NIH GUIDE

For Grants and Contracts

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

Vol. 20, No. 33 (Part I of II)
September 6, 1991

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ERRATUM

ONGOING PROGRAM ANNOUNCEMENTS

NATIONAL WORKSHOPS ON THE PROTECTION OF HUMAN SUBJECTS

P.T. 43; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

I. NORTH MIDWESTERN WORKSHOP

DATES: October 17 and 18, 1991

WORKSHOP SITE:
Westin Hotel
Renaissance Center
Detroit, MI
Telephone: (313) 568-8000

SPONSORS:
Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201

Wayne State University
4237 Scott Hall
Detroit, MI 48201

REGISTRATION CONTACT:
Mr. Jerome Wilczynski
Vice President for Operations
Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201
Telephone: (313) 745-5450

TOPIC: Protection of Human Subjects in Research: The Vulnerable Patient

II. WEST COAST WORKSHOP

DATES: JANUARY 23 and 24, 1992 (REVISED DATES)

WORKSHOP SITE: Los Angeles, CA

SPONSORS:
University of Southern California
Los Angeles, CA 90089-4014

California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202

REGISTRATION CONTACT:
Ms. Lily Patterson
Assistant to the Director
Research and Sponsored Programs
California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202
Telephone: (213) 343-3820

TOPIC: Protection of Human Subjects

III. SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS:
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, TX 78284-7972

St. Mary's University
One Camino Santa Maria
San Antonio, TX 78228-8572

REGISTRATION CONTACT:
Ms. Angie Khan
Institutional Coordinator of Research Review
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive (Room 402L)
San Antonio, TX 78284-7972
Telephone: (512) 567-2351

TOPIC: Protection of Human Subjects

IV. NORTHEASTERN WORKSHOP

DATES: April 27 and 28, 1992

WORKSHOP SITE: Philadelphia, PA

SPONSORS:
University of Pennsylvania
133 South 36th Street
Suite 300
Philadelphia, PA 19104-3246

Lincoln University
Lincoln University, PA 19352

REGISTRATION CONTACT:
Ms. Lynn Bevan
Assistant Director
Office of Research Administration
University of Pennsylvania
133 South 36th Street, Suite 300
Philadelphia, PA 19104-3246
Telephone: (215) 898-2614

TOPIC: Protection of Human Subjects

For further information regarding these workshop or future NIH/FDA National Protection of Human Subjects Workshops, contact:

Ms. Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

ESTIMATED TOTAL COSTS OF PROPOSED PROJECTS

P.T. 34; K.W. 1014006

National Institutes of Health

BACKGROUND

In response to the House of Representatives and Senate Appropriation Reports (101-591 and 101-516, respectively), NIH has developed a financial management plan to increase stability and predictability in funding biomedical research. One element of this plan is for National Advisory Councils and Boards, in their review of applications, to consider not only scientific merit and programmatic issues but also total costs of proposed projects. In order to consider this information as part f their review, Councils/Boards must be provided with an estimate of the total costs for each application reviewed.

To provide Councils/Boards with this information, each summary statement will include an estimate of the total costs of the proposed project. This will begin with summary statements for applications reviewed during the October-November 1991 round of Initial Review Group (IRG) meetings. Previously, only requested and recommended direct costs for each budget period were included on summary statements.

CALCULATION METHOD

Estimated total costs will be based on information provided in the applications as well as on the direct costs recommended by the IRG for applications where negotiated indirect cost rates are applicable. The following calculation method will be used t estimate total costs:

1) Total Costs Required for Entire Project will be divided by the Total Direct Costs Requested for the Entire Project.

2) This figure will then be multiplied by the Direct Costs Recommended for Each Year.

Total costs requested and total direct costs requested are provided in the application.

APPLICABILITY

Estimated total costs will be included on summary statements for the first year, all future years, and for the total project period (competitive segment). These data will be helpful to Councils, Boards, and institute staff primarily for applications at or near the margin of fundability. Where total costs could be a determining factor in the funding decision, a more precise calculation will be made using actual base and rate information. This will be done before any final funding decision is made.

NCI BRIEFING ON SPORE PROGRAM

P.T. 42; K.W. 0715035

National Cancer Institute

The National Cancer Institute (NCI) plans to release Requests For Applications (RFA) to invite P50 grant applications for Specialized Programs of Research Excellence (SPORE) in Breast Cancer, Lung Cancer, and Prostate Cancer. The RFAs are expected to be released in mid-September.

The NCI plans to conduct a briefing session on the SPORE program on Tuesday, October 8, 1991, at the St. Louis Airport Marriott, I-70 at Lambert Airport, St. Louis, Missouri. The briefing will begin at 8:30 a.m. and will adjourn by noon. There will be ample time for questions and answers. A summary of the proceedings of this meeting including questions and answers will be available upon request.

Interested parties are invited to attend. Rooms for the night of October 7 are available at a special rate of $58 plus tax. Reservations must be made directly to the hotel at (314) 423-9700. To receive the special rate, make the reservation by September 27 and mention the National Cancer Institute meeting. Free shuttle service is available from the airport to the hotel. Passenger pick-up for the Marriott shuttle is at exit 7 in the airport terminal.

For further information and to request a summary of the meeting, please contact:

Dr. Andrew Chiarodo
Organ Systems Coordinating Branch
Division of Cancer Biology, Diagnosis and Centers
National Cancer Institute
Bethesda, MD 20892
Telephone: (301) 496-8528

NOTICE OF MEETING - KIDNEY AND UROLOGIC DISEASES RESEARCH CENTERS

P.T. 42; K.W. 0705075, 0785220, 1014006

National Institute of Diabetes and Digestive and Kidney Diseases
A meeting of Center Directors for the George M. O'Brien Kidney and Urologic Diseases Research Centers Program supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is scheduled for September 15, 1991, at the Crystal City Gateway Marriott Hotel in Crystal City, VA. The purpose of the meeting is to inform investigators of current Institute policies and guidelines concerning research centers. The meeting is open on a space-available basis. For further information contact:

Dr. Ralph L. Bain
Program Director
Kidney and Urologic Diseases Research Centers Program
National Institute of Diabetes and Digestive and Kidney Diseases Westwood Building, Room 621
Bethesda, MD 20892

AVAILABILITY OF BLOOD SAMPLES FROM PATIENTS ENROLLED IN THE EARLY TREATMENT DIABETIC RETINOPATHY STUDY

P.T. 34; K.W. 0755015, 0715080, 0780005

National Eye Institute

The Early Treatment Diabetic Retinopathy Study (ETDRS), a multicenter collaborative clinical trial supported by the National Eye Institute, was designed to assess laser photocoagulation and aspirin treatment in patients with mild-to- severe nonproliferative and early proliferative diabetic retinopathy. Follow-up of these patients extended for up to nine years. The study design and results of the clinical trial are published in Ophthalmology 1991;98:739-840.

