

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific
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DATED ANNOUNCEMENTS (RFPs AND RFAs AVAILABLE)

NUCLEIC ACID SEQUENCE DATA BASE

RFP AVAILABLE: NIH-GM-87-04

P.T. 34; K.W. 0755045, 0780015

National Institute of General Medical Sciences

The receipt date for proposals for the renewal of the GenBank Contract has been extended from February 5, 1987 to March 30, 1987. GenBank is a Data Base which contains all published nucleic acid sequences.

Copies of the RFP can be obtained from the office referenced below.

Ms. Grace Bruce
Contract Specialist
National Institutes of Health
Research Contracts Branch, DCG
Building 31, Room 1B32
9000 Rockville Pike
Bethesda, Maryland 20892
Telephone: (301) 496-4487

LONG-TERM MORTALITY STUDY OF MEN WHO HAVE UNDERGONE
VASECTOMY - SOURCES SOUGHT

P.T. 34; K.W. 0705075, 1002012, 0411005

National Institute of Child Health and Human Development

The Contraceptive Evaluation Branch, Center for Population Research, National Institute of Child Health and Human Development, is seeking to identify sources capable of performing a long-term mortality study of men who have undergone vasectomy. The study is intended to be a cohort study wherein eligible subjects are identified retrospectively through medical records and followed for vital status. Interested organizations should be capable of performing some or all of the following technical requirements: (1) Identify a cohort of men who underwent vasectomy. (2) Identify a comparison cohort of non-vasectomized men. (3) Obtain the necessary information for the members of each cohort which will permit vital status determination (e.g. Social Security Number, birth date, state of last residence). (4) Trace both cohorts for vital status ascertainment for a period of at least 15 years following entry into the cohort. This may be accomplished through the National Death Index, State Offices of Vital Statistics, State Motor Vehicles Department, etc. (5) Perform appropriate mortality analyses to examine differences between the two groups. It is expected that the cohorts will be sufficiently large to produce enough deaths to consider cause-specific mortality as well as overall mortality.

Sources that believe they have the capabilities necessary to perform these studies should submit a brief Capability Statement containing the following information: (1) Evidence of expertise in the area of epidemiology, biostatistics and reproductive health and expertise in management of large data bases. (2) Evidence of experience in carrying out large studies which require extensive record searching and retrieval, follow-up or tracing of individuals for vital status. (3) Evidence documenting a potential pool of available records for large numbers of vasectomized men. (4) Description of facilities and equipment available for such a project.

This announcement is not a Request for Proposals (RFP). There is no commitment by NICHD to issue a Request for Proposals, but if such a request is issued, those answering this Sources Sought announcement will be so notified. Five copies of the Capability Statement should be submitted to:

Paul J. Duska, Contracting Officer
Contract Management Section, OGC
National Institute of Child Health and Human Development
Landow Building, Room 6C25
7910 Woodmont Avenue
Bethesda, Maryland 20892

Capability Statements must be received no later than close of business, 5:00 p.m. EST, March 31, 1987.

DEVELOPMENT AND CLINICAL EVALUATION OF NEW DESIGNS FOR THE
INTRAORAL FLUORIDE RELEASING SYSTEM

RFP AVAILABLE: NIH-NIDR-4-87-2R

P.T. 34; K.W. 0745050, 0755015

National Institute of Dental Research

The National Institute of Dental Research plans to issue RFP-NIH-NIDR-4-87-2R for the development and clinical evaluation in children of four Intraoral Fluoride Releasing Systems (IFR Systems). Each IFR System shall comprise an Intraoral Fluoride Releasing Device (IFRD) and the method of retaining and protecting the IFRD in the mouth. The IFRD portion of these systems will be furnished by the Government.

Phase I of the study shall include development of four IFR Systems suitable for 180 days of continuous intraoral use and which can be attached in a patient within 20 minutes. At least one of the systems shall be suitable for use in patients undergoing orthodontic treatment. Three specimens of each IFR System shall be delivered to the Government within 90 days of initiation of the contract. Upon approval of the completed IFR Systems by the Government, 60 of each system shall be produced.

Phase II shall comprise a six-month clinical pharmacology study of the four IFR Systems in four groups of 10 children aged 12 through 15 years. Each patient shall wear two IFR Systems of a given design. System retention, IFRD wear, oral tissues, and patient acceptance shall be monitored. Samples of saliva shall be collected periodically and analyzed for fluoride.

Offerors are required to identify a population of 40 noninstitutionalized children aged 12 through 15 years, 10 of whom are expected to be undergoing orthodontic treatment during the clinical phase of the study. The subjects shall be in good general health and have two fully erupted first molars and second bicuspids.

