# NIH GUIDE

# for GRANTS

# and CONTRACTS

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

Vol. 7, No. 18, November 27, 1978

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Availability of *Guide* to be used in conjunction with the policy <u>Responsibility</u> for Care and Use of Animals published in the *NIH Guide for Grants and Contracts*, Vol. 7, No. 17, November 10, 1978.

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Application forms will be mailed on or about November 30, 1978, to current BRSG grantees and to those institutions which appear to be eligible: if application is not received by December 8, contact Division of Research Resources.

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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: Crants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20014, 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.

Supplements, printed on yellow paper, are published by the respective awarding units concerning new projects, solicitations of sources, and requests for proposals.

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#### GUIDE FOR THE CARE AND USE OF

#### LABORATORY ANIMALS

#### AVAILABLE



The completely revised 1978 Guide for the Care and Use of Laboratory Animals has been published and is ready for distribution by the Division of Research Resources of the National Institutes of Health.

The purpose of the *Guide* is to assist scientific institutions in using and caring for laboratory animals in ways judged to be professionally appropriate. The recommendations contained in the 70-page booklet, compiled by a committee appointed by the Institute of Laboratory Animal Resources of the National Research Council, are based on scientific principles, expert opinion, and experience with methods and practices that have proved to be consistent with high quality animal care.

The Guide was first published in 1963 under the title Guide for Laboratory Animal Facilities and Care. It was revised in 1965, 1968, and 1972. More than 250,000 copies of this publication have been distributed, and it is accepted as a primary reference on standards of animal care in scientific institutions.

Included among the subjects treated in detail are laboratory animal management, laboratory animal quality and health, institutional policies, and physical plant recommendations. The National Institutes of Health guidelines for the use of experimental animals are also contained in this new edition of the *Guide*.

A single free copy of the 1978 revised *Guide for the Care and Use of Laboratory Animals* may be secured by writing to the Office of Science and Health Reports, Division of Research Resources, National Institutes of Health, Bethesda, Maryland 20014. Bulk orders may be placed with the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Stock number is 017-040-00427-3. The price per copy is \$2.20.

#### BIOMEDICAL RESEARCH SUPPORT GRANTS,

#### DIVISION OF RESEARCH RESOURCES



The Biomedical Research Support Grant (BRSG) Program is specifically designed to complement other forms of biomedical research support. Its main thrust is to strengthen, balance, and stabilize public health—supported biomedical and behavioral research studies that develop new knowledge about fundamental processes related to health. A distinguishing feature of this program is that it provides opportunity for the grantee institution to exercise on-site judgment in decisions regarding emphasis and specific direction of their research activities. It enables institutions to respond quickly and effectively to new opportunities and unpredictable requirements, to enhance creativity, to encourage innovation, to provide for pilot studies and initial support of new investigators, and to improve research resources — both physical and human. Awards are used to support short-term, nonrecurring, low-cost or core resource support needs that are not feasibly or appropriately supported by other PHS grant programs.

Health professional schools; academic institutions other than health professional schools; hospitals; State and municipal health agencies; and nonprofit nonacademic research organizations that have received a minimum of three allowable PHS biomedical and/or health-related behavioral research grants, totaling \$200,000 (including direct and indirect costs), awarded during FY 1978 (October 1, 1977, through September 30, 1978) are eligible to apply for a FY 1979 BRSG. Federal institutions and institutions located in a foreign country are not eligible.

BRSG applications will be mailed on or about November 30 to all current BRSG grantees and to those institutions that appear to be eligible according to NIH/PHS records.

If an institution believes that it is eligible to apply for a BRSG and does not receive an application by December 8, please write or call:

Biomedical Research Support Program Division of Research Resources Office of Grants and Contracts Management National Institutes of Health Bethesda, Maryland 20014

Attention: Mrs. Gilda Polletto

Grants Technical Assistant

#### NIAID POLICY REGARDING PROGRAM PROJECTS

#### AND

#### **CENTER GRANT APPLICATIONS**



In the June 9, 1978, issue of the NIH Guide for Grants and Contracts, Vol. 7, No. 8, p. 1, the NIAID announced that it will accept Center grant applications only in response to published requests for applications (RFAs). The Institute also announced that there would be RFAs for program projects and advised principal investigators to contact program staff if they were considering the submission of a program project which was unsolicited, that is, not in response to an RFA.

This announcement is to explain more fully Institute policies adopted by the NIAID in the last year with the concurrence of its Advisory Council.

Centers are regarded as instruments to exploit research advances and to be funded only in pursuit of well defined Institute programmatic objectives. Some mixture of fundamental research, applied or clinical research, and technology transfer characterizes NIAID Centers.

Program projects are multidisciplinary research efforts carried out by collaborating teams of investigators and may or may not include clinical research and technology transfer. These consist of several individual grant proposals which could have been individually submitted and supported, but in which there is a definable advantage to the institution or to the NIAID by combining these into a single overall proposal. The NIAID RFA will define the expected benefit to the Institute.

NIAID policy derives from a desire to give payment priority to large, multidisciplinary projects which relate to well defined programmatic objectives. The program objectives described in RFAs are reviewed and endorsed by the NIAID Advisory Council initially and at periodic intervals thereafter. For this reason unsolicited program projects which cannot be related to such objectives may be at a competitive disadvantage for funding.

