NIH GUIDE for GRANTS and CONTRACTS

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

Vol. 6, No. 9, April 26, 1977

IN THIS ISSUE:

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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: Room 2A14, 5333 Westbard Avenue, National Institutes of Health, Bethesda, Maryland 20014, and attach your address label to your letter. Prompt notice of your change of address will prevent your name being removed from our mailing list.

The GUIDE is published at irregular intervals to provide policy and administrative information to individuals and organizations who need to be kept informed of 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.

IN THIS ISSUE: (continued)

THE PROPHET SYSTEM

A N N O U N C E M E N T

The PROPHET System is a specialized national computer resource for those who study the mechanisms of drug action and other chemical/biological interrelationships. PROPHET's easy-to-use data-handling capabilities and experienced staff help investigators to organize, peruse, analyze, and communicate research results - often in ways that are impossible or impractical with manual methods or conventional computer facilities. Users access the PROPHET central computer directly from their laboratories/clinics via graphic display terminals connected to a telecommunications network.

The Chemical/Biological Information-Handling Program is seeking to identify investigators who need PROPHET's special capabilities and wish to participate in the continuing national collaborative effort to evaluate and refine this research tool. The Program is particularly interested in working with investigators who have not yet made extensive use of computers but are able to visualize with reasonable specificity how access to PROPHET's facilities and services might help them increase their research productivity.

Investigators seeking further information about the PROPHET System - including how to request access - should write to Director, Chemical/Biological Information-Handling Program, Division of Research Resources, National Institutes of Health, Room 6A-04, Building 31, Bethesda, Maryland 20014.

INSTRUCTIONS FOR SUBMISSION OF GRANT APPLICATIONS

NOTICE

The Division of Research Grants (DRG), in spite of instructions to the contrary, continues to receive applications, the original and six copies, either bound or stapled. Applicants are urged not to bind or to staple applications being submitted to the DRG. This delays processing.

The instructions for applications ask for the original typed copy to be forwarded with six duplicated copies. We request the original for two reasons: First, with appropriate signatures it is the legal document and forms a part of the official file. Second, in the typing process only one side of each page is used. This makes it possible to provide the printer with good copy material and allows duplication to occur rapidly with minimal chances of error. With new xerox equipment which has the capability of duplicating on both sides of a single page, applications are arriving accordingly. Applicants are urged to provide the original with print on only one side. The other six copies may be xeroxed on both sides of the pages, with its subsequent savings in postage and bulk.

If there are questions in regard to duplication of a proposal, such questions can be directed to the Referral Branch, DRG, (301) 496-7447.

NOTICE

PAGE CHARGE POLICY

As a result of recent memoranda on this subject, it appears useful to restate the current Government policy regarding payment of page charges from grant or contract funds, as shown below. The policy remains unchanged as approved in 1974 by the Federal Council for Science and Technology.

Excerpt from *Federal Register* [FR Doc. 74-27016 Filed 11/18/74]:

> "The publication of research results is an essential part of the research process. This has been recognized in part through authorization to pay publication costs from Federal research grant and contract funds. It is the intention of the Federal Government when making research grants or contracts that costs of such publications, including page charges, should continue to be borne from the grant or contract, if other sources are not available.
>
> "Scientific policy representatives of Federal agencies that constitute the Federal Council for Science and Technology have established the following criteria for honoring page charge bills submitted by ournal publishers.
>
> "(1) The research papers report work supported by the Government.
>
> "(2) Mandatory or voluntary page charge policies are acceptable, provided that the page charge policy of the publication is administered impartially for Government and non-Government sponsored research reports.
>
> "(3) The journals involved are not operated for profit."

MALOCCLUSION RESEARCH GRANT

APPLICATIONS SOUGHT BY THE

NATIONAL INSTITUTE OF DENTAL RESEARCH A N N O U N C E M E N T

The National Institute of Dental Research invites applications in both clinical and basic research relevant to the etiology and treatment of malocclusion of teeth and jaws. Clinical studies of interest include those related to (1) growth and development, (2) improved methods of growth prediction, (3) early diagnosis and interceptive procedures, (4) tooth eruption and its role in the development of occlusion, (5) skeletal remodeling, (6) the effects of malocclusion and its treatment on dental health, (7) improvement of treatment methods, (8) factors affecting treatment stability, and (9) patient motivation.

Applications for more basic biological studies are sought which will lead to a better understanding of craniofacial growth and development and treatment methods. Examples of such studies include (1) mechanism of tooth eruption and root resorption, (2) the role of the periosteum in bone formation and remodeling, (3) migration of muscle attachments on growing bones, (4) the nature of the physical stimuli which determine the shape and trabecular pattern of bone, and (5) augmentation of bone deposition and resorption.