Between April 1980 and September 1983, approximately 2,000 fasting baseline blood specimens were drawn from ETDRS patients and analyzed for: hemoglobin A1C, cholesterol, triglyceride, high-density lipoprotein cholesterol (HDLC), low-density lipoprotein cholesterol (LDLC), creatinine, uric acid, glucose, C-peptide, albumin, fibrinogen, alpha-2-macroglobulin, and thromboxane B2. At that time a 3 cc aliquot of each serum specimen was stored in a sealed glass Wheaton vial at -70 degrees Centigrade at the Centers for Disease Control in Atlanta, GA. The ETDRS database includes extensive information on baseline characteristics (systemic and ocular) as well as seven-to-nine-year outcome information (morbidity, mortality, and ocular) for these 2000 Type I and Type II diabetics. Investigators interested in using these reserved frozen serum specimens for research projects are invited to contact:

Frederick L. Ferris, III, M.D.
Chief, Clinical Trials Branch
National Eye Institute
National Institutes of Health
Building 31, Room 6A24
Bethesda, MD 20892

DISCONTINUATION OF THE NIAID IMMUNOLOGIC AND INFECTIOUS DISEASES ACADEMIC AWARD

P.T. 34; K.W. 0710070, 1014002

National Institute of Allergy and Infectious Diseases

Beginning with the October 1, 1991, application receipt date, the National Institute of Allergy and Infectious Diseases (NIAID) will no longer accept new or amended applications for the NIAID Immunologic and Infectious Diseases Academic Award (K07). However, NIAID will continue to receive new and amended applications for the other career award programs, namely the Clinical Investigator Award (K08), the Physician Scientist Academic Award (K11), and the Modified Research Career Development Award (K04).

This decision was reached because of the paucity of applications received for the K07 Award in recent years, and the desire of the NIAID to focus its career award resources to the K04, K08, and K11 mechanisms, particularly in keeping with its efforts to increase the recruitment and retention of minority and women scientists in biomedical research.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

DEVELOPMENT OF DOSAGE FORMS AND DELIVERY SYSTEMS FOR NEW DRUGS

RFP AVAILABLE: NCI-CM-27710-19

P.T. 34; K.W. 0740021, 1003008

National Cancer Institute

The Pharmaceutical Resources Branch of the Developmental Therapeutics Programs, Division of Cancer Treatment, National Cancer Institute (NCI), is seeking contractors to develop acceptable dosage forms for compounds to be subsequently evaluated in cancer and HIV patients and to carry out innovative studies leading to more effective approaches for the intravenous delivery of compounds that possess limited solubility and/or stability. NCI will select and provide the compounds to be studied. In addition to solubility problems, the projects will require considerable analytical work, particularly the development of a stability-indicating assay to monitor the integrity of the parent compound during the formulation studies. These investigations will be directed toward a pharmaceutical dosage form that will meet certain solubility and stability targets predetermined by the Government. The Principal Investigator on this project must possess a Ph.D. in pharmaceutics or medicinal chemistry and must also have at least three years experience in the development of injectable formulations. A portion of this project is a recompetition of two NCI contracts. The incumbent contractors are the University of Kansas and the University of North Carolina at Chapel Hill.

RFP No. NCI-CM-27720-19 will be issued upon request to Zetherine Gore, Contract Specialist, on or about September 9, 1991. Proposals will be due approximately 45 days thereafter. The contract period is to be for five years beginning approximately June 1991.

Mail requests for the RFP to:

Ms. Zetherine Gore
Contract Specialist
National Institutes of Health
National Cancer Institute
Treatment Contract Section
6120 Executive Blvd, Room 603
Rockville, MD 20852

PREPARATION OF ANTI-AIDS BULK DRUGS AND CHEMICALS FOR PRECLINICAL TOXICOLOGY, PHARMACOLOGY, AND CLINICAL USE

RFPs AVAILABLE: NCI-CM-27722-71 (open competition)
NCI-CM-27723-71 (small business set-aside)

P.T. 34; K.W. 0710080, 1003012, 0740020

National Cancer Institute

The National Cancer Institute (NCI) is seeking contractors with the capability to provide and operate material preparation laboratories for (a) the development of existing or new processes, procedures, and techniques for the preparation of compounds; and (b) the synthesis of varying amounts of material not readily available from other sources in the quantity and/or quality needed by the NCI. Offerors will be expected to provide an operating, large-scale facility with at least one and preferably two large (200 gallons or larger) glass-lined reactors and the necessary supporting equipment and facilities. Quantities of drugs may range from 50 grams to multi-kilograms. Process development for scale-up and access pilot plant equipment is essential. Specific assignment of the materials for preparation will be made by the NCI and may include synthesis of all types of chemicals and drugs. The contractor will be responsible for preparing approximately 20-30 lots of bulk drugs per year. Quality specifications will be determined by the NCI. All materials must be evaluated by the synthesis laboratory for identity and purity before submitted to the NCI.

The Principal Investigator must be trained in organic and medicinal chemistry, preferably at the Ph.D. level, or possess equivalent experience. The Principal Investigator must have extensive experience in chemical synthesis and synthetic process development.

At the time of submission of a best and final offer, the offerer must be registered with the Food and Drug Administration (FDA) as a manufacturer of bulk drugs and shall have submitted a facilities Drug Master File to the FDA. Facilities shall meet FDA standards in accordance with the Current Good Manufacturing Practices.

RFP No. NCI-CM-27722-71, "Preparation of Anti-AIDS Bulk Drugs for Preclinical Toxicology, Pharmacology, and Clinical Use" is an open competition. RFP No. NCI-CM-27723-71, "Preparation of Anti-AIDS Bulk Drugs and Chemicals for Preclinical Toxicology, Pharmacology, and Clinical Use" is a 100 percent Set-Aside for Small Business. The Standard Industrial Code (SIC) is 8731.

Offerors who qualify as a small business are encouraged to submit proposals under both RFPs.

It is anticipated that four incrementally funded, cost-reimbursement contracts will be awarded with the contract period beginning on or about May 4, 1992. The contract period will be five years. RFP Nos: NCI-CM-27722-71 and NCI-CM-27723-71 will be issued upon written request to Joseph Bowe, Contract Specialist, on or about September 3, 1991. Proposals will be due on or about October 17, 1991. Requests for the RFP must be addressed to:

Joseph Bowe
Contract Specialist
National Institutes of Health
National Cancer Institute
Treatment Contracts Section
Research Contracts Branch
Executive Plaza South, Room 603
9000 Rockville Pike
Bethesda, MD 20892

No calls will be accepted.

