NIH GUIDE for GRANTS and CONTRACTS

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

Vol. 8, No. 9, July 6, 1979

IN THIS ISSUE:

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The GUIDE is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

IN THIS ISSUE: (continued)

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

RESEARCH PATIENT CARE COSTS

SUPPORTED BY

NIH SPONSORED AGREEMENTS

POLICY

A. Purpose This issuance provides guidelines in the management of sponsored agreements, that provide funds for the support of research patient care activities. In serving as the NIH implementation of the PHS Grants Administration Manual Chapter 6-50, Research Patient Care Costs, this issuance also provides supplemental guidelines for NIH-supported grants and awards and establishes the requirement for compliance with 45 CFR Part 74, Appendix E, Cost Principles for Hospitals, for NIH-supported contracts. To utilize this issuance effectively, it should be used in conjunction with the two documents cited above since pertinent parts of these documents are not repeated herein.

B. Applicability This issuance is applicable to all NIH-sponsored agreements that provide funds for reimbursement of research patient care costs.

C. References

1. Grants Administration Manual Chapter PHS: 6-50, Research Patient Care Costs

2. Grants Administration Manual Chapter PHS: 1-510, Prior Approval of Use of Grant Funds Including Rebudgeting

3. A Guide for Hospitals, DHEW, OASC-3, Revised July 1974

4. Title 18 (Medicare Program), Social Security Act, Principles of Reimbursement for Provider Costs

5. Title 45, CFR Part 74, DHEW - Administration of Grants

D. Definitions

1. Sponsored Agreement - for purposes of this issuance, means any grant, contract, or other agreement between the NIH and a grantee/contractor institution.

2. Research Patient Care Costs - the costs of routine and ancillary services provided by hospitals to patients participating in research programs. The costs of these services are normally assigned to individual research projects through the development and application of research patient care rates or amounts (hereafter collectively referred to as "rates").

NOTE: Research patient care costs do not include the otherwise allowable items of personal expense reimbursement such as patient travel or subsistence, consulting physician fees, or any other direct payments related to all classes of patients, including inpatients, outpatients, subjects, volunteers and donors.

3. Hospital - For purposes of this issuance the term "hospital", as referred to in the Grants Administration Manual Chapter PHS: 6-50, will also cover all types of medical, psychiatric, and dental facilities such as clinics, infirmaries, sanatoria, etc.

4. Research Patients - inpatients and outpatients admitted to a hospital primarily to participate in a research protocol.

5. Research/Service Patients - Inpatients or outpatients admitted primarily for the purposes of diagnoses or treatment according to established regimens, and who are also participating in a research protocol that may or may not be related to their condition.

6. Routine Services - The regular room, dietary and nursing services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made.

7. Ancillary Services - those special services for which charges are customarily made in addition to routine services, e.g., X-ray, operating room, laboratory, pharmacy, blood bank, pathology.

8. Outpatient Services - services rendered to subjects who are not hospitalized.

9. Usual Patient Care - items and services (routine and ancillary) ordinarily furnished in the treatment of patients by providers of patient care under the supervision of the physician or other responsible professional. Such items or services may be diagnostic, therapeutic, rehabilitative, medical, psychiatric or any other related professional health services. These expenses are for the care that would have been incurred even if the research study did not exist. The patient and/or the third party insurance will usually provide for reimbursement of charges for "usual patient care" as opposed to nonreimbursement for those charges generated solely because of participation in a research protocol.

10. Discrete Centers - a group of beds that have been set aside for occupancy by research patients and are physically separated from other hospital beds in an environment that normally permits an ascertainable allocation of costs associated with the space they occupy and the service needs they generate.

11. Scatter Beds - These beds are not physically separate from nonresearch beds. Scatter beds are geographically dispersed among all the beds available for use in the hospital and are not usually distinguishable in terms of services or costs from other general service beds within the hospital.

12. Cost Finding Process - the technique of apportioning or allocating the costs of the nonrevenue producing cost centers to each other and to the revenue producing centers on the basis of the statistical data that measure the amount of service rendered by each center to other centers.

E. Policy The NIH provides funds for the cost of research patient care through its various sponsored agreements. Research patients may receive routine services in discrete centers or scatter bed environments. Such patients may also receive various ancillary services either as inpatients or outpatients. With certain specific exceptions, as identified in Section I of this issuance, patient care costs whether expressed as a rate or amount are subject to negotiation by authorized staff of the Divisions of Cost Allocation in the ten Department of Health, Education, and Welfare Regional Administrative Support Centers.

F. Implementing Instructions

1. Allowability of Research Patient Care Costs Under Sponsored Agreements The determining factors for allowing research patient care costs as charges to sponsored agreements depend on the patient and the type of services received. If the patient is receiving service or care that does not differ from that usually provided nor results in expenses greater than those which would have been incurred if the study had not existed, then the patient is considered to be hospitalized for usual care purposes and the sponsored agreement will not support the costs. When the research extends the period of hospitalization beyond that ordinarily required for usual care, or imposes procedures, tests or services beyond usual care, whether in an inpatient or outpatient setting, the sponsored agreement may pay the additional costs. The grantee or contractor must decide whether, in fact, the hospitalization period, the tests, or the services have been extended beyond or added to what would ordinarily have been expected, and to what extent.

Patient care costs for individuals who are receiving accepted treatment according to standard regimens would not ordinarily be the responsibility of the sponsored agreement. Similarly, in certain kinds of clinical trials where accepted treatments are compared against new therapies, research patient care costs generally may be charged to a sponsored agreement only insofar as they are measurements or services above and beyond those which constitute usual patient care and are specified by the study protocol.

2. Exceptions NIH funds may pay all costs (whether usual care costs or research care costs) for the entire period of hospitalization or research tests or services for patients who would not have been hospitalized or received such tests or services except for their participation in the research study.

