

NIH Guide for Grants and Contracts

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U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

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The NIH 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.

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.

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NOTICE

INDEX TO NIH GUIDE FOR GRANTS AND CONTRACTS

P.T. 04, 22, 34, 42, 44; K.W. 1200170, 1200180

The index to the NIH Guide for Grants and Contracts has been updated through December 1983. Approximately 1,500 copies will be mailed directly to the offices of sponsored research in all institutions currently receiving one or more National Institutes of Health (NIH) grants or contracts and to NIH staff who receive the Guide.

A limited number of copies are available for individuals who request them. To obtain a single copy please send a self-addressed mailing label to:

Office of Extramural Research and Training
National Institutes of Health
Building 1 - Room 111
Bethesda, Maryland 20205

NOTICE

NEW INSTITUTIONAL TRAINING GRANT

NONCOMPETING CONTINUATION APPLICATION FORM

P.T. 44; K.W. 1200170

The Division of Research Grants (DRG), National Institutes of Health (NIH), will convert to a new institutional training grants noncompeting continuation application form on or about March 1, 1984. The new training grant continuation form is identified by the form number PHS 6025-2 (1/83). It replaces the form numbered PHS 2499-2. DRG will continue to mail the forms directly to the program director of the grant. The forms will not be distributed through institutional control offices.

NOTICE

RECEIPT AND REFERRAL OF APPLICATIONS

P.T. 04, 22, 34, 42, 44; K.W. 1200170, 1200180

DIVISION OF RESEARCH GRANTS

The Division of Research Grants (DRG) is the central receipt point for all research grant and cooperative agreement applications submitted for consideration by the Public Health Service (PHS). More than 25,000 competitive applications annually are processed and assigned to review committees and to awarding organizations by the Referral Section. The following information is provided with the hope of reducing the time and effort of both applicants and NIH staff in the handling of research applications.

1. Waiver of Receipt Dates

- o The Referral Section considers requests for waivers only after the application has been received by the DRG.
- o A request for a waiver should be made in a covering letter submitted with the application. The letter should describe the extenuating circumstances that would justify special treatment.
- o Requests for waiver of a specified receipt date can be considered only after those applications which have arrived by the announced receipt dates have been processed. The regular receipt dates are specified in the grant application kit. Special or one-time dates are identified in the published announcement.

2. Unacceptable Applications

Unacceptable applications include those that are:

- o Not appropriately signed by an authorized official of the applicant institution and the principal investigator.
- o Not sufficiently relevant to the research programs of the PHS.
- o Not prepared in accordance with instructions in terms of page limitations, human subject certification, number of copies, typing with black ribbon, etc.
- o Not revised in accordance with the instructions in the application kit when resubmitted following a previous review.
- o Lacking sufficient information to permit reviewers to make an assessment of technical merit.
- o Supplemental requests to applications not yet funded.

3. Communications from Principal Investigators Prior to Assignment

- o Investigators who wish to provide information to facilitate the assignment and review of their applications should do so by including a covering letter with their application at the time of submission. This will assure consideration of the communication at the time of assignment and the effective use of NIH staff and consultants.
- o Although Referral staff will consider requests for specific assignments for review, the final decision on assignment is made by staff based upon a number of factors. Among these are the subject matter of the application, potential conflicts of interest, timing relative to meeting date, history of the application, availability of review resources, and assigned review responsibilities of the committees as they relate to the content of the application.
- o Pre-assignment communications should be addressed to:

Chief of the Referral Section
Referral and Review Branch
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

4. Post-Assignment Communications

- o Post-assignment communications prior to the review by the study section, should be addressed to the Executive Secretary identified on the "notification of assignment card" which is mailed to the applicant. Communications following review should be addressed to the Program Director of the awarding organization.

NOTICE

WORKSHOP ON HUMANS AS RESEARCH SUBJECTS: ISSUES AND CONCERNS

FACING REVIEW BOARDS AND RESEARCH INVESTIGATORS

P.T. 42; K.W. 0701028, 1200270

A one and one-half day program on March 15-16, 1984, jointly sponsored by the National Institutes of Health, (NIH), Food and Drug Administration (FDA), and The University of Oklahoma Health Sciences Center will be held at the following location:

Center for Continuing Education
Fifth Floor - Nicholson Tower
Oklahoma Children's Memorial Hospital
940 NE 13th Street
Oklahoma City, Oklahoma 73104

The meeting will convene at 1:00 p.m. on March 15, with a plenary session overview of the responsibilities for protection of human subjects in research. On March 16, the program will continue until 5:00 p.m.

This regional conference on humans as research subjects will provide technical assistance to institutions, their staffs, research and clinical investigators, and members of their institutional review boards by identifying and clarifying their respective roles and responsibilities.

