

NIH Guide for Grants and Contracts

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 you 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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National Institute on Aging

National Institute of Child Health and Human Development

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NOTICE

HEARINGS ON PROPOSED PHS POLICY ON HUMANE CARE AND
USE OF LABORATORY ANIMALS BY AWARDEE INSTITUTIONS

P.T. 34; K.W. 0201011, 1014002

In the April 5, 1984 Special Edition of the NIH Guide for Grants and Contracts (Vol. 13, No. 5) the Public Health Service (PHS) published a proposed Policy on Humane Care and Use of Animals by Awardee Institutions. Written public comment on the proposed policy was requested and it was announced that the PHS intends to hold three open hearings to give the public an opportunity to make oral comments on the proposed changes and requirements.

The schedule for the hearings will be as follows:

July 19, 1984

Federal Office Building
Room 140
601 East 12th Street
Kansas City, Missouri

July 24, 1984

John F. Kennedy Federal Building
Government Center
Room 2003
Boston, Massachusetts

August 2, 1984

Third and Broad Building
2901 Third Avenue
Room 180
Seattle, Washington

All hearings will convene at 9:00 a.m. and will be open to the public, subject to the limitation of available space. Any person wishing to speak at a hearing should file a written request and receive prior confirmation from the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH). Requests to speak will be granted on a first-come, first-served basis. Copies of presentations may be submitted for the record. Oral presentations will be limited to ten minutes. Requests to speak at hearings should be received at least ten days prior to the hearing at the following address:

Ms. Carol Young
Office for Protection from Research Risks
National Institutes of Health
Building 31 - Room 4B09
Bethesda, Maryland 20205

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA****84-CA-09****METABOLISM AND PHYSIOLOGY OF RETINOIDS AND CAROTENOIDS IN HUMANS****P.T. 34; K.W. 1200780, 0202022, 1200400, 1007009****NATIONAL CANCER INSTITUTE**

Letter of Intent Receipt Date: August 10, 1984

Application Receipt Date: October 5, 1984

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to support research on human metabolism and physiologic effects of retinoids and carotenoids. Studies of interest include metabolism in the intestinal mucosa, intestinal absorption, regulation of gastrointestinal uptake and tissue concentrations, and extra-intestinal metabolism of these compounds. The studies should span a range of dietary intakes from RDA levels to levels suspected of being toxic. The proposed research requires innovative approaches to determine the dynamics of absorption and metabolism, target tissue levels, and specificities of the various vitamin A compounds and how these determinations would elucidate the roles of dietary retinoids and carotenoids in cellular integrity and resistance to tumor promotion.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. As more completely described later in this announcement, the recipients will have primary responsibility for the development and conduct of the research. NCI involvement will be in regard to coordinating and synthesizing the research effort in regard to approaches, methodologies and exchange of information.

Copies of the complete Request for Applications and additional information may be obtained from:

Elaine Lanza, Ph.D.
Diet and Cancer Branch
Blair Building - Room 617
National Cancer Institute
Bethesda, Maryland 20205

Telephone: (301) 427-8753

To ensure their review, applications should be received by October 5, 1984.

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-14

INVOLUNTARY EXPOSURE TO TOBACCO SMOKE AND CANCER RISK

P.T. 34; K.W. 1002014, 0701013, 1007003, 1007005

NATIONAL CANCER INSTITUTE

Application receipt date: October 15, 1984

I. BACKGROUND

In recent years some epidemiological studies have indicated an association between involuntary or passive smoking and an increased risk for cancer. The reactions to brief exposure to tobacco smoke in enclosed environments range for the nonsmoker from slight irritation of the eye to serious allergic reaction. The reaction usually disappears following a period free from exposure to tobacco smoke. Also reported is a dysfunction of small airways in nonsmokers chronically exposed to tobacco smoke. It has also been reported that nonsmoking subjects of either sex whose spouses were current smokers of at least 10g of tobacco a day had significantly lower forced mid-expiratory flow rate than those married to nonsmokers.

Many chemical substances of mainstream smoke have been reported in sidestream smoke, with some substances released into the sidestream smoke in markedly higher amounts than into the mainstream smoke. The actual absorption of individual smoke components by nonsmokers in smoke-filled environments has been reported only for a few components. The pattern of involuntary inhalation of tobacco smoke is probably different from that of voluntary inhalation by the smoker. This difference would influence the site of deposition and absorption of smoke constituents in nonsmokers compared to active smokers. Therefore, the question arises whether a person exposed involuntarily and for many years to the smoke of others inhales sufficient amounts of carcinogens to elicit a carcinogenic response.

In recent years, a number of epidemiologic studies have been carried out to examine the influence of long-term involuntary exposure to cigarette smoke in nonsmoking women. A large prospective study in Japan reported a significant increase in lung cancer risk among nonsmoking wives of smoking husbands compared with nonsmoking wives of nonsmoking husbands. Wives of husbands who smoked had a two-fold excess of cancer mortality compared to wives of nonsmoking husbands, with suggestive evidence of a dose-response relationship. A recent update of this study also reported an increased risk of cancer of the paranasal sinuses in nonsmoking wives of smoking husbands.

Two case-control studies, one from Greece and the other from the U.S., supported the findings of the Japanese study. However, an analysis of prospective data from the American Cancer Society failed to show a statistically significant association between passive smoking by wives of smoking husbands and lung cancer mortality. This discrepancy may be partly due to differences in methodology of the two prospective studies, or differences between countries in the patterns of involuntary exposures to tobacco smoke. A study carried out in Hong Kong also did not find a relationship between husbands' smoking status and cancer risk among working environment were not taken into account.

A case-control study from the U.S. reported that heavy smoking by wives may increase the lung cancer risk of the light-smoking husband, but smoking by husbands did not significantly affect the risk in women who smoked. Moreover, it was noted that the smoking behavior of the mother, but not that of the father, influenced the lung cancer risk of offspring who smoked. Differences in the histologic distribution of tumors in active smokers and those involuntarily exposed suggest that the differences in physicochemical nature and absorption of mainstream smoke and sidestream smoke may produce different proportions of histological types of tumors.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to stimulate research to assess the effect of involuntary exposure to tobacco smoke on cancer risk. Research of interest includes, but is not limited to (1) studies designed to quantify involuntary exposure to tobacco smoke. For example, the development and field testing of a questionnaire designed to measure involuntary exposure to tobacco smoke, with subsequent validation by appropriate means, (2) ad hoc refinement or modification of existing epidemiologic studies by addition of questions relating to involuntary smoke exposure, and (3) development of case-control studies of tobacco-related cancers in settings that lend themselves specifically to evaluation of the effects of involuntary tobacco smoke exposure.

III. INQUIRIES

Inquiries may be directed to:

Dr. A.R. Patel
Extramural Programs Branch
Epidemiology and Biostatistics Program
Division of Cancer Etiology
National Cancer Institute
Landow Building - Room 8C-16
Bethesda, Maryland 20205

Telephone: (301) 496-9600 (9601, 9602 or 9603)

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-16

BASIC RESEARCH IN FACTORS INFLUENCING NUCLEAR MAGNETIC RESONANCE

(NMR) RELAXATION TIMES IN BIOLOGICAL TISSUES

P.T. 34; K.W. 1013034, 1200380, 1013004, 1003002, 1013020, 1002021

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 15, 1984

I. BACKGROUND

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites investigator-initiated research grant applications for basic studies to elucidate quantitatively the factors and mechanisms which influence and determine the T_1 and T_2 NMR relaxation times in in vitro systems and normal and abnormal mammalian tissues.

Rapid progress has been made over the past several years in the development of new NMR imaging and spectroscopic techniques for research and diagnostic applications. There is a special need for a more scientific understanding of the imaging and tissue characterization information that is generated by these NMR systems.

The interdisciplinary nature of this study will require some combination of expertise included in, but not limited to, the areas of nuclear magnetic resonance phenomena; biophysics and biochemistry at molecular, cellular, tissue, organ, and whole body levels; in vitro cell and tissue cultures; histopathology; animal and/or human physiology and pathology; and a probable variety of additional disciplines and instrumentation techniques as needed to study the complex substances and phenomena that are involved.

II. GOALS AND SCOPE

The objective is to encourage creatively designed, basic experimental studies of the properties of biological materials and tissues in magnetic fields and of the physical

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment Research. Awards are made under authorization of the Public Health Service Act, Title III, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) 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.

and biological phenomena which influence and determine the T_1 and T_2 NMR relaxation times. The ultimate purposes of acquiring this knowledge are potentially to permit definitive noninvasive characterization of tissues by NMR and to enhance the abilities of NMR clinicians of the future to obtain superior imaging and tissue characterization information and to interpret its diagnostic significance.

The scope of studies needed to gain the insight desired will be determined by the ingenuity of the investigator and the experimental approach and will be limited principally by the bounds of reasonable cost. It may be limited to certain specific aspects of the problem or it may include a wide variety of sub-projects ranging from molecular to whole organism studies. The complex biochemical nature of tissues suggests that fundamental studies of some simple in vitro and in vivo systems will be required to establish the basis for understanding more complicated biological systems. Proof of the knowledge achieved might eventually be demonstrated by obtaining quantitatively predictable NMR results in controlled scientific experiments with living tissues or in simpler systems.

III. MECHANISM OF SUPPORT

Applicants funded under the RFA will be supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with all PHS policies applicable to Research Grants, including cost sharing. 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 be typically three years as a balance between the long-range nature of this type of research and the exploratory character of the studies at this stage of development. Studies should not be proposed to exceed five years. The intent is to fund approximately four to eight projects, with total program costs for all grants under this RFA equal to approximately \$750,000 of FY 85 funds for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is included in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose. The issuance of this RFA does not represent a guarantee that any funds will be awarded. No funds are available for the purchase of a large cost capital equipment.

The present RFA announcement is for a single competition with a specified deadline of November 15, 1984, for receipt of applications.

