

NIH GUIDE

For Grants and Contracts

NOTICE OF MAILING CHANGE

Check here if you wish to
discontinue receiving this
publication

Check here if your address has
changed and you wish to con-
tinue receiving this publication.
Make corrections below and
mail this page to:

NIH Guide
Printing & Reproduction Branch
National Institutes of Health
Room B4BN08, Building 31
Bethesda, Maryland 20892

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICIAL BUSINESS
Penalty for Private Use, \$300

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

Vol. 20, No. 42
November 8, 1991

First Class Mail Postages & Fees Paid PHS/NIH/OD Permit No. G-291
--

NOTICES

<u>WORLD AIDS FOUNDATION</u>	2
Fogarty International Center	
INDEX: FOGARTY INTERNATIONAL CENTER	
<u>BIOMEDICAL INITIATIVE SUPERCOMPUTING TECHNIQUES WORKSHOP</u>	2
National Center for Research Resources	
INDEX: RESEARCH RESOURCES	
<u>NIH/ADAMHA PEER REVIEW CONSULTANT FILE: ADDRESS CHANGE</u>	3
National Institutes of Health	
Alcohol, Drug Abuse, and Mental Health Administration	
INDEX: NATIONAL INSTITUTES OF HEALTH	
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH	
<u>POLICY ON SUPPLEMENTATION OF STIPENDS ON NATIONAL RESEARCH SERVICE AWARD TRAINING GRANTS AND FELLOWSHIPS</u>	3
National Institutes of Health	
Alcohol, Drug Abuse, and Mental Health Administration	
INDEX: NATIONAL INSTITUTES OF HEALTH	
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH	

NOTICES OF AVAILABILITY (RFPs AND RFAs)

<u>EVALUATION OF CHEMOPREVENTION AGENTS BY IN VIVO SCREENING ASSAYS (RFP NCI-CN-25407-20)</u>	3
National Cancer Institute	
INDEX: CANCER	
<u>MASTER AGREEMENT FOR CEREBROVASCULAR CLINICAL RESEARCH (MAA/RFP NIH-NINDS-92-06)</u>	4
National Institute of Neurological Disorders and Stroke	
INDEX: NEUROLOGICAL DISORDERS, STROKE	
<u>CHEMICAL EFFECTS IN TRANSGENIC HUMAN CELLS (RFP NIH-ES-92-15)</u>	5
National Institute of Environmental Health Sciences	
INDEX: ENVIRONMENTAL HEALTH	
<u>ENHANCING VACCINE IMMUNOGENICITY (RFA AI-92-02)</u>	5
National Institute of Allergy and Infectious Diseases	
INDEX: ALLERGY, INFECTIOUS DISEASES	
<u>CLINICAL RESEARCH ON BENIGN PROSTATIC HYPERPLASIA (BPH) AND CHRONIC PROSTATITIS (RFA DK-92-12)</u>	8
National Institute of Diabetes and Digestive and Kidney Diseases	
INDEX: DIABETES, DIGESTIVE, KIDNEY DISEASES	
<u>ALZHEIMER'S AMYLOID BETA PROTEIN PRECURSOR IN HEMOSTASIS AND THROMBOSIS (HL-92-05-B)</u>	10
National Heart, Lung, and Blood Institute	
National Institute on Aging	
INDEX: HEART, LUNG, BLOOD	
AGING	

NOTICES

WORLD AIDS FOUNDATION

P.T. 22, 34, 42; K.W. 0715008

Fogarty International Center

The World AIDS Foundation (WAF), jointly sponsored by the U.S. Department of Health and Human Services and the Institut Pasteur of Paris, France, announces its intent to support research and education relating to AIDS in the developing world. The goal of the WAF is to facilitate information exchange and to assist developing countries in responding to the AIDS pandemic.

