NIH GUIDE for GRANTS and CONTRACTS

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

Vol. 9, No. 6, April 25, 1980

IN THIS ISSUE:

(over)

HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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

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

SPECIAL NOTICE

OUTBREAK OF ECTROMELIA (MOUSE POX)

(Follow-Up Information)

The NIH Guide for Grants and Contracts (Vol. 9, No. 1, January 3, 1980) recently published a notice alerting the scientific community of an outbreak of ectromelia in a laboratory at the NIH and that of an NIH contractor.

This particular episode of ectromelia infection apparently has been controlled and no longer should represent a hazard; however, increased surveillance continues at the NIH. We are providing more detailed information directly to NIH-supported investigators who may be utilizing mice in their research.

We would appreciate your continued cooperation in reporting to us any evidence of the disease. Please address such information and other inquiries to:

Dr. Robert A. Whitney, Jr.
Chief, Veterinary Resources Branch
Division of Research Services
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 496-2527

SUPREME COURT RULES ON DATA IN POSSESSION OF GRANTEES

NOTICE

The U.S. Supreme Court has ruled that certain data in the possession of grantees are not NIH records and are therefore not subject to release under the Federal Government's Freedom of Information Act (FOIA). The ruling's effect is that NIH is not required to ask that grantees hand over their raw research data for release to requestors.

The decision will not affect NIH practice, because it has never demanded raw research data from grantees for FOIA release.

Also, the Supreme Court stated that grantees themselves are not generally regarded as U.S. government agencies "absent extensive, detailed and virtually day-to-day supervision." This means that grantees are not required to respond to requests addressed to them that cite the Federal Government's FOIA.

The case, Forsham v. Harris, involved records that grantees had accumulated under the University Group Diabetes Program (UGDP). Scientists had gathered data at 12 centers on the effectiveness of treatment regimens for diabetes. They had funneled these records to a coordinating center at the University of Maryland. A group of physicians who treat diabetics criticized the study's conclusions and requested that NIH release the raw data for restudy.

The Government contended in opposing the request that since the data had been generated by grantees and had never come into NIH hands, they were not U.S. Government "agency records." The court agreed with the Government's argument in its 7-2 decision.

The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) had funded the grants. NIAMDD did have a right of access to the records to assure compliance with the grants, or could have taken permanent custody of the records, according to the requestors. Even so, this did not make agency records of these raw data, according to the court. Justice William H. Rehnquist wrote, for the court: "...but in this context FOIA applies to records which have been in fact obtained and not to records which merely could have been obtained."

Reference: Forsham v. Harris, Case No. 78-1118, decided March 3, 1980. All law schools will have received the decision, which is reported in 48 LW 4232, March 4, 1980.

Address queries to:

Bowen Hosford, J.D.
NIH Freedom of Information Coordinator
Room 2B37, Building 31
National Institutes of Health
Bethesda, Maryland 20205

CONTINUED SUPPORT OF A RESEARCH PROJECT WHEN THE PRINCIPAL INVESTIGATOR LEAVES THE GRANTEE INSTITUTION

POLICY

A. Purpose This issuance states the NIH's policy and the procedures to be used for continued support of a research project previously approved by the NIH when the principal investigator departs the grantee institution or leaves the project for any reason. It implements for NIH the PHS Grants Administration Manual Chapter 1-502, Change of Grantee Institution, and supersedes *NIH Guide for Grants and Contracts*, No. 16, pages 19-24, January 14, 1972.

B. Applicability This policy applies to all NIH discretionary project grants. It is not applicable to fellowship awards, other awards to individuals, or transfers of grants to or between foreign institutions. A training grant or a research resource, center grant, or construction grant may be transferred only under unusual circumstances.

C. Definitions

1. Change of Grantee Institution - A process whereby the legal and administrative responsibility for administering a grant-supported project or activity is transferred from one eligible, qualified grantee to another prior to the ending date of the approved project period for the grant being transferred.

2. Successor in Interest - A process whereby the rights and obligations to an NIH grant or grants are acquired incidental to the transfer of all of the assets of the grantee or all of that part of the assets involved in the performance of the grant. Such transfer may result from legislative or other legal actions such as a merger, divestiture, or other corporate change.