For further information, call or write:

Office of Research Administration
University of Oklahoma Health Science Center
P.O. Box 26901/L1B-115,
Oklahoma City, Oklahoma 73190

Telephone: (405) 271-2090

NIH/FDA also have planned regional workshops in other parts of the United States. For further information regarding these workshops contact:

Ms. Roberta Garfinkle
Education Program Coordinator
Office for Protection from Research Risks
Building 31 - Room 4B09
National Institutes of Health
Bethesda, Maryland 20205

NOTICE

CANCER CONTROL SCIENCE PROGRAM

P.T. 34; K.W. 1002014, 0701042

NATIONAL CANCER INSTITUTE

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) announces the conversion of its previous Request for Applications (RFA) entitled "Cancer Control Science Program: Program Projects" (NIH Guide for Grants and Contracts), Vol. 12, No. 9, September 23, 1983) into a traditional investigator initiated program project grant mechanism. No future RFA's for CCSP grants are anticipated. Under the NCI Program Project mechanism, applicants are requested to submit a letter of intent four to six months in advance of the regular due date for application (June 1, October 1, February 1).

Interested investigators should obtain copies of the 1983 "Guidelines for Cancer Control: Areas of Programmatic Interest" from:

Chief, Cancer Control Applications Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 1A07
9000 Rockville Pike
Bethesda, Maryland 20205

The 1983 "Guidelines for the Program Project Grant of the NCI" can be obtained from:

Referral Officer
Grants Review Branch
Division of Extramural Activities
National Cancer Institute
2115 E. Jefferson Street - Room 401
Rockville, Maryland 20852

NOTICE

WITHDRAWAL OF PROGRAM ANNOUNCEMENTS - SMOKING, TOBACCO AND
CANCER PROGRAM

NATIONAL CANCER INSTITUTE

The National Cancer Institute (NCI) hereby withdraws its program announcements entitled "Smokeless Tobacco and Non-Tobacco Smoking Product Use: Identification of Initiation Mechanisms in Children and Adolescents" and "Tobacco and the Blue Collar Worker," which appeared in the NIH Guide for Grants and Contracts, Vol. 11, No. 14, December 31, 1982. Please contact the NCI Smoking, Tobacco, and Cancer Program (Dr. Thomas Glynn, (301) 427-8735) if there are any questions concerning these announcements.

ANNOUNCEMENT

REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

84-HD-03

DATA COORDINATING CENTER FOR COOPERATIVE CLINICAL COMPARISON OF
CHORION VILLUS SAMPLING AND AMNIOCENTESIS

P.T. 34; K.W. 1200280, 1200370, 1010013

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: April 30, 1984

The National Institute of Child Health and Human Development (NICHD) invites applications from organizations to serve as the Data Coordinating Center in a multicenter cooperative clinical study comparing the safety and accuracy of chorion villus sampling (CVS) with amniocentesis. Clinical centers to participate in this study were previously sought under RFA 84-HD-01.

This clinical study is planned to consist of four sequential phases in which the experience and results from each phase will determine whether or not, and in what manner, the next phase will be undertaken. Phasing of this study is envisioned as follows:

- Phase I. Development of a protocol by consensus among the participating centers, preparation of an operations manual, and training of personnel (6 months).
- Phase II. Initiation of the project in participating centers.
- Phase III. a) Recruitment of additional centers and completion of enrollment (28 months).
b) Follow-up of enrolled patients (8 months).
- Phase IV. Data analysis and reporting (12 months).

Applicants for the Data Coordinating Center award should provide an outline of their perception of the clinical study and an in-depth description of their plans and capabilities for data handling and analysis.

The mechanism of support for this Data Coordinating Center will be a cooperative agreement. Additional information and copies of a more detailed RFA which outlines the data coordinating center requirements for participation in the proposed study and the method for applying should be obtained from:

George G. Rhoads, M.D., M.P.H.
Chief, Epidemiology Branch
Epidemiology and Biometry Research Program
National Institute of Child Health
and Human Development
National Institutes of Health
Landow Building - Room 8A04
Bethesda, Maryland 20205

Telephone: (301) 496-1711

The deadline for receipt of applications by the NIH Division of Research Grants is April 30, 1984. Logistics and managerial practicality dictate that only applicant institutions in the United States are eligible.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

