NIH GUIDE for GRANTS and CONTRACTS

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

Vol. 9, No. 4, March 14, 1980

IN THIS ISSUE:

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HAVE YOU MOVED?

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

IN THIS ISSUE: (continued)

CHANGES IN PROJECT PERIOD SYSTEM FOR NIH GRANTS - A CLARIFICATION

PROCEDURE NOTICE

A Procedural notice on the above subject was published in the *NIH Guide for Grants and Contracts*, Vol. 9, No. 2, dated January 25, 1980. Based on inquiries received from various grantee institutions, it has become apparent that clarification of a major point in the original notice is necessary.

Under the section on Financial Management, reference was made to a significant aspect of the change in policy which permits the carry-over of unexpended funds between competing segments of the project period. Further, it was indicated that the funds awarded in support of each budget period will remain available for the total time for which support of a project has been approved. This language was not intended to convey the idea that NIH will now allow automatic carry-over of unexpended funds (for increased funding purposes) between competing segments of the "new" project period as redefined. Rather, the point to be made is that NIH and the grantee will now be able to have the same fiscal flexibility in going from one segment of support to the next competing segment that has been available for many years in going from one budget period to the next budget period within any given project period. Previously, at the close of the final budget period of an "old" project period, any remaining free balance was withdrawn and reverted to the Federal appropriation from which the grant had been awarded.

Considering the timing of submission, a competing continuation application (Type 2) includes no Section III - "Fiscal Data for Current Budget Period" and, accordingly, no presentation of an estimated unobligated balance is made. Therefore, information on unexpended balances from the last budget period of the immediately prior competitive segment of support will not be available until a Report of Expenditures (ROE) is submitted - some months after the competing continuation award has been made.

The NIH Division of Financial Management in processing the ROE's will, for accounting purposes, automatically move the unexpended balances shown on the ROE forward to the Type 2 grant account. However, in keeping with what is already stated (also under the Financial Management section of the January 25th issuance) the options available to NIH awarding components on "when" and "how" to utilize the balances will be the same as in the previous approach to dealing with noncompeting continuation (Type 5) awards. The options are: (1) use the balance for funding offset (deduction); or (2) provide increased funding authorization either immediately (through the issuance of a revised award statement) or at the time of processing the next Type 5 award.

While indicating that the new concept will permit the same fiscal flexibility in moving unexpended balances forward to competing continuation awards as has been previously possible with noncompeting continuation awards, one significant procedural difference should be identified. In preparing the Type 5 application, which includes the fiscal data sheet as Section III, the principal investigator may make a request that all or part of the estimated unobligated balance as presented be carried over as increased authorization

in the subsequent budget period for what he/she believes are justified project needs. It is Public Health Service policy that such requests actually be built into the application. For reasons indicated above, such an approach is not possible in dealing with a Type 2 application. However, a principal investigator will have the option of submitting a letter to the NIH awarding component at an appropriate time, through the grantee institution, documenting the basis for a carryover request. The timing would normally relate to that point when the actual unobligated balance is known. Such requests will be considered by the awarding components in making their determinations as to appropriate use of the balances. If NIH elects to provide increased funding authorization it will be reflected in an approved budget shown on a Notice of Grant Award.

NOTICE
(FOR CLARIFICATION)

PREVENTIVE ONCOLOGY ACADEMIC AWARD,

NATIONAL CANCER INSTITUTE

Application receipt date, May 1, 1980.

The National Cancer Institute seeks applications for the Preventive Oncology Academic Award, announced in the *NIH Guide for Grants and Contracts,* Vol. 9, No. 1, January 3, 1980 (pages 63-66). In addition to the one-time March 1, 1980 application receipt date cited in that announcement, NCI notes that the first regular, annual receipt date will be May 1, 1980. Applicants desiring a start date of July 1, 1981, should submit applications by May 1, 1980. For subsequent years the receipt date will be May 1, with a start date of July 1 of the following year.

ANNOUNCEMENT

SHORT-TERM TRAINING: STUDENTS IN HEALTH PROFESSIONAL SCHOOLS

NATIONAL RESEARCH SERVICE AWARDS

The *NIH Guide for Grants and Contracts,* Vol. 8, No. 13, dated October 26, 1979, contained the announcement of a new NIH program that would expose talented students in health professional schools to the opportunities inherent in a research career. Those planning to meet the May 1, 1980 application receipt date for awards to be made in the Spring of 1981 should write for revised instructions designed to accompany form PHS 6025 when used for Short-Term Training: Students in Health Professional School.

Application forms and instructions may be obtained from:

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

(301) 496-7441

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

NIH-NIAID-80-4

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

TITLE: *TROPICAL DISEASE RESEARCH UNITS*

Application receipt date, June 16, 1980

I. BACKGROUND INFORMATION

The National Institute of Allegy and Infectious Diseases (NIAID) invites applications for a program project grant to be initiated FY 1981 for participation in a Tropical Disease Research Unit (TDRU). The Institute plans to solicit applications for TDRUs only periodically and at designated times.

The Tropical Disease Research Unit is intended to bring together relevant biomedical knowledge and technology in a multidisciplinary attack on the world's tropical and parasitic diseases. The TDRU is expected to develop programs of basic and applied research in one or more disease areas related to the basic biology and immunology of host-parasite relations, pathogenesis, improved diagnostic procedures, immunotherapy and immunoprophylaxis, chemotherapy and chemoprophylaxis, vector biology and control, and other approaches to treatment and prevention.

