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The 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.*

Supplements, printed on yellow paper, are published by the respective awarding units concerning new projects, solicitations of sources, and requests for proposals.

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REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

NATIONAL CANCER INSTITUTE

TITLE: *IDENTIFICATION AND EVALUATION OF COUNSELING TECHNIQUES FOR CANCER PATIENTS*

The Division of Cancer Control and Rehabilitation (DCCR) of the National Cancer Institute is inviting grant applications from interested investigators for the purpose of identifying and evaluating the effectiveness of selected counseling techniques utilized in helping cancer patients cope with the psychological and emotional problems commonly associated with the diagnosis and treatment of cancer.

This type of solicitation (the RFA) is utilized when the Division wishes to stimulate investigator interest in a particular area that is important to the National Cancer Program. Unlike the Request for Proposals (RFPs), the RFA is supported through the customary NIH grant-in-aid and is governed by the policies for investigator-initiated grants. All applications in response to the RFA will be reviewed by an appropriate peer review group of NIH. Approved applications that receive grant awards will be administered in the same fashion as all NIH grants.

Applications should be prepared in accordance with the aims and requirements which are described in the following sections.

I. PROGRAM SPECIFICATIONS

- A. Division of Cancer Control and Rehabilitation
- B. Statement of the Problem
- C. Objectives
- D. Scope of Solicitation
- E. Mechanism of Support

II. METHOD AND CRITERIA FOR REVIEW

- A. Review Procedure
- B. Review Criteria

III. METHOD OF APPLYING

- A. Letter of Intent
- B. Application Format
- C. Application Procedure

Questions concerning this announcement should be directed to:

Mr. Lawrence D. Burke
Program Director for Rehabilitation
National Cancer Institute
Room 617, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

I. PROGRAM SPECIFICATIONS

A. DCCR - DCCR has the principal Federal responsibility for assuring the rapid and effective application from cancer research findings to the fields of prevention, detection, diagnosis, treatment, rehabilitation, and continuing care. Its primary objective is to develop innovative approaches which will reduce the incidence, morbidity, and mortality from cancer. This objective is accomplished through the identification, field testing, and demonstration of the effectiveness of cancer control knowledge and techniques in well-designed study or structured programs. The purpose of this RFA is to identify, test, and evaluate selected counseling techniques for specific psychological problems common to cancer patients.

B. Statement of the Problem - In an age of specialization and fragmentation, the treating oncologist may become primarily focused upon the disease process to the exclusion of the cancer patient's emotional and psychological reactions to the disease and its treatment. It is generally known that the cancer patient experiences a wide range of emotional difficulties and symptoms which often have a devastating effect on his personality, behavior, and relationships with others. Psychological studies and empirical observations have clearly documented a causal relationship between the diagnosis and treatment of cancer and increased states of anxiety, depression, and immobilization.

A significant number of cancer patients have expressed a need for guidance and support in coping with their emotional and psychological reactions. While there has been a variety of counseling approaches employed to improve the emotional well-being of the cancer patient, little objective evidence exists to document the benefit of any given counseling technique for cancer patients.

It is imperative that effective counseling techniques be identified and evaluated in order to lessen the negative psychological and emotional effects of cancer and its treatment on the long-term cancer survivor.

C. Objectives - It is the intent of this RFA to stimulate research to identify and evaluate the effectiveness of selected counseling techniques for cancer patients with identified specific psychological problems. Greater specificity must be achieved in the area of cancer patient counseling. It is hoped that this research will lead to innovative approaches for cancer patient counseling.

For the purpose of this RFA, counseling techniques can be defined as those methods of therapeutic intervention which seek to aid, guide, and support the cancer patient in better understanding, confronting, and coping with the emotional and functional problems encountered as a result of the disease and its treatment. The primary recipient of the counseling in this study should be the patient.

The investigator should select and define a specific counseling technique(s) which allegedly has universal application to the psychosocial problems of a cancer patient. The specific technique(s) should be applied to a designated, diagnosed cancer related, emotional problem(s). While the value and benefit of family counseling is well-recognized, it is the purpose of this RFA to address more directly the need for patient-directed counseling.

D. Scope of Solicitation - In their proposals, applicants should address the following points, although support is not limited to these subjects:

1. Identification and description of the patient population to be studied. Patients should be subdivided into groups according to such common characteristics as age, stage of disease, and organ site. Rationale for sample selection should be explained. Control groups are recommended.

2. Identification of specific emotional and psychological problems that require counseling. The problems selected for study should include those which are commonly associated with a majority of cancer patients.

