



December 18, 2023

Carolyn M. Mazure, PhD  
Chair  
White House Initiative on Women's Health Research  
White House Gender Policy Council  
1600 Pennsylvania Ave NW  
Washington, D.C. 20500

Dear Dr. Mazure:

The Society for Women's Health Research (SWHR)—a national nonprofit dedicated to advancing women's health through science, policy, and education while promoting research on sex differences to optimize women's health—was overjoyed to see last month's announcement about the first-ever White House Initiative on Women's Health Research. Since its inception, SWHR has called for equity and parity in research into women's health, and we believe that the equivalent of a Cancer Moonshot<sup>SM</sup> for women's health would accelerate scientific discoveries, enhance federal prioritization and coordination of women's health research, and improve sharing of data. We believe this new White House Initiative has the potential to serve as this 'Moonshot,' remedying decades of lost research into the health of women, spurring innovation and advancing knowledge, and, ultimately, transforming how we view women's health in the United States.

As you consider the various recommendations put forth by Initiative members, SWHR would like to share some of our own recommendations for your consideration. SWHR has more than 30 years of experience and success in advocating for policies that advance the health of women across the lifespan and equity in health outcomes.

### **Considerations Related to the NIH Research Structure and Accountability Mechanisms**

- I. **Office of Research on Women's Health (ORWH) Reporting.** The ORWH serves at the National Institutes of Health (NIH) hub for coordinating women's health research. As such, it ensures women are appropriately represented in the biomedical and behavioral research supported by the NIH. In its more than 30-year history, the ORWH has helped transform what we think of as "women's health," improved our understanding of the influences of sex and gender on health and disease, and developed resources to help scientists more effectively and efficiently recruit and retain women participants in clinical studies. We believe that elevating the coordination, collaboration, and accountability of the ORWH is essential to ensuring that research into women's health is taken seriously across the NIH. As such, the director of the ORWH should report directly to the director of the NIH, rather than to the director of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the Director.
- II. **Infrastructure and Capacity at ORWH.** SWHR was pleased that the ORWH's grantmaking authority was confirmed in fiscal year 2023 appropriations legislation. This

was an important step forward in elevating the work of ORWH and ensuring that the Office can issue and administer grants to “promote the interests in women in research.” However, SWHR is concerned that, despite this new authority, certain barriers, such as an insufficient budget, limited office space, and a lack of full-time employees who could administer grants, are hindering the Office’s ability to administer grants. SWHR encourages members of Congress to increase the funding level provided to ORWH in future funding cycles to allow the entity to reach its full potential and fund women’s health research into areas that are not being examined at other NIH Institutes and Centers and encourages the director of the NIH to examine ways in which the NIH can support ORWH’s grantmaking authority.

**III. Accountability for the NIH Sex as a Biological Variable (SABV) Policy.** NIH’s SABV policy, which went into effect in January 2016, set forth NIH’s expectation that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. As noted in the 2020 *Journal of Women’s Health* article, “Sex as a Biological Variable: A 5-Year Progress Report and Call to Action,”<sup>1</sup> “Integrating SABV into basic and preclinical research to identify potential differences in drug safety is far more efficient than discovering them during clinical trials or in postmarketing surveillance. Investments in preclinical research that consider SABV may also help avoid differential effectiveness outcomes.”

However, despite the implementation of this policy, SWHR believes that greater enforcement and accountability of the SABV policy is needed. More could be done to incorporate SABV into the biomedical research enterprise. A November 2022 article<sup>2</sup> published in *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences* examined whether the SABV policy was being considered in preclinical aging research. For the study, the authors searched for research articles that reported NIH extramural research funding support from January of 2020 through May of 2021, yielding 507 articles the authors felt were relevant to their analysis. While the authors note some limitations to their review, they ultimately found that “more than 50% of NIA-funded studies published [from 2020 through 2021] are not considering SABV, despite the NIH mandate being in place since 2016.” Specifically, the article shares the following statistics:

- Approximately half incorporated both sexes in the design of all or a subset of experiments (40.6% and 7.1%, respectively), while 43% reported single-sex data (30.4% male-only; 12.6% female-only), and 9.3% failed to specify sex at all
- Just 17.4% of male- or female-only experiments offered any justification as to why
- Of the articles that included both sexes in some or all experiments, only 46.3% reported comparisons between male and females

