EVALUATION OF ORWH'S FIRST TEN YEARS

Submitted to the

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Office of the Director
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by

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ACKNOWLEDGMENTS

On behalf of the Office of Research on Women's Health (ORWH), I am pleased to share with you the results of the Evaluation of ORWH's First Ten Years. The study is one of the most comprehensive evaluations of a program within the Office of the Director, National Institutes of Health (NIH). It represents a collaborative effort on the part of many dedicated individuals.

The members of the evaluation advisory committee played a key role in improving the algorithms for identifying research relevant to women's health, assessing the preliminary results of the evaluation, and providing ORWH with recommendations for monitoring future progress. The committee was composed of senior administrators representing a variety of NIH components and one member who provided an external viewpoint. The names and affiliations of the members of the evaluation advisory committee are presented in Appendix A.

Several ORWH administrators and staff contributed a significant amount of time to the project. I acknowledge with gratitude the assistance of Joyce Rudick, who served as the task leader for the study, and Margaret Chesney, Ph.D., who served as a visiting scientist at ORWH and played a major role during the feasibility study and launch of the full-scale evaluation.

ORWH contracted with Carlyn Consulting to design and conduct the evaluation. Marcia Carlyn, Ph.D. served as the project director and the evaluation team included Mary Look, Ph.D. (Senior Vice President, Macro International Inc.), June Bray, Ph.D. (a senior research consultant with expertise in women's health), and Vaishali Joshi (a programmer/analyst at QRC Division of Macro International Inc.). An important factor in the success of the study was QRC's extensive experience working with the NIH databases used in the evaluation.

I am very thankful to all of the above-mentioned individuals for their significant contributions to this important project.

Vivian W. Pinn, M.D.
Director, NIH Office of Research on Women's Health

EXECUTIVE SUMMARY

The Office of Research on Women's Health (ORWH) is the focal point for women's health research at the National Institutes of Health (NIH). It was established in September 1990 to serve as a catalyst in mobilizing the different NIH institutes and centers (ICs) and the broader scientific community to address gaps in knowledge related to women's health. Located within the Office of the Director, ORWH is responsible for working in partnership with the various ICs to address a three-fold mandate to:

- Promote research related to diseases, disorders, and conditions that affect women;
- Ensure that women are appropriately included as subjects in biomedical and behavioral research studies supported by NIH; and
- Develop opportunities and support for the recruitment, retention, reentry, and advancement of women in biomedical careers.

Under the NIH Revitalization Act of 1993, Congress codified the Office's mission and included directives that expanded its leadership role in identifying and promoting research on women's health. The Act required the establishment of two committees to assist the ORWH Director: a broad-based external Advisory Committee on Research on Women's Health (ACRWH) and an internal Coordinating Committee on Research on Women's Health (CCRWH) composed of IC directors or their designees.

Like other program offices within the Office of the Director, ORWH does not have direct funding authority for research studies but rather transfers funds to individual ICs to encourage and support specific projects. Although ORWH is a relatively small office, its staff and budget have grown substantially since its inception. The number of full-time-equivalent staff increased from 3 to 16 and its annual budget increased from $1.5 to $20.4 million from FY 1991 to FY 2000. These resources, along with resources provided by the various ICs to promote research on women's health, have been instrumental in helping the Office pursue its mandate.

In the fall of 2000, ORWH celebrated its 10th anniversary. During its first decade, the Office defined its primary goals, emphasized strategic planning, and used a variety of approaches to help achieve its goals. Given the tenure of the Office and the continuing strong interest in research on women's health, the ORWH Director decided in 2001 that a comprehensive evaluation of ORWH's first ten years was needed to assess the progress that had been made, enhance future planning, and contribute to program accountability. A two-phase program evaluation was begun in May 2001, with phase 1 consisting of a feasibility study to determine

the design and data collection strategy for a comprehensive evaluation. The present phase 2 study, which was implemented during 2002-2003, incorporated the phase 1 design and the recommendations of ORWH staff and an ad hoc evaluation advisory committee. The study is one of the most comprehensive evaluations ever conducted of a program within the Office of the Director, NIH.

Evaluation Design

This study was primarily an outcome evaluation aimed at determining the extent to which ORWH's intermediate and long-term goals were achieved during its first ten years (FY 1991 through FY 2000). The design also included elements of a process evaluation in its examination of the major activities conducted by the Office to achieve these goals and the output produced. The conceptual framework for the evaluation (shown in Exhibit 1) illustrates how ORWH's activities, most of which involved collaborations with ICs and organizations outside NIH, were expected to influence the achievement of its goals.

The following strategies were employed to collect data on the different variables in the conceptual framework and answer the study questions:

- Analyzing the content of ORWH publications and program records.
- Analyzing the content of other documents produced by NIH and external organizations.
- Obtaining information from websites maintained by ORWH and other NIH components.
- Performing queries of two large NIH databases, the Consolidated Grant Applicant File (CGAF) and the Computer Retrieval of Information on Scientific Projects (CRISP) system, using analytical methodologies and algorithms developed and pilot-tested in phase 1.
- Developing an ORWH activities database to summarize key information on the major program activities conducted by the Office during the ten-year period.
- Holding discussions with the ORWH Director and staff, other NIH personnel, and members of the evaluation advisory committee.

Four broad study questions were addressed, with most of the data analyses comparing performance during FY 1999-2000 with performance during the baseline period FY 1989-1990 (prior to the establishment of ORWH). Wherever possible, graphs and tables were used to summarize the results, and standard statistical tests (chi-square tests) were conducted to assess the significance of the findings. The study's primary focus was to assess the extent to which ORWH's goals had been achieved during the ten-year period; it was not designed to determine whether there was a direct cause-and-effect relationship between specific ORWH activities and goal achievement given the difficulty in eliminating other factors that undoubtedly contributed to the achievement of these broad goals.

Findings

Study Question 1: What were ORWH's major activities during its first ten years and how were they implemented?

Study Question 1 involved identifying the primary activities that ORWH conducted during FY 1991-2000, examining how they were implemented, and assessing the output produced during this period. The ORWH activities database that was designed for the evaluation proved to be essential in understanding the nature and extent of the different activities conducted by the Office.

The results showed that in addressing its mandate, ORWH actively participated in over 1,700 program activities during its first decade, a noteworthy record for a relatively small program. Six major types of activities were identified:

1. Interacting with scientists, professional organizations, and advocacy groups to exchange information on issues related to women's health research.
2. Developing a research agenda on women's health for the NIH community.
3. Collaborating with NIH ICs to promote women's health research and career opportunities.
4. Co-funding NIH research studies on women's health and career development awards.
5. Overseeing implementation of the NIH policy on the inclusion of women and minorities in study populations.
6. Promoting women's health research through the dissemination of scientific publications, policy documents, and educational materials.

The evaluation found that ORWH was exceptionally proactive throughout the decade in reaching out to a broad range of scientists, professional organizations, and advocacy groups to exchange information and solicit recommendations for achieving common goals. Altogether, nearly 250 research conferences, seminars, and workshops were sponsored or co-sponsored by the Office during this period. After reaching early consensus on a comprehensive NIH-wide research agenda on women's health, ORWH worked closely with the different NIH institutes and centers to encourage them to support research on high-priority women's health topics and address other aspects of its mandate. The Office organized 16 trans-NIH committees/task forces, many of which are still meeting on a regular basis. During its first ten years, ORWH also co-sponsored 48 requests for applications (RFAs) and program announcements (PAs) in collaboration with one or more ICs.

The study also found that ORWH co-funded over 1,000 NIH research studies and over 125 career development awards during its first ten years, providing nearly $95 million to ICs to support specific projects. The research studies focused primarily on the topics in the NIH

research agenda on women's health and the highest priority topics were generally given the most attention, demonstrating the effectiveness of the Office's strategic planning and agenda development process. In addition, five new NIH programs were developed by ORWH to address the numerous barriers faced by women pursuing biomedical careers. With respect to the NIH inclusion policy, ORWH initiated and supported over 90 activities aimed at ensuring that women and minorities were appropriately included as subjects in clinical research studies supported by NIH. In addition, ORWH developed and/or co-sponsored over 120 scientific publications, policy documents, and educational programs to promote women's health research and career opportunities.

Given ORWH's limited staff and budget, its strong emphasis on interdisciplinary collaboration was regarded as essential for the achievement of its goals. In pursuing its activities, the Office worked closely with the ACRWH, CCRWH, IC representatives, senior staff in other government agencies, scientists and advocacy groups throughout the country, and other interested parties.

Study Question 2: To what extent were ORWH's intermediate goals achieved during its first ten years?

1. More RFAs and program announcements to stimulate and expand research on women's health. The number of official IC notices (RFAs and PAs) that invited grant applications addressing women's health issues increased by 143%, which was much higher than the 20% overall increase in NIH RFAs and PAs from FY 1989-1990 to FY 1999-2000. An additional content analysis was conducted to determine the number of RFAs and PAs that specifically mentioned a need for research on sex/gender differences in a particular area (going beyond the standard NIH language). The results showed that the number of RFAs/PAs encouraging research on sex/gender differences also increased significantly over the ten-year period, rising from an average of 5 to 41 per year.

2. Increased NIH funding for women's health research. NIH research funding specific to women's health increased by 60% from FY 1993 to FY 2000, which was slightly higher than the 57% overall increase in NIH research funding during the period. The results were based on budget figures reported by individual ICs for research specific to women, to men, and to both women and men. However, given the inherent difficulties in determining non-overlapping budget allocations for interdisciplinary research specific to women, the results should be interpreted with caution.

3. More NIH grant applications involving women's health research. The number of research project grant (RPG)[1] applications involving women's health research increased by 48% during ORWH's first ten years, which was nearly twice the 25% overall increase in the number of RPG

[1] Research project grants (RPGs) are the most common type of investigator-initiated research grants awarded by NIH; they include activity codes R01, R03, R15, R21, R29, R33, R37, R55, P01, P42, U01, and U19 (excluding NLM grants, FIC grants for FY 1989-1990, and NCRR grants for FY 1989).

applications during the period. The greatest gains were found for R03 grants (small research grants which are often awarded to new investigators), P01 grants which involve an interdisciplinary team of investigators, and U01 cooperative agreements.

4. More women receiving postdoctoral fellowships to pursue biomedical careers. The number of postdoctoral F32 fellowship applications submitted by women increased by 4% during the period, which was much greater than the 17% *decrease* in the number of applications from men. The number of F32 fellowships awarded to women increased by 10%, compared to a 3% decrease in the number of awards to men. With respect to both applications and awards, F32 fellowships had the highest proportion of female PIs of all the NIH grant mechanisms investigated in the ORWH evaluation. Although at the end of ORWH's first ten years a majority of NIH postdoctoral fellows were male, the proportion of females was substantial (42%). Perhaps more importantly, the results indicate that by FY 1999-2000, a large number of female scientists were approaching the end of the academic pipeline and would soon be ready to begin their careers as independent research scientists.

5. More women applying for NIH research grants. The number of RPG applications submitted by women increased by 56% during ORWH's first ten years, which was much higher than the 18% increase in applications from men. The percent of female applicants increased for every type of grant analyzed, although there was considerable variance among the different types of grant mechanisms. However, despite the sizeable gains, only 25% of the RPG applications and 13-18% of the P30, P50, and T32 applications were submitted by female PIs in FY 1999-2000.

Study Question 3: To what extent were ORWH's long-term goals achieved during its first ten years?

1. More NIH-sponsored research on women's health in high-priority areas. The number of RPG awards involving the 37 high-priority areas of women's health increased by 70%, which was substantially higher than the 56% overall increase in RPG awards from FY 1989-1990 to FY 1999-2000. An additional analysis of project titles found that the number of RPG awards having titles relevant to women's health also increased significantly (by 79%). Given the importance of this ORWH goal, the results were especially heartening.

2. More women successfully competing for NIH research grants. The number of RPGs awarded to women increased by 84%, which was considerably higher than the 49% increase in awards to men. The percent of awards to female PIs increased for every type of grant analyzed and female applicants had approximately the same probability of success as male applicants in FY 1999-2000, indicating there was no systemic bias against female applicants. However, despite all of these gains, only 23% of the RPG grants and 13-17% of the P30, P50, and T32 grants were awarded to female PIs in FY 1999-2000. These results and the findings for Intermediate Goal 5 underscore the importance of increasing the number of female investigators who *apply* for NIH grants.

3. High percentage of participants in ORWH career development programs becoming independent research scientists. Of the 26 individuals who participated in the initial ORWH Reentry Program during FY 1992-1994, 88% had published in peer-reviewed journals after finishing the program, 73% had secured a permanent research position, 54% had applied for an NIH grant, 19% had received an NIH grant, and 27% had obtained some type of external research funding by FY 2001. The percentages were higher than the performance targets set by ORWH, although the 27% success rate in obtaining external research funding was disappointing. The results illustrate how challenging it can be to obtain such funding (particularly an NIH grant), even for fully trained biomedical scientists intent on reestablishing their research careers.

4. Increased institutional commitment to women's health research. The number of NIH-supported institutions with major research and training centers involving women's health increased by 87%, from an average of 15 per year in FY 1989-1990 to 28 per year in FY 1999-2000. The evaluation also found that a relatively high proportion of these large institutional grants had female PIs. For example, 33% of the principal investigators of P01 grants involving women's health were female, compared to 15% of the PIs of all P01 grants awarded in FY 1999-2000.

5. Stronger evidence that women and minorities are being appropriately included as subjects in clinical research supported by NIH. Substantial evidence was found that ORWH's efforts and those of other NIH offices and ICs were effective in strengthening NIH's inclusion policy. The GAO report issued in 2000 concluded that NIH had made significant progress since 1990 in implementing a stronger policy for including women in clinical research and "ORWH played a key role in implementing the inclusion guidelines." From FY 1995 to FY 2000, the percent of new NIH extramural grant applications involving human subjects that were found to have unacceptable sex/gender and/or minority inclusion fell from 7.3% to 5.6%, demonstrating an improved level of investigator compliance with NIH's inclusion policy. In addition, the number of NIH-supported research studies that examined sex/gender and/or racial/ethnic differences in disease etiology and treatment increased from an average of 101 to 398 per year (an increase of 394%) during ORWH's first ten years. An unexpected finding was that nearly all of these studies focused on either sex/gender or racial/ethnic differences; only a small fraction of the studies (3% in FY 1999-2000) examined differences in both areas.

Study Question 4: Which areas of NIH-sponsored women's health research grew the fastest during the ten-year period?

The evaluation found that for 29 of the 37 high-priority research topics (78%), the number of RPGs involving the topic grew by more than the overall increase in RPG awards during the period. Also, for 31 of the 37 topics (84%), the number of different ICs funding research on the topic increased. The following 8 topics had exceptionally large increases in RPGs ($p < .001$): cultural and lifestyle factors, breast cancer, adolescent health, HIV/AIDS, behavioral change and risk-taking behavior, violence, menopausal hormone therapy, and menopause (in general).

Comparing the broader research areas, the largest increases in new RPG awards were found in behavioral research, aging, cancer, and infectious diseases and immune disorders. The research area that had the lowest growth in terms of new RPG awards was reproductive and maternal health, which was unexpected since ORWH had co-funded nearly 400 research studies involving reproductive and maternal health during the ten-year period.[2] Overall, the findings were very positive and consistent with the earlier findings for Long-Term Goal 1.

Recommendations

After reviewing the evaluation findings, the evaluation advisory committee concluded that NIH had clearly increased its commitment to women's health research during the 1990s. Taken together, the findings indicate that ORWH's strong emphasis on collaboration and strategic planning, its development of a comprehensive trans-NIH research agenda for women's health, and its success in leveraging funds to encourage high-priority projects were major factors in raising the awareness of women's health across NIH. The result was a gradual culture change that had a very positive impact on the achievement of ORWH's goals. There was consensus that ORWH's approach could well serve as a model for other interdisciplinary programs pursuing trans-NIH issues and goals.

While emphasizing that a great deal of progress had been made, the members of the advisory committee also felt that there was more work to be done. To track future progress, the committee recommended that ORWH take the following steps:

1. Ensure that the NIH research agenda on women's health is updated on an annual basis. Consider developing an improved "master list" of diseases, disorders, and conditions affecting women which minimizes overlap among the topics while recognizing the multisystemic nature of many of the diseases. Using such a master list and a methodology similar to the one used in the evaluation, identify the highest priority research topics in accordance with the recommendations of the CCRWH research subcommittee, ACRWH members, and the working groups participating in recent agenda-setting conferences sponsored by ORWH.
2. For each high-priority research topic, continue to track the average number of new RPGs awarded per year involving that topic by employing the CRISP methodology developed for the evaluation. Given the increasing importance of interdisciplinary research, consider expanding the methodology to include non-RPG research center awards, such as P30, P50, M01, U10, U54, M01, and G12 grants. Examine the

[2] A subsequent analysis revealed that the lack of expansion in RPGs involving reproductive and maternal health was probably due to the strategy employed by the National Institute of Child Health and Human Development (NICHD) during this period to develop a broad network of maternal-fetal medicine units and reproductive health centers using non-RPG grant mechanisms (primarily U10 and U54 cooperative agreements and K12 awards), with nearly $16 million of co-funding provided by ORWH.

feasibility of using CRISP analyses for grant applications as well as awards after the IMPAC II system is expanded to include research abstracts for applications.

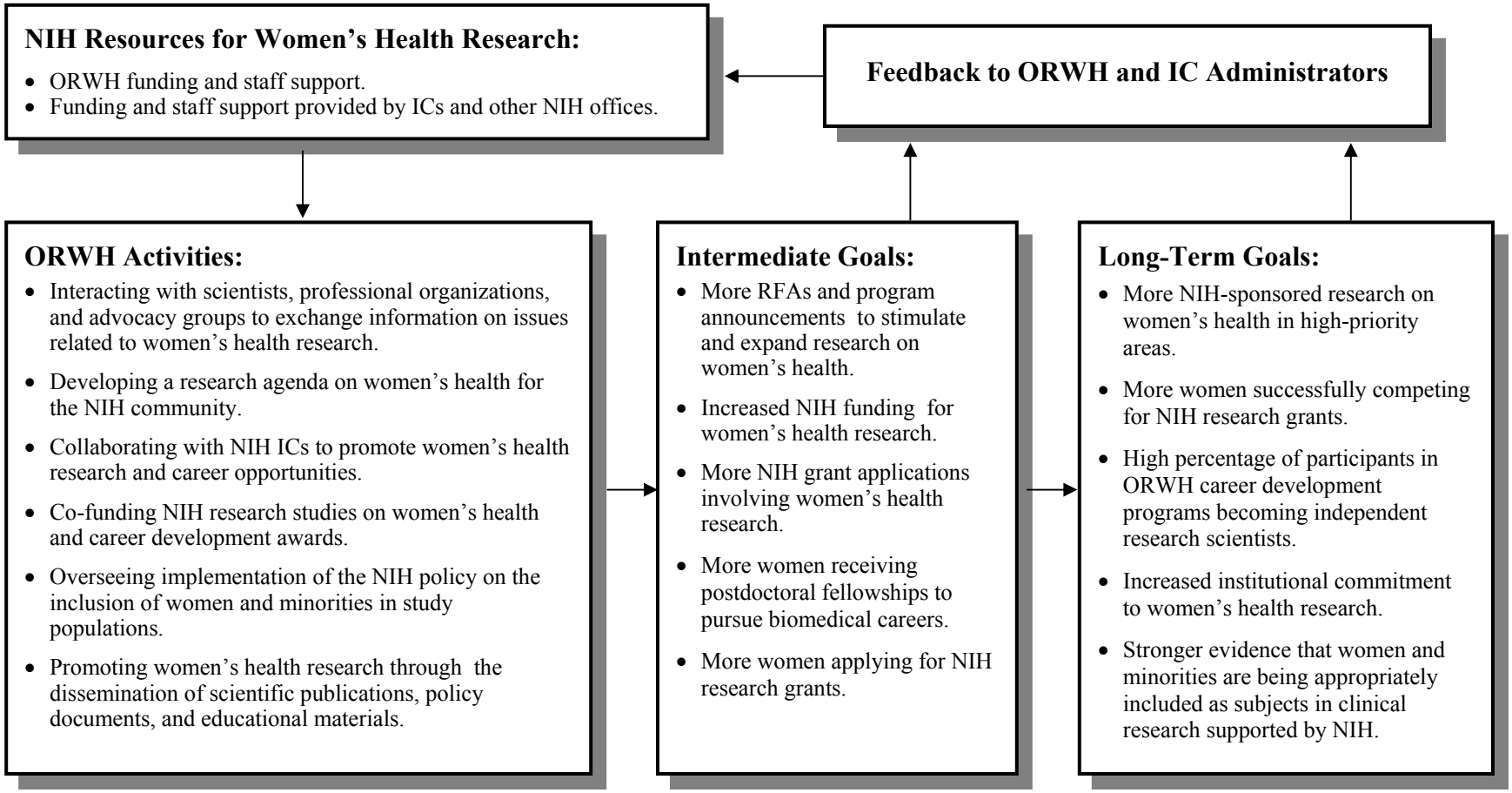
3. Continue to track the number of RPG, P30, P50, F32, and T32 grant applications submitted by female PIs and the number awarded to female PIs, summarizing the results in tables and pie charts, and consider expanding the CGAF methodology to include non-RPG career development awards and collaborating investigators (co-PIs) of major research center grants.
4. Continue to track the number of NIH-supported institutions with major research and training centers involving women's health by analyzing CGAF project titles.
5. Continue to monitor ORWH activities, expanding the ORWH activities database and updating the graphs showing trends through time for different types of activities. Develop a logging system within the Office to document ORWH activities on a daily or weekly basis to ensure that all outreach projects and other major activities are counted.
6. Post the results of the above analyses on the ORWH website and include the results in ORWH's biennial reports so that IC staff and others interested in particular research topics and career development programs can track progress in a timely way to determine whether specific strategies should be revised.
7. Continue to promote the NIH inclusion policy and encourage the various ICs, including their intramural researchers, to support more studies examining sex/gender and racial/ethnic differences in disease etiology and treatment.
8. Conduct a followup evaluation in FY 2006 to assess ORWH's progress during the five-year period from FY 2001 to FY 2005. Include an analysis of the new investigators who participated in ORWH's Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program and those who received ORWH Transitional Career Development Awards in Women's Health Research during the first two years of each program.

In conclusion, the Evaluation of ORWH's First Ten Years was a comprehensive assessment of the progress that was made from FY 1991 to FY 2000 in achieving ORWH's intermediate and long-term goals. The findings were generally positive and quite remarkable for a relatively small program office. The extensive amount of data collected for the evaluation will serve as a valuable resource in tracking ORWH's future progress. In addition to contributing to program accountability, the study included the development of new analytical methodologies designed to be useful to ORWH as well as other IC administrators and researchers interested in assessing changes in an NIH research portfolio over a specified time period. It is hoped that all those who manage, fund, or provide other support for projects involving women's health will be encouraged by the evaluation results and find them helpful in developing and improving a variety of interdisciplinary research programs.

Exhibit 1

EVALUATION OF ORWH'S FIRST TEN YEARS

CONCEPTUAL FRAMEWORK



SECTION 1: INTRODUCTION

Overview of the Office of Research on Women's Health

The Office of Research on Women's Health (ORWH) is the focal point for women's health research at the National Institutes of Health (NIH). It was established in September 1990 to serve as a catalyst in mobilizing the different NIH institutes and centers (ICs) and the broader scientific community to address gaps in knowledge related to women's health.[3] Located within the Office of the Director, ORWH was given the responsibility of working in partnership with the various ICs to expand NIH-supported research on diseases and conditions that affect the health of women, enhance NIH's efforts to increase the participation of women in clinical studies, and promote career opportunities for women scientists.

Prior to 1990, several key events increased the general awareness that most of the existing knowledge about diseases and health conditions had been derived primarily from studies of men. Women had traditionally been excluded as clinical research participants for several reasons: (1) a 1977 policy of the Food and Drug Administration (FDA) restricted the inclusion of women of childbearing potential in Phase I clinical trials because of fear of unintended birth defects; (2) many clinical researchers thought the inclusion of women in clinical trials would introduce additional variables (in the form of hormonal cycles) and decrease the homogeneity of study populations; and (3) despite the possibility of confounding variables, there was a general belief among researchers that men and women would not differ significantly in response to treatment in most situations.[4] This long-standing policy of exclusion led to the following series of events:

1983 The Public Health Service (PHS) Task Force on Women's Health Issues was established by the Assistant Secretary for Health.

1985 The task force concluded that health care for women and the quality of health information available to women had been compromised by the historical lack of research on women's health issues. The group published a report delineating the breadth of women's health issues across the life span, strongly recommending that biomedical and behavioral research be expanded to ensure emphasis on conditions and diseases unique to, or more prevalent in, women in all age groups.[5]

[3] During ORWH's first ten years, the number of NIH institutes and centers increased from 24 to 27. Appendix B includes a full listing of the ICs, including their acronyms, individual missions, and the years they were established.
[4] Society for Women's Health Research website. June 2003. <www.womens-health.org>.
[5] U.S. Public Health Service. *Women's Health: Report of the Public Health Service Task Force On Women's Health Issues, Volume I*. Washington, DC: February 1985.

1986 In response, NIH issued a new policy encouraging the inclusion of women in clinical research and requested its grant applicants to provide justification for excluding women. In addition, an inventory was made of the research activities supported by NIH to determine how much of its budget was being spent on health issues specific to women, specific to men, and specific to both women and men.

1989 Using the task force's rather broad criteria for defining gender-specific women's health issues, NIH reported that 13.5% of its FY 1987 budget had been spent on women's health and 6.5% on men's health; the remaining 80% had been spent on basic research and health issues affecting both women and men.

1990 Based on these findings and the historical reluctance of investigators to include women of child-bearing potential in clinical studies, the Congressional Caucus on Women's Issues asked the U.S. General Accounting Office (GAO) to review NIH's policy and practices regarding the inclusion of women as research subjects in NIH-sponsored studies. GAO found that NIH had been slow to implement the 1986 policy and it was being applied inconsistently during grant reviews. In response to the GAO report, NIH published an expanded interpretation of its inclusion policy which required a compelling justification for excluding women and minorities from clinical studies.

As a result of this accelerating series of events, particularly the GAO findings and subsequent media coverage and public reaction, NIH established by executive action the Office of Research on Women's Health in September 1990. Ruth L. Kirchstein, M.D. (Director of the National Institute of General Medical Sciences) was named Acting Director of the new office. Dr. Kirchstein had been involved with women's health issues for many years. She co-chaired the PHS Coordinating Committee on Women's Health Issues (which grew out of the PHS Task Force on Women's Health Issues that she helped organize in the mid-1980s). Over the years she had also represented NIH on several other Department of Health and Human Services (DHHS) committees involving women's health.

In November 1991, Vivian W. Pinn, M.D. was appointed as the first full-time ORWH Director, a position which she continues to hold. Dr. Pinn joined NIH with a strong track record in biomedical research and long-standing commitment to women's health. Her experiences as a student and faculty member at leading academic institutions (Wellesley College, University of Virginia School of Medicine, Harvard Medical School, Tufts University School of Medicine, and Howard University College of Medicine) had given her a broad perspective and extensive scientific and administrative leadership experience. In the months preceding her appointment, she had worked closely with ORWH staff and other scientists, clinicians, and women's health advocates to develop a trans-NIH research agenda on women's health for the next decade. When appointed as Director, Dr. Pinn was in an ideal position to help ORWH forge stronger alliances with the ICs and the broader scientific community and to coordinate the Office's efforts to implement NIH's new research agenda on women's health.

ORWH Mandate

When ORWH was established in 1990, its responsibilities included serving as a liaison to the ICs and advising the NIH Director on matters relating to research on women's health. The Office was also given a three-fold mandate to:

- Promote research related to diseases, disorders, and conditions that affect women;
- Ensure that women are appropriately included as subjects in biomedical and behavioral research studies supported by NIH; and
- Develop opportunities and support for the recruitment, retention, reentry, and advancement of women in biomedical careers.

Under the NIH Revitalization Act of 1993 (Public Law 103-43), Congress codified the Office's mission and included directives that expanded its leadership role in identifying and promoting research on women's health. In addition to requiring the NIH Director to establish more explicit guidelines on the inclusion of women and minorities in NIH-supported research, the Act formalized ORWH's mandate and increased its responsibilities in several areas, including the following:

- Appointing and working with an Advisory Committee on Research on Women's Health (ACRWH), composed of non-federal scientists, health care providers, policymakers, administrators, and women's health advocates. The ACRWH was charged with advising the ORWH Director on appropriate research activities to be undertaken by NIH related to women's health (including research on sex/gender[6] differences in disease etiology and treatment), providing recommendations regarding ORWH activities, and helping the ORWH Director monitor NIH's compliance with the inclusion guidelines and determine the extent of IC expenditures for women's health research.
- Appointing and working with a Coordinating Committee on Research on Women's Health (CCRWH), composed of the IC directors or their designees. The CCRWH was charged with assisting the ORWH Director in identifying specific needs for research on women's health, determining the conditions under which it is appropriate to collect data on the inclusion of women in clinical trials, and encouraging the ICs to support and conduct such research.
- Recommending an NIH research agenda on women's health and encouraging the ICs to support such research and collaborate on interdisciplinary research studies involving women's health.

[6] Because there continues to be general confusion regarding use of the terms 'sex' and 'gender,' the term 'sex/gender' was used throughout the report. For more information on the distinction between the two terms, see "The Use of 'Sex' and 'Gender' to Define and Characterize Meaningful Differences Between Men and Women" (Fishman, Wick, and Koenig) in *The Agenda for Research on Women's Health for the 21st Century*, 1999, pp. 15-20.

- Assisting in the administration of improved guidelines and other mechanisms for including women and minorities in clinical research funded by NIH.
- Preparing a biennial report describing NIH-supported research and other efforts related to women's health, including IC expenditures for women's health research.

The NIH Revitalization Act of 1993 defined "women's health conditions" as diseases, disorders, and conditions: (1) that are unique to, more serious, or more prevalent in women; (2) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women; or (3) for which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

Like other program offices within the Office of the Director, ORWH does not have direct funding authority for research studies but rather transfers funds to individual ICs to encourage and support specific projects. Although ORWH is a relatively small office, its staff and budget have grown substantially since its inception. The number of full-time-equivalent staff increased from 3 to 16 and its annual budget increased from $1.5 to $20.4 million from FY 1991 to FY 2000. These resources, along with resources provided by the various ICs to promote research on women's health, have been instrumental in helping the Office pursue its mandate.

Need for a Broad-Based Evaluation

In the fall of 2000, ORWH celebrated its 10th anniversary. During its first decade, the Office defined its primary goals, emphasized strategic planning, and used a variety of approaches to help achieve its goals. Given the tenure of the Office and the continuing strong interest in research on women's health, the ORWH Director decided in 2001 that a comprehensive evaluation of ORWH's first ten years was needed to assess the progress that had been made, enhance future planning, and contribute to program accountability.

A two-phase program evaluation was begun in May 2001, with phase 1 consisting of a feasibility study to determine the design and data collection strategy for a comprehensive evaluation to be implemented in phase 2. Based on the results of the feasibility study, ORWH was able to secure NIH One Percent Evaluation Set-Aside funds for the broader study. In May 2002, a contract to conduct the Evaluation of ORWH's First Ten Years was awarded to Carlyn Consulting, a firm specializing in the evaluation of government programs. In addition to the project director, the evaluation team included the Senior Vice President and a programmer/analyst at QRC Division of Macro International Inc. (hereafter called QRC) as well as a senior research consultant with expertise in women's health. An important factor was QRC's extensive experience working with the NIH databases used in the evaluation.

The present phase 2 study incorporated the phase 1 design and the recommendations of ORWH staff and an ad hoc evaluation advisory committee. The members of the advisory committee are

presented in Appendix A. During the course of the study, the committee provided input regarding the study design, data collection strategies, and interpretation of the findings as well as recommending ways for ORWH to track future progress. Although the committee felt that it was too early to assess ORWH's ultimate impact, they strongly supported the decision to conduct the present study, which is one of the most comprehensive evaluations ever conducted of a program within the Office of the Director, NIH.

SECTION 2:
STUDY DESIGN AND METHODOLOGY

The Evaluation of ORWH's First Ten Years was primarily an outcome evaluation aimed at determining the extent to which ORWH's intermediate and long-term goals were achieved during its first decade (FY 1991 through FY 2000). The design also included elements of a process evaluation in its examination of the major activities conducted by the Office to achieve these goals and the output produced. The conceptual framework for the evaluation (shown in Exhibit 1) illustrates how ORWH's activities, most of which involved collaborations with ICs and organizations outside NIH, were expected to influence the achievement of its goals.

Four study questions were addressed:

1. What were ORWH's major activities during its first ten years and how were they implemented?
2. To what extent were the following intermediate goals achieved during ORWH's first ten years?
    - More RFAs and program announcements to stimulate and expand research on women's health.
    - Increased NIH funding for women's health research.
    - More NIH grant applications involving women's health research.
    - More women receiving postdoctoral fellowships to pursue biomedical careers.
    - More women applying for NIH research grants.
3. To what extent were the following long-term goals achieved during ORWH's first ten years?
    - More NIH-sponsored research on women's health in high-priority areas.
    - More women successfully competing for NIH research grants.
    - High percentage of participants in ORWH career development programs becoming independent research scientists.
    - Increased institutional commitment to women's health research.
    - Stronger evidence that women and minorities are being appropriately included as subjects in clinical research supported by NIH.
4. Which areas of NIH-sponsored women's health research grew the fastest during the ten-year period?

The first three study questions focused on the major ORWH activities and goals specified in the conceptual framework, and the last question involved a more detailed analysis of the most important long-term goal: more NIH-sponsored research on women's health in high-priority areas.

The following strategies were employed to collect data on the different variables in the conceptual framework:

- Analyzing the content of ORWH publications and program records.[7]
- Analyzing the content of other documents produced by NIH and external organizations.[7]
- Obtaining information from websites maintained by ORWH and other NIH components.
- Performing queries of two large NIH databases, the Consolidated Grant Applicant File (CGAF) and the Computer Retrieval of Information on Scientific Projects (CRISP) system, using analytical methodologies and algorithms developed and pilot-tested in phase 1.
- Developing an ORWH activities database to summarize key information on the major program activities conducted by the Office during the ten-year period.
- Holding discussions with the ORWH Director and staff, other NIH personnel, and members of the evaluation advisory committee.

The operational definitions of the variables examined during the evaluation and the data sources used in addressing each study question are presented in Section 3, which describes the evaluation findings. Coding systems, based on the operational definitions of the variables, were developed to summarize in a standard format the information collected, and several training sessions were held with members of the evaluation team to ensure that the data collection strategies and coding procedures were well understood. Quality control measures were also employed to ensure that the information collected was as accurate and complete as possible. Most of the analyses involved comparing performance during FY 1999-2000 with performance during the baseline period FY 1989-1990 (prior to the establishment of ORWH); two-year periods were used rather than one-year periods to improve the validity of the results. Appendix C provides a detailed account of the data methods and analyses employed. Wherever possible, graphs and tables were used to summarize the results, and standard statistical tests (primarily chi-square tests) were conducted to assess the significance of the findings. The study's primary focus was to assess the extent to which ORWH's goals had been achieved during the ten-year period; it was not designed to determine whether there was a direct cause-and-effect relationship between specific ORWH activities and goal achievement given the difficulty in eliminating other factors that undoubtedly contributed to the achievement of these broad goals.

[7] See Appendix F for a bibliography listing the major publications used as data sources for the evaluation.

SECTION 3:
EVALUATION FINDINGS

The Evaluation of ORWH's First Ten Years was based on a conceptual framework of specific program activities that were expected to influence the achievement of ORWH's most important intermediate and long-term goals. The findings with respect to the four study questions addressed in the evaluation are presented in this section of the report.

Study Question 1: Implementation of Program Activities

> *What were ORWH's major activities during its first ten years and how were they implemented?*

Study Question 1 involved identifying the primary activities that ORWH conducted during FY 1991-2000, examining how they were implemented, and assessing the output produced during this period. Extensive document reviews and content analyses were conducted to identify and code information on each ORWH activity. Data sources included the comprehensive biennial reports prepared by ORWH for FY 1991-1992, FY 1993-1994, FY 1995-1996, FY 1997-1998, and FY 1999-2000; minutes of ACRWH and CCRWH meetings; reports of major NIH conferences sponsored by ORWH; other government reports relevant to ORWH activities; the *NIH Guide for Grants and Contracts*; websites maintained by ORWH and other NIH offices; and discussions with ORWH and other NIH staff.

In preparation for the analyses, 16 types of program activities were defined (see Exhibit 2) and an ORWH activities database was developed which proved to be essential in understanding the nature and extent of the different activities conducted by the Office. Each major activity identified in the document review was coded and entered into the database, including the following information:

- Activity name (e.g., title of the report, conference, committee)
- Type of activity
- Fiscal year the activity was implemented
- ICs or other organizations involved (if any)
- Research topics or issues on which the activity was focused
- ORWH funding (if any)
- Optional notes describing other aspects of the activity.

The results showed that in addressing its mandate, ORWH participated in over 1,700 program activities during its first ten years, a noteworthy record for a relatively small program. Six major types of activities were identified:

1. Interacting with scientists, professional organizations, and advocacy groups to exchange information on issues related to women's health research.
2. Developing a research agenda on women's health for the NIH community.
3. Collaborating with NIH ICs to promote women's health research and career opportunities.
4. Co-funding NIH research studies on women's health and career development awards.
5. Overseeing implementation of the NIH policy on the inclusion of women and minorities in study populations.
6. Promoting women's health research through the dissemination of scientific publications, policy documents, and educational materials.

The analyses focused on ORWH's implementation of each type of activity and its productivity with respect to the output produced over the ten-year period.

Exhibit 2

EVALUATION OF ORWH'S FIRST TEN YEARS

TYPES OF ORWH ACTIVITIES

Activity Abbreviation[1]	Definition
CARDEV	Co-funding a fellowship or career development grant to enhance an investigator's skills in research relevant to women's health.
COMM	Convening an NIH-sponsored committee or task force to exchange information on women's health research or other ORWH issues.
CONF	Organizing an NIH conference to disseminate and exchange information on women's health research or other ORWH issues.
CONFRPT	Producing a report summarizing the proceedings and recommendations of an NIH conference or group of meetings relevant to women's health research.
EDUC	Producing and/or distributing educational materials on women's health issues (e.g., brochure, fact sheet, poster, videotape, information packet, media kit, website).
PA	Co-sponsoring an NIH program announcement (PA) to encourage research in a high-priority area of women's health.
PAPER	Producing a manuscript or article on women's health research or another ORWH issue.
PPDOC	Producing a policy notice or other document explaining NIH policy or procedures developed by ORWH.
REAP	Providing supplemental funds (Research Enhancement Award) for a meritorious NIH research grant involving women's health that otherwise would not be funded.
RFA	Co-sponsoring an NIH request for applications (RFA) to encourage research in a high-priority area of women's health.
RPT	Publishing an NIH report or monograph on women's health research or another ORWH issue (excluding conference reports).
SEM	Organizing an NIH seminar or symposium to disseminate and exchange information on women's health research or other ORWH issues.
SPECIAL	Co-funding a special research initiative having exceptional potential to increase scientific knowledge on women's health.
SUPPL	Providing supplemental funds (administrative supplement) to a meritorious NIH research grant involving women's health.
TARGET	Co-funding a large-scale targeted research initiative in a high-priority area of women's health.
WKSHOP	Organizing an NIH workshop or training course to disseminate and exchange information on women's health research or other ORWH issues.

