

BUILDING INTERDISCIPLINARY RESEARCH CAREERS IN WOMEN'S HEALTH

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RFA: RFA-OD-02-001

Office of Research on Women's Health

(<http://www4.od.nih.gov/orwh/>)

National Institute on Aging

(<http://www.nia.nih.gov/>)

National Institute on Alcohol Abuse and Alcoholism

(<http://www.niaaa.nih.gov/>)

National Institute of Arthritis and Musculoskeletal and Skin Diseases

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National Institute of Child Health and Human Development

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National Institute of Dental and Craniofacial Research

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National Institute of Diabetes and Digestive and Kidney Diseases

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National Institute of Mental Health

(<http://www.nimh.nih.gov/>)

Office of Dietary Supplements

(<http://dietary-supplements.info.nih.gov/>)

Agency for Healthcare Research and Quality

(<http://www.ahrq.gov/>)

Letter of Intent Receipt Date: February 14, 2002

Application Receipt Date: March 14, 2002

THIS RFA IS A REISSUANCE OF OD-99-008.

PURPOSE

The Office of Research on Women's Health (ORWH) and cosponsors invite institutional career development award applications for Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Career Development Programs, hereafter termed "Programs." Programs will

support research career development of junior faculty members, to be known as Interdisciplinary Women's Health Research (IWHR) Scholars, who have recently completed clinical training or postdoctoral fellowships, and who are commencing basic, translational, clinical and/or health services research relevant to women's health.

The goal of this initiative is to promote the performance of research and transfer of findings that are relevant to women's health, including sex/gender similarities or differences in biology, health or disease. The Programs will accomplish this by bridging advanced training with research independence, as well as bridging professions, scientific disciplines, or areas of interest. This will increase the number and skills of investigators at awardee institutions through a mentored research and career development experience leading to an independent interdisciplinary scientific career addressing women's health.

The NIH Institutes and Centers support biomedical and behavioral research and research training. The Agency for Healthcare Research and Quality (AHRQ) supports health services research and research training. The cosponsors are partnering with ORWH to support the career development of researchers in women's health within their respective missions.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This Request for Applications (RFA) is related to one or more of the priority areas. Potential applicants may obtain "Healthy People 2010" at <http://www.health.gov/healthypeople/>.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit non-Federal organizations, public or private, such as hospitals, medical or other health professional schools, or other institutions of higher education. Foreign institutions are not eligible for this institutional career award.

Applicant institutions must have the clinical specialties and subspecialties and the clinical and research facilities sufficient to meet the purposes of the BIRCWH Program, namely, to bridge clinical or postdoctoral training with a career in interdisciplinary basic, translational, clinical and/or health services research relevant to women's health. Racial/ethnic minority individuals, persons with disabilities, and women are encouraged to apply as Principal Investigators.

Eligible institutions are those that do not have a current BIRCWH Program. A list of institutions that have received a BIRCWH award may be obtained at <http://www.nichd.nih.gov/RFA/OD-02-001/OD-02-001.htm> and from the program staff listed under INQUIRIES, below.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) Mentored Research Scientist Development Program Award (K12) mechanism. The K12 awards will be for a period of five years. The anticipated award date is September 30, 2002. Planning, direction, and execution of each component of the research and career development program will be the responsibility of the IWHR Scholar with the guidance of his or her mentor.

This RFA is a one-time solicitation. ORWH has not yet determined whether or how this program will be continued beyond the commitments expressed in the present RFA.

FUNDS AVAILABLE

ORWH and cosponsors intend to commit approximately \$4 million in total costs [direct plus Facilities and Administrative (F & A) costs] for the first year of support of the entire program. It is anticipated that up to eight awards will be made. K12 awards will be for up to \$500,000 total costs (direct plus F & A) per year, and will support a minimum of four IWHR Scholars. F & A costs for these awards are limited to eight percent of modified total direct costs. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of awards also will vary. Although the financial plans of ORWH and cosponsors provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

RESEARCH OBJECTIVES

Background

A need has been identified for expanded support for interdisciplinary research bridging the completion of training with an independent career in research addressing women's health, including sex/gender similarities or differences. Efforts to address this need were recommended in "A Report of the Task Force on the NIH Women's Health Research Agenda for the 21st Century," Volume 2, pp. 187-198, Career Issues for Women Scientists, and pp. 223-228,

