TEM's Book

NIH GUIDE for GRANTS and CONTRACTS

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

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IN THIS ISSUE:

HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: 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)

PRIOR APPROVAL OF USE OF NIH GRANT FUNDS INCLUDING REBUDGETING

POLICY

A. *PURPOSE* This issuance states the NIH policies and procedures with respect to prior approval requirements relative to the use of grant funds including rebudgeting. It implements PHS Grants Administration Manual Chapter 1-510, dated September 8, 1975, and revises and supersedes *NIH Guide for Grants and Contracts*, Vol. 1, No. 22, December 15, 1972, pp. 1-6, Rebudgeting of Funds Within NIH Grants.

B. *APPLICABILITY* This policy covers all NIH grants with coded prefixes of "R", "M", "P", and "T". It also applies to the National Library of Medicine's Medical Library Resources Project grants (G08) and the Division of Research Resources' Minority Biomedical Support grants (S06) and Biomedical Research Development grants (S08). It does not apply to Scientific Review and Evaluation grants, nor to conference grants.

C. *BACKGROUND* Grant budgets are reviewed and receive the approval of the NIH awarding unit for specific categories of expenditures such as personnel, equipment, supplies, and travel. In certain instances, NIH policy has permitted the grantee institution to depart from the approved budget and use grant funds for other direct cost items required for the project. In other cases, prior approval by the NIH awarding unit has been required. At one time all grantees were required to obtain prior approval in writing from the NIH awarding unit for rebudgeting of essentially all grant funds prior to the performance of the act which required the expenditure of funds. In 1964, the NIH on behalf of the PHS initiated a pilot study of increasing the role of the grantee institution in the management of projects funded through research grants. Selected institutions were assigned the responsibility to review and approve requests from principal investigators and program directors within their own institutions for changes in certain categories of expenditures. Based on results of the pilot study, the rebudgeting authority was broadened to cover certain training programs and was gradually extended to other institutions. Subsequently, the PHS announced a consolidated prior approval policy, including rebudgeting, in the *PHS Grants Policy Statement* issued effective July 1, 1974 and in the PHS Grants Administration Manual Chapter 1-510.

D. *REFERENCES*

1. Code of Federal Regulations, Title 45, Part 74, Subpart L, Budget Revision Procedures
2. Office of Management and Budget Circulars A-21, A-87, A-101, and A-102; General Services Administration, Federal Management Circulars 73-7, 73-8, 74-4, and 74-7
3. DHEW and PHS Grants Administration Manual Chapter 6-00, Cost Principles

4. DHEW Grants Administration Manual Chapter 6-150, Reimbursement of Indirect Costs
5. PHS Grants Administration Chapter 1-510, Prior Approval of Use of Grant Funds Including Rebudgeting
6. PHS Grants Policy Statement
7. NIH Guide for Grants and Contracts, Vol. 1, No. 9, p. 9, Grant Support of Scientific Meetings
8. NIH Guide for Grants and Contracts, Vol. 3, No. 18, p. 1, Grant Appeals Procedure
9. NIH Guide for Grants and Contracts, Vol. 4, No. 5, p. 1, Predoctoral and Postdoctoral Trainee and Fellowship Support
10. NIH Guide for Grants and Contracts, Vol. 4, No. 8, p. 4, Guidelines for Establishing and Operating Consortium Grants

E. *DEFINITIONS*

1. Prior Approval

Written permission provided by an authorized official in advance of an act that would result in either (a) the obligation or expenditure of funds or (b) the performance or modification of an activity under the grant-supported project, where such approval is required. Documentation of the approved budget on the Notice of Grant Award constitutes prior approval for the performance of activities and the expenditure of funds for specific purposes and items described in the grant application unless otherwise restricted by the Notice of Grant Award.

2. Rebudgeting

Any reallocation of funds by a grantee between cost categories in a grant budget. For such actions requiring prior approval, the request is usually initiated by the principal investigator or the program director and must be approved by the NIH awarding unit or the designated grantee institution official, as provided for in this policy.

3. Grant Budget

The financial plan approved by the NIH awarding unit for use of Federal funds to carry out the purpose of the grant as shown on the award notice.

4. Pre-award Costs

For purposes of this policy, pre-award costs are those costs incurred prior to the effective date of new or competitive extension (renewal) awards only.

