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DATED ANNOUNCEMENTS (RFPs and RFAs AVAILABLE)

CLINICAL COORDINATING CENTER FOR A STUDY OF THE PULMONARY
COMPLICATIONS OF HTLV-III/LAV INFECTION

RFP AVAILABLE: RFP-NHLBI-HR-87-10

P.T. 34; K.W. 0715120, 0715165, 0755015, 1010013, 0785055

National Heart, Lung, and Blood Institute

The Division of Lung Diseases, National Heart, Lung, and Blood Institute (NHLBI), in cosponsorship with the AIDS Program, National Institute of Allergy and Infectious Diseases (NIAID), is soliciting proposals from offerors who are willing to serve as a clinical coordinating center for a longitudinal study on the pulmonary complications associated with Human T-Lymphotropic Virus, type II/Lymphotropic-Associated Virus (HTLV-III/LAV) infection. The specific objectives of this program are: 1) to collect information on pulmonary complications due to HTLV-III/LAV infection in individuals in various transmission categories (risk groups); and 2) to determine the types, incidence, course and outcome of pulmonary disorders in recently diagnosed patients with acquired immune deficiency syndrome (AIDS), in recently diagnosed (i.e., within 3 to 6 weeks) AIDS-related complex (ARC) patients, and in individuals asymptotically infected with HTLV-III/LAV.

Physicians who have examined many AIDS patients have the recent impression that a shift is occurring in the types and incidence of pulmonary complications associated with HTLV-III/LAV infection. There appears to be an increased incidence of serious infection with pyogenic bacterium; both pulmonary and extra pulmonary infections with M. tuberculosis have been noted with increased frequency. Nonspecific interstitial pneumonitis appears to be on the rise, and cases of lymphoid interstitial pneumonitis, which is diagnostic of AIDS in children under 13 years old who are HTLV-III/LAV antibody positive, is being seen with increased frequency in adults.

A separate RFP, NHLBI-HR-87-09, has been issued for 6 clinical centers. The participating clinical centers are expected to recruit a minimum of 200 participants, age 18 years and older, during a 12-month recruitment period. The distribution of participants should be: 50 AIDS patients, 50 ARC patients and 100 asymptomatic HTLV-III/LAV-infected individuals. Offerors for clinical centers are also expected to provide a plan for evaluating pulmonary status of each study participant and a plan for maintaining contact with participants over the four-year recruitment and study phase of the project.

The clinical coordinating center will be responsible for: 1) participating in the development and preparation of specific study protocol, reporting forms and manual of operations; 2) standardizing, printing and distributing the study protocol, the reporting forms and the manual of operations; 3) collecting, processing, storing and analyzing data collected from the participating clinical centers; 4) preparing and distributing technical and statistical reports to the clinical centers; 5) assisting the program office in coordinating and managing quarterly meetings of the steering committee and; 6) assisting the program office in establishing a method to review periodically the clinical data.

The clinical coordinating center will be involved actively in the development of the study protocol and manual of operations and will be developing new and/or modified methods of analysis to meet the needs of the clinical centers. Because this program involves research on HIV infections, a burgeoning research area, and because the clinical coordinating center will work closely on a daily basis with the clinical centers, it is anticipated that the clinical coordinating center will require the commitment for a minimum of 10 to 15 hours per week of a physician with knowledge and experience in pulmonary medicine and in the diagnosis, care and treatment of AIDS and ARC patients. In addition, the clinical coordinating center will be required to have senior biostatistical/epidemiological staff who will monitor the clinical centers to ensure that data are forwarded according to an established time schedule, that data are reviewed for completeness, and that quality control is maintained prior to processing. The clinical coordinating center staff will also be responsible for development of computer software necessary for the above mentioned functions.

The study will be conducted in three phases. Phase I (6 months) will include the design of the collaborative protocol, manual of operations and data forms. Phase II will involve the recruitment (1 year) and study and follow-up (3 years) of participants. Phase III (6 months) will be devoted to data analysis.

This announcement is not a Request for Proposals (RFP). It is anticipated that RFP-NHLBI-HR-87-10 will be available on or about January 21, 1987, with proposals due on April 6, 1987. Copies of the RFP may be obtained by written requests addressed to:

Douglas W. Frye, Contracting Officer
for the Division of Lung Diseases
Contracts Operations Branch
National Heart, Lung, and Blood Institute
Westwood Building, Room 654
5333 Westbard Avenue
Bethesda, Maryland 20892

This request should include (3) self addressed mailing labels.

DEVELOPMENT AND IMPROVEMENT OF ANALYTICAL METHODOLOGY FOR ANIMAL
DRUG RESIDUES IN TISSUES

RFA AVAILABLE: FDA-CVM-87-1

P.T. 34; K.W. 0710100, 0755010, 0740025

Food and Drug Administration

Application receipt date: March 3, 1987

The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), is announcing the availability of approximately \$300,000 for fiscal year 1987 for cooperative agreements to support studies on the development and improvement of analytical methodologies for animal drugs and associated residues in tissues. Funds are not presently available for these studies. The government's obligation hereunder is contingent upon the availability of appropriated funds.