Multidisciplinary Perspectives (NIH Publication 99-4386, 1999). Therefore, ORWH has as one of its priorities "facilitating research initiatives that foster multidisciplinary collaborations." Further, a recent report by the Institute of Medicine, "Exploring the Biological Contributions to Human Health: Does Sex Matter?" encouraged interdisciplinary research on sex differences. Research on sex/gender similarities or differences is a continuing priority for ORWH. Program grant awards resulting from this RFA will meet the specified needs by providing clinical, health or life sciences, or public health departments, centers, and institutes, both developing and established, an opportunity to build a national capacity for junior investigators in women's health research, including research on sex/gender differences, as well as research on factors that contribute to disparities in health status or health outcomes for different populations of women.

Investigators with established research programs covering a broad range of basic and applied biomedical and behavioral science or health services research, in the Principal Investigator's ("sponsoring") and collaborating departments, centers, or institutes, should form an inter-professional intellectual and technical research base for mentoring IWHR Scholars. Mentors from collaborating departments are encouraged to provide needed expertise and resources, as long as the emphasis of IWHR Scholars' projects is on research relevant to women's health. Projects may be basic, translational, clinical, or health services research, but must be within the biomedical and behavioral purview of NIH and/or the health services research purview of AHRQ. Health services research includes the study of the quality, appropriateness, outcomes, and effectiveness of health care services, as well as the cost, use, and access to health care services.

Research Scope

A number of research priority areas have been identified by the ORWH and cosponsors as major research goals, based in part on the "Agenda for Research on Women's Health for the 21st Century" cited above. The Programs may have one or more than one research theme, focus or emphasis, but the research activities must be responsive to this RFA. The following list should by no means be viewed as exhaustive, and is intended only to provide examples:

- o Biologic and molecular bases of sex/gender similarities or differences in health or disease.

- o Prevention research, in particular, the biological, behavioral and cultural influences on risk and lifestyle changes, including nutrition and exercise; addictive behavior including alcohol, drugs, and tobacco; obesity, eating disorders, type 2 diabetes; cardiovascular diseases; cancer; and sexually transmitted diseases.

- o Change across the lifespan as a central factor in women's biological and psychosocial health, functioning, and choices of and effectiveness of treatment. Chronic diseases, including those of aging, such as osteoporosis, arthritis, degenerative joint disease, cardiovascular disease, diabetes, or Alzheimer's and other neurodegenerative diseases, that result in disabilities; quality of life in women with chronic diseases, including cancer; changes in neural functions impacting cognition; alterations in sleep.

- o Pharmacokinetics, pharmacodynamics, and pharmacogenetics, including hormone and drug interaction, in drug-drug interactions, drug-supplement interactions, and in pharmacokinetics and pharmacodynamics during pregnancy.

- o Eliminating health disparities, including understanding and targeting the biological or psychosocial origins of the variable burden of disease, disability, and mortality among people belonging to different ethnic and racial groups and other populations with disparate health status, living in different parts of the United States, experiencing different socioeconomic status, and engaging in different patterns of behavior.

- o Oral health research, including sex/gender differences in oral disorders or diseases, linkages between oral disease and systemic diseases, or in treatment outcomes. Included is research on effects of oral infections, such as periodontal diseases, on pregnancy outcomes and on disorders of the temporomandibular joint (TMJ), involving orofacial pain and tenderness localized to the masticatory muscles or the TMJ.

- o Developmental biology of the vascular system and role of the fetal environment in programming lifelong cardiovascular function. Molecular and physiological mechanisms of hormone action in the cardiovascular system. Cardiovascular complications of diabetes and obesity. Prevention, detection, and management of cardiovascular disease in high-risk populations, such as octogenarian and older women from racial and ethnic minorities. Impact of patient and health care professional behaviors on cardiovascular disease developments and prevention in women.

