

# NIH Guide for Grants and Contracts

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U.S. DEPARTMENT OF HEALTH  
AND HUMAN SERVICES

Vol. 15, No. 3, February 28, 1986

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

#### Have You Moved?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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**SPECIAL ANNOUNCEMENT**

**THE FIRST INDEPENDENT RESEARCH SUPPORT AND TRANSITION (FIRST) AWARD**

**P.T. 34; K.W. 0710030, 0404000, 1014002**

**NATIONAL INSTITUTES OF HEALTH**

The National Institutes of Health (NIH) is replacing its current New Investigator Research Award (R23) with the new FIRST award which will provide an opportunity for first-time investigators to apply for NIH support for longer periods of time and for increased levels of funding. The next issue of the NIH Guide for Grants and Contracts will provide the details about this new award. The principal features are: a) new investigators may receive awards for up to a period of five years; b) the maximum level for these awards is \$350,000 for a 5-year period; and c) the award will permit optional carry-over of unobligated balances from one budget period to the next.

The first receipt date for FIRST applications will be June 1, 1986.

**NOTICE****PHS POLICY REGARDING SMALL BUSINESS INNOVATION RESEARCH GRANT APPLICATIONS THAT DO NOT MEET ELIGIBILITY REQUIREMENTS****P.T. 34; K.W. 0710035****PUBLIC HEALTH SERVICE****BACKGROUND**

Public Law 97-219, the Small Business Innovation Development Act of 1982, requires certain federal agencies to reserve a specified amount of their extramural research and development (R&D) budgets for a Small Business Innovation Research (SBIR) Program. The legislation is intended to:

- o stimulate technological innovation;
- o use small business to meet federal research and development needs;
- o increase private sector commercialization of innovations derived from federal research and development;
- o foster and encourage participation by minority and disadvantaged persons in technological innovation.

The SBIR Program, which involves the participation of 12 different federal departments, is now in its fourth year of implementation within the Public Health Service (PHS), whose largest component is the National Institutes of Health (NIH).

The Small Business Administration (SBA) issued implementing regulations (Policy Directives) for the SBIR Program in November 1982. These regulations included, among other provisions, eligibility requirements of the Program. The two primary ones address organizational eligibility and principal investigator eligibility. An organization seeking SBIR funding must:

- o be organized for profit;
- o be independently owned and operated;
- o not be dominant in the field of operation in which it is proposing; and
- o has its principal place of business in the United States.

For an individual to be eligible to serve as the principal investigator of an SBIR project, he/she must be in the employ of the small business more than one-half time, i.e., the small business must be the primary employer of the principal investigator. Both sets of eligibility requirements are explicitly stated in the PHS SBIR solicitations.

As the Program has evolved, the PHS from time to time has received applications and proposals from principal investigators or organizations that did not and could not meet such requirements. In most of these cases, it was the principal investigator who did not appear to meet eligibility requirements. Because this seems to be a growing problem, the PHS is publishing this notice as a reminder.

#### PHS POLICY

In order to obviate this problem and to help ensure that the PHS SBIR Program operates in accordance with Congressional and Executive Branch expectations, the PHS agencies will check all SBIR grant applications and contract proposals for eligibility prior to subjecting them to scientific and technical merit review. Organizations submitting applications or proposals identified as questionable will be requested to submit information by a specific date to verify or substantiate the eligibility of the principal investigator or organization, whichever is in question. If the principal investigator's eligibility is not established by the specified deadline, the grant application or contract proposal will be returned without further review to the applicant/offeree organization. If the organization's eligibility is not verified by the deadline, the application or proposal will be referred to the SBA regional office, in accordance with Federal Acquisition Regulations, Subpart 19.3, for determination of eligibility. Pending the outcome of SBA's investigation, the application or proposal will undergo review for scientific merit but no award, if any, will be made until the SBA has certified that the applicant/offeree organization is a small business, as defined by the SBIR Policy Directives.

Principal investigators who appear to be employed by a university must submit a letter from the university stating that the principal investigator, if awarded an SBIR grant/contract, will become a less-than-half-time employee of the university. By the same token, a principal investigator who appears to be a staff member of both the applicant/offeree organization and another employer must submit a letter from the second employer stating that, if awarded an SBIR grant/contract, he/she will become a less-than-half-time employee of such organization.

Organizations whose status as a small business appears to be questionable will likewise be requested to submit supporting documentation.

The above policy will apply to any SBIR grant application or contract proposal submitted to any component of the PHS on or after December 1985, even if such an application/proposal is from a principal investigator or organization that has had a prior SBIR award from a PHS agency.

#### RELATED ISSUES

In accordance with SBA's Policy Directives, research to be conducted under both Phase I and Phase II awards must be performed in the United States, i.e., the several states, territories and possessions of the U.S., the Commonwealths of Puerto Rico and the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and the District of Columbia.

Inasmuch as the SBIR Program is intended to support research and development, the PHS has stated clearly in its SBIR solicitations that marketing studies will not be supported with its SBIR funds.

These policies are intended to ensure that the eligibility requirements of the SBIR Program are implemented in good faith and that awards are made to organizations and individuals specifically targeted by the Small Business Innovation Development Act.



**NOTICE**

**PHYSICIAN SCIENTIST AWARD, NCI**

**P.T. 34; K.W. 0710030, 0785035**

**NATIONAL CANCER INSTITUTE**

The National Cancer Institute (NCI) will act as a participant in future announcements of the Physician Scientist Award. The NCI will continue to use its present Clinical Investigator Award as well, thereby offering candidates as much latitude as possible in planning their research career development.

Inquiries about applying for the Physician Scientist Award should be addressed to:

Program Director  
Cancer Training Branch  
Division of Cancer Prevention and Control  
National Cancer Institute  
Blair Building - Room 424  
Bethesda, Maryland 20892-4200

Telephone: 301 - 427-8898

Please note that a reannouncement of the Physician Scientist Award, with NCI participating, appears on page 45 of this issue.

**NOTICE****TRAINING OPPORTUNITIES IN GERIATRICS AND GERONTOLOGY****P.T. 22,44; K.W. 0720005, 0710010****NATIONAL INSTITUTE ON AGING**

The National Institute on Aging (NIA) announces a new information packet on NIA-sponsored research training and career development opportunities. The folder contains descriptions of the different support mechanisms awarded by the NIA, with a table categorizing information on each training program by type, eligibility, and level of career development. It is designed so that prospective applicants may view all opportunities and readily select the most suitable sources of funding. A copy may be obtained by writing to:

TRAINING  
NIA Information Center  
2209 Distribution Circle  
Silver Spring, Maryland 20910

**NOTICE****CHANGE OF ADDRESS IN THE GUIDELINES FOR THE PROGRAM PROJECT GRANT  
OF THE NATIONAL CANCER INSTITUTE****NATIONAL CANCER INSTITUTE**

The address listed on pages ii and 6 of the Guidelines for the Program Project Grant of the National Cancer Institute has been changed. The letter of intent and the two complete copies of the application should be sent to the address listed below:

Referral Officer  
Grants Review Branch, DEA  
National Cancer Institute  
Westwood Building - Room 826  
5333 Westbard Avenue  
Bethesda, Maryland 20892

NOTICE

**NIADDK, DDEMD SCIENTIFIC INSTRUMENTATION GRANTS**

**P.T. 34; K.W. 1014001, 1014002**

**NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, DIGESTIVE AND KIDNEY DISEASES**

The Division of Diabetes, Endocrinology and Metabolic Diseases (DDEMD) announces the cancellation of its program for the purchase of moderately priced scientific instrumentation. This cancellation refers specifically and solely to that prior program announcement appearing in the NIH Guide to Grants and Contracts, Volume 13, No. 13, p. 31 (December 7, 1984) with a prospective reply date of April 15. Biomedical researchers in need of such equipment are referred to the ongoing mechanisms of grant support which remain in operation (i.e., competitive supplement application to an existing R01, Biomedical Research Support Program of the Division of Research Resources, Shared Instrumentation Program of the National Institute of General Medical Sciences).

The DDEMD intends to reannounce this program at a future date pending the availability of sufficient resources.

Inquiries can be addressed to:

Robert E. Silverman, M.D., Ph.D.  
DPB/DDEMD/NIADDK  
Westwood Building - Room 605  
National Institutes of Health  
Bethesda, Maryland 20892

Telephone: (301) 496-7888

## NOTICE

## NIH/FDA REGIONAL WORKSHOP - PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards, (IRBs), and institutional officials for the protection of human subjects in biomedical and behavioral research. The workshop in Little Rock, at the University of Arkansas, will be an intensive one-day workshop in IRB functions and responsibilities. The workshop will focus on selected case studies, illustrating representative problems of interpreting and applying the human subjects regulations. Participants will serve as IRB members in "mock IRB" meetings and compare strategies and solutions to issues raised by the cases. Enrollment will be restricted to 35-40 participants. Written materials will be supplied in advance to participants.

| Date           | Location        | Contact   |
|----------------|-----------------|---|
| March 12, 1986 | Little Rock, AR | Ms. Kathleen Masterson<br>University of Arkansas Med. Ctr.<br>4301 W. Markham<br>Mail Slot 636<br>Little Rock, AR 77205<br>(501) 661-5502 |

A final list of dates and locations will be published at a later date. For specific program and registration information, contact:

Roberta H. Garfinkle  
Office for Protection from Research Risks  
National Institutes of Health  
Building 31 - Room 4B09  
9000 Rockville Pike  
Bethesda, Maryland 20892

