AMERICAN MEDICAL ASSOCIATION WOMEN PHYSICIANS SECTION

Resolution: (Assigned by HOD)
(A-25)

Introduced by: Megan Sousa, Elizabeth Suschana

Subject: Establishment of NIH Research Institute for Women's Health

Referred to: Reference Committee (Assigned by HOD)

Whereas, gaps in women's health research exist due to a number of factors including historical exclusion of women from clinical trials, long-standing focus on male physiology, and lack of analysis of sex-specific differences[1]; and

Whereas, both cisgender women and gender-diverse individuals face significant gaps in gender-affirming care, resulting in healthcare outcomes that are suboptimal due to historical exclusion from clinical research, contributing to higher rates of adverse drug reactions (ADRs) and other healthcare disparities[2]; and

Whereas, in 1986, a National Institutes of Health (NIH) policy urged the inclusion of women in clinical trials but did not mandate their inclusion[3]; and

Whereas, in 1990, the NIH established the Office of Research on Women's Health (ORWH) to serve as a focal point for women's health research[1]; and

Whereas, the National Institute Revitalization Act of 1993 mandated the inclusion of women in clinical trials[1]; and

Whereas, in 1994, the Food and Drug Administration created the Office of Women's Health to promote inclusion of women in clinical trials[5]; and

Whereas, despite efforts to include women in clinical trials, sex-based gaps continue to exist in clinical trials[1]; and

Whereas, a 2022 study examining 1,433 trials with over 300,00 participants found an average trial enrollment of 41.2% for female participants[5]; and

Whereas, research gaps result in a lack of knowledge on prevention, diagnosis, and treatment of conditions in women including but not limited to female-specific conditions such as endometriosis[1]; and

Whereas, sex differences influence disease prevalence, progression, and response to treatment, with women and gender-diverse individuals experiencing unique health challenges due to biological factors such as disease presentations, risk factors, and varying drug responses[1]; and

Whereas, a 2020 study found women to have nearly twice the risk of experiencing ADRs across all drug classes compared to men[6]; and

Whereas, a study published in *JAMA Network Open* in 2021 found that male-dominant conditions often receive disproportionately high funding relative to their burden, with research funding for these conditions exceeding what would be expected based on their prevalence and impact[7]; and

Whereas, inadequate representation of women and gender-diverse individuals in clinical research leads to inefficient treatment protocols, misdiagnoses, and adverse health outcomes, which contribute to higher healthcare costs that burden the public health system[8]; and

Whereas, studies indicate that the underrepresentation of women and gender-diverse individuals in clinical research contributes to significant healthcare inefficiencies, with estimates suggesting that healthcare costs for women could be up to $2 billion higher annually due to the lack of gender-specific research and tailored treatments[8]; and

Whereas, the National Center for Advancing Translational Sciences (NCATS), the most recently established NIH institute, has demonstrated the impact of institute-backed, focused research by significantly accelerating the translation of scientific discoveries into effective treatments[9]; and

Whereas, a 2025 congressionally mandated report from the National Academies of Sciences, Engineering, and Medicine evaluated the current organizational structure and funding of the NIH for women's health research, finding that only 8.8% of NIH grant spending from 2013 to 2023 was allocated to women's health research despite increases in overall NIH funding[8]; and

Whereas, the report found the current NIH organizational structure for women's health research including the ORWH is unfunded and limited effectiveness in addressing gaps in women's health research[10]; and

Whereas, women's health conditions such as polycystic ovary syndrome and vulvodynia and women- specific life stages such as menopause do not fall within the purview of the existing NIH institutes or center[11]; and

Whereas, report recommendations include the establishment of a new institute to cover female-specific conditions, female physiology, sex differences, and reproductive phases not covered by an NIH institute or center[10]; therefore be it

RESOLVED, that our American Medical Association support the establishment of a new institute focused on women's health and the health of gender-diverse populations within the National Institutes of Health; and be it further

RESOLVED, that our AMA will advocate for Congress to allocate appropriate funding to support the establishment of a new institute focused on women's health within the National Institutes of Health

Fiscal Note: (Assigned by HOD)