- o Health services research on the outcomes, effectiveness, and cost-effectiveness of prevention and clinical treatment approaches. Research on the quality, outcomes or access to health care services among racial and ethnic minorities and other populations with disparate health status. Development of gender-based models of prevention and treatment services.

o Antecedents and consequences of women's multiple roles across the lifespan (e.g., family, work, care giving, and volunteer roles). The influence of economics and competing roles on health behaviors and health outcomes. Survivorship issues including treatment effects on sexual function and fertility.

o Natural history of menopause and its endocrinological, biological, psychosocial, cultural, lifestyle, and environmental determinants, concomitants, and/or sequelae; role of menopause in the chronic diseases of aging; menopause-related pathophysiology; effects of hormone replacement therapy and/or selective estrogen receptor modulators as preventives and their potential role in cancer etiology; and the development of new strategies, including dietary supplements and complementary and alternative medicine, for alleviating the short-term, clinical problems of the peri- and postmenopausal periods and the prevention of menopause-related diseases of old age.

o Multidisciplinary basic, translational, behavioral, and clinical research relevant to women's health, especially on conditions, such as chronic fatigue syndrome, chronic pain, or autoimmune diseases, which may be chronic and/or multi-systemic.

o Influence of toxic environmental factors on women's health. Examples include, but are not limited to, role of gender in biologic response, metabolism and disease patterns resulting from exposure to toxic agents found in the environment, including products used by women; action of environmental estrogenic compounds; biomarkers of exposure and disease in women; gene-environmental interactions, such as environmental exposures, diet, and environmental tobacco smoke, in diseases that particularly impact women; differences in susceptibility to environmental carcinogens; critical exposure windows during sexual development and aging; role of maternal exposure to toxicants in fetal development, disease, and pregnancy outcomes.

o Allergic, immune, and autoimmune diseases, in particular, resistance/susceptibility genes, environmental influences, mechanisms of sex/gender differences, immunological mechanisms, target organ influence, role of innate immunity, development of surrogate markers, and immune therapy.

o Neurological diseases, in particular, the influence of sex/gender differences, the effect of life events such as pregnancy and menopause on neurological disease, the roles of hormonal, genetic, or environmental factors in etiologies and outcomes of neurological diseases, and development of animal models. Sex/gender differences in acute and chronic pain conditions or syndromes, the perception of pain, and analgesic response.

- o Kidney disorders including the impact of pregnancy, diabetes, and hypertension on renal function; preeclampsia; causes of altered renal hemodynamics during pregnancy; sex/gender differences in renal transplantation, dialysis, and acute renal failure; mechanisms of analgesic nephropathy; effect of hormones and the menstrual cycle on renal function and drug pharmacokinetics; and the effect of collagen vascular diseases on the kidney.

- o Urologic and urogynecologic disorders including recurrent and chronic urinary tract infections; vesicoureteral reflux during pregnancy; effect of hormones on bladder function; interstitial cystitis; pelvic floor disorders encompassing genital prolapse and consequent urinary incontinence; sexual dysfunction; impact of bladder physiology of childbirth, exercise, diet, obesity, and hormone deficiency; and outcome measures for surgical, medical, and behavioral treatment of urinary incontinence, diabetes and bladder dysfunction.

- o Gastrointestinal and digestive health and diseases, including the effect of hormones and the menstrual cycle on the digestive system; irritable bowel syndrome; functional bowel disorders and gut motility.

- o Obstetrical issues, including low birth weight infants, effects of infectious, inflammatory, and other disease manifestations and treatments during pregnancy; prevention, diagnosis, and management of pregnancy complications, including fetal loss and neural tube defects.

- o Gynecological issues, including reducing morbidity and mortality from leiomyoma, endometriosis, abnormal uterine bleeding, uterine prolapse, polycystic ovarian syndrome, HPV-associated neoplasia, epithelial ovarian cancer and endometrial adenocarcinoma, and other gynecologic diseases. Promoting increased safety and acceptability of contraceptive options.

- o Addiction and mental health, in particular, the biological and behavioral risk factors, including sex/gender differences, in the development of addictive behaviors, schizophrenia, mood, anxiety, and eating disorders. Adverse health consequences of alcohol and tobacco, licit and illicit drug use, addiction, trauma, and abuse, including the role of sex/gender differences, and interactions with HIV/AIDS and cancer.

SPECIAL REQUIREMENTS

A. IWHR Scholars: The Scholar position is a junior faculty appointment, not a fellowship. At the time of the award, candidates for support as IWHR Scholars must: (1) have a clinical doctorate

or Ph.D. degree or its equivalent; (2) have completed any postgraduate training normally expected for a faculty appointment in their field (including clinical or postdoctoral fellowship training, or residency if they have chosen not to subspecialize); (3) identify a mentor with extensive research experience; (4) be able to spend at least of 75 percent of full-time professional effort conducting research and research career development; (5) not be or have been a Principal Investigator on an R01, R29 or subproject of a Program Project (P01), Center (P50, P60, U54) grant, mentored career development (K-series) grants, or other equivalent research grant awards; and (6) be a U.S. citizen or noncitizen national, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-155) or some other verification of legal admission as a permanent citizen. Individuals on temporary or student visas are not eligible.

