

# NIH Guide for Grants and Contracts

Vol. 12, No. 7, July 15, 1983

U.S. DEPARTMENT OF HEALTH  
AND HUMAN SERVICES

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

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

#### Have You Moved?

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

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NOTICE

TAXABILITY OF NRSA STIPENDS

**All Holders of National Research Service Awards (NRSA),  
NRSA Institutional Training Grant Program Directors,  
Directors of Sponsored Programs and Business Officers**

Since the enactment of the NRSA Act of 1974, there has been some ambiguity related to the interpretation of awards made under the Act as scholarship or fellowship grants under section 117 of the Internal Revenue Code that has required repeated legislative action to resolve.

The Director, NIH, recently requested an IRS opinion as to whether NRSAs made under section 472 of the Public Health Service Act (42 U.S.C. 289 1-1), as amended by section 924 of the Omnibus Reconciliation Act of 1981 (Pub. L. 97-35), are entitled to treatment as scholarships or fellowship grants within the meaning of section 117 of the Internal Revenue Code in light of statutory amendments made to section 472 in 1981 and certain facts concerning the program as it has developed over the past several years.

In his response to Dr. Wyngaarden dated June 24, 1983, Gerald G. Portney, Associate Chief Counsel (Technical), Office of Chief Counsel, IRS, Department of the Treasury stated

"...it is our opinion that National Research Service Awards received by individuals pursuant to the provisions of the National Research Service Awards Act of 1974, as amended, are excludable from the recipients' gross incomes as scholarships or fellowship grants under section 117 of the Code."

Section 117 is that part of the internal revenue code which applies to the treatment of all scholarships and fellowships. In general, it provides that, subject to certain limitations, degree candidates may exclude the full amount of their scholarships or fellowships from their gross income for purposes of taxation and non-degree candidates may exclude up to \$300 per month of such awards for up to 36 months.

The interpretation and implementation of the tax laws are the domain of the Internal Revenue Service and the courts. The purpose of this notice is to inform interested parties that there has been a new statement of opinion concerning the law. NIH takes no position on what this change may mean for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the new law to their situations and for information on the proper steps to be taken regarding their tax obligations or claims for current and past tax years.

NOTICE

INSTITUTIONAL TRAINING GRANTS: TRAINING RELATED EXPENSES

**National Research Service Award (NRSA) Institutional Training Grant Directors,  
Directors of Sponsored Programs and Business Officers**

The current level of funds available for training related expenses (formerly called institutional allowances) is such that it is no longer practical to require itemization of the costs for which these funds provide the necessary support. Itemization, therefore, of training related expenses ("above the line") will not be required for awards to be made from FY 1984 funds on NRSA institutional training grants.

Competing and noncompeting applications and awards for FY 1984 NRSA T32 and T35 institutional training grants subject to the ceiling of \$1,500 per predoctoral and \$2,500 per postdoctoral trainee should no longer itemize the categories from which the expenditures will be made. Training related expenses should be identified as a single figure under SUBTOTAL (Section A) of both PHS 6025-1 and PHS 6025-2. No explanation of this figure is required.

All expenditures charged to NRSA's must continue to be made in accordance with PHS grants policy; however, rebudgeting of funds awarded in lump sum for training related expenses and which have previously required awarding unit prior approval are entirely delegated to the Institutional Prior Approval System. Prior approval of the awarding unit still obtains for the transfer of amounts previously awarded for trainee costs (stipends, tuition and fees) to other categories of expense.

All progress reports should specify the way in which essential program enhancement was achieved through the availability of training related expenses.

NOTICE

CHANGE IN RECEIPT DATE

REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: RFA

NIH-NCI-DRCCA-OSP-83-2

ADMINISTRATIVE COORDINATING CENTER FOR THE ORGAN SYSTEMS PROGRAM

NATIONAL CANCER INSTITUTE

This RFA was originally published in the March 25, 1983 issue of the NIH Guide for Grants and Contracts, Vol. 12, No. 3. This announcement extends the application receipt date to August 15, 1983.

The Division of Resources, Centers and Community Activities (DRCCA) of the National Cancer Institute (NCI) invites cooperative agreement applications from institutions capable and interested in establishing a Coordinating Center for the Organ Systems Program. This Request for Applications (RFA) will be utilized to initiate a program in an area of special importance to the National Cancer Program. All applications received in response to this RFA will be reviewed by the same National Institutes of Health (NIH) initial review group. An applicant if funded under this RFA will be supported through the cooperative agreement award in accordance with the policies of the Public Health Service (PHS) and NIH.

The awardee will have the primary responsibility for the planning and direction of the proposed Organ Systems Coordinating Center (OSCC). This will involve active participation and interaction with the NCI Organ Systems Program staff. NCI staff will work closely with the Coordinating Center staff on both administrative and scientific program activities as well as in the annual evaluation of program priorities. NCI staff will periodically review progress to ensure that the Center conforms to the purposes and objectives of the program, as well as conditions of the award. The Board of Scientific Counselors of the DRCCA and the National Cancer Advisory Board will oversee these activities.

Inquiries regarding this announcement or requests for copies of the original RFA should be directed to:

Andrew Chiarodo, Ph.D.  
Chief, Organ Systems Program Branch  
Division of Resources, Centers and  
Community Activities  
National Cancer Institute  
Blair Building - Room 3A05  
8300 Colesville Road  
Silver Spring, Maryland 20910

Telephone: (301) 427-8818

ANNOUNCEMENT

NOTICE OF AVAILABILITY: RFA

COOPERATIVE AGREEMENTS FOR NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS

DIVISION OF CANCER TREATMENT (DCT)

NATIONAL CANCER INSTITUTE (NCI)

**Application Receipt Date: October 17, 1983**

A prior announcement, "**Participants Sought for National Cooperative Drug Discovery Groups**" (NIH Guide for Grants and Contracts, Vol. 11, No. 13, December 3, 1982) invited leading scientists from academia, research institutions, and industry to submit expressions of interest in participating in National Cooperative Drug Discovery Groups (NCDDG) and indicated DCT plans to issue a Request for Application (RFA) outlining the specifics of the program.

The RFA is available from:

Dr. John M. Venditti  
Chief, Drug Evaluation Branch  
Blair Building - Room 428  
National Cancer Institute  
Bethesda, Maryland 20205

The closing date for applications is October 17, 1983.

Applicants are not restricted to those who responded to the December 1982 Announcement.

**SUMMARY**

Exciting leads in molecular biology, medicinal and organic chemistry, biochemistry, and pharmacology present unprecedented opportunities for design and pre-clinical evaluation of powerful new entities and strategies for the treatment of cancer. Exploitation of these leads and their extrapolation to new treatments can be accomplished by mobilizing the most creative scientists in a number of scientific disciplines regardless of their organizational affiliation. The NCDDG program will assist these scientists to interact, with NCI support, as a unit. It is envisioned that each NCDDG will be multi-disciplinary and multi-institutional; and will consist of a Group Director and a number of Program Leaders. The Group Director will be responsible for the application and for performance of the Group and will be accountable for funds awarded. Thus, each NCDDG will have capacity to generate new inventions, to translate rapidly their concepts into new treatments, to

conduct adequate pre-clinical biological evaluations, to carry out biochemical and pharmacological studies at the pre-clinical level, and to identify new treatment entities worthy of development to clinical trial.

Awards will be made as Cooperative Agreements. These are assistance relationships involving substantial involvement of NCI staff during performance of the project. The nature of NCI staff participation is included in the RFA. However, the applying Group must define its objectives in accord with its own interests and perceptions of novel approaches to the discovery of more effective cancer treatment. The role of NCI staff will be to provide assistance, advice, and guidance via information input at Group meetings. Final decision-making authority during performance will rest with the Group Director.

NCI hopes to make multiple awards for project periods of five years and has set aside \$2,000,000 for the initial year's awards.



ANNOUNCEMENT

NOTICE OF AVAILABILITY: RFA

COOPERATIVE AGREEMENTS FOR A PHASE III TRIAL OF A LOW FAT DIET IN  
WOMEN WITH STAGE II BREAST CANCER

NIH-NCI-DRCCA-DCB 83-5

NATIONAL CANCER INSTITUTE

Letter of Intent Receipt Date: September 15, 1983  
Application Receipt Date: October 17, 1983

The Division of Resources, Centers, and Community Activities (DRCCA), and the Division of Cancer Treatment (DCT), National Cancer Institute (NCI), invite applications for cooperative agreements to support participation in a multi-institution randomized clinical trial of a low fat diet (20% of calories) aimed at prolonging the disease-free survival and overall survival in surgically-staged breast cancer patients who have involvement of the axillary lymph nodes. The investigators will identify, enroll and follow participants in this trial using a protocol developed jointly by the investigators and NCI staff.

Applications are solicited to fund participants in three categories: 1) clinical units, 2) nutritional coordinating unit(s), and 3) a statistical coordinating unit. Applicants may apply for more than one category (clinical, nutrition, statistical), but the applications should be cast as separate documents for review. The requirements for each of these units are outlined in the complete Request for Application (RFA).

The trial, a single protocol, will be initiated in three stages. The first stage will involve a meeting between the investigators and NCI staff for the purpose of writing the protocol for this study. The second stage will be a feasibility study, during which the protocol will be implemented at three institutions (selected on the basis of priority score and accrual potential) with particular emphasis on documenting protocol adherence in the study and control groups. In stage three the protocol will be implemented in all remaining clinical units.

Copies of the complete RFA and additional information may be obtained from:

Ritva Butrum, Ph.D.  
Diet, Nutrition and Cancer Branch  
National Cancer Institute  
Blair Building -Room 619  
Bethesda, Maryland 20205

Telephone: (301) 427-8753

To ensure their review, applications must be received by October 17, 1983.

ANNOUNCEMENT

PHYSICIAN SCIENTIST AWARD

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

Initial Application Receipt Date: October 17, 1983  
Subsequent Receipt Dates: February 1, June 1, October 1

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.

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 physicians 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 within a basic science department 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 also offer the program award.