NOTICE

NIH/FDA REGIONAL WORKSHOP - PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. The current schedule includes:

| Date                        | Location    | Contact  |
|-----------------------------|-------------|--|
| Feb. 27-28,<br>Mar. 1, 1986 | Sate Fe, NM | Pat Johnson or Ann Armijo<br>IRB/Sante Fe Conference<br>Lovelace Medical Foundation<br>Research Division<br>5400 Gibson Blvd., SE<br>Albuquerque, NM 87108<br>(505) 262-7415 |
| May 15-16, 1986             | Seattle, WA | Susan Charrier<br>Fred Hutchinson Cancer Research Ctr.<br>1124 Columbia Street<br>Mail Stop 1725U<br>Seattle, WA 98104<br>(206) 467-4867                                     |

Additional workshops will be announced later. For further information regarding education programs contact:

Roberta H. Garfinkle  
Education Program Coordinator  
Office for Protection from Research Risks  
National Institutes of Health  
Building 31 - Room 4B09  
9000 Rockville Pike  
Bethesda, Maryland 20892

## NOTICE

**NIH REGIONAL WORKSHOP ON THE HUMANE CARE AND USE OF LABORATORY ANIMALS BY AWARDEE INSTITUTIONS**

**P.T. 42; K.W. 0201011, 1014003**

The National Institutes of Health (NIH) Office for Protection from Research Risks (OPRR) is continuing to sponsor a series of workshops on implementing the revised "Public Health Service Policy on the Humane Care and Use of Laboratory Animals by Awardee Institutions" and the NIH Guide for the Care and Use of Laboratory Animals. The workshops are open to institutional administrators, and others who share in responsibility for sound management of humane animal research. The current schedule includes:

| Date             | Place           | Contact  |
|------------------|-----------------|--|
| March 11, 1986   | Little Rock, AR | Ms. Kathleen Masterson<br>Univ. of Arkansas Medical<br>Ctr.<br>Mail Slot 636<br>Little Rock, AR 77205<br>(501) 661-5502  |
| April 4, 1986    | Boston, MA      | Mrs. Virginia B. Werwath<br>Harvard Medical School,<br>NERPRC<br>One Pine Hill Drive<br>Southborough, MA 01772<br>(617)481-0400 Ext. 202                         |
| May 8, 1986      | Atlanta, GA     | Dr. M. S. Silberman<br>Emory University<br>Robert Woodruff Health<br>Sciences Ctr.<br>P. O. Drawer KK<br>Atlanta, GA 30322<br>(404)321-0111 Ext. 4388 or<br>4389 |
| June 10-11, 1986 | Chicago, IL     | Sue Korienek or<br>Bettie Cleveland<br>Conferences and Institutes<br>912 South Wood Street<br>Chicago, IL 60612<br>(312) 996-8025                                |

Additional workshops will be announced later. For further information regarding education programs contact:

Roberta H. Garfinkle  
Education Program Coordinator  
Office for Protection from Research Risks  
National Institutes of Health  
Building 31 - Room 4B09  
9000 Rockville Pike  
Bethesda, Maryland 20892

**ANNOUNCEMENT****GRANTS ASSOCIATES PROGRAM****P.T. 44; K.W. 0901026, 1014002****PUBLIC HEALTH SERVICE**

Scientists interested in an administrative career with Federal programs supporting research and training in health-related fields may wish to consider the Grants Associates Program of the U. S. Public Health Service. The program is governed by the Grants Associates Board and is administered by the Office of Extramural Research and Training, Office of the Director, National Institutes of Health (NIH).

The program prepares each Grants Associate for a responsible position in Health Science Administration in the Federal Government. For a 12-month period, the Grants Associate participates in an individually structured training experience including on-the-job training assignments, courses, and seminars. The program provides opportunities for participation in the development and administration of policies in Federal support by health related research, and in the fundamentals of effective management. The program also attempts to develop a sensitivity to the consequences of program decisions on other Federal health programs, research institutions, and national health needs.

Admission to the program is highly competitive for the few positions available. Motivation for a career in science administration, good interpersonal skills, and evidence of executive potential are important. If you are a U.S. citizen and hold a doctorate or equivalent in a discipline related to the biomedical or behavioral sciences, have significant independent research experience beyond the doctorate and are attracted to Health Science Administration as a profession, you should inquire about the Grants Associates Program. Administrative experience is not required.

Grants Associates may be appointed either in the U.S. Civil Service at grade levels General Schedule (GS) 12 (\$31,619), GS-13 (\$37,599), or GS-14 (\$44,430) or in the Commissioned Corps of the U.S. Public Health Service at ranks beginning with senior grade (O3 Lieutenant, salary dependent on prior military experience, but beginning at \$15,798).

The NIH does not discriminate in employment on grounds of race, color, sex, national origin, age, or handicap.

For further information, write to:

Director  
Grants Associates Program  
Office of Extramural Research and Training  
Office of the Director, NIH  
Building 31 - Room 1B-62  
National Institutes of Health  
Bethesda, Maryland 20892



ANNOUNCEMENT

**SUPERCOMPUTER INITIATION GRANTS FOR BIOLOGICAL, BIOMEDICAL,  
BEHAVIORAL, SOCIAL AND ECONOMIC SCIENTISTS**

**P.T. 36, 34; K.W. 1004000, 0780000**

**NATIONAL INSTITUTES OF HEALTH  
NATIONAL SCIENCE FOUNDATION**

The National Institutes of Health (NIH) and the Directorate for Biological, Behavioral and Social Sciences (BBS) of the National Science Foundation (NSF) announce a joint program designed to encourage the broadened use of supercomputers by biological, biomedical, behavioral, social and economic scientists. The actual CPU hours on supercomputers will be provided by the Office of Advanced Scientific Computing (OASC) of the NSF.

Through this joint NSF/NIH Program, NSF will make peer-reviewed awards of up to 25 hours of supercomputer CPU time to promote the exploratory use of supercomputers by researchers including those with little or no experience with supercomputers but who anticipate that supercomputers might make a significant impact on their research. Funds for travel, training, and remote access are not included under this program. CPU time will be made available at one of the NSF Supercomputer Centers; their computational facilities are described on the following page.

To be considered for an award, an investigator should submit a brief proposal outlining the nature of the problem to be studied and the potential advantages of supercomputer usage. The proposal should include a cover page (with appropriate institutional signatures), a short abstract, a list of current research support, curriculum vitae (including publications during the past 5 years), and up to a 5 page justification of the proposed use of the supercomputer time. This section should describe the investigator's relevant research program, the level of current computational usage/involvement, and the proposed new activity/advance to be made possible by the use of a supercomputer. Access to a particular type of supercomputer or to a particular Center may be requested. The proposals will be reviewed by a panel comprised of individuals knowledgeable about the relevant research disciplines and the applications of advanced computing.

The competition for these initiation level awards is open to all biological, biomedical, behavioral, and social scientists, and does not replace any of the other NSF mechanisms for providing supercomputer access. Researchers who anticipate an immediate need for more than 25 hours of supercomputer time are encouraged to discuss their needs with NSF.

The deadline for receipt of proposals is April 18, 1986. Fifteen copies of the proposals should be sent to:

Dr. John C. Wooley  
BBS:Advanced Scientific Computing  
National Science Foundation  
1800 G Street N. W.  
Room 325  
Washington, D.C. 20550

For further information about the competition call:

Ms. Brenda C. Flam  
National Science Foundation  
Biophysics Program  
Telephone: (202) 357-7050

Dr. Suzanne S. Stimler  
National Institutes of Health  
Biomedical Research Technology Program  
Telephone: (301) 496-5411

The Office of Advanced Scientific Computing has supercomputer hours available at the following national centers:

| CENTER  | CONFIGURATION   | CONTACT PERSON                         |
|---|---|--|
| John Von Neumann Center for Scientific Computing<br>Princeton, N.J.                           | Cyber 205 with upgrade to an ETA-10 expected in 1987 with 1MB communications to 13 institutions | Dr. Brendan McNamara<br>(609) 734-8191 |
| Cornell Center for Theory and Simulation in Science and Engineering<br><br>Cornell University | IBM 3084 QX with four FPS 264 Scientific Processors attached plus three FPS 164's               | Ms. Linda Morris<br>(607) 256-8686     |
| San Diego Supercomputer Center, U. of Calif. at San Diego                                     | CRAY X-MP/48 with 56KB communications 19 institutions   | Dr. Wayne Pfeiffer<br>(619) 455-3467   |
| National Center for Supercomputing Applications, U. of Illinois at Urbana                     | CRAY X-MP/24 with 32 MW-SSD   | Ms. Patricia Wenzel<br>(217) 244-0074  |
| Pittsburgh Center for Advanced Computing  | CRAY X-MP/48 with 128 MW-SSD  | Ms. Georgette Demes<br>(412) 268-4960  |

Supercomputer hours are also available at the following resource centers:

|                                   |                        |                                      |
|-----------------------------------|------------------------|--------------------------------------|
| U. of Minnesota                   | CRAY 2 (256 MW Memory) | Ms. Angela Vail<br>(612) 376-8323    |
| AT&T Bell Labs<br>Murray Hill, NJ | CRAY X-MP/24           | Dr. Herbert Fisher<br>(201) 582-6184 |
| Colorado State U.                 | Cyber 205              | Dr. Bruce Loftis<br>(303) 491-6900   |

Questions concerning the centers and facilities should be directed to the centers.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATION: RFA

86 EY-03

CONSTRUCTION, ALTERATION AND RENOVATION, AND INSTRUMENTATION

P.T. 02, 36; K.W. 1014001

NATIONAL EYE INSTITUTE

Application Receipt Date: May 15, 1986

I. BACKGROUND

The National Eye Institute (NEI) announces the availability of a Request for Applications (RFA) for a program that will support grants in three different areas:

- A. New Construction
- B. Alteration and Renovation of Existing Facilities
- C. Acquisition of Specialized Laboratory Instrumentation

Approximately \$3,000,000 will be available for a Vision Research Facilities Program in Fiscal Year 1986.

