the NICHD research networks, including the RMN and the National Centers for Translational Research in Reproduction and Fertility. We discussed the importance of NICHD-supported training programs, and Dr. Bianchi agreed with us on the importance of supporting the research workforce. We will continue to engage with NICHD and discussed the potential of holding a congressional briefing with them this year.

NASEM Panel on the Assessment of NIH Research on Women's Health

The NASEM panel on the Assessment of NIH Research on Women's Health met on <u>January 25</u> and <u>March 7</u> to hear from speakers in the federal government and private sector stakeholders. The panel also released a request for information, and the WFRC is finalizing our response. During the January 25 meeting, WFRC past co-chairs Drs. Lisa Barroilhet and Irina Burd presented to the panel, stressing the need for great investments in the women's health research workforce, improvements to the grant review process, additional funding for ORWH to allow them to issue grants to fill gaps in women's health research, and specific issues that require additional investment like fibroids, endometriosis, and reproductive health access.

Agency Activities

White House Issues Executive Order on Women's Health Research

On March 18, President Biden signed a new <u>Executive Order on Women's Health Research and</u> <u>Innovation</u>. WFRC representative Erika Miller was invited to the White House for the Women's History Month reception and signing of the Executive Order. The White House also released a <u>fact sheet</u>.

A few highlights from the initiative and the Executive Order:

- A \$200 million investment in FY 2025 to launch a new NIH-wide effort to fund interdisciplinary women's health research, which does not require a new appropriation from Congress;

- The development or strengthening of research and data standards to enhance women's health research in federally funded research;
- Addressing research gaps in our understanding of women's health diseases and conditions associated with midlife, including menopause;
- The Office of Management and Budget will identify current gaps in Federal funding for women's health research and develop recommendations on additional funding and programming needed to fill them; and
- This Initiative is not limited to NIH and other HHS agencies but also includes the National Science Foundation, Department of Veterans Affairs, the Department of Defense, and the Environmental Protection Agency.

ARPA-H Sprint for Women's Health

On February 21, First Lady Dr. Jill Biden <u>announced</u> that ARPA-H is launching a "Sprint for Women's Health," which will invest \$100 million to fund life changing research and make investments to advance women's health research. ARPA-H released a draft <u>request for solutions</u> for the ARPA-H Sprint for Women's Health, which provides a more detailed program description. It sets out six topics of interest in women's health, with more detail about these topics provided <u>here</u>. Submissions opened on March 13 and are due by April 12.

Funding Opportunities from NIH I/Cs

NOSI: Women's Health Research (<u>NOT-OD-24-079</u>) First available application due date: May 6, 2024

NOSI: Reproductive Health, Pregnancy, and Parenting among Women with Disabilities (<u>NOT-HD-</u> 21-025)

Application due date: May 31, 2024

NOSI: Promoting Vaccine Access, Acceptance and Uptake among Children, Adolescents, Pregnant and Lactating Women, and Persons with Disabilities (<u>NOT-HD-21-038</u>) Application due date: May 31, 2024

NOSI: Research to Improve Pre-Pregnancy Care and Enhance Healthy Birth Intervals (<u>NOT-HD-23-003</u>)

Application due date: May 8, 2024

NOSI: Health Influences of Gender as a Social and Structural Variable (<u>NOT-OD-24-038</u>) Application due date: January 25, 2024

Understanding Chronic Conditions Understudied Among Women (R21 Clinical Trial Optional) (RFA-OD-23-013) Letter of latent due date: May 20, 2024

Letter of Intent due date: May 20, 2024

Building Interdisciplinary Research Careers in Women's Health (BIRCWH) (K12 Clinical Trial Optional) (RFA-OD-24-013) Application due date: May 30, 2024