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.

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NOTICES

DATED ANNOUNCEMENTS (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

CHANGE IN MAXIMUM DOLLAR LIMIT THAT MAY BE REQUESTED FOR PROGRAM PROJECT APPLICATIONS ASSIGNED TO NIDDK

P.T. 34; K.W. 1014002, 0710030

National Institute of Diabetes and Digestive and Kidney Diseases

Program project grants provide support for broadly based multi-disciplinary research programs each having well-defined research objectives and employing the coordinated efforts of a number of individual project leaders. The typical program project consists of several interrelated projects and one or more supporting resources (core components).

In 1984, this Institute placed a limit on the amount of dollars that may be requested for program project applications assigned to it. This limit was $5 million over 5 years ($1 million average per year) in direct costs. The NIDDK has now determined the need to increase this limit.

Beginning immediately (i.e., with the February 1, 1989, receipt date), all new and competing continuation applications for program projects may request up to $6.25 million over 5 years (an average of $1.25 million per year) in direct costs.

For supplemental applications, the maximum direct cost amount that may be requested for any grant year cannot exceed the difference between $1.25 million and the IRG-recommended amount for any given year.

In all instances, prospective applicants are encouraged to discuss potential applications with the appropriate NIDDK program staff member. For information in this regard, please contact:

Dr. Walter Stolz
Director, Division of Extramural Activities
Westwood Building, Room 657
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7277

HEALTH AND SAFETY GUIDELINES FOR GRANTEES AND CONTRACTORS

P.T. 34; K.W. 1014002, 0725020

National Institutes of Health (NIH)
Alcohol, Drug Abuse, and Mental Health
Administration (ADAMHA)

Organizations receiving grant or contract awards are responsible for protecting their personnel from hazardous conditions. The Government is not legally liable for accidents, illnesses, or claims arising out of research performed under its awards, but NIH and ADAMHA are nonetheless aware that a variety of hazards threaten the safety and health of both laboratory and clinical research personnel. Accordingly, the guidelines that follow are designed to: (1) identify potential hazards; (2) advise awardee organizations and investigators of certain standards that should be considered in order to address particular health and/or safety concerns; and (3) emphasize that concerns about potentially hazardous conditions could result in grant or contract funding delays until those concerns have been resolved to the satisfaction of the awarding component.

1. Sources of potential danger to research personnel include the following classes of hazard:

   a. Biohazards (e.g., Human Immunodeficiency Virus, HIV; other infectious agents; oncogenic viruses).

   b. Chemical hazards (e.g., carcinogens; chemotherapeutic agents; other toxic chemicals; flammable or explosive materials).

   c. Radioactive materials.

2. The following guidelines and standards contain information designed to assist grantees and contractors in providing a safe work environment for research personnel. Therefore, depending upon the particular safety hazard at issue, grantees and contractors are expected to consult these standards.

a. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and the NIH. HHS Publication No. (CDC) 88-8395.

b. Recommendations for Prevention of HIV Transmission in Health-Care Settings. Morbidity and Mortality Report, August 21, 1987, Vol. 35, No. 2S.

c. Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. Morbidity and Mortality Weekly Report, June 24, 1988, Vol. 37, No. 24.

d. Agent Summary Statement for Human Immunodeficiency Viruses (HIV); Included are HTLV-III, LAV, HIV-1, and HIV-2. Morbidity and Mortality Weekly Report, April 1, 1988, Vol. 37, No. S4.

e. Recommendations for the Safe Handling of Parenteral Antineoplastic Drugs, NIH Publication No. 83-2621.

f. NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication NO. 81-2385.

g. Guidelines for Research Involving Recombinant DNA Molecules (49 FR 46266 or latest revision) and Administrative Practices Supplement.

h. Procedures for the Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents, National Committee for Clinical Laboratory Standards, July 17, 1985, Vol. 5, No. 1.

i. Standards issued pursuant to the National Occupational Safety and Health Act of 1970 (29 CFR 1910).

j. Standards issued pursuant to the Atomic Energy Act of 1954 (42 USC 2021).

3. Grant applications and contract proposals posing special hazards typically are identified during the initial review process, but such concerns can formally be expressed by agency staff or consultants at any time prior to award. Regardless of the timing of the described concern, grant or contract funding could be delayed until the matter has been resolved to the satisfaction of the awarding component.