SUPPORT OF THE NATIONAL HORMONE AND PITUITARY PROGRAM

RFP AVAILABLE: NIH-NIDDK-91-6

P.T. 34; K.W. 0760025, 0785050

National Institute of Diabetes and Digestive and Kidney Diseases

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Division of Diabetes, Endocrinology and Metabolic Diseases, is conducting this project for the purpose of providing continuing support to the National

Hormone and Pituitary Program (NHPP), a component of the Hormone Distribution Program of NIDDK. The NHPP is responsible for storage and distribution of materials procured by NIDDK for use by researchers in endocrinology. The contractor will receive, store, and distribute purified human, rat, ovine, bovine, and porcine pituitary hormones, selected other hormones, antisera to these hormones, and frozen human pituitaries. Currently, the NHPP distributes approximately 160 distinct research materials and approximately 2000 individual awards of materials are made annually. The contractor will also disseminate information to the scientific community about the materials available.

This Request for Proposals (RFP) No. NIH-NIDDK-91-6 will be issued on or about September 12, 1991 with responses due by December 11, 1991. The NIDDK expects to award one contract from this solicitation.

To receive a copy of this RFP, supply this office with two self-addressed mailing labels and cite the RFP number referenced above. Requests must be in writing and addressed to:

Ms. Linda Cameron
Contract Specialist
Contracts Management Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 602
Bethesda, MD 20892
Telephone requests will not be honored.

This advertisement does not commit the Government to make an award.

NINDS LOGISTICAL RESEARCH SUPPORT

SOURCES SOUGHT: NIH-NINDS-91-002

P.T. 34; K.W. 1002030, 1013004, 1002004, 1002008

National Institute of Neurological Disorders and Stroke

The Division of Intramural Research (DIR), National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), is seeking to identify sources capable of providing logistical and research support. The DIR, NINDS, has operated its Laboratories of Biophysics, Neurobiology, Molecular and Cellular Neurobiology and Neurochemistry at an outside marine laboratory on a part-time basis over the last three years. A five-year program beginning in May 1992 is anticipated. This program will support important research on neural cells and neural cell membranes, neuronal signaling, and short- and long- term memory mechanisms. It is based on the need in the DIR, NINDS, for live squid and other marine invertebrates to investigate the cellular functions underlying central nervous system function. Since live squid cannot be transported, this work must be done at the collecting site.

The contractor shall provide the personnel, equipment, and facilities necessary to support this research. Approximately 11 DIR, NINDS scientists per year will require support. The following is a general description of the support required. The contractor shall collect Loligo Pealeii (4-24" body length) from May to November each year of the contract period and store them in appropriate live holding tanks. The contractor shall supply the NINDS investigators with specific mariculture services supportive of their research program on marine nudibranches. A qualified aquavet shall be in residence at the contractor's facility to take care of any health problems of the marine animals. An animal holding facility with appropriate veterinary support shall be on site to hold small numbers of mice and rabbits (for antibody production). A full-service biomedical library with a wide range of current periodicals must be on site. The contractor shall also provide machine and instrument shop services, photo and graphic services, computer programming and applied mathematics, telephone, facsimile, mail, and shipping services. The NINDS investigators will also require the use of special equipment (e.g., ultracentrifuges, liquid scintillation counters, atomic absorption spectrometers, osometers, scanning electron microscope, transmission electron microscope, ultramicrotome, and equipment for preparing tissues for ultramicrotomy and darkroom for processing electron micrographs). A specialized light microscopy facility capable of performing fluorescence and video microscopy is also required. The research space needs from May to November each year are 2,700 square feet. Separate office space is not necessary. Fluorescent lighting of the space is required. Four units of laboratory space that includes fume hoods and a laboratory sink for each unit shall be provided. Low benches, chairs, air filters, and a refrigerator shall be provided for each unit. Seawater holding tanks shall also be provided to each of the four units.

This is not a Request For Proposals (RFP). It is a request for capability/ qualification statements. The Government does not intend to award a contract on the basis of responses to this announcement nor to make payment for preparation of any information that may be submitted. Potential sources that respond to this notice shall be added to the appropriate solicitation mailing list for subsequent solicitation if an RFP is issued.

Acknowledgement will not be made by the Government of receipt of responses nor will respondents be notified of the Government's evaluation of information submitted. Five copies of a capability statement that addresses the aforementioned requirements must be received at the following address no later than 3:30 p.m., local time, on September 23, 1991. The capability statement should reference NIH-NINDS-91-002.

Eileen D. Webster
Contracting Officer
Contracts Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892
Attention: NIH-NINDS-91-002

EVALUATION OF THERAPIES FOR TREATMENT OF PNEUMOCYSTIS CARINII, MYCOBACTERIUM AVIUM, TOXOPLASMA GONDII, AND PATHOGENIC FUNGI INFECTIONS

RFP AVAILABLE: NIH-NIAID-DAIDS-92-07

P.T. 34; K.W.0715125, 0715103, 0715165, 0745070

National Institute of Allergy and Infectious Diseases

The Developmental Therapeutics Branch, Basic Research and Development Program, Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID) has a requirement for the evaluation of promising therapies for the following opportunistic infections (OIs) associated with AIDS: Pneumocystis carinii, Mycobacterium avium, Toxoplasma gondii, and Pathogenic Fungi. The offeror must at the time of proposal, have available an animal system, including relevant strains of organisms (as applicable), suitable for evaluation of therapies with potential for treatment of the organisms specified. The proposed test system must approximate the clinical manifestations of the infection as it occurs in AIDS or should have documented utility as a model of drug efficacy in human disease. Basic model development is not part of this effort. Additional studies will be required such as in vitro tests, determination of plasma drug concentrations, and prophylaxis evaluation. At the present time, NIAID has seven contracts that are scheduled to end in 1992 to evaluate new drugs for the following organisms: P. carinii, M. avium, and C. albicans.

This Request for Proposals (RFP) will be divided into four parts (by organism) consisting of: (1) Pneumocystis carinii, (2) Mycobacterium avium, (3) Toxoplasma gondii, and (4) Pathogenic Fungi (which includes Cryptococcus, Histoplasma, and Candida). There will be a separate work statement and competitive range established for each part. Offerors may respond to one or more parts. It is anticipated that one or more contracts will be awarded per part. This NIAID-sponsored project will take approximately five years to complete. A cost reimbursement/completion contract is anticipated.

This is an announcement for an anticipated RFP. RFP NIH-NIAID-DAIDS-92-07 shall be issued on or about September 20, 1991, and proposals will be due on or about December 20, 1991. Requests for the RFP shall be directed in writing to:

Cyndie Cotter
Contract Specialist
Contract Management Branch
National Institute for Allergy and Infectious Disease
Control Data Building, Room 326P
6003 Executive Blvd.
Bethesda, MD 20892

To receive a copy of the RFP, supply this office with two self-addressed mailing labels. All responsible sources may submit a proposal that will be considered. This advertisement does not commit the government to make awards.

