

NIH GUIDE

Mary Miller
for GRANTS

and CONTRACTS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Vol. 10, No. 4, March 6, 1981

IN THIS ISSUE:

- Protection of Human Subjects
Temporary Requirement for Form HHS-596
Index - Human Subjects Page 1
- Request for Applications: RFA
NIH-NIDR-NCP-81-1
National Research Service Awards for Institutional,
Postdoctoral Training Programs in Cariology
National Institute of Dental Research
Application receipt date--June 15, 1981
Index - NIDR Page 3
- Minority Hypertension Research Development Summer Program
National Heart, Lung, and Blood Institute
Application receipt date--September 15, 1981
Index - NHLBI Page 7
- Research on Consequences of Therapeutic Apheresis
National Heart, Lung, and Blood Institute
Index - NHLBI Page 9
- Support of Research Center and Program Project Grants
National Institute of General Medical Sciences
Index - NIGMS Page 11
- Withdrawal of NCI Preventive Oncology Academic Award
Pending Evaluation (Vol. 9, No. 1; Vol. 9, No. 4)
National Cancer Institute
Index - NCI..... Page 17

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 B3B10, 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

PROTECTION OF HUMAN SUBJECTS

TEMPORARY REQUIREMENT FOR FORM HHS-596

(forms rev. 4-75 and 5-80 only)

On January 26, 1981, final regulations amending basic Health and Human Services policy for the protection of human research subjects were published in the Federal Register (46 FR 8366). These new regulations contain exemptions for broad categories of research which involve little or no risk to research subjects (see listing below). **Submission of the Form HHS-596 (Protection of Human Subjects Assurance/Certification/Declaration) is still required for all research involving human subjects (as defined in 45 CFR 46), whether exempt or not.** However, no response need be made to item number 4 on the Form HHS-596 when an exemption is claimed.

When an exemption to the human subjects regulations is claimed, the application or proposal must be accompanied by Form HHS-596 which should include the following statement: "Exemption is claimed based on number(s) *." (*Insert the identification number(s) of exemption(s) claimed by using the numbers in 45 CFR 46.101(b) 1 through 5.) This statement should appear on the front page of the Form HHS-596 in the block entitled "5. and 6. See Reverse Side."

If there is any question concerning the interpretation of exempted categories please contact the Office for Protection from Research Risks, Westwood Building, Room 3A-18, National Institutes of Health, Bethesda, Maryland 20205; telephone (301) 496-7041. An inappropriate claim for exemption may lead to delays in processing an application for funding.

These changes will necessitate revision of the grant application instructions; however, in the interim, supplemental instructions will be developed for use in application kits.

This requirement is effective for applications submitted on or after June 1, 1981.

Exemption categories (45 CFR 46.101(b))

Research activities in which the only involvement of human subjects will be in one or more of the following categories:

- (1) Research conducted in established or commonly accepted educational settings, involved normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests, (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

REQUEST FOR APPLICATIONS: RFA

NIH-NIDR-NCP-81-1

NATIONAL RESEARCH SERVICE AWARDS FOR INSTITUTIONAL, POSTDOCTORAL
TRAINING PROGRAMS IN CARIOLOGY

NATIONAL INSTITUTE OF DENTAL RESEARCH

Application receipt date: June 15, 1981

The NATIONAL CARIES PROGRAM (NCP), NATIONAL INSTITUTE OF DENTAL RESEARCH (NIDR), is a targeted research and development program designed to develop methods to prevent and ultimately eliminate dental caries as a public health problem. The progressive tooth destruction characteristic of the disease results from interactions among three primary factors: oral bacteria, capable of fermenting dietary substrates to produce acid, which dissolves the tooth enamel of a susceptible host. Elimination of any one of these three factors prevents the disease. Social and behavioral factors are also important in determining caries incidence and the success of preventive measures. NCP research strategies are dictated by the multi-factorial etiology of the disease. They focus on combatting the microbial agent, increasing tooth resistance and modifying the diet. Efforts are also being made to improve the delivery and acceptance of caries preventive methods.