The purpose of these agreements is to provide financial assistance to support research for new or improved tissue extraction, clean-up and quantitative procedures, including multi-residue analytical technology for high priority animal drugs. Projects designed to test and evaluate the reliability, performance and practicality of immunoassays in animal drug residue analysis and screening are also of interest.

FDA anticipates making three or four awards averaging \$75,000 to \$100,000 (direct and indirect costs) each per year. Support for this program may be for a period of up to three years.

FDA encourages prospective applicants to submit a brief one page letter of intent by February 6, 1986. The letter, which should include a short synopsis of the work plan, is not binding and it will not enter into the review of the proposal subsequently submitted. The letter of intent and questions concerning the programmatic aspects of the RFA should be addressed to:

Dr. David B. Batson
CVM/FDA, HFV-500, Room 8-89
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-6510

Request for copies of the RFA and application kits should be addressed to:

Olia M. Hopkins
State Contracts and Assistance Agreements Branch (HFA-520)
Food and Drug Administration, Room 15A-17
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-6170

STUDIES OF THE OPPORTUNISTIC INFECTIONS ASSOCIATED WITH
THE ACQUIRED IMMUNODEFICIENCY SYNDROME

RFA AVAILABLE: 87-AI-10

P.T. 34; K.W. 0715125, 0715165, 0785055, 0710075, 1002008

National Institute of Allergy and Infectious Diseases

Application receipt date: March 19, 1987

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for innovative regular research grants to study the basic biology, pathogenesis, diagnostic tests, and epidemiology of the opportunistic infections associated with infection with HTLV-III/LAV (HIV).

BACKGROUND

The opportunistic infections associated with AIDS produce significant morbidity and mortality among individuals infected with HTLV-III/LAV. It has been difficult to develop effective methods to treat and prevent the opportunistic infections for a variety of reasons. The epidemiology and pathogenesis of a number of the opportunistic infections, e.g., Pneumocystis carinii pneumonia and Mycobacterium avium-intracellulare infections, are incompletely understood. The lack of rapid and reliable diagnostic tests have hindered studies of the natural reservoirs, modes of acquisition, organism variation, and natural history of several of the infections associated with AIDS. Available treatments are not always successful and are commonly associated with significant toxicity; relapses are common. Vaccines are generally not available for these organisms.

Pneumocystis carinii pneumonia (PCP) is a particular problem in AIDS. PCP is the most common life-threatening opportunistic infection in individuals with AIDS and has been diagnosed in about 60 percent of patients at some time during their illness. The organism, its natural reservoir(s), modes of transmission and natural history are incompletely understood.

OBJECTIVES AND SCOPE

The NIAID wishes to encourage ongoing investigations and to stimulate new research to study the basic biology, pathogenesis and epidemiology of the opportunistic infections associated with AIDS and especially wishes to encourage investigations to develop a rapid, reliable, non-invasive test for PCP. Applicants are encouraged to consider research in areas of molecular biology, genetic variation or determinants of virulence of the opportunistic organisms, or immunopathogenesis and the host's response to these infections. The infections of interest are limited to the following: pneumocystosis, toxoplasmosis, cryptosporidiosis, candidiasis, cryptococcosis, mycobacteriosis, herpes simplex virus and cytomegalovirus infections. Such research should lead to an improved fundamental understanding of the pathogenesis of the opportunistic infections and eventually may lead to improved approaches for diagnosis, treatment and prevention.

INQUIRIES

Additional information and copies of the full RFA may be obtained from:

Harold M. Ginzburg, M.D., J.D., M.P.H.
Chief, Epidemiology Branch, AIDS Program
Westwood Building - Room 753
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-0545

STUDIES OF HETEROSEXUALS WITH AIDS OR AT RISK FOR ACQUIRED
IMMUNODEFICIENCY SYNDROME

RFA AVAILABLE: 87-AI-08

P.T. 34; K.W. 0715120, 0785055, 0715220

National Institute of Allergy and Infectious Diseases

Application receipt date: March 19, 1987

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for NIH traditional research projects to study the epidemiology and natural history of HTLV-III/LAV (HIV) infection in non-homosexual, non-intravenous drug abusing men and non-intravenous drug abusing women at risk for AIDS.

BACKGROUND

As of October 13, 1986, 983 (4 percent) of AIDS cases reported to the CDC have denied homosexuality, intravenous drug abuse and a history of blood transfusions, but have reported heterosexual contact as the likely source of HTLV-III/LAV infection. Heterosexual contact cases include 441 persons who have had heterosexual contact with a person with AIDS or at risk for AIDS, and 542 persons without other identified risks who were born in countries in which heterosexual transmission is believed to play a major role. The mechanisms and relative efficiency of heterosexual transmission of HTLV-III/LAV is currently unclear.

The NIAID wishes to study heterosexual men and women in the United States who are at risk for HTLV-III/LAV infection and AIDS to refine our knowledge of the epidemiology, routes and mechanisms of transmission, and relative risk for transmission of the infection. Results of such studies will direct the development of appropriate strategies for prevention and treatment of HTLV-III/LAV infection and AIDS.

