

# NIH GUIDE

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## For Grants and Contracts

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NOTICES

PHS INVITES COMMENTS ON ALERT SYSTEM FOR MISCONDUCT IN SCIENCE

P.T. 34; K.W. 1014002

Public Health Service

The Public Health Service recently published a notice of intent to expand the existing National Institutes of Health "ALERT" system to other PHS agencies funding research, research training, and related activities. The notice, which is published in accordance with requirements of the Privacy Act, appears on pages 19929-19932 of the May 28, 1987 issue of the FEDERAL REGISTER (Vol 52, No. 102).

The ALERT system is used to collect, control, and disseminate to PHS agency officials on a need-to-know basis information that an individual 1) is under investigation for possible misconduct in science or misappropriation of funds, or a decision has been made to undertake such an investigation; or 2) has been subjected to a sanction at the conclusion of an investigation for misconduct or misappropriation of funds. Investigations relating to possible misconduct in science are conducted in accordance with the "PHS Policies and Procedures for Dealing with Possible Misconduct in Science" published in the NIH GUIDE FOR GRANTS AND CONTRACTS July 18, 1986 (Vol. 15, No. 11).

The comment period for this notice was given as 30 days from the date of publication in the Federal Register. However, in order to be sure this is brought to the attention of the research community, PHS is extending the comment period until August 26, 1987.

DATED ANNOUNCEMENTS (RFPs AND RFAs AVAILABLE)

SYNTHESIS OF CONGENERS AND PRODRUGS OF ANTI-AIDS COMPOUNDS

RFP NCI-CM-87216-16

P.T. 34; K.W. 0740020, 0755025, 1003012

National Cancer Institute

The announcement of this RFP appeared earlier in the May 22, 1987, Guide Vol. 16, No. 17, p.4.

The NCI is amending the request for proposed to extent the due date of proposals one week, to July 27, 1987, and to provide the following definition of pharmaceutical and chemical companies: A pharmaceutical or chemical company is defined as an organization which sells drugs and/or chemicals to the general public for profit.

Patricia L. Shifflett  
National Cancer Institute  
Blair Building, Room 216  
Bethesda, Maryland 20892  
Telephone: (301) 427-8737

MASTER AGREEMENTS FOR RECOLLECTION OF MARINE ORGANISM,  
TERRESTRIAL PLANTS AND LARGE SCALE FERMENTATION OF  
MICROORGANISMS FOR ANTI-AIDS DRUGS

RFP AVAILABLE: NCI-CM-87233-44

P.T. 34; K.W. 0740020, 1002027, 0780010

National Cancer Institute

The Natural Products Branch, Developmental Therapeutics Program, Division of Cancer Treatment, National Cancer Institute is interested in receiving proposals from and establishing Master Agreements with organizations to collect/ferment sufficient quantities of selected macro and microorganisms of specific taxonomy to enable NCI to proceed with advanced preclinical and clinical evaluation of pure natural products as potential agents for the treatment of acquired immune deficiency syndrome (AIDS).

Suitably equipped and staffed organizations which can collect or grow these organisms are required, and proposals to carry the work scope shown below will be solicited by NCI as the need arises.

Since the expertise and facilities required for the work varies according to biological sources from which the selected products are derived, proposals will be considered for one or more of the following Work Areas, in the amounts specified. Proposals also will be considered for specified taxonomic groups or geographic areas within each of these Work Areas.

Area A - Collection of shallow-water, marine macroorganisms (10 to 5,000 kg wet wt.)

Area B - Collection of deep-water, marine macroorganisms (10 to 5,000 kg wet wt.)

Area C - Collection of terrestrial plants (10 to 5,000 kg dry wt.)

Area D - Growth of non-phototropic microorganisms (80 to 12,000 L volume), concentration of biologically-active substances.

Area E - Growth of phototrophic microorganisms (80 to 12,000 L volume), concentration of biologically-active substances.

Development of methods for collection/fermentation may be necessary. Quality specifications will be determined by the Government. All materials shall be assayed by the Contractor for identity and purity before being submitted to NCI.

Master Agreements are competitively negotiated and awarded to more than one contractor. It is planned that such Agreements will be awarded on or about May 23, 1988, for a five-year period of performance but will not be funded perse. After award, Master Agreement holders will be invited to bid competitively on appropriate Master Agreement Orders (MAOs) as they are issued. Each MAO will be designed to accomplish a specific task as promptly as possible and will be awarded on a completion or term (level of effort) basis as determined by the Contracting Officer.

