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A New Vision for Women's Health Research

Transformative Change at the National Institutes of Health

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Presentation to ACRWH

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Statement of Task

- Analyze the proportion of research that the NIH funds on conditions that are female-specific, more common amongst women, or that differently impact women.
- Establish how these conditions are defined and ensure that it captures conditions across the lifespan.
- Define women's health for the purpose of the report.
- Determine the appropriate level of funding that is needed to address gaps in women's health research at NIH.
- Provide recommendations on NIH research priorities; NIH training and education efforts needed to build, support, and maintain a robust women's health research workforce; NIH structure, systems, and review processes to optimize women's health research; and the allocation of funding needed to address gaps in women's health research at NIH

Committee Process

- Study requested by Congress as part of the Consolidated Appropriations Act of 2023
- Funded by the NIH Office of Research on Women's Health
- Held 6 information-gathering and deliberative meetings
  - Received input from a broad range of stakeholders
  - Information gathering ended in May 2024
- Prepared a 9-chapter report with 15 conclusions and 8 recommendations
  - External peer review by 17 expert reviewers

Important Definitions Used Throughout the Report

Women's health:
Includes physical, biological, reproductive, psychological, emotional, and cultural/ spiritual health and wellness across the life course.

- Includes the experiences and needs of those assigned female at birth or identify as a woman, girl, female, nonbinary, transgender (men or women), genderfluid, or Two-Spirit.

Women's health research:
The scientific study of the range of and variability in women's health as defined and the mechanisms and outcomes in disease and non-disease states across the life course.

- Considers both sex and gender, disease risk, pathophysiology, symptoms, diagnosis, and treatment; addresses interacting concerns related to women's bodies and roles and social and structural determinants and systems.

Background

- The U.S. is a leader in research innovation and health discoveries, but scientific enterprises have not yielded the anticipated breakthroughs to improve health and well-being for over half the population: women and girls.
  - Lack of baseline understanding of basic sex-based differences in physiology (e.g., chromosomal and hormonal)
  - Lack of attention and support for research into conditions specific to, more common among, or that affect women and girls differently
- Advances in women's health research are critical to contributing to overall scientific progress and innovation.

The Need for Women's Health Research

- Healthy women are vital to a healthy society and growing economy.
  - Women spend more years living with disability and poor health—on average, 9 years, or 25 percent longer than men.
  - Historical exclusion of women from research has led to persistent gaps in the evidence base on women's health that still impact research today.
  - Women face intersecting barriers to care, including economic, geographic, institutional, social, and cultural barriers, discrimination and bias, lack of education and health literacy, and stigma.
  - Breakthroughs in women's health improve understanding of health for everyone.

Committee's Funding Analysis: NIH Spending on Women's Health Research

- Conducted a committee-designed analysis of NIH funding (FY 2013-2023)
  - multimethod and multistage approach, including the use of large language models.
- FY 2013–FY 2023: total grant funding for women's health research = 8.8% of all NIH research grant spending.
  - FY 2023 7.9%
- A similar pattern of low funding holds for intramural research, too.

Committee Funding Analysis: NIH Spending on Women's Health Research is a Small Fraction of Overall Grant Spending