Clinical doctorate degrees include, but are not limited to, the M.D., D.O., D.D.S., D.M.D., O.D., D.C., Pharm.D., N.D. (Doctor of Naturopathy), as well as nurses with doctoral degrees. In addition, other clinicians holding doctoral degrees may be eligible. Completion of clinical subspecialty training is not required of candidates in general practice in their specialty; however, those who choose to subspecialize must have completed their fellowships. In order to accommodate the needs of those interested in participating in this program who may have had a career hiatus because of family responsibilities, uniformed service, etc., there is no limit on time elapsed since completion of training. However, Scholars cannot have more than six years of research training experience beyond their last doctoral degree. Support is in the form of a minimum of two consecutive 12-month appointments, renewable in annual increments for up to five years total, and is contingent upon satisfactory progress as reported to the Advisory Committee and to NIH in the annual progress report of the Program. IWHR Scholars may not accept or hold any other PHS award that duplicates the provisions of this career award. Programs are encouraged to recruit members of underrepresented minorities, women, and candidates with disabilities. During the period of this award, IWHR Scholars are encouraged to apply for, and may accept and hold, independent research grant support.

B. Program Composition: Applicants must describe or propose an interdisciplinary career development program that will maximize the use of relevant research and educational resources to foster education, training, mentoring, and professional development of scholars, including women and minorities, in biomedical careers. The Program must have a strong research base, comprising the investigations of established scientists who will provide expertise, resources, and mentoring to the IWHR Scholars. The research base must be broad and relevant to current areas of research interest and need in women's health. The environment should be one that will stimulate and increase the interactions among disciplines, which may include basic, clinical,

social, and population sciences. Of major importance, the Program must have a scientifically sound and equitable procedure for recruiting and selecting IWHR Scholars and projects to be supported. There must be documented evidence of an institutional commitment to support the Program's human and tangible resources and its goal of developing and retaining productive, independent investigators in areas of women's health concerns. There should be a plan for ongoing evaluation of the Program in terms of recruitment and retention goals, including for women and minorities, completion success, overall outcome, the curriculum, and program staff. For purposes of evaluating the impact of research career development programs, awardees must agree to provide ORWH with information on career outcomes for those appointed to the program. The Principal Investigator will supply this information at least annually. There should be a plan for periodic research meetings and networking for all Scholars and mentors. The ORWH will hold an annual meeting for Scholars and relevant program personnel at the NIH.

C. Principal Investigator: The Principal Investigator of a Program must be a senior faculty member such as Dean, Department Chair, or Director of a research center or interdisciplinary institute. He/she should possess the scientific background, leadership, and administrative capabilities required to coordinate and supervise a multidisciplinary research and development program of this scope. As an option, the application may request a co-investigator to serve as the Program Director, with responsibility for some or all of the day-to-day operations of the Program. The Program Director should be an experienced investigator and have experience and qualifications complementing those of the Principal Investigator.

D. Career Development Program: The K12 award provides five years of funding for the Program. The Program will support IWHR Scholars for periods of two to five years consisting of consecutive 12-month appointments. The program may be divided into two distinct phases if appropriate -- a basic and/or clinical science-training component and an intensive research experience under the general guidance of a qualified mentor. At least 75 percent of the IWHR Scholar's full-time professional effort must be devoted to the K12 program per se. The remainder of the recipient IWHR Scholar's time may be devoted to developing other clinical or academic pursuits consonant with the objectives of the award. The 75 percent minimum effort in this program is intended to be primarily devoted to research; however, Scholars may, as needed, receive formal didactic coursework to support their career development, which may include, for example, biostatistics, epidemiology, health economics, clinical evaluation sciences, and clinical trials.

E. Advisory Committee: The Advisory Committee will be a group of scientists from the sponsoring department, and other departments or institutions as appropriate, with interests

relevant to the Program's research programs. It may include mentors. The two major functions of the committee are to evaluate: 1) applications from IWHR Scholar candidates, and 2) the overall conduct of the Program. Specifically, the committee makes recommendations to the Principal Investigator as to IWHR Scholar appointments, evaluates ongoing research activities annually (including the interaction and integrated nature of the Scholars' research experience), makes recommendations regarding their continuation, and makes recommendations to the Principal Investigator regarding priorities for use of the Resource Laboratory, if applicable. The committee may use institutional or outside consultants if needed. Plans to include members or consultants from outside institutions may be described, but such individuals should not be named. The committee is a formal part of the structure of the Program. It should meet regularly, and keep written minutes, which may be reviewed as part of a competing or noncompeting application. In addition, an annual evaluation by the Advisory Committee is recommended.