3. Name Change - An action whereby the name of an organization is changed without otherwise affecting the rights and obligations of the parties involved.

D. Policy

1. When the principal investigator or program director of an NIH-supported research project expects to leave the grantee institution or the project for any reason (except a temporary absence), the appropriate NIH awarding unit must be notified as soon as practicable by the principal investigator or an official of the grantee institution. The options available for continued support of the research project by the NIH are:

a. The original grantee institution may request that the project be retained at the institution under the direction of another principal investigator to be approved by the NIH: OR

b. The remainder (see Section F.5.) of the project period may be supported at the new institution in behalf of the same investigator provided the first option is not used. In this case, the new institution must submit an application (form PHS 398) for support of the project, with no significant change in research objectives or level of budget.

If neither option is proposed, support of the project will be terminated.

E. Responsibilities

1. When a change of institution is expected, it is the responsibility of the institution to maintain a reasonable spending pattern and rate so as not to adversely or unduly affect continued support at the proposed new institution. The original grantee must not presuppose the transfer and therefore may not expend any grant funds for use at the proposed new institution without prior approval from the NIH awarding unit.

2. A change of grantee institution for a research grant, on behalf of the same investigator transferring between two domestic institutions or from a foreign institution to a domestic institution, may be made without competitive review. Such change may be for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for the remaining portion of the project period provided: (a) the change of grantee action meets all other applicable requirements of this policy, (b) there is no significant change in research objectives or in the level of funding for direct costs from that described in the project previously approved, (c) the facilities and resources at the new location allow for the successful performance of the project. However, if the proposed change of grantee action does not clearly meet these stipulations or other programmatic and administrative requirements, the NIH awarding unit may require that the application for the replacement grant receive a competitive review in accordance with the usual peer review procedures.

3. A relinquishment statement (see Exhibit I) from the original grantee relinquishing its interests and rights to the grant is required when the grant to be transferred involves the relocation of a principal investigator to another institution. Acceptance of a relinquishment statement and subsequent termination of grant support by NIH does not guarantee NIH approval of a replacement application for the continued funding of the project.

4. In those cases where the grant is to be terminated by mutual consent, or when the grant is unilaterally terminated by the grantee, a written statement in lieu of the formal relinquishment statement may be submitted by the grantee institution to the awarding unit which includes an estimate of the unobligated balance of funds expected to remain at the time of termination.

5. A change of grantee action for a training, resource, or center grant will generally be approved only when all of the permanent benefits attributable to the original grant can be transferred. This would include the transfer of all equipment costing $1,000 or more in accordance with the requirements of Title 45, Part 74, Subpart O, Property, and curriculum developed under a training grant. Such action must be thoroughly documented in the official grant file.

F. Implementing Procedures

1. WHEN A PRINCIPAL INVESTIGATOR DEPARTS AND THE GRANTEE INSTITUTION REQUESTS CONTINUATION OF THE PROJECT UNDER THE DIRECTION OF ANOTHER PRINCIPAL INVESTIGATOR

When the principal investigator of an ongoing project leaves the grantee institution or the project for any reason, the grantee institution may request that the project be continued at the same institution under the direction of another principal investigator for the remainder of the project period and at the level previously recommended. The request will be made in writing explaining the reason for the proposed change and should include a biographical sketch of the proposed new investigator. If the grant is to be continued, the individual proposed by the grantee institution as the new principal investigator must be found acceptable by the NIH awarding unit following review of his or her qualifications and re-evaluation of the project in the light of the proposed change. National Advisory Council or Board review is not required for such change of principal investigator.

2. WHEN A PRINCIPAL INVESTIGATOR DEPARTS FROM AN INSTITUTION WHEN THERE IS AN NIH-APPROVED BUT NOT YET AWARDED OR ACTIVATED GRANT

When a principal investigator leaves an institution which has an approved competing application, but prior to the award or activation of the grant, the original applicant institution may request that the project be supported at that institution of behalf of another principal investigator. (See F.1. above.) Alternatively, the project may, upon request, be supported at the new institution to which the principal investigator moves. This will require (a) formal withdrawal of the application by the original applicant institution, and (b) submission of an application (form PHS 398) from the new institution. This application, if it proposes no

significant change in the project or level of expenditure, and provides for satisfactory facilities and resources, may be acted upon administratively by the NIH awarding unit and does not require Council or Board action.