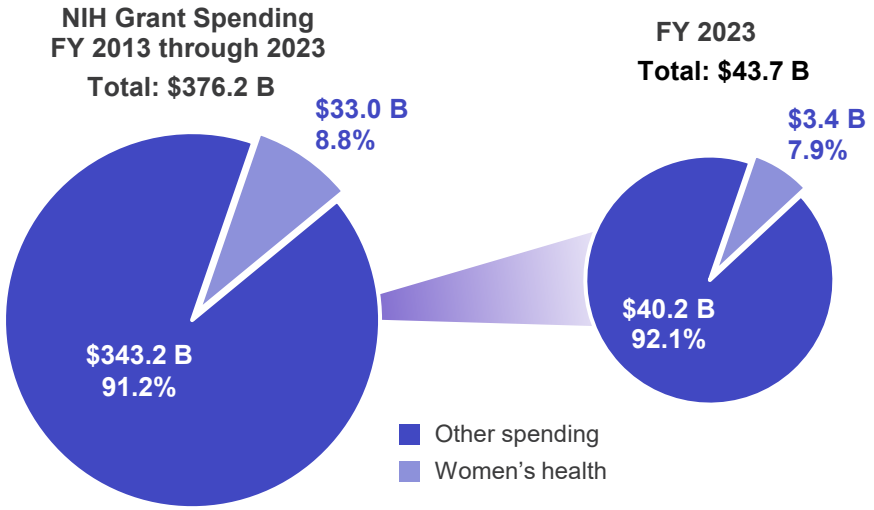


FIGURE. Total NIH grant funding on women's health research, FY 2013–2023 and for FY 2023.
SOURCE: Committee analysis.

Committee's Funding Analysis: The Share of NIH Grant Spending on Women's Health has Shrunk in the Past Decade

- While NIH grant funding has steadily increased from FY 2013–FY 2023 in both dollars spent ($26.3 billion-$43.7 billion) and the number of projects funded, the proportion of **funding for research related to women's health remained low and decreased** during the same period (9.7%-7.9%).

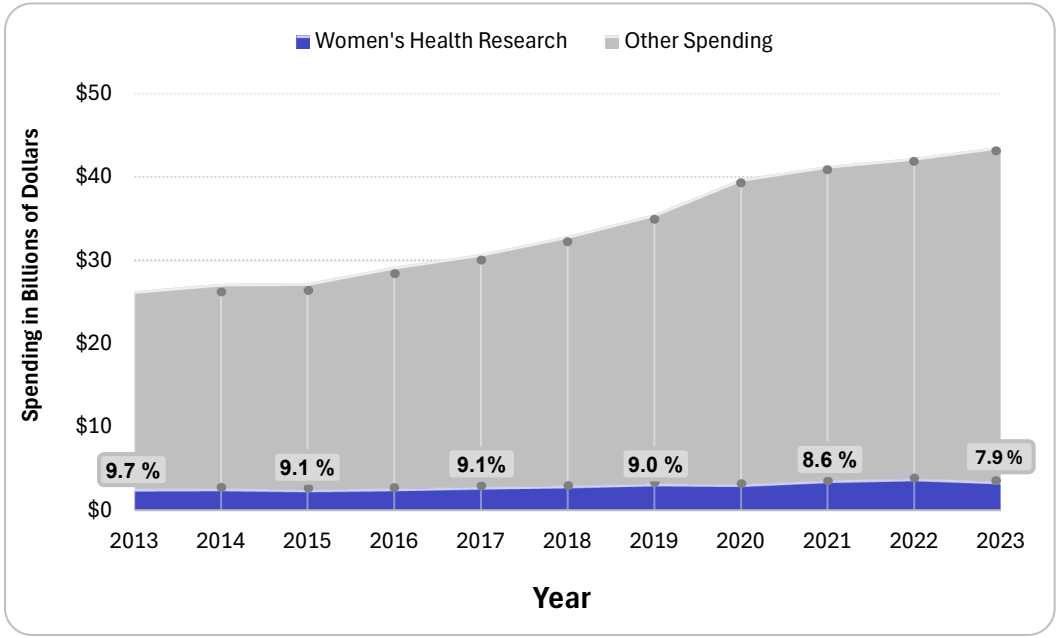


FIGURE. Overall NIH grant funding and the proportion of NIH funding on women's health research, FY 2013–2023; share of NIH grant spending on women's health has shrunk in the past decade.
SOURCE: Committee analysis.