IV. COPIES OF THE RFA MAY BE OBTAINED FROM:

Mr. Roger S. Powell
Program Director
Diagnostic Imaging Research Branch
Radiation Research Program
Division of Cancer Treatment
National Cancer Institute
Landow Building - Room 8C09
Bethesda, Maryland 20814

Telephone: (301) 496-9531

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

AI-84-08

SEXUALLY TRANSMITTED DISEASES RESEARCH UNIT

P.T. 34; K.W. 1201360, 1200670, 1200410, 1200370, 0701013, 0701042, 0415000,
1004005, 1002027

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: October 15, 1984

I. BACKGROUND INFORMATION

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for a program project grant to be initiated during FY 1985 for participation in an ongoing program of research in Sexually Transmitted Diseases (STD). This RFA will not be reissued in fiscal year 1985.

One of the major health problems in the U.S. today is that of sexually transmitted (venereal) diseases. The explosive rise in gonococcal infections in the last decade, for example, with an estimated 2,000,000 gonococcal cases per year, can be considered a major infectious disease epidemic. Many other diseases, such as chlamydial infections, genital herpes, enteric infections, and hepatitis B, are known to be transmitted by the sexual route; these are now being recognized with increasing frequency. Pelvic inflammatory disease, the most serious sequela of gonococcal and chlamydial infection in females, costs the health services an estimated \$1.25 billion annually.

II. RESEARCH GOALS AND SCOPE

- A. As one means of achieving the major goal of further needed research in this area, the NIAID proposes to maintain support of a number of STD research units, or centers of excellence, to serve as foci for research and training in STD. This RFA is for support of one such STD unit; these units are funded as multidisciplinary program project grants. A strong clinical component should be a major part of the application, with individual investigators heading separately identifiable research subprojects within the overall cover of the program project. The fields of research to be considered for emphasis in this program project can be on any or all of the STDs that are currently recognized as significant public health problems.
- B. The research efforts will focus on diseases known, or believed to be transmitted by sexual contact or the sexual route. The diseases of interest in this program are: gonorrhea; syphilis; chlamydial infection; trichomonas

infection; viral infections such as genital herpes, genital warts, hepatitis B; nonspecific vaginitis; enteric diseases; parasitic infestations. Specific areas of research can include: basic biology and virulence factors of the causal organism; the hosts' immune responses; animal model systems; diagnosis, therapy, and preventive measures; epidemiology, including computer modeling studies.

An educational component to advance learning experiences in STD of medical staff and fellows, as well as a community outreach program, can be considered an appropriate part of the STD Research Unit.

C. Mechanism of Support

Eligibility - domestic universities, medical colleges, hospitals, and laboratories of public or private institutions are eligible.

The program project (STD Research Unit) can be supported for up to five years; renewability is dependent on successful competition and the availability of funds. Earliest start date is July 1, 1985. This request is an open competition; one currently funded STD Research Unit is competing for renewal support.

III. IDENTIFICATION OF CONTACT POINT

Direct inquiries and requests for the full text of the RFA to:

Milton Puziss, Ph.D., Chief
Bacteriology and Virology Branch
MIDP
National Institute of Allergy and
infectious diseases
National Institutes of Health
Westwood Building - Room 738
Bethesda, Maryland 20205

Telephone: (301) 496-7728

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-HD-05

INTRAUTERINE GROWTH RETARDATION - PERINATAL EMPHASIS RESEARCH CENTER

P.T. 34; K.W. 1201040, 1201070, 1200370, 1201270, 1002019, 0607024, 0701005

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: October 15, 1984

The Pregnancy and Perinatology Section of the Clinical Nutrition (CNPP) and the Early Development Branch of the Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD) invites grant applications (P-50) for a Perinatal Emphasis Research Center (PERC) focused on intrauterine growth retardation (IUGR).

The PERC's are organized around problem/need themes and are established where research can be coordinated with existing programs of health care to insure the rapid assimilation of new scientific knowledge into health care delivery. PERC's are located throughout the United States and presently are addressing issues in high risk pregnancies (diabetes, hypertension), prevention of prematurity, and fetal hypoxia.

I. RESEARCH GOALS AND SCOPE

This PERC is proposed to deal with promising research areas in IUGR. They include etiologic mechanisms, improvement of diagnostic techniques, and various aspects of prevention and management of IUGR. Investigators are invited to propose studies with a significant clinical component encompassing a wide spectrum of normal and abnormal fetal growth and development as well as fetal-maternal interactions. Supported research may be done with patients or in experimental animals. Studies are encouraged on embryogenesis, cell proliferative growth, and organogenesis as well as on such factors as "specific limiting substances" which may control intrauterine development and/or serve as markers

This program is described in the Catalog of Federal Domestic Assistance No. 13.865 Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

of development. Investigations on the genetics or the influence of viral infections and teratogens that may restrict cell proliferation and fetal growth also would be appropriate. Studies may focus on the placenta as it may affect IUGR. Factors affecting the availability of nutrients or substrates to the fetus offer another area of considerable interest, both in terms of placental function and fetal response to these factors or substrates. Another important area concerns improved methods for assessing fetal health and development and for early detection of developmental anomalies. These may include safety studies on ultrasound or nuclear magnetic resonance as well as a wide variety of biochemical markers for adequacy of fetal growth, growth retardation, or congenital anomalies. Correlation of these indicators with pre-natal conditions and post-natal development would be important. Research also is needed on the most suitable methods for managing IUGR infants so as to maximize infant growth, health, and development.

II. ELIGIBILITY

Domestic non-profit organizations and institutions are eligible to apply.

III. MECHANISM OF SUPPORT

Perinatal Emphasis Research Center grants (P-50) will be supported through the customary grant-in-aid mechanism.

IV. ESTIMATED NUMBER OF AWARDS

This is a one-time announcement with plans to make one award in fiscal year 1985.

V. OFFICE WHERE FULL RFA MAY BE OBTAINED

A complete Request for Applications entitled "Intrauterine Growth Retardation" and guidelines concerning "NICHD Research Center Programs" may be obtained from:

Dr. Charlotte Catz
Head
Pregnancy and Perinatology Section
Clinical Nutrition and Early
Development Branch
Center for Research for Mothers and
Children
National Institute of Child Health
and Human Development
Landow Building - Room 7C09
Bethesda, Maryland 20205
Telephone: (301) 496 5575

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-HD-06

ACCEPTABILITY AND UTILIZATION OF THE CONTRACEPTIVE SPONGE

P.T. 34; K.W. 0413002, 1200320, 0701014, 1002034, 1200180, 0404000

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: November 15, 1984

I. PROGRAM OBJECTIVES

The Demographic and Behavioral Sciences Branch (DBSB), Center for Population Research (CPR), National Institute of Child Health and Human Development (NICHD), has a high degree of interest in the antecedents and consequences of fertility and fertility regulation. The RFA invites scientists to submit grant applications for the support of research on the acceptability, utilization, and effectiveness of the contraceptive sponge. Scientists have an unusual opportunity to conduct research on the contraceptive sponge while it is in the relatively early stages of its use. Investigators will be able to analyze the progress of this method as it becomes part of the armamentarium of fertility regulating methods. Analysis and evaluation of this method in comparison with other contraceptive methods will enhance the scope and implications of the research. Multidisciplinary or unidisciplinary investigations may be conducted. Comparative, crosscultural, transnational or historical approaches may be utilized. Investigators may use extant data, new data, or a combination of both. Appropriate statistical methods, including life table techniques, may be employed. The following questions are among those which the research may be designed to answer. How many contracepting and non-contracepting women are switching to the sponge or using it as their initial contraceptive? What are the factors that influence some women to adopt a relatively new method? Does the sponge have special appeal for women in groups that have a high risk of unintended pregnancy? How do women perceive the sponge in terms of its possible positive and negative effects on health and the role it might play in relation to sexually transmitted diseases? What factors encourage the use of the contraceptive sponge? What factors, such as somatic complaints and other side effects, discourage the use of the sponge?

This program is described in the Catalog of Federal Domestic Assistance No. 13.864, Population 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. This program is not subject to Health Systems Agency review.

II. MECHANISM OF SUPPORT

The support mechanisms for this program will be the individual research project grant and the New Investigator Research Award (NIRA). Copies of the complete RFA may be obtained from:

Sidney H. Newman, Ph.D.
Demographic and Behavioral Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building - ROOM 7C25
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1174

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

CLINICAL STUDIES OF THE EFFECT OF LITHIUM AND PHENYTOIN

IN VIOLENT PATIENTS

P.T. 34; K.W. 1200280, 0404023

FOOD AND DRUG ADMINISTRATION

Application Receipt Date: October 1, 1984

SUMMARY

The Food and Drug Administration (FDA), Office of Orphan Products Development (OPD) is announcing the availability of funds for Fiscal Year 1985, for awarding a grant(s) to support a randomized double-blind placebo-controlled study of lithium and phenytoin in adult patients who manifest episodes of extreme violence and aggressiveness. FDA has approximately \$250,000 available to award a grant(s) to support this research in Fiscal Year 1985. FDA anticipates that one or two awards will be made. Support for this program may be for a period of up to three years.

Applications must be received by October 1, 1984. The earliest date for award is February 1, 1985.

A Request for Application (RFA) is to be published in the Federal Register in June announcing the details.