   These patients may include:

   a. Persons to whom no health advantages may be expected to accrue as a result of the hospitalization. Examples would be: normal controls for metabolic or other studies; persons with genetic or certain abnormalities of interest to the investigator; sick persons brought to the hospital solely for studies when they otherwise would not require hospitalization.

   b. Sick persons of research importance to the investigator but without funds of their own or without funds available to them through a responsible third party to pay hospitalization expenses at the hospital where the investigator is conducting the studies. This includes patients for whom some third party payer, such as city, county, or state government might pay hospitalization expenses in some other hospital but has no responsibility to pay in the hospital in which the approved clinical research is being conducted.

   c. Sick persons with limited personal funds or health insurance but who are not willing to spend their own money or use their hospital plan coverage at that particular time. (Fear or more urgent need in the future for both personal funds and health insurance might be one reason for the patient's reluctance to participate in the study.) The investigator has a special responsibility in making the decision to include patients in this third group with full charges to the sponsored agreement. Ordinarily, by guidelines laid down in this document the patient or third party would be expected to pay usual care portions of the hospitalization. However, as an exception to the general rule, the investigator may decide to pay the total expenses for hospitalization, research services, or tests from the sponsored agreement if this is required to secure timely cooperation of a valuable study patient not otherwise available.

3. Methods of Computing Research Patient Care Costs Chargeable to Sponsored Agreements Reimbursement of research patient care costs incurred under NIH sponsored agreements will be computed using research patient care rates established by HEW. Such rates rates must be shown in all requests and/or claims for the reimbursement of research patient care costs.

When provisional rates are used as a basis for the award and payment of research patient care costs, the amount awarded shall constitute the maximum amount which the NIH awarding component is obligated to reimburse a hospital for research patient care costs under the sponsored agreement. 45 CFR Part 74, Appendix E states that costs related to the treatment of research patients "... whether expressed as a rate or amount, shall be computed in a manner consistent with the procedures used to determine reimbursable costs under Public Law 89-97 (Medicare Program) set forth in the Principles of Reimbursement for Provider Cost (under Title XVIII of the Social Security Act) published by the Social Security Administration (SSA) of the Department of Health, Education, and Welfare."

The policy further provides that separate cost centers must be established for each discrete bed unit for purposes of allocating or distributing allowable routine costs to the discrete unit. The allocation or distribution of allowable routine costs should be made during the normal "step down" of costs for Medicare purposes. Routine costs are funded by this discrete method or by a scatter bed method. Discrete bed reimbursement for routine care is based on a total dollar amount method. Scatter bed reimbursement is based on an average hospital per diem rate. All allowable costs for Medicare determinations are allowable in determining research patient care cost. Ancillary costs will be determined by applying the departmental (radiology, pathology, etc.) ratio of costs to charges to the actual departmental charges generated by the research patients. The charges for ancillary services provided to research patients must be on the same basis as charges made to any other patient for like service.

In addition to the routine cost rate and ancillary ratio of cost to charges determined from the cost finding process, offset rates must be negotiated where appropriate. These offset rates are negotiated to allow a credit to the patient care category for each research/service patient day, and to allow for the reduction from an average per diem for those items funded directly by the sponsored agreement. The types of offsets negotiated are as follows:

a. The offset for the discrete bed unit routine cost is normally the average cost of all routine beds in the hospital.

b. The offset from the routine per diem rate is a rate which allows for a reduction from the average routine per diem those items directly funded by the sponsored agreement, i.e., nursing or dietary services.

G. Other Elements of Cost Reimbursement of other elements of cost, consistent with the needs of the sponsored agreement may be made in accordance with the cost principles prescribed in 45 CFR 74, Appendix E.

H. Indirect Costs Indirect costs should not be paid on any component of research patient care. However, a special indirect cost rate may be applicable to nonhospital type salaries or costs, e.g., principal investigator, laboratory assistant, animal caretaker, etc. Such special rates will exclude, for example, depreciation, operations and maintenance, housekeeping and other space costs for the discrete facilities which are already included in the direct cost component of research patient care.

The research patient care amount also includes indirect costs related to hospital type employees supported as a direct cost by the sponsored agreement regardless of the identity of the employer. Therefore, the salaries and wage base used to claim indirect costs must exclude all hospital type salaries and fringe benefits (nurses, dieticians, social workers, etc.) If other than a salary and wage base is used, e.g., total allowable direct costs, the total amount of research patient care reimbursement in addition to the hospital type salaries and fringe benefits must be deleted from the base before applying the indirect cost rate.

When a hospital is the direct recipient of a sponsored agreement, no indirect costs will be allowed as a separate cost element since all costs have been stepped down into the routine cost of the patient care rates.

I. Special Procedures for Certain Hospitals

1. Requirements for submission of research patient care proposals do not apply to hospitals which are awarded $25,000 or less in research patient care costs under each individual sponsored agreement awarded by any of the components of HEW. Hospitals which meet this condition will instead be subject to the following alternate procedures:

   a. If the hospital is a sub-awardee, the recipient of the sponsored agreement will be responsible for negotiating reasonable fees for research patient care services provided by the hospital.

   b. If the hospital is the direct recipient of a sponsored agreement, it must support its claims for the reimbursement of research patient care costs by preparing a research patient care rate computation for each fiscal year during which the costs are claimed. The computation must be based on section IX.B.23. of the Department's cost principles for hospitals (Appendix E to 45 CFR Part 74) and must conform to the proposal formats shown on pages 9 through

11 of the DHEW document, "A Guide for Hospitals." The computation, along with the supporting documentation described in the Guide, must be retained by the hospital for possible review and audit by, or on behalf of, the Department. The retention period shall be in accordance with the Department's records retention regulations (Subpart D of 45 CFR Part 74). The rates developed by the hospital will be treated as predetermined rates. However, the research patient care costs reflected in the hospital's expenditure reports based on these rates will be subject to adjustment if an audit or other review by, or on behalf of, the Department results in a reduction in the rates. A contracting officer may request the computation and supporting documentation on research patient care pursuant to FPR 1-3.807-3.