5. Equipment

An article of non-expendable personal property which is complete in itself, is of a durable nature, has an expected useful life of more than one year, and an acquisition cost of $300 or more per unit except that recipients subject to Cost Accounting Standards Board (CASB) regulations may use the CASB standards. Equipment falls into two classes: (a) special purpose and (b) general purpose. Classification of an item of equipment depends on the nature of the item regardless of its intended use or planned location.

a. Special Purpose Equipment All items of equipment that generally are usable only for research, medical, scientific, or technical activities. Included are such items as microscopes, centrifuges, spectrophotometers, scintillation counters, etc.

b. General Purpose Equipment All items of equipment that generally are usable for other than research, medical, or specialized scientific, or technical activities, whether or not special modifications are needed to make them suitable for use on a project. Included are such items as office equipment and furnishings, computing and automatic data processing devices and equipment, reproduction equipment, refrigerators, portable heating and cooling units, vehicles, cameras, etc. General purpose equipment does not lose this characterization merely because of a scientific or technical purpose for which it is purchased or the location where it is used.

6. Travel

a. Domestic travel is travel performed within the grantee's own country and travel between the U.S. and Canada for grants made to institutions within the U.S. or Canada. The U.S. includes Guam, American Samoa, Puerto Rico, the Virgin Islands, and the Canal Zone, and the Trust Territory of the Pacific Islands.

b. Foreign travel is travel outside the U.S. or Canada, or not within the grantee's own country. Travel within the U.S. or Canada enroute to or returning from a foreign destination is considered foreign travel.

7. Patient Care Costs

Includes only those costs related to routine and ancillary medical services provided to individuals on either an in-patient or outpatient basis. Patient care costs do not include the otherwise allowable items of personal expense reimbursement (patient or attendant travel, subsistence, etc.),

consulting physician fees, or any other direct payments related to all classes of study participants, including inpatients, outpatients, subjects, volunteers, and donors.

8. Trainee Costs

Stipends, tuition, and fees in training or manpower grants.

9. Special Budgetary Restrictions

Any specific limitation or condition imposed by the awarding unit in addition to the general policy restrictions on expenditures of funds in an individual grant. All special budgetary restrictions must be stated on, attached to, or referenced on the award notice. Any other communication to the grantee, which might include information considered restrictive in nature, may not be used as a substitute for the requirement of conveying all special budgetary restrictions on the award notice.

10. Contractual or Third Party Costs

All appropriate costs (including applicable indirect costs, if any) associated with research services purchased from third parties. These costs may include, but are not necessarily limited to, consortia or collaborative agreements.

F. *POLICY* The NIH expects the grantee institution to anticipate the full extent of its financial requirements when applying for a grant, to justify them in terms of essentiality to the project or program, and to budget for those costs in each grant application. Award of a grant budget by the NIH constitutes prior approval for expenditure of funds for costs as included in the approved budget.

Depending on the type of institution, grantees have varying degrees of flexibility under the prior approval authorities extended them to meet certain unanticipated requirements in research and manpower projects, provided that grant funds are used in compliance with existing Federal policies and regulations governing the respective grant program(s). Such departures must enhance and not impede progress of the project toward its stated objective and be in conformance with this policy statement and the policies and procedures of the grantee institution. They may further be conditioned by restrictions imposed by the NIH awarding unit as a condition of the individual award. No prior approval requirements in addition to those provided for in this issuance may be imposed by the NIH awarding unit on any class of grants or expenditures without prior approval of the Associate Director for Extramural Research and Training, NIH.

For all grants subject to this policy, grantee institutions may rebudget funds within the total amount of the approved grant budget to meet unanticipated expenditures, provided:

1. The expenditures are necessary to the successful continuation or completion of the project;

2. The purposes for which the expenditures are made are allowable under regulations and policies governing the grant program and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74;

3. Prior approval is obtained from the awarding unit whenever the proposed rebudgeting action:

   a. Results from changes in the scope or objectives of the grant-supported activities, including subgranting or contracting out any of the principal activities of the grant;

   b. Indicates a need for additional Federal funding, excluding those situations where the need for additional funding results from an increase in the amount of indirect costs that may be claimed because of an otherwise allowable rebudgeting action which increases the direct cost base against which indirect costs are calculated; amounts for additional indirect costs shall be provided in accordance with the settlement provisions indicated in DHEW Grants Administration Manual Chapter 6-150, Reimbursement of Indirect Costs;

   c. Involves the transfer of amounts budgeted for indirect costs into direct costs;

   d. Involves any purposes disapproved or restricted as a condition of the award;

4. Prior approval is obtained from the appropriate level designated (awarding unit or grantee) whenever the proposed rebudgeting action:

   Involves the expenditure of funds for any item or purposes requiring prior approval by the applicable cost principles, regulations, Grants Administration Manual chapters, and other HEW/PHS/NIH duly promulgated policies.

   (Note: See exhibit attached. To assist in identifying prior approval items subject to this requirement, a summary of items related to different types of institutions is provided as an exhibit to this chapter. The summary does not constitute a complete list of all prior approval items. It is intended to list those items most common to NIH grant programs.)