In order to receive a copy of the RFA, and further information, contact:

Benjamin P. Lewis
Health Scientist Administrator
Office of Orphan Products Development
FDA/HF-35
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4903

ANNOUNCEMENT**AVAILABILITY OF REQUESTS FOR APPLICATIONS: (RFA)****84-HL-15-B****SPECIALIZED CENTERS OF RESEARCH IN THROMBOSIS/NATIONAL RESEARCH AND
DEMONSTRATION CENTER IN THROMBOSIS NIH 84-HL-15-B****P.T. 34, 04; K.W. 1200230, 1200240, 1200180, 1200370, 0701042, 0415000, 0403004****DIVISION OF BLOOD DISEASES AND RESOURCES****NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application Receipt Date February 15, 1985

The Division of Blood Diseases and Resources (DBDR) of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH) supports a comprehensive research program in thrombosis and hemostasis. This comprehensive research program is intended to be a multidisciplinary approach directed at expediting the development and application of new knowledge essential for improved diagnosis, treatment, and prevention of hemostatic disorders. As part of this comprehensive program, the NHLBI announces competition for Specialized Centers of Research (SCOR) in thrombosis and for National Research and Demonstration Centers (NRDC) in thrombosis. Applications received in response to this request will participate in a single competition. A NRDC in thrombosis is conceived as an enhancement of the SCOR program. It must include basic and clinical research (the traditional SCOR components) along with demonstration and education research and an essential coordinating and integrating effort. Applicants may apply for either a NRDC or a SCOR. The submission of a NRDC application may, in some instances, result in the award of a SCOR grant. In other words, the applicant institution may apply for support as a NRDC but, after appropriate peer review, it may be approved only as a SCOR if the other components (demonstration and education research and integration) are significantly weaker.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.839, Blood Diseases and Resources. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal regulations, most specifically 42 CFR Part 74. This program is not subject to Health Systems Agency review.

The requirements and formats for applications submitted in response to this announcement and additional information regarding the characteristics of these mechanisms of support can be obtained from:

Anne P. Ball, Ph.D.
Chief, Blood Diseases Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 5A12
Bethesda, Maryland 20205

Telephone: (301) 496-5911

SUMMARY OF SELECTED CAREER DEVELOPMENT AWARDS

The following four announcements describe some of the mechanisms employed by the National Institutes of Health (NIH) to encourage the development of research investigators. The first, the Dentist Scientist Award (DSA), is a new mechanism introduced by the National Institute of Dental Research (NIDR). Its purpose is to provide opportunities for dentists with a strong commitment to oral health research to develop into independent biomedical investigators. Although specially tailored to the experience and capabilities of dentists, it is similar in most respects to the Physician Scientist Award (PSA) initiated in July 1983 by several NIH Institutes, including NIDR.

The second announcement is a reissuance, with minor modifications of the PSA.

The third announcement invites applications for the Clinical Investigator Award (CIA). As explained in the announcement, the CIA differs from the PSA, intended for newly-trained physicians, and the Research Career Development Award (RCDA), aimed at junior faculty members who have demonstrated research potential. This announcement includes minor modifications in this award.

Changes of special interest to investigators seeking CIA funds from the National Institution of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) appear in the fourth announcement.

The table on the following page summarizes the major features of the CIA, PSA, and RCDA.

| | CLINICAL INVESTIGATOR AWARD | PHYSICIAN SCIENTIST AWARD | RESEARCH CAREER DEVELOPMENT AWARD |
|---------------------------|--|--|---|
| Purpose | To prepare clinical investigators who have had some research experience for independent research careers | To provide clinicians who have had essentially no research experience for independent research careers | To support further development of junior faculty by allowing maximum effort to be spent in research |
| Eligibility | Clinical degree | Clinical degree | Training completed |
| Clinical Experience | Normally have finished clinical training | May have had only one year clinical training | N/A |
| Research Experience | Yes | Normally no | Yes |
| Sponsor Requirement | Yes | Yes | No |
| Sponsor Salary Support | No | Yes, for Phase I | N/A |
| Salary Support | Up to \$40,000 plus commensurate fringe benefits | Up to \$40,000 plus commensurate fringe benefits | Up to \$40,000 plus commensurate fringe benefits |
| Research Support Included | Yes | Yes | No; holder normally holds a research project grant |
| Duration of Award | 5 years | 5 years | 5 years |
| Indirect Cost | 8% | 8% | 8% |

ANNOUNCEMENT**DENTIST SCIENTIST AWARD****P.T. 34; K.W. 0701012, 1200180****NATIONAL INSTITUTE OF DENTAL RESEARCH**

Initial Application Receipt Date: October 1, 1984
Subsequent Receipt Dates: February 1, June 1, October 1

The National Institute of Dental Research (NIDR) announces the availability of the Dentist Scientist Award (DSA). The DSA is specifically designed to provide opportunities for dentists with a strong commitment to oral health research to develop into independent biomedical investigators. Two forms of the award are available: the program award and the individual award.

This award will enable dentists to undertake five years of study to prepare for careers in oral health research. There are three distinct but overlapping and integrated components to the DSA: advanced basic science development, advanced clinical science development, and a supervised research experience. The advanced basic science development component is designed to develop knowledge and research skills in basic science areas relevant to dentistry. This component will include both didactic and laboratory experiences in a fundamental science. This will most typically consist of a doctoral level program, e.g., Ph.D., Sc.D., provided that the respective institution's degree requirements are consistent with the objectives of the DSA. The advanced clinical science development component is to ensure that the candidate has requisite advanced knowledge and skills in a recognized clinical speciality or other appropriate dental clinical discipline. The research experience component is designed to facilitate transition to an active research career. This component requires a research program plan using a basic science or clinical five-year research development program each candidate will require the close sponsorship of an individual mentor with an extensive research background.

The purpose of the DSA is the development of competent dental clinical scholars for research careers. Candidates will be limited to those dentists prepared to make a serious career commitment to dental science and who demonstrate high research potential.

Institutions and individuals wishing complete details on eligibility, mechanisms of award, application procedures and review criteria should contact:

Thomas M. Valega, Ph.D.
Special Assistant for Manpower Development
Extramural Program
National Institute of Dental Research
Westwood Building - Room 510
Bethesda, Maryland 20205

Telephone: (301) 496-7807

ANNOUNCEMENT

PHYSICIAN SCIENTIST AWARD

P.T. 34; K.W. 1200180, 1200270

NATIONAL INSTITUTE ON AGING*
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE
AND KIDNEY DISEASES*
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF DENTAL RESEARCH
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES*
NATIONAL EYE INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Institutes of Health (NIH) announces the availability of the Physician Scientist Award to be supported by those institutes listed. The award is intended to encourage newly trained clinicians to develop independent research skills and experience in a fundamental science. The PSA is targeted to newly trained clinicians who wish to receive training in a basic scientific discipline for application to a research problem that may not yet be well defined.

These awards provide the opportunity for clinically trained professionals with a commitment to research to develop into independent biomedical investigators. Two types of awards are available: the program award and the individual award.

The awards will enable individuals with clinical training to undertake up to five years of special study in basic science with a supervised research experience. The first phase (two to three years) of the program will include both didactic study and laboratory experience conducted under the close sponsorship of an individual with extensive research experience in fundamental sciences. The second phase (up to three years) under the continuing guidance of this primary sponsor, will be to apply laboratory-based research in either a basic science or clinical department. This award requires a commitment from a sponsor with extensive fundamental research experience in a basic science such as (but not limited to) biochemistry, molecular biology, genetics, or immunology, and a research program plan using a fundamental or clinical science approach to disease related problems.

In summary, the Physician Scientist Award is designed to encourage the individual with clinical training to develop research skills in a fundamental science. To help support the transition from clinical training status to that of a productive investigator able to compete successfully for NIH research support, the Physician Scientist Award will provide the opportunity for clinicians to develop into independent investigators, to obtain research experience under the sponsorship of a basic research scientist and to initiate a research program.

* These three institutes offer the individual and the program award. The remaining institutes offer the individual award only.

I. ELIGIBILITY

- A. These awards are designed to provide an intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health professional degrees in the clinical sciences (M.D., D.D.S., D.V.M., D.O. or equivalent). Ordinarily physicians holding the PhD are ineligible. Exceptions may be made to this requirement (1) for individuals with Ph.D.s unrelated to the biomedical and behavioral sciences or (2) for those who were involved in other than research activities after receipt of the Ph.D. where the elapsed time was such as to require two or more years of development to update basic science skills. Candidates ordinarily will have completed at least one post-graduate year of clinical training by the time the award is made.
- B. Candidates should demonstrate competence in clinical activities, and should show research potential. Candidates must provide evidence of a serious intent for research and academic careers.
- C. Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.
- D. Applicants for a Physician Scientist Award may not submit a concurrent application for an NIH Research Career Development Award, Academic Award, a Clinical Investigator Award or a Special Emphasis Research Career Award. Physician scientist awardees may subsequently apply for a New Investigator Research Award or a research project grant.
- E. Ordinarily a candidate with previous independent NIH research support or its equivalent will not qualify.

II. MECHANISMS OF AWARD

This award may be supported through two mechanisms: the individual award and the program award.

A. Individual Awards

1. The Environment

Applications will be accepted from a domestic university, medical school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic sciences and commitment and capability to provide guidance to clinically trained individuals in the development of independent research careers. The environment desired is one which will stimulate and increase the interaction between basic scientists and clinical investigators.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for

a research career. Evidence of the commitment of the institution to the candidate's research and development must be provided.

2. The Program

The individual's program should be designed in two phases. The candidate must provide a description of the research development plan. It should start with a creative and detailed basic science learning experience in Phase I and progress to culminate in intensive research activity in Phase II under the general guidance of a qualified sponsor. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of Phase I. This report is to contain specific information concerning progress and accomplishments and, in particular, an appropriately detailed Phase II research plan and protocol for administrative review and approval.

3. Sponsor

Each candidate must identify a primary sponsor who is recognized as an accomplished investigator in the basic science research area proposed, who has experience in training independent investigators and who will provide the guidance for the awardee's development and research plan. The primary sponsor must be committed to continue this involvement through the individual's total period of development under the award. In some cases candidates may elect to have a secondary clinical sponsor for the research intensive years.