Low Proportion Of Funding For Women's Health Research (WHR) Seen Across All Institutes and Centers (ICs)

- National Institute of Child Health and Human Development (NICHD; 37%) had largest proportion of WHR funding;
  - other ICs spent less than 20%, and many less than 10%.
- Of the $33 billion NIH spent on WHR grants:
  - National Cancer Institute (NCI): $9.2 billion
  - NICHD: $5.3 billion
  - National Institute of Allergy and Infectious Diseases: $4.1 billion
  - Other ICs: about $2 billion or less

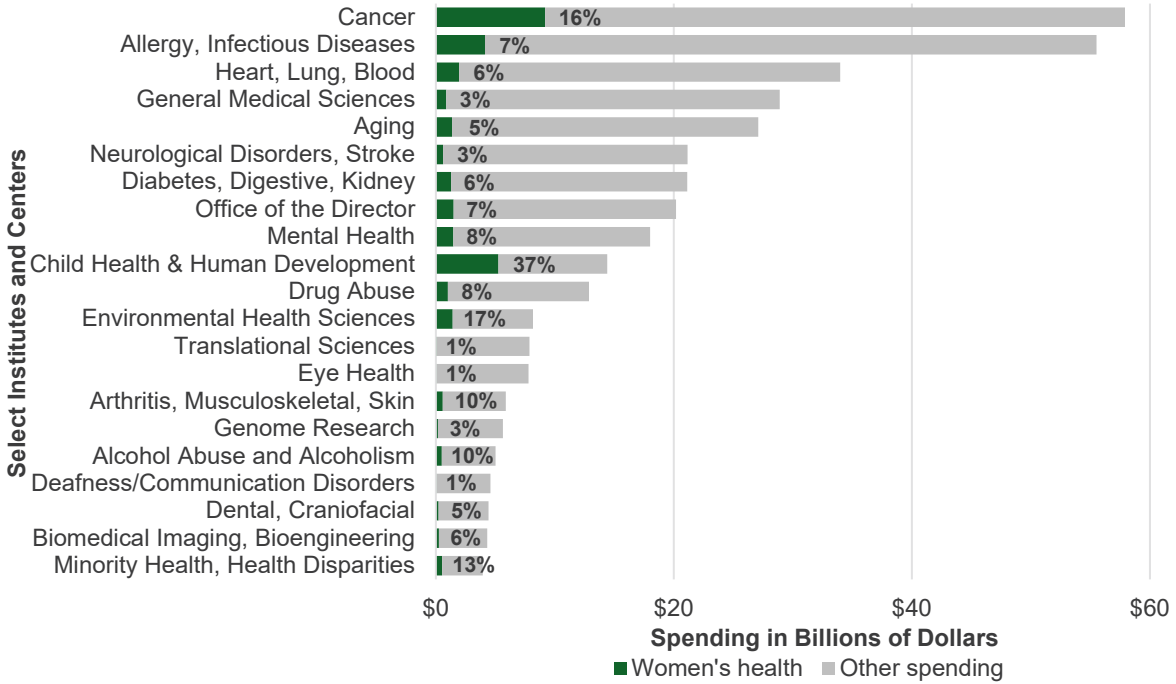


FIGURE. NIH grant funding for women's health research, FY 2013 through 2023.
SOURCE: Committee analysis.

Committee's Funding Analysis: Distribution of NIH Funding for Women's Health

- Grants funded to study conditions relevant to women's health **favored certain conditions**.
  - **Top 10:** breast cancer and some female-specific cancers, pregnancy and infertility, and perimenopause and menopause, as well as conditions that also affect men (e.g., HIV/AIDS, diabetes, and depressive disorders).
- **Low levels of funding for many female-specific conditions**.
  - Endometriosis, fibroids, pelvic floor disorders, polycystic ovary syndrome (PCOS), postpartum depression, uterine cancer, vulvodynia, and others;
  - Yearly funding has been flat over the last decade for many of these conditions.