F. Institutional Environment: Applicant institutions should show commitment to the Program's goals, and provide assurances that the institution intends the Program and the supported IWHR Scholars to be an integral part of its research endeavor. Research facilities and training opportunities will be a critical part of the environment. Applicant institutions should provide a guarantee of 75 percent protected time for the IWHR Scholars for research. As part of its commitment to support women's health research, the applicant institution may choose internally to designate the Program as a Center, supported in part by the K12 Program award. Applicant institutions should demonstrate commitment to recruitment and retention of racial and ethnic minorities and individuals with disabilities by collaborating with less research intensive and minority institutions.

G. Mentors: Each IWHR Scholar appointed under the K12 award must have a primary sponsor who is recognized as an independent investigator and who is actively involved in basic, translational, clinical, and/or health services research relevant to this initiative, and who has a successful record of providing research training of a type expected in this Program. An assigned mentor will provide guidance for the development of each IWHR Scholar assigned to the program. The mentor must be committed to continue this involvement throughout the IWHR Scholar's total period of development under the award.

H. Resource Laboratory: The laboratory resources of the Program comprise the research laboratories of the established investigators serving as mentors, as well as a shared resource laboratory to be utilized by the mentors and the IWHR Scholars whose activities they will supervise. With strong justification, a shared Resource Laboratory may be requested as part of the Program, within the total budget. Such a resource would provide skilled technical services to

complement and extend the capabilities of the mentors to promote the career development of the IWHR Scholars. The shared Resource Laboratory might include scientific services such as, but not limited to, assays, molecular biology or biostatistics. Requests for this Resource Laboratory must be justified in terms of cost-effective enhancement of the research resources that will serve at least four IWHR Scholars' projects. The laboratories of the mentors are not supported directly by the K12 grant. The Resource Laboratory, if any, must be a new entity, not an extension or enhancement of an existing facility. The award may support professional direction of the Resource Laboratory, up to 50 percent effort, as well as technical assistance, supplies, equipment, and appropriate costs of operation. Institutional commitment to the shared Resource Laboratory must be demonstrated, and may take the form of providing or renovating space, purchase of required equipment, and/or support of personnel. The Principal Investigator, Program Director and Resource Laboratory Director are responsible for efficient and equitable utilization of the Resource Laboratory on the basis of recommendations from the Advisory Committee.

I. Allowable Costs:

1. The Program structure may have these elements:

a) Administration: Salary and fringe benefits for the Program Director, if any, up to 10 percent effort, as well as a part-time secretary, may be requested. No compensation may be requested for the Principal Investigator. Travel to an annual Directors' meeting for the Principal Investigator and the Program Director, as well as travel to an annual meeting for current Scholars, both at NIH, must be requested. Travel must also be requested for one additional training or scientific meeting per year for current Scholars.

b) Resource Laboratory: Budgets may include salaries and fringe benefits for a Resource Laboratory Director (up to 50 percent), other technical staff, supplies, animals, equipment purchase and maintenance. The sum of the budgets for Administration and a Resource Laboratory may not exceed \$100,000 total costs per year.

c) Facilities and Administrative costs: Facilities and Administrative (formerly, indirect) costs will be reimbursed at eight percent of modified total direct costs, or at the actual Facilities and Administrative cost rate, whichever is less.

2. As part of the Program budget, an application must request a minimum of four IWHR Scholar positions, at least half of which must be for individuals with a clinical doctoral degree as defined

above in Section A. Applications requesting more than four positions may designate up to half the total number for candidates with a non-clinical doctoral degree. New Scholar appointments will have start dates of July 1 and January 1.

a) Salary: The NIH will provide support for each IWHR Scholar position up to \$100,000 total costs per year, toward salary, fringe benefits, and research costs. The institution may supplement the NIH salary contribution up to a level that is consistent with the institution's salary scale; however, supplementation may not be from Federal funds unless specifically authorized by the Federal program from which such funds are derived. In no case may PHS funds be used for salary supplementation. Institutional supplementation of salary must not require extra duties or responsibilities that would interfere with the purpose of the Program.