3. WHEN THE PRINCIPAL INVESTIGATOR DEPARTS THE INSTITUTION AND REQUESTS THAT THE PROJECT BE SUPPORTED AT ANOTHER INSTITUTION

When the principal investigator departs the institution that was awarded the grant, and requests the project be supported at another institution, the project in behalf of the same investigator may be supported at the new institution for a period up to the remainder (see Section F.5.) of the previously approved project period and in an amount generally not to exceed that previously recommended for the remaining period. National Advisory Council/Board review and recommendation is not required. Support may be continued at the new institution without competitive review provided that:

- the project is no longer supported by grant funds at the original institution
- the investigator plans no significant change in the research objectives or in the level of the budget from those described in the previously approved project; and
- the new institution submits an application for support of the project.

If the investigator wishes to depart from the previously recommended project, or if any other condition above is not met, the old grant will be terminated, the replacement application will compete for available funds along with other new applications.

4. For continued support at a new institution of a currently ongoing research project, the following shall be submitted:

a. Information required from the original grantee institution

(1) A relocation application will not be processed until an official statement, signed by the proper institution official, relinquishing interests and rights in the grant has been received by the NIH awarding unit. For a list of information to be included in the relinquishment statement see Exhibit I.

(2) Following the termination of the grant, the original grantee institution will submit to the awarding unit:

- a final expenditure or financial status report
- a final Invention Statement, Form HEW 568

Note: No terminal progress report will be required if the grant is transferred. The progress report required in the PHS 398 application from the new institution will serve in lieu of a final progress report for the project at the original institution.

b. Information required from the new institution

(1) Request for support previously approved

The new institution should submit a completed research grant application, form PHS 398, with "CHANGE OF GRANTEE INSTITUTION" typed in capital letters across the top of the face page and budget page. This application should contain all the information requested in the instructions. (The comprehensive progress report will serve in lieu of a final progress report from the original institution.) The application must include:

- a description of the research plan,
- a description of the facilities at the new institution,
- the probable effects of the move on the project,
- biographical sketches of all professional personnel to be associated with the project,
- a list of all equipment to be transferred by the original grantee institution to the project which was purchased in whole or in part with grant funds, and which had a acquisition cost of $1,000.

Such a listing in the application represents the new institution's acceptance of title and responsibility for the equipment.

The application will receive administrative review by the NIH awarding unit as a change of institution (Type 7) application.

(2) Request for additional years beyond those previously approved

If support is to be requested for additional years beyond those of the previously approved project period, a separate face page and budget page for the additional years may be included with the Type 7 application so that the same presentation (main body of the application) can be utilized for both the administrative review (above) and a competitive review for the additional years. The total number of additional years requested may not exceed five. The face page and budget pages for the previously approved support should

be attached to the extra copies of the application and will receive administrative review by the awarding unit. The face page and budget pages for additional years will be attached to the original copy of the application and will be assigned as a Type 2 (competing continuation application) to compete for additional funds.

(3) Emergency interim support to prevent a lapse in the project

If in the preliminary review of a Type 7 proposal it is found there is a significant change in the proposed project or level of expenditure, a new application for competitive review will be required for continued support. However, should this requirement for competitive review cause an undesirable interruption in research support, the NIH awarding unit may give administrative approval for the award of interim emergency support at the new institution while the Type 2 application is being reviewed. This may only be done (a) if there are remaining years in the previously approved project period, (b) at a prorated level no greater than that previously recommended, and (c) for only enough time to complete the competitive review and, if approved, make an award. In no case may the interim award be made for a period longer than 18 months.

5. The length of time to be approved for the first budget period of the replacement grant will utilize a 12-month budget period whenever possible. Less than 6 months will be considered for award only under very unusual circumstances. The award to the replacement grantee will show the first year of support under a new grant number.

6. If an estimated unobligated balance in the original grant is used to determine the award level of the replacement grant, the awarding unit may subsequently adjust such a grant (either upward or downward) in accordance with the actual, unobligated balance remaining from the original grant as shown on the final expenditures report.

