NIH GUIDE for GRANTS and CONTRACTS

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

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IN THIS ISSUE:

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.

IN THIS ISSUE: (continued)

REVISED INSTRUCTIONS FOR COMPLETION OF RESEARCH GRANT APPLICATIONS (Form PHS 398)

NOTICE

In the near future, there will be published a revised version of the grant application form PHS 398 that will encourage more concise presentations of Research Plans. The National Institutes of Health (NIH) is prepared to do all it can to help investigators accommodate to the new form.

IMPORTANT Institution business or application control offices who have on hand a supply of research grant application kits (forms NIH or PHS 398) should request a similar supply of the revised instruction flyer (see below) for insertion in those kits. Call or write:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7441

THE FOLLOWING CHANGES ARE EFFECTIVE IMMEDIATELY FOR ALL NIH RESEARCH GRANT APPLICATIONS, OTHER THAN THOSE LISTED ON PAGE 1 OF THE CURRENT INSTRUCTION SHEET FOR FORM PHS 398, DATED FEBRUARY 1973, FOR WHICH SUPPLEMENTAL INSTRUCTIONS ARE AVAILABLE. FOLLOW CAREFULLY THE REST OF THE CURRENT INSTRUCTIONS.

1. Provide biographical sketches only for the key professional personnel engaged on the project. Do not exceed 2 pages for each individual.

2. Ignore Sections A through D on pages 8-9 of the current Instructions for form PHS 398. Instead, organize the Research Plan to answer these questions:

   WHAT do you intend to do? WHY is the work important? WHAT has already been done? HOW are you going to do the work?

   Include sufficient information to facilitate an effective review without reference to any previous application. Be specific and informative and avoid redundancies. Reviewers often consider brevity and clarity in the presentation as indicative of a

principal investigator/program director's approach to a research objective and ability to conduct a superior program. THOSE WHO FIND IT ABSOLUTELY ESSENTIAL TO EXCEED THE PAGE LIMITATIONS STIPULATED MUST EXPLAIN WHY IN A STATEMENT AT THE BEGINNING OF THE RESEARCH PLAN.

The suggested format is as follows:

A. Specific Aims State concisely and realistically what the research described in the application is intended to accomplish and/or what hypothesis is to be tested. Do not exceed one page.

B. Significance Briefly sketch the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. State concisely the importance of the research described in the application by relating the specific aims to longer term objectives. Do not exceed three pages.

C. Progress Report/Preliminary Studies A progress report is required for COMPETING CONTINUATION and SUPPLEMENTAL applications. NEW applications may employ this section to provide an account of the principal investigator/program director's preliminary studies pertinent to the application and/or any other information which will help to establish the experience and competence of the investigator to pursue the proposed project.

For COMPETING CONTINUATION and SUPPLEMENTAL applications, give the beginning and ending dates for the period covered since the project was last reviewed competitively. List all professional personnel who have worked on the project during this period, their titles, their dates of service and percentage of time or effort. Summarize the previous application's specific aims and provide a succinct account of published and unpublished results indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the project's specific aims during the previous project period. List the titles and complete references to all publications, completed manuscripts, patents, invention reports, and other printed materials that have resulted since the project was last reviewed competitively. Submit six copies of each publication and completed manuscript as an APPENDIX. Graphs, diagrams, tables, and charts relevant to the progress report should also be submitted as APPENDIX material. NEW applications may also list and have appended to them six sets of similar background material pertinent to the application. Do not exceed eight pages for the progress report/preliminary studies, excluding the lists of professional personnel and publications and the APPENDIX.

D. Methods Discuss in detail the experimental design and the procedures to be used to accomplish the specific aims of the work described in the application. Describe the protocols to be used and the tentative sequence of the investigation. Include the means by which the data will be analyzed and interpreted. Describe new methodology and its advantage over existing methodology. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Include information about species of animals to be used. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. Although no page limitation is specified for this part of the application, make every attempt to be succinct.

3. Literature Cited Mention the principal author's name when citing literature in the text, but provide the complete references in a list at the end of the Research Plan. Do not scatter references throughout the text. The list may include, but may not replace, the list of publications in the progress report required for COMPETING CONTINUATION and SUPPLEMENTAL applications. Each citation must include the names of all authors, the name of the book or journal, volume number, page numbers, and year of publication. Although no page limitation is specified for this part of the application, make every attempt to be judicious in compiling the bibliography. It should be relevant and current. It need not be exhaustive.