Received: XX/XX/2025

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RELEVANT AMA POLICY

Sex and Gender Differences in Medical Research H-525.988

Our AMA: (1) reaffirms that gender and sex exclusion in broad medical studies questions the validity of the studies' impact on the health care of society at large; (2) affirms the need to include people of all sexes and gender identities and expressions in studies that involve the health of society at large and publicize its policies; (3) supports increased funding into areas of women's health and sexual and gender minority health research; (4) supports increased research on women's health and sexual and gender minority health and the participation of women and sexual and gender minority communities in clinical trials, the results of which will permit development of evidence-based prevention and treatment strategies for all women and sexual and gender minority individuals from diverse cultural and ethnic groups, geographic locations, and socioeconomic status; (5) recommends that all medical/scientific journal editors require, where appropriate, a sex-based and gender-based analysis of data, even if such comparisons are negative; and (6) recommends that medical and scientific journals diversify their review processes to better represent women and sexual and gender minority individuals; (7) supports the FDA's requirement of actionable clinical trial diversity action plans from drug and device sponsors that include women and sexual and gender minority populations; (8) supports the FDA's efforts in conditioning drug and device approvals on post-marketing studies which evaluate the efficacy and safety of those products in women and sexual and gender minority populations when those groups were not adequately represented in clinical trials; and (9) supports and encourages the National Institutes of Health and other grant-making entities to fund post-market research investigating pharmacodynamics and pharmacokinetics for generic drugs that did not adequately enroll women and sexual and gender minority populations in their clinical trials, prioritizing instances when those populations represent a significant portion of patients or reported adverse drug events.

[Res. 80, A-91 Appended: CSA Rep. 4, I-00 Modified: CSAPH Rep. 1, A-10 Reaffirmed: CSAPH Rep. 05, A-16 Modified: Res. 004, A-23 Modified: CSAPH Rep. 04, A-24]

Increasing Participation in Clinical Research of People Identifying with Minoritized and Marginalized Groups H-460.911

1. Our American Medical Association advocates that: (a) The Food and Drug Administration (FDA) and National Institutes of Health (NIH) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations. (b) The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and

participation in this research. (c) Resources be provided to community level agencies that work with those minorities, females, and other underrepresented groups who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care. These minorities include Black Individuals/African Americans, Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans.

2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities, females, and other underrepresented groups in clinical trials: (a) Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders' support, and listening to community's needs. (b) Increased outreach to all physicians to encourage recruitment of patients from underrepresented groups in clinical trials. (c) Continued education for all physicians and physicians-in-training on clinical trials, subject recruitment, subject safety and possible expense reimbursements, and that this education encompass discussion of barriers that currently constrain appropriate recruitment of underrepresented groups and methods for increasing trial accessibility for patients. (d) Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions. (e) Fiscal support for minority, female, and other underrepresented groups recruitment efforts and increasing trial accessibility.

3. Our AMA advocates that specific results of outcomes in all clinical trials, both pre- and post-FDA approval, are to be determined for all subgroups of gender, race and ethnicity, including consideration of pediatric and elderly populations; and that these results are included in publication and/or freely distributed, whether or not subgroup differences exist.

4. Our AMA will collaborate with AHRQ, FDA, NIH and other interested parties to increase public and physician awareness and education on the topic of inclusivity in clinical trial participation.

[BOT Rep. 4, A-08 Reaffirmed: CSAPH Rep. 01, A-18 Modified: Res. 06, I-22 Modified: Res. 913, I-24]

An Expanded Definition of Women's Health H-525.976

Our AMA recognizes the term "women's health" as inclusive of all health conditions for which there is evidence that women's risks, presentations, and/or responses to treatments are different from those of men, and encourages that evidence-based information regarding the impact of sex and gender be incorporated into medical practice, research, and training.

[CSAPH Rep. 05, A-16]

Inclusion of Women in Clinical Trials H-525.991

Our AMA: (1) encourages the inclusion of women, including pregnant women when appropriate, in all research on human subjects, except in those cases for which it would be scientifically irrational, in numbers sufficient to ensure that results of such research will benefit both men and women alike; (2) supports the National Institutes of Health policy requiring investigators to account for the possible role of sex as a biological variable in vertebrate animal and human studies; and (3) encourages translation of important research results into practice.

[Res. 183, I-90 Reaffirmed: Sunset Report, I-00 Reaffirmed: CSAPH Rep. 1, A-10 Modified: CSAPH Rep. 05, A-16 Reaffirmed: Res. 909, I-16]