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**For Grants
and
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The NIH Guide announces scientific
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NOTICES

PUBLIC HEARINGS TO BE HELD BY THE NATIONAL KIDNEY AND UROLOGIC DISEASES ADVISORY BOARD

P.T. 42; K.W. 0785095, 0785220

National Institute of Diabetes and Digestive and Kidney Diseases

The National Kidney and Urologic Diseases Advisory Board is soliciting oral and written testimony from members of the kidney and urologic disease communities. This input will be applied to the development of the first national long-range plan to combat kidney and urologic diseases.

Oral testimony will be received at the following public hearings:

- o May 23, 1988, in Dallas, Texas.
- o May 24, 1988, in Atlanta, Georgia.
- o June 8, 1988, in Boston, Massachusetts.
- o June 9, 1988, in New York, New York.
- o June 23, 1988, in Chicago, Illinois.

If you are interested in presenting oral testimony, a one-paragraph summary of your presentation must be submitted to the Board office four weeks prior to the hearing date involved. Oral testimony will be limited to 3 to 5 minutes.

Written testimony should be submitted to the Board office by April 15, 1988. For more information, please contact:

The Office of National Advisory Boards
Suite 500
1801 Rockville Pike
Rockville, Maryland 20852
Telephone: (301) 496-6045

NATIONAL RESEARCH SERVICE INDIVIDUAL POSTDOCTORAL FELLOWSHIP AND SENIOR FELLOWSHIP AWARDS LETTERS OF REFERENCE

P.T. 22; K.W. 0720005, 1014002

Division of Research Grants

The NIH is working to reduce the time required for completion of the receipt, referral, review, and award of individual postdoctoral fellowship (F32) and senior fellowship (F33) applications. The goal is to cut the current time of eight to nine months in half. Accomplishing this goal would benefit candidates and their sponsors by giving them more time for planning future research training activities.

To help expedite the review process, NIH is now requiring that at least three completed, sealed letters of reference be submitted with each individual fellowship and senior fellowship application.

Four copies of the reference forms are included in each fellowship application kit. Candidates should:

1. Send these forms to their referees well in advance of the application submission date, and advise the referees to complete the form and return it to the candidate in a sealed envelope as soon as possible;
2. Request reference reports only from individuals who will be able to return them in time for the application submission. Consider any factor (e.g., illness or overseas sabbatical, etc.) that might cause an inordinate delay;
3. Choose individuals, other than the sponsor of the application, who can make the most meaningful comments about the candidate's qualifications for a research career;
4. If applicable, include a reference from the current mentor or immediate supervisor. If not submitting a reference from the thesis advisor or chief of service, explain why in Item 23 of the application;
5. Where possible, select at least one respondent who is not in the candidate's current department; and

6. Select graduate or medical school referees rather than those from undergraduate schools.

To protect the utility and confidentiality of reference letters, candidates are asked not to open the envelopes. The sealed envelopes should be attached to the original application.

Applications with fewer than three references will be returned. Candidates reapplying (competing continuations or revised applicants) must submit new reference forms to facilitate the expedited review process.

These procedures are effective as of the May 10, 1988, receipt deadline.

REFERENCE LETTERS FOR RESEARCH GRANT APPLICATIONS

P.T. 34; K.W. 1014002

Division of Research Grants

Applications for the Research Career Development Award (RCDA) and the First Independent Research Support and Transition (FIRST) Award require letters of reference. To expedite the referral and review process, the NIH is now asking that applicants include these reference letters with the submitted application package.

Therefore, RCDA applicants should send the reference forms included in the PHS 398 kit to their referees well in advance of the application submission and advise them to complete the forms and return them to the applicant in sealed envelopes as soon as possible. Similarly, FIRST applicants should request reference letters early so that these may be submitted with the applications. To protect the utility and confidentiality of reference letters, applicants are asked not to open the sealed envelopes. The sealed envelopes should be attached to the original applications. (This same procedure for submission of reference letters is now being used for individual and senior National Research Service Award fellowship applications.) These procedures are effective as of the June 1, 1988, receipt deadline.

DATED ANNOUNCEMENTS (RFPs AND RFAs)

CLONING AND SEQUENCING OF IMMUNODEFICIENCY VIRUS

RFP AVAILABLE: NIAID-AIDSP-88-27

P.T. 34; K.W. 1002045, 0755045, 0755040, 0780005

National Institute of Allergy and Infectious Diseases

The NIAID, NIH, has a requirement for molecular cloning and nucleotide sequencing of five (5) immunodeficiency virus isolates the first year and ten (10) per year thereafter. From seed stocks of virus provided by NIAID, the Contractor shall grow sufficient volumes of infected peripheral blood lymphocytes of appropriate cell line to generate at least 200 micrograms of Hirt supernatant DNA or sufficient proviral DNA for molecular cloning purposes.

This NIAID-sponsored project will take five years to complete. A cost-reimbursement contract is anticipated. Three awards are expected to be made. This is a new requirement. RFP NIH-NIAID-AIDSP-88-27 will be issued o/a March 22, 1988 with a closing date for receipt of proposals set for May 12, 1988.