3. Analysis of the relations of specific emotional and psychological problems to specific counseling techniques. The investigator should clarify the rationale for matching a given counseling technique to a given psychological problem. The theoretical basis for the counseling should be fully articulated. Enumerate any special skills, qualifications, or experience requisite for the counselor or professional giving the counseling.

4. The methodology for testing and evaluating selected counseling techniques, as well as the method of data collection and data analysis. The investigator should describe the measures for assessing and quantifying the benefit of the identified counseling techniques to the patient or patient group.

5. Establishment of a timetable for accomplishing objectives and presentation of findings.

E. Mechanism of Support - The support mechanism for this program will be the traditional NIH grant-in-aid; successful applicants will plan and execute their own programs. Although this program is included and provided for in the financial plans for fiscal year 1979, award of grants pursuant to this request for application is contingent upon availability of funds for this purpose.

II. METHOD AND CRITERIA FOR REVIEW

A. Review Procedure - Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) and the NCI staff for responsiveness to this announcement. If the application is judged

unresponsive, the applicant will be given an opportunity to withdraw the application or to submit it for consideration in the traditional grant program of NIH.

Applications judged responsive will be reviewed initially for scientific merit by an NIH peer review group and secondly by the National Cancer Advisory Board.

B. Review Criteria - The factors considered in evaluating each application will be:

1. Relevance of the proposal to the scope and objectives provided in this announcement.

2. The technical merit of the proposed approach. Technical merit includes soundness of methodological approach and research design.

3. The expertise and qualifications of the Principal Investigator and proposed staff.

4. Sufficient commitment of time by the Principal Investigator and proposed staff.

5. Evaluation plan and timetable.

6. Relationship of cost proposal to the research endeavor.

III. METHOD OF APPLYING

A. Letter of Intent - Each prospective applicant should submit a letter of intent containing a brief description of the proposed project. Due dates are:

Letters of Intent	Applications
December 1, 1978	January 15, 1979
February 1, 1979	March 1, 1979
June 1, 1979	July 1, 1979

The letter of intent should be addressed to:

Mr. Lawrence D. Burke
Program Director for Rehabilitation
National Cancer Institute
Room 617, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

Such letters provide an indication of the number and nature of applications, are not binding, and will not enter into the review of any proposal submitted.

B. Application Format - Applications should be submitted on form PHS 398. The conventional presentation for grant applications should be utilized and the points identified under the Review Criteria must be fulfilled. The words "PROPOSAL IN RESPONSE TO RFA: IDENTIFICATION AND EVALUATION OF COUNSELING TECHNIQUES FOR CANCER PATIENTS" must be typed in bold letters across the top of the face page of the application.

C. Application Procedure - Applications must be received on or before the application receipt dates in III.A. above. The original and six copies of the application should be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Room 240, Westwood Building
Bethesda, Maryland 20014

A brief covering letter should accompany the application indicating that it is in response to this RFA. A copy of the covering letter should be sent to:

Mr. Lawrence D. Burke
Program Director for Rehabilitation
National Cancer Institute
Room 617, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

to indicate that the application has been submitted.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

NATIONAL CANCER INSTITUTE

TITLE: *"PATTERNS OF CARE" IN ONCOLOGY*

The Division of Cancer Control and Rehabilitation (DCCR) is inviting grant applications for the purpose of determining existing patterns and standards for the management of the more common tumor types.

This type of solicitation (the RFA) is utilized when the Division wishes to stimulate investigator interest in a particular area that is important to the National Cancer Program. Unlike the Request for Proposals (RFPs), the RFA is supported through the customary NIH grant-in-aid and is governed by the policies for investigator-initiated grants. All applications in response to the RFA will be reviewed by an appropriate peer review group of NIH. Approved applications that receive grant awards will be administered in the same fashion as all NIH grants.

Applications should be prepared in accordance with the aims and requirements which are described in the following sections.

I. PROGRAM SPECIFICATIONS

- A. Division of Cancer Control and Rehabilitation
- B. Objectives
- C. Scope of This Solicitation
- D. Mechanism of Support

II. METHOD AND CRITERIA FOR REVIEW

- A. Review Procedure
- B. Review Criteria

III. METHOD OF APPLYING

- A. Letter of Intent
- B. Application Format
- C. Application Procedure

Questions concerning this announcement should be directed to:

Harry Handelsman, D.O.
Program Director for Clinical
Cooperative Groups
Division of Cancer Control and
Rehabilitation
National Cancer Institute
Room 616, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

I. PROGRAM SPECIFICATIONS

A. DCCR - DCCR has the principal Federal responsibility for assuring the rapid and effective application of cancer research findings in the areas of prevention, detection, diagnosis, pretreatment evaluation, treatment, rehabilitation, and continuing care. This is accomplished through the identification, field testing, demonstration, and promotion of proven effective cancer control knowledge and techniques. DCCR also supports investigator-initiated research efforts in the areas of rehabilitation and continuing care.

