Feasibility Study
for Conducting an

EVALUATION OF ORWH'S FIRST TEN YEARS

Submitted to the

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

by

Carlyn Consulting

December 2001

Introduction

The Office of Research on Women's Health (ORWH), a component of the National Institutes of Health (NIH), is seeking NIH One Percent Evaluation Set-Aside funds to conduct an outcome evaluation of ORWH's achievements during its first ten years (FY 1991 - 2000). The following proposal for the outcome evaluation incorporates the results of a phase 1 feasibility study that was initiated by ORWH to determine the optimal design for the phase 2 evaluation. The feasibility study was conducted from June to December, 2001 by Dr. Marcia Carlyn, an independent consultant with expertise in program evaluation.

A major component of the feasibility study was the development of a conceptual framework to illustrate how the ORWH was intended to work during its first ten years (see Exhibit 1). Specifically, the framework shows how funding and other resources provided by ORWH and the various NIH Institutes and Centers (ICs), in conjunction with specific ORWH activities conducted during this period, were expected to influence the achievement of the program's intermediate and long-term goals. In addition to the conceptual framework, the feasibility study produced the following products:

- A set of five study questions to be answered as part of the evaluation.
- An operational definition for each key variable identified in the conceptual framework.
- Recommended data sources for obtaining information on the key variables, most of which involve archival data that was previously collected for other purposes.
- For each intermediate and long-term goal, the recommended performance period, baseline period, and a specific performance target for the ten-year period.
- Recommended data collection and data analysis strategies to be used in answering each study question.
- A list of ORWH's 35 highest priority research areas during its first ten years, based on an analysis of the 1991 NIH Research Agenda for Women's Health.
- Recommended report formats for showing the results of the evaluation.

Additional information regarding each of these products is presented in the present proposal. The proposal has been written in the format recommended by the *NIH Program Evaluation Guide: How to Develop a Proposal for One Percent Evaluation Set-Aside Funding*.

Section 1:
Program to be Evaluated

Overview of ORWH

The Office of Research on Women's Health was established in September 1990 within the Office of the Director, NIH, to serve as the focal point for women's health research at NIH, working in collaboration with the various NIH Institutes and Centers (ICs). ORWH was given a broad mission that included:

- Promoting research related to diseases, disorders, and conditions that affect women;
- Ensuring that women are appropriately included as subjects in biomedical and behavioral research studies supported by NIH;
- Developing opportunities and support for recruitment, retention, reentry, and advancement of women in biomedical careers; and
- Advising the NIH Director and staff on matters relating to research on women's health.

In 1993, ORWH was legislatively mandated by Congress as part of the NIH Revitalization Act of 1993 (Public Law 103-43), with directives that intensified ORWH's leadership role in identifying and promoting research on women's health.

Like other offices within the Office of the Director, ORWH cannot fund research studies directly but rather provides funds through the various ICs. Although ORWH is a small program, both its budget and full-time-equivalent personnel (FTEs) have grown substantially since its inception at the end of FY 1990. Specifically, ORWH's annual budget has increased from an average of $5.9 million in FY 1991-1992 to an average of $20.1 million in FY 1999-2000. Also, ORWH's staff has also increased from an average of 7.0 FTEs in FY 1991-1992 to an average of 15.0 FTEs in FY 1999-2000. These resources, along with resources provided by the various ICs to enhance research on women's health, have been instrumental in helping the Office pursue its mission.

Major Activities

The feasibility study revealed that ORWH focused primarily on the following six types of program activities during its first ten years:

- Interacting with scientists, professional organizations, and advocacy groups to exchange information on issues related to women's health research.
- Developing a research agenda on women's health for the NIH community.
- Collaborating with ICs to promote women's health research and career opportunities.
- Funding and co-funding NIH initiatives related to women's health research and career development for women scientists.

- Overseeing implementation of the NIH policy on the inclusion of women and minorities in study populations.
- Promoting women's health research through professional and public presentations, dissemination of information, and events co-sponsored with other organizations.

