



NATIONAL INSTITUTES OF HEALTH

**REPORT OF THE
ADVISORY COMMITTEE
ON RESEARCH ON
WOMEN'S HEALTH**

FISCAL YEARS 2013–2014

Office of Research on Women's Health and
NIH Support for Research on Women's Health



National Institutes of Health
Office of Research on Women's Health

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Letter from the ORWH Director

I am honored to share with you the many accomplishments in this fiscal year (FY) 2013–FY 2014 biennial report. This report bears witness to the phenomenal growth in women’s health research and related programs over the past 2 years. It reflects major ORWH research programs, initiatives, and activities, as well as research highlights from NIH Institutes and Centers and program offices. Chief among these developments is a policy shift, announced in May 2014, that will ensure the study of both sexes in NIH-funded preclinical research. This is sure to inspire a transformation in the way science is done and will go a long way toward improving the health of women and men.

When we talk about how biomedical research can benefit women and diverse populations, immense credit must go to Congress’ vision in enacting the NIH Revitalization Act of 1993, which mandated the inclusion of women and minorities in NIH clinical research. Two decades later, more than half of participants in NIH-funded clinical trials are women. Enrolling women in clinical research has paid dividends for millions of Americans, as we learned that conditions such as heart disease, the number one killer of both men and women, can appear differently in women, with symptoms that could be ignored without this knowledge. We also learned that certain drugs, such as aspirin, zolpidem, and antihistamines, can have different effects on women than on men. But there is more that we need to do.

Standing on the shoulders of the groundbreaking change that followed enactment of the 1993 law is the 2014 announcement that NIH will require scientists to take sex into account in preclinical research. This deliberate approach aims to create a more fluid connection between clinical research, which is research done on humans, and preclinical studies that employ animals and cells as models for human disease. Preclinical research is a crucial area of discovery that precedes the development of more expensive, higher-risk clinical studies that enroll human subjects.

Sex is a fundamental variable in biomedical research that must be considered from the very start of the scientific process. Considering the influence of sex in preclinical research will yield findings that better inform our clinical studies, ensuring that men and women get the full benefit of medical research. Copious evidence shows that research that considers sex is rigorous and powerful, and it can lead to discoveries that allow us to deliver person-centered care appropriate to each American. Taking sex into account is a key turn on the road toward precision medicine.

We are calling for this paradigm shift in medicine based on today’s knowledge and understanding. Being male or female is a critical determinant of health. Health care providers must choose the best treatment in the context of every individual patient. Optimal treatments can differ by sex, affecting outcomes for men and women. Delivering customized clinical care for men and women alike is within our grasp.

Studying both sexes also strengthens science. Publicly funded biomedical research must adhere to high standards, one of which is the guiding principle to take sex into account as a fundamental variable. Incomplete study of both sexes and failure to specify the sex used in experiments affect our ability to verify and duplicate results. By requiring that scientists take sex into account in preclinical research, NIH is funding the highest-quality science.

Transforming science is not a solitary pursuit. NIH needs all stakeholders to be a part of the solution. It is working with journal editors, publishers, medical schools, and professional and scientific societies to emphasize the importance of including sex-specific data in publications, curricula, and conferences.

It is a tremendously exciting era for science, and all Americans should have the opportunity to participate in the amazing pursuit of knowledge for improved health. ORWH is working to make sure that women have access to opportunities in research and medicine. We know from seminal work in the behavioral and social sciences that diversity promotes synergy and excellence, paving the way for the inventive problem solving that has been a proud hallmark of America's investments in biomedical research. Promoting the recruitment, retention, reentry, and advancement of women in biomedical careers is a vital aspect of the ORWH mission and is critical in strengthening the scientific workforce that will develop the scientific breakthroughs of the 21st century.

Thank you for the opportunity to share this exciting new chapter in the story of research on women's health at NIH. We are committed to improving the health of women, and we recognize the importance of all stages of the research process in contributing to that goal. I hope that this report enhances your appreciation of the value of studying both sexes in health and disease to deliver customized clinical care to improve the health of women and men.

Janine A. Clayton, M.D.

Associate Director for Research on Women's Health

Director, Office of Research on Women's Health

National Institutes of Health

August 2015





Preface

The members of the Advisory Committee on Research on Women's Health (ACRWH) are pleased to submit to the National Institutes of Health (NIH) Director, through the Associate Director of Research on Women's Health, the **Report of the Advisory Committee on Research on Women's Health for Fiscal Years 2013 and 2014**.

