The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

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FISCAL YEAR 1991 BUDGET ISSUES
P.T. 34; K.W. 1014006

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

The purpose of this notice is to provide the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) research grantees and contractors with information on the potential impact of the Gramm-Rudman-Hollings (GRH) Act on the Fiscal Year (FY) 1991 budget and associated grant and contract funding.

The GRH Act requires that appropriations for each fiscal year be consistent with the need to reduce the national budget deficit to a predetermined amount. If actions on the appropriation do not satisfy the requirements of the GRH Act, a process called "sequestration" automatically begins. This process results in mandatory across-the-board spending reductions for Federal agencies.

There are several key dates in the sequestration process. An initial sequester order was issued on August 25 and specified a spending cut of 32.4 percent between October 1 and 15. A final sequester order must be issued on October 15 to specify the spending cuts required from October 15, 1990, through September 30, 1991. These sequester orders will be cancelled, or become unnecessary, if the Congress passes--and the President signs--legislation that meets the deficit reduction requirements.

All Federal agencies are now faced with the necessity of developing contingency plans in the event that these sequesters do occur. What this means, in more specific terms, is that some restrictions on Federal spending may be imposed, and most agencies will be required to reduce their costs for numerous activities including grants and contracts.

As further details regarding operating budgets for FY 1991 are obtained, the NIH and ADAMHA will broadly disseminate them to the scientific community.

NEW NIH/ADAMHA PEER REVIEW CONSULTANT FILE
P.T. 34; K.W. 1014002

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) have established a new consultant file of peer reviewers. Reviewers will be selected from a national pool of scientists who are engaged in basic or applied research. Data from qualified respondents will be entered into a new computerized NIH/ADAMHA data base. This unique data base will be used as one source from which candidates for membership on NIH/ADAMHA committees and for other peer review activities are drawn. All qualified scientists are requested to participate. Qualified women and minority scientists are encouraged to apply.

A Consultant File Information Form has been sent to every PHS grantee and the solicitation announcement will appear in major journals. Other scientists who are interested in participating should respond by letter requesting a copy of the NIH/ADAMHA Consultant File Information Form. Since the new file will be established based solely on positive responses, your response is needed even if you are already a consultant or are a member of a Reviewer's Reserve. This file is independent of other consultant files. Your request should be sent to:

NIH/ADAMHA Consultant File
4733 Bethesda Avenue, Suite 725, Dept. 02
Bethesda, MD 20814
THANK YOU TO PHS 398 RESPONDENTS

P.T. 34; K.W. 1014002

Division of Research Grants

The staff of the Public Health Service would like to thank the many individuals who responded to the March 30 and April 27, 1990 NIH Guide Announcements inviting comments and suggestions to improve the Public Health Service Grant Application Kit (Form 398). The response from the scientific community was substantial and many useful and constructive comments were received. These comments have been carefully analyzed and many are being incorporated into the new version of the Form PHS 398 which should be available in late 1991.

E-GUIDE ACCESS - REPORT OF THE MEETING

P.T. 16; K.W. 1014002

National Institutes of Health

On September 7, nearly one hundred people from institutions located across the United States and Canada attended a meeting concerning the electronic version of the NIH Guide for Grants and Contracts (E-Guide). Attendees had a wide range of technical and administrative backgrounds and came from academic and medical institutions, large and small. The meeting was intended to bring people together for information exchange about receiving and dealing with the E-Guide, as well as to identify changes that should be made in its format which would maximize its usefulness to users. It included didactic presentations, discussion, and on-line demonstrations.

Hope was expressed at the meeting that the E-Guide could be developed to the point that it is truly an electronic document, rather than an electronic version of a paper document. Efforts will be dedicated toward accomplishing this goal but may be limited by the extent to which the NIH can provide financial resources. Attendees expressed the desire that the electronic format as transmitted by the NIH be kept simple, with most of the manipulation performed at the receiver end.