Master Agreement Announcement No. NCI-CM-87233-44 will be issued on or about July 10, 1987, and proposals will be due approximately six weeks thereafter. To expedite requests for solicitation, please furnish three self-addressed labels with your request. Copies of the RFP No. NCI-CM-87233-44 may be obtained by sending a written request to:

Dorothy M. Coleman  
Contracting Officer  
Treatment Contracts Section, RCB  
National Cancer Institute, NIH  
Blair Building, Room 216  
Bethesda, Maryland 20892  
Telephone: 301-427-8737

#### FATTY-ACID DERIVED MEDIATORS OF INFLAMMATION

RFA AVAILABLE: 87-AI-23

P.T. 34; K.W. 0715110, 0760075, 0755010, 0755020

National Institute of Allergy and Infectious Diseases

Application Receipt Date: October 22, 1987

#### BACKGROUND INFORMATION

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for grants to be initiated during FY 1988.

The Asthma and Allergy Branch of the Immunology, Allergic, and Immunologic Diseases Program of the NIAID sponsors fundamental and clinical research grants and contracts and the procurement and application of research resource and reference reagents concerned with asthma, allergic and immunologic diseases and with relevant mechanisms of hypersensitivity and inflammation.

Fatty-acid derived mediators of inflammation are increasingly thought to be of importance in allergic disease. To this end, a workshop entitled "Potential Therapeutic Uses of Inhibitors of Leukotriene Generation and Function" sponsored by the National Institute of Allergy and Infectious Diseases and the World Health Organization Collaborating Center for Allergic Diseases was convened in Bethesda, Maryland on June 23, 1986. The proceedings of the workshop have been summarized and published (Prostaglandins 32:4 October 1986, p. 481).

#### RESEARCH GOALS AND SCOPE

Research recommendations resulting from this workshop form the basis of this RFA which is designed to encourage the submission of new and renewal applications in this research area. Of particular interest are applications dealing with:

1. Biochemistry of the 5-lipoxygenase pathway.
2. The development of animal models to examine the role of the leukotrienes in diseases such as asthma, rheumatoid arthritis and psoriasis.
3. The development of sensitive, specific and reproducible clinical assays for the measurement of 5-lipoxygenase products in body fluids e.g., plasma and urine and in tissue of target organs.
4. Studies on structure and function of the leukotriene receptors.
5. Studies to define the role of platelet activating factor in allergic or other diseases.

#### MECHANISMS OF SUPPORT

The administrative and funding mechanism to be used to support the studies carried out under this RFA will be the Research Project Grant. The regulations (Code of Federal Regulations, Title 42, Part 52 and Title 45, Part 74) and policies that govern the research grant programs of the Public Health Service will prevail. This RFA is a one time invitation. The duration of proposed projects may be up to five years. The start date for funded applications will be approximately July 1, 1988. The NIAID is prepared to fund up to ten awards dependent upon the scope and quality of the approved projects and the availability of appropriated funds. Grant applications will be reviewed as a single competition by an initial review group convened by the NIAID Program and Project Review Branch.

The NIAID plans to make up to ten awards, contingent upon receipt of applications of substantial scientific merit and the availability of funds.

#### STAFF CONTACT

A more detailed RFA may be obtained from:

Dorothy D. Sogn, M.D.  
Chief, Asthma and Allergy Branch  
National Institute of Allergy  
and Infectious Diseases  
Westwood Building, Room 752  
National Institutes of Health  
Bethesda, Maryland 20892  
Telephone: (301) 496-8973

Inquiries concerning this announcement are encouraged and should be directed to Dr. Sogn at the address shown above.

## ONGOING PROGRAM ANNOUNCEMENTS

### CLINICAL VISION RESEARCH DEVELOPMENT

P.T. 34; K.W. 1002046, 0785035

National Eye Institute

#### BACKGROUND INFORMATION AND GOALS

The National Eye Institute (NEI) currently supports a large number of clinical and epidemiologic research projects. These include major multicenter, randomized clinical trials, natural history studies, and risk factor analyses using case-control and prospective cohort methods. These projects all have the goal of improving the understanding, the prevention, and management of visual system disorders. Yet, there is still an important need for a larger number of vision research groups to provide leadership in the design, coordination, and conduct of such projects. This announcement outlines new mechanisms of NEI grant support to help meet this need.