Failure to obtain prior approval in accordance with the provisions of this chapter for all actions requiring such approval may result in the disallowance of costs. PHS and NIH policy permits the officials who would have been authorized to give approval originally to grant retroactive approval in highly unusual or exceptional circumstances and when denying such approval would affect in a material manner the successful performance of the project objectives. Approval officials shall be held responsible to fully document the grant file with:

1. The reasons why prior approval was not obtained in a timely manner,

2. The manner in which the project objectives would be adversely affected, and

3. A certification that approval would have been given had the request been submitted on time.

G. *PRIOR APPROVAL AUTHORITIES*

1. Colleges, Universities, Hospitals, Research Institutes, and Research Foundations

   a. Grantee institutions which are colleges or universities, hospitals, research institutes, and research foundations are required to establish and utilize an Institutional Prior Approval System for obtaining prior approval for each of the following types of rebudgeting actions:

      (1) Expenditure in the equipment category for each individual item of special purpose equipment having an acquisition cost of $1,000 or more;

      (2) Cumulative expenditures in the equipment category during a budget period which will cause the amount awarded for equipment to be exceeded by $1,000 or 25 percent of the amount shown on the latest award statement, whichever is greater;

      (3) Cumulative expenditure in the domestic travel category during a budget period which will cause the amount awarded for such travel to be exceeded by $500 or 25 percent of the amount shown on the latest award statement, whichever is greater;

      (4) Expenditures in the patient care cost category which will cause expenditures in that category to exceed the amount originally awarded in the grant budget provided the need for patient care in the project was specifically approved by the awarding unit.

   b. Colleges, universities, hospitals, and research institutes and foundations must obtain prior approval from the awarding

unit for all other rebudgeting actions which require such approval.

(Note: For summary guidance on prior approval requirements applicable to these grantees, refer to the attached exhibit.)

2. Other Private Nonprofit Institutions and Individuals as Grantees

Private, nonprofit grantee institutions, other than colleges, universities, hospitals, and research institutes or research foundations (e.g. professional societies and associations, museums, national health agencies, service and demonstration organizations) and individuals as grantees must obtain prior approval from the awarding unit for all proposed rebudgeting actions for which prior approval is required.

(Note: For summary guidance on prior approval requirements pertinent to private, nonprofit institutions and individuals as grantees refer to the attached exhibit.)

3. State and Local Government Agencies (Does not include State or local institutions of higher education and hospitals.)

a. Grantees which are State and local government agencies are required to establish and utilize an Institutional Prior Approval System for obtaining prior approval of the following types of rebudgeting actions:

(1) Expenditure in the equipment category for each individual item of special purpose equipment having an acquisition cost of $1,000 or more; or

(2) Expenditures in the patient care costs category which will cause expenditures in that category to exceed the amount originally awarded in the grant budget provided the need for patient care in the project was specifically approved by the awarding unit.

b. State and local government agencies must obtain prior approval from the awarding unit for all other proposed rebudgeting actions which require such approval.

(Note: For summary guidance on prior approval requirements applicable to these grantees, refer to the attached exhibit.)

H. *INSTITUTIONAL PRIOR APPROVAL SYSTEM*

1. Implementing Guidelines

Where institutional prior approval is required, the system must be operated in accordance with the following principles:

a. The institution must designate an appropriate official or officials to review and approve rebudgeting requests for those items which require institutional prior approval. Preferably, the official(s) should be the same official(s) who sign or countersign those types of rebudgeting requests which require submission to, and approval by, the awarding unit. In any event, the designated official(s) may not be the program or project director or any official having direct responsibility for the conduct of the project, or a subordinate of such individual. When independence of the designated official cannot be maintained, such as where the head of the grantee institution is also the project director on a grant, the Institutional Prior Approval System does not apply to that grant.

The grantee institution should take the responsibility to notify the appropriate awarding unit(s) promptly where such situations exist. All required prior approvals must then be obtained from the awarding unit in accordance with Section I. below.

(Note: See special reference to H.1.a. under Section K., *EFFECTIVE DATE*.)

b. The rebudgeting action must neither impair the institution's ability to complete the project or activity as approved, nor increase the total direct costs to the grant.

c. The funds may not be used for any purpose disallowed as a condition of the award.

d. Decisions affecting rebudgeting must be well-documented and retained in the institution's records available for inspection or audit for a period consistent with the records retention requirements of PHS Chapter 1-100. Specific documented actions required for each authorized prior approval are:

(1) Justification, with informative documentation of the rebudgeting requested including identification of the budget categories affected, by the principal investigator.

(2) Review at grantee management level for policy permissibility and grant funds availability, by appropriate grantee official(s).

(3) Review for scientific propriety, project relevance, and effective utilization of institutional resources by appropriate grantee official(s), at an administrative level above that of the initiator of the request.