Special hazards that are identified after an award is made may lead to suspension of work under the grant or contract pending corrective action by the awardee. (See 45 CFR 74, Subpart M, concerning grant suspension and 48 CFR 12.5 concerning contract "stop work" orders.)

4. The materials identified in section 2 of this notice may be obtained as follows.

ITEMS a-f: Division of Safety
Office of Research Services
National Institutes of Health
Building 31, Room 1C02
Bethesda, Maryland 20892.

ITEM g: Office of Recombinant DNA Activities
Office of Science Policy and Legislation
National Institutes of Health,
Twinbrook Building 2, Room 58
Rockville, Maryland 20852.

ITEM h: National Committee for Clinical Laboratory Standards
771 East Lancaster Avenue
Villanova, Pennsylvania 19085

ITEM i: NIOSH Grants Management Office
Centers for Disease Control
Building 1, Room 3057
Atlanta, Georgia 30333

ITEM j: Nuclear Regulatory Commission
Office of the General Counsel
One White Flint North Building, Room 16D3
Washington, D.C. 20555

5. Grantee and contractor organizations are not required to submit documented assurance of their specific attention to the guidelines and standards identified in section 2 of this notice. However, where dictated by the circumstances, grantees and contractors should be able to provide evidence that pertinent health and safety standards have been considered and, where necessary, have been put in practice. Such evidence may be requested by appropriate NIH and ADAMHA staff; for example, during a site visit.

DATED ANNOUNCEMENTS (RFPs AND RFAs)

IDENTIFICATION AND EVALUATION OF MOLECULAR PROBES FOR PATHOLOGICAL CLASSIFICATION OF HUMAN ASTROCYTOMAS

RFA: 88-CA-18

P.T. 34; K.W. 1002004, 1002008, 1002015, 1002058, 0710075, 0785035

National Cancer Institute

Application Receipt Date: January 16, 1989

On September 2, 1988, the availability of a Request for Applications entitled "Identification and evaluation of molecular probes for pathological classification of human astrocytomas" was published in the NIH Guide, Vol. 17, No. 28. The initial announcement was limited to include only applicant institutions in the United States. After further consideration, the National Cancer Institute believes that there may be opportunities for institutions in Canada or Mexico to submit applications for this RFA and to participate effectively in this multi-institutional cooperative study. This expansion will ensure that important patient populations, scientists and clinicians in these countries will not be excluded. Past experience has shown that the exchange of information and clinical samples between the United States and these countries has proved to be feasible.

The submission date for letters of intent from these countries is extended to November 25, 1988. Specific information concerning application and review procedures are contained in the original RFA.

A copy of the complete RFA describing the research goals and scope, the Cooperative Agreement mechanism, the review criteria and the method of applying can be obtained by contacting:

Doris Balinsky, Ph.D.
Program Director for Biochemistry and Immunodiagnosis
Division of Cancer Biology and Diagnosis
National Cancer Institute
Room 10A10, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-1591

ONGOING PROGRAM ANNOUNCEMENTS

MAPPING AND DNA SEQUENCE DETERMINATION OF THE GENOME OF THE HUMAN AND MODEL ORGANISMS

P.T. 34; K.W. 1002019, 0790010, 0755045, 1002008, 1002058

National Institute of General Medical Sciences

INTRODUCTION

This Program Announcement restates the interest of the National Institutes of Health (NIH) in receiving research grant applications for studies related to mapping and determining the DNA sequences of the genomes of the human or of model organisms; the present announcement supersedes the previous (May 29, 1987) NIH-wide program announcement on this topic. The goals of the genome program are to develop an important set of resources, the genetic and physical maps and the DNA sequences of the genomes of the human and of model organisms,

and to make these resources available to be utilized both for basic research and for studies on the prevention, treatment, and diagnosis of human disorders. The NIH is strongly committed to supporting competitive research programs that further the objectives of the genome project.

BACKGROUND INFORMATION

In recent years, the science of genetics has undergone revolutions in both knowledge and technology. Research programs initiated and supported by the NIH have contributed to this genetic revolution and will continue to play important roles in a wide range of studies from the most basic to targeted and clinical programs. NIH remains strongly committed to these programs.

