NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 19, No. 7
February 16, 1990

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GRANTEE REQUIREMENTS WHEN DESCRIBING PROJECTS OR PROGRAMS FUNDED WITH FEDERAL MONEY

P.T. 34; K.W. 1014002, 1014006

Public Health Service

The purpose of this notice is to advise grantees about a requirement set forth in Section 511 of the Appropriations Act of the Department of Health and Human Services for fiscal year 1990 (Public Law 101-166). Specifically, Section 511 reads as follows:

"When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds, including but not limited to State and local governments, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources."

All recipients of Public Health Service (PHS) grants and cooperative agreements involving fiscal year 1990 appropriated funds must comply with the requirements of Section 511.

This provision is similar to the government-wide requirements of the "Stevens Amendment" contained in the Department of Defense Appropriations Act for fiscal year 1989, as published in the NIH GUIDE FOR GRANTS AND CONTRACTS, Vol. 18, No. 11, March 31, 1989.

Because this is the second consecutive fiscal year for this legislative provision, PHS has determined that the requirement for notice will remain in effect until December 8, 1994, unless rescinded at an earlier date, as prescribed in PHS Grants Administration Manual Circular 89.03, dated December 8, 1989.

DATED ANNOUNCEMENTS (RFPs AND RFAs)

THROMBOCYTOPENIC PURPURA IN HIV INFECTION

RFA AVAILABLE: 90-HL-07-B

P.T. 34, FF, II; K.W. 0715008, 0785070, 0710070, 1003018, 1002004

National Heart, Lung, and Blood Institute

Application Receipt Date: September 14, 1990

The Blood Diseases Branch of the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute (NHLBI), announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI. Awards to foreign institutions will be made only for research of very unusual merit, need, and promise.

This special program will support research on the pathophysiology of thrombocytopenias such as immune thrombocytopenic purpura and thrombotic thrombocytopenic purpura in persons infected with Human Immunodeficiency Virus. Information generated from this research will be utilized to develop new and more effective therapy of thrombocytopenias. This announcement may be of particular interest to investigators with expertise in hematology, immunology, platelet biochemistry, cell biology and retroviral infection.

The support mechanism for this five-year program will be the traditional, individual research grant. Although approximately $1,200,000 (for direct plus indirect costs) for this program is included in the financial plans for fiscal year 1991, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. The specific number of awards to be funded depends on the merit and scope of the applications received and the availability of funds.

Women and minority individuals should be included in the study population; otherwise a clear rationale for their exclusion must be provided in the application. Minority institutions are encouraged to apply, and other institutions are encouraged to establish collaborative arrangements with minority institutions.

Requests for copies of the RFA may be addressed to:

Dr. Pankaj Ganguly
Division of Blood Diseases and Resources
National Heart, Lung and Blood Institute
Federal Building, Room 5A12
Bethesda, MD 20892
Telephone: (301) 496-5911

GENETIC AND METABOLIC FACTORS IN OBESITY

RFA AVAILABLE: 90-HD/DK-05

P.T. 34, AA; K.W. 1002019, 0715135, 0715145, 0403001, 0411005

National Institute of Child Health and Human Development
National Institute of Diabetes and Digestive and Kidney Diseases

Application Receipt Date: June 11, 1990

The Endocrinology, Nutrition and Growth Branch of the Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD), and the Obesity, Eating Disorders, and Energy Regulation Program of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invite research grant applications for studies of genetic and metabolic factors associated with the development of obesity in childhood, adolescence and adulthood, as well as genetic and metabolic factors discernible in childhood that predict the onset of obesity later in life. By issuing this request for applications (RFA), the NICHD and the NIDDK are encouraging investigators' interest in a research area important to their mission. Applications are invited from investigators to enter a national competition for awards anticipated to be made by NICHD/NIDDK in fiscal year 1991.

Research Goals:

The primary focus of this RFA is to identify genetic and metabolic markers in children, adolescents and adults that predict the development of obesity. Recent evidence points to a genetic component of variations in energy expenditure and implies that a tendency to obesity is a consequence of increased efficiency of energy storage or conservation. Thus, analyses are needed of the basis for individual differences in energy expenditure for basal metabolic rate, thermic effect of food and activity. The identification of genetic components of energy metabolism in childhood could lead to the development of robust predictors of obesity in certain individuals and families. The ultimate goal is to discover genetic and metabolic markers of the pre-obese state in order to identify those individuals at high risk of becoming obese and to design preventive programs to meet their needs.

Linkage studies of candidate genes contributing to obesity should be performed in families predisposed to severe obesity and in animal models of hereditary obesity. Animal models may be useful for intensive metabolic studies of the pre-obese state in fetal and neonatal life. A search should be made of the central nervous system and hypothalamic-pituitary axis in these animals for neurohumoral factors leading to obesity. Differences in the mechanism leading to the development of obesity, including regional distribution of adipose tissue among subjects of different age, gender and ethnic origin, are important to ascertain and may be associated with different biological or genetic markers.