To receive a copy of the RFP, please send two self-addressed mailing labels to:

Dorothy Tyler, Contracting Officer
Contract Management Branch, NIAID
National Institutes of Health
Westwood Bldg., Room 707
5333 Westbard Avenue
Bethesda, Maryland 20892

All responsible sources may submit a proposal which will be considered by NIAID. This advertisement does not commit the government to award a contract.

MASTER AGREEMENT FOR THE CLINICAL EVALUATION OF
INVESTIGATIONAL ANTIPILEPTIC DRUGS

MASTER AGREEMENT ANNOUNCEMENT/RFP AVAILABLE: NINCDS-88-10

P.T. 34; K.W. 0740010, 0755015

National Institute of Neurological and Communicative
Disorders and Stroke

The Epilepsy Branch (EB), Division of Convulsive, Developmental, and Neuromuscular Disorders (DCDND), NINCDS, plans to reissue Master Agreement Announcement (MAA)/RFP entitled 'Master Agreement for the Clinical Evaluation of Investigational Antiepileptic Drugs' with the intent of seeking new sources and enlarging the pool of current Master Agreement holders who are capable of performing clinical evaluations of investigational antiepileptic drugs. Current Master Agreement (MA) holders under this program are not required to respond to this RFP unless they wish to be considered for a particular study category for which they are not currently qualified. The antiepileptic drugs to be clinically evaluated will have been selected from EB's Antiepileptic Drug Development (ADD) Program. Under this program, a MA holder will be qualified to compete for future tasks, i.e., the clinical evaluation of drugs in accordance with specified protocols as defined within the following study categories:

CATEGORY 1: In normal male volunteers: (a) an indication of tolerance, safety and side effects; and (b) estimates of pharmacokinetic parameters following administration of single or multiple doses of the investigational drug.

CATEGORY 2: In patients with uncontrolled seizures: (a) an indication of tolerance, safety and side effects; and (b) an estimation of possible drug interactions and pharmacokinetic parameters.

CATEGORY 3: In patients with uncontrolled seizures: evaluation of the efficacy and safety of the investigational drug in controlled clinical trials.

A MA is an agreement issued to sources which respond to MAA/RFP's and which are judged to be qualified to compete for future tasks issued under the general study areas described in the MA. These agreements contain general terms, conditions and parameters of performance for a particular study category for which the organization is deemed qualified, but do not contain any specific work task, period of performance for a specific task, nor funding commitment. Award of a MA under this RFP will certify an offeror as having the facilities, staff expertise, and access to adequate study populations necessary to perform and compete for future drug evaluation studies within one or more of the categories indicated above. Competition for specific clinical investigational studies will be restricted to all qualified MA holders. Successful MA competitors for future tasks will be awarded a Master Agreement Order (MAO).

A MAO is a bilateral contract and operational addendum to a MA. It includes a definitized Statement of Work and outlines the specific performance requirements, delivery schedule and funding for the study task.

Award of MA's under this RFP will be valid through September 30, 1991. Once awarded a MA, holders will be required to certify on an annual basis that the capabilities of the organization that led to issuance of a MA initially are still valid and remain in place.

NINCDS will consider proposals from all responsible sources. These proposals may cover one, two or all three of the study categories mentioned above. Review of MA proposals will be conducted by the Scientific Review Branch, NINCDS. The technical merit of each proposal will be evaluated in terms of the study requirements with emphasis on the scientific and administrative capabilities of prospective offerors. Offerors must be able to provide concise information regarding their capability to accrue the required number of qualified subjects specified for each category. The technical evaluation shall also include consideration of the offeror's available personnel, facilities and equipment and the suitability of the proposed research plans and strategies to achieve the study objectives. As a result of this MAA/RFP, NINCDS expects to add a number of new sources to the current pool of MA holders.

MAA/RFP No. NIH-NINCDS-88-10 will be issued on or about March 15, 1988, with responses due approximately 60 days thereafter. Prospective offerors are asked to provide two (2) self-addressed mailing labels with their request.

Requests for a copy of this MAA/RFP must be made in writing and must indicate MAA/RFP No. NIH-NINCDS-88-10 and should be addressed to:

Mr. Kirkland L. Davis
Contracting Officer
National Institutes of Health
National Institute of Neurological and Communicative
Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, Maryland 20892

KIDNEY DISEASE OF DIABETES MELLITUS: NEW BASIC STUDIES OF THE PATHOGENETIC MECHANISMS AND CLINICAL AND EPIDEMIOLOGIC FEATURES

RFA AVAILABLE: NIDDK-88-12

P.T. 34; K.W. 0715075, 0785095, 0765035, 1003002, 1002059, 0710070, 0785055

National Institute of Diabetes and Digestive and Kidney Diseases

Application Receipt Date: July 15, 1988

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announces the availability of a Request for Applications (RFA) for studies concerned with Kidney Disease of Diabetes Mellitus.