84-AGDN-01

CLINICAL TRIALS OF BEHAVIORAL THERAPIES FOR URINARY INCONTINENCE
IN THE ELDERLY

P.T. 34; K.W. 1200080, 1200280, 1200120, 1200890, 1201340, 0404002, 0701039

NATIONAL INSTITUTE ON AGING

DIVISION OF NURSING
BUREAU OF HEALTH PROFESSIONS
HEALTH RESOURCES SERVICES ADMINISTRATION

Application Receipt Date: May 20, 1984

The National Institute on Aging (NIA) and the Division of Nursing (DN) announce the availability of funds to support clinical trials of behavioral therapies for urinary incontinence in the elderly, beginning in fiscal year 1984. Behavioral interventions to be tested may include, but are not limited to: "bladder training" or "habit retraining", pelvic floor exercises, "contingency management", "shaping", and biofeedback approaches. Combinations of these techniques are also appropriate. Pharmacologic, surgical, and/or environmental interventions may be used in addition to "control" regimens for additional comparisons. Subjects for behavioral training may include elderly incontinent subjects and/or their care providers (e.g., nursing home staff). Female incontinent subjects should be over 55 years old; male incontinent subjects should be than 65 years old.

The proposed trials may include an initial "feasibility" phase to validate the operability of the applicants' recruitment techniques, treatment protocol, and other organizational variables, before proceeding to a full-scale trial. However, all proposed projects must include a "full-scale" trial; applications for feasibility studies alone will be considered to be nonresponsive.

The administrative and funding mechanism to be used to support these clinical trials will be a cooperative agreement between each of the awardees and NIA/DN. The major difference between a cooperative agreement and a research grant is that there will be substantial programmatic involvement of NIA and DN staff above and beyond the levels regularly required for traditional program management of grants. Under the terms of the cooperative agreement, the awardee defines the details of the project within the guidelines of the RFA, retains primary responsibility for performance of the activity, and agrees to accept close coordination, and participation of NIA/DN staff in all aspects of the scientific and technical management of the project in accordance with terms formally negotiated and mutually agreed upon prior to the award.

I. ELIGIBILITY

Eligibility is restricted to U.S. institutions; there are no other restrictions other than those specified in Public Health Service (PHS) policy. Because adequate

conduct of these trials will generally require a combination of expertise in behavioral sciences, nursing, geriatrics, and urodynamics, proposed projects should generally include personnel with expertise in all these fields. The adequacy of expertise in these fields will be used as a criterion for review of applications.

II. LENGTH OF SUPPORT

The duration of proposed projects may be up to five years. Funding beyond the first year will be contingent on satisfactory progress and availability of funds. Renewal applications may be submitted, but no funds have been specifically reserved for renewals at this time.

III. START DATE AND FINANCING

The start date for funded projects will be approximately September 30, 1984. A total of up to \$800,000 (\$400,000 by NIA and \$400,000 by the Division of Nursing) will be allocated to fund the initial year's awards. The number of awards will depend on the quality and research scope of approved applications.

The deadline for receipt of applications will be May 20, 1984. Prospective applicants should obtain a copy of the RFA before applying. The RFA and additional information are available from:

Evan Hadley, M.D.
Geriatrics Branch, BRCM
National Institute on Aging
Nation Institutes of Health
Building 31 - Room 5C-21
Bethesda, Maryland 20205

Telephone: (301) 496-1033

Doris Bloch, Dr. P.H., R.N.
Chief, Research Support Section, NRAB
Division of Nursing, BHP
Health Resources and Services Administration
Parklawn Building - Room 5C-09
Rockville, Maryland 20857

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-05

SMOKING PREVENTION AND CESSATION AMONG BLACK POPULATIONS

P.T. 34; K.W. 0404019, 0701042, 1200540

NATIONAL CANCER INSTITUTE

Application Receipt Date: June 15, 1984
Letter of Intent Receipt Date: May 15, 1984

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute (NCI) is interested in supporting studies to determine the long-term effect of interventions designed to prevent the onset and/or reduce the prevalence of cigarette smoking among U.S. Black populations.

The proposed studies should seek to: (1) develop and evaluate innovative intervention strategies to prevent or reduce cigarette smoking among U.S. Black populations and (2) develop and evaluate assessment procedures for determining the long-term effectiveness of smoking interventions among U.S. Black populations.

I. PROGRAM OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing innovative intervention programs focused on U.S. Black populations and determining the long-term effectiveness of these programs on the prevention and cessation of habitual cigarette smoking among Blacks, especially high risk Black groups (e.g., adolescents, low-income).

The focus of the studies envisioned thus must be on the long-term effectiveness of interventions aimed at Black populations. It is anticipated, in keeping with the goals of the NCI Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a sample of the population in such a way that the results obtained are representative of results in large target populations) investigations. It is recognized, however, that there are substantial gaps in our knowledge concerning smoking among Blacks and, in particular, knowledge that may be essential to the development of an effective and durable intervention program. Therefore, where necessary and specifically justified in the application, highly controlled studies of the acquisition process, epidemiological issues, or other related research questions which could influence the effectiveness of prevention/cessation efforts may be addressed in the

intervention studies. These research questions should not, however, become the overriding interest of the study, but rather be integrated as complementary adjuncts to the interventions.

