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U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

IN THIS ISSUE:

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.

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ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA 85-AI-05

STUDIES OF ACQUIRED IMMUNODEFICIENCY SYNDROME

P.T. 34; K.W. 0715120, 0785055, 0745055, 0755015, 0411005

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: September 15, 1985

I. BACKGROUND INFORMATION

Because of its mission to support research in immunology and infectious diseases, the NIAID has played a central role in the investigation of the Acquired Immunodeficiency Syndrome (AIDS), an infectious disease of the immune system. Since the discovery of the retrovirus HTLV-III/LAV as the etiological agent of AIDS, research efforts directed toward the epidemiology, prevention, pathogenesis, and adequate treatment of both the underlying disease and its sequellae have been intensified.

Since 1981, NIAID, in collaboration with other Government agencies, has supported research grants, cooperative agreements and contracts aimed at clarification of a variety of AIDS-related issues. This present announcement is designed to encourage continuation and extension of AIDS research efforts taking advantage of the ever-expanding knowledge base. It is intended that these efforts will be conducted in the context of a "Working Group;" i.e. a group of institutions carrying out various research projects funded as a result of the RFA or other mechanisms. Consistent with the Cooperative Agreement mechanism, NIAID Staff will serve as a resource of information and work to facilitate exchange of information and material among involved investigators. It is NIAID's assessment that such collaboration between investigative groups will rapidly and efficiently enhance achievement of the goals of the RFA; i.e., definition of the biology of the etiologic agent, clarification of the pathogenesis and immunologic mechanisms of the disorder, and improvement of prevention and treatment, including immune reconstitution. It is emphasized that this RFA is designed to accommodate both new and renewal applications in this programmatic area.

II. RESEARCH GOALS AND SCOPE

Studies proposed should stress innovative approaches to the problem and should include and/or emphasize any or all the following:

A. Epidemiologic studies, particularly those designed to identify risk factors or determinants (behavior, drug use, etc.) of the disease manifestations of AIDS or AIDS Related Complex in individuals at risk.

B. Laboratory research on the pathogenesis, treatment, and prevention of AIDS. Projects could include in vitro or in vivo studies of the biology of HTLV-III/LAV, interactions of HTLV-III/LAV with other infectious agents or cofactors, development of assays for antigen detection, and development of animal models, antiviral agents and vaccines. Projects could also include studies of affected immune system components leading to loss of function and disturbances in immunoregulatory balance.

C. Clinical trials to treat or prevent HTLV-III/LAV infection, the resultant opportunistic infections or repair the immunologic deficiency in AIDS patients. Efforts to reconstitute the patients' immune system could include immune interferon, interleukin-2, other amplifiers of T and/or B lymphocytes, bone marrow transplantation, histocompatible lymphocyte transfusions, or other approaches.

III. MECHANISM OF SUPPORT

Awards will be made as Cooperative Agreements. These are assistance awards requiring substantial involvement by NIAID Staff. NIAID anticipates making multiple awards as a result of this request; it is expected that a total of $1,000,000 will be allocated for funding the first year's awards. Awards will be generally made for project periods of three to five years. All policies and requirements which govern the PHS grants programs apply.

IV. STAFF CONTACT

Investigators seeking information relevant to the infectious disease aspects should contact:

Harry W. Haverkos, M.D.
Clinical and Epidemiologic Studies, MIDP
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Building 31 - Room 7A-51
Bethesda, Maryland 20205

Telephone: (301) 496-5893

For information concerning the immunologic aspects, applicants should contact:

Robert A. Goldstein, M.D., Ph.D.
Chief, Immunopathology Branch, IAIDP
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 755
Bethesda, Maryland 20205

Telepphone: (301) 496-7104

A more detailed version of this request is available from either of these contacts. Prospective applicants also are encouraged to submit to the appropriate Staff contact a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. The NIAID requests such letters by July 15, 1985, 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.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS

85-CA-13

CLINICAL EVALUATION OF MODELS OF BIOCHEMICAL MODULATION

P.T. 37; K.W. 0745005, 0755020, 0755015, 0740015, 0710100

NATIONAL CANCER INSTITUTE

Application Receipt Date: September 15, 1985

The National Cancer Institute's (NCI), Division of Cancer Treatment, invites applications for cooperative agreements to support a program of laboratory and clinical investigations directed toward the development and optimal clinical use of a combination of drugs which is synergistic in vitro.