4. Duration and Effort

This five year non-renewable award is based on up to five full-time 12 month appointments. All funds must be used on behalf of the original candidate. Support is divided into two distinct phases that relate to the individual's progress in becoming an independent investigator. It is required that a minimum of 75 percent effort be devoted to the research and research training program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with the program goals, i.e., the awardee's development into an independent biomedical research investigator or necessary to maintain clinical skills necessary for an academic clinical career.

It is desirable for individuals to complete both phases without interruption. It may be permissible, however, to interrupt the award and delay the start of Phase II in order to engage in further clinical training. In the event such a contingency arises, the awardee and the sponsor must justify the interruption to the awarding institute to assure that funds will be available to resume the award so that the candidate may complete the program.

5. Allowable Costs

- a. Salary -- Individual compensation based on the institution's salary scale for residents or junior faculty at an equivalent experience level but funding from this award for salary not to exceed \$40,000

per year per individual plus commensurate fringe benefits for essentially full-time (75-100 percent) effort to the endeavor.*

- b. Sponsor's Support -- A sum of up to 10 percent of the primary sponsor's salary and commensurate fringe benefits during Phase I.
- c. Research and Development Support -- \$10,000 per year in Phase I increasing to \$20,000 per year in Phase II for research project requirements and related support, e.g., technical personnel costs, supplies, equipment, candidate travel, medical insurance premiums and tuition for necessary courses.
- d. Indirect Costs -- reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees and expenditures for equipment.

6. Concurrent Awards

Individuals entering Phase II are encouraged to apply for additional research support, e.g., New Investigator Research Award (R23) or Research Project award (ROI). Such support may be applied for and held with no reduction in the \$20,000 provided as research support. However, salary support from PHS sources above the \$40,000 provided by this award is not allowable.

- B. Program Award - Institutions with Program Awards may recruit and select candidates into their programs on a local basis rather than submitting a separate application on behalf of each prospective candidate. In all other respects, Program Awards are intended to provide support for the development of physician scientists in the same manner and under the same terms as the individual awards.

1. The Environment

Applications will be accepted from an association of departments and divisions and/or clinical departments representing a range of research interests. The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs with adequate numbers of highly trained faculty in clinical and basic sciences and with the interest and capability to provide guidance to clinically trained individuals in the development of research independence. The environment sought is one which will stimulate and increase the interaction between basic scientists and clinical investigators.

2. Program Director

The proposed Program Director should possess the scientific expertise,

* NIH policy encourages supplementation from non-government sources, e.g., voluntary or professional organizations.

leadership and administrative capabilities required to coordinate and supervise an interdisciplinary research and development program of this scope. The Director should also be experienced in the design and management of programs for developing investigators, and should be able to demonstrate a superior record in the preparation of clinical investigators for independent research. In addition, a committee with representatives from the appropriate basic and clinical science departments shall be established to advise the Program Director.

3. Sponsor

Each candidate appointed on the grant must have a primary sponsor who is recognized as an accomplished investigator, actively involved in basic science research who will provide the guidance for the candidate's development and research plan. The primary sponsor must be committed to continue this involvement through the individual's total period of development under the award. In some cases candidates may elect to have a secondary clinical sponsor for the research intensive years.

4. Program

The Program award provides five years of renewable support. The award is intended to provide up to five years support of consecutive full-time 12 month appointments to each individual candidate appointed. This support is divided into two distinct phases that relate to the individual's progress in becoming an independent investigator. The support starts with Phase I which is to be a creative and detailed basic science learning experience and culminates in Phase II which requires intensive research under the general guidance of a qualified sponsor.

It is desirable for individuals to complete both phases without interruption. It is permissible, however, to delay the start of Phase II in order to engage in clinical training. In the event such a delay occurs, it is expected that the program director will plan to provide the necessary resources for the awardee to reenter and complete the program. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of Phase I. This report is to contain specific information concerning progress and accomplishments and, in particular an appropriately detailed Phase II research plan and protocol for administrative review and approval.

5. Duration, Effort and Allowable Costs: Support may be requested for up to two postdoctoral candidates entering Phase I per budget period.
 - a. Salary -- Compensation for candidate based on the institution's salary scale for residents at an equivalent experience level but funding from this award is not to exceed \$40,000 per year per

individual plus commensurate fringe benefits for essentially full-time (75-100 percent) effort to the endeavor.*

- b. Sponsor's Support -- A sum of up to 10 percent of the primary sponsor's salary and commensurate fringe benefits during Phase I.
- c. Research and Development Support -- \$10,000 per year in Phase I increasing to \$20,000 per year in Phase II per candidate for research project requirements and related support, e.g., technical personnel costs, supplies, equipment, candidate travel, medical insurance premiums and tuition for necessary courses.
- d. Indirect Costs -- reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees and expenditures for equipment.

6. Budgeting for Future Years

Critical to the success of this program award is the ability of the Program Director to make detailed mid-course assessments of each candidate's developing research skill and of the proper time for transition from one phase to another. It is expected that applicant institutions will initiate their activities under this award in a staged manner. That is, the first requested year of support would include funds for candidates in Phase I only. The second year would request funds for new candidates in Phase I as well as for continued funding of the first year's supported individuals. In this way, the requested level of support would increase steadily from the 01 through the 05 budget period as new candidates were appointed.

7. Concurrent Awards

Individuals entering Phase II are encouraged to apply for separate research support. Such support may be applied for and held with no reduction in the \$20,000 provided as research support. However, salary support from PHS sources above the \$40,000 provided by this award is not allowable.

III. EVALUATION

Awardees must agree to inform the National Institutes of Health annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

IV. MECHANISM OF SUPPORT

The mechanism of support for this activity will be the research grant, awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public

* NIH policy encourages supplementation from non-government sources, e.g., voluntary or professional organizations.

Law 78-410, as amended, 42 USC 241). The regulations (Code of Federal Regulations, Title 42 Part 52, and Title 45 Part 74) and policies which govern the research grant programs of the National Institutes of Health (NIH), will prevail.

The award of grants pursuant to this announcement is contingent upon availability of appropriate funds.

V. METHOD AND CRITERIA OF REVIEW

Applications will be received by the NIH Division of Research Grants (DRG), and, governed by normal programmatic considerations as specified in the NIH Referral Guidelines, will be assigned to the appropriate institute for possible funding.

Applications in response to the Announcement will be reviewed in nationwide competition, and in accordance with the usual NIH peer review procedures. They will first be reviewed for potential for research development and scientific and technical merit by an institute review group composed mostly of non-Federal scientific consultants (initial review group). Following this review, the applications will be evaluated by the appropriate Institute Advisory Council (IAC).

VI. APPLICATION PROCEDURES

The original and five copies should be mailed to DRG and one copy to the institute contact person. The outside of the envelope should be identified as **PHYSICIAN SCIENTIST AWARD**.

Deadlines for receipt of applications by the Division of Research Grants, NIH, are as follows:

| Applications Received by | Presented to Council in | Earliest Requested Beginning Date |
|--------------------------|-------------------------|-----------------------------------|
| February 1 | September/October | December 1 |
| June 1 | January | April 1 |
| October 1 | May | July 1 |

For further details and in order to obtain an application kit contact the person listed below in the institute offering awards in your area of research interest.

NATIONAL INSTITUTE ON AGING

Edward L. Schneider, M.D.
Associate Director, Biomedical Research and
Clinical Medicine, NIA, NIH
Building 31 - Room 5C11
Bethesda, Maryland 20205

Telephone: (301) 496-4996

NATIONAL INSTITUTE OF ALLERGY
AND INFECTIOUS DISEASES

John W. Diggs, Ph.D.
Director, Extramural Activities Program, NIAID, NIH
Westwood Building - Room 703
Bethesda, Maryland 20205

Telephone: (301) 496-7291

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

Alan Moshel, M.D.
NIADDK, NIH
Westwood Building - Room 405
Bethesda, Maryland 20205

Telephone: (301) 496-7326

or

Walter S. Stolz, Ph.D.
NIADDK, NIH
Westwood Building - Room 657
Bethesda, Maryland 20205

Telephone: (301) 496-7277

NATIONAL INSTITUTE OF CHILD
HEALTH AND HUMAN DEVELOPMENT

Duane Alexander, M.D.
Deputy Director, NICHD, NIH
Building 31 - Room 2A04
Bethesda, Maryland 20205

Telephone: (301) 496-1848

NATIONAL INSTITUTE OF DENTAL RESEARCH

Anthony Rizzo, D.M.D.
Deputy Associate Director for
Extramural Programs, NIDR, NIH
Westwood Building - Room 507
Bethesda, Maryland 20205

Telephone: (301) 496-7748

**NATIONAL INSTITUTE OF ENVIRONMENTAL
HEALTH SCIENCES**

Christopher Schonwalder, Ph.D.
Scientific Director for Extramural
Training Programs, NIEHS, NIH
P.O. Box 12233
Research Triangle Park, North Carolina 27709

Telephone: (919) 541-7634

NATIONAL EYE INSTITUTE

Ronald Geller, Ph.D.
Associate Director for Extramural and
Collaborative Programs, NEI, NIH
Building 31 - Room 6A03
Bethesda, Maryland 20205

Telephone: (301) 496-4903

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Jerome G. Green, M.D.
Director, Division of Extramural Affairs, NHLBI, NIH
Westwood Building - Room 7A17
Bethesda, Maryland 20205

Telephone: (301) 496-7416

ANNOUNCEMENT

CLINICAL INVESTIGATOR AWARD

P.T. 34; K.W. 1200180, 1200270

NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY
DISEASES
NATIONAL CANCER INSTITUTE
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Dates: October 1, February 1, June 1

I. PURPOSE

The Clinical Investigator Award (CIA) is designed to provide the opportunity for promising clinically-trained individuals to develop into independent biomedical investigators. It enables candidates to investigate a well-defined problem under a sponsor (or sponsors) competent to provide guidance in the chosen area of research. The award is intended to facilitate transition from postdoctoral training to a career as an independent investigator.