II. TYPES OF FACILITIES AND INSTRUMENTATION

- A. New construction is defined as the construction of new buildings, additions to existing facilities, or the completion of "shell" space in new or existing buildings. It is expected that the facilities be utilized by investigators currently supported by the NEI. The NEI will provide 50% of the total allowable cost of the project up to a maximum of \$500,000. Requests exceeding \$500,000 will require exceptional justification.

Eligibility: Any domestic public, or non-profit institution, organization, or association is eligible to apply. Applications will be evaluated to determine how the facilities to be constructed expand an existing clinical vision research program.

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This program is described in the Catalog of Federal Domestic Assistance No.13.985, Eye Research Construction Grants. Construction grants made under this program are subject to Executive Order 12372. Awards in support of alteration and renovations or specialized instrumentation are not subject to Executive Order 12372. All awards will be made under the authority of the Public Health Service Act, Title IV, Section 453 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 54.

Method of Application: Applicants must use NIH Form 2575 (formerly PHS Form 5162-1), "Application for Federal Assistance for Construction Programs".

B. Alteration and Renovation:

Alteration and renovation support is intended for the costs of modifying existing space and utilities within a finished structure and/or adapting interior building features to the needs of a vision research group. Some examples of projects are alteration or renovation of space for clinical research, remodeling laboratory space, redesigning specialized instrumentation space, or upgrading animal care facilities that are dedicated to vision research groups. The NEI will provide up to 50% of the total allowable cost of the project up to a maximum NEI share of \$200,000.

Eligibility: Any domestic public, or non-profit institution, association, or organization is eligible to apply.

Method of Application: Applicants must use PHS Form 398 "Application for Public Health Service Grant".

C. Acquisition of Specialized Laboratory Instrumentation:

Support may be requested for specialized laboratory instrumentation. The instrumentation may be project specific, but, also may be shared among investigators conducting vision research, and which otherwise might not be justified on an individual project grant. The NEI will provide up to 50% of the total purchase price of major laboratory equipment costing in the range of \$50,000 to \$300,000 up to a maximum NEI share of \$25,000 to \$150,000.

Eligibility: Any domestic public, or non-profit institution, association, or organization is eligible to apply.

Method of Application: Applicants must use PHS Form 398 "Application for Public Health Service Grant".

### III. APPLICATION RECEIPT

Grant applications in response to this RFA should be submitted to the Division of Research Grants, National Institutes of Health. A receipt date of May 15, 1986 has been established. Applications received after this date will not be accepted for review in this competition.

### IV. APPLICATION PROCEDURE

Prospective applicants are strongly encouraged to contact staff of the NEI before any application procedures are initiated to discuss the feasibility of the proposal. Each of the support mechanisms for construction, renovation, and instrumentation must be applied for separately.

Application forms, specific application guidelines, and detailed program assistance may be obtained from either of the following individuals:

Israel A. Goldberg, Ph.D. OR  
Deputy Associate Director for  
Extramural & Collaborative Programs  
National Eye Institute  
Building 31 - Room 6A03A  
Bethesda, Maryland 20892  
(301) 496-5983

Geoffrey E. Grant  
Chief, Extramural Services Branch  
National Eye Institute  
Building 31, Room 6A48  
Bethesda, Maryland 20892  
(301) 496-5884

**ANNOUNCEMENT****AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****CA-86-09****INHERITANCE AND MARKERS OF COLORECTAL CANCER AND POLYPS****P.T. 34; K.W. 0715035, 1002019****NATIONAL CANCER INSTITUTE**

Application Receipt Date: June 15, 1986

The Organ Systems Program of the Division of Cancer Prevention and Control, National Cancer Institute (NCI) invites grant applications for studies aimed at identifying and comparing populations at high risk for colorectal cancer. A major goal of this announcement is to solicit applications which integrate research on the genetic epidemiology of adenomatous polyps with new findings on markers for colorectal cancer.

**I. BACKGROUND**

A small percentage of colorectal cancer cases is associated with inherited syndromes that display well-known patterns of genetic segregation and inheritance. A much larger percentage of cases exhibits familial aggregation but displays no readily apparent pattern of mendelian inheritance. This latter group represents a significant fraction of colorectal cancer cases. Further delineation of this group by polyp and marker studies would lead to direct clinical benefits. There is a need for collaborative investigations which would further identify polyp etiologic factors and clinically useful markers for high-risk populations. The adenomatous polyp is a much more common lesion than colorectal cancer, and polyps are thought to occur in response to the same genetic and environmental factors which lead to malignancy. Thus, polyps from a spectrum of populations at high-risk for colorectal cancer would provide valuable clinical material for testing cancer markers and for testing hypotheses of gene-environment interactions.

Human colon cancer is a good system in which to determine in a rigorous way whether new reagents, such as monoclonal antibodies or cloned gene sequences, can be of significant value in the diagnosis, prognosis, and classification of solid tumors. The identification of high-risk groups in addition to the readily recognized genetic syndromes, would permit close monitoring of a much larger segment of the

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This program is described in the Catalog of Federal Domestic Assistance No. 13.393, Cancer Prevention Research. Awards will be made under authorization of the Public Health Service Act, Title III, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This Program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

population at risk for colorectal cancer. The subsequent application of preventive measures, early removal of preneoplastic lesions and early surgical intervention would reduce incidence and improve prognosis in these groups.

## II. Research Goals and Scope

The overall goal of this initiative is to stimulate the development of collaborative studies between marker experts and clinical research groups having access to populations at high-risk for colorectal cancer. A specific objective is to define population groups which differ in their inherited risk for colorectal cancer. Emphasis is placed on familial aggregates of adenomatous polyps and colorectal cancer in order to extend observations from the currently well-known high-risk genetic groups into the larger population of sporadic colon cancer. Biochemical, immunologic, genetic, cytogenetic and molecular markers will be identified and applied to individuals in these defined population groups to identify which individuals are predisposed to adenomatous polyps and colorectal cancer, and to classify stages in the progression from normal colonic mucosa to invasive and metastatic carcinoma.

A long-range goal would be to define a major gene for adenomatous polyps, or to define a marker that might lead to the successful chromosomal mapping of a colorectal cancer gene.

## III. MECHANISM OF SUPPORT:

Policies that govern research grant programs of the NIH will prevail. NCI plans to fund up to five awards for project periods of three years and has set aside \$1,000,000 for the initial year of funding. The expected starting date for these awards is December 1, 1986. Renewability would be dependent on successful competition in the regular NIH grant review system. Although this program is provided for in the financial plans of the NCI, awards are contingent upon availability of funds for this purpose and the receipt of applications of high scientific merit. There are no plans for future reissuance of this RFA.

## IV. STAFF CONTACT

A more detailed RFA is available upon request from the staff contact. Please direct all inquiries and requests to:

Dr. Vincent J. Cairoli  
Organ Systems Section  
Cancer Centers Branch  
Blair Building - Room 727  
National Cancer Institute  
Bethesda, Maryland 20892-4200.

Telephone: (301) 427-8818

Applicants are encouraged to submit a letter of intent, identifying the proposed principal investigator and collaborating institutions, to Dr. Cairoli by April 15, 1986. A letter of intent is not binding and will not be used in the review of any application submitted.

**ANNOUNCEMENT****AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA****86-CA-06****COOPERATIVE HUMAN TISSUE NETWORK****P.T. 34, 36; K.W. 0780005, 0780015, 0715035, 1002008, 0710070, 1002019****NATIONAL CANCER INSTITUTE**

Application Receipt Date: July 15, 1986

The Diagnosis Program of the Division of Cancer Biology and Diagnosis (DCBD), National Cancer Institute (NCI) invites applications for cooperative agreements from institutions capable of and interested in participating in a cooperative network of human cancer tissue laboratories located in or near major centers of biomedical research in the United States. The purpose of this network is to stimulate, for the good of the public, cooperative efforts to collect and distribute human tumor tissues and thereby to stimulate research utilizing those tissues. These activities are expected to encourage basic and developmental studies in many areas of cancer research, including molecular biology, immunology and genetics. Numerous investigators have indicated that a major obstacle to cancer related research is the lack of access to cancer tissue and related control tissue from the same patient. The major benefit from the development of a human cancer tissue network will be to the scientific community and will involve improved access to human tumor tissue and improved techniques for its collection and distribution. All applications received in response to this request will be reviewed by the same National Cancer Institute (NCI) review group. Applicants, if funded under this RFA, will be supported through cooperative agreement awards in accordance with the policies of the Public Health Service and the NIH.

The investigators in the cooperative tissue network will be responsible for planning and directing the program with the assistance of NCI Program Staff. NCI will assist in setting priorities and in annually evaluating progress, and will approve operating policies prior to implementation. An applicant institution may apply for a period of support of up to three years under this RFA. A maximum of three awards will be made.

The support mechanism for this program will be the NIH cooperative agreement. This mechanism is used when the NCI, with concurrence of a Board of Scientific Counselors, wishes to stimulate investigator interest and proposes to advise in planning in an

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This program is described in the Catalog of Federal Domestic Assistance No. 13.394, Cancer Detection and Diagnosis Research. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, 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 the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.



important and opportune area of research support. In the initial year, \$1,036,000 has been set aside in support of this program. The deadline for receipt of applications is July 15, 1986.

#### REQUIREMENTS FOR PARTICIPATION IN THE COOPERATIVE HUMAN TISSUE NETWORK

The principal investigator (PI) of a human tissue laboratory should be an experienced pathologist and have demonstrated research experience in an area related to cancer. The PI should also be actively involved in the operation of a pathology laboratory with demonstrated access to a wide range of human cancer tissues. The general duties and responsibilities of the PI should be clearly delineated in the application. The applicant should also clearly describe the relationships among major collaborators and tissue sources.