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<sup>1</sup> Arnegard, M. E., Whitten, L. A., Hunter, C., & Clayton, J. A. (2020). Sex as a Biological Variable: A 5-Year Progress Report and Call to Action. *Journal of women's health* (2002), 29(6), 858–864. <https://doi.org/10.1089/jwh.2019.8247>

<sup>2</sup> Carmody, C., Duesing, C. G., Kane, A. E., & Mitchell, S. J. (2022). Is Sex as a Biological Variable Still Being Ignored in Preclinical Aging Research?. *The journals of gerontology. Series A, Biological sciences and medical sciences*, 77(11), 2177–2180. <https://doi.org/10.1093/gerona/glac042>

We encourage the NIH to make SABV a priority across its Institutes and Centers and to take the next steps to better integrate SABV across the biomedical research enterprise. Steps that could help improve this, as outlined in the *Journal of Women's Health* article referenced above, are adding sessions at meetings, focusing attention on sex differences in funding opportunity announcements, and training the next generation of researchers. Moreover, leadership from funding organizations, research entities, and editors of peer-reviewed journals should incorporate the consideration of SABV into their organizations' roles.

Further, we urge NIH to seriously consider whether journal articles and published research results that do not comply with SABV or Sex and Gender Equity in Research (SAGER) guidelines should be posted and linked in the National Library of Medicine.

#### **IV. Dedicated Funding Line for the Office of Autoimmune Disease Research (OADR).**

SWHR was thrilled to see Congress, at the recommendation of the National Academies of Sciences, Engineering, and Medicine (NASEM),<sup>3</sup> call for the establishment of OADR in the Consolidated Appropriations Act, 2023.<sup>4</sup> The incidence of autoimmune diseases in the United States is rising, and women constitute nearly 80% of the patients diagnosed with autoimmune diseases.<sup>5</sup> Understanding the influences of sex and gender on autoimmune diseases and conditions will be key in combatting the rise of these diseases.

Within the 2023 Consolidated Appropriations Act, Congress provided ORWH with \$10 million to establish the OADR, providing the Office with the foundational investment it needed to begin this important work. However, it is not clear how funding for the OADR will be handled in future appropriations cycles, such as whether Congress would provide dedicated funding for the Office or whether the funding is expected to come out of the topline of funding provided to the ORWH. Autoimmune diseases constitute a group of more than 80 chronic conditions. Research into such a large range of conditions requires more funding than the ORWH can provide without jeopardizing its other programs and initiatives. SWHR would like to see robust funding for OADR that supplements, not supplants, the foundational investments being made into the ORWH. SWHR also encourages the Office of Management and Budget and future President's budgets to include a dedicated funding line for the OADR.

#### **V. Bolster Existing Infrastructure for Research on Women's Health at the NIH.** As we await the results of the National Academies for Science, Engineering, and Medicine's (NASEM) Assessment of NIH Research on Women's Health, the White House should work to prioritize existing research avenues across the NIH – for example, research occurring at the *Eunice Kennedy Shriver* National Institute of Child Health and Human

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<sup>3</sup> National Academies of Sciences, Engineering, and Medicine. 2022. Enhancing NIH research on autoimmune disease. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26554>.

<sup>4</sup> Division H—Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2023 Explanatory Statement, Consolidated Appropriations Act, 2023 (Public Law 117-328). <https://www.appropriations.senate.gov/imo/media/doc/Division%20H%20-%20LHHS%20Statement%20FY23.pdf>.

<sup>5</sup> Invernizzi, P., Pasini, S., Selmi, C., Gershwin, M. E., & Podda, M. (2009). Female predominance and X chromosome defects in autoimmune diseases. *Journal of autoimmunity*, 33(1), 12–16. <https://doi.org/10.1016/j.jaut.2009.03.005>

Development (NICHD), the National Institute of Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), as well as all of the other Institutes, Centers, and Offices. Concerted efforts through additional funding and prioritization would go a long way to further innovation and discoveries in women's health across the lifespan.

## Investing in the Health of Women Across the Research Enterprise

- I. **Diversity in Clinical Trials.** Since its founding, SWHR has sought to improve the representation of women in clinical trials. Today, we continue that work to ensure that not only are women represented in clinical trials, but that diverse populations of women are represented in clinical trials.

