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for **GRANTS** and **CONTRACTS**

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

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

Supplements, printed on yellow paper, are published by the respective awarding units concerning new projects, solicitations of sources, and requests for proposals.

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INSTITUTIONAL CONTROL OF RESEARCH GRANT APPLICATION FORMS

A procedure for institutional control of application forms was established in January 1974, whereby each grantee institution was given the the opportunity to provide to the Division of Research Grants (DRG), NIH, the title and address of a central application control office to serve all components of the institution within the same geographical area, i.e., city. Under the central control procedure, the institution became responsible for maintaining and stocking grant application forms and distributing them to investigators.

The central application control office serves as the sole source of application kits for applicant investigators for new, supplemental, and competing continuation (renewal) grant applications (PHS 398) and noncompeting continuation applications (PHS-2590-1).

On the first of each month the DRG provides to the institution's application control office a listing of all noncompeting grants for which applications for continuation will be due 4-6 months hence, depending upon the program. Accompanying the list is a computerprepared application face page to be used in completing each of the grant applications involved. The institution control office is responsible for forwarding a complete application kit to each investigator so that it can be prepared in accordance with NIH and institutional policy and for establishing in-house deadline dates to ensure return of completed applications to the DRG generally 60 days before the beginning date of the next grant period.

Noncompeting continuation applications which are entering their <u>terminal</u> year of support will be identified on the DRG listing with an asterisk. No further reminder of terminating support will be furnished by the DRG.

This is a reissuance of the instructions originally published in the NIH Guide for Grants and Contracts, Vol.2, No. 8, October 26, 1973.

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REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

BUREAU OF RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

FDA-BRH-DTMA-79-1

TITLE: UTILITY OF DIAGNOSTIC X-RAY EXAMINATIONS (Application receipt date not later than June 1, 1979)

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. Grants will be made under the legislative authorization in Section 356 (b)(2) of the Public Health Service Act and will be administered according to the policies applicable to research project grants, with additional requirements for cooperation between investigators and staff of the Bureau of Radiological Health.

Potential applicants are requested to send, by April 13, 1979, 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 June 1, 1979. A brief covering letter should be enclosed indicating that the application is being submitted in response to the RFA, FDA-BRH-DTMA-79-1: UTILITY OF DIAGNOSTIC X-RAY EXAMINATIONS. Applications should be prepared in accordance with the aims and requirements described in the following sections.

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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 gastrointestinal examinations. (See selected bibliography, page 13.)

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). These studies would be directed toward establishing referral criteria or algorithms for specific procedures.

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. Exposure and dose considerations;
- 5. Estimated yield of examination in symptomatic and/or asymptomatic groups; and
- 6. 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.

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The total project period of this proposal must not exceed three years, and single-year applications are encouraged. Starting dates as early as September 15, 1979, 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:

- 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 April 13, 1979, at the following address: Dr. DeWitt Hazzard (HFX-14) Acting Director Extramural Research Staff OMS, BRH, FDA 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 the traditional research grant. 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 1, 1979. 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 - 79-1."

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.

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E. Inquiries

Inquiries may be directed to:

Mr. James Morrison, Chief Medical Branch (HFX-70) Division of Training and Medical Applications Bureau of Radiological Health 5600 Fishers Lane Rockville, Maryland 20857 Telephone: (301) 443-4600

REFERENCES

Selected Bibliography

Bell, R.S. and Loop, J.W. - The Utility and Futility of Radiographic Skull Examination for Trauma. <u>New England Journal of Medicine</u>, 284: 236-239, February 1971.

Phillips, L.A. - A Study of the Effect of High-Yield Criteria for Emergency Room Skull Radiography. <u>Department of Health, Education,</u> and Welfare, Food and Drug Administration, Rockville, Maryland. HEW Publication (FDA) 78-8069, July 1978.

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

Marton, K., Alexander, J., and Sox, H. - Patient Attitudes Toward Tests: The UGI Series. Unpublished.