Program Goals

The feasibility study also revealed that ORWH focused on achieving seven intermediate goals and six long-term goals during its first ten years. The following intermediate goals served as early indicators of program performance:

- More NIH initiatives encouraging women's health research.
- More NIH-sponsored workshops, seminars, and conferences on issues related to women's health research.
- Increased NIH funding and staff allocated to women's health issues.
- More NIH grant applications to conduct women's health research.
- More NIH programs to help women overcome barriers to pursuing careers as research scientists.
- More NIH publications highlighting research findings, career opportunities, and other women's health issues.
- More collaborations between NIH and other organizations to promote women's health research and career opportunities.

Although several of these intermediate goals involve output measures (such as the number of workshops held or publications produced per year), they are considered to be outcome goals rather than process goals because they are broader than the program itself and reflect ORWH's success in affecting NIH as a whole.

The following long-term outcome goals served as ultimate measures of ORWH's performance during its first ten years:

- More NIH-sponsored research studies on women's health issues in high-priority areas.
- More women applying for NIH research grants.
- High percentage of the participants in ORWH career development programs becoming independent research scientists.
- Increased awareness in the scientific community of the importance of women's health research.
- Increased commitment to women's health research by academic institutions.
- Establishment of comprehensive guidelines and procedures for implementing the NIH policy on the inclusion of women and minorities in study populations.

The five study questions to be answered during the phase 2 evaluation address ORWH's implementation of its major activities and the extent to which the Office achieved its intermediate and long-term goals.

Section 2:
Need for an Evaluation

Type of Evaluation and Primary Purpose

A comprehensive outcome evaluation is proposed, with a primary purpose of determining the extent to which ORWH achieved its intermediate and long-term goals during its first ten years (FY 1991 - 2000). The evaluation will also include elements of a process evaluation since program operations involving six types of ORWH activities will be examined. Five study questions will be answered, which are presented in Section 3. As mentioned in the Introduction, a feasibility study (phase 1) was conducted to determine the optimal design for the outcome evaluation (phase 2).

Use of Results

The evaluation results will be used primarily by ORWH program administrators to assess the extent to which the Office achieved its goals during its first decade, identify program characteristics that are related to success, and obtain key data for tracking ORWH's future progress. It is anticipated that the methodology and results of the Evaluation of ORWH's First Ten Years will also be useful to high-level IC administrators, IC planning and evaluation officers, and members of other government agencies and organizations interested in promoting research in a particular area and/or evaluating program success.

Review of the Literature

The feasibility study included a review of the literature, which focused primarily on the following reports published by ORWH:

- *Report of the National Institutes of Health: Opportunities for Research on Women's Health* (research agenda developed at the ORWH-sponsored Hunt Valley conference held in September 1991, which included recommendations from a two-day public hearing held at NIH).
- *Agenda for Research on Women's Health for the 21st Century* (research agenda developed at a series of ORWH-sponsored workshops culminating in the Beyond Hunt Valley conference held in November 1997).
- *Women in Biomedical Careers: Dynamics of Change* (report of an ORWH workshop held in June 1992).
- *NIH Support for Research on Women's and Men's Health Issues (FY 1988-1990, FY 1991-1992).*
- Biennial *Report of the Office of Research on Women's Health (FY 1993-1994, FY 1995-1996, FY 1997-1998)*, which includes NIH support for research on women's health issues during each period.

The literature review revealed that the following 14 major research areas have been used by the U.S. Department of Health and Human Services (DHHS) since FY 1993 to define the funding that NIH and other Public Health Service (PHS) agencies have invested each year in health research specific to women, men, and both:

- Cancer
- Cardiovascular and Pulmonary
- Reproductive and Maternal, Child, and Adolescent Health
- Aging
- Metabolism and Endocrinology
- Substance Abuse
- Behavioral Studies and Programs
- Mental Health
- Infectious Diseases
- Immune Disorders
- Neurologic, Muscular, and Bone
- Opthalmic, Otolaryngologic, and Oral Health
- Health Effects of the Environment
- Crosscutting Categories and Special Initiatives.

There are a total of 122 research topics (budget categories) within these broad research areas. Given the standardization of the reporting procedures and longitudinal nature of the data, a conclusion of the feasibility study was that the DHHS-NIH research budget categories should be used in defining women's health research for the Evaluation of ORWH's First Ten Years.

