

Full Text AG-97-004

WHI MINORITY INVESTIGATOR CAREER DEVELOPMENT AWARD

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Office of Research on Women's Health

Office of Research on Minority Health

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Application Receipt Dates: April 18, 1997

PURPOSE

The purpose of this Request for Applications (RFA) is to increase the number of underrepresented minority investigators participating in the clinical trial and observational study of the Women's Health Initiative (WHI) using the mechanism of the NIH Mentored Career Development Awards.

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 RFA, WHI Minority Investigator Career Development Award, is related to the priority area of human resource development. Potential applicants may obtain a copy of "Healthy People

2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

In general, candidates should be an underrepresented minority scientist or physician, in possession of a doctoral degree or equivalent. The NIH Career Development Grant Mechanisms are described in the NIH GUIDE, Volume 24, Number 15, April 28, 1995. All applicants are encouraged to contact one of the program officials listed in this RFA regarding their eligibility for the K01 or K08. Applications may be submitted by institutions on behalf of candidates at:

- (1) the site of the clinical coordinating center or one of the 40 clinical centers that are participating in the Women's Health Initiative; or
- (2) any other institution recognized as a minority institution or with significant minority enrollment.

The candidate must identify a mentor at the site of the clinical coordinating center or one of the 40 clinical centers that are participating in the Women's Health Initiative. The mentor must have extensive research experience and provide guidance for the awardee's development and research. The candidate must be willing to spend a minimum of 75 percent of full-time professional effort conducting research and research career development activities for the period of the award. Research will be conducted primarily at the mentor's institution.

MECHANISM OF SUPPORT

Awards in response to this RFA will use the K01 or K08 mechanism.

- o MENTORED RESEARCH SCIENTIST DEVELOPMENT AWARD (K01)--an award to provide research scientists with an additional period of mentored research experience as a way to gain expertise in a research area new to the applicant or in an area which would demonstrably enhance the applicant's scientific career. This award is generally reserved for individuals interested in switching to a new research field, for individuals who have interrupted their career because of illness or pressing family care responsibilities, or for faculty at minority institutions who wish to enhance their capacity for independent research.

o MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD (K08)--an individual award for clinicians who need an intensive period of mentored research experience.

Planning, direction, and execution of the program will be the responsibility of the candidate and her/his mentor on behalf of the applicant institution. The project period may be for three, four, or five years and will depend upon the number of years of prior research experience and the need for additional experiences to achieve independence. Awards are not renewable.

FUNDS AVAILABLE

The NIH will allocate approximately \$300,000 during fiscal year 1997. The actual amount may vary depending on the response to this RFA and the availability of funds. Three to four awards are anticipated.

RESEARCH OBJECTIVES

Background

The NIH Women's Health Initiative is a research study focused on the major causes of morbidity and mortality in postmenopausal women. It is designed to test whether long term preventive measures will decrease the incidence of cardiovascular disease, breast and colon cancer, and osteoporosis. Over 160,000 women in 40 clinical centers throughout the United States will be enrolled as participants in either clinical intervention trials or in a long term epidemiologic study. Ten of the clinical centers are specifically recruiting minority participants and all of the centers are committed to optimizing the diversity of the populations recruited. This project is currently underway and will provide training opportunities in epidemiology and clinical trials over the next decade and beyond.

The Women's Health Initiative Policy Advisory Committee, a group that provided advice to the Director of NIH during the initial years of this project, and the Special Populations Committee, composed of scientists and clinicians within the study, have both suggested that the WHI would benefit from greater participation by minority investigators in the scientific and clinical activities of the project.

Information on the background, current status and the participating clinical centers of the WHI can be accessed on the World Wide Web at: <http://www.nih.gov/od/odp/whi> or by contacting:

Nancy Morris
Women's Health Initiative Project Office
National Institutes of Health
Federal Building, Room 6A-09
Bethesda, MD 20892
Telephone: (301) 402-2900
Email: Nancy_Morris@NIH.GOV

Career development awards to minority scientists to facilitate participation in the WHI will serve two purposes: first, to enhance the research skills, training and development of the individual awardees, and second, to enhance the diversity of the investigator teams currently carrying out this project. Scientists and clinicians thus trained will be available to contribute to the next generation of clinical investigations.