There seemed to be consensus that unobtrusive delimiters for individual items and the various sections of the Guide would be useful if they did not interfere with clarity. A test of such delimiters will be enacted in the near future. In addition, some attendees asked that standards be developed and a manual be provided that describes the standards and other relevant characteristics of the files so that institutional users can maximize their use. This is a point that will be considered for future implementation.

Institutions use a variety of approaches for local distribution, the list server being a popular one that seems likely to see expanded use. Considerable interest was expressed in the distribution systems and software that were demonstrated by representatives from the University of California at San Francisco, Johns Hopkins University, and the University of North Carolina. Attendees felt that the publication of an up-to-date list of designated institutional recipients of the E-Guide would facilitate inter- and intra-institutional communication, including the exchange of ideas and information on methods of internal distribution.

Questions arose as to the length of time that individual issues of the E-Guide should be retained. Key policy announcements are republished approximately every six months, and most requests for applications or for proposals have a specific receipt date, but some program announcements might be effective for a very long time. Back E-Guide issues probably always will be attainable from the NIH in electronic and/or hard copy. Nevertheless, archival maintenance should receive additional attention, policy development, and implementation.

Comments also illustrated the need for tutorials in the use of the E-Guide, as well as identification of approaches to help faculty and staff to use the electronic format effectively and frequently. In order to be fully successful, the E-Guide must offer advantages that do not exist for the paper version. The potential for such advantages exists but further development is necessary before it can be fully realized.

Attendees generally found the meeting to be very useful, and most felt that it should be held again, perhaps on a regional basis or in conjunction with other meetings, or with better and larger facilities so that several individuals can attend from a single institution for better coordination in use of the E-Guide.
NOTICES OF AVAILABILITY (RFPs AND RFAs)

DEVELOPMENT OF NOVEL DRUG FORMULATION AND DELIVERY SYSTEMS FOR ANTI-TUMOR AND ANTI-AIDS AGENTS

RFP AVAILABLE: NCI-CM-17527-49

P.T. 34; K.W. 0715008, 0715035, 0740020

National Cancer Institute

The National Cancer Institute (NCI), Division of Cancer Treatment, Developmental Therapeutics Program, Pharmaceutical Resources Branch, is interested in receiving proposals from organizations that have innovative research ideas concerning improving intravenous delivery and other routes of administration of chemotherapeutic agents. A workload-per-year of 1-2 compounds having diverse chemical structures of either natural or synthetic origin is anticipated. The contractor's studies will be directed towards resolving specific deliverability and/or stability problem(s) culminating in an acceptable dosage form prepared on laboratory scale. The contractor will deliver to the NCI, small quantities (less than 50 units) of the experimentally formulated products for preliminary evaluation for efficacy and toxicity in rodents.

The Principal Investigator should possess a Ph.D. in chemistry, pharmacy, or a related discipline, and have extensive experience with the development of novel drug delivery systems. The contractor should be experienced with drug analysis procedures including UV, NMR and infrared spectroscopy, plus the development of stability indicating assays using high performance liquid chromatography (HPLC).

The contractor should have access to the necessary analytical equipment to perform the required work, including animal facilities for biologic evaluation.

This procurement is unrestricted. The Standard Industrial Classification (SIC) code is 8731.

This RFP will be available on or about October 23, 1990, and will be due approximately seven (7) weeks thereafter. It is anticipated that two (2) cost-reimbursement, incrementally funded type contracts for a period of three (3) years each, beginning approximately June 1991, will be awarded. Requests for the solicitation should reference the RFP number and be sent to the address below. No collect calls will be accepted.