As part of the literature review, a detailed analysis was conducted of the research agendas recommended by the participants at the 1991 Hunt Valley conference and the 1997 Beyond Hunt Valley conference, two major events that were organized by ORWH to develop and update a comprehensive research agenda on women's health for the NIH community. Several differences were found between the two agendas, but the differences were not dramatic. Because the second agenda was not broadly disseminated until 1999, a conclusion of the feasibility study was to use the 1991 research agenda for the ORWH evaluation, defining high-priority women's health issues as the 35 research topics that were recommended most often by the Hunt Valley conference participants (see Exhibit 2). Each of these topics was recommended by at least two of the ten working groups at the conference.

Timeliness of the Evaluation

In the fall of 2000, ORWH celebrated its 10^{th} anniversary. During its first ten years, the Office focused on getting organized, defining its primary goals, and using a variety of strategies to help achieve its goals. During this period, there was no formal evaluation of ORWH's progress in meeting its goals. Given the tenure of the Office and the continuing strong interest in research on women's health, the need for a comprehensive outcome evaluation was clear. In addition to assessing the Office's achievements during its first decade, the Evaluation of ORWH's First Ten Years is expected to be instrumental in enhancing ORWH's future strategic planning.

Section 3:
Evaluation Design

Conceptual Framework

As mentioned in the Introduction, the feasibility study included the development of a conceptual framework to illustrate how the ORWH was intended to work during its first ten years (see Exhibit 1). Specifically, the framework shows how ORWH and IC resources, in conjunction with the major activities conducted by ORWH during this period, were expected to influence the achievement of the program's intermediate and long-term goals.

Study Questions

The Evaluation of ORWH's First Ten Years will answer five broad study questions:

1. What were ORWH's major activities during its first ten years and how were they implemented?
2. To what extent were ORWH's intermediate goals achieved during its first ten years?
3. To what extent were ORWH's long-term goals achieved during its first ten years?
4. Which areas of NIH-sponsored women's health research grew the fastest during the ten-year period? Why did they advance more rapidly than other areas?
5. Which NIH Institutes and Centers were most successful in supporting the development of women's health research during the ten-year period?

The first three study questions focus on the major groups of variables in the conceptual framework, and the last two questions involve more detailed analyses of the most important long-term goal (achieving more NIH-sponsored research studies on women's health issues in high-priority areas). Unlike many program evaluations, the set of study questions for the ORWH evaluation will require analyses of a variety of individuals and objects (e.g., grant applicants, research studies, publications, collaborations) rather than a particular target population.

Key Variables

To answer the study questions, data will be collected for each of the 24 key variables shown in the conceptual framework (see Exhibit 1). The variables are categorized as follows:

- ORWH resources (2 variables).
- IC resources (3 variables).
- ORWH activities (6 variables).
- Intermediate goals (7 variables).
- Long-term goals (6 variables).

Detailed information on each of the key variables is presented in Exhibit 3, including the variable's operational definition, the performance period(s) for which data will be collected, and

recommended data sources for collecting information on the variable. Most of the intermediate and long-term goals will be assessed by comparing performance during FY 1999-2000 with baseline performance during FY 1989-1990 (prior to the establishment of ORWH). ORWH's performance target for each of the goals is also shown in Exhibit 3.

Section 4:
Data Collection and Analysis

Data Sources

A variety of potential data sources were examined during the feasibility study for each of the variables in the conceptual framework. Nearly all of the data sources selected for the ORWH evaluation were archival in nature, involving data previously collected for other purposes. The data sources judged to be most appropriate and feasible for the evaluation are specified in Exhibit 3.

Data Collection Strategies

Three strategies will be used to collect archival data:

- Document reviews;
- Website reviews; and
- Database extraction (e.g., extracting data from the CRISP system, Consolidated Grant Applicant File, Science Citation Index).

After the bulk of the information has been gathered using secondary data sources, additional data may be collected for some of the variables through informal in-person and telephone discussions (and possibly short e-mail communications) with the ORWH Director, ORWH staff, other NIH staff, and a few participants in the ORWH Reentry Program. Because no new data collection instruments are needed and no more than nine program participants will be contacted, OMB clearance will not be required.