G. Other Changes

1. Changes Involving a Foreign Institution Investigators transferring to or between foreign institutions are required to submit a new application from the new institution; administrative approval may not be given. The application will be reviewed as any new application and must compete for available funds. A grant made to a foreign institution may be administratively relocated to a domestic institution.

2. Other Changes in Location or Institutional Sponsorship

a. Relocation in the Same University System If moving a research project from one "campus" to another in the same university system results in a major geographic change, e.g. from Dallas to Galveston or from Berkeley to San Diego, the move should be considered a change of institution and be subject to the procedures outlined in F.3.

b. Change of Institutional Sponsorship at Same Geographic Location If there is a request for change of grantee institution on a project which does not, however, affect the geographic location, facilities, resources, or objectives of the project, this is still considered a change of institution and subject to the procedures outlined in F.3.

H. Effective Date This policy is effective on date of release.

Exhibit I

REQUIREMENTS FOR A STATEMENT RELINQUISHING INTEREST IN A PHS GRANT

The following items must be included in the official statement relinquishing interest in an NIH grant.

1. Date
2. Grant Number
3. Name and address of grantee institution
4. Name of Principal Investigator/Project Director
5. A brief statement of the reasons for relinquishing interest in the grant
6. A statement indicating the grantee's willingness to terminate the grant and to relinquish all claims to any unobligated funds remaining in the grant, as well as to all recommended future support, if any, of this project.
7. Effective date of termination
8. An estimated unexpended balance (direct and indirect costs) on the termination date of the project.
9. A list of all items of equipment with an acquisition cost of $1,000 or more, purchased in whole or in part with grant funds.
10. The signatures of the official authorized to sign in behalf of the grantee organization and of the financial officer.

SPECIALIZED CLINICAL RESEARCH CENTERS FOR PERIODONTAL DISEASES

ANNOUNCEMENT

NATIONAL INSTITUTE OF DENTAL RESEARCH

Application receipt date, October 1, 1980

INTRODUCTION

The National Institute of Dental Research (NIDR) is currently supporting three Specialized Clinical Research Centers for Periodontal Diseases at Forsyth Dental Center, Boston; State University of New York, Buffalo; and and Virginia Commonwealth University, Richmond. The first two centers will complete a 5 year project period in 1982 and the third in 1983. The original announcement (*NIH Guide for Grants and Contracts*, Vol. 5, No. 22, December 20, 1976) stated that the grants would be awarded to the centers for an initial period of five years, and that support for subsequent project periods would be determined by competitive reviews of new and renewal applications. Accordingly, the NIDR now invites applications from all institutions wishing to compete for center grant support. The present announcement provides revised guidelines for preparing an application. Applicants are advised to contact Dr. Paul Parakkal, Extramural Programs, National Institute of Dental Research, Room 519, Westwood Building, Bethesda, Maryland 20205, (301) 496-7784 for additional information.

The Periodontal Diseases Centers were established to accelerate the acquisition of new information for preventing, diagnosing and treating periodontal diseases and to bring their resources, facilities and manpower to bear on these problems in a concerted way. In the span of three years, the centers have already made significant progress in microbiological and immunological research. They have identified numerous new species of bacteria from the diseased periodontal pockets, and are continuing the task of classifying the total flora of the periodontal pockets. The basic finding that polymorphonuclear leucocytes show impaired chemotactic function in patients with juvenile periodontitis has now been confirmed and amplified. The role of complement in host response to periodontal disease has also been further clarified. The centers will continue these efforts and also focus their attention on the many other cellular and chemical reactions which may protect the host, or cause soft tissue and bone destruction. The development of therapeutic techniques and preventive measures has been slow and the centers are expected to accelerate their efforts in this area.

This program is described in the Catalog of Federal Domestic Assistance number 13.841. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

BACKGROUND

Periodontal diseases include inflammatory conditions which affect the tissues around the roots of the teeth and lead to tooth loss. It is estimated that 94 million Americans have active periodontal disease, and approximately 32 million of these individuals have an advanced stage of the disease. Thus, these diseases constitute a major health problem of increasing concern in our society. Not only are the current treatment methods difficult, but the results are uncertain. The American public pays approximately $1.5 billion every year for periodontal therapy even though only a fraction of those who need treatment actually receive it.