II. SCIENTIFIC PROGRAM REQUIREMENTS

The complexity of the major tropical diseases is such that a multidisciplinary attack is desirable. The primary goal of TDRUs is to apply recently developed innovative biomedical technologies to the problems of one or more of the following diseases of interest to NIAID: parasitic diseases - malaria, schistosomiasis, filariasis, trypanosomiasis, and leishmaniasis; viral diseases - arena viruses and selected tropical rhabdoviruses; bacterial diseases - leprosy and yaws. The TDRU will represent a multidisciplinary and cooperative program between scientists in basic and applied fields for the study of one or more of these major diseases. Such disciplines as biochemistry, cell biology, entromology, pharmacology, immunology, and genetics should join those of parasitology, virology, and bacteriology in seeking new approaches to complex and refractory tropical infections.

This program is described in the Catalog of Federal Domestic Assistance number 13.856. 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 52 and CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

A program project grant is a mechanism for the support of a broadly based multidisciplinary research program that has a well-defined central research focus or objective. This contrasts with the usually narrower thrust of the traditional individual research project. The responsibility for leadership of the program resides with the program director (P.D.) who must possess demonstrated scientific and administrative competence. The program project grant consists of a number of interrelated projects that contribute to the program objective. Each of these scientifically meritorious projects usually is under the leadership of an established investigator who would be the principal investigator (P.I.) for the specific project. The grant also can provide support for certain common resources (cores). Such resources (e.g. laboratory or clinical facilities) should be utilized by two or more projects within the program when such sharing facilitates the total research effort. In addition, a program project consists of scientifically meritorious projects whose interrelationships will result in a greater contribution to its program goals than if each project were pursued individually.

DISTINGUISHING FEATURES OF A PROGRAM PROJECT GRANT

1. There must be a unifying well-defined goal or problem area of research to which each project relates and contributes thereby producing a research environment that allows each research effort to share the creative strengths of the others.

2. The P.D. must possess recognized scientific and administrative competence. The P.D. must show a substantial commitment of time and effort to the program and exercise leadership in the maintenance of its quality control.

3. Each research project included in the program project grant application must, as assessed by peer review, stand on its own independent scientific merit, as well as complement other projects whenever feasible.

4. These multiple projects require the participation of investigators in several disciplines or such persons with special expertise in several areas of one discipline. All investigators must contribute to, and share in, the responsibilities of fulfilling the program objective.

5. Only institutions with strong ongoing research programs and resources that can focus on a multidisciplinary attack on tropical diseases will be considered for program project support under the provisions of this program.

III. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants may submit a brief, one-page letter stating their intent to submit an application and describing the general area of research to be proposed. The letter of intent should be submitted 60 days prior to the deadline for receipt of applications

and should be addressed to:

Dr. Kenneth Phifer
Parasitology Program Officer
Molecular Microbiology and Parasitology Branch
Microbiology and Infectious Diseases Program
National Institutes of Allergy
and Infectious Diseases
Room 737, Westwood Building
National Institutes of Health
Bethesda, Maryland 20205

The Institute requests such letters only to provide an indication of the number and scope of applications which will require consideration. A letter of intent is not binding and it will not enter into the review of any application.

B. Format for Applications

Applications should be submitted on Form PHS 398, which is available from most institutional business offices or the Division of Research Grants, NIH. An Information Brochure on NIAID Program Project Grant is available and provides special instructions for program project grant applications. This brochure may be requested now or in the letter of intent.

C. Application Procedures

The submission date for receipt of applications has been set for June 16, 1980. Therefore, letters of intent and receipt of applications will be due as stated below:

Letter of Intent	Applications
April 15, 1980	June 16, 1980

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

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

It is important that a brief covering letter accompany the application indicating that it is in response to this program announcement. A copy of the covering letter and one additional copy of the application should be sent to Dr. Kenneth Phifer. Applications that are not responsive to the RFA or are not received by June 16, 1980, will not be accepted for review and will be returned to the applicant.

IV. REVIEW PROCEDURES AND CRITERIA

Applications in response to this RFA will be reviewed on a nationwide basis in competition with each other, and in accord with the usual National Institutes of Health peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (Microbiology and Infectious Diseases Advisory Committee) in November 1980, and then by the National Advisory Allergy and Infectious Diseases Council at its January 1981 meeting.

The program project grant application should include a justification for the appropriateness of that granting mechanism. Review criteria include evaluation of the following, not necessarily in order of importance:

- The scientific merit of the program as a whole, as well as that of each individual project. Each project should be supportable on its own merit.

- The significance of the overall program goals and the development of a well-defined central research focus.

- The cohesiveness and multidisciplinary or multifaceted scope of the program and the coordination and interrelationships among the individual projects and core(s). The relationship of each core(s) to the central focus of the overall program.

- The qualifications, experience, and commitment of the investigators responsible for the individual research projects or core(s) and their contribution to the program, including their ability to devote adequate time and effort to the program.

- Accomplishments of the program to date (for renewal applications).