[1] List of abbreviations used in coding different types of ORWH activities for inclusion in the ORWH activities database.

Activity 1. Information Exchange Activities

ORWH's promotion of information exchange activities was operationally defined as follows:

> The extent to which the ORWH Director and staff interacted with scientists, professional organizations, and advocacy groups to exchange information on issues related to women's health research, as measured by the number and types of external advisory committees and task forces convened by ORWH and the number and types of research conferences, seminars, and workshops sponsored or co-sponsored by ORWH from FY 1991 to FY 2000.

The evaluation team found extensive evidence that the ORWH Director and staff sought out and worked closely with a broad range of scientists, professional organizations, and advocacy groups to exchange information on issues related to women's health research. Beginning in its first year, the Office realized the importance of convening committees and task forces of outside experts to provide advice in implementing different areas of its mandate. An analysis of the ORWH activities database found that the Office convened 18 different external advisory committees and task forces during its first ten years, many of which continued to meet for several years. The number of these information exchange activities peaked in FY 1995 and 1996 when ORWH was working with more than 10 external advisory committees and task forces per year (see Exhibit 3). As ORWH's focus shifted from the planning phase to implementation, there was less need to meet regularly with all of the groups and the number of external advisory committees and task forces decreased to 3-5 per year.

The evaluation also found that ORWH sponsored or co-sponsored nearly 250 research conferences, seminars, and workshops during its first ten years; the number steadily increased from FY 1991 to FY 1998, leveling off at approximately 40 such conferences per year in FY 1999-2000 (see Exhibit 4). Altogether, ORWH sponsored or co-sponsored 90 research conferences, 52 seminars, and 116 workshops during its first decade.

Major information exchange activities initiated by ORWH during this period included the following:

- 1991 Hunt Valley workshop to develop the first NIH research agenda on women's health, preceded by a public hearing involving testimony from over 80 organizations (described in more detail under Activity 2).
- 1992 National public hearing and workshop on the recruitment, retention, and advancement of women in biomedical careers. The three-day workshop, involving over 100 participants representing organizations across the country, resulted in the development of the ORWH Reentry Program.
- 1993 National public hearing and scientific meeting on the recruitment and retention of women in clinical studies, which resulted in the identification of successful

recruitment strategies and recommendations for establishing more specific NIH inclusion guidelines.

Women's Health Seminar Series, sponsored by ORWH in coordination with a committee of representatives of different ICs. Beginning in FY 1993, several seminars were conducted each year for the general public to communicate information about current NIH research findings and the impact on women's health.

1994 First meeting of the legislatively mandated Coordinating Committee on Research on Women's Health (which replaced the NIH Advisory Committee on Women's Health Issues). The CCRWH is described in more detail under Activity 3.

NIH workshop for Institutional Review Board (IRB) chairs to discuss their role in implementing the revised NIH policy on the inclusion of women and minorities in study populations.

1995 First meeting of the legislatively mandated Advisory Committee on Research on Women's Health. The ACRWH, which meets twice a year, established numerous working groups and ad hoc subcommittees to work with ORWH and other NIH staff on specific issues. The ACRWH has played a key role in helping ORWH maintain an ongoing dialogue with the broader scientific community to better understand the community's needs and work collaboratively to address issues involving women's health.

1996 Followup meeting with IRB chairs to discuss their experiences in implementing the revised NIH inclusion policy.

1997 Beyond Hunt Valley conference to update the NIH research agenda on women's health for the 21st century, preceded by a series of three workshops held at regional sites across the country which involved over 1,500 participants (described in more detail under Activity 2).

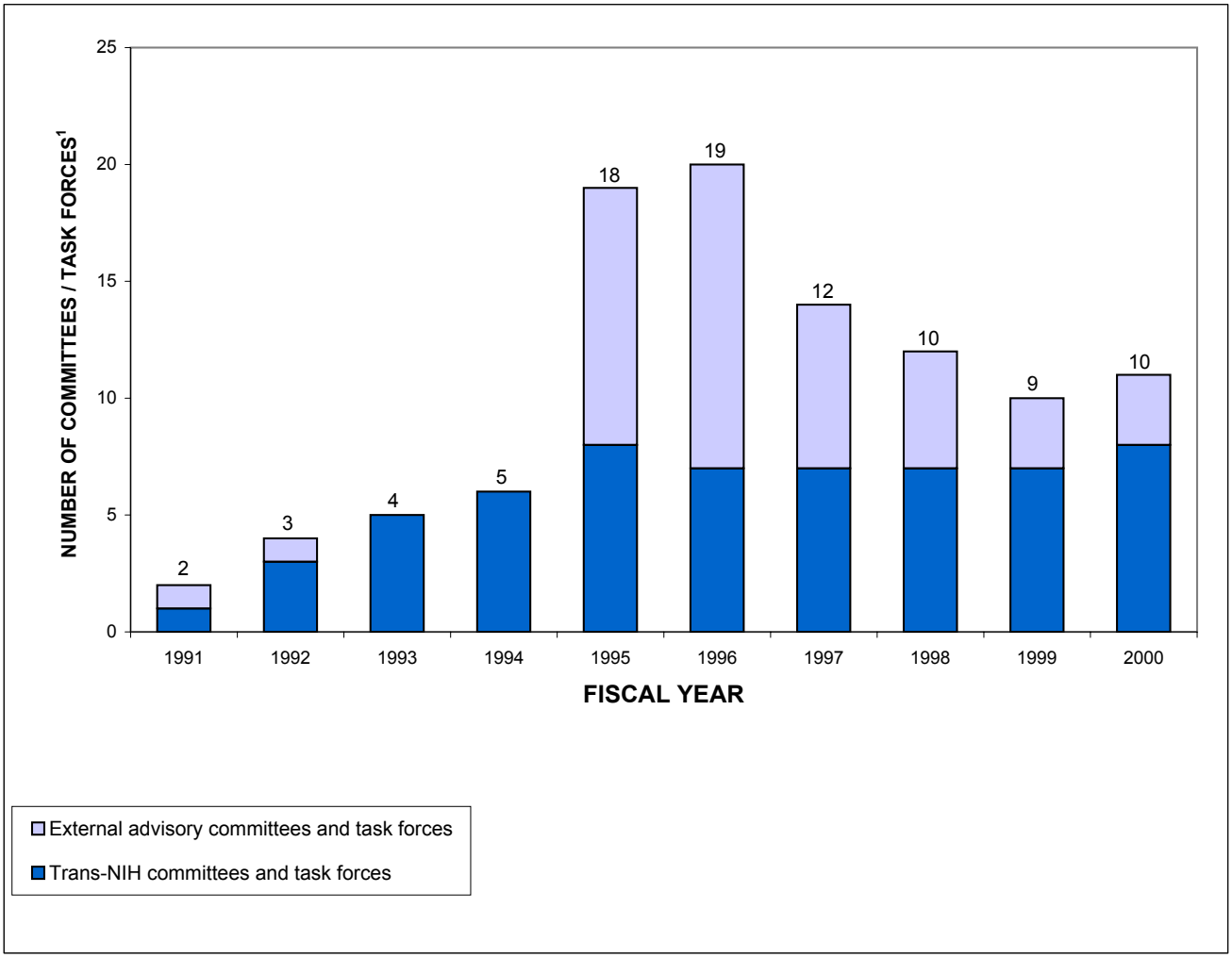
In summary, the evaluation found that ORWH was exceptionally proactive throughout the decade in reaching out to a broad range of scientists, professional organizations, and advocacy groups to exchange information and solicit recommendations for achieving common goals. During its first ten years, ORWH convened 18 different external advisory committees and task forces, many of which continued to meet for several years, and the Office sponsored or co-sponsored nearly 250 research conferences, seminars, and workshops.

Exhibit 3

EVALUATION OF ORWH'S FIRST TEN YEARS

COMMITTEES AND TASK FORCES CONVENED BY ORWH TO PROMOTE WOMEN'S HEALTH RESEARCH

FY 1991-2000



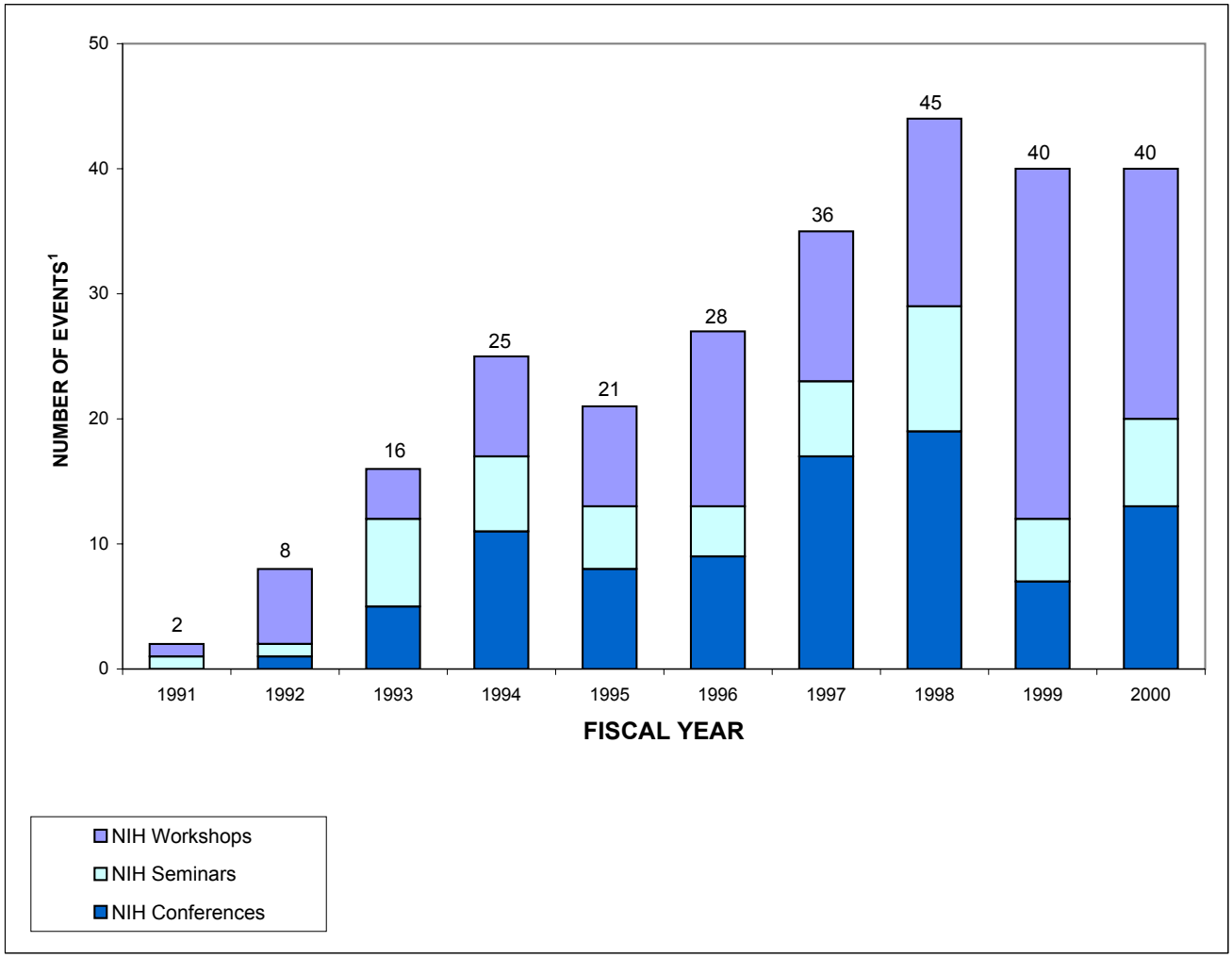
[1] Primary data source: Report of the Office of Research on Women's Health (five ORWH biennial reports on activities conducted during FY 1991-2000).

Exhibit 4

EVALUATION OF ORWH'S FIRST TEN YEARS

CONFERENCES AND OTHER RESEARCH EXCHANGE ACTIVITIES SPONSORED OR CO-SPONSORED BY ORWH

FY 1991-2000



[1] Primary data source: Report of the Office of Research on Women's Health (ORWH biennial reports on activities conducted during FY 1991-2000).

Activity 2. NIH Research Agenda on Women's Health

The development of a trans-NIH research agenda on women's health was operationally defined as follows:

> The extent to which ORWH was successful in developing a comprehensive trans-NIH agenda identifying the highest priority areas of women's health research, as measured by the types of agenda-related activities undertaken by ORWH from FY 1991 to FY 2000 and the achievement of a broad consensus on the topics that should be given the highest priority throughout the decade.

The evaluation team found strong evidence that ORWH gave a high priority to spearheading the development of an NIH-wide research agenda to identify the most important health issues for women and address current gaps in scientific knowledge. Achieving consensus on a comprehensive agenda was regarded by ORWH as a critical first step in addressing its primary mandate to promote research related to diseases, disorders, and conditions that affect women.

To foster collaboration between NIH and the broader research community, ORWH recruited scientific leaders from around the country to serve on a new Task Force on Opportunities for Research on Women's Health. A two-day public hearing was held in June 1991, and the written and oral testimony presented by over 90 organizations and individuals provided guidance to ORWH and the task force in planning a three-day workshop which was held in Hunt Valley, Maryland on September 4-6, 1991. Workshop participants included a range of scientists with expertise in basic, clinical, epidemiological, and behavioral research, health care providers, and representatives of women's organizations and other advocacy groups. The Hunt Valley workshop participants discussed at length the diseases and other impairments that might affect a woman's health across her life span and the corresponding research needs. Each of the ten working groups focused on a specific scientific area or segment of the life span, assessing the current status of women's health research in that area, identifying current gaps in knowledge, and recommending approaches for taking advantage of the most promising research opportunities.

The deliberations and findings of the Hunt Valley workshop participants, published by ORWH in a two-volume document which became known as the Hunt Valley Report (*Report of the National Institutes of Health: Opportunities for Research on Women's Health*), served as the NIH research agenda on women's health for most of ORWH's first ten years. The Hunt Valley Report emphasized the importance of interdisciplinary research encompassing the health of women across the life span (from infancy to old age) and across the full research spectrum (from basic research to clinical, epidemiological, and health outcomes research). In addition, the report redefined the parameters of women's health to include research aimed at understanding differences in health and disease between women and men, as well as research on populations of women that had been especially underrepresented in clinical research (e.g., minorities, women of low socioeconomic status, lesbians, and women with disabilities).

During the next few years, ORWH appointed and worked closely with its two primary advisory committees (the CCRWH composed of IC directors or their designees, and the ACRWH composed of non-federal scientists, clinicians, and administrators) to expedite implementation of the NIH research agenda on women's health. The CCRWH Research Subcommittee and the ACRWH Ad Hoc Subcommittee on the Research Agenda were instrumental in helping ORWH assess progress and address emerging issues. By FY 1996, there was a general consensus that it was time to update the NIH research agenda and ORWH sponsored a series of meetings entitled "Beyond Hunt Valley: Research on Women's Health for the 21st Century." In planning the meetings, ORWH used a model similar to the first Hunt Valley workshop where broad participation through public hearings and working groups had proven to be very effective. A task force was appointed by ORWH and three regional workshops were held in Philadelphia, New Orleans, and Santa Fe, New Mexico, which were followed by a national conference in Bethesda in November 1997. The two-year effort was intensive and involved the participation of over 1,500 individuals representing a broad spectrum of interests and expertise in women's health. Under the guidance of the task force members and working group co-chairs, the participants evaluated the progress made to date, identified critical gaps in knowledge, and formulated recommendations for future directions in research. The result was a seven-volume publication which became known as the Beyond Hunt Valley Report (*Agenda for Research on Women's Health for the 21st Century*), published by ORWH in FY 1999.

As part of the present evaluation, a content analysis was conducted to identify the highest priority research topics in the FY 1991 NIH research agenda for women's health. As shown in Exhibit 5, 37 topics were identified and rank-ordered based on the number of different Hunt Valley working groups recommending that NIH promote women's health research on each topic. The list was limited to those topics recommended by at least two working groups. Topics with the same number of group recommendations were ranked within their group based on the extent to which the topic was emphasized in the conference report. The title of each topic and the major research area under which it falls were taken from the budget categories used in the "DHHS-NIH Research Budget for Women's and Men's Health," which is produced on a biennial basis by ORWH and the NIH ICs. Of the 37 topics, 14 were designated as being primarily female topics and 23 were designated as being relevant to males as well as females, based on the discussions of the Hunt Valley participants and recommendations of the evaluation advisory committee. The evaluation team also analyzed the updated research agenda for women's health which was finalized in FY 1998. Several differences were found between the two agendas but the differences were not major; for example, only 4 of the 37 topics in the 1991 agenda were given a substantially higher priority in the Beyond Hunt Valley Report, as noted in Exhibit 5.

In summary, ORWH was successful in achieving broad consensus on a comprehensive NIH-wide research agenda on women's health which identified the topics that should be given the highest priority during the decade.

Exhibit 5

EVALUATION OF ORWH'S FIRST TEN YEARS

HIGHEST PRIORITY RESEARCH TOPICS IN THE 1991 NIH RESEARCH AGENDA FOR WOMEN'S HEALTH

Rank[1]	Primarily Female Topic[2]	Research Topic[3]	Major Research Area[3]	Number of Working Group Recs[1]
1		Cultural and Lifestyle Factors	Behavioral Research	10
2	Y	Pregnancy and Maternal Health	Reproductive and Maternal Health	7
3		Behavioral Change and Risk-Taking Behavior	Behavioral Research	7
4	Y	Reproductive Cancers (Ovarian, Cervical, Uterine)	Cancer	7
5		Heart Disease	Cardiovascular / Pulmonary Conditions	6
6		Psychosocial Stress	Mental Health and Chronic Pain	6
7	Y	Breast Cancer	Cancer	5
8	Y	Osteoporosis	Aging	5
9		Lung Cancer	Cancer	5
10		Obesity and Physical Activity	Metabolism and Endocrinology	5
11		Depression and Mood Disorders	Mental Health and Chronic Pain	5
12		Nutrition[4]	Metabolism and Endocrinology	5
13	Y	Menopausal Hormone Therapy	Aging	5
14		Colorectal Cancer	Cancer	5
15		Diabetes	Metabolism and Endocrinology	4
16		Adolescent Health	Child and Adolescent Health	4
17		Disability Research and Services	Crosscutting Categories	4
18		Contraception	Reproductive and Maternal Health	4
19		Tobacco Use	Substance Abuse	4
20		Illegal Drug Use/Abuse	Substance Abuse	4
21	Y	Menopause	Aging	4
22		Alcohol Use/Abuse	Substance Abuse	4
23		Stroke and Hypertension	Cardiovascular / Pulmonary Conditions	3
24	Y	Lupus Erythematosus	Infectious Diseases / Immune Disorders	3
25		Violence	Behavioral Research	3
26		Child Health	Child and Adolescent Health	3
27	Y	Rheumatoid Arthritis	Infectious Diseases / Immune Disorders	3
28	Y	Female Reproductive Physiology[4]	Reproductive and Maternal Health	3
29	Y	Infertility	Reproductive and Maternal Health	3
30		HIV/AIDS[4]	Infectious Diseases / Immune Disorders	2
31	Y	Sexually Transmitted Diseases (excluding HIV/AIDS)	Infectious Diseases / Immune Disorders	2
32		Access to Health Care and Financing	Crosscutting Categories	2
33		Alzheimer's Disease	Aging	2
34		Chronic Pain Conditions[4]	Mental Health and Chronic Pain	2
35	Y	Endometriosis and Fibroids	Reproductive and Maternal Health	2
36	Y	Incontinence	Aging	2
37	Y	Women as Caregivers	Behavioral Research	2

[1] Research topics were rank-ordered based on the number of different working groups at the 1991 Hunt Valley workshop (out of a total of 10 working groups) recommending that NIH promote women's health research on this topic. Topics with the same number of group recommendations were ranked within their group based on the extent to which the topic was emphasized in the conference report, Report of the National Institutes of Health: Opportunities for Research on Women's Health.

[2] Of the 37 topics, 14 were designated as being primarily female topics and 23 were designated as being relevant to males as well as females, based on the discussions of the Hunt Valley participants and recommendations of the evaluation advisory committee.

[2] Highest priority research topics (budget categories used by NIH Institutes and Centers in calculating the DHHS-NIH Research Budget for Women's and Men's Health) and the major research area under which each one falls.

[4] Research topics that were given a substantially higher priority in the 1998 NIH research agenda for women's health.

Activity 3. Collaborations with NIH Institutes and Centers

ORWH's effort to develop collaborations with the 27 NIH institutes and centers was operationally defined as follows:

> The extent to which the ORWH Director and staff interacted with IC directors and their representatives to solicit their input on issues related to women's health research, discuss strategies for achieving different goals, and coordinate implementation of the NIH research agenda on women's health, as measured by the number and types of trans-NIH committees and task forces convened by ORWH and the number of requests for applications (RFAs) and program announcements (PAs) ORWH co-sponsored in collaboration with one or more ICs from FY 1991 to FY 2000.

The evaluation found that in addition to its work with numerous external advisory committees and task forces, ORWH convened and worked closely with 16 trans-NIH committees and task forces during its first ten years, many of which are still meeting on a regular basis. The Office also collaborated with individual NIH institutes and centers to encourage research on women's health in high-priority areas, co-sponsoring numerous RFAs and PAs in collaboration with one or more ICs.

Trans-NIH committees and task forces. An analysis of the activities database revealed that the number of trans-NIH committees and task forces convened by ORWH steadily increased from FY 1991 to FY 1995 and then remained relatively stable for the remainder or the decade (as shown in Exhibit 3). During FY 1995-2000, ORWH met regularly with at least seven committees/task forces per year; several of these groups are still working together on various NIH-wide issues related to women's health. The most important committees included the following:

- The Coordinating Committee on Research on Women's Health (CCRWH), composed of IC directors or their designees, was constituted in January 1994 and has continued to meet with ORWH every two to three months. During FY 1996-2000, an average of 20 IC representatives and 8 ORWH staff attended each CCRWH meeting, as well as occasional guests from outside NIH. The ORWH Director has worked closely with the CCRWH, participating in every meeting except one since its inception in FY 1994. In order to pursue specific issues in more depth, three CCRWH subcommittees (the Executive Subcommittee, Research Subcommittee, and Career Development Subcommittee) were established in FY 1995 and have continued to meet with ORWH on a regular basis. The evaluation team found substantial evidence that the members of the CCRWH and its subcommittees have played a major role in enhancing ORWH's collaborations with the various ICs.

- The NIH Tracking and Inclusion Committee, co-chaired by the ORWH Director and a senior IC official, was established by ORWH in FY 1994 to help the NIH Director develop and implement improved guidelines on the inclusion of women and

minorities in clinical research and to assist in the development and implementation of a centralized database system for tracking the enrollment of women and minorities in NIH-funded clinical studies. The committee, with members representing each IC director, has met regularly since that time with ORWH and the NIH Office of Extramural Research, Office of Intramural Research, and Office of Research on Minority Health.[8] The group has been instrumental in designing trans-NIH data collection and reporting methodologies for tracking the enrollment of women and minorities in NIH studies, including Phase III clinical trials, and developing training programs for IC staff responsible for administering the NIH inclusion policy.

- The ORWH Seminar Series Committee, which includes representatives from the different ICs, was established in FY 1993 and has continued to work closely with ORWH to identify topics and speakers for the Women's Health Seminar Series.

- The ORWH Director, as co-chair of the Women's Health Initiative (WHI), has served on the WHI Institute Director's Committee since its initial meeting in FY 1993. The Women's Health Initiative is one of the largest U.S. prevention studies of its kind, involving over 165,000 postmenopausal women of diverse racial and ethnic backgrounds residing in communities throughout the country. NIH launched the 15-year $628 million prospective study in 1991 to examine the most common causes of death, disability, and poor quality of life in older women: cardiovascular disease, cancer, and osteoporosis. ORWH's role in the WHI is primarily advisory in nature. Due to the magnitude of the project, the WHI Program Office has always been located outside ORWH; it currently resides within the Office of the Director, NHLBI. The first director of the WHI, Dr. Loretta Finnegan, now serves as the Medical Advisor for ORWH.

RFAs and program announcements. In addition to its work with trans-NIH committees and task forces, ORWH has encouraged research on women's health in priority areas by co-sponsoring numerous requests for applications and program announcements in collaboration with one or more ICs. These official NIH notices, published each week in the *NIH Guide for Grants and Contracts*, are defined as follows:

- A request for application (RFA) is an official notice that invites grant or cooperative agreement applications to accomplish a specific program purpose; the request includes the amount of funds set aside for the competition and generally identifies a single application receipt date.
- A program announcement (PA) is an official notice that invites grant applications in a particular scientific area for which funds are not usually set aside beforehand.

[8] The Office of Research on Minority Health is now called the National Center on Minority Health and Health Disparities (NCMHD).

To determine the extent of ORWH's co-sponsorship of RFAs and PAs during its first ten years and identify which research topics were most commonly encouraged, the ORWH activities database was analyzed. Each RFA and PA had been coded using information published in the *NIH Guide for Grants and Contracts* and the ORWH biennial reports.

The analysis revealed that from FY 1991 through FY 2000, ORWH co-sponsored a total of 48 official notices (36 RFAs and 12 PAs) in collaboration with one or more ICs, most of which involved more than one research topic (see Exhibit 6). Of the 48 initiatives, 75% encouraged research on one or more of the 37 high-priority research topics in the FY 1991 NIH research agenda for women's health, and 25% were focused primarily on another topic involving women's health. As shown in Exhibit 7, the most frequently mentioned research topics in the initiatives co-sponsored by ORWH were behavioral change and risk-taking behavior, autoimmune disease (including diabetes, rheumatoid arthritis, and lupus erythematosus), cultural and lifestyle factors, and chronic pain conditions. Of the ten topics ranked highest by the Hunt Valley working groups, the three cancer topics (reproductive cancers, breast cancer, and lung cancer) had the fewest number of RFA/PAs; specifically, no RFAs or PAs involved lung cancer and only one RFA focused on reproductive cancers (which was the same RFA that addressed breast cancer). Colorectal cancer, which was ranked a bit lower in the NIH research agenda on women's health, was also mentioned in only one RFA. Of the other topics in the research agenda, all except three (sexually transmitted disease, Alzheimer's disease, and women as caregivers) were highlighted in at least one of the RFA/PAs that ORWH co-sponsored during its first ten years.

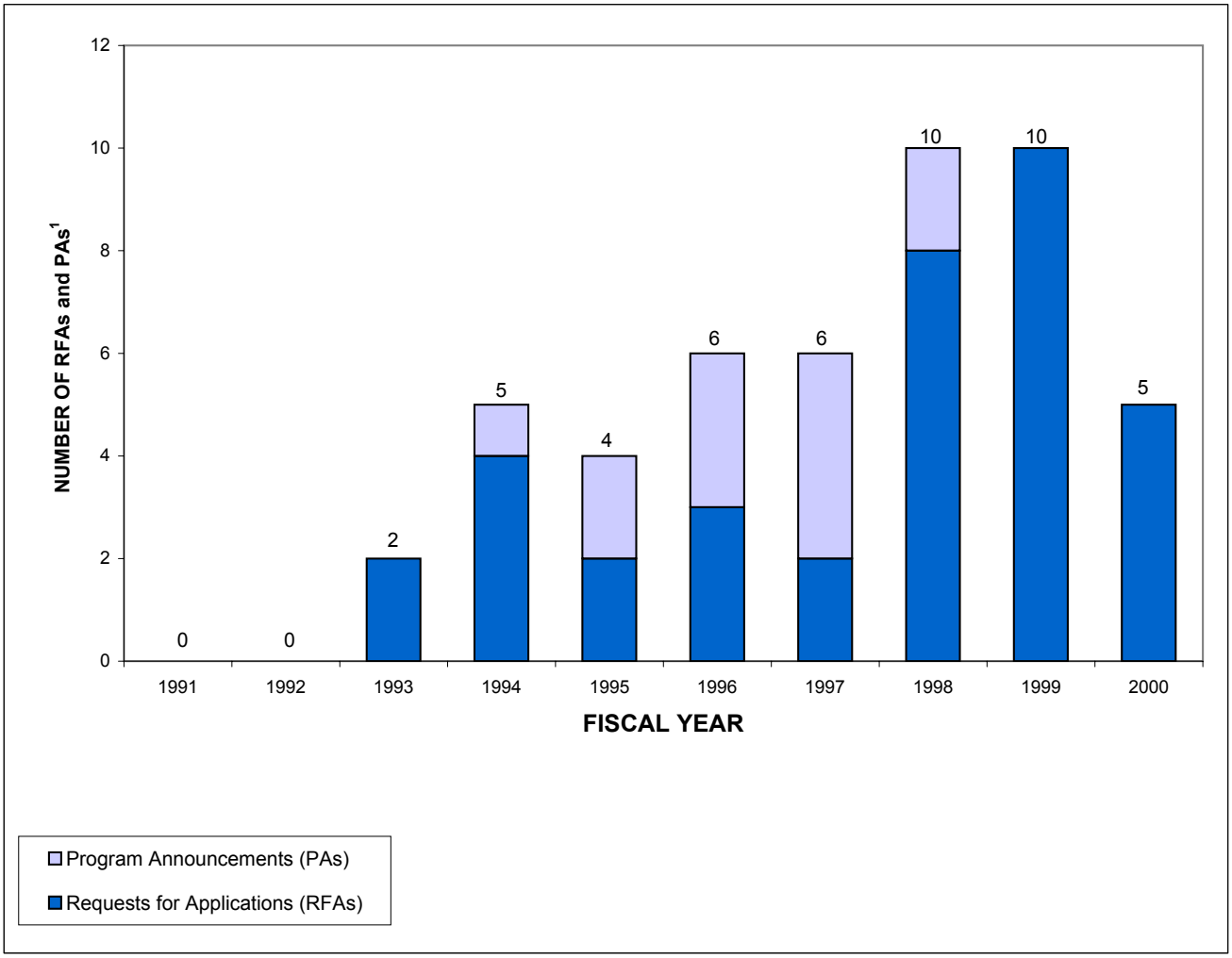
In summary, the evaluation found that ORWH collaborated extensively with the different NIH institutes and centers during its first ten years to encourage them to support research on women's health and help achieve other aspects of its mandate. The Office convened and worked closely with 16 trans-NIH committees and task forces and collaborated with individual NIH institutes and centers to stimulate and expand research on women's health in high-priority areas, co-sponsoring 48 RFAs and PAs in collaboration with one or more ICs. Given ORWH's limited staff and budget, its strong emphasis on interdisciplinary collaboration was regarded as essential for the achievement of its goals.

Exhibit 6

EVALUATION OF ORWH'S FIRST TEN YEARS

RFAs AND PROGRAM ANNOUNCEMENTS CO-SPONSORED BY ORWH

FY 1991-2000



[1] Primary data sources: NIH Guide for Grants and Contracts (FY 1991-2000); Report of the Office of Research on Women's Health (ORWH biennial reports on activities conducted during FY 1991-2000).

Exhibit 7

EVALUATION OF ORWH'S FIRST TEN YEARS

RFAs AND PROGRAM ANNOUNCEMENTS CO-SPONSORED BY ORWH INVOLVING HIGH-PRIORITY RESEARCH TOPICS

FY 1991-2000

Rank[1]	Research Topic[2]	Major Research Area[2]	Number of RFAs and PAs[3]
1	Cultural and Lifestyle Factors	Behavioral Research	9
2	Pregnancy and Maternal Health	Reproductive and Maternal Health	4
3	Behavioral Change and Risk-Taking Behavior	Behavioral Research	12
4	Reproductive Cancers	Cancer	1
5	Heart Disease	Cardiovascular and Pulmonary Conditions	4
6	Psychosocial Stress	Mental Health and Chronic Pain	4
7	Breast Cancer	Cancer	1
8	Osteoporosis	Aging	3
9	Lung Cancer	Cancer	0
10	Obesity and Physical Activity	Metabolism and Endocrinology	5
11	Depression and Mood Disorders	Mental Health and Chronic Pain	3
12	Nutrition	Metabolism and Endocrinology	6
13	Menopausal Hormone Therapy	Aging	1
14	Colorectal Cancer	Cancer	1
15	Diabetes	Metabolism and Endocrinology	10
16	Adolescent Health	Child and Adolescent Health	5
17	Disability Research and Services	Crosscutting Categories	1
18	Contraception	Reproductive and Maternal Health	1
19	Tobacco Use	Substance Abuse	1
20	Illegal Drug Use/Abuse	Substance Abuse	2
21	Menopause	Aging	1
22	Alcohol Use/Abuse	Substance Abuse	3
23	Stroke and Hypertension	Cardiovascular and Pulmonary Conditions	2
24	Lupus Erythematosus	Infectious Diseases and Immune Disorders	10
25	Violence	Behavioral Research	1
26	Child Health	Child and Adolescent Health	6
27	Rheumatoid Arthritis	Infectious Diseases and Immune Disorders	9
28	Female Reproductive Physiology	Reproductive and Maternal Health	6
29	Infertility	Reproductive and Maternal Health	1
30	HIV/AIDS	Infectious Diseases and Immune Disorders	2
31	Sexually Transmitted Diseases	Infectious Diseases and Immune Disorders	0
32	Access to Health Care and Financing	Crosscutting Categories	2
33	Alzheimer's Disease	Aging	0
34	Chronic Pain Conditions	Mental Health and Chronic Pain	8
35	Endometriosis and Fibroids	Reproductive and Maternal Health	3
36	Incontinence	Aging	4
37	Women as Caregivers	Behavioral Research	0

[1] Ranking of the topic in the NIH research agenda on women's health, based on the number of different working groups at the 1991 Hunt Valley Conference recommending that NIH promote women's health research on this topic.

[2] Highest priority research topics (budget categories used by NIH Institutes and Centers in calculating the DHHS-NIH Research Budget for Women's and Men's Health) and the major research area under which each topic falls.

[3] Number of NIH requests for applications (RFAs) and program announcements (PAs) co-sponsored by ORWH that involved each research topic. ORWH co-sponsored a total of 12 PAs and 36 RFAs from FY 1991-2000, most of which involved more than one research topic. Data sources: NIH Guide for Grants and Contracts;Report of the Office of Research on Women's Health (ORWH biennial reports on activities conducted during FY 1991-2000).

Activity 4. Co-Funding NIH Research Studies and Career Development Awards

Because ORWH is not an NIH institute or center, the Office cannot fund research and training grants directly but rather provides co-funding for extramural and intramural studies sponsored by the various ICs. ORWH's co-funding of NIH research studies and career development awards was operationally defined as follows:

> The extent to which ORWH co-sponsored and provided funding for four types of research studies (targeted research initiatives, research enhancement awards, administrative supplements, and special research initiatives) and career development awards, as measured by the number and types of research studies and career development awards and the amount of ORWH funding provided for different types of studies from FY 1991 to FY 2000.[9]

The evaluation found that ORWH took full advantage of its ability to function as a catalyst, using its relatively small budget to leverage additional IC funding for a variety of research studies involving women's health and awards to assist researchers in becoming independent investigators.

Research studies. From the start, ORWH's primary mandate has been to promote research related to diseases, disorders, and conditions that affect women. After achieving a broad consensus on an NIH-wide research agenda, the Office used the agenda and its funding capability to encourage the ICs to sponsor women's health research on high-priority areas relevant to the different IC missions. During its first ten years, ORWH focused primarily on co-funding extramural research studies, although it also encouraged NIH intramural scientists to conduct research in high-priority areas of women's health.

To determine the extent of ORWH's co-funding and identify which research topics were most commonly co-funded, the ORWH activities database was analyzed. Each study's research topic (or topics) had been coded based on a content analysis of the research abstract provided in an ORWH biennial report.

The results showed that from FY 1991 through FY 2000, ORWH provided nearly $95 million to ICs and co-funded a total of 1,060 research studies. Exhibits 8 and 9 show trends through time with respect to the amount of ORWH co-funding and the number of studies co-funded each year. ORWH funds were used to augment new research programs, expand current studies in high-priority areas, and increase the accrual of women in clinical research studies. Four types of co-funding were provided by ORWH:

[9] Although the term "initiative" generally refers to an official NIH notice inviting research applications in a specific area (e.g., RFA or PA), ORWH also used the term internally to refer to specific types of research studies co-sponsored by the Office.

- Co-funding *special research initiatives* having exceptional potential to increase scientific knowledge on women's health.
- Providing *administrative supplements* to meritorious NIH research grants involving women's health.
- Providing supplemental funding under the *Research Enhancement Award Program (REAP)* for meritorious NIH research grants that otherwise would not be funded.
- Co-funding large-scale *targeted research initiatives* in high-priority areas of women's health.

Further analysis revealed that 89% of the research studies co-funded by ORWH involved one or more of the 37 high-priority topics in the FY 1991 NIH research agenda for women's health; only 11% were focused primarily on another topic involving women's health. The number of studies co-funded by ORWH involving each topic was generally consistent with the overall ranking of the topics (see Exhibit 10). The four topics that were ranked the highest by the Hunt Valley working groups (cultural and lifestyle factors, pregnancy and maternal health, behavioral change and risk-taking behavior, and reproductive cancers) had the highest number of co-funded research studies, averaging 111 studies per topic. The next 10 topics (recommended by five or six working groups) averaged 47 studies per topic, the 15 topics recommended by three or four working groups also averaged 47 studies per topic (which dropped to 41 studies per topic if female reproductive physiology was excluded), and the 8 topics recommended by only two working groups averaged 37 studies per topic.

Although ORWH's co-funding of IC research studies was in overall accordance with the NIH research agenda for women's health, there were a few notable inconsistencies between the relative priorities of the topics in the research agenda and the number of studies co-funded by ORWH. For example, only 8 studies focused on colorectal cancer and only 16 focused on lung cancer, both of which were among the highest priority topics in the agenda and had been recommended by five working groups. Reproductive cancers also had fewer co-funded studies than expected given that it was ranked #4 in the research agenda. Of the other topics, female reproductive physiology had the highest number of co-funded research awards (131 studies) which was partly due to the broad nature of this particular topic, and Alzheimer's disease had the lowest number (only 11 studies).

Career development awards. In addition to encouraging research relevant to women's health, ORWH's mandate included promoting the recruitment, retention, reentry, and advancement of women in biomedical careers. An analysis of the ORWH activities database found that ORWH co-funded 128 career development awards during FY 1991-2000 (as shown in Exhibit 11) and helped develop five major career development programs during its first ten years:

- ORWH Reentry Program.
- Professional Opportunities for Women in Research and Education (POWRE).
- WHI Minority Investigator Career Development Awards.

- Building Interdisciplinary Research Careers in Women's Health (BIRCWH).
- Transitional Career Development Awards in Women's Health Research

The process ORWH used to achieve these results illustrates the collaborative approach the Office employed in implementing all of its major activities.

A first step taken by ORWH with respect to career development was to achieve consensus on the major barriers encountered by women seeking biomedical careers and to identify potential strategies for overcoming the barriers. Early in FY 1992, scientific leaders from around the country were recruited to serve on a new Task Force on the Recruitment, Retention, and Advancement of Women in Biomedical Careers. The 26-member task force, co-chaired by an African-American scientist and a Hispanic scientist, was composed of 50% ethnic and racial minorities; 80% of the members were women and 20% were men. ORWH held a two-day public hearing in March 1992 and written and oral testimony was received from representatives of more than 70 organizations. Major issues and barriers that women face when considering a biomedical career were identified during the hearing and the testimony provided guidance to ORWH and the task force in planning a workshop entitled "Women in Biomedical Careers: Dynamics of Change, Strategies for the 21st Century," which was held in Bethesda on June 11-12, 1992. Over 400 biomedical professionals participated in the national workshop, which included a series of panel sessions, keynote speakers, creative strategy sessions, and breakout sessions where 11 working groups developed recommendations for addressing different issues. Each working group summarized the major issues and barriers relevant to the group's topic and developed specific recommendations for addressing the problems. The discussions and recommendations from the workshop were synthesized in a report published by ORWH, *Women in Biomedical Careers: Dynamics of Change*. An important conclusion of the workshop was that the recommended strategies for improving the recruitment and advancement of women scientists needed the strong support of a wide range of individuals and groups, including professional societies, academic institutions, foundations, private industry, and federal agencies as well as the support of ORWH and the NIH ICs.