2. In the absence of a Research Patient Care Negotiation Agreement published by the Office of Grant and Contract Financial Management, Office of the Assistant Secretary for Management and Budget/OS, the awarding agency may provide funds for research patient care costs based on the rates proposed by the recipient of the sponsored agreement, provided that the amount awarded under the agreement does not exceed $25,000 for each hospital involved and the hospital(s) does not have any other HEW awardswhich individually provide research patient care support in excess of $25,000.

J. Financial Responsibilities Where the costs of patient care are funded by the sponsored agreement, and whether such costs are classified as usual patient care or research patient care, the amount recovered from third parties must be credited to the sponsored agreement. However, patient care charges must be adjusted to cost for both routine and ancillaries, pursuant to the principles of this issuance, prior to applying the third party recoveries. The recipient of the sponsored agreement is obligated to pursue recovery to the fullest extent possible and should be able to document such efforts.

K. Specific Information Required in Applications and Proposals Involving Research Patient Care Costs To effectively review any anticipated need for research patient care costs, it is necessary for the application or proposal to include certain basic information and supporting data. Funds for research patient care can be used only after justification and supporting data have been reviewed and accepted by appropriate staff of the NIH awarding component. The following information should be provided in any application or proposal (competitive or noncompetitive) that includes a request for research patient care costs:

Inpatient Costs - Scatter Beds

1. The name of the hospital(s) to be used, and the amounts requested for each.

2. An indication of whether the hospital(s) has a currently effective HEW-negotiated hospitalization rate agreement. If not, the basis to be used for calculating charges.

3. A presentation of the research protocols under which patients will be hospitalized. In addition, the following information should be provided by protocol:

   a. The service or ward (e.g., medicine, surgery, intensive care unit, coronary care unit) where inpatients will be located.

   b. The number of patients anticipated.

   c. The number of patient days anticipated.

   d. The rate or basis on which the scatter bed costs have been calculated.

   e. An indication of the anticipated charges per patient day for routine costs.

   f. An indication of the anticipated charges per patient day for ancillary costs.

   g. An estimated percentage of the total costs per patient day which will be charged to third party coverage.

Inpatient Costs - Discrete Beds

1. The name of the hospital(s) to be used, and the amounts requested for each.

2. An indication of whether the hospital(s) has a currently effective HEW-negotiated hospitalization rate agreement. If not, the basis to be used for calculating charges.

3. A presentation of the research protocols under which patients will be hospitalized.

4. The number of beds in the discrete research unit.

5. The basis for determining costs for the routine care requested.

6. The anticipated occupancy rate of the beds requested with an indication of the number of patients that are expected to be "research" versus the number that are expected to be research/service."

7. An indication of the average ancillary cost per day for "research" patients and "research/service" patients.

8. An indication of the related costs (e.g., laboratory, drugs) that will be generated outside of the discrete unit.

9. An estimate of the anticipated rate of third party recovery.

Outpatient Costs

1. The name of the hospital(s) to be used, and the amount requested for each.

2. An indication of whether the hospital(s) has a currently effective HEW-negotiated hospitalization rate agreement. If not, the basis for calculating charges.

3. A presentation of the research protocols under which outpatients are to be involved. In addition, the following information should be provided by protocol:

   a. The types of tests or procedures which will be performed.

   b. The number of outpatients to be involved.

   c. The number of outpatient visits.

   d. An estimate of the average cost per visit.

L. Program Requirements An individual NIH awarding component may adopt special implementing procedures to meet the specific needs of its own program provided that such procedures do not conflict with this issuance.

M. Effective Date This policy is effective for all grants having budget period dates beginning on and after July 1, 1979, and for all contracts awarded on and after July 1, 1979.

PROPOSALS INVOLVING RECOMBINANT DNA

PROCEDURE NOTICE

The current NIH Guidelines for Research Involving Recombinant DNA Molecules, The Administrative Practices Supplement, and announcements of modifications and changes to the Guidelines are available from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20205. All research involving recombinant DNA techniques which is supported by the National Institutes of Health (NIH) must meet the requirements of these Guidelines, which were developed in response to the concerns of the scientific and the lay communities about the possible effects of recombinant DNA research. Their purpose is to specify practices for the construction and handling of recombinant DNA molecules and organisms or viruses containing recombinant DNA. As defined by the Guidelines "recombinant DNA" corresponds to (1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules which result from the replication of a molecule described in (1) above.

Several types of studies involving recombinant DNA are exempt from the Guidelines while others are prohibited by the Guidelines. For the remainder it is required that the applicant organization shall establish and implement policies that provide for the safe conduct of the research in full conformity with the Guidelines. This responsibility includes establishing an Institutional Biosafety Committee to review all recombinant DNA research to be conducted at or sponsored by the applicant organization, and to approve those projects it finds are in conformity with the Guidelines. For each approved project, a valid Memorandum of Understanding and Agreement shall be submitted for review by the NIH Office of Recombinant DNA Activities. The Memorandum of Understanding and Agreement is considered approved after acceptance by the NIH Office of Recombinant DNA Activities.

Grant application forms are being revised to include a check block indicating whether or not recombinant DNA research subject to NIH Guidelines is involved. Until such time as these forms are available, the applications concerned should show in capital letters at the bottom of the first page "THIS APPLICATION INVOLVES RECOMBINANT DNA RESEARCH SUBJECT TO NIH GUIDELINES." Labeling the face page of the application will assist in expediting the processing of the application.