- The academic and physical environment in which the research will be conducted, including the availability of space, equipment, patients, and the potential for interaction with active scientists from other departments and/or institutions.

- A sound administrative and organizational structure that facilitates attainment of the objective(s) of the program.

- Arrangements for internal quality control of on-going research, allocation of funds, day-to-day managements, internal communications and cooperation among the investigators involved in the program, contractual agreements, and replacement of the Program Director, if required, on an interim or permanent basis.

The applications received in response to this solicitation will compete for fiscal year 1981 funds. Because there is considerable uncertaintv as to the level of funds that will be available then, it is probable that only one award will be made. The earliest possible award date will be April 1, 1981.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NICHD-CPR-RS-80-1

ANNOUNCEMENT

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

TITLE: *HUMAN INFERTILITY*

Application receipt date, June 16, 1980

I. BACKGROUND INFORMATION

The Reproductive Sciences Branch (RSB) of the Center for Population Research at the National Institute of Child Health and Human Development (CPR/NICHD) is inviting research grant applications for investigations of human infertility. This is its second solicitation in this research area. The first solicitation was March 1, 1977.

The Request for Applications (RFA) is used when CPR wishes to stimulate investigator interest in a particular research area that is important to its mission and when the solicitation is not suitable for a Request for Proposals (RFP) under the contract program which is usually quite specific. Applications submitted in response to an RFA are supported through the customary NIH research project grant mechanism but differ from other research grants in that they are specifically problem oriented.

The Reproductive Sciences Branch supports research on the biomedical aspects of reproduction. This RFA is intended to encourage clinicians and other biomedical and behavioral scientists to submit research grant proposals designed to study the causes and treatment of human infertility.

Concern for human infertility has always been within the mandate of the CPR and has been designated as a problem of high priority. This request for applications will be limited to studies in men and women. In this solicitation infertility is defined as the inability of a couple to have children when they wish.

II. RESEARCH GOALS AND SCOPE

A number of areas of concern have been identified. Appropriate collaboration among clinical and other biomedical or behavioral scientists may be necessary to achieve some of the objectives of the RFA. The research areas for which applications are sought are:

A. Evaluation of current therapy

An important source of confusion in this field is the lack of precision in quantifying the effect of treatment currently employed. Modern techniques of epidemiological and statistical analysis should be applied to evaluate these methods.

B. Male factors

A variety of conditions in the male have been identified as warranting special study. These include cryptorchidism, varicocoele (particularly its incidence and establishment of its true relationship to male infertility), infections (such as mycoplasma and PPLO infections), congenital and secondary occlusions of the male reproductive tract, environmental effects on sperm production (particularly toxins, drugs, and heat), the importance of genetic factors in abnormal sperm production (such as poor motility and necrospermia), the contribution of male factors to habitual abortion, local events affecting sperm (such as circulatory changes, local endocrine factors, and enzyme defects), autoimmunity, and psychological factors affecting sexual activity and semen quality.

C. Female factors

High priority problems in the female include studies of the cervix (such as the importance of certain infections including mycoplasma infections, mucus production, and the effect of cryosurgery and other treatments), the uterine environment (particularly the importance of infection and events preceding and concurring with implantation), tubal factors (particularly anatomical defects, biophysical and biochemical environmental factors, infection, the effect of ectopic pregnancy on subsequent infertility), and studies of the ovary (particularly ovarian dysfunction, polycystic disease, and local factors such as environmental toxins, effects of surgical treatment, etc.). Other problems identified for study include the importance of psychological stress in producing infertility, endometriosis, factors controlling follicular atresia and ovarian senescence, and post-contraceptive infertility and habitual abortion.

D. Couple factors

Topics in this category include immunological studies (with emphasis on the clinical significance of new developments in this field), marital and coital problems, and studies of the psychological effects of the processes leading to and involved in diagnosis and treatment.

E. Improved diagnostic and therapeutic techniques

Included in this category are semen analysis (with establishment of criteria for normal and abnormal findings, including age-specific parameters), new measures of analysis (including determination of sperm fertilizing ability and evaluation of spermatogenesis by morphological and biochemical means), methods for the detection of fertilization and implantation, means to monitor the migration of sperm in the female reproductive tract, and improved post-coital semen tests.

III. MECHANISM OF SUPPORT

This announcement is for a single competition with a specified deadline (June 16, 1980) for receipt of applications. The earliest requested start date for the grants would be April 1, 1981. Applications in response to this RFA will compete for funding in the general, ongoing research grant program of NICHD. This program is described in the Catalog of Federal Assistance number 13.864. Awards will be made under the authority of the Public Health Service Act, Title X, Section 1004 (Public Law 91-572, 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.

IV. REVIEW PROCEDURES AND CRITERIA

Technical merit review of applications submitted in response to this RFA will be managed by the Division of Research Grants, NIH. The National Advisory Child Health and Human Development Council will review the applications in January 1981, and the earliest requested start date would be April 1, 1981. Applications will be reviewed by NICHD staff for responsiveness to the RFA. Applicants submitting a non-responsive application will be contacted and given an opportunity to withdraw the application or to have it considered along with all other unsolicited grant applications in the next review cycle.