While women's representation in clinical trials has improved (using ClinicalTrials.gov<sup>6</sup> data, women, on average, represent 41.2 percent of trial participants), an analysis on clinical trials between 2000-2020 found that women are underrepresented in clinical trials in cardiology, oncology, neurology, immunology, and hematology.<sup>7</sup>

The statistics related to the inclusion of women of color are even more bleak. According to a 2022 article in *Cell Reports Medicine*,<sup>8</sup> in U.S. Food and Drug Administration (FDA) oncology trials over 2017-2020, the total percentage of participants (of which women comprised less than half) who were Black or African American ranged from 2-5 percent, and of Hispanic or Latino ethnicity from 4-6 percent (Black and African American individuals represent 12.1 of the U.S. population, and Hispanic or Latino individuals represent 18.7 percent of the population). Authors also noted that while sex and race are reported for these trials, the interaction of sex and race are not, which limits our ability to study important intersectional characteristics within trial populations. Additionally, the authors emphasize, "In addition to FDA-regulated trials, numerous reports confirm the underrepresentation of women of diverse racial and ethnic backgrounds in post-approval trials, NIH-supported trials, comparative effectiveness trials, vaccine trials, and others."

Beyond SWHR's concern about these populations being overlooked in research, SWHR also advocates for the appropriate inclusion of pregnant and lactating populations in clinical trials. Despite there being more than 3.5 million women in the United States who give birth each year, pregnant and lactating women have historically been excluded from clinical trials, leading to significant evidence gaps impacting the health outcomes of mothers and infants. This lack of data creates challenges for women who live with chronic conditions like narcolepsy or epilepsy, who require continued medication use, or for women who become sick while pregnant. It forces health care providers to make

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<sup>6</sup> Vadali, M. More Data Needed, Study Shows Females Underrepresented in Key Disease Clinical Trials. Accessed 15 December 2022. <https://hms.harvard.edu/news/more-data-needed#:~:text=After%20examining%20%2C433%20trials%20with,of%20trial%20participants%20were%20female>

<sup>7</sup> Steinberg JR, Turner BE, Weeks BT, et al. Analysis of Female Enrollment and Participant Sex by Burden of Disease in US Clinical Trials Between 2000 and 2020. *JAMA Netw Open*. 2021;4(6):e2113749. doi:10.1001/jamanetworkopen.2021.13749

<sup>8</sup> Bierer, B. E., Meloney, L. G., Ahmed, H. R., & White, S. A. (2022). Advancing the inclusion of underrepresented women in clinical research. *Cell reports. Medicine*, 3(4), 100553. <https://doi.org/10.1016/j.xcrm.2022.100553>

health care decisions with no or limited evidence, and it puts both moms and babies at risk. Ensuring the appropriate inclusion of these populations in research will better equip health care providers, mothers, and families to make the best health care decisions for them and their families.

- II. **Considerations for Prioritizing Research Investments.** Women’s health is not limited to the conditions that are exclusive to women (e.g., reproductive health). Women’s health comprises everything that differently or disproportionately affects women, such as Alzheimer’s disease, autoimmune and immune-mediated diseases and conditions, cardiovascular disease, major depressive disorders, osteoporosis, and more.

There are myriad opportunities to advance women’s health research and drive innovation – and women’s health would benefit tremendously from advancements in each of these spaces.

As the Initiative team considers which areas of science would be most transformational in the health of women across the lifespan, SWHR would emphasize the need to better understand sex differences in disease as well as fundamental hormonal drivers of women’s health. We see the need for this understanding across diseases and conditions. Areas that would benefit from additional research include, but are not limited to, the role of biological sex on the development of autoimmune disease, symptom manifestation, and symptom severity; sex differences in target organ susceptibility to immune-mediated damage; the role of hormones on autoimmune symptom outcomes, including during life stages, such as pregnancy and menopause; the role of biological sex differences in heart health; the role of sex and gender differences in neurodegenerative disease risk factors, progression, and prevalence; the intersection between pregnancy, bone health, and osteoporosis outcomes later in life; the disparities of lung cancer in women, particularly in women non-smokers, who have a higher incidence of lung cancer than men; the role of puberty and menarche in changes in the female body; the impact of menopause on aging and health; and more.

Further, the Initiative team may find it beneficial to focus on diseases and conditions that affect all individuals, but that differently or disproportionately affect women. Historically, research funding does not fall on the side of women. A 2021 analysis of NIH funding by Arthur A. Mirin, PhD, in the *Journal of Women’s Health*<sup>9</sup> found that “in nearly three-quarters of the cases where a disease afflicts primarily one gender, the funding pattern favors males, in that either the disease affects more women and is underfunded (with respect to burden), or the disease affects more men and is overfunded.” Moreover, the article notes, the “disparity between actual funding and that which is commensurate with burden is nearly twice as large for diseases that favor males versus those that favor females.”