Do not submit a Memorandum of Understanding and Agreement until it is solicited by an appropriate NIH staff member.

FLUORIDE RESEARCH GRANT APPLICATIONS

SOUGHT BY

THE NATIONAL INSTITUTE OF DENTAL RESEARCH

ANNOUNCEMENT

I. PROGRAM SPECIFICATIONS

A. Program Objectives The use of fluoride in drinking water is the single most therapeutically effective and cost effective weapon against dental caries. There has also been widespread use of topical fluorides in the form of professionally applied agents, mouthwashes, prophylactic paste and dentifrices. Additional knowledge of how the fluoride ion exerts its protective effects is still needed in order to develop alternative and more effective application methods. Research efforts to achieve these important goals are encouraged by the Institute. Moreover, the use of fluoride in its many forms has given rise to a number of scientific questions concerning its biological activities. It is the program's objective, through this announcement, to stimulate the submission of research grant proposals which will address these important questions concerning biological activity.

B. Research Scope The emphasis of this program announcement is upon basic and clinical research opportunities dealing with (1) nutrition - fluoride interrelationships, and (2) effects of fluoride on biological systems. Specific research interests are listed below. The list is not in order of priority nor is it complete with respect to all possible subjects of interest to the program.

1. Nutritional Studies Animal and/or human studies are encouraged to establish the role of fluoride for optimal growth, development, and health; to determine the possible relationship(s) between nutritional deficiencies or excesses and mottling of teeth and other biological effects; and to identify specific factors in the diet, such as trace elements and vitamins which affect fluoride utilization and biological activity.

   Studies are also encouraged in animals maintained on high and low fluoride intake for several generations to examine possible enzyme adaptation, effects on growth, reproduction, longevity, and oral flora, etc. A starter source of animals living on defined fluoride diets for several generations will be made available to successful applicants.

The legislative authority for this program is found in Section 301 of the Public Health Service Act and in P.L. 78-410, as amended. The Catalog of Federal Domestic Assistance number is 13.878.

2. Biological Effects Studies are encouraged which deal with the effect of fluoride on the metabolism and function of cells of mineralizing tissue such as ameloblasts, odontoblasts and osteoblasts. Studies of the effect of fluoride on metabolism of collagen, proteoglycans and other organic constituents of bones and teeth are also encouraged. Studies are encouraged which deal with the possible systemic human health benefits of fluoride such as in the treatment of osteoporosis or its effect in lowering the incidence of hip fractures.

   Proposals are sought which will deal with the basic conditions and mechanism(s) by which excessive amounts of fluoride causes dental fluorosis, the relationships between fluoride ingestion and cyclic AMP levels of various organ and/or tissue systems, the question of the source, absorption and excretion of non-ionic fluorides, studies of renal clearance in normal humans and patients with chronic renal disease, studies of tissue fluoride distribution, influence of fluoride on other cellular processes, and studies designed to provide additional information concerning the long term consequences of fluoride ingestion and the margin of safety of water fluoridation. The latter studies might include changes in dietary fluoride intake because of recent changes in food processing and dietary habits as well as laboratory studies to redetermine the urine and bone fluoride levels in people living in fluoridated communities.

C. Mechanism of Support The mechanism of support for this program will be through the traditional research project grant. Policies that govern research grant programs of the National Institutes of Health will prevail. The award of grants pursuant to this request for grant applications is contingent upon receipt of proposals with high scientific merit and the availability of appropriated funds.

II. METHOD AND CRITERIA OF REVIEW

A. Assignment of Applications Applications will be received by the Division of Research Grants (DRG), National Institutes of Health. DRG will refer the proposals to the appropriate study section for scientific review and will make the Institute assignment for possible funding and management. Referral decisions will be governed by programmatic considerations as specified in the DRG Referral Guidelines. It is possible that studies proposed in response to this announcement could overlap with the referral guidelines of more than one Institute at NIH. In such cases the DRG will make the final assignment decision.

B. Review Procedures Applications in response to this announcement will be reviewed in accordance with the usual National Institutes of Health peer review procedures (study section). Factors considered in the scientific merit evaluation of each application will include an assessment of the importance of the proposed research problem, the novelty and originality of the approach,

the training experience and research competence of the investigator(s), the adequacy of the experimental design, the suitability of the facilities, and the appropriateness of the requested budget relative to the work proposed. Following study section review, the application will be evaluated for program relevance by the appropriate Institute Advisory Council. Funding decisions will be based upon relative scientific merit and the Institute's ability to fund.

C. Deadlines Applications will be accepted in accordance with the usual dates for new applications on an indefinite basis. The deadline for receipt of new applications for the next three review cycles are:

November 1, 1979
March 1, 1980
July 1, 1980

III. METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the business or grants office at most academic or research institutions. If not, an application form may be obtained from:

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

The phrase "PREPARED IN RESPONSE TO NIDR FLUORIDE ANNOUNCEMENT" should be typed across the top of the first page of the application. The original and six copies of the application should be sent or delivered to:

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

Further information may be obtained by contacting:

Chief, Soft Tissue Stomatology
and Nutrition Program Branch
National Institute of Dental Research
National Institutes of Health
Room 510, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7808

BIOMEDICAL RESEARCH DEVELOPMENT GRANT PROGRAM

NOTICE

The Division of Research Resources, National Institutes of Health, plans to accept no additional applications for the Biomedical Research Development Grant Program in 1980 or thereafter. Applications will be accepted through the next deadline of October 1, 1979. Currently active grants, and new awards made following the next review, will continue to be funded through the full period of approved support.

Biomedical Research Development Grants are competitive institutional awards to strengthen and/or expand health-related research for the purpose of improving training for clinical professions or health-related research, or both. Training per se is not supported. The program is not intended to increase the number of persons being trained, but it is expected to result in high quality health-related research and to improve the quality of training in health fields. The focus of the program is health research development, and it is not an alternative to other PHS research grant programs.