Investigation of the diverse factors implicated in caries etiology and the development and evaluation of preventive methods necessitates participation by investigators from numerous disciplines. These include organic and physical chemists, microbiologists, immunologists, pharmacologists, nutritionists, behavioral scientists, statisticians, epidemiologists and dentists experienced in conducting clinical trials and demonstration programs.

In addition, there is a need for individuals with capabilities spanning several of these disciplines and with the potential to lead multidisciplinary caries research and development teams. These "cariologists" must be familiar with dental and oral anatomy and physiology, composition and functions of saliva, microbial and dietary factors in caries etiology, use of animal models in caries research, principles of epidemiology and biostatistics and the design and conduct of clinical trials.

To meet these human resource requirements the NCP sponsors post-doctoral training of researchers in specific disciplines through individual fellowships and development of cariologists via two institutional training grants. These activities are supported through individual and institutional National Research Service Awards (NRSA). Because of the continuing need for additional cariologists the NCP now plans to award a third institutional training grant in cariology.

Applications are invited for NRSA institutional grants to provide post-doctoral training of cariologists. Processing and review of applications and award of grants

will be subject to the general provisions for NRSA institutional grants and the specific requirements of the NCP. This RFA may be reissued at a later date.

GENERAL PROVISIONS FOR NRSA INSTITUTIONAL GRANTS

Announcements concerning NRSA institutional grants were published in the **NIH Guide for Grants and Contracts**, November 14, 1977, Vol. 6, No. 20, as amended February 22, 1980, Vol. 9, No. 3; July 18, 1980, Vol. 9, No. 9. Copies of these announcements may be obtained from NCP staff. In summary, awards are made by the NIH under authority of Section 472 of the Public Health Service Act as amended (42 USC 2891-1). Title 42 of the Code of Federal Regulations Part 66 is applicable to these awards. This program is not subject to review by a Health Systems Agency and is not subject to requirements of OMB Circular A-95. This program is described in the Catalog of Federal Domestic Assistance number 13.840, Caries Research.

Domestic non-profit, private or public institutions may apply for grants to support research training. Awards may be made for project periods of up to 5 years. Competitive renewal of the awards for subsequent 5 year project periods is possible. The program director at the training institution will be responsible for selection and appointment of trainees and for the overall direction of the program. The program must offer supervised research training which may be part of a research degree program. The awards cannot support study leading to M.D., D.D.S., or similar professional degrees, nor will they support residency training. Individuals appointed as trainees must be citizens, non-citizen nationals of the United States or must have been lawfully admitted to the United States for permanent residence. Individuals on temporary or student visas are not eligible. Support for post-doctoral trainees is limited to 3 years. Trainee stipends are determined by the number of years of prior relevant post-doctoral experience and range from \$13,380 to \$18,780 per year. The awards are subject to payback provisions. Additional funds for trainees' tuition, travel and fees may be requested. An annual institutional allowance, not exceeding \$5,000 per trainee, for costs deemed essential to carry out the training, such as faculty salaries, equipment and supplies may be requested.

SPECIFIC REQUIREMENTS OF THE NCP

Applicant institutions must have the faculty, facilities, and ongoing basic and clinical caries research to provide trainees with in-depth exposure to all of the component subdisciplines listed below. This training must include didactic instruction and clinical and laboratory experiences. Trainees must be offered supervised research opportunities in combinations of at least two of these subdisciplines. If an institution is unable to provide the full range of research exposures, suitable collaborative arrangements with other institutions may be acceptable.

1. Dental and Oral Anatomy and Physiology. Experiences will include studies on the normal integuments of enamel; enamel ultrastructure; demineralization and remineralization; histochemistry of the carious lesion and techniques for investigating developing caries.