Applications will be evaluated by the initial review group in accordance with the usual review criteria for research project grants, as follows:

- The relevance and significance of the proposed approach to the goals described in this announcement.
- The scientific merit of the proposal: the questions proposed for study, the research design, the methodology, the 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. This form is available in most institutional business offices or from the Division of Research Grants, NIH. The conventional presentation for research grant applications should be used.

The original and six (6) copies of the application must be received before 5:00 p.m. Eastern time on June 16, 1980. Applications should be sent or delivered to:

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

The face page of the application should be labeled "IN RESPONSE TO RFA NIH-NICHD-CPR-RS-80-1 HUMAN FERTILITY." One copy of the application should be sent to:

Ms. Julia Lobotsky
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Room C729, Landow Building
National Institutes of Health
Bethesda, Maryland 20205

STAFF CONTACT

Questions relating to this announcement may be directed to Ms. Julia Lobotsky (address above), or on (301) 496-6515.

CLINICAL INVESTIGATOR AWARD

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

ANNOUNCEMENT

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of Clinical Investigator Awards. The clinical investigator award program is intended to:

- encourage newly trained clinicians to develop clinical and basic research interests and skills in the areas of cardiovascular, pulmonary, or blood diseases and blood resources;
- increase the pool of physician investigators in the areas of cardiovascular, pulmonary, or blood diseases and blood resources.

These awards provide the opportunity for clinically-trained physicians with a commitment to research to develop into independent biomedical research investigators.

The award will enable candidates to undertake up to five years of special study and supervised experience tailored to individual needs with a sponsor (or sponsors) competent to provide research guidance. This award is intended to cover the transition between postdoctoral experience and a career in independent investigation. The clinical investigator award differs from the NIH Research Career Development Award (RCDA) in that it seeks to develop research ability in individuals with a clinical background early in the candidate's career rather than to promote the further development of research skills of individuals already demonstrating significant research achievement.

BACKGROUND

Despite a recent decline in the death rate from coronary heart disease, cardiovascular disease continues to be the number one cause of death in the United States. Arteriosclerosis and hypertension account for almost one million deaths annually. An estimated 40 million Americans have diseases of the heart and blood vessels, resulting in a large burden of acute and chronic illness and disability. Heart and blood vessel diseases cost the economy more than $50 billion per year in wages, lost productivity, and expenses for medical care.

This program is described in the Catalog of Federal Domestic Assistance numbers 13.837, 13.838, and 13.839. 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.

Diseases of the lung constitute a major national health problem. An estimated 10 million Americans, both young and old, are currently affected by these diseases with an annual estimated cost to the nation of over $17 billion. In the newborn, the most common cause of death is neonatal respiratory distress syndrome. Neonatal RDS is implicated in the development of adult respiratory diseases as well. Fibrotic and immunologic lung diseases are major causes of lung problems in the young adult and may cause chronic obstructive pulmonary diseases. Of the adult respiratory diseases, emphysema and chronic bronchitis are the major causes of death.

Asthma, emphysema and chronic bronchitis represent particularly pressing health problems, since the death rate and prevalence of these conditions have increased at an alarming rate over the past 15 years. As a disabling disease, emphysema is the third leading cause of worker retirement on Social Security disability payments.

Blood and clotting disorders underlie or are major contributors to many disease processes and, as a consequence, are major causes of death and disability in the United States. No valid estimate of their adverse economic impact can be realistically made, since disorders of the blood not only affect the blood itself, but all of the organs and tissues through which it flows. Similarly, when estimating the economic consequences of an inadequate blood resource system, quantitative figures are difficult to determine, since the supply and management of blood and blood products underlie much routine and emergency medical practice. Small but significant segments of the population have Sickle Cell Disease or other hemolytic diseases. The economic impact of these disorders is serious.

The clinical investigator award program is designed to encourage recently trained physicians to develop their clinical and basic research interests and research capabilities in heart, lung, or blood disease areas. To help support the transition from clinical training status to that of a productive research investigator, the clinical investigator award will provide early support for clinicians with potential for developing into independent researchers.

IMPLEMENTATION

Beginning in Fiscal 1980, under the authorizations in Public Health Service Act, Section 301(c) and Section 413(a), the National Heart, Lung, and Blood Institute has funded clinical investigator awards. Each grant will have a duration of five years. Funding beyond the first year of the grant will be contingent on satisfactory progress during the preceding year.

The status of the clinical investigator award program will be reviewed four years from the date of the first awards to determine whether the program should be continued. In addition, to assess the effectiveness of the program in fulfilling its objectives, the Institute intends, after completion of each grant, to follow the progress of the recipient for a period of five years to determine (1) the investigator's professional affiliation(s), (2) his/her record of subsequent grant or contract support, and (3) his/her record of

scientific publications. It is anticipated that the experience and results achieved by the awardee from this special grant program, in the majority of cases, will provide the basis for successful competition in the regular research support programs of the Institute.

The receipt date for applications will be August 1, 1980 and on that date each year thereafter. They will be evaluated by an initial review group and by the National Heart, Lung, and Blood Advisory Council. The earliest start date for successful applications will be on July 1 of each subsequent year.

PROVISIONS OF THE AWARD

The clinical investigator awardee will be supported for a maximum of five years. All funds must be used to support the original awardee. Support is based on a full-time, twelve-month appointment. The awardee will be provided salary support of up to $25,000 in the first year with annual increases up to a ceiling of $30,000, plus fringe benefits. The actual salary must be consistent with the established salary structure of the institution for persons of equivalent qualifications, experience, and rank.