The total salary requested for each IWHR Scholar must be based on a full-time, 12-month staff appointment. It must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

b) Research Development Support: Within each IWHR Scholar's total award, grant funds may be used toward the following expenses: (1) salary as above; (2) tuition, fees, and books related to career development; (3) research expenses, such as supplies, equipment, and technical personnel; (4) travel to one training or scientific meeting per year, in addition to the annual NIH meeting for Scholars; (5) statistical services including personnel and computer time; and other project infrastructure including relevant data sets.

Grant funds may not be requested for the following: Compensation for the Principal Investigator or mentors; direct support of the mentors' laboratories; compensation of administrative personnel normally paid from institutional overhead charges; administrative activities such as public relations, or health or educational services; travel of the Principal Investigator, Program Director or mentors to scientific meetings; costs of clinical care; and alterations and renovations.

J. Evaluation: In carrying out its stewardship of human resource-related programs, the NIH may begin requesting information essential to an assessment of the effectiveness of this Program. Accordingly, awardee institutions are hereby notified that IWHR Scholars may be contacted after the completion of their career development experiences for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and

awards, professional activities, and other information helpful in evaluating the impact of the program.

K. Other Income: Fees resulting from clinical practice, professional consultation, or other comparable activities required by the research and research-related activities of this award may not be retained by the candidate. Such fees must be assigned to the grantee institution for disposition by any of the following methods:

The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefit payments must be within the established policies of the grantee institution.

The funds may be used for health-related research purposes.

The funds may be paid to miscellaneous receipts of the U.S. Treasury. Checks should be made payable to the Department of Health and Human Services, NIH, and forwarded to the Director, Division of Financial Management, NIH, Bethesda, Maryland 20892. Checks must identify the relevant award account and reason for the payment.

Program personnel supported by the K12 award may retain royalties and fees for activities such as scholarly writing, service on advisory groups, or honoraria from other institutions for lectures or seminars, provided these activities remain incidental and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

Usually, funds budgeted in an NIH- or AHRQ-supported research or training grant for the salaries or fringe benefits of individuals, but freed as a result of a career award, may not be rebudgeted. An institute will give consideration to approval for use of released funds only under unusual circumstances. Any proposed retention of funds released as a result of an NIH or AHRQ career award must receive prior written approval of the institute-awarding component.

L. Special Leave: Candidates appointed to this program career award may engage in research experiences at another institution, including a foreign site, if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed three months. For longer periods, prior written approval of the awarding component is required. To obtain prior approval, the Principal Investigator must submit a letter describing the plan, countersigned by the appropriate institutional official, to the awarding component. A copy of a letter or other evidence

from the performing institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the career award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the PHS funding component and will be granted only in an unusual situation. Support from other sources is permissible during the period of leave. Such leave does not reduce the total number of months of program support for which an individual is eligible. Parental leave will be granted consistent with the policies of the NIH and the grantee institution.

M. Termination: The Director of the NIH may discontinue a Program award upon determination that the purpose or terms of the award are not being fulfilled. For a Program co-funded by AHRQ, any such determination would encompass the recommendation of the Administrator of AHRQ. In the event, an award is terminated, the Director of the NIH shall notify the grantee institution in writing of this determination, the reasons therefor, the effective date, and the right to appeal the decision.

A final progress report, invention statement, and Financial Status Report are required upon termination or relinquishment of an award.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>);

a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and

updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>.

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

URLS IN NIH GRANT APPLICATIONS AND APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000, at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed Program, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of this RFA. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent to Dr. Estella Parrott at the address listed under INQUIRIES, below, by February 14, 2002.

APPLICATION PROCEDURES

Prospective applicants are strongly encouraged to contact program staff at the address listed under INQUIRIES early in the planning phase, to ensure that applications are responsive to the goals of this initiative.

The PHS 398 research grant application instructions and forms (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> must be used in applying for these grants. This version of the PHS 398 is available in an interactive, searchable format. For further assistance contact GrantsInfo, Telephone 301-435-0714, Email: GrantsInfo@nih.gov.

Application Instructions

All application instructions accompanying the PHS 398 (rev 5/2001) are to be followed, except for those items modified below. Page limitations on research project grant applications, as stated in the guidelines and instructions for PHS Form 398, do not apply to these K12 applications, although applicants are encouraged to be concise. Applicants should ensure that all materials directly applicable to the review criteria (see below) are included in the body of the application, not in an appendix. The Modular Grant Application and Award procedures DO NOT APPLY.