However, the Institute recognizes that good ideas for multidisciplinary research approaches relevant to the Institute's mission can arise in the scientific community and be useful in areas where there are no announced program needs. While it is expected that the regular grants mechanism should be used for most of these, at times the size and scope of the project will require classification as a program project. If an investigator desires to prepare and submit an unsolicited application for such multidisciplinary research, the following advice should be heeded to improve the chance of success:

A. The investigator, before preparing and submitting a program project application, should send to the Director of the Institute or Director of the Extramural Activities Program, NIAID, a letter of intent containing information as to the content of the proposed application, its size, staff, research

approach, and the approximate date for submission and subsequent funding, if approved. There should be a clear statement as to why the program project, rather than one or more regular research grants is the preferred method of work. This letter will be reviewed by the Director with program staff in terms of relevance to the programs and the probable availability of funds. After review, the investigator will receive advice as to the most appropriate course of action:

- 1. Submit as a program project application.
- 2. Submit one or more regular research project grant applications, in lieu of a program project request.
- 3. Redirect the project toward problems of NIAID program priority.
- 4. Contact other NIH Institutes or other Federal agencies which may be more appropriate to receive the application.

The investigator is, of course, free to accept or reject the advice.

B. Review of program project and center applications will be conducted initially by an NIAID initial review group. Final review will be by the NIAID National Advisory Council.

Unsolicited applications will be in competition for funds with other program projects submitted in response to the Institute Request for Applications (RFA) and not with individual research grant (RO1) applications.

#### REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

TITLE: THE IMPLICATIONS OF SUSTAINED LOW FERTILITY



The Population and Reproduction Grants Branch (PRGB) of the Center for Population Research at the National Institute of Child Health and Human Development (CPR/NICHD) is inviting research grant applications for investigations of "The Implications of Sustained Low Fertility."

The CPR supports research in the population sciences with a variety of funding mechanisms. This type of announcement (the RFA) is used when CPR wishes to stimulate investigator interest in a particular area that is important to its mission. The RFA identifies the scope of the Center's interest but does not require that proposals conform to narrowly specified research requirements. Applications submitted in response to an RFA are supported through the customary NIH research grant project mechanism but differ from other research grants in that they are specifically problem oriented. Ongoing evaluation, in addition to the usual review of formal progress, may include periodic visits.

This program announcement is for a single competition with a specified deadline (July 1, 1979) for receipt of applications. Applications in response to this RFA will compete for funding in the general, ongoing research program of NICHD and will be reviewed by a special review group or groups in the Division of Research Grants, NIH. The National Advisory Child Health and Human Development Council will review the applications in February of 1980, and the earliest requested start date for grants would be April 1, 1980. Applications should be prepared in accordance with the aims and requirements described in the following sections.

#### PROGRAM SPECIFICATIONS

- A. The PRGB Program
- B. RFA Program Objectives

#### II. METHOD OF APPLYING

- A. Application Format
- B. Application Procedure

If you have questions relating to this announcement, you may contact Dr. V. Jeffery Evans, RFA Officer, PRGB, CPR, NICHD at (301) 496-6515.

#### I. PROGRAM SPECIFICATIONS

A. Population and Reproduction Grants Branch Program The Population and Reproduction Grants Branch supports research on biomedical aspects of reproduction and on the behavioral and social aspects of the antecedents and consequences of population change. This announcement is intended to encourage scientists to submit research grant applications on the topic of "The Implications of Sustained Low Fertility." The competition is open to anyone affiliated with a nonprofit organization.

B. Program Objectives Since the late 1950s U.S. fertility has been falling and is now at a level which, if continued, will mean that our population will grow at a decreasing rate until the year 2020 and stabilize or decline at that time. Accordingly, CPR wishes to improve our understanding of the relationship between population change and social well-being. In the Spring of 1977, CPR sponsored two conferences on this topic. The first was entitled "The Social, Economic and Health Aspects of Low Fertility," which will be published in 1978 by the U.S. Government Printing Office. The second focused on an area of special concern and was entitled "The Economic Consequences of Slowing Population Growth." These papers will be published by Academic Press in late 1978 in a volume of the same name edited by Thomas Espenshade and William Serow.

The proposition was derived from these conferences that a reduction in the rate of population growth is both inevitable and desirable but that zero or negative population growth will require societal adjustments in order to avoid a misallocation of our health, social, and economic resources. It was recommended that more knowledge about the relationship between fertility and our health, social, and economic subsystems is needed to understand how society can make the best use of its resources under conditions of slowing population growth.

This solicitation is intended to allow individual investigators maximum flexibility in designing studies of the implications of sustained low fertility. It is recognized that interdisciplinary efforts and cross-cultural comparisons with and within the United States may be necessary.

Presented below are a number of research areas that comprise the scope of this RFA. Since all of the areas are interrelated, investigators are free to design studies that cut across several. It is not anticipated that any one application will answer all the questions posed herein.

The research areas are as follows:

1. The Relationship of Slowing Population Growth to the Health Environment An obvious effect of sustained low fertility is a shift in the age structure of the population with an increasing proportion of two dependency groups - the dependent young and the dependent elderly. This will generate two disparate classes of health problems, and society must be in a position to make informed choices in allocating resources. The RFA specifically encourages studies to examine how the changing structure of population will affect the incidence and type of health problems and health institutions in the U.S., particularly as they will affect the dependent young.

