

NIH Guide for Grants and Contracts

Vol. 12, No. 8, August 19, 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 you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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ERRATUM

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

An Announcement in the **July 15, 1983, NIH Guide for Grants and Contracts (Vol. 12, No. 7)** printed on page 7, from the above Institutes, had an error in paragraph A under I. ELIGIBILITY. The correct paragraph A is as follows:

- A. These awards are designed to provide an intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health professional degrees in the clinical sciences (M.D., D.D.S., D.V.M., D.O. or equivalent). Physicians holding the Ph.D. are ineligible. Candidates ordinarily will have completed at least one post-graduate year of clinical training by the time the award is made.

There is a slight change on page 13 in the title of the Director and the telephone number under the heading listed for the **National Institute of Allergy and Infectious Diseases**. The correct title and telephone number for John W. Diggs, Ph.D. is as follows:

Director, Extramural Activities Program

(301) 496-7291

NOTICEPROGRAM PROJECT GRANT APPLICATIONSAVAILABILITY OF REVISED NCI GUIDELINES**NATIONAL INSTITUTES OF HEALTH**

The National Institutes of Health (NIH) makes a substantial commitment to the support of research through the program project grant mechanism. Approximately one-fifth of the research project support is currently provided through the program project grant. A program project grant is intended to support a broadly based multidisciplinary research program that has a well-defined central research focus or objective. The grant consists of a number of interrelated projects that contribute to the program objective. The grant may also include common supporting resources (cores) required for the conduct of the component research projects. Interrelationships between component projects result in a greater contribution to the program goals than if each project were pursued separately.

In recent years, NIH staff have noted with concern the differing concepts of what appropriately constitutes a program project. Members of the research community have expressed similar concerns, focusing primarily on the adequacy and uniformity of the peer review process for program projects. A committee of NIH staff responsible for the review process is developing new proposed guidance for agency staff and applicants. Any major changes will reflect a consensus of all institutes using the program project mechanism. Concurrently, a subcommittee of the National Cancer Advisory Board (NCAB) has studied this award mechanism in detail and has recommended the adoption of several changes in NCI's program project guidelines. In particular, the NCAB has recommended greater attention to the cohesiveness of the entire program project in the review process. The NCAB suggests that individual projects be reviewed for scientific merit not only as free-standing entities but also in the context of the program project as a whole. In this vein, some projects may be judged irrelevant to the program while other projects may be recognized as of particular value when related to the program as a whole.

NIH endorses the intent of the NCAB's recommendations and reminds prospective applicants that it is the responsibility of the principal investigator to bring together a cohesive, synergistic program focused on a central theme. Inclusion of projects which are of marginal quality or are unrelated to the program as a whole reflects poorly on the leadership of the principal investigator.

NIH is continuing to explore ways in which the review process might better ensure that individual projects are reviewed both on their own merits and as contributors to the program project as a whole. In the meantime, applicants are encouraged to structure program project applications to reflect the intended synergistic relationships of the component projects.

NCI's revised guidelines will be implemented with respect to applications received for the October 1983 deadline. Copies of the guidelines will be sent to all NCI program

project grantees and to others who have indicated their intention to submit an application for the October receipt date, and will be available on request from:

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

NOTICE

SITE VISITS TO ANIMAL CARE FACILITIES

NATIONAL INSTITUTES OF HEALTH

As announced in the **June 17, 1983, NIH Guide for Grants and Contracts**, the National Institutes of Health (NIH), Office of Extramural Research and Training (OERT), has embarked on a series of ten site visits to awardee institutions to assess the adequacy of the current process for promoting proper care and use of animals in biomedical research funded by NIH. The institutions were selected randomly, one from each of the ten Department of Health and Human Services (DHHS) geographic regions within three categories of total annual NIH funding. In addition, the sample was designed to ensure that none of the ten institutions selected were among those accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). The University of Washington was among those named because at the time the selection was made NIH had not been notified that the University had received full accreditation. The site visit, however, will be conducted as scheduled even though the NIH is now aware that the University of Washington has received AAALAC accreditation.

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH IN ARTERIOSCLEROSIS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Heart, Lung, and Blood Institute announces its intent to allow current Specialized Centers of Research (SCOR) in Arteriosclerosis to compete for designation as National Research and Demonstration Centers (NRDC). To attain this status, current SCOR grantees will have to submit a competing supplemental application that details plans for demonstration and education research activities that are thematically related to arteriosclerosis and for core activities that will serve to coordinate and integrate the various components of the NRDC.

A Request for Applications (RFA) has been issued to the current SCOR grantees in Arteriosclerosis. The application receipt date is December 1, 1983; after initial technical merit review these competing applications will be reviewed by the National Heart, Lung, and Blood Advisory Council in May 1984. The award date for successful applicants will be June 1 or July 1 and the duration of these supplemental grants will be approximately 2-1/2 years.

Although the competition is limited to current SCOR grantees in Arteriosclerosis, other interested parties may receive an informational copy of the RFA by writing to the following:

Dr. Bernard J. Krask
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 4C12
Bethesda, Maryland

The issuance of the RFA for NRDC on Arteriosclerosis does not imply any intent to discontinue support for a separate and distinct Arteriosclerosis SCOR program. The NRDC and SCOR grant mechanisms of support, together with that of investigator-initiated research, training, and contract support, represent means to promote the Institute's comprehensive research program; the support of each of these mechanisms will be continued.

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DCCP-CPCB-83-13

NEW NATURAL AND SYNTHETIC INHIBITORS OF CARCINOGENESIS

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 15, 1983

The Division of Cancer Cause and Prevention (DCCP) of the National Cancer Institute (NCI) invites grant applications from interested investigators for studies on new natural and synthetic inhibitors of carcinogenesis. The proposed studies would seek, as their major objectives, to determine the extent to which inhibitors of carcinogenesis occur naturally, as in foods consumed by man, the role and potential of these substances as cancer preventive agents, their mechanisms of action, and their pharmacokinetic properties.

Grants are awarded to profit and to nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary NIH grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to the RFA will be reviewed by the same National Institutes of Health (NIH) Initial Review Group.

The present RFA announcement is for a single competition with a specified deadline of November 15, 1983, for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

- I. BACKGROUND
- II. OBJECTIVES AND SCOPE
- III. MECHANISM
- IV. REVIEW PROCEDURES AND CRITERIA
- V. METHOD OF APPLYING
- VI. INQUIRIES

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law-78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

I. BACKGROUND

Strategies for cancer prevention involving reduction or elimination of human exposure to environmental carcinogens may not always be possible.

Further, significant portions of the human cancer burden may be due to endogenous carcinogens, cocarcinogens, and promoters. Inhibition of the development of cancer by administration of chemical, biochemical, and biological compounds, which directly and/or indirectly inhibit the cancer-producing effects of neoplastic and promoting substances, may offer an alternate approach to cancer prevention.

Naturally occurring substances are one of the most promising sources of these inhibitors of carcinogenesis, particularly those which are present in foods consumed by man. In this regard, epidemiologic studies have implicated diet and nutrition as important factors in the occurrence of human cancer, with both positive and negative correlations indicated for incidence or mortality at many sites with consumption of particular nutrients or food items. High intakes of legumes and cereals such as corn, rice, and beans have been associated with reduced risk for breast, colon, and prostatic cancers, for example, and an increased consumption of cruciferous vegetables such as cabbage, broccoli, Brussels sprouts, and turnips has been associated with decreased cancer frequencies for colon, rectum, and bladder. Experimental studies, also, in several animal models have demonstrated in direct feeding studies that certain foods or crude food components provide significant protection against chemically induced or radiation induced tumorigenesis. Examples include the cruciferous vegetables (cabbage, cauliflower, broccoli, Brussels sprouts), celery, orange oil, beverage sources such as coffee and cocoa beans, and edible legumes such as soybeans or soybean concentrates. Diverse types of chemical compounds present in these foods have also been shown to inhibit the neoplastic process, including phenols, coumarins, isothiocyanates, flavonoids, and indoles. Topically applied onion and garlic oils, too, appear to act as anti-promoting agents in two-stage mouse skin tumorigenesis. Further, in *in vitro* studies a large number of fruits and vegetables have been shown to contain antimutagenic or "desmutagenic" factors with activity against several mutagens and carcinogens. Finally, some naturally occurring plant phenols have been shown to inhibit the mutagenicity and cytotoxicity of the only known ultimate carcinogenic metabolite of the polycyclic aromatic hydrocarbon, benzo(a)pyrene, in bacterial and mammalian cell assays; and naturally occurring tetrapyrroles, both porphyrins and open chain types, have also been shown to inhibit mutagenesis induced by certain classes of carcinogens. All of these laboratory and epidemiologic results suggest the possible importance to human cancer prevention of naturally occurring inhibitors of carcinogenesis, particularly those occurring as constituents of the human diet. The purpose of this RFA is to encourage additional research on these substances since their extent of occurrence, their role and potential as cancer preventive agents, and how their protective effects might be enhanced are little known at the present time.

II. OBJECTIVES AND SCOPE

Research conducted under this RFA will seek to expand knowledge and understanding of naturally occurring inhibitors of carcinogenesis and their potential for human cancer prevention. However, it is not the intent of this RFA to stimulate studies on retinoids (including natural vitamin A), vitamins C and E, or selenium; applications dealing with these agents will be considered non-

responsive. Areas for emphasis (A, B, C, D) are shown below. All applications must respond to area A and at least one of the other areas (B, C, D) to be considered responsive to this RFA.

- A. Identification of new naturally occurring inhibitors with special attention to appropriate methods of isolation of specific constituents or chemical forms. It is expected that foods consumed by man will constitute a primary source for these efforts. In this regard, the selected methods of isolation of specific constituents or chemicals from natural products or food materials should be the same as, or similar to, that of the natural food intake of man. That is to say, drastic methods of isolation should be avoided wherever possible, and where employed, should be specifically and carefully designed for the specific step(s) necessary. Isolation, purification, and identification procedures which are developed for these inhibitors should represent quantitative, reproducible, analytical methodologies which will permit analyses for their precise content in foods, so that a data-base can be established for such food-derived anti-carcinogenic substances.
- B. Thorough studies on mechanisms of action of newly identified inhibitors and their pharmacokinetics. Studies on mechanisms of action are a most important part of the proposed efforts which are regarded not simply as a wide range screening of foods or other natural products for inhibitors of carcinogenesis, but as integrated studies which will not only use the most advanced knowledge, techniques, and instrumentation of modern natural product chemistry for isolation, purification, and identification of inhibitors, but will also seek to determine the biochemical and biological bases for the inhibitions which are found. Very little is known about the absorption, distribution, metabolism, and excretion of natural inhibitors of carcinogenesis; studies on their pharmacokinetics will importantly complement studies on their mechanisms of action.
- C. Improvement in current systems and development of new systems for identifying and studying naturally occurring inhibitors. A critical need exists for improvement of present models, and for development of new models, for identifying new naturally occurring inhibitors of carcinogenesis. This need exists for both in vitro and in vivo systems, and for both short-term reliable assay systems and systems for long-term studies. Development of shorter term assays for anti-promotion agents or anticarcinogenic agents active during the post-initiation phases of the neoplastic process is particularly needed.
- D. Determination of the range of conditions under which efficacy of natural inhibitors is demonstrable. These investigations should include dose-response studies, species in which inhibition can be demonstrated, the range of carcinogens or spontaneous tumors against which activity exists, the anti-promoting activity of the natural inhibitor or its activity during the post-initiation period, the anti-initiation capacity of the agent, the precise time relationships between administration of inhibitor and carcinogen necessary for inhibition of tumorigenesis, and potential additive, synergistic or potentiating properties which the inhibitor may have in conjunction with other naturally occurring constituents of the diet.

Applications will also be accepted in which research is proposed on new synthetic inhibitors of carcinogenesis. However, such studies must fall into

the areas of research given above, and substantial justification for performing the studies must be given. Such justification must be equivalent to that indicated in the Background section of this RFA (Section I). Analogues of known natural inhibitors of carcinogenesis synthesized as part of structure-activity investigations are one example of synthetic compounds acceptable for study. Such studies can be considered further attempts at defining mechanisms of action and pharmacokinetic properties with the aim of optimizing efficacy, decreasing toxicity, and altering distribution, disposition, and bioavailability.