## I. ELIGIBILITY

- A. These awards are designed to provide an intensive, supervised research experience or 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). Physicians holding the PhD are ineligible. 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 science departments, 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 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 consecutive 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 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.

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 at an equivalent experience level but funding from this award for salary not to exceed \$30,000 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 increasing to \$20,000 per year in Phase II for research project requirements

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

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 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 \$30,000 provided by this award is not allowable.

### B. Program Award

#### 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, 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 awardee 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 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 awardees 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 \$30,000 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 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

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

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 \$30,000 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 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 appropriated 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 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

Initial Receipt Date: October 17, 1983, will be the first receipt date for applications to be considered by the February 1984 National Advisory Councils for Awards to be made in the spring of 1984. Normally, an original and six copies of an application are mailed to the Division of Research Grants (DRG). For the initial receipt date, October 17, 1983, 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.

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

<u>Applications Received by</u>	<u>Presented to Council in</u>	<u>Earliest Requested Beginning Date</u>
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 OF AGING

Edward L. Schneider, M.D.,  
Associate Director  
Biomedical Research and Clinical Medicine  
National Institute on Aging  
National Institutes of Health  
Building 31 - Room 5C11  
Bethesda, Maryland 20205

Telephone: (301) 496-4996

NATIONAL INSTITUTE OF ALLERGY  
AND INFECTIOUS DISEASES

John W. Diggs, Ph.D.,  
Director of Extramural Activity Programs  
National Institute of Allergy and  
Infectious Diseases  
National Institutes of Health  
Westwood Building - Room 703  
Bethesda, Maryland 20205

Telephone: (301) 496 7291

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

Alan Moshel, M.D.,  
National Institute of Arthritis, Diabetes, and  
Digestive and Kidney Diseases  
National Institutes of Health  
Westwood Building - Room 405  
Bethesda, Maryland 20205

Telephone: (301) 496-7326



NATIONAL INSTITUTE OF CHILD HEALTH  
AND HUMAN DEVELOPMENT

Duane Alexander, M.D., (301) 496-1848  
Deputy Director  
National Institute of Child Health  
and Human Development  
National Institutes of Health  
Building 31 - Room 2A04  
Bethesda, Maryland 20205

Telephone: (301) 496-1848

NATIONAL INSTITUTE OF DENTAL RESEARCH

Anthony Rizzo, D.M.D., (301) 496-7748  
Deputy Associate Director for  
Extramural Programs  
National Institutes of Dental Research  
National Institutes of Health  
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  
National Institute of Environmental  
Health Sciences  
National Institutes of Health  
P.O. Box 12233  
Research Triangle Park, North Carolina 27709

Telephone: (919) 541-7634

NATIONAL EYE INSTITUTE

Ronald Geller, Ph.D., (301) 496-4903  
Associate Director for Extramural and  
Collaborative Programs  
National Eye Institute  
National Institutes of Health  
Building 31 - Room 6A03  
Bethesda, Maryland 20205

Telephone: (301) 496-4903

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Jerome G. Green, M.D., (301) 496-7416  
Director, Division of Extramural Affairs  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Westwood Building - Room 7A17  
Bethesda, Maryland 20205

Telephone: (301) 496-7416

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

RFA-NIH-NHLBI-DBDR-83G-K

ASSAY METHODS TO DETECT THE CARRIER STATE OF ACQUIRED

IMMUNODEFICIENCY SYNDROME (AIDS)

**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application receipt date: October 17, 1983

I. PURPOSE

The Division of Blood Diseases and Resources (DBDR) invites grant applications for the development of tests to identify the carrier state of acquired immunodeficiency syndrome (AIDS) and to evaluate the sensitivity and specificity of these tests. The major purpose of this special grant program is to determine whether there are markers for AIDS that can be used to rapidly, simply, and specifically identify individuals who are asymptomatic carriers of AIDS.

II. DISCIPLINES AND EXPERTISE

Among the disciplines and expertise that may be appropriate for this research program are immunology, virology, microbiology, hematology, pathology, blood banking sciences, oncology, hepatology (gastroenterology), and infectious diseases.

III. BACKGROUND

- A. Administrative Background: The Blood Resources Branch (BRB) of the DBDR designs and administers programs related to the safety of blood therapy. The Branch specifically supports research on the development of methods to detect transfusion-transmitted diseases. The AIDS epidemic has become a major public health problem. The etiology and mode of transmission of the disease are unknown. However, there is increasing concern that a possible mode of transmission is through blood transfusion. The National Heart, Lung, and Blood Institute (NHLBI) has been designated as the lead Institute at the National Institutes of Health (NIH) for the development and evaluation of screening procedures for identifying donors who are at increased risk for transmitting AIDS.

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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 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

- B. Scientific Background: Since the summer of 1981, more than 1,500 cases of a disorder characterized by a defect in the cell-mediated immune system have been reported to the Centers for Disease Control (CDC) from 34 states, the District of Columbia, and 15 countries; this disease is now known as acquired immunodeficiency syndrome (AIDS). The chief clinical manifestations are Kaposi's sarcoma and opportunistic infections. Reported cases have increased from an average of one case per day in 1981, to three to four daily in late 1982 and early 1983. Over 550 persons have died, with the case-fatality rate exceeding 60 percent for cases diagnosed more than 1 year previously.

Previously, Kaposi's sarcoma was a rare disorder usually manifested in elderly males while opportunistic infections, such as *Pneumocystis carinii* pneumonia, generally occurred in immunocompromised patients. The cases of AIDS encompass different risk groups—young male homosexuals, male and female heterosexuals who abuse intravenous drugs, and recent male and female Haitian immigrants. Patients also include heterosexual hemophiliacs with no history of intravenous drug abuse and no previous underlying immunosuppressive disorder. AIDS has also been reported in children of mothers whose sexual partners have developed the syndrome as well as in some transfusion recipients who are in none of the risk categories mentioned above.

The etiology of AIDS is unknown. It has been proposed that viral infection or antigenic overload could lead to this immune deficiency. Either mechanism would affect blood product recipients as well as most of the risk groups identified above. This solicitation, however, is based on the assumption that a specific infectious agent(s) is involved, that the disease is transmissible parenterally, and that methods can be found to identify asymptomatic individuals who carry the putative agent(s). The distribution and mode of spread of AIDS are believed to be similar to those of hepatitis B virus, which occurs frequently in AIDS patients as well as in groups at high risk for AIDS.

A number of tests have been suggested to identify asymptomatic individuals with AIDS; however, none has the sensitivity or specificity necessary for identifying asymptomatic AIDS victims or excluding their blood from the donor pool. Furthermore, the more specific tests are very complicated and unsuitable for routine use. Direct and indirect tests currently in use include the identification of various serum proteins related to the immune system, measurement of T-cell subset ratios, lymphocyte function evaluations, and measurement of hepatitis B core antigen. Several indirect tests for identifying carriers of AIDS have recently been suggested, including procedures for quantitating alpha-1-thymosin, beta-4-thymosin, beta-2-microglobulin, and acid-labile-alpha interferon. Recent reports suggest that antibody to human T-cell lymphoma-leukemia virus (HTLV) might be of value as a marker for AIDS. Alpha-1-thymosin, beta-4-thymosin, and beta-2-microglobulin have been studied in AIDS patients, New York City homosexuals, and apparently normal blood donors. Results from these assays have been ambiguous; however, in two homosexuals, beta-2-microglobulin levels increased progressively over the 3-year period before the onset of AIDS. Acid-labile-alpha interferon is also a possible marker. One study showed that over 60 percent of homosexual males with AIDS had higher serum concentrations of acid-labile-alpha interferon; three hemophiliacs with AIDS had higher concentrations of acid-labile-alpha interferon while interferon levels in 48 normal hemophiliacs were normal; and in two of the three

hemophiliacs with AIDS, circulating acid-labile-alpha interferon rose to detectable levels 3 to 10 months before the appearance of any clinical symptoms. A recent study detected antibody to HTLV in 25 percent of homosexuals with AIDS and in only 1 percent of individuals in the control group.

While the significance of these preliminary observations is not yet known, such markers might be useful as an interim screening procedure in identifying symptomatic carriers of AIDS. Further evaluation of the sensitivity and specificity of these and other assays, as well as the development of new, rapid, simple, specific, sensitive direct tests, is urgently needed.

#### IV. OBJECTIVES AND SCOPE

Although the etiology of AIDS is unknown, the theory that a specific infectious agent is involved has gained support within the scientific community. Currently, there are no laboratory methods that specifically identify individuals who are asymptomatic carriers of AIDS. A test to identify such individuals would be extremely helpful in excluding them from the blood donor pool, particularly if it were applicable at the time of blood donation.

The purpose of this special grant program is to develop and validate methods that can rapidly, simply, and specifically identify individuals who have AIDS, either diagnosed or asymptomatic.

There is no validated animal model for AIDS. Therefore, studies supported by this RFA will deal primarily, if not exclusively, with human material. Precautionary measures for clinical and laboratory staff have been published and should be followed (CDC Morbidity and Mortality Weekly Report, Vol. 31, No. 43, November 5, 1982); these are similar to those used with patients and material suspected to have hepatitis B virus.

The research supported by this program will have as its objective the identification of specific markers for AIDS. Studies that focus on isolation of virus(es), development of animal models, or clinical diagnostic criteria for AIDS will not be responsive.

Investigators are encouraged to initiate new and innovative approaches that may lead to the development and validation of new tests that are more specific, more discriminating and more cost-effective than existing procedures. The knowledge gained in such a basic science approach is also likely to enhance our understanding of the pathophysiology of the disease.

#### V. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional, individual, investigator-initiated research project grant. The NHLBI plans to designate for fiscal year 1984 the sum of \$1,500,000 for the total (direct and indirect) costs of this program. It is anticipated that 8 to 10 grants will be awarded under this program. The specific amount of grant support will, however, depend on the merit

and scope of the applications received and the availability of funds. Since a variety of approaches would represent valid responses to this announcement, it is anticipated that there will be a range of costs among individual grants awarded.