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REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

BUREAU OF RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

FDA-BRH-DTMA-79-2

ANNOUNCEMENT

TITLE: A QUALITY CONTROL SYSTEM FOR ASSURING ACCEPTABLE DENTAL RADIOGRAPHS (Application receipt date not later than June 1, 1979)

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. This RFA is directed to the Quality Assurance and Training Branch of the Division, which designs and implements systems for quality control in medical x-ray procedures. They develop systems to indicate exposure problems, their causes, and possible solutions as either a part of the x-ray procedure or as separate self-evaluation methods.

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.

Applications should be prepared in accordance with the aims and requirements which are described in the following sections.

- I. BACKGROUND INFORMATION
- **II. OBJECTIVE AND SCOPE**
- III. MECHANISM OF SUPPORT
- IV. METHOD AND CRITERIA FOR REVIEW
- V. METHOD OF APPLYING
- VI. LITERATURE CITATIONS

If you have any questions relating to this announcement, you should contact Dr. C. Larry Crabtree of the Quality Assurance Branch at (301) 443-2436.

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I. BACKGROUND INFORMATION

Estimates of workload, projected for the Public Health Service X-Ray Exposure Study, 1970,¹ indicate that over 300 million dental radiographs are made annually. On the average, each U.S. dental office is exposing and processing about 3,000 radiographs a year.

Data from the Nationwide Evaluation of X-Ray Trends $(NEXT)^2$ and the Dental Exposure Normalization Technique $(DENT)^3$ programs showed that about 40 percent of the dental x-ray units used exposures in excess of recommended exposure ranges. Much of this overexposure was caused by poor darkroom practices, inadequate equipment or conditions, or depleted processing chemicals. In many cases the dentist overexposed the film in order to compensate for deficiencies in processing or darkroom design.

The DENT program has been effective in identifying high exposure units, and where a subsequent visit was made by a trained surveyor who identified the cause of the high exposure and demonstrated correct procedures, the exposure per film was reduced by an average of 200mR. Some dentists even expressed an improvement in the quality of their radiographs.

Beideman, R.W., et al. (1976),⁴ reported that the majority of radiographs submitted to a dental insurance carrier were substandard. Twenty percent of the films were judged unsatisfactory because of poor density or improper processing.

A dental study (FDA 76-8011)⁵ conducted in Nashville, Tennessee, 1972-73, revealed some poor practices in film processing. About 15 percent of the facilities changed their processing solution less frequently than recommended. Severe light leaks in the darkroom were found in 10 percent of the facilities. Over 40 percent of the darkrooms did not have a thermometer, and over 20 percent did not have a timer. Optimum processing of dental film requires the use of time-temperature techniques. Facilities that used the sightdeveloping technique showed a much higher mR exposure per film than facilities that used the time-temperature technique.

An important advance in the field of dental radiography has been the development of automatic processors. Fortier⁶ and Thunthy⁷, in separate reports have warned the dentist of potential problems with automatic processors, and subsequent loss in image quality. They have reported poor quality radiographs because of unclean or improperly cleaned processors, failure to keep fresh solutions at proper levels, inserting film too fast or too close to one another, or inserting bent film.

11. OBJECTIVES AND SCOPE

The objective of this study is to develop a simple and effective system that can be used in a dental office by dentists and/or dental auxiliaries to identify exposure and processing problems which can be corrected before they adversely affect the diagnostic image. The -r##P

level of effort is seen as partly on the professional plane, requiring knowledge of the production of x-rays, factors in radiographic imaging, chemistry of development, and film sensitometry. The grantee will review the factors that influence the quality of a dental radiograph, with special emphasis on the exposure and processing aspects of the radiographic procedure. He/she shall identify the relative importance of each factor in relation to its influence on the diagnostic quality of the radiographic image.

The grantee will construct a simple and inexpensive testing system (hardware and software) that, when radiographed, will identify exposure and processing changes which need to be corrected before they adversely affect the diagnostic image. The system must distinguish exposure problems from processing deficiencies and be sensitive enough to detect potential problems before they are manifested in clinical radiographs. It should also simulate as far as practical the radiographic appearance of the hard structure of the dental apparatus (human hard tissues and restorative materials). The grantee will also document the effectiveness of the testing device to assure quality control through the exposure and processing steps. The system needs to be as inexpensive as possible and the cost should not exceed \$200. The grantee will deliver to BRH a prototype of the testing system, plus a report on its monitoring capability and performance. He will also submit one copy of an operational manual for the testing system and an estimated cost for mass production.