INCLUSION OF MINORITIES IN STUDY POPULATIONS: Applicants are urged to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in a given study, a clear rationale for their exclusion should be provided.

INCLUSION OF FEMALES IN STUDY POPULATIONS: Applicants are urged to consider the inclusion of females in study populations for all clinical research

efforts. Exceptions would be studies of diseases which exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If females are not to be included, a clear rationale should be provided for their exclusion.

In order to provide more precise information to the treatment community, it is recommended that publications resulting from research in which the study population was limited to one sex for any reason other than that the disease or condition studied exclusively affects that sex, should state, in the abstract summary, the gender of the population studied, e.g., "male patients," "male volunteers," "female patients," "female volunteers."

Mechanism of Support:

Applications in response to this RFA will be funded through the traditional individual research award programs of the NICHD and the NIDDK. This announcement is for a single competition with the deadline for receipt of applications of May 28, 1990. The earliest possible start date for grants would be April 1, 1991. It is anticipated that eight (8) grants will be awarded under this program, contingent upon receipt of a sufficient number of meritorious applications and the availability of funds.

Review Procedures and Criteria:

Applications will be reviewed by NICHD and NIDDK staff for responsiveness to the RFA. Applications judged to be nonresponsive will be returned. The applicant may resubmit the application and have it assigned for review in the same manner as unsolicited grant applications. An application will be considered nonresponsive to this RFA if it is identical to one already submitted to the NIH for review, unless the previous application is withdrawn.

Responsive applications may be subjected to a triage by a peer-review group to determine their scientific merit relative to the other applications received in response to this RFA. NIH will withdraw from competition those applications judged to be noncompetitive and notify the applicant and institutional business official. Those applications judged to be competitive will be further evaluated for scientific/technical merit by a review convened solely for this purpose by the Scientific Review Program, NICHD. Criteria for the initial review include the significance and originality of research goals and approaches; the feasibility of research and adequacy of the experimental design; the research experience and competence of the investigator(s) to conduct the proposed work; the adequacy of investigator effort devoted to the project; and the appropriateness of the project duration and cost relative to the work proposed. Following review by the Initial Review Group, applications will be evaluated by either Institute's Advisory Council for program relevance and policy issues before awards for meritorious proposals are made.

Application Procedure:

Applications should be submitted on Form PHS 398 (rev. 10/88), available in business or grants offices at most academic research institutions or from the Division of Research Grants, NIH. The complete RFA which contains background information and detailed instructions for application is available on request.

Additional Information:

Gilman D. Grave, M.D.
Chief, Endocrinology, Nutrition and Growth Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Executive Plaza North, Room 637
Bethesda, MD 20892
Telephone: (301) 496-5593

OR

Van S. Hubbard, M.D., Ph.D.
Director
Obesity, Eating Disorders, and Regulation Program
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Bldg., Room 3A18
Bethesda, MD 20892
Telephone: (301) 496-7823

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

This program is described in the catalog of Federal Domestic Assistance No. 13.848, Digestive Diseases and Nutrition. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and

Federal Regulations most specifically at 42 CFR Part 52 and CFR Part 74; this Executive Order 12372 or Health Systems Agency review.

NEW APPROACHES TO UNDERSTANDING TRANSFORMATION BY SV40 VIRUS, POLYOMAVIRUSES AND ADENOVIRUSES

RFA AVAILABLE: 90-CA-09

P.T. 34; K.W. 1002019, 1002045, 0755020, 0785140

National Cancer Institute

Letter of Intent Receipt Date: June 15, 1990
Application Receipt Date: August 24, 1990

INTRODUCTION

Simian virus 40 (SV40), mouse polyomavirus and adenovirus are DNA tumor viruses that are important model systems in the study of virally induced tumors in susceptible animals and the transformation of cells in culture. The primary cause of these neoplastic events is the introduction into cells of viral transforming genes that encode viral oncoproteins (SV40/polyoma T-antigens and the adenovirus E1 proteins). The transformation mechanism of these viruses is unknown, but recent evidence suggests that it is mediated by interactions with cellular proteins. Support for this model comes from the discovery of strong binding interactions between the viral oncoproteins and cellular proto- and anti-oncogene products. The first such association to be identified was the complex between middle T-antigen of polyomavirus and the product of the c-src proto-oncogene. More recently, the large T-antigens of SV40 and polyomavirus and the E1A protein of adenovirus each were shown to form complexes with the product of the Rb anti-oncogene (the retinoblastoma tumor suppressor gene). Current research is focused primarily on the interactions of these viral oncoproteins and cellular genes. However, cellular transformation is a complex mechanism involving many different metabolic and regulatory pathways in addition to the cellular processes associated with the Rb, p53 and c-src proteins. The goal of this Request for Applications (RFA) is to stimulate research on the interaction of viral oncoproteins with other cellular proteins that also may play a role in transformation.