4. Appendix Six sets of the appendix material should be included in the application package. Do not mail this material separately. Identify each of the six sets with the name of the principal investigator/program director and the project title. Appendix material will not be duplicated with the rest of the application, but will be made available to the primary reviewers and to any other reviewer who specifically requests it. For COMPETING CONTINUATION and SUPPLEMENTAL applications, submit six sets of all publications and completed manuscripts that have resulted from this project since it was last reviewed competitively. NEW applications may also have appended to them six sets of similar background material pertinent to the application. For ALL applications, photographs, oversized documents or materials that do not reproduce well should also be submitted in six sets. Graphs, diagrams, tables, and charts may also be submitted as APPENDIX material.

RESPONSE TO THE REQUEST FOR NOMINATIONS FOR MEMBERS OF NIH SCIENTIFIC REVIEW GROUPS

NOTICE

The announcement describing the NIH peer review system and requesting nominations for upcoming vacancies on NIH scientific review groups was published in the *NIH Guide for Grants and Contracts*, Vol. 8, No. 2, January 31, 1979.

NIH is now in the process of requesting each responder to provide a curriculum vitae and to complete an information form designed for computer processing. A file of potential consultants is being developed. Names will be referred to the staff of the review groups designated by the responder. In addition, the entire file will be available to NIH staff to supplement the usual sources of information used to select review group members and to identify site visitors and special reviewers.

The response received by NIH has been very large; over 8,000 names have been received. The number of vacancies on scientific review groups is approximately 400 for terms beginning July 1, 1980. All responses received will be kept in an active file for one year. At that time the NIH will contact all those in the file to determine whether they wish their names to be retained in the system.

AVAILABILITY OF "EXCHANGE-LABELED TRITIATED SAXITOXIN" FOR BIOMEDICAL RESEARCH PURPOSES

NOTICE

The National Institutes of Health for some time has been making saxitoxin available to qualified biomedical researchers. This program will continue as long as the supply lasts.

In addition, upon the recommendation of the Toxicology Study Section, Division of Research Grants, NIH, it has been undertaken (with the kind assistance of Professor J. Murdoch Ritchie, Yale University School of Medicine) to prepare and make available to meritorious researchers, a batch of radioactively-labeled saxitoxin.

A description of this batch of saxitoxin follows:

> "The saxitoxin concentration in the solution supplied is 0.9 mM. The apparent specific activity is 18.9dpm/fmole. The radiochemical purity is 0.48 and the true specific radioactivity is 9.1dpm/fmole. Binding of this preparation to rabbit brain is comparable (as far as saturable and linear binding components are concerned) to those obtained with purer samples of saxitoxin (for discussion on purity, see Ritchie and Rogart, 1977, Reviews of Physiology, Biochemistry, and Pharmacology, 79, 1-50). If further purification is required, the method described by Henderson, Ritchie and Strichartz (J. Physiol. 1973, 235, 783-804) may be used. The toxin must be stored in a freezer (non-defrosting); and experiments using it should be done at low temperatures to minimize back exchange of tritium into water."

The tritiated saxitoxin is available in 0.5 ml vials, each containing 3.56 mc.

For detailed information concerning how and where to apply for an allocation of either saxitoxin or tritiated saxitoxin, interested investigators should contact:

Dr. Raymond Bahor
Executive Secretary
Toxicology Study Section
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7570

RESEARCH SUPPORT FOR COMPUTERS IN MEDICINE, NATIONAL LIBRARY OF MEDICINE

ANNOUNCEMENT

INTRODUCTION

The National Library of Medicine plans to continue its computer-in-medicine program which was initiated in fiscal year 1979. In that year, following an intensive review of proposals, four research program projects were selected for award. NLM plans to fund several additional projects in fiscal year 1980. Applicants are asked to submit proposals by November 1, 1979, so that they may compete for possible FY 1980 funds.

BACKGROUND

The National Library of Medicine has traditionally sponsored research leading to improved utilization and communication of medical information. Results of these efforts include a series of major medical bibliographic databases, a variety of projects at the Lister Hill National Center for Biomedical Communications, and a wide array of research and development activities sponsored by grants.

Recently, a distinguished task force recommended further NLM efforts to foster the growth and advance of the computer sciences in the health field. NLM has endorsed and accepted this recommendation as a logical extension of its long-term goals.