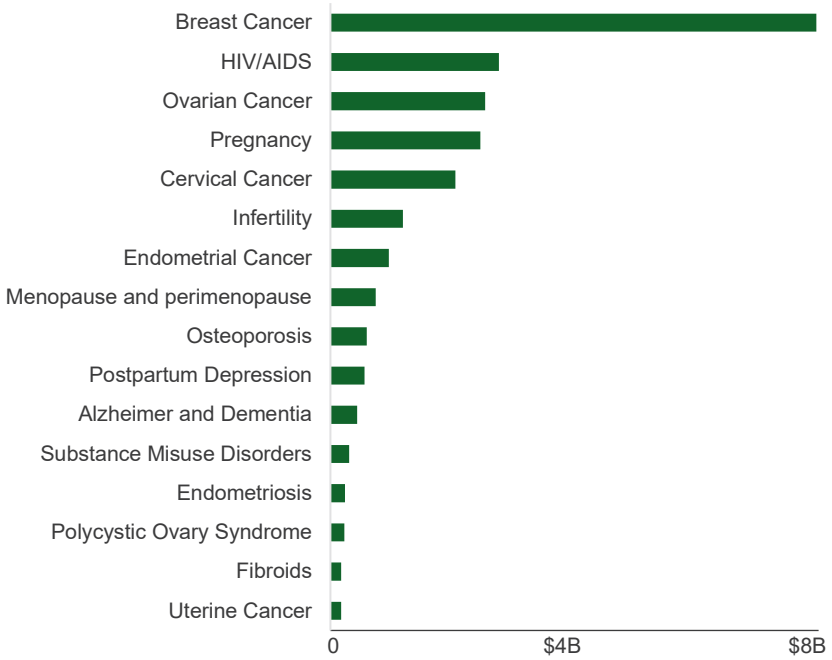


FIGURE NIH grant funding for select conditions relevant to women's health, FY 2013–FY 2023.
SOURCE: Committee funding analysis.