The WAF is particularly interested in projects that are catalytic and, once in place, could have a multiplicative effect. The WAF is specifically interested in supporting:

- A) short-term, in-country training for clinicians, allied health professionals, and technicians;
- B) fellowships to support training for national experts;
- C) development and testing of new concepts and demonstrations for preventing the spread of HIV; and
- D) highly focused workshops that enhance the scientific process and transfer knowledge needed in the effort against HIV infections and AIDS.

The limit of any single funding request to the WAF is \$200,000.

APPLICATION PROCEDURES

Concept letters and applications may be prepared in either English or French. Applicants must submit concept letters for initial consideration. Following review of concept letters, applicants may be invited to submit complete applications. The annual deadline for receipt of concept letters is February 1.

INQUIRIES

Concept letters, full applications, and inquiries concerning the programs of the WAF may be directed to either:

World AIDS Foundation
Assistant Secretary for Health
c/o Director, Fogarty International Center
National Institutes of Health
Building 31, Room B2C02
Bethesda, MD 20892
U.S.A.

or

World AIDS Foundation
c/o Director
Institut Pasteur
28 rue du Docteur Roux
75724 Paris, Cedex 15
FRANCE

BIOMEDICAL INITIATIVE SUPERCOMPUTING TECHNIQUES WORKSHOP

P.T. 42; K.W. 1004000, 1004008

National Center for Research Resources

The Pittsburgh Supercomputing Center (PSC) is conducting a five-day Supercomputing Techniques Workshop for biomedical researchers to be held January 27-31, 1992. The workshop is funded by a National Institutes of Health (NIH) grant from the Biomedical Research Technology Program, National Center for Research Resources.

The workshop is aimed at experienced FORTRAN and C programmers, but prior supercomputing experience is not necessary. Topics will include the PSC programming and computing environment, FORTRAN programming on the CM-2, an overview of C programming on the CM-2, scientific and low-level programming libraries, special I/O features of the CM-2, and graphics facilities at the PSC.

Travel, meals, and hotel accommodations for U.S. academic participants are supported by the grant. A limited number of openings for industrially based biomedical researchers may be available for a fee of \$1,000. Enrollment is limited to 20 participants. THE DEADLINE FOR THE SUBMISSION OF APPLICATIONS IS DECEMBER 6, 1991.

NIH Guide for Grants and Contracts - Vol. 20, No. 42 - November 8, 1991

For application forms and inquiries contact:

Nancy Blankenstein
Biomedical Coordinator
Pittsburgh Supercomputing Center
4400 Fifth Avenue
Pittsburgh, PA 15213
Telephone: (412) 268-5206

NIH/ADAMHA PEER REVIEW CONSULTANT FILE: ADDRESS CHANGE

P.T. 34; K.W. 1014002

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

The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) have established a new consultant file of peer reviewers. Reviewers will be selected from a national pool of scientists who are engaged in basic or applied research. Data from qualified respondents will be entered into a new computerized NIH/ADAMHA data base. This unique data base will be used as one source from which candidates for membership on NIH/ADAMHA committees and for other peer review activities are drawn. All qualified scientists are requested to participate. Qualified women and minority scientists are encouraged to apply. There are currently 13,000 potential consultants listed in the file.

A Consultant File Information Form has been sent to PHS grantees and the solicitation announcement will appear in major journals. Other scientists who are interested in participating must submit a written request for the NIH/ADAMHA Consultant File Information Form. The new file is based solely on positive responses. A response is needed from consultants and members of a Reviewer's Reserve who wish to be included in the consultant file. This file is independent of other consultant files. Your request should be sent to:

NIH/ADAMHA Consultant File
7101 Wisconsin Avenue
Suite 1125, Dept 02
Bethesda, MD 20814

POLICY ON SUPPLEMENTATION OF STIPENDS ON NATIONAL RESEARCH SERVICE AWARD TRAINING GRANTS AND FELLOWSHIPS

P.T. 22, 44; K.W. 0720005, 1014006

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

It is the policy of the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) to ensure that the full amount of any stipend increase is received by all individuals supported on National Research Service Award (NRSA) training grants and fellowships. The NIH and ADAMHA recognize that many NRSA grantee institutions supplement NRSA stipends provided to trainees and fellows; institutions should maintain the level of supplementation currently provided when stipends are increased. When making award decisions, the extent to which an institution maintains the supplementation currently provided will be considered in determining the adequacy of the resources available at the applicant institution, consistent with 42 CFR 66.206(a)(3)(ii).