A. Environment: The institution must be one of the 40 clinical centers or the clinical coordinating center participating in the Women's Health Initiative or a qualifying minority institution willing to enter into an arrangement with one of the WHI centers. The WHI institution will provide a well-established research and/or clinical career development program(s) and qualified faculty to serve as mentors. The WHI Clinical or Coordinating Center must be able to demonstrate a commitment to the development of the candidate as a productive, independent investigator. If the minority institution submits an application on behalf of a candidate a letter signed by an institutional official must indicate that the candidate has the necessary research time available and that the institution has a strong commitment to the career development of the candidate. The candidate, mentor and institution must be able to describe a multi-disciplinary career development program that will maximize the use of relevant research and educational resources.

B. Program: The award provides three to five consecutive 12 month appointments. At least 75 percent of the recipient's full-time professional effort must be devoted to the program and the remainder devoted to other research-related and/or teaching pursuits consistent with the objectives of the award. The candidate must develop knowledge in the clinical or biomedical sciences and research skills relevant to his or her career goals. The candidate should include relevant didactic and laboratory or field research experiences.

C. Mentor(s): The recipient must receive appropriate mentoring throughout the three to five year program. Where feasible, women and minority mentors are encouraged to be involved as role models.

D. Allowable Costs:

1. Salary: The NIH will provide salary and fringe benefits for the K award recipient. The awardee may receive up to a maximum of \$50,000 per year plus fringe benefits for five years.

The institution may supplement the NIH 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 MR/CSDA. Under expanded authorities, however, institutions may rebudget funds within the total costs awarded to cover salaries consistent with the institution's salary scale.

The total salary requested 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.

2. Research Development Support: Up to \$20,000 per year may also be awarded for the following expenses: (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment, and technical personnel; (c) travel to research meetings or training; (d) statistical services including personnel and computer time.

3. Ancillary Personnel Support: Salary for mentors, secretarial and administrative assistance, etc., is not allowed.

4. Indirect costs: Indirect costs will be reimbursed at eight percent of modified total direct costs, or at the actual indirect cost rate, whichever is less.

F. 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, recipients are hereby notified that they may be contacted after the completion of this award 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.

G. 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 career award recipient. 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.

H. Special Leave: Awardees from minority institutions not at a WHI site are granted prior approval by NIH to spend the requisite time at a participating center of the Women's Health Initiative. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made.

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 subpopulations must be included in all NIH supported biomedical and behavioral 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 have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), and reprinted in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994.

APPLICATION PROCEDURES

Applications kits are available at most institutional offices of sponsored research and may be obtained 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, email: ASKNIH@odrockm1.od.nih.gov.

Applicants are advised to consult the NIH Guide, Vol. 25, No. 10, March 29, 1996, and Vol. 25, No. 16, May 17, 1996 for additional information concerning "just-in-time" procedures to be used in completing mentored career award applications.

The application must address the following issues:

Candidate

- o Establish the candidate's commitment to a career in biomedical or behavioral research
- o Establish the candidate's potential to develop into a successful independent investigator.
- o Summarize the candidate's immediate and long-term career objectives, explaining how the award will contribute to their attainment.
- o Letters of recommendation. Three sealed letters of recommendation attesting to the candidate's potential for a research career must be included as part of the application

Career Development Plan

- o Describe the career development plan, incorporating consideration of the candidate's goals and prior experience. It should describe a systematic plan to obtain the necessary basic biomedical or behavioral science background and research experience to launch or re-initiate an independent research career.
- o Candidates must describe plans to receive instruction in the responsible conduct of research. These plans must detail the proposed subject matter, format, frequency, and duration of instruction as well as the amount and nature of faculty participation. No award will be made if an application lacks this component.

Research Plan

- o Describe the research plan and the use of a basic or clinical approach to a biomedical or behavioral problem. The candidate and mentor together must describe the research plan as outlined in form PHS 398 including sections on the Specific Aims, Background and Significance, Progress Report/Preliminary Studies, Research Design and Methods. Although it is understood that this application does not require the detail of regular research grant proposals, a

fundamentally sound research plan should be provided. The research will involve either the main study or an ancillary project being carried out as part of the NIH Women's Health Initiative.

Mentor's Statement

o The application must include information on the mentor(s) including information on research qualifications and previous experience as a research supervisor. The application must also include information that describes the nature and extent of supervision that will occur during the proposed award period.

Environment and Institutional Commitment

o The mentor's institution must document a strong, well- established research program related to the candidate's area of interest including a high-quality research environment with staff capable of productive collaboration with the candidate. The sponsoring institution must also provide a statement of commitment to the candidate's development into a productive, independent investigator.