- III. **Research Workforce Needs.** It is well documented that diversity contributes to better science and to improving the diversity of clinical trial participation among underserved

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<sup>9</sup> Mirin A. A. (2021). Gender Disparity in the Funding of Diseases by the U.S. National Institutes of Health. *Journal of women's health* (2002), 30(7), 956–963. <https://doi.org/10.1089/jwh.2020.8682>

populations. A 2022 NASEM report on why diverse representation in clinical research matters<sup>10</sup> found that a lack of representation in trials: compromises generalizability of clinical research findings to the U.S. population, may hinder innovation, may lead to lack of access to effective medical interventions, compounds health disparities, and may undermine trust. To the last point, the Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials cited research demonstrating that knowledge and trust in the process of influenza vaccine development and testing was associated with a higher degree of vaccine uptake for the influenza vaccines in Black populations.<sup>11</sup>

Although women account for about half of medical graduates and doctoral recipients in the biological sciences, they are underrepresented at all levels of leadership in the biomedical field.<sup>12</sup> Women in research earn less,<sup>13</sup> receive less funding at the beginning of their careers,<sup>14</sup> and are cited less frequently.<sup>15</sup> Women are also more likely to switch to part-time work, change careers, or leave the workforce. Furthermore, they also disproportionately face sexual harassment and discrimination.<sup>16,17</sup>

Disparities are even greater for women of color, who encounter both significant racial and gender biases. These biases can present differently, but they can have a detrimental impact on those forced to confront them. For example, Black women are significantly more likely to report having to provide more evidence of competence to prove themselves to colleagues, and Latinas are more frequently perceived as “angry” or “emotional.” Black women are also more likely to report feeling isolated in their work environment.<sup>18</sup>

Among the suggestions SWHR has made in this space include thinking strategically about the roles of sex and gender and sexual and gender minorities and analyzing how the current landscape may affect different populations—including how implicit or

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<sup>10</sup> Bibbins-Domingo K., Helman A., editors. (2022). *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups* by the National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research. National Academies Press (US). Available from: <https://www.ncbi.nlm.nih.gov/books/NBK584396/>.

<sup>11</sup> Quinn, S. C., Jamison, A., An, J., Freimuth, V. S., Hancock, G. R., & Musa, D. (2017). Breaking down the monolith: Understanding flu vaccine uptake among African Americans. *SSM - population health*, 4, 25–36. <https://doi.org/10.1016/j.ssmph.2017.11.003>

<sup>12</sup> Clayton et al. Women’s Careers in Biomedical Sciences: Implications for the Economy, Scientific Discovery, and Women’s Health. *Journal of Women’s Health*, 2017. doi: 10.1089/jwh.2016.6012

<sup>13</sup> Scientists’ salary data highlight US\$18,000 gender pay gap. *Nature*. January 22, 2019.

<sup>14</sup> Sege, Nykiel-Bub, Selk. Sex Differences in Institutional Support for Junior Biomedical Researchers. *JAMA*. 2015; 314(11): 1175-1177. doi: 10.1001/jama.2015.8517

<sup>15</sup> Why women are cited less often in research than men. *The Hill*. December 17, 2019.

<sup>16</sup> Sexual harassment of women: Climate, culture, and consequences. National Academies (2018).

<sup>17</sup> Funk and Parker. Women and Men in STEM Often at Odds Over Workplace Equity. Pew Research Center. January 2018. <https://www.pewresearch.org/social-trends/2018/01/09/women-and-men-in-stem-often-at-odds-over-workplace-equity/>

<sup>18</sup> Williams, Phillips, & Hall (2014). Tools for change: Boosting the retention of women in the STEM pipeline. UC Hastings College of the Law. [https://worklifelaw.org/publications/Double-Jeopardy-Report\\_v6\\_full\\_web-sm.pdf](https://worklifelaw.org/publications/Double-Jeopardy-Report_v6_full_web-sm.pdf)

subconscious bias and harassment against LGBTQ+ and other populations may serve as a barrier to advancement—and how future policies could resolve the unique disparities faced by these populations in order to create a truly inclusive and welcoming workforce.