MODEL DEVELOPMENT AND EVALUATION OF THERAPIES FOR CRYPTOSPORIDIUM INFECTION

RFP AVAILABLE: NIH-NIAID-DAIDS-92-08

P.T. 34; K.W. 0755020, 0715103

National Institute of Allergy and Infectious Diseases

The Developmental Therapeutics Branch, Basic Research and Developmental Program, Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), has a requirement for the Model Development and Evaluation of Therapies for Cryptosporidium Infection. This initiative will consist of two phases. In Phase I, contractors will develop, over a period of two years, a standardized and reproducible small animal model for cryposoridiosis that is suitable for evaluation of therapies with potential for treatment of cryptosporidium parvum infection in humans. Offerors will be evaluated on the applicability and suitability of the proposed animal model for development of a therapy evaluation system for the Cryptosporidium infection. The Government will have the option to extend the performance period for one or more contractors who have satisfactorily completed the requirements of Phase I, for an additional three years (Phase II). In Phase II, contractors will evaluate new drugs using the animal models developed.

The Request for Proposals (RFP) will contain qualification criteria requiring offerors to provide documentation of an adequate source and delivery schedule of viable Cryptosporidium parvum oocysts. This announcement is a new solicitation. Multiple awards are anticipated for this procurement.

The issuance of this RFP (NIH-NIAID-DAIDS-92-08) will be on or about October 7, 1991, and proposals will be due by close of business on or about January 7, 1992. This NIAID-sponsored Phase I project will take approximately two years to complete. A cost-reimbursement contract is anticipated. Requests for the RFP shall be directed to:

Mr. Ross Kelly
Contract Specialist
Contract Management Branch
National Institute for Allergy and Infectious Disease
Control Data Building, Room 326P
6003 Executive Boulevard
Bethesda, MD 20892

To receive a copy of the RFP, supply this office with two self-addressed mailing labels. All responsible sources may submit a proposal that will be considered. This advertisement does not commit the Government to make awards.

PLASMODIUM FALCIPARUM VACCINE DESIGN AND PRODUCTION

RFP AVAILABLE: NIH-NIAID-DMID-92-06

P.T. 34; K.W. 0715125, 0740075, 0755041

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases has a requirement for a facility and team of scientists to construct recombinant malaria antigens, test these antigens for safety and immunogenicity in small animal models, and formulate experimental vaccines for clinical testing using Good Manufacturing Practices. This requirement is part of a cooperative initiative with the Agency for International Development. Respondents must have facilities and equipment to allow the construction of recombinant antigen genes from known sequences and cloned DNA specimens, the efficient expression of recombinant proteins, protein purification, and vaccine formulation. Quality control, including toxicological evaluation of vaccines, and other Good Manufacturing Practices elements must also be a part of the capability. The Government will work closely with the contractor in the design of vaccines. Aspects of the preclinical evaluation and clinical trials will be conducted at other facilities.

Any contract awarded will be subject to DHHS regulations regarding the animal subjects in research.

One contract may be awarded as a result of this solicitation. It is expected that the contract will have a three-year period of performance with options for two additional years.

The issuance of the Request for Proposals (RFP) will be on or about September 6, 1991, and proposals will be due by the close of business on December 2, 1991. Any responsible offeror may submit a proposal that will be considered by the Government.

To receive a copy of this RFP, supply this office with a request in writing and two self-addressed mailing labels addressed to:

Mr. Carl R. Henn
Contract Specialist
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Control Data Building, Room 326P
Bethesda, MD 20892

This advertisement does not commit the Government to make an award.

ENDOCRINOLOGY OF BODY COMPOSITION

RFA AVAILABLE: DK/HD-92-01

P.T. 34; K.W. 0785050, 0760025, 0760020, 0715006

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Child Health and Human Development

Letter of Intent Receipt Date: January 15, 1992
Application Receipt Date: February 14, 1992

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Child Health and Human Development (NICHD) encourage investigator-initiated research grant (R01) applications for support of basic and clinical studies on the role of both endogenous and administered hormones in the determination of body composition.

BACKGROUND

There is a clear link between a number of hormones and body composition, yet the roles of these hormones in the regulation of body composition remain to be elucidated. A precise understanding of the endocrine regulation of body composition in humans, and of other health outcomes relating to intervention in this system, is critical to a wide range of clinically and ethically significant issues. A recent report that growth hormone administration to a selected small group of elderly men increased bone density and lean body mass, and reduced adiposity, led some to suggest that growth hormone treatment may have potential beneficial effects in the elderly. However, significant questions about risks and benefits of growth hormone treatment in elderly men remain to be answered, as do questions about a possible role of growth hormone administration in older women, growth hormone deficient adults, burn victims, and other conditions associated with increased catabolism.

The recent rise in abuse of so called performance enhancing drugs by athletes and more recently by teenagers wishing to improve their appearance has focussed attention on the physiologic role of these hormones in determining body composition, on metabolism, and on athletic performance. Variable results have been reported on the effects of treatment with high dose anabolic steroids and/or growth hormone on muscle mass and athletic performance. A precise understanding of the effects of these hormones on peri- and post-pubertal growth, body composition and performance is a requisite part of any attempt to stem the abuse of these drugs.

The balance between nutrient intake and energy expenditure in normal individuals is influenced by a number of determinants such as age, exercise, gender, and nutrient type. Against this background, the role and mechanisms of hormones such as growth hormone, thyroid hormone, anabolic and other steroids, and locally or systemically acting growth factors in determining body composition require elucidation and are the subjects of this announcement.

SCOPE

Some examples of research topics that would be considered responsive to this announcement include the following:

o effects of recombinant human growth hormone (rhGH), thyroid hormone, insulin-like growth factors, anabolic and other steroids or other hormones on carbohydrate, fat, protein, and mineral metabolism;

o relationship between growth hormone levels and loss of lean body mass with age;

o effects of rhGH therapy in specific populations including the elderly, growth hormone deficient adults, burn victims, and other conditions associated with increased catabolism;

o the effects of drugs used for performance or image enhancement, such as anabolic steroids or growth hormone, on body mass and composition, metabolic function, athletic performance, strength and/or growth and development;

o identification of other short- or long-term effects of anabolic steroids or growth hormone on the endocrine reproductive or immune systems, neoplasia, behavior, or other parameters;

o the effects of exercise on growth hormone, androgenic steroid, or other hormone levels;

o the role of hormones in the etiology of obesity or in determining the obese phenotype (upper or lower body obesity);

o identification of sites or mechanisms of neuroendocrine control of lean body mass at the molecular or cellular level.

These areas of interest are not listed in any particular order nor do they represent a comprehensive inventory of research topics that would be fostered under this RFA. While work proposed may utilize human or animal models, or cell lines, the goal of the research should be an understanding of the endocrine processes involved in the regulation of body composition in humans.