Eligibility is limited to nonprofit institutions in the United States and its territories which, during the latest 12-month period ending September 30 immediately prior to the October 1 deadline for submission of applications, will have received less than $200,000 (direct and indirect costs) in PHS research grants; also, eligible institutions must be engaged in the training of health or health research manpower.

Further information may be obtained from:

Biomedical Research Development Grant Program
Division of Research Resources
Room 5B23, Building 31
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-6743

MATERNAL SMOKING AND PREGNANCY OUTCOME,

NATIONAL INSTITUTE OF CHILD HEALTH

AND HUMAN DEVELOPMENT

ANNOUNCEMENT

I. BACKGROUND INFORMATION

Cigarette smoking is recognized as a health hazard which extends to fetuses of smoking pregnant women. Adverse effects on pregnancy range from increased risk for reproductive loss, fetal mortality, preterm birth, and neonatal death, to retardation in fetal growth as reflected in birth measurements of lower mean body weight, shortened body length, and smaller head circumference, as well as to a number of problems of adaptation in the neonatal period. In addition, there is suggestive evidence of long-term impairments in physical growth, diminished intellectual function, and deficiencies in behavioral development for those babies who survive the first four weeks of life. An updated review of the scientific literature is available in the Report of the Surgeon General on Smoking and Health, Chapter 8, entitled "Pregnancy and Infant Health."

II. RESEARCH GOALS AND SCOPE

This announcement highlights the special interest that exists to determine if observed alterations in the developing fetus of a smoking mother are indicators of processes which may be detrimental to either the immediate or long-term health of the fetus and child. The Pregnancy and Perinatology Section, Center for Research for Mothers and Children, is interested in initiating research studies focusing on the epidemiologic, biologic, and pharmacologic facets of cigarette smoking during pregnancy and its impact on fetal and infant well-being. Two specific study areas are anticipated:

1. Identification of risk for perinatal losses or damage in offspring of women who smoke during pregnancy. These investigations also cover determinations of circulatory changes in placenta and fetus, hypoxic and anoxic events and their consequences for the infant.

2. Definition of maternal and neonatal (biologic and physiologic) effects resulting from maternally inhaled tobacco smoke, including general studies on lactation and breast feeding and specific effects on adequacy of milk secretion (quantity and quality: nutritional composition and presence of contaminants).

This program is described in the Catalog of Federal Domestic Assistance Number 13.865. 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.

Since this announcement addresses a complex research area, a variety of approaches are possible, either limited to the study of one specific aspect or extended to an interdisciplinary collaboration to probe several problems. A proposal should reflect the research strengths of the investigator(s) rather than attempt to explore all conceivable parameters.

III. MECHANISM OF SUPPORT

The support mechanism for this program will be the grant-in-aid. This type of announcement is used when CRMC wishes to stimulate investigator interest in a particular area that is important to its mission.

This announcement is for continuous competition with applications to be received on the regularly scheduled deadlines: November 1, March 1, and July 1.

Any nonprofit institution is eligible to apply to this program. A variety of approaches would represent valid responses to this announcement; accordingly, it is anticipated that there will be a range of costs among individual grants awarded. A program project could be submitted if mutually agreed upon by the applicant and the CRMC. Applicants are requested to furnish their own estimates of the time required (up to 5 years) to achieve the objectives of the proposed research project. Near the end of the project period, renewal proposals may be submitted for competitive review. Current NIH policies and regulations which govern research grants will prevail. The earliest requested start date for grants should be November 1, 1980.

IV. REVIEW PROCEDURES AND CRITERIA

The initial review of applications will be arranged by the Division of Research Grants, NIH. Proposals in response to this invitation will be reviewed on a nationwide basis in competition with each other. Initial review will be conducted by a group composed primarily of non-Federal scientific consultants; secondary review will be by the National Advisory Child Health and Human Development Council. Applicants will be informed of the results of the competition as soon as possible after the meeting of the Council.

The major factors considered in evaluating each application will be:

The relevance and significance of the proposed approach to the goal described in this announcement.

The scientific merit of the proposal: the questions proposed for study, the research design, the methodology, analysis, and interpretation of data.

The research experience and competence of the applicants to carry out the proposed investigations, including expertise in the disciplines that the study may require.

Adequacy of time (effort) to be devoted to the project by investigators and technical staff.

Adequacy of collaborative arrangement(s), if applicable.

Adequacy of existing and proposed facilities and resources.

The costs in relation to the scope of the project.

V. METHOD OF APPLYING

Applications should be submitted on form PHS 398, the application form for the traditional research grant. The conventional presentation in format and detail for regular research grant applications should be used, ensuring that the points identified under the Review Criteria are fulfilled. A statement from collaborators (if any) indicating their willingness to work and interact in the project should be included. In the upper left hand corner of the face page under the words "Grant Application," the proposal should be labeled "IN RESPONSE TO ANNOUNCEMENT: MATERNAL SMOKING AND PREGNANCY OUTCOME." Application kits may be obtained at most universities and hospitals in the United States. If not available, application kits may be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Room 448, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

VI. IDENTIFICATION OF CONTACT POINT

Any further information relating to this announcement may be obtained by contacting:

Dr. Charlotte Catz
Pregnancy and Perinatology Section
Center for Research for Mothers
and Children
National Institute of Child Health
and Human Development
Bethesda, Maryland 20205

Telephone: (301) 496-1485

FUNCTION OF THE AGING MUSCULOSKELETAL SYSTEM, BIOPHYSIOLOGY AND PATHOBIOLOGY PROGRAM, NATIONAL INSTITUTE ON AGING

ANNOUNCEMENT

I. BASIC INFORMATION

The National Institute on Aging (NIA) was established in 1974 to conduct and support biomedical, social, and behavioral research and training related to the aging processes and the diseases and other special problems and needs of the aged.