OBJECTIVES AND SCOPE

The NIAID wishes to encourage ongoing investigations and to stimulate new research to study the natural history - including, but not limited to, questions concerning modes of sexual transmission, relative importance of male to female and female to male transmission, and the role of cofactors, if any - of HTLV-III/LAV infection in non-homosexual, non-intravenous drug abusing men and non-intravenous drug abusing women with AIDS or at risk for AIDS.

Proposed studies may include case-control studies or prospective studies of heterosexuals at risk for AIDS. Recruiting potential participants may employ a wide variety of techniques such as newsletter or public media announcements, or surveys. Preferably, recruitment will include sexual contact tracing of heterosexual partners of persons with AIDS or HTLV-III/LAV seropositive individuals such as sexual partners of hemophiliacs, intravenous drug abusers, recipients of contaminated blood products, or female partners of bisexual males. Preferable sites of recruitment include, but are not limited to, blood donation sites, drug and alcohol abuse treatment programs, sexually transmitted diseases clinics or other screening sites. Other recruitment approaches will be considered, including enrollment through prostitution services or heterosexual clubs.

INQUIRIES

Additional information and copies of the full RFA may be obtained from:

Harold M. Ginzburg, MD, JD, MPH
Chief, Epidemiology Branch, AIDS Program
Westwood Building - Room 753
Bethesda, Maryland 20892
Telephone: (301) 496-0545

COOPERATIVE AGREEMENTS FOR THE NETWORK OF ACQUIRED IMMUNODEFICIENCY SYNDROME CLINICAL RESEARCH GROUPS

RFA AVAILABLE: 87-AI-09

P.T. 34; K.W. 0715120, 0785035, 0785055, 0415000, 0710030, 0710070, 0710100, 0403004, 0745045, 1002045

National Institute of Allergy and Infectious Diseases

Letter of Intent Date: February 15, 1987
Application Receipt Date: April 1, 1987

The purpose of this RFA is to establish a network of "Acquired Immunodeficiency Syndrome Clinical Research Groups" (AIDS-CRG) whose common research thrust will be the development of new and improved treatment interventions for AIDS. Each of these Groups may also establish a related basic research component and an education and outreach component to disseminate information about treatments and other issues related to the disease.

There is a nationally recognized need to establish AIDS-CRG's. By 1984, AIDS was primarily seen in large coastal metropolitan areas; the epidemic is now spreading to other areas of the country where health care providers have not had the experience of dealing with large numbers of AIDS patients. The AIDS-CRG, as envisioned within this RFA, is an assistance mechanism to enable clinicians at the local level to participate in a national network of facilities whose function will be in part to develop new or improved treatment interventions. A second goal of this RFA is to

encourage clinicians to form a cadre of knowledgeable professionals whose research interests will lead to a better understanding of this disease. Groups may be organized with a basic research component that will interact strongly with the clinician or alternatively a group may direct its efforts towards education and outreach to disseminate information about the disease, its treatment, and other issues which may arise.

Awards will be made as Cooperative Agreements. Assistance via a Cooperative Agreement differs from the traditional research grant in that, in addition to the normal programmatic and administrative stewardship responsibilities, the component iNational Institute of Allergy and Infectious Diseases awarding the Cooperative Agreement anticipates substantial involvement during performance of the project. However, the applying Group must define its objectives in accord with its own interests and perceptions of novel and exploitable approaches and must develop the detail of the research design following the guidance given in this RFA. It is the primary responsibility of the Principal Investigator to clearly state the objectives of the AIDS CRG, to perform the research stipulated in the application and to ensure that the results obtained are published in a timely manner.

The composition of an AIDS CRG is envisioned as consisting of up to three (3) major components; treatment, basic research and outreach programs each headed by a Research Investigator and appropriate staff. Research Investigators will be directly responsible to the Principal Investigator. The expertise of the Research Investigators and supporting staff may be in somewhat diverse scientific disciplines appropriate to the realization of a particular Group's research objectives.

Copies of the complete RFA are available from:

Dr. John R. La Montagne
Director, Acquired Immunodeficiency Syndrome Program
National Institute of Allergy and
Infectious Diseases
Bethesda, MD 20892
Telephone: (301)-496-0545

COOPERATIVE AGREEMENTS FOR INVESTIGATIONS ON VACCINE ADJUVANTS

RFA AVAILABLE: 87-AI-11

P.T. 34; K.W. 0715120, 0740075, 0710070

National Institute of Allergy and Infectious Diseases

The Prevention Branch of the Acquired Immunodeficiency Syndrome Program of the National Institute of Allergy and Infectious Diseases invites applications for Cooperative Agreements to support research projects to investigate the development and characterization of vaccine adjuvants for eventual clinical usage. The purpose of this RFA is to encourage studies on new formulations of adjuvants; the mechanism of action of adjuvants; evaluation of vaccine-adjuvant mixtures as immunogens in appropriate animal models, including protection against challenge; and, after appropriate preclinical testing has been done, evaluation in clinical trials.