The CIA differs from the Research Career Development Award (RCDA). The RCDA is intended for those who have already demonstrated outstanding potential for contributing, as independent investigators, to health-related research. The CIA and the Physician Scientist Award (PSA) differ from the RCDA in that both are limited to health professionals, and specifically to those that have not had sufficient research experience to demonstrate such potential. The CIA is further targeted to those who have completed their postdoctorate clinical training, have had some research experience, have defined an area of research interest, and are now seeking supervised research experience in a basic or clinical science discipline to further develop their capabilities. The PSA is intended for physicians at an earlier stage of their postdoctoral clinical training who wish to obtain intensive training in a basic scientific discipline for a two to three year period; these individuals may not yet have identified a specific research problem or protocol.

Awards are authorized by the Public Health Service Act (Title III, Section 301(c) and applicable sections pertaining to specific Bureaus, Institutes, and Divisions.

This issuance combines all NIH Clinical Investigator Award announcements that were previously published separately by each Institute. POTENTIAL APPLICANTS ARE ENCOURAGED TO CONTACT THE INDIVIDUAL NIH STAFF MEMBERS WHOSE NAMES ARE APPENDED TO THE MAIN TEXT FOR SPECIFIC DETAILS CONCERNING THE INSTITUTES' SPECIAL AREAS OF INTEREST. Policies and guidelines in this combined announcement become effective for Clinical Investigator Award applications received on or after February 1, 1985. Awards based on applications received prior to that date will be guided by the program announcements and policies in effect at that time.

II. ELIGIBILITY

Applications may be made by institutions on behalf of candidates who hold the M.D. or equivalent degree (D.D.S., D.V.M. or equivalent). Ordinarily those holding the Ph.D. are ineligible. Exceptions may be made to this requirement (1) for individuals with Ph.D.s unrelated to the biomedical and behavioral sciences or (2) for those who were involved in other than research activities after receipt of the Ph.D. where the elapsed time was such as to require two or more years of development to update basic science skills. Individuals who are, or have been, principal investigators on PHS supported research grants or who have, or have had, comparable responsibility for the conduct of a research project, are not eligible. In general, candidates should have no fewer than two years and no more than seven years of postdoctoral experience. (In selected circumstances, these restrictions may be waived, but this will require special justification.) Candidates should provide evidence of a serious intent to enter upon an academic research career. Only U.S. citizens or non-citizens lawfully admitted for permanent residence are eligible.

It is expected that CIA applicants will have completed their clinical training and will have had some postdoctoral research experience before the award is initiated.

The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs in the chosen area, adequate numbers of highly trained faculty in clinical and basic science disciplines, and interest, capability, and commitment to provide guidance to clinically trained individuals in the development of research independence.

III. CONDITIONS OF THE AWARD

Three of the participating Institutes specify a maximum of three years and four offer up to five years of support. (For details, see the Supplemental Instructions.) The award is non-renewable, usually non-transferable, and is based on a full-time (75-100%) research development effort.

The award provides salary support not to exceed \$40,000 annually. The actual salary must be consistent with the established salary structure of the grantee institution for persons of equivalent qualifications, experience and rank. Supplementation of salary from non-government sources is allowable. Up to a total of \$10,000 annually may be requested for supplies, equipment, travel, tuition, etc. (In the case of NIADDK, up to \$20,000 may be provided annually for personnel other than the awardee, supplies, travel, equipment, etc.) The indirect cost rate may not exceed 8% of the total allowable direct costs. The grantee institution's share of the fringe benefits may be paid as a direct cost (if not treated as an indirect cost) on that portion of the salary provided by the Clinical Investigator

Award. Applicants may not hold or apply for research project grants or their equivalent at the time of CIA application, nor may they apply concurrently for a PSA or other type of NIH Academic Award. However, they may apply for, and hold, the regular research project grant or New Investigator Research Award subsequent to award of the CIA.

Candidates must be nominated by an institution on the basis of qualifications, interests, motivation and potential for an academic or research career. The institution should provide evidence of its commitment to the candidate's research development. The candidate's sponsor(s) must provide a description of the development and research plan for the candidate, an updated curriculum vitae with bibliography and research support, and a letter indicating his/her willingness to provide guidance and support for the period of the award. Candidates must provide a full description of the proposed research and career development plan for the period of the award.

IV. REVIEW CRITERIA

Applications for the NIH Clinical Investigator Award will receive initial technical merit review by an initial review committee appointed by the Institute and secondary review by the corresponding Advisory Council or Board.

Criteria for review include:

- A. The candidate's potential for a career in independent research;
- B. The candidate's commitment to a research career;
- C. The overall merit of the candidate's plan for research and the development of research skills;
- D. The quality of the candidate's clinical training and experience;
- E. The institution's ability to provide adequate facilities, resources, and opportunities necessary for the candidate's research development;
- F. The quality of the faculty in the departments relevant to the area of study;
- G. The ability and plans of the sponsor or sponsors who will guide the candidate in his/her career development;
- H. The candidate's conformance to the eligibility requirements; (see Section II of this announcement.)
- I. NIEHS applicants will also be evaluated regarding their plans for development of a clinical research program at their home Institutions.

V. METHOD OF APPLYING

Applications should be submitted on the research grant application (Form 398, Rev. 5/82). If unavailable at the applicant institution's office of sponsored programs, it may be requested from the:

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

Telephone: (301) - 496-7441

Applications for CIA must be received by the NIH for review by the following receipt dates:

| <u>Application Receipt Dates</u> | <u>Initial Review</u> | <u>Council Meeting</u> | <u>Earliest Start Date</u> |
|--------------------------------------|---------------------------|----------------------------|--------------------------------|
| October 1 | Feb/March | May/June | July 1 |
| February 1 | June | Sept/Oct | December 1 |
| June 1 | Oct/Nov | Jan/Feb | April 1 |

VI. Research Areas of Emphasis and BID Contacts

National Institute on Aging

Research in Geriatric Medicine
Organic Brain Diseases of Old Age
Clinical Nutrition and Aging
Clinical Immunology and Aging
Clinical Pharmacology and Aging
Endocrinology and Aging
Maturity Onset Diabetes and Aging
Dermatology and Aging
Epidemiology and Aging

Inquiries about the program should be directed to:

Don Gibson, D.V.M.
Associate Director, PEA
National Institute on Aging
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) - 496-9374

National Institute of Allergy and Infectious Diseases

NIAID supports the development of basic research skills in the fields of immunology, allergy and immunologic diseases, bacteriology, virology, mycology, parasitology, and epidemiology.

Inquiries about the program should be directed to:

Robert Goldstein, M.D.
 Chief, Allergy and Clinical Immunology Branch
 Westwood Building - Room 757
 Bethesda, Maryland 20205

Telephone: (301) - 496-7551
 or

Robert Edelman, M.D.
 Chief, Clinical and Epidemiological Studies Branch
 Building 31 - Room 7A49
 Bethesda, Maryland 20205

Telephone: (301) - 496-5893

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

Arthritis, Musculoskeletal, and Skin Diseases
 Diabetes, Endocrine, and Metabolic Diseases
 Digestive Diseases and Nutrition
 Kidney, Urologic, and Blood Diseases

NIADDK limits the CIA to individuals who have had at least two years of previous postdoctoral research training.

Inquiries about the program should be directed to:

Director Division of Extramural Activities
 National Institute of Arthritis, Diabetes, and
 Digestive and Kidney Diseases
 Westwood Building - Room 657
 Bethesda, Maryland 20205

Telephone: (301) - 496-7793

National Cancer Institute

This award is intended to promote research career development in any of the basic and applied sciences relevant to cancer. The NCI is especially interested in the research career development of physicians trained in the following areas:

Surgical Oncology
 Radiation Oncology
 Physiatry
 Preventive Oncology
 Epidemiology and Nutrition

Inquiries about the program should be directed to:

Barney Lepovetsky, Ph.D., J.D.
Chief, Cancer Training Branch
National Cancer Institute
Blair Building - Room 717
8300 Colesville Road
Silver Spring, Maryland 20205

Telephone: (301) - 427-8898

National Institute of Child Health and Human Development

Research on Maternal and Child Health and Reproductive Sciences:

Pregnancy and Perinatology
Congenital Abnormalities
Clinical Nutrition
Reproductive Biology
Child and Adolescent Development
Mental Retardation
Fertility and Infertility

Inquiries about the program should be directed to:

Duane F. Alexander, M.D.
Deputy Director
National Institute of Child Health
and Human Development
Building 31 - Room 2A04
Bethesda, Maryland 20205

Telephone: (301) - 496-1848

National Institute of Environmental Health Sciences

The award seeks to foster the development of clinical investigators in the field of environmental health/human toxicology and to support clinicians who work with research teams on problems arising from the exposures of human populations to environmental chemicals. (It is not meant to support the activities of "poison centers" and related researchers who deal with the effects of acute exposures to self-inflicted or accidentally inflicted toxic materials or clinical research on the toxicities of pharmaceuticals and other drugs.)

Inquiries about the program should be directed to:

Christopher O. Schonwalder, Ph.D.
Program Director
Research Manpower Development Section
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, North Carolina 27709

Telephone: (919) - 541-7634

National Heart, Lung, and Blood Institute

Cardiovascular, pulmonary, blood diseases and blood-banking sciences.

Inquiries about specific programs should be directed to:

Fann Harding, Ph.D.
Research Training and Development Officer
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building - Room 5A08
Bethesda, Maryland 20205

Telephone: (301) - 496-1817

Donald M. MacCanon, Ph.D.
Research Training and Development Officer
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building - Room 3A-08
Bethesda, Maryland 20205

Telephone: (301) - 496-1724

Sydney R. Parker, Ph.D.
Chief, Division of Prevention, Education, and Manpower
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building - Room 6A-12
Bethesda, Maryland 20205

Telephone: (301) - 496-7668

Letters of reference, inquiries regarding review procedures and two copies of the application should be directed to:

Executive Secretary
Research Manpower Review Committee
National Heart, Lung, and Blood Institute
Westwood Building - Room 550
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) - 496-7361

NOTICE

MODIFICATION OF CLINICAL INVESTIGATOR AWARD

K.W. 34; P.T. 1200180, 1200270

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

I. PURPOSE

The purpose of this notice is to announce the following changes in the terms of the Clinical Investigator Award (CIA) as offered by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK).