The objective of these studies is to develop and evaluate the effectiveness of innovative intervention strategies to prevent or reduce cigarette smoking among U.S. Black populations. No restrictions are placed on the type of interventions (e.g., media-based, self-help, commercial methods), subgroups that may be studied (e.g., adolescents, females, low-income groups), or intervention sites (e.g., schools, physician's office, community-wide).

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable by others with only minor modifications and little or no external economic or technical aid.

II. ELIGIBILITY REQUIREMENTS

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group. Assignments for possible funding will be governed by the usual referral guidelines.

III. MECHANISM OF SUPPORT

This RFA will use the NIH grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years.

IV. ANTICIPATED NUMBER OF AWARDS

The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.5 million for the first year.

V. LETTER OF INTENT AND APPLICATION RECEIPT DATE

Prospective applicants are asked to submit a one-page letter of intent, including a brief synopsis of proposed areas of research and identification of any other participating institutions, to Dr. Thomas J. Glynn (see address in Section VI) by May 15, 1984.

Applications prepared on Form PHS 398 should be received by the Division of Research Grants, NIH, by June 15, 1984 to ensure their review.

VI. REQUESTS FOR COPIES OF RFA AND INFORMATION

To obtain a copy and/or other information, please contact:

Thomas J. Glynn, Ph.D.
Program Director for Smoking Research
Office of the Director, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 101
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****84-CA-06****SMOKING PREVENTION AND CESSATION AMONG HISPANIC POPULATIONS****P.T. 34; K.W. 0404019, 0701042, 1200540****NATIONAL CANCER INSTITUTE**

Application Receipt Date: June 15, 1984
Letter of Intent Receipt Date: May 15, 1984

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute is interested in supporting studies to determine the long-term effect of interventions designed to prevent the onset and/or reduce the prevalence of cigarette smoking among U.S. Hispanic populations.

The proposed studies should seek to: (1) develop and evaluate innovative intervention strategies to prevent or reduce cigarette smoking among U.S. Hispanic populations and (2) develop and evaluate assessment procedures for determining the long-term effectiveness of smoking interventions among U.S. Hispanic populations.

I. PROGRAM OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing and evaluating innovative intervention programs focused on U.S. Hispanic populations and determining the long-term effectiveness of these programs on the prevention and cessation of habitual cigarette smoking among Hispanics.

The focus of the studies envisioned thus must be on the long-term effectiveness of interventions aimed at Hispanic populations (including, e.g., sub-populations such as Mexican-Americans and Puerto Ricans and high-risk Hispanic groups such as adult males and adolescents). It is anticipated, in keeping with the goals of the NCI Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a large, distinct, and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results in large target populations) investigations. It is recognized, however, that there are substantial gaps in our knowledge concerning smoking among Hispanics and, in particular, knowledge that may be essential to the development of an effective and durable intervention program. Therefore, where necessary and specifically justified in the application,

highly controlled studies of the acquisition process, epidemiological issues, or other related research questions which could influence the effectiveness of prevention/cessation efforts may be addressed in the intervention studies. These research questions should not, however, become the overriding interest of the study, but rather be integrated as complementary adjuncts to the interventions.

The objective of these studies is to develop and evaluate the effectiveness of innovative intervention strategies to prevent or reduce cigarette smoking among U.S. Hispanic populations. No restrictions are placed on the type of interventions (e.g., mediabased self-help, commercial methods), subgroups that may be studied (e.g., adolescents, females, low-income groups), or intervention sites (e.g., schools, physician's office, community-wide).

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable by others with only minor modifications and little or no external economic or technical aid.

II. ELIGIBILITY REQUIREMENTS

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group. Assignments for possible funding will be governed by the usual referral guidelines.

III. MECHANISM OF SUPPORT

This RFA will use the NIH grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years.

IV. ANTICIPATED NUMBER OF AWARDS

The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.5 million for the first year.

V. LETTER OF INTENT AND APPLICATION RECEIPT DATE

Prospective applicants are asked to submit a one-page letter of intent, including a very brief synopsis of proposed areas of research and identification of any other participating institutions, to Dr. Thomas J. Glynn (see address in Section VI) by May 15, 1984.

Applications prepared on Form PHS 398 should be received by the Division of Research Grants, NIH, by June 15, 1984 to ensure their review.