The present RFA is for a single competition with deadlines of August 24, 1990 for receipt of applications and June 15, 1990 for receipt of letters of intent.

RESEARCH GOALS AND SCOPE

The major goal of this RFA is to stimulate research leading to an understanding of SV40, polyomavirus, and adenovirus transformation of cells in terms of the cellular processes which are altered by viral oncoproteins. The scope of this RFA includes studies of SV40, polyomaviruses (including BK virus and JC virus) and adenoviruses. Functional studies of viral oncoprotein-cellular protein complexes will be encouraged. Studies on the Rb, p53, and c-src interactions with oncoproteins should not be the focus of the proposed studies since they are already being extensively studied. (Applications focusing only on these will be considered unresponsive to the RFA and returned to investigators.). Where appropriate, some experiments dealing with these cellular proteins may be included for comparisons or to extend mechanistic ideas involving several cellular proteins. Examples of the research objectives (which are not all inclusive) that may be supported under this RFA are: 1) investigations of the impact of viral oncoprotein/cellular protein complexes on elements of cellular regulation related to transformation such as (but not limited to) second messenger regulation, cell cycle control, transactivation of cellular protein synthesis, and alteration of plasma membrane properties (e.g., contact inhibition); 2) development and application of new approaches to understand the regulatory activities of pertinent cellular proteins and second messenger molecules and assessment of the role of these processes in cellular transformation; 3) functional and structural characterization of cellular proteins that bind to viral oncoproteins; 4) development and application of new techniques and reagents to identify and characterize additional cellular proteins that bind to viral oncoproteins.

Where appropriate, collaborative arrangements to facilitate the achievement of research goals should be considered.

MECHANISM OF SUPPORT

This RFA will use the traditional National Institutes of Health (NIH) research project (R01). Responsibility for the planning, direction and execution of the proposed project will be solely that of the applicant. Except as stated in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50,000, revised January 1, 1987.

Approximately $750,000 in total costs per year for five (5) years will be committed to specifically fund applications which are submitted in response to this RFA. The funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to the present RFA should not exceed five (5) years. The earliest feasible start date for the initial awards will be April 1, 1991. Although this program is provided for in the financial plans of the National Cancer Institute (NCI), award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose. Non-profit and for-profit institutions, and foreign as well as domestic institutions, are eligible to apply.

This RFA is a one-time solicitation. Generally future unsolicited competing renewal applications will compete as research project applications with all other investigator-initiated applications and be reviewed in a standing Division of Research Grants study section. However, should the NCI determine that there is a sufficient continuing program need, NCI may announce a request for renewal applications.

INQUIRIES

Written or telephone inquiries concerning the objectives and scope of this RFA or about whether or not specific proposed research would be responsive are encouraged and should be directed to Dr. Susan B. Spring at the address below. The program director welcomes the opportunity to clarify any issues or questions from potential applicants.

Dr. Susan B. Spring
Program Director
DNA Virus Studies I
Biological Carcinogenesis Branch
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Room 540
Bethesda, MD 20892
Telephone: (301) 496-4533

EXTRAMURAL RESEARCH FACILITIES CONSTRUCTION PROJECTS

RFA AVAILABLE: OD-90-01

P.T. 34; K.W. 1014002, 1014006

National Institutes of Health

Letter of Intent Receipt Date: March 23, 1990
Application Receipt Date: May 7, 1990

BACKGROUND INFORMATION

The Congress has recently addressed the issue of extramural research facilities construction through the Fiscal Year 1990 appropriations process. The DHHS Appropriations Act for Fiscal Year 1990, Public Law 101-166, states in part that the Secretary shall transfer $14,800,000 from "appropriations available to each of the Institutes which shall be available for extramural facilities construction grants if authorized in law and if awarded competitively including such amount as he may deem appropriate for research animal production facilities." As stated, the appropriations are available for grant awards under current construction grant authority. Conference language accompanying the Appropriations Act further states that such construction projects be "identified by the Director of NIH as being of urgent national importance." In addition, the conference language states, "The conferees have deleted the earmarks for seven extramural construction projects as proposed by the Senate without prejudice. The conferees believe that these are meritorious projects which should be well received in the normal competitive process." Subsequently, with enactment of Public Law 101-190, the National Institutes of Health (NIH) is authorized to award a contract to "a public or nonprofit, private entity for constructing facilities for the

purpose of the development and breeding of specialized strains of mice (including inbred and mutant mice) for use in biomedical research." The NIH intends to award a grant for this purpose either under its existing authority, or pursuant to an amendment of Public Law 101-190 to authorize a grant award.