#### MECHANISMS OF SUPPORT

A limited number of awards will be made to help investigators develop the staff and other resources needed to enhance programs of clinical vision research through the application of epidemiologic and biostatistical methodology to clinical problems. These activities may range from the strengthening of biostatistician-clinical investigator interactions in the design and conduct of single-center studies to the development of clinical trial coordinating center capabilities. Support will be provided by Clinical Vision Research Development Awards (R21), or by the funding of new modules on NEI Core Grants (P30). With either mechanism, up to five years of support at a maximum of \$60,000 in direct costs per year will be provided. Funds may be requested, for example, for the support of a biostatistician (up to 75% effort), other staff, and for supplies and equipment.

**Clinical Vision Research Development Award--**To be eligible to apply, at least two Principal Investigators from the immediate research group must have a current NEI grant, contract, or cooperative agreement to conduct clinical research. Institutions that apply for or already receive NEI Core Grant support are not eligible for this award. This award cannot be renewed.

**Core Grant Award--**The NEI encourages the addition of a Clinical Vision Research Development Module to NEI Core Grants and it will raise the current funding ceiling (\$750,000 direct costs over five years) for this specific purpose. New and supplemental applications will be accepted, and support for this Module generally can be renewed. However, the development of clinical trial coordinating center capabilities will be supported for a maximum period of five years. Thereafter, it is expected that such a unit will be in a position to seek independent support for specific projects.

#### REVIEW PROCEDURES AND CRITERIA

Applications will be reviewed for scientific merit by the NEI Vision Research Review Committee. Second level review will be by the National Advisory Eye Council.

The most important review criterion will be the applicant's potential for success, as documented in his or her plans for developing, designing, and conducting well-designed clinical research on the etiology, prevention, diagnosis, and treatment of visual system disorders. This documentation should include the following types of evidence of a strong commitment to, and potential for, the establishment and continuation of a high-quality program in vision research:

1. The quality of the proposed program and the significance of the research area(s) in which development of an enhanced clinical research capability is proposed; relationship of this area to NEI's published program priorities as set forth in VISION RESEARCH--A NATOPMAL PLAN: 1983-1987 and more recent NEI program planning evaluations;

2. Specific description of the initial problem(s) proposed for study and outline of long-range plans for continuing the studies after termination of the requested support;
3. Realistic identification of any potential difficulties that may arise in carrying out these plans and strategies for remedial action;
4. The professional background and training of key personnel, with special reference to research interests (current and/or planned), experience, and administrative capability;
5. Recognition of the roles and importance of epidemiologic/biostatistical expertise in the planned research; identification, even if tentative, of the specific person or category of person to be sought and this person's training and background; specific and detailed plans for involvement of this person in the development of an enhanced clinical vision research capability;
6. The identification and expertise of a "critical mass" of potential investigators who can reasonably be expected to contribute to the development of a clinical vision research capability;
7. Existence of the requisite research facilities and other resources; evidence of institutional commitment to achievement of the program's goals through allocation of appropriate personnel, space, and institutional resources for this purpose; institutional commitment to the continuation of the program beyond the period of NEI support;
8. Possible future directions for clinical vision research by the applicant group; the need for, and probable impact of, further development of clinical vision research capability; and,
9. Current grant, contract, or cooperative agreement support of participants from NEI and other sources.

#### METHOD OF APPLICATION

Use the standard Research Grant Application form PHS 398 (Rev. 9/86). For purposes of identification and processing, the words "NEI CLINICAL RESEARCH DEVELOPMENT AWARD" should be typed in item 2 on the face page of the application. The initial receipt date for all applications is October 1, 1987. Thereafter, there will be only one receipt date each year; June 1. Mail the completed application and 4 copies to:

Division of Research Grants  
Westwood Building, Room 240  
Bethesda, Maryland 20892

To expedite the review, 2 exact copies should be sent directly to:

Executive Secretary  
Visual Research Review Committee  
National Eye Institute  
Building 31, Room 6A06  
Bethesda, Maryland 20892

Potential applicants are strongly encouraged to contact the NEI Program Director for detailed information regarding the specific application procedures.

Peter A. Dudley, Ph.D.  
Core Grant Program Director  
National Eye Institute  
Building 31, Room 6A51  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-5983