

NIH GUIDE

for GRANTS and CONTRACTS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Vol. 9, No. 5, April 7, 1980

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HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

The GUIDE is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

NOTICE

REQUEST FOR PUBLIC COMMENT ON THE QUESTION OF WHETHER PHS
SHOULD MAKE FINANCIAL ASSISTANCE AWARDS TO PROFIT-MAKING ORGANIZATIONS

The February 28, 1980 issue of the Federal Register, Vol. 45, No. 41 includes a notice inviting public comment on the question of whether the Public Health Service (PHS) should make financial assistance awards (grants and cooperative agreements) to organizations operated for profit. This proposal applies to all six PHS agencies, of which the National Institutes of Health is one.

Comments received will be an important factor in developing a formal PHS position. Comments must be received by April 28, 1980 and should be addressed to:

Mr. Theodore J. Roumel, Chief
Grants Management Branch
Division of Grants and Contracts, ORM/OM
Parklawn Building, Room 18A-03
5600 Fishers Lane
Rockville, Maryland 20857

For further information, Mr. Roumel may also be reached at telephone number (301) 443-1874.

NOTICE

WITHDRAWAL OF REQUEST FOR RESEARCH

GRANT APPLICATIONS: RFA, NIAID-80-4

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

TITLE: *TROPICAL DISEASE RESEARCH UNITS*

The subject RFA, published in the *NIH Guide for Grants and Contracts*, Vol. 9, No. 4, March 14, 1980, has been withdrawn. The Institute has reassessed its support of this field of research and decided that in the immediate future no additional resources can be allocated to tropical disease research.

PRICE INCREASE ON FISCHER 344 RATS



NATIONAL INSTITUTE ON AGING

Investigators currently using Fischer 344 rats from the National Institute on Aging (NIA) contract supported colonies are hereby notified that an increase in the per diem cost of the Fischer 344 rats reared and maintained under commercial contract for the NIA became effective on March 1, 1980. Letters to investigators were sent from the NIA on February 25, 1980. Investigators on new and renewal applications should use the new cost figures in estimating cost needs on grant applications.

Virgin male and female rats currently cost \$2.60 per month of age. The cost for these animals will increase to \$3.16 per month of age. Therefore, the cost of a 24 month old virgin Fischer 344 rat will be \$75.84.

Retired breeder male rats now cost approximately \$2.90 plus the cost of acquisition at nine months of age. This price will increase to \$3.16 per diem costs plus the acquisition cost of approximately \$4.44. The cost of a 24 month old retired breeder male Fischer 344 rat will now be approximately \$51.84. These animals are slightly less because they are maintained under the contract for a shorter period of time.

Prices are subject to market fluctuations, and are charged at the per diem rates set by the contract. Notices of change will be printed in this publication and individually to current users.

Questions concerning these price changes should be directed to:

Program Chief
Biophysiology and Pathobiology
Aging Program
Biomedical Research and Clinical Medicine
National Institute on Aging
Room 5C-35, Building 31
Bethesda, Maryland 20205

CLINICAL INVESTIGATOR AWARD



NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The National Institute of Child Health and Human Development (NICHD) supports research on maternal and child health and on research in the reproductive sciences.

The National Institute of Child Health and Human Development announces the availability of NICHD Clinical Investigator Awards in the following selected areas relevant to maternal and child health and to the reproductive sciences:

Pediatrics
Clinical Nutrition
Obstetrics and Gynecology
Reproductive Biology
Andrology

These awards provide the opportunity for promising, clinically trained individuals with demonstrated aptitude for research to develop into independent biomedical investigators in several clinical areas relevant to maternal and child health and to the biology and medicine of reproduction.

The award, made to an academic or non-profit research institution, is designed to foster growth of superior candidates toward independent research. It enables candidates to investigate, for up to three years, a well-defined problem with a sponsor, or sponsors, competent to provide guidance in a chosen area of research. It is planned that this award would provide a transition between fellowship or trainee experience and a career as an independent investigator. The Clinical Investigator award differs from the NIH Research Career Development Award in that it seeks to develop research ability in individuals with clinical background and training rather than to foster the further development of research skills of individuals already having shown significant research achievement.