OBJECTIVES

The main objective of the clinical research centers is to facilitate the application of basic research findings in the areas of pharmacology, microbiology, and immunology in clinical investigations of patients having periodontal disease. Even though these centers should emphasize studies of human patients, it is recognized that laboratory and animal studies may also be needed to aid in understanding the disease processes. Specifically, these centers should develop programs to accomplish some or all of the following objectives:

1. Develop preventive measures;
2. Improve therapeutic techniques and regimens;
3. Establish the causative organisms in periodontal diseases;
4. Determine the host response to these causative organisms.

The substance of each research program may vary according to local expertise, interest, resources, and recruitment possibilities, but the projects developed by each center must relate to the above objectives. Applicants should attempt to develop a unique program which is complementary rather than duplicative of ongoing research. The Institution must be willing to make a commitment of resources and staff to ensure the development, operation, and function of the proposed center.

CHARACTERISTICS OF A CLINICAL RESEARCH CENTER

Within the institution, the clinical research center must become an identifiable organizational unit which can develop relevant clinical investigations. The Institution must have an adequate base of ongoing research in at least one of the following areas: pharmacology, microbiology, or immunology. The director of each clinical research center should be an established scientist who can provide both scientific and administrative leadership and is willing to make a significant time and effort commitment to the center. The director will be responsible for organizing and operating the center and for communicating with the NIDR on scientific and operational matters. An internal review board consisting of staff members of the center and other expert consultants who are not members of the clinical center program should be established. This board will assess the center's progress on current projects, will inform the director of its findings, and will conduct an initial review of new initiatives.

ADMINISTRATIVE ITEMS AND COSTS

The center grant may include funding for pilot projects as well as for a cluster of interrelated regular projects. Funds may be used for central support services, equipment, supplies, renovations, consultation services, travel, publication costs, and also for professional, technical, and administrative personnel. Only those patient costs directly related to research may be charged to the center grant. The program does not provide funds for new construction. Each participating scientist is expected to obtain independent research support from sources other than the center grant during the award period, thereby releasing the center funds to attract other scientists to enter the center's research program. New applicants may request up to $250,000 for the first year with appropriate increases in subsequent years.

MECHANISM AND LENGTH OF SUPPORT

These centers will be supported by the research grant mechanism for a period of five years; support for subsequent project periods will be contingent upon program needs, successful competitive reviews (new and renewals) and the availability of funds. Once a clinical research center grant has been awarded, a cooperative relationship will be established between the NIDR and the grantee institution. A program officer will be designated by the NIDR to work closely with the center to discuss progress and to provide assistance. Each center is also expected to collaborate with other centers. As part of an overall evaluation, annual site visits will be made to each center. The budget will be negotiated yearly, and will be based upon the assessment of progress of each center, and the availability of funds.

REVIEW PROCEDURES

The applications will be reviewed by the NIDR Special Grants Review Committee and the National Advisory Dental Research Council.

REVIEW CRITERIA

Applications will be judged on the basis of the following criteria:

1. Scientific merit of the proposed research and its relevance to periodontal diseases;

2. Adequacy of ongoing research in basic pharmacology, microbiology, or immunology;

3. Availability of competent clinical investigators;

4. Access to appropriate patient populations;

5. Adequacy of facilities for clinical research;

6. A favorable environment for research training.

APPLICATION PROCESS

Applications should be prepared on form PHS 398, "Application for Research Grant," and should include:

1. A table of contents;

2. A complete, consolidated first-year budget for the entire center and detailed sub-budgets for the component projects with appropriate justification;

3. Detailed information for each item listed below:

   a. Rationale and justification for the center;

   b. Description of intended projects;

   c. Description of ongoing basic and clinical research related to periodontal disease;

   d. Description of available laboratory facilities;

   e. Description of available clinical facilities;

   f. Specific information on patient availability;

   g. Evidence of capability of performing statistical and data analysis;

   h. Curriculum vitae of the program director and his immediate staff;

   i. Planned collaboration with other research groups and a delineation of the roles and modus operandi of expected interation.