Up to a total of $10,000 annually may be provided for supplies, equipment, travel, etc., which are necessary for pursuit of the awardee's research program. An appropriate sponsor must assume responsibility and provide guidance for the development of the candidate's research program.

Institutions may apply for awards on behalf of named individuals meeting the criteria for this award. Evidence of the commitment of the institution and sponsors to the candidate's research and career development is to be included in the application.

The grant will be made annually to the awardee's parent institution for each of the five annual budget periods. Costs allowed may include:

1. Awardee's Salary

   Up to a maximum of $25,000 in the first year with annual increases up to a ceiling of $30,000 for full-time support; in addition, fringe benefits will be provided. Institutional supplementation is permitted.

2. Research Support

   Up to a maximum of $10,000 per year.

   - Equipment: specialized research equipment essential to the proposed program. The available facilities should include most of the necessary equipment;

   - Supplies: consumable supplies essential to the propsed program;

   - Travel: domestic travel essential to the proposed program;

- Tuition for training courses: if essential to the awardee's individual research development program; and

- Other: publication costs, patient costs, etc., necessary for the research program.

3. Indirect Costs

Funds will be provided for the reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees, and expenditures for equipment.

ELIGIBILITY

1. The award is designed to provide intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health-professional degrees in the clinical sciences (M.D., D.O., or equivalent). Candidates ordinarily will have completed their clinical experience by the time the award can be made. Ordinarily a candidate in the following categories will not qualify:

   a) with more than 6 years of postdoctoral experience at the time of award;

   b) with previous independent NIH research support or its equivalent;

   c) with less than three years total postdoctoral clinical experience at the time of the award.

   In exceptional circumstances, individuals in one or more of the above categories may qualify for the award. However, the applicant must provide sufficient justification for such an exception.

   Candidates should have broad clinical training, should demonstrate individual competence in clinical activities, and should show research potential in the chosen area of interest. Candidates must provide evidence of a serious intent for research and academic careers.

2. The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic departments, and commitment and capability to provide guidance to clinically oriented individuals in the development of independent research careers.

   Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for a research career. Evidence of the commitment of the institution to the candidate's research and development must be provided.

3. The candidate must have a sponsor(s) or advisor(s) who is recognized as an accomplished investigator in the research proposed at the applicant's institution. The sponsor must provide: 1) his/her concept of a development and research plan for the awardee; 2) his/her curriculum vitae (updated) with complete bibliography and research support; and 3) a letter indicating his/her evaluation of the proposed awardee and his/her willingness to provide guidance and support.

4. The candidate must provide a description of the proposed research and career development plan for the five-year period of the award. The candidate must be prepared to commit full-time effort to the objectives of this award. It is required that a minimum of 75 percent effort be devoted to the research program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with the program goals.

5. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of their third year of support. This report is to contain specific information concerning progress and accomplishments and, in particular, an appropriately detailed research plan and protocol.

6. Candidates must agree to inform the National Heart, Lung, and Blood Institute annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

7. Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.

APPLICATION

Detailed instructions for completion of applications should be requested from the NHLBI staff contacts shown on pages 18&19.

Applications must be submitted on form PHS 398 which is available at the grantee institution. The original and six (6) copies of the application should be clearly labeled "NHLBI CLINICAL INVESTIGATOR AWARD PROGRAM."

The chairperson of the department sponsoring the candidate should submit a signed statement, as part of the application, detailing the departments commitment to the candidate.

Completed grant applications should be mailed to the Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205. Upon receipt of each application at NIH, a postal card acknowledging receipt will be mailed to the applicant.

The applicant should ask three present or former supervisors or preceptors to send a letter to the Review Branch, Division of Extramural Affairs, NHLBI, attesting to his/her potential for conducting independent research. The applicant is responsible for making necessary arrangements to ensure that the reference letters are mailed by the supervisors/preceptors directly to the Review Branch.

Applications for this award are due August 1, 1980. The earliest start date for awards is July 1, 1981.

Subsequent competitions will occur on a once-a-year basis and the receipt dates will be August 1 of each year.

REVIEW CRITERIA

Applications for clinical investigator awards will undergo initial merit review in the Review Branch, Division of Extramural Affairs, NHLBI. Secondary review will be by the National Heart, Lung, and Blood Advisory Council. Criteria for review include:

- The candidate's potential for a career in independent research;
- The candidate's commitment to a research career;
- The eligibility of the candidate as defined in the program announcement;
- The overall merit of the candidate's five-year plan for research and the development of research skills;
- The quality of the candidate's clinical training and experience;
- The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development;
- Presence of highly trained faculty in clinical and basic departments relative to the area of study; and
- The ability and plans of the sponsor (or sponsors) who will provide the candidate with the guidance necessary for career development in research.