I. BACKGROUND

The synergistic interaction of drugs at a biochemical level has been demonstrated in both in vitro and in vivo systems. These leads have not been successfully applied to clinical trials in a rational and systematic manner. Studies which reproduce in the clinical setting the preclinical conditions necessary for optimal synergy have not been performed. Synergy of two agents in murine tumors has previously been the justification for combining such agents in clinical trials. However, the design of these trials has failed to translate accurately dosage and scheduling considerations from the in vitro and preclinical in vivo models to the clinic. The potential for defining and maximizing the synergistic interaction of antitumor agents can only be realized by careful study in the preclinical setting, and by confirming and refining this interaction through detailed biochemical studies in the initial clinical trials. Having established in Phase I trials the optimal doses and schedules to maximize both synergy and selectivity in this manner, the regimen should then be carried forward in appropriate comparative trials. The execution of such trials requires a major commitment of resources by both clinician and laboratory scientist. The experimental findings of each will modify the design and conduct of the other's study. Strong program planning under a single funding instrument is required to effect the integration of laboratory and clinic.

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards will be made under the authority of Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) 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 Systems Agency review.

II. RESEARCH GOALS AND SCOPE

Proposed studies should emphasize:

A. Delineation of the mechanism of modulation at a molecular level in an in vitro setting;

B. Measurement of the antitumor efficacy of such combinations in in vitro systems.

C. Confirmation and validation of this enhanced efficacy and where feasible the mechanism of modulation at an in vivo preclinical level, and refinement of the therapeutic index based on any new in vivo findings.

D. Advancement of the combination into clinical testing, and in such trials to establish that the projected modulation is indeed occurring in the target tissue, examine the pharmacokinetics and pharmacodynamics of such schedules for later activity trials, and describe the alteration in selectivity by the modulation at a biochemical and clinical level.

The awardees will participate in the NCI sponsored drug development meetings three times a year in order to review progress, to plan and design research objectives, to establish priorities and to promote the development of collaborative arrangements between investigators. This will facilitate the step-wise progression of the awardee's proposed plans for biochemical modulatory development. NCI staff will serve as a resource of information and will work to facilitate exchange of information and material and collaboration between involved investigators.

Many of the NCI sponsored IND drugs are leading candidates with biochemical modulatory properties. Applications are encouraged which focus on these NCI sponsored IND drugs in order to provide leads to the most rational use of these chemotherapeutic agents in the treatment of cancer patients.

III. MECHANISM OF SUPPORT:

Awards will be made as Cooperative Agreements. These are assistance relationships involving substantial involvement of NCI staff during performance of the project. The terms of NCI staff participation are included in the complete RFA.

NCI anticipates making multiple awards as a result of this request. It is anticipated that $750,000 will be set aside to fund the initial year's awards. Awards will be made for a period of up to five years. It is anticipated that the starting date for the initial annual period will be between April 1, 1986 and July 1, 1986. No set-aside funds have been provided for renewals.

All policies and requirements that govern the grant program of the U. S. Public Health Service apply, including the requirement for cost sharing. Although this program is provided for in the financial plans of the NCI, the award of cooperative agreements pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. STAFF CONTACT

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

Ann Carpenter
Program Administrator
Cancer Therapy Evaluation Program
National Cancer Institute
Landow Building - Room 4C33
Bethesda, Maryland 20205

Telephone: (301) 496-8866

ANNOUNCEMENT

RENEWAL OF CLINICAL INVESTIGATOR AND PHYSICIAN SCIENTIST AWARDS

P.T. 34; K.W. 1200180, 1200270

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates August 1, 1985,
and June 1 in subsequent years

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of competitive renewals of Clinical InvestigatorAwards and Physician Scientist Awards to assist awardees in achieving the status of independent investigator. In view of the limited amount of research training and/or research experience that most awardees have at the beginning of the award period, the Institute recognizes that some individuals may need up to three additional years to become independent investigators with adequate research grant support.