- A. A change in duration from three to five years.
- B. A change in the awardee's maximum base salary reimbursement from \$25,000 per year to \$40,000 per year, plus applicable fringe benefits.
- C. A change in the prohibition against serving as Principal Investigator on a research project grant while continuing to hold a CIA.

Details regarding these changes and a schedule for their implementation are given below.

II. BACKGROUND

The CIA is designed to support promising clinically-trained individuals as they develop into independent biomedical investigators. It enables candidates to investigate a well-defined problem under the sponsorship of one or more senior investigators and is intended to facilitate the transition from postdoctoral training to a career as an independent investigator. Eligibility is restricted to those holding health professional degrees in the clinical sciences (M.D., D.O., D.V.M., etc) who are citizens or permanent residents of the U.S. It is expected that candidates will have between four and seven years of postdoctoral experience including at least two years of clinical training and two years of research training. Holders of the Ph.D. award, with or without an accompanying health professional degree, are ordinarily not eligible. Such individuals might more appropriately consider applying for a Research Career Development Award. An investigator with appropriate seniority and background to supervise the development of the candidate must be identified as sponsor at the time of application. Provisions of the award require that the candidate spend at least 75% time on activities directly related to the objectives of the award. The candidate's base salary and applicable fringe benefits are available under the award as are funds of up to \$20,000 per year for research expenses.

III. MODIFICATIONS IN THE TERMS OF THE AWARD

- A. The duration of the NIADDK Clinical Investigator Award will be increased from three years to five years. Applications received for the October 1984 receipt date and thereafter should describe activities and request support for a five year period.
- B. The maximum base salary available under the award will be increased from \$25,000 per year to \$40,000 per year, plus applicable fringe benefits. The increased amount can be requested on competing and non-competing applications with requested start dates of October 1, 1984 or later. For non-competing awards, the higher salary and fringe benefits will be provided effective on the anniversary date of the award issued on or after October 1, 1984. Salary supplementation from non-Federal sources will be possible as it is currently.
- C. The terms of the original NIADDK Clinical Investigator Award specified that a recipient of that award could not also simultaneously serve as Principal Investigator on a research project grant or a New Investigator Research Award. That restriction is now lifted, and recipients of the CIA are encouraged to apply for and hold a regular research award or a New Investigator Research Award during the later years of the CIA. However, concurrent applications for a CIA and a regular research project award or New Investigator Research Award are not appropriate. No additional salary for the Principal Investigator may be drawn from a concurrently held research grant.

Further details concerning the NIADDK CIA may be obtained by contacting the following office:

Director
Division of Extramural Activities
Nation Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7793

NOTICE

TERMINATION OF SPECIAL EMPHASIS RESEARCH CAREER AWARDS: DIABETES
MELLITUS

P.T. 34; K. W. 1200350

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE
AND KIDNEY DISEASES
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Effective immediately, no applications for the Special Emphasis Research Career Award: Diabetes Mellitus (SERCA) will be accepted by these Institutes. This does not represent a decreased commitment of investigators in this important field, but rather the availability of other award mechanisms, both established and newly created, for this purpose.

Existing SERCAs are in no way affected by this announcement and will be funded through their expected termination dates.

Those applications for the SERCA which already have been received by the NIH Division of Research Grants to meet the annual receipt date of June 1, 1984, will be processed, reviewed for scientific merit, and a funding decision reached.

Future applicants are encouraged to apply for one of the several career development awards, both established and newly created, offered by these Institutes. Interested applicants should contact the appropriate Institute representative for more information:

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

Lois F. Lipsett, Ph.D
Chief, Special Programs Branch,
Division of Diabetes, Endocrinology,
and Metabolic Diseases
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Westwood Building - Room 603
Bethesda, Maryland 20205

Telephone: (301) 496-7433

NATIONAL INSTITUTE ON AGING

Evan C. Hadley, M.D.
Chief, Geriatrics Branch
National Institute on Aging
National Institutes of Health
Building 31 - Room 5C-23
Bethesda, Maryland 20205

Telephone: (301) 496-1033

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Gilman Grave, M.D.
Chief, Nutrition and Endocrinology Section
National Institute of Child Health
and Human Development
National Institutes of Health
Landow Building - Room 7C-17
Bethesda, Maryland 20205

Telephone: (301) 496-5575

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Jerome G. Green, M.D.
Director, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building - Room 7A-17
Bethesda, Maryland 20205

Telephone: (301) 496-7416

ANNOUNCEMENT

INTEGRATED ACADEMIC INFORMATION MANAGEMENT SYSTEMS (IAIMS)

PLANNING, MODEL DEVELOPMENT, AND IMPLEMENTATION

P.T. 14; K.W. 1200700, 1004020, 0701025, 1004008

NATIONAL LIBRARY OF MEDICINE

Application Receipt Dates: November 1, March 1, July 1

I. PURPOSE

The National Library of Medicine (NLM) invites Resource Project Grant applications for planning and development projects leading to the implementation of Integrated Academic Information Management Systems (IAIMS) in medical centers and institutions with significant health sciences education, research, and/or patient care components.

The purpose of the IAIMS is to assist institutions in linking the library systems and the multitude of additional information systems that underpin the complex modern medical center into an integrated computer-based network.

Applications will be accepted on or before the standard NIH deadlines of November 1, March 1, and July 1 of each year. Institutional planning, development, and implementation of IAIMS prototypes represent a continuing priority interest of NLM. This initiative, however, does not preclude other Resource Grant applications that are not specifically related to this new NLM initiative, nor does it preclude grant applications in other NLM program areas (e.g., Research, Publication, or Career Development Awards) that may be conceptually related to IAIMS development.

II. BACKGROUND

Under the sponsorship of the NLM, the Association of American Medical Colleges undertook an analysis of trends in biomedical information transfer and their implications for health sciences libraries over the next decade (1). This report, as well as other publications (2-3), indicate that effective transfer and utilization of

This program is described in the Catalog of Federal Domestic Assistance, No. 13.879, Medical Library Assistance. Grants will be awarded under the authority of the Public Health Service Act, Section 395 (42 USC 280b-7) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 59a and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

recorded knowledge in the coming decades will require interactive network capabilities within medical centers. Such institutions now contain numerous information files. The efficiency and effectiveness of these files depend on a smooth, uninterrupted flow of accurate, daily operational information among functionally dependent areas, such as the laboratory, the nursing station, and the patient record. Optimal functioning of these institutions also depends on a smooth flow of accurate, relevant information generated by external sources; scientific publications and computerized databases are two such essential sources of new knowledge. While the biomedical community uses these kinds of information daily, ready access to this information through the many everyday operational information sources is rare. Information useful in decision making needs to be available at the time and place of demand and accessible in conjunction with other data.

III. OBJECTIVES

NLM support is available for: 1) institution-wide IAIMS planning and policy analysis; 2) IAIMS model development involving some segment or cross-section of the institution-wide strategic plan; and 3) implementation of detailed plans for a full-scale IAIMS prototype. These phases are sequential and are described as follows:

Planning Phase: Various models for strategic planning exist. Some functions to be considered in the particular planning model selected are: the preparation of an environmental forecast for the institution's next decade, the development of an institution information policy, the conduct of self-studies to assess the technological capabilities of the institution, and the assessment of the long- and short-range information management system needs and requirements in patient care, education, research, policy analysis, and administration. The development of scenarios as examples of IAIMS expected outcomes are very effective in illustrating the concept. Thus the resulting plan will assist in understanding what the IAIMS will accomplish, what the network architecture will be, who will execute the plan, and how the goals and objectives will be achieved.

Model Development Phase. Based upon the institution-wide IAIMS plan (described above), NLM assistance is available for testing IAIMS concepts on a small-scale basis in the environment involving information related to the research, education, and/or patient care mission of the institution. Any development model or test must relate to the IAIMS plan.

Implementation Phase: Those health science institutions which have completed an IAIMS plan and can demonstrate examples of successful modelling of critical elements of their plan may request NLM assistance to proceed with full-scale implementation.

IV. MECHANISM OF SUPPORT

IAIMS proposals will be funded under the Resource Project Grant Program. The IAIMS initiative is an ongoing and high priority NLM program. Depending on appropriations received and on commitments to other NLM grant programs, between \$500,000 and \$1,000,000 could be available in FY 1985 and 1986 for IAIMS

strategic planning, pilot development, and/or implementation. As has been the case since the inception of IAIMS, cost sharing continues to be significant in all projects.

Applicants for IAIMS Resource Project Grants may be hospitals and medical centers, academic health science centers, and colleges and universities with strong health sciences programs. For planning phase applications, the libraries must have online local access to their bibliographic records and other information delivery services or have made a commitment to implementing such a system within the planning period. For model development applications, a prerequisite is the existence of an IAIMS institutional plan including an information policy and an appropriate organizational structure. For implementation phase applications, an IAIMS institutional plan and evidence of successful outcomes of the modelling effort are prerequisites.

V. REVIEW PROCEDURES AND CRITERIA

Applications submitted in response to this announcement will be evaluated for scientific and technical merit by the National Library of Medicine's initial review group, the Biomedical Library Review Committee (BLRC). The Board of Regents of the National Library of Medicine provides secondary review in terms of policy considerations and program goals. In the administration of awards, the policies and requirements of the grant programs of the Public Health Service (PHS) will apply.