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. It is anticipated that this proposal need not exceed one year. A starting date as early as September 15, 1979, or later may be requested. Support of grants pursuant to this request for applications is contingent upon ultimate receipt of appropriate 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. METHOD AND CRITERIA FOR REVIEW

A. Review Method

The applications will be evaluated on a competitive basis. The initial scientific review will be arranged by the Division of Research Grants, NIH.

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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. Demonstrated experience in quality assurance activities and scientific merit of the research design, approaches, and methodology.
- 2. Experience in the development of equipment and radiographic systems.
- 3. Qualified personnel who are knowledgeable about the physical and clinical aspects of Dental Radiology.
- 4. Accessibility of ongoing radiographic practices as to evaluate the need and to test effectiveness of a system.
- 5. Availability and consent to test the system for a 60-day period in at least two facilities in each of the following categories:
 - (a) Solo dental practice with manual processing
 - (b) Solo dental practice, automatic processing
 - (c) Dental clinic (private and institutional) with hand processing
 - (d) Dental clinic (private and institutional) with automatic processing.

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 April 13, 1979, at the following address:

> Dr. DeWitt Hazzard (HFX-14) Acting Director Extramural Research Staff OMS, BRH, FDA 5600 Fishers Lane Rockville, Maryland 20857

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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. 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 1, 1979. 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 - 79-2:"

A very brief covering letter must accompany the application indicating that it is submitted in response to this program announcement: A QUALITY CONTROL SYSTEM FOR ASSURING ACCEPTABLE DENTAL RADIOGRAPHS. 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:

C. Larry Crabtree, D.D.S. Quality Assurance Branch (HFX-70) Division of Training and Medical Applications Bureau of Radiological Health 5600 Fishers Lane Rockville, Maryland 20857

Telephone: (301) 443-2436

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VI. LITERATURE CITATIONS

- 1 Bureau of Radiological Health and National Center for Health Statistics. "Population Exposure to X-Rays, U.S. 1970." HEW Publication No. (FDA) 73-8047, Superintendent of Documents, GPO, Washington, D.C. 20402, November 1973.
- 2 Bureau of Radiological Health. "Nationwide Evaluation of X-Ray Trends." DHEW Publication No. (FDA) 76-8003, Bureau of Radiological Health, Rockville, Md. 20857, June 1975.
- 3 Bureau of Radiological Health. "Dental Exposure Normalization Technique 'DENT' Instruction Manual." HEW Publication (FDA) 76-8042. Bureau of Radiological Health, Rockville, Md. 20857, May 1976.
- 4 Beideman, R.W., et al. "A Study to Develop a Rating System and Evaluate Dental Radiographs Submitted to a Third Party Carrier." JADA 89:1010, November 1976.
- 5 Bureau of Radiological Health. "Nashville Dental Project: An Educational Approach for Voluntary Improvement of Radiographic Practice." HEW Publication (FDA) 76-8011. Bureau of Radiological Health, Rockville, Md. 20857, July 1975.
- 6 Fortier, A.P. "Preventive Care and Maintenance of the Automatic Processor." Journal of Preventive Dentistry, 3:20, September-October 1977.
- 7 Thunthy, K.H. "Automatic Film Processing." Journal of Preventive Dentistry, 4:18, November-December 1977.

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MINORITY HYPERTENSION RESEARCH DEVELOPMENT

SUMMER PROGRAM,

DIVISION OF HEART AND VASCULAR DISEASES,



NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (Application receipt date not later than July 1, 1979)

Under authority of Section 472 of the Public Health Service Act as amended (42 USC 2891-1), the Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute is accepting applications for Institutional National Research Service Awards for research training under the Minority Hypertension Research Development Summer Program.

