



EXECUTIVE ORDER

14120

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ADVANCING WOMEN'S HEALTH RESEARCH AND INNOVATION

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. My Administration is committed to getting women the answers they need about their health. For far too long, scientific and biomedical research excluded women and undervalued the study of women's health. The resulting research gaps mean that we know far too little about women's health across women's lifespans, and those gaps are even more prominent for women of color, older women, and women with disabilities.

The notion of including women in clinical trials used to be revolutionary -- which means many diagnostics and treatments were developed without women in mind and thus failed to account for women's health. Over 30 years ago, the Congress passed the landmark National Institutes of Health Revitalization Act of 1993 (Public Law 103-43) to direct the National Institutes of Health (NIH), the largest public funder of biomedical research in the world, to include women and people of color in NIH-funded clinical research. In 2016, the Congress built on these requirements in the 21st Century Cures Act (Public Law 114-255), which directed the NIH to further its pursuit of women's health research, including by strengthening clinical trial inclusion and data analysis, developing research and data standards to advance the study of women's health, and improving NIH-wide coordination on women's health research.

These policies led to significant increases in women's participation in clinical trials, and ongoing investments in biomedical research have supported breakthroughs in women's

health. Through the discovery of genetic factors that increase the risk of breast cancer and innovations in mammography, we have transformed our approach to prevention, early detection, and treatment, and have improved outcomes for women facing a breast cancer diagnosis. We have improved access to life-saving treatments for women with severe heart failure by ensuring that the devices they need are the right size for a woman's body. We have also identified some of the most characteristic symptoms of heart attack in women, which are different from those in men -- discoveries that have helped deliver faster treatment to women when every second counts. This is what we can achieve when we invest in women's health research.

It is time, once again, to pioneer the next generation of discoveries in women's health. My Administration seeks to fundamentally change how we approach and fund women's health research in the United States. That is why I established the first-ever White House Initiative on Women's Health Research (Initiative) -- which is within the Office of the First Lady and includes a wide array of executive departments and agencies (agencies) and White House offices -- to accelerate research that will provide the tools we need to prevent, diagnose, and treat conditions that affect women uniquely, disproportionately, or differently.

Together with the First Lady's tireless efforts, the Initiative is already galvanizing the Federal Government to advance women's health, including through investments in innovation and improved coordination within and across agencies. We are also mobilizing leaders across a wide range of sectors, including industry, philanthropy, and the medical and research communities, to improve women's health.

It is the policy of my Administration to advance women's health research, close health disparities, and ensure that the gains we make in research laboratories are translated into real-world clinical benefits for women. It is also the policy of my Administration to ensure that women have access to high-quality, evidence-based health care and to improve health outcomes for women across their lifespans and throughout the country.

I will continue to call on the Congress to provide the transformative investments necessary to help our researchers and scientists answer today's most pressing questions related to women's health. Investing in innovation in women's health is an investment in the future of American families and the economy. At the same time, agencies must use their existing authorities to advance and integrate women's health across the Federal research portfolio, close research gaps, and make investments that maximize our ability to prevent, diagnose, and treat health conditions in women.

Sec. 2. Definitions. For purposes of this order:

(a) The term "women's health research" means research aimed at expanding knowledge of women's health across their lifespans, which includes the study and analysis of conditions specific to women, conditions that disproportionately impact women, and conditions that affect women differently.

(b) The term "White House Initiative on Women's Health Research" means the interagency, advisory body established by the Presidential Memorandum of November 13, 2023 (White House Initiative on Women's Health Research), to advance women's health research.

(c) The term "agency Members of the Initiative" refers to the Secretary of Defense, the Secretary of Agriculture, the

Secretary of Health and Human Services, the Secretary of Veterans Affairs, the Administrator of the Environmental Protection Agency, and the Director of the National Science Foundation.

Sec. 3. Further Integrating Women's Health Research in Federal Research Programs. (a) Building on research and data standards issued by the NIH in 2016, agency Members of the Initiative shall consider actions to develop or strengthen research and data standards that enhance the study of women's health across all relevant, federally funded research and other Federal funding opportunities. Agency Members of the Initiative shall consider issuing new guidance, application materials, reporting requirements, and research dissemination strategies to advance the study of women's health, including to:

- (i) require applicants for Federal research funding, as appropriate, to explain how their proposed study designs will consider and advance our knowledge of women's health, including through the adoption of standard application language;
- (ii) consider women's health, as appropriate, during the evaluation of research proposals that address medical conditions that may affect women differently or disproportionately;
- (iii) improve accountability for grant recipients, including, as appropriate, by requiring regular reporting on their implementation of, and compliance with, research and data standards related to women's health, including compliance with recruitment milestones; and
- (iv) improve the recruitment, enrollment, and retention of women in clinical trials, including, as

appropriate, by reducing barriers through technological and data sciences advances.

(b) Within 30 days of the date of this order, the Chair of the Initiative and the Director of the NIH Office of Research on Women's Health, in consultation with the Director of the Office of Management and Budget (OMB), shall establish and co-chair a subgroup of the Initiative to promote interagency alignment and consistency in the development of agency research and data standards to enhance the study of women's health.