BACKGROUND

Renal diseases leading to failure that results in replacement therapy represent an important public health problem. Data from the Health Care Financing Administration (HCFA) indicate that in 1986 over 90,000 patients received dialysis care from Medicare-certified providers; over 30,000 new patients began dialysis; more than 15,000 patients died, and over 9,000 end stage renal disease (ESRD) patients received kidney transplants. The largest single cause of renal disease is now diabetes mellitus and the number of patients with ESRD due to kidney disease of diabetes mellitus has risen steadily over the last decade. At present, nearly 30 percent of new patients entering the ESRD program have kidney disease of diabetes mellitus. Since this number is increasing at a rate of approximately two percent annually, within the next decade this will likely account for more than 50 percent of all patients in the ESRD program. Thus, kidney disease of diabetes mellitus, being the predominant cause of ESRD in the United States, represents a significant and growing problem. However, the pathogenesis remains controversial, therefore prevention and treatment of this complication requires intensive investigation. Indeed, comprehensive studies using state of the art approaches and methodology are needed in a concerted effort to help define the mechanisms underlying the initiation and evolution, and to identify approaches to prevent this complication.

RESEARCH OBJECTIVES AND SCOPE

The overall goal of the RFA is to encourage new studies and new investigators to enter this field to broaden the base of research disciplines addressing issues pertinent to kidney disease of diabetes mellitus. The RFA is intended to stimulate the development and submission of research proposals aimed at understanding the pathogenetic mechanisms and the development of diagnostic measures and approaches to effective prevention, control and treatment. The scope of these projects is intended to include studies of the biochemistry, physiology, pathology, immunology and clinical and epidemiological features, including studies of glomerular and tubular structure and function; mechanisms operative in the genesis and early morphological and/or other markers of progression of the glomerular injury in humans and experimental models; genetic markers, genetically determined susceptibility, and environmental factors that contribute to the risk of diabetic renal disease; mechanisms that mediate early glomerular hemodynamic abnormalities; consequence of sustained microcirculatory abnormalities; prevention-interventional strategies; markers of progressive renal disease in renal allografts; study and approaches for the interpretation of confounded factors, etc.

MECHANISM OF SUPPORT

Support for this program will be through the grant-in-aid mechanism and will be governed by the current policies applicable to such grant programs of the National Institutes of Health. New applications may be submitted for traditional, individual research-project grants (ROIs) only. Although plans

for Fiscal Year 1989 include approximately \$3.5 million for the total (direct and indirect) costs of this program, the funding of applications submitted in response to this RFA is contingent on the actual availability of funds, and receipt of applications of sufficient scientific merit, as determined by the rigorous standards of NIH Study Section review. It is anticipated that 10 - 15 awards will be made, for up to 5 years under this program. The specific amounts to be funded will depend on the merit and scope of the applications received. Furthermore, since a variety of approaches would represent valid responses to this announcement, it is anticipated that there will be a range of costs among individual awards. Awards in response to this announcement will be made to foreign institutions for research of unusual merit and promise, and in accordance with PHS policy governing such awards.

APPLICATIONS AND REVIEW PROCEDURES

Applications in response to this RFA will be reviewed for scientific and technical merit by an Initial Review Group which will be convened by the Division of Extramural Activities, NIDDK, solely to review these applications. Upon receipt, applications will be evaluated for their responsiveness to the objectives of the RFA. If an application is judged unresponsive at this stage, the applicant will be contacted and given the opportunity to withdraw the application or have it considered for the regular Research Grant Program of the NIH. Should the proposal submitted in response to the RFA be substantially similar to a research grant application already under consideration at the NIH, the applicant will be asked to withdraw either application. Simultaneous submission of identical applications will not be allowed.

Funding decisions will be based on recommendations by the Initial Review Group and by the National Diabetes and Digestive and Kidney Diseases Advisory Council, and relevance to the Objectives and Scope of the RFA. Applicants should request a start date of March 1, 1989.

The RFA label (found in the 9/86 revision of application form PHS 398) must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in delayed processing of your application such that it will not reach the review committee in time for review.

For further information and copies of the complete RFA, please contact:

Gladys H. Hirschman, M.D.
Director, Chronic Renal Disease Program (DKUHD)
NIDDK, National Institutes of Health
Westwood Building, Room 621
Bethesda, Maryland 20892
Telephone: (301) 496-7571

ERRATUM

ROLE OF GLYCATION IN AGING AND DIABETES

P.T. 34; K.W. 0710010, 0715075, 1003018, 0760005

National Institute on Aging and
National Institute of Diabetes and Digestive and Kidney Diseases

This program announcement was originally published in the March 4, 1988 (Vol. 17, No. 8). The following paragraph is being reprinted in its entirety as several words were missing from the original announcement.

SPECIFIC OBJECTIVES

The NIA and NIDDK seek applications to test hypotheses and elucidate mechanisms including, but not limited to, the following three general areas:

- o Structure of glycated products, mechanisms of their formation, and processes for their removal from biological systems, and the role of these glycation products in aging, and the long term complications of diabetes.
- o The relationships between glycation products and the etiology of age-related diseases, such as cardiovascular disease, cancer, cataracts, arthritis, osteoporosis, etc.
- o The relationship between control of diabetes and the reversible and irreversible formation of these glycation products.

The contacts remain the same as the original announcement.