The support of major studies in this field should make possible the investigation of significant questions. These efforts should also contribute to a productive institutional environment which will attract creative minds from a variety of disciplines and specialties. Appropriate disciplines include the computer sciences and related fields such as computational linguistics, medicine in its various specialties, the information sciences including librarianship, educational psychology, and operations research, among others. Collaborative endeavors will surely lead not only to the discovery of new knowledge but also to expedited dissemination and adaptation of the knowledge gained. To attain major significant results, support can be provided for up to five years.

Areas of interest to the National Library of Medicine include, but are not limited to, artificial intelligence in clinical decision-making, human and machine languages in computer systems, retrieval mechanisms for medical knowledge databases, computer-student interaction in health education, human cognition and machine-assisted learning, improved man-machine interfaces, and behavioral implications of access to major automated information

and communication systems. It is expected that these research activities will result in important contributions to the literature, to the dissemination into practice of theoretical discoveries, and to the cohesiveness of the health computer sciences field. NLM-sponsored studies are intended as scientific investigations to gain new knowledge; consequently, primary engineering development leading to new devices or equipment would be less relevant to the program goals.

PROGRAM MECHANISM

A program objective is to promote research in an environment of fruitful interdisciplinary collaboration. Investigators, therefore, should not be unduly restrained by the specifications of an award mechanism. It is intended to administer the program flexibly and constructively. Several approaches are available to applicants, such as the following:

Research Project Grant A major study could take the form of a single research project of sufficient scale to address a large problem. The project application would follow the usual organization of a typical NIH research grant proposal. A grant could support a principal investigator and a multidisciplinary team of associates at various levels.

Program Project Grant A program project application could request support for a group of separately identifiable, discrete research subprojects which have a common focus. Such proposals would include one or more core projects to support and integrate the overall effort. The program project principal investigator and the investigators of the subprojects would function as members of a coordinated research team. Proposals should explain the following:

- The rationale and justification of the broad program contemplated, with a description of resources and facilities already available.
- The hypothesis and methodology for each proposed core project and subproject.
- Related career development support for project team members, if any.
- Subproject budgets and a consolidated budget.

APPLICATION

Applicants should submit proposals by November 1, 1979, on application form PHS 398. Application forms may be obtained in institutional application control offices or upon request from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Room 448, Westwood Building
Bethesda, Maryland 20205

REVIEW PROCESS

An initial review group will submit recommendations to the Board of Regents of the National Library of Medicine. Reviewers will expect a carefully defined methodology or procedural statement which gives evidence that the research will yield significant results of interest to the biomedical scientific community. Reviewers will also seek evidence of a favorable institutional environment.

The National Library of Medicine cannot be certain at this time that funds will be available to support new proposals in FY 1980. If the necessary funds do not materialize, NLM will notify the interested community as soon as possible. In the interim, the applications received will be reviewed in the normal review cycle, as described above. Applications recommended for approval will be considered for payment from FY 1980 funds, if available, or will be held over for possible payment in the succeeding year.

Because of the special nature of this program, interested persons are encouraged to discuss project ideas with NLM program staff. For further information, write or telephone:

Computers-in-Medicine
Extramural Programs
National Library of Medicine
Bethesda, Maryland 20209

Telephone: (301) 496-4221

MULTIPURPOSE ARTHRITIS CENTERS, NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

ANNOUNCEMENT

This announcement by the National Institute of Arthritis, Metabolism, and Digestive Diseases supersedes previous announcements for Multipurpose Arthritis Centers published in the *NIH Guide for Grants and Contracts*, Vol. 5, No. 20, November 30, 1976; Vol. 6, No. 4, March 1, 1977; and Vol. 6, No. 16, August 17, 1977. Revised guidelines to prepare an application for this Centers program are available immediately.

A Multipurpose Arthritis Center is defined as a resource which consists of the facilities of a single institution or a consortium of cooperating institutions through which a group of formally cooperating health personnel can be brought together to demonstrate and foster the prompt and effective application of available knowledge and the development of urgently needed new knowledge. Each application must include activities in three major fields: research, education, and community-related activities.

Each Center, in accord with the National Arthritis Act of 1974, should carry out the following:

A. conduct basic and clinical research into the cause, diagnosis, control, and treatment of arthritis and complications resulting from arthritis, including research into implantable biomaterials and biomechanical and other orthopedic procedures and in the development of other diagnostic and treatment methods;

B. conduct training programs for physicians and other health and allied professionals in current methods of diagnosis, control, and treatment of arthritis, and in research in arthritis;

C. conduct information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis; and

D. conduct programs for the education of patients, and for the dissemination of information to the general public.

All applications should be prepared in accordance with the revised guidelines (June 1979). In order that the Institute staff be of maximum assistance, potential applicants are requested to submit a letter of intent before making application.