III. MECHANISM OF SUPPORT

This RFA will use the traditional National Institutes of Health grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed four years. The intent is to fund multiple projects, with total costs amounting to approximately \$1.0 million for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by (1) an appropriate review panel of the Division of Research Grants, National Institutes of Health, and (2) the National Cancer Advisory Board. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals and fall within one or more of the specified research categories (see II. OBJECTIVES AND SCOPE). If the application is judged by the National Cancer Institute not to be responsive, the applicant will have the opportunity of having the application considered along with other unsolicited applications received by the National Institutes of Health in the review cycle which is current at that time

The factors considered by the initial review group in evaluating each response to the RFA will be:

1. Scientific merit of research approach, design, and methodology.
2. Scientific, technical, or medical significance and originality of the proposed research.
3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.

4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
5. Adequacy of existing/proposed facilities, equipment, instrumentation, and other resources. Applications which specify a proposed use of human cells/tissues/fluids/excreta, need to provide assurance and details concerning the nature, source, and availability of those specimens.
6. Adequacy of practices, procedures, and facilities relative to the safe handling and use of chemical, biological and/or physical carcinogens.
7. Reasonableness of the proposed budget and duration.

V. METHOD OF APPLYING

A. Format of Application

Applications must be submitted on form PHS-398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants, NIH. The conventional presentation in format and detail applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (IV. B.) must be fulfilled. The words "RFA-NIH-NCI-DCCP-CPCB-83-13, NATURAL AND SYNTHETIC INHIBITORS OF CARCINOGENESIS" should be typed in section 2 on the face page of the grant application form.

B. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

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

To ensure their review, applications should be received by November 15, 1983.

If applications are received after that date, the applicants will have the opportunity of having them considered in the next regular review cycle as unsolicited grant applications. Also, the Division of Research Grants (DRG) will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

Dr. Carl E. Smith
Chemical and Physical Carcinogenesis Branch
Division of Cancer Cause and Prevention
National Cancer Institute
Landow Building - Room 8C37
Bethesda, Maryland 20205

Telephone: (301) 496-4141

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DCT-CTEP-83-11

EXPLORATORY GRANT (P20) TO SUPPORT THE PLANNING AND DEVELOPMENT

OF RESEARCH PROGRAMS IN SURGICAL ONCOLOGY

NATIONAL CANCER INSTITUTE

Application Receipt Date: November 15, 1983

The National Cancer Institute's (NCI) Division of Cancer Treatment (DCT) desires to expand support of surgical oncology research. This announcement solicits applications for exploratory grants (P20s), to support the planning and development of a research program in surgical oncology and contains specific instructions for P20 applications. A separate program announcement invites applications for individual research project (R01) and program project (P01) grants on an ongoing basis.

Grants are awarded to nonprofit and profit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with PHS policies applicable to research project grants including cost-sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to the RFA will be reviewed by the same NIH initial review group.

The present RFA announcement is for a single competition with a specified deadline of November 15, 1983, for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

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, Part a (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.

- I. BACKGROUND INFORMATION
- II. OBJECTIVES AND SCOPE
- III. MECHANISM OF SUPPORT
- IV. REVIEW PROCEDURES AND CRITERIA
- V. METHOD OF APPLYING
- VI. INQUIRIES
- VII. NEGOTIATION AND AWARD
- VIII. REPORTING REQUIREMENTS

I. BACKGROUND INFORMATION

The treatment of cancer has evolved as a multidisciplinary effort involving (but not limited to) the disciplines of medical, pediatric, surgical and radiation oncology. The disciplines of medical, pediatric and radiation oncology have developed strong programs in clinical investigations but academic development in surgical oncology has not kept pace. For most cancers surgery is the keystone of primary treatment, which is the setting for advances in multidisciplinary therapy. Such advances are an important long-range objective of the DCT. The attainment of this goal requires substantial strengthening of academic programs in surgical oncology.

II. OBJECTIVES AND SCOPE

The purpose of this grant is to support the planning and development of a research program in surgical oncology. Examples of proposals that NCI considers for support include (but are not limited to):

- Planning the development of a research program in surgical oncology within the context of available staff and resources.
- Coordination of an institution's staff and resources for the purpose of preparing and submitting a large and complex grant application in surgical oncology (for example, preparation of a program project (P01) grant application).
- Assessment of an institution's needs in both personnel and material resources for the creation of an effective research program in surgical oncology. This might include feasibility studies in which the applicant would determine the potential for developing such a program and the validity of various approaches for implementing it.

The proposal should contain information on the following points:

- A. Specific objectives of the planning effort for surgical oncology research programs at the principal investigator's institution.
- B. Organization of the staff, facilities, and relevant existing programs in oncology and related disciplines at the institution.
- C. Evidence of institutional commitment to a surgical oncology research program.
- D. Specific information about what will be included in the planning effort. Activities whose major goals are training and research are not to be included.

- E. Interaction of surgical oncology activities with other units or disciplines within the institution.

It is important to note that the award of an exploratory grant does not imply a commitment by NCI to future funding of any program planned and developed with the support of such a grant. Separate applications must be submitted for such projects which are then reviewed on the basis of merit.

III. MECHANISM OF SUPPORT

This RFA will use the NIH grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals (see II. OBJECTIVES AND SCOPE). If the application is judged by the NCI not to be responsive, the applicant will have the opportunity of having the application considered along with other unsolicited applications received by the NIH.

The total project period for applications submitted in response to the present RFA should not exceed three years. Although there is no specific limitation on the amount of a grant request, NCI program staff intends to make approximately five to ten awards with total costs amounting to approximately \$500,000 the first year. This funding level is dependent on the receipt of a sufficient number of meritorious applications. The number of grants funded may be increased depending on the availability of resources.

Also, although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose.

Allowable direct costs may include:

1. Salaries.
2. Supplies and pilot activities relative to the planning effort.
3. Payment of consultation and technical assistance needed for feasibility surveys and identification of special problems and alternatives. Consultant fees should not be paid to an employee of the United States Government. The applicant must include the following information when applying for consultant services in an Exploratory Grant.
 - a. Evidence that the services to be provided are essential and cannot be provided by persons receiving salary support or otherwise compensated for their services under the grant.
 - b. Evidence that a selection process has been or will be employed to secure the most qualified consultant available, considering the nature and extent of services required.
 - c. Evidence that the proposed charges are appropriate, considering the qualifications of the consultant and normal charges for this type of service.

It should be emphasized that the applicant must not enter into a binding agreement with a consultant for expenditure of these grant funds prior to an award.

4. Other related costs.

Costs of alteration and renovation are not allowed.

Expenditures under these grants are subject to policies applicable to research project grants supported by the NIH as described in the current PHS Grant Policy Statement.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

All grant applications submitted to NIH are received by the Division of Research Grants (DRG). "The Planning and Development of Research Programs in Surgical Oncology" grant applications will be referred to an NCI review committee for initial scientific and technical review. Recommendations of all review committees are presented to the National Cancer Advisory Board (NCAB) for final review and recommendation to the NCI.

B. Review Criteria

The factors considered in evaluating each response to this RFA will be:

1. Objectives:

- Feasibility of the objectives.
- Clarity and appropriateness of the grant application.
- Relevance of the proposal to the goals of the National Cancer Program.

2. Planning:

- Composition and competence of the planning group.
- Appropriate utilization of available staff and resources.

3. Applicant's commitment to cancer programs:

- Background of applicant organization's commitment to cancer programs with reference to program content, personnel, facilities, and financial obligations and commitments.
- Current priority of the cancer program with reference to such organizational or managerial requirements as those relating to delegation of authority, role of the cancer program within the organization, and commitment of personnel, facilities, and funds.

- Current organization of interdisciplinary cancer programs.
4. Project Director:
 - Background, training, and experience.
 - Leadership, scientific and administrative capabilities, and potential for development.
 5. Scientific and other technical considerations:
 - Review and evaluation of the proposed planning effort.
 - Listing of professional staff in surgical oncology unit or in departments collaborating with surgical oncology.
 - Background and experience of the professional staff.
 6. Administrative and organizational considerations:
 - Relationship of surgical oncology as an academic section or division to the department of surgery and other clinical and preclinical departments.
 - Letters of agreement from applicant organization, affiliated and other related or associated institutions.
 - Management capabilities pertaining to:
 - Fiscal administration
 - Procurement
 - Property management
 - Personnel management
 - Facilities management
 - Planning and budgeting
 - Inventions and patents
 7. Intellectual environment of applicant organization:
 - Description of existing academic programs in surgical oncology.
 - Description of academic programs in oncology and other biomedical disciplines other than surgical oncology.
 - Appropriate relationship of cancer program to applicant organization or parent institution.
 - Effect of cancer program on other programs of the institution or organization.

V. METHOD OF APPLYING

A. Format of Applications

Applications must be submitted on form PHS 398 (Rev. 5/82), the application form for research project grants. Application kits are available at most

institutional business offices, or may be obtained from the DRG, NIH. The title "RFA, NIH-NCI-DTC,CTEP-83-11 - The Planning and Development of Research Programs in Surgical Oncology" should be typed in section 2 of the first page of the application.

B. Application Procedure

The completed original application and four copies of the application must be sent or delivered to:

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

To ensure their review, applications must be received by November 15, 1983. Applications received after that date will be returned. Also, the DRG will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

Two copies of the application should be sent to:

Referral Officer
Grants Administration Branch
Division of Extramural Activities
National Cancer Institute
2115 East Jefferson Street, Room 401
Rockville, Maryland 20852

A copy of the covering letter should also be sent to Dr. deMoss at the address shown below.

VI. INQUIRIES MAY BE DIRECTED TO:

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

Telephone: (301)496-4844

VII. NEGOTIATION AND AWARD

Applications recommended for approval by the NCAB and selected for funding will be negotiated by the NCI staff with the applicant institution. There will be a limit of one award per institution. A Notice of Grant Award will summarize the results of the negotiations.

VIII. REPORTING REQUIREMENTS

As with research grants, interim and terminal progress reports must be submitted to the NCI in accordance with the current PHS Grants Policy Statement. Terminal progress reports must be submitted within 90 days after the end of the project. The report should include the following information:

1. Summary statement or critique of progress toward achieving originally stated aims.
2. Description or listing of results, positive or negative, considered significant by the investigator.
3. List of publications emanating from the exploratory grant.
4. Presentation and evaluation of consultants' reports in cases where outside consultants have been used in planning the program. Copies of the consultants' written report shall also be included in the appendix of the terminal report.

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DRCCA-OD-83-7

LONGITUDINAL EVALUATION OF SCHOOL-BASED SMOKING PREVENTION PROGRAMS

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 1, 1983

Letter of Intent Receipt Date: October 15, 1983

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute, (NCI) is interested in supporting studies which a) develop and evaluate school-based interventions to prevent the onset of habitual cigarette smoking, and provide for the long-term follow-up of the study cohorts and their controls; or, b) provide for the long-term follow-up of study cohorts and their controls who have been a part of previous, school-based programs that have been recognized as state-of-the-art interventions in smoking prevention.

The proposed studies should aid in determining the long-term effect that school-based smoking prevention programs have on the rates of adoption of habitual cigarette smoking among adolescents.

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group.

The present RFA announcement is for a single competition with a specified deadline of December 1, 1983 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301 (c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

I. BACKGROUND

Recent Surgeon General's Reports have identified cigarette smoking as the single most important environmental factor contributing to premature cigarette smoking. The major single cause of cancer mortality in the United States, contributing an estimated 30 percent to all cancer deaths. The most desirable approach to reducing tobacco-related cancer is to delay, reduce, or prevent the onset of habitual smoking behavior. Since the adolescent years are those in which the greatest risk for adoption of the smoking habit exists, it is also during these years, and those immediately preceding it, that the greatest opportunity for delay, reduction, or prevention of onset exists. Efforts to intervene in the smoking behavior of adolescents may be best served through school-based programs because more youth may be reached through this institution than any other and because schools provide an excellent structure for careful measurement of the effects of such programs.