Contact:

Dr. Walter T. Schaffer
Research Training and Research Resources Officer
National Institutes of Health
Building 31, Room 5B44
Bethesda, MD 20892
Telephone: (301) 496-9743

NOTICES OF AVAILABILITY (RFPs AND RFAs)

EVALUATION OF CHEMOPREVENTION AGENTS BY IN VIVO SCREENING ASSAYS

RFP AVAILABLE: NCI-CN-25407-20

P.T. 34; K.W. 0740018, 0755010, 0755020

National Cancer Institute

The National Cancer Institute, Division of Cancer Prevention and Control, Chemoprevention Branch, plans to award Master Agreement contracts for the above study. The required services will be defined by Master Agreement

Orders (MAO) issued during the five-year period of performance. This is a recompetition of the entire pool of Master Agreement Holders. All Master Agreement Holders must requalify to be eligible to compete for future MAO RFPs. Pursuant to the MAOs, the contractor shall conduct in vivo screening studies in small rodents using gavage and other routes to administer the designated chemopreventive agents in animal models using any carcinogenic mechanism (that is consistent with the Evaluation Criteria), such as carcinogens, promoters, hormones, irradiation, cells, and other carcinogenic agents. Agents to be tested are potentially hazardous. The animal model systems also involve the use of carcinogens. Laboratory practices shall be employed that will keep any element of risk to personnel at an absolute minimum. Where indicated, tissue and compound handling must be performed in (at least) Class I laminar flow agents. It shall be required that the animal facilities be maintained in accordance with the NIH Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act as administered by the U.S. Department of Agriculture, and the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used for Testing Research and Training. This research will be performed under cost-reimbursement and/or fixed-price MAOs. Offerors will not be considered eligible for award unless they can conduct specific individual MAOs in accordance with the Food and Drug Administration Good Laboratory Practices Regulations. The contractor must have all the equipment necessary to accomplish the studies including, but not limited to, animal racks and caging, hazardous chemical storage cabinets and refrigerators, pathology equipment such as microscopes and microtomes, and miscellaneous laboratory equipment. The laboratory must have or have access to appropriate terminal and computer facilities and equipment for data collection and storage. It is estimated that four to five Task Orders per year will be issued pursuant to the Master Agreement contracts. The Master Agreement Announcement No. NCI-CN-25407-20 will be available on approximately November 5, 1991. The proposal due date will be approximately December 24, 1991.

Copies of the RFP may be obtained by sending a written request to:

Mr. Charles Lerner, Contract Specialist
National Cancer Institute
Research Contracts Branch, PCCS
Executive Plaza South, Room 635
Bethesda, MD 20892
Telephone: (301) 496-8603

No collect calls will be accepted.

MASTER AGREEMENT FOR CEREBROVASCULAR CLINICAL RESEARCH

MAA/RFP AVAILABLE: NIH-NINDS-92-06

P.T. 34; K.W. 0705010, 0705015, 0715042, 0715200, 0785035

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke (NINDS) is seeking proposals with the intent of awarding Master Agreements (MAs) to sources capable of performing clinical evaluations of new investigational forms of therapies and intervention efforts aimed at preventing and/or treating cerebrovascular diseases in an attempt to reduce disability, optimize functional recovery, and improve the quality of life. Offerors may qualify under any number of the six specific project categories listed below. It is possible for an organization to qualify under all six categories. Recipients of MA awards may compete for award under future "quick reaction" MA Order (MAO)/Request for Proposals (RFP) for studies in the category(ies) for which they receive an MA award. Current MA holders will not be required to compete and requalify unless they wish to be considered for award under a category for which they have not already qualified.