Given the breadth of activities that may be appropriate for support in response to these Congressional actions, the National Institutes of Health is issuing two concurrent Requests for Applications (RFA's) to solicit construction proposals. RFA Number OD-90-01 will be limited to applications for the construction of facilities for biomedical research and/or services to support such research (which may include a laboratory animal production component); RFA Number OD-90-02 will be limited to applications for construction of a large-scale, specialized, mouse production facility. The main objective of each is to facilitate the conduct of biomedical research by providing funds for construction of new facilities and for the purchase of fixed equipment essential for the operation of these facilities.

The purpose of this RFA is to invite grant applications for the construction of research/research support facilities.

OBJECTIVES AND SCOPE

Support may be requested for the construction of new facilities and additions or renovations to existing facilities to meet the biomedical research or biomedical research support needs of an institution, or of a research group at that institution or elsewhere that utilizes the resources of that institution. The purpose of the proposed facility must be within the scope of one of the statutes authorizing the awards. Those statutes authorize construction grants which would benefit the fields of cancer, vision and heart, lung and blood research. Associated fixed equipment necessary for operation of these facilities may also be requested as part of the application.

MECHANISM OF SUPPORT

Any domestic non-Federal institution, organization, or association which conducts or supports biomedical research is eligible to apply. Construction grant applications from non-Federal institutions, organizations, or associations, previously submitted to and peer-reviewed by NIH but which currently remain unfunded, will automatically be considered under this RFA without the submission of a new application if they are responsive to the objectives described above. Up to $2,000,000 of the $4,800,000 available under this RFA has been identified for funding of the highest rated of the applications in this category. The remainder of these applications will be considered along with the applications submitted in response to this RFA. However, if the design or plans for construction differ markedly from that which was peer-reviewed, a new application will be required. These applicants are strongly encouraged to request a copy of the complete RFA and special instructions for completion of the application to determine their need to submit additional assurances and certifications, as well as other information they may feel relevant to their proposal in relation to the RFA.

NIH staff will verify application and award eligibility. Those judged to be unresponsive or ineligible will be returned to the investigator.

The award mechanism will be the construction grant award. Awards will be administered under Federal Regulation 42 CFR Part 74 - Administration of Grants, and for cancer construction projects, 42 CFR Part 52b. Organizations operated for profit are directed to 45 CFR 74.710 for guidance regarding title to real property and equipment acquired under this program.

This one-time solicitation based on the Fiscal Year 1990 appropriation will make available $2,800,000 for this initiative. Up to 75 percent of the allowable costs of a project may be provided, not to exceed $2,800,000. Prior to a grant award, the applicant must provide an assurance of required matching funds and that other funds have been secured to meet any projected costs in excess of the award amount. Requests of less than $500,000 will not be accepted. No indirect costs or continuation costs will be awarded.

For additional information and a copy of the complete RFA and application Standard Form 424 materials, please contact:

Mr. Kenneth Brow
Chief, Research Facilities Branch
Division of Cancer Biology and Diagnosis
National Cancer Institute
Executive Plaza North, Room 300
Bethesda, MD 20892
Telephone: (301) 496-8534

Grants for research facilities construction programs of the National Institutes of Health are subject to Executive Order 12372. Awards will be made under the construction grant authorities in the Public Health Service Act, Sections 413(b)6(B), 421(b)(2)(B), and 455, and administered under PHS grant policies and Federal Regulations 45 CFR Part 74 and 42 CFR Part 52b for cancer construction only. This program is described in the Catalog of Federal Domestic Assistance, Number 13.392, Cancer-Construction.

CONSTRUCTION OF A MOUSE PRODUCTION FACILITY

RFA AVAILABLE: OD-90-02

P.T. 34; K.W. 1002002, 1014002, 1014006

National Institutes of Health

Letter of Intent Receipt Date: March 23, 1990
Application Receipt Date: May 7, 1990

BACKGROUND INFORMATION

The Congress has recently addressed the issue of extramural research facilities construction through the Fiscal Year 1990 appropriations process. The DHHS Appropriations Act for Fiscal Year 1990, Public Law 101-166, states in part that the Secretary shall transfer $14,800,000 from "appropriations available to each of the Institutes which shall be available for extramural facilities construction grants if authorized in law and if awarded competitively including such amount as he may deem appropriate for research animal production facilities." Conference language accompanying the Appropriations Act further states that such construction projects be "identified by the Director of NIH as being of urgent national importance." In addition, the conference language states, "The conferees have deleted the earmarks for seven extramural construction projects as proposed by the Senate without prejudice. The conferees believe that these are meritorious projects which should be well received in the normal competitive process." Subsequently, with enactment of Public Law 101-190, the National Institutes of Health (NIH) is authorized to award a contract to "a public or nonprofit, private entity for constructing facilities for the purpose of the development and breeding of specialized strains of mice (including inbred and mutant mice) for use in biomedical research." The NIH intends to award a grant for this purpose either under its existing authority or pursuant to an amendment of Public Law 101-190 to authorize a grant award.