Recent studies have demonstrated at least short-term reductions in cigarette use as a result of school-based interventions. Based on sound theoretical grounds, these studies have employed a wide array of approaches (e.g., teacher vs. peer-led programs, films and videotapes, life and social skills training, broad health promotion activities, family involvement) and methodologies (e.g., thiocyanate measurement for self-report validation, analysis of distinct levels of smoking, true random designs with schools as units of analysis). Nevertheless, the published research, as well as research in progress, leave remaining a number of important gaps in the knowledge base necessary to implement effective interventions. Additionally, it is essential to verify the long-term impact of such school-based interventions before resources are devoted to the significant problem of assuring that such interventions are disseminated to and used by school systems throughout the nation.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing school-based smoking intervention programs (or following up already existing ones) and determining the long-term effectiveness of these programs on the delay, reduction, or prevention of habitual cigarette smoking among adolescents.

The focus of the studies of interest must be on longitudinal intervention trials of school-based programs. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a large, distinct and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results in large target populations) investigations. Where justified and necessary, however, highly controlled substudies which focus on basic processes involved in cigarette use may be embedded in the intervention studies. These research questions should not, however, become the overriding interest of the study, but, rather, be integrated as complementary adjuncts to the interventions.

The studies sought are of two broad types:

- A. New studies of promising school-based prevention programs (focused on youth at any point or set of points from kindergarten through 12th grade) which incorporate longitudinal follow-up (preferably into young adulthood, up to age 24); and
- B. Longitudinal follow-up of existing cohorts of youth who have been part of a well-designed existing intervention program but have been subjected only to short-term evaluation, and whose size and composition justify generalizable conclusions.

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable and affordable by those schools desiring to do so.

It is recognized that experimentation in school settings with long-term follow-up is a difficult and complex task. Considering this and the current state of the art in school-based prevention programs, as well as the aims of this RFA, studies should consider and address where appropriate, the following research questions and issues (as well as numerous others not listed):

- o Can school-based intervention programs produce long-term reductions in smoking onset? And, is the population and/or technique chosen for this study sufficiently stable to permit such long-term follow-up?
- o Is the research design and data analysis plan rigorous enough to provide valid, reliable data yet flexible enough to accommodate field setting conditions?
- o Are there a sufficient number of classrooms/schools to insure that any observed effects are not classroom/school specific?
- o Is there sufficient justification (i.e. validity, reliability data) for the selection of program materials to be utilized or developed?
- o Is the process evaluation design able to monitor the implementation of key program components, identify which are most responsible for any program impact, and determine which are best/least well-received by the program participants?
- o What type of self-report validation techniques are appropriate for the interventions planned? If none, what arguments support this position?
- o Is it possible to identify and design appropriate interventions for youth who are at particularly high-risk for habitual cigarette smoking?
- o What specific techniques are needed for interventions and follow-up studies of youth who are non-middle-class, minority, highly mobile or school dropouts? How will sociocultural differences in the study population affect the study design?

- o Is there a role for the family (e.g., parents, siblings) or other support groups in school-based smoking intervention programs? If so, how could these groups be integrated into such efforts?
- o How do environmental factors (e.g., school climate, community attitudes) interact with program components and affect the impact of the interventions?
- o Will these interventions be more effective if they are designed as specific smoking education approaches or embedded within broader health education/behavior approaches? Which type of approach are schools more likely to utilize after the research has been completed?
- o How useful are booster sessions in achieving long-term effects? How often are they needed? What should their focus be?
- o What consideration must be given to the multiple domains of adolescent health and social behavior (e.g., psychological health, problem behaviors other than cigarette smoking, personal adjustment factors) in the design, content, and material development of the interventions?
- o Can effective school-based prevention programs be sufficiently standardized or packaged so that they can be maintained and implemented by school personnel in the absence of continuing external funding sources?
- o What is the optimum curriculum time needed for an intervention to have a positive impact? What ages/grade levels are most appropriate for intervention?

III. MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) grant-in-aid. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. Although the total project period for applications submitted in response to the present RFA should not exceed five years, it is anticipated that up to ten years of support may be necessary to carry through some longitudinal designs (e.g., following youth who participate in an intervention at age 12 through age 22). Renewal applications for such studies will be required at 3-5 year intervals after the initial period of support. The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.5 million for the first year. This level of activity is dependent on the receipt of a sufficient number of applications of scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the NIH; and (2) the National Cancer Advisory Board at one of its scheduled quarterly meetings. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals. The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of the research approach, design, generalizability, follow-up concerns, and quality assurance of the research.
2. Scientific and technical significance and originality of the proposed research.
3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.
4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
5. Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.
6. Identity of sources of data and procedures for their analysis and assurances as to their accessibility.
7. Adequacy of steps taken to optimize and fully evaluate the durability of the intervention effects.
8. Likelihood of the intervention to be readily adoptable and affordable by those schools desiring to do so.
9. Generalizability of the findings to large segments of the population.
10. A willingness to work cooperatively with other projects of a similar nature and with the NCI on the project.
11. Reasonableness of the proposed budget and duration of the research.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This letter of intent should be addressed to Dr. Thomas J. Glynn at the address located under VI. The Institute requests such contact to provide an indication of the number and the scope of applications to be received and for the purposes of identification of overlap and/or redundancy with currently funded research. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted nor is it a mandatory requirement for the submission of the application. Telephone inquiries are welcomed at any time prior to application.

B. Format of Application

Applications must be submitted on Form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants (DRG), NIH. The conventional presentation format and details applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (see section IV., B.) must be fulfilled. The words **"PROPOSAL IN RESPONSE TO RFA NIH-NCI-DRCCA-OD-83-7, "Longitudinal Evaluation of School Based Smoking Prevention Programs"** must be typed in bold letters in space number 2 on the face page of the application.

C. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

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

To ensure their review, applications should be received by December 1, 1983. Applications received after that date will not be considered under this RFA, but the applicant will have the opportunity of having them considered in the next regular grant review cycle. Also, the DRG will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

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

Telephone: (301) 427-8735

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DRCCA-OD-83-8

THE USE OF SELF HELP STRATEGIES IN SMOKING PREVENTION AND CESSATION

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 1, 1983

Letter of Intent Receipt Date: October 15, 1983

The Smoking, Tobacco, and Cancer Program, National Cancer Institute is interested in supporting studies directed at reducing the long-term incidence/prevalence of cigarette smoking through the use of self-help strategies.

The proposed studies should seek to (1) develop and evaluate individual and/or group self-help strategies to eliminate, prevent, or reduce cigarette smoking and/or (2) develop and evaluate assessment procedures for determining the long-term effectiveness of existing self-help strategies in eliminating, preventing, or reducing cigarette smoking.

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program.

Applicants funded under the RFA are supported through the customary NIH grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified dead-line for receipt of applications. All applications received in response to this RFA will be reviewed by an appropriate National Institutes of Health (NIH) Initial Review Group.

The present RFA announcement is for a single competition with a specified deadline of December 1, 1983 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

I. BACKGROUND

Recent Surgeon General's Reports have identified cigarette smoking as the single most important environmental factor contributing to premature mortality in the United States. Further, these reports conclude that cigarette smoking is the major single cause of cancer mortality in the United States, contributing an estimated 30 percent to all cancer deaths. The most desirable approach to reducing tobacco-related cancer is to eliminate, prevent, or reduce habitual cigarette smoking.

Since the first Surgeon General's Report on the health consequences of cigarette smoking was published in 1964, an estimated 30 million people have quit smoking. Subsequent reports have suggested that a significant majority of those who have stopped smoking have done so without the aid of organized smoking cessation programs and that, indeed, most current smokers prefer to quit with a procedure they may use on their own.

In response to this preference, a number of self-help smoking interventions have been developed over the past decade. These strategies have included, as examples, the use of pamphlets, manuals and books, audiotape cassettes, and mass media messages and presentations.

Unfortunately, most self-help interventions for smoking have not been systematically evaluated and those that have, have been evaluated for only a brief period of time. Additionally, existing studies have not identified, for example, which self-help strategies or programs are most effective, which types of self-help materials are most effective with smokers during different stages of change, (e.g., pre-quit, decision making, quitting and maintenance), what generalizations may be drawn across self-help strategies, under what conditions smokers make use of available self-help materials, and what interactions may exist among self-directed change, changes in an individual's environment, and environmental factors that may facilitate or interfere with self-quit.

Although some valuable data have been obtained regarding self-initiated smoking interventions (e.g., identification of factors related to successful and unsuccessful self-quit), a substantial gap exists in how to apply this information across broad populations and achieve long-lasting results.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in studying the use of self-help strategies in the durable prevention, elimination, or reduction of cigarette smoking.

The focus of the studies envisioned thus must be on the long-term effectiveness of self-help strategies. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a large, distinct and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results in large target populations) investigations. Where justified and necessary, however, highly controlled studies of the acquisition process, personality factors or other related research questions which could influence the self-help process may be

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

The studies sought are of two broad types:

- A. Development and long-term evaluation of the effectiveness of individual and/or group self-help strategies to eliminate, prevent, or reduce cigarette smoking; and
- B. Development and long-term evaluation of assessment procedures for determining the effectiveness of existing, well-designed self-help strategies to eliminate, prevent, or reduce cigarette smoking.

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable and affordable by those desiring to do so.

Considering the current state of the art in self-help smoking interventions, as well as the aims of this RFA, studies of the broad types called for above should consider, and address where appropriate, the following research questions and issues (as well as numerous others not listed):

- o Can self-help intervention programs produce long-term cessation, reduction, prevention of cigarette smoking? And, is the population and/or technique chosen for this study sufficiently stable to permit such long-term follow-up?
- o Is the research design and data analysis plan rigorous enough to provide valid, reliable data yet flexible enough to accommodate field setting conditions?
- o Are there a sufficient number of individuals or groups to insure, to the extent possible, that any observed effects are linked to the intervention?
- o Is there sufficient justification (i.e. validity, reliability data) for the selection of intervention materials to be utilized or developed?
- o Is the process evaluation design able to monitor the implementation of key intervention components, identify which are most responsible for any intervention impact, and determine which are best/least well-received by the intervention participants?
- o What type of self-report validation techniques are appropriate for the interventions planned?
- o Is it possible to identify and design appropriate self-help intervention for individuals who are at particularly high-risk for starting or continuing habitual cigarette smoking?

- o Are specific self-help techniques needed for interventions with individuals who are non-middle-class, minority, highly mobile, or less educated? How will sociocultural differences in the study population affect the study design?
- o Is there a role for the family or other support groups in self-help smoking intervention programs? If so, how could these groups be integrated into such efforts?
- o How do environmental factors (e.g., peer smoking status, community attitudes) interact with program components and affect the impact of the interventions?
- o Will these interventions be more effective if they are designed as specific smoking self-help approaches or embedded within broader health behavior self-help approaches? Which type of approach are individuals more likely to utilize after the research has been completed?
- o How useful are booster sessions in achieving long-term effects? How often are they needed? What should their focus be?
- o What consideration must be given to the multiple domains of individual health and social behavior (e.g., psychological health, problem behaviors other than cigarette smoking, personal adjustment factors) in the design, content, and material development of the interventions?
- o Can effective self-help intervention programs be sufficiently standardized or packaged so that they can be successfully used by a broad range of individuals in the absence of continuing external involvement?
- o What is the optimum time needed for a self-help intervention to have a positive impact? What type of individual and what level of smoking involvement are the most appropriate for intervention?
- o How should a self-help intervention approach the issue of smoking relapse?
- o Is it possible that there may be a reactance effect to self-monitoring in these interventions and, if so, how might this affect the research?
- o Have the broad range of self-help intervention delivery methods (e.g., in-person, mail, computer, mass-media) been considered?
- o Is it possible to determine why self-quitting seems to be the most effective method of smoking cessation and thus identify individuals who may be in a pre-quitting stage and most amenable for a successful self-help program?

III. MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health grant-in-aid. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in

response to the present RFA should not exceed five years; nevertheless, it is NCI's intent to support quality studies to their completion. Where more than five years is required, and the case is made for such, the possibility for longer studies will exist through competing renewal grant applications. The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.4 million for the first year. This level of activity is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the National Institutes of Health, and (2) the National Cancer Advisory Board at one of its scheduled quarterly meetings. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals. The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of the research approach, design, and methodology.
2. Scientific and technical significance originality of the proposed research.
3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.
4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
5. Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.
6. Identity of sources of data, intervention materials, etc., and procedures for their analysis and assurances as to their accessibility.
7. Adequacy of steps taken to optimize and fully evaluate the durability of the intervention effects.
8. Likelihood of the intervention to be readily adoptable and affordable by those desiring to do so.
9. Generalizability of the findings to large segments of the population.
10. Willingness to work cooperatively with other projects of a similar nature and with the NCI on the project.
11. Reasonableness of the proposed budget and duration of the research.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This letter should be sent to Dr. Thomas J. Glynn (see address in following section).