Clinical Investigator and Physician Scientist awardees may request a three year renewal of their awards if they meet all of the following conditions:

- Awardees are not recipients of a Research Career Development Award or an Academic Award.
- Awardees will devote at least 50 percent effort to heart, lung, and/or blood research during the renewal period.
- The grantee institution makes a commitment to provide the necessary facilities and resources and submits the competing application.

Guidelines for the renewal will be mailed to NHLBI Clinical Investigator and Physician Scientist awardees. The guidelines will include directions for completing the renewal application and criteria to be applied in the review of renewal applications.

For further information, NHLBI Clinical Investigator and Physician Scientist awardees may contact the program staff shown on their Notice of Grant Award at the following addresses:

Fann Harding, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5A08
Bethesda, Maryland 20205

Telephone: (301) 496-1817

Max A. Heinrich, Jr., Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A12
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Joan Wolle, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 612A
Bethesda, Maryland 20205

Telephone: (301) 496-7668

This program is described in the Catalog of Federal Domestic Assistance No. 13.839, Blood Diseases and Resources; No. 13.837, Heart and Vascular Diseases; and No. 13.838, Lung Diseases. Awards will be made 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.

ANNOUNCEMENT

PREVENTIVE ONCOLOGY ACADEMIC AWARD

P.T. 34; K.W. 0785140, 0745055

NATIONAL CANCER INSTITUTE

Competition for the Preventive Oncology Academic Award (K07) is being resumed. There will be one receipt date annually, namely October 1. Please write or call the person listed below to discuss your interest in this program and obtain a copy of the program guidelines to use in writing an application. Again, please note that the next receipt date is October 1, 1985.

Please address inquiries to:

Program Director, K07
Cancer Training Branch, CCSP, DCPC
National Cancer Institute
Blair Building - Room 424
Bethesda, Maryland 20205-4200

Telephone: (301) 427-8898

ANNOUNCEMENT

ASSESSMENT OF MENTAL HEALTH PROBLEMS IN DISASTER VICTIMS

MH-86-03

P.T. 34; K.W. 0715095, 0785055, 0404021, 0715210, 0413000

NATIONAL INSTITUTE OF MENTAL HEALTH

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

The purpose of this announcement is to encourage researchers to estimate the type and the incidence of mental health disorders, including Post Traumatic Stress Disorder, resulting from exposure to disaster; to study factors associated with the development and continuance of these disorders in victims exposed to different types of disaster events; and to assess changes in life functioning and other early behavioral problems following disaster exposure which may or may not lead to a mental health disorder.

A new instrument, the Diagnostic Interview Schedule/Disaster Supplement (DIS/DS) is designed to provide a comprehensive picture of the emergency experience and is applicable across a wide range of emergencies. The instrument assesses the type of emergency, type and extent of loss, individual and family risk factors, use of formal and informal support systems, and psychosocial and behavioral response to the traumatic event.

Several activities are under way for users of the DIS/DS to facilitate standardized assessment and cross-study comparisons of the mental health effects of different types of emergencies. The core of the instrument is the Diagnostic Interview Schedule (DIS), a comprehensive instrument originally covering 34 DSM-III diagnoses. Incorporated into the DIS during the ECA studies were questions about generalized anxiety, Post Traumatic Stress Disorder, and traumatic life events, a standardized supplement describing use of medical services, family history of disorder, assessments of social support, and functioning levels in occupational and interpersonal arenas.

In the course of adapting the DIS for use in disaster situations, questions regarding disorders of low incidence or irrelevance to the disaster experience were eliminated. The Disaster Supplement (DS) adds questions about disaster exposure, including such factors as damage, losses, news coverage, attributions for the event, and traumatic response of significant others.

This program is described in the Catalog of Federal Domestic Assistance No. 13.242, Mental Health Research Grants. Awards will be made 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.

The object of this announcement is to encourage, stimulate, and support studies that will use the DIS/DS for disaster-related investigations of interest to the applicants. Applicants may add measures of particular relevance to their study and adapt the DIS/DS to the emergency in question. Applications should have as their focus a particular mental health issue rather than a particular emergency event, allowing for review, approval, and funding prior to the emergency.