Although there is a need for such adjuvants for many new potential vaccine antigens, it is anticipated that the need may be particularly acute for AIDS vaccines because of the relatively low titers of neutralizing antibodies observed in experimental situations and the current thrust for vaccine development which is predominantly aimed at small subviral antigens. A successful adjuvant for HTLV-III/LAV protein, glycoprotein or peptide antigens should also have a high probability of success when used with chemically similar antigens derived from the many other infectious agents in which the NIAID is interested.

Awards will be made as Cooperative Agreements. Cooperative agreements are awarded to both nonprofit and profit organizations and institutions. This type of solicitation is utilized when it is desired to encourage investigator initiated research projects in areas of special importance to the NIH and where substantial programmatic involvement by staff is anticipated

Copies of the complete RFA may be obtained from:

Chief, Prevention Branch, AIDS Program
National Institute of Allergy and Infectious Diseases
Westwood Building - Room 753
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-0545

COOPERATIVE AGREEMENTS FOR POSTMENOPAUSAL ESTROGEN/PROGESTIN INTERVENTIONS (PEPI)

RFA AVAILABLE: 87-HL-06-H

P.T. 34; K.W. 0755015, 0760025, 0411005, 0765030, 0785025, 0785050, 0785135

National Heart, Lung, and Blood Institute

Application receipt date: April 17, 1987

The Lipid Metabolism-Atherogenesis Branch of the Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Cooperative Agreement Applications (RFA) on the above subject. The National Institute of Child Health and Human Development, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute on Aging are also participating in the funding of this RFA. Copies of the RFA are currently available from staff of the NHLBI.

This program will support Clinical Centers and a Coordinating Center to participate with the NHLBI in the design and performance of a collaborative randomized clinical study to assess the effects of various postmenopausal estrogen replacement therapies on selected cardiovascular disease risk factors and osteoporosis risk factors, as well as other parameters. It is expected that research will involve a variety of oral and parenteral treatment arms and interdisciplinary expertise in lipidology, gynecology, bone metabolism, hematology, endocrinology, internal medicine, cardiology, epidemiology, biostatistics and quality control.

Requests for copies of the RFA should be addressed to:

Ms. Irma L. Mebane
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 401
7550 Wisconsin Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-1681

NEW INITIATIVES IN DRUG ABUSE

P.T. 34, AA, FF; K.W. 0404009, 0725020, 0411005, 0755025, 0415000, 0745055

National Institute on Drug Abuse

Application receipt date: April 1, 1987

The National Institute on Drug Abuse (NIDA) wishes to announce considerable expansion of its research program. The President and Congress have undertaken several new initiatives that have greatly increased the availability of research funds in the areas of drug abuse and drug abuse-related AIDS. There is now a unique opportunity for scientists working in widely disparate disciplines to focus their talent on finding solutions to these serious national problems.

Researchers not already working in the field of drug abuse are invited to consider whether their work may have direct relevance to our research mission. Recent advances in many fields, such as those that have occurred in molecular biology, computer modeling of complex social systems, or analyses of animal and human behavior, may have drug abuse applications. While NIDA is interested in any study that will increase our scientific knowledge, we are especially interested in receiving grant applications in the following areas of research:

- o INTRAVENOUS DRUG USE AND AIDS: relationships between drug use and AIDS; prevention of infection; drug effects as co-factors for AIDS; perinatal and heterosexual transmission of the virus; drug treatment and AIDS, incidence/prevalence; studies of at-risk individuals; and, the impact of drug abuse related AIDS on the community.
- o COCAINE AND "CRACK": populations at risk; physiological and psychological hazards of use; etiology and prevention; innovative treatment approaches; natural history of drug use; basic mechanisms of action and effects; and, the drug distribution network.
- o DRUGS IN THE WORKPLACE: incidence/prevalence; techniques for detecting the problem and measuring its impact; prevention of drug abuse in the workplace; effect of drugs on performance; evaluations and strategies for EAP programs; and, policy studies related to drugs in the workplace.

- o VULNERABILITY TO DRUG ABUSE: studies of genetic and environmental factors; special populations at risk; family and community studies; and, development of genetically focused animal models.
- o BIOMEDICAL ASPECTS OF DRUG ABUSE: studies of the neurobiology of reinforcement; studies of the dynamics of drug detection; development of new treatment drugs; pharmacokinetics of abused drugs; behavioral and biological factors in the psychotropic response to drugs; and, molecular biological studies of drug-receptor interactions.
- o PREVENTION: new early intervention techniques, testing and evaluation of prevention strategies; development of new scales and methods to identify and measure effects; and, studies of the etiology of drug abuse.
- o TREATMENT: development and testing of new treatment drugs and new treatment strategies for drug addiction; studies of strategies for getting and retaining drug abusers in treatment; studies of recidivism and techniques for dealing with it; nosology and diagnosis; and, development of diagnostic instruments.
- o ETHNIC, MINORITY, JUVENILE, AND SPECIAL POPULATIONS: etiology, prevention, incidence, and treatment of drug abuse in these and in especially hard-to-reach groups such as school drop-outs, the homeless, or run-away youth.