Upon initiation of the program, the DBDR will sponsor periodic meetings to encourage exchange of information among investigators in this program. In the preparation of the budget for the grant application, applicants should request travel funds for a 2-day meeting each year, most likely to be held in Bethesda, Maryland. Applicants should also include a statement in their application indicating their willingness to participate in such meetings.

Applicants will plan and execute their own research programs. They are requested to furnish estimates of the time required to achieve the objectives of the proposed research project. At the end of the initial award period, renewal applications may be submitted for further competitive review through the regular grant program of the NIH. It is anticipated that support will begin on April 1, 1984.

## VI. REVIEW PROCEDURES AND CRITERIA

- A. Review Method: All applications submitted in response to this RFA will be reviewed for scientific and technical merit by an initial review group, which will be convened by the Division of Extramural Affairs, NHLBI, solely to review these applications. Upon receipt, applications will be reviewed for their responsiveness to the objectives of this RFA. If an application is judged unresponsive at this stage, the applicant will be contacted and given an opportunity to withdraw the application or to have it considered for the regular research grant program of the NIH.

If a proposal submitted in response to this RFA is substantially similar to a research grant application already submitted to the NIH for review, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed.

- B. Review Criteria: The factors to be considered in the evaluation of scientific merit of each application will be similar to those used in the review of traditional research-project grant applications, including the novelty, originality, and feasibility of the approach; the training, experience, and research competence of the investigator(s); the adequacy of the experimental design; the suitability of the facilities; and the appropriateness of the requested budget to the work proposed. An additional review criterion will be an assessment of the importance of the proposed research to the objectives of this RFA.

## VII. METHOD OF APPLYING

- A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institution(s). The Institute requests such letters for the

purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding, and it will not be considered in the review of any application later submitted, nor is it a requirement for application. The letter of intent, which should be received no later than August 15, 1983, should be sent to:

Dr. Charles L. Turbyfill  
Westwood Building-- Room 553  
Review Branch, DEA, NHLBI  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Bethesda, Maryland 20205

Telephone: (301) 496-7351

#### B. Format for Applications

Submit applications on form PHS 398, the application form for the traditional research-project grant. This form is available in an applicant institution's office of sponsored research or business office. Use the conventional format for research-project grant applications and ensure that the points identified in the Section on "Review Procedures and Criteria" are fulfilled.

To identify the application as a response to this RFA, check "yes" on item 2 of page 1 of the application and enter the title ASSAY METHODS TO DETECT THE CARRIER STATE OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) and the RFA number NIH-NHLBI-DBDR-83G-K.

#### C. Application Procedure

Send or deliver the completed application and six (6) signed, exact photocopies of it to:

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

Send an additional 20 copies of the application to:

Review Branch, DEA, NHLBI  
Westwood Building - Room 5A15  
National Institutes of Health  
Bethesda, Maryland 20205

Applications must be received by October 17, 1983. If an application is received after this date, the applicant will be contacted and given the option of having the application returned or considered in the next regular application review cycle.

D. Timetable

Letter of intent: August 15, 1983  
Application receipt date: October 17, 1983  
Review by the National Heart,  
Lung, and Blood Advisory  
Council: February 9-10, 1984  
Expected award date: April 1, 1984

E. Inquiries

Inquiries regarding this announcement may be directed to the program administrator:

Dr. Luiz H. Barbosa  
Federal Building - Room 5C06  
Blood Resources Branch, DBDR,  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Bethesda, Maryland 20205

Telephone: (301) 496-1537



**ANNOUNCEMENT****TRANSFUSION MEDICINE ACADEMIC AWARDS****NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application Receipt Date: October 17, 1983

The Division of Blood Diseases and Resources (DBDR), National Heart, Lung, and Blood Institute (NHLBI), announces a second national competition for Transfusion Medicine Academic Awards to: 1) encourage the development of curricula in transfusion medicine, and 2) allow the awardee to broaden his or her experiences in transfusion medicine so that he/she can contribute to the teaching, research, and clinical needs of this discipline. This five-year award supports experienced investigator-faculty members, who are skilled organizers and negotiators, in their efforts to implement a transfusion medicine program. Each school of medicine or osteopathy in the United States or its possessions and territories is eligible for one award (non-renewable) which provides salary, fringe benefits, supporting costs, and indirect costs.

For the purposes of the Transfusion Medicine Academic Award, the term "transfusion medicine" is used to define a multidisciplinary area concerned with the proper use or removal of blood and its components in the treatment or prevention of disease states (other than in renal hemodialysis).

The DBDR initiated the Transfusion Medicine Academic Award Program in January 1983 to encourage a systematic approach to the development of teaching programs in transfusion medicine. Presently, teaching, research, and clinical responsibilities in transfusion medicine are rarely coordinated into a definable program. These components are usually dispersed among basic and clinical science disciplines and among activities of the local transfusion services or blood center facility. In the development of the Transfusion Medicine concept it is important to remember that the teaching of transfusion medicine may not require additional curriculum time. Existing teaching materials (components of other disciplines) may be coordinated into an overall program and organized to focus on emerging and important areas of transfusion medicine. Some schools may find it desirable to assemble the appropriate components into a specific unit. Others may wish to retain the transfusion medicine discipline as part of another major clinical or laboratory department.

This award is intended to:

- encourage the development of effective multidisciplinary curricula in transfusion medicine through the continuum of medical education;

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, 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.

- attract and develop faculty, outstanding students, and promising young physicians and scientists who can serve the teaching, research, and clinical aspects of transfusion medicine;
- facilitate interchange of information and educational techniques among research, medical, and blood service communities; and
- allow time for the grantee institution to develop the ability to continue the transfusion medicine program, using local funds, when this award terminates.

Applications must be received by October 17, 1983, for review at the May 1984 meeting of the National Heart, Lung, and Blood Advisory Council. Awards will be made September 1984, depending on the availability of funds.

To receive a copy of the Program Guidelines, please contact:

Fann Harding, Ph.D.  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Federal Building - Room 5A08  
7550 Wisconsin Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-1817

ANNOUNCEMENTREQUEST FOR RESEARCH GRANT APPLICATIONS: RFARFA-NIH-NICHD-CPR-DBSB-83-1ANTECEDENTS AND CONSEQUENCES OF VOLUNTARY CONTRACEPTIVE  
STERILIZATION

## NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: December 15, 1983

## I. BACKGROUND

The Demographic and Behavioral Sciences Branch ((DBSB), Center for Population Research (CPR), supports research on the antecedents and consequences of fertility and family planning. This RFA invites scientists to submit grant applications for the support of research on an important aspect of fertility and family planning, the antecedents and non-medical consequences of voluntary contraceptive sterilization of women and men.

Contraceptive sterilization is widely used in the United States and throughout the world, and the utilization of the method continues to increase. However, well-designed behavioral-social research leading to definitive results has failed to keep pace with the use of sterilization. Enough is known about the demographic, social, psychological, and economic significance of the operation to emphasize the need for research aimed at increasing knowledge and understanding of its antecedents and consequences.

There have been a considerable number of studies of contraceptive sterilization which have provided some interesting and useful data. However, many of the studies are open to question because of problems of theory, design, methodology, or data analysis. Previous studies have tended to be primarily descriptive. This suggests that more attention could be paid to the interactive effects of antecedents as well as to the improvement of approaches to data analysis. There is need, also, for research which will provide better developed theoretical-conceptual frameworks than some of those which have been used. Among other things, more consideration might be given to the role of sterilization in family planning programs and in fertility regulation by individuals.

This program is supported under Title III, Section 301 and Title IV, Section 441 (Public Law 78-410, as amended; 42USC 241) and described under the Catalog of Federal Domestic Assistance No. 13.864, Population Research. Awards will be 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.

It is anticipated that researchers will attempt to develop well-defined and reliable measures of the antecedents and consequences of sterilization. Furthermore, standardized measuring instruments might be utilized where possible. Applicants should be aware that the design of research on sterilization needs to deal with some special problems, particularly with regard to the establishing of control groups and the utilization of sampling techniques. Innovative approaches to such problems would contribute to research efforts in this field.

## II. RESEARCH GOALS AND SCOPE

This RFA is meant to encourage investigators to develop necessary and significant research projects which will deal with the limitations of many of the past studies. To accomplish this objective, a thorough analysis of the literature relevant to a proposed project is required. On the basis of this review, the applicant can indicate the reasons for conducting the proposed study, whether it be to fill gaps in knowledge, clarify controversial findings, test hypotheses, and/or improve the research design and methodology relevant to studies of sterilization. The research may be multidisciplinary or may be conducted within a single discipline. Comparative, crosscultural, transnational, or historical approaches may be utilized.

Antecedents - The antecedents of the utilization of contraceptive sterilization may also, together with the operation itself, contribute to the consequences of the sterilization. What are the factors which facilitate or inhibit the choice and use of contraceptive sterilization by individuals and couples, and by family planning clinics? How is the use of sterilization related to the use of other methods of fertility regulation? At what points in the life span are decisions made concerning the use of sterilization, including the decision as to which member of the couple should have the operation? What factors affect decisions concerning the use of contraceptive sterilization? Such factors may include age, sex, marital status, number of children, family size preferences, health, relevant knowledge, education, religion, socioeconomic status, race, ethnic background, and place of origin and residence. There is need to ascertain the contributions of such psychosocial factors as motivations, partner and family relations, attitudes, personality characteristics, psychological and social adjustments, and emotional stability to the decision-making process. Experiences with and attitudes toward prior contraceptive practices, reasons for previous switching of contraceptives, if any, and present desire to change, should be taken into consideration. How do access to services as well as characteristics of service providers and delivery systems affect the decision to be sterilized? What part do various kinds of counseling play in the process?

How do such contextual factors as living situations and events, the media, and societal attitudes affect the decisionmaking?

One goal of the studies of antecedents would be to develop measuring instruments which would indicate the degree of risk of adverse effects as well as the probability that reversal of the operation might be desired some time after the procedure.