NHLBI STAFF CONTACTS

Inquiries about the program should be directed to:

Research Training and Development Officer
DIVISION OF BLOOD DISEASES AND RESOURCES
National Heart, Lung, and Blood Institute
Room 514A, Federal Building
Bethesda, Maryland 20205

Telephone: (301) 496-1817

Research Training and Development Officer
DIVISION OF HEART AND VASCULAR DISEASES
National Heart, Lung, and Blood Institute
Room 3A-08, Federal Building
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Research Training and Development Officer
DIVISION OF LUNG DISEASES
National Heart, Lung, and Blood Institute
Room 6A-05, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7668

Letters of reference and inquiries regarding review procedures should be directed to:

Centers and Special Projects Review Section
Review Branch, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Room 553, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7351

SENIOR INTERNATIONAL FELLOWSHIPS OF THE FOGARTY INTERNATIONAL CENTER, NIH IN SPECIAL FIELDS

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- EPILEPSY
- TROPICAL DISEASES

As part of its Senior International Fellowship Program and in cooperation with certain Institutes of NIH, the Fogarty International Center announces that several Senior International Fellowship awards will be allocated each year to specified fields for research and study abroad. The fields and cooperating Institutes are:

Aging	- National Institute on Aging
Arthritis	- National Institute of Arthritis, Metabolism, and Digestive Diseases
Diabetes	- National Institute of Arthritis, Metabolism, and Digestive Diseases
Epilepsy	- National Institute of Neurological and Communicative Disorders and Stroke
Tropical Diseases	- National Institute of Allergy and Infectious Diseases

These awards will be in addition to those made under the broad range of fields of its regular program. The number will be dependent upon the availability of special funds for this purpose and the merit of applications.

The eligibility requirements, award levels and general terms are the same as for regular Senior International Fellowships.

Annual Application Deadline - October 1

Annual Notification of Final Selection Decisions - April

Fellowships may be activated at any time within 12 months of issuance of the Notice of Research Fellowship Award (PHS Form 416)

Concurrent Applications - An applicant cannot submit concurrent applications to both the regular Senior International Fellowship Program and the Special Emphasis Fellowship Program. Because of the possibility that an application may be approved but cannot be funded by the applicant's designated Program, an applicant may request consideration by the appropriate administrative agency for the alternate Program. Such dual consideration would apply only to those applications whose objectives are relevant to either Program. Such consideration will be granted only upon written request at the time of submission of an application.

An applicant must be a U.S. citizen or permanent resident, be an experienced investigator at mid-career, hold a full-time staff position at a non-Federal U.S. biomedical research or graduate-level educational institution, be nominated by the institution, and have an invitation by a foreign host institution. Awards are made for periods of 3 to 12 months abroad and provide a stipend, travel costs, host institution allowance and a foreign living allowance. To be given particular consideration in one of the specified fields, the study proposal in the application must be clearly and directly related to that field but may range from basic biological mechanisms to clinical aspects.

Individuals interested in being considered for these special Fellowships should first familiarize themselves with the general program guidelines for Senior International Fellowships. Application kits will be sent only to offices of Deans or equivalent institutional officials upon request. Information brochures will be sent to individuals upon request. In order to assure proper processing, all inquiries and application materials submitted should be clearly identified in the following manner:

"SENIOR INTERNATIONAL FELLOWSHIP - SPECIAL FIELD "(_____)".
(name of field)

Further information may be obtained from:

Senior International Fellowship Program
Scholars and Fellowships Program Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

SENIOR INTERNATIONAL FELLOWSHIPS OF THE FOGARTY INTERNATIONAL CENTER FOR 1981 - 1982

ANNOUNCEMENT

The Senior International Fellowship Program of the Fogarty International Center, NIH, provides opportunities to non-Federal U.S. biomedical research and graduate-level educational institutions to nominate outstanding staff members at mid-career, who have demonstrated productive scholarship and have recognized stature in their profession, to go abroad to study and share their expertise as representatives of the best in the American health sciences. It is intended that this award be a career-enhancing educational experience with mutual benefits to all involved.

Fellowship awards are made for periods of 3 to 12 months for research and study in the health sciences at foreign host institutions. An applicant must be a U.S. citizen or permanent resident, have a full-time appointment at the U.S. institution, have at least five years' experience beyond the doctorate, and possess the linguistic skills appropriate to the host institution. Transportation costs, host institution allowance, stipend and foreign living allowance are provided.

During the Fellowship period at the host institution the applicant is expected to pursue a specific, well-designed project of mutual interest related to his or her ongoing work as well as to that which will be continued upon return. The type of project would be dependent upon the professional discipline of the applicant, such as basic laboratory or clinical research, data collection and analysis, or operational research. The intrinsic technical merit of the project is one of several important factors to be considered in evaluating the totality of an application as to its fulfillment of the basic purposes of the Program. The following factors will be given weight in review of an application:

- qualifications of the applicant
- potentiality for career enhancement
- opportunity for close, interpersonal technical interchange
- benefit to the U.S. nominating institution
- benefit to the foreign host institution
- technical merit and significance of the project.

Applications cannot be considered as fulfilling the purposes of the Program where there is not a sufficient period of time for in-depth interaction by the applicant with the host institution or where the benefit is primarily for only one of the parties. Thus applications having any of the following as the major feature cannot be accepted:

- visits to multiple institutions for brief periods
- attendance at conferences
- attendance in formal training courses
- provision of full-time clinical or teaching services
- completely independent study.