Given the breadth of activities that may be appropriate for support in response to these Congressional actions, NIH is issuing two concurrent Requests for Applications (RFA's) to solicit construction proposals. RFA Number OD-90-01 will be limited to applications for the construction of facilities for biomedical research and/or services to support such research (which may include a laboratory animal production component); RFA Number OD-90-02 will be limited to applications for construction of a large-scale, specialized, mouse production facility. The main objective of each is to facilitate the conduct of biomedical research by providing funds for construction of new facilities and for the purchase of fixed equipment essential for the operation of these facilities.

The purpose of this RFA is to invite grant applications for the construction of a mouse production facility.

OBJECTIVES AND SCOPE

Support may be requested for the construction of new facilities and additions or renovations to existing facilities which will be dedicated to the breeding and production of specialized strains of mice, including inbred and mutant mice, necessary to meet the nation's needs in conducting biomedical research on a broad range of topics. Associated fixed equipment necessary for operation of these facilities may also be requested as part of the application.

MECHANISM OF SUPPORT

Any domestic non-Federal public or non-profit private institution, organization, or association which conducts or supports biomedical research is eligible to apply.

NIH staff will verify application and award eligibility. Those judged to be unresponsive or ineligible will be returned to the investigator.

The award mechanism will be the construction grant award. Awards will be administered under Federal Regulation 45 CFR Part 74 - Administration of Grants, and for cancer construction projects 42 CFR Part 52b.

This one-time solicitation based on the Fiscal Year 1990 appropriation will make available $10,000,000 for this initiative. Final amount to be determined based on the peer-review evaluation. Up to 75 percent of the allowable costs of a project may be provided, not to exceed $10,000,000. Prior to a grant award, the applicant must provide an assurance of required matching funds and that other funds have been secured to meet any projected costs in excess of the award amount. Requests of less than $500,000 will not be accepted. No indirect costs or continuation costs will be awarded.

For additional information and a copy of the complete RFA and application Standard Form 424 materials, please contact:

Mr. Kenneth Brow
Chief, Research Facilities Branch
Division of Cancer Biology and Diagnosis
National Cancer Institute
Executive Plaza North, Room 300
Bethesda, MD 20892
Telephone: (301) 496-8534

Grants for research facilities construction programs of the National Institutes of Health are subject to Executive Order 12372. All awards will be made either under the authority of the Public Health Service Act, Title IV, Section 413(b)6(A) as amended by Public Law 99-158 (42 USC 285a-2) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52b and 45 CFR Part 74, or under the authority of an appropriation amendment of Public Law 101-190 to authorize a grant award. This program is described in the Catalog of Federal Domestic Assistance, Number 13.392, Cancer-Construction.

ONGOING PROGRAM ANNOUNCEMENTS

SMALL GRANTS PROGRAM

P.T. 34; K.W. 0755018, 0755015, 0403004

National Heart, Lung, and Blood Institute

I. INTRODUCTION

The National Heart, Lung, and Blood Institute (NHLBI) supports an extensive portfolio of clinical trial, population research, and demonstration and education studies that result in gathering large amounts of data essential to the specific aims of the original project. Often, these types of studies present unique opportunities to look at unusual or unanticipated outcomes. At present, there is no mechanism specifically targeted for the analyses of data not originally documented in the specific aims of the proposal. Therefore, the NHLBI is instituting a small grant program to allow investigators the opportunity to analyze areas of interest from readily available data bases.

II. PURPOSE

The NHLBI Small Grant Program is intended to provide limited support for meritorious research projects to support extended analyses of research data generated by clinical trial, population research, and demonstration and education studies.

III. MECHANISM OF SUPPORT

The mechanism of support will be the NIH small grant (R03). Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. Except as otherwise stated in this announcement, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50,000, revised January 1, 1987.

The small grant (R03) mechanism provides research support specifically limited in time and amount for studies in categorical program areas. Small grants provide flexibility for initiating studies, which are generally for short-term projects and are non-renewable. Furthermore, the time interval from application to funding is shortened under the R03 mechanism, thus allowing new ideas to be investigated or pursued in a more expeditious manner.