RFP NIH-NIDR-4-87-2R will be available approximately March 6, 1987, with a due date for proposals of May 6, 1987. Requests for a copy of the RFP should be in writing to:

Mr. William C. Roberts
Contracting Officer
National Institute of Dental Research
Westwood Building, Room 521
Bethesda, Maryland 20892

SPECIAL RESEARCH GRANT ANNOUNCEMENT- RESEARCH CENTER ON
DRUG ABUSE VULNERABILITY- DA-87-21

P.T. 34; K.W. 0404009, 0755030, 0404000, 0710030, 1002019, 0745055

National Institute on Drug Abuse

PURPOSE

The National Institute on Drug Abuse (NIDA) is inviting applications for clinical research centers for the study of vulnerability to drug abuse. A center grant would support interrelated behavioral, biomedical, and clinical studies, integrating the efforts of behavioral science and behavioral genetic researchers with clinical investigations to better understand the genetic and environmental factors involved in the etiology of drug abuse.

A clinical research center is expected to provide an environment in which clinical researchers can examine factors associated with vulnerability to drug abuse. Priority will be given to applications that address both biomedical and behavioral aspects of vulnerability. The center should be multidisciplinary, involving (at a minimum) investigators from the fields of psychology, psychiatry and genetics. Also, applicants are encouraged to examine a broad range of drug classes; in no case should studies be restricted to alcohol or tobacco use only. The areas of study within the clinical research center may include the following: 1) inheritance of drug abuse--including family, twin, and adoption/half-sibling studies; 2) markers for vulnerability to drug abuse; 3) mechanisms of inheritance; and 4) preventive interventions during early childhood and preadolescence.

Further information and consultation on program requirements can be obtained from:

Roy W. Pickens, Ph.D.
Director, Division of Clinical Research
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-38
Rockville, MD 20857
Telephone: (301) 443-6697

APPLICATION RECEIPT AND REVIEW SCHEDULE

Applications are invited for a special receipt date of April 1, 1987 for funding in FY 1987. Applications not submitted by April 1, 1987 cannot be considered for funding in FY 1987. Contingent on the availability of funds, applications are also being invited for the October 1, 1987 receipt date for consideration for funding in FY 1988. For review and award criteria and the conditions of support potential applicants are referred to the full text of this announcement available from the Grants Management Branch at the above address.

AVAILABILITY OF FUNDS

Applications received under this special announcement will be considered for funding on the basis of overall scientific and technical merits of the proposal as determined by peer review. It is estimated that one or two centers will be funded at approximately \$750,000 total costs per center during FY 1987. Initiation of new projects after FY 1987 will depend on availability of funds. Support will be provided for a period of up to five years (renewable for subsequent periods) subject to continued availability of funds and progress achieved.

SPECIAL RESEARCH GRANT ANNOUNCEMENT - DRUG ABUSE PREVENTION RESEARCH CENTERS - DA-87-15

P.T. 34; K.W. 0404009, 0745055, 0755030, 0710030, 0404000, 0785055, 0404021

National Institute on Drug Abuse

PURPOSE

The purpose of this announcement is to encourage the development of multidisciplinary research centers that will improve our ability to prevent drug abuse. The proposed Centers are designed to: 1) improve our understanding of etiologic factors that predispose individuals to initiate drug use; 2) identify factors involved in the progression from initial drug use to drug dependence; 3) develop criteria and early identification methodologies for use with children and adolescents at high risk for drug abuse; 4) design and test preventive interventions at the individual and small group level through controlled randomized studies; and, 5) assess the progression of drug use through prospective longitudinal studies of high risk populations.

Applications for Center grants will be encouraged but not restricted to four areas: Minority Research; Families and Multi-Generational Factors; High-Risk Children, Adolescents, and Young Adults; and Women and Drugs. For this grant announcement, the term drug abuse includes use of illicit drugs as well as inappropriate use of over-the-counter and prescription medication. Research on alcohol and tobacco in relation to other drugs of abuse may also be included.

Further information and consultation on program requirements can be obtained from:

Chief, Prevention Research Branch
Division of Clinical Research
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-20
Rockville, Maryland 20857
Telephone (301) 443-1514

APPLICATION RECEIPT AND REVIEW SCHEDULE

Applications are invited for a special receipt date of April 1, 1987 for funding in FY 1987. Applications not submitted by April 1, 1987 cannot be considered for funding in FY 1987. Contingent on the availability of funds, applications are also being invited for the October 1, 1987 receipt date for consideration for funding in FY 1988.

For specific review and award criteria and the terms of support potential applicants are encouraged to obtain the full text of this announcement.