The two primary databases from which data will be extracted are the Computer Retrieval of Information on Scientific Projects (CRISP) system and the Consolidated Grant Applicant File (CGAF). CRISP is a biomedical database system containing information on 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 principal investigators (PIs) working at universities, hospitals, and other research institutions. The CGAF is a data file containing records for all individuals who have applied for grants and contracts from NIH and other PHS agencies since the grant system was first established in 1938. Each record includes information on the name of the principal investigator, the PI's sex/gender (if reported), the project title, the activity code (e.g., a specific category of extramural activity, such as an R01 research project grant or a P50 research center grant), the status of the application (funded or not funded), and the dates of review and award. The file is maintained and updated annually by QRC under a contract with NIH.

Data Integrity

Several pilot tests of specific data procedures to be used in the Evaluation of ORWH's First Ten Years were conducted during the feasibility study. In some cases, the proposed procedure was dropped after conducting the pilot, and in other cases, the procedure was found to be useful for the phase 2 evaluation. To enhance the reliability and validity of the study data, both inter-rater and intra-rater reliability checks will be conducted on different types of data collected during the evaluation.

Ethical Considerations

Participation in the project is entirely voluntary, and individual responses will be kept strictly confidential as is customary with evaluation projects of this type. The findings of the evaluation will be presented as summaries of aggregated data and the participants will not be identified by name or position. Because the CGAF is covered by the Privacy Act of 1974, authorization to use the file will be obtained from NIH before the analyses are conducted.

Data Preparation

Relevant information from the document and website reviews and the database extractions will be identified, coded (if appropriate), and entered into an evaluation database designed to summarize key data on each of the variables in the study's conceptual framework. User-friendly input screens for collecting different types of data will be designed to expedite data entry, and standard data verification procedures (such as input masks) will be developed to validate the data entered and maximize the integrity of the database.

Data Analysis

A mixed methodological design will be used for the Evaluation of ORWH's First Ten Years, employing a variety of analytical techniques to answer the five study questions. Qualitative analysis, descriptive statistics, and (where possible) inferential statistics will be used, employing 95% confidence intervals to test for significant differences between the performance measures and comparison measures (e.g., outcome vs. baseline data). Unlike many program evaluations, outcome data will also be compared to specific performance targets for each intermediate and long-term goal, an approach designed to provide a more comprehensive assessment of ORWH's achievements during its first ten years. The analytical strategies for addressing each study question are presented below.

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

During the baseline period (FY 1989-1990) there were no ORWH activities being conducted because the Office had not yet been established. Study Question 1 will therefore not involve comparison analyses. Instead, a structured content analysis of a broad range of documents will be conducted to present a detailed description of the major activities undertaken by ORWH during its first ten years (FY 1991-2000), including how they were implemented.

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

ORWH's success in achieving five of the seven intermediate goals will be analyzed using a two-step process: (1) determining as accurately as possible through document reviews the number of NIH-sponsored initiatives, workshops, programs, publications, and collaborations involving women's health research that occurred during FY 1989, 1990, 1999, and 2000; and (2) comparing the average number produced each year during the baseline period (FY 1989-1990) with the average number produced each year during the followup period (FY 1999-2000). A similar process will be used to assess ORWH's success in achieving the third intermediate goal, comparing NIH funding and staff allocated to women's health research during the baseline and followup periods.

Because the fourth intermediate goal involves NIH grant applications, an analysis of CGAF records will be conducted. Specifically, stratified random sampling will be used to identify a random sample of applications for competitive research project grants (RPGs) that were submitted to each IC during the baseline period and followup period. The analyses will be limited to the 20 ICs that were in existence during the baseline period (including NIAAA, NIDA, NIMH, and the Office of the Director). With 20 strata, the total sample size will be 2,800 grant applications; the sample size for each IC will be 140 applications (70 baseline and 70 followup applications). Weighting will be used to estimate the actual number of RPG applications involving women's health research that were received by each IC during the baseline and followup periods (with the weights based on each IC's total number of RPG applications during the respective periods). The project title of each sampled application will then be analyzed to determine if the proposed research study involved one or more of the 35 highest priority research topics in the NIH research agenda on women's health (see Exhibit 2), with the content analysis based on a protocol approved by ORWH. The number of sampled grant applications received during the baseline and followup periods that clearly focused on at least one high-priority research topic will then be calculated for each IC, and weights will be applied to assess whether the performance target was achieved for NIH as a whole.