Following the workshop, several career development projects were initiated and funded by ORWH, the most important being a pilot program called Reentry into Biomedical Careers (which became known as the ORWH Reentry Program). During the program's first year in FY 1992, ORWH awarded nine administrative supplements, totaling nearly $1 million, to enable fully trained women and men to participate on a research grant after they had taken time off to attend to family needs. The ORWH Reentry Program required the principal investigator receiving the grant supplement to provide the reentering scientist with substantial mentoring and an opportunity to update and enhance his/her research skills through full participation in the research project. During FY 1992-1994, a total of 26 awardees (24 women and 2 men) and 26 mentors participated in the pilot program and 3 additional awardees and mentors participated in a similar intramural program developed by ORWH and the NIH Office of Education (OE) for reentering scientists interested in working in NIH laboratories. In FY 1995, ORWH surveyed the 26 participants and sponsored a workshop to assess the early results of the Reentry Program,

concluding that the pilot program was serving a clear need and should be formalized. A new program announcement for the Reentry into Biomedical Careers Program was issued in FY 1997. The expanded program included broader eligibility criteria to better accommodate the needs of reentering scientists, provided the ICs with more flexibility in the review process, and expanded the mentoring component. In the present evaluation, the analysis for Long-Term Goal 3 addressed how many of the 26 participants in the initial ORWH Reentry Program succeeded in becoming independent research scientists after finishing the program.

ORWH initiated two other career development programs in FY 1997, signing an interagency collaboration with the National Science Foundation (NSF) to support the Professional Opportunities for Women in Research and Education (POWRE) program, and co-sponsoring an RFA with NIAMS and NIA to provide career development awards to minority scientists to facilitate their participation in the Women's Health Initiative (WHI).[10] The POWRE program provided 18-month grants in basic research to women investigators to help ameliorate the underrepresentation of women in the science and engineering workforce. ORWH supported a total of 30 POWRE investigators during FY 1997-2000. The new program co-sponsored by NIAMS and NIA established multi-year WHI Minority Investigator Career Development Awards. These awards served two purposes, to augment the awardees' research skills and to enhance the diversity of the WHI investigator teams. ORWH funded four WHI minority investigators during FY 1997-2000.

In FY 1999-2000, in response to specific needs identified during the Beyond Hunt Valley working groups, ORWH worked closely with the CCRWH Career Development Subcommittee to launch two major programs: Building Interdisciplinary Research Careers in Women's Health (BIRCWH) and Transitional Career Development Awards in Women's Health Research. Both of these new programs were specifically designed to promote women's health research as well as career development. BIRCWH was established as a major institutional award to help new investigators, known as Interdisciplinary Women's Health Research (IWHR) scholars, make a successful transition to become independent researchers in areas relevant to women's health. The BIRCWH program was designed to encourage institutions to foster interdisciplinary collaborations focused on specific areas of women's health research. In FY 2000, 12 universities received BIRCWH awards and a total of 56 IWHR scholars and 278 mentors participated in the program. ORWH contributed $5.5 million to the BIRCWH program, which was co-sponsored by 14 ICs as well as the Agency for Health Care Policy and Research (AHCPR). Transitional Career Development Awards in Women's Health Research, first announced in January 2000, was designed as a two-phase program to encourage new investigators to pursue research related to women's health; awardees were given a two-year intramural appointment at NIH followed by two years of salary and research support at an extramural institution. In addition to ORWH, 12 ICs co-sponsored this innovative career development program, which was also supported by Pfizer Women's Health and the National Foundation for Biomedical Research. Both the

[10] Appendix B includes a full listing of the NIH institutes and centers, including their acronyms and individual missions.

BIRCWH awards and the Transitional Career Development Awards place a strong emphasis on having established researchers serve as mentors for the junior investigators.

In addition to the central role that ORWH played in developing these five career development programs, the Office participated in several other projects sponsored by individual ICs, OD offices, and organizations outside NIH to encourage the recruitment, retention, reentry, and advancement of women in biomedical careers. Examples include the following:

- Extramural Associates program, for which ORWH provided supplemental funds for predoctoral and postdoctoral students at minority institutions and women's colleges to participate in a five-month NIH residency program.
- Institutional and individual National Research Service Award (NRSA) program, including an interdisciplinary training program in gender and mental health initiated by NIMH in FY 1997.
- Women's Reproductive Health Research (WRHR) Career Development Centers, initiated by NICHD in FY 1998.
- Advancing Women's Contributions to Science through Professional Societies (AXXs), a career program co-sponsored by ORWH, NIEHS, several other ICs, and the American Society for Cell Biology, which included workshops in FY 1999 and FY 2000 to explore the roles of professional societies in advancing the careers of women scientists.
- Comer Award for Minority Medical Students, a mentored summer research program offered by NIMH and the American Academy of Adolescent and Child Psychiatry.
- NIH Fellows Award for Research Excellence (FARE) for postdoctoral fellows working in the NIH Intramural Research Program. ORWH supported over 500 FARE awardees from FY 1996 to FY 2000 who received travel awards to present abstracts at scientific meetings.

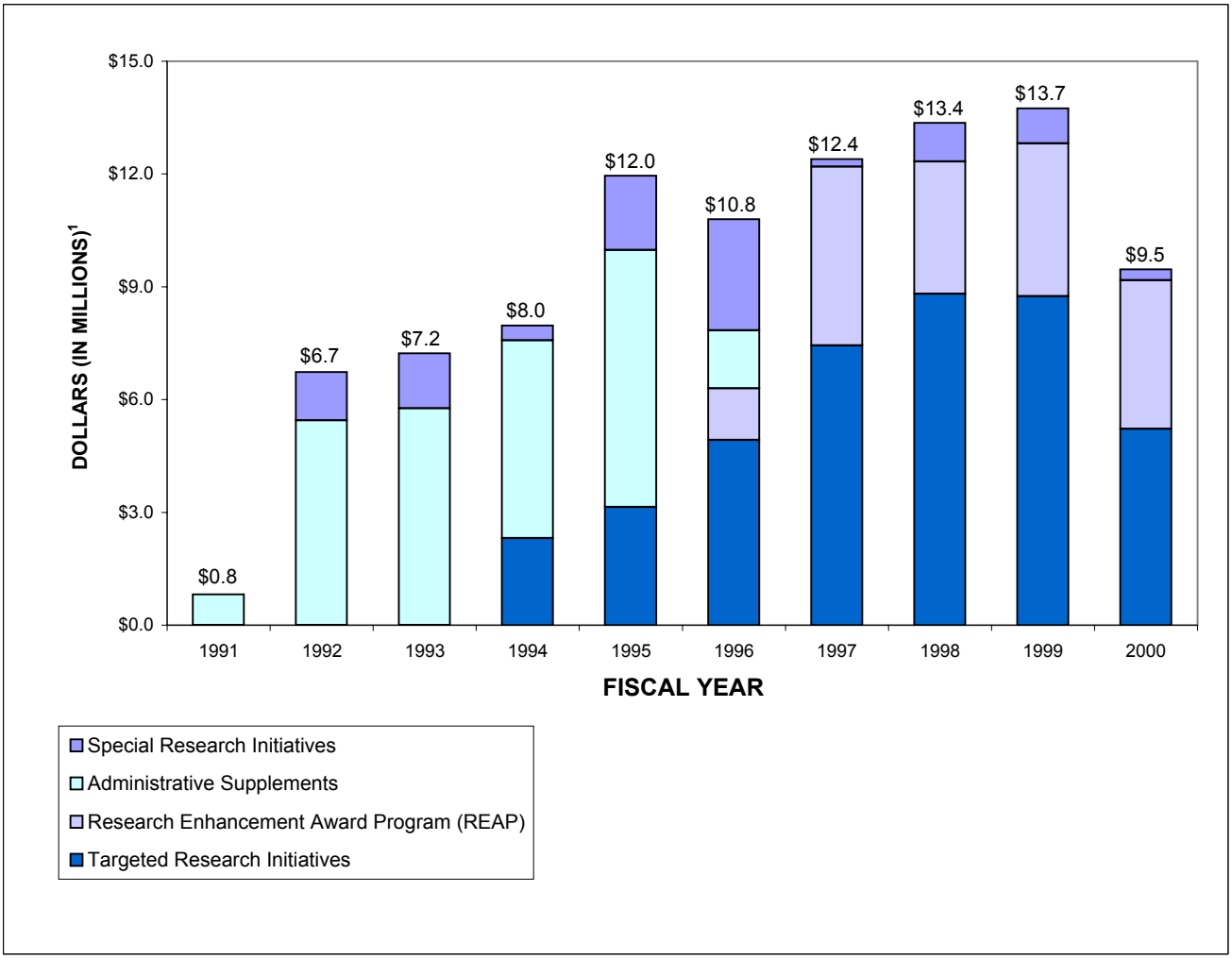
In summary, the evaluation found that ORWH co-funded over 1,000 NIH research studies and over 125 career development awards during its first ten years, providing nearly $95 million to ICs to support specific projects. The research studies focused primarily on the topics in the NIH research agenda on women's health and the highest priority topics were generally given the most attention, demonstrating the effectiveness of the Office's strategic planning and agenda development process. In addition, several different types of programs were supported to promote the recruitment, retention, and advancement of women in biomedical careers. ORWH worked collaboratively with the CCRWH Career Development Subcommittee, ACRWH, individual ICs, external agencies, associations, and academic institutions to develop five new NIH programs to address the numerous barriers faced by women pursuing biomedical careers. Based on the Office's previous experience, the programs that were launched near the end of the decade placed a strong emphasis on women's health research while also promoting the advancement of women in biomedical careers.

Exhibit 8

EVALUATION OF ORWH'S FIRST TEN YEARS

ORWH CO-FUNDING OF NIH RESEARCH STUDIES

FY 1991-2000



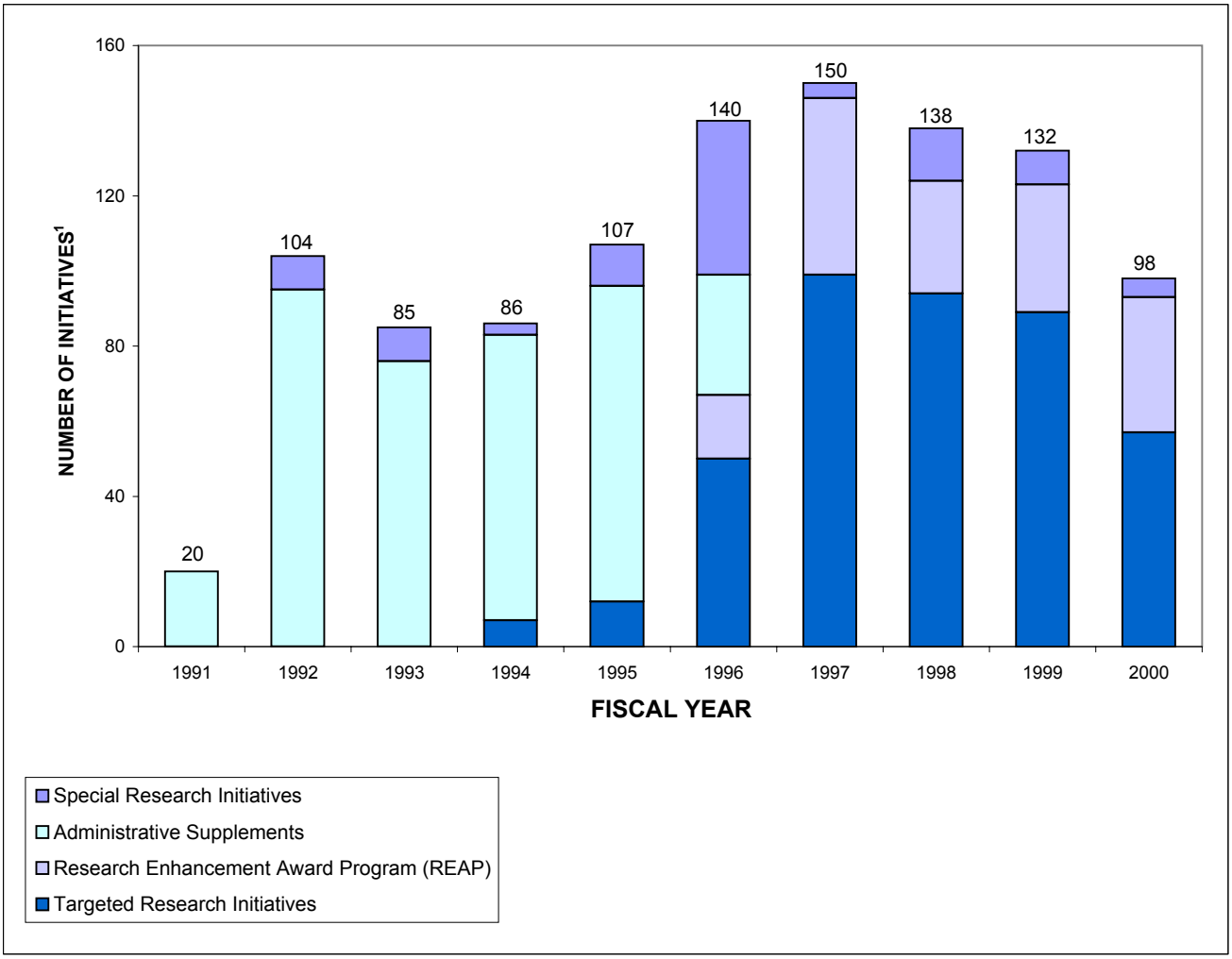
[1] Current dollars (in millions) provided by ORWH to NIH ICs to co-fund NIH research studies under four types of ORWH programs. Primary data source: Report of the Office of Research on Women's Health (ORWH biennial reports on activities conducted during FY 1991-2000).

Exhibit 9

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RESEARCH STUDIES CO-FUNDED BY ORWH

FY 1991-2000



[1] Primary data source: Report of the Office of Research on Women's Health (ORWH biennial reports on activities conducted during FY 1991-2000).

Exhibit 10

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RESEARCH STUDIES CO-FUNDED BY ORWH INVOLVING HIGH-PRIORITY RESEARCH TOPICS

FY 1991-2000

Rank[1]	Research Topic[2]	Major Research Area[2]	Number of Research Studies[3]
1	Cultural and Lifestyle Factors	Behavioral Research	101
2	Pregnancy and Maternal Health	Reproductive and Maternal Health	166
3	Behavioral Change and Risk-Taking Behavior	Behavioral Research	145
4	Reproductive Cancers	Cancer	33
5	Heart Disease	Cardiovascular and Pulmonary Conditions	60
6	Psychosocial Stress	Mental Health and Chronic Pain	52
7	Breast Cancer	Cancer	67
8	Osteoporosis	Aging	55
9	Lung Cancer	Cancer	16
10	Obesity and Physical Activity	Metabolism and Endocrinology	56
11	Depression and Mood Disorders	Mental Health and Chronic Pain	48
12	Nutrition	Metabolism and Endocrinology	65
13	Menopausal Hormone Therapy	Aging	47
14	Colorectal Cancer	Cancer	8
15	Diabetes	Metabolism and Endocrinology	49
16	Adolescent Health	Child and Adolescent Health	47
17	Disability Research and Services	Crosscutting Categories	40
18	Contraception	Reproductive and Maternal Health	20
19	Tobacco Use	Substance Abuse	21
20	Illegal Drug Use/Abuse	Substance Abuse	37
21	Menopause	Aging	52
22	Alcohol Use/Abuse	Substance Abuse	48
23	Stroke and Hypertension	Cardiovascular and Pulmonary Conditions	23
24	Lupus Erythematosus	Infectious Diseases and Immune Disorders	38
25	Violence	Behavioral Research	43
26	Child Health	Child and Adolescent Health	72
27	Rheumatoid Arthritis	Infectious Diseases and Immune Disorders	38
28	Female Reproductive Physiology	Reproductive and Maternal Health	131
29	Infertility	Reproductive and Maternal Health	43
30	HIV/AIDS	Infectious Diseases and Immune Disorders	44
31	Sexually Transmitted Diseases	Infectious Diseases and Immune Disorders	37
32	Access to Health Care and Financing	Crosscutting Categories	29
33	Alzheimer's Disease	Aging	11
34	Chronic Pain Conditions	Mental Health and Chronic Pain	99
35	Endometriosis and Fibroids	Reproductive and Maternal Health	34
36	Incontinence	Aging	25
37	Women as Caregivers	Behavioral Research	20

[1] Ranking of the topic in the NIH research agenda on women's health, based on the number of different working groups at the 1991 Hunt Valley Conference recommending that NIH promote women's health research on this topic.

[2] Highest priority research topics (budget categories used by NIH Institutes and Centers in calculating the DHHS-NIH Research Budget for Women's and Men's Health) and the major research area under which each topic falls.

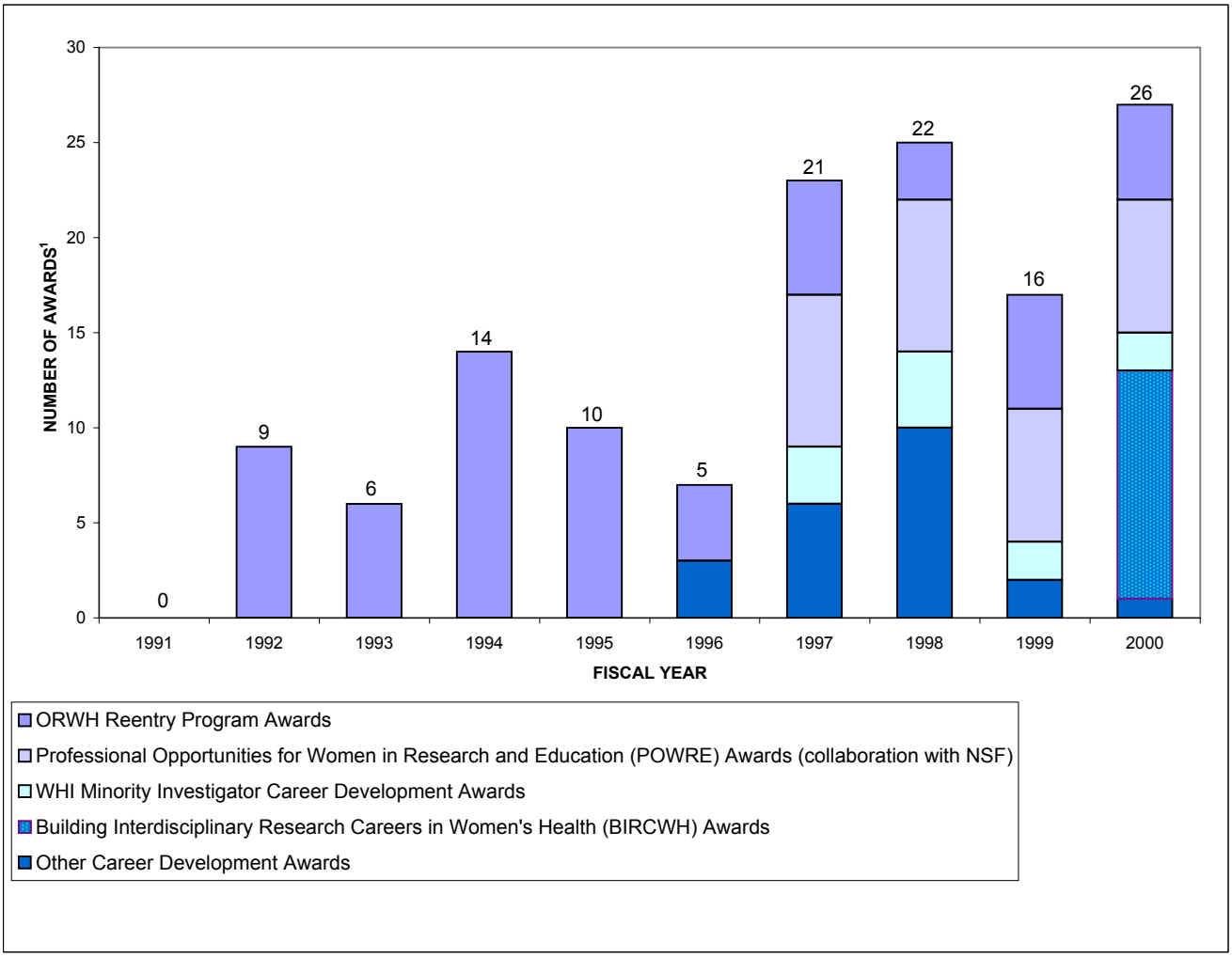
[3] Number of NIH research studies co-funded by ORWH that involved each research topic. ORWH co-funded a total of 1,060 research studies from FY 1991-2000, most of which involved more than one research topic. Primary data source: research abstracts published in the Report of the Office of Research on Women's Health (ORWH biennial reports on activities conducted in FY 1991-2000).

Exhibit 11

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH CAREER DEVELOPMENT AWARDS CO-FUNDED BY ORWH

FY 1991-2000



[1] Primary data source: Report of the Office of Research on Women's Health (ORWH biennial reports on activities conducted during FY 1991-2000).

Activity 5. Inclusion of Women and Minorities in Study Populations

ORWH's efforts to develop and implement an enhanced NIH inclusion policy were operationally defined as follows:

> The extent to which the ORWH Director and staff worked with IC directors and their representatives to strengthen the NIH policy on the inclusion of women and minorities in study populations and ensure that the new policy was being implemented throughout NIH in an appropriate and timely manner, as measured by the number and types of relevant planning, training, implementation, and monitoring activities undertaken by ORWH in collaboration with other NIH offices, ICs, and organizations outside NIH from FY 1991 to FY 2000.

As mentioned in the Introduction, two catalysts in the establishment of ORWH were (1) an increased awareness that most of the existing knowledge about diseases and health conditions had been derived primarily from studies of men; and (2) the 1990 GAO finding that NIH's policy on the inclusion of women in study populations was not being implemented uniformly and completely across NIH. Faced with the prospect of quick congressional action, NIH promptly issued an expanded interpretation of its inclusion policy (requiring a compelling justification for excluding women and minorities from clinical studies) and established the Office of Research on Women's Health in September 1990. The following year, NIH launched the Women's Health Initiative.

Three years after ORWH was established, Congress passed the NIH Revitalization Act of 1993 which gave statutory authority to the Office of Research on Women's Health. The Act also required NIH to establish stronger guidelines for the inclusion of women and minorities in clinical research. NIH responded by publishing revised inclusion guidelines in March 1994 which applied to all extramural applications/proposals and intramural projects seeking FY 1995 support. The new guidelines broadened the definition of clinical research to include all research involving human subjects, instructed NIH peer review groups to consider the planned study population when assessing the scientific merit of a grant proposal, and required that Phase III clinical trials include women and minorities in sufficient numbers to allow for valid analyses of sex/gender or race/ethnicity differences in intervention effects. In addition, the guidelines stated that cost was not an acceptable reason for excluding women and minorities from clinical trials. To facilitate compliance with the stronger inclusion policy, NIH revised its application form for new grants, requiring investigators to (1) report data on the sex/gender and racial/ethnic composition of the study population using a specified format, and (2) include current enrollment data in their annual progress reports and competitive renewal applications.

The evaluation found that ORWH played a major role in implementing NIH's inclusion policy throughout its first decade, initiating or co-sponsoring over 90 activities designed to ensure that women and minorities were being appropriately included as subjects in NIH-supported clinical research. The most important activities are summarized below.

Soon after its establishment in 1990, ORWH asked the Institute of Medicine (IOM) to prepare a report analyzing the various issues surrounding the inclusion of women in clinical trials and possible ways to resolve them. Based on this initial study, ORWH commissioned the IOM in 1992 to establish a committee of experts to investigate in detail the ethical and legal issues related to the inclusion of women in clinical studies, particularly pregnant women and women of childbearing age, and provide practical advice to NIH administrators, IRB chairs, and clinical investigators.

In 1993, ORWH formed a Task Force on the Recruitment and Retention of Women in Clinical Studies. Representatives from 20 organizations identified barriers to recruiting and retaining women in clinical studies, reviewed strategies for enhancing their participation, and developed a summary report for the NIH Director with recommendations for improving the recruitment and retention of women from all racial/ethnic groups and socioeconomic strata. ORWH also held a public hearing in 1993 to identify barriers and solicit suggestions for improving NIH's inclusion policy. Recommendations from this hearing were incorporated into the planning of a scientific conference held in July 1993. In the fall of 1994, ORWH published the conference report, *Recruitment and Retention of Women in Clinical Studies*.

The IOM committee's report, *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies*, was published in 1994. It emphasized the importance of expanding research on women's health, ensuring informed consent, and revising certain DHHS regulations to increase the participation of pregnant women and women of childbearing age in clinical studies. Although the FDA had recently lifted its broad restriction on the inclusion of women of childbearing age in Phase 1 trials, the IOM committee cited other DHHS policies and regulations restricting the participation of women in clinical research. Also in 1994, ORWH convened a meeting of IRB chairs to discuss their role in implementing the revised NIH inclusion policy and published an *Outreach Notebook* to help investigators understand the revised NIH inclusion policy. The notebook presented the full text of the new guidelines, provided practical advice on implementing an effective outreach process for increasing the participation of women and minorities in clinical studies, and included a Q&A document providing answers to frequently asked questions.

Soon after the publication of the revised inclusion policy in 1994, ORWH established the NIH Tracking and Inclusion Committee to ensure that uniform standards and definitions were used to report inclusion data and monitor compliance with the new requirements. The committee, consisting of representatives from each of the ICs and co-chaired by the ORWH Director and a senior IC official, has met on a regular basis since that time. Working with ORWH and other NIH staff, the committee coordinated an extensive training effort to communicate the new policy to over 1,000 NIH scientific review administrators, program officers, and grants management staff, who in turn communicated the requirements to grant applicants, scientific review groups, and other members of the research community. In 1995, a centralized database system for tracking the enrollment of women and minorities in NIH-sponsored studies was implemented, which has subsequently been used by the committee to monitor NIH's compliance with the

revised inclusion guidelines. Using the database, the Tracking and Inclusion Committee has published biennial tracking reports showing aggregate enrollment data for Phase III clinical trials, all extramural research protocols, and intramural research protocols funded by NIH since FY 1997. Since FY 1995, the committee has also reported on the number and percent of extramural grant applications that did not meet the inclusion requirements based on scientific peer review assessments, including the primary reasons for noncompliance

During 1995 and 1996, ORWH worked closely with the ACRWH and its Subcommittee on Compliance with Inclusion Guidelines, whose members provided advice and assistance in monitoring compliance with the revised NIH inclusion policy. Also in 1996, ORWH reconvened the IRB chairs, along with members of the Recruitment and Retention Task Force, other experts, and representatives from NIH ICs, to discuss their experiences in implementing the guidelines. The results were summarized in a paper published by ORWH later that year entitled, "NIH's Response to Researchers' Concerns."

Near the end of the decade, GAO conducted a formal assessment of NIH's progress in implementing the 1994 inclusion guidelines in response to a congressional request. The resulting report, *Women's Health: NIH Has Increased Its Efforts to Include Women in Research*, was issued by GAO in May 2000. The report concluded that in the previous ten years, NIH had made significant progress in implementing a strengthened policy on including women in clinical research and "ORWH played a key role in implementing the inclusion guidelines." It included two specific recommendations for the NIH Director: (1) improve implementation of the requirement that Phase III clinical trials be designed and conducted to allow for valid analyses of sex/gender and racial/ethnic differences; and (2) ensure that NIH staff who transmit enrollment data to the centralized tracking system receive ongoing training on the requirements and purpose of the system.

ORWH responded immediately following the release of the GAO report, working with the other members of the NIH Tracking and Inclusion Committee to establish a special NIH Subcommittee Reviewing Inclusion Issues. Within three months, the subcommittee had reexamined NIH's guidelines for analyzing sex/gender and racial/ethnic differences and recommended changes for improving the accuracy and performance of the NIH tracking system, which were implemented over the next few months. More detailed information is presented in the analysis of Long-Term Goal 5.

In summary, the evaluation found that ORWH was very proactive throughout the decade in strengthening NIH's inclusion policy. The Office initiated and supported over 90 activities aimed at ensuring that women were appropriately included as subjects in clinical research studies supported by NIH.

Activity 6. Promoting Women's Health Research Through Information Dissemination

ORWH's promotion of women's health research and career opportunities through information dissemination was operationally defined as follows:

> The extent to which ORWH disseminated research findings and other information relevant to women's health, as measured by the number and types of scientific publications, policy documents, and educational materials developed and/or disseminated by ORWH from FY 1991 to FY 2000.

To determine the extent of ORWH's information dissemination and outreach efforts, the ORWH activities database was analyzed. The different types of publications, policy documents, and educational products had been coded based on information provided in the ORWH biennial reports.

The evaluation found that during its first ten years, ORWH developed and/or co-sponsored 123 scientific reports, journal articles, policy documents, and educational programs and materials to promote women's health research and career opportunities. Trends through time are shown in Exhibit 12. From FY 1991 through FY 2000, 55 journal articles and 32 scientific reports, monographs, and policy documents were published, and 36 other educational programs and materials (e.g., brochures, videotapes, websites, posters, media kits, course curricula) were produced and disseminated. Many of these informational products were developed in collaboration with other NIH offices and ICs as well as organizations and individuals outside NIH who understood the needs of the broader scientific community and general public.

About half of the scientific publications and policy documents focused on specific health topics and half involved more generic issues relevant to women's health, such as the NIH agenda for women's health research, the inclusion of women and minorities in clinical studies, the advancement of women scientists, and the promotion of equity in biomedical research. Many of these documents summarized the findings and recommendations of the various committees, task forces, workshops, and scientific conferences sponsored by ORWH. The educational programs involved both general issues relevant to women's health and specific topics designed to address the needs of different audiences. Several major community outreach programs were developed with the NIH Office of Science Education (OSE) and the Office of Education (OE).

The following are examples of different types of outreach activities ORWH supported to promote women's health research and encourage young women to pursue scientific careers:

- Health Science Curriculum Online (collaboration with OSE and DHHS offering interactive websites in English and Spanish providing health information and career options for girls in grades 7-12 and their teachers).
- Snapshots of Science and Medicine (three-part website developed by ORWH and OSE to bring cutting-edge research into high school science classrooms).

- Women in Science poster series and video/poster series featuring women scientists (two ORWH/OE programs offering free posters, companion websites, and videos to encourage middle-school girls to pursue careers in science).
- National Hispanic Youth Initiative (collaboration with NINDS offering summer sessions and preceptorships to encourage high school students, especially girls, to pursue science careers).
- Medical school and dental school curricula on women's health (collaboration with HRSA, AAMC, AACOM, and AADS to evaluate and develop model curricula for medical and dental students).[11]
- Museum project (national traveling women's health exhibit and website designed for science museums by ORWH and the Centers for Disease Control and Prevention).
- Job Fair for Postdocs (collaboration with OE to produce a database to facilitate NIH fellows' access to employment opportunities). Other ORWH/OE career development activities for NIH postdoctoral fellows included establishing an employment opportunities website and offering a variety of "survival skill" workshops to enhance their scientific writing, oral presentation, and grantsmanship skills.
- Women's Health Research at NIH (ORWH's booth at the annual NIH Health Fair).

Altogether, the evaluation found substantial evidence that ORWH supported a broad range of information dissemination activities during its first ten years, developing and/or co-sponsoring over 120 scientific publications, policy documents, and educational programs to promote women's health research and career opportunities.

. . . . .

In summary, ORWH's strong emphasis on interdisciplinary collaboration was evident with respect to all of its major activities. In pursuing its goals, the Office worked closely with the ACRWH, CCRWH, IC representatives, senior staff in other government agencies, scientists and advocacy groups throughout the country as well as other interested parties. Given its limited staff and budget, ORWH's active participation in over 1,700 major activities is clearly a noteworthy accomplishment. However, the extent to which its goals were achieved as a result of these efforts was the primary focus of the evaluation. The remainder of the report presents the findings with respect to each of ORWH's intermediate and long-term goals.

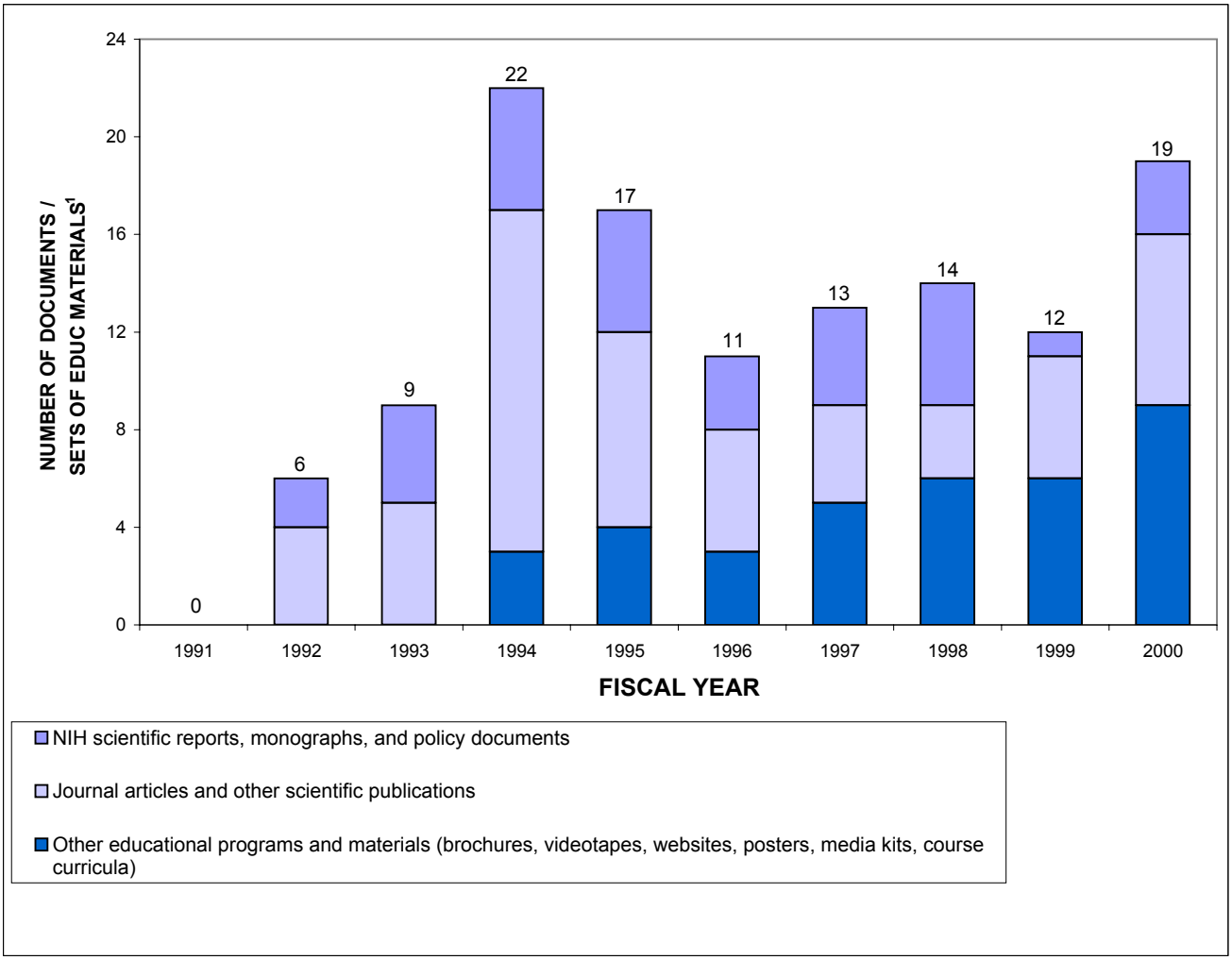
[11] Collaborating organizations included the Health Resources and Services Administration (HRSA), American Association of Medical Colleges (AAMC), American Association of Colleges of Osteopathic Medicine (AACOM), and American Association of Dental Schools (AADS).

Exhibit 12

EVALUATION OF ORWH'S FIRST TEN YEARS

SCIENTIFIC REPORTS, ARTICLES, AND EDUCATIONAL PROGRAMS PRODUCED OR CO-SPONSORED BY ORWH

FY 1991-2000



[1] Primary data source: Report of the Office of Research on Women's Health (ORWH biennial reports on activities conducted during FY 1991-2000).

Study Question 2: Achievement of Intermediate Goals

To what extent were the following intermediate goals achieved during its first ten years?

1. *More RFAs and program announcements to stimulate and expand research on women's health.*
2. *Increased NIH funding for women's health research.*
3. *More NIH grant applications involving women's health research.*
4. *More women receiving postdoctoral fellowships to pursue biomedical careers.*
5. *More women applying for NIH research grants.*

A variety of data sources and analyses were used to answer Study Question 2, which are described under each goal along with the study findings. In most cases, performance during FY 1999-2000 was compared to baseline performance during FY 1989-1990. Detailed information on the data methods and analyses is provided in Appendix C.

Intermediate Goal 1. More RFAs and Program Announcements to Stimulate and Expand Research on Women's Health

An increase in the number of NIH requests for applications (RFAs) and program announcements (PAs) that encouraged women's health research was regarded as an important measure of ORWH's success, demonstrating effective collaboration with the different ICs. The intermediate goal was operationally defined as follows:

> Increase in the number and percent of RFAs and PAs issued by ICs that encouraged research on women's health, comparing FY 1999-2000 with FY 1989-1990.

As previously mentioned for Activity 3, RFAs and PAs are official notices issued by one or more ICs that invite grant applications in a particular scientific area. New RFAs and PAs are published each week in the *NIH Guide for Grants and Contracts*, which is available on the NIH grants website. In preparation for the analysis, a content analysis was conducted of each RFA and PA published in FY 1989, 1990, 1999, and 2000 for the purpose of identifying initiatives that specifically encouraged women's health research, going beyond the standard language for NIH's policy on the inclusion of women and minorities in clinical research. Notices that met the following criteria were selected: (1) requesting proposals for research on a disease affecting primarily women (e.g., breast cancer); (2) requiring that the study population include females or emphasizing the importance of including females; or (3) stating a need for research on sex/gender differences in a particular area.

The evaluation found that the number of RFAs and PAs that invited grant applications to address women's health issues increased by 143%, from an average of 47 per year in FY 1989-1990 to 113 per year in FY 1999-2000 (see Exhibit 13). The percentage increase was much higher than the 20% overall increase in RFAs and PAs issued during the period. Of the RFAs and PAs of

this type that were issued in FY 1999-2000, 7% were co-sponsored by ORWH. Separate analyses of the number of RFAs and PAs encouraging women's health research revealed that the percentage increase was higher for PAs (204%) than for RFAs (119%). An additional analysis was conducted to determine the number of RFAs and PAs that specifically mentioned a need for research on sex/gender differences in a particular area (going beyond the standard NIH language). The results (presented in Exhibit 14) showed that an average of only 2 RFAs and 3 PAs per year specifically encouraged research on sex/gender differences in FY 1989-1990, but ten years later the number had jumped to an average of 18 RFAs and 23 PAs per year (an overall increase of 720%). As also shown in Exhibits 13 and 14, the percent of all RFAs and PAs encouraging women's health research increased from 16% in FY 1989-1990 to 33% in FY 1999-2000, an increase that was statistically significant ($p<.01$ applying a chi-square test). The percent of RFAs and PAs that specifically encouraged research on sex/gender differences was lower, but the increase (from 2% to 12% of all RFAs/PAs) was statistically significant ($p<.001$).