The last regular receipt date for all NIDA grant applications for FY 1987 funding is February 1, 1987. However, a special receipt date of April 1, 1987 has been established for certain areas in this fiscal year. This date is for applications submitted under new program announcements, which have recently been issued or are about to be issued. These announcements invite applications in particular areas, which are targeted for emphasis in connection with the additional AIDS funds and the enhanced drug abuse program. Applications also are encouraged on an ongoing basis in all of the above areas.

For further information about our research programs, announcements, and particularly about areas in which applications may be submitted for the April 1, 1987 receipt date, call:

Biomedical Sciences, Neurosciences, and Pharmacology
 Dr. Marvin Snyder
 Director, Division of Preclinical Research
 Telephone: (301) 443-1887

AIDS, Behavioral Studies, Prevention, and Treatment
 Dr. Roy Pickens
 Director, Division of Clinical Research
 Telephone: (301) 443-6697

Epidemiology, Incidence, Prevalence, Natural History,
 Etiology
 Mr. Edgar Adams
 Director, Division of Epidemiology/Statistical Analysis
 Telephone: (301) 443-6504

Drugs in the Workplace, Employees Assistance Programs,
 Work Policy
 Dr. Michael Walsh
 Office of Workplace Studies, Performance Initiative
 Telephone: (301) 443-1263

Drug Abuse and Minorities
 Ms. Catherine Bell
 Office of Science
 Telephone: (301) 443-1514

AIDS COMMUNITY OUTREACH DEMONSTRATION PROJECT

P.T. 34; K.W. 0715120, 0403004, 0502017, 1004017, 0404000

National Institute on Drug Abuse

Application Receipt Date: April 1

The Acquired Immunodeficiency Syndrome (AIDS) Outreach Demonstration Program has been established to provide grant support to approximately five Standard Metropolitan Statistical Areas (SMSAs) in order to demonstrate the effectiveness of comprehensive community-based outreach and intervention strategies in reducing the spread of the acquired immunodeficiency syndrome (AIDS) among intravenous drug abusers and their sexual partners.

BACKGROUND

Intravenous drug users comprise the second largest group at risk for AIDS. As of October 1, 1986, more than 4,500 cases of AIDS among heterosexual intravenous (IV) drug users had been reported to the Centers for Disease Control. This constitutes 17 percent of the overall AIDS cases reported in the United States. In addition, 8 percent of AIDS cases are homosexual or bisexual IV drug users. Reported AIDS patients who are IV drug abusers are predominately black (51%) or Hispanic (30%).

It is estimated that 250,000 to 350,000 IV drug abusers are already infected with the virus and that 25 percent of those infected will develop AIDS by the end of 1991. The latency period between infection with the virus and development of AIDS currently averages four or more years. In the meantime, those who are seropositive will--through the sharing of needles and sexual contact--be infecting many thousands of others. Intravenous drug users are the primary link to two other groups at risk--heterosexual partners and children.

Drug abuse treatment is one method of preventing the spread of AIDS among IV drug users and reducing chances of AIDS exposure by allowing clients to eliminate their needle use and to learn about other risk reduction activities (i.e., safe sex). There is a crucial need to reach IV drug users not in treatment and to target AIDS prevention messages to those who will not enter treatment. It has been estimated that, for every IV drug abuser in treatment, there are seven IV drug users not in treatment. Critical questions for the field are: Who can provide the outreach/early intervention? Who can take the AIDS prevention messages to the IV drug abusers in the community? Who is going to reach the sexual partners of IV drug abusers?

Community-based treatment programs are in a position to establish or expand outreach components, to attract high-risk heroin addicts into treatment and to get IV drug abusers not in treatment to modify their behavior.

INSTRUCTIONS

Proposals should include detailed descriptions of approaches to reach target populations of IV drug abusers, potential users and sex partners of IV drug abusers, educate them about AIDS, and change their behavior in ways that will reduce the risk and spread of AIDS. Special efforts should be made to encourage IV drug users to enter and get maximum help from treatment.

Community demonstration grant applications should address:

1 Community Resource Network

Applicants should submit a method and schedule for development of a resource network that will integrate activities of hospitals, agencies, and community organizations in the target area. The applicant shall describe the services offered, and how they will be used. Drug abuse treatment programs involved in the effort should be described, with information about the clients served, caseload capacity, staff training and involvement in AIDS activities. Information should be given about programs that have had HTLV-III/LAV testing; available findings regarding seropositive rates should be provided. Alternative HTLV-III/LAV test sites should be identified. Agreements with agencies and organizations that will be supporting the community demonstration project should be submitted as part of the application.