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

ORWH's success in achieving the six long-term goals will be analyzed in a variety of ways. Specifically, the first long-term goal will involve an analysis of CRISP data. For each of the 35 highest priority research topics in the 1991 NIH research agenda on women's health, the CRISP Advanced Query Form will be used to search the database system for all relevant NIH-funded extramural research projects conducted during the baseline and followup periods. For each project identified using one or more keywords relevant to a particular research topic, the project title will be assessed (using an agreed-upon algorithm) to rule out studies that are not appropriate, including studies that focused exclusively on issues relevant to men's health (e.g., incontinence research involving subjects with prostate cancer). If it is unclear whether a particular project involved one of the high-priority research topics or whether it focused exclusively on issues relevant to men's health, the abstract for the study will be assessed to make

a final decision. The average number of extramural research projects involving high-priority women's health issues that were funded during the baseline period (FY 1989-1990) will then be compared with the average number funded during the followup period (FY 1999-2000).

Because the second, third, and fifth long-term goals involve NIH grant applications and awards, analyses of CGAF records will be conducted with an emphasis on the following CGAF variables: activity code, project title, and name and sex/gender of the principal investigator. For example, the analysis of the second goal will focus on the sex/gender of the PI of each competitive RPG application received by NIH during the baseline and followup periods. The number of grant applications submitted by female PIs during the two periods will be compared to the number submitted by male PIs during the same time periods to determine if the performance target was achieved for NIH as a whole. It is expected that the sex/gender of the PI will be reported for at least 80% of the grant applications and the findings for the present study will not be biased due to some PIs not reporting this information; these assumptions are based on the results of a 1992 study conducted for NIH by QRC, which revealed that the proportion of PIs who reported their sex/gender as "female" was very similar to the estimated proportion who chose not to report their sex/gender.

ORWH's success in achieving the fourth long-term goal will be analyzed by comparing the average number of peer-reviewed scientific journals focusing on one or more areas of women's health research during the baseline period (FY 1989-1990) with the average number during the followup period (FY 1999-2000).

For the sixth long-term goal, a qualitative analysis will be conducted to assess NIH's success in establishing comprehensive guidelines and procedures for implementing its policy on the inclusion of women and minorities in study populations. Specifically, a structured content analysis of a broad range of documents will be conducted to assess the comprehensiveness of NIH guidelines and procedures during three time periods: the baseline period (FY 1989-1990), the period immediately after NIH was directed as part of the NIH Revitalization Act of 1993 to establish inclusion guidelines (FY 1994-1995), and the followup period (FY 1999-2000).

Study Question 4: Which areas of NIH-sponsored women's health research grew the fastest during the ten-year period? Why did they advance more rapidly than other areas?

To answer the first part of Study Question 4, a more extensive CRISP database analysis will be conducted than was required for Study Question 3. Specifically, for each of the 35 highest priority research topics in the 1991 NIH research agenda on women's health, the average number of relevant extramural research projects that were funded during the baseline period (FY 1989-1990) will be compared with the average number funded during the followup period (FY 1999-2000).

To help explain why some areas of women's health research grew faster than others (the second part of Study Question 4), the types of activities conducted by ORWH and the amount of ORWH and IC resources allocated to women's health research during ORWH's first ten years will be analyzed. Congressional language directing individual ICs to address particular women's health issues will also be analyzed. The primary analytical techniques to be used in this qualitative

analysis will be pattern coding and explanation building. It is anticipated that Pearson product moment correlation coefficients will also be computed to examine the relationship between growth in specific areas of NIH-sponsored research on women's health and each of the predictor variables (ORWH activities, ORWH resources, and IC resources).

Study Question 5: Which NIH Institutes and Centers were most successful in supporting the development of women's health research during the ten-year period?