Requests for this RFP should be addressed to:

Ms. Sandra A. Lehner, Contracts Specialist
National Cancer Institute
Research Contracts Branch
Treatment Contracts Section
Executive Plaza South, Room 602
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-8620
CLINICAL CENTERS FOR A CHILDHOOD ASTHMA MANAGEMENT PROGRAM

RFP AVAILABLE: NHLBI-HR-90-13

P.T. 34, AA, FF; K.W. 0715013, 0715026, 0785035

National Heart, Lung, and Blood Institute

The purpose of this solicitation is to establish clinical centers for a collaborative study of a Childhood Asthma Management Program (CAMP). The objective of this program is to determine, in a population of 5-9 year old children with asthma, if regular use of either of two types of antiinflammatory medications (inhaled corticosteroids or cromolyn sodium), compared to regular bronchodilator medication and to each other, results in greater lung function and less bronchial hyperresponsiveness over a five-year period. The program will require a clinical coordinating center (CCC) to collect data from approximately 8 participating clinical centers, each studying a minimum of 132 children with asthma aged 5-9 years, including 44 from minority groups, e.g., Blacks, Hispanics and Native Americans, over a 6 1/2-year period. The clinical centers will be responsible for: 1) participating in the development and preparation of the study protocol, reporting forms, and manual of operations; 2) training staff to conduct the study as outlined in an approved study protocol and manual of operations; 3) during an 18-month period recruit 132 children (of both sexes) with asthma aged 5-9 years, including 44 from minority groups, e.g., Blacks, Hispanics, and Native Americans; 4) performing follow-up assessment of the subjects in the manner specified in an approved manual of operations; 5) collecting and forwarding subject data to the CCC; 6) interacting with the CCC to provide data and information necessary for data analysis; and 7) working with other study investigators in the preparation and writing of reports and manuscripts for publication.

This announcement is for clinical centers only, and the Institute expects to make 8 awards. A separate Request for Proposals (RFP) for the coordinating center will appear later.

This announcement is not an RFP. It is anticipated that RFP NHLBI-HR-90-13 will be available on or about October 1, 1990, with proposals due on February 28, 1991. Copies of the RFP may be obtained by submitting a written request along with three (3) self-addressed mailing labels to the address identified below.

Pamela S. Randall
Contracts Operations Branch, DEA
Westwood Building, Room 654, 5333 Westbard Avenue
National Heart, Lung, and Blood Institute
Bethesda, MD 20892

EPIDEMIOLOGY OF CANCER IN U.S. ETHNIC/MINORITY POPULATIONS

RFA AVAILABLE: CA-91-02

P.T. 34, FF; K.W. 0715035, 0785055, 1002019, 0411005

National Cancer Institute

Application Receipt Date: February 15, 1991

INTRODUCTION

The Division of Cancer Etiology of the National Cancer Institute invites grant applications for epidemiologic studies of possible causes of cancer in U.S. ethnic/minority populations.

RESEARCH GOALS AND SCOPE

The purpose of this Request for Applications (RFA) is to stimulate analytical, site-specific studies of cancer etiology in ethnic/minority populations of the United States. Research strategies may involve cohort, case-control, or genetic epidemiology designs as well as laboratory methodology. Innovative approaches that involve new inter-disciplinary collaboration, or include the application of diagnostic or exposure measurements, are particularly encouraged. Whenever possible, studies should make cost-efficient use of existing resources such as population-based cancer registries or specimen repositories. Emphasis should be placed on etiologic studies of the more common cancers affecting the U.S. population, or on cancer sites with rising...
incidence rates. Projects will be evaluated on their potential for impact on the overall understanding of cancer etiology and means of prevention.

The initiative permits a wide range of epidemiologic investigations of cancer in U.S. ethnic/minority populations including, but not limited to, the following:

- Cross-cultural studies of cancers with striking ethnic disparities in incidence rates, among groups residing in the same or different geographic areas, to identify more specifically the etiologic factors, and to study their relationship with biomarkers of exposure.

- Analytic studies of specific cancer sites to determine the impact of age-specific changes in exposures over time, due to waves of migration within the U.S. as well as from other countries, and/or to secular changes in lifestyle, occupation, and environment.