The Minority Hypertension Research Development Summer Program is intended to (1) encourage the recruitment and development of minority investigators in specialized areas of research, prevention, control, and education related to hypertension and (2) stimulate hypertension research, prevention, control, and education by offering minority school faculty members and graduate students the opportunity to enhance their research capabilities in these areas.

Training will be offered through HYPERTENSION TRAINING CENTERS which have well-established hypertension research and training programs and are within 100 miles of (a) minority school(s) or provide satisfactory alternative arrangements for communication and exchange. The CENTERS will collaborate with MINORITY SCHOOLS to work out plans for the identification, selection, and development of participating MINORITY SCHOOL FACULTY MEMBERS OR GRADUATE STUDENTS. The Training Center is expected to make commitments for hypertension training, establish communications with the minority schools, and select training center members for a joint panel which selects participants. Alternatively, a minority school may identify a hypertension training center and initiate communication toward development of a summer training program.

Minority schools are those in which a majority or significant proportion of its enrollment is comprised of students of minority ethnic groups including, but not limited to, Blacks, Spanish speaking Americans, Native Americans, and Pacific-Asian Americans and has a demonstrated commitment to the special encouragement of minority faculty, students, and investigators. The Minority School must commit itself to encouraging appropriate faculty members or graduate students to participate in this program, to continue the faculty member or graduate student in status after the summer session(s), and guarantee at least limited resources for his or her hypertension research and teaching activities.

Participating faculty members or graduate students must be nominated by the Minority School, be accepted by the Training Center, and agree to report annually for six years after training on his or her academic status, publications, grants or contracts, and teaching activities related to hypertension.

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Institutions wishing to participate as Hypertension Training Centers should submit an application after communications have been established with one or more Minority Schools. The National Heart, Lung, and Blood Institute proposes to award up to 5 more Minority Hypertension Research Development Summer Program grants, each with a duration of five years. Applications may request funds to provide stipends for the duration of a summer program of \$192-\$269 per week for minority school faculty participants and \$75 per week for minority school graduate student participants. In addition, funds may be requested for tuition and fees essential to the training; health insurance coverage for participants during the summer session; and up to 25% of the total award for personnel, including laboratory and secretarial; supplies, not to exceed \$1,000 per trainee; equipment essential to the program; and consultant costs when specifically justified. Indirect cost allowances will be limited to 8% of the total allowable direct costs or the actual rate, whichever is lower.

The present announcement is for a single competition with a specific deadline of no later than July 1, 1979, for receipt of applications. These will be reviewed at the February 1980 meeting of the National Heart, Lung, and Blood Advisory Council to be awarded for the summer of 1980. Applications not received by July 1, 1979, will be returned to the applicant. Guidelines for the development of the application may be obtained by contacting Dr. George A. Hayden at (301) 496-1724.

LETTER OF INTENT

Prospective applicants should submit a letter of intent not later than May 1, 1979, to:

Dr. George A. Hayden Manpower Branch Division of Heart and Vascular Diseases National Heart, Lung, and Blood Institute Room 3A-08, Federal Building Bethesda, Maryland 20205

The Institute requests such letters to obtain an indication of the number and scope of applications which will require merit review. A letter of intent is not binding and will not enter into the review of any proposal subsequently submitted. The letter should briefly describe the composition of the prospective Hypertension Training Center, participating Minority Institutions, the overall approach, and areas of interest envisioned for the Minority Hypertension Research Development Summer Program.

Minority Schools desirous of participating in such a program are also invited to write. Every possible effort will be made to place them in communication with a Hypertension Center in their vicinity.

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ANNOUNCEMENT

SPECIAL EMPHASIS RESEARCH CAREER AWARD:

DIABETES MELLITUS - OBSTETRICAL, PERINATAL,

AND PEDIATRIC ASPECTS,

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

<u>AND</u>

NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM,

AND DIGESTIVE DISEASES

This award is intended to:

- encourage qualified individuals in the early stages of their postgraduate medical and scientific careers to develop research interests and skills in the obstetrical, perinatal, and pediatric aspects of diabetes mellitus;
- provide support for individuals to pursue a program of research in various fundamental and clinical research disciplines related to diabetes mellitus during pregnancy and its associated neonatal morbidity and mortality;
- create a pool of highly qualified investigators with experience and skills in the obstetrical, perinatal, and pediatric aspects of diabetes mellitus for a future role in research, teaching, and clinical care.