Additionally, to improve diversity, equity, and inclusion in the research workforce, SWHR has called for actions,<sup>19</sup> such as:

- Establishing, sustaining, and enhancing partnerships with higher education institutions to improve talent pipeline initiatives
- Expanding partnerships to community colleges, technical colleges, and historically Black colleges and universities (HBCUs) to enhance training and credentials and recruit from traditionally underrepresented populations
- Establishing and/or encouraging employer-institution partnerships—including networking, mentorship, and job shadowing programs—at non-traditional institutions to enhance exposure opportunities for workers
- Creating goals and metrics to. Understand successes, failures, and opportunities for change across partnership
- Engaging in thorough program planning, development, and analysis across all partnerships of this nature, with the ultimate goal of disseminating learning to inspire replication and scale through the scientific community

## **Coordination and Collaboration of Women’s Health Activities Across the Federal Agencies**

The U.S. Department of Health and Human Services (HHS) [Coordinating Committee on Women’s Health](#) (CCWH) was established in 1983, but was codified into law under the 2010 Affordable Care Act. The Committee is required to write a report every other year. Yet, it seems that the profile of the CCWH is not as visible as it has been in the past. A broader, more public effort, including public meetings of the coordinating committee—or at least open communication—could be beneficial.

### **Offices of Women’s Health**

There are still federal agencies – under the HHS jurisdiction and outside of it – that do not have Offices of Women’s Health or concentrated research efforts related to women’s health.

As one example, the Centers for Medicare and Medicaid Services (CMS) does not have an Office of Women’s Health. From SWHR’s perspective, there is a need for a women-specific guide for female Medicare beneficiaries as well as the women who are covered by Medicaid. Further, given the rising maternal mortality rates, the extension of Medicaid for one year postpartum, and the proportion of female Medicare beneficiaries (55.2 percent of Medicare beneficiaries in 2022 were female<sup>20</sup>), a concerted effort to prioritize and elevate women’s health would be appropriate.

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<sup>19</sup> SWHR Comments to NIH UNITE Initiative Committees on Diversity in Biomedical Careers (2021). [https://swhr.org/swhr\\_resource/swhr-comments-to-nih-unite-initiative-committees-on-diversity-in-biomedical-careers/](https://swhr.org/swhr_resource/swhr-comments-to-nih-unite-initiative-committees-on-diversity-in-biomedical-careers/)

<sup>20</sup> Distribution of Medicare Beneficiaries by Sex (2022), State Health Facts. Kaiser Family Foundation. <https://www.kff.org/medicare/state-indicator/medicare-beneficiaries-by->

Additionally, the Department of Defense does not have an Office on Women's Health, although the Department does engage in women's health, in terms of both coverage and research through its Congressionally Directed Medical Research Programs (CDMRP), which include several areas where women's health research might be included.

Within the U.S. Department of Veterans Affairs (VA), there is a growing proportion of beneficiaries who are women, and there are concerted efforts to address women's health. However, when SWHR attended a Women's Health Task Force roundtable hosted by the House Veterans Affairs Committee, the bulk of the discussion was around breast cancer screening and access to mammograms and follow up. With environmental health factors, mental health, uterine health, menopause, bone health, Alzheimer's disease, and the myriad other conditions that could impact these women, there is far more that should be done to ensure this population is served appropriately.

Federal agencies as well as those in the women's health and public health communities would greatly benefit from continued collaboration and coordination at the federal level beyond just at the NIH. SWHR encourages HHS to convene the CCWH regularly and publicly to allow for greater interaction, opportunities for public comment, and better coordination of the Offices on Women's Health. Including non-HHS agencies, such as those named in the White House Initiative, will be imperative to more thorough collaboration and coordination of women's health activities across the federal government.

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Again, SWHR appreciates the opportunity to provide input to the White House Initiative on Women's Health Research and thanks the Administration for prioritizing women's health research at the federal level.

As demonstrated by the announcement of the Initiative and the information provided above, there are tremendous opportunities to advance the health of women across the lifespan and to achieve equity and parity for women in health and health care. This Initiative represents a key first step in moving these opportunities into policy and practice. The Society for Women's Health Research looks forward to collaborating with our partners in the Administration and Congress as the White House Initiative moves into future phases of this work. Now is the time for a national strategy to advance equity and parity in the health of women. This is an important first step.

Should you have questions or require additional information, please contact SWHR President and CEO Kathryn Schubert, MPP, CAE, at [kathryn@swhr.org](mailto:kathryn@swhr.org).