IV. TERMS AND CONDITIONS OF THE AWARD

The proposed project may be related to, but the aims must be distinctly different from those of pending grant applications or funded research projects. The request may not be used to supplement projects currently supported by Federal or non-Federal funds, or to provide interim support for projects under review by the Public Health Service.

Applicants may request up to $50,000 (direct costs) per year for a 2-year grant period for technical assistance, supplies, and small equipment required by the project. Compensation for the principal investigator may be requested only with strong justification.

V. ELIGIBILITY

Domestic non-profit and for-profit institutions are eligible to apply. Foreign institutions are ineligible. This award is appropriate for all investigators who document that they have access to, and demonstrate that they understand the data necessary to meet the specific aims and objectives of the proposed project.

VI. REVIEW PROCEDURES AND CRITERIA

A. Review Procedures

Upon receipt, applications will be evaluated by NHLBI staff to determine whether they are responsive to the program requirements and criteria stated in this announcement. Applications that are judged non-responsive will be returned to the applicant. Questions concerning the responsiveness of the proposed research should be directed to staff as described in Section VIII.

A review committee convened by the Division of Extramural Affairs, NHLBI, will conduct the initial scientific merit review of applications submitted in response to this announcement. Second level review will be conducted by NHLBI senior program staff.

B. Review Criteria

The factors to be considered in the evaluation of each application will be similar to those used in the review of traditional research project grant applications. The major factors to be considered in the evaluation of application will include:

1. The scientific merit of the proposed project, including the originality and feasibility of the approach, and the adequacy of the experimental design;

2. The competence of the investigator(s) to accomplish the proposed research goals, and the effort that they will devote to the project;

3. The adequacy of facilities for performance of the proposed research;

4. Documentation that the principal investigator will have access to the data to be analyzed.

5. Demonstration that the investigator(s) have an understanding of the extent and limits of the original data base, and how it may affect the proposed research.

VII. METHOD OF APPLYING

The research grant application form PHS 398 (revised 10/88) must be used in applying for these grants. These forms are available at most institutional business offices, or from the Office of Grant Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892.

Please refer to the supplemental instructions at the end of this announcement when completing the application. In addition, it is important to include with the application, written documentation that the data to be examined will be available to the principal investigator.

Send or deliver the original and FOUR, signed exact photocopies in one package to the Division of Research Grants, using the mailing label enclosed in the application kit, as specified in the General Instructions.

In order to expedite the review of the application, mail or deliver TWO additional exact photocopies of the signed application to:

Chief,
Contracts, Clinical Trials and Training Review Section
Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 548
Bethesda, MD 20892

The review schedule is planned as follows:

Application Receipt Date	Initial Review	Earliest Possible Funding Date
October 1	Feb/Mar	May
February 1	May/June	August
June 1	Oct/Nov	January

VIII. STAFF CONTACTS

For further information regarding the scientific review, prospective applicants should contact the Chief, Contracts, Clinical Trials and Training Review Section, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, at the address listed above.

For inquiries about the programmatic aspects of this announcement, applicants should contact:

Director
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 416
Bethesda, MD 20892

Director
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Federal Building, Room 212
Bethesda, MD 20892

Director
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A16
Bethesda, MD 20892

Charles Hollingsworth, Dr. P.H.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 518
Bethesda, MD 20892

The programs of the Institute are described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases; No. 13.838, Lung Diseases; and No. 13.839, Blood Diseases and Resources. Awards will be made under authority of the Public Health Service Act, Title IV, Section 421(b)(2)(B) (Public Law 99-158; 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 the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SUPPLEMENTAL INSTRUCTIONS FOR THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE SMALL GRANTS PROGRAM

Applications are to be submitted on the standard PHS research grant application form PHS-398, Rev. 10/88, following the instructions supplied with those forms EXCEPT for the items listed below (See pages 12-23, Instructions Sheet for PHS-389):

SECTION 1.

1. Face page of application:

Item 2: Mark "YES" and enter: Small Grants Program, NHLBI;

Item 6: A maximum of 2 years of support may be requested;

Item 10: Not applicable; Mark N/A.

2. Application page 4 and 5:

Detailed budget for the first and second year must be limited to the following categories: personnel (technical assistance), supplies, and small equipment items. The total award request for a 2-year period may not exceed a maximum of $100,000 direct costs, or $50,000 direct costs per year.

3. Biographical data:

Not to exceed one page for principal investigator. List most important positions and relevant publications.

SECTION 2.

1. Introduction: Use only for revised or amended applications. Otherwise, not applicable.

2. Research Plan:

A. Specific Aims: Not to exceed one-half page.

B. Background and Significance: Not to exceed one page.

C. Progress Report/Preliminary Studies: A progress report is not applicable. If data from preliminary studies are available, the report should not exceed one-half page.