2 Outreach Component

One focus should be on outreach in a variety of settings. Outreach approaches should include: (a) The use of indigenous outreach workers to identify, reach and communicate with IV drug abusers and associates in their natural communities. Indigenous outreach workers should be trained to survey high impact neighborhoods, identify social networks of IV drug users and the sites where they congregate (copping areas, shooting galleries, hangouts, etc.), contact IV drug users, their associates and neighborhood residents, assess risk factors (needle sharing, sexual practices, etc.), provide a range of viable alternatives, reinforce adoption of risk reduction measures, and make referrals to drug abuse treatment programs and other agencies. (b) The use of community outreach workers employed by drug abuse treatment programs to contact neighborhood groups, "network" (identify and contact associates, sex partners, and families of IV drug users); (c) Outreach to hospital emergency rooms, health care, and social service agencies to identify, contact, and counsel IV drug users. (d) Outreach to criminal justice settings, contact with the probation and parole officers of IV drug abusers.

Innovative outreach methods designed to reach target populations, are encouraged. Special attention should be given to methods of reaching and communicating with minority and ethnic populations.

Applicants should delineate criteria to be used in hiring outreach workers and describe how staff will be trained, and supervised. Estimates should be given of the types and projected numbers of individuals and community agencies/resources likely to be reached.

3 AIDS Prevention Education

Applicants should define specific education goals, describe the AIDS prevention education messages to be delivered to target groups, and the ways in which these messages will be delivered. Prevention efforts should include at least four levels:

Providing basic factual information about AIDS and HTLV-III/LAV as a context for behavioral change; o Engaging people at-risk in a realistic assessment of their risk for HTLV-III/LAV infection and their potential for transmitting the virus to others to prepare them for making changes; o Interacting directly with at-risk individuals to negotiate behavioral changes, i.e., risk-reduction activities to prevent infection or transmission of virus; o Information programs for spouses and sexual partners.

Since minority drug abusers are at high risk for AIDS, it is important to be sensitive to ethnic/cultural factors and capable of effectively communicating to minority populations both the risks and steps for overcoming the risks. Applicants should describe methods and approaches to be used in reaching and communicating with minorities.

4 Assessment and HTLV-III LAV Testing

All individuals in the target groups, particularly those who shared needles and syringes ("works") since 1978, are at risk for HTLV-III/LAV infection. Confidential voluntary antibody testing must be made available to this group and to their sexual partners/ children born since 1978. IV drug users who initially test negative shall also be offered retesting four months later.

Studies indicate that the majority of IV drug users who learn about the HTLV-III/LAV test want to know their antibody status. Therefore, outreach workers and treatment program staff must be prepared to respond to questions about testing and must be familiar with information concerning what the HTLV-III/LAV antibody tests are and how they are administered; what the tests confirm; confidentiality issues associated with testing; and ways of transmitting this information. Educational materials have been developed by NIDA as appropriate.

Applicants should describe plans for training outreach staff to help individuals decide when testing is appropriate and to tailor education to the seropositivity status of particular individuals; how HTLV-III/LAV testing will be made available at no cost to individuals who desire such testing--the estimated numbers to be tested, and the testing sites; how test results will be given to individuals tested and the specific steps that will be taken to make sure that individuals know the meaning of results and are referred for counseling; procedures to guarantee the confidentiality of test results; how individuals tested will be provided counseling regarding risk/transmission reduction.

5 AIDS Referral System

This grant program is also intended to help communities establish outreach and intervention services, organize existing resources, and add basic components that do not currently exist for IV drug abusers who are seropositive, have ARC or AIDS. It is not intended to replace or duplicate services. It is therefore important for applicants to describe referral services and how existing services will be used. The types of services which staff, including outreach workers, will be expected to pursue for clients include emergency and routine medical care; legal counseling and services; military benefits; financial aid; housing assistance; family services; educational assistance; recreational services; and special services.

6 Procedures for Achieving Behavioral Change

Applications should describe procedures for individuals and/or groups to achieve each type of targeted behavioral change that will reduce risk of HTLV-III/LAV infection and AIDS; plans for training staff to help individuals achieve behavioral change goals; and methods for followup to sustain and reinforce changes in behavior.

7 Evaluation

Evaluation will be conducted at two levels:(a.) The process evaluation which should describe the methodology for (1) clues as to how an outcome evolved and the components that helped produce the results; and (2) help to determine whether a particular intervention by itself caused something to happen or if other factors were also involved. The evaluation should document activities at the community level, who is involved and accomplishment. It should include identification of the target groups, a description of the outreach efforts, the use of resources for the programs and the qualifications of the staff participating in the efforts. The process evaluation should be designed to capture the dynamics and characteristics of the operational program. Techniques used in the process evaluation should be described and data collection forms and systems elaborated. The applicant should present staff capabilities for conducting the process evaluation.(b.) The national outcome evaluation which will be conducted by NIDA, under contract, to determine the effectiveness of the project nationally, compare outcomes in different communities, and obtain information about seropositive rates.

The grantee will participate in across-site studies to achieve these ends and will make use of questionnaires developed by NIDA. Grantees will be required to administer two questionnaires:(1) The AIDS Initial Assessment (AIA); and (2) the AIDS Followup Assessment (AFA). The AIA will be administered to each user targeted for outreach/treatment upon initial contact. The AFA will be administered to the same individual four months and one year after the AIA and yearly thereafter. For those persons participating in HTLV-III/LAV testing, the AIA should be given prior to testing. Clients who are seronegative will be offered retesting for HTLV-III/LAV 4 months later when the first AFA is given.