#### INQUIRIES

Potential applicants are strongly encouraged to consult with NCI staff and to obtain a copy of the complete RFA before submitting an application in response to this announcement. Requests for the full RFA as well as requests for further information and other inquiries concerning development of the application should be directed to:

Roger L. Aamodt, Ph.D.  
Program Director for Pathology/Cytology  
Diagnosis Program  
Division of Cancer Biology and Diagnosis  
Westwood Building - Room 10A15  
5333 Westbard Avenue  
Bethesda, Maryland 20892

Telephone: (301) 496-7147

**ANNOUNCEMENT****AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****86-CA-11****INCREASING THE USE OF MAMMOGRAPHY AND BREAST PALPATION FOR EARLY DETECTION OF BREAST CANCER****P.T. 34; K.W. 0745055, 0715035, 0706030, 0785190****NATIONAL CANCER INSTITUTE**

Application Receipt Date: July 14, 1986

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites applications for community intervention studies aimed at increasing and sustaining the use of state-of-science mammography and breast palpation for the early detection of breast cancer in women 50 years of age and older. These studies are limited to applicants from within the United States. The intent is to fund up to three awards for four years apiece.

**I. BACKGROUND**

A priority goal of the National Cancer Institute is to reduce cancer mortality by 50% by the year 2000. Until more is known about the possibility of primary prevention of breast cancer, early detection is the key to cancer control at this site. The Health Insurance Plan of Greater New York (HIP) demonstrated a 30 percent ten-year reduction in breast cancer mortality among women screened by mammography and physician examination. There is general agreement that HIP showed an unequivocal screening benefit for women 50 years of age and older. For younger women, the benefit/risk ratio is still the subject of scientific discussion. More recent studies in the U.S., Holland, and Sweden support the thesis that mammography combined with breast palpation or mammography alone can substantially reduce mortality from breast cancer.

Based on scientific evaluation, the National Cancer Institute and the American Cancer Society recommend the routine use of state-of-science mammography and breast palpation for women 50 years of age and older. However, national data indicate that this position has not been accepted or adopted by the medical

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This program is described in the Catalog of Federal Domestic Assistance No. 13.399, Cancer Control. Awards will be made under the authority of Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 286c) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health System Agency review.

profession and its clientele. Studies report that only 4 to 15 percent of women over the age of 50 are receiving mammography annually. Breast palpation by a health professional is a much more popular procedure. However, little is known about the quality of these examinations, and an inverse relationship exists between age and the frequency of breast palpation.

## II. RESEARCH GOALS AND SCOPE

The interventions that will be developed, implemented, and evaluated in this research are expected to address and remedy the barriers to routine and competent use of state-of-science mammography and breast palpation among women 50 years of age and older. Unless exceptions can be justified, the research should focus on geographically defined population areas. No community should have fewer than 10,000 women 50 years of age and older. It is anticipated that separate, but complementary, interventions will be designed for the women and their health-care providers. If subgroups of women do not have established sources of care, special attention should be given to expediting their access to mammography and breast palpation within the existing health care system or through creative outreach programs. No funds in the grant are to be used to offset the cost of screening procedures, screening equipment, or stationary or mobile facilities; but the funds can be used to stimulate plans and consortiums for lowering cost.

Applicants should address the issue of quality assurance measures for mammography and breast palpation by health professionals. The intention of NCI is to improve and sustain the quality of mammography and breast palpation over time. Therefore, the Institute is encouraging applicants to select quality assurance approaches that will be acceptable to the target community during the years of the study and in the future.

An evaluation of the effectiveness of the health-promotion activity must be undertaken by the applicant per se or by one or more subcontractors. It can be assumed that NCI funds for the intervention activity will expire in three years. However, the evaluation effort should be budgeted for an additional year -- four years altogether. The applicant should address the measurement of process variables that link the interventions to behavioral change or nonchange among specific groups of women and their health-care providers. To control for behavioral change that occurs independent of the intervention strategies, applicants should address the issue of control communities or subcommunities as well as baseline assessments.

## III. STAFF CONTACT

A copy of the complete RFA including the research goals and scope, the review procedures and criteria, the method of applying, and an extensive bibliography can be obtained by contacting:

Dr. Jan Howard  
Health Promotion Sciences Branch  
Division of Cancer Prevention and Control  
National Cancer Institute  
Blair Building, Room 415  
Bethesda, Maryland 20892-4200  
Telephone: (301) 427-8656

**ANNOUNCEMENT****AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****86-AI-07****PROGRAM PROJECTS IN TRANSPLANTATION IMMUNOLOGY****P.T. 34; K.W. 0710125, 0745040, 0745065, 0710070****NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

Application Receipt Date: September 15, 1986

**I. BACKGROUND INFORMATION**

The Genetics and Transplantation Biology Branch of the Immunology, Allergic and Immunologic Diseases Program of the National Institute of Allergy and Infectious Diseases (NIAID) supports basic and applied research in immunogenetics and transplantation immunology. Program Projects in Transplantation Immunology represent an award mechanism which the Branch has employed to meet this objective. They are intended to offer an opportunity for the investigation of the human immune system which has been subjected to deliberate manipulations, and to investigate the hazards associated with graft rejection and with immunosuppressive therapy employed to prevent or control it. Three such program projects are currently funded although support for one is scheduled to conclude in 1987. This request for applications (RFA) is intended to encourage the development of applications from collaborating investigators and to coordinate the submission and review of new and renewal program project applications.

**II. RESEARCH GOALS AND SCOPE**

The goal of Program Projects in Transplantation Immunology is the clarification and the capability to successfully manipulate the immune system in transplant recipients. Specific emphasis will be on immune regulation prior to transplantation, during preparation for transplantation (when tolerance is induced), during maintenance immunosuppression and during episodes of rejection. Methods of immunomodulation will be studied and new procedures developed. The program project will present a multidisciplinary approach with a well defined central theme and interrelated individual projects. Collaboration between immunologists and transplant clinicians will be an integral part of the program, thus facilitating extension of the basic discoveries from the laboratory into clinical practice.

**III. MECHANISMS OF SUPPORT**

Program project grants are awarded to an institution in behalf of a program director for the support of a broadly based, multidisciplinary, long-term research program which has a specific major objective or basic theme. A program project generally involves the organized efforts of groups of investigators who conduct research projects related to the overall program objective. The grant can provide

support for the projects and for certain core resources shared by individuals where the sharing facilitates the total research effort. Each component project, supported under a program project grant, is expected to contribute and be directly related to a common theme; the projects should demonstrate an essential element of unity and interdependence. At least one award is planned for fiscal year 1987.

#### IV. STAFF CONTACT

A more detailed RFA may be obtained from:

Jane S. Schultz, Ph.D.  
Chief, Genetics and Transplantation  
Biology Branch  
National Institute of Allergy and  
Infectious Diseases  
Westwood Building - Room 754  
National Institutes of Health  
Bethesda, Maryland 20892

Telephone: (301) 496-5598

Prospective applicants are encouraged to submit a one-page letter of intent identifying the proposed principal investigator and any other participating institutions. The NIAID requests such letters by June 15, 1986, for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding. It will not enter into the review of any application subsequently submitted and is not a necessary requirement for application. Letters of intent and inquiries should be directed to Dr. Schultz at the address shown above.

**ANNOUNCEMENT****AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****86-AI-08****SEXUALLY TRANSMITTED DISEASES RESEARCH UNITS - CHLAMYDIAL INFECTIONS AND PELVIC INFLAMMATORY DISEASE****P.T. 34; K.W. 0715220, 0715125, 0785055, 0710070, 0755020, 0745020, 0745055, 0415000, 0403004****NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

Application Receipt Date: July 15, 1986

**I. BACKGROUND INFORMATION**

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for program project grants to be initiated in FY 1987, as part of this Institute's continuing commitment to research in Sexually Transmitted Diseases (STDs).

A major new initiative is required to expand the Institute's program on chlamydial infections as well as on pelvic inflammatory disease (PID). Chlamydia trachomatis (C.t.) is an obligate intracellular bacterium with an unusual life cycle. Chlamydial infections are among the most prevalent STDs in the U.S. today. No firm statistics are available, but the best estimates from the Centers for Disease Control (CDC) are that about 3,000,000 cases of C.t. infections occur annually. The most important aspect of these infections is the serious sequelae of PID in women. These include endometritis, salpingitis, ectopic pregnancy, and involuntary sterility as a result of tubal scarring. The costs of PID to the health care systems of the U.S. are estimated by CDC to be over \$1.5 billion annually, if one considers costs of hospitalization, surgical procedures, fetal wastage, time lost from employment or education, and general poor health and recurring illness of the women involved.

**II. RESEARCH GOALS AND SCOPE**

- A. As one means of achieving the major goal of needed research in this area, the NIAID maintains support of a number of STD Research Units that function as centers of excellence to focus on research and training in STDs. This RFA is for support of two new Research Units that will have as their major objective research on PID and the problem of chlamydial infection. These units will be

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This program is described in the Catalog of Federal Domestic Assistance No. 13.856, Microbiology and Infectious Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Sec. 301 (c), Public Law 78-410, 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 the intergovernmental review of Executive Order 12372 or Health Systems Agency review.

supported as multidisciplinary program project grants (PO1) with individual principal investigators who will head clearly identifiable research subprojects within the overall structure of the program project, under the leadership of the Program Director. A strong clinical component must be a major part of the proposal. The research to be considered in these program projects will be on PID, with special emphasis on the role of C.t., either alone or with mixed infections including gonorrhea. Non-sexually transmitted disease agents as causes of PID will not be considered for support as part of these program projects.

- B. The research efforts should have as their central focus the major complications of STD infections resulting in PID. The underlying causal organisms, C.t. or the gonococcus, either alone or as a mixed infection, will also be studied intensively as the initiating focus of infection leading to PID. Specific areas of research can include, but are not limited to: basic biology and virulence factors of C.t.; the host's immune responses, both cellular and humoral; improved methods of diagnosis, therapy, and preventive measures for PID; animal model systems; epidemiology of C.t. infections as it relates to PID; computer modeling studies to provide means of understanding the spread and the control of C.t. and PID.

