

BUILDING INTERDISCIPLINARY RESEARCH CAREERS IN WOMEN'S HEALTH

Release Date: September 7, 1999

RFA: OD-99-008

Office of Research on Women's Health
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Cancer Institute
National Institute of Child Health and Human Development
National Center for Complementary and Alternative Medicine
National Institute of Deafness and Other Communication Disorders
National Institute of Dental and Craniofacial Research
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute on Drug Abuse
National Institute of Environmental Health Sciences
National Institute of Neurological Disorders and Stroke
Agency for Health Care Policy and Research

Letter of Intent Receipt Date: October 11, 1999

Application Receipt Date: December 10, 1999

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 will benefit the health of women. The Programs will accomplish this by bridging advanced training

with research independence, as well as bridging scientific disciplines or areas of interest. This will increase the number and skills of investigators at awardee institutions through a mentored research experience leading to an independent scientific career addressing women's health concerns.

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

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Building Interdisciplinary Research in Women's Health, is related to several priority areas. Potential applicants may obtain a copy of "Healthy People 2000" at <http://odphp.osophs.dhhs.gov/pubs/hp2000>.

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.

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 July 1, 2000.

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) 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 Facilities and Administrative) per year, and will support a minimum of four IWHR Scholars. 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 applications of outstanding scientific and technical merit.

RESEARCH OBJECTIVES

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. This is described in the "Agenda for Research on Women's Health for the 21st Century, 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." Program grant awards from this RFA will meet the specified need by providing clinical, health or life sciences, or public health departments, centers, and institutes, both developing and established, an opportunity to build national capacity for junior investigators in women's health research, here defined as including research on sex and/or 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, form an 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 AHCPH. 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.

A number of research priority areas have been identified by the ORWH and cosponsors as major research goals, based in part on the ORWH report cited above. The following should by no means be viewed as exhaustive, and are intended only as examples:

- o Biologic and molecular bases of sex and/or gender differences in pharmacokinetics, pharmacodynamics and pharmacogenetics including hormone and drug interaction, in drug-drug interactions, and in pharmacokinetics and pharmacodynamics during pregnancy.
- o Kidney disorders including the impact of pregnancy, diabetes, and hypertension on renal function; preeclampsia; causes of altered renal hemodynamics during pregnancy; sex and/or 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 Prevention research: behavioral and cultural influences on risk and lifestyle changes, including nutrition and exercise; addictive behavior including alcohol, drugs and tobacco; obesity; type II diabetes; cardiovascular diseases; cancer; and sexually transmitted diseases.
- 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 and gynecological research encompassing both pregnancy and non-pregnancy issues, including the roles of infectious, inflammatory, and other somatic diseases and disorders (such as oral infection) in adverse pregnancy outcomes, prevention and management of pregnancy complications, reducing morbidity and mortality from benign and malignant gynecologic diseases, and promoting increased safety and acceptability of contraceptive options.

- o Natural history of menopause and the endocrinologic, biologic, psychosocial, cultural, lifestyle and environmental determinants, concomitants and/or sequelae; role of menopause in the chronic diseases of aging; menopause-related pathophysiology; and the development of new strategies, including complementary and alternative medicine, for alleviating the short-term, clinical problems of the peri- and postmenopause and the prevention of menopause-related diseases of old age.
- o Aging and development as a central factor in women's biological and psychosocial health, functioning, and effectiveness of treatment. Chronic diseases, including those of aging, such as osteoporosis, arthritis, degenerative joint disease, cardiovascular disease, or diabetes, that result in disabilities; quality of life in women with chronic diseases.
- o Sex and/or gender differences in acute and chronic pain conditions or syndromes, the perception of pain, and analgesic response.
- o Antecedents and consequences of women's multiple roles across the lifespan (e.g., family, work, caregiving and volunteer roles). The influence of economics and competing roles on health behaviors and health outcomes.
- o The influence of environmental factors on women's health, including genetic-environmental interactions in disease etiology; studies which focus on critical windows for exposures during different periods of sexual development and aging, e.g., in utero, childhood, puberty, pregnancy, lactation and menopause.
- o Allergic, immune and autoimmune diseases, in particular, resistance/susceptibility genes, environmental influences, mechanisms of sex and/or gender differences, immunological mechanisms, target organ influence, role of innate immunity, development of surrogate markers, and immune therapy.
- o Drug abuse research, both human and animal, directed at identifying sex and/or gender differences in the biological and behavioral mechanisms of abuse and dependence; antecedents, pathways, risk and protective factors; consequences of drug use and addiction, including interactions with HIV/AIDS; and development of gender-based models of drug abuse prevention, treatment and treatment services.
- o Oral influences on systemic health; oral health and manifestations of disease, for example, temporomandibular joint disorders; and oral factors which may influence transmission of HIV.