Even with fertility remaining below the replacement level, the U.S. population will continue to grow for some time. It is likely that growth will continue at a decreasing rate for the next two generations producing a population ultimately 20% to 40% larger than the one now existing and thereafter the population will stabilize or decline. If the present trends in population distribution continue, most of this population will live in or near urban areas. The relationship between congestion and the overall health environment is uncertain, but the combination of deteriorating environmental quality associated with urbanization and levels of dependency will certainly challenge health policy. This RFA encourages investigations into the relationship between these factors and the health environment.

2. The Social Implications of Sustained Low Fertility One characteristic of a population with sustained low fertility is that families tend to be smaller. Smaller families are associated with changes in the function of the family, the roles of members of the family, and the allocation of family resources for the care of dependents. The future may very well witness a growing number of childless families and these units may function quite differently from the traditional family with children present. A growing number of wives have been entering the labor force and the resulting effects on fertility have been documented in recent years. However, it is uncertain whether the magnitude of effects are changing over time.

Moreover, the above-mentioned changes may result in different allocations of resources for the care of dependents within families. Also, more public resources may be substituted for private resources in the care of dependents. Research on the relationship between changes in the family and the allocation of public and private resources for the care of dependent age groups is specifically encouraged by this RFA.

Rates of marital formation and dissolution have been volatile in recent years and may be associated with the uneven and rapidly changing age structure of the population. Accordingly, studies relating changes in the structure of population to the rates of marital formation and dissolution are encouraged. Given the present high levels of divorce the number of families headed by a single parent is likely to increase. This RFA also encourages research on the demographic and societal implications of these trends.

A consequence of smaller family sizes and families with fewer functions, especially in the care of dependents, is that the number of households has increased dramatically in recent years. In fact, while the population has shown a diminished rate of growth, the number of households has undergone a marked increase. Research relating changes in family size to the rate of household formation is encouraged. Also, it is important to understand the consequences of changing rates of household formation for society at large.

3. The Health and Economic Implications of Sustained Low Fertility

This RFA is intended to encourage research on the health and economic consequences of slowing population growth, rather than the antecedents. Many of the interrelationships involved can be studied with growth models. However, in most models, population is considered as an exogenous variable (i.e., the value is determined by factors outside of the model), whereas we are also interested in new ways of building models that explicitly account for population as an endogenous variable (i.e., that the model be constructed to include the estimation of population).

We also deem it important to understand the relationship between population change and economic growth and development at the sub-national level, particularly as these factors affect health. In such studies, migration is a critical element because shifting population movement have and will continue to shape the profiles of various regions within the United States. It is important to understand the relationships among migration, population distribution and composition, and economic growth and development in an era of generally slowing population growth.

Finally, future fertility trends are likely to have an impact on income distribution. The presence of young children in the home frequently inhibits labor force participation of mothers and, moreover, when fertility declines it frequently declines by different amounts for different income groups. The prevalence of poverty is also affected by the number of children in the family. We are interested in how the distribution of income will be changed by zero or negative rates of population growth and what effect this change will have on the extent of poverty in the United States. Again, special attention should be given to health issues because income groups will vary as to the incidence and type of health problems experienced.

#### II. METHOD OF APPLYING

- A. Format for Applications Applications should be submitted on form PHS 398, the application form for the traditional research grant. The conventional presentation for research grant applications should be used.
- B. Application Procedure The original and six copies of the application must be received before 5:00 p.m. Eastern time on July 1, 1979. Applications should be sent or delivered to:

Division of Research Grants National Institutes of Health Room 240, Westwood Building 5333 Westbard Avenue Bethesda, Maryland 20016 NIH Guide for Grants and Contracts Vol. 7, No. 18, November 27, 1978

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Applications may be obtained at most universities and hospitals in the United States. If not, application kits may be obtained from:

Office of Grants Inquiries Division of Research Grants National Institutes of Health Room 448, Westwood Building 5333 Westbard Avenue Bethesda, Maryland 20016

The first sentence of the research abstract on page 2 of the application should read as follows: THIS APPLICATION IS SUBMITTED IN RESPONSE TO THE RFA ENTITLED "THE IMPLICATIONS OF SUSTAINED LOW FERTILITY," NIH-NICHD-PRGB-79-1. The remainder of the abstract should contain the conventional information. An additional copy of the application should be sent to:

Dr. V. Jeffery Evans, RFA Officer PRGB, CPR, NICHD Room C-733, Landow Building 7910 Woodmont Avenue Bethesda, Maryland 20014

#### NEW INVESTIGATOR RESEARCH GRANTS

#### IN MEDICAL INFORMATION SCIENCE,

#### NATIONAL LIBRARY OF MEDICINE



The National Library of Medicine (NLM) announces initiation of a new program to support investigators who are seeking independent research support for the first time for meritorious research ideas of their own design. The program is intended to bridge the transition from doctoral and postdoctoral training status to that of an independent and productive research scientist.

#### Research Interests of NLM

The Medical Library Assistance Act of 1965, as amended, provides the National Library of Medicine with authority to assist in the conduct of research, investigations, and demonstrations in the field of medical library science, and related activities, and in the development of new techniques, systems, and equipment for processing, storing, retrieving, and distributing information in the sciences related to health. Within this very broad research mandate, the National Library of Medicine has identified the following areas for particular program emphasis:

New methods for representation of medical knowledge. Applications of computer technology will, over the next several decades, exert major changes in the health care system and create new systems for information handling. The Library wishes to encourage studies on how medical knowledge can better be represented in computer-based systems so that information can be retrieved and made available in the context of the actual problems with which the health professional is confronted.