2. Microbial Etiology of Caries. This includes training in the distribution of microorganisms in different locations in the oral cavity; formation, composition, ultrastructure and ecology of plaque; metabolism of plaque organisms; interspecies differences in cariogenic potential; genetics of microbial virulence characteristics; antigenicity of bacterial components.
3. Dietary Factors in Caries Etiology. Training will cover methods for assessment of cariogenicity of foods; development of noncariogenic sweeteners and anticariogenic dietary additives; influence and mechanism of action of trace elements in caries development.
4. Host Immunity and Susceptibility Factors. This section will emphasize salivary factors which influence caries, including changes in saliva composition and flow; salivary contributions to pellicle formation and mineralization; the secretory immune system; nonspecific salivary antibacterial factors.
5. Use of Animal Models in Caries Research. Research training will include design of experiments; selection of appropriate animal models; the importance of adequate nutrition; diet composition and preparation; control of cariogenic flora in experimental animals, gnotobiotic techniques; assessment of caries; statistical treatment of data.
6. Epidemiological Surveys and Clinical Trials of Chemotherapeutic Agents in Caries Research. This includes project design; experience in obtaining and working with study populations; diagnostic caries indices; biostatistical analysis and interpretation of results; fundamental aspects of delivery, acceptance and cost of caries preventive measures.

Funds may be requested for training a maximum of 8 trainees during a 5 year project period. Trainees should be clinically qualified individuals (D.D.S., D.M.D., or equivalent). Appointment of a trainee (Ph.D., M.D., D.V.M.) without prior clinical training in dentistry will only be permitted under exceptional circumstances. Consideration should be given to integrating the cariology training with a research degree (M.S., M.P.H., Ph.D.) or clinical residency. However, the award may only be used to support that portion of the residency which is required for training in clinical caries research.

Close cooperation between the training program director, faculty and trainees and NCP staff will be expected to ensure that Program objectives are met.

APPLICATION PROCEDURES

There will be a single competition with a receipt date of June 15, 1981. Applications received after that date will be accepted at the discretion of Division of Research Grants (DRG) staff. Applicants should use form PHS 6025, available in most institutional business offices or from the Division of Research

Grants, NIH. The face page must be labeled "In response to RFA NIDR-NCP-81-1." The original and six copies should be mailed to:

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

Because of funding limitations and the highly specialized nature of the training it is probable that only one new award will be made. The earliest start date will be July 1, 1982. Applications will be evaluated initially by the NIDR Special Grants Review Committee and subsequently by the National Advisory Dental Research Council in January or February 1982. Results of the competition will be announced shortly thereafter.

LETTER OF INTENT

Proposals judged to be nonresponsive to this request will be returned to the applicant. To ensure that proposals will be responsive to NCP needs, potential applicants are strongly urged to submit a letter of intent providing an outline of the proposal in 3 pages or less. Such letters should be received on or before April 15, 1981. Letters of intent, questions concerning cariology training and requests for NRSA institutional grant announcements and application forms should be addressed to:

John D. Townsley, Ph.D.
Chief, Caries Research Grants and Contracts Branch
National Caries Program
National Institute of Dental Research
Westwood Building, Room 522
5333 Westbard Avenue
Bethesda, Maryland 20205
Telephone: (301) 496-7884

ANNOUNCEMENT

MINORITY HYPERTENSION RESEARCH DEVELOPMENT SUMMER PROGRAM

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application receipt date: September 15, 1981

The Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute is accepting competing and renewal applications for Institutional National Research Service Awards for research training under the Minority Hypertension Research Development Summer Program.

The Minority Hypertension Research Development Summer Program is intended to (1) encourage the recruitment and development of minority investigators in specialized areas of research, prevention, control and education related to hypertension and (2) stimulate hypertension research, prevention, control and education by offering minority school faculty members and graduate students the opportunity to enhance their research capabilities in these areas.

Training will be offered through HYPERTENSION TRAINING CENTERS which have well-established hypertension research and training programs and are within 100 miles of (a) minority school(s) or provide satisfactory alternative arrangements for communication and exchange. The CENTERS will collaborate with MINORITY SCHOOLS to work out plans for the identification, selection and development of participating MINORITY SCHOOL FACULTY MEMBERS OR GRADUATE STUDENTS.