VI. REQUESTS FOR COPIES OF RFAs AND INFORMATION.

To obtain a copy and/or for further information, please contact:

Thomas J. Glynn, Ph.D.
Program Director for Smoking Research
Office of the Director, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 101
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT

REQUEST FOR APPLICATIONS: RFA

84-AM-03

PRESERVATION OF THE DONOR LIVER AND ASSESSMENT OF FUNCTION

P.T. 34; K.W. 1201300, 1200400, 0603000

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES AND DIGESTIVE AND KIDNEY
DISEASES

Application Receipt Date: July 16, 1984

I. BACKGROUND INFORMATION

The number of institutions now performing liver transplantation and the number of liver transplants being performed is increasing. A Consensus Conference on Liver Transplantation held at the National Institutes of Health on June 20-23, 1983, concluded that "liver transplantation is a therapeutic modality for end-stage liver disease that deserves broader application".* The need for donor livers may prove to be a limiting factor in transplantation, especially the need for livers in children. The availability of patients receiving transplants offers an important new resource for research into a variety of important questions, some of which were addressed in a multi-institute announcement in the NIH Guide, January 1984. Improved methods of preserving donor livers and of assessing the adequacy of their function prior to transplantation could make a major difference in the number of livers available for necessary transplants.

Many cadaveric liver donors are individuals who have been involved in automobile accidents, sustained closed head injuries, and have been maintained on respirators. Frequently they have had a period of hypoxemia and/or hypotension at the time of their injury or during some point in their resuscitation. The effect of a short period of hypoxemia and/or hypotension on donor liver tissue is unknown. A prolonged time of hypoxemia (i.e. four hours) causes massive and irreversible liver damage. As a consequence such donors are no longer used.

*Digestive Diseases Advisory Board Report of 1983 - copies available from National Digestive Diseases Advisory Board, NIH Liver Consensus Conference of June 20-23, 1983 - copies available from Office of Medical Applications of Research, NIH

The programs are described in the Catalog of Federal Domestic Assistance (CFDA) No. 13.848, Digestive Diseases and Nutrition. 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 42CFR Part 52 and CFR Part 74. This program is not subject to Health Systems Agency review.

VI. IDENTIFICATION OF CONTACT POINT

Sarah C. Kalser, Ph.D.
Liver and Biliary Diseases Program
National Institute of Arthritis, Diabetes
and Digestive and Kidney Diseases

Telephone: (301) 496-7858

ANNOUNCEMENT

1985 WHO FELLOWSHIPS FOR TRAVEL/STUDY ABROAD

P.T. 22, 48; K.W. 0701015, 0701018, 0701043, 0701026

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Application Receipt Date: September 30, 1984

The World Health Organization (WHO) will make available in 1985 a limited number of short-term fellowships for travel/study abroad related to the improvement and strengthening of health services in the United States. This support is limited to United States citizens engaged in operational or educational aspects of health, allied health, environmental health and engineering activities employed by state or local governments or educational agencies. Federal employees are not eligible to apply.

A selection committee of health professionals will recommend the awarding of fellowships based on the applicant's professional background; need, objectives and locale of travel; and the utilization of the experience upon return to the United States. Applications will not be considered for such as basic research, attendance at international meetings nor from undergraduate or graduate students. Medical interns and residents are considered to be in graduate training.

The fellowship award will include per diem and transportation. Employers of successful applicants are expected to endorse the application and continue the applicant's salary through the fellowship period. Except in unusual circumstances, the fellowships will be limited to short-term programs of one to two months. The number of fellowships awarded will be governed by the amount of funds available. Deadline for the submission of the application is September 30, 1984.

Additional information and application forms may be obtained from the following:

Secretary
WHO Fellowships Selection Committee
Health Resources and Services Administration
Parklawn Building - Room 16A-17
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: 301 - 443-6580

ANNOUNCEMENT

BIOMEDICAL RESEARCH FELLOWSHIP OPPORTUNITIES ABROAD

P.T. 22, 48; K.W. 1200180, 0104000

**JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED
STUDY IN THE HEALTH SCIENCES**

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) of the National Institutes of Health announces the availability of postdoctoral fellowships to U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical, behavioral and health sciences.

Programs Available to U.S. Citizens or Permanent U.S. Residents:

**ALEXANDER VON HUMBOLDT FOUNDATION POSTDOCTORAL RESEARCH
FELLOWSHIPS**

(Supported by the Federal Republic of Germany)

**FRENCH NATIONAL INSTITUTE OF HEALTH AND MEDICAL RESEARCH
POSTDOCTORAL FELLOWSHIPS**

(Supported by the Government of France)

**NIH-FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH EXCHANGE
PROGRAM**

(Jointly Supported by the Governments of France and the United States)

IRISH MEDICAL RESEARCH COUNCIL POSTDOCTORAL FELLOWSHIP

(Supported by the Government of Ireland)

SENIOR INTERNATIONAL FELLOWSHIPS

(Supported and administered by the FIC)

SWEDISH MEDICAL RESEARCH COUNCIL FELLOWSHIPS

(Supported by the Government of Sweden)

SWISS NATIONAL SCIENCE FOUNDATION POSTDOCTORAL FELLOWSHIPS

(Supported by the Government of Switzerland)

The eligibility requirements of each program vary and this information is provided in each program's brochure which is available upon request. However, at a minimum, each candidate must have an earned doctoral degree in one of the behavioral, biomedical or health sciences and some postdoctoral experience.