The DCCR is currently funding a study entitled "Clinical and Research Radiation Therapy in Cancer Care" which is popularly referred to as the "Patterns of Care Study," which includes an analysis of current patterns of radiation therapy.

The purpose of this RFA is to determine current patterns of management for one or more of the common malignancies, using the well-developed model of the American College of Radiology in their "Patterns of Care Study" or other appropriate strategies.

B. Objectives - The intent of this RFA is to generate grant proposals from organizations having the capability of determining existing patterns and standards of cancer management for one or more of the common cancers. Proposals should be limited to what could reasonably be accomplished on a regional basis (area that provides statistically valid results) and regarded as a "pilot" study for potential expansion to a national program. The applicant shall select one or a group of cancers diagnosed and treated within a medical speciality or managed primarily by one speciality. The application shall define the scope of the assessment in terms of specialities and interventions involved and the rationale for the selection.

C. Scope of This Solicitation - Applicants should address all of the following points, although support is not limited to items noted.

1. Description of the research plan including facilities, personnel, and patient population.

2. Methodology for accomplishing tasks.

3. Costs.

4. Description of evaluation plan.

5. Timetable for accomplishing objectives and producing final results of program.

Award of a grant under this solicitation to a given institution or organization neither implies nor guarantees favorable action on any subsequent application for a demonstration grant.

D. Mechanism of Support - The support mechanism for this program will be the traditional NIH grant-in-aid; successful applicants will plan and execute their own study effort. Although this program is included and provided for in the financial plans for fiscal year 1979, award of grants pursuant to this request for applications is contingent upon availability of funds for this purpose.

II. METHOD AND CRITERIA FOR REVIEW

A. Review Procedure - Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) and the NCI staff for responsiveness to this announcement. If an application is judged unresponsive, the applicant will be given an opportunity to withdraw the application or to submit it for consideration in the traditional grant program of NIH. Applications judged responsive will be reviewed initially for scientific merit by an NIH peer review group and secondly by the National Cancer Advisory Board.

B. Review Criteria - The following will be considered in evaluating each application:

1. Relevance of the proposal to the scope and objectives provided in this announcement.
2. Approaches to the problem.
3. Adequacy of the facilities and patient population.
4. Qualifications of staff.
5. Evaluation plan and timetable.
6. Costs.

III. METHOD OF APPLYING

A. Letter of Intent - Each prospective applicant should submit a letter of intent containing a brief description of the proposed project. Due dates are:

Letters of Intent	Applications
December 1, 1978	January 15, 1979
February 1, 1979	March 1, 1979
June 1, 1979	July 1, 1979

The letter of intent should be addressed to:

Harry Handelsman, D.O.
Program Director for Clinical
Cooperative Groups
Division of Cancer Control and
Rehabilitation
National Cancer Institute
Room 616, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

Such letters provide an indication of the number and nature of applications, are not binding, and will not enter into the review of any proposal submitted.

B. Application Format - Applications should be submitted on form PHS 398. The conventional presentation for grant applications should be utilized and the points identified under the Review Criteria must be fulfilled. The words "PROPOSAL IN RESPONSE TO RFA: 'PATTERNS OF CARE' IN ONCOLOGY" must be typed in bold letters across the top of the face page of the application.

C. Application Procedure - Applications must be received on or before the application receipt dates in III.A. above. The original and six copies of the application should be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Room 240, Westwood Building
Bethesda, Maryland 20014

A brief covering letter should accompany the application indicating that it is in response to this RFA. A copy of the covering letter should be sent to:

Harry Handelsman, D.O.
Program Director for Clinical
Cooperative Groups
Division of Cancer Control and
Rehabilitation
National Cancer Institute
Room 616, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

to indicate that the application has been submitted.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

NATIONAL CANCER INSTITUTE

TITLE: *THE ROLE OF NUTRITION IN THE REHABILITATION OF CANCER PATIENTS*

The Division of Cancer Control and Rehabilitation (DCCR) of the National Cancer Institute is inviting grant applications from interested investigators for the purpose of studying the effects of specially designed nutrition programs on the cancer rehabilitation process.