MECHANISM OF SUPPORT

The mechanism of support for this program will be the traditional, grant (R01). The NIDDK plans to support approximately five applications and the NICHD plans to support two to three applications submitted in response to this solicitation; however, the specific number to be funded will depend upon the overall merit, the scope of the applications received, and availability of funds. Up to $1.4 million for first-year expenses, and additional expenses for up to five years, will be committed to fund applications submitted in response to the RFA. Although this solicitation is included in the sponsoring Institutes funding plans for Fiscal Year 1992 support for this solicitation is contingent upon receipt of appropriated funds for this purpose. Since a variety of approaches would represent valid responses to this solicitation, it is anticipated that there will be a range of costs among individual grants awarded. With respect to post-award administration, the current policies and requirements that govern the regular research grant programs of the PHS, as described in the PHS Grants Policy Statement, will prevail.

REVIEW PROCEDURES AND CRITERIA

Upon receipt, applications will initially be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Applications also will be reviewed by staff for their responsiveness to the objectives of this RFA. Applications will first be reviewed for scientific and technical merit by an Initial Review Group, that will be convened by the Review Branch, Division of Extramural Activities, NIDDK. The applications will then be reviewed by the National Diabetes and Digestive and Kidney Disease Advisory Council and the National Advisory Child Health and Human Development Council. Review criteria include the extent of relevance and/or contribution of the proposed research to the overall goals and objectives of the RFA; the novelty, originality, and feasibility of the approach; the adequacy of the experience, and research competence of the investigator(s); the adequacy of the experimental design; the suitability of the facilities; and the appropriateness of the requested budget to the work proposed.

METHOD OF APPLYING

Applications must be submitted on form PHS 398 (rev. 10/88), that is available from an applicant institution's Office of Sponsored Research and from Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892 telephone (301) 496-7441. Use the conventional format for research project grant applications and ensure that the points identified in the RFA in the section on "Review Procedures and Criteria" are fulfilled. To identify the application as a response to this RFA check "yes" on item two of page one of the application and enter the title "Endocrinology of Body Composition" and the RFA number DK/HD-92-01. Applications must be received by February 14, 1992, to be considered.

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

NIH policy requires that applicants for clinical research grants and cooperative agreements include minorities and women in study populations so that research findings can benefit all persons with the disease, disorder or condition under study. Specific information concerning the NIH policy on inclusion of women and minorities can be found in the NIH Guide for Grants and Contracts Vol. 19, No. 31, August 24, 1990, pages 18-19, and Vol. 19, No. 35, September 28, 1990, respectively.

INQUIRIES

For copies of the RFA or for further information, investigators are encouraged to contact the following individuals:

Philip F. Smith, Ph.D.
Director, Endocrinology Research Program
Division of Diabetes, Endocrinology, and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Westwood Bldg, Room 603
Bethesda, MD 20892
Telephone: (301) 496-7341

Gilman D. Grave, M.D.
Chief, Endocrinology, Nutrition and Growth Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
National Institutes of Health
Executive Plaza North, Room 637
Bethesda, MD 20892
Telephone: (301) 496-5593

Bruce R. Butrum
Grants Management Specialist
Grants Management Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Bldg, Room 649
Bethesda, MD 20892
Telephone: (301) 496-7467

E. Douglas Shawver
Grants Management Branch
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
Bethesda, MD 20892
Telephone: (301) 496-1303

This program is described in the Catalog of Federal Domestic Assistance 93.846; No. 93.847, Diabetes, Endocrinology, and Metabolism; and No. 93.855, Research for Mothers and Children. 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.

EPIDEMIOLOGIC STUDY OF ADENOCARCINOMAS OF THE ESOPHAGUS AND GASTRIC CARDIA

RFA AVAILABLE: CA-91-21

P.T. 34; K.W. 0715035, 0785055, 0715085

National Cancer Institute

Letter of Intent Receipt Date: November 15, 1991
Application Receipt Date: December 11, 1991

PURPOSE

The Epidemiology and Biostatistics Program (EBP) of the Division of Cancer Etiology (DCE) invites cooperative agreement applications from investigators to participate, with the assistance of the National Cancer Institute (NCI), in an epidemiologic study to identify risk factors for adenocarcinomas of the esophagus and gastric cardia and contrast them with risk factors for other cancers of the esophagus and stomach. Subjects for study will be patients newly diagnosed with these cancers and appropriate controls. The assistance mechanism used to support these studies will be the cooperative agreement, which is similar to a traditional research grant, but in which NCI scientific staff participate with study investigators as partners in the research effort.

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 Request for Applications (RFA) entitled, Epidemiologic Study of Adenocarcinomas of the Esophagus and Gastric Cardia, is related to the priority area of prevention of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 783-3238.

BACKGROUND

Recent analyses of incidence data from the Surveillance, Epidemiology and End Results (SEER) program of cancer registration covering approximately 10 percent of the U.S. population have revealed sharply rising rates during 1976-87 for adenocarcinomas of the esophagus and gastric cardia. The increases among males in this period ranged from 4 to 10 percent per year, outpacing rises in skin melanoma, non-Hodgkin's lymphomas, and other cancers. In contrast, there were relatively stable trends for squamous cell carcinoma of the esophagus and slight declines for adenocarcinoma of more distal portion of the stomach. The adenocarcinomas of the esophagus and gastric cardia disproportionately affected white males and rarely occurred among women. The male:female ratios for these cancers exceeded five, the greatest relative excess for any cancer except lip cancer. By the mid-1980s, among white males, adenocarcinomas accounted for about one-third of all esophageal cancers, while cardia cancers accounted for about one-half of all stomach cancers with subsite specified. The annual age-adjusted incidence rate for white males for adenocarcinomas of the esophagus and gastric cardia combined was 5.1 per 100,000.

The unexplained increase in incidence rates, which has also been observed in western Europe, points to the need for investigation into the causes of these poorly understood cancers. Reasons for the striking racial differences between these cancers and squamous cell carcinomas of the esophagus or adenocarcinomas occurring elsewhere in the stomach also remain to be determined. Because of their rarity in the past, however, few epidemiologic studies have evaluated risk factors for esophageal adenocarcinoma and/or gastric cardia cancer.

RESEARCH GOALS AND SCOPE

This initiative proposes new research into the etiology of these emergent cancers. It will be the first systematic analytic epidemiologic study of adenocarcinomas of the esophagus and gastric cardia and enable exploration of associations with a variety of possible environmental and host determinants. Its objectives are to identify risk factors for adenocarcinomas of the esophagus and gastric cardia and contrast them with risk factors for other cancers of the esophagus and stomach.