Consequences - In conducting research on the consequences of contraceptive sterilization, the interacting effects of the operation and its antecedents on such consequences should be elucidated whenever possible. In general terms, what are the demographic, psychological, sexual, health, social, economic, and

other consequences of sterilization at the individual, familial, and societal levels? How and why do such consequences change over time? Are there differences in the effects of the various surgical methods?

What is the effect of contraceptive sterilization, when compared with other methods of fertility regulation, on birth rates, particularly in the United States? For purposes of clarification and hypothesis testing, comparative studies of the United States and other countries could be made.

Quite a number of studies of consequences, especially psychological and sexual ones, have been conducted. However, there is still need for investigations with better defined and measured antecedents and consequences, as well as improved research design and sampling. Many previous studies tend to provide relatively simple statistical indicators of consequences without the use of control groups. Others do not present a conceptual framework which would contribute to both study design and interpretation of results. How does the operation affect such factors as emotional stability, psychological and social adjustment, relevant attitudes and personality characteristics, partner relations, sexual behavior, and familial relationships? How do the various consequences relate to and interact with one another?

Do changes in consequences occur over time and, if so, what are the factors contributing to such changes? Will it be possible to develop techniques to predict adverse changes over time with a view toward finding ways of eliminating them?

How frequently do sterilized individuals seek a reversal of the operation? What contributes to such requests? What are the effects of being unable to obtain a reversal?

### III. MECHANISM OF SUPPORT

The support mechanisms for this program will be the individual research project grant and the New Investigator Research Award (NIRA). Although this solicitation is included in the plans for Fiscal Year 1984, the support of grants to be awarded as a result of this RFA is contingent upon the receipt of funds for this purpose. It is anticipated that up to five grants will be awarded, depending on the overall merit of the applications and available funds. It is probable that there will be a range of costs among the grants which are awarded.

Applicants will furnish estimates of the time which will be required to conduct the proposed research. Ordinarily, grants are supported from one to a maximum of five years, but may be renewed according to the conventional processes available through the NIH grant program.

The current policies and requirements that govern the research grant programs of NIH will prevail.

### IV. REVIEW PROCEDURES AND CRITERIA

Applications submitted in response to this RFA will be reviewed for scientific merit by an initial review group (IRG) established and administered by the Division of Research Grants (DRG) of the National Institutes of Health (NIH). Applications judged by the DRG and the National Institute of Child Health and Human

Development (NICHD), as nonresponsive to this RFA will be assigned to the most appropriate regular grant program in the Public Health Service (PHS). If such an assignment is not possible, the application will be returned to the applicant. If an application submitted in response to this RFA is the same as one already submitted to the NIH, the applicant will be asked to withdraw the pending application before the new one is accepted.

The factors to be used in evaluating the scientific merit of each application will be similar to those used in judging individual research project grant applications, including originality of the proposed research and feasibility of approach; quality of theoretical-conceptual framework; adequacy of research design; appropriateness of data analysis techniques; suitability of facilities; training, experience, and research competence of investigators; and soundness of proposed budget.

#### V. METHOD OF APPLYING

Applicants are asked to notify the Demographic and Behavioral Sciences Branch, NICHD (See address below) at least one month prior to formal submission of an application. Include name of principal investigator, institutional address, title of application, and abstract of proposed research. Indicate that the application is in response to this RFA. When preparing the formal application, use form 398 (Rev. 5/82) for the individual research projects and the NIRAs. If your institution does not have this application booklet, copies may be obtained from:

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

Telephone: (301) 496-7441

In order to identify the application as being in response to this RFA check "yes" on item 2, page 1, of the application form and enter the title "**Antecedents and Consequences of Voluntary Contraceptive Sterilization**" and the RFA number. A cover letter repeating that this application is in response to the RFA of the NICHD, DBSB, will expedite the routing of the application.

Send or deliver the completed application and six (6) signed, complete copies of it to:

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

Applications must be received by December 15, 1983. An application which is not received by this date will be considered ineligible and returned.

## VI. TIMETABLE

Application receipt date - December 15, 1983  
Initial review date - February/March 1984  
Review by National Institute of Child Health and Human Development Advisory Council - June 1984  
Anticipated award date - July 1, 1984

Inquiries regarding this announcement may be directed to:

Sidney H. Newman, Ph.D.  
Behavioral Scientist Administrator  
Demographic and Behavioral Sciences Branch  
National Institute of Child Health and  
Human Development  
Landow Building - Room 7C25  
7910 Woodmont Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-1174

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NICHD-CR-83-2

REPRODUCTIVE DISORDERS

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: October 17, 1983

I. BACKGROUND

The Reproductive Sciences Branch (RSB), of the Center for Population Research (CPR), of the National Institute of Child Health and Human Development (NICHD), is inviting research grant applications for investigations in selected topics in Reproductive Medicine. By issuing a Request for Applications (RFA), CPR is indicating its intention to encourage investigator interest in specific research areas important to its mission, and currently not supported at levels appropriate to the health care of women.

The RSB supports research dealing with the biomedical basis of reproduction and its application to patient care. Reproductive Medicine, one of the four programs of the RSB, funds research into the clinical implications of that information, encompassed in two subdivisions, Human Infertility and Reproductive Disorders. Reproductive Disorders is concerned with the studies of selected impairments or modifications of human reproductive systems which are recognized disease entities. This RFA will be restricted to studies in Reproductive Disorders. Excluded is research in malignant conditions, infectious disease and the aging process, supported by other Institutes of the National Institutes of Health (NIH).

II. RESEARCH GOALS AND SCOPE

The purpose of this RFA is to encourage clinicians and other biomedical and behavioral scientists to conduct investigations aimed at the alleviation of selected human reproductive tract disorders known to cause significant morbidity and/or progressive impairment of reproductive capacity. Since these disturbances, many of them common in occurrence, are at times marked by recurrent physical suffering and may eventuate in the need for distressing, costly and temporarily incapacitating infertility management protocols, there seems to be clear reason to encourage investigation in their optimal management.

Among possibly useful approaches to investigation are the following:

1. studies of pathophysiology and disturbed biological mechanisms;
2. applications of new modes of investigation, such as immunoreactivity, laparoscopy and hysteroscopy, ultrasonography, imaging techniques employing magnetic resonance, hormone-receptor interactions;



3. delineation of the natural course of disease; and
4. studies of behavioral concomitants of disease and their implications.

The research areas for which applications are sought with this RFA are described below:

A. Disturbances in hypothalamic-ovarian function

As knowledge of normal endocrine relationships in the female reproductive system has grown, physicians have found it possible to apply increased specificity to the characterization of menstrual abnormality during reproductive life. In some cases this has led to recognition of increased importance of clinical entities, and to redefinition of others. Among such disorders the following are deemed of special importance:

1. Hypothalamic amenorrhea is a common diagnosis of exclusion made in young women. Mechanisms underlying its relationship to environmental stress and its long-term implications to impaired fertility are uncertain.
2. Amenorrhea associated with high levels of physical exercise or with weight reduction associated with anorexic syndromes has become increasingly common. In both instances, fundamental pathophysiology warrants further study.
3. Polycystic ovarian disease needs sharpened definition as a clinical entity, and data pertaining to its several hypothetical causations, as well as study of its impact on extended reproductive performance, are required.
4. Luteal phase defect appears to be part of the basis of menstrual dysfunction and relative infertility in some women. Its management would benefit by clarification of diagnostic criteria, its impact on long term reproductive capacity and efficacy of treatment.
5. Premature ovarian failure shortens reproductive life through the interplay between genetic and environmental factors. Techniques for its prediction, early recognition and prevention are important.

B. Endometriosis

External endometriosis is, for many women, a progressively discomfoting disease, at times crippling and life threatening, associated with behavioral alterations and infertility. Adenomyosis, a common concomitant of and/or indication for hysterectomy is associated with pelvic pain, altered menses and possibly impaired fertility. Evaluation of pain syndromes, objective indicators of impaired function, and adequacy of fertility-preserving treatment remain important problems.

C. Ectopic Pregnancy

Increasing in incidence, extrauterine gestation carries acute risks. The hazard of spontaneous and/or surgical tubal destruction and the likelihood of pelvic peritoneal scarring with impaired fertility represent jeopardy to

reproductive capacity in the long term. The occurrence of ectopic pregnancy after tubal reparative surgery, an increasing concern, underscores the need for investigation. Detailed knowledge of the mechanisms underlying external migration of the ovum, endosalpingiosis and tubal diverticulae remains imperfect.

### III. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional grant-in-aid (R01). The receipt date for this single-competition announcement is October 17, 1983. The earliest requested start date for grants would be July 1, 1984. Applications will be reviewed in competition with each other, and it is anticipated that 10-12 grants will be awarded under this program.

### IV. REVIEW PROCEDURES AND CRITERIA

#### A. Procedures

Research grant applications should be submitted on form PHS 398, and labelled in item 2 of the face page "In Response to RFA NIH-NICHD-CR-83-2." This form is available in most institutional business offices or from the Division of Research Grants (DRG), NIH. Applications will be reviewed by NIH staff for responsiveness to the RFA. Applicants judged to have submitted a non-responsive application will be contacted and given an opportunity to withdraw the application, or to have it assigned for review in the same manner as unsolicited grant applications. A proposal submitted in response to this RFA identical to a research grant application already submitted to NIH for review, is not acceptable for this RFA.

Applications submitted in response to this RFA will be reviewed for technical merit by an initial review group convened by the DRG solely to review these applications. The National Advisory Child Health and Human Development Council will review the applications in June 1984.

#### B. Review Criteria

Criteria for evaluation by the initial review group will be the same as for other research grant proposals. They are as follows:

1. scientific merit--the significance of proposed questions, research design, methodology, data analysis and interpretation;
2. research experience and competence of the applicant(s);
3. adequacy of time and effort dedicated to the project by investigators and staff;
4. adequacy of collaborative relationships, if applicable;
5. adequacy of existing and proposed facilities and resources; and
6. costs in relation to scope of the project.