Minority schools are those with a majority or significant proportion of enrollment comprised of students of minority ethnic groups (including, but not limited to, Blacks, Spanish-speaking Americans, Native Americans, Pacific Islanders and Asian Americans) as well as a demonstrated commitment to the special encouragement of minority faculty, students, and investigators. The Minority School must commit itself to encouraging appropriate faculty members or graduate students to participate in this program, to continue the faculty members or graduate students in status after the summer session(s) and guarantee at least limited resources for their hypertension research and teaching activities.

Participating faculty members or graduate students must be nominated by the Minority School, be accepted by the Training Center, and agree to report annually

This program is described in the Catalog of Federal Domestic Assistance Number 13.837, Heart and Vascular Diseases Research. Awards will be made under the authority of the Public Health Service Act, Section 472, 42 USC 289l-1, and administered under PHS grants policy and Federal Regulation 42 CFR Part 66. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

for six years after training on their academic status, publications, grants or contracts and teaching activities related to hypertension.

Applicants may request funds to provide stipends for the duration of a summer program of \$260-\$365 per week for minority school faculty member participants and \$98 per week for minority school graduate student participants. In addition, funds may be requested for tuition and fees essential to the training; health insurance coverage for participants during the summer session; and up to \$1,250 per faculty member and \$750 per graduate student for institutional allowances which includes personnel, supplies, equipment essential to the program and consultant costs when specifically justified. Indirect cost allowances will be limited to 8 percent of the total allowable direct costs or the actual rate, whichever is lower.

The present announcement is for a single competition with a September 15, 1981 receipt date for applications. These applications will be reviewed at the February 1982 meeting of the National Heart, Lung, and Blood Advisory Council. Awards will be made beginning May 1, 1982. Applications not received by September 15, 1981, will be returned to the applicant. Guidelines for the development of the application may be obtained by contacting Dr. George A. Hayden at (301) 496-1724.

LETTER OF INTENT

Prospective Training Center applicants should submit a letter of intent not later than May 15, 1981 to:

Dr. George A. Hayden
Research Training and Development Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 3A-08
Bethesda, Maryland 20205

The Institute requests such letters to obtain an indication of the number and the scope of applications which will require merit review. A letter of intent is not binding and will not enter into the review of any proposal subsequently submitted. The letter should briefly describe the composition of the Hypertension Training Center, participating Minority Institutions, the overall approach, and areas of interest for the Minority Hypertension Research Development Summer Program.

ANNOUNCEMENT

RESEARCH ON CONSEQUENCES OF THERAPEUTIC APHERESIS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Grant applications are sought by the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute for studies to assess the consequences of removing plasma or cellular blood components from patients being treated by apheresis.

The Division of Blood Diseases and Resources supports research programs designed (1) to improve the effective administration and removal of blood components for the prevention, diagnosis and treatment of disease; and (2) to ensure the safety of (a) donors and patients from whom blood or its components are removed and (b) recipients of blood or its components.

The use of therapeutic apheresis has increased dramatically in recent years for two reasons. First, technical advances in cell separation devices and in membrane and column filtration systems have made this form of therapy possible. Second, anecdotal reports citing clinical improvement in patients suffering from a variety of disorders have stimulated its use. However, little research related to either specific diseases or specific apheresis procedures has been done to characterize the component(s) removed.

Examples of needed research include:

- o Studies, using animal models, to assess the immediate and long-range effects of various apheresis techniques;
- o Development and application of affinity adsorption columns for selective removal of specific plasma components;
- o Development of simple, reproducible tests to monitor the removal of components associated with specific disease processes. Such tests would enable more objective determination of the therapeutic efficacy of apheresis.

Investigator-initiated grant applications are encouraged in these and other areas related to the consequences of therapeutic apheresis.

This program is described in the Catalog of Federal Domestic Assistance number 13.839, Blood Diseases and Resources Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

Applicants should use the regular research grant application (PHS 398). If the institution's business office or central application control office does not have these, an individual copy may be requested by writing to Division of Research Grants, NIH. The original and six copies of the application should be mailed to:

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

All applications will be reviewed through the Division of Research Grants Study Section mechanism and by the National Heart, Lung, and Blood Advisory Council. Applications recommended for approval will compete for available funds with all other approved applications assigned to NHLBI. There are three receipt dates each year for new applications: March 1, July 1, and November 1.