Cooperative agreements will be sought to enable the conduct of a multi-center, case-control study. Cases will be patients newly diagnosed during a recent period with adenocarcinoma of the esophagus or gastric cardia. To compare characteristics of these patients with those of persons with other esophageal and stomach cancers, it is anticipated that approximately equal numbers of squamous cell carcinomas of the esophagus and adenocarcinomas elsewhere in the stomach of similar age, sex, and race will also be included. Controls from the populations from which the cases arose would be selected for comparison with the cancer patients. To ensure sufficient numbers of cases for pooled statistical analyses of a variety of environmental and host factors it is anticipated that, across all centers, at least 250 patients recently or newly diagnosed with esophageal adenocarcinoma and at least 250 with gastric cardia cancer will need to be enrolled.

MECHANISM OF SUPPORT

Support of this program will be through the cooperative agreement, an assistance mechanism in which substantial NIH programmatic involvement with the recipient during performance of the planned activity is anticipated. Applicants will be responsible for the planning, direction, and execution of the proposed project.

Approximately $750,000 in total costs per year for three years will be committed to specifically fund applications which are submitted in response to this RFA. It is anticipated that three to four awards will be made. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to the present RFA should not exceed three years. The earliest feasible start date for the initial awards will be June 1, 1992. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to the RFA is also contingent upon the availability of funds for this purpose.

ELIGIBILITY REQUIREMENTS

Non-profit and for-profit organizations and institutions, governments and their agencies are eligible to apply. Foreign institutions are also eligible.

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.

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of the RFA and inquiries about whether or not specific proposed research would be responsive are encouraged and are to be directed to the following:

Administrative Coordinator
G. Iris Obrams, M.D., Ph.D.
National Cancer Institute
EPN, Room 535
Bethesda, MD 20892
Telephone: (301) 496-9600
Fax: (301) 496-9146

Grants Management Contact
Sara Stone
National Cancer Institute
EPN, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800
Fax: (301) 496-8601

Scientific Coordinator
William J. Blot, Ph.D.
National Cancer Institute
EPN, Room 431
Bethesda, MD 20892
Telephone: (301) 496-4153
Fax: (301) 402-0081

This program is described in the Catalog of Federal Domestic Assistance No. 93.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal regulation 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.

MECHANISMS OF MULTISTAGE CARCINOGENESIS IN THE PROSTATE

RFA AVAILABLE: CA-91-31

P.T. 34; K.W. 0715035, 0715085, 0715085, 0785140, 0755020

National Cancer Institute

Letter of Intent Receipt Date: October 1, 1991
Application Receipt Date: December 20, 1991

PURPOSE

The Chemical and Physical Carcinogenesis Branch, Division of Cancer Etiology (DCE), National Cancer Institute (NCI), invites investigator-initiated research grant applications (R01s) to elucidate the basic, complex mechanisms of multistage carcinogenesis in the prostate. New advances in prostate tissue and cell culture and descriptions of potentially useful animal models, coupled with rapid advancements in molecular biology and improvement in the general understanding of human carcinogenesis processes, may provide the foundation for major new insights, including identification of the cellular and molecular mechanisms and environmental causes of transformation to invasive cancer forms in normal and latent prostatic epithelial cells. New and experienced investigators in relevant fields and disciplines may apply for funds to pursue investigations in animal and human prostatic epithelial cells.

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 Request for Applications (RFA), Mechanisms of Multistage Carcinogenesis in the Prostate, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017- 001-00474-0 or 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 REQUIREMENTS

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

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) grant-in-aid (R01). Applicants will be responsible for the planning, direction, and execution of the proposed project. The total project period for applications submitted in response to this RFA may not exceed five years. The earliest feasible start date for the initial awards will be July 1, 1992.

FUNDS AVAILABLE

$1,000,000 per year for five years will be committed to specifically fund applications submitted in response to this RFA. It is anticipated that five to seven awards will be made. This funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose.

RESEARCH GOALS AND SCOPE

The goal of this initiative is to accelerate further understanding of carcinogenesis in the prostate gland in animals and man. Integrated studies are encouraged in one or more of the following categories: (a) cell biology and carcinogenesis, including identification of prostatic epithelial cells undergoing change; (b) carcinogen metabolism, including comparative metabolism, repair, and adduct formation between animals and man and from inter/intra individual donors; (c) molecular mechanisms, including molecular markers of change throughout transformation of an epithelial cell; (d) cellular mechanisms, including cell-cell interactions and responses to endogenous and exogenous factors; and (e) appropriate models, including suitable in vitro or animal models for prostate epithelial cell carcinogenesis.

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. Due to the specific subject of this RFA, i.e., prostate cancer, the inclusion of women is not applicable. However, the inclusion of minorities remains relevant.

APPLICATION PROCEDURES

Applications must be received by close of business December 20, 1991. The research grant application form PHS 398 (revised 10/88) must be used in applying for awards under this RFA. The application package is available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441; and from the NCI Program Director named below.

LETTER OF INTENT

Prospective applicants are asked to submit, by October 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 other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted. Such letters are requested for the purpose of obtaining an indication of the number and scope of applications to be received. A letter of intent is not binding, is not a requirement of submission, and does not enter into the review of the application. The letter of intent is to be sent to:

Dr. David G. Longfellow
Chief, Chemical and Physical Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Suite 700
Bethesda, MD 20892
Telephone: (301) 496-5471
FAX: (301) 496-1040

INQUIRIES

This Notice of Availability is an abbreviated version of the RFA. Copies of the complete RFA and written and telephone inquiries concerning the objectives and scope of the RFA, and inquiries about whether or not specific proposed research would be responsive, are encouraged and are to be directed to Dr. Longfellow at the above address. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants.

Written and telephone inquiries of a budgetary, administrative, and/or policy nature are to be directed to:

Ms. Sara Stone
Grants Management Team Leader
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Ext. 66
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.393, Cancer Cause and Prevention Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) 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.

THE DECISION PROCESS SURROUNDING THE CHOICE OF NORPLANT AS A CONTRACEPTIVE BY U.S. WOMEN

RFA AVAILABLE: HD-92-03

P.T. 34; K.W. 0750020, 0404000

National Institute of Child Health and Human Development

Application Receipt Date: December 20, 1991

The Center for Population Research (CPR) of the National Institute of Child Health and Human Development (NICHD) invites scientists to submit grant applications for the support of research on behavioral aspects of the adoption and utilization of NORPLANT by U.S. women. Research on the behavioral aspects of contraceptive use is an important part of the program of the Demographic and Behavioral Sciences Branch within the Center for Population Research.

The recent Food and Drug Administration (FDA) approval of NORPLANT provides an opportunity for observing the introduction and adoption process in the U.S. of a new method of reversible contraception. Initial research on the product indicates that it promises ease of use and high efficacy, although it has a variety of side effects that may trouble some unknown proportion of users or potential users. Most of the prior research on this contraceptive has been done in developing countries. As of now, there has been little research on how U.S. women, with different contraceptives available, will accept this method.