AVAILABILITY OF FUNDS

Initial Center awards are limited to \$500,000 (direct costs) for the first year of the grant and up to \$650,000 (direct costs) for each subsequent year. It is anticipated that approximately three grants will be awarded under this announcement in Fiscal Year 1987.

REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS - INNOVATIVE TARGETED APPROACHES TO ANTIVIRAL THERAPY

RFA AVAILABLE: 87-AI-14

P.T. 34; K.W. 0740020, 1002045, 0715125, 0755025, 0710100

National Institute of Allergy and Infectious Diseases

Application Receipt Date: May 15, 1987

The Development and Applications Branch of the National Institute of Allergy and Infectious Diseases (NIAID) announces the availability of a Request for Applications (RFA) on the above subject. Grant applications are invited from interested investigators for research which applies molecular knowledge of the mechanisms of virus replication and/or pathogenesis to the development of targeted antiviral agents.

BACKGROUND

The search for effective therapeutic agents to combat serious infections was long delayed by the widely-held belief that the intracellular nature of virus replication made the development of clinically useful drugs improbable. More recently, as molecular knowledge of the mechanisms of virus replication and pathogenesis has become available, it is evident that there are viral functions which may be specifically, or at least selectively, inhibited. The efficacy of acyclovir at inhibition of herpes simplex infection is a dramatic example. The detailed molecular knowledge of virus replication cycles that is rapidly accumulating should be exploited to design additional innovative approaches to the targeting of antivirals.

RESEARCH GOALS AND SCOPE

The purpose of this RFA is to stimulate research in the development of novel targeted approaches to antiviral therapy. The strategies proposed should involve a molecular rationale for anticipated antiviral activity without significant concomitant cellular toxicity. The preparation and testing of derivatives of previously proven nucleoside analogue antiviral agents, such as a search for acyclovir derivatives, does not constitute a novel approach. Investigators will choose the virus and system they prefer for these studies, but the selected virus should either be a human pathogen or serve as a model for a human viral pathogen. The development of agents inhibitory to HTLV-III/LAV is the focus of a separate RFA and therefore proposals to target HTLV-III/LAV should not be submitted in response to this initiative. Proposals should include a discussion of the rationale for the selection of the approach and model system as well as a detailed description of the intended mechanism of preparation and testing of the putative antiviral agent.

MECHANISM OF SUPPORT

Award(s) 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.

REVIEW PROCEDURES AND CRITERIA

Applications will be received by the NIH Division of Research Grants (DRG) and assigned to NIAID. Initial peer review will be done by the Microbiology and Infectious Diseases Research Committee (MIDRC), a chartered Institute review committee.

Copies of the complete RFA may be obtained from:

Catherine Laughlin, Ph.D.
Antiviral Substances Program Officer, Development & Applications Branch
Westwood Building - Room 750
National Institutes of Health
Bethesda, Maryland 20892

RESEARCH ON SEXUAL IMPOTENCE IN THE MALE

P.T. 34; K.W. 0413002, 0705075, 1002034

National Institute of Diabetes and Digestive and Kidney Diseases

Application Receipt Dates: February 1, June 1, October 1

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announces an interest in supporting clinical and basic research on erectile function/dysfunction in the male. Support will be through individual research project grants.

BACKGROUND

Erectile dysfunction in adult males is a widespread problem. Large scale studies of middle-aged men suggest an organic basis for a high percentage of erectile failures. Disruption of penile arterial blood flow, and abnormal leakage from the corpus cavernosum (CC) are among the most frequently cited organic causes of failure to achieve erection. Estimates of impotence in diabetic men range between 25-70 percent as a result of microvascular disruptions of blood flow. Most diabetic males with neuropathy become impotent. These findings make clear the need for more intensive study of the organic components essential for normal penile erection. Such studies should contribute to a database that would aid our understanding of those pathological conditions which may be disruptive to erection.

Medications often have been neglected as causes of impotence. Numerous medications may influence penile blood supply, and as such have significant potential to interfere with penile erection. Antihypertensives, diuretics, tranquilizers, anorectics and CNS depressants may cause impotence. As many as 25 percent of cases of impotence have been considered to be the result of medications. One study has noted that 16 of the 200 most prescribed drugs in the U.S. have been associated with impotence. Systemic diseases and the medications used to treat the diseases may interfere with both endocrine and nonendocrine functions causing disruption in normal penile erection.

Androgens are known to influence sexual interest, fertility, erections during sleep and sexual responses of hypogonadal men. Androgens do not appear to be necessary for responses to erotic stimuli nor necessary for sexual interest and behavior in 50 percent of males castrated as sexually experienced adults. Studies are needed on certain systemic diseases (e.g., end stage renal disease) known to influence androgen levels and potency, to determine if impotence results from loss of sexual interest, or other androgen mediated changes in the vascular/neural elements necessary for erection. There is an absence of data on androgenic influences on the vascular and neural components thought to mediate erection in the adult male.