Over the past two years, a major new initiative - the genome project - has been proposed and supported by a broad spectrum of scientists, by the United States Congress, by federal and private agencies, as well as by the governments of Japan and several European countries. The NIH has emerged as a leader in supporting the initiative to map and determine the DNA sequences of the genomes of the human and of model organisms. The maps and sequences obtained within the genome project will be a resource for studies of gene structure and function and will promote research into human genetic disorders. To facilitate attainment of this goal, the Director, NIH, has established an Office of Human Genome Research, which will coordinate the planning and review the progress of the NIH initiative, as well as coordinate interaction between NIH and other agencies.

The Director has also received advice on the research directions to be followed from several advisory groups, the most recent of which met on February 29 - March 1, 1988. The latter group identified both short-term and long-term goals for the genome project and recommended that NIH should, at this time, focus on specific areas, such as expansion of genetic maps, construction of physical maps, and pilot projects for large-scale DNA sequence determination, as well as the development of improved technology for physical mapping, for the determination of DNA sequences, and for the management of the information that accrues. Creative, novel approaches in all these areas will be essential to the success of the genome project. Therefore, among the research projects that will be supported by the NIH under the genome project, some will focus on developing and implementing novel ideas and technologies, while others will focus on assembling and analyzing large amounts of data. In this regard, the advisors have strongly recommended that the NIH support a wide range of research activities and encourage interdisciplinary programs that draw from fields such as information science, chemistry, physics, and engineering in addition to the biological sciences.

RESEARCH SCOPE

This program announcement is intended to emphasize the ongoing commitment of the NIH to the specific goals of the genome project - expansion of genetic maps, development of physical maps, and, ultimately, determination of the sequences of human DNA and the DNA of model organisms - and to the development of tools and resources which would support this effort, including the storage and retrieval of materials and data. Applications responsive to this announcement will comprise a broad spectrum of research approaches to mapping and DNA sequence determination. Development of new and imaginative technological resources needed to support the genome project are especially encouraged. The topics described below are not intended to limit the types of applications that are encouraged by this announcement, but rather to illustrate the range of work that will be needed to advance the knowledge and research capabilities to attain the goals of the genome project.

Technology Development

- Improving methods for fragmenting DNA, including the isolation and characterization of new restriction enzymes, studies of the mechanism of action of restriction enzymes, and the development of methods for sequence-specific DNA cleavage;

- Improving the large-scale separation and purification of DNA fragments, including techniques for obtaining pure preparations of individual human chromosomes and subchromosomal fragments and techniques for purification of DNA fragments based on sequence;

- Cloning large (more than 100,000 base pairs) DNA fragments, with special emphasis on mammalian DNA fragments, and with emphasis on the development of new cloning vehicles for large DNA fragments;

- Devising techniques for cloning DNA regions that are refractory to currently available cloning techniques, including studies to determine the extent to which current cloning techniques do provide complete genomic libraries or can be improved;

- Improving methods for ordering DNA fragments in the genome, including the development of mathematical techniques and computer software to support such a process;

- Improving techniques for DNA sequence determination, including automation of all steps of the determination, technological or biochemical advances that would enhance the speed and accuracy of methods of sequence determination, and novel approaches to DNA sequence determination;

- Improving storage methods which preserve the integrity of long DNA fragments, including studies on the stability and selective loss of cloned DNA fragments and associated vectors;

- Developing software to support data management and analysis of genetic linkage mapping, physical mapping, and DNA sequences.

Mapping and DNA Sequence Determination

- Expanding the genetic map of the human, or of model organisms which serve to promote the objectives of the overall program;

- Expanding the physical maps of the chromosomes of the human and of model organisms, or developing techniques and resources which would facilitate physical mapping efforts, software for data management within and between laboratories, approaches to analyzing and comparing physical mapping data, and pilot projects for large-scale physical mapping;

- Determining the sequence of the DNA of model organisms or regions of the human genome as assays of large-scale efforts to determine DNA sequences;

- Determining the relationships between genetic and physical maps in the human and model organisms;

- Determining the amount and significance of genomic variation in the human and in model organisms, with special emphasis on variation in DNA sequences within and among populations.