TIMETABLE FOR REVIEW

A. Deadline for receipt of application - October 1, 1980.

B. The earliest beginning date for award of grants - July 1, 1982.

The original and six copies of the completed application should be mailed to:

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

In addition, two copies should be sent under separate cover to:

Dr. Paul Parakkal
Periodontal Diseases Program Branch
Extramural Programs
National Institute of Dental Research
Room 519, Westwood Building
National Institutes of Health
Bethesda, Maryland 20205

NIH CONTRACT COMPLIANCE PROGRAM

ANNOUNCEMENT

Background

The National Institutes of Health is responsible for the awarding of thousands of contracts each year to academic institutions, hospitals, medical research centers, and commercial firms. Many people in various occupational areas are employed through these federally funded contracts. Discrimination is prohibited according to Executive Order 11246, as amended, that states "No federally funded contractor can discriminate against any employee or applicant for employment because of race, sex, creed, religion, color, national origin." In response to this directive and related Civil Rights policies and procedures, NIH has developed a Contract Compliance Program in the Division of Contracts and Grants (DCG).

Objective

The NIH is concerned that contractors with which it does business have an updated and approved Affirmative Action Program in employment, and that affirmative action measures are taken to ensure that minorities, females, handicapped and Vietnam era veterans receive equal opportunity.

The NIH began the implementation of the Contract Compliance Program November 1, 1977. Contracting Officers and Contract Specialists are implementing the first phase of the program. Project Officers are responsible for implementing the second phase of the compliance program.

In April, 1980, Project Officers will begin administering the NIH Principal Investigator's EEO Contract Compliance Abbreviated Check List (ACL). The questions about Equal Employment Opportunity (EEO) practices should be answered by the Contractor's Principal Investigator/Project Director and reviewed by the Project Officer during a site visit or a reverse site visit at the first opportunity after award of the contract. Questions to be answered are summarized below.

The EEO Check List concerning the Equal Employment Opportunity Program that the Contracting Officers/Contract Specialists use has been revised. These questions are also listed below.

Staff Contact

For further information, contact:

Ms. Maureen B. E. Miles
NIH Contracts and Grants Compliance Officer
National Institutes of Health
9000 Rockville Pike
Room 1B-34, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-6385

NIH Principal Investigator's EEO Contract Compliance Report

Principal Investigator's EEO Contract Compliance Abbreviated Check List (ACL)

The following questions about Equal Employment Opportunity (EEO) practices should be answered by the Contractor's Principal Investigator/Project Director and reviewed by the Government Project Officer during a site visit or reverse site visit at the first opportunity after award of the contract. Citations refer to the Code of Federal Regulations, Chapters 19-100.

1. Are you aware of your responsibilities for implementing your institution's/organization's AAP?

2. Have the employees under your supervision received an explanation of the AAP within the past year?

   60-2.20 and 60-2.12

3. Does your institution's/organization's AAP include goals and timetables for hiring and promoting: Minorities? Females?

   60-2.20

4. In your unit, do women with comparable training and experience performing comparable work as men receive equal pay for their efforts?

   60-2.20

5. In your unit, do racial minorities with comparable training and experience performing comparable work as non-minorities receive equal pay for their efforts?

   60-741

6. Are affirmative steps taken to accommodate handicapped employees?

   60-2.20

7. In your unit among individuals with comparable training and experience, are hiring and promotional opportunities the same for: Minorities? Women? Handicapped? Vietnam Era Veterans? Various Religious/Ethnic Groups?

   60-50.2

Questions will not be asked of Principal Investigator/Project Director if the questions have been asked to Principal Investigator/Project Director within the last year.

EEO Check List Concerning the Contractor's

Equal Employment Opportunity Program

The following items should be covered informally by the Contracting Officer/Contract Specialist with the contractor's authorized representative about Equal Employment Opportunity (EEO) practices at the time of face-to-face negotiations.

1. Does the institution, organization, or corporation maintain an Affirmative Action Program which has been updated within the past year, and meets the requirements of Executive Order 11246, (41CFR) 60-2, Section 503 of the Rehabilitation Act of 1973 (41CFR) 60-741, 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974, (41CFR 60-250)? 1/

2. Has the Department of Labor/Office of Federal Contract Compliance Programs reviewed and approved the institution's, organization's, or corporation's AAP within the past year?