OBJECTIVES AND SCOPE OF RESEARCH

Normal penile erection depends on a complex interaction among psychological, neurological, hormonal and vascular events. The goals of this announcement are to increase our knowledge and understanding of the neural and vascular events responsible for normal penile erection, of the potential or known effects of medications on penile erection and of systemic disease states which are known, or have the potential, to disrupt penile erection. Specific objectives follow with some examples of pertinent research areas. The examples are not exhaustive nor exclusive of other worthwhile endeavors.

PENILE SMOOTH MUSCLE STUDIES

Studies are needed on the regulation of penile vascular smooth muscle; this tissue has not been defined biophysically. It is known that pharmacological agents that cause smooth muscle relaxation may induce erection. It is not known which endogenous factors regulate the ability of the CC to contract and to relax. The role of steroid hormones, neurotransmitters and their receptors and the possible interaction of sex hormones and the neurotransmitter receptors require study. The pathology of vascular smooth muscle requires evaluation as does the electrophysiology of aged and normal tissue.

ENDOTHELIAL CELL STUDIES

The growth, biochemistry and pharmacology of endothelial cells and their possible role in erectile function requires study. It is known that endothelial cells synthesize and contain neurotransmitters and receptors, but more information is required on the extent that these systems are functional in the CC and the vessels responsible for erection. Detailed studies are needed of vascular disease of the penis (e.g., using the diabetic model), and of vascular growth factors. The effects of chronic penile injections used to stimulate erection require careful study.

NEUROLOGICAL/NEUROPATHY ASSESSMENTS

There is a strong need to develop more reliable and sensitive measurements for clinical assessment of neural contributions to impotence. A number of neurotransmitters remain to be studied in the penis as well as the possible role of crosstalk in regulating penile function. Do receptor systems change as a function of age, as a result of normal/abnormal penile function, or as a result of specific systemic diseases? Do chronic penile injections influence neurotransmitters and their receptors? Sensory as well as motor functions related to sexual stimulation and responsiveness require study. The central-peripheral feedback loops permitting normal sexual function have not been identified in detail in the human and need study. Nerve-striated muscle relationships have not been evaluated, and it is not clear if such relationships are important for normal penile erection.

SYSTEMIC DISEASE AND MEDICATIONS

The literature concerning impotence in diabetics is unclear, and further studies are required differentiating insulin and non-insulin dependent diabetes, differentiating vascular from neural effects and development of a viable animal model allowing manipulation of some of the basic substrates possibly responsible for impotence in the diabetic. Other diseases such as atherosclerosis, uremia, hypertension, and benign prostatic hyperplasia should be assessed in relation to sexual functioning. The substrates and(or) mechanisms by which many drugs induce erectile failure require study, and equally effective alternate medications without effects on erection need to be elucidated.

APPLICATION AND REVIEW PROCEDURES

Applications in response to this announcement will be reviewed in accordance with the usual Public Health Service peer review procedures for research grants (Study Section). Review criteria include the significance and originality of the research goals and approaches; feasibility of the research and adequacy of the experimental design; training, research competence, and dedication of the investigator(s); adequacy of available facilities; provision for the humane care of animals; and appropriateness of the requested budget relative to the work proposed. Funding decisions will be based on Initial Review Group and National Diabetes and Digestive and Kidney Diseases Advisory Council recommendations.

Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH Division of Research Resources may wish to identify the Center as a resource for conducting the proposed research. In such a case, a letter of agreement from the GCRC Program Director should be included in the application.

Applications should be submitted on form PHS-398, available in the business or grants office at most academic or research institutions, or from the Division of Research Grants, National Institutes of Health. Applications will be accepted in accordance with the dates for new applications on an indefinite basis:

February 1, June 1, October 1

The phrase "RESPONSE TO NIDDK PROGRAM ANNOUNCEMENT: RESEARCH ON SEXUAL IMPOTENCE IN THE MALE" should be typed on line 2 of the face page of the application. The original and five copies should be sent or delivered to:

Grant Application Receipt Office
Division of Research Grants
Westwood Building, Room 240
National Institutes of Health
Bethesda, Maryland 20892-4500

In order to alert the Urology Program to the submission of responses to this announcement are encouraged to contact:

Charles H. Rodgers, Ph.D.
Urology Program Director, DKUHD, NIDDK
Westwood Building, Room 609C
National Institutes of Health
Bethesda, Maryland 20892-4500
Telephone: (301) 496-7573

This program is described in the Catalog of Federal Domestic Assistance No. 13.849, Kidney, Urologic, and Hematologic Diseases Research. 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.