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.

o Eliminating health disparities, including understanding and targeting the origins of the variable burden of disease, disability and mortality among people belonging to different ethnic and racial groups, living in different parts of the United States, experiencing different socio-economic status, and engaging in different patterns of behavior.

SPECIAL REQUIREMENTS

A. 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 (c.f. Environment, under "Review Considerations"). Research facilities and training opportunities (see B, below) 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 of 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.

B. Program Composition: Applicants must describe or propose a multidisciplinary career development program that will maximize the use of relevant research and educational resources. 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 which will stimulate and increase the interactions among disciplines, which may include basic, clinical, social and population sciences. There should be an adequate pool of junior investigators likely to benefit from mentored research career development. Of major importance, the Program must have a scientifically sound and equitable procedure for selecting which IWHR Scholars and projects are 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.

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 expertise, 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 coinvestigator to serve as Program Director, with responsibility for some or all of the day-to-day operations of the Program. There are no specific requirements for the Program Director, but if one is included, he/she should have experience and qualifications complementing those of the Principal Investigator.

D. 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 Core, 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.

E. 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.

F. 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. IWHR Scholars appointed under this program should, 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. 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.

G. IWHR Scholars: The Scholar position is a junior faculty appointment, not a fellowship. Candidates for support as IWHR Scholars must have a clinical doctorate or Ph.D. degree or its equivalent, must 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), must identify a mentor with extensive research experience, and must be willing to spend a minimum of 75 percent of full-time professional effort conducting research and research career development. 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 fellowship. 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. 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.

Programs are encouraged to recruit members of underrepresented minorities, women, and candidates with disabilities. Candidates must be U.S. citizens or noncitizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551) or some other verification of legal admission as a permanent resident. Noncitizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S. They are usually born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration. Individuals on temporary or student visas are not eligible.

At the time support begins, IWHR Scholars may not have served as the principal investigator or equivalent on an NIH research project (R01), Mentored Research Scientist Development Award (K01), Mentored Clinical Scientist Development Award (K08) or their equivalent, a subproject of a program project (P01) or center grant (P50, U54), or equivalent PHS research grant awards. IWHR Scholars may not accept or hold any other PHS award that duplicates the provisions of this career award.

During the period of this award, IWHR Scholars are encouraged to apply for, and may accept and hold, independent research grant support.

H. Core facility: With strong justification, a scientific Core facility may be requested as part of the Program, within the total budget. Such a Core would provide skilled technical services to complement and extend the capabilities of the mentors to promote the career development of the IWHR Scholars. Such a Core might provide scientific services such as, but not limited to, assays, molecular biology or biostatistics. Requests for a Core must be justified in terms of cost-effective enhancement of the research resources that will serve at least four IWHR Scholars' projects. The Core, if any, must be a new entity, not an extension or enhancement of an existing facility. The award may support professional direction of the Core lab, up to 50 percent effort, as well as technical assistance, supplies, equipment, and appropriate costs of operation. Institutional commitment to the Core must be demonstrated, and may take the form of providing or renovating space, purchase of required equipment, and/or support of personnel.

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 or the Program Director must be requested.

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

c) Facilities and Administrative costs: Facilities and Administrative (formerly, indirect) costs will be reimbursed at 8 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 three of which must be for individuals with a clinical doctoral degree. Support for each IWHR Scholar position may not exceed \$100,000 total costs per year.

a) Salary: The NIH will provide salary and fringe benefits for the IWHR Scholar, within the statutory NIH annual salary cap, currently \$125,900. 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; (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.

In accord with directives included in the Labor, HHS, and Education Fiscal Year 1999 Appropriations Bill enacted into law (Public Law 105-277) on October 21, 1998, funds provided for the awards made from this RFA must only be used in compliance with the following directive:

"Sec. 511. (a) None of the funds made available in this Act may be used for: (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498 (b) of the Public Health Service Act (42 U.S.C. 289g (b)).

(b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."

Per NIH policy, publications resulting from work supported by the award must cite the grant number in a footnote. The citation must include a disclaimer that no Federal funds were used for the performance of in vitro fertilization - embryo transfer, if any such activities may have been reported in the publication.