An appropriate addition to the STD Unit on PID can include an educational component to advance learning experiences in chlamydial infections and PID, for medical staff and research fellows. A community outreach program and behavioral studies would also be acceptable. Individual postdoctoral training, however, will not be supported by the program project; training stipends for support of postdoctoral fellows are provided for by other NIH mechanisms.

C. MECHANISM OF SUPPORT

Eligibility - domestic universities, medical colleges, hospitals, laboratories, and other public or private research institutions, including state and local governmental units, are eligible.

Ongoing STD Research Units currently supported by the NIAID STD program will not be considered for support under the terms of this RFA.

The program project can be supported for up to five years. Renewal of a program project for an additional five year period will be competitive and will depend on progress made as well as on the availability of funds. Funds available for support of these PID Research Units total \$600,000 for direct costs. It is the Institute's intention to support two such units within this level of available funds. Earliest start date for the successful units will be April 1, 1987.

III. All inquiries and requests for the full text of this RFA should be directed to:

Milton Puziss, Ph.D., Chief  
MIDP, NIAID, NIH  
Westwood Building - Room 738  
Bethesda, Maryland 20892

Telephone: (301) 496-7728

**ANNOUNCEMENT****AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****86-HD-03****DETERMINATION OF MECHANISMS AFFECTING TRANSDERMAL ADMINISTRATION OF CONTRACEPTIVE DRUGS****P.T. 34; K.W. 0750020, 0710100****NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT**

Application Receipt Date: July 15, 1986

**I. BACKGROUND**

The Contraceptive Development Branch (CDB) of the Center for Population Research (CPR) of the National Institute of Child Health and Human Development (NICHD), is inviting research grant applications for investigations into the determination of mechanisms affecting transdermal administration of contraceptive drugs. By issuing a Request for Applications (RFA), CPR is indicating its intention to encourage investigator interest in this specific research area.

The Contraceptive Development Branch as part of its program to develop more effective and safe agents for the regulation of fertility is sponsoring several projects on transdermal administration of progestagens with or without concomitant estrogen. Although progress on these projects is satisfactory, it is apparent that even though the transport phenomena in the delivery devices themselves can be well characterized, the factors determining uptake by the skin and eventual bioavailability are less clearly understood. It is the intent of this RFA to improve upon the largely empirical approach to this field by sponsoring investigations on the mechanisms controlling transdermal administration of contraceptive drugs.

**II. RESEARCH GOALS AND SCOPE**

Research projects submitted in response to this RFA should have as their goal the elucidation of mechanisms involved in the percutaneous absorption of contraceptive drugs. The projects should include but need not be limited to the development and validation of appropriate animal models. Factors such as metabolism and pharma-

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This program is described in the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, III Section 301 (Public Law 78-410, 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 Health Systems Agency review.



cokinetics should be considered in addition to the characterization of the structural aspects of the skin. The ultimate objective of the research should be a better understanding of transport mechanisms which will help in the design of more reliable and predictable drug delivery systems.

### III. STAFF CONTACT

Requests for further information or copies of the full RFA should be addressed to:

Henry L. Gabelnick, Ph.D.  
Contraceptive Development Branch  
Center for Population Research  
National Institute of Child Health  
and Human Development  
National Institutes of Health  
Landow Building - Room 7A-04  
Bethesda, Maryland 20892

Telephone: (301) 496-1661

**ANNOUNCEMENT****TRANSFUSION MEDICINE ACADEMIC AWARD****P.T. 34; K.W. 0785035, 0750010, 0785070****NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application receipt date: October 15, 1986

The Transfusion Medicine Academic Award (TMAA) was initiated in January 1983, to (1) encourage the development of curricula in transfusion medicine, and (2) allow the awardee to broaden his or her expertise in transfusion medicine so as to contribute more effectively to the teaching, research, and clinical needs of this discipline. The term "transfusion medicine" is used to define a multidisciplinary area concerned with the proper use or removal of blood and its components in the treatment or prevention of disease states (other than in renal hemodialysis). Schools of medicine, osteopathy, or veterinary medicine (United States or its possessions and territories) singly or in concert one with another, are eligible to apply for one 5-year TMAA (nonrenewable), providing they possess the requisite blood bank, patient care, and research facilities required for such an activity. Applications from schools of veterinary medicine must indicate the specific relationships of their program to the human medicine objectives of the award. The TMAA may provide salary, fringe benefits, supporting costs, and indirect costs to faculty members who are established investigators, and skilled organizers and negotiators. The number of awards made each year will depend on the availability of funds.

The Division initiated the Transfusion Medicine Academic Award Program to encourage the development of teaching programs in transfusion medicine. At present, teaching, research, and clinical responsibilities in transfusion medicine are rarely coordinated into a definable program but are dispersed among basic and clinical science disciplines and among activities of the local transfusion services or blood center facility. It is important to note that establishing a transfusion medicine curriculum may not require additional curriculum time; existing teaching materials (components of other disciplines) may be coordinated into an overall program and organized to focus on emerging and important areas of transfusion medicine. Some schools may find it desirable to assemble the appropriate components into a specific unit. Others may wish to retain the transfusion medicine discipline as part of another major department.

This award is also intended to:

- attract to the field of transfusion medicine outstanding students and promising young clinicians and scientists who can serve in the teaching, research, and clinical aspects of transfusion medicine;

The programs of the Division of Blood Diseases and Resources of the National Heart, Lung, and Blood Institute are identified in the Catalog of Federal Domestic Assistance, No. 13.839. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

- encourage the development of faculty capable of providing appropriate instruction in the field of transfusion medicine;
- facilitate interchange of information, and evaluation and educational techniques among research, medical, and blood service communities; and
- enable the grantee institution to develop a continuing transfusion medicine program, using local support, when this Award terminates.

Requests for the TMAA Program Guidelines should be directed to:

Fann Harding, Ph.D.  
National Heart, Lung, and Blood Institute  
Federal Building - Room 5A08  
Bethesda, Maryland 20892

Telephone: (301) 496-1817

**ANNOUNCEMENT****NIADDK MINORITY INVESTIGATOR RESEARCH ENHANCEMENT AWARD****P.T. 34 FF; K.W. 0710030****NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES****I. DESCRIPTION**

The Minority Investigator Research Enhancement Award (MIREA) provides support for faculty members of minority institutions to allow them to collaborate with Principal Investigators of active regular research grants funded by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK).

Any domestic institution wishing to include faculty of minority institutions in one of its NIADDK-funded research projects may submit a supplemental grant application for this purpose. Approved applications will be funded as supplements to active NIADDK grants. These may include, but are not limited to, individual projects (R01), program projects (P01), and selected components of center grants (P30, P50, P60).

**II. OBJECTIVES**

The MIREA is a component of the overall NIADDK program to strengthen biomedical research and training in institutions with significant commitments to minorities and thereby to increase the participation of minority scientists in biomedical research. The MIREA supports faculty members of minority institutions (hereafter referred to as "Minority Investigators") to collaborate with Principal Investigators currently funded by NIADDK research grants or center programs. The MIREA is targeted on Minority Investigators who have completed their training but who have not served as Principal Investigators on NIH regular research grants. The MIREA is intended to enhance opportunities for long-term productive collaborations among investigators and eventually to increase the number of Minority Investigators holding their own research grants.

**III. ELIGIBILITY AND TERMS OF AWARD****A. Minority Institution**

A minority institution is defined as a medical or non-medical college, university or equivalent school in which students of under-represented

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This program is described in the Catalog of Federal Domestic Assistance, 13.846, 13.847, 13.848, and 13.849. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

minorities (including but not limited to Blacks, Hispanics, American Indians, and Asian or Pacific Islanders) comprise the majority or significant proportion of the school enrollment and which has a commitment to the special encouragement of minority faculty, students and investigators. The commitment of the institution to the faculty candidate's research and development must be clearly presented in the application, including a statement from the candidate's supervisor.

B. Minority Investigator

A Minority Investigator is defined as a faculty member of a minority institution who is engaged in biomedical research. Candidates for this award are Minority Investigators who (1) are citizens of the United States or permanent residents at the time of application, (2) have a doctoral degree or equivalent in a biomedical or behavioral science, and (3) have the background to benefit from this program. The Minority Investigator should not already have spent an extended period of time in the applicant laboratory and should not have been a Principal Investigator on any traditional grant mechanism from NIH. This does not exclude from candidacy Minority Investigators who have been supported by the NIH Minority Biomedical Research Support (MBRS) Program, training grants, fellowships or other similar awards. The program is not intended to pay stipends for student trainees or support candidates without previous research background.

C. Principal Investigator

All Principal Investigators of active NIADDK grants are eligible to submit supplemental applications on behalf of a Minority Investigator. Although not excluded, MIREA applications from Principal Investigators in the final year of their project period will be evaluated on a case-by-case basis.

D. Research Project

The proposed research project for the supplement must be closely related to the currently funded research grant. It may represent an increased effort relative to an already approved objective of the research project or propose to enhance the effectiveness of the overall research. The proposed investigation must provide the minority investigator an opportunity to contribute intellectually to the program and to enhance his/her own potential as an independent investigator. The scope of the proposed work should be consistent with the Minority Investigator's proposed level of effort and length of tenure in the Principal Investigator's laboratory.

E. Length of Tenure

The length of tenure should be not less than three months and nor more than 15 months. Short tenures (3-4 months) must represent the full-time effort of the Minority Investigator. For longer tenures, part-time commitments are acceptable but should not be less than 30% effort for any part of the award period.