(c) Within 90 days of the date of this order, agency Members of the Initiative shall report to the Chair of the Initiative on actions taken to strengthen research and data standards to enhance the study and analysis of women's health and related conditions.

(d) Within 180 days of the date of this order and on an annual basis thereafter, agency Members of the Initiative shall report to the President on the status of implementation of research and data standards.

Sec. 4. Prioritizing Federal Investments in Women's Health Research. (a) Agency Members of the Initiative shall identify and, as appropriate and consistent with applicable law, prioritize grantmaking and other awards to advance women's health research, with an emphasis on:

- (i) promoting collaborative, interdisciplinary research across fields and areas of expertise;
- (ii) addressing health disparities and inequities affecting women, including those related to race, ethnicity, age, socioeconomic status, disability, and exposure to environmental factors and contaminants that can directly affect health; and

(iii) supporting the translation of research advancements into improved health outcomes.

(b) Agency Members of the Initiative shall take steps to promote the availability of federally funded research and other Federal funding opportunities to advance women's health, including through the development and inclusion of standard language related to women's health, as appropriate, in all relevant notices of funding opportunity and through better facilitating potential grant applicants' access to information about funding opportunities related to women's health research.

(c) To advance innovation, commercialization, and risk mitigation, agency Members of the Initiative shall:

(i) identify and, as appropriate and consistent with applicable law, seek ways to use innovation funds, challenges, prizes, and other mechanisms to spur innovation in women's health;

(ii) invest in innovation to accelerate women's health research, including through or in collaboration with the Advanced Research Projects Agency for Health and the Congressionally Directed Medical Research Programs;

(iii) support the role of small businesses and entrepreneurs in advancing innovation in women's health research, including through Small Business Innovation Research Programs and Small Business Technology Transfer Programs; and

(iv) invest in translational science to convert research findings and discoveries into treatments and interventions that improve women's health outcomes and reduce health disparities, including through the

Department of Agriculture National Institute of Food and Agriculture research programs.

(d) In implementing section 8(b) of Executive Order 14110 of October 30, 2023 (Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence), the Secretary of Health and Human Services, in consultation with the Director of the National Science Foundation, shall consider the opportunities for and challenges that affect women's health research in the responsible deployment and use of artificial intelligence (AI) and AI-enabled technologies in the health and human services sector.

Sec. 5. Galvanizing Research on Women's Midlife Health. (a) Within 90 days of the date of this order, to address research gaps in understanding women's health and diseases and conditions associated with women's midlife and later years, the Secretary of Health and Human Services shall:

(i) launch a comprehensive assessment of the current state of the science on menopause to develop an evidence-based research agenda that will guide Federal and private sector investments in menopause-related research;

(ii) evaluate evidence-based interventions and strategies to improve women's experiences in the menopausal and perimenopausal periods, including the delivery of treatments for women experiencing menopause in clinical care settings;

(iii) consider developing new common data elements and survey tools to expand the ethical and equitable collection of data on issues related to women's midlife health; and

(iv) develop new comprehensive resources to help ensure that the public has evidence-based information about menopause, including menopause-related research initiatives, findings, and symptom-prevention and treatment options.

(b) The Secretary of Defense and the Secretary of Veterans Affairs shall evaluate the needs of women service members and veterans related to midlife health and shall develop recommendations to support improved treatment and targeted research of midlife health issues, including menopausal symptoms.

Sec. 6. Assessing Unmet Needs to Support Women's Health Research. The Director of OMB and the Assistant to the President and Director of the Gender Policy Council (Directors) shall lead an effort, in collaboration with the Initiative, to identify current gaps in Federal funding for women's health research and shall submit recommendations to the President describing the additional funding and programming necessary to catalyze research on women's health, including in priority areas within women's health as identified by the Initiative, as follows:

(a) Within 90 days of the date of this order, the Directors shall, in consultation with the Initiative, develop guidance for assessing additional funding that agencies need to close research gaps in women's health.

(b) Within 180 days of the date of this order, Members of the Initiative shall consult the guidance described in subsection (a) of this section and shall each submit a report to the Directors that identifies the funding needed to catalyze research on women's health.

(c) Based on the reports described in subsection (b) of this section, the Directors shall develop and submit

recommendations to the President on steps the Federal Government should take to catalyze research on women's health. These recommendations shall identify any statutory, regulatory, budgetary, or other changes that may be necessary to ensure that Federal laws, policies, practices, and programs support women's health research more effectively.

(d) Following the submission of the recommendations described in subsection (c) of this section, each Member of the Initiative shall report annually to the Directors on progress made in response to those recommendations and to improve the study of women's health. The Director of OMB shall provide a summary of Members' progress and any new recommendations to the President on an annual basis, consult with each Member on their women's health research funding needs during the annual budget process, and calculate Federal funding for women's health research on an annual basis.

Sec. 7. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or
- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,

March 18, 2024.

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