- Category I - Clinical Research Studies on Transient Ischemic Attack;
- Category II - Clinical Research Studies of Acute Ischemic Stroke;
- Category III - Clinical Research Studies of Generalized Cerebral Ischemia;
- Category IV - Clinical Research Studies on Intracranial Aneurysms and Subarachnoid Hemorrhage;
- Category V - Clinical Research Studies on Intracerebral Hemorrhage;
- Category VI - Clinical Research Studies on Dementia Secondary to Cerebrovascular Disease.

An MA is an agreement issued to sources who qualify under MAA/RFP solicitations to compete for future tasks issued under the general study areas described in an MA. These agreements contain general terms, conditions, and parameters of performance for the particular study category(ies) that the MA holder is judged capable of competing for and performing. Award of a MA under the MAA/RFP will certify that an offeror has demonstrated that it has the staff expertise, capability, facilities, and access to an adequate study population to compete for future MAO task requirements issued under the Cerebrovascular Clinical Research project. The agreements will not contain specific work tasks nor any funding commitments.

Competition of future MAO tasks will be restricted to qualified MA holders, and successful MA competitors may

receive an MAO award. An MAO is a bilateral contract and an operational addendum to an MA. The MAO outlines the specific performance requirements, including a detailed Statement of Work and Delivery Schedule, and indicates the negotiated funding commitment for the particular study task.

It is anticipated that as a result of this solicitation, multiple MA awards will be made. MA awards resulting from this RFP will be valid through May 31, 1994. It is important that offerors review carefully the six individual category descriptions and requirements and the evaluation criteria contained in the MAA/RFP prior to preparing a response to the solicitation. Offerors must provide concise information regarding their capability to accrue the required number of specific subjects indicated in the MAA/RFP.

This is an announcement of an anticipated MAA/RFP. The MAA/RFP will be issued on or about November 11, 1991, with the closing date for receipt of proposals set approximately for January 14, 1992. All responsible sources may submit a proposal that will be considered by the Agency. Copies of the MAA/RFP may be obtained by sending a written request to:

Contracting Officer
Contracts Management Branch, DEA
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892
Attention: MAA/RFP No. NIH-NINDS-92-06

CHEMICAL EFFECTS IN TRANSGENIC HUMAN CELLS

RFP AVAILABLE: NIH-ES-92-15

P.T. 34; K.W. 0780015, 1002058

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), is soliciting proposals from offerors having the capability to develop cultured human cell systems through the transduction of specific genes so that the effects of the transduced genes on cellular properties can be studied and the resulting phenotypes used to measure and better understand chemically induced effects. Genes derived from human tissues must receive consideration. The first phase will be to characterize various transgenic human cell lines for various phenotypic properties. The goal of this phase is the selection of appropriate subclones to be further studied by selected chemical exposures. The second phase shall be to use selected chemicals to modulate the effects of the transgene on cell growth characteristics, phenotypic and genomic stability, gene expression, transformation, tumorigenicity, or other parameters related to neoplastic progression and sensitivity to chemical toxicity transformation. The Government estimates the level of effort to perform this requirement to be approximately 4.124 person years per year. It is anticipated that one contract will be awarded for a 12-month period starting approximately May 1, 1991, with five one-year options. Issuance of the Request for Proposals (RFP) is estimated to be November 12, 1991 with responses due by December 31, 1991.

Requests for a copy of the RFP must reference RFP NIH-ES-92-15 and must be sent to:

National Institute of Environmental Health Sciences
Contracts and Procurement Management Branch, OM
ATTN: Jo Ann Lewis
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, NC 27709
FAX: (919) 541-2712

ENHANCING VACCINE IMMUNOGENICITY

RFA AVAILABLE: AI-92-02

P.T. 34; K.W. 0740075, 0710065

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: December 30, 1991
Application Receipt Date: February 24, 1992

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID) announces the availability of a Request for Applications (RFA) for innovative preclinical research on efficient methods to increase the immunogenicity of vaccines for eventual human use.