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, The Decision Process Surrounding the Choice of NORPLANT As a Contraceptive By U.S. Women, is related to two of the priority areas: health promotion -- family planning; and preventive services -- maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 783-3238.

Proposed research must include investigation into the decision processes leading to consideration, adoption, continuation, and discontinuation of this method. The incidence and prevalence of side effects and which side effects convince which women to discontinue the method are also of interest.

Another important question is how NORPLANT acceptability may vary among groups of women for whom the method is clinically appropriate.

This research will require longitudinal follow-up of women who do choose NORPLANT as a contraceptive method, and may additionally involve appropriate comparison groups. The nature of the research encourages cross- disciplinary applications. However, the grant will not provide payment for NORPLANT, its insertion, and removal.

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.

For a copy of the full RFA please contact:

Susan F. Newcomer, Ph.D.
Demographic and Behavioral Science Branch
National Institute of Child Health and Human Development
Executive Plaza North, Room 611
Bethesda MD 20892
Telephone: (301) 496-1174
FAX: (301) 496-0962

For questions concerning budget and fiscal matters, contact:

Metorda Nelson
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
Rockville, MD 20892
Telephone: (301) 496-5481

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population 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 requirements of Executive Order No. 12372 or to Health Systems Agency review.

UNDERSTANDING THE MECHANISMS OF HORMONAL CARCINOGENESIS

RFA AVAILABLE: CA-91-30

P.T. 34; K.W. 0715035, 0760025, 0785140

National Cancer Institute

Letter of Intent Receipt Date: October 1, 1991
Application Receipt Date: December 12, 1991

PURPOSE

The Chemical and Physical Carcinogenesis Branch, Division of Cancer Etiology (DCE), National Cancer Institute (NCI), invites investigator-initiated research grant applications (R01s) to elucidate the basic, complex mechanisms of hormonal carcinogenesis. Included are the basic mechanisms of steroid hormones, particularly sex hormones, in the etiology of cancer. This area of research is in need of an enhanced level of interaction between endocrinologists, toxicologists, pharmacologists, biochemists, organic chemists, epidemiologists, pathologists, and cell and molecular biologists. New and experienced investigators in relevant fields and disciplines may apply for funds to pursue investigations on mechanisms of hormonal carcinogenesis in experimental animal systems, in vitro and in vivo, and in human tissues in vitro.

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 Request for Applications (RFA), Understanding the Mechanisms of Hormonal Carcinogenesis, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or 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 REQUIREMENTS

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

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) grant-in-aid (R01). Applicants will be responsible for the planning, direction, and execution of the proposed project. The total project period for applications submitted in response to this RFA may not exceed five years. The earliest feasible start date for the initial awards will be July 1, 1992.

FUNDS AVAILABLE

$1,500,000 per year for five years will be committed to specifically fund applications submitted in response to this RFA. It is anticipated that seven to ten awards will be made. This funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose.

RESEARCH GOALS AND SCOPE

The goals of this initiative are two-fold: (1) to elucidate basic mechanisms of steroid hormone action that relate to the possible roles of hormones, particularly sex hormones, as carcinogens; and (2) to provide a means to enhance multidisciplinary investigations, including consortial arrangements. Research to be funded under this RFA includes, but is not limited to, studies on: (1) the hormonal metabolites that could lead specifically to genetic damage or chromosomal malfunction, i.e., chromosomal fragmentation, non-disjunction, altered repair processes, or shifts in DNA methylation states; (2) karyotypic, cytogenetic, and morphologic changes in models of hormonal carcinogenesis; (3) the role of androgens, anabolic agents and progestins in hormonal carcinogenesis in organ sites such as the liver and mammary gland; (4) establishment of new in vitro experimental models for studying hormonal carcinogenesis in various understudied organ sites such as pituitary, testis, and uterus; (5) the role of specific hormones in the oncogenic process through the use of transgenic animals or gene transfected cells; and (6) molecular mechanisms of hormonally induced carcinogenesis, e.g., DNA base sequence changes, genetic or epigenetic mechanisms.

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.

APPLICATION PROCEDURES

Applications must be received by close of business December 12, 1991. The research grant application form PHS 398 (revised 10/88) must be used in applying for awards under this RFA. The application package is available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-7441; or from the NCI Program Director named below.

LETTER OF INTENT

Prospective applicants are asked to submit by October 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 other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted. Such letters are requested for the purpose of obtaining an indication of the number and scope of applications to be received. A letter of intent is not binding, is not a requirement of submission, and does not enter into the review of the application. The letter of intent is to be sent to:

Dr. Lea I. Sekely
Carcinogenesis Mechanisms
Chemical and Physical Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Suite 700
Bethesda, MD 20892
Telephone: (301) 496-5471
FAX: (301) 496-1040

INQUIRIES

This Notice of Availability is an abbreviated version of the RFA. Copies of the complete RFA and written and telephone inquiries concerning the objectives and scope of the RFA, and inquiries about whether or not specific proposed research would be responsive, are encouraged and are to be directed to Dr. Sekely at the above address. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants.

Written or telephone inquiries of a budgetary, administrative, and/or policy nature should be directed to:

Ms. Sara Stone
Grants Management Team Leader
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Ext. 66
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.393, Cancer Cause and Prevention Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) 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.

EVALUATION OF ADHERENCE INTERVENTIONS IN CLINICAL TRIALS

RFA AVAILABLE: HL-91-08-P

P.T. 34; K.W. 0755015, 0715040, 0715165, 0715032

National Heart, Lung, and Blood Institute
National Center for Nursing Research

Letter of Intent Receipt Date: October 1, 1991
Application Receipt Date: November 19, 1991

The National Heart, Lung, and Blood Institute (NHLBI) and the National Center for Nursing Research (NCNR) announce the availability of a Request for Applications (RFA). The purpose of this initiative is to evaluate the effectiveness of intervention strategies designed to enhance patient adherence in clinical trials of pharmacologic therapies in the areas of cardiovascular, lung, and blood diseases. Studies responsive to this solicitation must systematically compare the effects of two or more intervention strategies on patient adherence within a clinical trial, using experimental designs, well-defined measures of adherence, and comparisons of the cost-effectiveness of the different strategies tested. Respondents must demonstrate knowledge of adherence theory and research and clinical trial methodology and must demonstrate access to an appropriate clinical trial within which to conduct the study.

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, Evaluation of Adherence Interventions in Clinical Trials, is related to the priority area of heart disease and stroke. 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, D.C. 20402-9325 (telephone 202-783-3238).

MECHANISM OF SUPPORT

The support mechanism for this program will be the cooperative agreement (U01). Although approximately $2.7 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 four 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.