To be accepted for review, applications should:

- Propose a clearly discernible research activity, involving generation and testing of hypotheses.
- Demonstrate clear and direct relevance to the mental health of victims, their their families, and/or significant others.
- Be prospective epidemiological surveys, collecting at least two waves of longitudinal data following disaster impact: near-immediate assessment and assessment one year after impact.
- Articulate rationales for either substituting, supplementing, or omitting portions of the DIS/DS, in terms of the instrument's relation to the population and type of emergency event to be sudied.
- Indicate the problem area, the research design, and the characteristics of the emergency situation for which the objectives and methodology would be appropriate.
- Include a comparison group of respondents selected in such a way that a significant theoretical question can be tested.
- Indicate the extent to which the assessed dimensions will permit generalization.
- Include a designated advisory group of three to five members for scientific oversight, selected on the basis of experience in conducting studies of emergencies.
- Articulate procedures established to insure that the project advisory group will be available to fulfill its function and that the project team will be able to mobilize its resources at the time of the emergency event.

Applicants should be concerned with projects with substantive emphasis on any one or more of the following areas:

- Studies of different population subgroups in order to establish differential risk of negative effect.
- Studies which examine families as interactional systems in their response to emergency situations.
- Studies of immediate and long-term mental and physical health impact of disaster on individual victims and their significant others.

- Studies of the mental health consequences of perceptual aspects of traumatic events, such as extreme fear, perceived aspects of responsibility, perception of lasting consequences, and expectation of the recurrence of such an event.

- Studies of the mental health consequences of treatment of victims by non-mental health community and Federal agencies.

- Studies of both short-term crisis intervention and long-term mental health treatment and service delivery for victims of all ages and/or their significant others.

- Studies of social support systems and coping mechanisms as mediators of psychological response to emergency events.

NIMH research grants are available to any public or nonprofit institution such as a university, college, hospital, or community agency, units of State or local government, and authorized units of the Federal Government and to for-profit institutions and entities.

Applications submitted in response to this announcement will be reviewed in accordance with the usual Public Health Service peer review procedures for research grants and in accordance with the usual NIMH receipt, review, and award schedule.

Review criteria include the significance and originality of the researcgh goals; the state of knowledge in the field; the feasibility of the research; the competence and dedication to the project of the principal investigator and his or her supporting staff; the adequacy of available facilities; the potential usefulness, generalizability, or heuristic value of the results; provision for the protection of human subjects; and the appropriateness to the proposed budget for the work outlined.

Initial review group and National Mental Health Advisory Council recommendations, program balance in type of emergency event, and availability of funds are taken into consideration in determining which projects will be funded.

For terms and conditions of support, application procedures, and a copy of the DIS/DS to be used for responding to this announcement, applicants may contact:

Susan Solomon, Ph.D. or Mary Lystad, Ph.D.
Center for Mental Health Studies of Emergencies
5600 Fishers Lane, Room 6C-12
Rockville, Maryland 20875

Telephone: (301) 443-1910

ANNOUNCEMENT

RESEARCH ON FAMILY STRESS AND THE CARE OF ALZHEIMER'S DISEASE VICTIMS

MH-86-07

P.T. 34; K.W. 0715180, 0715195, 0730010, 0715095, 0415000, 0730050

NATIONAL INSTITUTE OF MENTAL HEALTH

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

The National Institute of Mental Health (NIMH) through the Center for Studies of the Mental Health of the Aging (CSMHA) seeks applications for studies which will increase knowledge and improve research methodology on family stress related to the care of individuals with Alzheimer's disease (AD) and the development of family care and service delivery models. Applications should focus on the generation of systematic information on the nature, consequences, and interplay of stress associated with caregiving; factors associated with understanding and enhancing family support; the identification, treatment, and management of excess disability in AD patients and strategies to maximize their functional level at all stages of the disease; the prevention of psychopathology and the promotion of mental health among family caregivers; and research on the design and delivery of services which provide treatment and clinical interventions for individuals with AD and for the family members who care for them.