ELIGIBILITY REQUIREMENTS

Universities, medical colleges, hospitals, public and private institutions, and non-profit and for-profit organizations are eligible. Awards to foreign institutions under this request will be made only for research of unusually high merit, need, and promise, and in accordance with Public Health Service policy governing such awards. Applications from minority investigators and women are encouraged.

BACKGROUND

Developing and testing vaccines is a major component of research supported by the NIAID. This effort supports a wide spectrum of research from basic molecular, biologic, and immunologic studies through efficacy trials of candidate vaccines and includes research on vaccines for pertussis, influenza, Haemophilus influenzae, Neisseria meningitidis, rotavirus, Escherichia coli, Salmonella, malaria, and other diseases. The interest of the NIAID in these areas has been given additional impetus by of the recently launched international effort termed the Children's Vaccine Initiative. The focus of this effort is on developing improved vaccines that can be used ultimately to decrease the number of clinic visits that a child requires before he/she is adequately immunized against a variety of infectious diseases. In some cases, this will require that new vaccines be developed, but, in other cases, it is possible that existing vaccines could be either reformulated or modified to make them more immunogenic.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Enhancing Vaccine Immunogenicity, is related to the priority area of immunization and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

RESEARCH GOALS AND SCOPE

The purpose of this RFA is to stimulate innovative preclinical research on methods to increase the immunogenicity of existing and candidate vaccines for human use. The major emphasis will be on safe and efficient methods to enhance protective immune responses against a wide variety of infectious diseases of interest to the NIAID. These include, but are not limited to, pertussis, bacterial meningitis, bacterial and viral diarrheas, acute respiratory infections, sexually transmitted diseases, and malaria. (Research on vaccines against the Human Immunodeficiency Virus (HIV) and related viruses will not be considered under this initiative.)

Because of the emphasis on inducing high-quality protective immune responses, research using experimental challenge studies in relevant animal models will be encouraged. Alternatively, immunization strategies for diseases for which established correlates of immunity exist (e.g., serum antibodies to Haemophilus influenzae capsule after immunization with conjugate vaccines) can also be proposed. The most important consideration will be the relevance of these studies for protection against human disease.

Applications to test innovative immunization strategies, such as the use of yeast Ty elements or hepatitis B virus core-antigen fusion proteins, are strongly encouraged, as are other types of novel conjugate vaccines that offer an improvement over existing or candidate vaccines. Applications to test vaccine vectors (e.g., Salmonella, adenovirus, or BCG expressing heterologous antigens), in the context of enhancing immune responses to target antigens, will also be considered; however, applications to construct such vectors will not be considered. Again, the long-term goal is to develop vaccine candidates that warrant eventual study in humans.

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional individual research grant (R01). Responsibility for planning, direction, and execution of the proposed project will be solely that of the applicant.

The NIAID anticipates making five to seven awards, totaling \$1,000,000, as a result of this request. However, the number of awards to be made is dependent upon receipt of a sufficient number of applications with high scientific merit and programmatic relevance and upon the availability of funds. If appropriate, collaboration with other investigators or institutions is encouraged. It is expected that the initial year award for successful applications will be in the range of \$125,000 to \$200,000 in total (direct plus indirect) costs for each award, although individual awards may be slightly higher or lower. Awards will be made for a project period of up to four years. (Awards to foreign applicant institutions will be limited to three years and will not include indirect costs.) The earliest possible award date is September 30, 1992.

REVIEW PROCEDURES AND CRITERIA

Applications will be received by the NIH Division of Research Grants (DRG). Applications will be reviewed by NIAID staff to determine administrative and programmatic responsiveness to this RFA; those judged to be non-responsive will be returned to the applicant without review. By mutual agreement between the applicant and NIAID staff, a non-responsive application may also be retained at NIH and processed as an unsolicited R01

application for the next review cycle.

Those applications considered responsive to the RFA may be subjected to a triage review by an NIAID peer review group, before or during the initial review committee meeting, to determine competitiveness relative to the other applications in response to the RFA. The NIAID will withdraw from further competition those applications judged by the triage peer review group to be noncompetitive for award and will notify the applicant Principal Investigator and the institutional business official.