**V. METHOD OF APPLYING**

Applications should be submitted on form PHS 398. The conventional mode of preparation should be employed. The original and six (6) copies should be received by the DRG no later than October 17, 1983. Applications should be directed to:

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

In addition to those mailed to the DRG, three (3) copies of the application should be sent to:

Thomas Kirschbaum, M.D.  
Reproductive Sciences Branch  
Center for Population Research  
National Institute of Child Health and  
Human Development  
National Institutes of Health  
Landow Building - Room 7C33  
Bethesda, Maryland 20205

Telephone: (301) 496-6515

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NICHD-CPR-83-3

HUMAN FEMALE INFERTILITY

**NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT**

Application Receipt Date: October 17, 1983

I. BACKGROUND

The Reproductive Sciences Branch (RSB) of the Center for Population Research (CPR) of the National Institute of Child Health and Human Development (NICHD) is inviting research grant applications for investigations in selected topics in human infertility. By issuing a Request for Applications (RFA), CPR is indicating its intention to encourage investigator interest in specific research areas important to its mission and currently not supported at levels appropriate to the health care of women.

The RSB supports research dealing with the biomedical basis of reproduction and its application to patient care. Reproductive Medicine, one of the four programs of the RSB, funds research into the clinical implications of that information, encompassed in part in human infertility. Infertility is defined as the inability of couples to reproduce as they wish.

Concern for human infertility lies within the purview of CPR and has been designated an area of high priority for research support by NICHD. Increasing numbers of couples are presenting to physicians with complaints of infertility, and the diagnosis and management of such problems has become a significant concern of Americans. New research methodologies have expanded investigative opportunities in this area. A vigorous research effort is essential to continued progress.

This RFA will be restricted to studies in the biologic basis for infertility in women and the evaluation and management of such problems. Similar investigations in the male and interrelationships between male and female reproductive functions will be the subject of subsequent RFAs. Excluded is research in malignant conditions, infectious diseases, and the aging process supported by other Institutes of the NIH.

II. RESEARCH GOALS AND SCOPE

There is a compelling general need in research in human infertility for studies of normal reproductive tract function, of the natural history of disturbances of function, and for controlled observations of interventions obtained through rigorous application of the scientific method. Several areas of particular interest and

concern have been defined but do not constitute an inclusive list of topics appropriate for research in human infertility.

A. Normal Ovarian Cycle

Clinical investigation of infertile couples has rapidly incorporated new investigative techniques. As examples, ultrasonic pelvic scanning has been employed to estimate the number and size of maturing ovarian follicles, positron emission tomography has been used to follow changes in pelvic architecture with time, and follicle aspiration has disclosed evidence of polyovular ovarian follicles. There is need to characterize the normal ovarian cycle through studies in couples of unquestionable fertility with respect to changes in the reproductive tract discerned by ultrasound and other imaging techniques, by endoscopy, and by the measurement of biologically active materials in blood and other body fluids.

B. Immunology

The role of immunoreactivity in human reproduction and immunologic aspects of reproductive failure continue to comprise important directions for new research. Study of the mechanisms by which the human conceptus is rendered immunologically privileged from rejection have important implications both to infertility and/or early reproductive failure. Failure of development of blocking antibodies or of locally produced hormonal immunosuppression as by progesterone may be manifest clinically as infertility, spontaneous abortions, congenital anomalies, or later as pregnancy-induced hypertension or intrauterine growth retardation. The apparent role of HLA compatibility between mates in diminishing reproductive capacity warrants further research, both as to its significance in clinically defined infertility and to operant mechanisms. Further exploration of multipartite agents such as early pregnancy factor (EPF), a possibly very potent immunosuppressant requiring contribution from ovarian follicle, tube, and zygote as well as pituitary prolactin, is desirable. The nature of the apparent relationship between thymic and ovarian function deserves investigation.

C. Human LHRH Agonists

The availability of LHRH agonists provides an important tool in the investigation, differential diagnosis and possible treatment of endocrine related causes of infertility in women. Exploration of their usefulness of these agents in humans and other mammals seems appropriate.

D. Oocyte Development and Release

Research in oocyte selection, maturation and release has become increasingly important as has the study of patterns of hormone secretion and concentration during normal and abnormal ovarian cycles. Abnormalities in such patterns and altered relationships between ovarian and endometrial cycles may account for some cases of unexplained infertility. There is continued need for an inexpensive, easy to use means of detecting ovulation, employing urine, blood, saliva or other biological substances. Such a

technique would be useful in the appraisal of infertility, in the evaluation of treatment, and in periodic abstinence for reproductive control.

E. Androgens

There is need to evaluate the role of androgens in follicle development, oocyte maturation, ovulation, and implantation. Atypically excessive androgen exposure may render the endometrium incapable of normal implantation mechanisms. Methods effective in diminishing the impact of androgen-induced modifications of normal female reproductive functions are needed.

F. Tubal Function

The detailed mechanics of modulation of uterine tubal function by sex steroids, prostaglandin species, neurotransmitters and proteins requires further elucidation, as does the effect of prostaglandin synthetase inhibitors and other antagonists on tubal mechanics. The possible roles of these and other substances produced by the uterus in normal and disturbed tubal function have been incompletely explored.

Technical developments have enabled the possible study of the nutrient uptake and requirements of the preimplantation embryo in tubal and uterine fluids, and such research has potential importance to the study and treatment of human infertility.

The increasing performance of restoration procedures following surgical tubal sterilization makes exploration of optimal surgical approaches important. Similarly, investigation into the prevention of subsequent ectopic pregnancy and other forms of reproductive wastage has general interest.

G. The Cervix

The biochemical characterization of cervical mucus continues to be important to understanding its role in human infertility, both in terms of sperm transport and its possible role in maintaining the intrauterine environment prior to implantation. Studies of the impact of prior cervical surgical procedures, including conization and multiple biopsy, and of spontaneously occurring cervical stenosis on sperm transport and implantation have importance to the evaluation of infertile couples.

III. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional grant-in-aid (R01). The receipt date for this single-competition announcement is October 17, 1983. The earliest requested start date for grants would be July 1, 1984. Applications will be reviewed in competition with each other, and it is anticipated that 10-12 grants will be awarded under this program.

#### IV. REVIEW PROCEDURES AND CRITERIA

##### A. Procedures

Research grant applications should be made on form PHS 398, and labelled in item 2 of the face page "In Response to RFA NIH-NICHD-CPR-83-3." This form is available in most institutional business offices or from the Division of Research Grants (DRG), NIH. Applications will be reviewed by NIH staff for responsiveness to the RFA. Applicants judged to have submitted a non-responsive application will be contacted and given an opportunity to withdraw the application or to have it assigned for review in the same manner as unsolicited grant applications. An application will be considered unresponsive to this RFA if it is identical to one already submitted to the NIH for review.

Applications submitted in response to this RFA will be reviewed for technical merit by an initial review group convened by the DRG solely to review these applications. The National Advisory Child Health and Human Development Council will review the applications in June 1984.

##### B. Review Criteria

Criteria for evaluation by the initial review group will be the same as for other research grant proposals. They are as follows:

1. scientific merit—the significance of proposed questions, research design, methodology, data analysis and interpretation;
2. research experience and competence of the applicant(s);
3. adequacy of time and effort dedicated to the project by investigators and staff;
4. adequacy of collaborative relationships, if applicable;
5. adequacy of existing and proposed facilities and resources; and
6. costs in relation to scope of the project.

#### V. METHOD OF APPLYING

Applications should be submitted on form PHS 398. The conventional mode of preparation should be employed. The original and six (6) copies should be received by the DRG no later than October 17, 1983. Applications should be directed to:

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

In addition to those mailed to the DRG, three (3) copies of the application should be sent to:

Thomas Kirschbaum, M.D.  
Reproductive Sciences Branch  
Center for Population Research  
National Institute of Child Health and  
Human Development  
National Institutes of Health  
Landow Building - Room 7C33  
Bethesda, Maryland 20205

Telephone: (301) 496-6515



## ANNOUNCEMENT

### RESEARCH GRANTS FOR CLINICAL TESTING OF ORPHAN PRODUCTS FOR RARE DISEASES

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 DENTAL RESEARCH  
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES  
NATIONAL EYE INSTITUTE  
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES  
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE  
NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS  
AND STROKE

This announcement is intended to inform interested individuals of the intention of the above-listed Institutes to support the clinical testing of orphan products for rare diseases.

#### I. BACKGROUND

There are many diseases and conditions which affect such small numbers of individuals in this country that the diseases and conditions are considered rare. Because of development costs and a relatively small market, drugs, vaccines, and devices for the diagnosis, prevention or treatment of these rare diseases are referred to as "orphan products." Effective therapy often does not exist, although existing or experimental drugs, vaccines, or devices might prove effective in rare diseases if adequate clinical trials were to be conducted. Therefore, the above-named Institutes are encouraging submission of research grant applications for support of clinical testing of orphan products (drugs, vaccines, devices) for rare diseases or conditions. Research grants and/or contracts are available for the preliminary basic research and for the development of drugs, vaccines, and devices through the other program activities of the above Institutes and do not fall within the scope of this announcement.

#### II. RESEARCH GOALS AND SCOPE

The emphasis in this Program Announcement is on the clinical testing, in humans, of drugs and devices potentially efficacious in the prevention or treatment of rare diseases or conditions. Clinical testing can include evaluation of toxicity and/or efficacy. Submitted applications should therefore specifically address the conceptual, experimental, and ethical problems of clinical testing in situations in which the total patient population may be very small. Criteria for patient entrance into the trial, including but not limited to criteria for diagnosis of the rare disease or condition, should be discussed. If a multicenter study is proposed, procedures for ensuring uniform diagnosis and adherence to a common protocol should also be discussed. Realistic projections of the rate of patient acquisition should be

presented. The application should also discuss existing information about the orphan product such as pharmacology and toxicity data in animals and/or man, existing clinical evidence for efficacy, etc.