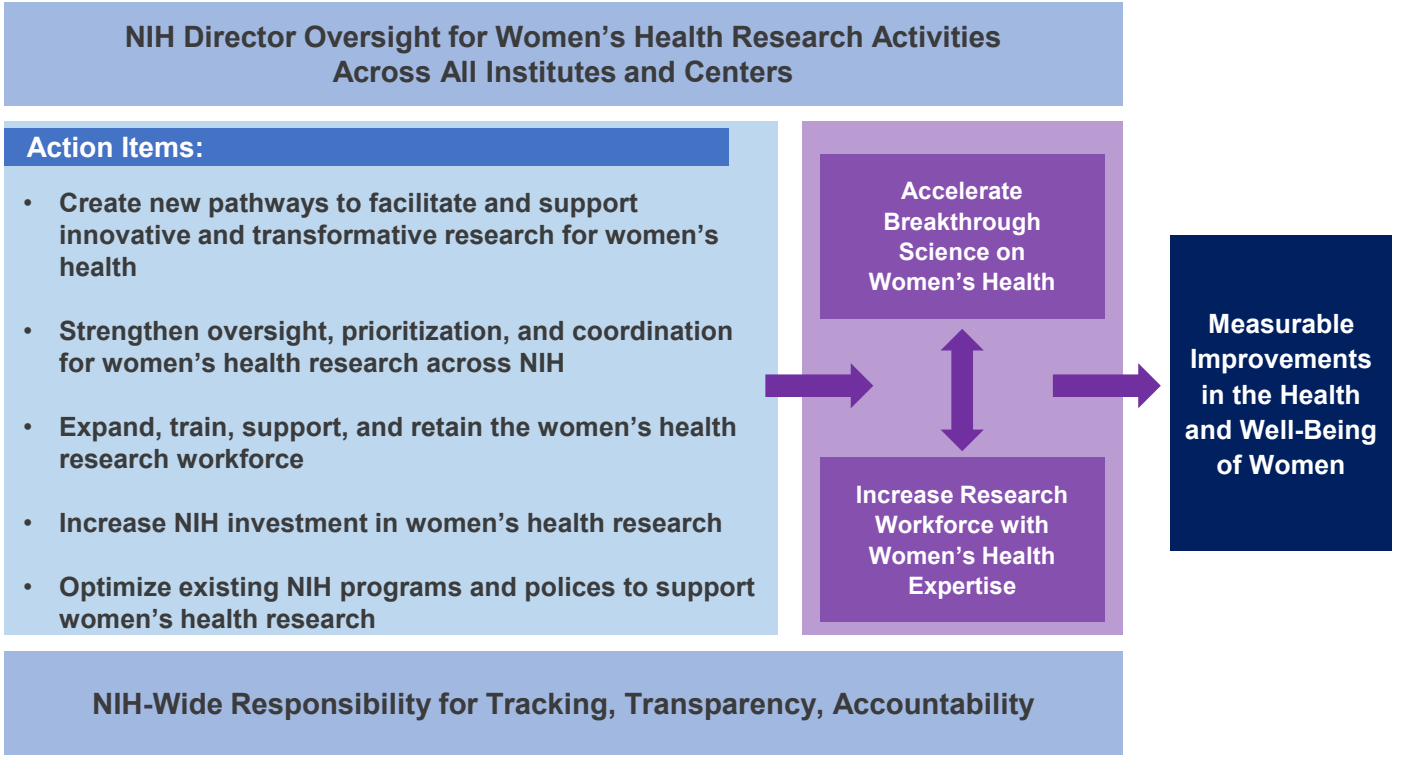
Overarching Conclusions from the Report

1. A comprehensive approach is needed to develop a robust women's health research (WHR) agenda and establish a supportive infrastructure at the NIH. **Augmented funding for WHR, while crucial, needs to be complemented by enhanced accountability, rigorous oversight, prioritization, and seamless integration** of women's health research across NIH.

2. **NIH is underspending on women's health.**

3. **The current organizational structure of the NIH limits its ability to address gaps in WHR.** There is inadequate oversight, limited ability for the Office of Research on Women's Health to incentivize ICs to prioritize research, and many women's health conditions and women-specific life stages do not easily align within the purview of the 27 existing ICs despite the millions of women who experience the burdens of these conditions.

Structural Elements of Committee Recommendations to Fill Research Gaps



Create Pathways to Facilitate and Support Innovative and Transformative Research for Women's Health

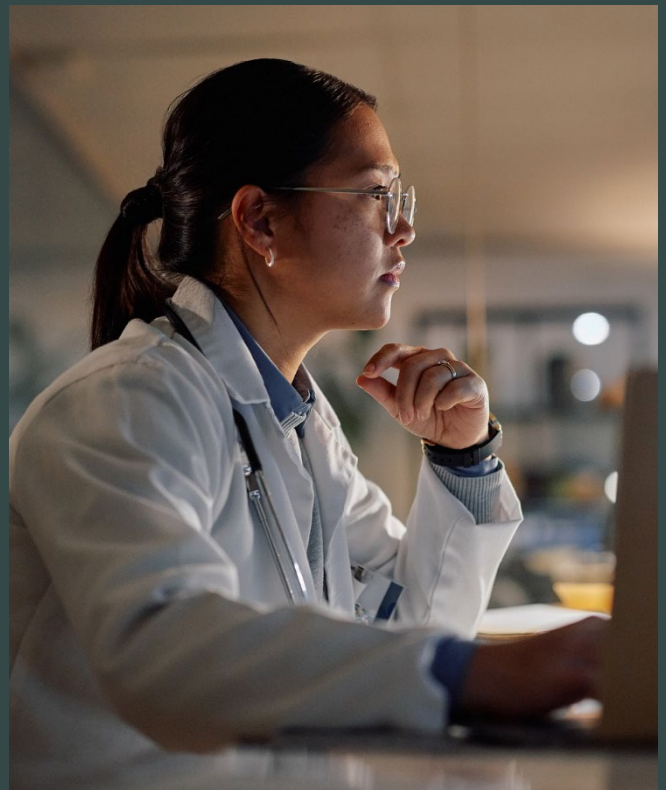
Recommendation 1: NIH Organizational Structure

Congress should:

- **Elevate the Office of Research on Women's Health to an Institute** with primary responsibility to lead, conduct, and support research on female physiology and chromosomal differences, reproductive milestones across the life course, and female-specific conditions that do not fall under the purview of other ICs.
- **Establish a new fund for women's health research (WHR) in the Office of the Director**.