Those applications judged to be competitive will be reviewed for scientific and technical merit by a review committee convened by the Division of Extramural Activities, NIAID, during June 1992. The second level of review will be provided by the National Advisory Allergy and Infectious Diseases Council in September 1992.

APPLICATION PROCEDURES

The research grant application form PHS 398 kit (revised 10/88) must be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, telephone 301/496-7441.

Applications must be received by February 24, 1992. Applications received after the above date will be returned without review. If the application submitted in response to this RFA is substantially similar to a grant application already submitted to the NIH for review, but has not yet been reviewed, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. An application cannot be submitted in response to this RFA that is essentially identical to one that has already been reviewed. This does not preclude the submission of substantial revision(s) of an application already reviewed, but such applications must include an introduction addressing the previous critique.

Letter of intent: Prospective applicants are asked to submit a letter of intent by December 30, 1991. This letter is to include the name of the institution, any other participating institutions, the Principal Investigator and other key investigators, and a descriptive title. A letter of intent is not binding and will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for application. Letters of intent are requested solely for review planning purposes. NIAID staff will not provide responses to such letters. Letters of intent are to be sent to:

Dr. Olivia T. Preble
Chief, Microbiology and Immunology Review Section
Scientific Review Branch
National Institute of Allergy and Infectious Diseases
Control Data Building, Room 4C-20
6003 Executive Blvd.
Rockville, MD 20852
Telephone: (301) 496-8208

The RFA may be obtained from:

Dr. Dale R. Spriggs
Enteric Diseases Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Control Data Building, Room 3A-05
6003 Executive Blvd.
Rockville, MD 20852
Telephone: (301) 496-7051

For fiscal and administrative matters, contact:

Mrs. Barbara Huffman
Microbiology and Infectious Diseases Grants Management Section
Division of Extramural Activities
Control Data Building, Room 4B-35
6003 Executive Blvd.
Rockville, MD 20852
Telephone: (301) 496-7075

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856 - Microbiology and Infectious Disease Research. Grants are awarded under the authority of the Public Health Service Act, Title IV, Section 301 as amended, Public Law 78-410; Public Law 97-219; Public Law 99-158; Public Law 99-500; and Report 99-711 to accompany HR 5233 and administered under PHS grants policies and Federal Regulations 42 CFR 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.

CLINICAL RESEARCH ON BENIGN PROSTATIC HYPERPLASIA (BPH) AND CHRONIC PROSTATITIS

RFA AVAILABLE: DK-92-12

P.T. 34; K.W. 0715105, 0785035, 0765033, 0745020

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: December 1, 1991

Application Receipt Date: February 11, 1992

PURPOSE

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announces the availability of the above-referenced Request for Applications (RFA). This RFA invites new and experienced investigators to submit research grant applications that will investigate the clinical aspects of two of the major diseases of the prostate: benign prostatic hyperplasia (BPH) and chronic prostatitis. The purpose of this RFA is to increase the knowledge of the clinical pathogenesis of these diseases, investigate the interrelationship between these two diseases, and explore new and unique techniques for early detection, genetic predilection, and more accurate assessment of the growth and severity of these diseases.

BACKGROUND

BPH is a major cause of morbidity in the adult male. Surgical intervention still remains the most effective therapy for obliteration of the enlarged portion of the gland. The following aspects of the disorder remain to be explored: preventing the onset of hyperplastic growth, predicting who will develop symptomatic BPH and at what rate established BPH will increase, determining whether or not there are genetic or racial differences in onset and growth, and determining whether or not systemic diseases such as diabetes mellitus have any effect on the development of BPH.

Chronic abacterial prostatitis remains a clinical enigma. There have been very few studies that define its pathogenesis, natural history, and interrelationship with the development of BPH, and any racial or genetic differences in onset and pathology.