Inquiries should be directed to: Chief, Blood Resources Branch, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, Federal Building, Room 5A08, 7550 Wisconsin Avenue, Bethesda, Maryland 20205; telephone: (301) 496-1537.

NOTICE

SUPPORT OF RESEARCH CENTER AND PROGRAM PROJECT GRANTS

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

This announcement consolidates and summarizes the position of the National Institute of General Medical Sciences (NIGMS) regarding its Program Project and Research Center Grants. It is not an announcement of any new program or initiative. Since many investigators have inquired about the intent and purposes of research center and program project grants and about their relationship to other support mechanisms, the following description and summary is intended to be helpful to potential applicants.

The National Institute of General Medical Sciences (NIGMS) supports research in the broad areas of Cellular and Molecular Basis of Disease, Genetics, Pharmacological Sciences, and Physiology and Biomedical Engineering through the award of individual grants (R01s), program project grants (P01s) and research center grants (P50s).

Whereas applications for individual grants and program project grants are investigator-initiated, research center grant applications are accepted only in the six fields listed in this announcement. Applicants should use form PHS 398 (available in most institutional business offices or from the Division of Research Grants, NIH) and follow the application procedures as stated below. The receipt dates for new and renewal grant applications are June 1, October 1, and February 1. The earliest possible award dates will be approximately nine months after receipt dates. Applications received too late for one cycle of review will be held for the next.

RESEARCH CENTER GRANTS

The purpose of an NIGMS research center grant is to encourage the development of new concepts, promote the application of basic research findings to clinical problems, and allow scientific progress that would not take place through, or would only be made more slowly by, separately funded efforts. These goals are expected to be achieved through the collaboration between basic and clinical scientists and through the support of a group of interrelated research projects which focus on a biomedical research problem within one of the fields specified below.

The initial award of a research center grant usually will be for a period of five years. Funding of renewal applications beyond this period will be contingent on evidence that the grant has, in fact, stimulated the kind of new scientifically meritorious approaches and interactions needed to achieve the goal for which the center grant is intended. A center grant should not be looked upon as a permanent mechanism for the funding of a group of investigators, but as a mechanism which serves a particular purpose at a particular time in the scientific development of the group. It would be expected that some projects initiated under center grant funding might evolve or expand in such a way as to warrant separate funding, while new projects would emerge to take their place. When a research center

grant no longer fulfills the intended purpose, it would be expected to come to a natural end. At such time, support of ongoing research may, of course, be sought under other mechanisms, such as program project grants or individual project grants.

Application Procedures

Special emphasis areas of the NIGMS in which research center grant applications will be accepted and the officials to contact are:

1. - Anesthesiology - Program Director, PBME - (301) 496-7253
2. - Trauma and Burns - Program Director, PBME - (301) 496-7253
3. - Biomedical Engineering - Program Director, PBME - (301) 496-7253
4. - Pharmacological Sciences - Program Director, PS - (301) 496-7707
5. - Genetics - Program Director, GEN - (301) 496-7087
6. - Molecular Pathology - Program Director, CMBD - (301) 496-7021

A prospective applicant for an NIGMS research center grant (new or renewal) is required to submit a letter of intent to the appropriate NIGMS Program Director (see above) prior to submission of a formal application. Since it is recognized that the preparation of an application for a large multi-investigator grant requires substantial investment of time, effort, and resources by a center director, the associated investigators, and the grantee institution, consultation with NIGMS staff before submission of such an application will allow a determination as to whether the proposed research and mechanism fit the mission of the NIGMS.

The letter of intent should include a concise description of the proposed research to be conducted under the center grant. The description should indicate: (1) how such a grant would fulfill the above stated purpose of an NIGMS research center; (2) the overall scientific focus or unifying theme; (3) the research goals of the proposed individual projects; (4) how each individual project relates to the other projects and to the overall scientific focus; (5) the names and curricula vitae of responsible investigators; (6) existing research resources and requested renovations; and (7) an estimate of the necessary level of support for each project and the core.

A letter of intent should be submitted at least three months in advance of the receipt date for applications to allow adequate time for consultations with and review by NIGMS program staff prior to preparation and submission of a formal application.