Applicants responding to this announcement should use the standard NIH grant application kit and follow the procedures described therein. Applications will be received by the Division of Research Grants and reviewed by the normal process. There are three receipt dates each year for new applications: March 1, July 1, and November 1.

Preliminary drafts of the proposal and other inquiries regarding this program may be addressed to either Dr. Richard L. Christiansen, or Dr. Jerry D. Niswander, Craniofacial Anomalies Program Branch, National Institute of Dental Research, National Institutes of Health, Room 520, Westwood Building, Bethesda, Maryland 20014. Telephone (301) 496-7807.

AVAILABILITY OF NIH GRANTS PEER REVIEW STUDY TEAM RECOMMENDATIONS

NOTICE

The NIH Grants Peer Review Study Team has completed an intensive examination of the agency's research review system and forwarded to Director Donald S. Fredrickson a three volume report with more than 50 specific recommendations for preserving and strengthening the NIH peer review system.

The Study Team was established in April 1975 to examine in critical detail the entire process of peer review and make, where necessary, recommendations for modification and change. The 13-member Study Team was made up of senior NIH program and management officials and chaired by Dr. Ruth Kirschstein, Director of the National Institute of General Medical Sciences.

In the course of its study the Team conducted open hearings in San Francisco, Chicago, and Bethesda and solicited written comments from scientists, research administrators, and the public at large. The Study Team will publish an analysis of written comments as well as those presented in the hearings in a Phase II report scheduled for late 1977.

The Study Team concluded that peer review exercises the most powerful influence on the continued high quality of the Nation's biomedical research effort and that confidence in the system is justified.

The NIH Director, Dr. Fredrickson, in thanking the Study Team for its work advised them that he would give the report early attention. Certain of the recommendations would require action either by the Congress or higher administrative authorities, and the Director must decide whether or not to advocate such changes. Other recommendations fall within the authority of NIH and will be given thorough consideration. Following is a summary of the findings and recommendations which are described in detail in Volume I of the Team's report:

> The NIH grants peer review system is and has been extremely effective in identifying biomedical research activities of high quality. The principle of separation of grant application review and program staff functions at NIH is strongly endorsed. The assessment of the scientific merit of research activities being considered for support should be maintained as a major element in decision-making at NIH.

Selection of Initial Review Group Members

> NIH should publish periodically an announcement of upcoming vacancies on Initial Review Groups (IRG's) which invites suggestions regarding candidates for specific IRG's.

NIH should implement a formal procedure whereby an applicant-investigator may identify unique or unorthodox aspects of proposed research and suggest possible reviewers who are considered to be leaders in his/her area of research.

Special Initial Review Groups

It is essential that NIH continue to have the flexibility and opportunity to establish ad hoc or Special Initial Review Groups (SIRG's).

NIH and HEW should oppose any legislative proposal extending the Federal Advisory Committee Act to ad hoc or special review groups.

The roster of consultants to be included in an SIRG should be provided to all investigators whose applications are to be reviewed by the SIRG.

Nomination, Selection, and Appointment of National Advisory Council Members

Authority for selection and appointment of members of National Advisory Councils/Boards should be delegated to the Assistant Secretary for Health, HEW.

Scheduled Council vacancies should be announced along with the criteria for selection and the duties and terms of appointment.

The names and qualifications of the selected Council members should be published.

When a selection for a Council vacancy has been made other than from nominations submitted by the Director, NIH, the appointment should not be made final until the Director, NIH, has had the opportunity to comment on the selection.

Considerations in Regard to Conflict of Interest

NIH should develop detailed instructions for determination of conflict of interest for members of review and advisory groups.

NIH should adopt a procedure under which Form HEW 474 (Confidential Statement of Employment and Financial Interests) is returned to a member as incomplete, when such member makes no entry in a section of the form but does not write "none" or some equivalent.

All executive secretaries of IRG's should be given access to and should review, at least annually, the Form HEW 474 of members and should be required

periodically to attend training sessions on evaluation of conflict of interest situations.

All initial invitations to serve on review and advisory groups should make it explicit that final appointment is contingent upon review of the completed Form HEW 474 for conflicts of interest, or potential conflicts of interest, and that the new member should be formally notified of the appointment after the appointment process (including review of the Form HEW 474) has been completed.

The names of new members of review and advisory groups should not be released to the news media or other members of the public until such time as final appointment has occurred after completion of review of the Form HEW 474.