Classifying, indexing, and abstracting information. The development of non-conventional information systems will demand new methodologies for the organization of biomedical knowledge. Although these functions may be covered under the topic cited above, they are of sufficient interest and importance to be identified separately.

User needs and behavior. Improved information delivery systems must be based upon an understanding of the information needs and requirements of health personnel. In order to promote the efficiency and effectiveness of libraries and information systems, the Library wishes to stimulate a greater research effort into the properties of the user/system interface.

The listing of the above areas of special emphasis is intended to imply a set of programmatic priorities which will support the objectives of the National Library of Medicine, but it is not intended to exclude the submission of proposals from new investigators to conduct research in other areas identified in the Medical Library Assistance Act.

#### Eligibility Requirements

Candidates for the NLM New Investigator Research Awards must be scientists and/or health professionals who at the time the application is submitted:

- have received a doctoral degree (or provide evidence of its receipt prior to grant award);
- 2. have not had more than five years' postdoctoral research experience;
- 3. have not been the principal investigator of a Federallysupported research grant or contract (except for a fellowship or traineeship);
- 4. meet U.S. citizenship or permanent residency requirements;
- 5. present a well-defined research plan with relevance to areas which support the mission of the National Library of Medicine;
- 6. agree to devote at least 50% time and effort to the proposed research project.

#### Provisions of the Award

Applicants for the NLM New Investigator Research Grant Program may request support for a period of up to three years in an amount not to exceed \$90,000 direct costs, of which no more than \$35,000 may be requested for any twelve-month period. Indirect costs are allowable in accordance with the PHS policy for regular research grants. Salary support for the new investigator may not exceed \$20,000 from this grant and must reflect at least 50% time and effort devoted to the research project. Other expenses which are justified in terms of the proposed research, such as equipment, supplies, publication costs, travel to a national scientific meeting, etc., may also be requested.

#### Program Implementation

For fiscal year 1979, applications will be accepted for a February 1, 1979, receipt date with final review by the NLM Board of Regents in May 1979, and announcement of awards shortly thereafter.

#### Additional Information

Potential candidates are encouraged to request additional information and application forms from:

Division of Biomedical Information Support Extramural Programs National Library of Medicine 8600 Rockville Pike Bethesda, Maryland 20014

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#### Application Procedure

Applications should be forwarded by February 1, 1979, to:

Division of Research Grants National Institutes of Health Bethesda, Maryland 20014

#### RESEARCH CAREER DEVELOPMENT AWARDS

#### IN MEDICAL INFORMATION SCIENCE,

#### NATIONAL LIBRARY OF MEDICINE



The National Library of Medicine (NLM) invites applications for Research Career Development Awards under the standard NIH policies and guidelines for this program. The NLM Research Career Development Award is a special full-time salary grant to enhance the research capability of individuals in the formative stages of their careers who have demonstrated outstanding potential for research contributions to the health-related information sciences. The award is for a single support period of five years at a salary (up to a maximum of \$30,000 per annum) consistent with the policy of the sponsoring institution. The grantee institution may supplement the salary from non-Federal sources and from Federal sources where authorized, except that in no case may NIH funds be used for this purpose.

#### Research Interests of NLM

The Medical Library Assistance Act of 1965, as amended, provides the National Library of Medicine with authority to assist in the conduct of research, investigations, and demonstrations in the development of new techniques, systems, and equipment for processing, storing, retrieving, and distributing information in the sciences related to health. Within this very broad research mandate, the National Library of Medicine has identified the following areas for particular program emphasis:

New methods for representation of medical knowledge. Applications of computer technology will, over the next several decades, exert major changes in the health care system and create new systems for information handling. The Library wishes to encourage development of investigators who will devote their attention to studies on how medical knowledge can better be represented in computer-based systems so that information can be retrieved and made available in the context of the actual problems with which the health professional is confronted.

Classifying, indexing, and abstracting information. The development of non-conventional information systems will demand new methodologies for the organization of biomedical knowledge. Although these functions may be covered under the topic cited above, they are of sufficient interest and importance to be identified separately.

User needs and behavior. Improved information delivery systems must be based upon an understanding of the information needs and requirements of health personnel. In order to promote the efficiency and effectiveness of libraries and information systems, the Library wishes to stimulate a greater research effort into the properties of the user/system interface.

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The listing of the above areas of special emphasis is intended to imply a set of programmatic priorities which will support the objectives of the National Library of Medicine.

#### Candidate's Qualifications

Candidates must have had three or more years of relevant postdoctoral experience prior to the proposed beginning date of the award. Normally, they would come from the fields of health sciences, computer sciences, or information sciences. The application must document accomplishments that demonstrate research potential; it must also present a plan for additional experience in a productive scientific environment that enhances the candidate's development as an independent investigator.

The adequacy of the candidate's background is to be evaluated as a guide to his future development into a creative, independent investigator. Factors to be considered include the quality and extent of past education, scientific training, and research experience; the need for further research experience and/or training; evidence of superior performance, originality, independence, and productivity; the quality of any independent research publications; the commitment to health-related research; and letters of reference.

#### Candidate's Plans

The details of the proposed research to be undertaken during the award period must be included. The traditional NIH outline is to be followed: objective, background, rationale, specific aims, methods of procedure, significance, facilities available, and collaborative arrangements.

If research support is already available to the candidate, the above outline must still be included as a part of the RCDA application. Please indicate the source of such research support.