This statement will include a description of a multi-disciplinary career development program that will maximize the use of relevant research and educational resources. If a minority institution is the sponsoring organization a commitment to the candidate's career development as well as approval of leave should be documented.

Budget

o Budget requests must follow "just-in-time" procedures described in the NIH Guide, Vol. 25, No. 10, March 29, 1996, and Vol. 25, No. 16, May 17, 1996.

The RFA label available in the PHS 398 (rev. 5/95) application form must be affixed to the bottom of the face page of the application. 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.

Submit a signed, original of the application with Checklist, and three signed photocopies, in one package to:

DIVISION OF RESEARCH GRANTS

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 must be sent to:

Chief, Scientific Review Office
National Institute on Aging
7201 Wisconsin Avenue, Suite 2C212 - MSC 9205
Bethesda, MD 20892-9205
ATTN: WHI Minority Investigator Career Development Award

REVIEW CONSIDERATIONS

Applications will be reviewed for completeness by the Division of Research Grants (DRG) and responsiveness to the RFA by the appropriate WHI project office staff. 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 National Institute on Aging in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

The following review criteria will be applied:

Candidate

- o Commitment to an independent research career;
- o Potential to develop (or evidence of the capacity to develop) as an independent investigator;
- o Quality and breadth of prior scientific training and experience, including, where appropriate, the record of previous research support and publications.

Career Development Plan

- o Likelihood that the plan will contribute substantially to the scientific development of the candidate and the achievement of scientific independence;
- o Appropriateness of the research plan to the career goals of the candidate;
- o Appropriateness of the plan to update conceptual and theoretical knowledge, and the proposed award duration;
- o Consistency of the career development plan with the candidate's prior research and academic experience and the stated career goals;
- o Relevance to the goals of the Women's Health Initiative;
- o Clarity of the goals and scope of the plan and the need for the proposed research experience; and
- o Quality of the proposed training in the responsible conduct of research.

Research Plan

Candidates for this award will have had previous research experience and in some cases will have been Principal Investigators in other scientific fields. A sound research plan that is consistent with the career development plan and the candidate's level of research development must be provided.

- o Usefulness of the research plan as a vehicle for enhancing existing research skills as described in the career development plan;
- o Scientific and technical merit of the research question, design and methodology, judged in the context of the candidate's previous training and experience;
- o Relevance of the proposed research to the candidate's career objectives and to the research goals of the Women's Health Initiative; and
- o Adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

Mentor

- o Appropriateness of mentor's research qualifications in the area of this application;
- o Quality and commitment of the mentor to supervising and guiding the candidate throughout the award period;
- o Previous experience in fostering the development of researchers; and
- o History of research productivity and support.

Institutional Environment and Commitment

- o Applicant institution's commitment to the scientific development of the candidate and assurances that the institution intends the candidate to be an integral part of its research program;
- o Adequacy of research facilities and training opportunities;
- o Quality of environment for scientific and professional development; and
- o Applicant institution's willingness to develop an appropriate mix of research, teaching and administrative responsibilities for the candidate.

AWARD CRITERIA

The awarding component of the NIH will notify the applicant of the national advisory board or council's action shortly after its meeting. Funding decisions will be made based on the recommendations of the initial review group and council/board, the need for research personnel in specific program areas, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged, especially during the planning phase of the application.

For general information about the Women's Health Initiative, call:

Loretta Finnegan, M.D.
Women's Health Initiative
National Institutes of Health
Federal Building, Room 6A-09
Bethesda, MD 20892
Telephone: (301) 402-2900
FAX: (301) 480-5158
Email: loretta_finnegan@nih.gov:

For programmatic information about eligibility for career development awards or about the interests of specific institutes, call:

Joan A. McGowan, Ph.D.
Musculoskeletal Diseases Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-43E, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: mcgowanj@ep.niams.nih.gov

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7201 Wisconsin Avenue, Room 2C218, MSC 9205
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Joyce Rudick
Office of Research on Women's Health
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Building 1, Room 201
Telephone: (301)-402-1770
FAX: (301)-402-1798
Email: rudickj@od1tm1.od.nih.gov

AUTHORITY AND REGULATIONS

Awards made in this program are described in the Catalog of Federal Domestic Assistance No. 93.846, 93.866. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grant policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to 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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