Critical review elements will include:

- o Evidence of an appropriate institutional environment for successful IAIMS planning, development, or implementation. The demonstration of executive leadership and the involvement of faculty/staff in managing institutional information resources will be important review considerations.
- o The presence of well-developed computer and communications systems on which to establish expected or future IAIMS development. Such systems may include medical records, research databases, clinical data management, educational programs, biomedical communications, and health sciences library and learning resources.
- o The clarity and specificity of the IAIMS goals and objectives, including projected tasks, the expected outcomes, and the attendant risks. Scenarios depicting the anticipated outcomes in the planning, development, and implementation phases are strongly encouraged. A design for assessing the project and its attainments is an essential component. The project plan shall conform to the requirements of the application instructions.
- o The institutional commitment of appropriate technical and program personnel and evidence of successful introduction of new technologies. Previous work and preliminary studies pertinent to the proposal should be cited. Proposed projects must include a clear and substantial role for the health sciences library.

- o The identification and commitment of institutional resources to support and further develop IAIMS. The NLM Resource Grant Program provides initial investment, seed money, or start-up costs. The rules and regulations governing the program require assurance of "adequate and continuing financial support of the applicant's proposed activity from other non-Federal sources during and after the period of the award."

VI. METHOD OF APPLYING

Application forms, instructions, and additional information may be obtained from:

Biomedical Information Support Branch
Extramural Programs
National Library of Medicine
Bethesda, Maryland 20209

Telephone: 301-496-4221

Applicants should clearly identify the application as a response to this announcement by entering the title **"IAIMS PLANNING—NLM RESOURCE GRANT PROGRAM"** or **"IAIMS MODEL DEVELOPMENT—NLM RESOURCE GRANT PROGRAM"** or **"IAIMS IMPLEMENTATION—NLM RESOURCE GRANT PROGRAM"** as appropriate.

The total project period may not exceed 3 years. Indirect costs are not applicable.

Applications must be received by the standard NIH deadlines, i.e., November 1, March 1, and July 1. Late submissions will be held over for the subsequent review cycle.

VII. REFERENCES

1. Matheson, Nina, and John A.D. Cooper. "Academic Information in the Academic Health Sciences Center: Roles for the Library in Information Management," *Journal of Medical Education*, Vol. 57 (10), October 1982, Part 2.
2. Piemme, Thomas E. and Marion J. Ball. *Executive Management of Computer Resources in the Academic Health Center; A Staff Report*. Washington, Association of Academic Health Centers, January 1984. 34 pp.
3. Wilson, Marjorie, et al. *The Management of Information in Academic Medicine; An Assessment of the Application of Technology, Policy Consequences, and Needed Changes in the Present System*. Washington, Association of American Medical Colleges, 1982. 2 volumes.

ANNOUNCEMENT

BIOMEDICAL RESEARCH FELLOWSHIP OPPORTUNITIES ABROAD

P.T. 22, 48; K.W. 1200170, 1200180, 0404000

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:

ACADEMY OF FINLAND POSTDOCTORAL RESEARCH FELLOWSHIPS

ALEXANDER VON HUMBOLDT FOUNDATION POSTDOCTORAL RESEARCH FELLOWSHIPS

FRENCH NATIONAL INSTITUTE OF HEALTH AND MEDICAL RESEARCH POSTDOCTORAL FELLOWSHIPS

NIH-FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH EXCHANGE PROGRAM

IRISH MEDICAL RESEARCH COUNCIL POSTDOCTORAL FELLOWSHIP

ISRAELI MINISTRY OF HEALTH POSTDOCTORAL RESEARCH FELLOWSHIPS

NORWEGIAN RESEARCH COUNCIL FOR SCIENCE AND THE HUMANITIES POSTDOCTORAL FELLOWSHIPS

SWEDISH MEDICAL RESEARCH COUNCIL FELLOWSHIPS

SWISS NATIONAL SCIENCE FOUNDATION POSTDOCTORAL FELLOWSHIPS

VISITING SCIENTISTS PROGRAM OF THE NATIONAL SCIENCE COUNCIL, TAIWAN

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 all applications except those to the Alexander von Humboldt Foundation and the Visiting Scientists Program for the National Science Council, Taiwan is October 1, 1984. Applications for the Alexander von Humboldt Foundation Postdoctoral Research Fellowships and the Visiting Scientists Program for the National Science Council, Taiwan 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.

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

CHARACTERIZATION OF MULTI-DRUG RESISTANT HUMAN AND OTHER MAMMALIAN
TUMOR CELL LINES

P.T. 34; K.W. 0701038, 1200250, 1200260, 1002004

DIVISION OF CANCER TREATMENT

NATIONAL CANCER INSTITUTE

Application Receipt Dates: November 1, March 1, July 1

The National Cancer Institute (NCI) is seeking grant applications for support of research projects to identify and characterize multi-drug resistant tumor cells. The development of drug resistance in tumor cell populations treated with chemotherapeutic agents has been recognized as a major problem in cancer treatment. The Division of Cancer Treatment (DCT) desires to support research in this area in order to increase understanding of drug resistance phenomena and develop therapeutic strategies to overcome or circumvent the problem.

This announcement is specifically targeted to stimulate research in the area of multi-drug resistance, also referred to as pleiotropic drug resistance (PDR). Detailed studies in Chinese hamster and murine cell systems have shown that under some selective conditions, e.g. Colchicine, Vincristine, or Adriamycin treatment, cell populations demonstrating a multi-drug resistant (PDR) phenotype emerge. In many of these cells, broad spectrum resistance to multiple agents of different modes of action is associated with reduced intracellular accumulation of drug and the appearance of a membrane glycoprotein marker. Recently, laboratory evidence has been presented that multi-drug resistant cells also occur in human tumor cell populations. This latter evidence is consistent with clinical experience, particularly with previously treated patients, wherein resistance to multiple agents of different modes of action is observed.

While some potentially important collateral sensitivities to established antitumor drugs have been observed among mammalian cell types showing the multi-drug resistant phenotype, it seems likely that new agents specifically useful in treating these resistant cells will be needed. Development of such agents will require additional insight into the mechanism(s) of PDR and an adequate number of well characterized multi-drug resistant cell lines in which new agents can be studied. This announcement is intended to stimulate applications for grants which propose to develop and characterize multi-drug

This program is described in the Catalog of Federal Domestic Assistance No. 13.395, Cancer Treatment 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. This program is not subject to Health Systems Agency review.

resistant human or mammalian tumor cell lines which have potential for this purpose. The primary emphasis in applications submitted in response to this program announcement should be on elucidating the mechanism of resistance in multi-drug resistant cell populations.

Multi-drug resistant cells may be selected in vitro or derived directly from patients or animals bearing tumors which have been shown to be resistant to chemotherapy. While the specific approaches and methods for development and characterization of the resistant cells will be left to the applicant, it is suggested that the following areas be addressed in the application.

- A. Mechanism(s) of multi-drug resistance
- B. Stability of the drug resistant phenotype
- C. Extent of cross resistance
- D. Tumorigenicity of the drug resistant cells
- E. Verification of the origin of the cells

Applications in response to this announcement will be reviewed in accordance with the usual National Institutes of Health (NIH) peer review procedures. They will first be reviewed for scientific and technical merit by a review group (Study Section) composed mostly of non-government scientific consultants. Following this initial review, the application will be evaluated for program relevance by the National Cancer Advisory Board. The review criteria customarily employed by the NIH for regular research grant applications will be utilized. All Public Health Service (PHS) grants policies, including cost sharing, apply to applications received in response to this program announcement.

I. DEADLINE

Applications will be accepted in accordance with the usual NIH receipt dates for new applications. Deadline dates are November 1, March 1 and July 1.

II. METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the grants and contracts business office at most academic and research institutions or from the Division of Research Grants (DRG), NIH. In space #2 on the first page of this form, indicate the title of this program announcement. Additionally, a brief covering letter should accompany the application indicating that it is being submitted in response to this program announcement. The original and six copies of the application should be submitted to:

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

For further information, contact:

Dr. Robert H. Shoemaker
Acting Head, Cell Culture Section
Drug Evaluation Branch
Developmental Therapeutics Program
Division of Cancer Treatment
National Cancer Institute
Blair Building - Room 419
Bethesda, Maryland 20205

Telephone: (301) 427-8700

ANNOUNCEMENT

AUTISM AND RELATED BEHAVIORAL DISORDERS

P.T. 34; K.W. 0701007, 0701029, 1002019, 1002030, 1200890, 1201160, 0404000, 1200430, 1200900, 1200220, 1200280

NATIONAL INSTITUTE OF MENTAL HEALTH

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the National Institute of Mental Health (NIMH) jointly request the submission of research grant applications on autism and related behavioral disorders. Both NINCDS and NIMH are interested in research on neurobiological and genetic factors in autism and related behavioral disorders. In addition, NIMH encourages studies of relevant environmental factors and treatments. Applications will be assigned to the appropriate Institute(s) for funding consideration based on Public Health Service (PHS) referral guidelines.

I. BACKGROUND

Autism affects about 5 out of 10,000 children; related behavioral disorders affect an additional 10 out of 10,000 children. Autism and related behavioral disorders have come to be regarded as complicated central nervous system disorders involving communication (including language), motility patterns, attention, responses to environmental stimuli, and (most specifically) social interactions. These disorders seem to have their origin before, at, or shortly after birth.

A consensus among investigators as to the general neurobiologic nature of the defects underlying autism and related behavioral disorders leads to the need for research on the specific localization of the various dysfunctions implicated in autism, characterization of the dysfunctions, and causation of these severely handicapping conditions. Recent clinical studies of autism have suggested that brain lesions may be concentrated in deep subcortical regions (mesalimbic and basal ganglia). Epidemiologic evidence suggests that causations may be multiple, ranging from association with viral encephalitides to genetic predisposition, and may produce deficiencies in a number of cognitive, linguistic, affective, and social domains that are broader than autism per se. A major issue is whether communication or social defects are more central to the brain dysfunction of autistic and similar persons.