- **NIH director should assume oversight** and responsibility for the WHR portfolio and implementation of priorities and policies relevant to women's health.
- **IC directors should increase support for WHR** that falls under their purview.
- **NIMHD's should expand its role** to include women, girls, and females among the populations that experience disparities.

Expand, Train, Support, and Retain the Women's Health Research Workforce



Workforce Career Pathways and Development: Key Conclusions

- A robust infrastructure for research in women's health and sex differences at NIH is needed to cultivate a vibrant women's health workforce.
- Inadequate funding of women's health research (WHR) has led to an insufficient number of WHR investigators.
- Current grant mechanisms are inadequate to support career trajectories in WHR.
- Mentorship and career development are vital to the development of the WHR workforce.
- Gender-based bias and sexism persist, including in health and research systems; these biases affect the grant review and award making process.
- In addition to sexism, bias related to race and ethnicity have been identified as independent and intersectional contributors to gaps in health research generally and WHR specifically.

Recommendation 4: Career Pathways

NIH should **augment existing programs and develop new initiatives to attract researchers and support career pathways** for scientists through all stages of the careers of women's health researchers. NIH should:

- Create a **new subcategory within the Loan Repayment Program** for investigators conducting research on women's health or sex differences.
- **Allow financial support of up to 10 percent for mentors** on all mentored grants that support careers of early and midcareer investigators in women's health and sex differences research.
- Create new and expand existing early and midcareer grant mechanisms.
- Support early career mentored institutional K-awards for up to 5 years.

Recommendation 5: Expand Workforce Development Programs

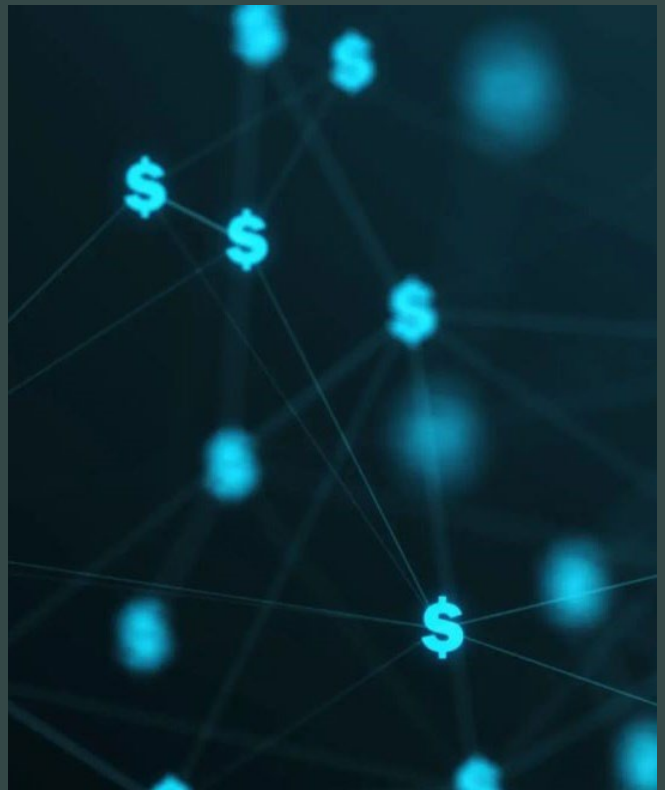
NIH should augment existing programs and develop new grant initiatives designed to promote interdisciplinary science and career development related to women's health. NIH should expand:

- **Building Interdisciplinary Research Careers in Women's Health (BIRCWH)**
- **Specialized Centers of Research Excellence (SCORE) on Sex Differences**
- **Women's Reproductive Health Research (WRHR**, and
- **Research Scientist Development Program (RSDP)**

NIH should also fund additional **multi-project program grants.**

NIH should also prioritize and promote participation of women and investigators from underrepresented communities.