In summary, the findings were very positive and showed that RFAs and program announcements encouraging research on women's health increased significantly during ORWH's first ten years. The 143% increase in the number of RFAs and PAs that specifically addressed women's health was much higher than the 20% overall increase in RFAs and PAs during the period. With respect to both RFAs and PAs, there were major gains in the number and percent of initiatives mentioning issues relevant to women's health as well as the number that specifically encouraged research on sex/gender differences. The results indicate that ORWH was very successful in collaborating with the ICs and encouraging them to include women's health issues in the RFAs and PAs they issued inviting grant applications from the scientific community.

Exhibit 13

EVALUATION OF ORWH'S FIRST TEN YEARS

RFAs AND PROGRAM ANNOUNCEMENTS ENCOURAGING WOMEN'S HEALTH RESEARCH

FY 1989-1990 vs FY 1999-2000

Type of Notice[1]	Number of RFAs and PAs / Year Encouraging Women's Health Research[2]			% Change for All Initiatives of Each Type	Percent of all NIH RFAs and PAs Encouraging Women's Health Research		
	FY 1989-1990	FY 1999-2000	% Change		FY 1989-1990	FY 1999-2000	Change
All RFAs and PAs	93	226	143%**	20.1%	16.4%	33.2%	16.8%**
RFA	67	147	119.4%**	-1.6%	17.7%	39.4%	21.7%**
PA	26	79	203.8%**	63.8%	13.8%	25.6%	11.8%**

[1] Analyses were conducted for all NIH requests for applications (RFAs) and public announcements (PAs) published in the NIH Guide in FY 1989, 1990, 1999, and 2000. Data source: NIH Guide for Grants and Contracts.

[2] A content analysis was conducted of each RFA and PA for the purpose of identifying notices that encouraged women's health research (beyond simply stating NIH's policy regarding the inclusion of women and minorities in clinical research). Examples include mentioning a disease affecting primarily women (e.g., breast cancer), emphasizing the importance of including women in the study population, or stating a need for research on sex/gender differences in a particular area.

** $p<.01$ applying chi-square tests to determine if the increase in the proportion of RFAs or PAs encouraging women's health was significantly greater in FY 1999-2000 than it had been in FY 1989-1990.

Exhibit 14

EVALUATION OF ORWH'S FIRST TEN YEARS

RFAs AND PROGRAM ANNOUNCEMENTS ENCOURAGING RESEARCH ON SEX/GENDER DIFFERENCES

FY 1989-1990 vs FY 1999-2000

Type of Notice[1]	Number of RFAs and PAs / Year Encouraging Research on Sex/Gender Differences[2]			% Change for All Initiatives of Each Type	Percent of all RFAs and PAs Encouraging Research on Sex/Gender Differences[2]		
	FY 1989-1990	FY 1999-2000	% Change		FY 1989-1990	FY 1999-2000	Change
All RFAs and PAs	5	41	720.0%***	20.1%	1.8%	12.0%	16.9%***
RFA	2	18	800.0%***	-1.6%	1.1%	9.6%	21.7%***
PA	3	23	666.7%***	63.8%	3.2%	14.9%	12.1%***

[1] Analyses were conducted for all NIH requests for applications (RFAs) and public announcements (PAs) published in the NIH Guide in FY 1989, 1990, 1999, and 2000. Data source: NIH Guide for Grants and Contracts.

[2] A content analysis was conducted of each RFA and PA notice for the purpose of identifying notices that encouraged research on sex/gender differences (beyond simply stating NIH's policy regarding the inclusion of women and minorities in clinical research). The above findings show the number and percent of notices that specifically stated a need for research on sex/gender differences in a particular area.

*** p<.001 applying chi-square tests to determine if the increase in the proportion of RFAs or PAs encouraging research on sex/gender differences was significantly greater in FY 1999-2000 than it had been in FY 1989-1990.

Intermediate Goal 2. Increased NIH Funding for Women's Health Research

An increase in NIH funding for women's health research was viewed as a reasonable indicator of ORWH success. The intermediate goal was operationally defined as follows:

> Increase in the total dollars per year (adjusted for inflation) that NIH ICs reported as being allocated to research on diseases, disorders, or conditions that affect women, comparing FY 2000 with FY 1993.

As required by the NIH Revitalization Act of 1993, IC expenditures on research specific to women, men, and both women and men have been compiled since FY 1993 by each of the ICs for inclusion in the biennial "DHHS-NIH Research Budget for Women's and Men's Health." Although total NIH expenditures for research specific to women, to men, and to both women and men were also calculated during FY 1988-1992, the methodology used to define women's and men's health research and estimate funding was not consistent with the approach used throughout the FY 1993-2000 period. The analysis of this goal was therefore limited to the eight-year period from FY 1993 to FY 2000.

The evaluation team found that the process of estimating NIH expenditures on women's health research is especially difficult for a variety of reasons:

- There is no precise definition of what constitutes a women's or a men's health issue, and the methodology used to identify the amount of funding NIH has allocated each year to research benefiting women, men, or both has been revised twice since the figures were first reported for FY 1988. The most recent revision was in FY 1993, so comparisons between FY 1989-1990 and FY 1999-2000 expenditure data would not be valid.
- It is often impossible to predict who will benefit from particular research studies, especially those involving basic research (the largest area of NIH's research budget).
- Women's health research is typically interdisciplinary in nature, with studies involving several research topics (for example, research addressing diabetes in women may involve obesity and physical activity, nutrition, pregnancy and maternal health, behavioral change and risk-taking behavior, cultural and lifestyle factors, and disability research and services).
- The current methodology for determining budget allocations relevant to women's and men's health is based on two sets of guidelines: (1) general principles for budget allocation prepared by the DHHS Coordinating Committee on Women's Health; and (2) recommended procedures for budget allocation prepared by the NIH Coordinating Committee on Research on Women's Health (CCRWH).
- In order to exclude overlap and double-counting, the current methodology for determining budget allocations requires that each study (including a interdisciplinary study involving several research areas) be assigned to only one of 122 possible

research topics. As a result, the figures clearly underestimate NIH expenditures for many topics (particularly those typically involving interdisciplinary research) and they do not agree with NIH funding reports summarizing total NIH spending in different disease areas.

Despite these difficulties, the evaluation team concluded that it would be informative to summarize the amount of annual NIH funding that had been reported for women's health research from FY 1993 through FY 2000, a period during which the same general approach was used for estimating expenditures for health research benefiting women, men, or both. NIH's spending on women's health in FY 1993 and FY 2000 could then be compared, after making adjustments for inflation.

The primary source of data was the group of eight budget tables published on a biennial basis as the "DHHS-NIH Research Budget for Women's and Men's Health." The tables, compiled each year by IC budget officers working with their respective IC contacts for women's health, are included in the ORWH biennial reports. As a step toward establishing a uniform procedure for determining the amount of dollars for particular research studies that should be allocated to women's health, men's health, or both, ORWH has consistently requested that the ICs apply the following criteria (recommended by the CCRWH):

1. For research on diseases, disorders, or conditions that occur primarily in women (such as breast cancer and osteoporosis), the entire amount for programs in these areas should be entered under the column listed "women," including clinical, applied, and basic research.
2. For research on diseases, disorders, or conditions that occur primarily in men (such as prostate cancer), the entire amount for programs in these areas should be entered under the column listed "men," including clinical, applied, and basic research.
3. For research on diseases, disorders, or conditions that affect both women and men:
    - When it can be readily determined what amount may be allocated to women or to men, those amounts should be entered in the appropriate columns. Examples include clinical research studies where enrollment data or prevalence data give an accurate picture of the respective benefit of the study for women and men.
    - When the amount that may be allocated to men and women cannot be readily determined, the total amount may be entered in the column listed "both." Examples include many basic research studies, research that is exploring the role of sex and gender differences, and clinical research on diseases, disorders, and conditions that affect both women and men.

ORWH and its principal advisory committees (the ACRWH and CCRWH) have acknowledged that it is difficult to allocate NIH expenditures on women's health research and there are inconsistencies in the currently evolving method for collecting budget data. For all of these

reasons, the study's findings with respect to NIH expenditures on women's health should be interpreted with caution.

The evaluation found that total NIH research funding specific to women's health (adjusted to FY 2000 dollars using the NIH Biomedical Research and Development Price Index) increased from $1.7 billion in FY 1993 to $2.7 billion in FY 2000, an increase of 60% during the eight-year period (see Exhibit 15). In comparison, spending for research relevant to both women and men (nearly 80% of the NIH research budget) increased by 57% during this period, and spending on research relevant to men increased by 34%. The 60% increase in spending on research specific to women was slightly higher than the 57% increase for research relevant to both women and men and much higher than the 34% increase for men's health research. As a proportion of NIH's total research budget, the percentage spent on women's health grew from 14.3% in FY 1993 to over 16% in FY 1995-1998, dropping back to 14.7% in FY 2000.

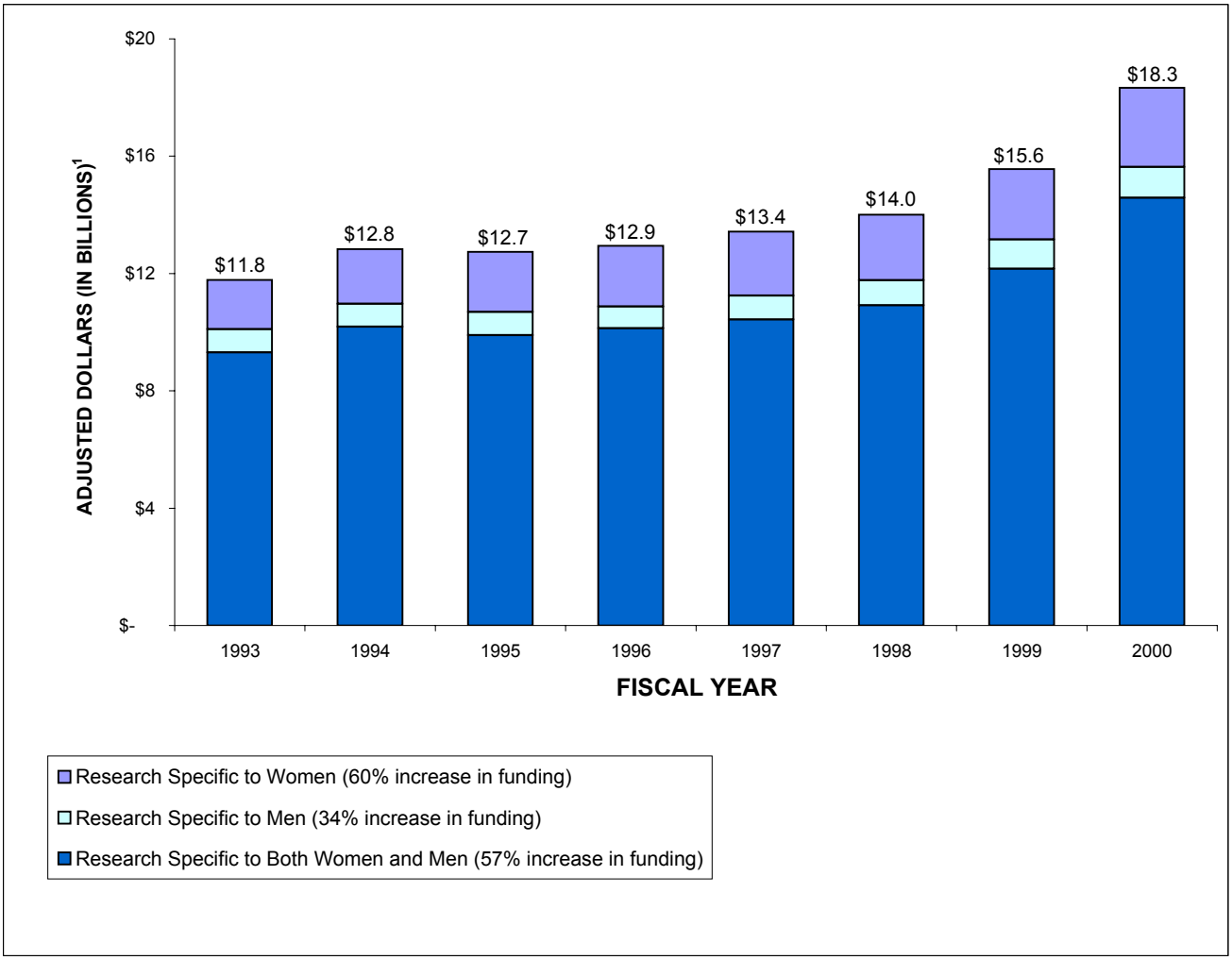
In summary, the findings indicate that the total dollars per year (adjusted for inflation) that NIH allocated to women's health research increased by 60% during the eight-year period, slightly greater than the overall increase in NIH research funding during the period. The results should be interpreted with caution, however, given the inherent difficulties in determining non-overlapping budget allocations for interdisciplinary research, which is the nature of most research on women's health.

Exhibit 15

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH FUNDING FOR HEALTH RESEARCH SPECIFIC TO WOMEN, MEN, AND BOTH WOMEN AND MEN

FY 1993-2000



[1] Dollars (in billions) were adjusted to FY 2000 dollars using the NIH Biomedical Research and Development Price Index (BRDPI). They reflect the total amount of funding NIH invested each year from FY 1993 to FY 2000 for research specific to the health of women, men, or both women and men. The budget figures are exclusive of overlap and will not agree with funding reported for total NIH spending on disease areas. Primary data source: DHHS-NIH Research Budget for Women's and Men's Health (FY 1993-2000).

Intermediate Goal 3: More NIH Grant Applications Involving Women's Health Research

An increase in the number of research project grant (RPG) applications involving women's health was viewed as an important indicator of ORWH's success in promoting research related to diseases, disorders, and conditions that affect women. It was expected that a rise in applications would precede a rise in grant awards. The intermediate goal was operationally defined as follows:

> Increase in the number and percent of competing RPG applications submitted to NIH with project titles involving women's health, comparing FY 1999-2000 with FY 1989-1990.

RPGs are awards to eligible institutions to support a principal investigator (PI) working on a specific research project or a group of investigators working on research projects that contribute to a broadly based interdisciplinary research program.[12] The analyses focused on RPGs because they are the most common type of investigator-initiated research grants awarded by NIH, representing approximately 80% of NIH extramural awards. RPGs are also prestigious awards that are selected using a highly regarded peer review process in which individual grant applications are evaluated by prominent scientists from around the country.

In addition to analyzing trends for all competing RPG grant applications (i.e., new and competing continuations), separate analyses were conducted for five types of RPGs (R01, R03, R15, P01, and U01 grants) which are defined as follows:

- R01 Grant to support a specific research project to be performed by the PI.
- R03 Small grant to support a short-term research project to be performed by the PI, generally used to provide flexibility for initiating larger studies.
- R15 Academic Research Enhancement Award (AREA) grant to support a small-scale research project to be performed by the PI, generally a faculty member at a baccalaureate degree-granting institution.
- P01 Research program project grant to support a broadly based, multicenter, and often long-term research program having a central research focus, usually involving a relatively large group of established investigators.
- U01 Cooperative agreement to support a specific research project to be performed by the PI as a joint venture with an IC.

The primary data source for the analysis of this goal was the NIH Consolidated Grant Applicant File (CGAF), a set of records on all individuals who have applied for grants and contracts from NIH and other PHS agencies since the grant system was first established in 1938. The database includes an individual record for each grant or contract application, including the name and

[12] As previously mentioned, RPGs include activity codes R01, R03, R15, R21, R29, R33, R37, R55, P01, P42, U01, and U19 (excluding NLM grants, FIC grants for FY 1989-1990, and NCRR grants for FY 1989).

institution of the principal investigator, fiscal year of application, project title, administering IC, and total dollars awarded (if any). In accordance with the Privacy Act of 1974, authorization to use the CGAF was obtained from NIH before analyses were conducted.

Because CGAF records do not include abstracts of the research proposed and because there was no other database that included abstracts for unfunded NIH grant applications, the project title was the only CGAF variable that could be used to assess whether more NIH grant applications to conduct women's health research were submitted in FY 1999-2000 than in FY 1989-1990. A methodology was therefore developed to identify grant applications involving women's health from their project titles alone. Although the resulting counts would underestimate the actual number of applications involving women's health, employing the same methodology for each time period would be expected to produce comparable results which could be used to assess the extent to which this intermediate goal had been achieved.

In preparation for the analysis, a list of 244 keywords relevant to women's health was developed, which included revisions suggested by ORWH staff and the evaluation advisory committee (the final list of keywords is presented in Appendix D). The keywords (text strings) were then used to query the project titles of all competing NIH RPG grant applications submitted in FY 1989, 1990, 1999, and 2000, for the purpose of identifying studies focusing on research particularly relevant to women's health. The keyword list included diseases/conditions that affect only women (such as endometriosis), diseases/conditions that affect women much more than men (such as lupus, eating disorders, and chronic fatigue syndrome), and sexually transmitted diseases that affect both men and women. Studies that focused primarily on infants or children or on congenital diseases were excluded, except for conditions directly related to maternal health (such as infant mortality and fetal alcohol syndrome). The data methods and analyses used for the CGAF queries are described in detail in Appendix C.

The evaluation found that the number of competing RPG applications with project titles containing at least one keyword relevant to women's health increased by 48%, from an average of 1,971 per year in FY 1989-1990 to 2,925 per year in FY 1999-2000 (see Exhibit 16). The percentage increase was nearly double the 25% increase in all competing RPG applications submitted during the period. With respect to specific types of RPG applications, very positive findings were found for R03 grants which are often awarded to new investigators (369% increase), P01 grants which require the PI to lead an interdisciplinary team of investigators (117% increase), and U01 cooperative agreements (141% increase), all of which increased significantly more than the R03s, P01s, and U01s that did *not* have titles relevant to women's health ($p<.001$). As shown in Exhibit 16, the percent of all RPG applications having project titles relevant to women's health increased from 8% in FY 1989-1990 to 10% in FY 1999-2000, an increase that was statistically significant ($p<.001$). The analyses of the different types of RPG grants revealed similar trends, although the increase was less for R01 applications (the most prestigious type of RPG which has the largest number of applicants).

In summary, the findings were generally positive and showed that RPG grant applications involving women's health research increased significantly during ORWH's first ten years. The 48% increase in the number of such applications was nearly twice the overall increase in RPG applications during the period. The greatest gains were found for R03 grants, P01 program project grants, and U01 cooperative agreements. Because the analysis was limited to project titles alone, the results underestimate the actual number of RPG applications in FY 1989-1990 and FY 1999-2000 that involved research on women's health. However, despite the limited analysis, the findings indicate that the number of RPG applications directly related to women's health increased substantially during ORWH's first ten years.

Exhibit 16

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG APPLICATIONS
WITH TITLES RELATED TO WOMEN'S HEALTH RESEARCH
FY 1989-1990 vs FY 1999-2000

Type of Grant Application[1]	Number of Applications / Year with Titles Including a Keyword[2]			% Change for All Applications of Each Type	Percent of All Grant Applications with Titles Including a Keyword[2]		
	FY 1989-1990	FY 1999-2000	% Change		FY 1989-1990	FY 1999-2000	Change
All RPGs	1,971	2,925	48.4%***	25.4%	8.3%	9.9%	1.6%***
R01	1,630	2,096	28.6%	24.9%	8.5%	8.8%	0.3%
R03	68	319	369.1%***	182.2%	9.6%	16.0%	6.4%***
R15[3]	68	56	-17.6%	-28.7%	9.5%	10.9%	1.4%
P01	18	39	116.7%**	19.0%	4.7%	8.5%	3.8%**
U01	34	82	141.2%***	38.3%	7.7%	13.4%	5.7%***

[1] Analyses were conducted for all research project grants (RPGs) and five types of RPG grants (R01, R03, R15, P01, and U01 grants). RPGs are defined as investigator-initiated research grants having activity codes R01, R03, R15, R21, R22, R29, R33, R35, R37, RC1, P01, P42, U01, U19, and UC1 (also P41 for NIGMS) and exclude NLM, FIC for FY 1989-1990, and NCRR for FY 1989. The above findings show the number and percent of competing applications (i.e., new and competing continuations) for each type of grant. Data source: NIH Consolidated Grant Applicant File (CGAF).

[2] A list of 244 keywords (text strings) relevant to women's health was used to query the project titles of competing grant applications submitted to NIH in FY 1989, 1990, 1999, and 2000, for the purpose of identifying projects focusing on research particularly relevant to women's health. The above findings show the number and percent of applications having project titles that included at least one of these keywords. The actual number of grant applications involving women's health research is higher than those that could be identified from their project titles alone, which should be taken into consideration when interpreting the above findings.

[3] Although there was a decrease in the number of R15 applications with project titles involving women's health, the decrease was less than the 28.7% decrease in all R15 applications submitted over this time period.

*** p<.001 ** p<.01 applying chi-square tests to determine if the increase in the proportion of grant applications of this type involving women's health was significantly greater in FY 1999-2000 than it had been in FY 1989-1990.

Intermediate Goal 4: More Women Receiving Postdoctoral Fellowships to Pursue Biomedical Careers

An increase in NIH postdoctoral fellowship awards to female principal investigators was viewed as an early indicator that more women were pursuing biomedical careers. The intermediate goal was operationally defined as follows:

> Increase in the number and percent of competing NIH postdoctoral fellowships (F32 grants) awarded to female principal investigators, comparing FY 1999-2000 with FY 1989-1990.

The data source was the Trainee and Fellow File (TFF), which contains detailed information about each trainee and fellow who has received training support from NIH and/or other PHS agencies since 1938, including the name of the trainee or fellow and the person's sex/gender (if available). TFF information on fellows is obtained primarily from the NIH IMPAC system (now called IMPAC II) and information on trainees is obtained primarily from the Trainee Appointment File (TAF). QRC began maintaining the TFF for NIH in 1989, and many of the data items have been edited to improve data quality. For example, the MFSEX variable (which indicates the sex/gender of the trainee or fellow) was given special attention by QRC several years ago at NIH's request.

Analyses were conducted for all competing F32 grant awards (i.e., new and competing continuations), which are defined as follows:

> F32 Individual National Research Service Award (NRSA) fellowship grant to provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

The sex/gender of the PI was available for 95.3% of the FY 1989-1990 awards and 95.0% of the FY 1999-2000 awards. The analyses were based on the assumption that the proportion of females in the relatively small group of PIs whose sex/gender was unknown was the same as the proportion of females in the group of PIs whose sex/gender was known.

The evaluation found that the number of competing F32 grants awarded to female PIs increased by 10%, from an average of 291 per year in FY 1989-1990 to 320 per year in FY 1999-2000 (as shown in the last row of Exhibit 22). The percentage increase was greater than the 3% *decrease* in competing F32 grants awarded to male PIs during the period, but the increase in the proportion of F32s awarded to women was not statistically significant. Perhaps more importantly, the percent of F32 grants awarded to women was relatively high (39%) in FY 1989-1990 and it increased to 42% in FY 1999-2000. To obtain more information, an additional analysis was conducted which focused on competing F32 *applications* submitted by female PIs. The results were positive; the number of F32 applications from women increased from an average of 893 per year in FY 1989-1990 to 924 per year in FY 1999-2000 (as shown in the last

row of Exhibit 17). Although the number of F32 applications submitted by female PIs increased by only 4% during the period, it was much greater than the 17% *decrease* in applications from male PIs, and the increase in the proportion of F32 applications from women was statistically significant ($p<.001$). The percent of all F32 applications from women increased from 39% to 45% over the ten-year period, closer to the 50% level than was found for F32 awards.

In summary, the findings were positive and showed that the number of postdoctoral F32 fellowship applications submitted by female PIs increased significantly during ORWH's first ten years. The 4% increase in the number of F32 applications from women was much greater than the 17% *decrease* in the number of applications from men. The number of F32 fellowships awarded to women increased by 10%, compared to a 3% decrease in the number of awards to men. With respect to both applications and awards, F32 fellowships had the highest proportion of female PIs of all the NIH grant mechanisms investigated in the ORWH evaluation (as graphically illustrated in Exhibits 19 and 24). Although at the end of ORWH's first ten years a majority of NIH postdoctoral fellows were male, the proportion of females was substantial (42%). Perhaps more importantly, the results indicate that by FY 1999-2000, a large number of female scientists were approaching the end of the academic pipeline and would soon be ready to begin their careers as independent research scientists.

Intermediate Goal 5: More Women Applying for NIH Research Grants

An increase in NIH grant applications submitted by female PIs was viewed as an important indicator that more women were pursuing biomedical careers. It was expected that a rise in applications would precede a rise in grant awards. The intermediate goal was operationally defined as follows:

> Increase in the number and percent of competing RPG applications submitted to NIH by female principal investigators, comparing FY 1999-2000 with FY 1989-1990.

The data source was the CGAF database, which contains detailed information about each NIH grant or contract application, including the name of the principal investigator and the PI's sex/gender (if available). A strength of the CGAF is the validity of its data, which has been continuously improved by QRC since 1989, the year QRC began maintaining the CGAF database for NIH. For example, the MFSEX variable (which indicates the sex/gender of the PI) was given special attention by QRC several years ago at NIH's request; the validity of the sex/gender data was improved (and continues to be improved) by basing the MFSEX variable on all records available for an individual, including relevant records in the Trainee and Fellow File (TFF), Doctorate Records File, and the Association of American Medical Colleges' Faculty Roster System. The methodology used to extract data from the CGAF was very similar to the approach used to extract data from the TFF for Intermediate Goal 4, except that the focus was on RPG applications rather than F32 applications.

Analyses were conducted for all competing RPG grant applications (i.e., new and competing continuations) and for five types of RPGs (R01, R03, R15, P01, and U01 grants). In response to a request by the evaluation advisory committee, additional analyses were conducted for three types of non-RPG applications (P30, P50, and T32 grants), which are defined as follows:

- P30 Center core grant to support shared resources and facilities for a group of investigators from different disciplines who are focusing on a common research problem.
- P50 Specialized center grant to support a group of investigators from different disciplines who are focusing on a specific biomedical area, usually developed in response to a program announcement issued by an IC to address a regional or national research need.
- T32 Institutional National Research Service Award (NRSA) grant to enable institutions to offer NRSA awards to individuals selected by them for predoctoral and postdoctoral training in a specific area.

The sex/gender of the PI was known for a large proportion of the applicants for each type of grant. With respect to RPGs, the PI's sex/gender was available for 99.2% of the FY 1989-1990 RPG applicants and 91.6% of the FY 1999-2000 RPG applicants. As before, the analyses were based on the assumption that the proportion of females in the relatively small group of PIs whose

sex/gender was unknown was the same as the proportion of females in the group of PIs whose sex/gender was known.

The evaluation found that the number of competing RPG applications submitted by female PIs increased by 56%, from an average of 4,700 per year in FY 1989-1990 to 7,337 per year in FY 1999-2000 (see Exhibit 17). The percentage increase was much greater than the 18% increase in applications from male PIs and it was more than double the 25% overall increase in NIH RPG applications submitted during the period. Very positive findings were found with respect to R01, R03, R15, and P01 grants (all of the primary RPGs except U01s) as well as for P30 and T32 grants ($p<.001$ in every case). There was a 60% increase in R01 grant applications from women and increases exceeded 250% for R03, P01, and P30 grants. Although there was a 9% decrease in the number of R15 applications from female PIs, the decrease was much less than the 37% decrease in R15 applications from male PIs. As shown in Exhibit 17, the percent of all RPG applications submitted by female PIs rose from 20% in FY 1989-1990 to 25% in FY 1999-2000, an increase that was statistically significant ($p<.001$). The analyses of the different types of RPG and non-RPG applications revealed similar trends, with R03 and R15 grants having the highest percent of female applicants in FY 1999-2000 (39% and 38%, respectively). Although the percent of women applying for program project grants (P awards) was lower, major gains had been made. Specifically, 15-18% of the P01 and P30 applicants were female in FY 1999-2000 compared to only 3-5% in FY 1989-1990. P50 grants had the lowest percent of female applicants in FY 1999-2000 (only 13%), slightly higher than the 12% rate ten years earlier. The F32 results included in Exhibit 17 were previously discussed with respect to Intermediate Goal 4.

In summary, the findings were very positive and showed that RPG applications submitted by female PIs increased significantly during ORWH's first ten years. The 56% increase in the number of RPG applications from women was much higher than the 18% increase in applications from men. The percent of female applicants increased for every type of grant analyzed, although there was considerable variance among the different types of grant mechanisms. However, despite the sizeable gains, only 25% of the RPG applications and 13-18% of the P30, P50, and T32 applications were submitted by female PIs in FY 1999-2000 (as graphically illustrated in Exhibits 18 and 19).

Exhibit 17

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH GRANT APPLICATIONS FROM FEMALE PRINCIPAL INVESTIGATORS

FY 1989-1990 vs FY 1999-2000

Type of Grant[1]	Number of Applications / Year from Female PIs[2]			% Change for Male PIs	Percent of All Grant Applications from Female PIs[2]		
	FY 1989-1990	FY 1999-2000	% Change		FY 1989-1990	FY 1999-2000	Change
All RPGs	4,700	7,337	56.1%***	17.8%	19.9%	24.8%	4.9%***
R01	3,545	5,665	59.8%***	16.9%	18.6%	23.8%	5.2%***
R03	207	781	277.3%***	142.8%	29.3%	39.1%	9.8%***
R15[3]	215	196	-8.8%***	-37.1%	30.0%	38.3%	8.3%***
P01	19	67	252.6%***	6.6%	4.9%	14.6%	9.7%***
U01	84	119	41.7%	37.5%	19.0%	19.5%	0.5%
P30	3	22	633.3%***	14.8%	3.3%	17.9%	14.6%***
P50	12	28	133.3%	112.9%	12.2%	13.4%	1.2%
T32	62	101	62.9%***	-10.6%	10.1%	16.9%	6.8%***
F32	893	924	3.5%***	-17.1%	39.2%	44.6%	5.4%***

[1] Analyses were conducted for all research project grants (RPGs), five types of RPGS (R01, R03, R15, P01, and U01 grants), and four types of non-RPGs (P30, P50, T32, and F32 grants). RPGs are defined as investigator-initiated research grants having activity codes R01, R03, R15, R21, R22, R29, R33, R35, R37, RC1, P01, P42, U01, U19, and UC1 (also P41 for NIGMS) and exclude NLM, FIC for FY 1989-1990, and NCRR for FY 1989. The above findings show the number of competing applications (i.e., new and competing continuations) for each type of grant. Data source: NIH Consolidated Grant Applicant File (CGAF).

[2] The sex/gender of the principal investigator (PI) was known for a large proportion of the applicants for each type of grant. The above figures are based on the assumption that the proportion of females in the relatively small group of PIs whose sex/gender was unknown is the same as the proportion of females in the group of PIs whose sex/gender was known.

[3] Although there was a decrease in the number of R15 applications from female PIs, the decrease was less than the 37.1% decrease in R15 applications from male PIs and the 28.7% decrease in all R15 applications submitted over this time period.

*** p<.001 applying chi-square tests to determine if the increase in the proportion of grant applications of this type submitted by female PIs was significantly greater in FY 1999-2000 than it had been in FY 1989-1990.

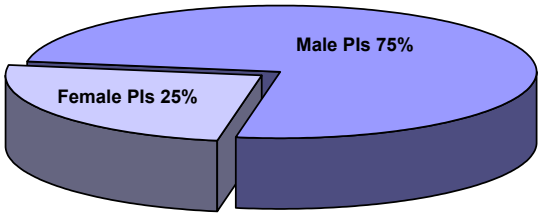
Exhibit 18

EVALUATION OF ORWH'S FIRST TEN YEARS

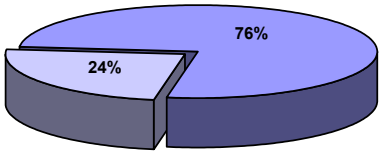
PERCENT OF NIH RPG GRANT APPLICATIONS FROM FEMALE INVESTIGATORS

FY 1999-2000

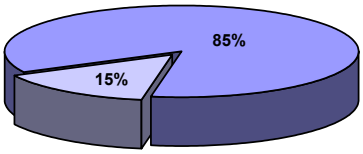
ALL RPG GRANT APPLICATIONS



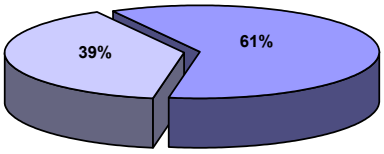
R01 GRANTS



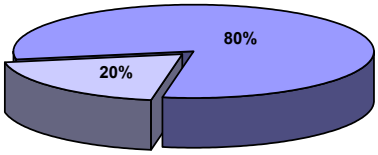
P01 PROGRAM PROJECT GRANTS



R03 SMALL GRANTS



U01 COOPERATIVE AGREEMENTS



R15 AREA GRANTS

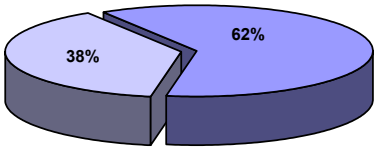


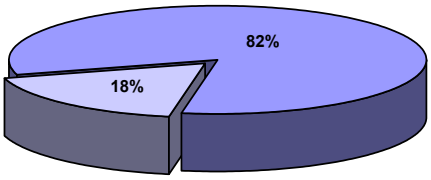
Exhibit 19

EVALUATION OF ORWH'S FIRST TEN YEARS

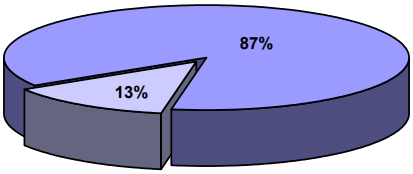
PERCENT OF NON-RPG GRANT APPLICATIONS FROM FEMALE INVESTIGATORS

FY 1999-2000

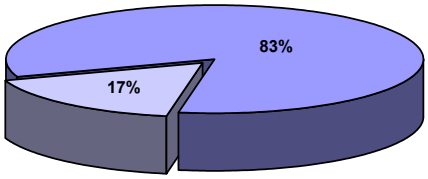
P30 CENTER CORE GRANTS



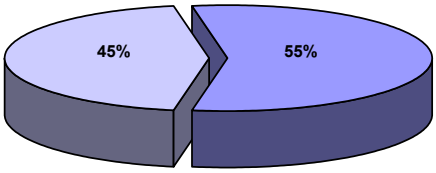
P50 SPECIALIZED CENTER GRANTS



T32 INSTITUTIONAL NRSA GRANTS



F32 POSTDOCTORAL FELLOWSHIPS



Study Question 3: Achievement of Long-Term Goals

To what extent were the following long-term goals achieved during ORWH's first ten years?

1. *More NIH research on women's health in high-priority areas.*
2. *More women successfully competing for NIH research grants.*
3. *High percentage of participants in ORWH career development programs becoming independent research scientists.*
4. *Increased institutional commitment to women's health research.*
5. *Stronger evidence that women and minorities are being appropriately included as subjects in NIH clinical research studies.*

A variety of data sources and analyses were used to answer Study Question 3, which are described under each goal along with the study findings. In most cases, performance during FY 1999-2000 was compared with baseline performance during FY 1989-1990.

Long-Term Goal 1: More NIH Research on Women's Health in High-Priority Areas

An increase in NIH-sponsored research studies relevant to women's health has always been ORWH's primary long-term goal, directly related to its mandate to promote research related to diseases, disorders, and conditions that affect women. The goal was operationally defined as follows:

> Increase in the number and percent of competing NIH RPG awards involving women's health research in the 37 highest priority areas identified in the 1991 research agenda on women's health, comparing FY 1999-2000 with FY 1989-1990.

The analysis was based on the 37 high-priority topics (shown in Exhibit 5) that were recommended most frequently by the 1991 Hunt Valley working groups and emphasized in the subsequent report, which served as the NIH research agenda on women's health for most of ORWH's first ten years.[13] Of the 37 topics, 14 were designated as being primarily female topics and 23 were designated as being relevant to males as well as females, based on the discussions of the Hunt Valley participants and recommendations of the evaluation advisory committee.

The primary data source for the analysis of this goal was the CRISP system, a searchable database containing information on all research projects and programs supported by NIH and other DHHS agencies from 1972 to the present, most of which have been funded through competitive extramural grants awarded to PIs working at universities, hospitals, and other

[13] The deliberations and findings of the Hunt Valley workshop participants were published by ORWH in a two-volume publication (*Report of the National Institutes of Health: Opportunities for Research on Women's Health*) which became known as the Hunt Valley Report.

research institutions. The CRISP database, maintained by the NIH Office of Extramural Research (OER), is a component of the NIH IMPAC system; it is directly searchable within the IMPAC system and is also accessible via an online search engine through the OER website. Authorization to access the CRISP component of the IMPAC system for use in the ORWH evaluation was obtained from NIH before analyses were conducted.

A major strength of the CRISP system is that each record contains an abstract of the research study (usually submitted by the PI in the grant application) and a list of diseases/conditions and scientific terms relevant to the study (selected from the CRISP thesaurus by indexers who have access to the full application and/or by a software routine). The CRISP thesaurus contains over 8,000 terms which are organized in a hierarchical structure and cross-referenced to help the indexers assign terms relevant to a particular study. In addition to the abstract and thesaurus terms, each CRISP record contains other key information about the grant, including the project title, name and institution of the principal investigator, fiscal year of award, grant number, administering IC, and project start and end dates. The CRISP system only includes research projects and programs that were funded, not unsuccessful grant applications.

In preparation for the analysis, algorithms (sets of rules) were developed to identify competing RPG awards relevant to each of the 37 high-priority topics. Each algorithm listed specific keywords (text strings) related to a particular topic as well as directions for ruling out irrelevant grant records and identifying records that should be reviewed on a case-by-case basis. The CRISP database was then queried (using a set of SAS programs that incorporated the algorithms) to identify competing RPG grants awarded in FY 1989, 1990, 1999, and 2000 that were relevant to each topic.[14] Specifically, the project titles, abstracts, and the thesaurus terms in the CRISP database were searched to identify studies that included one or more keywords relevant to the particular topic. The results for the group of 37 high-priority topics are presented in this section and the results for individual topics are presented under Research Question 4, which examined the fastest growing areas of women's health research. Although the methodology developed to query the CRISP database was not expected to identify *all* of the RPG grants involving research beneficial to women's health in each area, it is unlikely that a systematic bias was introduced using this approach because the same analysis was used for each time period. A detailed description of the data methods and analyses used for the CRISP queries is included in Appendix C and the algorithms are presented in Appendix E.

The evaluation found that for 29 of the 37 high-priority research topics, the number of RPGs involving the topic increased by more than the 56% overall increase in RPGs awarded during the ten-year period (see Exhibit 20). The average percentage increase for the 37 different topics was 160%, nearly three times as large as the 56% overall average for NIH. As expected, the highest percentage increases occurred in areas where there had been very few RPGs awarded in FY 1989-1990, which should be taken into account when interpreting these results.

[14] For program project and center grants involving subprojects, only the primary grant was identified.