The Institute requests such letters only to provide an indication of the number and the scope of applications to be received. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted nor is it a necessary requirement for application. Telephone inquiries are welcomed at any time prior to application.

B. Format of Application

Applications must be submitted on Form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants, NIH. The conventional presentation format and details applicable to regular research grant applications should be followed, and the requirements specified under Review-Criteria (IV.B.) must be fulfilled. The words **"PROPOSAL IN RESPONSE TO RFA NIH-NCI-DRCCA-83, The Use of Self-Help Strategies in the Prevention and Cessation of Smoking"** must be typed in bold letters in space number 2 on the face page of the application.

C. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

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

To ensure their review, applications should be received by December 1, 1983. Applications received after that date will not be considered under this RFA, but the applicant will have the opportunity of having them considered in the next regular grant review cycle. Also, the Division of Research Grants (DRG) will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

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

Telephone: (301) 427-8735

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DRCCA-OD-83-9

EVALUATION OF PHYSICIAN/DENTIST DELIVERED INTERVENTIONS FOR SMOKING

PREVENTION AND CESSATION

NATIONAL CANCER INSTITUTE

Application Receipt Date: January 1, 1984

Letter of Intent Receipt Date: October 15, 1983

The Smoking, Tobacco, and Cancer Program (STCP). National Cancer Institute (NCI) is interested in supporting studies directed at reducing the long-term incidence/prevalence of cigarette smoking by enhancing the effectiveness of physicians and dentists in prevention and cessation counseling and support.

The proposed studies should seek to (1) identify/develop, implement, and evaluate brief structured interventions for physicians and dentists to assist their patients with smoking prevention or cessation; and/or (2) develop and evaluate mechanisms to encourage physician and dentist utilization of smoking prevention and cessation interventions; and/or (3) develop and evaluate mechanisms to encourage patients to request assistance with smoking cessation from their physician or dentist.

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group.

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

The present RFA announcement is for a single competition with a specified deadline of January 1, 1984 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

I. BACKGROUND

Recent Surgeon General's Reports have identified cigarette smoking as the single most important environmental factor contributing to premature mortality in the United States. Further, these reports conclude that cigarette smoking is the major single cause of cancer mortality in the United States, contributing an estimated 30 percent to all cancer deaths. The most desirable approach to reducing tobacco-related cancer is to eliminate, prevent, or reduce habitual cigarette smoking.

Physicians and dentists are in a unique position to influence patients to change their smoking habits. Not only do they enjoy prestige and credibility as sources of health-related information, but there is also evidence that these groups are receptive to playing an increasing role in discouraging smoking. Preliminary data on the role that physicians may play in smoking intervention are encouraging but, even as these initial findings foster enthusiasm for this intervention approach, they raise important questions about the nature, importance, and efficacy of provider influence. We know very little about such issues as the most effective methods physicians and dentists can use to motivate patients to consider cessation and to assist patients in actually quitting and maintaining nonsmoking, about what kinds of patients are most readily influenced by provider messages, and what is involved in encouraging patients to request assistance concerning smoking from their physician or dentist. It is to these and numerous other related issues that this RFA is addressed.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing (or implementing already existing) physician/dentist delivered smoking interventions and determining the long-term effectiveness of these programs on the durable prevention, reduction, and cessation of cigarette smoking among patient populations.

The focus of the studies envisioned thus must be on the long-term effectiveness of physician/dentist interventions. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a distinct and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results in the large target populations) investigations.

Where justified and necessary, however, highly controlled studies of the acquisition process, physician/dentist attitudes or other related research questions which could influence the effectiveness of provider messages may be embedded in the intervention studies. These research questions should not, however, become the overriding interest of the study but, rather, be integrated as complementary adjuncts to the interventions.

The objective is to increase the effectiveness of physicians/dentists in providing smoking prevention and cessation interventions to their patients. The primary focus is on the role of physicians and dentists in the smoking interventions, although other health professionals (e.g., nurses, dental hygienists, pharmacists) may be included. No restrictions are set on physician, dentist, or patient populations, nor on settings or organizations (e.g., HMO's, work sites, clinics, and general speciality practice) that may be studied. Applicants are encouraged to seek the cooperation of physician/dentist professional organizations in obtaining large numbers of these professionals for study participation.

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable by a broad range of physicians and dentists.

Considering the current state of the art in physician/dentist smoking interventions, as well as the aims of this RFA, studies of the broad types called for above should consider and address where appropriate, the following research questions and issues (as well as numerous others not listed, depending on factors specific to the proposed study's objectives):

- o Can physician/dentist intervention programs produce long-term reductions in smoking behavior? And, is the population and/or technique chosen for this study sufficiently stable to permit such long-term follow-up?
- o Is the research design and data analysis plan rigorous enough to provide valid, reliable data yet flexible enough to accommodate field setting conditions?
- o Are there a sufficient number of individuals or groups to insure, to the extent possible, that any observed effects are linked to the intervention?
- o Is there sufficient justification (i.e., validity, reliability data) for the selection of intervention materials to be utilized or developed?
- o What consideration must be given to the multiple domains of individual health and social behavior (e.g., psychological health, problem behaviors other than cigarette smoking, personal adjustment factors) in the design, content, and material development of the interventions?
- o Can effective intervention programs be sufficiently standardized or packaged so that they can be successfully used by a broad range of physicians/dentists in the absence of continuing external involvement?
- o What is the optimum number of contacts needed for this intervention to have a positive impact? What type of individual and what level of smoking involvement is most appropriate for intervention?
- o How should this type of intervention approach the issue of smoking relapse?

- o Is the process evaluation design able to monitor the implementation of key intervention components, identify which are most responsible for any intervention impact, and determine participants?
- o What type of self-report validation techniques are appropriate for the interventions planned?
- o Is it possible to identify and design appropriate interventions for individuals who are at particularly high-risk for starting or continuing habitual cigarette smoking?
- o Are specific techniques needed for interventions with individuals who are non-middle-class, minority, highly mobile, or less educated? Do the interventions consider sociocultural differences among the participants?
- o Is there a role for the family (e.g., spouse, children) or other support groups in physician/dentist smoking intervention programs? If so, how could these groups be integrated into such efforts?
- o How do environmental factors (e.g., physician/dentist smoking status, community attitudes) interact with program components and affect the impact of the interventions?
- o Will these interventions be more effective if they are designed as specific smoking interventions or embedded within broader health behavior approaches? Which type of approach are physicians/dentists more likely to utilize after the research has been completed?
- o How useful are booster sessions in achieving long-term effects? Can they be integrated into this type of program? How often are they needed? What should their focus be?
- o How do physician/dentist smoking behavior, perceptions and attitudes affect their effectiveness as intervenors?
- o How does the physician/dentist's views of their patients' ability to control their smoking affect their effectiveness as intervenors?
- o How will physician/dentist compliance with the interventions be monitored?
- o Will health professionals other than physicians/dentists be involved in the intervention? What will their roles be?

III. MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health grant-in-aid. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years; nevertheless, it is NCI's intent to support quality studies to their completion. Where more than five years is required, and the case is made for such, the possibility for longer studies will exist through competing renewal grant applications. The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.3 million

for the first year. This level of activity is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the NIH; and (2) the National Cancer Advisory Board at one of its scheduled quarterly meetings. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals. The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of the research approach, design, and methodology.
2. Scientific and technical significance and originality of the proposed research.
3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.
4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
5. Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.
6. Identity of sources of data, intervention materials, etc., and procedures for their analysis and assurance as to their accessibility.
7. Adequacy of steps taken to optimize and fully evaluate the durability of the intervention effect.
8. Likelihood of the intervention to be readily adoptable by a broad range of physicians and dentists.
9. Generalizability of the findings to large segments of the population.
10. Willingness to work cooperatively with other projects of a similar nature and with the NCI on the project
11. Reasonableness of the proposed budget and duration of the research.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This letter should be sent to Dr. Thomas J. Glynn (see address in following section).

The Institute requests such letters only to provide an indication of the number and the scope of applications to be received. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted nor is it a necessary requirement for application. Telephone inquiries are welcome at any time prior to application.

B. Format of Application

Application must be submitted on Form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants (DRG), NIH. The conventional presentation format and details applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (IV.B.) must be fulfilled. The words **"PROPOSAL IN RESPONSE TO RFA NIH-NCI-DRCCA-OD-83-9, Evaluation of Physician/Dentist Delivered Interventions for Smoking Prevention and Cessation"** should be typed in bold letters in space number 2 on the face page of the application.

C. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

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

To ensure their review, applications should be received by January 1, 1984. Applications received after that date will not be considered under this RFA, but the applicant will have the opportunity of having them considered in the next regular grant review cycle. Also, the DRG will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

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

Telephone: (301) 427-8735

ANNOUNCEMENT**REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA****NIH-NCI-DRCCA-OD-83-10****DEVELOPMENT AND EVALUATION OF SMOKING PREVENTION AND CESSATION****INTERVENTIONS USING THE MASS MEDIA****NATIONAL CANCER INSTITUTE**

Application Receipt Date: January 1, 1984

Letter of Intent Receipt Date: October 15, 1983

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

The proposed studies should seek to (1) develop and evaluate innovative techniques that significantly increase the long-term effect of single or multiple mass media interventions for smoking prevention or cessation; and/or (2) develop and evaluate innovative techniques for the reinforcement and maintenance of positive prevention and cessation behaviors generated as a result of mass media interventions; and/or (3) provide for the long-term follow-up of study cohorts and their controls who have been a part of previous, mass media interventions directed at smoking prevention and cessation.

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary National Institutes of Health (NIH) grant-in-aid, in accordance with PHS policies applicable to Research Project Grants, including cost sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group.

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

The present RFA announcement is for a single competition with a specified deadline of January 1, 1984 for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

I. BACKGROUND

Recent Surgeon General's Reports have identified cigarette smoking as the single most important environmental factor contributing to premature mortality in the United States. Further, these reports conclude that cigarette smoking is the major single cause of cancer mortality in the United States, contributing an estimated 30 percent to all cancer deaths. The most desirable approach to reducing tobacco-related cancer is to durably prevent, eliminate, or reduce habitual cigarette smoking.

Among the many approaches to smoking prevention and cessation available, it is the mass media which have the potential to reach many thousands of smokers at one time, offer a convenient and relatively inexpensive means for obtaining assistance with quitting, can substantially reduce the burden of providing such assistance through the health care system, and contribute to developing a social climate that is more supportive of prevention and cessation behavior. Mass media campaigns directed at smoking behavior have been used with increasing frequency in recent years. However, few studies have been conducted to assess the effects of specific campaigns. Those that have been done most often reveal minor, short-term effects on behavior change, but even the majority of these studies have been criticized for various aspects of their study design. Beyond that, little is known about the long-term effects of these interventions, and such issues as the relative effectiveness of their various components, their cost-effectiveness, and their generalizability. It is to these and other related issues which this RFA is addressed.

II. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing media-based smoking intervention programs (or following up already existing ones) and determining the long-term effectiveness of these programs on the prevention and cessation of habitual cigarette smoking among defined populations.

The focus of the studies envisioned thus must be on the long-term effectiveness of media-based interventions. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out with a large, distinct and well-characterized population or a sizeable sample of the population in such a way that the results obtained are representative of results in large target populations) investigations. Where justified and necessary, however, highly controlled studies of the acquisition process, personality factors or other related research questions which could influence the effectiveness of the media process may be embedded in the intervention studies. These research questions should not, however, become the overriding interest of the study but, rather, be integrated as complementary adjuncts to the interventions.

The studies sought are of two broad types:

- A. New studies of promising media-based intervention programs (focused either on broad, defined populations or on specifically-targeted populations) which incorporate longitudinal follow-up (i.e., no less than 1 year following the conclusion of the intervention; wherever justified, longer periods of follow-up to measure durability of intervention effects are encouraged); and
- B. Longitudinal follow-up of existing cohorts which have been part of a well-designed media-based intervention program but have been subjected only to short-term evaluation, and whose size and composition justify generalizable conclusions.