I. TOPICS OF RESEARCH INTEREST

Specific research topics of interest include but are not limited to:

- Studies of the nature, consequences, and interplay of stress associated with caregiving on the individual family caretaker, family unit, and the AD patient
  - nature of risk factors associated with the development of stress-related dysfunction in individual caretakers and family units
  - nature of short- and long-term physical, psychological, social and financial consequences of family caretaking, particularly studies on the development or exacerbation of physical (e.g., diabetes, hypertension) or psychological conditions in the caregiver
  - the interaction of family stress, coping strategies, and the management of the AD patient
  - stress and bereavement in the context of the clinical course of AD
- Systematic research on family support, broadly conceived
  - investigations of the nature, type, and extent of family support

- identification and analysis of individual and family characteristics, interactions, and other variables most amenable to the particular caretaking functions associated with AD, including the identification of factors associated with caregiver satisfaction, positive aspects of caregiving experiences, and effective coping strategies

- determination of the efficacy of and best approaches to teaching behavioral management or other strategies to caregivers and development of valid assessment instruments

- identification and development of strategies to aid the family in the early recognition of symptoms, the decision to seek medical care, and the decision to assume and play a primary caregiver role

- identification of the most effective coping strategies and interventions used by caregivers; and identification of the kinds of information, education, support, and treatment that best reinforce the increased coping abilities of families with AD members.

o Systematic research aimed at the treatment and management of excess disability and the maximizing of AD patients' functional level

- examination of factors in the psychosocial and physical environment which shape and maintain positive behaviors in AD patients

- development of strategies to maximize the functional level of the AD patient, at all stages of the disease, through the application of mental health treatment modalities

- development of new approaches for managing behaviors most frequently leading to institutionalization

- identification and reduction of excess disability, including accurate diagnosis and treatment of coexisting physical and psychiatric symptoms

o Systematic research on the prevention or reduction of psychopathology, symptoms caused by stress, and the promotion of mental health among family caregivers

- the effectiveness of supportive interventions for the primary caregiver and other family members

- development of methodologies for assessing specific types of interventions for preventing/moderating stress among family caretakers

o Systematic research on the design and delivery of services and service systems for AD victims and their caregivers

- identifying an optimal range of community and institutional services relevant to AD in terms of design, staffing, timing of use during the progression of the disorder, mix, and coordination with other services

- studies of the best methods of delivering services such as comprehensive assessment, case (care) management, outpatient treatment, home health care, respite care, adult day care, partial hospitalization, and nursing home care

- strategies for the most effective integration of formal support services provided by health care professionals with informal support interventions provided by family, friends, and neighbors

- application of research in the development of new services for AD patients

- services research demonstration aimed at developing models for providing a state-of-the-art clinical management, treatment, and care, taking into consideration the context of where treatment and services are provided (e.g., the home, the community, a nursing home)

II. ELIGIBILITY

Private, nonprofit, or for-profit and public institutions, such as units of State or local government and authorized units of the Federal Government (including Veterans Administration hospitals and other facilities), are eligible to apply for grants under this announcement.

III. REVIEW

Applications will be reviewed according to the regular NIMH review schedule and according to the standard review procedures of the Public Health Service.

Criteria for scientific/technical merit review will include the following:

o Scientific or technical significance of the goals of the proposed research

o Adequacy of the methodology proposed to carry out the research

o Qualifications and experience of the principal investigator and proposed staff

o Potential contributions to the objectives and scope of this announcement

o Adequacy of the conceptual and theoretical framework for the research

o Evidence of familiarity with relevant research literature

o Scientific merit of the research design, approaches, and methodology

o Adequacy of the data analysis plan

o Adequacy of the existing and proposed facilities and resources

o Appropriateness of the budget, staffing plan, and timeframe to complete the project

o Adequacy of proposed procedures for protecting human subjects

IV. AWARD CRITERIA

In making decisions to fund applications, the following will be considered:

- o Quality of the proposed project as determined during the review process
- o Availability of funds
- o Balance among research areas of the announcement

V. STAFF CONSULTATION

For further information concerning terms and conditions of support, and application procedures and assignment, applicants should contact:

Enid Light or Barry D. Lebowitz, Ph.D.
Center for Studies of the Mental Health of the Aging
National Institute of Mental Health
5600 Fishers Lane, Room 11C-03
Rockville, Maryland 20857

Telephone: (301) 443-1185

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