Another factor to be considered was the overlap among the topics. Although the algorithms used in the CRISP queries were designed to use keywords that would minimize overlap, women's health research is typically interdisciplinary in nature and some overlap among the different topics was unavoidable. To address this issue, all of the RPG grants that had been selected for any of the 37 topics were merged and the duplicate records were eliminated. The results revealed that the number of unduplicated RPG awards increased by 70%, from an average of 1,002 per year in FY 1989-1990 to 1,701 per year in FY 1999-2000. A chi-square test revealed that the proportion of RPG awards involving any of the high-priority topics was significantly greater in FY 1999-2000 than it had been in FY 1989-1990 ($p<.05$).

In addition to the CRISP analyses, the CGAF database was queried (using a SAS program) to identify competing RPG awards (e.g., new and competing continuations) relevant to women's health from their titles alone. The methodology was identical to the approach used for Intermediate Goal 3, except that the focus was on RPG awards rather than applications. The results showed that the number of competing RPG awards with project titles containing at least one keyword relevant to women's health increased by 79%, from an average of 425 awards per year in FY 1989-1990 to 759 awards per year in FY 1999-2000 (see Exhibit 21). The percentage increase was substantially greater than the 56% overall increase in competing RPG grants awarded by NIH during the period. The findings were very similar to the trends for applications (examined for Intermediate Goal 5). Very positive findings were found with respect to R03 grants having titles relevant to women's health (400% increase) as well as P01 grants (260% increase) and U01 cooperative agreements (500% increase), all of which increased significantly more than the R03s, P01s, and U01s that did *not* have titles relevant to women's health ($p<.01$). The 260% increase in P01 awards involving women's health was especially positive since P01s are large program project grants that support broadly based, multicenter, and often long-term research programs. As also shown in Exhibit 21, the percent of all RPG awards having project titles relevant to women's health increased from 8% in FY 1989-1990 to 9% in FY 1999-2000, an increase that was statistically significant ($p<.01$) but not as large as was found for RPG *applications*. The analyses of the different types of RPG grants revealed similar trends, although the increase was less for R01 awards. As with Intermediate Goal 3, the results underestimate the actual number of RPG awards that involved women's health research because the analysis was limited to project titles alone.

In summary, the CRISP findings were positive and revealed that RPG awards involving the 37 high-priority areas of women's health increased significantly during ORWH's first ten years. The 70% increase in the number of such awards was substantially higher than the 56% overall increase in competing RPG awards. An additional analysis of project titles found that RPG awards relevant to women's health also increased significantly during the period (by 79%). Given the importance of this ORWH goal, the results were especially heartening.

Exhibit 20

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS FOR RESEARCH ON WOMEN'S HEALTH

FY 1989-1990 vs FY 1999-2000

Rank[1]	Research Topic	Major Research Area	Average Number of New RPG Awards/Year[2]			
			FY 1989-1990	FY 1999-2000	Difference	% Change
1	Cultural and Lifestyle Factors	Behavioral Research	168	348	180	107%***
2	Pregnancy and Maternal Health	Reproductive and Maternal Health	288	292	4	1%
3	Behavioral Change and Risk-Taking Behavior	Behavioral Research	17	65	48	282%***
4	Reproductive Cancers	Cancer	71	122	51	72%
5	Heart Disease	Cardiovascular and Pulmonary Conditions	46	103	57	124%**
6	Psychosocial Stress	Mental Health and Chronic Pain	56	93	37	66%
7	Breast Cancer	Cancer	87	290	203	233%***
8	Osteoporosis	Aging	29	67	38	131%*
9	Lung Cancer	Cancer	22	44	22	100%
10	Obesity and Physical Activity	Metabolism and Endocrinology	42	90	48	114%*
11	Depression and Mood Disorders	Mental Health and Chronic Pain	51	92	41	80%
12	Nutrition	Metabolism and Endocrinology	105	146	41	39%
13	Menopausal Hormone Therapy	Aging	2	33	31	1550%***
14	Colorectal Cancer	Cancer	18	48	30	167%**
15	Diabetes	Metabolism and Endocrinology	31	55	24	77%
16	Adolescent Health	Child and Adolescent Health	62	140	78	126%***
17	Disability Research and Services	Crosscutting Categories	34	54	20	59%
18	Contraception	Reproductive and Maternal Health	22	28	6	27%
19	Tobacco Use	Substance Abuse	33	63	30	91%
20	Illegal Drug Use/Abuse	Substance Abuse	70	96	26	37%
21	Menopause	Aging	7	32	25	357%***
22	Alcohol Use/Abuse	Substance Abuse	72	84	12	17%
23	Stroke and Hypertension	Cardiovascular and Pulmonary Conditions	39	68	29	74%
24	Lupus Erythematosus	Infectious Diseases and Immune Disorders	21	39	18	86%
25	Violence	Behavioral Research	10	38	28	280%***
26	Child Health	Child and Adolescent Health	368	419	51	14%
27	Rheumatoid Arthritis	Infectious Diseases and Immune Disorders	21	44	23	110%
28	Female Reproductive Physiology	Reproductive and Maternal Health	64	64	0	0%
29	Infertility	Reproductive and Maternal Health	43	41	-2	-5%
30	HIV/AIDS	Infectious Diseases and Immune Disorders	53	139	86	162%***
31	Sexually Transmitted Diseases	Infectious Diseases and Immune Disorders	49	104	55	112%*
32	Access to Health Care and Financing	Crosscutting Categories	28	67	39	139%**
33	Alzheimer's Disease	Aging	10	26	16	160%
34	Chronic Pain Conditions	Mental Health and Chronic Pain	2	16	14	700%**
35	Endometriosis and Fibroids	Reproductive and Maternal Health	5	5	0	0%
36	Incontinence	Aging	6	15	9	150%
37	Women as Caregivers	Behavioral Research	8	15	7	88%
		Total number of unduplicated RPG awards/year[3]	**1,002**	**1,701**	**699**	**70%***
		Average % change in all NIH RPG awards				**56%**

[1] Research topics are rank-ordered based on the number of different working groups at the 1991 Hunt Valley workshop recommending that NIH promote women's health research on this topic. Topics with the same number of group recommendations were ranked within their group based on the extent to which the topic was emphasized in the conference report, Report of the National Institutes of Health: Opportunities for Research on Women's Health.

[2] RPG counts for each topic were calculated by querying the CRISP database (project titles, research abstracts, and thesaurus terms) using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Although the algorithms were designed to minimize the overlap between specific topics, grants involving research in several areas could be selected for more than one topic.

[3] Total number of unduplicated RPG awards/year involving any of the high-priority topics, eliminating overlap.

*** p<.001 ** p<.01 * p<.05 applying chi-square tests to determine if the increase in the proportion of RPG awards involving this topic was significantly greater in FY 1999-2000 than it had been in FY 1989-1990.

Exhibit 21

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS
WITH TITLES RELATED TO WOMEN'S HEALTH RESEARCH
FY 1989-1990 vs FY 1999-2000

Type of Grant[1]	Number of New Grants / Year with Titles Including a Keyword[2]			% Change for All Awards of Each Type	Percent of All New Grant Awards with Titles Including a Keyword[2]		
	FY 1989-1990	FY 1999-2000	% Change		FY 1989-1990	FY 1999-2000	Change
All RPGs	425	759	78.6%**	56.2%	7.6%	8.7%	1.1%**
R01	334	538	61.1%	59.4%	7.8%	7.9%	0.1%
R03	18	90	400%**	214.6%	9.7%	15.5%	5.8%**
R15	8	16	100.0%	43.9%	7.0%	9.6%	2.6%
P01	5	18	260%**	41.1%	3.2%	8.1%	4.9%**
U01	5	30	500%**	149.6%	4.5%	10.7%	6.2%**

[1] Analyses were conducted for all research project grants (RPGs), five types of RPG grants (R01, R03, R15, P01, and U01 grants), and three types of non-RPGs (P30, P50, and T32 grants). RPGs are defined as investigator-initiated research grants having activity codes R01, R03, R15, R21, R22, R29, R33, R35, R37, RC1, P01, P42, U01, U19, and UC1 (also P41 for NIGMS) and exclude NLM, FIC for FY 1989-1990, and NCRR for FY 1989. The above findings show the number and percent of competing awards (i.e., new and competing continuations) for each type of grant. Data source: NIH Consolidated Grant Applicant File (CGAF).

[2] A list of 244 keywords (text strings) relevant to women's health was used to query the project titles of competing grant awards submitted to NIH in FY 1989, 1990, 1999, and 2000, for the purpose of identifying projects focusing on research particularly relevant to women's health. The above findings show the number and percent of awards having project titles that included at least one of these keywords. The actual number of grant awards involving women's health research is higher than those that could be identified from their project titles alone, which should be taken into consideration when interpreting the above findings.

** $p<.01$ applying chi-square tests to determine if the increase in the proportion of grant awards of this type involving women's health was significantly greater in FY 1999-2000 than it had been in FY 1989-1990.

Long-Term Goal 2: More Women Successfully Competing for NIH Research Grants

An increase in NIH grants awarded to female PIs was regarded as an important outcome for ORWH, indicating that more women were successfully pursuing biomedical careers. The long-term goal was operationally defined as follows:

> Increase in the number and percent of competing NIH research project grants awarded to female principal investigators, comparing FY 1999-2000 with FY 1989-1990.

The data source was the CGAF database and the methodology for extracting data was identical to the approach used for Intermediate Goal 5, except that the focus was on RPG awards rather than applications.

Analyses were conducted for all competing RPGs (i.e., new and competing continuations), for five types of RPGs (R01, R03, R15, P01, and U01 grants), and for three types of non-RPGs (P30, P50, and T32 grants). The sex/gender of the PI was known for a large proportion of the awards for each type of grant. With respect to research project grants, the PI's sex/gender was available for 99.6% of the FY 1989-1990 RPG awards and 93.7% of the FY 1999-2000 RPG awards. As before, the analyses were based on the assumption that the proportion of females in the relatively small group of PIs whose sex/gender was unknown was the same as the proportion of females in the group of PIs whose sex/gender was known. Average award rates for female PIs were also calculated for each type of grant by dividing the average number of competing grants awarded during a fiscal year by the average number of competing applications submitted that year. The results using this approach will not exactly match the official NIH "success rate" figures produced by the NIH Office of Reports and Analysis.

The evaluation found that the number of competing RPGs awarded to female PIs increased by 84%, from an average of 1,110 per year in FY 1989-1990 to 2,046 per year in FY 1999-2000 (see Exhibit 22). The percentage increase was considerably higher than the 49% increase in awards to male PIs and more than the 56% overall increase in RPGs awarded by NIH during the period. The results were similar to those found for RPG applications (Intermediate Goal 5) and even more encouraging; for all five types of RPGs as well as for RPGs as a group, the percent of RPG *awards* to female PIs increased by more than the percent of RPG *applications* submitted by female PIs. Very positive findings were found with respect to R01, R03, R15, P01, P30, and T32 grants ($p<.01$ in every case). Interestingly, although there was a 9% decrease in the number of R15 applications from female PIs during the ten-year period, the number of R15 awards to women increased by 116% (compared to a 16% increase in R15 awards to men). As shown in Exhibit 22, the percent of all RPG awards having a female PI increased from 20% in FY 1989-1990 to 23% in FY 1999-2000, an increase that was statistically significant ($p<.001$) even though it did not reach the 25% level found for RPG applications. The analyses of the different types of RPG and non-RPG applications revealed similar trends, with R03 and R15 grants having the highest percent of female awardees in FY 1999-2000 (39% and 42%, respectively). As was the case for applications, although a lower percent of women received program project grants (P

awards), major gains had been made. Specifically, 15-17% of the P01 and P30 awardees were female in FY 1999-2000, compared to only 4% in FY 1989-1990. P50 grants had the lowest percent of female awardees in FY 1999-2000 (only 13%), but it was higher than the 10% rate ten years earlier.

During the 1990s, the award rates for most types of grants increased as a result of NIH's expanding research budget. The most noteworthy findings for female PIs involved three types of grants: U01, R15, and P01 grants. In each case, female applicants became much more successful during the decade, achieving award rates higher than male applicants in FY 1999-2000. The award rates for females rose from 23% to 50% for U01 cooperative agreements, from 15% to 35% for R15 grants, and from 32% to 49% for P01 grants. The evaluation results were not all positive, however (as shown in Exhibit 22) and the award rates for female PIs applying for P30 and P50 grants declined during the period. With respect to P50s, however, the 6 percentage point decrease in the award rate for female PIs (from 42% to 36%) was less than the 15 percentage point decrease for male PIs.

In summary, the findings were mostly positive and showed that the number of competing RPGs awarded to female PIs increased significantly during ORWH's first ten years. The 84% increase in the number of RPG awards to women was considerably higher than the 49% increase in awards to men. The percent of awards to female PIs increased for every type of grant analyzed and female applicants had approximately the same probability of success as male applicants in FY 1999-2000, indicating there was no systemic bias against female applicants. However, despite all of these gains, only 23% of the competing RPG grants and 13-17% of the competing P30, P50, and T32 grants were awarded to female PIs in FY 1999-2000 (as graphically illustrated in Exhibits 23 and 24). These results and the findings for Intermediate Goal 5 underscore the importance of increasing the number of female investigators who *apply* for NIH grants.

Exhibit 22

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH GRANT AWARDS TO FEMALE PRINCIPAL INVESTIGATORS

FY 1989-1990 vs FY 1999-2000

Type of Grant[1]	Number of New Grants / Year Awarded to Female PIs[2]			% Change for Male PIs	Percent of All New Grants Awarded to Female PIs[2]			Average Award Rate for Female PIs[3]			Award Rate for Male PIs in FY 1999-2000
	FY 1989-1990	FY 1999-2000	% Change		FY 1989-1990	FY 1999-2000	Change	FY 1989-1990	FY 1999-2000	Change	
All RPGs	1,110	2,046	84.3%***	49.3%	19.8%	23.4%	3.6%***	23.6%	27.9%	4.3%	30.1%
R01	809	1,526	88.6%***	52.5%	18.9%	22.4%	3.5%***	22.8%	26.9%	4.1%	29.2%
R03	54	226	318.5%***	173.1%	29.2%	38.9%	9.7%***	26.1%	28.9%	2.8%	29.2%
R15	32	69	115.6%**	15.7%	27.8%	41.6%	13.8%**	14.9%	35.2%	20.3%	30.4%
P01	6	33	450%***	25.0%	3.8%	14.8%	11%***	31.6%	49.3%	17.7%	48.7%
U01	19	59	210.5%	138.5%	17.0%	21.1%	4.1%	22.6%	49.6%	27.0%	45.0%
P30	2	13	550%**	42.2%	4.3%	16.9%	12.6%**	66.7%	59.1%	-7.6%	63.4%
P50	5	10	100.0%	52.3%	10.2%	12.8%	2.6%	41.7%	35.7%	-6.0%	37.0%
T32	35	66	88.6%***	1.0%	10.1%	17.4%	7.3%***	56.5%	65.3%	8.8%	63.4%
F32	291	320	10.0%	-2.5%	39.3%	42.3%	3.0%	32.6%	34.6%	2.0%	38.0%

[1] Analyses were conducted for all research project grants (RPGs), five types of RPGS (R01, R03, R15, P01, and U01 grants), and four types of non-RPGs (P30, P50, T32, and F32 grants). RPGs are defined as investigator-initiated research grants having activity codes R01, R03, R15, R21, R22, R29, R33, R35, R37, RC1, P01, P42, U01, U19, and UC1 (also P41 for NIGMS) and exclude NLM, FIC for FY 1989-1990, and NCRR for FY 1989. The above findings show the number of competing awards (i.e., new and competing continuations) for each type of grant. Data source: NIH Consolidated Grant Applicant File (CGAF).

[2] The sex/gender of the principal investigator (PI) was known for a large proportion of the applicants for each type of grant. The above figures are based on the assumption that the proporation of females in the relatively small group of PIs whose sex/gender was unknown is the same as the proportion of females in the group of PIs whose sex/gender was known.

[3] Average Award Rate was calculated by dividing the average number of competing grants awarded during a fiscal year by the average number of competing applications submitted that year. The results using this approach will not exactly match the official NIH "success rate" figures produced by the NIH Office of Reports and Analysis.

*** p<.001 ** p<.01 applying chi-square tests to determine if the increase in the proportion of grants of this type awarded to female PIs was significantly greater in FY 1999-2000 than it had been in FY 1989-1990.

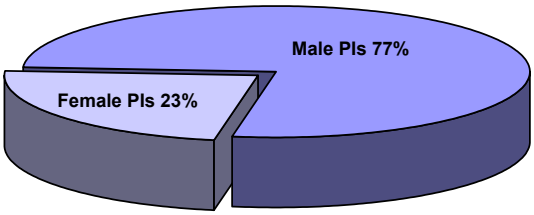
Exhibit 23

EVALUATION OF ORWH'S FIRST TEN YEARS

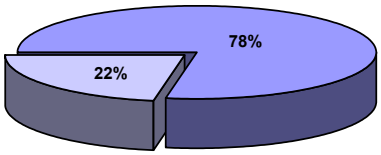
PERCENT OF NIH RPG GRANT AWARDS TO FEMALE INVESTIGATORS

FY 1999-2000

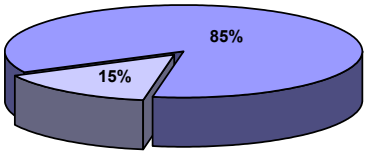
ALL RPG GRANT AWARDS



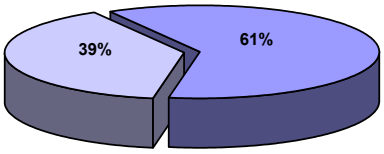
R01 GRANTS



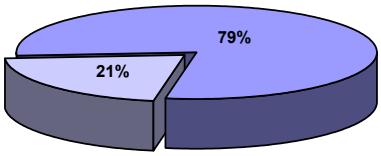
P01 PROGRAM PROJECT GRANTS



R03 SMALL GRANTS



U01 COOPERATIVE AGREEMENTS



R15 AREA GRANTS

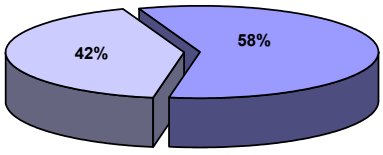


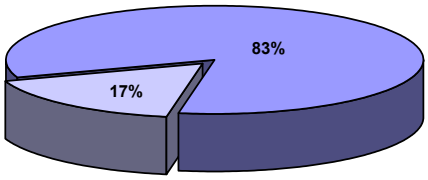
Exhibit 24

EVALUATION OF ORWH'S FIRST TEN YEARS

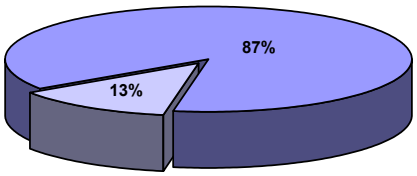
PERCENT OF NON-RPG GRANT AWARDS TO FEMALE INVESTIGATORS

FY 1999-2000

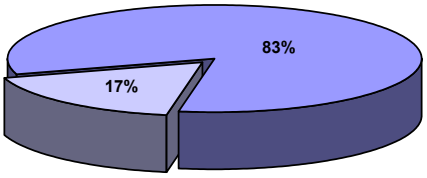
P30 CENTER CORE GRANTS



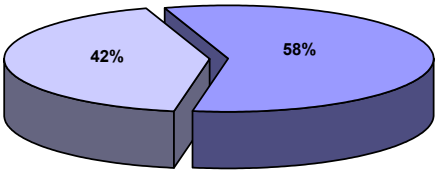
P50 SPECIALIZED CENTER GRANTS



T32 INSTITUTIONAL NRSA GRANTS



F32 POSTDOCTORAL FELLOWSHIPS



Long-Term Goal 3: Participants in ORWH Career Development Programs Becoming Independent Research Scientists

Given ORWH's emphasis on career development programs, an important long-term goal was having a high percentage of the participants in these programs achieve success in becoming independent research scientists. The goal was operationally defined as follows:

> At least 50% of the individuals who participated in the ORWH Reentry Program during FY 1992-1994 will secure a permanent research position and at least 25% will obtain external research funding by FY 2001.

As previously mentioned for Activity 4, a total of 26 individuals (24 women and 2 men) participated in the extramural ORWH Reentry Program during FY 1992-1994, which was designed to assist fully trained scientists in reestablishing their careers after taking time off for family responsibilities. Two participants had M.D. degrees, one had a Sc.D. degree, and the other 23 had Ph.D. degrees. The participants had been away from their careers for an average of 4.4 years, primarily to care for children or aging parents. The evaluation team was able to track down the current status of 23 of the 26 individuals (88%).

The primary data sources were the CGAF database, IMPAC system, ORWH program records, the National Library of Medicine's PubMed database, and websites of academic institutions. No contacts were made with individual participants. The initial step was to conduct CGAF queries to determine how many of the 26 Reentry Program participants had subsequently applied for an NIH grant and how many of them had been successful in receiving a grant award by FY 2001 (the most recent year that CGAF records were available). The IMPAC system was also queried to determine if any of the participants had served on an NIH committee (such as a special emphasis panel or scientific review group). Searches were performed on the PubMed database to identify each participant's peer-reviewed publications (if any) and his/her current institution. A variety of website searches were also conducted to obtain additional information on each participant, including his/her current position and any professional awards or honors received.

The evaluation found that of the 26 participants, 23 of them (88%) had published in peer-reviewed journals since FY 1994, 14 (54%) had applied for an NIH grant, and 5 (19%) had received an NIH grant award by FY 2001. At least two more had obtained research funding from other government agencies and/or foundations and, based on their research accomplishments, it is likely that several more had obtained non-NIH grants. A total of 7 participants (27%) were known to have received external research funding by FY 2001.

The 14 participants who applied for an NIH grant submitted a total of 20 grant applications, the largest number being R01s:

Type of Grant	Number of Applications
R01	8
R03	2
R25	1
R29	3
R43	3
K01	1
K08	1
F33	1

Of these 20 NIH grant applications, 7 were funded:

Type of Grant	Number of Awards
R01	1
R03	1
R29	1
R43	2
K01	1
K08	1

The findings indicate that the returning research scientists had much more success competing for relatively small RPGs, career development grants, and Small Business Innovation Research (SBIR) R43 grants than they did competing for a more prestigious R01 grant. Of the R01 applicants, two of the three who applied the earliest (all in FY 1996) were apparently discouraged and did not submit another NIH grant application of any type; however, the third applicant submitted another R01 application two years later to the same IC and this time was successful in being funded. Three of the other four R01 applicants waited until they had obtained other grants before applying for their first R01 in FY 2000-2001; the likelihood of these individuals receiving an R01 grant in the near future is therefore higher.

With respect to securing a permanent research position, the evaluation found that by FY 2001, at least 19 of the 26 participants (73%) were working as research scientists in positions that were assumed to be tenured or tenure-track positions, one individual was working as an adjunct assistant professor (assumed not to be tenure-track), and one person founded and co-chaired a

national cancer foundation which serves as a strong advocacy group for research on DES, a women's health issue. These 21 individuals were working in the following types of institutions:

Type of Institution	Number of Individuals
Medical school	8
Other health sciences center	4
University	3
Government or non-profit public health organization	3
Private industry	3

A surprisingly high proportion of the 26 Reentry Program participants (46%) were working as research scientists in medical schools or other types of health sciences centers. Several of these researchers also had an academic appointment at a university affiliated with the medical institution (the joint appointments are not shown in the above chart). Of those working in an academic setting whose current position could be determined, two were full professors, two were associate professors/research scientists, and nine were assistant professors/research scientists. Only one individual had served on an NIH committee (a special emphasis panel), although others had served on scientific advisory committees of other organizations. A clear majority of the participants were conducting basic research, primarily in areas not directly related to women's health. As previously mentioned for Activity 4, the BIRCWH and Transitional Career Development programs that ORWH developed in FY 1999-2000 were quite different from the early Reentry Program in that they placed a strong emphasis on women's health research while also promoting the advancement of women in biomedical careers.

In summary, a high percentage of the participants in the initial ORWH Reentry Program were successful in becoming independent research scientists. Of the 26 individuals who participated in the program during FY 1992-1994, 88% had published in peer-reviewed journals after finishing the program, 73% had secured a permanent research position, 54% had applied for an NIH grant, 19% had received an NIH grant, and 27% had obtained some type of external research funding by FY 2001. The percentages were higher than the performance targets set by ORWH, although the 27% success rate in obtaining external research funding was disappointing. The results illustrate how challenging it can be to obtain such funding (particularly an NIH grant), even for fully trained biomedical scientists intent on reestablishing their research careers. Perhaps future career development programs of this type should place more emphasis on grant writing skills and strategies for securing external support, especially for participants who have never previously had a grant. Overall, the findings were positive and showed that ORWH achieved its basic objectives for its first career development program.

Long-Term Goal 4: Increased Institutional Commitment to Women's Health Research

An increase in the number of NIH-supported institutions establishing major research and training centers to conduct women's health research was viewed as an important indicator of increased institutional commitment to pursuing research in this area. The long-term goal was operationally defined as follows:

> Increase in the number of universities, hospitals, and other research institutions receiving major competing NIH research program, center, and/or training awards (P01, P50, and/or T32 grants) having project titles relevant to women's health, comparing FY 1999-2000 with FY 1989-1990.

The data source was the CGAF database and the methodology for extracting data was similar to the approach used for Intermediate Goal 3 and Long-Term Goal 1, except that the focus was on P01, P50, and T32 applications and awards, and the 8-digit IPF code identifying the grantee institution was used in the analysis. The CGAF was queried (using a SAS program) to identify competing grant applications and awards (e.g., new and competing continuations) having project titles that included one or more of the 244 female-oriented keywords. The final counts did not include all of the major NIH institutional grants involving women's health, in part because the selections were based on project titles alone and also because the analysis purposely excluded grant mechanisms that were added after FY 1990 (such as U54 grants). The results are informative, however, because the same analysis was used for each time period.

The evaluation found that there was a substantial increase in the number of different research institutions receiving major NIH research center and/or training grants involving women's health (see Exhibit 25). The number of universities, hospitals, and other institutions that received P01, P30, and T32 grants focused on women's health research increased by 87%, from an average of 15 per year in FY 1989-1990 to 28 per year in FY 1999-2000. The findings for P01 and P50 grants were especially positive, with the number of institutions receiving these major interdisciplinary program grants to conduct women's health research increasing by over 150% in each case. An analysis of the number of institutions *applying* for major NIH research center and/or training grants revealed that the biggest change over the ten-year period involved P50 grants; the number of institutions applying for P50 grants involving women's health increased by more than 350%. With respect to both applications and awards, the number of institutions using the T32 grant mechanism to conduct women's health research showed the least change. The evaluation also found that in both periods (FY 1989-1990 and FY 1999-2000), a relatively high proportion of these large institutional grants had female PIs. For example in FY 1999-2000, 33% of the PIs of the P01 grants involving women's health were female, compared to 15% of the PIs of all P01 grants awarded during this period (see Exhibits 22 and 25). This finding was not surprising since female scientists are likely to be interested in research on women's health, and it illustrates the interrelationship between two of ORWH's major goals: promoting women's health research and supporting career development for women scientists.

In summary, the findings were positive and showed that during ORWH's first ten years, the number of NIH-supported institutions with major research and training centers involving women's health increased by 87%, from an average of 15 per year in FY 1989-1990 to 28 per year in FY 1999-2000. The evaluation also found that a relatively high proportion of these large institutional grants had female PIs. The results provide strong evidence of an increased commitment to women's health research on the part of many academic institutions, an important long-term goal for ORWH.

Exhibit 25

EVALUATION OF ORWH'S FIRST TEN YEARS

INSTITUTIONS APPLYING FOR AND RECEIVING MAJOR NIH RESEARCH AND TRAINING CENTER GRANTS INVOLVING WOMEN'S HEALTH

FY 1989-1990 vs FY 1999-2000

Type of Grant[1]	Number of Institutions / Year Applying for a Major Grant Involving Women's Health Research[2]			Number of Institutions / Year Receiving a Major Grant Involving Women's Health Research[2]			Percent of Major Grants Involving Women's Health Research Awarded to Female PIs[2]		
	FY 1989-1990	FY 1999-2000	% Change[3]	FY 1989-1990	FY 1999-2000	% Change[3]	FY 1989-1990	FY 1999-2000	% Change[3]
All P01, P50, and T32 Grants	33	48	45.5%	15	28	86.7%	16.8%	26.2%	9.4%
P01	17	31	82.4%	5	16	220.0%	14.3%	32.9%	18.6%
P50	3	14	366.7%	2	5	150.0%	50.0%	22.5%	-27.5%
T32	16	16	0.0%	10	11	10.0%	6.3%	18.3%	12.0%

[1] Analyses were conducted for three major NIH research program, center, and training grants: P01, P50, and T32 grants. Data source: NIH Consolidated Grant Applicant File (CGAF).

[2] Average number of universities, hospitals, and other research institutions per year that applied for and received a competing P01, P50, and/or T32 grant involving women's health research. A list of 244 keywords (text strings) relevant to women's health was used to query the project titles of competing applications and awards (i.e., new and competing continuations) for the purpose of identifying projects focusing on research particularly relevant to women's health. The above findings show the number of different institutions with applications and awards having project titles that included at least one of these keywords. The actual number of institutions with major NIH research program, center, and/or training grants involving women's health research is higher because the analysis focused only on project titles, which should be taken into consideration when interpreting the above findings.

[3] Because the analyses of this goal focused on research institutions rather than grants, chi-square tests were not used to test for significance.

Long-Term Goal 5: Stronger Evidence that Women and Minorities are Being Appropriately Included as Subjects in NIH Clinical Research Studies

A major long-term goal for ORWH was the implementation of a more comprehensive NIH policy on the inclusion of women and minorities as subjects in biomedical and behavioral research studies supported by NIH. Three types of evidence were examined with respect to this broad goal, which was operationally defined as follows:

> Overall improvement in NIH's efforts to include women in research as determined by independent assessments conducted by the U.S. Government Accounting Office, comparing the 2000 GAO report with the 1990 GAO report.
>
> Decrease in the percent of NIH extramural grant applications involving human subjects that were found to be noncompliant with respect to the NIH inclusion policy, comparing FY 2000 with FY 1995 (the first year NIH scientific review groups were instructed to consider applicants' planned study populations and level of compliance with the inclusion policy when assessing the scientific merit of grant proposals).
>
> Increase in the number and percent of NIH research grants examining sex/gender differences and racial/ethnic differences in disease etiology and treatment, comparing FY 1999-2000 with FY 1989-1990.

A variety of data sources were used to analyze the extent to which this goal was achieved, including the GAO reports issued in 1990 and 2000, ORWH biennial reports, biennial tracking reports published by the NIH Tracking and Inclusion Committee, and the CRISP system.

The document review revealed that the NIH Revitalization Act of 1993 proved to be a major factor in strengthening NIH's inclusion policy. NIH's response to this congressional mandate was broad-ranging:

- Rapid publication of stronger and broader guidelines for the inclusion of women and minorities in clinical research.
- Revision of the NIH grant application form.
- Creation of a standardized format for investigators to use in reporting study population data by sex/gender and by racial/ethnic group.
- Extensive training to communicate the new inclusion policy to NIH staff, scientific review groups, and the scientific community.
- Implementation of a centralized database system for tracking the enrollment of women and minorities in NIH-supported clinical studies.
- Development of biennial tracking reports showing aggregate enrollment data.
- Establishment of a new process requiring the advisory council of each IC to review and approve the IC's internal procedures for implementing the NIH inclusion policy.

By FY 1999, all of the NIH advisory councils had reported that their ICs were in full compliance with the revised inclusion guidelines.

ORWH played a central role in all of these activities (as described under Activity 5), working closely with a broad range of NIH administrators and representatives of the scientific community throughout the decade. The Office's primary aim was to ensure that the 1994 NIH inclusion policy was clearly understood by NIH administrators, grant reviewers, researchers, and IRB members and that it was implemented as quickly as possible. Another aim was to develop effective strategies for improving the recruitment and retention of women and minorities to clinical research, particularly strategies that addressed the various barriers that existed such as the widespread distrust of experimental trials in many minority communities and the research community's concerns about cost and liability issues. As mentioned earlier, ORWH established task forces (including the NIH Tracking and Inclusion Committee), sponsored workshops and studies, and conducted numerous educational and outreach activities to expand the participation of women and minorities in clinical research studies supported by NIH.

The GAO report issued in May 2000 (which focused on NIH's inclusion policy with respect to women) was much more positive than the 1990 GAO report in its assessment of NIH's efforts to include women in research. The report concluded that NIH had made significant progress since 1990 in implementing a strengthened policy on including women in clinical research and that "ORWH played a key role in implementing the inclusion guidelines." A major improvement was cited by GAO with respect to NIH grant reviews; first-level peer reviewers were now routinely examining the planned study populations when evaluating a proposal's scientific merit and their concerns about the adequacy of inclusion or recruitment/retention strategies (if any) were being documented in summary statements. The GAO audit also included two recommendations: (1) that NIH staff and reviewers increase their efforts to ensure that Phase III clinical trials allow for valid analyses of sex/gender and racial/ethnic differences; and (2) that NIH staff who use the centralized tracking system receive ongoing training on the requirements and purpose of the system.

ORWH responded immediately following the release of the GAO report, working closely with the newly established NIH subcommittee reviewing inclusion issues. By August 2000, an expanded interpretation of the 1994 NIH inclusion policy had been drafted and issued, emphasizing that Phase III clinical trials must allow for a valid analysis of sex/gender and racial/ethnic differences. A revised Terms and Conditions of Award statement was also approved for NIH grant recipients, requiring a compelling justification for excluding women and minorities from clinical studies. By the end of FY 2000, revised instructions and training programs were being developed to ensure that research proposals involving Phase III clinical trials were appropriately reviewed, proposed analyses of sex/gender and racial/ethnic differences were properly documented in summary statements, and principal investigators' compliance with policy requirements were reviewed and documented on an annual basis. Also in FY 2000, the subcommittee collected comments on the data tracking system, which was undergoing

significant re-engineering to provide IC staff with user-friendly data entry screens and project monitoring capability to reduce the time required to prepare reports summarizing the demographics of NIH study populations.

Analyses of FY 2000 aggregate enrollment data compiled by the NIH Tracking and Inclusion Committee showed that substantial numbers of women (including minority women) were included as research subjects in Phase III clinical trials and other human subject research sponsored by NIH extramural and intramural programs. A total of 412,379 females were enrolled in extramural Phase III research protocols, representing approximately 71% of the subjects. Among female subjects whose race/ethnicity was known, approximately 12% were Black (non-Hispanic), 5% were Hispanic, 2% were Asian/Pacific Islanders, and 1% were American Indian/Alaskan Natives. Excluding male-only and female-only protocols, the percent of females enrolled in Phase III trials was lower (approximately 45% in FY 2000).

The biennial tracking reports also revealed that a high percentage (94.5%) of the extramural grant applications involving human subjects were fully compliant with the NIH inclusion policy by FY 2000. Examining trends through time, it was found that the percent of applications with unacceptable sex/gender and/or minority inclusion fell from 7.3% to 5.5% from FY 1995 to FY 2000. Taken together, these findings demonstrate an improved level of investigator compliance with the inclusion policy and provide additional evidence that substantial numbers of women and minorities were being included in NIH-supported clinical studies.

To assess whether there had been an increase during ORWH's first ten years in the number of NIH-supported research studies that examined sex/gender or racial/ethnic differences in disease etiology and treatment, a CRISP analysis was conducted. The CRISP database was queried (using a SAS program) to identify research studies funded in FY 1989-1990 and FY 1999-2000 having project titles, research abstracts, and/or thesaurus terms that included one or more of the following text strings:

- sex differences
- gender differences
- racial differences
- ethnic differences.

All competing and noncompeting research grants (excluding noncompeting supplements) awarded each year and all intramural research projects that met the criteria were counted.[15] The results showed that there had been a large increase during the decade in the number of NIH-supported research projects that examined sex/gender or racial/ethnic differences (see Exhibit 26). The number of studies examining sex/gender differences increased by 248%, from an average of 73 per year in FY 1989-1990 to 254 per year in FY 1999-2000. In addition, the number of studies examining racial/ethnic differences increased by 424%, from an average of 29

[15] For program project and center grants involving subprojects, only the primary grant was identified.

per year in FY 1989-1990 to 152 per year in FY 1990-2000. Although the overwhelming majority of studies focusing on these topics were extramural grants, the study found that the number of intramural projects examining sex/gender and racial/ethnic differences also increased during the ten-year period. Specifically, the number of intramural research projects examining sex/gender differences increased from an average of 3 per year in FY 1989-1990 to 15 per year in FY 1999-2000 (500% increase), and the number of intramural projects examining racial/ethnic differences increased from an average of 2 per year in FY 1989-1990 to 3 per year in FY 1999-2000 (150% increase). These results indicate that there were surprisingly few studies being conducted on the NIH campus that were investigating either sex/gender or racial/ethnic differences in disease etiology and treatment. Across the board, however, the percentage increases in studies examining sex/gender and racial/ethnic differences were much higher than the 56% overall increase in RPG awards and the 43% increase in all intramural studies that occurred over the same time period. Interestingly, a further analysis revealed that nearly all of these extramural and intramural studies focused on either sex/gender differences or racial/ethnic differences; only a small fraction of the studies (2% in FY 1989-1990 and 3% in FY 1999-2000) examined differences in both areas. Altogether, the number of extramural and intramural research studies that examined sex/gender *and/or* racial/ethnic differences increased from an average of 101 to 398 per year (an increase of 394%).

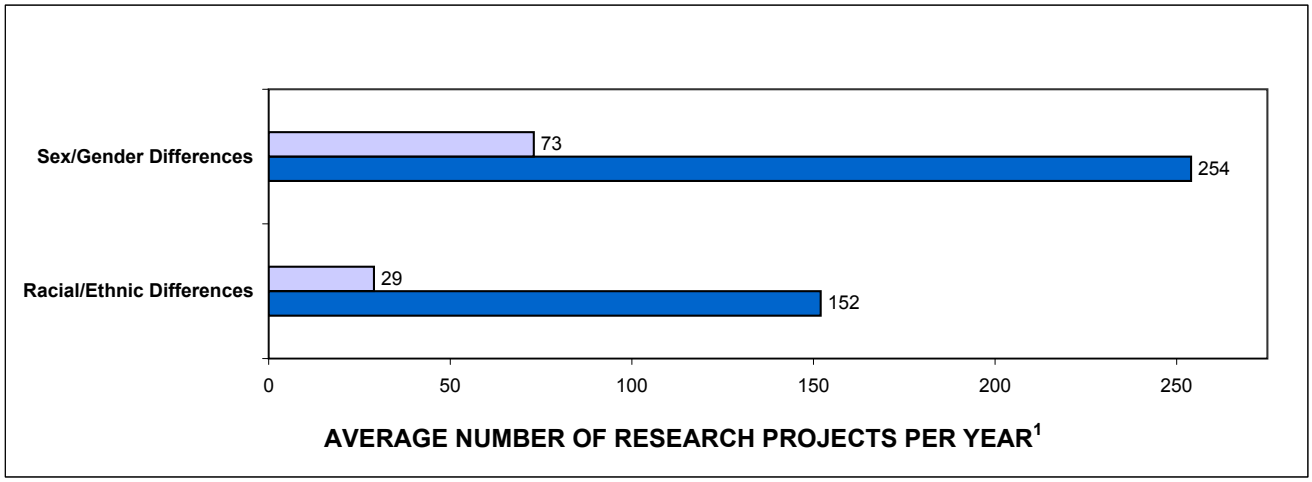
In summary, substantial evidence was found that ORWH's efforts and those of other NIH offices and ICs were effective in strengthening NIH's inclusion policy. The GAO report issued in 2000 concluded that NIH had made significant progress since 1990 in implementing a stronger policy for including women in clinical research and that ORWH had played a key role in implementing the inclusion guidelines. From FY 1995 to FY 2000, the percent of new NIH extramural grant applications involving human subjects that were found to have unacceptable sex/gender and/or minority inclusion fell from 7.3% to 5.6%, demonstrating an improved level of investigator compliance with NIH's inclusion policy. In addition, the number of NIH-supported research studies that examined sex/gender and/or racial/ethnic differences in disease etiology and treatment increased from an average of 101 to 398 per year (an increase of 394%) during ORWH's first ten years. Taken together, these findings provide convincing evidence that the efforts of ORWH efforts and other NIH offices and ICs were effective in establishing a stronger and more comprehensive inclusion policy for NIH.