In this collaborative evaluation effort, the grantee will provide staff to administer the AIA and the AFA and collect required information on testing. The NIDA contractor will provide copies of the instruments, train grantee staff to administer the instruments, conduct data analyses and prepare the national evaluation report.

FACILITIES

Applicants should identify the type and location of facilities, including office space, locations where individuals in the target population can meet with outreach workers and counselors; and facilities in target areas to support outreach efforts.

ELIGIBLE APPLICANTS

For-profit and non-profit public and private entities, located or providing services in the 15 SMSAs named below are eligible to apply for these grant awards. These include public or private agencies, local health departments, and consortia of health care and community organizations which are capable of implementing a comprehensive AIDS outreach demonstration project.

NIDA intends to make available approximately \$5 million per year to be expended by grantees over a 3-year period to support Demonstration Program projects in 5 of the 15 SMSAs listed below. Only one grant award will be made per State. The following SMSAs (with highest incidence of AIDS cases) qualify for funding under this grant announcement: New York City, Nassau County, Newark, Jersey City, Patterson, San Francisco, Los Angeles, Miami, Washington, D.C., Philadelphia, San Juan, Houston, Dallas, Chicago, and Boston.

APPLICATION PROCESS:

Applicants should use the standard grant application form (PHS 398, rev. 5/82); however, state and local government agencies may use form PHS 5161.

Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 10-25
Rockville, Maryland 20857
Telephone: (301) 443-6710

Further information on the program can be obtained from:

Chief, Community Research Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-37
Rockville, Maryland 20857
Telephone: (301) 443-6720

LOCAL REVIEW AND COORDINATION

A copy of the application should be submitted to the State drug abuse authority no later than April 1, 1987, for review along with notice that the State drug abuse authority may, if it wishes, send comments to the Chief, Community Research Branch at above address by May 1, 1987.

REVIEW PROCESS:

Applications received under this announcement will be reviewed in accordance with the usual Public Health Service peer review procedures for research grants. Review criteria will include overall technical merit, evidence of collaborative arrangements, organizational capability to implement demonstration program and conduct a process evaluation, the ability of the applicant to participate in collaborative national evaluation; potential contribution of the demonstration program to new knowledge, and evidence of coordination with appropriate drug abuse and public health agencies, community organizations, social service agencies, educational institutions and law enforcement authorities. It is estimated that five projects will be funded under this announcement during FY 1987. Initiation of new projects after FY 1987 will depend on availability of funds. Applications received in response to this announcement will compete for approximately \$5 million in new grant money that has been made available for this purpose. Support will be provided for a period of up to three years (renewable for subsequent periods) subject to continued availability of funds and progress achieved.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NO. 13.279. Awards will be made under authorization Section 301 of Public Health Service Act, as amended, 42 USC 241, and administered under PHS grant policies and Federal Regulations 42 CFR Part 52. This program is not subject to the intergovernmental review requirements of Executive Order 12372 as implemented through HHS regulations at 45 CFR Part 100.

STUDIES ON PAPILOMAVIRUS-HOST INTERACTIONS

RFA AVAILABLE: 87-CA-19

P.T. 34; K.W. 0705040, 0715035, 1002004, 1002008, 1002045

National Cancer Institute

Application Receipt Date: August 3, 1987

INTRODUCTION

The Biological Carcinogenesis Branch, Division of Cancer Etiology, National Cancer Institute is inviting grant applications from interested investigators to elucidate the mechanisms of interaction between papillomaviruses and their host tissues, the squamous epithelium, which may lead to the development of malignant tumors of these tissues. Both the cellular processes leading to the transformation of individual cells and the immune response mechanisms responsible for the spontaneous regression of papillomavirus associated lesions are the focus of this request. The present RFA announcement is for a single competition with a deadline of August 3, 1987 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the complete RFA document and summarized in the following sections.

RESEARCH GOALS AND SCOPE

The major emphasis of research to be funded under this RFA will be basic studies on papillomavirus-host interactions at both the cellular and immune response levels. The scope of this RFA will include human and animal papillomaviruses (PVs). Examples of studies (which are not all encompassing) are: 1) characterization of the viral and cellular control mechanisms which govern the relationship between viral gene expression or viral latency and the differentiation or transformation state of squamous epithelial cells; 2) characterization of the phenotype of PV transformed squamous epithelial cells; 3) investigations of the mechanisms of viral entry into cells and the tissue selectivity of PVs; 4) development and utilization of novel cell culture or other systems for PV propagation and transformation assays; 5) identification and determination of the mechanism of action of co-factors in PV transformation of cells such as physical/chemical co-carcinogenes or other viral infections; 6) identification of viral or cellular epitopes on infected or transformed cells which may mediate the regression of PV lesions; 7) isolation and characterization of immunocompetent cells (e.g. cytotoxic T-lymphocytes) and humoral antibodies specific for PV proteins or other markers of PV associated neoplastic lesions and the development of specific assays to measure the immune response of patients to these markers.