(4) Final approval, by a designated grantee official(s).

e. Grantee institutions may be more, but not less, restrictive concerning rebudgeting of the specified items. In addition, they may establish prior approval requirements within their own institution for cost categories in addition to those specified herein. Approval for rebudgeting in these other categories may be established at any level set by the grantee institution.

2. Referral of Problems Encountered in the Institutional Prior Approval System to the Awarding Unit

If, in the opinion of the designated grantee official(s), no procedure, policy, or precedent clearly applies to the rebudgeting question, such official(s) should seek advice from the awarding unit.

Also, issues may be referred to the awarding unit by the responsible official(s) of the grantee institution if they cannot be decided internally in the grantee institution. This latter procedure does not constitute a mechanism for the principal investigator or program director to appeal the institution official's decisions directly to the awarding unit.

If during the budget period it becomes apparent to the grantee institution or the principal investigator that a restriction made by the awarding unit at the time of award is working to the disadvantage of the project, the responsible grantee institution official(s) may request in writing that the awarding unit rescind the restriction in question. If the awarding unit approves the request in writing, subsequent budget changes permitted by the removal of the restriction may be authorized by the grantee official(s).

3. NIH Right to Disallow Costs

Grantee institutions are expected to exercise care and discretion in proposing obligations or expenditures for any cost items in order to avoid their being incurred too late in the project for effective use. Unless specific justification can be made for effective utilization on the project for which the funds were derived, the costs may be challenged and subject to possible disallowance.

Approval of rebudgeting actions under an Institutional Prior Approval System administered in accordance with this chapter satisfies the PHS prior approval requirements. However, as with other costs charged to grants, they must meet the required tests of allowability, allocability, necessity, reasonableness, etc. Where it is determined, through audit or otherwise, that such costs do not meet these tests, the costs shall be disallowed.

I. *PRIOR APPROVAL BY THE NIH AWARDING UNIT*

1. As previously indicated the NIH requires that certain items of cost and/or budget modification must have prior approval by the NIH awarding unit. Those items are displayed in the exhibit to this chapter which is entitled Summary of Principal Prior Approval Requirements for Use of NIH Grant Funds Including Rebudgeting.

2. All rebudgeting requests which require such approval must be signed by the originator of the request and the appropriate grantee institution official and submitted to the Grants Management Officer of the awarding unit. After review of the request by grants management and scientific staff, as appropriate, a prompt reply signed or countersigned by the GMO will be made to the individuals who submitted the request.

J. *GRANTEE'S RIGHT TO APPEAL*

1. An awarding unit's decision to disapprove a grantee's written request for permission to incur an expenditure during the term of a grant may be appealed under the PHS Grant Appeals Procedures as set forth in 42 CFR Part 50. Failure of an awarding unit to respond to a grantee's request within 30 days after the post-marked date of the grantee's request shall be deemed as a disapproval for purposes of this section.

2. Appeals made in connection with this policy must be submitted in accordance with the provisions of the PHS Grant Appeals Procedures (42 CFR Part 50) as detailed and explained in Chapter PHS 1-520 of the HEW Grants Administration Manual and the *NIH Guide for Grants and Contracts*, Vol. 3, No. 18, pp. 1-5, November 13, 1974.

K. *EFFECTIVE DATE*

This policy shall have an effective date of February 1, 1976. However, for that portion of H.1.a. which relates to the required exclusion of certain grants from Institutional Prior Approval Systems, an effective date of October 1, 1976, will be utilized to provide additional time for administrative review and determination.

Exhibit

SUMMARY OF PRINCIPAL PRIOR APPROVAL REQUIREMENTS FOR USE OF NIH GRANT FUNDS INCLUDING REBUDGETING

Type of Expenditure	Approvals Required - by Type of Grantee Institution: Colleges, Universities, Hospitals, Research Institutes, Res. Fdns.	Individuals as Grantees, Other Private Nonprofit Institutions or Organizations	State and Local Governments
1. Alteration/Renovation			
a. $1,001 to $75,000	AU	AU	AU
b. Over $75,000	NIH-OD	NIH-OD	NIH-OD
2. Consultant Fees - payment to employees of institution to which grant is awarded	HI	HI	HI
3. Equipment			
a. Special Purpose $1,000 or more per item	IPAS	AU	IPAS
b. General Purpose $300 or more per item	AU	AU	AU
c. Cumulative expenditures which exceed awarded amount by $1,000 or 25% whichever is greater	IPAS	AU	N/A
d. Equipment Insurance (as a direct cost)	AU	AU	AU
4. General			
a. Any budgetary revisions resulting from changes in scope or objective of the grant-supported program	AU	AU	AU
b. Use of funds for any purpose disapproved or restricted as a condition of award	AU	AU	AU
5. Indirect Costs - transfer of funds budgeted for indirect costs to absorb increases in direct costs	AU	AU	AU
6. Motion Picture and Television Production	AU	AU	AU
7. News Release Costs	AU	AU	AU
8. Patient Care Costs			
a. Authority to incur under grant	AU	AU	AU
b. Additional expenditures to those already approved by the awarding unit	IPAS	AU	IPAS
9. Pre-award Costs	AU	AU	AU
10. Salaries			
Use of project grant salary funds released as a result of research or academic career award	AU	AU	AU
11. Subgranting or Contracting out any principal activities of the grant (Third party costs)	AU	AU	AU
12. Trailers and Modular Units	AU	AU	AU
13. Trainee Costs - any transfer out of Trainee Cost category (i.e., stipends, tuition and fees)	AU	AU	AU
14. Travel			
a. Each foreign trip and its costs	AU	AU	N/A
b. Cumulative domestic travel expenditures which exceed awarded amount by $500 or 25%, whichever is greater	IPAS	AU	N/A

