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February 1, 2021 NASEM Meeting



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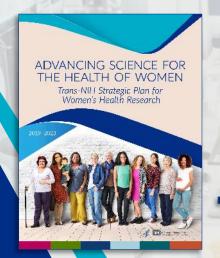
ORWH Mission



Enhance and expand women's health research

Include women and minority

groups in clinical research



NIH Vision



Sex and gender integrated into biomedical research



Every woman receives evidence-based care



Promote career advancement for women in biomedical careers



Women in science careers reach their full potential

Organizational Home for ORWH at NIH

- ORWH is one of 14 offices within the Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI) that is within the Office of the NIH Director, https://dpcpsi.nih.gov/
- DPCPSI plans and coordinates trans-NIH initiatives, with its mission to identify emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps that merit further research
- Some of the other 13 offices include those focusing on AIDS research, behavioral and social sciences research, and disease prevention
- ORWH does not have the legislative authority to accept or fund grant applications so
 ORWH partners with the ICs to cofund meritorious research



ORWH 30th Anniversary Virtual Meetings December 14 - 16, 2020

Building Interdisciplinary Research Careers in Women's Health





National Institutes of Health | 1990 – 2020

Specialized Centers of Research Excellence on Sex Differences



December 14, 2020

December 15, 2020

December 16, 2020

https://orwh.od.nih.gov/orwh-anniversary



NIH Policy on Sex as a Biological Variable

- Women now account for roughly half of all participants in NIH-supported clinical research, which is subject to NIH's Policy on the Inclusion of Women in Clinical Research.
- However, basic and preclinical biomedical research has focused on male animals and cells.
 An over-reliance on male animals and cells may obscure understanding of key sex influences on health processes and outcomes.
- Accounting for sex as a biological variable begins with:
 - 1. The development of research questions and study design
 - 2. Data collection and analysis of results, as well as reporting of findings
 - 3. Consideration of sex being critical to the interpretation, validation, and generalizability of research findings. Adequate consideration of both sexes in experiments and disaggregation of data by sex allows for sex-based comparisons and may inform clinical interventions
 - 4. Appropriate analysis and transparent reporting of data by sex may therefore enhance the rigor and applicability of preclinical biomedical research



NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research

- The NIH Revitalization Act of 1993, PL 103-43, signed into law in 1993, directed the NIH to establish guidelines for inclusion of women and minorities in clinical research
- The purpose of the 2017nNIH <u>Inclusion Across the Lifespan Policy</u> is to ensure individuals are included in clinical research in a manner appropriate to the scientific question under study so that the knowledge gained from NIH-funded research is applicable to all those affected by the researched diseases/conditions. The policy expands the <u>Inclusion of Children in Clinical Research Policy</u> to include individuals of all ages, including <u>children</u> and <u>older adults</u>; Policy first published in 1998 and updated in 2015



Extramural Funding of Women's Health and Sex Differences Research & Career Development

ORWH, in collaboration with 27 NIH Institutes and Centers and individual Offices within the Office of the Director, supports women's health research in multiple areas of science, including cancer, human genetics, drug and alcohol abuse, cardiovascular diseases, immune disorders, lupus, infectious diseases, mental health, pain, obesity, pulmonary dysfunction, pregnancy, ovarian dysfunction, and stress

Examples of ORWH-created funding opportunities:

- 1. Building Interdisciplinary Research Careers in Women's Health (BIRCWH), career development program
- 2. Specialized Centers of Research Excellence on Sex Differences (SCORE)
- 3. Understudied, Underrepresented, and Underreported (U3) interdisciplinary research
- 4. Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers (called Re-Entry Supplements) are administrative supplements given to existing
 NIH research grants to support full- or part-time research by women or men returning to the scientific workforce



ORWH and the Coordinating Committee on Research on Women's Health (CCRWH)

NIH Institute and Center (IC) Directors or their designees comprise the NIH CCRWH. As established by legislative mandate in the NIH Revitalization Act of 1993, and expanded in the 21st Century Cures Act, CCRWH members serve as direct liaisons between the ORWH and the NIH ICs. The CCRWH provides valuable guidance, collaboration, and support to ORWH program goals, including ORWH's career development programs and outreach efforts. Specific CCRWH support involves:

- Serving as a resource for women's health activities across the NIH
- Supporting methods to gather data by age and ethnic/racial groups of women's participation in clinical trials
- Supporting the development and expansion of clinical trials necessary to the health of women
- Encouraging and supporting research on women's health
- Identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities



NIH Working Group on Women in Biomedical Careers (WGWBC)

The NIH Working Group on Women in Biomedical Careers was created in 2007 in response to the National Academies report, Beyond Bias and Barriers: Fulfilling the Potential of Women in Academic Science and Engineering, which called for broad, innovative action to overcome institutional and environmental barriers to advancement at all career stages for women

- To maximize the potential of women scientists and engineers
- To consider the broader context of girls and women in science
- To provide special attention to issues of barriers, minority women scientists, and mentoring



Examples of how ORWH partners across the NIH

- The Trans-NIH Strategic Plan for Women's Health Research, https://orwh.od.nih.gov/about/trans-nih-strategic-plan-womens-health-research, provides a framework that incorporates the congressionally mandated mission of ORWH with the scientific expertise of the NIH ICs, and it works in synergy with the NIH-wide strategic plan, *Turning Discovery Into Health*.
- The Trans-NIH Sex as a Biological Variable (SABV) Working Group, established in 2014, that is chaired by the ORWH Director. Members include senior staff members from the ICs and the OD. The mandate is to inform SABV policy development and implementation
- The CCRWH and the Biomedical Careers WG, which were previously mentioned



Additional Resources

- The main ORWH website, https://orwh.od.nih.gov/, for more details
- Please feel free to email Dr. Lisa Begg at, beggl@od.nih.gov