Appointment of Employees of "For-profit" Organizations to NIH Initial Review Groups

Employees of "for-profit" organizations should be eligible for membership on all initial review groups considering grant applications (including National Research Service Award applications). The basis for selection of such scientists shall be the same as for those employed by "nonprofit" organizations.

All "conflict of interest" statements (HEW Form 474) submitted by employees of profit-making organizations must be reviewed by the agency head, who must be satisfied that the individual can serve on the specific committee to which that person has been nominated without being in violation of the conflict of interest statutes.

Legal Considerations Regarding Grants Peer Review

The Public Health Service (PHS) Act should be amended to provide statutory exemption from the requirements of the Freedom of Information Act (FOIA) for disclosure of research designs and protocols presented in grant applications.

Those portions of the meetings of advisory groups which involve the review of grant applications should continue to be closed to the public (including those submitting applications), either under current exemptions to the open-meeting requirement or through a statutory amendment.

The current system of dual review should be preserved, with grant applications being reviewed first by initial review groups consisting solely of scientific and technical experts and then by National Advisory Councils and Boards including representatives of the public.

In releasing reviewers' opinions under the Privacy Act, an adequate legal basis should be established for protecting the reviewers' anonymity either through reinterpretation of existing law, or enactment of new legislation.

The NIH and HEW should establish a mechanism for special, periodic assessment of the impact of this new legislation ("sunshine laws") on the quality of grant applications and on the quality of peer review of such applications. Such assessment should be reported to the legislative and executive branches of the Government.

Impact of Review Workload on Quality of Initial Merit Review

The Director, NIH, should take immediate steps to limit the workload of all initial grant review groups to a level which is compatible with maintaining the high quality of peer review.

Authority to establish or discontinue initial review groups as the peer review workload dictates should be delegated to the Director, NIH.

Additional resources should be provided for peer review of grant applications where acceptable alternative approaches to reduction of workload will not permanently and effectively resolve long-standing review overloads.

The Director, NIH, should establish a permanent mechanism to determine an appropriate ceiling or maximum workload for each NIH Initial Grant Review Group.

NIH-wide Standards and Guidelines for Peer Review Procedures

The proposed peer review regulations prepared under Section 475 of the Public Health Service Act by HEW should be finalized.

NIH standards and guidelines should be prepared or revised as soon as possible after consideration and evaluation of recommendations made in the study by the Executive Secretaries Review Activities Committee.

In order to maintain and improve the level of excellence of the grants peer review system at NIH, a staff position should be established within the Office of Extramural Research and Training to provide for quality assurance of the system.

Training curricula should be developed by NIH for extramural program and review staff in order to provide orientation and to refresh and reiterate principles concerning the philosophy, objectives, and procedures for peer review.

Open forums and workshops for program and review staff should be established on a continuing basis so as to encourage and improve exchange and communication of ideas concerning issues relevant to the peer review system.

Orientation sessions should be held annually for all Initial Review Group and Council members by the Director, NIH, the BID Directors and their staffs.

Review of Business Management Practices

It should be recognized as an NIH policy position that the use of business management consultants as reviewers is a necessary adjunct to the scientific review of the large, complex, and multifaceted program projects, and centers, or of those grants involving consortium arrangements. Considering the nature of the traditional, investigator-initiated research project application and its review, the use of business management consultants should not usually be considered necessary or appropriate.

The principal criteria used to determine the need for business management consultant support should be related to the organizational or administrative complexity existing in any particular grant application.

NIH should develop a policy issuance covering the role of and need for assessment of business management in the review of the large program project and center grant applications and uniform guidelines to be followed by the business management consultants in their roles as members of project site visit teams and advisory groups.

Business management consultants should contribute to overall recommendations on project site visits and at Initial Review Group meetings, but they should not vote or give a priority rating. In addition, they should prepare a specific portion of project site visit reports and/or IRG summary statements

which should be recognized as separate from scientific review and evaluation, but should be carefully considered in reaching recommendations for each project.

Procedures should be developed which would allow the reports of the business management consultants, including specific recommendations for management improvement, to be made available to the applicant-institution.

Grants management staff of the BID's should participate with the IRG executive secretaries in the determination of need for and selection of business management consultants for review and whenever possible they should accompany the site visit teams on reviews of the complex projects as staff resources only.

The Role of Peer Review in Support of Unorthodox, Innovative Research

NIH should:

1. Require the applicant to identify and support in detail any contention that the research project being proposed is unorthodox or innovative;

2. Request initial review groups to identify applications they consider to be especially unorthodox or innovative, whether or not the applications were so identified by the applicants;

3. Encourage IRG members (as a group or individually) to prepare a statement in addition to the regular summary statement pointing out the unorthodox or innovative aspects of the application and its significance;

4. Consider the feasibility of developing an experiment involving limited support for certain speculative, high-risk, unorthodox, or innovative research proposals. Such a study might be part of a larger, much-needed effort to examine the processes of decision-making in allocating research support.