If research support is not available, an application may be submitted simultaneously with the RCDA application. When such support is being requested, the research plans (which may be identical) must accompany both applications. In such cases each application should provide cross reference to the other. (Use application form 2557-1 for the Research Career Development Award and form PHS 398 for the research grant.)

#### Environment

The adequacy of the environment for the candidate's research career development will be evaluated in terms of the availability of space and equipment resources, facilities, technical assistance, and opportunities for critical professional interaction with senior colleagues as pertinent to the proposed research plan and any other development plans. A preferred environment is one that fosters continual interaction among health, computer, and information scientists.

The applicant institution is expected to permit the candidate to spend essentially full time in the actual conduct of research and research-related activities and, accordingly, be willing to reduce or defer demands for teaching, service, or committee duties which would not directly contribute to the candidate's research career development.

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#### Program Implementation

For FY 1979, applications will be accepted for a February 1, 1979, receipt date with final review by the NLM Board of Regents in May 1979 and announcement of awards shortly thereafter.

#### Additional Information

Potential candidates should request additional information and application forms prior to submission from:

Division of Biomedical Information Support Extramural Programs National Library of Medicine 8600 Rockville Pike Bethesda, Maryland 20014

Telephone: (301) 496-4221

#### Application Procedures

Applications should be forwarded by February 1, 1979, to:

Division of Research Grants National Institutes of Health Bethesda, Maryland 20014

#### NATIONAL INSTITUTE OF NEUROLOGICAL

AND

#### COMMUNICATIVE DISORDERS AND STROKE,

#### THE FIELD OF CHRONIC PAIN



Chronic pain is a problem of great clinical significance and one for which treatment has not been generally satisfactory. This includes the pain of chronic nerve and nerve root compression, of the chronic neuritides, of muscle pain, headache, backache, and of tic douloureux, post herpetic neuralgia, phantom pain, etc.

The NINCDS is interested in receiving research grant applications dealing with chronic pain in any aspect or combination of aspects. These might include the basic physiology of pain, specific mechanisms involved in chronic pain syndromes, the relation of particular diseases to chronic pain, and investigation of various types of diagnostic procedures and treatment.

These applications may be for regular research grants, program projects, or for clinical research centers. If the interest, ability and facilities are available, applications for interdisciplinary studies on chronic pain will be welcome. These could include basic studies (anatomy, physiology, neurochemistry) and clinical studies, such as controlled clinical trials, perhaps in the setting of a pain clinic.

Applications should be submitted in accordance with the standard NIH forms, procedures, and schedules. Each application will be reviewed on its scientific merit in competition for available funds. Although there is no deadline or expiration date for this announcement, the usual dates apply for receipt of applications.

Inquiries concerning this announcement may be directed to:

Dr. Maury Hanson
National Institute of Neurological
and Communicative Disorders and Stroke
Room 8A-13, Federal Building
7550 Wisconsin Avenue
Bethesda, Maryland 20014

Telephone: (301) 496-4226

Also, Dr. Hanson should be notified at the time of submission of application.

#### RESEARCH GRANT APPLICATIONS

#### SOUGHT BY THE NATIONAL EYE INSTITUTE

#### ON CANNABINOIDS IN THE TREATMENT OF GLAUCOMA



The National Eye Institute has a continuing interest in basic and clinical research to develop new therapeutic modalities in the treatment of all forms of glaucoma, to define the mechanisms of action of drugs used in glaucoma therapy, and to evaluate new approaches to drug delivery. There is experimental evidence that marihuana and certain cannabinoid derivatives lower intraocular pressure (IOP) in certain experimental animals and normal humans. However, it is still not known how effectively these drugs will lower IOP in glaucomas of differing etiology or if they will prevent loss of vision, to what extent ocular or systemic side effects may accompany their chronic use, or what behavioral changes may occur.

Research is required to determine if marihuana or certain of its derivatives will have a place in treatment of glaucoma. The effectiveness of these drugs needs to be evaluated in treatment of primary open angle glaucoma, angle closure glaucoma, and secondary glaucomas (e.g. consequent to uveitis, neovascularization or trauma; phacolytic or hemolytic glaucomas), and their value should be assessed in cases where present medications inadequately control IOP. The use of such drugs should be considered with respect to short and long-term clinical efficacy, pharmacologic and physiologic effects in normal and glaucomatous eyes, and systemic and ocular side effects. Also, physiologic and behavioral changes following long-term use at dosages effective in lowering IOP should be determined.

To define the possibilities for use of cannabinoids in treatment of the glaucomas, the following questions must be answered: How well will they control the disease in comparison with existing drugs and will there be any specific advantages attributable to them? Will they be compatible with, or augment the effects of, other drugs now in use? Will tachphylaxis or tolerance to the effects of cannabinoids be developed? Will there be significant adverse ocular or systemic side effects, in particular, cardiovascular and central nervous system risks to elderly glaucoma patients? What will be the optimal drug formulations, dosages, and routes of administration? It will also be of interest to determine if there are sex, age, racial, or heritable differences in responses of glaucoma patients to cannabinoids.

Experimental studies should be directed to production of improved drugs which would retain the properties desirable for treating glaucoma while minimizing undesirable physiologic and behavioral effects. Investigations are encouraged which would define the cellular and molecular basis for the effects of cannabinoids on ocular tissues and aqueous humor dynamics.

#### APPLICATION RECEIPT AND REVIEW

The receipt dates for new applications are March 1, July 1, and November 1. The earliest possible award date will be approximately nine months after receipt dates. An application received too late for one cycle of review will be held for the next.