#### F. Project Report

The Principal Investigator will be asked to prepare (at the time of the annual report and/or final progress report) a section summarizing the work conducted during the tenure of the minority investigator. This report will be due 60 days after completion of the project. This portion of the report should include, but not be limited to, the following elements: 1) a summary of the research project; 2) a summary of all pertinent results; 3) titles and/or copies of manuscripts or publications resulting from this research association, and 4) a statement or an outline of how the research experience will be integrated into the minority investigator's long range or continuing research effort.

#### IV. PROJECT EVALUATION AND REVIEW CRITERIA

Proposals submitted in response to this announcement will be reviewed for eligibility by the NIADDK Minority Program Advisory Committee, an NIADDK staff committee of intramural and extramural scientists, using the following criteria:

- A. The proposed research as described in the supplemental application should fit within the general scope of the approved and funded project.
- B. The qualifications of the Principal Investigator and the Minority Investigator should indicate a high likelihood that the proposed work will be successful.
- C. The proposed work should further the objectives of the MIREA.
- D. The length of time and budget requested should be appropriate for the proposed work.

Where questions of scientific content or expansion of project scope are involved, a review by non-Federal scientists will be conducted. Recommendations will be forwarded through the Program Staff to the National Arthritis Diabetes Digestive and Kidney Diseases Advisory Council for second level review.

#### V. FUNDING

Successful applications will be funded as administrative supplements to the NIADDK investigator's grant. The maximum award (total direct costs) is \$30,000 on an annualized basis, with projects of greater than 12 months duration prorated accordingly. The actual amount of the award awards made under this program are for the sole purpose of facilitating participation by Minority Investigators as described above.

#### VI. HOW TO APPLY

All potential applicants are encouraged to contact the NIADDK Office of Extramural Activities at (301) 496-7277 prior to preparing an application.

The Principal Investigator must submit a supplemental grant application through his/her institution on the Standard Form PHS 398, limited to the following: (1) Face page -- Item 2 should give the grant number of the active grant and specifically state "Minority Investigator Research Enhancement Award" (for example grant number AM 12345-06 "Minority Investigator Research Enhancement Award");

(2) budget page; (3) complete curriculum vitae of the minority investigator; (4) statement of commitment and support from the Minority Investigator's institution; and (5) outline of the research project as it relates to the parent grant.

Applications may be submitted at any time; however, applications received less than 90 days prior to a scheduled NIADDK Council meeting will be reviewed at the subsequent NADDK Council meeting.

The original and six copies of the application should be sent to:

Division of Research Grants  
National Institute of Health  
Westwood Building - Room 240  
5333 Westbard Avenue  
Bethesda, Maryland 20892

**ANNOUNCEMENT****PHARMACEUTICALS FROM THE SEA****P.T. 34; K.W. 0750025, 0740020, 0740025, 0755010, 0710080, 1003012****NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

Application Receipt Dates: June 1, October 1, and February 1

The National Institute of Allergy and Infectious Diseases (NIAID) invites investigator-initiated research grant applications that will increase our knowledge and understanding of natural products obtained from marine invertebrates.

From antiquity to the present, most searches for new antimicrobial agents and other drugs for the treatment of infectious diseases, and human disease in general, have been confined to the land, while only a very few have been marine oriented.

President Reagan proclaimed the 1984 - 1985 period as the "Year of the Ocean." This proclamation was made in recognition of the importance of increasing public awareness and knowledge of the ocean and its resources.

In the recent past, many interesting natural products relevant to infectious disease treatment have been recovered from marine invertebrates including sponges, tunicates (i.e., sea squirts, ascidians), and nudibranch molluscs (without shells or true gills in the adult stage). These invertebrates have been obtained from the floor of the Caribbean Sea together with numerous other marine environments in proximity to Australia, Belize, Florida, Guam, Mexico, New Zealand, Palau, Ponape and Fanning islands, and Eniwetok Atoll.

Some of the natural products elaborated by these invertebrates demonstrate antibacterial, antifungal, antiviral and cytotoxic activities. Didemnin B, obtained from a Caribbean tunicate, possesses activity against Herpes simplex 2, and Rift Valley fever in mice. It is also exceedingly potent as an immunosuppressive agent, giving essentially the same results as the current clinical choice, cyclosporin A, but at 1/1,000 the concentration.

If possible, on site bioassays should be conducted for the following activities: antiviral, cytotoxic, antifungal and antibacterial. Further characterization of those natural products showing promise can await evaluation until they are taken to more sophisticated land-based laboratories.

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This program is described in the Catalog of Federal Domestic Assistance No. 13.856, Microbiology and Infectious Diseases Research. Awards will Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulation 42 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12382 or Health Systems Agency review.



Applications in response to this announcement will be assigned and reviewed in accordance with the National Institutes of Health (NIH) peer review procedures. Applications usually will be assigned primarily to the NIAID, but may also receive secondary assignment to another Institute such as the NCI because of overlapping interests. Applications will first be reviewed for scientific and technical merit by a group composed mostly of non-Federal scientific consultants. Following this initial review, applications assigned to NIAID will be evaluated for program relevance by the National Advisory Allergy and Infectious Diseases Council. Applications assigned to other institutes will be reviewed by the appropriate Councils and/or Boards. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

All PHS and NIH grant policies governing regular research project grants, including cost sharing, apply to applications received in response to this program announcement.

#### METHOD OF APPLYING

Applications will be accepted in accordance with the usual NIH receipt dates for new applications. Deadline dates are: June 1, October 1, February 1.

Applications should be submitted on form PHS 398, which is available in the grants and contracts business office at most academic and research institutions or from the Division of Research Grants (DRG, NIH). In space #2 on the first page of this form, indicate the title of this program announcement. The original and six copies of the application should be submitted to:

Application Receipt Office  
National Institutes of Health  
Westwood Building - Room 240  
Bethesda, Maryland 20892

For further information contact:

Irving P. Delappe, Ph.D.  
Chief, Molecular Microbiology  
National Institute of Allergy  
and Infectious Diseases  
National Institute of Health  
Building 31 - Room 7A51  
Bethesda, Maryland 20892

Telephone: (301) 496-5893

**ANNOUNCEMENT****PREVENTION AND CESSATION OF USE OF SMOKELESS TOBACCO****P.T. 34; K.W. 0745055, 0502000, 0403004, 0785055****DIVISION OF CANCER PREVENTION AND CONTROL****NATIONAL CANCER INSTITUTE**

Application Receipt Dates: June 1, October 1, February 1

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute (NCI) is interested in supporting studies designed to develop and evaluate the effectiveness of interventions to prevent the onset and reduce the prevalence of use of smokeless tobacco in the United States.

The proposed studies should seek to: (a) identify patterns of smokeless tobacco use and the primary factors influencing such use; (b) develop and evaluate intervention strategies to reduce the incidence and prevalence of smokeless tobacco use; and (c) develop and evaluate assessment procedures to determine the long-term effectiveness of these intervention strategies.

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals.

**I. BACKGROUND**

Smokeless tobacco includes both chewing tobacco (loose leaf, plug, twist) and snuff (moist or dry, fine cut). Use of smokeless tobacco has been linked to oral and pharyngeal cancer, as well as oral leukoplakia and periodontal disease.

Sales of smokeless tobacco products have increased substantially in the past ten years. Market analyses indicate this growth is due to the creation of new markets that differ demographically from the traditional smokeless tobacco market. Products are being aggressively promoted in campaigns that target young adults and teenagers, and there are widespread reports of increased use among youth. Industry reports claim increased social acceptance and use among white collar workers as well. Very little is known about the patterns of use and factors influencing use of smokeless tobacco products within these new populations of users. Specifically, the relationship of use to cigarette smoking is unclear.

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This program is described in the Catalog of Federal Domestic Assistance No. 13.399, Cancer Control. Awards are under authorization of the Public Health Service Act, Section 301(c) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirement of Executive Order 12372 or Health Systems Agency review.

## II. OBJECTIVES AND SCOPE

The purpose of this program announcement is to solicit applications from qualified investigators interested in developing innovative intervention programs focused on the use of smokeless tobacco and determining the long-term effectiveness of these programs on the prevention and cessation of smokeless tobacco use. The focus of the studies envisioned must be on the long-term effectiveness of interventions. It is anticipated, in keeping with the goals of the National Cancer Institute's Cancer Control Program, that studies funded under this PA will be Phase III (i.e., for the purposes of this PA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out within a large and defined population in such a way that the results obtained are representative of results in large target populations) investigations.

It is recognized, however, that there are substantial gaps in our knowledge concerning use of smokeless tobacco which may be essential to the development of an effective and durable intervention program. In particular, little is known about the demographics of users and those at risk for use, patterns of use, biological markers of use, factors influencing use, and the relationship to use of other forms of tobacco, particularly cigarettes. Therefore, applicants will have the option of using a phased-in approach in which, during the first year, data describing the target population, prevalence, and patterns of use are obtained, unless such data are already available, and proposed interventions are pilot tested. At this point interventions would be initiated on a full scale. Information collected during the first year could be used to modify and adapt the proposed interventions as needed. In subsequent years interventions should be expanded with a major focus on evaluation of the interventions' effectiveness.

It is important that data collected in the studies funded under this PA be comparable so that comparisons can be made of patterns of smokeless tobacco use in different geographic and demographic populations. For this reason some standardization of data collection techniques and instruments will be encouraged. All funded investigators will meet with NCI staff as a group periodically to discuss appropriate measures for assessing use of smokeless tobacco, to share informal progress reports, and exchange information and ideas. Budgets should include travel expenses from the home institutions to Bethesda, Maryland, for the principal investigator and one co-investigator to attend two two-day meetings each year for those purposes.

The objective of these studies is to develop intervention strategies and to evaluate their effectiveness in preventing or reducing the prevalence of smokeless tobacco use. No restrictions are placed on the type of interventions, including the use of oral exams or the involvement of dentists and oral hygienists to deliver interventions. Any population subgroup may be chosen for study provided there is reasonable evidence that it contains a sizeable number of smokeless tobacco users or individuals who are at risk for initiating use (e.g., targeted by tobacco advertising; observed trends toward increased use; use by an immediately older cohort).