A program of research on function of the musculoskeletal system in the elderly can properly address the areas of prevention, diagnosis, treatment and rehabilitation. Among all age groups, musculoskeletal disabilities are the primary cause for limiting the quality of life, rank second only to circulatory diseases in health costs, and third in frequency of occurrence among acute conditions. Also musculoskeletal disabilities rank second in number of visits to hospitals, and third in number of operations in hospitals.

Impaired functions of the musculoskeletal system, however, have their greatest impact on the elderly, accounting for 20 percent of Medicare hospitalization costs. For example, clinical evidence of osteoporosis is present in almost all women over 75 years old. Since musculoskeletal disabilities are so prevalent in the elderly, an expanded research program on the musculoskeletal system, addressing exercise physiology and orthopaedics research, can effectively improve the quality of life for the fastest growing segment of our population at the least cost to benefit ratio for the public.

II. GOALS AND SCOPE

The Biophysiology and Pathobiology Program of the National Institute on Aging is encouraging the submission of applications that utilize either animal models or clinical studies to investigate areas in function of the aging musculoskeletal system. Examples of selected topics are as follows:

A. Exercise Physiology

- benefits of acute versus chronic exercise for the elderly;

This program is described in the Catalog of Federal Domestic Assistance Number 13.866. 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.

- optimal exercises for maintenance of strength, proprioception, mobility, and flexibility of bones, muscles, tendons, and joints of the elderly;

- capacity of the elderly to adapt to chronic exercise and its role in preventive and rehabilitative medicine; also specific muscular exercises for adaptations in the elderly; e.g., cardiovascular and respiratory benefits that accrue to the elderly from exercise;

- the effects of exercise on age associated changes in tissue metabolism; endocrine response to exercise and endocrine regulation of metabolism in the elderly;

- psychological and social benefits of exercise for the elderly.

B. Orthopaedic Research

- special aspects of treatment and rehabilitation of fractures in the elderly;

- prevention, treatment and rehabilitation for disk and spinal ailments in the elderly;

- studies in osteoporosis as it affects the quality of life or related health problems in the elderly;

- regulation and control of bone, muscle and collagen by digestive, metabolic, hormonal or other homeostatic mechanisms with special relevance to the processes of aging or studies in aged human or animal models;

- studies in the elderly on hormone and vitamin effects on gastrointestinal absorption and renal function as related to bone metabolism and loss of bone mass.

Although this announcement has emphasized selective research areas on function of the aging musculoskeletal system, research grant applications in response to this announcement are not limited to the specific topics addressed above.

III. MECHANISM OF SUPPORT, FUNDING

The support for this program will be via the traditional NIH research project grant. Applicants are expected to plan and execute their own research programs. Support of grants pursuant to this announcement is, of course, contingent upon ultimate receipt by NIA of appropriated funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Application Review

Upon receipt, all applications will be assigned by the Division of Research Grants according to accepted Referral Guidelines to

an Initial Review Group for scientific merit review and to an appropriate Institute or Division for final review by their National Advisory Council/Board.

B. Review Criteria

Applications must be relevant to the goals of this announcement. The factors considered in evaluating applications are:

- scientific merit of the research design, approaches, and methodology;
- adequacy of existing and proposed facilities and resources;
- qualifications and experiences of the principal investigator and proposed staff for the conduct of the proposed investigations;
- reasonableness of the subject and duration in relation to the proposed research;
- adequacy of time to be devoted by proposed project staff.

V. METHOD OF APPLYING

Use the standard research grant application form PHS 398. If the institution's business office or central application control office does not have this form an individual copy may be requested by writing to:

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

Telephone: (301) 496-7441

Follow the instructions with the application form PHS 398 making sure that the items noted in Section IV of this announcement are covered appropriately.

Type the phrase "PREPARED IN RESPONSE TO NIA PROGRAM ANNOUNCEMENT FUNCTION OF THE AGING MUSCULOSKELETAL SYSTEM" along the side of the face page and at the top of the abstract. Forward to:

Division of Research Grants
National Institutes of Health
Room 240, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

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

VI. INQUIRIES AND CORRESPONDENCE

Inquiries and correspondence should be directed to:

Chief, Biophysiology and Pathobiology
of Aging Program
Biomedical Research and Clinical Medicine
National Institute on Aging
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 496-1033

IMMUNOLOGY PROGRAM,

MOLECULAR AND BIOCHEMICAL AGING PROGRAM,

NATIONAL INSTITUTE ON AGING

ANNOUNCEMENT

I. BACKGROUND INFORMATION

The National Institute on Aging (NIA) was established in 1974 to conduct and support biomedical, social, and behavioral research and research training related to the aging processes and the diseases and other special problems and needs of the aged. The Molecular and Biochemical Aging Program (MBAP), located in the Extramural and Collaborative Research Program has responsibility for research and planning in the immunological sciences as related to the aging process.

II. GOALS AND SCOPE

An expansion of grant-supported research and training in immunology is currently being sought. The objectives of the Immunology Program are to understand: (1) the fundamental molecular and cellular changes responsible for the decline in immune competence with age; (2) the relationship between immune dysfunction and age-related pathologies at the molecular, cellular, and organismic levels using human and animal models; (3) the development of replacement therapies and other treatment modalities to augment immune function; and (4) the application of new knowledge to clinically relevant situations involving elderly subjects.

Grant applications are encouraged for individual research initiatives, postdoctoral fellowships, and training programs. Areas in the Immunology Program for which expansion of grant-supported research and training is sought are listed below.