Increase NIH Investment in Women's Health Research



New Funding to Fill Women's Health Research (WHR) Gaps

New WHR Fund

to support and foster interdisciplinary research on women's health and sex differences

Year 1 ($900m)
Year 2 ($1.5b)
Years 3-5 ($3b/year)

New WHR Institute

on female physiology and chromosomal differences, reproductive life course, and female-specific conditions not under purview of other ICs

$800m/year

Workforce Programs

Year 1 ($42.8m)
Year 2 ($56.8m)
Year 3 ($66.8m)
Years 4-5 ($74.3m/year)

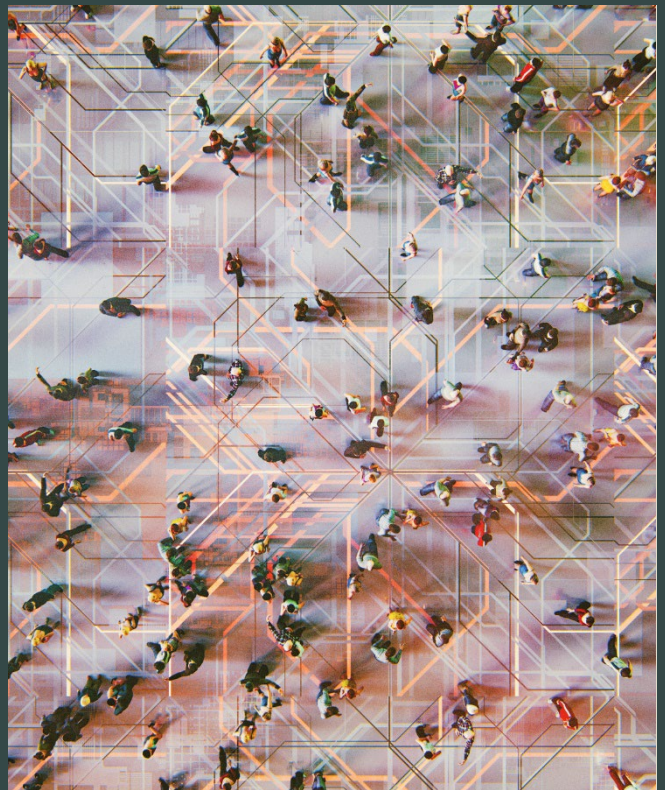
Total New Gap Funding*

A 5-year Investment of **$15.71 billion**

Reaching ~$3.87 billion/year in new funding in Years 4–5

*Does not included additional funds needed to support increased operational costs, increased oversight by the NIH director, and other related costs

Strengthen Oversight, Prioritization, and Coordination for Women's Health Research Across NIH



Tracking NIH Investments in Women's Health Research

Recommendation 2:

NIH should **reform its process for tracking and analyzing its investments** in research funding to improve accuracy for reporting to Congress and the public. NIH should:

- **Improve the accuracy of grants coded** as Women's Health.
- Update its process for **reviewing, revising, and adding** new RCDC categories.
- Make **transparent and accessible** the process and data used for portfolio analysis.

Priority Setting for Women's Health Research

Key Conclusions

- NIH Institutes and Centers (ICs) strategic plans to inform their research priorities, rarely mention women's health and lack elements of the NIH-Wide Strategic Plan for Research on the Health of Women.
- Variations in the timing of the IC plans complicate NIH's ability to set, implement, and oversee cohesive and cross-agency priorities for women's health research.