The Multipurpose Arthritis Centers Program is established under authority of Part D of Title IV of the Public Health Service Act as amended by the National Arthritis Act of 1974 (P.L. 93-640; 42 USC 289c) and the Arthritis, Diabetes, and Digestive Disease Amendments of 1976 (P.L. 94-562; 42 USC 289c).

The National Institute of Arthritis, Metabolism, and Digestive Diseases plans to make awards for the Centers program contingent upon the appropriation of funds and in accordance with an appropriate peer review.

Receipt dates for applications and respective letters of intent are:

Letter of Intent	Application
November 1	February 1
March 1	June 1
July 1	October 1

The letter of intent plus one copy should be sent to:

Associate Director for Extramural Activities Program
National Institute of Arthritis, Metabolism, and
Digestive Diseases
National Institutes of Health
Bethesda, Maryland 20205

Copies of the revised guidelines and grant application kits (form PHS 398) as well as further information about the program are available from:

Multipurpose Arthritis Centers Program Director
National Institute of Arthritis, Metabolism, and
Digestive Diseases
National Institutes of Health
Room 403, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7495

THE EFFECTS OF SMOKING ON THE BLOOD AND CARDIOVASCULAR AND RESPIRATORY SYSTEMS, NHLBI

ANNOUNCEMENT

The National Heart, Lung, and Blood Institute is interested in expanding research activities on the effects of smoking tobacco on the cardiovascular system, on the respiratory system, and on the hemostatic properties of the blood.

The recent report of the Surgeon General on the Health Consequences of Smoking documents many acute and chronic adverse effects of tobacco smoking on aspects of health and disease that are the responsibility of the National Heart, Lung, and Blood Institute. Many opportunities for further research exist.

Areas of particular interest include the effects of smoking on: the function of the sympathetic nervous system with respect to cardiovascular events; normal and ischemic cardiac conduction, metabolism, and function; coronary, cerebral, peripheral, and pulmonary circulation; malignant hypertension; the pharmacokinetics of appropriate smoke components; mechanisms pertinent to atherogenesis; effects on lipoprotein metabolism; platelet physiology and the thrombotic process; interactions between chemicals in smoke and hemoglobin structure and function; and mechanisms responsible for development of chronic obstructive lung disease. Studies on the acute or chronic toxicity of gaseous and particulate components in cigarette smoke in relation to cardiovascular or respiratory disease and studies on smoking avoidance, cessation, and long term maintenance of smoking cessation particularly in those at high risk of cardiovascular or respiratory disease are also of interest.

The areas of interest noted above do not preclude the submission of applications involving other research problems relevant to the general subject of smoking and cardiovascular and pulmonary disease.

Application Submission and Review

Application receipt dates are November 1, 1979; March 1, 1980; and July 1, 1980. Applications received after any one receipt date are considered and reviewed together with those received by the next receipt date. The earliest possible award date is approximately nine months after the receipt date.

This program is described in the Catalog of Federal Domestic Assistance under numbers 13.837, 13.838, and 13.839. 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.

National Institutes of Health peer review procedures will be followed for all responses to this announcement. Applicants should use the regular research grant application form PHS 398 which is available at institutional central application control offices. Please identify grant applications submitted in response to this announcement by writing at the top of the face sheet of the application "SUBMITTED IN RESPONSE TO NHLBI PROGRAM ANNOUNCEMENT ON EFFECTS OF SMOKING." The completed application should be mailed to:

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

All applications will be assigned for consideration and review by the Division of Research Grants according to the NIH process for regular research grants. Approved applications will compete for available funds with all other approved applications assigned to the National Heart, Lung, and Blood Institute.

Additional information may be obtained by contacting:

Dr. G. C. McMillan
Division of Heart and Vascular Diseases

Telephone: (301) 496-1613

Dr. Suzanne Hurd
Division of Lung Diseases

Telephone: (301) 496-7440

RESEARCH FELLOWSHIPS TO SWEDEN, SWITZERLAND, AND FRANCE, FOGARTY INTERNATIONAL CENTER

ANNOUNCEMENT

The Fogarty International Center, NIH, has been asked to announce that the Swedish Medical Research Council, the Swiss National Science Foundation, and the French National Institute of Health and Medical Research (INSERM) each will make available in 1980 several postdoctoral research fellowships to qualified U.S. biomedical scientists. These fellowships will provide training in basic or clinical medical research.