The Special Emphasis Research Career Award provides the opportunity for an obstetrician or pediatrician with developing research interests to acquire experience and skill in the broad fundamental and clinical scientific disciplines essential for a multidisciplinary approach to the endocrinologic and metabolic aspects of diabetes mellitus in obstetrical, perinatal, and/or pediatric contexts. In contrast to existing NIH awards which encourage the development of skills in a single discipline within a single laboratory, this SERCA emphasizes in-depth experience in several fundamental and clinical scientific disciplines which are not dependent upon a single laboratory or institution.

Provisions of the Award

This nonrenewable award provides support for a five-year period of fulltime research and related activities. The latter may include research development activities as well as involvement in patient care to the extent that it will strengthen research skills. The SERCA grant made to the awardee's parent institution provides up to \$30,000 per year for fulltime salary support plus fringe benefits. A maximum of \$8,000 per year

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during the first three years and up to \$20,000 per year during the last two years will be provided for necessary research costs including technical assistance, equipment, supplies, consultant costs, domestic travel, patient care costs, publication, and other costs.

Working closely with an advisor, the candidate is expected to develop capabilities in fundamental, applied, or clinical research in the metabolic and endocrinologic aspects of diabetes in gestational, perinatal, or pediatric contexts. These activities should be oriented around the initiation of a specific research program of the applicant's own design. Exposure to multiple disciplines, such as physiology, biochemistry, biophysics, pharmacology, nutrition, and epidemiology should be included in the candidate's plans. Investigators are encouraged to pursue these activities in more than a single laboratory. At the completion of this five-year award, the individual should be in a position to compete in regular NIH research grant and award programs.

Eligibility Requirements

Candidates for the SERCA Award must (1) hold an M.D. or equivalent professional degree (e.g., D.D.S., D.O., D.V.M., etc.); (2) by the beginning date of the award have a minimum of three years post-M.D. experience, including one year of clinical training in obstetrics, pediatrics, or endocrinology-metabolism, or two years post-M.D./Ph.D. experience or equivalent. M.D./Ph.D. applicants should possess significant experience in metabolism, endocrinology, obstetrics, pediatrics, physiology, biochemistry, pharmacology, or other relevant areas of interest, such as epidemiology; (3) be citizens or noncitizen nationals of the United States or its possessions or territories or must have been lawfully admitted to the U.S. for permanent residence at the time of application; (4) meet certain other eligibility requirements specified in the SERCA Program Guidelines (see "For Additional Information").

Deadline for Receipt of Applications

Beginning in June 1979 and annually thereafter, SERCA applications will be received according to the following schedule:

Application Date	Council Review	<u>Start Date</u>
June 1	Jan./Feb.*	July 1*

*of the year following application receipt

For Additional Information

Prospective applicants are encouraged to request and review the <u>SERCA</u> <u>Guidelines</u> (dated November 1, 1978) which further detail eligibility requirements and application procedures. In addition, prior to preparing an application, individuals are strongly encouraged to discuss their potential eligibility as well as their areas of research interest with the Program Director listed below. Requests for copies of the SERCA Guidelines as well as questions related to eligibility, etc., should be directed to:

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Manpower Development Program Director Diabetes, Endocrine, and Metabolic Diseases National Institute of Arthritis, Metabolism, and Digestive Diseases Room 626, Westwood Building Bethesda, Maryland 20205

Telephone: (301) 496-7851

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NATIONAL INSTITUTES OF HEALTH

AND

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

BEHAVIORAL STUDIES RELATED TO DIABETES MELLITUS

National Institute of Arthritis, Metabolism, and Digestive Diseases National Institute of Child Health and Human Development National Institute of Mental Health National Institute on Aging National Heart, Lung, and Blood Institute

The above-named Institutes of the NIH and ADAMHA invite applications for research project grants in the general area of behavioral studies related to diabetes mellitus.