MECHANISM OF SUPPORT

The mechanism of support for this RFA will be the traditional National Institutes of Health (NIH) research project grant. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years. Approximately \$750,000 will be set aside to specifically fund applications which are submitted in response to this RFA. It is anticipated that five to six applications will be funded. 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 awards will be April 1, 1988. Although this program is provided for in the financial plans of the National Cancer Institute (NCI), the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose. Non-profit and for-profit institutions are eligible to apply. Foreign as well as domestic institutions are eligible. All applications submitted in response to this announcement will be classified as new grants (Type 1). Future competitive renewal applications of grants funded under this RFA will compete with all other unsolicited applications received by the NCI. PHS grant policies governing regular research project grants apply to applications received in response to this request.

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. Alan A. Schreier
Program Director, DNA Virus Studies II
Biological Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 9A22
Bethesda, Maryland 20892
Telephone: (301) 496-1953

Inquiries concerning this announcement are encouraged and should be directed to Dr. Alan A. Schreier at the above address and phone number. The program staff would appreciate the opportunity to clarify any issues or questions.

STUDIES OF FUNCTIONAL ANTI-SENSE RNA IN ONCOGENIC VIRAL SYSTEMS

RFA AVAILABLE: RFA-87-CA-18

P.T. 34; K.W. 1002045, 0715035, 0790010, 0755040

National Cancer Institute

Application Receipt Date: August 3, 1987

INTRODUCTION

The Biological Carcinogenesis Branch, Division of Cancer Etiology, National Cancer Institute is inviting grant applications from interested investigators to systematically evaluate the function of anti-sense RNA in animal cells using in vitro oncogenic virus model systems. The present RFA announcement is for a single competition with a deadline of August 3, 1987 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements which are described in the complete RFA document and summarized in the following sections.

RESEARCH GOALS AND SCOPE

The major emphasis of the research to be funded under this RFA is the development and utilization of an in vitro model for the systematic evaluation of the function of anti-sense RNA in animal cells, using oncogenic human or animal viruses as model systems. Since the long term goal of this research is to ascertain the potential usefulness of anti-sense RNA in suppressing oncogenic viral products, the model chosen should have specific applicability to such a system and should preferably involve an inducible promoter. The model should be suitable for studying such parameters as: 1) the genetic/regulatory elements of molecular constructs/vectors needed for optimal expression of the anti-sense RNA, including determination of the requisite regions of complementarity between the normal sense gene and/or gene transcript and the anti-sense RNA, 2) the stage of gene expression (transcription vs. translation) at which anti-sense RNA acts, 3) the stability of the anti-sense RNA, 4) the site of action (nucleus vs. cytoplasm) of anti-sense RNA, 5) the quantitation of the sense product and/or of the alteration of the sense phenotype,

6) the effects of cell type on the expression and function of anti-sense RNA, and 7) the detection of the action of other compensatory genes which may obscure or reverse the effects of anti-sense RNA.

MECHANISM OF SUPPORT

The mechanism of support for this RFA will be the traditional National Institutes of Health (NIH) research project grant. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years. Approximately \$500,000 will be set aside to specifically fund applications which are submitted in response to this RFA. The earliest feasible start date for the initial awards will be April 1, 1988. Although this program is provided for in the financial plans of the National Cancer Institute (NCI), the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose. Non-profit and for-profit institutions are eligible to apply. Foreign as well as domestic institutions are eligible. The present RFA announcement is for a single competition with a deadline of August 3, 1987 for receipt of applications. All applications submitted in response to this announcement will be classified as new grants (Type 1). PHS grant policies governing regular research project grants apply to applications received in response to this request.

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. Susan B. Spring
Program Director, DNA Virus Studies I
Biological Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Landow Building, Room 9A22
Bethesda, Maryland 20892
Telephone: (301) 496-4533

Inquiries concerning this announcement are encouraged and should be directed to Dr. Susan B. Spring at the above address and phone number. The program would appreciate the opportunity to clarify any issues or questions.

ERRATUM

RESEARCH INTO METHODS OF RESEARCH THAT DO NOT USE VERTEBRATE ANIMALS, USE FEWER VERTEBRATE ANIMALS, OR PRODUCE LESS PAIN AND DISTRESS IN VERTEBRATE ANIMALS USED IN RESEARCH

P.T. 34; K.W. 0755020, 0710030, 1002027, 0780015, 0780020

Division of Research Resources

The above-captioned announcement incorrectly listed four staff contacts for the National Heart, Lung, and Blood Institute (NHLBI). Please direct all inquiries related to NHLBI research in this area to:

National Heart, Lung, and Blood Institute
Dr. Henry G. Roscoe
Westwood Building, Room 7A17A
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7225

In addition, a contact point for the National Eye Institute (NEI) was omitted from the original announcement. For information regarding NEI programs, please contact:

National Eye Institute
Dr. Michael D. Oberdorfer
Director, Amblyopia and Visual Processing Program
Building 31, Room 6A47
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-5301