



Advancing Women's Health Research and Innovation

Elevating and prioritizing research on women's health at the highest levels

The Big Picture

The National Institutes of Health (NIH) supports women's health research and policy advances to foster innovation and discovery to improve prevention, diagnosis and treatment of diseases and conditions that affect women uniquely, differently, or disproportionately. Gaps in knowledge about the impact of biological and social factors throughout a woman's lifetime contribute to poorer health outcomes at great costs to women and society.

While women live longer than men on average, women spend more years of life in poor health and with disability. For longer, healthier lives, research is needed to address the health needs of women across the life course, from puberty through midlife and menopause and beyond.

Following the launch of the White House Initiative on Women's Health Research, President Biden signed <u>Executive Order 14120</u> on March 18, 2024, ushering in a transformative path to advance women's health research and innovation in the United States.

In response, the NIH is expanding its comprehensive approach to women's health research by emphasizing interdisciplinary research across the life course, further catalyzing innovation and training in women's health, and emphasizing the importance of evaluating and ensuring that women are appropriately included in clinical studies and <u>Sex as a Biological Variable (SABV)</u> is studied in research from the lab to the clinic to improve the health of women.

NIH Meets Women's Health Needs Through Research

To maximize the impact of women's health research, NIH has:



COMMITTED \$200 million in FY25 towards new interdisciplinary research with a central focus on the health needs of women, expanding the scope of opportunities and attracting new investigators. This NIH-wide effort is co-chaired by the NIH Office of the Director, the Office of Research on Women's Health, and the institute directors from the National Institute on Aging; the National Heart, Lung, and Blood Institute; the National Institute on Drug Abuse; the Eunice Kennedy Shriver National Institute of Child Health and Human Development; the National Institute on Arthritis, Musculoskeletal and Skin Diseases.



IDENTIFIED over 175 women's health priority topics and expanded paths for research applications across the entire agency on a wide range of diseases that affect women uniquely, disproportionately, or differently through a first of its kind funding program across all NIH Institutes or Centers (ICs) (NOT-OD-24-079). Through this first-ever Notice of Special Interest, NIH has already received and is considering nearly 300 new applications for women's health research projects across nearly every IC.



DEVELOPED a novel NIH discovery resource for women's health. This centralized resource, <u>DiscoverWHR</u>, simplifies access to women's health information by patients, caregivers, medical professionals, researchers, and the public. This new comprehensive resource includes the latest data and information on NIH-supported research, clinical trials, literature from PubMed, and patient-friendly summaries on topics that include menopause, polycystic ovary syndrome, and autoimmune diseases.



NIH currently supports
~150 funding
opportunities

and notices for research on maternal mental health, menopause, endometriosis, and heart disease among other topics spanning the life course.



CHARTED the NIH course for the future of women's health research with the 2024-2028 NIH-Wide Strategic Plan for Research on the Health of Women.

To address the health needs of women across the life course—from puberty through midlife and menopause and beyond—NIH is:

- **IDENTIFYING** and addressing areas where more evidence is needed to help women and their health care providers navigate health concerns important to women, such as postpartum health and menopause. For example, in 2025, the NIH will dedicate its next <u>Pathways to Prevention (P2P) Program</u>—an independent, expert review process—to synthesize evidence on menopause, identify existing research gaps, and develop an action plan to advance menopause research and care across the federal government and research community.
- IMPROVING the quality and quantity of data collected, analyzed, and reported on women's health. For example, NIH partnered with the Centers for Disease Control and Prevention to develop detailed questions about menopause to be added to the National Health Interview Survey in 2025. The National Health Interview Survey has been fielded since 1957 and serves as the principal source of information about the health of the U.S. population. New questions on menopause will significantly expand the amount of data and information we collect on women's midlife health, enabling additional insights about how menopause affects women's health.
- IMPROVING the quality of research by developing common data elements on women's health, including those specifically focused on menopause. Once finalized in 2025, NIH's new indicators will be widely adopted in both research and clinical settings and enable researchers to more easily share and combine data across research studies and ultimately improve the accuracy of research information on women's health. By helping capture and combine more data about women's health, NIH will give researchers and clinicians the tools they need to enable more meaningful data collection, analysis, and reporting.
- SHARING cutting-edge research advances through a quarterly publication, WOMEN'S HEALTH In Focus AT NIH. For example, laboratory research that has identified potential therapeutic targets for postpartum depression in the brain. New treatments will build on these discoveries, showing how insights from the laboratory can translate to the clinic and ultimately improve care for the one in eight women with postpartum depression.

NIH Catalyzes Innovation to Address Women's Health Needs

To accelerate small business and technology research and development in women's health, NIH is:

- LAUNCHING the RADx® Tech ACT ENDO Challenge competition to develop new noninvasive technologies for diagnosing endometriosis, a debilitating condition which affects 10% of women in the U.S. and often takes years to be diagnosed. NIH will award \$3 million in prizes to develop new technologies to make it easier and quicker to diagnose endometriosis. The first round of awardees will be announced in spring 2025.
- **SPURRING** innovation and technology development with U.S.-owned and operated small businesses to conduct research and development in women's health through a joint funding opportunity with the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA).
- **INCREASING** investments in private-sector innovations and small businesses engaged in research and development on women's health through the competitive Small Business Innovation Research Program and the Small Business Technology Transfer Program. This builds on the NIH's increased investments in women's health research through small businesses by almost 25% between FY21 and FY23.
- **TAKING** an artificial-intelligence/advanced analytics-driven, systems-biology approach to improve the prediction, diagnosis, and treatments of multiple diseases across diverse populations and the lifespan. The National Heart, Lung, and Blood Institute (NHLBI) is initially committing \$20M to target women's health research as the first use case under this initiative, with mid-life as the starting focus.

NIH Advances Cross-cutting Policies to Strengthen Women's Health Research

To advance the study of women's health through research and data standards, NIH is:



LEVERAGING each aspect of the NIH funding process to ensure that women's health and potential sex and gender differences are considered at each step of the research funding process by:

- Instructing grant applicants on NIH requirements to use appropriate data and standards to advance women's health research.
- Ensuring grant review panels include reviewers with expertise relevant to the women's health topic under investigation, as appropriate.
- Requiring that inclusion of women and how investigators account for SABV be evaluated during the scientific and technical review of applications and contribute to the scored assessment of the rigor and feasibility of the research, as outlined in the Simplified Review Framework, to go into effect in January 2025.
- Enhancing reviewer training on consideration of SABV during the grant review process, and training on SABV for NIH scientific staff.



DIRECTING each IC to develop customized plans to enhance SABV policy application in the context of the IC's mission area.



EXPANDING the role of the NIH SABV Working Group to promote and support more standardized and consistent approaches to SABV policy application and implementation across the NIH ICs.



CONSULTING with other agencies, such as the Department of Defense, to promote comprehensive research and data standards across the federal government's research portfolio, including a <u>new SABV policy</u> adopted by the Congressionally Directed Medical Research Programs for FY25.



An NIH funded,
interdisciplinary study
used artificial
intelligence to reveal
meaningful sex-based
differences in the brain.