Release of Summary Statements to Principal Investigators

Summary statements (with the priority scores displayed) concerning grant applications should be routinely sent to the principal investigator as soon as practical after completion of the review by the particular National Advisory Council/Board. This recommendation is contingent upon the understanding that these documents will be released only to these individuals. If this procedure could reasonably lead to a requirement that NIH make these documents available to applicant institutions then the summary statements should be released only

upon receipt of an appropriate request from the individual concerned.

When a summary statement is released, upon a principal investigator's request, prior to final action by a National Advisory Council/Board, the document should be provided with the priority score displayed and the requestor should be advised that the information is interim in nature and that any attempt to modify the original application or provide commentary for considerations by the Council/Board may result in deferral or consideration of the application.

NIH should request authorization, through either regulation or legislation as appropriate, to release an initial review group summary statement to the principal investigator named in the application only after the review of his/her grant application is complete, i.e., after Council/Board action.

Priority Scores on Summary Statements

A "single priority score" convention should be adopted throughout NIH but until this occurs only the type of priority score used by the BID to make decisions should be displayed on the summary statements released to principal investigators.

The system of developing priority scores as a numerical indication of scientific merit of grant applications should be studied in order to assess whether the present procedure should be retained or a new procedure is needed.

NIH should conduct studies of:

1. Variations in individual reviewer and review group behavior in rating applications, over a period of time, and among different IRG's, and of the factors which act to increase or decrease such variability;

2. Variations in the quality of grant applications assigned to a given IRG from one review round to the next, over a period of time; and to variations in the quality of grant applications assigned to the IRG's;

3. The effects on the review process of displaying the raw priority score to the initial review group members immediately after they assign their individual scientific merit ratings, and of giving them the option, at that point, to reopen discussion and rerate the application.

Grants Peer Review Appeals System

A formalized NIH Grants Peer Review Appeals System should be established to correct or eliminate the deficiencies noted.

An OMBUDSMAN should be appointed by the Director, NIH.

To provide the needed higher levels of review related to appeals, a Grants Peer Review Appeals Board (a permanent committee), should be established.

Specific criteria should be established for reconsideration (appeal) of NIH action on grant applications.

Mechanisms and procedures should be established for appeals concerning assignment of grant applications.

Mechanisms and procedures should be established for appeals concerning scientific review of grant applications.

Single copies of Volume I are available upon request at no charge. Requests should be address to the Office of the Director, Room 317, Building 1, National Institutes of Health, Bethesda, Maryland 20014.

AVAILABILITY OF GUIDELINES

NOTICE

Guidelines for Institutional Programs in Interdisciplinary Research Supported by the Center for Population Research, National Institute of Child Health and Human Development

The Population and Reproduction Grants Branch (PRGB), Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD) has available for distribution copies of its new guidelines for Program Projects, Population Research Centers, and Specialized Population Research Centers. This publication describes the guidelines and procedures adopted by the CPR for new and renewal applications as well as for extant Program Projects and Centers. Effective June 1, 1977, PRGB, CPR, NICHD will accept only applications for institutional grants which conform to these new guidelines.

This announcement does not reflect a new or expanded initiative and should not be considered to be a request for applications. Rather, the guidelines have been developed to clarify the purposes and procedures under which PRGB, CPR will continue to use this research support mechanism.

It is important that potential applicants consult with PRGB, CPR staff prior to submission of new, renewal, and supplemental applications to determine if the proposed program satisfies the criteria for a Program Project, Population Research Center, or Specialized Population Research Center. Further information and copies of the guidelines may be obtained from:

Chief, Population and Reproduction
Grants Branch
Center for Population Research
National Institute of Child Health
and Human Development
National Institutes of Health
Bethesda, Maryland 20014

DIABETES RESEARCH AND TRAINING CENTERS, ANNOUNCEMENT AND SUPPLEMENTAL GUIDELINES OCTOBER 3, 1977, SUBMISSION DATE

A N N O U N C E M E N T

The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) wishes, with this supplemental announcement, to clarify and extend the guidelines for potential applicants for Diabetes Research and Training Centers (DRTC) grants. The original announcement and guidelines were published in October 1976 and copies are available from the Office of the Associate Director for Extramural Program Activities.