This type of solicitation (the RFA) is utilized when the Division wishes to stimulate investigator interest in a particular area that is important to the National Cancer Program. Unlike the Request for Proposals (RFPs), the RFA is supported through the customary NIH grant-in-aid and is governed by the policies for investigator-initiated grants. All applications in response to the RFA will be reviewed by an appropriate peer review group of NIH. Approved applications that receive grant awards will be administered in the same fashion as all NIH grants.

Applications should be prepared in accordance with the aims and requirements which are described in the following sections.

I. PROGRAM SPECIFICATIONS

- A. Division of Cancer Control and Rehabilitation
- B. Statement of the Problem
- C. Objectives
- D. Scope of This Solicitation
- E. Mechanism of Support

II. METHOD AND CRITERIA FOR REVIEW

- A. Review Procedure
- B. Review Criteria

III. METHOD OF APPLYING

- A. Letter of Intent
- B. Application Format
- C. Application Procedure

Questions concerning this announcement should be directed to:

Mr. Lawrence D. Burke
Program Director for Rehabilitation
National Cancer Institute
Room 617, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

NATIONAL CANCER INSTITUTE

TITLE: *PROGRAM FOR IMPROVED CARE OF CANCER PATIENTS WITH TERMINAL DISEASE*

The Division of Cancer Control and Rehabilitation (DCCR) is inviting grant applications for the purpose of implementing and evaluating innovative projects for the improved care of cancer patients with terminal disease.

This type of solicitation (the RFA) is utilized when the Division wishes to stimulate investigator interest in a particular area that is important to the National Cancer Program. Unlike the Request for Proposals (RFPs), the RFA is supported through the customary NIH grant-in-aid and is governed by the policies for investigator-initiated grants. All applications in response to the RFA will be reviewed by an appropriate peer review group of NIH. Approved applications that receive grant awards will be administered in the same fashion as all NIH grants.

Applications should be prepared in accordance with the aims and requirements which are described in the following sections.

I. PROGRAM SPECIFICATIONS

- A. Division of Cancer Control and Rehabilitation
- B. Statement of the Problem
- C. Objectives
- D. Scope of This Solicitation
- E. Mechanism of Support

II. METHOD AND CRITERIA FOR REVIEW

- A. Review Procedure
- B. Review Criteria

III. METHOD OF APPLYING

- A. Letter of Intent
- B. Application Format
- C. Application Procedure

Questions concerning this announcement should be directed to:

Mr. Lawrence D. Burke
Program Director for Rehabilitation
National Cancer Institute
Room 617, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

I. PROGRAM SPECIFICATIONS

A. DCCR - DCCR has the principal Federal responsibility for assuring the rapid and effective application of the findings from cancer research to the fields of prevention, detection, diagnosis, treatment, rehabilitation, and continuing care. Its primary objective is to develop innovative approaches to reduce the incidence, morbidity, and mortality from cancer. This objective is accomplished through the identification, field testing, and demonstration of the effectiveness of new knowledge and techniques, vis-a-vis the management of cancer. The purpose of this RFA is to encourage and promote grant proposals for the implementation and evaluation of innovative study projects for the improved care of cancer patients with terminal disease.

B. Statement of the Problem - The cancer patient with terminal disease requires a different clinical approach than the cancer patient under treatment directed toward effecting a cure. The terminal cancer patient needs active palliative care, sophisticated medical management of symptoms, and psychological and social support for the patient and family.

Currently, 750,000 patients a year are diagnosed with cancer, and the Fact and Figure Book of the American Cancer Society has predicted that 10 million people will be diagnosed with cancer by the 1990's. Despite marked improvement in the medical management of cancer and increased survival rates, a significant percent of diagnosed cancer patients will succumb to their disease. Yet, most modern hospitals are acute care-cure-oriented facilities that are neither physically well equipped nor psychologically well prepared to meet the total needs of the terminal cancer patient.

The emphasis on cure and maintenance of health might not always be compatible with caring and continued active medical attention to symptom management when cure is not possible.

Cancer affects not only the patient, but also the family to a degree that is both economically and sociologically significant. Proposals may address the morbidity to the family as well as to the patient.

The anticipated millions of people who will be affected by a death from cancer constitutes a significant population. Innovative programs to accurately identify and resolve problems associated with terminal disease argues for a high DCCR priority.

C. Objectives - The intent of this RFA is to solicit proposals from investigators who are prepared to investigate and evaluate innovative approaches for the improved care of terminal cancer patients.