Application kits will be available from March 15 - September 15, 1980 and will be sent only upon request from the offices of deans or equivalent institutional officials. Information brochures will be sent to individuals on request. In addition to a project description and other supporting material, applications require nomination by the U.S. institution and a letter of invitation by a foreign host institution. The deadline for applications is October 1, 1980 with selection of awards April 1981.

Further information may be obtained from:

Senior International Fellowship Program
Scholars and Fellowships Program Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

BIOBEHAVIORAL APPROACHES TO THE TREATMENT OF HYPERTENSION, NHLBI

ANNOUNCEMENT

The Behavioral Medicine Branch of the National Heart, Lung, and Blood Institute wishes to encourage clinical research projects dealing with evaluation of combinations of pharmacologic and non-pharmacologic therapies in the treatment of patients with diagnosed essential hypertension and requests investigators to consider applying for regular research grant support in this area.

Pharmacologic antihypertensive therapy has been particularly effective in reducing blood pressure in severely and moderately hypertensive patients. Lifetime maintenance of lowered blood pressure by pharmacologic means has proven particularly nettlesome, with long term (five year) compliance with drug regimes estimated to be less than 20% of the target population. Short term side effects, cost and the unknown long-term implications of lifetime drug regimens have been major contributors to the compliance problem.

Exercise, diet, relaxation techniques, biofeedback, meditation, psychotherapy, as examples of non-pharmacologic approaches, have been less effective in lowering blood pressure than pharmacologic agents, but pilot studies have demonstrated their potential utility in maintaining pharmacologically lowered pressure. Medication requirements have been significantly reduced or completely eliminated by such procedures. Apparently, the combinations of pharmacologic and non-pharmacologic therapies may also produce a synergistic effect, i.e., the non-pharmacologic techniques may potentiate the effect of the drugs. The above issues need further exploration in well-controlled studies which can assess the efficacy and preferred configuration of "biobehavioral" approaches to the treatment of hypertension.

This is the first of three announcements of this research interest to be made during the coming year prior to the regular application receipt dates of July 1, 1980 and November 1, 1980. Applications should be made in the usual manner (except for the two items noted below), and the regular review procedure will be followed.

Individuals who submit proposals in response to this announcement are asked to:

This program is described in the Catalog of Federal Domestic Assistance number 13.837. 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.

1. Use the STANDARD TITLE: "Biobehavioral Approaches to the Treatment of Hypertension" and mail the completed PHS 398 form directly to the Division of Research Grants as instructed in the application kit; and

2. Submit a brief LETTER OF INTENT stating that such an application has been, or will be, submitted. The letter should be addressed to:

Behavioral Medicine Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
Room 3A-13, Federal Building
Bethesda, Maryland 20205

Questions about this announcement should be directed to the Behavioral Medicine Branch; telephone (301) 496-9380.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

FDA-BRH-DTMA-80-4

BUREAU OF RADIOLOGICAL HEALTH,

FOOD AND DRUG ADMINISTRATION

TITLE: *UTILITY OF DIAGNOSTIC X-RAY EXAMINATIONS*

Application receipt date, May 28, 1980

The Division of Training and Medical Applications (DTMA) of the Bureau of Radiological Health (BRH), Food and Drug Administration (FDA), conducts a nationwide program to reduce unnecessary exposure from the use of radiation in the healing arts with special emphasis on studies and evaluation of conditions of exposure to medical diagnostic radiation. The Division identifies trends in medical radiation practices and procedures which cause unnecessary patient exposure and plans, develops, and implements action programs that encourage improvement in radiological practices to ensure that radiation exposure to patients is the minimum consistent with the highest standards of medical care. This request for applications (RFA) is intended to foster research that will lead to improved radiological practices.

This RFA will use the customary grant-in-aid mechanism which will be governed by the policies for regular research grants. The responsibility for planning, directing, and executing the proposed research project will be solely that of the applicant.

The present RFA announcement is open to all interested investigators for a single competition with a specified deadline for receipt of applications. It is anticipated that all applications in response to the RFA will be reviewed at the same time by a single review panel. The legislative authority for radiological health grants is Section 356(b) (2) of the Public Health Service Act. Grants will be administered according to the same policies as for regular research grants, with additional requirements for cooperation between investigators and staff of the Bureau of Radiological Health. This program is outlined in 13.103 of the Catalog of Federal Domestic Assistance.

Potential applicants are requested to send, by May 1, 1980, a letter of intent to submit an application. The original and six (6) copies of the application are to be sent to the Division of Research Grants by May 28, 1980. A brief covering letter should be enclosed indicating that the application is being submitted in response to the RFA, FDA-BRH-DTMA-80-4: UTILITY OF DIAGNOSTIC X-RAY EXAMINATIONS. Applications should be prepared in accordance with the aims and requirements described in the following sections.