If notified that the proposed research center grant program would be appropriate to NIGMS, the applicant institution should submit the proposal on the regular research grant application form PHS 398.

NOTE: An application (including a competing renewal) received without a prior letter of intent showing evidence of responsiveness of the proposed research center grant application to this announcement will be returned to the applicant.

Each research center grant application must propose a Principal Investigator or Center Director who is knowledgeable of, and can assume responsibility for, the scientific and administrative activities proposed within the research center grant application. Since limited resources are available through the NIGMS research center program, and in order to assure the appropriate close collaboration, the number of individual projects to be supported under the center grant should not exceed eight. Investigators who are not to be supported by the research center grant, but whose collaborative efforts would enhance and strengthen the activities of the research center grant, are encouraged to submit individual research project or program project applications. The relationship of these investigators to the center grant can be cited in the center grant application as part of the overall aims and objectives of the center grant. The requested budget of a center grant application, whether new or renewal, should not exceed \$2,750,000 (direct costs only) over a five-year period.

The research center grant proposal should be structured as a series of separate but related project proposals. Each research center grant application must be submitted in the following format:

- A. Overall proposal: 1) face page; 2) a description of the aims and research objectives of the center, including brief summaries of the discrete projects and their relationships; 3) names of the center director and all associated investigators; 4) the complete consolidated budget for the entire center (summarizing sub-budgets for the component parts and core); 5) a description of facilities available, including major instruments and special program resources; 6) the benefits to be achieved by funding as a center grant, rather than as a series of individual projects; 7) administrative arrangements for overall scientific leadership and management of the center grant, including any plans for consultation of an advisory committee; and 8) a separate overall listing of percent of effort, and actual and pending research support from all sources for each participating investigator.
- B. Core: A description of the core facility(ies), including major instruments, special program resources and core projects (if any) together with an itemized budget for this core.
- C. Individual Projects: Each proposed scientific project within the center should be prepared as a discrete project grant application, including the customary face page and budget pages, biographical information, detailed description of the research to be conducted, a separate human experimentation certification and a memorandum of understanding and agreement (MUA) for recombinant DNA research, if applicable. Reference should be made as appropriate to the core program support and other aspects of the center showing its importance and relationship to the specific research proposal described.

The application should be submitted in a packet with parts arranged in the order described.

Review Of Applications

The individual projects within a center grant, as well as the center grant as a whole, must meet the same standards of scientific merit as those required of regular research project grants. In order to assure that a center grant application receives the best possible review by appropriate peers of all the participating investigators, the scientific merit of each component project will be assessed in a manner comparable to the assessment that an individual research project grant would receive. In addition, the scientific merit of the center grant application as a whole, as well as its coherence as a center, will be assessed.

The initial review usually will be conducted by the Office of Review Activities, NIGMS, and in all cases a project site visit will precede the committee's deliberations. Resulting recommendations will be sent to the National Advisory General Medical Sciences Council.

- A. Review by NIGMS Committee: The Executive Secretary will assemble a site visit team consisting of committee members and other scientists as warranted by the scope and content of the application. When there is not appropriate standing Institute Committee, a special review committee will be assembled. The site visit team will gather information and assess the application as a whole in relation to the announced center grant guidelines (see above), scientific direction, and relation of the projects to each other and to the overall goals of the center. The team will summarize its findings and report to the review committee. This committee will assess the scientific merit of each component project in a manner comparable to the assessment given to individually submitted research grant applications and assign a priority rating to each project. In addition, the overall center application will be assessed as to its fulfillment of the purpose of an NIGMS research center grant and its relevance to the program goals. The scientific merit of the entire research effort proposed by the research center team of investigators, the coherence of the projects to the central theme, and the relationship of all the investigators to each other and to the proposed center director will be assessed. An overall priority score will be assigned.
- B. Review by Advisory Council: Final review and recommendations by the National Advisory General Medical Sciences Council will take into account the scientific merit review of both the individual projects and the overall center grant application. In addition, the Council will judge the appropriateness of the center grant to the overall program of NIGMS.