Macromolecular Synthesis and Regulation of Lymphocyte Activity
Applications are encouraged on macromolecular synthetic activities of lymphocytes and plasma cells; intracellular regulation studied by somatic cell hybridization between young and senescent lymphocytes; and comparative studies of enzyme activity and chromatin structure in young and senescent lymphocytes. Studies on the regulatory functions of T-lymphocytes, the effect of complement components, C-reactive proteins and other factors on T-lymphocytes are also emphasized.

This program is described in the Catalog of Federal Domestic Assistance Number 13.866. Awards will be made under the authority of the Public Health Service Act, Sections 301 (Public Law 78-410, as amended; 42 USC 241) and 472, 42, USC 2891-1, and administered under PHS grants policies and Federal Regulations 42 CFR Parts 52 and 66 and 45 CFR Part 74.

Lester Smith, Ph.D.
Chief, Molecular and Biochemical
Aging Program
Biomedical Research and Clinical
Medicine Program
National Institute on Aging
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 496-9350

NATIONAL RESEARCH SERVICE AWARDS FOR INDIVIDUAL POSTDOCTORAL FELLOWSHIPS, NINCDS

ANNOUNCEMENT

Speech and/or Language Disorders in Children

I. BACKGROUND INFORMATION

The Communicative Disorders Program (CDP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is inviting individual postdoctoral fellowship applications for investigators interested in study speech and language disorders in children including: impaired language development with unknown etiology, language impairment in infantile autism, dyslexia, stuttering, and impaired speech development. Of particular interest are applications aimed at gaining skills necessary for the study of brain behavior relationships in individuals with these disorders.

II. GOALS AND SCOPE

Postdoctoral research fellowship training is being encouraged by the Communicative Disorders Program to help meet the needs of NINCDS supported programs in these research areas and to increase the participation of investigators trained in fields relating to the study of speech and language disorders in children including but not limited to: neurolinguistics, neuropsychology, clinical neurophysiology, language pathology, pediatric neurology, speech science, speech pathology, and speech perception. Applicants may have not previously been involved in research on speech and language disorders in children, but may propose to bring to the study of these disorders, methods and knowledge they have gained in other fields which would be appropriate for determining the brain organization and functioning of children with speech and language impairments. Conversely, applicants who have already begun to pursue a research career in the areas of speech and language disorders in children may propose postdoctoral research fellowship training aimed at providing them with training in a related field of the neurosciences or behavioral sciences which will be relevant to their goals for research on speech and language disorders in children.

Applicants must demonstrate an active interest in pursuing research on speech and language disorders in children with particular emphasis on determining brain behavior relationships for speech and language functioning in the following disorders: impaired speech and/or language development, infantile autism, dyslexia, and stuttering.

This program is described in the Catalog of Federal Domestic Assistance Number 13.851. Awards will be made under the authority of the Public Health Service Act, Section 472, 42 USC 2891-1, and administered under PHS grants policy and Federal Regulations 42 CFR Part 66.

Applicants should propose fellowship training under the leadership of scientists qualified and willing to offer and direct appropriate research fellowship training.

III. REVIEW PROCEDURES AND CRITERIA

A. Review Procedures

Applications will be reviewed for scientific merit by an NIH peer review group.

B. Review Criteria

Factors considered in evaluating each application will be:

1. Relevance of application to scope and objectives provided in this announcement.

2. Merit of proposed approaches to the training.

3. Qualifications of the applicant and the appropriateness of the training program proposed.

4. Expertise and qualifications of proposed mentors.

5. Evaluation of resources and environment.

IV. METHOD OF APPLYING

A. Application Procedure

Use the research fellowship application form PHS 416-1. If the institution's business office or central application control office does not have this form, an individual copy may be requested by writing to:

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

or by calling (301) 496-7441.

The applicant must submit a signed assurance that the service or payback requirements will be complied with, if an award is made.

If a noncitizen, a notarized statement of permanent residence must be submitted.

A complete application includes the sponsor's facilities and commitment statement; therefore, a form PHS 416-2 must be submitted with the application. In addition, an applicant will arrange for the submission of a reference report, form PHS 416-3.

B. Application receipt deadline dates are October 1, February 1, and June 1. The application kits are self-explanatory. The words "POSTDOCTORAL FELLOW IN SPEECH AND LANGUAGE" should be typed in block letters in the upper right hand corner of the first page of the application. A brief letter should accompany the application indicating that it is in response to this program announcement. A copy of the letter should be sent to:

Dr. Christy L. Ludlow
Communicative Disorders Program
National Institute of Neurological
and Communicative Disorders and Stroke
Room 1C-11, Federal Building
7550 Wisconsin Avenue
Bethesda, Maryland 20205

NATIONAL RESEARCH SERVICE AWARDS FOR INDIVIDUAL POSTDOCTORAL FELLOWSHIPS, NINCDS

ANNOUNCEMENT

Clinical Research in Otolaryngology

I. BACKGROUND INFORMATION

The Communicative Disorders Program (CDP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is inviting individual postdoctoral fellowship applications in the area of clinical research in otolaryngology.

Awards for a period of not less than 12 months may be made to applicants proposing research in such areas as otosclerosis, otitis media, sensorineural deafness, diseases of the vestibular system, diseases of the nasal cavity, pharynx, and larynx.

II. GOALS AND SCOPE

Clinical research training is being encouraged to help meet the needs of NINCDS supported programs in these research areas and to increase the opportunities for participation in otolaryngological clinical research by qualified persons. Applicants must have an active interest in clinical research in otolaryngology and prepare for training under the leadership of scientists qualified and willing to offer and direct appropriate clinical research training. Under the authority of the National Research Act, the Institute cannot support residency training. A resident can receive NRSA training support if a specified period of fulltime research training is creditable toward specialty board certification or if he/she drops out of his/her residency to receive such training. The Institute (NINCDS) considers "clinical investigation" to be an area in which clinicians may apply for support for training in research.