I. BACKGROUND INFORMATION

A major contributor to the problem of x-ray overutilization is a lack of scientific data for use by health practitioners in judging the circumstances when a particular examination would be likely to produce information useful for patient management. Initial work performed in this area by individual clinicians has yielded promising results. For example, Bell and Loop derived a high-yield criteria list after review of 1,500 skull examinations following trauma. They noted that if skull examinations had been ordered only on patients meeting one or more of the high-yield criteria, 92 of 93 fractures would have been detected. In addition, a 29 percent reduction in x-ray examinations would have been achieved without adverse effect on patient care. Phillips, in applying a refinement of the Bell and Loop criteria list, achieved a 39 percent reduction in the use of skull x-rays, despite a compliance rate among referring physicians of only 55 percent. In addition, Campbell has studied the use of pelvimetry, and Marton has developed criteria for upper gastro-intestinal examinations. (See selected bibliography, page 32)

II. GOALS AND SCOPE

The objective of the proposed study is to encourage research that will evaluate selected diagnostic radiological procedures in terms of benefits (clinical productivity and contribution to patient care) and cost (economic considerations and radiation exposure factors). The four examinations that are of interest are as follows:

Presurgery chest x-ray examinations
Periodic chest x-ray screening examinations
Frequent chest x-ray examinations in intensive care units or other hospital departments
Dental bitewing examinations

Presurgery chest x-ray examinations are used as a routine screen for cardiopulmonary disease which could cause complications during the administration of anaesthesia. Presurgery chest x-ray examinations may also be performed to establish a baseline in case of postoperative complications or as a defense in potential malpractice suits. Data are needed that will evaluate the efficacy of this examination among groups of patients about to undergo surgery. For example, presurgery chest x-rays may have some impact on the clinical management of children and the elderly but may not on the management of patients in other age groups.

Prospective studies should be directed toward establishing referral criteria or algorithms for ordering presurgery chest x-rays. Blue Cross/Blue Shield has recommended that member plans not pay for routine tests (including diagnostic x-rays) unless the tests are specifically ordered by the surgeon. Sound referral criteria can be useful to the physician in determining whether or not to order presurgery chest x-rays.

Periodic chest x-ray screening examinations may be performed on healthy people during annual or biannual physical checkups. The efficacy of these examinations is in question and studies are therefore needed that will establish their value in detecting diseases that might otherwise go unnoticed. Referral criteria are needed that will help the physician determine whether periodic chest x-ray screening examinations are useful in patient management.

Frequent chest x-ray examinations are often performed in intensive care units or other hospital departments. The efficacy of repeated chest x-ray examinations on very ill patients has been questioned. Data are needed that will help to determine the value of daily or more frequently repeated chest x-ray examinations. Analysis of the data should result in referral criteria to be used by the physician in ordering frequent or daily chest x-ray examinations on patients in intensive care units or other hospital departments.

The efficacy of dental bitewing examinations is unclear. There is no general agreement among dentists on which patients should undergo dental bitewing examinations, how often bitewing examinations should be performed, or whether bitewing examinations should be performed in combination with other (periapical) dental x-ray examinations. Studies should be directed toward the development of referral criteria for use by dentists in identifying those patients who should undergo dental bitewring x-ray examinations.

The factors to be addressed in developing studies should include, but not necessarily be limited to:

1. Frequency of examination or procedure;
2. Total dollar costs;
3. Distribution by population characteristics such as age, sex, occupation, and location;
4. Estimated yield of examination in symptomatic and/or asymptomatic groups; and
5. Contribution of examination to diagnosis and treatment.

III. MECHANISM OF SUPPORT

The support for this program will be the traditional grant-in-aid. Applicants who are expected to plan and execute their own research programs, are requested to furnish an outline of the phases into which the program can be logically divided, their own estimates of the time required to achieve specific objectives of the proposed work, and a schedule for completion of the work.

Single-year applications are encouraged. Starting dates as early as September 15, 1980, or later may be requested.

Support of grants pursuant to this request for applications is contingent upon ultimate receipt of appropriated funds for this purpose. The award of grants will be influenced by the amount of funds available to the Bureau, by the overall merit of proposals, and by their critical relevance to the program goal.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

The applications will be evaluated on a competitive basis. The initial scientific merit 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 evaluating each application will be:

1. Scientific merit of the research design, approaches, and methodology;
2. Methods of analyses;
3. Adequacy of existing and proposed facilities and resources;
4. Research experience and competence of the staff to conduct the proposed investigations;
5. Adequacy of time (effort) to be devoted to the project by the investigators and the technical staff;
6. Availability of patients, where applicable;
7. Evidence of institutional commitment to the program;
8. Cost reasonableness of the program; and
9. Willingness to cooperate with BRH and coordinate with other investigators.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a brief 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 1, 1980, at the following address:

Dr. DeWitt Hazzard
Acting Director
Extramural Research Staff
OMS, BRH, FDA
Room HFX-14, Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

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, the application form for traditional research grants. 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 May 28, 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 face page "RESPONSE TO RFA, FDA-BRH-DTMA-80-4."

A brief covering letter must accompany the application indicating that it is submitted in response to this program announcement: UTILITY OF DIAGNOSTIC X-RAY EXAMINATIONS. A carbon copy of this covering letter should be sent to Dr. DeWitt Hazzard at the address shown under item A.

E. Inquiries

Inquiries may be directed to:

Mr. James Morrison, Chief
Medical Branch
DTMA, BRH, FDA
Room HFX-70, Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4600

REFERENCES

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Campbell, J.A. - X-Ray Pelvimetry: Useful Procedure or Medical Nonsense. Journal of the National Medical Association, 68:6, 514-520, November 1976.

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*U.S. GOVERNMENT PRINTING OFFICE: 1980 311-215/16 1-3