Prospective investigators should note (1) that the outcome measure of these studies should be smokeless tobacco use, not cancer incidence/ mortality, and (2) that the desired overall outcome of studies eventually supported through this PA are

interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; and d) readily adoptable by others with only those modifications that are necessary for a broad community/population impact.

### III. MECHANISM OF SUPPORT

Awards will be made as research project grants. The planning, direction, and execution of the proposed research will be the responsibility of the applicant. The total project period should not exceed five years. Where more than five years is required, and the case is made for such, the possibility for longer studies will exist through competing renewal grant applications.

Consideration will be given to researches's willingness to interact and cooperate with the NCI to facilitate the Institutes goals for reductions of cancer morbidity and mortality.

### IV. REVIEW PROCEDURES AND CRITERIA

Each application submitted in response to the PA will be reviewed by (1) an appropriate review panel of the NIH and (2) the National Cancer Advisory Board at one of its scheduled quarterly meetings. All applications recommended for approval will compete with other regular R01 approved grant applications for available funds. All PHS and NIH grant policies governing regular research project grants apply to applications received in response to this program announcement.

Applications must be responsive to this PA, in the sense of being directed towards the attainment of the stated programmatic goals. The factors considered in evaluating each response to this PA will be:

- o Scientific merit of the research approach, design, and methodology.
- o Scientific and technical significance and originality of the proposed research.
- o Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.
- o Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
- o Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.
- o Identity of sources of data, intervention materials, etc., and procedures for their analysis and assurance as to their accessibility.
- o Adequacy of steps taken to optimize and fully evaluate the durability of the intervention effect.
- o Likelihood of the intervention to be readily adoptable by others.
- o Generalizability of the findings to large segments of the population.

- o Theoretical and scientific justification for the intervention proposed.
- o Reasonableness of the proposed budget and duration of the research.

V. INQUIRIES

Additional information is available. Inquiries may be directed to:

Gayle M. Boyd, Ph.D.  
Smoking, Tobacco, and Cancer Program  
Office of the Director, DCPC  
National Cancer Institute  
National Institutes of Health  
Blair Building - Room 427  
9000 Rockville Pike  
Bethesda, Maryland 20892-4200

Telephone: (301) 427-8620

**ANNOUNCEMENT****PHYSICIAN SCIENTIST AWARD****P.T. 34; K.W. 0710030, 0785035****NATIONAL INSTITUTE ON AGING  
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES  
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE  
AND KIDNEY DISEASES  
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT  
NATIONAL INSTITUTE OF DENTAL RESEARCH  
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES  
NATIONAL EYE INSTITUTE  
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE  
NATIONAL CANCER INSTITUTE**

The National Institutes of Health (NIH) announces the availability of the Physician Scientist Award to be supported by those institutes listed. The award is intended to encourage newly trained clinicians to develop independent research skills and experience in a fundamental science. The PSA is targeted to newly trained clinicians who wish to receive training in a basic scientific discipline for application to a research problem that may not yet be well defined.

These awards provide the opportunity for clinically trained professionals with a commitment to research to develop into independent biomedical investigators. Two types of awards are available: the program award and the individual award. At this time only the National Institute on Aging and the National Institute of Environmental Health Sciences support the program award.

The awards will enable individuals with clinical training to undertake up to five years of special study in basic science with a supervised research experience. The first phase (two to three years) of the program will include both didactic study and laboratory experience conducted under the close sponsorship of an individual with extensive research experience in fundamental sciences. The second phase (up to three years) under the continuing guidance of this primary sponsor, will be to apply laboratory-based research in either a basic science or clinical department. This award requires a commitment from a sponsor with extensive fundamental research experience in a basic science such as (but not limited to) biochemistry, molecular biology, genetics, or immunology, and a research program plan using a fundamental or clinical science approach to disease related problems.

In summary, the Physician Scientist Award is designed to encourage the individual with clinical training to develop research skills in a fundamental science. To help support the transition from clinical training status to that of a productive investigator able to compete successfully for NIH research support, the Physician Scientist Award will provide the opportunity for clinicians to develop into independent investigators, to obtain research experience under the sponsorship of a basic research scientist and to initiate a research program. Women and minorities are encouraged to apply.

## I. ELIGIBILITY

- A. These awards are designed to provide an intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health professional degrees in the clinical sciences (M.D., D.D.S., D.V.M., D.O. or equivalent). Ordinarily physicians holding the Ph.D. are ineligible. Exceptions may be made to this requirement (1) for individuals with Ph.D.s unrelated to the biomedical and behavioral sciences or (2) for those who were involved in other than research activities after receipt of the Ph.D. where the elapsed time was such as to require two or more years of development to update basic science skills. Candidates ordinarily will have completed at least one post-graduate year of clinical training by the time the award is made.
- B. Candidates should demonstrate competence in clinical activities, and should show research potential. Candidates must provide evidence of a serious intent for research and academic careers.
- C. Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.
- D. Applicants for a Physician Scientist Award may not submit a concurrent application for an NIH Research Career Development Award, Academic Award, a Clinical Investigator Award or a Special Emphasis Research Career Award. Physician scientist awardees may subsequently apply for a New Investigator Research Award or a research project grant.
- E. Ordinarily a candidate with previous independent NIH research support or its equivalent will not qualify.

## II. MECHANISMS OF AWARD

This award may be supported through two mechanisms: the individual award and the program award.

### A. Individual Awards

#### 1. The Environment

Applications will be accepted from a domestic university, medical school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic sciences and commitment and capability to provide guidance to clinically trained individuals in the development of independent research careers. The environment desired is one which will stimulate and increase the interaction between basic scientists and clinical investigators.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for a research career. Evidence of the commitment of the institution to the candidate's research and development must be provided. Three

letters of recommendation attesting to the candidate's academic qualifications, motivation and research potential should be submitted.

## 2. The Program

The individual's program should be designed in two phases. The candidate and sponsor are jointly responsible for the preparation of the research development plan. It should start with a creative and detailed basic science learning experience in Phase I and progress to an intensive research activity in Phase II under the general guidance of a qualified sponsor. The sponsor may form an advisory committee, similar to a graduate student training committee, to develop a Phase I program for the candidate which should include course work, seminars, initial research experience, and other educational experiences necessary for intensive research in Phase II. The criteria for the transition of the candidate from Phase I to Phase II may also be developed by this committee. Only a general research plan for Phase II is required at this time. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of Phase I. This report is to contain specific information concerning progress and accomplishments and, in particular, an appropriately detailed Phase II research plan and protocol for administrative review and approval.

## 3. Sponsor

Each candidate must identify a primary sponsor who is recognized as an accomplished investigator in the basic science research area proposed, who has experience in training independent investigators and who will provide the guidance for the awardee's development and research plan. The primary sponsor must be committed to continue this involvement through the individual's total period of development under the award. In some cases candidates may elect to have a secondary clinical sponsor for the research intensive years.

## 4. Duration and Effort

This five year non-renewable award is based on up to five full-time 12 month appointments. All funds must be used on behalf of the original candidate. Support is divided into two distinct phases that relate to the individual's progress in becoming an independent investigator. It is required that a minimum of 75 percent effort be devoted to the research and research training program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with the program goals, i.e., the awardee's development into an independent biomedical research investigator or necessary to maintain clinical skills necessary for an academic clinical career.

It is desirable for individuals to complete both phases without interruption. It may be permissible, however, to interrupt the award and delay the start of Phase II in order to engage in further clinical training. In the event such a contingency arises, the awardee and the sponsor must justify the interruption to the awarding institute to assure that funds will be available to resume the award so that the candidate may complete the program.



5. Allowable Costs

- a. Salary -- Individual compensation based on the institution's salary scale for residents or junior faculty at an equivalent experience level but funding from this award for salary not to exceed \$40,000 per year per individual plus commensurate fringe benefits for essentially full-time (75-100 percent) effort to the endeavor.\*
- b. Sponsor's Support -- A sum of up to 10 percent of the primary sponsor's salary and commensurate fringe benefits during Phase I.
- c. Research and Development Support -- \$10,000 per year in Phase I increasing to \$20,000 per year in Phase II for research project requirements and related support, e.g., technical personnel costs, supplies, equipment, candidate travel, medical insurance premiums and tuition for necessary courses.
- d. Indirect Costs -- reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees and expenditures for equipment.

6. Concurrent Awards

Individuals entering Phase II are encouraged to apply for additional research support, e.g., New Investigator Research Award (R23) or Research Project award (R01). Such support may be applied for and held with no reduction in the \$20,000 provided as research support. However, salary support from PHS sources above the \$40,000 provided by this award is not allowable.

B. Program Award

Institutions with Program Awards may recruit and select candidates into their programs on a local basis rather than submitting a separate application on behalf of each prospective candidate. In all other respects, Program Awards are intended to provide support for the development of physician scientists in the same manner and under the same terms as the individual awards.

1. The Environment

Applications will be accepted from an association of departments and divisions and/or clinical departments representing a range of research interests. The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs with adequate numbers of highly trained faculty in clinical and basic sciences and with the interest and capability to provide guidance to clinically trained individuals in the development of research independence. The environment sought is one

\* NIH policy encourages supplementation from non-government sources, e.g., voluntary or professional organizations.

which will stimulate and increase the interaction between basic scientists and clinical investigators.

2. Program Director

The proposed Program Director should possess the scientific expertise, leadership and administrative capabilities required to coordinate and supervise an interdisciplinary research and development program of this scope. The Director should also be experienced in the design and management of programs for developing investigators, and should be able to demonstrate a superior record in the preparation of clinical investigators for independent research. In addition, a committee with representatives from the appropriate basic and clinical science departments shall be established to advise the Program Director.