   Indicate date of most recent compliance review.

   (Date) _____

3. Has the institution's, organization's, or corporation's EEO policy been communicated internally?

   (Internal communication may involve meetings with supervisors and employees, training programs, personnel manual, company newspapers, magazines and annual reports that include the company's Equal Employment Opportunity Policy).

4. Has the institution's, organization's, or corporation's EEO policy been disseminated externally?

   (External communication should include recruiting sources, minority/women's organizations, veterans and handicapped organizations, secondary schools and colleges. Purchase orders, leases, and subcontracts should include the required equal opportunity and Affirmative Action Clauses.

5. Does the AAP include goals and timetables for hiring minorities and women?

1/ These three authorities require each covered contractor with 50 or more employees and a contract in excess of $50,000 to develop and maintain a written AAP within 120 days of receipt of such a contract. Since most contractors have received previous Government contracts, they would be expected to have an AAP on file. For contracts where the company employs fewer than 50 employees or where the contract is under $50,000, the contractor is not required to have an AAP on file.

NEW INVESTIGATOR RESEARCH AWARD (NIRA)

IN ARTHRITIS, BONE DISEASES, AND SKIN DISEASES

ANNOUNCEMENT

The National Institute of Arthritis, Metabolism and Digestive Diseases wishes to announce that the areas of arthritis, bone diseases, and skin diseases have been added to the New Investigator Research Award Program. The Institute will consider applications for NIRA support in the following areas: arthritis, bone diseases, skin diseases, diabetes, endocrinology, metabolism, digestive diseases, liver diseases, pancreatic diseases, nutrition, hemotology, renal physiology, renal pathophysiology, urology and chronic renal diseases.

The NIRA program is described in the *NIH Guide for Grants and Contracts*, Vol. 9, No. 1, January 3, 1980. For further information on NIAMDD programs, contact:

Dr. George T. Brooks
National Institute of Arthritis,
Metabolism and Digestive Diseases
Room 655, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7277

REQUEST FOR RESEARCH COOPERATIVE AGREEMENT APPLICATIONS

ANNOUNCEMENT

BUREAU OF RADIOLOGICAL HEALTH, FDA-HFX-80-1

FOOD AND DRUG ADMINISTRATION

TITLE: *OPTIMIZATION OF MAMMOGRAPHIC EXAMINATIONS*

Application receipt date, June 15, 1980

I. BACKGROUND INFORMATION

The Medical Physics Program of the Bureau of Radiological Health, FDA, invites applications for a cooperative agreement to be awarded in FY-80 related to development of a mathematical model capable of predicting physical imaging performance in mammography as a function of the design parameters involved.

II. RESEARCH GOALS AND SCOPE

The competing requirements of high image quality and low patient dose in x-ray examinations of the breast have prompted much research in this area. Advances in mammographic imaging techniques have recently been demonstrated in three areas: 1) optimization of x-ray spectrum; 2) better scatter rejection; and 3) minimization of resolution loss due to the combined effects of focal spot and image receptor blurring. The optimization of the x-ray spectrum has been studied in detail at the Bureau of Radiological Health and elsewhere.

The purpose of this study is to develop a mathematical model capable of predicting physical imaging performance in mammography as a function of the design parameters involved. Since these areas of improvement are not independent of each other, it is necessary to develop optimized mammographic imaging systems that will reflect the largest possible improvement of all of these combined factors. An added complication to this problem is that imaging system performance is strongly dependent on the specific imaging task being studied.

To accomplish the objective stated above, the selected applicant will be expected to:

1. Develop a mathematical model as stated above. The model should include, but need not be limited to, consideration of anode material, anode heat limits, focal spot size, high voltage amplitude (KVp) and waveform, x-ray beam filitration, system geometry, scattered radiation and techniques for its suppression, patient size and composition distributions, image receptor characteristics, and appropriate evaluation criteria such as contrast, signal-to-noise ratio (SNR), latitude, and patient dose.