Proposals may select a single aspect of terminal care in cancer that needs further study or addresses terminal cancer care more comprehensively. Establishing practical and effective methods for better understanding and ameliorating specific problems common to terminal disease are an objective of this RFA.

Investigators responding to this RFA should have access to terminal cancer patients and also have had training in oncology and considerable experience in the clinical management of the terminally ill cancer patient. The terminally ill patient is defined in this RFA as that cancer patient who has received the maximum definitive treatment, but has not received a remission or significant eradication of his/her disease and whose medical doctor indicates that life expectancy is limited to a few months.

D. Scope of This Solicitation - Applicants should present a program for implementing and evaluating original methods and techniques for improved terminal care including, but not limited to, the following:

1. Description of the proposed project should include: (1) modes of treatment and care available to the study population, (2) statement of the problem in the particular population and environment, (3) implications of proposed study in terms of how it could alter present patterns of terminal cancer care for patients, and (4) review of research studies directed at identifying better means of managing clinical symptom states common to end stage disease in cancer.

2. Identification of specific problems in terminal illness which warrant new study.

3. Description of proposed study (method). Areas that might be explored could be: the best location for the treatment of terminal patients, the relationship of equipment to facilities for optimal care, the relationship of facilities relating to the type of care, the cost of care, the quality of care, improved means for providing pain relief, the role of health care support staff in relation to patient and family, methods and techniques effective for educating and communicating with the patient and family.

4. Outline of the research design, data collection and data analysis and evaluation, including protocols for implementation. This might include the sampling methods for accessing patients into the study, methods of assessing effectiveness of the proposed improved care, and the description of comparison and/or control groups to be accessed. Randomized trials for symptom relief should be considered.

5. Establishment of a timetable for carrying out the study - data collection, collation and analysis, and presentation of findings in camera ready copy. This should be included in the proposal.

6. Statement of clear objectives and the means to evaluate the of objectives. This must be included in the proposal.

E. Mechanism of Support - The support mechanism for this program will be the traditional NIH grant-in-aid; successful applicants

will plan and execute their own programs. Although this program is included and provided for in the financial plans for fiscal year 1979, award of grants pursuant to this request for applications is contingent upon availability of funds for this purpose. The following will not be considered under the scope of this RFA:

1. Duplication of ongoing Hospice demonstration programs which are currently funded under NCI contracts;

2. Funding for the provision of service only;

3. Funding for construction and/or renovation;

4. Evaluation of existing projects; and

5. Development of a new facility or expansion of an existing terminal care facility.

II. METHOD AND CRITERIA FOR REVIEW

A. Review Procedure - Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) and the NCI staff for responsiveness to this announcement. If application is judged unresponsive, the applicant will be given an opportunity to withdraw the application or to submit it for consideration in the traditional grant program of NIH. Applications judged responsive will be reviewed initially for scientific merit by an NIH peer review group and secondly by the National Cancer Advisory Board.

B. Review Criteria - The factors considered in evaluating each application will be:

1. Relevance of the proposal to the scope and objectives provided in this announcement;

2. The technical merit of the proposed approach - this includes methodological approach and study design;

3. The expertise and qualifications of the Principal Investigator and proposed staff;

4. Sufficient commitment of time by the Principal Investigator and proposed staff;

5. Evaluation plan and timetable; and

6. Relationship of cost proposal to the research endeavor.

III. METHOD OF APPLYING

A. Letter of Intent - Each prospective applicant should submit a letter of intent containing a brief description of the proposed project. Due dates are:

Letters of Intent	Applications
December 1, 1978	January 15, 1979
February 1, 1979	March 1, 1979
June 1, 1979	July 1, 1979

The letter of intent should be addressed to:

Mr. Lawrence D. Burke
Program Director for Rehabilitation
National Cancer Institute
Room 617, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

Such letters provide an indication of the number and nature of applications, are not binding, and will not enter into the review of any proposal submitted.

B. Application Format - Applications should be submitted on form PHS 398. The conventional presentation for grant applications should be utilized and the points identified under the Review Criteria must be fulfilled. The words "PROPOSAL IN RESPONSE TO RFA: PROGRAM FOR IMPROVED CARE OF CANCER PATIENTS WITH TERMINAL DISEASE" must be typed in bold letters across the top of the face page of the application.