Responses to this Program Announcement should focus on the specific goals of the genome project. As research on the application of genetic information to the diagnosis, prevention, or treatment of specific genetic disorders is currently supported by several ongoing programs at the NIH, it is not within the scope of the genome project. Information about these programs can be obtained from individual Institutes; potential applicants are encouraged to contact the representatives listed below for additional information.

MECHANISM OF SUPPORT

Support for this program will be through research grants, including project grants (R01), small grants (R03), program projects grants (P01), FIRST awards (R29), biomedical research technology resource grants (R24, P41), and Small Business Innovation Research (SBIR) grants (R43, R44). Because not all institutes support all of the above mechanisms, potential applicants are encouraged to contact the representatives listed below for additional information. Policies that govern research grant programs of the NIH apply to this program. Consortium arrangements and collaborative projects among scientists with skills in biological sciences, chemistry, physics, information sciences, and engineering are encouraged.

APPLICATION AND REVIEW PROCEDURES

Applications in response to this announcement will be reviewed in accordance with the usual NIH peer review procedures. They will first be reviewed for scientific and technical merit by a special study section organized for this purpose by the Division of Research Grants and composed mostly of non-Federal scientific consultants. Following the initial review, the applications will be considered by the appropriate National Advisory Board or Council. Review criteria are the following:

- Scientific merit, as is the case in regard to all research proposals;

- Potential value of the research for furthering the goals of the genome project;
- Significance and originality of the research and approaches as they relate to the genome project;
- Feasibility of the research and adequacy of the experimental design;
- Training, experience, research competence, and dedication of the investigator(s);
- Adequacy of available facilities;
- Provisions for the protection of human subjects and the humane care of animals; and
- Appropriateness of the requested budget for the work proposed.

METHOD OF APPLYING

Applications should be submitted on Form PHS 398 (rev. 9/86). Application kits are available in most institutional business offices and from the following NIH office:

Office of Grants Inquiries
Division of Research Grants
Westwood Building, Room 449
National Institutes of Health
Bethesda Maryland 20892

Applications will be accepted in accordance with the usual NIH receipt dates for new applications - October 1, February 1, and June 1. It is essential that applicants type "Mapping and DNA Sequence Determination of the Genomes of Humans and Model Organisms" in item 2 on the face page of the application form. The original and six copies of the application should be submitted to the following office:

Application Receipt Office
Division of Research Grants
Westwood Building, Room 240
National Institutes of Health
Bethesda Maryland 20892**
Telephone: (301) 496-7441

The conventional presentation for grant applications should be utilized.

Funding decisions will be based on recommendations of the initial review groups and the B/I/D's Advisory Council regarding scientific merit and program relevance and on the availability of funds.

INQUIRIES

It is strongly recommended, but not required, that potential applicants contact the appropriate NIH staff member to discuss research objectives.

B/I/D	CONTACT	BUILDING	ROOM	TELEPHONE
NIDDK	Robert Katz, Ph.D.	Westwood	607	496-7997
NCI	Cheryl Marks, Ph.D.	31	10A10	496-7028
FIC	Bettie Graham, Ph.D.	38A	613	496-6688
DRR	Suzanne Stimler, Ph.D.	31	5B39	496-5411
NIA	Huber R. Warner, Ph.D.	31	5C19	496-6402
NICHD	Delbert Dayton, M.D.	Executive Plaza North	643	496-5541
NINCDS	N.C. Myrianthopoulos, Ph.D.	Federal	8C16A	496-5821
NLM	Arthur Broering, Ph.D.	38A	5N503	496-4621
NIDR	John Townsley, Ph.D.	Westwood	506	496-7807
NIGMS	Irene Eckstrand, Ph.D.	Westwood	920	496-7137
NIAMS	Steven Hausman, Ph.D.	Westwood	403	496-7495
NHLBI	Carol Letendre, Ph.D.	Federal	518	496-6402
NIAID	William Duncan, Ph.D.	Westwood	754	496-5598
NEI	Jack McLaughlin, Ph.D.	31	6A51	496-5983

Mailing address for the above offices: Bethesda Maryland 20892
All Bethesda telephone numbers are in area code 301.

NIEHS Michael Galvin, Ph.D. Research Triangle Park
North Carolina 27709
(919) 541-7825

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