These programs are described in the Catalog of Federal Domestic Assistance Nos. 13.853, Stroke, Nervous System Trauma and 13.242, Mental Health Research Grants. Awards will be made under the authority of the Public Health Service Act, Title IV, 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. These programs are not subject to Health Systems Agency review.

Of interest to both NINCDS and NIMH are studies to define neuropsychological, neurophysiological, and neuropathological mechanisms, and neuropharmacological interventions associated with clinically and behaviorally well-characterized autism or disorders related to autism. Studies involving animals are also encouraged; including experiments which would include collaboration among physiological psychologists, behavioral veterinarians, and clinician-investigators familiar with human behavioral disorders including autism. In addition, NIMH encourages research grant applications to develop and assess behavioral, psychosocial, or somatic treatments for these disorders. The NIMH request is for research on highly specified treatment regimens and does not include the evaluation of the delivery of services.

II. RESEARCH GOALS

Delineation of neuropsychological deficits underlying the cognitive, affective, social, and communicative impairments of autistic persons should be focal points of human studies, both to facilitate comparison with animal models and to suggest localization of brain lesions. Genetic studies should also include detailed neuropsychological profiles of subjects and family members.

Of particular importance are studies using electrophysiological, biochemical, and imaging techniques which can contribute to differential localization of lesions with the brains of autistic compared to nonautistic (but otherwise neurodysfunctional populations). Research must progress beyond the ability to differentiate the normal from the abnormal. It must seek neuropsychological, neurophysiological, neurochemical, and behavioral markers necessary to differentiate autism from other functional disorders. Biochemical studies uncovering neurotransmitter/receptor/mechanisms in these same populations are also encouraged. Where neuropathological data can be obtained from autistic and other dysfunctional populations known to be affected by the same disease (e.g., congenital rubella, tuberous sclerosis), research should focus on the differential localization associated with autistic/nonautistic clinical pictures. Such neuropathological studies might include the post-mortem study of the cytoarchitectonic characteristics of the brains of autistics as compared to other developmentally disabled persons (e.g., language-disabled, dyslexic, etc.). Research should be directed toward the correlation of behaviors with brain mechanisms and the identification of risk factors for autism leading to studies of preventive interventions.

Longitudinal studies have shown that autistic children do not outgrow their disorder but, in most cases, remain impaired. There is a critical need for research to develop and evaluate new treatments or combinations of treatments. Both NINCDS and NIMH are interested in neuropharmacology; NIMH emphasis is on producing cognitive, affective and social improvements that generalize beyond the experimental situation, while NINCDS emphasizes studies revealing brain changes during and after intervention.

In addition to the above, NINCDS and NIMH encourage research on treatment of childhood autism which could lead to development of new therapies or treatment approaches, including studies of interactive, additive, or inhibitory effects of combined treatments; formulation and testing of hypotheses, experimental designs, and clinical or animal models of treatments; clinical trials to evaluate efficacy of single or multimodality treatments; studies on the adverse effects of special

treatment regimens; development of treatment assessment research strategies and methodologies; studies of treatment processes, including the role of nonspecific factors in treatment response such as patient/therapist interactions.

III. ELIGIBILITY

Private, nonprofit or for-profit and public institutions (such as units of State or local government and authorized units of the Federal Government) are eligible to apply for grants under this announcement.

IV. TERMS AND CONDITIONS OF SUPPORT

Support for applications submitted in response to this announcement will be through grants for individual research projects or for program projects. (Applicants for program projects should consult in advance with NIH staff.)

Applications will be assigned for funding consideration on the basis of the focus of the research and PHS referral guidelines. Generally, only one Institute will provide funding but it is possible, particularly for large projects, that the other may contribute toward funding a project.

Grant funds may be used only for those expenses clearly related to and necessary to carry out research projects, and must be expended in conformance with the Public Health Service Grants Policy Statement.

In general, grant funds may be used for: (1) direct costs which are necessary to carry out the project, including salaries, consultant fees, supplies and equipment, and essential travel; (2) actual indirect costs to cover related overhead.

V. METHOD OF APPLYING

State and local government agencies should use form PHS-5161. All other applicants should use the standard PHS-398 (revised 5/82) research grant application form. **"Autism and Related Behavioral Disorder"** should be typed in item #2 on the face page of the application.

Application kits including instructions may be obtained from most institutional business offices or from offices of sponsored research for most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following offices may be contacted for the necessary application material:

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

Grants Operations Section
National Institute of Mental Health
Parklawn Building - Room 7C-05
5600 Fishers Lane
Rockville, Maryland 20857

The original and 6 copies (2 copies if PHS-5161 is used) of the application must be sent directly to:

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

VI. REVIEW PROCEDURES AND CRITERIA

Review Procedures

Applications will be reviewed for scientific merit and relevance to program goals in accordance with the standard review procedures of the Public Health Service; that is, each application will be assessed first for scientific merit review by an appropriate Initial Review Group (IRG) of non-Government scientists and then for policy and program relevance by the appropriate National Advisory Council.

Review Criteria

- relevance of the application to the objectives, goals and scope of the announcement
- the significance of the proposed research
- the scientific and technical merit of the research protocol(s)
- expertise, qualifications, and commitment of the proposed personnel and their ability to devote adequate time and effort to the proposed research
- appropriateness of the resources and the environment
- a realistic plan and timetable for completing the research
- appropriateness of the budget for the proposed research
- adequacy of proposed procedures for protecting human subjects.

Applications in response to this announcement will be reviewed according to the usual schedule:

ANNOUNCEMENT

LIFE SCIENCES INVESTIGATIONS IN SPACE: Announcement of Opportunity

NASA AO NO. OSSA-2-84

P.T. 34; K.W. 1200180, 1015000, 0701044, 1200240, 1200840, 1200780, 1200270, 0608007, 0202022

LIFE SCIENCES FLIGHT EXPERIMENTS PROGRAM

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

I. BACKGROUND

On May 15, 1984, the National Aeronautics and Space Administration (NASA) issued an Announcement of Opportunity (AO No. OSSA-284) which invited scientists to propose life sciences studies which could be carried out on the Space Shuttle/Spacelab system between 1986 and 1991. The proposed investigations which may be self-contained or may involve procedures or measurements carried out by the Shuttle/Spacelab crew, should consist of distinct and innovative approaches for addressing one or both of the objectives described in Section II below.

The AO No. OSSA-2-84 describes the space flight opportunities, the broad life sciences objectives which NASA seeks to support during this period, and the specific instructions and regulations governing the submittal, evaluation, and selection of life sciences flight investigations for support by NASA. NASA is particularly interested in those investigations which are related to ensuring that a permanent human presence in space can be realized and sustained.

Investigations selected as a result of AO No. OSSA-2-84 will normally be accommodated on Shuttle flights of the Spacelab pressurized module, but other modes of accommodation are possible and will be used if appropriate. The Spacelab pressurized module is a laboratory facility which is capable of supporting complex, interdisciplinary life sciences research in space. In general, the Space Shuttle/Spacelab remains in orbit for approximately 7 to 10 days. The crew for Spacelab missions can consist of highly trained research scientists as well as career astronauts. NASA has developed and will maintain a number of special facilities and an inventory of standard and specialized life sciences laboratory equipment to facilitate research in space.

II. RESEARCH OBJECTIVES

Proposals submitted in response to AO No. OSSA-2-84 must address scientific questions related to one or both of the following objectives and must clearly require space flight for their accomplishment.

A. Biomedical Research

This objective is to investigate those areas of biomedical research which are concerned with the safety, well-being, comfort, and productivity of humans during space flight. The scope of the research proposed to address this objective can include, but is not limited to investigations in one or more of the following scientific areas: neurovestibular function, cardiovascular and pulmonary function, musculoskeletal function, metabolism and nutrition, human capability and performance, clinical medicine, and countermeasures.

B. Biological Research

This objective is to investigate fundamental questions in biology and relates to NASA's interest in those investigations which aim to develop an understanding of the role gravity plays in the form and function of organisms on Earth.

III. PROPOSAL SUBMISSION INFORMATION

The information contained in this Announcement is not sufficient to prepare a proposal in response to AO No. OSSA-2-84. Proposals submitted in response to AO No. OSSA-2-84 must be prepared and submitted in accordance with the instructions contained in the document entitled "**Announcement of Opportunity, Life Sciences Investigations in Space 1986-1991; AO No. OSSA-2-84**" issued by the National Aeronautics and Space Administration, Washington, D.C., May 15, 1984. Persons interested in receiving a copy of this Announcement of Opportunity should address a written request to:

Chief, Flight Programs Branch
Life Sciences Division
NASA Headquarters (EBF)
Washington, D.C. 20546

By making such a request, the individual's name will be added to NASA's Life Sciences mailing list.

IV. PROPOSAL SCHEDULE

This NASA Announcement of Opportunity will be in effect through 1987. Proposals may be submitted to NASA at any time; however, a Notice of Intent to Propose is required prior to the submission of a proposal. The following schedule is planned for the acquisition of investigations under this Announcement.

| | <u>First Period</u> | <u>Second Period</u> | <u>Third Period</u> |
|---------------------------------|---------------------|----------------------|---------------------|
| Notice of Intent to Propose Due | Aug. 1, 1984 | Feb. 1, 1986 | Aug. 1, 1987 |
| Proposal Due Dates | Oct. 1, 1984 | Apr. 1, 1986 | Oct. 1, 1987 |
| Selection Announcement | Nov. 1985 | May 1987 | November 1988 |

V. ACKNOWLEDGEMENT

This announcement has been inserted in the NIH Guide for Grants and Contracts through the courtesy of the Guide publications staff. The Life Sciences Division at NASA is grateful for the opportunity of having this information distributed to the broad community currently receiving this Guide.