This program is described in the Catalog of Federal Domestic Assistance numbers 13.864 and 13.865. Awards will be made under the authority of the Public Health Service Act, Title X, Section 1004 (Public Law 91-572, as amended; 42 USC 241) and 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 A-95 Clearinghouse or Health Systems Agency review.

ELIGIBILITY

Candidates are restricted to those holding health-professional degrees in the clinical sciences M.D., D.O., D.V.M., or Doctorates in nursing with four to seven years of total professional postdoctoral clinical and research experience by the projected start of the award. It is expected that candidates will have a minimum of two years of clinical experience and two years of research experience. In exceptional circumstances, individuals with less than four, and more than seven years of such experience may apply, but those special circumstances must be justified. The award is designed to provide intensive guided research experience for clinicians.

Individuals holding the academic position of associate professor or professor at the time of award are not eligible for the Clinical Investigator Award with the exception of doctorates in nursing. The Clinical Investigator Award will be terminated if the recipient becomes a principal investigator on a PHS supported project during the tenure of the award. Candidates should have broad training and should demonstrate individual competence in clinical activities and show research potential in the chosen area of interest. Candidates should also provide evidence of a serious intent for an academic career related to that area.

A non-citizen is not eligible to apply unless lawfully admitted to the United States for permanent residence. Determination of the acceptability of applications is made by the National Institutes of Health.

The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established, research and training programs in the chosen area. Adequate numbers of highly-trained faculty in the clinical and basic departments relevant to the chosen area, and interest and capability to provide guidance to clinically trained individuals in the development of research independence are also of great importance.

CONDITIONS OF THE AWARD

The Clinical Investigator Award is made on an annual basis, with additional years of recommended support, for a maximum non-renewable and non-transferable period of three years. Support is based on a full-time, twelve-month, staff appointment. The awardee will be provided salary support not to exceed \$30,000 annually from NICHD funds for the three-year period. The actual salary must be consistent with the established salary structure of the institution for persons of equivalent qualifications, experience, and rank.

The institution may supplement the awarded salary consistent with the institution's salary scale. No supplementation may be provided from Federal funds unless explicitly authorized by the program from which funds are to be derived. In no case may other NIH funds be used as a means of additional salary support.

In addition to the base salary, the institution's share of fringe benefits as are available to all other staff members of comparable rank at the institution, under established and consistently applied institutional policies, may be paid from award funds to the extent that they are consistently treated by the institution as direct rather than indirect costs.

The applicant is expected to spend a minimum of 75% of time in research. An appropriate sponsor (or sponsors) must assume responsibility and provide guidance for the research training in the chosen area.

Up to a total of \$10,000 annually will be provided for supplies, equipment, travel, tuition for training courses, etc., which are necessary for pursuit of the awardee's research program.

Funds will be provided for the reimbursement of actual indirect costs at a rate of up to, but not to exceed, 8% of the total direct costs of each award, exclusive of tuition, fees, and expenditure for equipment.

REVIEW PROCEDURES AND CRITERIA

Applications for the Clinical Investigator Award receive initial scientific merit review by an NIH peer review panel, and subsequently by the National Advisory Council on Child Health and Human Development. Elements for review include:

- the applicant's training in research and clinical experience in the specified area of interest;
- the applicant's proposed research project;
- the applicant's plan, potential, and commitment for a career in independent research in the area proposed;
- the commitment of the applicant's institution to provide the necessary facilities and opportunities essential to the applicant's research development;
- the background, ability and caliber of the sponsor or sponsors to provide the necessary guidance and experience to the career development of the applicant in clinical research;
- the presence of other highly trained faculty in clinical and basic departments relevant to the applicant's area of study.

APPLICATION PROCEDURE

To apply for the NICHD Clinical Investigator Award use application form PHS 398. (Note: This is the standard research grant application form.) If your institution's business office does not have this form, you can request it by writing to the Office of Grant Inquiries, Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205, or by calling (301) 496-7441.