III. 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 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. This program is not subject to Health Systems Agency review.

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

IV. METHOD AND CRITERIA OF REVIEW

Applications will be received by the NIH's Division of Research Grants (DRG), referred to an appropriate study section for scientific merit review, and assigned to individual Institutes for possible funding. These assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines.

Applications in response to this announcement will be reviewed in nationwide competition, and in accordance with the usual NIH peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (study section). Following this review, the applications will be evaluated by the appropriate Institute National Advisory Council. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

V. APPLICATION PROCEDURES

A. Deadline: Applications will be accepted in accordance with the usual dates for new applications:

<u>APPLICATION RECEIPT</u>	<u>INITIAL REVIEW</u>	<u>COUNCIL REVIEW</u>	<u>EARLIEST START DATE</u>
Nov. 1	Feb./March*	May*	July 1*
March 1	June	Sept./Oct.	Dec. 1
July 1	Oct./Nov.	Jan./Feb.*	April 1*

\* of the year following application receipt.

B. Method of Applying: Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 of page of the application and enter the title "NIH ORPHAN PRODUCT PROGRAM ANNOUNCEMENT."

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

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

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

NATIONAL INSTITUTE ON AGING

Dr. Alan L. Pinkerson  
Deputy Associate Director for Planning  
and Extramural Affairs  
National Institute on Aging  
National Institutes of Health  
Building 31 - Room 5C06  
Bethesda, Maryland 20205

Telephone: (301) 496-9322

NATIONAL INSTITUTE OF ALLERGY AND  
INFECTIOUS DISEASES

Dr. George J. Galasso  
Development and Applications Branch  
National Institute of Allergy and  
Infectious Diseases  
National Institutes of Health  
Westwood Building - Room 750  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-7051

NATIONAL INSTITUTE OF ALLERGY AND  
INFECTIOUS DISEASES

Dr. John E. Nutter  
Office of Program Planning and Evaluation  
National Institute of Allergy and  
Infectious Diseases  
National Institutes of Health  
Building 31 - Room 7A17  
Bethesda, Maryland 20205

Telephone: (301) 496-6752

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

Dr. Benjamin T. Burton  
OPA and SC  
National Institute of Arthritis, Diabetes,  
and Digestive and Kidney Diseases  
National Institutes of Health  
Building 31 - Room 9A03  
Bethesda, Maryland 20205

Telephone: (301) 496-4955

NATIONAL CANCER INSTITUTE

Dr. Saul S. Schepartz  
Division of Cancer Treatment  
National Cancer Institute  
National Institutes of Health  
Building 31 - Room 3A51  
Bethesda, Maryland 20205

Telephone: (301) 496-6404

NATIONAL INSTITUTE OF CHILD HEALTH AND  
HUMAN DEVELOPMENT

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

Telephone: (301) 496-1848

NATIONAL INSTITUTE OF DENTAL RESEARCH

Dr. James P. Carlos  
Associate Director, National Caries Program  
National Institute of Dental Research  
National Institutes of Health  
Westwood Building - Room 528  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-7239

NATIONAL INSTITUTE OF ENVIRONMENTAL  
HEALTH SCIENCES

Dr. Rajendra S. Chhabra  
National Institute of Environmental  
Health Sciences  
National Institutes of Health  
P.O. Box 12233  
Building 101, Mail Drop D4-02  
Research Triangle Park, North Carolina 27709

Telephone: (919) 629-3386

NATIONAL INSTITUTE OF ENVIRONMENTAL  
HEALTH SCIENCES

Dr. William M. Kluwe  
Pharmacologist  
National Institute of Environmental  
Health Sciences  
National Institutes of Health  
P.O. Box 12233 - D442  
Research Triangle Park, North Carolina 27709

Telephone: (919) 541-4177

NATIONAL EYE INSTITUTE

Dr. Douglas Gaasterland  
Chief, Glaucoma Section, Clinical Branch  
National Eye Institute  
National Institutes of Health  
Building 10 - Room 10D11  
Bethesda, Maryland 20205

Telephone: (301) 496-4050

NATIONAL INSTITUTE OF GENERAL MEDICAL  
SCIENCES

Dr. Sara A. Gardner  
Director, Pharmacological Sciences Program  
National Institute of General Medical Sciences  
National Institutes of Health  
Westwood Building - Room 919  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-7181

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Dr. Thomas L. Robertson  
Special Assistant to the Director  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Building 31 - Room 5A35  
Bethesda, Maryland 20205

Telephone: (301) 496-3245

NATIONAL INSTITUTE OF NEUROLOGICAL AND  
COMMUNICATIVE DISORDERS AND STROKE

Dr. F.J. Brinley, Jr.  
Director, Convulsive Developmental and  
Neuromuscular Disorders Program  
National Institute of Neurological and  
Communicative Disorders and Stroke  
National Institutes of Health  
Federal Building - Room 812  
Bethesda, Maryland 20205

Telephone: (301) 496-6541

## ANNOUNCEMENT

### BEHAVIORAL/BIOMEDICAL INTERDISCIPLINARY RESEARCH TRAINING

#### NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

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

#### I. INTRODUCTION

The Center for Research for Mothers and Children (CRMC), of the National Institute of Child Health and Human Development (NICHD), invites applications for National Research Service Awards (NRSA), (both individual postdoctoral fellowships (F32) and institutional training grants (T32) for pre- and postdoctoral trainees) in support of training individuals for research in the interdisciplinary areas of behavior and biomedicine.

#### II. BACKGROUND AND SCOPE

The research mission of the CRMC encompasses the study of development from conception to adulthood. Interdisciplinary research among biomedical specialties has been instrumental in discovering many of the basic biological mechanisms underlying development. In order to understand the complex interactions between those mechanisms and the behavioral determinants of development, scientists must learn the basic principles and methods used in both behavioral and biological research. The NICHD encourages applications for such interdisciplinary research training. Among the research fields relevant to this announcement are developmental behavioral genetics, behavioral pediatrics, developmental behavioral pharmacology, behavior and nutrition, and developmental behavioral biology (especially neurobiology and neuroendocrinology).

Research areas of the CRMC mission that will benefit from an experimental biobehavioral approach to development are:

- Studies of the relationship between hormone levels and development of gender-specific behaviors and social interactions.
- Studies of brain/behavior relationships including electrophysiological, anatomical and biochemical correlates of language, perception, memory, and sensory/motor development.
- Studies of temperament, learning, and sensory development in relation to genetics.

This program is described in the Catalog of Federal Domestic Assistance No. 13.895, Research for Mothers and Children. Awards will be made under authority of Section 472 of the Public Health Service Act as amended (42 USC 2891-1). Title 42 of the Code of Federal Regulations, Part 66, is applicable to these awards. This program is not subject to Health Systems Agency review.

- Studies in behavioral development consequent to pre- and postnatal exposure to drugs and to toxic agents related to lifestyle (e.g., cigarette smoke, alcohol, lead).
- Studies of biological and molecular substrates and correlates of developmental delays, learning disabilities, and mental retardation.
- Studies of biological and behavioral factors in children relevant to prevention and treatment such as health promotion, illness behavior, risk taking, compliance with medical regimens, and biofeedback.
- Studies of the relationship of early experience and the environment to the etiology of mental retardation and other developmental disabilities.
- Studies of behavior and nutrition (e.g., failure to thrive, obesity, learning deficits, hyperactivity, anorexia, control of appetite and satiety, and nutritional factors in brain/behavioral development).

### III. TRAINING GOALS

The Center wants to encourage the biobehavioral, interdisciplinary approach to the study of development and believes that the initiation and conduct of such research would be facilitated by increased emphasis on the interdisciplinary training of individuals at an early stage of their research careers. Thus, applicants trained in a biomedical discipline may wish to add the measures, methods and knowledge base of the behavioral sciences to their biomedical repertoire by proposing individual postdoctoral training under the sponsorship of scientists qualified to offer and direct appropriate research training. Conversely, individuals with research interests and educational backgrounds in areas of behavioral development may propose training in any of the biological sciences or medical specialties so as to become familiar with the theories and research methods of the biomedical disciplines. Similarly, institutions applying for interdisciplinary training grants under this announcement should propose training programs, curricula, and staff designed to offer pre- and postdoctoral trainees the opportunity for such multidisciplinary, biobehavioral training. The training environment should facilitate such training as evidenced by interdepartmental cooperation in terms of faculty, required course work and guidance of trainee research.

The goal of the training is to produce investigators with knowledge of the concepts and methodologies of behavioral science and of biomedical disciplines. The training, both formal and experiential, should be of sufficient depth to enable the investigator to formulate research projects which encompass concepts, tools, and methods of both behavioral and biomedical disciplinary areas.

### IV. MECHANISM OF SUPPORT

Support for this training will be through the NRSA.

### V. APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on form PHS 6025 for institutional training grants (T32), or on form PHS 416-1 for individual postdoctoral fellowships (F32). Application kits are available from most institutional business offices, or they may



be obtained from the DRG, at the address given below. Application kits contain instructions and information regarding eligibility requirements, selection of awardees, stipends and other allowable training costs, review cycles, submission deadlines, review criteria, and payback requirements. In addition to the review criteria specified in these instructions (**NIH Guide for Grants and Contracts, Special Edition, Vol. 11, No. 7, June 18, 1982, p. 7**), applicants for both institutional and individual training, and their qualifications for funding under this training initiative, will be judged upon the more specific criteria listed below.

Applications must be responsive to this program announcement and relevant to the goals of the NICHD. Applications not responsive or which focus on areas of primary interest to another Institute will be assigned to the appropriate Institute by DRG. For institutional training grant applicants, qualifications for funding under this training initiative will be judged upon the following criteria:

- Appropriate required training in fundamental principles and methods of both the behavioral and the biomedical sciences.
- Quality of laboratory research experiences in both behavioral and biomedical settings.
- Faculty and facilities sufficient to meet the needs of the training program.
- Individual research project requirements.