Exhibit 26

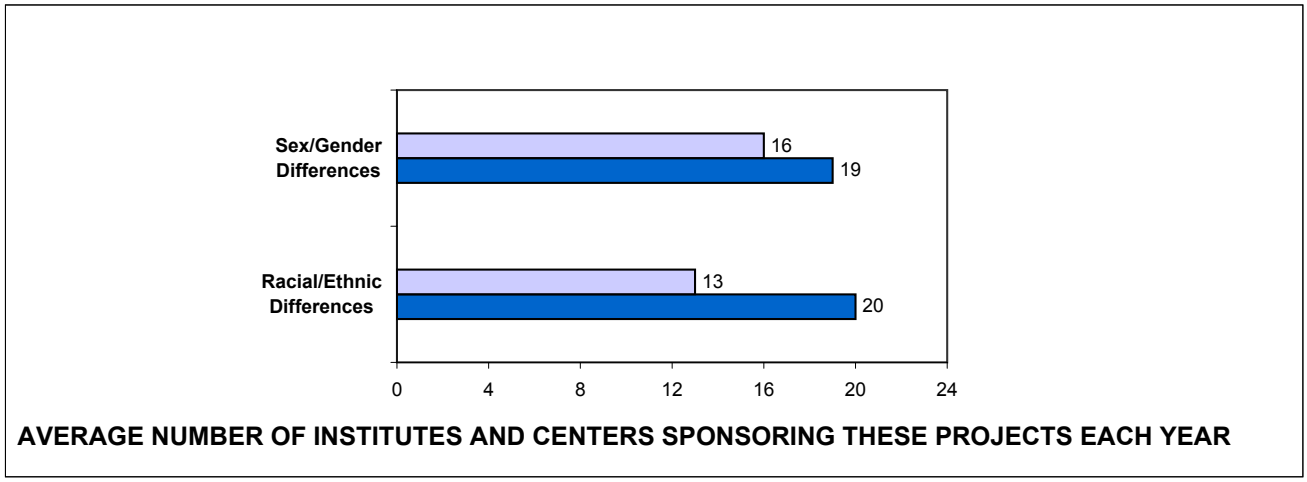
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH EXTRAMURAL AND INTRAMURAL RESEARCH PROJECTS INVESTIGATING SEX/GENDER AND RACIAL/ETHNIC DIFFERENCES

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RESEARCH PROJECTS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS SPONSORING THESE PROJECTS EACH YEAR

[1] Analyses were conducted for all competing and noncompeting research grants (excluding noncompeting supplements) awarded each year and for all intramural research projects. For program project and center grants involving subprojects, only the primary grant was selected. Data source: CRISP database system.

FY 1989-1990
FY 1999-2000

Study Question 4: Fastest Growing Areas of Women's Health Research

Which areas of NIH-sponsored women's health research grew the fastest during the ten-year period?

Study Question 4 involved a further examination of the analysis conducted for Long-Term Goal 1 to identify which areas of NIH-sponsored women's health research grew the fastest during ORWH's first ten years. The analysis focused on the 37 high-priority topics in the 1991 NIH research agenda on women's health, and the primary data source was the CRISP database. As described for Long-Term Goal 1, the methodology involved querying the CRISP database to identify competing RPG grants awarded in FY 1989, 1990, 1999, and 2000 that were relevant to each topic. Each query was conducted using a SAS program that incorporated a unique algorithm (set of rules) developed for the topic. A detailed description of the data methods and analyses used for the CRISP queries is presented in Appendix C.

For Long-Term Goal 1, the evaluation found that the number of RPG awards involving one or more high-priority topics increased by 70% during ORWH's first ten years, which was greater than the 56% overall increase in RPGs awarded by NIH during the period. To determine whether the proportion of competing RPG awards involving a particular topic was significantly greater in FY 1999-2000 than FY 1989-1990, chi-square tests were run for each topic. The findings showed that the proportion of RPG awards involving 15 of the topics increased significantly during the period (about half at the $p<.001$ level and half at the $p<.01$ or $p<.05$ level), as shown in Exhibit 20. The 15 topics with the largest gains are shown below, rank-ordered based on the chi-square results:

- Cultural and lifestyle factors
- Breast cancer
- Adolescent health
- HIV/AIDS
- Behavioral change and risk-taking behavior
- Violence
- Menopausal hormone therapy
- Menopause
- Chronic pain conditions
- Heart disease
- Colorectal cancer
- Access to health care and financing
- Sexually transmitted diseases
- Osteoporosis
- Obesity and physical activity.

For 13 of the remaining 22 topics, the increase in new RPGs exceeded the 56% overall average, 5 topics had increases ranging from 14% to 39% (less than the overall average), and 4 topics (all involving reproductive and maternal health) experienced very little change over the ten-year period in the number of new RPGs awarded per year.

Comparing the 11 major research areas, the largest increases in new RPG awards were found in the following four broad areas:

- Behavioral research (especially cultural and lifestyle factors, behavioral change and risk-taking behavior, and violence)
- Aging (especially menopausal hormone therapy)
- Cancer (especially breast cancer)
- Infectious diseases and immune disorders (especially HIV/AIDS).

During its first ten years, ORWH co-funded over 300 grants involving behavioral research and over 120 grants in each of the other three research areas that had the largest gains in RPG awards. In addition to ORWH's efforts, the increases in breast cancer, HIV/AIDS, and menopausal hormone therapy were undoubtedly due to the strong public interest in these topics during the 1990s. Similarly, the large growth in behavioral research was probably due to a variety of factors, including a growing emphasis throughout the scientific community on the prevention of disease through behavioral change, on improving the health of underserved communities to reduce health disparities, and on including women and minorities in clinical research (as required by NIH's stronger inclusion policy).

The research area that had the lowest growth in terms of new RPG awards was reproductive and maternal health. As mentioned above, for four of the five research topics in this area, there was hardly any change in the number of RPG grants awarded per year. With respect to pregnancy and maternal health, the average number of RPGs increased by only 1%; the baseline number had been quite high (288 RPGs per year in FY 1989-1990), however, which should be taken into account in interpreting the results. Nevertheless, the results were unexpected given that pregnancy and maternal health was ranked #2 in the research agenda. In fact, the results for the entire research area were surprising, particularly since ORWH co-funded a total of nearly 400 research studies involving reproductive and maternal health during the ten-year period.[16]

Overall, the findings were very positive. For 29 of the 37 high-priority research topics (78%), the number of RPGs involving the topic grew by more than the overall increase in RPG awards during the period. The results for the 11 major research areas are shown graphically in Exhibits 27 to 37, including changes through time in the average number of NIH institutes and centers

[16] As mentioned in the Executive Summary, a subsequent analysis revealed that the lack of expansion in RPGs involving reproductive and maternal health was probably due to the strategy employed by NICHD during this period to develop a broad network of maternal-fetal medicine units and reproductive health centers using non-RPG grant mechanisms (primarily U10 and U54 cooperative agreements and K12 awards), with nearly $16 million of co-funding provided by ORWH.

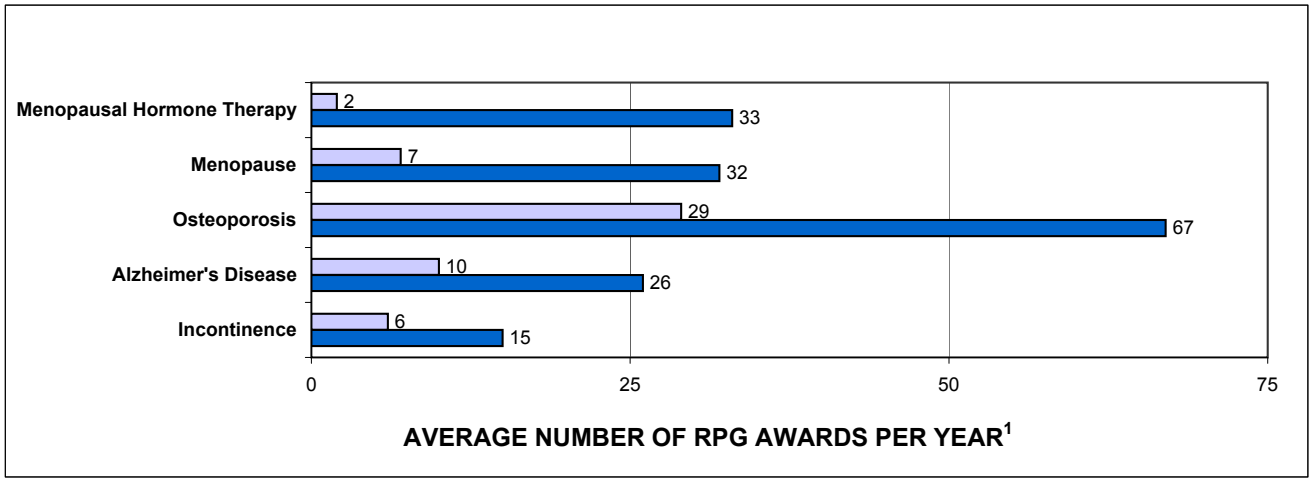
awarding RPGs involving each research topic. For 31 of the 37 topics (84%), the number of different ICs funding research on the topic increased. These findings, along with the findings for Long-Term Goal 1, provide strong evidence of an increased commitment by NIH to women's health research during ORWH's first ten years.

Exhibit 27

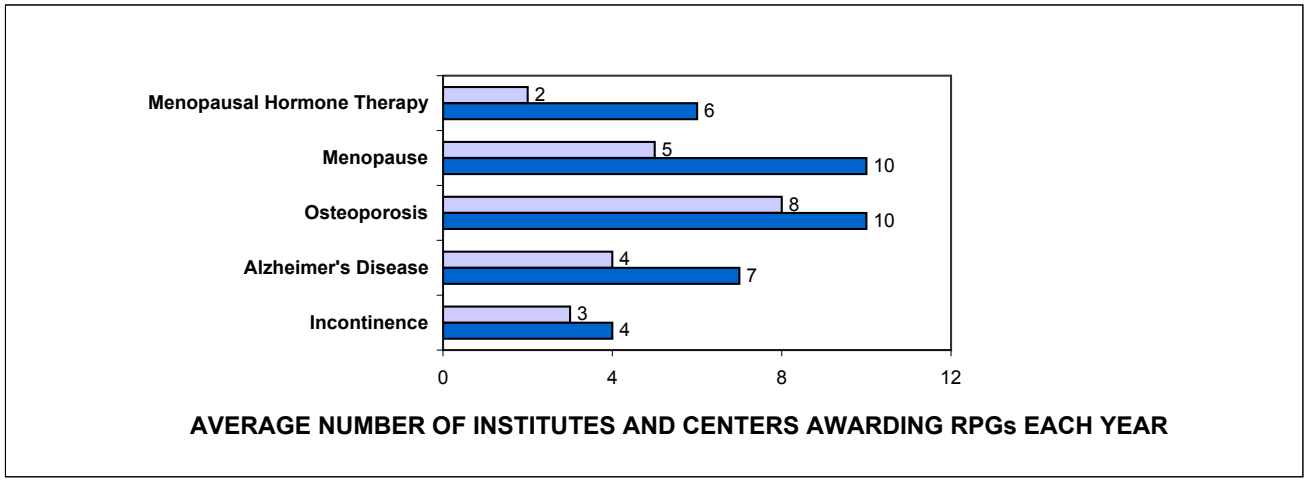
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH ON AGING

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RPG AWARDS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS AWARDING RPGs EACH YEAR

[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

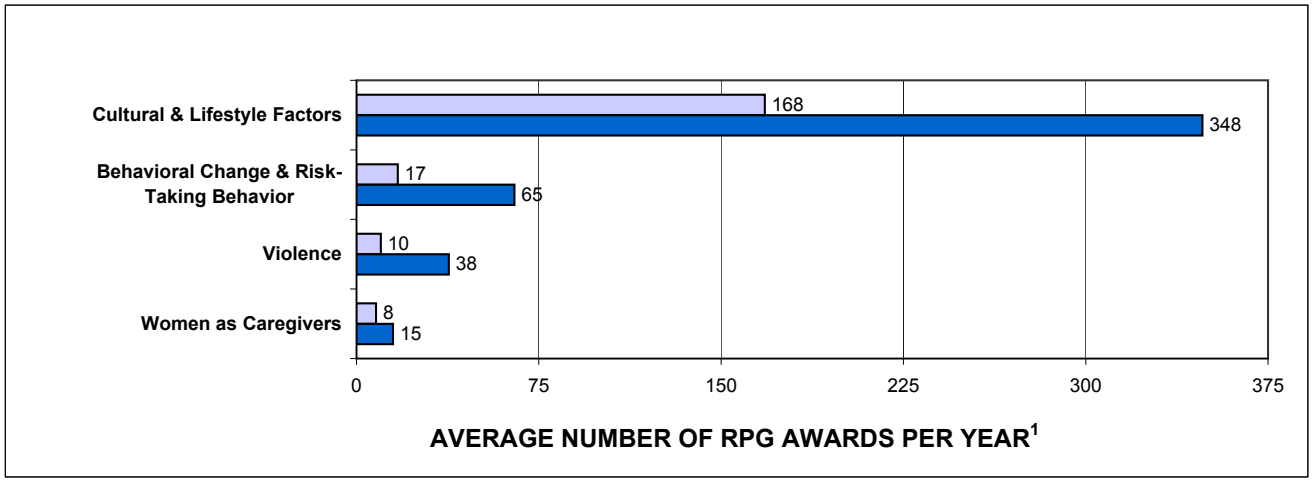
FY 1989-1990
FY 1999-2000

Exhibit 28

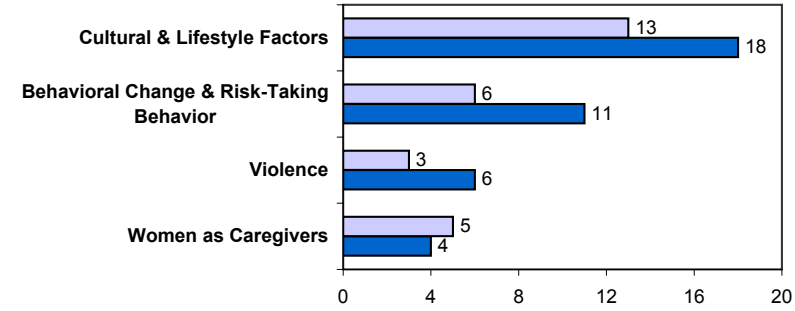
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH BEHAVIORAL RESEARCH

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RPG AWARDS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS AWARDING RPGs EACH YEAR

[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

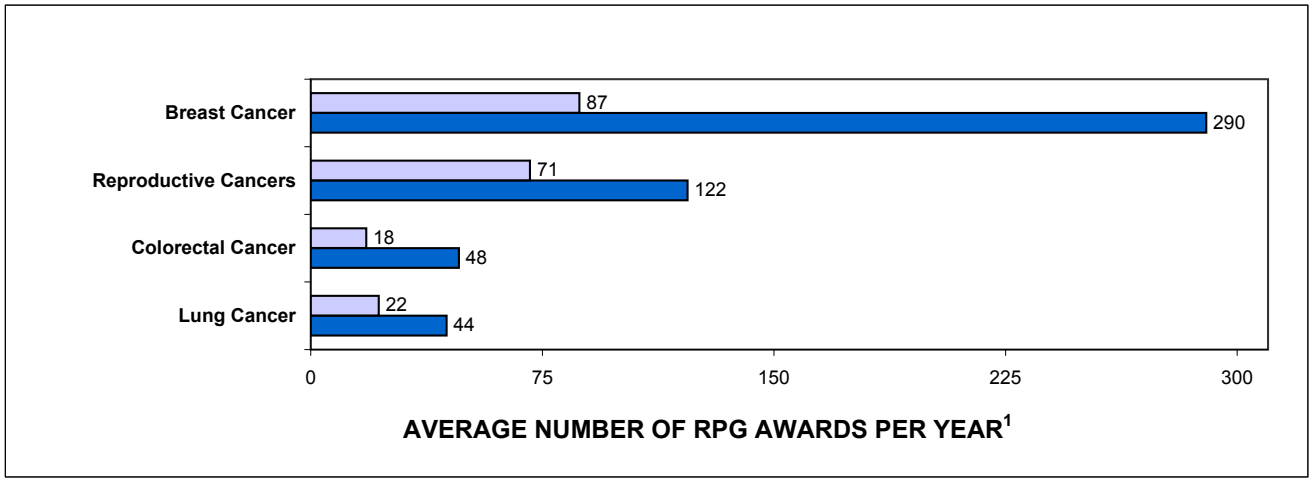
FY 1989-1990
FY 1999-2000

Exhibit 29

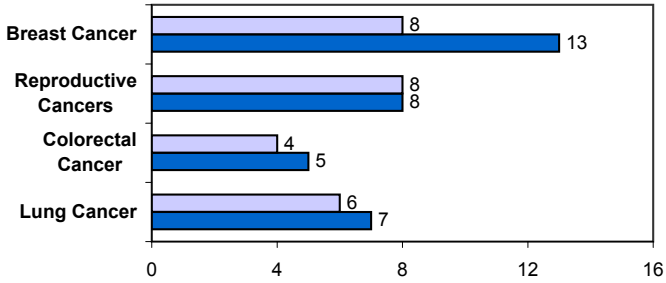
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH ON CANCER

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RPG AWARDS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS AWARDING RPGs EACH YEAR

[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

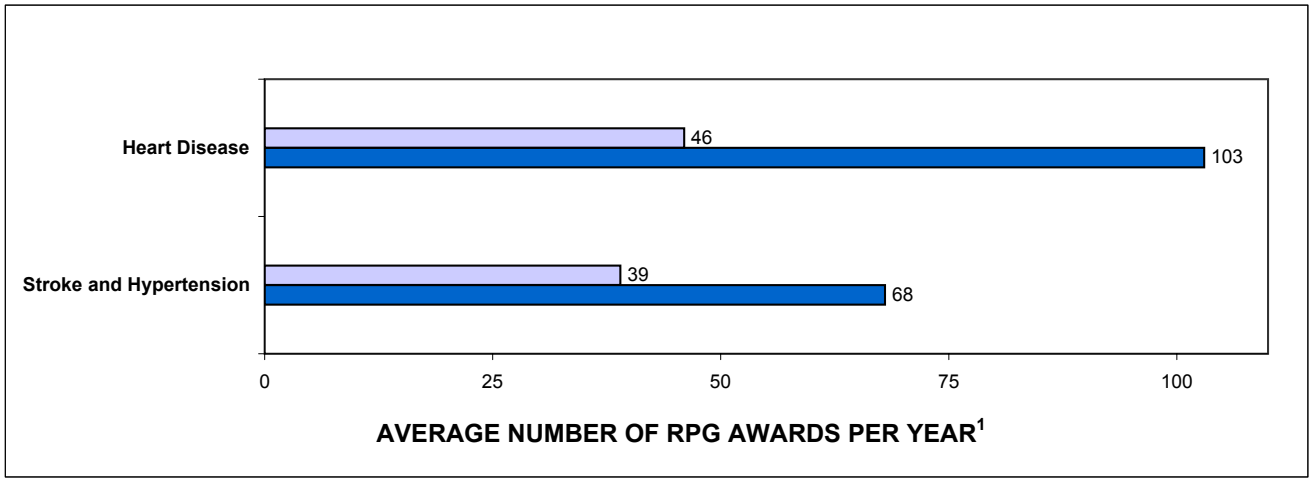
FY 1989-1990
FY 1999-2000

Exhibit 30

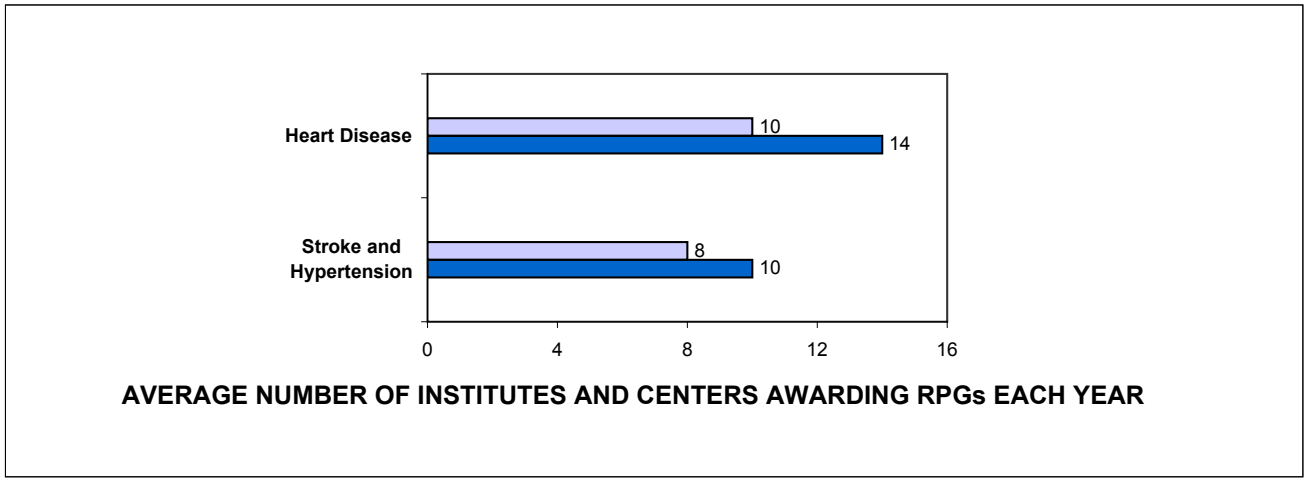
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH ON CARDIOVASCULAR AND PULMONARY CONDITIONS

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RPG AWARDS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS AWARDING RPGs EACH YEAR

FY 1989-1990
FY 1999-2000

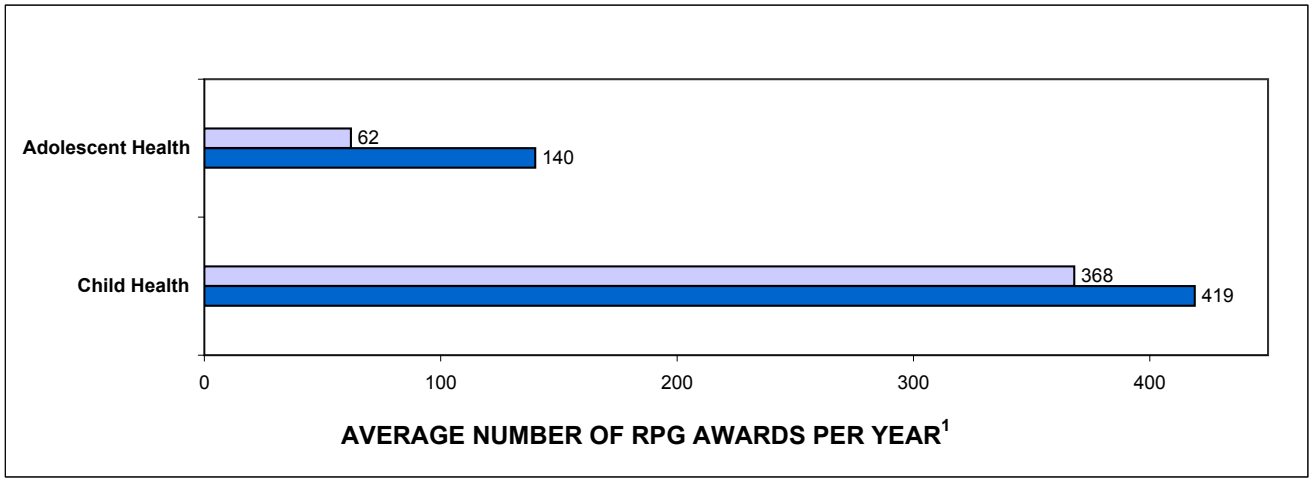
[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

Exhibit 31

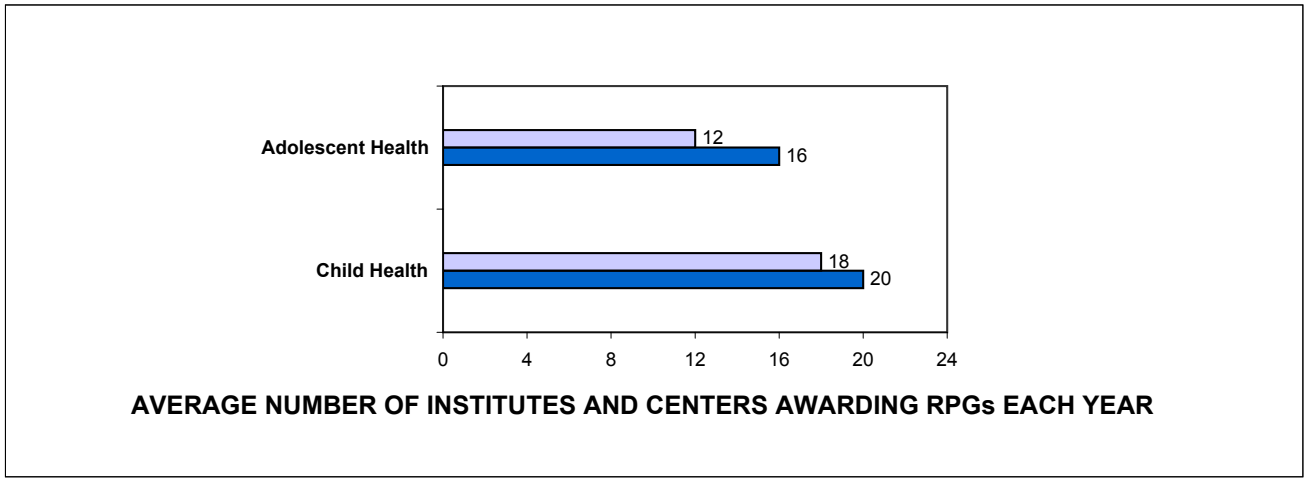
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH ON CHILD AND ADOLESCENT HEALTH

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RPG AWARDS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS AWARDING RPGs EACH YEAR

[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

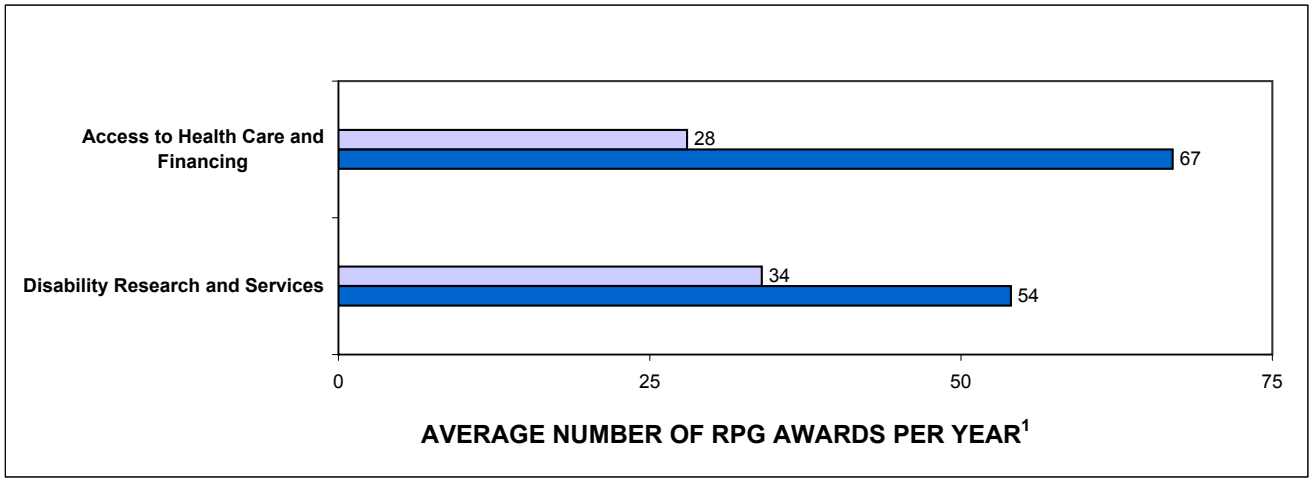
FY 1989-1990
FY 1999-2000

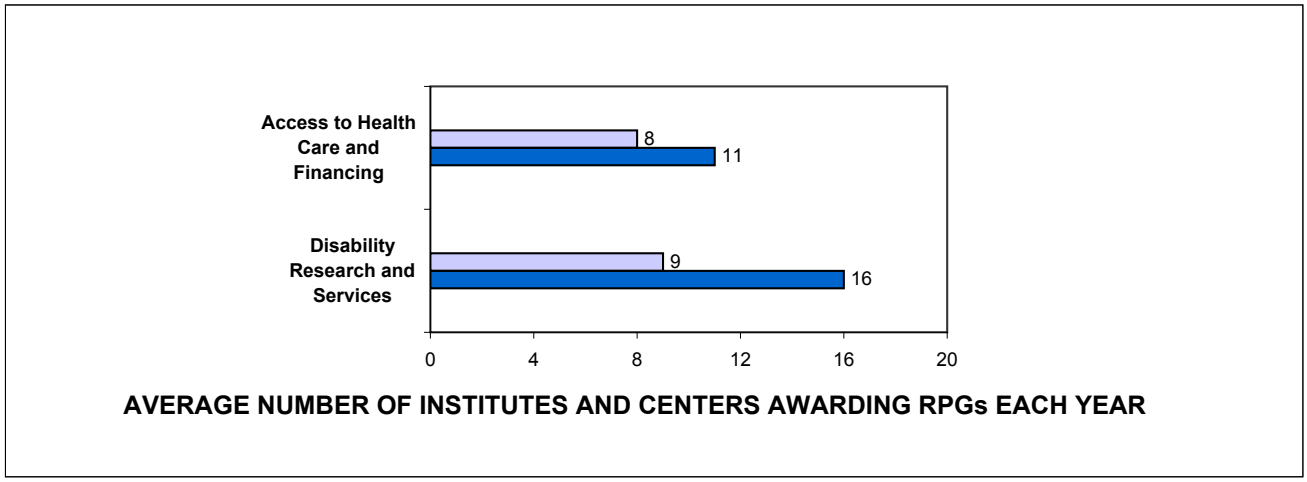
Exhibit 32

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH IN CROSSCUTTING CATEGORIES

FY 1989-1990 vs. FY 1999-2000





FY 1989-1990
FY 1999-2000

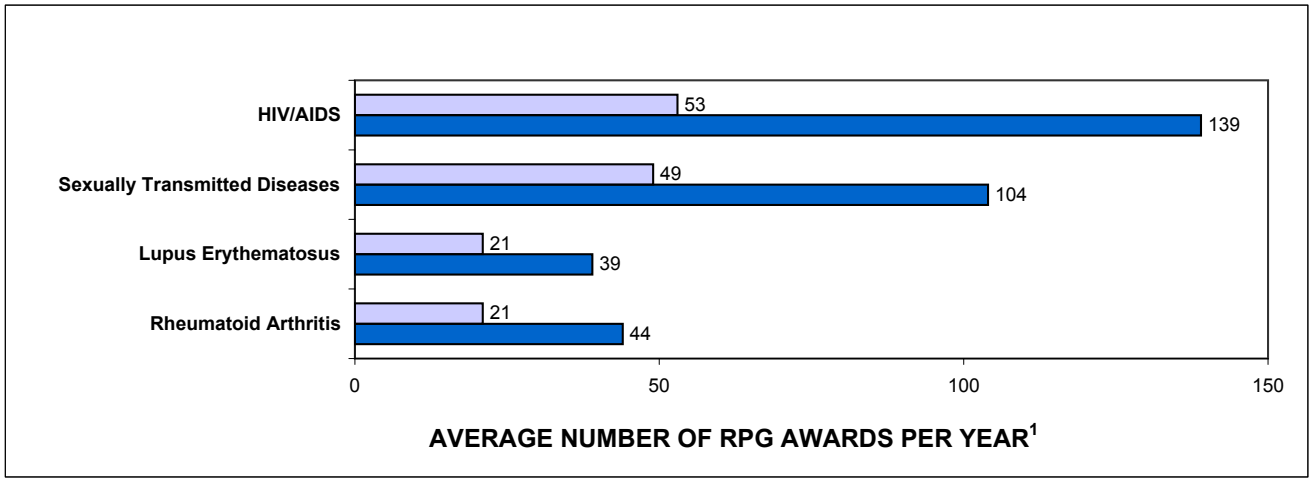
[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

Exhibit 33

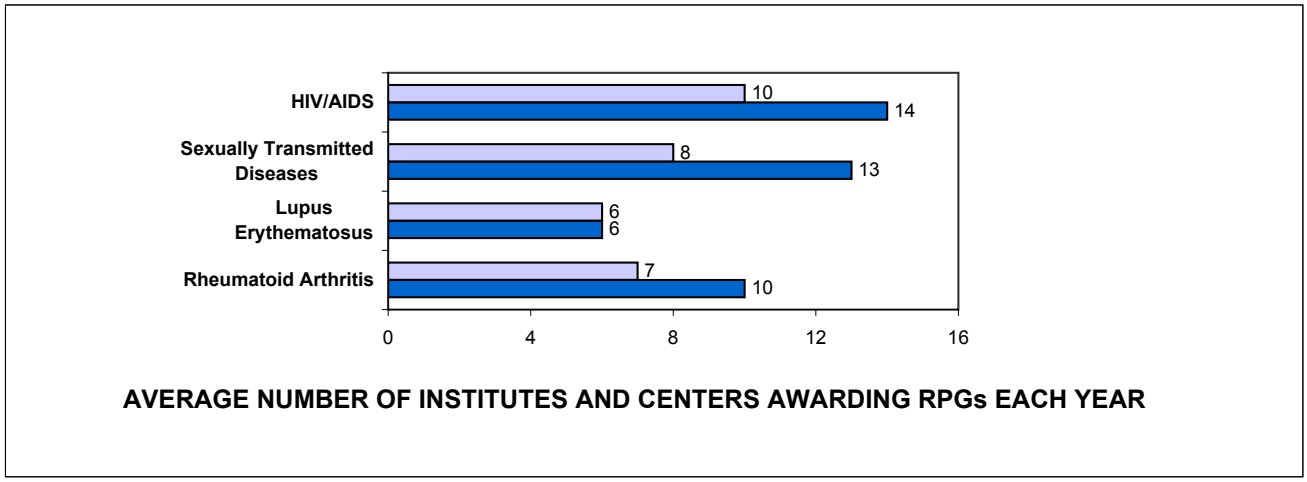
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH ON INFECTIOUS DISEASES AND IMMUNE DISORDERS

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RPG AWARDS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS AWARDING RPGs EACH YEAR

[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

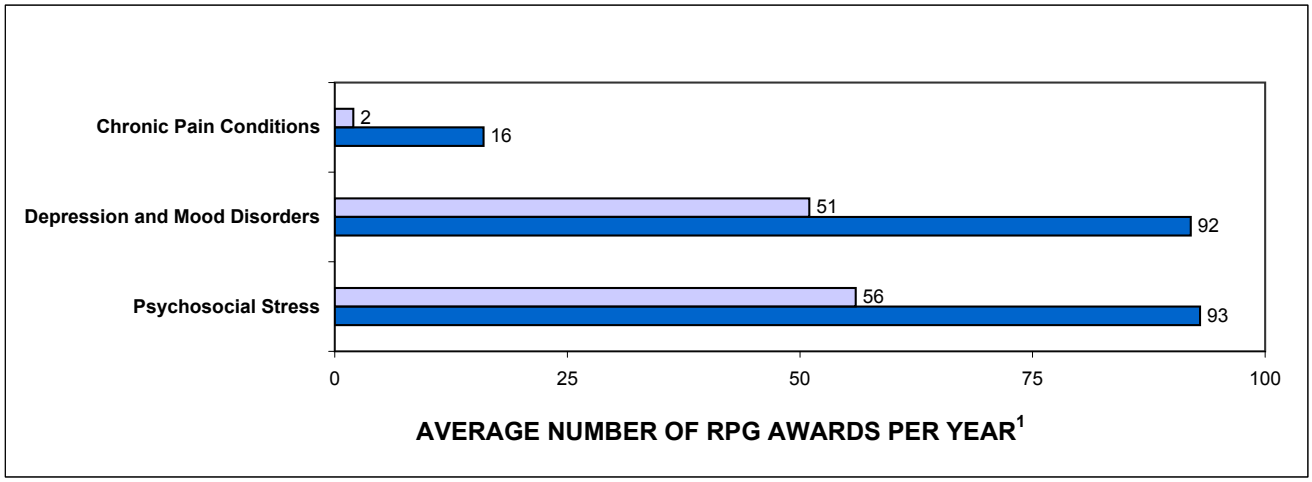
FY 1989-1990
FY 1999-2000

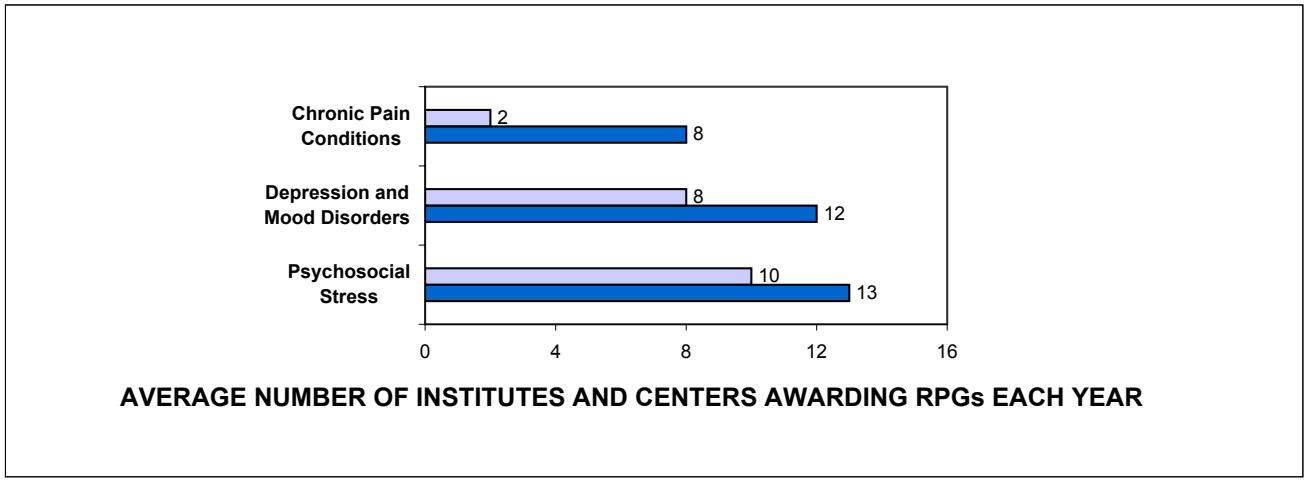
Exhibit 34

EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH ON MENTAL HEALTH AND CHRONIC PAIN