Applications for Clinical Investigator Awards must be received by the National Institutes of Health for review by the following receipt dates:

<u>Application Receipt Dates</u>	<u>Initial Review</u>	<u>Council Meeting</u>	<u>Approximate Start Date</u>
October 1	February/March	May	July 1
February 1	June	September/October	December 1
June 1	October/November	January/February	April 1

Type the phrase NICHD CLINICAL INVESTIGATOR AWARD on the front page of the application.

Special instructions for preparing applications to the NICHD Clinical Investigator Award Program must be obtained from NICHD. Address inquiries to:

Deputy Director
National Institute of Child Health
and Human Development
Room 2A-04, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-1848

NIH - FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH

PROGRAM FOR SCIENTIFIC COLLABORATION

FOGARTY INTERNATIONAL CENTER



PROGRAM DESCRIPTION

Under an agreement between the U.S. National Institutes of Health (NIH) and the French National Center for Scientific Research (CNRS), the two organizations share in the support of well-qualified U.S. scientists selected to work at laboratories in France and similar French scientists selected to work at U.S. laboratories. The purpose of the program is to advance biomedical knowledge through cooperation between U.S. and French scientists in fields of special interest to the NIH and CNRS. Approximately five scientists of each country will be exchanged annually. It is expected that these exchanges will serve as the basis for further and continuing substantive joint relationships, such as collaborative research projects and seminars.

The type of activity undertaken with a host laboratory may include the conduct of a basic or clinical research study, familiarization with or utilization of special techniques and equipment not otherwise available, and/or related cooperative efforts. The program does not provide support for activities which have as principal purposes brief observational visits, attendance at scientific meetings, or independent study. Priority will be given to certain biomedical areas specified by the NIH and the CNRS. (See attachment.)

The period of interaction of the foreign scientist with the host institution is expected to be of sufficient duration to achieve substantive, specific goals. Except under very unusual and strongly justified circumstances, the minimum period of support will be for 6 months and the maximum, 12 months. Requests for extension beyond 12 months will be considered.

The program is administered for the NIH by the Fogarty International Center (FIC).

ELIGIBILITY

U.S. applicants for the program must meet the following basic requirements:

- be a U.S. citizen or permanent U.S. resident;
- hold a doctorate degree in one of the biomedical sciences or related fields;
- have had professional experience in the health or biomedical fields appropriate to the proposed study;
- be affiliated with a U.S. public or private nonprofit educational, research, or clinical institution.

Working knowledge of the French language is highly desirable. It is primarily the responsibility of the applicant to ascertain if a language barrier might exist at the proposed foreign institution which would be a significant hindrance. Prospective long-term participants are urged to study the language intensively in preparation for their visits.

SUPPORT

Under the agreement between the two agencies, the sending side pays for all international transportation costs to the place of assignment and the receiving side provides in-country support costs. For U.S. participants, the following pertain:

- Travel The FIC will provide round-trip, jet economy class fare for the participant between the U.S. home city and the French host city. Travel will be in accordance with U.S. Government travel regulations, which require maximum use, where available, of U.S. air carriers. Additional costs of indirect routing at the option of the participant must be at his personal expense. An allowance for 22 pounds or unit of excess accompanied baggage will also be included. A travel allowance for dependents cannot be provided.
- Subsistence The CNRS will provide a subsistence allowance at the rate of 3,000 to 5,000 francs per month as determined on the basis of the research experience of the participant, the number of accompanying dependents, and the cost of living in the locale where he or she works. The CNRS will also provide for the costs of travel within metropolitan France and to and from European centers in neighboring countries to the extent that such travel is judged by the host institution to be required for research or study program of the participant.
- Health Insurance The CNRS will provide the participant and any officially accompanying family members with comprehensive health care for accidents or unanticipated medical needs during their stay in France.

Support for French participants for work in the U.S. under the auspices of the program is provided in a reciprocal manner.

DURATION OF PARTICIPATION

The period of participation which may be initially requested is a minimum of 6 months up to a maximum of 12 months. Requests for extension beyond 12 months will be considered.

APPLICATION AND SELECTION

Specific application information and material for U.S. health professionals interested in participation are provided by the Fogarty International Center. In addition to biodata and other supporting documentation, the applicant will

be required to submit a summary narrative description of the proposed activity to be carried out in France and of the expected benefits to be derived from the experience. It is expected that in most instances the applicant will have had prior contact with a colleague in France who can serve as host and be able to provide necessary facilities.