C. Application Procedure - Applications must be received on or before the application receipt dates in III.A. above. The original and six copies of the application should be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Room 240, Westwood Building
Bethesda, Maryland 20014

A brief covering letter should accompany the application indicating that it is in response to this RFA. A copy of the covering letter should be sent to:

Mr. Lawrence D. Burke
Program Director for Rehabilitation
National Cancer Institute
Room 617, Blair Building
8300 Colesville Road
Silver Spring, Maryland 20910

to indicate that the application has been submitted.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

NATIONAL EYE INSTITUTE

TITLE: *COOPERATING CLINICS IN THE MACULAR PHOTOCOAGULATION STUDY*

I. PROGRAM SPECIFICATIONS

The Macular Photocoagulation Study (MPS) is a collaborative research project recently initiated at eight clinical centers across the United States with a Coordinating Center and a Reading Center at the Wilmer Institute, Johns Hopkins Hospital. The Retinal and Choroidal Diseases Program of the National Eye Institute supports this study through research grants to each of the participating institutions under a cooperative arrangement.

The MPS is a pair of randomized, controlled clinical trials evaluating the efficacy and safety of argon laser photocoagulation therapy in the treatment of two ocular disorders: (1) senile macular degeneration and (2) presumed ocular histoplasmosis. For the former, more than 550 eligible patients will be required and for the latter, more than 750 eligible patients will be required. The natural courses of each of these ocular diseases are also followed in patients not randomly assigned to photocoagulation therapy as well as in additional patients who are not eligible for treatment by the criteria of the study. All participants in the study will be followed for five years under a detailed protocol and manual of procedures, which also specify eligibility criteria and procedures for application of treatment.

Present estimates indicate that the cooperation of from two to six additional clinics will be required in order to meet recruitment goals in a timely manner. The purpose of this announcement, therefore, is to request research grant applications from potential study participants.

Applicants must be eligible to compete for NIH research grants. They must demonstrate their capability to recruit fifteen or more eligible patients per year for the senile macular disease clinical trial, for the ocular histoplasmosis clinical trial, or for both trials. Patient eligibility criteria are summarized as follows:

This program is described in the Catalog of Federal Domestic Assistance, 13.867, and will be supported under authority of Section 451 of the Public Health Service Act as amended (42 USC, CH. 6A, subch. III). National Eye Institute research grants are administered in accord with law, regulation, and policy as described in the Public Health Service Grants Policy Statement, October 1, 1976 [DHEW Publication (OS) 77-50,000] and Addendum [DHEW Publication (OS) 77-50,000-A] and subsequent revisions.

A. Ophthalmoscopic evidence of macular degeneration (drusen) or ocular histoplasmosis (histo spots);

B. Visual acuity of 20/100 or better in one eye;

C. No prior photocoagulation treatment;

D. No glaucoma, diabetic retinopathy, or other concurrent ocular disease;

E. Angiographic evidence of choroidal neovascularization that does not involve the fovea;

F. Age between 18 and 55 (histoplasmosis study) and between 50 and 80 (senile macula study);

G. Willingness on the part of the patient and the physician to have an eligible eye randomly assigned to argon laser photocoagulation or to no treatment, and to meet the requirements of the study with respect to patient followup.

Applicants must also demonstrate their capability and their potential for participation in these clinical trials under fixed patient-treatment and examination protocols in cooperation with other investigators, with a coordinating center, and with a reading center. Applicants that were not successful in prior competition for this study should re-evaluate their application materials if reapplying.

II. METHOD OF APPLYING

A. Potential applicants should call the National Eye Institute, telephone (301) 496-5985, no later than April 1, 1979, and request a copy of the relevant portions of the fixed patient-treatment and examination protocols (manual of procedures).

B. Applications shall be submitted on the regular research grant application form PHS 398 which is available at institutional central application control offices or from the Division of Research Grants, NIH.

1. The following must be typed at the top of the face page of the application: "SUBMITTED IN RESPONSE TO RFA ON MACULAR PHOTOCOAGULATION STUDY, NATIONAL EYE INSTITUTE".

2. The budget request should be for five years and may include funds for investigators, a clinic coordinator, photographic support, travel to MPS meetings, and other expenses. However, the request should not exceed approximately $30,000 direct costs per year (consistent with the operating level of existing clinics) and may not include equipment costs.

3. The biographical sketches for the Principal Investigator and for other participating professional staff should demonstrate their experience with the ocular disorders under study and in clinical research.