FY 1989-1990 vs. FY 1999-2000





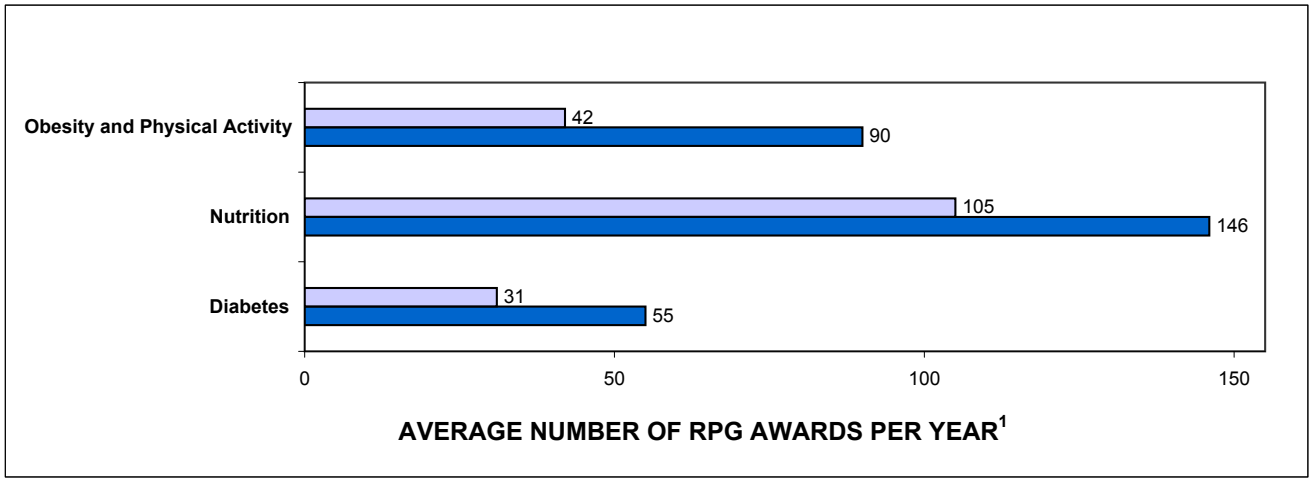
[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

Exhibit 35

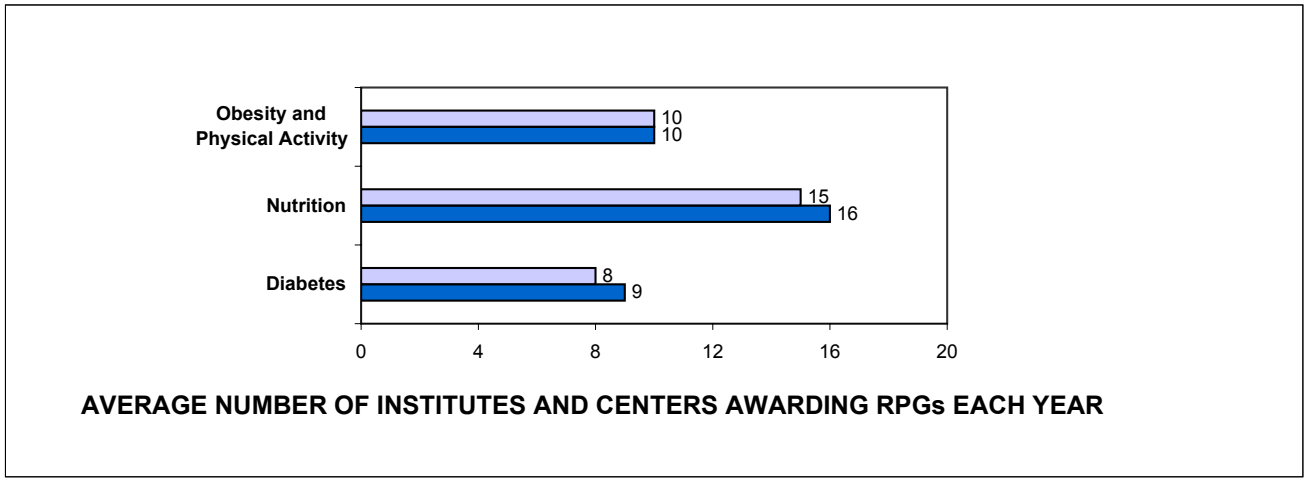
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH ON METABOLISM AND ENDOCRINOLOGY

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RPG AWARDS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS AWARDING RPGs EACH YEAR

FY 1989-1990
FY 1999-2000

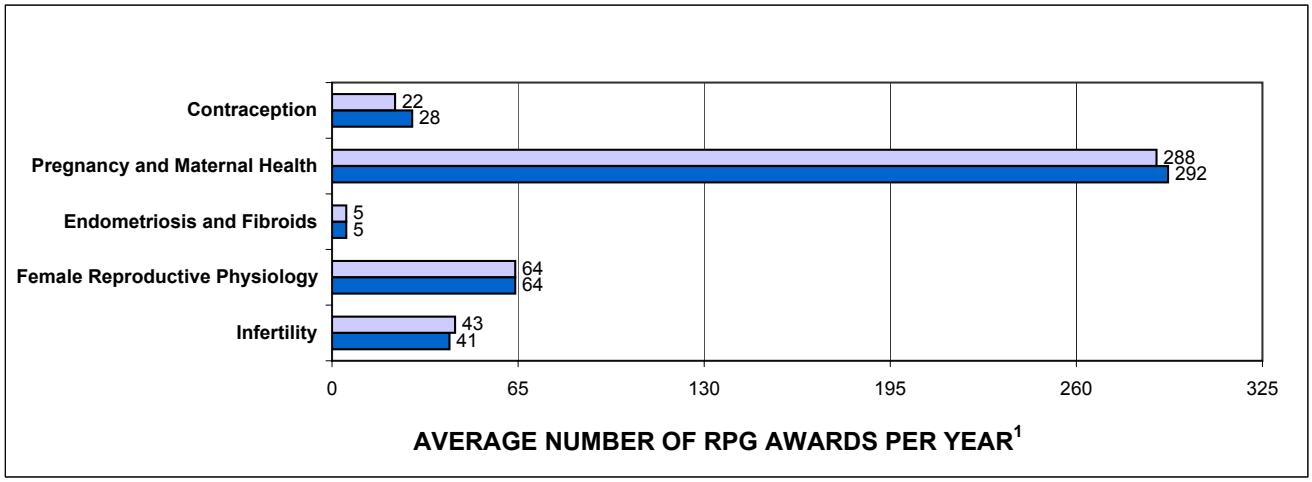
[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

Exhibit 36

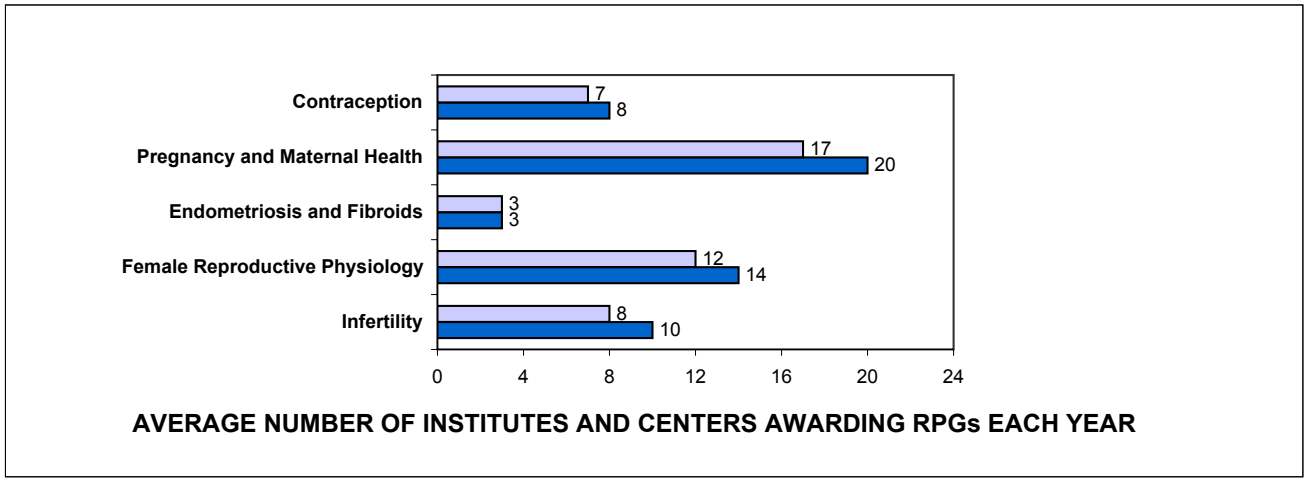
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH ON REPRODUCTIVE AND MATERNAL HEALTH

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RPG AWARDS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS AWARDING RPGs EACH YEAR

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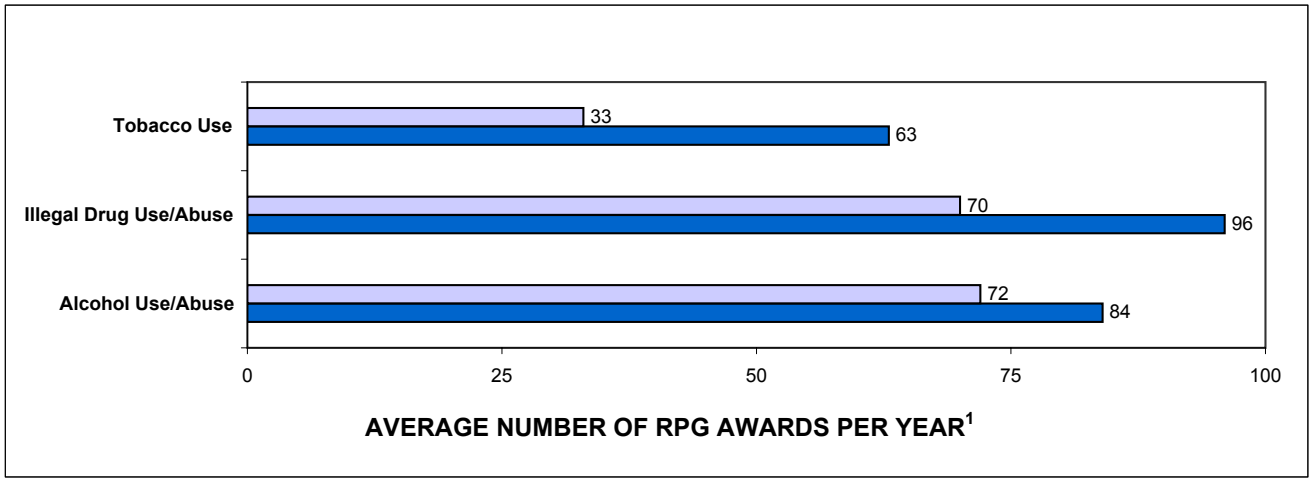
FY 1989-1990
FY 1999-2000

Exhibit 37

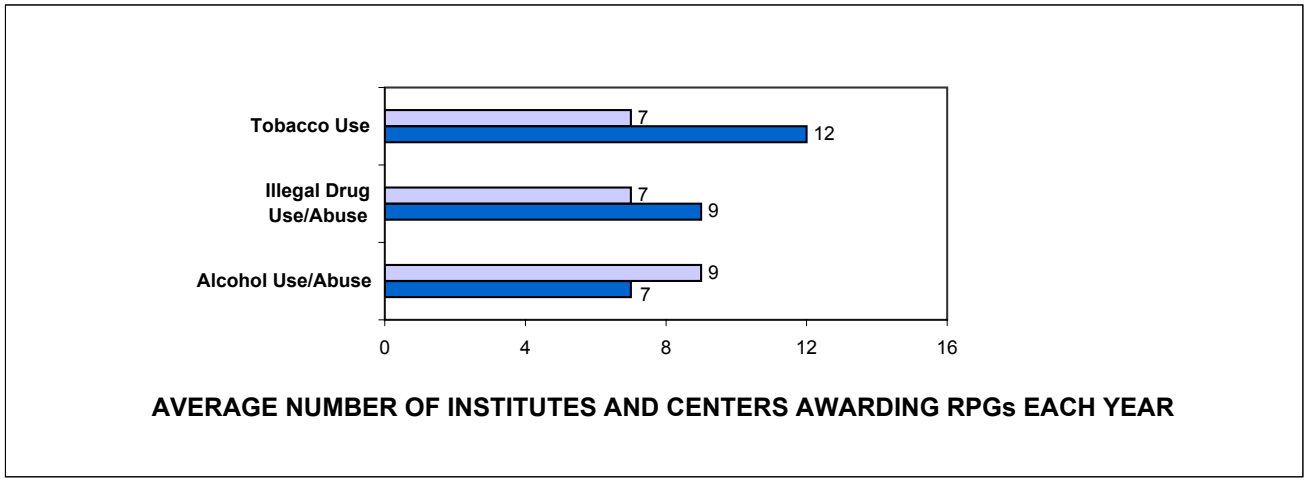
EVALUATION OF ORWH'S FIRST TEN YEARS

NIH RPG AWARDS INVOLVING WOMEN'S HEALTH RESEARCH ON SUBSTANCE ABUSE

FY 1989-1990 vs. FY 1999-2000



AVERAGE NUMBER OF RPG AWARDS PER YEAR[1]



AVERAGE NUMBER OF INSTITUTES AND CENTERS AWARDING RPGs EACH YEAR

FY 1989-1990
FY 1999-2000

[1] The above findings show the average number of competitive RPG awards (i.e., new and competing continuations) awarded per year that involved each topic and also focused on women's health. RPG counts for each topic were calculated by querying the CRISP database using a computerized algorithm and verification protocol to identify relevant grants that focused on women's health. Data source: CRISP database system.

SECTION 4:
CONCLUSIONS AND RECOMMENDATIONS

Conclusions

As the focal point for women's health research at NIH, the Office of Research on Women's Health has a broad and challenging mission. Soon after the Office celebrated its 10th anniversary in the fall of 2000, the ORWH Director decided that a comprehensive evaluation was needed to assess the progress that had been made during the first decade and enhance future planning. The Evaluation of ORWH's First Ten Years was designed to address this need and contribute to program accountability.

The study was primarily an outcome evaluation focusing on the extent to which ORWH's five intermediate and five long-term goals had been achieved during the ten-year period. The design also included elements of a process evaluation in its examination of six types of activities conducted by the Office to achieve these goals and the output produced. The evaluation design was based on a conceptual framework illustrating how ORWH's activities, most of which involved collaborations with ICs and organizations outside NIH, were expected to influence the achievement of its goals. Several strategies were employed to collect data on the different variables in the conceptual framework and answer four broad study questions. The primary focus of the evaluation was to assess the extent to which ORWH's goals had been achieved during the ten-year period; it was not designed to determine whether there was a direct cause-and-effect relationship between specific ORWH activities and goal achievement given the difficulty in eliminating other factors that undoubtedly contributed to the achievement of these broad goals.

After reviewing the evaluation findings, the evaluation advisory committee concluded that NIH had clearly increased its commitment to women's health research during the 1990s. Taken together, the findings indicate that ORWH's strong emphasis on collaboration and strategic planning, its development of a comprehensive trans-NIH research agenda for women's health, and its success in leveraging funds to encourage high-priority projects were major factors in raising the awareness of women's health across NIH. The result was a gradual culture change that had a very positive impact on the achievement of ORWH's goals. There was consensus that ORWH's approach could well serve as a model for other interdisciplinary programs pursuing trans-NIH issues and goals.

Recommendations

While emphasizing that a great deal of progress had been made, the members of the evaluation advisory committee also felt that there was more work to be done. To track future progress, the committee recommended that ORWH take the following steps:

1. Ensure that the NIH research agenda on women's health is updated on an annual basis. Consider developing an improved "master list" of diseases, disorders, and conditions affecting women which minimizes overlap among the topics while recognizing the multisystemic nature of many of the diseases. Using such a master list and a methodology similar to the one used in the evaluation, identify the highest priority research topics in accordance with the recommendations of the CCRWH research subcommittee, ACRWH members, and the working groups participating in recent agenda-setting conferences sponsored by ORWH.

9. For each high-priority research topic, continue to track the average number of new RPGs awarded per year involving that topic by employing the CRISP methodology developed for the evaluation. Given the increasing importance of interdisciplinary research, consider expanding the methodology to include non-RPG research center awards, such as P30, P50, M01, U10, U54, M01, and G12 grants. Examine the feasibility of using CRISP analyses for grant applications as well as awards after the IMPAC II system is expanded to include research abstracts for applications.

2. Continue to track the number of RPG, P30, P50, F32, and T32 grant applications submitted by female PIs and the number awarded to female PIs, summarizing the results in tables and pie charts, and consider expanding the CGAF methodology to include non-RPG career development awards and collaborating investigators (co-PIs) of major research center grants.

3. Continue to track the number of NIH-supported institutions with major research and training centers involving women's health by analyzing CGAF project titles.

4. Continue to monitor ORWH activities, expanding the ORWH activities database and updating the graphs showing trends through time for different types of activities. Develop a logging system within the Office to document ORWH activities on a daily or weekly basis to ensure that all outreach projects and other major activities are counted.

5. Post the results of the above analyses on the ORWH website and include the results in ORWH's biennial reports so that IC staff and others interested in particular research topics and career development programs can track progress in a timely way to determine whether specific strategies should be revised.

6. Continue to promote the NIH inclusion policy and encourage the various ICs, including their intramural researchers, to support more studies examining sex/gender and racial/ethnic differences in disease etiology and treatment.

7. Conduct a followup evaluation in FY 2006 to assess ORWH's progress during the five-year period from FY 2001 to FY 2005. Include an analysis of the new investigators who participated in ORWH's Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program and those who received ORWH Transitional Career Development Awards in Women's Health Research during the first two years of each program.

In conclusion, the Evaluation of ORWH's First Ten Years was a comprehensive assessment of the progress that was made from FY 1991 to FY 2000 in achieving ORWH's intermediate and long-term goals. The findings were generally positive and quite remarkable for a relatively small program office. The extensive amount of data collected for the evaluation will serve as a valuable resource in tracking ORWH's future progress. In addition, the evaluation was successful in developing and testing new methodologies for assessing changes in an NIH research portfolio over a specified time period.

In addition to helping the ORWH Director and other program administrators obtain a broader understanding of the progress that has been made and challenges that remain, the evaluation findings and the new methodologies should be useful to a broad spectrum of administrators at NIH, IC planning and evaluation officers, and members of other government agencies and research organizations interested in tracking trends through time and evaluating the achievement of program goals. It is hoped that all those who manage, fund, or provide other support for women's health projects will be encouraged by the study's results and find them helpful in developing and improving a variety of interdisciplinary research programs.

APPENDIX A

MEMBERS OF THE EVALUATION ADVISORY COMMITTEE

MEMBERS OF THE EVALUATION ADVISORY COMMITTEE

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APPENDIX B

NIH INSTITUTES AND CENTERS

NIH INSTITUTES AND CENTERS

IC Acronym[1]	Name of Institute or Center	Year Established	IC Mission
NCI	National Cancer Institute	1937	NCI leads a national effort to reduce the burden of cancer morbidity and mortality.
NEI	National Eye Institute	1968	NEI conducts and supports research that helps prevent and treat eye diseases and other disorders of vision.
NHLBI	National Heart, Lung, and Blood Institute	1948	NHLBI provides leadership for a national program in diseases of the heart, blood vessels, lung, and blood; blood resources; and sleep disorders.
NHGRI	National Human Genome Research Institute	1989	NHGRI supports the NIH component of the Human Genome Project, a worldwide research effort designed to analyze the structure of human DNA and determine the location of the estimated 30,000 to 40,000 human genes.
NIA	National Institute on Aging	1974	NIA leads a national program of research on the biomedical, social, and behavioral aspects of the aging process; the prevention of age-related diseases and disabilities; and the promotion of a better quality of life for all older Americans.
NIAAA	National Institute on Alcohol Abuse and Alcoholism	1970	NIAAA conducts research focused on improving the treatment and prevention of alcoholism and alcohol-related problems to reduce the enormous health, social, and economic consequences of this disease.
NIAID	National Institute of Allergy and Infectious Diseases	1948	NIAID research strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives.
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	1936	NIAMS supports research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases.
NIBIB	National Institute of Biomedical Engineering and Bioengineering	2000	NIBIB improves health by promoting fundamental discoveries, design and development, and translation and assessment of technological capabilities in biomedical imaging and bioengineering, enabled by relevant areas of information science, physics, chemistry, mathematics, materials science, and computer sciences.
NICHD	National Institute of Child Health and Human Development	1962	NICHD research on fertility, pregnancy, growth, development, and medical rehabilitation strives to ensure that every child is born healthy and wanted and grows up free from disease and disability.
NIDCD	National Institute on Deafness and Other Communication Disorders	1988	NIDCD conducts and supports biomedical research and research training on normal mechanisms as well as diseases and disorders of hearing, balance, smell, taste, voice, speech, and language that affect 46 million Americans.

NIH INSTITUTES AND CENTERS

IC Acronym[1]	Name of Institute or Center	Year Established	IC Mission
NIDCR	National Institute of Dental and Craniofacial Research	1948	NIDCR provides leadership for a national research program designed to understand, treat, and ultimately prevent the infectious and inherited craniofacial-oral-dental diseases and disorders that compromise millions of human lives.
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	1948	NIDDK conducts and supports basic and applied research and provides leadership for a national program in diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases.
NIDA	National Institute on Drug Abuse	1973	NIDA leads the nation in bringing the power of science to bear on drug abuse and addiction through support and conduct of research across a broad range of disciplines and rapid and effective dissemination of results of that research to improve drug abuse and addiction prevention, treatment, and policy.
NIEHS	National Institute of Environmental Health Sciences	1969	NIEHS reduces the burden of human illness and dysfunction from environmental causes by, defining how environmental exposures, genetic susceptibility, and age interact to affect an individual's health.
NIGMS	National Institute of General Medical Sciences	1962	NIGMS supports basic biomedical research that is not targeted to specific diseases. NIGMS funds studies on genes, proteins, and cells, as well as on fundamental processes like communication within and between cells, how our bodies use energy, and how we respond to medicines.
NIMH	National Institute of Mental Health	1949	NIMH provides national leadership dedicated to understanding, treating, and preventing mental illnesses through basic research on the brain and behavior, and through clinical, epidemiological, and services research.
NINDS	National Institute of Neurological Disorders and Stroke	1950	The mission of the NINDS is to reduce the burden of neurological diseases -- a burden borne by every age group, every segment of society, and people all over the world.
NINR	National Institute of Nursing Research	1986	NINR supports clinical and basic research to establish a scientific basis for the care of individuals across the life span--from the management of patients during illness and recovery to the reduction of risks for disease and disability, promotion of healthy lifestyles, promotion of quality of life in those with chronic illness, and care for individuals at the end of life.
NLM	National Library of Medicine	1936	NLM collects, organizes, and makes available biomedical science information to investigators, educators, and practitioners and carries out programs designed to strengthen medical library services in the United States.

NIH INSTITUTES AND CENTERS

IC Acronym[1]	Name of Institute or Center	Year Established	IC Mission
CIT	Center for Information Technology	1964	CIT incorporates the power of modern computers into the biomedical programs and administrative procedures of the NIH by focusing on three primary activities: conducting-computational biosciences research, developing computer systems, and providing computer facilities.
CSR	Center for Scientific Review	1946	CSR is the focal point at NIH for the conduct of initial peer review, the foundation of the NIH grant and award process.
FIC	John E. Fogarty International Center	1968	FIC promotes and supports scientific research and training internationally to reduce disparities in global health.
NCCAM	National Center for Complementary and Alternative Medicine	1992	NCCAM is dedicated to exploring complementary and alternative medical (CAM) practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information.
NCMHD	National Center on Minority Health and Health Disparities	1993	The mission of NCMHD is to promote minority health and to lead, coordinate, support, and assess the NIH effort to reduce and ultimately eliminate health disparities.
NCRR	National Center for Research Resources	1962	NCRR advances biomedical research and improves human health through research projects and shared resources that create, develop, and provide a comprehensive range of human, animal, technological, and other resources.
CC	Warren Grant Magnuson Clinical Center	1953	CC is the clinical research facility of the National Institutes of Health. As a national resource, it provides the patient care, services, and environment needed to initiate and support the highest quality conduct of and training in clinical research.

[1] Acronym of the Institute or Center.

APPENDIX C

TECHNICAL NOTES
ON
DATA METHODS AND ANALYSES

TECHNICAL NOTES ON DATA METHODS AND ANALYSES

The two primary data sources used throughout the evaluation were the NIH Consolidated Grant Applicant File (CGAF) and the Computer Retrieval of Information on Scientific Projects (CRISP) database system. A description of each database and the data collection and analysis methods used for the evaluation are presented below.

CGAF database. The CGAF is a set of records on all individuals who have applied for grants and contracts from NIH and other PHS agencies since the grant system was first established in 1938. The database includes an individual record for every grant and contract application, including new applications, competing and noncompeting continuations, supplements, extensions, and amended applications. The file is constructed primarily from the NIH IMPAC system (now called IMPAC II) and serves as the primary data source for analyzing NIH grant applications. The CGAF is maintained and updated annually by QRC Division of Macro International Inc. under a contract with NIH, and the QRC members of the evaluation team were very experienced in conducting a variety of analyses using the CGAF. Because the CGAF is covered by the Privacy Act of 1974, authorization to use the file was obtained from NIH before any analyses were conducted.

A major strength of the CGAF database is that each record contains detailed information about the grant or contract application, including the application number, name of the principal investigator, the PI's sex/gender (if available), fiscal year of application, project title, activity code (e.g., a specific category of extramural activity, such as an R01 research project grant or a P50 research center grant), award indicator, administering IC, institution code, total dollars awarded (if any), the dates of review and award, and many other variables. Another strength is the validity of CGAF data, which has been continuously improved by QRC. For example, the MFSEX variable (which indicates the sex/gender of the PI) was given special attention by QRC a few years ago at NIH's request; the validity of the sex/gender data was improved (and continues to be improved) by basing the MFSEX variable on all records available for an individual, including relevant records in the Trainee and Fellow File (TFF), Doctorate Records File, and the Association of American Medical Colleges' Faculty Roster System. The primary weakness of the CGAF (with respect to this study) was that the database does not include an abstract describing the proposed research. The project title was the only data item that could be used to assess whether more NIH grant applications to conduct women's health research were submitted in FY 1999-2000 than in FY 1989-1990. Not surprisingly, pilot studies conducted during the feasibility study involving the CRISP database (which contains abstracts as well as project titles for grants that were funded) found that the number of grant awards involving a particular topic (such as osteoporosis) that are identified from the project title alone is significantly less than the actual number of awards involving that topic.

CRISP database. CRISP is a searchable database containing information on all research projects and programs supported by NIH and other DHHS agencies from 1972 to the present, most of which are funded through competitive extramural grants awarded to PIs working at universities, hospitals, and other research institutions. The CRISP database, maintained by the NIH Office of Extramural Research (OER), is a component of the NIH IMPAC system; it is directly searchable within the IMPAC system and is also accessible via an online search engine through the OER website. Authorization to access the CRISP component of the IMPAC system for use in the ORWH evaluation was obtained from NIH before analyses were conducted.

A major strength of the CRISP system is that each record contains an abstract of the research study (usually submitted by the PI in the grant or contract application) and a list of diseases/conditions and scientific terms relevant to the study (selected from the CRISP thesaurus by the system and/or CRISP indexers who have access to the full application). The CRISP thesaurus contains over 8,000 terms which are organized in a hierarchical structure and cross-referenced to help indexers assign terms that are most relevant to a particular study. In addition to the abstract and thesaurus terms, each CRISP record includes other key information about the grant, including the project title, name and institution of the principal investigator, fiscal year of award, grant number, administering IC, and project start and end dates. The primary weakness of the CRISP system (with respect to this study) was that it only includes research projects and programs that were funded, not unsuccessful grant applications.

Analyzing CGAF project titles to identify studies involving women's health research. Because there was no NIH database that included abstracts for unfunded grant applications, a methodology was developed for the present evaluation to identify grant applications and awards involving women's health from their project titles alone. Although the resulting counts would underestimate the actual number of applications and awards involving women's health, employing the same methodology for each time period would produce comparable results which could be used to assess the extent to which a specific goal had been achieved. The strategy was used for Intermediate Goal 3, Long-Term Goal 1, and Long-Term Goal 4 to identify competing grant applications and awards (e.g., new and competing continuations) having project titles that included one or more keywords relevant to women's health.

In preparation for the analysis, a list of 244 keywords (text strings) relevant to women's health was developed, which included revisions suggested by ORWH staff and the evaluation advisory committee. The advisory committee played a critical "vetting" role in assessing the face validity of the proposed keywords and identifying those that should be excluded because they were only tangentially relevant to women's health. The final keyword list (presented in Appendix D) included diseases/conditions that affect only women (such as endometriosis), diseases/conditions that affect women much more than men (such as lupus, eating disorders, and chronic fatigue syndrome), and sexually transmitted diseases that affect both men and women. Studies that focused primarily on infants or children or on congenital diseases were excluded, except for conditions directly related to maternal health (such as infant mortality and fetal alcohol syndrome). The keywords (text strings) were then used to query the CGAF (using a SAS

program) to identify grant applications or awards having project titles that included one or more of the 244 female-oriented keywords.

Developing the list of general keywords relevant to women's health turned out to be more challenging than originally anticipated, given the potential breadth of women's health research and the need to ensure that the keywords were specific enough to identify only those research studies directly relevant to women's health. In a few cases, project titles that included one or more specific text strings were ruled out. For example, selected studies with titles including "birth" were ruled out if the title included "cell birth," "birth certif," or "from birth to."

Other challenges included developing the SAS programs for the CGAF queries and carefully reviewing the query results. For grant applications, because it is possible to have more than one application with the same grant number submitted during a particular fiscal year (if the first application was not successful and an amended application was submitted later that year), it was decided to select the most recent application in each of these cases. After every run, the evaluation team reviewed on a case-by-case basis the records whose titles also included any of the following male-oriented text strings (which was generally less than 4% of the selected records) to exclude any projects that appeared to focus primarily on men's health:

> _male_, _male-, _males, _men_, _men's, _mens_, boy, Y chromosom, sperm, testosterone, prostat, _BPH, penis, penile, semen, seminal, testis, testes, testicular, erectile, impoten, castrat, gay, homosexual, kaposi, androgen.[17]

The team also examined project titles to determine if certain keywords were producing false positives (i.e., studies that had been selected using a keyword but did not appear to be relevant to women's health research). The keyword list presented in Appendix D incorporates a few additional "rule out" words designed to eliminate these false positives in the future. For Intermediate Goal 3, 708 of 10,499 records (about 7%) were excluded as a result of these reviews, resulting in a final list of 9,791 RPG applications submitted during the four fiscal years that met the selection criteria. For Long-Term Goal 4, 9 of the 221 grant applications (4%) and 6 of the 107 grant awards (6%) were excluded because they focused on other issues (in most cases, men's health or pediatric research). As a final quality control check, the evaluation team reviewed a random sample of 1% of the records (every 100th record) to verify that their titles involved issues related to women's health. The results were positive (none were rejected) and it was concluded that the procedure for querying project titles using a well-developed keyword list is an effective way to identify grant applications involving a particular research area, even an area as broad as women's health.

Analyzing CRISP abstracts and thesaurus terms to identify studies involving women's health research. Both Long-Term Goal 1 and Study Question 4 required the evaluation team to determine the number of competing NIH RPG awards involving women's health research in each of the 37 highest priority areas in the 1991 NIH research agenda on women's health.

[17] A leading or trailing blank is represented by the underscore character: _.

Because the focus was on awards, it was decided that the best approach would be to analyze the CRISP abstract and thesaurus terms describing the research focus of each RPG award. In preparing for the analyses, 37 algorithms (sets of rules) were developed to identify studies relevant to the 37 high-priority topics. Each algorithm listed specific keywords (text strings) related to a particular topic as well as directions for ruling out irrelevant grant records and identifying records that should be reviewed on a case-by-case basis. The CRISP thesaurus proved to be a valuable resource in identifying relevant keywords for each topic and it was used extensively to develop the algorithms, along with ORWH biennial reports and other publications.

For each topic, an effort was made to exclude new terms that had emerged since FY 1989-1990 in order to avoid introducing bias into the trend estimates. Developing the algorithms was particularly challenging for some of the high-priority topics, especially those that were broad and encompassed one or more of the other topics. For example, female reproductive physiology is a very broad topic that is closely related to several other high-priority topics (e.g., pregnancy and maternal health, reproductive cancers, infertility, endometriosis and fibroids, etc.). For the present study, it was decided to define the broad topics using keywords that would minimize their overlap with other topics. However, grants involving interdisciplinary research involving several areas of women's health were likely to be selected for more than one topic. After a set of proposed algorithms had been developed for a particular research area, the algorithms were reviewed by the evaluation advisory committee, revised if needed, and pilot-tested by the evaluation team using the CRISP online search engine. As with the CGAF analysis, the advisory committee played an important role in assessing the face validity of the proposed keywords with respect to their relevance to a particular topic. The final set of algorithms is presented in Appendix E.

The CRISP database was then queried (using a set of SAS programs that incorporated the algorithms) to identify competing RPGs awarded in FY 1989, 1990, 1999, and 2000 that were relevant to each topic. The project titles, abstracts, and thesaurus terms in the CRISP system were searched to select studies that included one or more keywords relevant to the particular topic. Of the 37 topics, 14 were designated as being primarily female topics and 23 were designated as being relevant to males as well as females, based on the discussions of the Hunt Valley participants and recommendations of the evaluation advisory committee (the "primarily female" topics are shown in Exhibit 5). The algorithms were generally less complex for the 14 topics that were designated as being primarily female topics (such as breast cancer and osteoporosis). For the 23 topics that were designated as being relevant to both males and females (such as heart disease and lung cancer), additional selection criteria were employed to ensure that the selected CRISP records for these topics all involved research directly relevant to women's health. Specifically, the CRISP project title, abstract, and/or thesaurus terms had to include at least one of the following female-oriented text strings:

> female, women, girl, _mother, daughter, matern, X chromosom, birth, breast, estrogen, fetal, mammar, menopaus, menstrua, natal, osteopor, _ovar, pregnancy, pregnant, uterine, vagin, gender, sex difference.

Requiring the inclusion of a female-oriented text string for the 23 topics relevant to both males and females reduced the number of selected records considerably; studies involving basic research were generally excluded as were clinical trials that did not mention that the study population included females. Although applying these selection criteria reduced the counts in each fiscal year, it helped ensure that the selected CRISP records were all directly relevant to women's health research.

After potentially relevant CRISP records had been selected for each of the four fiscal years, those records that included any of the text strings to be ruled out for that topic (as specified in the algorithm) were deleted. Records that included any of the male-oriented text strings listed above were highlighted for the purpose of excluding research grants that focused primarily on men's health. Finally, the CRISP records selected for each topic were reviewed by the project director (referencing the abstracts when necessary) to rule out false positives (studies that were not directly related to the particular topic or women's health). The senior research consultant independently conducted a similar review for three high-priority topics involving different types of research (violence, lung cancer, and lupus erythematosus) and the resulting inter-rater reliability coefficients were quite high (87%, 92%, and 95%, respectively). Although the methodology developed to query the CRISP database was not expected to identify *all* of the RPG grants involving research beneficial to women's health in each area, it is unlikely that a systematic bias was introduced using this approach because the same analysis was used for each time period. Given the reassuring inter-rater reliability results, it was concluded that the methodology was sufficiently reliable to determine whether ORWH had been successful in achieving Long-Term Goal 1 and to answer Study Question 4.

Use of chi-square tests. Chi-square tests were used in many cases to compare the proportion of grant applications or awards of a particular type in FY 1999-2000 with the proportion during the baseline period (FY 1989-1990) to assess whether specific proportion increases were large enough to be representative of an underlying trend over the ten-year period. For example, after the proportion of RPG awards that involved osteoporosis and the proportion that did *not* involve osteoporosis had been estimated for FY 1989-1990 and FY 1999-2000 based on the results of the CRISP analyses, chi-square was used to assess whether the proportion involving osteoporosis was significantly different (and greater) in FY 1999-2000 than it had been in FY 1989-1990. Similarly, chi-square was used to assess whether the proportion of R01 applications submitted by female PIs was significantly different (and greater) in FY 1999-2000 than it had been in FY 1989-1990. In each case, 95% confidence intervals were employed to assess whether the differences were statistically significant at the .05 level (or lower).

In summary, the data methods and analyses the evaluation team used to query the Consolidated Grant Applicant File and the CRISP system proved to be reliable and effective in producing results that were very useful in evaluating the extent to which specific ORWH goals had been achieved.