3. Sponsor

Each candidate appointed on the grant must have a primary sponsor who is recognized as an accomplished investigator, actively involved in basic science research who will provide the guidance for the candidate's development and research plan. The primary sponsor must be committed to continue this involvement through the individual's total period of development under the award. In some cases candidates may elect to have a secondary clinical sponsor for the research intensive years.

4. Program

The Program award provides five years of renewable support. The award is intended to provide up to five years support of consecutive full-time 12 month appointments to each individual candidate appointed. This support is divided into two distinct phases that relate to the individual's progress in becoming an independent investigator. The support starts with Phase I which is to be a creative and detailed basic science learning experience and culminates in Phase II which requires intensive research under the general guidance of a qualified sponsor.

It is desirable for individuals to complete both phases without interruption. It is permissible, however, to delay the start of Phase II in order to engage in clinical training. In the event such a delay occurs, it is expected that the program director will plan to provide the necessary resources for the awardee to reenter and complete the program. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of Phase I. This report is to contain specific information concerning progress and accomplishments and, in particular an appropriately detailed Phase II research plan and protocol for administrative review and approval.

5. Duration, Effort and Allowable Costs: Support may be requested for up to two postdoctoral candidates entering Phase I per budget period.

- a. Salary -- Compensation for candidate based on the institution's salary scale for residents at an equivalent experience level but funding from this award is not to exceed \$40,000 per year per individual plus commensurate fringe benefits for essentially full-time (75-100 percent) effort to the endeavor.\*
- b. Sponsor's Support -- A sum of up to 10 percent of the primary sponsor's salary and commensurate fringe benefits during Phase I.
- c. Research and Development Support -- \$10,000 per year in Phase I increasing to \$20,000 per year in Phase II per candidate for research project requirements and related support, e.g., technical personnel costs, supplies, equipment, candidate travel, medical insurance premiums and tuition for necessary courses.
- d. Indirect Costs -- reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees and expenditures for equipment.

#### 6. Budgeting for Future Years

Critical to the success of this program award is the ability of the Program Director to make detailed mid-course assessments of each candidate's developing research skill and of the proper time for transition from one phase to another. It is expected that applicant institutions will initiate their activities under this award in a staged manner. That is, the first requested year of support would include funds for candidates in Phase I only. The second year would request funds for new candidates in Phase I as well as for continued funding of the first year's supported individuals. In this way, the requested level of support would increase steadily from the 01 through the 05 budget period as new candidates were appointed.

#### 7. Concurrent Awards

Individuals entering Phase II are encouraged to apply for separate research support. Such support may be applied for and held with no reduction in the \$20,000 provided as research support. However, salary support from PHS sources above the \$40,000 provided by this award is not allowable.

### III. EVALUATION

Awardees must agree to inform the National Institutes of Health annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

\* NIH policy encourages supplementation from non-government sources, e.g., voluntary or professional organizations.

#### IV. MECHANISM OF SUPPORT

The mechanism of support for this activity will be the research grant, awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended, 42 USC 241). The regulations (Code of Federal Regulations, Title 42 Part 52, and Title 45 Part 74) and policies which govern the research grant programs of the National Institutes of Health (NIH), will prevail. The award of grants pursuant to this announcement is contingent upon availability of appropriated funds.

#### V. METHOD AND CRITERIA OF REVIEW

Applications will be received by the NIH Division of Research Grants (DRG), and, governed by normal programmatic considerations as specified in the NIH Referral Guidelines, will be assigned to the appropriate institute for possible funding.

Applications in response to the Announcement will be reviewed in nationwide competition, and in accordance with the usual NIH peer review procedures. They will first be reviewed for potential for research development and scientific and technical merit by an institute review group composed mostly of non-Federal scientific consultants (initial review group). Following this review, the applications will be evaluated by the appropriate Institute Advisory Council (IAC).

##### A. The criteria for initial review of applications include:

1. Candidate - Candidate's competence in clinical activities, potential for a career in independent research, and commitment to, or interest to pursue a research career.
2. Sponsor - The sponsor's accomplishments in the basic science research area(s) proposed, and, where applicable, the accomplishments of the secondary clinical sponsor (Phase II); experience of the sponsor in training students; commitment of the primary sponsor for the duration of the candidate's development and research plan.
3. Environment - The institution's ability to provide adequate facilities, resources, and opportunities necessary for the candidate's training; the quality of the faculty in the clinical and basic sciences, and the extent of interactions between these faculty members; and the quality of the institution's research and research training programs.
4. Training Plan - The adequacy of: a) the plan for the Phase I (didactic) program; b) criteria for determining when Phase I has been successfully completed; and c) the overall plan for research experience in Phase II.

#### VI. APPLICATION PROCEDURES

The original and five copies should be mailed to DRG and one copy to the institute contact person. The outside of the envelope should be identified as **PHYSICIAN SCIENTIST AWARD**.

Deadlines for receipt of applications by the Division of Research Grants, NIH,  
are as follows:

| Applications<br>Received by | Presented to<br>Council in | Earliest Requested<br>Beginning Date |
|-----------------------------|----------------------------|--------------------------------------|
| February 1                  | September/October          | December 1                           |
| June 1                      | January                    | April 1                              |
| October 1                   | May                        | July 1                               |

For further details and in order to obtain an application kit contact the person  
listed below in the institute offering awards in your area of research interest.

**NATIONAL INSTITUTE ON AGING**

Chief, Geriatrics Branch  
Biomedical Research and  
Clinical Medicine, NIA  
Building 31 - Room 5C21  
Bethesda, Maryland 20892  
Telephone: (301) 496-1033

**NATIONAL INSTITUTE OF ALLERGY  
AND INFECTIOUS DISEASES**

Director, Extramural Activities Program  
NIAID, NIH  
Westwood Building - Room 703  
Bethesda, Maryland 20892  
Telephone: (301) 496-7291

**NATIONAL INSTITUTE OF ARTHRITIS, DIABETES,  
AND DIGESTIVE AND KIDNEY DISEASES**

Director, Division of Extramural Programs  
NIADDK, NIH  
Westwood Building - Room 657  
Bethesda, Maryland 20892  
Telephone: (301) 496-7277

**NATIONAL INSTITUTE OF CHILD  
HEALTH AND HUMAN DEVELOPMENT**

Deputy Director, NICHD, NIH  
Building 31 - Room 2A04  
Bethesda, Maryland 20892  
Telephone: (301) 496-1848

**NATIONAL INSTITUTE OF DENTAL RESEARCH**

Special Assistant for Manpower Development  
and Training  
NIDR, NIH  
Westwood Building - Room 510  
Bethesda, Maryland 20892  
Telephone: (301) 496-6324

**NATIONAL INSTITUTE OF ENVIRONMENTAL  
HEALTH SCIENCES**

Scientific Director for Extramural  
Training Programs, NIEHS  
P.O. Box 12233  
Research Triangle Park, North Carolina 27709  
Telephone: (919) 541-7634

**NATIONAL CANCER INSTITUTE**

Program Director  
Cancer Training Branch  
Division of Cancer Prevention and Control, NCI  
Blair Building - Room 424  
Bethesda, Maryland 20892-4200  
Telephone: (301) 496-8898

**NATIONAL EYE INSTITUTE**

Associate Director for Extramural and  
Collaborative Programs, NEI  
Building 31 - Room 6A03  
Bethesda, Maryland 20892  
Telephone: (301) 496-4903

**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Director, Division of Extramural Affairs, NHLBI,  
Westwood Building - Room 7A17  
Bethesda, Maryland 20892  
Telephone: (301) 496-7416

## NOTICE

**CHANGE IN APPLICATION RECEIPT DATES—CLARIFICATION****P.T. 04, 22, 34, 44; K.W. 0710030, 0404000**

The notice of new application receipt dates, published in the NIH Guide for Grants and Contracts on September 13 and November 8, 1985, did not include a date for supplemental applications for program project and center grants. Supplemental applications for such grants should be submitted for the February 1, June 1, and October 1 receipt dates. A chart showing all receipt dates appears on the following page.

APPLICATION RECEIPT DATES, REVIEW AND AWARD SCHEDULE

| Application Receipt Dates   |  |   |   | Initial Review Group Dates  | National Advisory Council/ Board Dates | Earliest Possible Beginning Date * |
|---|--|---|---|---|--|------------------------------------|
| Jan. 10<br>May 10<br>Sept. 10   | Feb. 1<br>June 1<br>Oct. 1   | Mar. 1<br>July 1<br>Nov. 1  | Apr. 15<br>Aug. 15<br>Dec. 15   | May/June<br>Oct./Nov.<br>Feb./Mar.  | Sept./Oct.<br>Jan./Feb.<br>May/June    | Dec. 1<br>Apr. 1<br>July 1         |
| for<br><br>All individual NRSA applications.*<br>All new and competing continuation Institutional NRSA Training grant applications. | for<br><br>All new research grant applications, <u>unless specified differently in a Program Announcement or Request for Applications.</u><br>Career Development awards and Conference grant applications.<br>New, competing continuation, and supplemental Program Project and Center applications. | for<br><br>Competing continuation & supplemental research grant applications. | for<br><br>Small Business Innovation (SBIR) Program, both Phases. (Phase II applicants must have completed a federally-funded Phase I project.) | * <u>Individual NRSA applications are not reviewed by Council. Their start dates are therefore approximately 4 months earlier than indicated.</u> |  |                                    |

All applications must be received by the above dates. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday. The receipt date will be waived only in extenuating circumstances. To request such a waiver, include an explanatory letter with the signed completed application. No waiver will be granted prior to receipt of the application. It is in an applicant's best interest to submit early and avoid the otherwise unavoidable rush associated with announced receipt dates.

effective January 1, 1986