- Studies among Hispanics with special consideration given to the subgroups within the population.

- Studies of ethnic differences in the histologic and cytologic parameters of particular cancers that may reflect differences in exposures or susceptibility.

- Meta-analysis of previous studies to further refine known associations or yield new information on risk factors.

- Studies addressing methodological issues related to the heterogeneity of ethnic groups, especially dietary and genetic parameters.

- Molecular epidemiologic studies exploring differences in genetic predisposition to cancer due to variations in carcinogen metabolism, DNA repair activities, response to tumor promoters, measures of immune function, chromosome sensitivity to mutagens, or other factors.

- Genetic epidemiologic studies of polymorphisms associated with ethnic differences in cancer risk.

In any studies involving human subjects, where feasible and appropriate, women should be included in the study population; otherwise a clear rationale for their exclusion must be provided in the application. Minority institutions are encouraged to apply, and other institutions are encouraged to establish collaborative arrangements with minority institutions.

Copies of the RFA may be obtained from:

Dr. A. R. Patel
Extramural Programs Branch
Epidemiology and Biostatistics Program
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Suite 535
Rockville, MD 20892
Telephone: (301) 496-9600

AIDS-LYMPHOMA NETWORK

RFA AVAILABLE: CA-91-01
P.T. 34; K.W. 0715008, 0715035, 0755015
National Cancer Institute
Application Receipt Date: January 16, 1991

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites applications (R01 mechanism) from interested investigators to participate in an AIDS-Lymphoma Network. The AIDS-Lymphoma Network will be composed of those institutions who successfully compete for funding in this Request for Applications (RFA) to perform new therapeutic AIDS-lymphoma clinical trials, or AIDS-lymphoma clinical trials with correlative laboratory studies. The purpose of the AIDS-Lymphoma Network is to foster interchange among different institutions and to coordinate activities of the different institutions working towards a common goal.
BACKGROUND

Adult and pediatric acquired immunodeficiency syndrome (AIDS) patients are surviving longer due to improved retroviral and opportunistic infection treatment and care. As a result, acquired immunodeficiency syndrome-associated malignancies have become more prevalent and are now a major concern. Lymphomas and Kaposi sarcomas are the malignancies most frequently seen in AIDS patients. Both non-Hodgkin's lymphoma (NHL) and Hodgkin's disease (HD) have been described in these patients. The etiology of NHL in AIDS patients remains unclear. The most prominent clinical features of NHL in HIV-positive patients are the aggressive nature and course of the disease and the presence of unusual extralymphatic disease in sites such as the CNS or bowel. Results of treatment using standard intensive multi-agent chemotherapy have been disappointing, with median survival of less than one year in treated patients, and difficult because conventional aggressive combination chemotherapy exacerbates the patient's immunodeficient state. The choice of therapy must be based on the nature of the disease and the overall condition of the patient. The precise relationship of HD to the underlying immunodeficient state in patients with HIV infection also remains unclear. Clinical observations suggest that HD in this setting may have a different natural history and therapeutic outcome when compared with HD in the general population. Patients with HIV infection and HD are likely to have a poor therapeutic outcome and to develop AIDS-associated opportunistic infections during therapy.

The NCI recognizes that research in AIDS-lymphoma is technically difficult to conduct because of the complexity of this disease and the relatively limited availability of study subjects at any single institution. Thus it is encouraging conduct of research relevant to this RFA in the context of an AIDS-Lymphoma Network. The AIDS-Lymphoma Network will serve as a resource of information and will work to facilitate patient accrual, obtaining tissue samples, and exchange of information and materials between involved investigators.

RESEARCH GOALS AND SCOPE

The major goal of this RFA is to develop more effective management and therapies for AIDS-lymphoma. This goal can be accomplished by supporting (1) the development of AIDS-lymphoma therapeutic clinical trials or (2) AIDS-lymphoma clinical trials with correlative laboratory studies.