Recommendation 3: Priority Setting

The director of NIH should **develop and implement a transparent, biennial process to set priorities for WHR** that is data driven, includes input from the scientific and practitioner communities and the public, and responds to gaps in the evidence base and evolving women's health needs. NIH should:

- Employ **data-driven methods to assess the public health effect** of conditions that are female specific, disproportionately affect women, or affect women differently.
- **Report this assessment publicly** and use it to **identify research priorities** and direct funding for WHR.
- In addition to current funding activities, issue Requests for Applications, Notices of Special Interest, Program Announcement, and similar mechanisms to ensure priorities for WHR are implemented.

Priority Research and Measurement

Recommendation 8: Looking Forward

Research Priorities: Recommendation 8 describes areas for prioritization needed to advance WHR across the research spectrum

- Research on the role of sex, gender, gender identity, and sex beyond the binary within each type of research will improve understanding of how these factors play a role in disease prevention, development of health conditions, and treatment outcomes.

The committee also suggests **measures to track progress** on advancing women's health in Chapter 9.

Optimize NIH Programs and Policies to Support Women's Health Research

Peer Review

Key Conclusions

- Representation of women's health expertise is essential during the NIH peer review process—including expertise of staff in the Center for Scientific Review, Institute and Center program officers and council members, and peer reviewers.
- Despite NIH efforts to expand the cadre of reviewers with women's health research (WHR) expertise, a large proportion of WHR–related grants are evaluated by special emphasis panels, not standing study sections, indicating that standing study sections do not yet have the required expertise to review WHR grants.

Recommendation 6: Peer Review

NIH should continue and strengthen its efforts to **ensure balanced representation and appropriate expertise** when evaluating grant proposals pertaining to women's health and sex differences research in the peer review process. NIH should:

- Employ data science methods and use professional networks to identify experts and recruit recently funded investigators.
- Expand the Early Career Reviewer program.
- Work with NIH-funded institutions to identify qualified individuals with expertise in women's health.

In the short term, use Special Emphasis Panels more often.

Sex as a Biological Variable Policy (SABV)

Key Conclusions

- SABV is not meaningfully factored into research designs, analyses, and reporting in vertebrate animal and human studies.
- Overall uptake and application of SABV in practice has not been optimal.
- Although guidance and trainings on the NIH SABV policy outline distinctions between sex and gender, language and implementation is not clearly geared toward studies of gender, gender identity, and intersex status.
- No cross-agency mechanism at NIH for assessing how SABV in grants is evaluated or for tracking appropriateness and completeness of SABV implementation.
- No consequences for grantees if they do not implement plans for SABV; no incentives.

Recommendation 7: Sex as a Biological Variable Policy (SABV)

NIH should revise how it supports and implements its SABV policy to ensure it fulfills the intended goals.

NIH should, for example:

- Expand and tailor education and training resources for investigators.
- Ensure that SABV is consistently and systematically reviewed in the grant review process.
- Expand the SABV policy in human studies to explicitly factor the effect of biological sex, gender, and gender identity in research designs, analyses, and reporting.
- Relevant studies should be exempt from across-the-board budget cuts to protect sample sizes and analyses needed to study sex difference and have access to administrative supplements, among other actions.

Recommendation 7: Sex as a Biological Variable Policy (SABV) (continued)

Applications that rigorously examine sex, gender, or gender identity differences should:

- Be exempt from across-the-board budget cuts to protect sample sizes and analyses needed to study sex differences.
- Have access to administrative supplements to ensure sex, gender, and gender identity differences can be studied rigorously and with adequate sample size.
- Have priority for funding when such projects fall in the discretionary range of the payline.
- Undergo a streamlined process for requesting higher budgets.

Intramural researchers should factor SABV in research design, analyses, and reporting.

Conclusion: Filling the Women's Health Research Gaps

- Increased investment in women's health research is only a first step.
- Improving quality of life and reducing morbidity and mortality from conditions that are female specific, disproportionately affect women, or affect women differently than men requires sustained commitment, additional funding, and accountability.
- The continued neglect of research on women's health ultimately impacts not only women but society as a whole.

To access the report and supporting materials, visit www.nationalacademies.org/womens-health-research

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