4. The research plan section of the proposal must demonstrate fully the capability and the potential to recruit, treat, and follow patients for either or both of the clinical trials in accord withthe manual of procedures. Plans for patient referral and recruitment must be provided. Applicants must also provide dated fundusphotograph slides and slides of fluorescein angiogram frames (two only) for each patient who was seen during a six to twelve month period beginning no earlier than January 1, 1977, and terminating no later than December 31, 1978, and who would have been eligible for entry into the study. In addition, where photocoagulation therapy has been performed, post-treatment slides should also be submitted (for two or three patients only) with the number of hours or days after treatment indicated. All photographic materials should be in the form of mounted slides ready for insertion by the reviewers in carousel trays. They should be clearly marked for identification and evaluation purposes and accompanied by a detailed list discussing the eligibility and/or treatment of each patient. Only original color slides and negative angiographic transparencies are acceptable. Photographic materials will be returned when the review is completed.

5. The facilities section must demonstrate that adequate space and equipment will be available for conduct of the study.

6. In addition to the form HEW-596, Protection of Human Subjects, applicants must also provide details of the procedures to be employed for the protection of study participants.

C. Applications must be received at NIH no later than May 15, 1979. It is not planned to have further application receipt dates requesting additional participating clinics for these cooperative studies.

D. All applications received will be evaluated by NIH staff for responsiveness to this announcement. Applications judged non-responsive or applications received after May 15, 1979, will be returned to the applicant.

III. METHODS AND CRITERIA FOR REVIEW

A. The Office of Review and Special Projects, National Eye Institute, will convene an ad hoc initial review committee to evaluate the technical merits of all applications responsive to this request. The primary review criteria will be:

1. Ability to recruit patients who would be eligible for either or both studies;

2. Ability to follow eligible patients as specified in the manual of procedures;

3. Quality of photographic documentation of eligibility and treatment;

4. Potential for continued compliance with the requirements of the study protocol;

5. Prior clinical experience of the investigators and institution with the ocular disorder(s) under study, and

6. Prior experience in clinical research.

B. The recommendations of the initial review committee will be considered by the National Advisory Eye Council in September 1979. The Council at that time will also consider the progress to date of the MPS.

C. The National Eye Institute will make grant awards (January 1980 start dates are anticipated) based upon the recommendations of the initial review committee, the recommendations of the Council, and the requirements for orderly progress of the study. However, it is expected that no more than six awards will be made.

FURTHER INFORMATION

Inquiries concerning this announcement may be addressed to:

Israel A. Goldberg, Ph.D.
Retinal and Choroidal Diseases Program
National Eye Institute
National Institutes of Health
Room 6A52, Building 31
Bethesda, Maryland 20014

Telephone: (301) 496-5985

VASCULAR AND CIRCULATORY ABNORMALITIES OF THE RETINA INCLUDING DIABETIC RETINOPATHY - RESEARCH AND TRAINING GRANT APPLICATIONS, NATIONAL EYE INSTITUTE

ANNOUNCEMENT

The Retinal and Choroidal Diseases Program of the National Eye Institute desires to expand the scientific knowledge base with respect to vascular and circulatory abnormalities of the retina including diabetic retinopathy. The program is, therefore, requesting applications for research grants and fellowships for basic and clinical studies which relate to the etiology, pathogenesis, prevention, diagnosis, and treatment of these disorders.

Vascular and circulatory disorders of the retina and choroid are the leading causes of new blindness in the U.S. today. In Vision Research - A National Plan: 1978-1982 (copies may be requested from the address below), the National Advisory Eye Council identifies opportunities in basic and clinical research into the etiology, pathogenesis, prevention, diagnosis, and treatment of diabetic retinopathy and other vascular and circulatory abnormalities of the retina and choroid. In addition, the National Eye Institute has recently joined with seven additional units of the National Institutes of Health in inviting applications for research grants in the general area of diabetes mellitus and related problems (see *NIH Guide for Grants and Contracts*, Vol. 7, No. 10, August 4, 1978).

The purpose of this announcement is to provide examples of the fundamental problems requiring emphasis for research and research manpower development, as identified by the National Eye Institute and its advisors. (These are examples; it is not intended to limit the nature or scope of research which might be proposed.)

- Conduct physiological studies on factors influencing blood flow, mechanisms of edema formation, closure of capillaries and large blood vessels, and protein transport into and across the neural retina.

- Compare differences in the anatomy and pathology of retinal blood vessels in different regions of the retina.

- Discover how the permeability of retinal blood vessels and pigment epithelium cells is controlled.