PROGRAM PROJECT GRANTS

The program project grant is generally intermediate in scope and budget between the investigator-initiated individual research grant and the larger, more complex, multi-investigator research center grant. While individual research grants are awarded to support the work of one principal investigator who, with supporting staff, is addressing a scientific problem, program project grants are available to a group of several investigators with differing expertise who wish to collaborate in research by pooling their talents and resources for work on a specific scientific problem that thus may be solved more expeditiously. The program project grant is

investigator initiated, closely defined around a specific scientific problem, and is usually smaller in both budget and size than the average research center grant. While three to five investigators are usually involved, one scientist is designated by the applicant institution as principal investigator and bears responsibility for the scientific and fiscal management of the program project grant. It is expected that most of the collaborating scientists will be independent investigators. For example, support of one senior investigator and several postdoctoral and research associate-level scientists is not appropriate. In most cases, investigators from more than one department or administrative unit will be represented. Applicants are reminded that the program project grant is not intended to be a vehicle for departmental research support. Equipment and other core resources necessary for the accomplishment of the objectives of the program project grant may be requested. However, the need of each investigator for use of a major piece of equipment or core facility does not, in itself, provide justification for a program project grant.

Application Procedures

Applicants should avail themselves of staff consultation prior to submission of a program project grant application. Requests for details of research areas supported by NIGMS and inquiries exploring the suitability of the program project grant mechanism should be directed to the Program Director of the appropriate NIGMS program.

- A. Overall Proposal: An introductory section should contain justification for the program project grant mechanism and describe those goals which are not as readily attainable through individual research project grants. This section should include: 1) face page; 2) a description of the objectives of the program as a whole; 3) a list of participating personnel; 4) the consolidated budget for the program project grant (summarizing sub-budgets for the component parts and core); 5) a description of facilities available, including major instruments and special program resources; 6) a description of the benefits to be achieved by funding as a program project grant rather than as a series of individual research grants; 7) administrative arrangements for overall scientific leadership, quality control, and management of the program project grant; and 8) a separate, overall listing of proposed percent of effort on the program project grant and actual and pending research support and the funding level from all sources for each participating investigator (including percent effort devoted to each project).
- B. Component Projects: Each component of a program project grant should represent an independent as well as an interdependent research effort, and should be prepared in the format of an individual research grant application, including budget pages, biographical information, detailed description of the research to be conducted, and separate human experimentation certification and a memorandum of understanding and agreement (MUA) for recombinant DNA research, if applicable. If support of core resources is requested, a separate section for this should be included.

Review Of Applications.

Assignment of program project grant applications to the appropriate initial review group is the responsibility of the Division of Research Grants. Final review by the National Advisory General Medical Sciences Council will take into account the scientific merit of the proposal and the relevance of the proposed work to the goals of the National Institute of General Medical Sciences.

This announcement is a revision of and supersedes the announcements contained in the **NIH Guide for Grants and Contracts**, Vol. 7, No. 4, March 10, 1978, and Vol. 8, No. 1, January 19, 1979.

NOTICE

WITHDRAWAL OF NCI PREVENTIVE ONCOLOGY ACADEMIC AWARD

PENDING EVALUATION

The NCI Preventive Oncology Academic Award (POAA) announced in the **NIH Guide for Grants and Contracts**, Vol. 9, No. 1, January 3, 1980, and Vol. 9, No. 4, March 14, 1980 is undergoing evaluation. The May 1, 1981 date and subsequent deadlines for receipt of applications are withdrawn. It is anticipated that a revised announcement with new receipt dates will be issued subsequent to review and recommendations by the Board of Scientific Counselors, Division of Cancer Cause and Prevention. Plans for reactivation of this award will be published in a future issue of the **NIH Guide for Grants and Contracts**.

For further information, investigators may contact:

Donald H. Luecke, M.D.
Chief, Special Programs Branch
Division of Cancer Cause and Prevention
National Cancer Institute
National Institutes of Health
7910 Woodmont Avenue
Landow Building, Room 8C18
Bethesda, Maryland 20205
Telephone: (301) 496-9600