To answer this question, an additional CRISP database analysis will be conducted, with the focus on the particular IC sponsoring each identified extramural research project. Specifically, for each of the 20 ICs that were in existence during the baseline period (FY 1989-1990), the average number of research projects involving high-priority women's health issues that were funded during the baseline period will be compared with the average number funded during the followup period (FY 1999-2000).

In addition to the data analyses mentioned above, statistical tests will be performed wherever possible. It is anticipated that one-tailed t-tests, chi-square tests, Wilcoxon's signed rank test, and/or Fisher's exact test will be conducted using individual IC data as well as trans-NIH data to determine if there were statistically significant improvements with respect to particular outcome variables during ORWH's first ten years.

Section 5:
Evaluation Results

Products of the Evaluation

The results of the Evaluation of ORWH's First Ten Years will be presented to ORWH in a draft report. Following an introduction and a background section summarizing the establishment of the Office of Research on Women's Health at NIH, the findings for each of the five study questions will be described. Wherever possible, analytical results will be presented in tables and graphs designed to highlight the study's findings. Two types of graphic displays were developed during the feasibility study, both of which involved Study Question 4 (see Exhibits 4 and 5). The conclusion of the report will include recommendations for improving ORWH's program activities in the future, based on the findings of the evaluation. After the draft report has been reviewed by ORWH staff, the ORWH Advisory Committee on Research on Women's Health (ACRWH), and the NIH Coordinating Committee on Research on Women's Health (CCRWH), a final report for the evaluation will be produced.

Dissemination of Results

As mentioned in Section 2, the primary audience for the final report of the Evaluation of ORWH's First Ten Years will be ORWH program administrators who plan to use the findings to assess the extent to which the Office achieved its goals during its first decade, identify program characteristics that are related to success, and obtain key data for tracking ORWH's future progress. A draft of the final report will also be disseminated to the members of the ACRWH and CCRWH. Based on the recommendations of these key stakeholders, the results of the evaluation may be disseminated to a broader audience.

Section 6:
Project Management

Project Implementation

The Evaluation of ORWH's First Ten Years will be conducted by an independent contractor who will be selected in accordance with NIH policies. The evaluation team (i.e., the contractor and any subcontractors proposed) must have expertise in program evaluation, data management, and statistical analysis; experience using the CRISP system and the Consolidated Grant Applicant File; and in-depth knowledge of NIH as well as ORWH. In addition, it is desirable for the evaluation team to have experience conducting outcome evaluations for other NIH Institutes and/or Centers.

Advisory Committee

A formal advisory committee will not be used for the evaluation. However, a draft of the final report will be disseminated to the members of the ACRWH and CCRWH for their review and recommendations. Throughout the project, the ORWH Director of Programs and Management and an ORWH Visiting Scientist will work closely with the ORWH Director to advise the contractor with respect to any unanticipated issues that may arise and to ensure that the study is implemented as planned.

Estimated Timeline for the Evaluation

It is expected that the Evaluation of ORWH's First Ten Years will require 14 months to complete, including a one- to two-month period to obtain One Percent Evaluation Set-Aside funding and select the contractor. A proposed timeline for performing the major tasks of the evaluation is presented in Exhibit 6, which assumes that work will begin on March 1, 2002.

Section 7:
Budget Estimate

Estimated Cost

The anticipated cost of the Evaluation of ORWH's First Ten Years is $100,000, with most of the budget allocated to direct labor costs. A three-person evaluation team is envisioned, consisting of a senior evaluation expert ($100/hour), a senior programmer with extensive CGAF experience ($65/hour), and an experienced data analyst ($50/hour), with these hourly rates including fringe benefits, overhead, and other indirect costs. Because less than $100,000 in One Percent Evaluation Set-Aside funds is being requested, a detailed budget estimate has not been included in this proposal.

Anticipated Funding Sources

The anticipated funding sources for the Evaluation of ORWH's First Ten Years are summarized in the following table:

		Estimated Amount from Each Funding Source		
Fiscal Year	**Estimated Cost**	**One Percent Evaluation Set-Aside Funds**	**ORWH Funds**	**Other Funds**
FY 2002	$58,310	$58,310		
FY 2003	$41,690	$41,650	$40	
PROJECT TOTAL	$100,000	$99,960	$40	