2. Use the model developed to determine the optimum system design for several imaging tasks associated with mammography for each of the evaluation criteria considered. The model will also be used to determine relative optima when certain system parameters are held constant. For example, the optimum configuration for an imaging system based on an existing x-ray tube design and image receptor could be determined. In this way, any intermediate improvements which can be achieved with existing equipment will be identified.

3. It is anticipated that the activities involved can be accomplished in a one-year period.

III. MECHANISM OF SUPPORT

The support mechanism for this program will be the cooperative agreement due to the requirement for substantial involvement on the part of the Food and Drug Administration.

To date, the Bureau of Radiological Health (BRH) has been deeply involved as one of the leading forces in the technology of optimization of x-ray spectrum in mammographic imaging. It is, therefore, important that any grantee be willing to work in close collaboration with BRH in the continuance of this project. Because of the computational complexity of the project, the model which is developed is to be implemented, in Fortran, on the Digital Equipment Corporation VAX 11/780 computer located in the Medical Physics Branch, Division of Electronic Products, BRH. It is anticipated that this will require several trips by the grantee to the facility identified above. The theoretical modeling will be supported by experimental work to generate input data and for verification of results. Laboratory facilities, either of FDA or the grantee, if available, may be used for this purpose. An investigator is to be available for consultation with BRH staff on a regular basis.

It is anticipated that at least one award will be made in Fiscal Year 1980 by the Food and Drug Administration and that the period of support need not exceed one year. The approximate level of support is $30,000.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method: The receipt date for application is June 15, 1980. The applications will be evaluated on a competitive basis and the initial scientific review will be arranged by the Division of Research Grants, NIH.

B. Review Criteria: Applications must be responsive to this RFA; that is, they must be relevant to the goals of this program announcement and guidelines. Applications judged by FDA not to be responsive will be returned to the applicant.

The factors considered in evaluation of each application will be:

1. Scientific merit of the research design.

2. Demonstrated experience in the analysis of image quality in mammography, in particular the optimization of x-ray energy, evaluation of scatter reduction devices and techniques, and prediction of optimum resolution and configurations.

3. Availability of personnel qualified to assist in the implementation of model developed on the VAX 11/780 computer, in Fortran.

4. Availability of investigator for consultation with the BRH staff on a regular basis (twice a month by phone; two visits per year).

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are requested to submit a one-page letter of intent which should include a very short synopsis of proposed areas of research and identification of any other participating institutions. This letter should be received no later than May 15, 1980, at the following address:

Dr. DeWitt G. Hazzard (HFX-14)
Director, Extramural Research Staff, OMS
Bureau of Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4190

The Bureau requests such letters only to provide an indication of the number and scope of applications to be received. A letter of intent is not binding and it will not enter into the review of any proposal subsequently submitted nor is it a necessary requirement for application.

B. Format for Application

Applications must be submitted on form PHS 398. These forms are available at all major schools through whichever office handles extramural funding activities or directly from the Division of Research Grants, NIH. The conventional presentation in format and detail for regular research grant applications should be utilized, with care taken to fulfill the points identified under review criteria. Attention is directed toward the inclusion of a statement indicating the willingness of the applicant to work cooperatively with other participants in the program and with the Bureau of Radiological Health.

C. Deadline for Submission

Applications must be received by June 15, 1980. Applications received after this date will be returned.

D. Application Procedure

The original and six (6) copies of the completed application should be sent or delivered to:

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

LABEL THE OUTSIDE OF THE MAILING PACKAGE AND THE TOP OF THE APPLICATION FACE PAGE "IN RESPONSE TO FDA-HFX-80-1."

A very brief covering letter must accompany the application indicating that it is submitted in response to this program announcement: OPTIMIZATION OF MAMMOGRAPHIC EXAMINATIONS. A carbon copy of this covering letter should be sent to Dr. DeWitt G. Hazzard at the address shown under Item A.

E. Inquiries

Inquiries may be directed to:

Robert J. Jennings, Ph.D.
Medical Physics Branch (HFX-250)
Division of Electronic Products
Bureau of Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-5020

This program is supported under the authorization of Section 356(b)(2) of the Public Health Service Act as amended (42 USC 263d). The Catalog of Federal Domestic Assistance number is 13.103. Cost-sharing is required. This program is not subject to OMB Circular A-95 Clearinghouse requirements or Health Systems Agency review.