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 AHCPH-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 AHCPR 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 cofunded by AHCPR, any such determination would encompass the recommendation of the Administrator of AHCPR. 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 and AHCPR that women and members of minority groups and their subpopulations must be included in all NIH and AHCPR supported biomedical, behavioral and health services research projects involving human subjects, unless a clear and compelling rationale and justification is provided 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 research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which was published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994, available on the web at:

<http://grants.nih.gov/grants/guide/notice-files/not94-100.html>

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.

LETTER OF INTENT

Prospective applicants are asked to submit, by October 11, 1999, 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 avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Donna L. Vogel at the address listed under INQUIRIES.

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 research grant application form PHS 398 (rev. 4/98), "Research Career Award" section, is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, E-mail: GrantsInfo@nih.gov. The forms may also be downloaded from the web at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

Application Instructions

The application must address the following issues under the headings for the Research Career Award table of contents:

Modular Grant Application and Award procedures DO NOT APPLY. Include all information requested under "Section I: Basic Administrative Data." Budget requests must be provided according to the instructions in form PHS 398. A composite page DD for the entire Program budget request should be followed by one page for the Scholars' costs and one for Administration and Core laboratory (if applicable). Provide page EE for the composite only. The requests for tuition and fees, books, travel, research development expenses, etc., must be justified and specified by category.

"Section II: Specialized Information" should be modified as follows:

The section may begin with an overview of the proposed Program.

(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 is composed largely of 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.

(4) Research Plan: For each faculty member proposed as a potential mentor, provide a paragraph on his or her 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. List up to five current or former students or fellows the faculty member has trained.

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.

Note: 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.

Submission Instructions

The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page of the application and must display the RFA number OD- 99-008. A sample modified RFA label is available at <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>. 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, "BIRCWH Career Development Programs," 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 three 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)

At the time of submission, two additional copies of the application should also be sent to:

Scott F. Andres, Ph.D.
Division of Scientific Review
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 5E01, MSC 7510

Bethesda, MD 20892-7510

Rockville, MD 20852 (for express/courier service)

Applications must be received by December 10, 1999. 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 responsiveness 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 NICHD on behalf of ORWH in accordance with the review criteria stated below. As part of the initial merit review, a process may be used by the initial review group in which applications receive a written critique and 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:

The probable impact of the Program award on enhancing the capacity of the grantee institution to develop well-qualified new investigators, thus enhancing women's health research locally and nationally. This includes the experience of the Principal Investigator/Program Director in preparing clinical, basic and/or health services research investigators for independent research careers.

Candidates:

- o Availability of an adequate pool of potential candidates;
- o Plans to identify, recruit, and select candidates (including minorities and women), with a commitment to research relevant to women's health, and the potential to develop as independent researchers.

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 phasing, 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 developing research skills as described in the career development plan;
- o Appropriateness of plans to comply with NIH policy on inclusion of women, minorities and children.

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.

Core facility, if applicable:

- o Nature and quality of the optional Core facility: technical merit, scientific justification, evidence of cost-effectiveness, procedures for quality control, allocation of resources among multiple users, qualifications of the Core facility 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.

Budget:

- o Justification of budget requests in relation to Program career development goals and research aims.

SCHEDULE

Letter of Intent Receipt Date: October 11, 1999
Application Receipt Date: December 10, 1999
Peer Review Date: April 2000
Council/Board Review: May/June 2000
Earliest Anticipated Start Date: July 2000

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:

Donna L. Vogel, M.D., Ph.D.
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
Email: dv1h@nih.gov

Direct inquiries regarding fiscal matters to:

Ms. Diane Watson
Chief, Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A17, MSC 7150
Bethesda, MD 20892-7510
Telephone: (301) 496-5001
Fax: (301) 402-0915
Email: dw40j@nih.gov

Although the National Institute of Mental Health (NIMH) and the National Heart Lung and Blood Institute (NHLBI) are not co-sponsors of this RFA, research involving mental health or heart, lung and blood aspects may nonetheless be relevant to the intent of the RFA. NIMH and NHLBI support training and career development related to women's health, including multidisciplinary training, through their existing programs.

For NIMH, see: <http://www.nimh.nih.gov/grants/rtcd.htm>) or contact Mary C.

Blehar, Ph.D., Chief, Women's Health Program; telephone (301) 443-2847; E-mail: mblehar@mail.nih.gov.

For NHLBI, contact Teri Maniolo, M.D., M.H.S., Director, Epidemiology and Biometry Program; telephone (301) 435-0707; E-mail:

ManolioT@gwgate.nhlbi.nih.gov.

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. 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 described in the Catalog of Federal Domestic Assistance No. 93.121 (NIH) and 93.226 (AHCPR). 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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