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

It is recognized that media-based experimentation with long-term follow-up is a difficult and complex task. Considering this and the current state of the art in media-based smoking interventions, as well as the aims of this RFA, studies of the broad types called for above should consider, and address where appropriate, the following research questions and issues (as well as numerous others not listed, depending on factors specific to the proposed study's objectives):

- o Can media-based intervention programs produce long-term effects on smoking behavior? And, is the population and/or technique chosen for this study sufficiently stable to permit such long-term follow-up?
- o Is the research design and data analysis plan rigorous enough to provide valid, reliable data yet flexible enough to accommodate field setting conditions?
- o Are there a sufficient number of individuals or groups to insure, to the extent possible, that any observed effects are linked to the intervention?
- o Is there sufficient justification (i.e., validity, reliability data) for the selection of intervention materials to be utilized or developed?
- o Is the process evaluation design able to monitor the implementation of key intervention components, identify which are most responsible for any intervention impact, and determine which are best/least well-received by the intervention participants?
- o What type of self-report validation techniques are appropriate for the interventions planned?

- o Is it possible to identify and design appropriate interventions for individuals who are at particularly high-risk for starting or continuing habitual cigarette smoking?
- o Are specific media approaches needed for interventions with individuals who are non-middle-class, minority, highly mobile, or less educated? How will sociocultural differences in the study population affect the study design?
- o Is there a role for the family or other support groups in media-based smoking intervention programs?
- o How do environmental factors (e.g., time of year, community attitudes) interact with program components and affect the impact of the interventions?
- o Will these interventions be more effective if they are designed as specific smoking approaches or embedded within broader health behavior approaches? Which type of approach are those with media access more likely to utilize after the research has been completed?
- o How useful are booster campaigns in achieving long-term effects in media-based interventions? Are they feasible? How often are they needed? What should their focus be?
- o What consideration must be given to the multiple domains of individual health and social behavior (e.g., psychological health, problem behaviors other than cigarette smoking, personal adjustment factors) in the design, content, and material development of the interventions?
- o Can effective media-based intervention programs be sufficiently standardized or packaged so that they can be afforded and successfully used by a broad range of groups in the absence of continuing external involvement?
- o What role will message and copy testing play in the study design?
- o Will these interventions be more effective if they are conducted through media approaches alone or in conjunction with other smoking prevention/cessation efforts?
- o What is the most effective programming tool to use for attracting and sustaining participation of smokers who want to quit? Are, for example, nightly news segments better than half hour programs broadcast over several weeks? Given the advantages and disadvantages of each of these approaches, how can they be used to achieve more effective results? Are there other programming formats that may be effective?
- o Which medium or combination of media (e.g., radio, television, newspapers) is most effective? How can cable television be utilized for this purpose?

- o What are the most effective promotion and publicity strategies for reaching those less predisposed to quit smoking?
- o How cost-effective is the use of mass media for conducting smoking cessation clinics? How can their cost-effectiveness be improved?
- o What types of media and/or interpersonal interventions would be effective for fostering maintenance of nonsmoking behavior? Would PSAs, for example, be adequate maintenance messages?
- o In what ways can the broadcast and print materials be utilized beyond their original use? For example, what are the effects of repeated broadcasts? How effective are these materials when used as "small media" by work sites, community groups, health care professionals?
- o What are the most effective approaches for developing and distributing the printed materials that accompany the broadcast programming?
- o Which program formats work best -- for example, use of an expert who instructs the audience in smoking cessation skills or use of a panel of smokers participating in a clinic? To what extent would an interactional component such as a live telephone call-in system enhance the effectiveness of the media intervention?

III. MECHANISM OF SUPPORT

This RFA will use the NIH grant-in-aid. Responsibility for the planning, direction and execution of the pro-posed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years; nevertheless, it is NCI's intent to support quality studies to their completion. Where more than five years is required, and the case is made for such, the possibility for longer studies will exist through competing renewal grant applications. The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.8 million for the first year. This level of activity is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the continuing availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the NIH; and (2) the National Cancer Advisory Board at one of its scheduled quarterly meetings. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals. The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of the research approach, design, and methodology.
2. Scientific and technical significance and originality of the proposed research.
3. Research experience and/or competence of the Principal Investigator and staff to conduct the proposed studies.
4. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
5. Relevancy and appropriateness of the specific target population along with assurance as to their accessibility.
6. Identity of sources of data, intervention materials, etc., and procedures for their analysis and assurance as to their accessibility.
7. Adequacy of steps taken to optimize and fully evaluate the durability of the intervention effect.
8. Likelihood of the intervention to be readily adoptable by others.
9. Generalizability of the findings to large segments of the population.
10. Willingness to work cooperatively with other projects of a similar nature and with the NCI on the project
11. Reasonableness of the proposed budget and duration of the research.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This letter should be sent to Dr. Thomas J. Glynn (see address in following section).

The Institute requests such letters only to provide an indication of the number and the scope of applications to be received. The letter of intent is not binding; it will not enter into the review of any proposal subsequently submitted nor is it a necessary requirement for application. Telephone inquiries are welcomed at any time prior to application.

B. Format of Application

Applications must be submitted on Form PHS 398, the application form for research project grants. Application kits are available at most institutional

business offices, or may be obtained from the DRG, NIH. The conventional presentation format and details applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (IV.B.) must be fulfilled. The words **"IN RESPONSE TO RFA NIH-NCI-DRCCA-83, Development and Evaluation of Smoking Prevention and Cessation Interventions Using the Mass Media"** should be typed in bold letters in space number 2 on the face page of the application.

C. Application Procedures

The completed original application and six (6) copies should be sent or delivered to:

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

To ensure their review, applications should be received by January 1, 1984. Applications received after that date will not be considered under this RFA, but the applicant will have the opportunity of having them considered in the next regular grant review cycle. Also, the Division of Research Grants (DRG) will not accept any application in response to this announcement that is the same as one currently being considered by any other NIH awarding unit.

VI. INQUIRIES

Inquiries may be directed to:

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

Telephone: (301) 427-8735

ANNOUNCEMENT

THE IMMUNE BASIS OF RENAL DISEASE

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

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

I. PURPOSE

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDDK) invites qualified investigators to submit research grant applications for the support of research directed to gaining a further understanding of the role of the immune system in human renal diseases. This need has not only been expressed by ad hoc Advisory Committee consultants to the Kidney Disease and Urology Program and experts knowledgeable in nephrology and immunology, but is based on progress in basic immunology in the past 5-10 years and upon concern about chronic renal failure to which the chronic glomerulonephritides contribute 1/3 to 2/3 of patients. It is hoped that this announcement will stimulate a sustained growth in the number of applications relating to immune mechanisms and renal diseases submitted to NIH in the future.

II. DISCIPLINE AND EXPERTISE

The interdisciplinary nature of such renal studies will require collaboration among experts in areas such as the major disciplines of immunology, (cellular immunology, immunogenetics, immunochemistry, immunopathology and immunopharmacology), nephrology, renal physiology and pathophysiology, biochemistry, pathology, molecular/cellular biology, genetics and epidemiology.

III. BACKGROUND

Glomerulonephritis (GN), a relatively infrequent medical problem, has a major impact on the quality of life and comprises an enormous loss of human potential when it progresses to chronic renal failure. Most frequently it affects children and young adults and in this country causes annual mortality of over 12,000, morbidity of at least 4 million days, work loss of 765,000 days, and an estimated loss of earning power of greater than \$15 M. Glomerular diseases are the leading causes of loss of renal function and are responsible for more than half of the patients (35,000-40,000), who require End Stage Renal Disease (ESRD) management by dialysis and/or renal transplantation, at an estimated annual expenditure of at least \$600 M (one-third of the ESRD/Medicaid costs in 1982).

Evidence accumulated in the last few decades implicates immunologic factors in a variety of renal diseases, particularly the glomerulonephritides and interstitial nephropathies. The majority of immunologically mediated glomerular diseases are associated with immune complexes in glomeruli in both primary (e.g., membranoproliferative GN) and systemic (e.g., lupus nephritis) diseases. The immunologic mechanisms thus far defined involve deposition of immune complexes

from the circulation or their formation in situ. Less common are diseases in which antibodies are directed against native glomerular basement membrane (anti-GBM), as in Goodpasture's syndrome.

Though these two immunopathologic mechanisms constitute the major forms of GN, it appears that additional immunological mechanisms are involved. Thus, some forms of GN lack antigen and/or antibody deposits but have clinical and laboratory features suggesting immunological causes. Examples are minimal change GN and the nephritis of systemic vasculitis. Lymphoid cell infiltrates in renal tissue also suggest that direct cell mediated immune injury may be a component of many forms of nephritis, with or without associated antibody deposition. In addition, the fundamental observations of cell mediated immune responses which underlie the humoral antibody and/or immune complex disturbances of the more common nephropathies require further exploration.

Although there is a paucity of information regarding the etiologies and pathogenesis of most immunologic renal diseases, nevertheless, during the past decade there have been major advances in understanding the pathophysiology of chronic renal failure. Notable also are advances related to factors which affect the expression of immune mediated renal injury: 1) the elucidation of the potential role of anionic charges on the basement membrane upon glomerular permeability and localization of antigen and antibody, and 2) the reporting of a significant influence of renal hemodynamic factors in renal damage with the potential of modifying glomerular filtration rate (GFR) and renal blood flow (RBF) by manipulations of dietary intake.

IV. OBJECTIVES AND SCOPE

This solicitation is prompted by a recognized need for an expanded research effort to gain greater insights into the immunopathogenetic mechanisms that may cause renal injury and to define mechanisms for arresting, treating and/or preventing immunologic renal disease.

Research on the involvement of the immune system relating to the development of immune renal injury is encouraged in the following areas:

- o investigation of host factors (genetic and immunologic) that predispose to the development of immune complex GN and other forms of antibody mediated injury;
- o studies to define the role of cell-mediated immunity in the pathogenesis of glomerulonephritis, such as minimal change disease;
- o development of animal models in which cell-mediated injury is demonstrable;
- o studies to better define the role of lymphoid cells (i.e., T suppressor and helper cells, cytotoxic T cells, natural killer cells, etc.) which may directly produce renal injury or which by immunoregulatory imbalance may cause disordered humoral immune responses;
- o development of new markers and new ways of assessing functional activity of cells within infiltrates;

- o studies of purported nonimmunologic mechanisms that may influence immunologically-initiated renal diseases;
- o basic laboratory or clinical studies which have relevance to immunologic basis of renal disease.

The above are examples only and should not be viewed as all inclusive.

V. MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid. The regulations (Code of Federal Regulations, Title 42, Part 52 and, as applicable to the state and local governments, Title 45, Part 74) and policies which govern the research grant programs of the National Institutes of Health (NIH) will prevail. This program is described in the Catalog of Federal Domestic Assistance No. 13.849, Kidney, Urologic, and Hematologic Diseases Research.

The award of grants pursuant to this Program Announcement is contingent upon receipt of appropriated funds for this purpose. Although this solicitation is included in the NIADDK funding plan for Fiscal Year 1984, support is contingent upon receipt of funds for this purpose. The specific amount to be funded will depend upon the merit of the applications. It is expected that funding will begin July 1984.

VI. REVIEW PROCEDURES AND CRITERIA

A. Assignment of Applications

Applications will be received by the NIH, Division of Research Grants (DRG), referred to an appropriate Study Section for scientific merit review, and assigned to NIADDK for possible funding, unless programmatic considerations indicate more appropriate assignment to another Institute. These decisions will be governed by normal DRG Referral Guidelines.

B. Review Procedures

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with other research grant applications, and in accord with the usual NIH peer review procedures. Applications will first be reviewed for scientific and technical merit by a review group composed mostly of non-federal scientific consultants (Study Section), and then by the National Advisory Council of the NIADDK or other appropriate Institute. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

VII. 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. The phrase **"PREPARED IN RESPONSE TO NIADDK KIDNEY PROGRAM ANNOUNCEMENT - THE IMMUNE BASIS OF RENAL DISEASE"** should be typed across the top of the first page of the applications.