RESEARCH GOALS AND SCOPE

The overall goal of this request is to increase the amount of clinical research on the pathology and pathogenesis of BPH and chronic abacterial prostatitis. Clinical research is defined, for the purposes of this RFA, as research that involves human subjects and/or specimens from human subjects. This does not exclude the use of non-human disease models such as animal or cell/tissue cultures for comparison with human clinical pathology.

Areas that might be investigated include, but are not limited to: non-steroidal testicular factors involved in the pathogenesis of BPH; serum markers that can quantify the onset and progression of BPH; growth hormones, interleukins, immunomodulators, in BPH; diagnostic techniques that will predict the development of symptoms in the asymptomatic male with BPH; cellular interactions between BPH tissue and tissue with chronic prostatitis; the role of urinary glycoproteins in the pathogenesis of chronic prostatitis and BPH; insights into the bladder dysfunction associated with BPH and with chronic prostatitis; and seminal fluid markers of men with BPH and with chronic prostatitis; racial differences in BPH and chronic prostatitis.

Topics that are NOT INCLUDED IN THE SCOPE OF THIS RFA include all those that solely examine treatment modalities and outcomes of treatment. However, applications that include a therapeutic intervention as a means to study the pathology and pathogenesis of a disease are acceptable. Research that utilizes malignant animal tumor models or cancer-derived cell/tissue cultures as a model for studies on benign diseases will not be funded through this RFA.

INCLUSION OF MINORITIES IN CLINICAL RESEARCH INVESTIGATIONS

Special attention must be given to the inclusion of minorities in the clinical study populations. If minorities are not included in the clinical study populations, a specific justification for this exclusion must be provided. Applications that do not document the inclusion of minorities in the study will not be accepted for review.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit, public and private organizations, such as universities, colleges, hospitals, laboratories, and eligible agencies of the Federal Government. Applications from minority individuals and from women are especially encouraged.

MECHANISM OF SUPPORT

Support for this program will be through the traditional investigator-initiated research grant (R01). The regulations and policies that govern the research programs of the National Institutes of Health will prevail. Support will be provided for up to five years (renewable for subsequent periods) subject to the availability of funds and progress achieved.

FUNDS AVAILABLE

For FY 1992, \$1.5 million in total costs per year will be committed to fund applications submitted in response to this RFA. It is anticipated that six to eight awards will be made. Applicants must limit the budget requests to no more than \$160,000 in direct costs for the first year.

REVIEW PROCEDURES

Applications received in response to this RFA will first be reviewed for scientific and technical merit by an Initial Review Group convened by the Review Branch, Division of Extramural Program Activities, NIDDK. A secondary review for policy and program relevance to the NIDDK mission will be made by the National Diabetes and Digestive and Kidney Diseases Advisory Council.

APPLICATION PROCEDURES

Applications must be submitted using form PHS 398 (rev. 10/88), available in the business or grants offices of most academic or research institutions and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441.

Applications must be received by the Division of Research Grants by close of business on February 11, 1992. Detailed instructions on submission procedures are described in the RFA.

LETTER OF INTENT

Prospective applicants are asked to submit by December 1, 1991, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of key personnel, the participating institutions, and the number and title of the RFA to which the applicant is responding. Such letters are requested for the purpose of obtaining an indication of the number and scope of applications to be received. The letter is not binding, is not a requirement for submission, and does not enter into the review of the application. The letter of intent is to be sent to:

Robert Hammond, Ph.D.
Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Westwood Building, Room 603
Bethesda, MD 20892
FAX: (301) 402-1277

INQUIRIES

It is IMPERATIVE that the RFA be obtained by all prospective applicants prior to developing an application. Requests for the RFA and any other inquiries regarding it may be directed to:

Leroy M. Nyberg, Jr., Ph.D., M.D.
Director, Urology Program, DKUHD
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A-05
Bethesda, MD 20892
Telephone: (301) 496-7133
FAX: (301) 496-9721