INTRODUCTION

Diabetes mellitus is a major health problem directly affecting over five million Americans and their families. An additional five million Americans are estimated to have diabetes but have not yet developed the overt symptoms. The National Commission on Diabetes has established that diabetics are 25 times more prone to blindness than nondiabetics, 17 times more prone to kidney disease, 5 times more prone to gangrene - often leading to amputation - and twice as prone to heart disease. Approximately half of all children with diabetes will die of renal disease within an average of 25 years after the initial diagnosis. Fourteen percent of diabetics are bedridden an average of one and one-half months per year. The diabetic patient is directly responsible for the continuous daily management of this condition; family, friends, and community are ultimately involved in the treatment process.

Persons with diabetes, faced with the prospect of a life-long disease, possible blindness, and a decreased life expectancy, are under considerable emotional pressures that may adversely influence the course of their disease. Several studies have demonstrated the impact of the emotional state of the patient on noncompliance with prescribed regimen, on triggering episodes of ketoacidosis, and on requiring frequent hospitalizations. Some patients, especially juveniles, have unique problems that impact on themselves, their families, and the community. The behavioral and psychosocial problems of the elderly diabetic are of concern because of the sometimes severe loss of control of physical and mental functions.

In spite of the well recognized association between diabetes and behavioral and psychosocial factors, the scope or depth of the problem is not known and there has been comparatively little research directed toward elucidating

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these interrelationships and their influence on the course of the disease. The purpose of this announcement is to stimulate the identification and study of behavioral and psychosocial factors associated with diabetes and its complications.

I. PROGRAM SPECIFICATIONS

A. PROGRAM OBJECTIVES

The objective of this program announcement is to encourage and stimulate behavioral research into diabetes to further define the scope, depth, and influence of the disease and thereby enhance capabilities related to the prevention, diagnosis, treatment, and control of diabetes and its complications. Interdisciplinary studies between behavioral and biomedical researchers are particularly encouraged.

B. RESEARCH SCOPE

The emphasis of this program announcement is upon behavioral research and research at or near the interface between biomedical and behavioral sciences related specifically to diabetes mellitus and its complications. Some areas of research interest are listed below. They are not presented in any order of priority and are examples only; other areas of behavioral research may occur to the applicant which are equally appropriate.

- 1. Studies that examine the influence of stress on metabolic homeostasis and on diabetic complications
- 2. Studies that examine the influence of attitudes and beliefs on prescribed regimen behavior
- 3. Studies of coping behaviors of the diabetic patient and/or the family of the diabetic
- 4. Studies that examine the psychosocial factors affecting diabetes therapy, including the impact of memory and other cognitive deficiencies often experienced by the elderly; problems associated with age-related decline in olfactory and gustatory senses and consequent effects on dietary discipline and appetite in the elderly diabetic; and influence of cultural beliefs and attitudes toward medical care of diabetes
- 5. Studies to identify predictor variables related to diabetes control and to develop predictive tests which will enable the clinician to identify patients and families at risk for developing serious psychosocial problems and/or serious problems of compliance with therapeutic regimens
- 6. Studies to identify specific behavioral or psychosocial problems associated with special populations including the aged, children, adolescents, parents of diabetics, and American Indians

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- Studies of the effects of blindness or co-existent disease, particularly in regard to the diabetic's ability to maintain optimum medical and dietary management
- Epidemiologic studies of diabetic families regarding measurements of prevalence of psychosocial problems and family disruptions as one component of a broader research study of behavioral or psychosocial aspects of diabetes
- 9. Studies which seek to determine psychosocial effect of insulindependent diabetics on other family members, including studies of intrafamily psychodynamics
- Studies of the use and effectiveness of behavior modification and other psychosocial treatment techniques in dietary control and diabetes mellitus.
- II. METHOD AND CRITERIA OF REVIEW
 - A. ASSIGNMENT OF APPLICATIONS

Applications will be received by the NIH Division of Research Grants, referred to an appropriate Initial Review Group for scientific review, and assigned to individual Institutes for possible funding. These decisions will be governed by normal programmatic considerations as specified in the DRG Referral Guidelines.