Applicants must use the regular research grant application (form PHS 398) which is available at institutional central application control offices. The completed application should be mailed to:

Division of Research Grants National Institutes of Health Room 240, Westwood Building Bethesda, Maryland 20014

All applications will be reviewed by a Division of Research Grants Study Section and the National Advisory Eye Council. All applications recommended for approval will compete for available funds with all other approved applications assigned to the NEI. Support through an NEI research project grant is subject to the applicable laws, regulations, and the policies to be found in the PHS Grants Policy Statement dated October 1, 1976, DHEW Publication No. (OS) 77-50,000 and the addendum DHEW No. (OS) 77-50,000-A. Applicants are encouraged to discuss their proposed research with NEI staff and submit preliminary drafts of proposals; however, discussions prior to the formal submission of an application will not influence evaluation of the proposal via the regular peer review process.

This program is announced under authority of Section 452 of the Public Health Service Act as amended (42 USC, Ch. 6A, Subch. III).

Inquiries regarding this announcement may be addressed to:

Director, Glaucoma Program Scientific Programs Branch National Eye Institute National Institutes of Health Bethesda, Maryland 20014

Telephone: (301) 496-5301

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 NEI PROGRAM ANNOUNCEMENT ON CANNABINOIDS IN TREATMENT OF GLAUCOMA."

#### STUDIES ON OVERNUTRITION AND OBESITY

NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF ALLERGY AND
INFECTIOUS DISEASES
NATIONAL INSTITUTE OF CHILD HEALTH AND
HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF NEUROLOGICAL AND
COMMUNICATIVE DISORDERS AND STROKE



#### I. PROGRAM SPECIFICATIONS

A. Program Objectives Obesity is a major public health problem in the United States, affecting both children and adults. Children today are, on the average, 50% heavier than they were a generation ago; 40% of the women and 30% of the men in the United States are considered obese with some subgroups reaching even higher percentages of obesity. Furthermore, obesity is either a risk factor or is associated with a number of diseases including diabetes, hypertension, coronary heart disease, complications of pregnancy, osteoarthritis, and some cancers and infections.

Despite the magnitude of the problem, the causes of exogenous obesity remain obscure. Overeating is only one aspect of a multifaceted etiology. The socioeconomic and behavioral causes of overeating have not been defined; we also lack definition of the reason for the differential metabolic consequences that lead to obesity in some, but not all, individuals who eat a similar diet.

- B. Research Scope The emphasis of this program announcement is upon basic, clinical, and behavioral research aspects of exogenous obesity. Some examples of areas of research interest are listed below. They are not listed in any order of priority.
  - 1. Heterogeneity of obesity Natural history, epidemiology, or genetic studies aimed at defining and locating biochemical markers for different kinds of obesity. Included in this category is the epidemiology of obesity as a factor for selective survival in the elderly.
  - 2. Physiological factors that affect eating behavior Metabolic factors that activate or inhibit food consumption; effects of dietary levels, balance of nutrients, energy density of the diet, and rates of absorption; potential interactions, diet patterns, energy substrates, hormone production, and appetite; effects of slightly suboptimal levels of one or more trace metals on increased desire to eat; identification of neurotransmitters associated with eating behavior; hypothalamic regulation of food intake, neural and hormonal signals of satiety and hunger, and central nervous system involvement in control of fat cell size and/or body burden of fat cells.

- 3. <u>Psychosocial factors that affect eating behavior</u> Cues that trigger eating behavior such as mother-child feeding interactions, role-modeling, and social attitudes toward eating.
- 4. Obesity as a risk factor Research designed to clarify whether obesity alone is an independent risk factor or is only an associated or interactive risk for one or more of the following diseases: diabetes, digestive diseases, and respiratory infections in children; genitourinary tract, upper respiratory tract, and skin infections in adults and/or children; cardiovascular diseases; hypertension; renal disease; degenerative joint disease; and certain cancers. These studies may be solely epidemiological surveys.
- 5. Energy balance and change in metabolic rate as a function of age Studies on changes that take place in nonobese populations and compensations in eating and other habits that do not take place in paired, obese populations.
- 6. Fat cell control and proliferation Research to determine whether fat cells grow in size or number as a function of age, the factors that control cellular growth in adipose tissues, and biochemical markers that can be used to identify populations of preadipocytes at various stages of differentiation.
- 7. Weight management At various ages and in different socioeconomic groups, the interaction of diet, physical activity,
  modification of psychsocial and nutritional environments on
  the maintenance of normal body weight and/or prevention and
  treatment of obesity; clarification of the factors that lead
  to success or failure of obese patients to stay reduced for
  extended periods (in excess of one year); and the effect of
  liquid protein diets on the overall metabolism of the obese
  patient, including changes in the cardiovascular and central
  nervous system. Special consideration should be given to
  weight management in people who have special dietary requirements due to already diagnosed chronic diseases, e.g., diabetes,
  hyperlipidemia, high blood pressure, arteriosclerosis, and
  renal disease.
- C. Mechanism of Support The mechanism of support for this program will be the grant-in-aid. The regulations (Code of Federal Regulations, Title 42, Part 52 and as applicable to the State and local governments, Title 45, Part 74) and policies that govern the research grant programs of the National Institutes of Health will prevail. The award of grants pursuant to this request for grant applications is contingent upon ultimate receipt of appropriated funds for this purpose.