D. Experimental Design and Methods: Not to exceed three pages.

E. Consortium/Contractual Arrangements: Not to exceed one-half page.

F. Literature Cited: Not to exceed one page.

NINTH ANNOUNCEMENT - TRANSFUSION MEDICINE ACADEMIC AWARD

P.T. 34; K.W. 0750010, 0710030, 0785035

National Heart, Lung, and Blood Institute

Application Receipt Date: November 20, 1990

The Transfusion Medicine Academic Award (TMAA) was initiated in January 1983, to: (1) stimulate the development of multidisciplinary curricula in transfusion medicine, and (2) permit the awardee to broaden his or her expertise in transfusion medicine so as to contribute more effectively to the teaching, research, and clinical needs of this discipline. "Transfusion Medicine" is defined as a multidisciplinary area concerned with the proper use or removal of blood and its components in the treatment or prevention of disease states. Schools of medicine, osteopathy, or veterinary medicine (United States or its possessions and territories), singly or in concert, are eligible to apply for one 5-year TMAA (nonrenewable), providing they possess the requisite blood bank, patient care, and research facilities required for such an activity. In the case of veterinary medicine, the focus of the program must be on its applicability to human health and disease and requires a demonstrated collaborative program between schools of animal and human medicine. The TMAA may provide salary, fringe benefits, and supporting costs of up to $85,000 annually to faculty members who are established investigators, and skilled organizers and negotiators. The number of awards will depend on the availability of funds. MINORITY MEDICAL SCHOOLS ARE ENCOURAGED TO APPLY.

THIS IS THE NINTH AND FINAL ANNOUNCEMENT FOR TRANSFUSION MEDICINE ACADEMIC AWARDS.

The Transfusion Medicine Academic Award encourages the development of teaching and research programs in transfusion medicine. Teaching, research, and clinical responsibilities in transfusion medicine usually have not been coordinated into a definable program but are dispersed among basic and clinical science disciplines and among activities of the local transfusion services or blood center facility. It is important to note that a transfusion medicine curriculum may not require additional curriculum time; existing course time and teaching materials, as 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 department.

This award is also intended to:

- o attract to the field of transfusion medicine outstanding students and promising young clinicians and scientists who can serve in the teaching, research, and clinical aspects of transfusion medicine;
- o encourage the development of faculty capable of providing appropriate instruction in the field of transfusion medicine;
- o facilitate interchange of information, and evaluation and educational techniques among research, medical, and blood service communities; and
- o enable the grantee institution to develop a continuing transfusion medicine program, using local support, when this Award terminates.

Requests for the TMAA Program Guidelines should be directed to:

Fann Harding, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 5A08
Bethesda, MD 20892
Telephone: (301) 496-1817

The programs of the Division of Blood Diseases and Resources of the National Heart, Lung, and Blood Institute are identified in the Catalog of Federal Domestic Assistance, number 13.839. 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 the intergovernmental review requirements of Executive Order 12372, or to Health Systems Agency Review.

COMPREHENSIVE PREVENTION RESEARCH IN DRUG ABUSE

P.T. 34; K.W. 0404009, 0745027, 0404000, 0403004

National Institute on Drug Abuse

PURPOSE

The purpose of this announcement is to encourage rigorous scientific study of multiple component substance abuse prevention technologies implemented across several social systems including schools, families, the peer group, the workplace, and residential neighborhoods to determine their efficacy in preventing the onset of drug use and progression to abuse. Studies should involve the use of randomized controlled clinical trials or well-controlled quasi-experimental research designs. A secondary goal of the research is the development of psychometrically-sound measures, instruments and data collection procedures to assess the process, outcome, and impact of comprehensive prevention strategies. Special attention should be given to populations at high risk of drug use onset and progression, particularly those living in communities threatened by drug distribution activities. Research should focus upon a broad spectrum of drug behaviors, such as the use of tobacco products, marijuana, cocaine/crack, methamphetamines, and the prevention of polydrug use/abuse.

RESEARCH OBJECTIVES

Epidemiologic research over the last ten years indicates a significant decrease in the use of marijuana and, more recently, a decline in the use of cocaine. Analyses of these data suggest that changes in drug use occurred because of an increased perception of the harmful consequences of drug use and abuse and personal and social disapproval of the use of illict substances. Controlled intervention research indicates that comprehensive drug prevention programs can prevent the incidence and reduce the prevalence of the use of cigarettes, alcohol, marijuana, and cocaine for adolescents exposed to comprehensive prevention programs in comparison to those youth not receiving these interventions. Comprehensive drug abuse prevention includes systematic implementation of multiple components to include: effective use of the media; drug education and intervention in the schools and workplace; parent education and formation of self-help groups; development of community coalitions to combat drug abuse and drug distribution; and enactment and enforcement of salient anti-drug policies within schools, the workplace, and communities.