Application materials may be obtained from the Scholars and Fellowships Program Branch, Fogarty International Center, NIH. The final receipt date of completed applications for the Swiss and Swedish programs will be February 1, 1980. The receipt date for the French program will be December 1, 1979. Applications will be reviewed for scientific merit at the Fogarty International Center. They will be forwarded to the appropriate countries for final selection.

SODIUM FLUORIDE IN THE TREATMENT OF SENSORINEURAL HEARING LOSS IN OTOSCLEROSIS, NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

ANNOUNCEMENT

The Communicative Disorders Program (CDP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is inviting grant applications from interested investigators for the purpose of conducting a controlled objective study of the efficacy of sodium fluoride in the treatment of sensorineural hearing loss due to otosclerosis.

I. BACKGROUND INFORMATION

Otosclerosis is a well-documented cause of adolescent to adult onset conductive hearing loss secondary to a focus of pathology in the stapedial footplate. There is evidence that indicates that involvement of the otic capsule by otosclerotic foci can lead to damage of the cochlea and sensorineural hearing loss. Histological studies have documented: (1) the cyclic nature of the destructive/resorptive phase and the deposition of mucopolysacchride and new bone phase, and (2) formation of highly mineralized bone in otosclerotic foci. Hydrolytic enzymes thought to be released from the otosclerotic foci have been suggested as possible causes for the sensorineural component of the hearing loss in some otosclerotic patients. Medical therapy with sodium fluoride has been suggested by some investigators to be beneficial in promoting maturation of existing otoslcerotic foci and preventing progression of sensorineural loss due to cochlea involvement. The study of otosclerosis presents several problems including the lack of an animal model, the dearth of information concerning the molecular biology of otosclerosis, and the minute quantities of bony tissue available for study.

II. GOALS AND SCOPE

It is the intent of the Institute that potential investigators retain the freedom to design a scientifically meritorious study utilizing the attributes of the investigator's institution(s) and patient population(s). A cooperative agreement between two or more institutions may constitute an acceptable response to this

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This program is described in the Catalog of Federal Domestic Assistance number 13.851. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410 as amended; 42USC 241 and administered under PHS grant policies and Federal Regulations 42 CFR Part 52.

announcement. In the design of an objective clinical trial many requirements should be met including, but not limited to: (1) an operational definition of the disease; (2) objective documentation of the disease (validity and reliability of observations); (3) appropriate randomization techniques; (4) documentation of control for other disorders or factors which may affect the natural course of the disease, the metabolism of pharmacologic agents, etc.; (5) an operational definition of successful treatment.

III. REVIEW PROCEDURES AND CRITERIA

A. Review Procedures

Applications will be reviewed initially for scientific merit in the Division of Research Grants by an NIH peer review group and secondly by the National Advisory Neurological and Communicative Disorders and Stroke Council (NANCDSC).

B. Review Criteria

Factors considered in evaluating each application will be:

1. Relevance of proposal to the scope and objectives provided in this announcement.
2. Merit of proposed approaches to the problem.
3. Expertise and qualifications of the proposed staff.
4. Commitment of time by proposed staff.
5. Evaluation plan and timetable.
6. Evaluation of resources and environment.

IV. METHOD OF APPLYING

A. Application Format

Applications should be submitted on form PHS 398. The conventional presentation for grant applications should be utilized. The PHS 398 kit is self-explanatory. If the institution's business office or central application control office does not have this form, an individual copy may be requested by writing to:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

or by calling (301) 496-7441.

B. **Application Procedure**

Prospective principal investigators are urged to contact the Communicative Disorders Program (Dr. Rolf F. Ulvestad) prior to the submission of a formal application.

The standard procedures for submitting grant applications to DRG should be followed. A brief letter should accompany the application indicating that it is in response to the program announcement, NINCDS-CDP on Fluorides and Sensorineural Hearing Loss in Otosclerosis. The words "FLUORIDES SENSORINEURAL LOSS AND OTOSCLEROSIS" should be typed in block letters in the upper right hand corner of the first page of the application. A copy of the letter should be sent to:

Dr. Rolf F. Ulvestad
Communicative Disorders Program
National Institute of Neurological and
Communicative Disorders and Stroke
National Institutes of Health
Room 1C17, Federal Building
7550 Wisconsin Avenue
Bethesda, Maryland 20205

C. Application Receipt Dates

Application receipt dates are: November 1, March 1, and July 1.

*U.S. GOVERNMENT PRINTING OFFICE: 1979 281-233/7 1-3