LEGEND: AU - Awarding Unit
IPAS - Institutional Prior Approval System
NIH-OD - Office of Extramural Research and Training
HI - Head of Institution or his designee
N/A - Not applicable

HERPES SIMPLEX VIRUS (HSV) RESEARCH

GRANT APPLICATIONS SOUGHT BY THE

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

The Soft Tissue Stomatology and Nutrition Program Branch of the National Institute of Dental Research is interested in expanding research activities concerned with herpetic gingivostomatitis and herpes labialis.

According to recent estimates, herpes simplex virus (HSV) infections are widespread, afflicting up to 50% of the U.S. population. About half of those affected experience recurrent oral episodes (herpes labialis). Clinical manifestations of the oral facial infections vary widely, and severity is somewhat higher in children and young adults. HSV also causes serious infections of the urogenital tract, eyes, and brain that may lead to blindness, lethal encephalitis, or cervical cancer.

Because of the ubiquitous nature of these viruses, the lack of successful treatment regimes, their oncogenic potential, and their general and oral health hazard, research grant applications are being sought which are designed to (1) characterize immunlogical aspects of oral herpes simplex virus infections, (2) further develop appropriate animal model systems for herpetic gingivostomatitis and herpes labialis, (3) examine factors associated with oral-facial tissue localization and reactivation of the virus, (4) investigate the possible involvement of herpesvirus in oral cancer, (5) identify and test potential chemotherapeutic or antiviral substances against HSV infections, (6) develop better methods of diagnosing preclinical stages of herpes infections, and (7) conduct studies aimed at developing a vaccine that will protect against oral-facial and perhaps other clinical manifestations of HSV infections.

Deadlines for the receipt of grant applications are November 1, March 1, and July 1. Review and award of applications concerned with studies on HSV will be through the usual NIH procedures. Proposals that include studies on HSV that are peripheral to those of oral-facial infections may be assigned to the National Institute of Allergy and Infectious Diseases or other appropriate Institutes or Divisions.

Preliminary drafts of the proposals and other inquiries regarding this program may be addressed to either Dr. Paul D. Frazier, Chief, or Drs. Matthew A. Kinnard and Robert J. Scheullein, Health Scientist Administrators, Soft Tissue Stomatology and Nutrition Program Branch, National Institute of Dental Research, National Institutes of Health, Bethesda, Maryland 20014, telephone (301) 496-7808.

RECURRENT APHTHOUS STOMATITIS (RAS)

RESEARCH GRANT APPLICATIONS SOUGHT BY

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

The Soft Tissue Stomatology and Nutrition Program Branch of the National Institute of Dental Research wishes to increase research efforts dealing with recurrent aphthous stomatitis (RAS) and related ulcerative disorders of the oral cavity.

Few oral disorders result in as much pain and discomfort or affect as many people as RAS. Estimates of affected persons in the United States range from 10 to over 50%. Multiple unrelated factors appear to contribute to the disease state. High rates of occurrence in adult populations have been associated with environmental stress; the incidence among children may exceed 90% when both parents experience recurrent lesions. Since the etiology of RAS is unknown, there are few effective criteria available for diagnosing or differentiating the disease from other ulcerative conditions. The severity of RAS commonly referred to as "canker sores" varies greatly and may involve extraoral sites, such as in Behcet's syndrome which affects both genital mucous membranes and portions of the eye. Pain and disability associated with these ulcerations results in an appreciable annual loss of schooling for children and adolescents as well as time lost from work by adults.