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

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

For further information, investigators are encouraged to contact the following individual:

M.J. Scherbenske, Ph.D.
Renal Physiology/Pathophysiology
Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
Westwood Building - Room 621
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7458

ANNOUNCEMENT

RESEARCH GRANTS IN THE FIELD OF NERVOUS SYSTEM MODULATION OF
IMMUNE RESPONSES AND INTERACTIONS BETWEEN THE NERVOUS AND
IMMUNE SYSTEMS

**NATIONAL INSTITUTE OF NEUROLOGICAL AND
COMMUNICATIVE DISORDERS AND STROKE**

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application receipt dates: November 1, March 1, July 1

The Fundamental Neurosciences Program (FNP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the Immunology, Allergic and Immunologic Diseases Program (IAIDP) of the National Institute of Allergy and Infectious Diseases (NIAID) will welcome the submission of applications in the field of nervous system modulation of immune responses and interactions between the nervous and immune systems.

The central and peripheral nervous systems modulate the immune responses of any part of the body. The interactions, including feedback loops originating in either system, can occur via circulatory pathways (hormones and other chemical messengers) or via direct neural pathways, or via both.

A few examples of current research in this field are:

1. Effects of brain lesions upon antibody production, cellular immunocompetence, anaphylaxis, thymus and bone marrow functions, etc..
2. Changes in immune responses associated with classical or instrumental conditioning, or other psychological changes.
3. Changes in unit activity of neurons in the central nervous system during the course of immunogenesis.
4. Influences of environmental changes, mediated by neural or neurohormonal mechanisms, leading to alteration of immune competence.

These programs are described in the Catalog of Federal Domestic Assistance No. 13.854, Fundamental Neurosciences and No. 13.855, Immunology, Allergic and Immunologic Diseases. Grants will be awarded 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.

5. Anatomical, biochemical and physiological studies of receptor sites on cellular elements of the immune system for neurohormones, neurotransmitters, neuromodulators, and other neurally-active polypeptides.
6. Common embryological origins and parallel development of various tissues of the immune and nervous systems.

The FNP, NINCDS and the IAIDP, NIAID wish to encourage present investigations and to stimulate new research in this potentially highly significant but not widely appreciated area. Such research should lead to a better fundamental understanding of the mechanisms of interactions among the nervous, endocrine, and immune systems. This, in turn, should have enormous potential for the development of better preventive medicine and for improvement of current approaches to many clinical problems.

APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on form PHS 398 following instructions contained in the application kit. These forms are available in the business or grant offices of most academic and research institutions. If not, single application kits may be obtained from the Division of Research Grants (DRG), address below. The applications will be judged on scientific merit in accord with NIH policy and procedures involving peer review. Initial review will be by the appropriate study section of the DRG. Secondary review will be by the National Advisory Neurological and Communicative Disorders and Stroke Council and the National Advisory Allergy and Infectious Diseases Council. Primary assignments will be given to NINCDS for applications concerned with investigations primarily focused on neurophysiologic and neuropathologic mechanisms and interactions with elements of the immune system. Where the thrust of the proposed study is concerned with effects of immune system functions in health and disease on neural tissues, primary assignment will be given to NIAID. Applications judged more responsive to program interests of other Institutes will be assigned accordingly.

Application receipt dates are November 1, March 1 and July 1.

The phrase, **"NEURAL MODULATION OF IMMUNE RESPONSES"** should be typed in Section 2 on the front page of the grant application form. The original and six exact photocopies of the application should be mailed to the following address:

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

For further information applicants may contact:

Dr. Novera Herbert Spector
FNP, NINCDS
National Institutes of Health
Federal Building - Room 916
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-5745

or

Dr. Bernard W. Janicki
Chief, Immunobiology and Immunochemistry Branch
IAIDP, NIAID
National Institutes of Health
Westwood Building - Room 757
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7551

ANNOUNCEMENT**RESEARCH ON THE PREVENTION OF ADM DISORDERS IN****CHILDREN AND ADOLESCENTS****ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION****NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM****NATIONAL INSTITUTE ON DRUG ABUSE****NATIONAL INSTITUTE OF MENTAL HEALTH**

Application Receipt Date: November 1, March 1

The Institutes of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are interested in improving the scientific basis for the conceptualization, design, implementation, and evaluation of preventive interventions to reduce the incidence of alcohol abuse, drug abuse, and mental health (ADM) disorders in children and adolescents. Toward that goal, this announcement invites methodologically rigorous applications which use existing longitudinal data sets to improve understanding of: (1) interactions among known risk factors and precursors of ADM disorders; (2) temporal sequences whereby these risk factors and precursors evolve into ADM disorders; (3) models which clarify appropriate points for intervening in the development of ADM disorders; and (4) methodological and statistical procedures for conducting risk-factor and preventive intervention research.

Research strategies must use existing longitudinal data but may also incorporate the generation of additional data to supplement an existing longitudinal data set. Applications should reflect the concerns of the ADAMHA Institutes and examine the commonalities and distinctions in the development and prevention of ADM disorders in children and adolescents. Applications must address the interests of at least two of the three ADAMHA Institutes.

I. BACKGROUND

During the past decade, there has been increasing attention to the design, implementation, and evaluation of strategies to reduce the incidence of ADM disorders in the Nation's youth. Although advances have been made in the understanding of the methodological complexities of identifying risk factors which cut across ADM disorders and of the programmatic difficulties inherent in

This program is described in the Catalog of Federal Domestic Assistance No. 13.242, Mental Health Research Grants, No. 13.273, Alcohol Research Programs, and 13.279, Drug Abuse Research Programs. Awards will be made under the authority of the Public Health Service Act Sections 301, 510 and 515, as amended and administered under PHS grant policies and Federal Regulations 42 CFR Part 52, Grants for Research Projects. This program is not subject to Health Systems Agency review.

preventive interventions aimed at multiple problems, to date, the development of demonstrably effective prevention strategies with such a focus has had only limited success.

Thus far, the majority of preventive intervention research efforts have been based on a conceptual model in which the precursors of ADM disorders are identified retrospectively. Rarely has the predictive validity of differences identified in this manner been substantiated, and even more rarely have the etiological and temporal processes involved in the evolution of the disorders been examined. Consequently, even when factors antecedent to a particular disorder have been accurately identified, preventive interventions may have failed because the intervention did not focus on those factors which mediated the development of underlying pathogenic processes.

II. RESEARCH CHARACTERISTICS

This announcement is intended to generate proposed research that will contribute to the development of preventive intervention models by examining prospectively the processes involved in the development of ADM disorders. A significant resource for that effort is the availability of longitudinal data sets which obtained initial assessments of individual, familial, cultural, and environmental variables on subject populations from infancy and early childhood on.

For purposes of this announcement, a longitudinal data set is expected to have the following minimal characteristics:

- o The cohort(s) under investigation must be of adequate size and representativeness to allow for scientifically valid verification of known risk factors and precursors of ADM disorders.
- o The cohort(s) under investigation must have been assessed on two or more separate occasions with adequate overlap of measurement procedures at each point.
- o If additional data are to be generated as part of the proposed research, the portion of the cohort(s) available for reassessment (or for which archival records are available) must be of adequate size and representativeness to allow for scientifically valid inferences.

Applicants are expected to discuss in detail the limitations of the data set to be used. Procedures for addressing limitations should be described. Investigators are encouraged to combine or compare existing data sets, if scientifically justified, in order to broaden the knowledge gained in the proposed research.

III. AREAS OF INVESTIGATION

Applications submitted under this announcement must address the concerns of more than one Institute and must be designed so that they apply directly to development or refinement of preventive interventions. Potential areas acceptable under this announcement include:

- o Risk-factor research which uses existing longitudinal data sets alone or in combination with supplemental newly generated data on ADM status in order to assess the unique and interactive contribution of known risk

factors and the precursors to the development of ADM disorders (e.g., family relationships, history of physical and/or psychological abuse, peer relationships, school adjustment problems, etc.).

- o Research on the temporal aspects of ADM disorders which uses longitudinal data sets alone or in combination with supplemental newly generated data on ADM status in order to assess the temporal sequences whereby risk factors, precursors, and related mediating factors evolve into ADM disorders and which examines the optimal points in that sequence for introducing preventive interventions.
- o Research on the factors related to the differential vulnerability/resistance to ADM disorders of individuals within known risk groups.
- o Research which increases understanding of interactions among ADM disorders in the individual and examines the feasibility of applying findings from the above-mentioned research to the design of preventive interventions.
- o Research on methodological/statistical obstacles to reanalysis of existing data sets, combining existing data with newly generated ADM assessments, archival records, and independently acquired data sets.

IV. APPLICATION CHARACTERISTICS

Applications submitted under this announcement must:

- o Address problem areas of concern to more than one Institute.
- o Focus on, or have potential for, early preventive interventions for ADM disorders, which are defined as actions which:
 - are implemented prior to or early in the development of the disorder or dysfunction and precede the need for treatment,
 - result in the demonstrable avoidance, abbreviation, or reversal of the disorder or dysfunction,
 - result in a demonstrable reduction of the incidence of the specific disorder or dysfunction.
- o For risk-factor research proposals, present the following:
 - existing empirical evidence which clearly links the identified risk-factor with the disorder(s) to be prevented,
 - a research plan designed to elucidate how specific risk-factors evolve and interact as a basis for directly using this information to develop or refine a specific preventive intervention strategy.
- o Reflect developmental and sociodemographic characteristics of the population being studied.

- o Have access to longitudinal data sets and staff with appropriate methodological skills.
- o Where indicated, reflect appropriate arrangements for collaboration with relevant prevention programs.

V. ELIGIBILITY

Grants are available to any nonprofit or profit-making institution, units of State or local government, and authorized units of the Federal Government.

VI. APPLICATION PROCEDURES

State and local government agencies should use form PHS-5161. All other applicants should use the standard PHS 398 (revised 5/82) research grant application form. **"Research on the Prevention of ADM Disorders in Children and Adolescents"** should be typed in item #2 on the face page of the application.

Application kits containing the necessary form and instructions may be obtained from most institutional business offices or offices of sponsored research for 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:

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

The signed original and six (6) permanent legible copies of the complete application should be sent to:

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

VII. CONSULTATION AND FURTHER INFORMATION

Potential applicants are encouraged to seek preapplication consultation.

Preapplication consultation and further information on program requirements of each of the individual Institutes can be obtained from:

National Institute on Alcohol Abuse and Alcoholism

Ernestine Vanderveen, Ph.D.
Chief, Clinical and Psychosocial Research Branch
Division of Extramural Research
Room 14C-17

Telephone: (301) 443-4223

National Institute on Drug Abuse

Meyer Glantz, Ph.D.
 Clinical Research Psychologist
 Prevention Research Branch
 Division of Clinical Research
 Room 10A-16

Telephone: (301) 443-1263

National Institute of Mental Health

Morton Silverman, M.D.
 Chief, Center for Prevention Research
 Division of Prevention and Special
 Mental Health Programs
 Room 11C-06

Telephone: (301) 443-4283

The mailing address for the above is:

Parklawn Building
 5600 Fishers Lane
 Rockville, Maryland 20857

VIII. REVIEW PROCESS

Applications received under this announcement will be assigned to a single Institute for review and administration if an award is made. Applications will be reviewed for scientific merit by a peer review group consisting primarily of non-Federal experts. Since these applications are expected to cut across several fields, special attention will be given to ensuring that appropriate expertise is available for their review.

Applications will receive a secondary review for scientific/technical merit and policy consideration by the National Advisory Councils of the ADAMHA Institutes. Notification of review outcome will be sent to the applicant by the Institute which is assigned primary responsibility for the particular application. Only applications recommended for approval by the relevant Councils can be considered for funding.

IX. APPLICATION RECEIPT AND REVIEW SCHEDULE

| <u>Receipt of Applications</u> | <u>Initial Review</u> | <u>Advisory Council Review</u> | <u>Earliest Award Date</u> |
|--------------------------------|-----------------------|--------------------------------|----------------------------|
| November 1, 1983 | Feb-Mar, 1984 | May-June, 1984 | July 1, 1984 |
| March 1, 1984 | May-June, 1984 | Sept-Oct, 1984 | December 1, 1984 |

X. REVIEW CRITERIA

Criteria for scientific/technical merit review of applications will include the following:

- o Significance and originality from a scientific or technical standpoint of the goals of the proposed research.
- o Adequacy of the methodology proposed to carry out the research.
- o The qualifications and experience of the principal investigator and proposed staff.
- o Reasonable availability of resources necessary for the research.
- o Reasonableness of the proposed budget and duration in relation to the proposed research.
- o The adequacy of provisions for the protection of human subjects.