Both adult and pediatric AIDS-lymphoma studies involving non-Hodgkin's and Hodgkin's disease are encouraged. The therapeutic clinical trials (pilot, phase I, or phase II) will usually involve a patient population ranging between 5-40 patients with survival, response, and/or quality of life end points. NCI does not envision the establishment of multi-institutional collaborative therapeutic clinical trials by the AIDS-Lymphoma Network at this time. Some examples of potential correlative laboratory studies could deal with the following: (1) What is the clinical significance of the abnormal patterns of distribution of disease sites? (2) What factors are involved in the different clinical responses observed in AIDS-lymphomas? (3) What are the potentially exploitable features with respect to etiology and pathogenesis of AIDS-lymphoma? (4) What is the clinical significance of the molecular and cytogenetic abnormalities specifically associated with AIDS-lymphoma? (5) What alterations occur in growth factors or oncogenes in AIDS-lymphoma patients that may potentially lead to new therapies? Investigators are not limited to the above categories of potential studies. Other scientific approaches may be proposed.

MECHANISM OF SUPPORT

This RFA will use the NIH grant-in-aid R01 mechanism. Approximately $3,000,000 in total costs per year for three years will be committed to specifically fund applications that are submitted in response to this RFA. It is anticipated that 10 to 15 awards will be made. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The earliest feasible start date for the initial award will be July 16, 1991. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the availability of funds appropriated for fiscal year 1991.

ELIGIBILITY REQUIREMENTS

Applicant organizations should be located in the United States and Canada. Non-profit and for-profit organizations and institutions, and government agencies are eligible to apply.
LETTER OF INTENT

Prospective applicants are asked to submit by December 16, 1990, a letter of intent that includes a descriptive title of the proposed research, the name and address of the principal investigator, the names of other key personnel, the participating institutions, and the number and title of this RFA. The letter of intent is requested in order to provide an indication of the number and scope of applications to be reviewed. This letter of intent does not commit the sender to submit an application, nor is it a requirement for submission of an application.

INQUIRIES

A copy of the complete RFA describing the research goals and scope, the review criteria and the method of applying can be obtained by contacting:

Dr. Roy S. Wu
Health Scientist Administrator
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 496-9384

Written or telephone inquiries concerning the objectives and scope of this RFA or inquiries about whether or not specific proposed research would be responsive are encouraged and should be directed to Dr. Roy S. Wu at the above address. The program director welcomes the opportunity to clarify any issues or questions from potential applicants.

ONGOING PROGRAM ANNOUNCEMENTS

STROKE IN BLACKS, OTHER MINORITIES, AND WOMEN

PA: PA-91-01
P.T. 34, FF, II; K.W. 0715200, 0785055, 0745020, 0745070, 0745027, 0411005

National Institute of Neurological Disorders and Stroke

The Division of Stroke and Trauma (DST), National Institute of Neurological Disorders and Stroke (NINDS), invites applications for support of research that will increase our knowledge and understanding of cerebrovascular disease in blacks, other minorities, and women.

BACKGROUND

The Report of the Secretary's Task Force on Black and Minority Health discusses the continuing disparity in the burden of death and illness experienced by blacks and other minority Americans compared with the population as a whole. In the United States, stroke remains a leading cause of death and a prime cause of disability. Nearly half a million Americans each year are known to suffer an acute stroke. The overall problem is even more imposing than annual incidence and mortality figures would indicate, since many strokes are not fatal and recurrent strokes are common in nearly all forms of cerebrovascular disease. Additionally, many transient attacks (TIA) and minor strokes frequently remain unreported. In the black population, age-adjusted death rates for stroke are almost twice that of the white population. Dramatic differences between the extent of the various cerebrovascular risk factors are thought to exist among minority populations as a whole. Women appear to comprise an important population at risk for stroke. Previous assumptions regarding the hormonal protection against heart disease and stroke are now being brought into question. Recent changes in employment patterns and lifestyles of women may be placing them in high-risk categories in a manner previously unrecognized. Whereas some factors, such as transient ischemic attacks, are well known, the existence of other factors and the interrelationship between various predisposing factors remain unclear. Limited information is available regarding differences between stroke subtypes, although clinical evidence suggests that such differences may exist.