The multiple causative factors which appear to contribute to the severity and onset of RAS have hampered the development of a successful regime for treatment and prevention of the disease. The National Institute of Dental Research therefore desires to expand both clinical and basic research activities dealing with RAS which are designed to (1) advance our knowledge of the clinical and epidemiological aspects of both RAS and Behcet's syndrome which will more precisely define the entire syndrome and its spectrum of severity, (2) develop appropriate animal models, (3) identify etiological factors associated with these ulcerative conditions, (4) analyze the immunological aspects of the disease to enhance diagnostic capabilities and to provide insight into possible preventive measures, (5) develop and test the efficacy of new treatment regimes.

Major medical centers and hospitals having expertise in oral medicine and oral pathology are especially encouraged to assume leadership in diagnostic, therapeutic, and basic studies related to these diseases.

Deadlines for the receipt of grant applications are November 1, March 1, and July 1. Review and award of applications concerned with studies of RAS will be through the usual NIH procedures.

Preliminary drafts of proposals and other inquiries regarding this program may be addressed to either Dr. Paul D. Frazier, Chief, or Drs. Matthew A. Kinnard or Robert J. Schuellein, Health Scientist Administrators, Soft Tissue Stomatology and Nutrition Program Branch, National Institute of Dental Research, National Institutes of Health, Bethesda, Maryland 20014, telephone (301) 496-7808.

NOTICE OF AVAILABILITY OF NONHUMAN PRIMATE MATERIAL FOR RESEARCH ON AGING

The National Institute on Aging (NIA) supports a contract to make available tissues, organs, and fluids and other biological materials from a group of 20-year-old Macaca nemestrina and a control group of 10-year-old animals. Investigators interested in acquiring access to these materials for characterization of age-related changes in Macaca nemestrina should write or call:

Dr. Douglas M. Bowden
Regional Primate Center SJ-50
University of Washington
Seattle, Washington 98195

(206) 543-1430

Deadline for application is October 16, 1976.

PROHIBITED OR RESTRICTED RESEARCH

NOTICE

Certain types of activities involving human subjects may not be supported or conducted with the aid of National Institutes of Health, Public Health Service, or Department of Health, Education, and Welfare funds regardless of the type of grant or contract mechanism involved:

1. Any research whatsoever involving in vitro fertilization of human ova, unless previously approved by the DHEW Ethical Advisory Board, National Institutes of Health, Bethesda, Maryland 20014. [Authority: 45 CFR 46.204(e)]

2. Any research involving pregnant women or fetuses, not strictly in compliance with the provisions of Subpart B of Part 46 of Title 45 of the Code of Federal Regulations, unless previously approved by the DHEW Ethical Advisory Board. (Authority: 45 CFR 46.211)

3. Any research in biomedical, contraceptive development, and behavioral aspects of family planning or population research related to or involving elective abortion. [Authority: 45 U.S.C. Ch. 6A, Sections 1004(b) (2) and 1008]

4. Any research project or program which is experimental in nature, without the written informed consent of each participant or subject, or if the participant or subject is under 18 years of age, without the written informed consent of his/her parents or legal guardian. (Authority: Public Law 93.206, Section 411)

These prohibitions extend to: use of funds provided by research grants (including program project grants, center grants, and other types of grants directly supporting research), research training grants, biomedical science grants, categorical clinical research center grants, general clinical research center grants, national research service award grants, research career awards, and all further types of grants and contracts supporting research, training, and development activities.

SPECIAL GRANTS FOR NEW INVESTIGATORS IN ANESTHESIOLOGY

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES A N N O U N C E M E N T

OBJECTIVES

The National Institute of General Medical Sciences (NIGMS) is establishing a new Special Grants Program in Anesthesiology in order to:

- encourage new investigators in the field of anesthesiology to develop their own research on: the mode of action of all types of anesthetics and muscle relaxants; basic studies on the physiologic, biochemical, pharmacologic, and metabolic effects of anesthetic agents; the nature and control of pain; postoperative respiratory failure; obstetrical and neonatal resuscitation; and the pulmonary and systemic effects of drowning.

- facilitate the transition from research training status to that of a productive investigator.

This program is to provide the initial support for independent research by talented physicians who wish to address the challenging research problems presented by anesthesiology.

BACKGROUND AND RATIONALE

The number and variety of anesthetic drugs continues to increase and hundreds of thousands of patients per year are exposed to them. Anesthetic complications continue to present a serious medical problem. A number of anesthesia-related deaths occur annually among surgical patients. Furthermore anesthesia has produced serious complications which prolong convalescence. Morbidity from improperly administered anesthesia costs the American people nearly one billion dollars per year.

The role of the anesthesiologist now extends to intensive care of both surgical and non-surgical patients and involves management of both chronic and intractable pain, obstetrical and neonatal resuscitation, inhalation therapy and management of respiratory complications. The Special Grants Program in Anesthesiology is designed to provide an opportunity for more anesthesiologists to perform independent research on these problems.