APPENDIX D

GENERAL KEYWORDS RELEVANT TO WOMEN'S HEALTH

Appendix D

EVALUATION OF ORWH'S FIRST TEN YEARS

GENERAL KEYWORDS RELEVANT TO WOMEN'S HEALTH

(TEXT STRINGS FOR QUERYING CGAF PROJECT TITLES)[1]

Keyword[2]	Brief Definition	Rule Out
abort		abortus
AIH	autoimmune hepatitis	
amnio	inner layer of fetal membranes (transparent sac which holds fetus suspended in amniotic fluid)	amniote
anorexi	eating disorder involving weight loss and refusal to maintain adequate weight	
antiphospholipid syndrome	autoimmune disorder that can cause miscarriages (associated with lupus)	
autoimmune hepatitis	autoimmune disease resulting in inflammation of the liver, affecting primarily women	
battered		
binge eating		
birth		cell birth, etc.[3]
blastocyst	early stage embryo	
BMD	bone mineral density	
bone density		
bone loss		
bone mineral density		
BRCA	breast cancer gene	
breast		
BSE_	breast self examination used for early detection of breast cancer	bovine, bystander
CEE	conjugated equine estrogen	
bulimi	eating disorder involving vomiting or taking laxatives to lose or control weight	
candida	vaginal yeast infection	oral candidiasis, candidate
cervi		cervical cord, etc. [3]
cesarean		
CFS	chronic fatigue syndrome	VCFS
childbearing		
chlamydi	bacterial STD	
choriocarcinoma	malignant tumor that develops during pregnancy from fetal tissue	
chorion	portion of the trophoblast which attaches to the endometrial lining of the uterus	
chronic fatigue		
clomiphene	fertility drug	
cohabitation	unmarried partners living together	
coit		
colostrum	yellowish fluid rich in antibodies secreted by the mammary gland prior to lactation	
colposcopy	procedure for examining the vagina and cervix for precancers and other abnormalities	
condom		
continence	include studies on urinary or fecal continence	
contracep	medications or devices designed to prevent fertilization or implantation of the ovum	
corpus luteum	ovarian site where eggs are released	
couples		
daughter		daughter cell

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EVALUATION OF ORWH'S FIRST TEN YEARS

GENERAL KEYWORDS RELEVANT TO WOMEN'S HEALTH

(TEXT STRINGS FOR QUERYING CGAF PROJECT TITLES)[1]

Keyword[2]	Brief Definition	Rule Out
DCIS	ductal carcinoma in situ	
decidua	endometrium of the pregnant uterus which is shed at parturition, except for the deepest layer	
DES	diethylstilbestrol	
diethylstilbestrol	DES - synthetic hormone used to prevent miscarriage that was shown to cause birth defects	
dieting		
divorce		
domestic violence		
douch		
ductal carcinoma in situ	noninvasive form of breast cancer	
eating disorder		
eclampsia	convulsions and coma associated with hypertension and edema in pregnant women	
egg + sperm		
embryo implantation		
endometri		
ERT	estrogen replacement therapy	
estradiol	type of estrogen	
estriol	type of estrogen	
estrogen	hormone that produces female characteristics and helps regulate the menstrual cycle	
estrous	related to menstrual cycle	
estrus	estrous	
fallop	tube that carries egg cells from the ovary to the uterus (also called oviduct)	
family dynamics		
family planning		
family structure		
family violence		
FAS	fetal alcohol syndrome	
fecundity	potential reproductive capacity	
female		
feminin		
fertil		
fetal		
fetus		c. fetus, campylobacter fetus
fibroid	benign tumor, commonly of the uterus (also called leiomyoma)	
fibromyalgia	chronic pain in the fibrous tissues of the body (muscles, ligaments), affecting primarily females	
FMS	fibromyalgia syndrome	C-FMS
follicle stimulating hormone	hormone essential for reproduction that stimulates the gonads in females and males	
follicle-stimulating hormone		
follicular atresia	ovary disorder	
follicular phase	phase of menstrual cycle	lymphoma, NHL, FCCL
folliculogenesis	development of follicles	

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EVALUATION OF ORWH'S FIRST TEN YEARS

GENERAL KEYWORDS RELEVANT TO WOMEN'S HEALTH

(TEXT STRINGS FOR QUERYING CGAF PROJECT TITLES)[1]

Keyword[2]	Brief Definition	Rule Out
Fraumeni	Li-Fraumeni syndrome is associated with early breast cancer	
FSH	follicle stimulating hormone	FSHD
gamet	reproductive cell (either an egg or sperm) containing one copy of each chromosome	
gender		
genital		congenital
gestational diabetes	glucose intolerance which onsets during pregnancy	
girl		
gonococc		
gonorrh		
graafian	mature ovarian follicle found in early phase of menstrual cycle	
granulosa	layer of ovarian cells in graafian follicle	
gynecol		
hCG	human chorionic gonadotropin (hormone normally produced during pregnancy)	
hormone replacement		growth, _GH_, thyroid, _PTH, goiter
hormone therapy		growth, _GH_, thyroid, _PTH, goiter
hot flash		
hot flush		
HPV	human papillomavirus	
HRT	hormone replacement therapy	
HSV 2	herpes simplex virus 2 (genital herpes), a viral STD	
HSV2	HSV 2	
HSV-2	HSV 2	
human embryo	fertilized human egg cell that has undergone one or more divisions	
human milk		
hysterec	surgical removal of the uterus	
hystero	pertaining to the uterus	
ICSI	intracytoplasmic sperm injection	
in utero		
incontinen	include studies on urinary or fecal incontinence	enuresis
induced labor		
infant mortality		
interstitial cystitis	inflammation of the tissues of the bladder, a painful chronic condition affecting primarily females	
IUD_	intrauterine device	
IVF	in vitro fertilization, the process of uniting a human egg and sperm cell outside the body	
labor_ + delivery		
lactati		
lactogen	placental hormone that increases during pregnancy to enhance milk production	
LAM	lymphangioleiomyomatosis (lung disease affecting almost exclusively women of childbearing age)	
LBW	low birth weight (infant weighing less than 2,500 grams at birth)	
lesbian		

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EVALUATION OF ORWH'S FIRST TEN YEARS

GENERAL KEYWORDS RELEVANT TO WOMEN'S HEALTH

(TEXT STRINGS FOR QUERYING CGAF PROJECT TITLES)[1]

Keyword[2]	Brief Definition	Rule Out
levonorgestrel	synthetic hormone that inhibits ovulation	
_LH	luteinizing hormone	LHX, left hemisphere, brain
lumpectomy	type of breast cancer surgery that removes the malignant tumor and surrounding tissue	
lupus	systemic lupus erythematosus, an autoimmune disease affecting primarily females	
luteal	phase of menstrual cycle	
luteinizing hormone	hormone essential for reproduction that stimulates the gonads in females and males	
mammalian embryo	fertilized mammalian egg cell that has undergone one or more divisions	
mammar	pertaining to the milk secreting glands in female mammals	
mammog	radiological procedure used to detect breast cancer	
marital		
marriage		
married		
mastectomy	surgical removal of a breast for the treatment or prevention of breast cancer	
matern		maternal antigen, maternal cell
menarche	first menstrual cycle	
menopaus		
menorrhe	pertaining to menstrual flow	
menses	menstrual cycle	
menstrua	cyclic production of hormones that culminates in the release of a mature egg (ovum)	
mifepristone	antiprogestin birth control pill (also called RU-486)	
migraine		
miscarriage		
morula	early stage embryo	
mother		chemother, tomother
myalgic encephalomyelitis	neurological disease (also called chronic fatigue syndrome), affecting primarily females	
myom	pertaining to the uterus	
natal		
neonat		
NHRT	natural hormone replacement therapy	
nurses health		
nurses' health		
OB/GYN		
OB-GYN		
obstetric		
oocyt	unfertilized egg cell that is early in development (which divides to form an ovum)	
oogen	oogenesis is the generation and formation of oocytes	
oophorect	surgical removal of an ovary (also called ovariectomy)	
osteopen		
osteopor		
ovar		novartis

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EVALUATION OF ORWH'S FIRST TEN YEARS

GENERAL KEYWORDS RELEVANT TO WOMEN'S HEALTH

(TEXT STRINGS FOR QUERYING CGAF PROJECT TITLES)[1]

Keyword[2]	Brief Definition	Rule Out
oviduct	fallopian tube	
ovulat		
ovum	unfertilized egg cell	
oxytocin	hormone that causes uterine contractions in childbirth and promotes bonding	
pap smear	papanicolaou	
pap test	papanicolaou	
papanicolaou	test to examine cervical/vaginal cells for signs of precancerous change or cancer	
papilloma virus	see papillomavirus	
papillomavirus	virus (HPV) that causes warts, including genital warts (an STD that can cause cervical cancer)	
parent		apparent, parenteral, transparent
parity	related to having given birth	disparity, policy
parous	related to having given birth	
partner violence		
partum		
parturition	birth process	
PCOS	polycystic ovary syndrome, an endocrine disorder causing infertility	
pelvic floor	muscles weakened in childbirth	
pelvic inflammatory	infection involving the uterus lining, ovaries, or fallopian tubes	
phytoestrogen	plant nutrient that has mild estrogen-like effects	
_PID	pelvic inflammatory disease	kinase
placenta		
PMS	premenstrual syndrome	PPMS, PMS2
pregnancy		
pregnant		
Premarin	most widely used ERT	
premature labor	onset of labor before full term	
Prempro	most widely used HRT	
premature rupture	premature rupture of membranes, spontaneous leakage of amniotic fluid prior to the onset of labor	
preterm	a delivery occurring before the 37th week of gestation	
primary biliary cirrhosis	autoimmune disease that destroys liver bile ducts, affecting primarily females	
progest	hormone that prepares the uterus for implantation and pregnancy	
prolactin	hormone essential for milk production and nursing	
prolapse	descension of the uterus or other pelvic organs, which is much more common in females	valve, MVP
PROM	premature rupture of membranes	
prostitut		
Provera	Depo-Provera, a synthetic hormone injected intramuscularly that prevents conception for 3 months	
puerperal	time period immediately following childbirth	
raloxifene	SERM drug used to treat and prevent osteoporosis (also called Evista)	
_rape		
relaxin	hormone that relaxes the birth canal during labor	

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EVALUATION OF ORWH'S FIRST TEN YEARS

GENERAL KEYWORDS RELEVANT TO WOMEN'S HEALTH

(TEXT STRINGS FOR QUERYING CGAF PROJECT TITLES)[1]

Keyword[2]	Brief Definition	Rule Out
reproducti		
resectoscop	procedure for removing fibroids or polyps through the cervix	
Rett Syndrome	progressive disorder affecting the cerebral cortex of females	
rheumatoid arthritis	chronic inflammatory disorder affecting primarily females	
RU 486	Mifepristone	
RU-486	Mifepristone	
RU486	Mifepristone	
salpingitis	inflammation of the fallopian tubes	
SERM_	selective estrogen receptor modulator, a class of drugs having some of the effects of estrogen	
sex		
sexual abuse		
sexual assault		
_SIDS	sudden infant death syndrome, the sudden and unexpected death of an apparently healthy infant	
single-parent		
sjogren	autoimmune disorder affecting mostly females (90% of patients) causing dry eyes, dry mouth	
SLE	systemic lupus erythematosus	
sperm capacitation	process by which sperm become capable of fertilizing an ovum after reaching fallopian tubes	
spermicid	agent that kills sperm	
spous		
_STD	sexually transmitted disease	stdy
suckling		
syphilis		
tamoxifen	estrogen antagonist used to prevent recurrence of breast cancer; also used to induce ovulation	
toxemia	pregnancy-induced hypertension (also called preeclampsia)	
toxic shock syndrome		
trichomon		
trimester		
trophoblast	blastocyst's outer layer of cells	
Turner	Turner syndrome is a chromosome abnormality affecting only females.	
urinary bladder sphincter disorder	Include studies on incontinence and spinal cord injury, etc.	
urination disorder	Include studies on incontinence and spinal cord injury, etc.	
urinary tract infect	infection of the urinary tract usually caused by bacteria, a condition affecting primarily females	
uterine		
uterus		
UTI	urinary tract infection	
vagin		
vulv	area surrounding the opening of the vagina	
widow		
wife		
wives		

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EVALUATION OF ORWH'S FIRST TEN YEARS

GENERAL KEYWORDS RELEVANT TO WOMEN'S HEALTH
(TEXT STRINGS FOR QUERYING CGAF PROJECT TITLES)[1]

Keyword[2]	Brief Definition	Rule Out
woman		
women		
X chromosom		
zona pellucida	membrane that protects the egg at conception and afterwards	
zygote	fertilized egg cell formed by the union of female and male gametes	

[1] Keywords (text strings) used to query the project titles of NIH grant applications and awards for FY 1989, 1990, 1999, and 2000, for the purpose of identifying projects focusing on research particularly relevant to women's health. Data source: NIH Consolidated Grant Applicant File (CGAF

Selected grant applications were reviewed by hand if the project title includes any of the following male-oriented keywords:

male, _male-, _males, _men_, _men's, _mens_, boy, Y chromosom, sperm, testosterone, prostat, _BPH, penis, penile, semen, seminal, testis, testes, testicular, erectile, impoten, castrat, gay, homosexual, kaposi, androger

[2] A leading or trailing blank is represented by the underscore character: _.

[3] For 'birth', rule out: cell birth, neuron birth, birth certif, from birth to.
For 'cervi', rule out: cervical cord, cervical spin, cervical vertebrae, cervical carotid, cervical interneurons, cervisiae, cervi

APPENDIX E

ALGORITHMS FOR IDENTIFYING NIH-SPONSORED RESEARCH RELEVANT TO WOMEN'S HEALTH

Algorithms for Identifying NIH-Sponsored Research Relevant to Women's Health

A. AGING

High-priority women's health topics involving aging:

1. Menopausal Hormone Therapy
2. Menopause
3. Osteoporosis
4. Alzheimer's Disease
5. Incontinence

1. MENOPAUSAL HORMONE THERAPY

Keywords (Text Strings)	Notes
hormone replacement	
estrogen replacement	
HRT	Hormone replacement therapy.
ERT	Estrogen replacement therapy.
CEE	Conjugated equine estrogen.
phytoestrogen	Nutrient found in plants that has mild estrogen-like effects.
Premarin	Most widely used ERT.
PremPro	Most widely used HRT.
raloxifene	Anti-estrogen drug used as an HRT alternative.
Rule out	Selected studies involving hormone therapies designed to treat diseases or conditions that are not relevant to aging and women's health (text strings = growth, _GH_, thyroid, _PTH, goiter).
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

2. MENOPAUSE

Keywords (Text Strings)	Notes
menopaus	
hot flash	
hot flush	
Review on a case-by-case basis	Selected records focusing on other conditions or diseases that reference pre- or post-menopausal populations, for the purpose of selecting those that specifically address issues relevant to menopause (text strings = pre-menopaus, premenopaus, post-menopaus, postmenopaus). Also review on a case-by-case basis those records that include any male-oriented text strings.

3. OSTEOPOROSIS

Keywords (Text Strings)	Notes
osteopor	Osteoporosis is a condition of decreased bone mass (diagnosed by measuring bone mineral density).
osteopen	Osteopenia is a condition of decreased bone mass, but not as severe as osteoporosis.
bone loss	
bone mineral density	
BMD	Bone mineral density.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

4. ALZHEIMER'S DISEASE

Keywords (Text Strings)	Notes
Alzheimer	
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

5. INCONTINENCE

Keywords (Text Strings)	Notes
incontinen	Include studies on urinary or fecal incontinence.
continence	Include studies on urinary or fecal continence.
urinary bladder sphincter disorder	
urination disorder	
Rule out	Selected studies involving bedwetting in children (text string = enuresis).
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

B. BEHAVIORAL RESEARCH

High-priority women's health topics involving behavioral research:

1. Cultural and Lifestyle Factors
2. Behavioral Change and Risk-Taking Behavior
3. Violence
4. Women as Caregivers

1. CULTURAL AND LIFESTYLE FACTORS

Keywords (Text Strings)	**Notes**
cultural	**Rule out** agricultural, studies on tissue/cell cultures.
lifestyle	
life style	
socioeconomic	
ethnic	
racial	**Rule out** racial studies focusing on genetics.
racism	
religio	
church	
SES	
income	
socioenvironment	
peer group	
social support	
social network	
social class	
social work	
community based	
community-based	
_urban	
rural	
neighborhood	
inner city	
poverty	
literacy	
homeless	
migrant	

public assistance	
family structure	
ethnograph	
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

2. BEHAVIORAL CHANGE AND RISK-TAKING BEHAVIOR

Keywords (Text Strings)	**Notes**
behavioral change	
behavior change	
high risk lifestyle	
high-risk lifestyle	
high risk life style	
high-risk life style	
risk-taking	
risk taking	
risk behavior	
risky	
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

3. VIOLENCE

Keywords (Text Strings)	**Notes**
violence	
violent	
sexual assault	
_rape	
sexual abuse	
sex abuse	
sexually abused	
spousal abuse	
spouse abuse	
partner abuse	

domestic abuse	
physical abuse	
physically abused	
abused women	
sexual aggression	
marital aggression	
sexual harassment	
crime	**Rule out** studies on crimes that do not have a direct impact on women, girls, or fetuses.
homicide	
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

4. WOMEN AS CAREGIVERS

Keywords (Text Strings)	**Notes**
caregiver	**Rule out** studies on medical caregivers.
care giver	
caregiving	
care-giving	
care giving	
caring for	
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

C. CANCER

High-priority women's health topics involving cancer:

1. Breast Cancer
2. Reproductive Cancers
3. Colorectal Cancer
4. Lung Cancer

1. BREAST CANCER

Keywords (Text Strings)	**Notes**
breast	
mammog	Procedure involving radiation used to detect breast cancer.
tamoxifen	Estrogen antagonist used to prevent recurrence of breast cancer; also used to induce ovulation.
BRCA	Breast cancer gene.
DCIS	Ductal carcinoma in situ, a noninvasive form of breast cancer.
mastectomy	Surgical removal of a breast for the treatment or prevention of breast cancer.
lumpectomy	Type of breast cancer surgery that removes the malignant tumor and surrounding tissue.
Fraumeni	Li-Fraumeni syndrome is associated with early breast cancer.
Additional selection criteria	Records must also include at least one of the following cancer-related text strings: cancer, neoplasm, tumor, malignan, carcino, metastasis.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

2. REPRODUCTIVE CANCERS

Keywords (Text Strings)	**Notes**
female reproductive system	
gynecol	
ovar	**Rule out** covariance, Novartis.
cervi	
uterine	
uterus	
endometri	
vagin	
vulva	Area surrounding the opening of the vagina.
pap smear	Papanicolaou test.
pap test	Papanicolaou test.

Papanicolaou	Test to examine cervical/vaginal cells for signs of precancerous change or cancer (also called pap smear or pap test).
vaginal smear	
colposcopy	Procedure for examining the vagina and cervix for precancers and other abnormalities.
choriocarcinoma	Malignant tumor that develops during pregnancy from fetal tissue.
Additional selection criteria	Records must also include at least one of the following cancer-related text strings: cancer, neoplasm, tumor, malignan, carcino, metastasis.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

3. COLORECTAL CANCER

Keywords (Text Strings)	**Notes**
colorectal	
colon	**Rule out** colony, colonies.
rectal	
rectum	
adenomatous polyp	Small benign growths in the large intestine which can progress to colorectal cancer.
Additional selection criteria	Records must also include at least one female-oriented text string and at least one of the following cancer-related text strings: cancer, neoplasm, tumor, malignan, carcino, metastasis.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

4. LUNG CANCER

Keywords (Text Strings)	**Notes**
lung	
pulmonary	
bronchial	
respiratory	
Additional selection criteria	Records must also include at least one female-oriented text string and at least one of the following cancer-related text strings: cancer, neoplasm, tumor, malignan, carcino, metastasis.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

D. CARDIOVASCULAR AND PULMONARY CONDITIONS

High-priority women's health topics involving cardiovascular and pulmonary conditions:

1. Heart Disease
2. Stroke and Hypertension

1. HEART DISEASE

Keywords (Text Strings)	Notes
heart	
cardi	
coronary	
_CHD	
CVD	**Rule out** studies on cholera vaccine and the Center for Vaccine Development (text strings = vaccine, CVD).
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that simply mention heart rate (text string = heart rate) or include any male-oriented text strings.

2. STROKE AND HYPERTENSION

Keywords (Text Strings)	Notes
stroke	
hypertensi	
blood pressure	**Rule out** studies focusing on other topics that simply measure blood pressure.
BP	**Rule out** studies using other 'BP' terms (text strings = binding potential, benzopyrene).
cerebrovascular	
cerebral vascular	
cerebral ischemia	Deficiency of oxygen to the brain caused by an obstruction in or the constriction of a blood vessel.
eclampsia	Pre-eclampsia is a pregnancy complication involving hypertension that can result in maternal and/or fetal death.
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

E. CHILD AND ADOLESCENT HEALTH

High-priority women's health topics involving cardiovascular and pulmonary conditions:

1. Child Health
2. Adolescent Health

1. CHILD HEALTH

Keywords (Text Strings)	Notes
child	
infan	
newborn	
baby	
babies	
toddler	
girl	
pediatric	
elementary school	**Rule out** text string = science education.
congenital	Condition present from birth.
birth defect	
low birth weight	Infant weighing less than 2,500 grams at birth, a major risk factor for infant morality and morbidity.
LBW	Low birth weight.
fetal alcohol	Syndrome involving neuropsychological deficits, found in children exposed to alcohol in utero (also called FAS).
_SIDS	Sudden infant death syndrome, the sudden and unexpected death of an apparently healthy infant.
cleft	
mental retardation	
autism	Severe mental disorder characterized by extreme self-absorption, language disturbances, and repetitive movements.
Downs syndrome	Genetic condition caused by a chromosome abnormality, usually resulting in mental retardation and other abnormalities.
Down syndrome	Downs syndrome
fragile X	Genetic condition caused by a mutated gene on the X chromosome, resulting in variable levels of mental retardation.
Rett syndrome	Progressive disorder affecting the cerebral cortex of females.
Turner	Turner syndrome is a chromosome abnormality affecting only females.
sickle cell	Disease involving abnormally shaped red blood cells, occurring primarily in people of African heritage.
cystic fibrosis	Inherited disorder affecting glands and characterized by progressive lung disease, occurring primarily in Caucasians.
muscular dystrophy	Degenerative disorder characterized by muscle weakness and atrophy without involvement of the nervous system.

cerebral palsy	Group of chronic disorders affecting body movements and muscle coordination caused by damage to the brain during fetal development.
dwarfism	Condition of severe growth retardation that persists throughout childhood, caused by a dysfunction of the pituitary gland.
neurofibromatosis	Neurologic genetic disorder causing noncancerous tumors to grow on nerves, also affecting the skin.
osteogenesis imperfecta	Congenital condition characterized by abnormal fragility of the bones.
phenylketonuria	Inherited metabolic disorder that can result in mental retardation and other neurological problems (also called PKU).
spina bifida	Congenital disorder in which the backbone and spinal canal do not close before birth, resulting in lower limb paralysis.
scoliosis	Deformity of the spine which usually starts in childhood, most commonly in girls.
type 1 diabetes	Chronic disease characterized by insulin deficiency which usually starts in childhood (also called insulin dependent diabetes or juvenile diabetes).
juvenile rheumatoid arthritis	Chronic inflammatory disease that may cause joint or connective tissue damage (also called JRA).
juvenile dermatomyositis	Disease causing weak muscles and skin rash in children (also called JDMS).
atopic dermatitis	Chronic skin disease characterized by itchy, inflamed skin, most often affecting infants and young children (also called eczema).
bacterial meningitis	Bacterial infection causing inflammation of the membranes covering the brain and spinal cord.
varicella zoster	Chickenpox virus.
measles	
mumps	
pertussis	Whooping cough.
precocious puberty	Sexual development before the age of 8 in girls and 10 in boys.
lead poisoning	
learning disab	
attention deficit	Learning disability characterized by distractibility and impulsivity, which may also include hyperactivity (also called ADD or ADHD).
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that focus on genetics and records that include any male-oriented text strings.

2. ADOLESCENT HEALTH

Keywords (Text Strings)	**Notes**
adolescen	**Rule out** studies that focus on preadolescence.
teen	
youth	
puberty	Period of life when a person becomes functionally capable of reproduction. **Rule out** studies that focus on prepuberty or text string = precocious puberty.

pubertal	Pertaining to puberty.
high school	**Rule out** text string = science education.
secondary school	**Rule out** text string = science education.
middle school	**Rule out** text string = science education.
junior high school	**Rule out** text string = science education.
juvenile delinquen	
juvenile periodontitis	Condition involving severe bone loss around the first molars and incisors, most commonly seen in girls (starting at puberty).
juvenile myocolonic epilepsy	Seizures involving jerks of the head and arms which may be followed by convulsions, most commonly seen in girls (starting at puberty).
eating disorder	
bulimi	Eating disorder involving vomiting or taking laxatives to lose or control weight.
anorexi	Eating disorder involving weight loss and refusal to maintain adequate weight.
acne	
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

F. CROSSCUTTING CATEGORIES

High-priority women's health topics involving cross-cutting categories:

1. Access to Health Care and Financing
2. Disability Research and Services

1. ACCESS TO HEALTH CARE AND FINANCING

Keywords (Text Strings)	**Notes**
access	**Rule out** accessory and studies that focus on access to self-care materials.
availability	**Rule out** bioavailability.
utilization	**Rule out** studies that focus on utilization fo self-care materials.
barrier	
underserved	
under-served	
insur	
health coverage	
Additional selection criteria	Records must also include at least one female-oriented text string and at least one of the following text strings: care, service.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

2. DISABILITY RESEARCH AND SERVICES

Keywords (Text Strings)	**Notes**
disab	**Rule out** studies that focus on temporary disabilities.
blindness	
deafness	
neuromuscular disorder	
amputation	
amputee	
paralysis	
paraplegi	Paralysis of the lower body and legs.
quadriplegi	Paralysis of all four limbs (also called tetraplegia).
tetraplegi	Quadriplegia.
assistive	Assistive device or technology to help individuals with disabilities.
prosthesis	
artificial limb	

wheelchair	
activities of daily living	
ADL	Activities of daily living. **Rule out** deadly, broadly.
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

G. INFECTIOUS DISEASES AND IMMUNE DISORDERS

High-priority women's health topics involving infectious diseases and immune disorders:

1. HIV/AIDS
2. Sexually Transmitted Diseases (other than HIV/AIDS)
3. Lupus Erythematosus
4. Rheumatoid Arthritis

1. HIV/AIDS

Keywords (Text Strings)	**Notes**
HIV	Human retrovirus that causes the disease AIDS. **Rule out** archival.
human immunodeficiency virus	
human immune deficiency virus	
AIDS	Collection of infections and cancers caused by HIV. **Rule out** training aids.
acquired immunodeficiency syndrome	
acquired immune deficiency syndrome	
SIV	Virus that causes a disease (SAIDS) in monkeys which is similar to AIDS in humans; used as a model for HIV infection.
simian immunodeficiency virus	SIV
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

2. SEXUALLY TRANSMITTED DISEASES (OTHER THAN HIV/AIDS)

Keywords (Text Strings)	**Notes**
sexually transmitted	
_STD	
gonorrh	Bacterial STD.
syphilis	Bacterial STD.
chlamydi	Bacterial STD.
trichomon	STD caused by a parasitic organism.
papillomavirus	Viral STD (also called HPV).
HPV	Human papillomavirus. **Rule out** studies that focus on hypoxic pulmonary vasoconstriction (HPV).
genital wart	HPV.
condyloma	HPV.
herpes simplex virus 2	Viral STD (also called HSV 2).

HSV 2	Herpes simplex virus 2.
HSV-2	Herpes simplex virus 2.
HSV2	Herpes simplex virus 2.
genital herpes	Herpes simplex virus 2.
hepatitis B	Viral STD (also called HBV).
HBV	Hepatitis B.
haemophilus ducreyi	Bacterial STD.
canchroid	Haemophilus ducreyi.
genital ulcer	Haemophilus ducreyi.
lymphogranuloma venereum	STD caused by a parasitic organism (also called LGV).
LGV	Lymphogranuloma venereum.
venereal	
prostitut	
sex worker	
Rule out	Studies related to HIV/AIDS (text strings = HIV, AIDS, SIV, deficiency virus, deficiency syndrome).
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

3. LUPUS ERYTHEMATOSUS

Keywords (Text Strings)	**Notes**
lupus	
SLE_	Systemic lupus erythematosus. **Rule out** studies that focus on St. Louis encephalitis (SLE).
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

4. RHEUMATOID ARTHRITIS

Keywords (Text Strings)	**Notes**
rheumatoid arthriti	
rheumatoid disease	**Rule out** studies that focus on rheumatic fever or rheumatic heart disease.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

H. MENTAL HEALTH AND CHRONIC PAIN CONDITIONS

High-priority women's health topics involving mental health and chronic pain conditions:

1. Chronic Pain Conditions
2. Depression and Mood Disorders
3. Psychosocial Stress

1. CHRONIC PAIN CONDITIONS

Keywords (Text Strings)	**Notes**
chronic pain	
persistent pain	
neuropathic pain	
cancer pain	
chronic back pain	
arthritic pain	
pain threshold	
nociceptor	Receptor for pain caused by damage to body tissue.
hyperalgesia	Excessive sensitivity to painful stimuli.
allodynia	Pain response to stimuli that are normally not painful.
migraine	Neural condition characterized by severe recurrent vascular headaches, occurring more frequently in women than men.
fibromyalgia	Chronic condition causing widespread pain in the fibrous tissues of the body (muscles, ligaments), affecting primarily females.
vulvodynia	Chronic burning vulvar pain of unknown cause.
interstitial cystitis	Inflammation of the tissues of the bladder, a painful chronic condition affecting primarily females.
vulvodynia	Chronic burning vulvar pain of unknown cause.
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

2. DEPRESSION AND MOOD DISORDERS

Keywords (Text Strings)	**Notes**
depression	**Rule out** studies that focus on sensory or respiratory depression due to anesthesia, etc.
depressed	**Rule out** immunodepressed.
depressive	
antidepressant	
anti-depressant	

mood disorder	
bipolar disorder	
bipolar illness	
bipolar patient	
unipolar disorder	
unipolar illness	
affective disorder	
affective illness	
suicid	**Rule out** other types of suicide (text strings = cell suicide, suicide gene, suicide inhibitor, suicide substrate).
sadness	
hopelessness	
despair	
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

3. PSYCHOSOCIAL STRESS

Keywords (Text Strings)	**Notes**
psychological stress	
social stress	
PTSD	Post-traumatic stress disorder
stress	**Rule out** distress and studies that focus on stress fractures, bone stress, in utero stress, stressed babies.
bereave	
Additional selection criteria	Records must also include at least one female-oriented text string.
Rule out	Selected studies involving other types of stress (text strings = oxidative stress, mechanical stress, cardiovascular stress, skeletal stress, muscle stress, prenatal stress, exercise stress, heat stress, stress protein, stress incontinence.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

I. METABOLISM AND ENDOCRINOLOGY

High-priority women's health topics involving metabolism and endocrinology:

1. Obesity and Physical Activity
2. Nutrition
3. Diabetes

1. OBESITY AND PHYSICAL ACTIVITY

Keywords (Text Strings)	**Notes**
obesity	
obese	
adiposity	
overweight	
weight control	
weight loss	
weight management	
dieting	
overeating	
binge eating	
physical activity	
fitness	
exercise	**Rule out** studies on exercises to strengthen pelvic muscles (text string = pelvic).
physical education	
sedentary	
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

2. NUTRITION

Keywords (Text Strings)	**Notes**
nutritio	
nutrient	
dietary	
vitamin	
food supplement	

fruit	**Rule out** fruitful, fruit fly.
vegetable	
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

3. DIABETES

Keywords (Text Strings)	**Notes**
diabet	**Rule out** studies on nephrogenic diabetes insipidus, a genetic disorder which is rare among women (text string = insipidus, NDI_).
IDDM	Insulin-dependent diabetes mellitus (text string = IDDM will also identify NIDDM studies involving noninsulin-dependent diabetes).
insulin	**Rule out** studies that focus on insulin-like growth factor (unless diabetes is mentioned).
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

J. REPRODUCTIVE AND MATERNAL HEALTH

High-priority women's health topics involving reproductive and maternal/child/adolescent health:

1. Contraception
2. Pregnancy and Maternal Health
3. Endometriosis and Fibroids
4. Female Reproductive Physiology
5. Infertility

1. CONTRACEPTION

Keywords (Text Strings)	**Notes**
contracep	Medications or devices designed to prevent fertilization or implantation of the ovum.
spermicid	Agent that kills sperm.
condom	
birth control	
intrauterine device	Device for preventing pregnancy which is inserted into the uterus by way of the vaginal canal.
IUD	Intrauterine device.
Provera	Depo-Provera, a synthetic hormone (medroxyprogesterone acetate) injected intramuscularly that prevents conception for 3 months.
mifepristone	Antiprogestin birth control pill (also called RU-486).
RU 486	Mifepristone.
RU-486	
RU486	
levonorgestrel	Synthetic hormone that inhibits ovulation.
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

2. PREGNANCY AND MATERNAL HEALTH

Keywords (Text Strings)	**Notes**
pregnancy	**Rule out** studies that focus on genetics, cloning.
pregnant	
matern	
human embryo	Fertilized human egg cell that has undergone one or more divisions.
mammalian embryo	Fertilized mammalian egg cell that has undergone one or more divisions.
egg	**Limit selection** to records that also include 'sperm' or 'fertil'.

oocyte	Unfertilized egg cell that is early in development (which divides to form an ovum).
ovum	Unfertilized egg cell.
gamete	Reproductive cell (either an egg or sperm) containing one copy of each chromosome.
zygote	Fertilized egg cell formed by the union of female and male gametes.
zona pellucida	Membrane that protects the egg at conception and afterwards.
morula	Early stage embryo.
blastocyst	Early stage embryo, formed from morula.
trophoblast	Blastocyst's outer layer of cells.
chorion	Portion of the trophoblast which attaches to the endometrial lining of the uterus.
decidua	Endometrial lining of the pregnant uterus which is shed at parturition, except for the deepest layer.
embryo implantation	
placenta	
in utero	
amnio	Inner layer of fetal membranes, a thin transparent sac which holds the fetus suspended in amniotic fluid.
fetal	
fetus	
hCG	Human chorionic gonadotropin (hormone normally produced during pregnancy).
natal	
neonat	
labor_	**Limit selection** to records that also include 'delivery'.
induced labor	Stimulation of uterine contractions prior to the time they normally would occur.
premature labor	Onset of labor before full term.
premature rupture	Premature rupture of membranes involving spontaneous leakage of amniotic fluid prior to the onset of labor.
PROM	Premature rupture of membranes.
birth	
partum	
parturition	Birth process.
parity	Related to having given birth.
parous	Related to having given birth.
preterm	Delivery occurring before the 37th week of gestation.
cesarean	
relaxin	Hormone that relaxes the birth canal during labor
prolactin	Hormone essential for milk production and nursing.

oxytocin	Hormone that causes uterine contractions in childbirth and promotes bonding.
lactati	
lactogen	Placental hormone that increases during pregnancy to enhance milk production.
colostrum	Yellowish fluid rich in antibodies secreted by the mammary gland prior to lactation.
human milk	
breast feeding	
breast-feeding	
suckling	
puerperal	Time period immediately following childbirth.
obstetric	
miscarriage	
trimester	
childbearing	
infant mortality	
pelvic floor	Muscles weakened in childbirth.
toxemia	Pregnancy-induced hypertension (also called preeclampsia).
eclampsia	Convulsions and coma associated with hypertension and edema in pregnant women (includes preeclampsia).
choriocarcinoma	Malignant tumor that develops during pregnancy from fetal tissue.
antiphospholipid syndrome	Autoimmune disorder that can cause miscarriages (associated with lupus).
DES	Diethylstilbestrol.
diethylstilbestrol	Synthetic hormone used to prevent miscarriage that was shown to cause birth defects (also called DES).
abort	
Review on a case-by-case basis	Selected records related to child health (text strings = child, infan, newborn, congenital, birth defect) and records that include any male-oriented text strings.

3. ENDOMETRIOSIS AND FIBROIDS

Keywords (Text Strings)	**Notes**
endometriosis	Painful disease in which abnormal tissue similar to the tissue that lines the uterus (the endometrium) grows in the abdomen and other places outside the uterus.
fibroid	Benign tumor, commonly of the uterus.
leiomyoma	Alternative name for uterine fibroids. **Rule out** lymphangioi<u>leiomyoma</u>tosis.
resectoscop	Procedure for removing fibroids or polyps through the cervix.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

4. FEMALE REPRODUCTIVE PHYSIOLOGY

Keywords (Text Strings)	Notes
female reproductive	**Rule out** studies that focus on genetics, cloning.
gynecol	
breast	
mammar	Pertaining to the milk secreting glands in female mammals.
uterus	
uterine	
cervi	
ovar	**Rule out** covariate.
ovulat	Periodic ripening and rupture of a mature graafian follicle followed by the discharge of an egg (ovum) from the ovary.
fallop	Tube that carries egg cells from the ovary to the uterus (also called oviduct).
oviduct	Fallopian tube.
vagin	**Rule out** invagination.
vulv	Area surrounding the opening of the vagina.
estrogen	Hormone that produces female characteristics and helps regulate the menstrual cycle.
progestin	Hormone that prepares the uterus for implantation and pregnancy.
myom	Pertaining to the uterus. **Rule out** myomorpha.
hystero	Pertaining to the uterus.
hysterec	Surgical removal of the uterus.
menstrua	Cyclic production of hormones culminating in the release of a mature egg (ovum).
menses	Menstrual cycle.
menarche	First menstrual cycle.
menorrhe	Pertaining to menstrual flow.
estrous	Related to menstrual cycle.
estrus	Estrous.
follicular phase	Phase of menstrual cycle.
luteal	Phase of menstrual cycle.
PMS	Premenstrual syndrome.
prolapse	Descension of the uterus or other pelvic organs, which is much more common in females.
corpus luteum	Ovarian site where eggs are released.
graafian	Mature ovarian follicle found in early phase of menstrual cycle.
granulosa	Layer of ovarian cells in graafian follicle.
folliculogenesis	Development of follicles.
follicular atresia	Ovary disorder.
oophorect	Surgical removal of an ovary (also called ovariectomy).

salpingitis	Inflammation of the fallopian tubes.
follicle stimulating hormone	Hormone essential for reproduction that stimulates the gonads in females and males.
follicle-stimulating hormone	Follicle stimulating hormone.
FSH	Follicle stimulating hormone.
luteinizing hormone	Hormone essential for reproduction that stimulates the gonads in females and males.
_LH	Luteinizing hormone.
estradiol	Type of estrogen.
estriol	Type of estrogen.
gamet	Cell involved in sexual reproduction containing one copy of each chromosome.
Review on a case-by-case basis	Selected records that focus on breast cancer or reproductive cancers and records that include any male-oriented text strings.

5. INFERTILITY

Keywords (Text Strings)	**Notes**
fertil	
fecundity	Potential reproductive capacity of an organism or population.
sperm capacitation	Process by which sperm become capable of fertilizing an ovum after reaching the fallopian tubes.
assistive reproductive	Assistive (or assisted) reproductive technology (ART) includes all fertility treatments in which both eggs and sperm are manipulated.
assisted reproductive	
IVF	In vitro fertilization, the process of uniting a human egg and sperm cell outside the body.
ICSI	Intracytoplasmic sperm injection.
polycystic ovar	Polycystic ovary syndrome is an endocrine disorder causing infertility (also called Stein-Leventhal syndrome).
PCOS	Polycystic ovary syndrome.
clomiphene	Fertility drug used to stimulate ovulation.
Review on a case-by-case basis	Selected records that include any male-oriented text strings.

K. SUBSTANCE ABUSE

High-priority women's health topics involving substance abuse:

1. Tobacco Use
2. Illegal Drug Use/Abuse
3. Alcohol Use/Abuse

1. TOBACCO USE

Keywords (Text Strings)	Notes
smok	**Rule out** studies involving only non-smokers.
tobacco	
nicotine	
cigarette	
cigar	
snuff	
Additional selection criteria	Records must also include at least one female-oriented text string.
Rule out	Selected studies involving marijuana (text strings = marijuana, cannabi, THC_).
Review on a case-by-case basis	Selected records that focus on alcohol or illegal drug use (text strings = alcohol, drug_abuse) and records that include any male-oriented text strings.

2. ILLEGAL DRUG USE/ABUSE

Keywords (Text Strings)	Notes
drug abuse	
drug use	
drug dependen	
illegal drug	
illicit drug	
intravenous drug	
substance abuse	
addict	
IVDU	Intravenous drug user.
IVDA	Intravenous drug abuser.
IDU	Intravenous drug user.
_IDUs	Intravenous drug users.
cocaine	
crack	
heroin	

opioid	
opiate	
opium	
hallucinogen	
PCP	
phencyclidine	PCP.
LSD	
lysergic	LSD (lysergic acid).
methamphetamine	
MDMA	Methylenedioxymethamphetamine (also called Ecstasy).
methadone	Maintenance treatment for recovering drug addicts.
marijuana	
cannabi	
hashish	
THC_	Tetrahydrocannabinol, the major psychoactive constituent of marijuana.
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that focus on alcohol use or smoking (text strings = alcohol, smok, tobacco, nicotine) and records that include any male-oriented text strings.

3. ALCOHOL USE/ABUSE

Keywords (Text Strings)	**Notes**
alcohol	
drinking	**Rule out** text string = drinking water.
ethanol	Specific alcohol found in intoxicating beverages.
ETOH	Ethanol.
acetaldehyde	Metabolite of alcohol.
sobriety	
FAS	Fetal alcohol syndrome. **Rule out** text strings = fatty acid, cancer (the fas ligand is a biomarker of cancer).
Korsakoff	Korsakoff's syndrome is an alcoholic psychosis caused by thiamine deficiency.
acamprosate	Treatment for recovering alcoholics.
disulfiram	Aversive treatment for recovering alcoholics (also called antabuse).
Additional selection criteria	Records must also include at least one female-oriented text string.
Review on a case-by-case basis	Selected records that focus on illegal drug use or smoking (text strings = drug_abuse, smok, tobacco, nicotine) and records that include any male-oriented text strings.

APPENDIX F

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