Individual applications for interdisciplinary training (F32) must be made in accordance with this program announcement and with the goals of the NICHD. The individual grant awards will be evaluated on the basis of the following criteria:

- The scientific merit of the proposal relative to training the applicant for interdisciplinary behavioral/biomedical research.
- Qualifications of the applicant and appropriateness of the proposed training.
- Expertise and qualifications of the proposed sponsor.
- Adequacy of resources and facilities.
- Appropriateness of the mix between formal course work and laboratory or clinical experience.

An initial review will be made by an appropriate NIH review group. Institutional training grants will receive a second-level review from a National Advisory Council. For individual postdoctoral fellowships, an Institute staff committee will provide a second review. The phrase "NICHD Behavioral/Biomedical Research Training Announcement" should appear in space 1B on form PHS 6025, and in space 2 of form PHS 416-1. The original and six copies of the application should be mailed to:

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

Two copies of the application should be mailed to:

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

Telephone: (301) 496-1848

## ANNOUNCEMENT

### SURGICAL ONCOLOGY RESEARCH

#### NATIONAL CANCER INSTITUTE

The National Cancer Institute's (NCI) Division of Cancer Treatment (DCT) desires to expand support of surgical oncology research. This announcement invites applications for individual research project (R01) and program project (P01) grants.

#### I. BACKGROUND

The treatment of cancer has evolved as a multidisciplinary effort involving (but not limited to) the disciplines of surgical oncology, medical oncology, pediatric oncology, and radiation oncology. The disciplines of medical oncology, pediatric oncology, and radiation oncology have developed strong cadres of academic investigators but academic development in surgical oncology has not kept pace. It is felt that surgical oncology is not keeping pace because of an insufficient number of surgical oncology research programs and an insufficient number of surgeons undertaking research related to cancer. Continued development of multidisciplinary treatment of cancer is the long range objective of the DCT and the attainment of the goal requires sufficient academic strength in surgical oncology.

#### II. GENERAL CONSIDERATIONS

The NCI's DCT is seeking applications for research grants concerned with research in surgical oncology. Examples of relevant studies include mechanisms of metastases, effect of surgery on tumor cell kinetics, and host responses to surgery. Preclinical and clinical research is encompassed in this program. Categories of research include (but are not confined to) the following:

- A. Pathophysiologic studies in laboratory models or in humans related to surgery and cancer.
- B. Laboratory and clinical studies which examine the biochemical, cytokinetic, immunological, or nutritional effects of cancer surgery.
- C. Therapeutic studies in which surgery or a surgical question is the primary treatment modality.
- D. Studies relevant to staging of patients and identifying prognostic factors relevant to the treatment of cancer patients.

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 IV, Section 301 (Public Law 78-410, as amended; 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.

- E. Surgical supportive care.
- F. Regional chemotherapy or hyperthermia in which a surgical approach to the treatment site is a major aspect of the procedure.

In making this program announcement it is not the intent of the NCI to make or imply any delimitation of investigator-initiated research in the cancer field.

### III. APPLICATION PROCEDURE

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions or from the Division of Research Grants, NIH. The title "Surgical Oncology Research" should be typed in section 2 of the first page of the application. Additionally a brief covering letter should accompany the application indicating it is being submitted in response to this program announcement.

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

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

In order to alert the DCT to the submission of the proposals with primary thrust directed to surgical oncology research, a copy of the covering letter and an additional copy of the application should be sent under separate cover to:

Ernest V. deMoss, M.D., M.P.H.  
Head, Surgery Section  
Clinical Investigations Branch  
Division of Cancer Treatment  
National Cancer Institute  
Landow Building - Room 4B04  
Bethesda, Maryland 20205

Telephone: (301) - 496-4844

In addition, for P01 grant applications, two complete copies should be sent under separate cover to the following address:

Referral Officer  
Grants Review Branch  
Division of Extramural Activities  
National Cancer Institute  
Westwood Building - Room 826  
Bethesda, Maryland 20205

### IV. REVIEW PROCEDURES AND CRITERIA

Applications in response to this announcement will be reviewed on a nation-wide basis in competition with each other, and in accord with the usual NIH peer review procedures. They will first be reviewed for scientific and technical merit by a

review group composed mostly of non-Federal scientific consultants. Following this initial review, the application will be evaluated for program relevance by the National Cancer Advisory Board.

Where applicable to a particular project review criteria will consist of the following:

1. Relevance of the project to surgical oncology research and to the national cancer effort.
2. Feasibility of reaching the proposal's objectives.
3. Significance and adequacy of pilot data to the proposal's objectives.
4. Qualifications of the principal investigator and supporting personnel to achieve the project goals.
5. Adequacy of core facilities and basic equipment to support the project.
6. Availability of suitable patient and control populations if required.

For further information regarding this announcement and the review criteria for the P01 grant application and the R01 grant application, investigators are encouraged to contact Dr. Ernest V. deMoss at the address and telephone number given above. Before submitting a P01 application, please discuss a letter of intent with Dr. deMoss.

## ANNOUNCEMENT

### SPECIAL PROGRAM AREAS OF INTEREST

#### **NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES**

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency for biomedical research on the effects of chemical, physical and biological environmental agents on man's health and well being. The Institute supports efforts to identify potentially hazardous environmental agents, including the development, testing, and validation of biological test systems which can be used to measure and predict human toxicity from exposure to environmental factors. The purpose of this general Announcement is to summarize those areas of research considered important to the Institute, as follows:

#### **ALTERNATIVE DESIGNS OF STANDARD CANCER BIOASSAY**

The objective is to stimulate interest in the development of alternative designs of the standard cancer bioassay in order to make the end results more amenable to low-dose extrapolation and risk estimation. Alternative designs should maintain the cancer screening potential of the current bioassay.

#### **STUDIES RELATING HUMAN HEALTH EFFECTS TO PBB**

The objective is to provide information which will aid in the assessment of the real and potential dangers to man from exposure to commercial preparations of PBB's. Areas of research currently of interest should emphasize information relative to toxicity of PBB congeners for humans, including storage, metabolism and excretion, additive, synergistic or otherwise interactive reactions with other pollutants, studies of immune functions in populations exposed to PBB's, studies of immune functions in populations exposed to PBB's, development of means for clearing the body of PBB's and similar compounds and central nervous system manifestations in children exposed to PBB.

#### **IMMUNOTOXICOLOGY OF ENVIRONMENTAL AGENTS**

The objective is to stimulate high quality research in areas of immunotoxicology including applications of immune function tests, changes in immune response following exposure to environmental chemicals, development of immunologic models to study hypersensitization and allergy, and the effects of inhalation exposure on immune elements in the lung.

#### **BIOLOGICAL EFFECTS OF CHEMICAL INTERACTIONS**

The objective is to study all facets of biological effects of interactions of chemicals of environmental concerns. Of particular interest are projects aimed at developing new methods for study of interactions.

#### **ENVIRONMENTAL MEDICINE**

The objective is to generate interest in the use of laboratory or clinical tests that aid in the detection and measurement of toxicity demand from chemical exposure

at levels which do not produce acute symptoms but which may produce detectable damage years later. Of particular interest are the effects of exposure that may occur in occupational settings, therapeutic levels of unexpected episodes of chemical exposure such as might occur with populations exposed to hazardous chemical wastes. The details of the individual programs can be obtained from:

Dr. Edward Gardner  
Program Director  
Regular Research Program Section  
Scientific Programs Branch, Extramural Program  
P.O. Box 12233  
Research Triangle Park, N.C. 17709

## I. REVIEW PROCEDURES AND CRITERIA

### A. Review Procedure

Applications received in response to this announcement will be considered along with other non-solicited applications and will be assigned in accordance with the NIH Referral Guidelines. The initial review will be for scientific merit and will be carried out by an appropriate peer review group. The secondary review for relevance and responsiveness to the announcement will be made by the appropriate National Advisory Council.

### B. Review Criteria

The factors considered to be important for review include a demonstrated knowledge of the applicable science, adequacy of facilities and commitment, availability of subject population when applicable and in-depth knowledge of the state-of-the-art to which the announcement is directed. The application will be judged upon the overall scientific merit, adequacy of methodology, facilities and resources, commitment of time and cost effectiveness of the proposal. The sponsoring institution should indicate a commitment of facilities and resources to the program.

## II. METHOD OF APPLYING

Applications should be submitted on form PHS 398, the application for the traditional research grant. Application kits containing this form and the necessary instructions are available in most institutional business offices or from the Division of Research Grants (DRG), NIH. Applications must be sent to the following:

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

This program is described in the Catalog of Federal Domestic Assistance, No. 13.112, Characterization of Environmental Health Hazards; 13.113, Biological Response to Environmental Health Hazards; 13.114, Applied Toxicological Research and Testing; and 13.115, Biometry and Risk Estimation. 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.

ANNOUNCEMENT

DRUG ABUSE PREVENTION RESEARCH

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NATIONAL INSTITUTE ON DRUG ABUSE

I. INTRODUCTION

The purpose of this announcement is to stimulate investigator interest in certain areas of prevention research which are of particular importance to the national drug abuse research program. Understanding of the drug abuse phenomenon has increased greatly over the past decade. Nevertheless, there remains a great deal to be learned. In particular, we need to develop and evaluate effective means of preventing the onset and habitual non-medical use of drugs. Research is needed to refine prevention intervention techniques and to develop and refine interventions targeted for specific groups at risk of drug abuse. Additional research is needed on factors which increase individuals' risk of drug abuse, and on factors which tend to make some individuals invulnerable to drug abuse. Research on risk factors and invulnerabilities must consider the implications for developing or refining preventive interventions. Background and guidance for research proposals in these areas are provided in this announcement.

II. OVERVIEW

The Department of Health and Human Services (DHHS) has launched a major health promotion initiative to improve the health of the American people. Specific health objectives have been established for reducing death and disability for fifteen areas, including misuse of alcohol and drugs. In keeping with the Department's overall thrust and the Institute's assessment of national needs, the National Institute on Drug Abuse (NIDA) is supporting a broad-based drug abuse prevention research program which includes research on (1) primary disease prevention and health promotion interventions aimed at reducing the incidence of drug abuse, (2) outreach and early intervention programs for novice drug users and abusers who have not been clinically identified, (3) methods for early identification and screening of persons at risk of drug abuse, and (4) risk factors as a basis for the design of preventive interventions.