This biennial report details the NIH-wide programs and accomplishments carried out in fulfillment of the Office of Research on Women's Health's (ORWH's) core mission, as outlined in the NIH Revitalization Act of 1993 (Public Law 103-43, Section 486B). That mission is to strengthen and enhance NIH basic, translational, and clinical research:

- **To increase the understanding of the diseases and conditions that affect women, including investigation and elucidation of the role of sex and gender factors in health and disease;**
- **To build NIH programs to develop a cadre of researchers, both women and men, who are trained to conduct interdisciplinary research in these areas;**
- **To ensure the appropriate representation of women in NIH research; and**
- **To support the advancement of women in biomedical careers.**

The members of the ACRWH have reviewed the information in this biennial report and find that it reflects the breadth and depth of research, programs, and related activities through which ORWH has achieved its mission in fiscal year (FY) 2013 and FY 2014. The report also provides highlights from research on women's health and on the

influence of sex and gender on health and disease supported by NIH Institutes and Centers (ICs) and program offices within the Division of Program Coordination, Planning, and Strategic Initiatives in the NIH Office of the Director. In addition, the report presents information on NIH budget allocations for women's health research during FY 2013 and FY 2014 by using information supplied by the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Financial Resources. Finally, the report documents the inclusion of women and minorities in NIH-funded clinical research during these years.

ORWH is the first U.S. Public Health Service office dedicated specifically to promoting women's health research within and beyond the NIH scientific community. Thus, the ACRWH recognizes the pivotal role that the ORWH Director plays in guiding the office's progress toward facilitating, encouraging, and executing a myriad of NIH-wide accomplishments in support of its mission. The ACRWH wishes to acknowledge the work of the Coordinating Committee on Research on Women's Health, which compiled, summarized, and submitted many exciting highlights of the wealth of research on women's health and on the influence of sex and gender on health and disease, which appear in this report. Finally, the ACRWH acknowledges the ORWH staff who meet the mandates underlying the office's establishment by providing leadership, both within NIH and with the extramural research community, to accomplish the many outstanding and important advances in NIH-funded science and in career support that this report describes.

Advisory Committee on Research on Women's Health, FY 2015

See Appendix A for a list of committee members for FY 2013 and FY 2014.

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Organization of the FY 2013–FY 2014 Report of the Advisory Committee on Research on Women’s Health

This report reflects the extraordinary progress made in women’s health research and related programs since ORWH was formed in 1990. It describes major ORWH research programs, initiatives, and activities and highlights from the NIH ICs and program offices. This report is not a comprehensive listing of all NIH research on women’s health, which would necessarily be encyclopedic, but it summarizes, under a single cover, examples of the wealth of NIH advances in women’s health research.

This report is divided into two major parts. Part 1 presents ORWH programs, and Part 2 provides individual reports on women’s health research from the NIH ICs and program offices in the NIH Office of the Director. **Part 1** is organized into the following five sections:

- I. ORWH Background
- II. ORWH Research
- III. ORWH Biomedical Career Development Activities
- IV. Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research
- V. NIH Budget for Women’s Health Research

Section I: ORWH Background describes ORWH’s development and mission. It also provides an overview of the NIH Strategic Plan for Women’s Health Research.

Section II: ORWH Research provides an overview of Office activities and programs in response to the mandate to strengthen and enhance research on women’s health and on the influence of sex and gender on health and disease. It describes the role that ORWH plays in integrating sex and gender perspectives into all NIH IC research and how ORWH leverages funding to increase support for research in targeted areas of its mission.

Section III: ORWH Biomedical Career Development Activities describes activities and programs in response to the mandate to improve the advancement of women in biomedical careers and to increase the number of researchers focused on women’s health research. It describes programs used to train and mentor junior faculty in women’s health research topics and a number of other programs and activities that promote women’s biomedical careers, facilitate reentry of women and men into the biomedical workforce after an extended absence, and provide training and workforce development opportunities.

Section IV: Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research provides an overview of activities and programs in response to the mandate to monitor the inclusion of women and minorities in NIH-funded clinical research. It includes aggregate data on the numbers of women, men, and minorities who participated in this research.

Section V: NIH Budget for Women’s Health Research provides information on NIH expenditures on women’s health research, including a breakdown of the expenditures by disease category and other major categories of interest.

Part 2 of the biennial report consists of individual reports that summarize NIH ICs’ and program offices’ major initiatives and activities and provide highlights of the research each has funded related to women’s health and the influence of sex and gender on health and disease, consistent with their specific missions.

The biennial report appendices are available online at orwh.od.nih.gov.