In addition, the following special factors will be considered in assessment of specific types of applications:

Risk-factor research

- o Linking the risk-factor(s) to be studied to specific ADM disorders.
- o Soundness of theoretical rationale for proposed approach to elucidating how the risk-factor(s) evolve into, or relate to, specific ADM disorders.
- o Scientific suitability of data set for proposed research.
- o Potential for direct and useful application of findings to development or refinement of specific preventive intervention strategies

Methodological research

- o Potential for direct and useful application to development or refinement of preventive intervention strategies or evaluation.

XI. AWARD CRITERIA

Applications recommended for approval will be considered for funding on the basis of:

- o Scientific and technical merit as determined by the peer review process.
- o Potential contribution to the areas identified in this announcement.
- o Availability of funds.

XII. TERMS AND CONDITIONS OF SUPPORT

Grant funds may be used for expenses clearly related and necessary to carry out prevention research projects, including both direct costs which can be specifically identified with the project and allowable indirect costs of the institution. Research grant support is not provided to establish, add a component to, or operate a preventive intervention program. Support for research-related costs of prevention programs may be requested only for those particular costs and for that period of time required by the research. Such costs must be justified in terms of research objectives, methods, and design which promise to yield important generalizable knowledge and/or make a significant contribution to theoretical concepts. If such costs are requested, applicants must provide a description of other sources of support that have been explored for them. Because of limited research funds, there is a need to keep these types of costs to a minimum in research projects, and, even where justified, the full amount requested may not be awarded.

Grants will be administered in accordance with the PHS Grants Policy Statement including the policy regarding cost sharing. In addition, the applicant should be aware that portions of the following regulations may be relevant and applicable:

- 42 CFR 2 Confidentiality of Alcohol and Drug Abuse Patient Records
- 42 CFR 52 Grants for Research Projects
- 45 CFR 46 Protection of Human Subjects
- 45 CFR 74 Administration of Grants

XIII. AVAILABILITY OF FUNDS

Applications received under this announcement will be considered for funding in Fiscal Year 1984 and in Fiscal Year 1985. It is estimated that up to \$500,000 will be available for new awards during this period.

XIV. PERIOD OF SUPPORT

Applications that propose to analyze data may request support for a period of up to 2 years. Applications that also propose to supplement data sets may request up to 3 years of support.

XV. ADDITIONAL SUPPORT FOR RESEARCH ON PREVENTION OF ADM DISORDERS IN CHILDREN AND ADOLESCENTS

This announcement is a specific initiative of the ADAMHA Institutes. The Institutes have ongoing programs to support a wide range of research on the prevention of ADM disorders in children and adolescents. The contact persons listed under Section VII - CONSULTATION AND FURTHER INFORMATION will provide information on those programs. Announcements of additional special initiatives may also be issued.

ANNOUNCEMENT

FAMILY THERAPY AND 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 a research area of particular importance to the national drug abuse research program which is authorized under Sections 301 and 515 of the Public Health Service Act (42 U.S.C. 241). This program is described in the Catalog of Federal Domestic Assistance No. 13.279, Drug Abuse Research Programs.

The research program called for in this announcement is the study of the efficacy of family therapy in:

- o The treatment of adolescent drug abusers, and
- o The prevention of drug abusing behavior in the younger siblings of those adolescent drug abusers.

Through the Family Therapy and Prevention Research Program, the National Institute on Drug Abuse (NIDA) intends to encourage and stimulate research on brief, systems oriented family therapy* in the treatment of adolescent drug abusers and in the prevention of drug use among their younger siblings. The view of family therapy represented here differs considerably from the tradition way of looking at family members as having influence on the index patient. Quite simply, it is seen as an intervention affecting the entire family. Although modification of the index patient's symptom(s) is an important goal, a further goal is that family functioning improve. Thus, it is anticipated that growth and change through family therapy can result not only in decreased drug use among adolescent drug abusers, but also in clear-cut primary prevention of future family problems, including drug misuse and abuse among siblings.

II. BACKGROUND

Considerable attention has been focused on familial factors which are related to drug abuse. Both structural factors, such as broken homes, and interpersonal factors, such as the quality of parent-child relationships, have been addressed, and there is a growing conviction that the family plays a powerful role in the initiation, maintenance, cessation and prevention of the drug using behavior of its members. In this context, since the early 1970's, there has been growing interest in the application of family therapy to the treatment of drug abuse, especially among

* For purposes of this announcement brief, systems oriented family therapy is defined as therapy in which the family is seen as a group, and in which the treatment focus is on the interaction among family members and the functions of symptoms in the maintenance of the family system. Duration of treatment is generally limited to 16 weeks or less.

adolescents. The applicability of family therapy to drug abuse prevention has more recently received attention. If family therapy is effective, a family system is changed, supporting the healthy development of the children.

Although the number is increasing, there have been relatively few controlled outcome studies which support the utility of family therapy in the prevention and treatment of drug abuse and other behavioral problems. The purpose of this announcement is to encourage rigorous controlled studies, within the outline described below.

A. Application Characteristics

1. Experimental Treatment: The research solicited under this announcement is limited to those brief, systems oriented family therapies which are prevalent in the drug abuse treatment and prevention field (i.e., structural, strategic, communications, and behavioral family therapies), and in which the length of family treatment does not exceed approximately 16 weeks. It is desirable that both parents or parent surrogates (i.e., individuals fulfilling the parental role) be involved in treatment. Individuals who have only one parent or parent surrogate should also be included.
2. Subjects: The target population for this program consists of families with adolescent drug abusers, ages 13-19. The presenting drug abuser should have a history of use or abuse of illicit drugs for a period of at least three months preceding treatment entry. Individuals who have used marijuana only should have used at least an average of three times weekly over the prior three month period to qualify for study inclusion. While individuals may be included who have combined drug and alcohol abuse problems, history of use of alcohol alone is not considered to be drug abuse for purposes of this research program. Since this research program is interested in the efficacy of family therapy for prevention as well as the treatment of drug abuse, the study sample is further limited to families in which there are one or more siblings younger than the presenting abuser to permit analysis of prevention effects. Families included in the study should represent a cross-section of sociodemographic characteristics.
3. Research Design: Research supported under this announcement must be able to differentiate the effects of family therapy per se from the effects of increased attention to the family or any non-therapeutic emphasis on family functioning. Thus, it is anticipated that the research will minimally require at least two comparison treatments, treatment as usual exclusive of family therapy services (e.g., drug abuse counseling provided within drug abuse treatment programs) and a presumably low yield non-therapeutic family intervention (e.g., didactic multi-family discussion groups in which there are no therapeutic or counseling interventions). It is anticipated that subjects will be randomly assigned to the treatment conditions.
4. Specification of Treatments: It is essential that the proposed treatments are clearly defined and that the treatments are delivered in accord with the stated treatment protocols. Thus, an important aspect of this study is the development and use of manuals which specify the

treatment protocols for the experimental family therapy intervention and the comparison family intervention(s). It is expected that the manuals will be an essential part of a total package of staff training. Procedures should contain sufficient and appropriate details to ensure that the family therapy approach studied can be differentiated from other types of family therapy and from the comparison family intervention, and that the treatment protocols are being followed in the delivery of client treatment. While the framework of the manuals and training programs should be included in the grant application, it is anticipated that these will be finalized during the first few months of the grant. Manuals should be suitable not only for specifying the treatment during the research project, but also for publication following study conclusion.

5. Characteristics of Treatment Staff: It is essential that treatment staff be well qualified. Minimum requirements for family therapists include an advanced degree in the helping professions (i.e., psychiatry, psychology, psychiatric social work or psychiatric nursing) and a minimum of two years of experience with family therapy. Preference should be given to therapists with experience in working with drug abuse clients. For the comparison family intervention, counselors shall have an advanced degree and a minimum of two years experience in group counseling or group work and shall be knowledgeable about family dynamics. Again, preference should be given counselors with experience in working with drug abuse clients.
6. Measurement: Three categories of outcome measurements are suggested, one category oriented toward the primary presenting problem (the adolescent's drug abuse) and its corollaries, a second category oriented toward the family dynamics and problems, and a third category oriented toward the younger sibling to evaluate the treatment's preventive effects. In regard to the presenting abuser and younger siblings, it is important to include such variables as employment or school performance and involvement with the criminal justice system, in addition to standard drug and alcohol use measures. Data for both the individual and family categories should be collected from multiple sources, such as self-reports, third-party reports, and objective tests and observations. Follow-up data should be gathered for at least two years following completion of treatment, with assessments occurring immediately following treatment, six months, one year, and two years thereafter.

Measures of individual dynamics such as the Psychiatric Status Schedule (Spitzer *et al.*) and the Behavior Problem Checklist (Quay and Peterson) and measures of family dynamics such as the Family Environment Scale (Moos), the Beavers-Timberlawn Family Evaluation Scale (Lewis *et al.*), and FACES II (Olson) are examples of appropriate instruments that may be considered for use in the study. Instruments must have established reliability and validity.

In addition to outcome assessment, a comprehensive process evaluation is required. This assessment should carefully document the nature and extent of recruitment and treatment efforts.

7. Availability of Subjects: Applicants should carefully document the availability of sufficient subjects for the effective implementation of the research project. If recruitment will depend on referrals from other agencies, detailed letters of cooperation with the relevant agencies should be included as appendices to the application. Special recruitment strategies for low income and ethnic minority groups are encouraged in order to assure sufficient subjects to permit analyses of these groups.
8. Collaboration: To enhance the generalizability of findings, comparability of research procedures and instrumentation among various grantees under this program is desirable. Thus, applications from collaborating investigators are encouraged. To further facilitate exchange of information and collaboration where possible among funded projects, NIDA will sponsor meetings for investigators. Applicants may request funds for two trips to the Washington, D.C. area during the first year of the grant and one trip in each subsequent year for this purpose.

III. APPLICATION

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 copies of applications (original and 2 copies if PHS 5161 is used) must be submitted to:

Division of Research Grants
Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

IV. FURTHER INFORMATION AND CONSULTATION

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

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

Investigators are encouraged to submit concept papers or outlines of their research to NIDA staff prior to preparing an application.

Investigators who wish to pursue other types of family therapy research than specified under this announcement, should contact:

Mr. George Beschner
Acting Chief, Treatment Research Branch
National Institute on Drug Abuse
Parklawn Building - Room 10A-30
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4060

V. 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.

VI. REVIEW CRITERIA

Criteria to be considered in evaluating applications include, but are not limited to:

- o Evidence that the applicant has the potential to assemble an appropriate team of experienced service providers and to successfully utilize the family therapy modality in the treatment and prevention of drug abusing behavior.
- o Qualifications and experience, specifically in treatment/prevention research of the investigative team; the challenges of this research call for the most experienced researchers.
- o Originality and potential significance of the proposed research.
- o Scientific soundness, appropriateness, and feasibility of the subject recruitment strategies, research design, outcome measures to be utilized, and data analysis plans for measuring treatment and prevention effects.
- o Adequacy of plans for treatment manuals and staff training.
- o Adequacy of the facilities, resources, and administrative structure for achieving the research objectives.
- o Potential replicability of the proposed family therapy approach in drug abuse treatment and prevention programs.
- o Adequacy of proposed budget and timeframes for the project.
- o Adequacy of proposed procedures for the protection of human subjects.

VII. AWARD CRITERIA

Criteria for funding of applications include the scientific merit of the proposal, as determined by peer review, balance and compatability among proposed projects, and relevance to national need as reflected in NIDA's research priorities and plans. The availability of funds will also be considered in determining which awards will be made.

VIII. AVAILABILITY OF FUNDS

Up to \$750,000 will be available to initiate research projects in response to this announcement during Fiscal Year 1984. It is anticipated that up to three projects will be funded. Funding for new projects in subsequent years will be dependent on available funds and program priorities.