III. REVIEW PROCEDURES AND CRITERIA

A. Review Procedures

Applications will be reviewed for scientific merit by an NIH peer review group.

B. Review Criteria

Factors considered in evaluating each application will be:

This program is described in the Catalog of Federal Domestic Assistance Number 13.851. Awards will be made under the authority of the Public Health Service Act, Section 472, 42 USC 2891-1, and administered under PHS grants policy and Federal Regulations 42 CFR Part 66.

1. Relevance of proposal to the scope and objectives provided in this announcement.

2. Merit of proposed approaches to the training.

3. Qualifications of the applicant and the appropriateness of the training program proposed.

4. Expertise and qualifications of proposed mentors.

5. Evaluation of resources and environment.

IV. METHOD OF APPLYING

A. Application Procedure

Use the research fellowship application form PHS 416-1. If the institution's business office or central application control office does not have this form, an individual copy may be requested by writing to:

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

or by calling (301) 496-7441.

The applicant must submit a signed assurance that the service or payback requirements will be complied with, if an award is made.

If a noncitizen, a notarized statement of permanent residence must be submitted.

A complete application includes the sponsor's facilities and commitment statement; therefore, a form PHS 416-2 must be submitted with the application. In addition, an applicant will arrange for the submission of a reference report, form PHS 416-3, in his/her behalf.

B. Individuals are encouraged to request the above forms and the general announcement for National Research Service Award by writing to Dr. Rolf F. Ulvestad.

Application receipt dates are October 1, February 1, and June 1. The application kits are self-explanatory. The words "POSTDOCTORAL FELLOW IN CLINICAL RESEARCH IN OTOLARYNGOLOGY" should be typed in block letters in the upper right hand corner of the first page of the application. A brief letter should accompany the application indicating that it is in response to this program announcement. A copy of the letter should be sent to:

Dr. Rolf F. Ulvestad
Communicative Disorders Program
National Institute of Neurological and
Communicative Disorders and Stroke
Room 1C-11, Federal Building
7550 Wisconsin Avenue
Bethesda, Maryland 20205

CLINICAL RESEARCH CENTERS FOR HUMAN CHEMOSENSORY STUDIES, NINCDS

ANNOUNCEMENT

The Communicative Disorders Program (CDP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is inviting grant applications from interested groups of investigators to establish clinical research centers for the study of human chemosenses (taste and smell).

I. BACKGROUND INFORMATION

Suitable staffed clinical research centers are needed to serve as foci for clinical studies of human chemosensory function. A center would consist of professional (e.g., otorhinolaryngology, neurology, endocrinology, pediatrics, neonatology, neurological surgery, and allergy) and technical staff, all located within the present facilities of an appropriate, research oriented, medical center or research institute affiliated with a medical institution.

Responsibilities of a clinical chemosensory research center would include neurophysiological investigations of human chemosensory responses; research on the role of the chemical senses in children, including the effect of early chemosensory experience; studies of the predictive significance of neonatal preferences; apnea induced by epiglottal chemoreceptors; malnutrition induced or maintained by food preferences; and the relationship between chemoreceptive function and disease (e.g., diabetes, obesity, central nervous system, nasal and paranasal sinus, and endocrinopathies).

II. GOALS AND SCOPE

The studies will be addressed to the problems of human taste and human smell. Chemosensory problems produced by therapeutic procedures, such as therapeutic drugs and chemotherapy, would be an area of immediate concern as would investigations of the prevalence, incidence, economic and quality of life consequences of olfactory and taste deficits in diseases (ageusia, dysgeusia, anosmia, and parosmia). The center will also address the problem of the development of animal models for chemosensory defects. Other areas of interest may include studies of the consequences of a polluted chemosensory environment as well as the monitoring of clinical trials of therapeutic interventions.

Several clinical chemosensory research centers will probably be needed to fully meet the national needs. However, in order to develop

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This program is described in the Catalog of Federal Domestic Assistance Number 13.851. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74.

proper procedures and because of the present shortage of suitably trained scientists and clinician/investigators, a gradual phase-in of centers, with an ongoing review is deemed appropriate.

III. REVIEW PROCEDURES AND CRITERIA

A. Review Procedures

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

B. Review Criteria

Factors considered in evaluating each application will be:

1. Relevance of proposal to the scope and objectives provided in this announcement.

2. Merit of proposed approaches to the establishment of a Chemosensory Clinical Research Center.

3. Expertise and qualifications of the proposed staff.

4. Commitment of time by proposed staff.

5. Evaluation of resources and environment.

IV. METHOD OF APPLYING

A. Application Format

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

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

or by calling (301) 496-7441.

The Clinical Research Center grant is awarded for a research program focused on a specific disease or group of diseases or disorders of the nervous system, muscular system, or in one or more of the special senses. The clinical research center provides resources for a multidisciplinary research program investigating a single disease or related disease entities. The grant provides for support of a combination of basic and clinical research at the center.

B. Application Procedure

Prospective principal investigators are urged to contact the Communicative Disorders Program (Dr. J. B. Ranney) prior to the submission of a formal application.

The standard procedures for submitting grant applications should be followed. A brief letter should accompany the application indicating that it is in response to the program announcement, NINCDS-CDP, on Clinical Centers for Human Chemosensory Studies. The words "CHEMOSENSORY CLINICAL RESEARCH CENTERS" should be typed in block letters in the upper right hand corner of the first page of the application. A copy of the letter should be sent to:

Dr. J. Buckminster Ranney
Deputy Director
Communicative Disorders Program
National Institute of Neurological and
Communicative Disorders and Stroke
Room 1C-11, Federal Building
7550 Wisconsin Avenue
Bethesda, Maryland 20205

C. Application Receipt Dates

Application receipt dates are: October 1, February 1, and June 1.

*U.S. GOVERNMENT PRINTING OFFICE: 1979 281-233/6 1-3