IMPLEMENTATION

Beginning in fiscal year 1977, the NIGMS is offering a small number (10-12) of Special Grants for New Investigators in Anesthesiology. Each grant will have a maximum support period of three years.

The status of the Special Grants for New Investigators in Anesthesiology will be reviewed after an appropriate interval to determine whether or not the program should be continued. To assess the effectiveness of the program in fulfilling its objectives the Institute intends, after the termination of each grant, to follow the progress of the recipient to determine (1) the investigator's professional affiliation, (2) subsequent grant or contract support, and (3) scientific publications.

It is anticipated that in a majority of cases the results achieved with this grant support will provide the basis for successful competition in regular research support programs of the NIH.

The first receipt date for applications will be November 1, 1976. The applications will be reviewed by study section in February - March and by the National Advisory General Medical Sciences Council in May 1977. July 1, 1977, will be the earliest starting date for successful applicants.

CRITERIA FOR ELIGIBILITY

The research project must:

- be a study designed to answer a specific question related to anesthesiology in basic scientific areas such as physiology, biochemistry, pharmacology, and metabolism;
- not be supplemental to a project supported by other funds;
- be designed for completion within the requested period and not more than three years; and
- meet the customary criteria of scientific merit.

The investigator must:

- have an M.D. degree at the time of the award;
- present evidence of prior research experience;

- not be the recipient of an NIH Special Fellowship, nor the principal investigator on a research grant or contract or the equivalent, either at present or in the past, nor actively supported on a research center grant; however, trainees or regular research fellows are not excluded;

- be a citizen or a non-citizen national of the United States or its possessions and territories, or have been lawfully admitted to the United States for permanent residence prior to signing the grant application;

- provide a well-thought-out plan for pursuing the research proposed, including a brief review of the pertinent literature;

- submit with the application the names of three persons who are present or past supervisors or preceptors and can attest to the applicant's ability to undertake the project;

- agree to devote at least 50 percent time to the project;

- agree to keep the NIGMS informed about scientific accomplishments, change in professional status, or institutional affiliation for a period of six years after termination of the grant.

The applicant institution must (for the period of the grant):

- provide space and facilities necessary to pursue the projects,

- offer expert guidance and counsel in anesthesiology research,

- release the award recipient from other responsibilities for the time devoted to the project.

Institutions may submit more than one application. Only domestic institutions may apply.

SUPPORT PROVIDED BY THE GRANT

The NIGMS Special Grants for New Investigators are made for a period of up to three years. Renewals will be considered as competing continuations in the regular research grant category. Supplemental applications will not be accepted. The total direct costs may not exceed $90,000 for the three-year period with no more than $35,000 of that amount for the first year.

Except where otherwise indicated in this announcement, the policies which apply to research project grants apply also to the Special Grants for New Investigators in Anesthesiology.

Personnel

- salary and fringe benefits for the award recipient to the extent that they reflect the time or effort devoted to the research project, not to exceed 70% of the total direct costs per year. One part-time technical assistant may receive salary from the grant if the need for technical assistance can be justified in terms of the research.

Equipment

- the facilities available should provide most of the equipment. The purchase of equipment essential to the specific research effort must receive special approval.

Supplies

- the cost of necessary supplies must be detailed and justified.

Travel

- expenses for attendance at one national meeting closely related to the project may be requested for each 12-month period.

Other Expenses

- if other items are necessary for performance of the research effort, these must be clearly justified in terms of that need.

Indirect Costs

- will be provided in accordance with established DHEW policies for regular research grants.

APPLICATION

Assignment of applications will in all cases be made by the Division of Research Grants on the basis of the NIH referral guidelines for research grants. Applications must be submitted on form PHS 398. The original copy and the folder in which it is submitted, should be clearly labeled, (in red ink) NIGMS SPECIAL GRANTS FOR NEW INVESTIGATORS IN ANESTHESIOLOGY. The proposed project should be presented using the format described in the "instructions" in the application kit.

The authorized institutional official must submit a signed statement, as part of the application, detailing the commitments made to the project.

The completed grant application should be mailed to the Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20014. A postal card will be mailed to the applicant acknowledging receipt of the application. When the application has been assigned to an initial review group (study section), the applicant will again be notified by mail. The applicant should then request each of three supervisors or preceptors to send a letter of reference to the study section. The letters need not comment on the merit of the project, but should attest to whether the applicant has the knowledge and skills to pursue the project proposed.

Applications must be submitted by the regular new research project grant dates: November 1, March 1, and July 1. Applications received too late for one round of review will be considered in the next round. Applicants will be informed of the results of the review shortly after final consideration by the National Advisory General Medical Sciences Council.