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.849. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 and Section 431 (b) (Public Law 78-410, as amended: 42 USC 241 and 42 USC 285c-5) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ALZHEIMER'S AMYLOID BETA PROTEIN PRECURSOR IN HEMOSTASIS AND THROMBOSIS

RFA AVAILABLE: HL-92-05-B

P.T. 34; K.W. 0715180, 0715040, 1002008, 0755030

National Heart, Lung, and Blood Institute
National Institute on Aging

Letter of Intent Receipt Date: February 15, 1992

Application Receipt Date: March 16, 1992

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) and the National Institute on Aging (NIA) announce the availability of a Request for Applications (RFA) on the above subject. The purpose of this initiative is to encourage research on the biochemistry and molecular biology of the beta amyloid precursor protein. The emphasis of this research is on the possible involvement of this protein in the function or dysfunction in hemostasis and thrombosis. It is hoped that the information generated will help to understand the molecular pathology of Alzheimer's disease and Down's syndrome.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Alzheimer's Amyloid Beta Protein Precursor in Hemostasis and Thrombosis, is related to the priority areas of thrombosis, and Alzheimer's disease. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY

All public and private, for-profit and non-profit, institutions and organizations are eligible to apply in response to this RFA. Awards in connection with this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards.

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional individual research project grant (R01). Although approximately \$2.5 million in total costs for this program is included in the financial plans for fiscal year 1992, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that 12 grants will be awarded under this program. The specific number to be funded, however, will depend on the merit and scope of the applications received and the availability of funds.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

METHOD OF APPLYING

Letter of Intent: Prospective applicants are requested to submit a letter of intent that includes a descriptive title of the proposed research and identification of any other participating institutions. Such letters are requested only for the purpose of providing an indication of the number and scope of applications to be received; therefore their receipt is usually not acknowledged. A letter of intent is not binding, and it will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for application. This letter of intent, is to be received by February 15, 1992, is to be sent to:

Dr. Charles L. Turbyfill
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building, Room 553
Bethesda, MD 20892

Format for Applications: Applications should be submitted on the research grant application form PHS 398 (rev. 10/88). This form is available in an applicant institution's office of sponsored research or business office and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892, telephone 301/496-7441.

Application Receipt Date: March 16, 1992

REVIEW PROCEDURES

Upon receipt, applications will be reviewed for their responsiveness to the objectives of this RFA. If an application is judged unresponsive, the application will be returned to the applicant.

Applications judged to be responsive will be reviewed for scientific and technical merit by an initial review group that will be convened by the Division of Extramural Affairs, NHLBI, solely to review these applications.

This initial review will include a preliminary evaluation to determine competitiveness relative to the other applications received in response to the RFA (triage); the NIH will withdraw from further consideration those applications judged to be noncompetitive and promptly notify the Principal Investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated for scientific/technical merit by the customary peer review procedures.

INQUIRIES

Inquiries regarding this program and requests for the RFA may be addressed to either program administrator:

Dr. Pankaj Ganguly
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 5A12
Bethesda, MD 20892
Telephone: (301) 402-2237
FAX: (301) 496-9940

Dr. Carl D. Banner
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
Building 31, Room 5C35
Bethesda, MD 20892
Telephone: (301) 496-9350
FAX: (301) 496-1494

For fiscal and administrative matters, contact either:

Ms. Jane R. Davis
Chief, Blood Division Grants Management Section
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11
Bethesda, MD 20892
Telephone: (301) 496-7257

Mr. Joseph Ellis
Grants Management Officer
Office of Extramural Affairs
National Institute on Aging
Building 31, Room 5C07
Bethesda, MD 20892
Telephone: (301) 496-1472

AUTHORITY AND REGULATIONS

The programs of the Division of Blood Diseases and Resources, NHLBI, and the Neuroscience and Neuropsychology of Aging Program, NIA, are described in the Catalog of Federal Domestic Assistance numbers 93.839 and 93.866 respectively. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grants policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372, or to Health Systems Agency Review.

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

5333 Westbard Avenue
Bethesda, MD 20816