The receipt date for applications to the FIC Senior International Fellowship Program is June 1, 1984. The receipt date for all other applications except those to the Alexander von Humboldt Foundation is October 1, 1984. Applications for the Alexander von Humboldt Foundation Postdoctoral Research Fellowships are available and are accepted throughout the year. For those fellowship programs with an October 1 receipt date,

application kits will be available from April 1, 1984 to September 15, 1984. The organization that provides financial support for each of the programs selects candidates for participation. While the maximum period of support for all programs is one year, the minimum period of support varies with each program.

Prospective applicants for Senior International Fellowships, the FIC sponsored program, may obtain information brochures from the address listed below. However, application kits for Senior International Fellowships may be requested only through the applicant's dean or equivalent institutional official any time between January 15 and May 15, 1984.

All correspondence should refer clearly to the specific program of interest. For further information, please send a self-addressed label with your request to:

International Research and Awards Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENT

RESEARCH ON ANORECTAL DISEASES AND DISORDERS

P.T. 34, 42, 44, 22; K.W. 1200400, 1200480, 1200410, 0404000, 0404002

**NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE
AND KIDNEY DISEASES**

NATIONAL INSTITUTE ON AGING

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) and the National Institute on Aging (NIA) announce a continuing interest in basic and clinical research and research training in anorectal diseases and disorders.

I. BACKGROUND

The diseases and disorders represented in this announcement include hemorrhoids, fissures, fistulas, rectal prolapse, constipation, anorectal pain, fecal incontinence, and congenital anomalies. Also included are those basic studies of anorectal structure and function, and relationship of the anorectum to the more proximal digestive tract, which are required for understanding of anorectal diseases and disorders and for understanding the relationship of the anorectum to gastrointestinal normal and abnormal functions and general health.

There is a marked ignorance of anorectal diseases and disorders on the part of the public, the general physician, and the biomedical research community. In fact, anorectal diseases and disorders represent a major national problem in terms of morbidity and detracting from the quality of life. For example, for treatment of hemorrhoids alone, there are over 2.5 million patient-physician visits per year resulting in about 240,000 hemorrhoidectomies requiring hospitalization.¹ Data on hemorrhoids, as with other anorectal disorders, are not current. In 1982, the prevalence of hemorrhoids was about 10 million and the annual incidence about 1 million in the U.S.² These figures have probably continued upward with increases in population, especially among adults. The magnitude of morbidity and compromise of the quality of life is similar for other anorectal problems such as fecal incontinence. Fecal incontinence is encountered in all age groups as a significant problem, and emerges as a problem of major proportions for the elderly. Congenital anorectal anomalies are frequently life-threatening for the neonate, and commonly leave the young patient with a lifetime of disfiguring and disabling problems.

This program is described in the Catalog of Federal Domestic Assistance No. 13.848, Digestive Diseases and Nutrition and No. 13.866, Aging Research. 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; and Section 472, 42 USC 289L-1 administered under PHS grant policies and Federal Regulations 42 CFR Part 66. This program is not subject to Health Systems Agency review.

In contrast to the national significance of anorectal health problems, this field has always been markedly underrepresented in biomedical research. There has been a dearth of applications to NIH that address these problems, and therefore there are neither research nor research training grants supported by NIH in this area. The types of knowledge sought to address anorectal diseases and disorders are very broad and must be pursued through all major categories of biomedical research. For example:

- A. Epidemiologic data on anorectal diseases and disorders are limited and should be developed to enable better understanding of the magnitude of anorectal problems, populations at particular risk, and as a guide to research on prevention, early diagnosis, and treatment.
- B. Physiological data on normal and abnormal functions of the anorectal area are sparse. The functional anatomy of the region, its neural control, the role of neuropeptides, the role of nutrition, and the integration of the anorectal area with other levels of the gastrointestinal tract are all in need of further exploration.
- C. Diagnostic and pathophysiological criteria for some anorectal diseases and disorders are inadequate. It is not uncommon, for example, that problems attributed to hemorrhoids frequently are not due to hemorrhoids. A tendency for the public to attribute all anal problems to hemorrhoids leads to a likelihood of postponement of needed evaluation and opportunity for more effective treatment of other anorectal or colonic problems.
- D. Preventive and therapeutic practices addressing anorectal problems vary widely in the medical community. Similarly, there is marked variability in the type of training experienced by physicians and other practitioners who treat persons with anorectal problems. Existing preventive measures require further testing, and the theoretical and experimental basis for prevention methods needs extensive exploration and development. Current treatments require testing for efficacy and cost-effectiveness.
- E. The knowledge foundation in basic science for research on anorectal problems is seriously inadequate. Embryogenesis and development of the anorectum require study, as do subsequent changes associated with childhood and adult years. Animal models of human anorectal problems should be sought and studied. Mathematical and computer-simulated models should be developed. Behavioral aspects of etiology and treatment are of major importance and require extensive study.
- F. The opportunities for anorectal research suggest a value in collaborative studies between basic and clinical scientists. Rigorous clinical data are needed on anorectal problems to clarify diagnostic criteria, achieve understanding of etiology, and determine the most suitable methods for prevention, early diagnosis, and treatment. The relationship of the anorectum to the more proximal gastrointestinal tract is largely unexplored, both in the expression of sequelae to proximal gastrointestinal problems and as the source of such problems.
- G. The most recent published Federal advisory position on anorectal disorders is that of the National Commission on Digestive Diseases (NCDD)³: "Anorectal disorders... contribute a disproportionate share of chronic discomfort and

disability due to gastrointestinal disease. Yet little is known of the etiology of rectal disorders, and treatment is based on clinical experience rather than controlled trials." The NCDD Workgroup on Clinical Research and Digestive Disease Centers and Specialized Facilities recommended "...support for studies of the etiology of these undramatic but important anorectal disorders, and for clinical trials of medical and surgical therapies." The National Digestive Diseases Advisory Board has recently endorsed this NCDD expression of research need. This announcement is in response to these Commission and Board expressions of research needs, and to the recommendations of a June 1983 NIH advisory workshop, "Opportunities in Anorectal Research."

REFERENCES:

1. Crossland, S. G., G. W. Geelhoed and D. G. Guy. 1981. Evaluation of benefits of different nutritional pre- and post-operative management of hemorrhoidectomy patients. *Am. J. Proc. Gastr. Col. Rect. Surg.* 32(5): 8, 10-12, 14.
2. 1972. Prevalence of Chronic Circulatory Conditions. United States, 1972. *Vital and Health Statistics. Series 10 Number 94.* 55 pp.
3. 1978. Report to the Congress of the U. S. of the National Commission on Digestive Diseases. Reports of the Workgroups. Research. Volume 4, Part 2A. pp. 513-514.

II. OBJECTIVES AND SCOPE OF RESEARCH AND RESEARCH TRAINING

Applications for research and research training in all areas of anorectal disorders, diseases, and related basic structure and function exclusive of neoplastic and infectious diseases are encouraged through this announcement.

III. MECHANISMS OF SUPPORT

Types of research applications considered appropriate to this announcement include the traditional project grant (R01), the new investigator research award (R23), the conference grant (R13), and the program project (P01). Career development and research training applications appropriate to this announcement include the clinical investigator award (K08), the research career development award (K04), the individual postdoctoral fellowship award (F32), the institutional training grant (T32) and the individual physician scientist award (K11). Specific forms are required when submitting an application: for the R01, R13, R23, K11, and P01 use PHS 398; for the F32 use PHS 416-1; and for the T32 use PHS 6025-1.

The responsibility for the planning, direction, and execution of the proposed research and/or research training will be solely that of the applicant. Applications will be reviewed competitively with all other applications considered for funding by the awarding institute. This is not a one-time announcement, but rather is a statement of ongoing NIADDK and NIA interest in research and research training in anorectal diseases and disorders.

IV. REVIEW PROCEDURES AND CRITERIA

Applications will be referred to the most appropriate initial review group and to a funding Institute upon receipt at NIH. Applications will be reviewed by the initial

review group for scientific merit and significance of the project, scientific and/or training competence of the proposed principal investigator and supporting faculty (where appropriate) in relation to the type of application involved, feasibility of the project, and the supportive nature of the research environment.

V. METHOD OF APPLYING

Applicants are encouraged to advise one of the sponsoring institutes, NIADDK or NIA, of intent to submit an application, and to seek advice and instructions if considering application for conference grant, program project, clinical investigator award, institutional training grant, or physician scientist award.

Application receipt dates, advisory council reviews, and awards dates will be 3 times per year as represented in the application forms.