After initial scientific review by the Division of Research Grants, final selection of U.S. participants from among applicants is made by the Fogarty International Center with the concurrence of CNRS authorities in accordance with the number of participants agreed to and funding availability. Notification of selection decisions is made to U.S. applicants by the Fogarty International Center.

The deadline for receipt of applications of U.S. scientists is October 1 for projects beginning at the earliest the following July or during the 12 months thereafter. Because of advance scheduling for the limited number of participants permitted annually, it may be necessary to defer or to decline consideration of applicants at certain times.

PASSPORTS AND VISAS

It is the responsibility of the individual U.S. participant to obtain his or her passport. The Fogarty International Center will assist the participant in applying for the appropriate French visa if necessary.

REPORTS AND PUBLICATIONS

U.S. participants must submit a summary report to the Fogarty International Center following their visit which covers the work accomplished. Technical articles may be submitted to scientific publications without prior clearance of the NIH or CNRS authorities. However, the support of the program should be acknowledged.

INQUIRIES AND APPLICATION MATERIALS

For U.S. applicants:

NIH-French CNRS Program for Scientific Collaboration
International Cooperation & Geographic Studies Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5903

U.S. NIH - FRENCH CNRS PROGRAM FOR BIOMEDICAL SCIENTIFIC COLLABORATION

PRIORITY INTEREST AREAS

The following areas are of priority interest to NIH and its component Institutes for support of U.S. scientists for work in France under the program:

- NHLBI Lung Diseases:
- Structure, function, and development of the lung
 - Emphysema and chronic bronchitis
 - Fibrotic and immunologic interstitial lung diseases
- Blood Diseases and Blood Resources:
- Bleeding and clotting disorders
 - Disorders of the red blood cell
 - Development of blood component therapy
- NCI ● Diseases of the lung - particularly basic and clinical research on lung cancer
- Nucleic acids - research pertaining to radiation, viral, or chemical carcinogenesis, e.g., misrepair and repair of DNA
 - Toxicology - testing, screening, and mechanism of action of mutagenic and carcinogenic substances
- NICHD Center for Population Research:
- Reproductive hormones and reproductive diseases
 - Fertility; fertility trends; demography; population change, movement, and distribution
- Center for Research for Mothers and Children
- Problems of pregnancy, embryonic and fetal growth, labor and neonatal adaptation
 - Congenital anomalies; structural, metabolic, and behavioral
- NIA ● Basic biomedical science
- Retirement
 - Animal resources

- NINCDS
 - Neurophysiology
 - Clinical investigation
 - Sensory physiology and biophysics

- NIAID
 - Molecular biology
 - Immunology
 - Arbovirology

- NIEHS
 - Pharmacology
 - Environmental mutagenesis
 - Environmental toxicology

The following areas have been identified by the CNRS for the support of French scientists for work in the U.S.:

- Pneumology
- Structure and sequences of nucleic acids
- Microbiology
- Dermatology
- Toxicology

LIVER DISEASES RESEARCH



NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM,
AND DIGESTIVE DISEASES

Many problems of basic and clinical importance have been cited in the report of the National Commission on Digestive Diseases.* Some of these problems are likely to be solved in the coming decade if basic and clinical investigators concentrate on some of the areas delineated below. Obviously, this is neither a comprehensive nor restrictive list. Rather, it may provide some indication of the broad area of research that the Liver Diseases Program of the National Institute of Arthritis, Metabolism, and Digestive Diseases supports and wishes to expand.