IX. APPLICATION RECEIPT AND REVIEW SCHEDULE

| <u>Receipt Dates Renewal/New</u> | <u>Initial Review Committee</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 |

X. PERIOD OF SUPPORT

Applications may request support for a period of up to five years. It is anticipated that five years of support will be needed to provide sufficient time to assess prevention effects on younger siblings as they mature, The treatment phase of the project should be completed within the first 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.

ANNOUNCEMENT

RESEARCH AND DEMONSTRATIONS RELATING TO OCCUPATIONAL SAFETY AND HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

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

For All Except Small Grants Which Have Receipt Dates Of:

October 1, February 1, and June 1

The Centers for Disease Control (CDC), National Institute for Occupational Safety and Health (NIOSH) announces that competitive grant applications are being accepted for research and demonstrations relating to occupational safety and health. These include innovative methods, techniques, and approaches for dealing with occupational safety and health problems in the general industry and in the mining industry.

Support in the form of project grants will be awarded for annual budget periods, within a project period not to exceed five years.

I. AUTHORITY

These grants will be awarded and administered by NIOSH under the research and demonstration grant authority of Section 20(a) (1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669 (a)(1) and section 501 of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951). Program regulations applicable to these grants are contained in Part 87 of Title 42, Code of Federal Regulations, "National Institute for Occupational Safety and Health Research and Demonstration Grants." Except as otherwise indicated, the basic grant administration policies of the Department of Health and Human Services and the Public Health Service are applicable to this program.

II. ELIGIBLE APPLICANTS

Eligible applicants include non-profit and for-profit organizations. Thus universities, colleges, research institutions and other public and private organizations including State and local governments and small, minority and or woman-owned businesses are eligible for these research and demonstration grants. For-profit organizations will be required to submit a certification as to their status as part of their application.

III. PROGRAM REQUIREMENTS

A. Research Project Grants

A research project grant application should be intended and designed to establish, discover, develop, elucidate, or confirm information relating to occupational safety and health, including innovative methods, techniques, and approaches for dealing with occupational safety and health problems. These studies may generate information that is readily available to solve problems or contribute to a better understanding of underlying causes and mechanisms.

B. Demonstration Grants

A demonstration grant application should address, either on a pilot or full-scale basis, the technical or economic feasibility or application of: (1) a new or improved occupational safety or health procedure, method, technique, or system, or (2) an innovative method, technique, or approach for preventing occupational safety or health problems.

C. Small Grants

A small grant application is intended to provide financial support to carry out exploratory or pilot studies, to develop or test new techniques or methods, or to analyze data previously collected. This small grant program is intended for predoctoral graduate students, post-doctoral researchers (within three years following completion of doctoral degree or completion of residency or public health training) and junior faculty members (no higher than assistant professor). If university policy requires that a more senior person be listed as principal investigator the application should specify that the funds are for the use of a particular student or junior level person and should include appropriate justification for this arrangement. Though biographical sketches are required only for the person actually doing the work, the application should indicate who would be supervising the research. Small grant applications should be identified as such on the application form.

The total small grant award may comprise direct costs of up to \$15,000 per year and additional indirect costs, as appropriate. The grants may be awarded for up to two years and are thereafter continuable by competitive renewal as a regular research grant. Salary of the principal investigator as well as that of the junior investigator, if university policy requires a senior person to be listed as the principal investigator, will not be allowed on a small grant, though salaries can be requested for necessary support staff such as laboratory technicians, interviewers, etc.

D. Program Project Grants

NIOSH will also accept applications for program project grants, but only after discussion with the individuals listed in this announcement.

IV. PROGRAMMATIC INTEREST

Examples of work-related programmatic interest to NIOSH which are applicable to all of the above types of grants are:

1. Occupational lung diseases: asbestosis, byssinosis, silicosis, coal workers' pneumoconiosis, lung cancer, occupational asthma*
2. Musculoskeletal injuries: disorders of the back, trunk, upper extremity, neck, lower extremity; traumatically induced Raynaud's phenomenon*
3. Occupational cancers (other than lung): leukemia; mesothelioma; cancers of the bladder, nose, and liver*
4. Amputations, fractures: eye loss, lacerations, and traumatic deaths*
5. Cardiovascular diseases: hypertension, coronary artery disease, acute myocardial infarction*
6. Disorders of reproduction: infertility, spontaneous abortion, teratogenesis*
7. Neurotoxic disorders: peripheral neuropathy, toxic encephalitis, psychoses, extreme personality changes (exposure-related)*
8. Noise-induced loss of hearing*
9. Dermatologic conditions: dermatoses, burns (scaldings), chemical burns, contusions (abrasions)*
10. Psychologic disorders: neuroses, personality disorders, alcoholism, drug dependency*
11. Control technology research: application of scientific principles to control strategies; preconstruction review; technology forcing/new source performance concepts; technology transfer; substitution; unit operations approaches*
12. Respirator research: new and innovative respiratory protective devices; techniques to predict performance; effectiveness of respirator programs; physiologic and ergonomic factors; medical surveillance strategies; psychological and motivational aspects; effectiveness of sorbents and filters, including chemical and physical properties*

*The conditions or examples listed under each category are to be viewed as selected examples, not comprehensive definitions of the category. It should be noted, however, that investigators may apply in any areas related to occupational safety and health. Applications responding to this announcement will be reviewed by staff for their responsiveness and relevance to occupational safety and health. Those

considered non-responsive will be assigned in accordance with regular program guidelines. Potential applicants with questions concerning the acceptability of their proposed work should contact the individuals listed in this announcement.

V. CRITERIA FOR REVIEW

Applications will be evaluated by a dual review process. The primary (peer) review is based on scientific merit and significance of the project, competence of the proposed staff in relation to the type of research involved, feasibility of the project, likelihood of its producing meaningful results, appropriateness of the proposed project period, adequacy of the applicant's resources available for the project, and appropriateness of the budget request.

Demonstration grant applications will be reviewed additionally on the basis of the following criteria:

- o Degree to which project objectives are clearly established, obtainable, and for which progress toward attainment can and will be measured.
- o Availability, adequacy, and competence of personnel, facilities, and other resources needed to carry out the project.
- o Degree to which the project can be expected to yield or demonstrate results that will be useful and desirable on a national or regional basis.
- o Extent of cooperation expected from industry, unions, or other participants in the project, where applicable.

Small grant applications will be reviewed additionally on the basis of the following criteria:

- o The review process will take into consideration the fact that the applicants do not have extensive experience with the grant process.

A secondary review will also be conducted. Factors considered in the secondary review will include:

- o The results of the initial review.
- o The significance of the proposed study to the research programs of NIOSH.
- o National needs and program balance.
- o Policy and budgetary considerations.

VI. APPLICATION AND AWARD

Applications should be submitted on Form PHS-398 (revised May 1982) or PHS-5161-1 for State and local government applicants. Forms should be available from the institutional business offices or from:

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

The original and six copies of the application must be submitted to the address below on or before the specified receipt dates in accordance with the instructions in the PHS-398 packet:

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

In developing the application please note that the conventional presentation for grant applications should be used and the points identified under "CRITERIA FOR REVIEW" must be fulfilled.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application that are made available to outside reviewing groups. If the applicant organization elects to exercise this option, use asterisks on the original and six copies of the application to indicate those individuals for whom salaries and fringe benefits are being requested; the subtotals must still be shown. In addition, submit an additional copy of page four of Form PHS-398, completed in full with the asterisks replaced by the amount of the salary and fringe benefits requested for each individual listed. This budget page will be reserved for internal PHS staff use only.

The instructions in the Form PHS-398 packet should be followed concerning deadlines for either delivering or mailing the applications. The application should be sent or delivered using the mailing label in the Form PHS-398 packet.

The proposed timetable for receiving applications and awarding grants is as follows:

All Except Small Grants

| <u>Application Deadline</u> | <u>Primary Review Group Meeting</u> | <u>Secondary Review Meeting</u> | <u>Expected Start Date</u> |
|-----------------------------|-------------------------------------|---------------------------------|----------------------------|
| March 1 | June | September | December 1 |
| July 1 | Oct./Nov. | January | April 1 |
| November 1 | Feb./Mar. | May | May/July 1 |

Small Grants

| | | | |
|------------|-----------|-----------|------------|
| February 1 | June | September | December 1 |
| June 1 | Oct./Nov. | January | April 1 |
| October 1 | Feb./Mar. | May | July 1 |

Awards will be made based on priority score ranking and emphasis area, as well as availability of funds.

VII. COST SHARING

Grantees will be expected to cost share a minimum of five percent.

VIII. FOR FURTHER INFORMATION CONTACT:

Mr. Ralph Touch
Acting Chief, Grants Administration
and Review Branch
National Institute for Occupational
Safety and Health
Centers for Disease Control
1600 Clifton Road, N.E.
Atlanta, Georgia 30333

Telephone: (404) 329-3773

or

Kenneth Bridbord, M.D.
Director, Office of Extramural Coordination
and Special Projects
National Institute for Occupational
Safety and Health
Westwood Building - Room 3A10
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-6723

(This program is described in the Catalog of Federal Domestic Assistance Program No. 13.262, Occupational Safety and Health Research Grants and is not subject to Health Systems Agency review.)

ANNOUNCEMENT

NURSING RESEARCH PROJECT GRANTS

NURSING RESEARCH PROGRAM GRANTS

NURSING RESEARCH EMPHASIS GRANTS FOR DOCTORAL PROGRAMS IN NURSING

HEALTH RESOURCES AND SERVICES ADMINISTRATION

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

The Division of Nursing (DN), Bureau of Health Professions, Health Resources and Services Administration (HRSA), makes the following announcements regarding three components of its research support program authorized under Section 301 of the Public Health Service Act.

Section 301 authorizes the Secretary to award grants to any corporation, public or private institution or agency or other legal entity to enlarge the body of scientific knowledge that underlies nursing practice, nursing education, and nursing services administration; and to strengthen these areas through utilization of such knowledge.

These programs are listed at 13.361 in the Catalog of Federal Domestic Assistance, Nursing Research Project Grants. Applications submitted in response to this announcement are not subject to review by State and area-wide clearinghouses under the procedures in the Office of Management and Budget Circular No. A-95.

Application materials are being made available without final action on the related Fiscal Year 1984 budget.

I. NURSING RESEARCH PROJECT GRANTS

Applications for Nursing Research Project Grants, which are the traditional, discrete research projects performed by the named investigator(s) in an area representing her/his specific interest and competency, will continue to be accepted. Application deadline dates are November 1, March 1, and July 1.

II. NURSING RESEARCH PROGRAM GRANTS

The ceiling of \$100,000 direct costs per year, which is currently a condition of application for an award of Nursing Research Program Grants is now eliminated. Instead, direct costs should be based solely on the fiscal needs of the component projects and any core requirements. Direct costs per year may, therefore, be either more or less than \$100,000. This policy is effective for all applications--both competing and noncompeting--submitted after the date of publication of this announcement. The application deadline dates are October 1, February 1, and June 1.

III. NURSING RESEARCH EMPHASIS GRANTS FOR DOCTORAL PROGRAMS IN NURSING

The specific purpose of this program is to stimulate the development of nursing research in areas that emphasize special health needs of the Nation and to enhance the research efforts and resources of faculty in schools of nursing which offer doctoral programs. Students should be enrolled in the nursing doctoral program at the time of submission of an application. Application deadline dates are November 1, March 1, and July 1.

IV. APPLICATION PROCEDURES

Research grant application kits, PHS 398 (Rev. 5/82), are available through the research offices of most institutions. Applications may be submitted at any time to the following:

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

Applications must be received by the above dates for consideration in the next review cycle. A package carrying a legible proof-of-mailing date assigned by the carriers, and which is no later than one week prior to the receipt date, is also acceptable. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following work day.

For further information contact:

Nursing Research Support Section
Nursing Research and Analysis Branch
Division of Nursing
Bureau of Health Professions
Health Resources and Services Administration
Parklawn Building - Room 5C-09
5600 Fishers Lane
Rockville, Maryland 20782

Telephone: (301) 443-6315

Questions regarding grants policy should be directed to:

Grants Management Officer
Bureau of Health Professions
Health Resources and Services Administration
Parklawn Building - Room 8C-22
5600 Fishers Lane
Rockville, Maryland 20782

Telephone: (301) 443-6915