#### II. METHOD AND CRITERIA OF REVIEW

- Assignment of Applications Applications will be received by the Division of Research Grants, NIH, referred to an appropriate study section for scientific review, and assigned to individual Institutes for possible funding. These decisions will be governed by normal programmatic considerations as specified in the DRG Referral Guidelines.
- B. Review Procedures Applications in response to this announcement will be reviewed on a nationwide 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 (study section). Following study section review, the application will be evaluated by the appropriate Institute Advisory Council or Board with respect to the adequacy of the technical merit review and the program relevance of the research proposed. The review criteria customarily employed by the National Institutes of Health for regular research grant applications will prevail.
- C. <u>Deadlines</u> Applications will be accepted in accordance with the usual receipt dates for new applications:

February 1, 1979 June 1, 1979 October 1, 1979

#### III. 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. The phrase "PREPARED IN RESPONSE TO NIH OBESITY PROGRAM ANNOUNCEMENT" should be typed across the top of the first page of the application.

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 20014

For further information, investigators are encouraged to contact one or more of the following individuals:

#### National Institute of Arthritis, Metabolism, and Digestive Diseases

Gerald F. Combs, Ph.D.
Nutrition Program Director
Extramural Programs
NIAMDD
Room 601, Westwood Building
Bethesda, Maryland 20014

Telephone: (301) 496-7823

#### National Heart, Lung, and Blood Institute

Basil Rifkind, M.D. Chief, Lipid Metabolism Branch NHLBI Room 302, Federal Building Bethesda, Maryland 20014

Telephone: (301) 496-1681

#### National Institute on Aging

Jacob A. Brody, M.D.
Associate Director for Epidemiology,
Demography, and Biometry
NIA
Room 5C12, Building 31
Bethesda, Maryland 20014

Telephone: (301) 496-1178

#### National Institute of Allergy and Infectious Diseases

Robert Edelman, M.D. Chief, Clinical Studies Branch NIAID Room 7A51, Building 31 Bethesda, Maryland 20014

Telephone: (301) 496-5893

#### National Institute of Child Health and Human Development

Gilman D. Grave, M.D.
Acting Chief, Developmental Biology
and Nutrition Branch
Center for Research for Mothers
and Children
NICHD
Room 7C17, Landow Building
Bethesda, Maryland 20014

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# National Institute of Neurological and Communicative Disorders and Stroke

Eugene Streicher, Ph.D. Fundamental Neurosciences Program NINCDS Room 1CO4, Federal Building Bethesda, Maryland 20014

#### REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

#### NATIONAL CANCER INSTITUTE

TITLE: NEW APPROACHES IN SURGICAL ONCOLOGY



The National Cancer Institute (NCI) is accepting applications for support of research projects relevant to cancer treatment by the introduction of new approaches in surgical oncology.

#### I. Scientific Program Requirement

The Division of Cancer Treatment (DCT), NCI, desires to support research studies that fall within three general areas of investigation, for which surgical oncology expertise and experience are needed. These fall in the following general areas:

- Investigations on the introduction of modified or new surgical procedures, possibly in conjunction with other modalities, as substitutes for standard surgical or other standard treatment approaches. For example, these studies may range from the use of laboratory animal models to explore clinically relevant combined modality treatment, to actual clinical trials in cancer patients designed to establish the value of less extensive surgery relative to standard radical approaches. These trials may be internally controlled studies or pilot programs designed to be adequate for comparison with appropriately matched historical controls. Novel surgical procedures or development and implementation of new methodologies and techniques with which to carry out new approaches would be relevant. For example, the introduction of limb-sparing operations in osteosarcomas with development of appropriate prosthesis would be investigations responsive to the aims of this announcement. In addition, studies evaluating the role of cytoreductive surgery in advanced ovarian or pulmonary cancer may also be considered responsive. Although a principal investigator with a primary interest in hyperthermia, immunotherapy, chemotherapy or radiotherapy may be acceptable, grants must reflect extensive surgical expertise for these approaches to be considered adequate for evaluation.
- 2. Development and testing of therapies dependent on vascular interruption or perfusion. These investigations could include animal laboratory studies or clinical studies in cancer patients either as comparative clinical trials or individual pilot programs evaluating new techniques. Studies to be included could test the value of graded or total interruption of vascular supply by a variety of techniques on local tumor control or resectability, or by studies including the isolation of a local area for perfusion with cytotoxic agents. The emphasis should lie in development and evaluation of new techniques and methodologies rather than testing of new chemotherapeutic agents by well-established techniques of vascular infusion. However, well-designed clinical trials comparing

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the addition of such local approaches to other therapeutic measures will be given appropriate consideration.

3. Studies on clinical and biological consequences of surgical procedures. These investigations could involve solely experimental tumor models, or cancer patients, or both. Pertinent topics could include, for example, assessment of cell kinetic changes, immunologic studies, metastatic behavior following primary surgery, and metabolic or nutritional changes occurring in the host as a result of tumor presence or surgical therapy.

All of the areas of investigation described above may include studies on biological markers in conjunction with clinical trials, including correlation of such markers with staging of the disease and with consequences of treatment.

#### II. Method and Criteria for Review

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) and the NCI staff for responsiveness to this announcement. If an application is judged unresponsive, the applicant will be given an opportunity to withdraw the application or to submit it for consideration in the traditional research grant program of NIH. Applications judged responsive will be reviewed initially for scientific merit by an NIH peer review group and secondly by the National Cancer Advisory Board.