Letter of Intent. Prospective applicants are asked to submit a letter of intent that includes a descriptive title, names of the Principal and Co-Investigators, and identify cooperating institutions. The NIH requests such letters only for the purpose of providing an indication of the number and scope of applications to be received and usually does not acknowledge their receipt. 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 applications. This letter of intent to be received no later than October 1, 1991, is to be sent to:

C. James Scheirer, Ph.D.
Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 548
5333 Westbard Avenue
Bethesda, MD 20892

INQUIRIES

Inquiries regarding this program and requests for the complete RFA document are to be addressed to any of the program administrators listed:

Susan M. Czajkowski, Ph.D.
Social Science Analyst
Behavioral Medicine Branch, DECA
National Heart, Lung, and Blood Institute
Federal Building, Room 216
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-9380
FAX: (301) 480-2435

Sharlene M. Weiss, Ph.D., R.N.
Chief, Health Promotion/Disease Prevention Branch
National Center for Nursing Research
Building 31, Room 5B03
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-0523
FAX: (301) 480-4969

Eleanor Schron, M.S., R.N.
Public Health Analyst/Scientific Project Officer
Clinical Trials Branch, DECA
National Heart, Lung, and Blood Institute
Federal Building, Room 5C-10
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-4323
FAX: (301) 402-0517

For fiscal and administrative matters, contact:

Ms. Jane Davis
Chief, Blood Diseases and Resources Section
Grants Operations Branch, DEA
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A-15
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7255
FAX: (301) 402-1200

The programs of the Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute, and the National Center for Nursing Research, are identified in the Catalog of Federal Domestic Assistance, numbers 93.837-93.839 and 93.361, respectively. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 U.S. 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 a Health Systems Agency review.

ERRATUM

NEW THERAPEUTIC APPROACHES TO THE TREATMENT OF PROSTATE CANCER

RFA: CA-91-16

P.T. 34; K.W. 0715035, 0745070

National Cancer Institute

Application Receipt Date: October 15, 1991

The Division of Cancer Treatment of the National Cancer Institute would like to amend Request for Applications (RFA) CA-91-16 titled "New Therapeutic Approaches to the Treatment of Prostate Cancer" published (in full RFA) May 24, 1991, Vol.20, No. 20. The statement under the "Research Goals and Scope" addressing potential racial differences in clinical and laboratory parameters is corrected to read:

"Analysis of potential racial differences in clinical and laboratory parameters must be considered, where relevant and feasible."

Written and telephone inquiries concerning the objectives and scope of this RFA and inquiries about whether or not specific proposed research would be responsive are encouraged and are to be directed to:

Ms. Diane Bronzert
Program Director
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

ONGOING PROGRAM ANNOUNCEMENTS

ACADEMIC AWARD IN SYSTEMIC AND PULMONARY VASCULAR DISEASE

PA: PA-91-86

P.T. 34; K.W. 0705015, 0705065, 0715165, 0715135, 0715115

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date; October 14, 1991
Application Receipt Date: December 9, 1991

The National Heart, Lung, and Blood Institute (NHLBI) announces the second competition for an Academic Award in Systemic and Pulmonary Vascular Disease. Copies of the Program Guidelines are currently available from staff of the NHLBI.

OBJECTIVES OF THE AWARD

(1) To stimulate the development and coordination of clinical, educational, and research programs in schools of medicine or osteopathy directed toward enhancement of diagnostic and therapeutic skills in the clinical management of patients with a wide variety of vascular diseases;

(2) to promote professional development of the awardee, where needed, so that he/she can serve as the focal point for multidisciplinary interactions promoting effectiveness in clinical care, teaching, and research in the field of vascular medicine; and

(3) to enable the grantee institution to continue clinical, educational, and research programs in vascular medicine once the award is concluded.

For the purposes of this award, vascular medicine is defined as the clinical discipline that has as its objectives: the clinical characterization of vascular diseases (arterial, venous, lymphatic, cerebral, coronary, pulmonary, aortic, renal, and peripheral), the pathogeneses of these diseases (including atherosclerosis, lipid metabolic disorders, systemic and pulmonary hypertension, lymphedema, thrombosis, vasculitis, and vasospastic disorders), and the diagnostic, therapeutic, and preventive approaches to these diseases.

ELIGIBILITY

Each school of medicine or osteopathy in the United States and its possessions or territories is eligible to compete for a nonrenewable Academic Award in Systemic and Pulmonary Vascular Disease for a project period that does not exceed five years. The awardee must hold the M.D. or D.O. degree or their equivalent. Women and minority applicants are encouraged to apply. Only one application per institution will be accepted for review for a given receipt date.

MECHANISMS OF SUPPORT

Subject to the availability of funds and consonant with the objectives of the Academic Award in Systemic and Pulmonary Vascular Disease, the NHLBI will provide support for a project period of five years. An average total (direct plus indirect) cost per award is anticipated to be about $150,000; however, this figure may vary according to the needs of each institution. Awards will be limited to one for each eligible school and are not renewable. The award may provide funds for salaries, travel, supplies, equipment, consultant fees, fringe benefits, and indirect costs under the terms and conditions explained in the guidelines for this award.

REVIEW OF APPLICATIONS

The initial review of applications will be by a special review committee managed by the Division of Extramural Affairs, NHLBI, composed of predominantly non-Federal scientists with expertise in various areas of vascular disease. Prospective awardees whose applications are determined to be competitive will be invited for an interview in Bethesda, Maryland. Travel expenses for this interview must be paid by the applicant institution.

LETTER OF INTENT

Each prospective applicant should forward a very brief letter of intent, that includes a descriptive title, the name and address of the Principal Investigator, the names and addresses or other key investigators and any other participating institutions. Such letters are requested for the purpose of obtaining an indication of the number and scope of applications to be received. A letter of intent is not binding, is not a requirement of submission, and does not enter into the review of the application. The letter of intent is requested by October 14, 1991, and is to be addressed to:

Dr. James Scheirer
Chief, Contracts, Clinical Trials and Training Review Section
Review Branch Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 548
National Institutes of Health
Bethesda, MD 20892

TIMETABLE

Letter of Intent (optional):	October 14, 1991
Application receipt date:	December 9, 1991
Scientific review:	February/March 1992
Advisory Council Review:	May 1992
Award date:	July 1, 1992

Copies of the Program Guidelines may be obtained from:

Dr. Carol H. Letendre
Associate Director for Scientific Programs
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 516
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-8966

Dr. David M. Robinson
Associate Director for Scientific Programs
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 416
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-5656

Dr Carol E. Vriem
Associate Director for Scientific Program Operations
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A16
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-7208

For fiscal and administrative matters, contact:

Marie Willett
Grants Operation Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11
Bethesda, MD 20892
Telephone: (301) 496-7536

The programs of the National Heart, Lung, and Blood Institute are identified in the Catalog of Federal Domestic Assistance, Number 93.837, 93.838, and 93.839. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant 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 review by a Health Systems Agency.