Research on the efficacy and effectiveness of comprehensive drug prevention programs is needed in two general areas: 1) to assess the long-term effects of comprehensive drug prevention, and 2) to determine the generalizability of these research findings to high-risk populations. Research focused upon the individual, the social/physical environment, and communities is required. Relevant to the individual, research indicates that a promising approach to drug prevention would be one that promotes self-regulated health behavior change. Intervention research is needed to test strategies that enhance the vital role played by family, peers, neighbors, teachers, and others to encourage and reinforce this process. Finally, research is needed to test drug preventive interventions that involve community organizations and institutions to establish an environment in which durable, positive self-regulated behavior change can be developed and maintained. This program will also support research to further develop and test process, outcome, and impact evaluation research techniques appropriate for comprehensive drug prevention programs.

It is recommended that research applications submitted under this grant announcement focus initially upon pre-adolescence through early adulthood. However, an applicant may propose expanding the research to include additional stages of the life span during later phases of the same study or planned for subsequent, related research. Proposed studies must directly assess program and research questions pertinent to subpopulations and communities that may be at high risk to drug use/abuse and related problems.

INCLUSION OF MINORITIES IN STUDY POPULATIONS

Applicants are urged to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in a given study, a clear rationale for their exclusion should be provided.

INCLUSION OF FEMALES IN STUDY POPULATIONS

Applicants are urged to consider the inclusion of females in study populations for all clinical research efforts. Exceptions would be studies of diseases which exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If females are not to be included, a clear rationale should be provided for their exclusion.

In order to provide more precise information to the treatment community, it is recommended that publications resulting from research in which the study population was limited to one sex for any reason other than that the disease or condition studied exclusively affects that sex, should state, in the abstract summary, the gender of the population studied, e.g., "male patients," "male volunteers," "female patients," "female volunteers."

MECHANISM OF SUPPORT

Support mechanisms include: Research Projects (R01), and Program Projects (P01).

ELIGIBILITY

Applications may be submitted by public or private nonprofit or for-profit organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply. Applications are especially encouraged from State governments with research units and/or State governments collaborating with university-based research units.

APPLICATION PROCEDURES

Applicants should use the research grant application form PHS 398 (Rev. 10/88). The title of this announcement "COMPREHENSIVE PREVENTION RESEARCH IN DRUG ABUSE" should be typed in item number 2 on the face page of the PHS 398 application form and check the YES box.

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

Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

RECEIPT AND REVIEW SCHEDULE

Receipt Date	Initial Review	Advisory Council	Earliest Start Date
April 9, 1990	June/July	Sept. 1990	Sept. 1990

Thereafter, the following application receipt dates and review schedule will apply. Applications received after April 9, 1990, will be reviewed in the next appropriate review schedule, as indicated below.

Receipt Date	Initial Review	Advisory Council	Earliest Start Date
Feb. 1/Mar.1*	June/July	Sept./Oct.	Dec. 1
June 1/July 1*	Oct./Nov.	Jan./Feb.	April 1
Oct. 1/Nov. 1*	Feb./Mar.	May/June	July 1

*Amended applications (new or renewal) are to be submitted on these dates apply for R01s only.

Consequences of Late Submission: Applications received after the above receipt dates are subject to the next review cycle or may be returned to the applicant.

REVIEW PROCESS AND CRITERIA

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. Criteria for scientific/technical merit review of applications will include the following: significance and originality from a scientific or technical standpoint of the goals of the proposed research; adequacy of the methodology proposed to carry out the research; feasibility of the proposed research; qualifications and research experience of the principal investigator and other key personnel; availability of adequate facilities, other resources, and collaborative arrangements necessary for the research; appropriateness of budget estimates for the proposed research activities; and adequacy of provisions for the protection of human subjects, as applicable.

AWARD CRITERIA

Applications recommended for approval by an appropriate National Advisory Council will be considered for funding on the basis of overall scientific, clinical and technical merit of the proposal as determined by peer review, appropriateness of budget estimates, program needs and balance, policy considerations, adequacy of provisions for the protection of human subjects, and availability of funds.

INQUIRIES

Further information and consultation on program requirements relevant to prevention/intervention research can be obtained from:

Dr. William Bukoski
Program Director and Acting Chief, Intervention Section
National Institute on Drug Abuse
5600 Fishers Lane, Room 10-A-20
Rockville, MD 20857
Telephone: (301) 443-1514

This program is described in the Catalog of Federal Domestic Assistance No. 13.279. Grants will be awarded under the authority of sections 301 and 515 of the Public Health Service Act (42 USC 241 and 290cc).

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS: 5333 Westbard Avenue, Bethesda, MD 20816

*U.S.GOVERNMENT PRINTING OFFICE:1990-261-138:00036