The application must use the "Research Career Award" (RCA) section of the PHS 398. The table of contents for the RCA should be followed, except for those items modified under Sections I and II.

The abstract should summarize the actual proposal, including the candidate pool, research topics, goal of the program regarding career development and the environment.

Section I - Basic Administrative Data:

Include all the information requested in this RCA section.

List as "Key Personnel" the Principal Investigator, Program Director, if any, Resource Laboratory Director, if any, and mentors. Do not list Advisory Committee members unless they are also mentors.

Budget requests must be provided according to the instructions in form PHS 398. A composite page 4 for the entire Program budget request should be followed by one page 4 for the Scholars' costs and one page 4 for Administration and shared Resource Laboratory (if applicable) costs. Provide page 5 for the composite only. The requests for tuition and fees, books, travel, research development expenses, etc., must be justified and specified by category.

Provide a Biographical Sketch and Other Support pages for all Key Personnel.

Section II - Specialized Information:

Make the following modifications in this RCA section.

The section should begin with an overview of the proposed Program including its interdisciplinary character.

(1) **The Candidate:** Describe in general terms the pool of potential candidates including information about the types of prior clinical and research training. Do not name prospective Scholars. Describe the criteria to be used for candidate evaluation for selection as IWHR Scholars. Describe plans to recruit candidates, including those from racial or ethnic groups that are currently underrepresented in biomedical, behavioral, or clinical sciences.

(2) **Statement by Sponsor:** Summarize the immediate and long-term career objectives of the Program, explaining how the Program will contribute to their attainment. Describe the career development plans for prospective candidates. Considering the Program goals and the likely goals of prospective candidates, describe a plan to provide the necessary research background and experiences, considering the expected range of prior research training in the applicant pool. For example, candidates with little previous research experience may require a phased developmental period in which the first phase of support under this program award may include didactic training in basic and/or clinical research sciences. For these candidates, a second phase would be an intensive, supervised research experience to complete a longer developmental program. More experienced candidates may benefit from entering immediately into a mentored research experience of at least two years supported by this Program award. The application should contain a description of how the career development plan will be tailored to the needs of the prospective candidates, and should distinguish the plan from fellowship training.

Describe the composition of the Advisory Committee, identifying by name and role the internal members, and the desired expertise (but not the name or affiliation) of external members, if any.

(3) **Environment and Institutional Commitment to Candidate:** Provide information establishing the commitment of the applicant institution, the Principal Investigator, and Program Director, if any, and the faculty mentors to providing developmental experiences that lead to independence in biomedical, behavioral, clinical, and/or health services research relevant to women's health. Include the specifics of institutional support. There is no dollar requirement, but significant commitment will be considered a strength. Letters from faculty mentors are not required unless

they are collaborators from other institutions. Collaborations between research-intensive and less-research-intensive institutions, and/or minority institutions, will be considered a strength.

(4) Research Plan: For each faculty member proposed as a potential mentor, provide a paragraph describing the proposed research relevant to the goals expressed in this RFA, that may be the foundation of a IWHR Scholar's research experience in the Program. The research experiences may include basic, translational, clinical, and/or health services research approaches to biomedical or behavioral problems in women's health. Lengthy, detailed protocols or plans for specific experiments should not be included. No limits are specified for the number of proposed mentors; however, fewer than six may not provide sufficient choice of projects, while more than 25 may dilute the focus on women's health. In a table, name up to five current or former students or fellows the faculty member has trained, with dates (month/year), where trained, title of project, academic level, and present position and institution. Include a list of current funded research for each proposed mentor.

Applicants who will be using a General Clinical Research Center (GCRC) are requested to include a letter with the application from either the GCRC Program Director or the Principal Investigator.

(5) Responsible Conduct of Research: Applications must include plans for instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction; and the amount and nature of faculty participation. No award will be made if an application lacks this component.

Submission Instructions

The RFA label available in the PHS 398 application form must be stapled to the bottom of the face page of the application and must display the RFA number OD-02-001. A sample RFA label is available at <http://grants.nih.gov/grants/funding/phs398/labels.pdf>. Please note this is the pdf format. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. Human subjects and vertebrate animals may be checked "NO" with an explanation in the research plan that appropriate assurances will be provided when the actual projects are known.