Applications will be reviewed by the NIH peer review group utilizing the same criteria as apply to all traditional research grant applications.

#### III. Method of Applying

Applications should be submitted on form PHS 398, utilizing the conventional presentation for grant applications. In both the covering letter and the application, reference should be made to RFA #NIH-NCI-DCT-7.

For further information, contact:

Dr. Gregory Wolf Special Assistant for Surgical Oncology Clinical Investigations Branch Cancer Therapy Evaluation Program Division of Cancer Treatment National Cancer Institute Room C819, Landow Building Bethesda, Maryland 20014

Dr. Raymond Weiss Chief, Clinical Investigations Branch Cancer Therapy Evaluation Program Division of Cancer Treatment National Cancer Institute Room C803, Landow Building Bethesda, Maryland 20014

Telephone: (301) 496-6056

Deadline for receipt of applications is March 1, 1979, for possible funding on or after December 1, 1979. Funding may be requested for a period of up to 5 years. Renewal of projects beyond the original funding period (under this announcement) is not contemplated, although successful applicants may then apply for traditional research grants.

Funds will be earmarked in support of these projects, although the specific amount cannot be determined at this time.

In order to encourage communication among investigators, an annual meeting of successful applicants will be arranged.

#### PROGRAM PROJECT SUPPORT FOR RESEARCH

#### IN BIOMEDICAL INFORMATION SYSTEMS,

#### NATIONAL LIBRARY OF MEDICINE



#### INTRODUCTION

The National Library of Medicine will initiate a program for major fundamental research studies into new and improved systems necessary for the representation of medical knowledge and the dissemination of biomedical information. It is anticipated that funds available will permit several awards during FY 79.

The large and increasing biomedical information base, created in large part from the purposeful investment in biomedical research by the National Institutes of Health, obligates NLM to assure the expeditious and effective transfer of information to the nation's health community.

The NLM has a major concern for both the principles and processes of information and communication science as they apply to medicine and the related health sciences. The National Library of Medicine wishes to encourage broadly based multidisciplinary approaches to the fundamental problems of knowledge representation, information transfer, and its utilization in the health sciences. The ultimate goal of this research effort is more efficient prevention, diagnosis, therapy, and care through improved information dissemination.

#### PROGRAM DESCRIPTION

More effective and efficient information systems are needed to collect, generate, validate, synthesize, correlate, and disseminate the substance of biomedical information to investigators and practitioners in the health sciences. Exploitation of the potential that computer and communication technologies hold for modern medicine requires the collaborative efforts of investigators from a variety of disciplines.

A program of fundamental research in the area of knowledge representation, linguistic theory, decision-making, problem-solving, data manipulation, information engineering, and related fields is being initiated. Attention should be given to the requirements of health scientists, educators, and practitioners so that the medical information systems developed will be responsive to their needs. Program emphasis should address fundamental gaps in design or methodology as related to biomedical information systems. Significant investment is required to develop information systems, from experimental prototypes to operating systems; therefore, when a proposed system application is considered, cost-evaluation at every stage is encouraged.

Although a variety of research activities described herein must be undertaken in concert to achieve the objectives of this announcement, it is not expected that a single research group will be willing to address the totality of research issues. Applicants must, however, demonstrate their ability to provide an interdisciplinary environment with facilities and personnel appropriate to the aims of their proposed research program.

It is the intent of the National Library of Medicine to stimulate multi-disciplinary research efforts, drawing from the skills of health professionals, computer and information scientists, librarians, engineers, linguists, evaluation experts, and others as needed, with the overall purpose of improving the means for knowledge synthesis and the communication of biomedical information. These activities will require systematic collaboration among medical, computer, and information scientists, both within and between institutions, including critical evaluation of existing information systems to identify unnecessary duplication in concept or application. Funding for at least five years is projected to insure stability.

#### PROGRAM MECHANISM

A program must consist of a number of individual subprojects and at least one core activity, each with a clearly identified research or support task and each with a principal investigator, research staff, and budget. A director will be responsible for the overall direction and administration of the total program. The director and principal investigators of each of the subprojects will function as members of a coordinated research team, the efforts of which are directed toward resolving major problems in biomedical information science. The review process will include an evaluation of the facilities and resources, the professional qualifications of the research team which contribute to the scientific merit of the research projects, and the overall program plan.

#### RECEIPT DATE

The deadline for FY 1979 will be February 1, 1979. All proposals will receive an initial peer review by the Biomedical Library Review Committee. Final review will be made by the NLM Board of Regents in May of 1979, and awards will be announced shortly thereafter. A subsequent announcement will be made as to future submission dates.

#### APPLICATION PROCESS

Prospective applicants are advised to contact the Office of Extramural Programs of NLM prior to the preparation of an application. Inquiries should be directed to:

Dorothy Stroup, Ph.D.
Program Officer
Division of Biomedical Information Support
Extramural Programs
National Library of Medicine
8600 Rockville Pike
Bethesda, Maryland 20014

Applications (on form PHS 398) should include:

- a. Description of the broad program contemplated, with rationale and justification of need and description of resources and facilities already available for the purpose.
- b. Similar description for each identifiable subproject or major program component.
- c. Any collaboration to be devloped with other parties either in the same institution or other institutions.
- d. Any career development of individuals to be afforded.
- e. Description of budget costs for the first year and estimate of costs for up to four additional years.

Applications should be received by February 1, 1979, at:

Division of Research Grants National Institutes of Health Room 240, Westwood Building Bethesda, Maryland 20014