RESEARCH GOALS AND SCOPE

The Division of Stroke and Trauma is seeking investigator-initiated research grant applications for basic, applied, and clinical studies related, in the
broadest sense, to the etiology, prevention, early diagnosis, and treatment of stroke, including rehabilitation, as these may relate to blacks, other minorities, and women.

Examples of important research topics for consideration might include, but should not necessarily be limited to:

- longitudinal epidemiology of the distribution and inter-relation between risk factors;
- relation of outcome from stroke to the differences in diagnostic methodology, acute management, post-stroke care, rehabilitation, and recurrent stroke;
- evaluation of treatment factors, including treatment compliance, in these special populations;
- special problems of blacks, other minorities, or women that may have an impact on the identification, diagnosis, treatment, management, follow-up, or long-term outcome;
- evaluation of emerging techniques for the analysis, diagnosis, treatment, and prevention of cerebrovascular disease; and
- comparative studies of identifiable populations at risk for stroke.

MECHANISM OF SUPPORT

The support mechanism for grants in this area will be the usual investigator-initiated research project grant (R01), the program project grant (P01), and the center grant (P50). Under these mechanisms, the principal investigator and any participating investigators will plan, direct, and perform the research. Applicants for program project grants should contact the NINDS representative listed below as early as possible in the planning stages.

APPLICATION AND REVIEW PROCEDURES

Applications must be prepared on form PHS 398 (rev. 10/88) according to the instructions included in the application kit. These kits are available from the business offices of most institutions eligible to receive Federal grants or from the Division of Research Grants, NIH. Applications for program project grants should request, from the address below, a copy of the NINDS GUIDELINES FOR THE PREPARATION OF A PROGRAM PROJECT GRANT APPLICATION.

Receipt dates for new research project grant (R01) applications and for program project grant (P01) and center grant (P50) applications are February 1, June 1, and October 1.

On page 1 of form PHS 398, check "yes" in item 2 and Type: "STROKE IN BLACKS, OTHER MINORITIES, AND WOMEN, PA-91-01."

Use the mailing label provided in the application kit to mail the signed original and six exact copies to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

If the application is for a program project or center grant, please send the original and four copies to the Division of Research Grants. An additional two copies sent to the address below would be useful for expediting the processing of applications for these multidisciplinary efforts. Any questions concerning this should be directed to:

Dr. Patricia A. Grady
Division of Stroke and Trauma, NINDS
Federal Building, Room 8A13
Bethesda, MD 20892
Telephone: (301) 496-4226

Research project grant (R01) applications will be reviewed for scientific and technical merit by an appropriate study section in the Division of Research Grants. Program project grant (P01) and center grant (P50) applications will be reviewed according to the assigned Institute's prevailing practice. Secondary review will be by an appropriate National Advisory Council.

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This program is described in the Catalog of Federal Domestic Assistance, Number 93.853, Clinical Research Related to Neurological Disorders, and 93.854, Biological Basis Research in the Neurosciences. Grants will be awarded under the authority of the Public Health Service Act, Title IV, 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 74. This program is not subject to Health Services Agency review of the intergovernmental review requirements of Executive Order 12372.

This announcement is a revision of the Ongoing Program Announcement entitled, "Cerebrovascular Disease in Blacks and Other Minorities," that appeared in the NIH GUIDE For Grants and Contracts, Volume 16, Number 10, March 13, 1987, pages 5-6.

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

5333 Westbard Avenue
Bethesda, Maryland 20816