Application kits are available at most institution business offices, or may be obtained from:

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

For item number 2, on page one of the application form check "YES" and type the title of this program announcement, "Research on Anorectal Diseases and Disorders." The completed original and six (6) copies should be sent to:

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

VI. INQUIRIES AND CORRESPONDENCE

Requests for information and letters of intent should be directed to one of the following offices:

For digestive diseases:

Donald G. Murphy, Ph.D.
Special Emphasis Areas Program Director
Westwood Building - Room 3A15
National Institute of Arthritis, Diabetes, and
Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7455

For aging and incontinence:

Evan C. Hadley, M. D.
Acting Chief, Geriatrics Branch
Biomedical Research and Clinical Medicine Program
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-1033

ANNOUNCEMENT

OTOSCLEROSIS AND EARLY PROGRESSIVE DEAFNESS

P.T. 34; K.W. 1200550, 1200990, 1200270, 1200280

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE
DISORDERS AND STROKE

Application Receipt Dates: July 1, November 1 March 1

The Communicative Disorders program (CDP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) invites grant applications for the purpose of conducting studies on the many facets of otosclerosis, including but not limited to the associated progressive sensorineural deafness, and the efficacy of sodium fluoride treatment.

I. BACKGROUND INFORMATION

Otosclerosis is a well-documented cause of adolescent and adult-onset conductive hearing loss, secondary to a focus of pathology in the otic capsule. There is, moreover, evidence to suggest that otosclerotic involvement of the otic capsule can lead to cochlear damage and thus to sensorineural hearing loss. Histological studies have documented slow and irregularly progressive foci of disease in the otic capsule. Early resorption of bone may occur either along the wall of a vascular channel or on a broader front. The mechanisms by which demineralization and resorption occur are incompletely understood; however, the processes of resorption and deposition of bone appear to continue and slowly extend to surrounding bone. Hydrolytic enzymes thought to be released from the otosclerotic foci have been suggested as possible causes for the sensorineural component of the hearing loss in some otosclerotic patients. Cases of unexplained progressive deafness of early onset may be a part of this larger problem. Medical therapy with sodium fluoride has been suggested by some investigators to be beneficial in promoting maturation of existing otosclerotic foci, and thus may assist in preventing progressive sensorineural hearing loss due to cochlear involvement. The study of otosclerosis presents several problems including the lack of a good animal model, the dearth of information concerning the molecular biology of otosclerosis, the possible implications of an autoimmune reaction, and the minute quantities of bony tissue available for study.

This program is described in the Catalog of Federal Domestic Assistance No. 13.853, Clinical Research, NINCDS. 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 Health Systems Agency Review.

II. GOALS AND SCOPE

It is the intent of the Institute that a potential investigator or groups of investigators design a scientifically meritorious study utilizing the attributes of the investigator's institution(s) and patient population(s). Investigators are encouraged to consult with and to establish collaborative arrangements within their own institution and/or in other institutions, particularly those conducting similar studies. In the design of an objective clinical trial, if one is planned, several requirements should be met, including but not limited to: (1) an operational definition of the disease in all its phases; (2) objective documentation of the disease (validity and reliability of observations); (3) appropriate statistical design; (4) documentation of control for other disorders or factors which may affect the natural course of the disease, (5) an operational definition of successful medical treatment.

This announcement is designed to offer support for innovative clinically-related otolaryngologic-audiologic research protocols with goals of diagnosis, prevention, treatment and successful remediation of otosclerosis and unexplained early progressive deafness.

III. METHOD OF APPLYING

A. Application Procedures

Detailed instructions for applying are included in the PHS 398 (Revised 5/82) Grant Application Kit. Your institution's business office or grants and contracts office should have the PHS 398 kits, or single copies may be requested by writing to:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
5333 Westbard Avenue
Bethesda, Maryland 20205

Please type **"OTOSCLEROSIS AND EARLY PROGRESSIVE DEAFNESS"** in item 2 on the face page of the application.

B. Eligibility

For-profit and non-profit organizations or institutions in the U.S. are eligible to apply. It should be noted that NINCDS will not support more than one study in a given department or specialty unit. Applicants are urged to contact the Program Administrator prior to submission of the formal application.

C. The Application

The applicant should prepare a complete application on research grant application form PHS 398 (Revised 5/82). The NINCDS recommends that the applicant consult with the Program Administrator, Communicative Disorders Program, NINCDS who will provide guidance in relation to budgetary and administrative details.

IV. TIMETABLE FOR RECEIPT AND REVIEW OF APPLICATIONS

A. Receipt

The original and six (6) copies of the application must be sent directly to:

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

B. Review Schedule

Applicants should note that there is approximately a 10-month time period from receipt of an application to activation of an award.

V. REVIEW PROCEDURES AND CRITERIA

A. Review Procedures

Applications will be reviewed for scientific and technical merit by an NIH initial review group and for program relevance by the National Advisory Neurological and Communicative Disorders and Stroke Council.

VI. STAFF CONTACT

For further information, potential applicants may write or call:

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

Telephone: (301) 496-1804