Further information about this program may be obtained by contacting:

Dr. Elizabeth M. O'Hern
National Institute of General
Medical Sciences
Room 955, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20014

Telephone (301) 496-7168

SPECIAL VISUAL SCIENCES RESEARCH AWARDS

NATIONAL EYE INSTITUTE — A N N O U N C E M E N T

This announcement revises and supersedes the announcement contained on page 1, Vol. 2, No. 5, of the *NIH Guide for Grants and Contracts*, dated July 30, 1973.

The Special Visual Sciences Research Award Program of the National Eye Institute is designed to encourage newly-trained investigators who have completed postdoctoral training to enter or remain active in eye research during the early stages of their research/academic careers.

These special awards will be made for the support of meritorious laboratory, clinical, and epidemiological research projects related to eye diseases and disorders of the visual system. It offers the newly trained investigator an opportunity to develop new concepts and techniques and to obtain preliminary results which may be of value in preparation of a regular research project application. A wide variety of disciplines and techniques may be used in the proposed protocol.

Applicants must have received a doctoral degree or its equivalent, or have completed research training no more than 5 years prior to the beginning date of the proposed project.

Applicants may request up to $10,000 (direct costs) per year for three years. These funds may be used for small items of equipment, supplies, travel, publication, and for salaries of technical personnel.

Awards cannot be used to pay the salary of the principal investigator, to support thesis research or to supplement projects already funded by the Public Health Service or other Federal agencies.

Except where otherwise indicated in this announcement, the policies and requirements which apply to regular research project grants apply also to the Special Visual Sciences Research Awards.

REVIEW

Applications will undergo the customary dual review. The initial scientific merit review will be conducted by the appropriate NIH study section. A second review will be conducted by the National Advisory Eye Council. The National Eye Institute will make an award only on applications which receive a recommendation for approval from the National Advisory Eye Council.

The NEI Special Visual Sciences Research Awards are made for a period of up to 3 years and are nonrenewable. Applications for continuing support beyond the initial approved project period will be considered as competing renewals in the regular research project grant program (R-01).

Applicants should use the regular research grant application (form PHS 398) and write SPECIAL VISUAL SCIENCES RESEARCH AWARD on the top of the face page. Applications are available at institutional central application control offices (see *NIH Guide for Grants and Contracts*, Vol. 2, No. 8, October 26, 1973).

The receipt dates for applications are November 1, March 1, and July 1. The earliest possible award dates will be approximately 9 months after the receipt dates.

For additional information contact:

Scientific Programs Branch
National Eye Institute
National Institutes of Health
Room 6A49, Building 31
Bethesda, Maryland 20014

Telephone: (301) 496-5303

MINORITY ACCESS TO RESEARCH CAREERS

(MARC PROGRAM)

FACULTY FELLOWSHIPS ANNOUNCEMENT

Under authority of Section 472 of the Public Health Service Act as amended (42 USC 2891-1), the National Institute of General Medical Sciences (NIGMS) is accepting applications for Faculty Fellowships under the Minority Access to Research Careers (MARC) Program. The program is designed to assist minority institutions in the training of greater numbers of scientists and teachers in health-related fields.

The MARC Faculty Fellowship program provides opportunities for advanced research training for selected faculty members of four-year colleges, universities, and health professional schools in which student enrollments

are drawn substantially from ethnic minority groups (American Indians, Blacks, Hawaiians, Mexican-Americans, Puerto Ricans, and other racial descent). These institutions may nominate faculty members to apply for MARC Fellowships to support a period of advanced study and research training in graduate departments and laboratories as candidates for the Ph.D. degree or for postdoctoral research training in specified areas in the biomedical sciences. MARC Faculty Fellows are selected on a competitive basis. Applications will be evaluated by an initial review group with minority representation and are subject to review and approval by the Advisory Council. Awards may be made for up to 3 years of support. When their training is completed the Fellows are expected to return to sponsoring schools to do research and teaching so as to inspire and assist minority students to prepare for professional careers in the biomedical sciences and in medicine.

The amount of the stipend to be paid shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has a permanent affiliation on the date of acceptance of the fellowship, but in no event shall the stipend exceed $25,000 annually.

Application Receipt Date	Advisory Council Review	Results Announced by	Earliest Possible Start Date
October 1	May	June	July 1
February 1	Sept./Oct.	November	December 1
June 1	Jan./Feb.	March	April 1

Further information regarding the specified areas of support, length of support, trainee eligibility and required payback provisions may be found in the *NIH Guide for Grants and Contracts*, Vol. 5, No. 9, July 2, 1976, pages 1-5 and attachment.

Application forms may be obtained from Mr. Elward Bynum, Director, MARC Program, National Institute of General Medical Sciences, National Institutes of Health, Bethesda, Maryland 20014, telephone (301) 496-7357. Appropriate institutional officials and faculty members may contact Mr. Bynum for counseling in the preparation of applications.

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