1. Humoral and cell-mediated immune mechanisms as involved in the pathogenesis of liver disease--
 - a. Immunogenic determinants of liver membranes.
 - b. Basic information regarding the relationship of the immune systems to:
 - (1) the production of inflammatory reactions; and
 - (2) the pathogenesis of chronic disease.
 - c. Better methods for isolation of lymphoid cells from liver and improved in vitro assays for cytotoxicity.
2. Fundamental problems in liver cell biology such as--
 - a. Role of cytoskeleton in hepatocyte structure and function.
 - b. Nature of liver membranes and their role in uptake, metabolism and secretion of substances.
 - c. Role of junctional complexes and gap junctions in intercellular interactions.
3. Study of the distinctive excretory and detoxification functions of the liver cell which should yield new approaches to the treatment of--
 - a. Cholestatic conditions, in which the secretory processes are impaired:

*DHEW Publication No. (NIH) 79-1885, Volume IV, Parts 2A + B.
For sale by Superintendent of Documents, U.S. Gvt. Printing Office,
Washington, D.C. 20402. Stock Number 017-045-00090-3

- (1) sequences involved in transport of substances from the sinusoid to the canaliculus; and
 - (2) the role of intracellular proteins and lipids in conveying and activating bound substrates.
- b. Acute intoxications in which the biotransformation apparatus is overwhelmed:
 - (1) regulation of hepatocellular transport and biotransformation by GI hormones and by bile acids; and
 - (2) therapeutic approaches such as: developing safe inducers of the metabolism enzymes, enhancing alternate pathways of metabolism and transport, modifying intestinal flora to selectively prevent deconjugation of polar metabolites, or improving specificity of binding resins for external hemoperfusion.
4. The nature of acute hepatic failure needs to be identified so that specific treatment can be formulated. Problems that need to be tackled are--
 - a. Identifying toxins that are accumulating.
 - b. Defining essential metabolites that become deficient.
5. Chronic liver disease continues to be a major killer yet effective treatment is limited to steroid treatment of some chronic active hepatitis and to removal of alcohol, iron, copper and galactose when they are the offending agents. We need to learn--
 - a. The mechanism and regulation of regeneration by the liver cells.
 - b. The natural history of the various forms of these diseases.
 - c. Improved methods for evaluating hepatic necrosis, inflammation and fibrosis.
 - d. Development of animal models for chronic viral, immunological and drug hepatitis.
 - e. Mechanism(s) whereby acute, self-limited liver disease, is transformed into chronic active hepatitis or massive hepatic necrosis.
6. Genetic liver diseases provide unusual opportunities to learn about normal metabolic processes and their disorders. There is need to examine--
 - a. Specific metabolic defects responsible for genetic liver diseases and the mechanisms by which the defects result in liver damage.

b. Methods for overcoming enzyme deficiencies by:

- (1) administration of substrates, cofactors or inhibitors;
and
- (2) replacement of enzymes by artificial (liposomes) or natural
(liver cell or organ transplantation) means.

This list is neither complete nor exclusive, but merely tabulates some of the opportunities which were published in the National Commission on Digestive Diseases report.

In making this program announcement, it is not the intent of the National Institute of Arthritis, Metabolism, and Digestive Diseases to make or imply any delimitation related to these areas of research, but rather to stimulate investigator-initiated research in liver disease.

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 described in the Catalog of Federal Domestic Assistance number 13.848. It is not subject to A-95 Clearinghouse or Health Systems Agency review.

Applications in response to this announcement will be reviewed on a nation-wide basis in competition with each other, and in accord with the usual National Institutes of Health peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants. Following this initial review, the application will be evaluated for program relevance by the National Advisory Council of the Institute. The review criteria customarily employed by the National Institutes of Health for regular research grant applications will prevail.

APPLICATION RECEIPT DATES

Applications will be accepted in accordance with the usual NIH receipt dates for new applications:

July 1

November 1

March 1

METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions or from the Division of Research Grants, NIH. The phrase, "PREPARED IN RESPONSE TO PROGRAM ANNOUNCEMENT ON LIVER DISEASES RESEARCH, NIAMDD" should be typed across the top of the first page of the application.

Additionally, a brief covering letter should accompany the application indicating it is being submitted in response to this program announcement.

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The original and six copies of the application should be sent or delivered to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Room 240, Westwood Building
Bethesda, Maryland 20205

For further information, investigators are encouraged to contact:

Dr. Sarah C. Kalser
Liver Diseases Program Director
Room 602, Westwood Building
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7858

In order to alert the Liver Diseases Program to the submission of proposals with primary thrust directed to liver diseases research, a copy of the covering letter should be sent under separate cover to Dr. Kalser.