Research supported under this announcement is intended to further the development of prevention intervention theories and technology. Intervention research must go beyond the evaluation of a specific program. Intervention research should have a carefully developed theoretical component, or should test a

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This program is described in the Catalog of Federal Domestic Assistance No. 13.279, Drug Abuse Research Programs. 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.



number of assumptions which will lead to new theories to guide intervention programs. Thus, the intervention must be based on scientific evidence about the etiology of drug abuse disorders. An additional goal is to develop intervention models which are replicable in other communities. Risk factor research must occur within the context of theory development applicable to preventive interventions. The intended focus here is to explore and clarify the role of identified risk factors in the onset of drug abuse behaviors and to consider their implications for the design or refinement of preventive interventions. (Etiological research which is outside the scope described in this announcement is also supported by NIDA's Prevention Research Branch. Investigators interested in such research should submit applications under the Institute's general Research Grants Program announcement.)

An important task in both intervention and risk factor research concerns identifying subpopulations at risk of drug abuse. Existing prevention theories have tended to focus on categories of drug users, typically distinguished by their stage in the life cycle or the particular drug which is being used. In risk factor research reliance on drug or age-group categories of users tends to minimize the importance of similarities among various user groups or various drugs or even various potentially addictive behaviors such as smoking, drinking, overeating, and gambling. Furthermore, in intervention research drug or age-group categories are not sufficiently specific to target interventions in accord with the participants' needs. Thus, an important step in intervention and risk factor research would be to distinguish specific subpopulations under study, going beyond distinctions of age or drug of abuse.

NIDA, along with the National Institute on Alcohol Abuse and Alcoholism, (NIAAA), is interested in applications which address issues common to the problems of alcohol and drug abuse. These would include, for example, studies of commonalities and differences in risk factors and common approaches, where appropriate, to the prevention of alcohol and drug abuse. Such applications may be funded jointly by both Institutes or funded solely by one Institute, depending on the emphasis.

While much of NIDA's drug abuse prevention effort is focused on adolescents, other groups in the life cycle, such as children of addicts, individuals in high risk occupations, housewives, and the elderly, also are of interest. Because of the paucity of prevention research focused specifically on ethnic minorities and the distinct needs of these populations, drug abuse among ethnic minorities is of special concern. Thus, research focused on minority populations found to be at high risk for drug abuse is especially encouraged.

### III. SUGGESTED AREAS OF STUDY

The following topics are provided as examples of areas that might be studied. Investigators are encouraged to consider any of these as well as related studies which might have value.

#### A. Intervention Research

The intervention process is only partially understood, and it appears unlikely that one single approach will work equally well with different groups. Research is needed to determine the effectiveness of intervention programs appropriate to specific target groups and specific drug abuse problems. In

intervention research, drug use behaviors and attitudes toward use should be primary outcome measures. However, it is essential that multiple outcome measures (e.g., school performance, personal goals and expectations, attitudes, and beliefs) and their interrelationship be considered.

Adolescents have been studied extensively and two important influences have been found. One is the parental/family influence, and it has led to activities such as parent/family skills training, family therapy, and the development of parent action groups. A second major influence comes from peer pressure. Some work has focused on teaching adolescents to resist undesirable peer pressure.

Further research in areas involving the family and/or peers is encouraged. Especially high priority is placed on research on:

1. parent/family skills training approaches which develop communication and limit-setting skills, and
2. school-based programs which develop skills in resisting peer pressures to use drugs. Issues pertaining to school-based programs which warrant special attention include the applicability of specific approaches to different sub-populations, the role of peer leaders in program implementation, and the importance of follow-up interventions to sustain program effects.

Research on brief community interventions is also encouraged. One suggested approach is to attach an evaluation component to a community program proposed or already in progress, such as a mass media campaign focused on a specific drug abuse problem. Research questions could deal with factors such as the content of the message, its type of delivery, its intent and its effect. A second approach is small scale field studies of community organization efforts by natural groups in the community, for example, a senior high school class which alters the school environment or a parent's group which alters the community environment to discourage drug use.

While intervention research focused on adolescents is a primary interest, there is also a need for more research on intervention approaches for other groups in the life cycle found to be at risk.

#### B. Methodology development

There is a need to develop new research protocols and methods and refine existing methods which will help make more useful and valid assessments of preventive intervention efforts. The ultimate criterion of whether a reduction or cessation in drug use has occurred is desirable, but other points are important as well; for example, the cost relative to the benefits, the broad impact on the community, and outcome measurement techniques. Studies are needed to develop improved methods in areas such as these.

#### C. Risk factors in drug experimentation

An important task concerns identifying subpopulations at risk of drug abuse and describing the specific risk factors for each population. Studies are needed which explore risk factors and their implications for preventive

interventions. Proposals for such studies must show how this knowledge sought could be used directly for developing or refining an intervention strategy.

Interpersonal risk factors associated with the beginning use of marijuana, cigarettes, or wine and beer by pre-teen and teenage children have received insufficient attention. Equally neglected is the transition from the experimental stage to the user state. The two most common foci for studies of experimentation and use of drugs have been the respective roles of parents and peers. Parents are thought to provide models through their use of tobacco and alcohol. Peers are thought to bring pressure through their insistence that one conform with the peer group's standards. By themselves these explanations are incomplete. There is a need to know more about the circumstances under which peer and parental influences work and their specific and direct implications for prevention. Attention to the importance and efficacy of parental limit-setting and other parental behaviors is especially encouraged.

In social environments which are particularly conducive to initiating a career in drugs, there are some adolescents who are invulnerable. The special factors which lead to this desirable condition need to be explored for their intervention implications.

The role of environmental factors in the promotion of healthy behaviors and in the initiation and maintenance of drug abusing behaviors is only partially understood. There is a need for research which looks beyond the factors which place individuals at risk of drug abuse to the structural and institutional factors which affect the immediate risk factors, such as school policies and procedures or management procedures in the workplace. Research should focus on environmental factors which could reasonably be modified.

Much of the research on risk factors related to drug abuse has been focused on adolescents. Less is known about factors which place other groups in the life cycle at risk. Thus, study is encouraged which explores the risk factors associated with drug initiation among various groups.

#### D. Secondary data analysis

While it is anticipated that much of the research supported under this announcement will involve the collection of original data, many prevention research questions can be addressed through the secondary analysis of large data bases which have current relevance. Such research is especially appropriate for large-sample studies which compare different populations or which explore the interrelationships among various risk factors.

### IV. APPLICATION PROCEDURES

The Institute wishes to encourage investigators to submit research grant proposals in the areas discussed in this announcement. Applications may be submitted by nonprofit, for-profit, or public organizations.

The regular research grant application form PHS 398 (Rev. 5/82) must be used in applying for these awards. However, State and local agencies should use form PHS 5161 (Rev. 3/79). Application kits are available in university grant offices or from the following:

Grants Management Branch  
National Institute on Drug Abuse  
Parklawn Building - Room 10-25  
5600 Fishers Lane  
Rockville, Maryland 20857

Telephone: (301) 443-6710

The original and six (6) copies of applications must be submitted to:

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

#### V. FURTHER INFORMATION AND CONSULTATION

Further information about the areas of interest described in this announcement may be obtained by contacting:

Dr. Robert J. Battjes  
Chief, Prevention Research Branch  
Division of Clinical Research  
National Institute on Drug Abuse  
Parklawn Building - Room 10A-16  
5600 Fishers Lane  
Rockville, Maryland 20857

Telephone: (301) 443-1514

#### VI. REVIEW PROCEDURES

Review procedures for applications to this program conform to peer review procedures applicable to all research grants programs sponsored by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). Applications are reviewed for scientific merit by an initial peer review group; the National Advisory Council on Drug Abuse performs a second review which may be based on policy as well as scientific merit considerations. After the Council provides final recommendations, applicants are notified of the results of the review by the Director, Officer of Extramural Policy and Project Review.

#### VII. REVIEW CRITERIA

The criteria for review of applications include overall quality and scientific merit of the proposed research. Scientific merit involves considerations such as originality, feasibility, soundness of the theoretical base in relation to previous research, soundness of approach and research design and data analysis plan, as well as the qualifications and experience of the investigators. The availability of

suitable facilities to perform the proposed studies, the supportive nature of the research environment, and the appropriateness of the proposed budget are also important evaluative factors. Additional criteria applicable to intervention research include appropriate commitments from and arrangements for collaboration with prevention programs and potential replicability and generalizability of the intervention.

#### VIII. AWARD CRITERIA

Criteria for funding of applications are based on the scientific merit of the proposal, as determined by peer review, and relevance to national need as reflected in NIDA's research priorities and plans. The availability of funds, the overall balance of the various topic areas in the program, the potential contribution of the study to the development and refinement of preventive intervention technology, and the cost effectiveness of the study also will be considered in determining which awards will be made.

#### ANNUAL RECEIPT AND REVIEW SCHEDULE

<u>Receipt Dates Renewal/New</u>	<u>Initial Review Group</u>	<u>Council Meeting</u>	<u>Earliest Possible Start Date</u>
Feb 1/Mar 1	June	Sept/Oct	December 1
Jun 1/Jul 1	October	Jan/Feb	April 1
Oct 1/Nov 1	February	May	July 1

#### IX. AVAILABILITY OF FUNDS

An estimated \$1-1.5 million will be budgeted for starting new and competing renewal prevention research projects in each of the fiscal years 1984, 1985, and 1986.

#### X. PERIOD OF SUPPORT

Applications may request support for a period of up to five (5) years. Most projects do not exceed three years. A competing continuation (i.e., a renewal) application may be submitted before the end of project period. A competing supplemental application may be submitted during an approved period of support to expand the scope or protocol during the project period.