B. REVIEW PROCEDURES

Applications in response to this program announcement will be reviewed on a nationwide basis in competition with each other and in accord with the usual Public Health Service peer review procedures for research grants. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (Initial Review Group) and then by the National Advisory Council of the appropriate Institute. An Institute, by law, may not make an award unless Council has recommended approval.

C. DEADLINE

Applications will be accepted with the usual receipt dates for new applications:

July 1 November 1 March 1

III. METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and

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research institutions. The phrase "PREPARED IN RESPONSE TO THE DIABETES BEHAVIORAL STUDIES PROGRAM ANNOUNCEMENT" should be typed across the top of the first page of the application. The original and six copies of the application should be sent or delivered to:

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

For further information, investigators are encouraged to contact one or more of the following individuals:

National Institute of Arthritis, Metabolism, and Digestive Diseases, NIH: Lois F. Lipsett Diabetes Program National Institute of Arthritis, Metabolism, and Digestive Diseases Room 628, Westwood Building Bethesda, Maryland 20205 Telephone: (301) 496-7433 National Institute of Child Health and Human Development, NIH: Dr. Gilman D. Grave Acting Chief, Developmental Biology and Nutrition Branch National Institute of Child Health and Human Development Room 7C-17, Landow Building Bethesda, Maryland 20205 Telephone: (301) 496-5575 National Institute of Mental Health, ADAMHA: Dr. Joseph Autry Division of Extramural Research Programs Clinical Research Branch National Institute of Mental Health Room 10C-18, Parklawn Building Rockville, Maryland 20857 Telephone: (301) 443-4527 National Institute on Aging Dr. Richard Irwin Extramural and Collaborative Research Program National Institute on Aging Room 5C-23, Building 31 Bethesda, Maryland 20205 Telephone: (301) 496-9350 National Heart, Lung, and Blood Institute, NIH: Dr. Margaret Mattson Behavioral Medicine Branch, DHVD National Heart, Lung, and Blood Institute Room 3A-15, Federal Building Bethesda, Maryland 20205

Telephone: (301) 496-9380

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CHANGE OF ZIP CODE NUMBER FOR THE

NATIONAL INSTITUTES OF HEALTH

AND FOR THE

NATIONAL LIBRARY OF MEDICINE

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Effective February 19, 1979, the zip code for all of the National Institutes of Health, including all rental buildings in the Bethesda area (Westwood, Landow, Federal, etc.), is 20205.

The new zip code for the National Library of Medicine is 20209.

ADDITIONAL APPLICATION RECEIPT DATE FOR RFA:

STUDY AND ANALYSIS OF CANCER CONTROL IMPLICATIONS

OF INFORMAL SELF-HELP APPROACHES TO SMOKING CESSATION

NATIONAL CANCER INSTITUTE

NIH Guide for Grants and Contracts, Vol. 8, No. 1, January 19, 1979, p. 37, carried an announcement from the National Cancer Institute of an RFA entitled STUDY AND ANALYSIS OF CANCER CONTROL IMPLICATIONS OF INFORMAL SELF-HELP APPROACHES TO SMOKING CESSATION. The announcement specified a single application receipt date of March 1, 1979. Because of the indicated interest and the very short time previously allowed for submission of applications in response to this RFA, the National Cancer Institute will continue to accept such applications until, but not later than, JULY 1, 1979. Applications received after that date will be returned.

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CHANGE IN INDEXING PROCEDURE FOR NIH GUIDE FOR GRANTS AND CONTRACTS

At the suggestion of a user of the NIH Guide for Grants and Contracts, we are beginning with this issue for your immediate convenience, indexing each article. In addition, we have provided an index for the first three issues of Vol. 8 (attached). An <u>annual</u> index will be furnished in January of each year; this annual index will also advise you which articles are no longer pertinent. Interim suggested indexing will be found on the cover pages of this issue.

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