Submit a signed, typewritten original of the application, including the

Checklist, and five signed photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA MD 20892-7710
BETHESDA MD 20817 (for express/courier service)

Applications must be received by March 14, 2002. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the CSR and for responsiveness to this RFA by program staff. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the CSR on behalf of ORWH in accordance with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

Program Overall:

- o The probable impact of the Program award on enhancing the capacity of the grantee institution to develop well-qualified new investigators, thus enhancing interdisciplinary women's health research locally and nationally.

This includes the scientific and administrative experience of the Principal Investigator/Program Director in preparing clinical, basic, and/or health services research investigators for independent research careers.

- o Quality of immediate and long-term career objectives of the Program.
- o Partnerships between research-intensive institutions and less-research-intensive institutions and/or minority institutions will be considered a strength.

Candidates:

- o Evidence of the availability of an adequate pool of potential IWHR Scholar candidates trained locally or recruited from elsewhere, who could benefit from receiving career development support;
- o Plans to identify, recruit, and select candidates, with a commitment to research relevant to women's health, and the potential to develop as independent researchers;
- o Efforts to develop a recruitment plan for women and those from racial and ethnic groups underrepresented in research.

Career Development Plan:

- o Likelihood that the career development plan will contribute significantly to the scientific development of the candidates;
- o Appropriateness of the content, the phrasing, and the proposed duration of the career development plan for achieving scientific independence for the prospective candidates;
- o Consistency of the career development plan with prospective candidates' career goals and the multidisciplinary aims of the RFA; and
- o Quality of the training in the responsible conduct of research.

Research Plan:

- o Usefulness of the research plan as a vehicle for ensuring interdisciplinary research training in women's health for all Scholars as described in the career development plan.

Mentors:

- o Appropriateness of the faculty mentors' qualifications in the areas of research relevant to this RFA;
- o Quality and extent of the mentors' proposed roles in providing guidance and advice to candidates; and
- o Previous experience of the mentors in fostering the development of researchers.

Resource Laboratory, if applicable:

- o Nature and quality of the optional new Resource Laboratory: technical merit, scientific justification, evidence of cost-effectiveness, procedures for quality control, allocation of resources among multiple users, qualifications of the Resource Laboratory Director and technical staff, and probable utility to the research projects of the IWHR Scholars.

Environment:

- o Applicant institution's commitment to the Program's scientific development of the IWHR Scholars, and assurances that the institution intends the Program and the supported IWHR Scholars to be an integral part of its research program;
- o Adequacy of research facilities including availability of a General Clinical Research Center, if applicable, and training opportunities, including demonstration of the research base;
- o Quality of the environment for scientific and professional development, including opportunities for faculty positions that emphasize research; and
- o Applicant institution's commitment to the appropriate balance of research and clinical responsibilities, including guarantee of 75 percent protected time for research for each IWHR Scholar.

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

- o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

- o The reasonableness of the proposed budget and duration in relation to the Program career development goals and research aims.

- o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

- o The adequacy of the proposed plan to share data, if appropriate.

SCHEDULE

Letter of Intent Receipt Date: February 14, 2002
Application Receipt Date: March 14, 2002
Peer Review Date: June/July 2002
Council/Board Review: September 2002
Earliest Anticipated Start Date: September 30, 2002

AWARD CRITERIA

Funding decisions will be based on scientific and technical merit as determined by peer review, the need for research personnel in specific program areas, and the availability of funds.

INQUIRIES

Written, e-mail, and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues and address the Letter of Intent to:

Estella Parrott, M.D., M.P.H
Center for Population Research
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8B01, MSC 7510
Bethesda, MD 20892-7510

Telephone: 301-496-6515

FAX: 301-496-0962

E-mail: ep61h@nih.gov

Direct inquiries regarding fiscal matters to:

Ms. Kathy Hancock

Grants Management Branch

National Institute of Child Health and Human Development

6100 Executive Boulevard, Room 8A17, MSC 7510

Bethesda, MD 20892-7510

Telephone: 301-496-5482

FAX: 301-402-0915

E-mail: kathy.hancock@nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121 (NIH) and 93.226 (AHRQ). Awards are made under authorization of Title III, Section 301 of the Public Health Service Act (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241). The Code of Federal Regulations, Title 42 Part 52, and Title 45 Part 74, are applicable to this program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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