These guidelines indicated that, in accord with the recommendation of the National Commission on Diabetes, an assemblage of strong, high-quality, existing research programs was to be an essential component of any DRTC. In the first competition for these awards, this requirement for an ongoing biomedical research component favored institutions with well established research programs both in a quantitative as well as qualitative sense.

The intent of the Commission's recommendations, and of the NIAMDD, however, is not to limit the establishment of DRTC's to institutions with large and well established quality programs in diabetes. Rather the intent is to extend this concept to institutions or consortia where high quality biomedical research programs in diabetes and related endocrine disorders are in existence, but which have not yet reached quantitatively the level or programs in the larger centers, i.e., institutions in which a real potential for further development of the essential biomedical research base can be demonstrated and in which other necessary components of the DRTC or plans for their development exist.

Letters of intent and applications are invited from potential applicants who feel that their ongoing program in basic and clinical research in diabetes and its management has sufficient quality and potential for development of the full range of activities of a DRTC. As indicated in the original guidelines, and in accordance with the recommendations of the National Commission on Diabetes, the institutions and consortia applying should also have an ongoing program in one of four other areas, and specific plans for development of the other three areas:

1. Training of postdoctoral fellows for research in diabetes and, management;
2. Training of health professionals in diabetes and its management;
3. Training of practitioners of the health professions in diabetes and its management in the form of continuing education and information programs; and
4. A model training-educational-treatment demonstration facility for diabetics in order to contribute to the other areas of endeavor in the DRTC.

Applicants are asked to take into consideration that budgetary requests in various categories should maintain a reasonable balance, and that the research component (basic and clinical research in the field of diabetes and its management) is an essential prerequisite component. It is re-emphasized that patient care cannot be provided in this program unless as a part of a specific research project.

Letters of intent should be brief, limited to one page, and are due July 1, 1977. The original and two copies should be sent to:

Associate Director for
Extramural Program Activities
National Institute of Arthritis,
Metabolism, and Digestive Diseases
National Institutes of Health
Bethesda, Maryland 20014

Completed grant applications, an original and six copies, should be mailed to the Division of Research Grants. Address labels are included in the NIH 398 application kit. The due date for applications is COB, October 3, 1977.

Simultaneously with submission of completed application, two copies of Section I and parts of Section II (budget and biographical sketch of Principal Investigator) of NIH Form 398 should be sent under separate cover to Acting Chief, Review Unit, Extramural Program Activities, NIAMDD, Room 655, Westwood Building, Bethesda, Maryland 20014.

Review Criteria

All criteria for review and evaluation as listed in the original guidelines dated October 1976 are applicable to this announcement. In addition, specific to this announcement is evaluation in terms of increasing the quantitative level of an existing research program of excellence. This will necessitate evaluation of the potential to expand as adjudged by the rationale for doing it at the applicant institution and the specific plans and mechanisms proposed to accomplish this task. Such plans should be discussed from a historical base of what has been accomplished in the past and what level of risk population exists in the proposed center community which shall be served by the increased training activities.

Review Procedures

All applications will be reviewed by a special review committee composed of experts in the field of diabetes and training. Review by Council is anticipated to occur in May 1978.

It should be emphasized that review of applications is a separate activity, performed by a special review committee established by the Review Unit of NIAMDD. Each application should, therefore, be prepared in such a way as to stand on its own merits, being as complete as possible at the time of submission.

Format

Standard application kits (NIH Form 398) should be used. Include a Table of Contents immediately under face page, referencing page numbers of key sections within the application.

Further information and copies of the original guidelines may be obtained by writing or calling:

Diabetes Special Programs Director
Extramural Programs
Room 622, Westwood Building
National Institute of Arthritis,
Metabolism, and Digestive Diseases
National Institutes of Health
Bethesda, Maryland 20014

Telephone: (301) 496-7418

NATIONAL CANCER INSTITUTE'S

CONSTRUCTION PROGRAM — POLICY CHANGE

On January 24, 1977, the National Cancer Advisory Board recommended to the Director, NCI, that the rate of Federal financial participation in a construction grant not exceed 50%. The Director, NCI, has accepted the recommendation. Therefore, effective for all construction applications submitted for the October 1, 1977, receipt date, requests shall be for no more than 50 percent Federal participation, with the remainder in non-Federal grantee participation.

Volume No. 6

Guide No. 1, January 7, 1977

Guide No. 2, January 12, 1977

Guide No. 3, February 4, 1977

Guide No. 4, March 1, 1977

Guide No. 5, March 7, 1977

Guide No. 6, March 14, 1977

Guide No. 7, March 17, 1977

Guide No. 8, March 25, 1977

Guide No. 9, April 26, 1977

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