This program is described in the Catalog of Federal Domestic Assistance, 13.867, and will be supported under authority of Section 451 of the Public Health Service Act as amended (42 USC, CH. 6A, subch. III). National Eye Institute research grants are administered in accord with law, regulation, and policy as described in the Public Health Service Grants Policy Statement, October 1, 1976 [DHEW Publication (OS) 77-50,000] and Addendum [DHEW Publication (OS) 77-50,000-A].

- Study how normal blood vessel structure is maintained, how tight junctions form, and what factors are necessary for them to remain functional.

- Search for angiogenic substances, antagonists, and inhibitors.

- Study biochemical abnormalities of diabetic retinas obtained from donor eyes and from animal models.

- Elucidate clotting mechanisms in diabetic retinopathy and other vascular and circulatory disorders.

- Investigate the metabolic relationship of neurons and glial cells.

- Determine how the retina is maintained under conditions of stress; specifically, how and to what extent the retina tolerates ischemia, hypoglycemia, and other derangements.

- Initiate additional clinical-research investigations of retinal vascular diseases.

- Design and evaluate new methods of treating these conditions.

- Study vascular and circulatory effects of disease in other parts of the eye.

It is expected that fundamental studies in these and related areas will eventually impact upon improved prevention, control, and cure of ocular circulatory and vascular disorders. In addition, it is hoped that such studies in the eye will provide new knowledge about angiopathy which could be applied to manifestations of disease in other organ systems.

The National Eye Institute, therefore, encourages further research and training on these as well as other approaches to the prevention, evaluation, and management of diabetic retinopathy and other vascular and circulatory abnormalities of the eye. Applications for grants and fellowships are invited from investigators and trainees in all relevant disciplines. Applications including collaboration between professionals involved in the laboratory and clinical sciences are particularly encouraged, as are those from investigators new to this problem area.

Vision Research Training

The National Eye Institute has long recognized that research productivity depends not simply on the number of laboratory and clinical investigators, but also on their training and the environments in which they work. The Institute, therefore, encourages individuals to receive research training with established investigators, especially in centers with multidisciplinary approaches to research on the visual system in health and disease. The primary mechanisms for the support of vision research training are the National Research Service Awards (NRSA) for individual (F32) and institutional (T32) postdoctoral fellowships.

The training activities supported through the Retinal and Choroidal Diseases Program of the National Eye Institute are designed to provide each trainee with a minimum of two (2) years of full-time research training in the concepts and methodologies of one or more of the following disciplines: immunology, genetics, pharmacology, epidemiology, biostatistics, physiology, biochemistry, developmental biology, psychophysics, physiological optics, and experimental and clinical pathology.

Additionally, National Eye Institute new investigator award mechanisms, such as the Special Visual Sciences Research Award (R23) and the Academic Investigator Award (K07), provide support for individuals with demonstrated research potential who require additional laboratory or clinical research experience in preparation for careers in vision research as independent investigators.

Applications and Review Procedures

National Institutes of Health peer review procedures will be followed for all responses to this announcement. Applications must be on the appropriate research or training grant application form and should include, at the top of the face sheet: "SUBMITTED IN RESPONSE TO NEI PROGRAM ANNOUNCEMENT: VASCULAR AND CIRCULATORY ABNORMALITIES OF THE RETINA." The completed application should be mailed to the Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20014, where it will then be assigned for consideration and review according to the NIH referral guidelines. The scientific quality and the technical merit of all applications will be evaluated by a National Institutes of Health initial review group and by the National Advisory Eye Council. Approved applications will compete for available funds with all other approved applications assigned to the National Eye Institute.

The receipt dates for new research project grant applications (R01, R23) are March 1, July 1, and November 1. These should be submitted on form PHS 398. The receipt dates for new training applications for individual postdoctoral fellowships (F32) and for institutional training grant programs (T32), as well as for the NEI Academic Investigator Award (K07) are February 1, June 1, and October 1. Applications for individual postdoctoral fellowships (F32) should be prepared on form PHS 416-1, for institutional training programs (T32) on form PHS 6025, and for the Academic Investigator Award (K07) on form PHS 2557-1. The earliest possible award dates are nine to ten months after the application receipt date.

The Institute encourages potential applicants to communicate with NEI staff. Inquiries concerning the research and training activities of the Retinal and Choroidal Diseases Program should be directed to the following address:

Retinal and Choroidal Diseases Program
National Eye Institute
National Institutes of Health
Room 6A52, Building 31
Bethesda, Maryland 20014

Telephone: (301) 496-5985

STUDIES ON ENDOTHELIUM IN RELATION TO ATHEROGENESIS, NHLBI

ANNOUNCEMENT

The Atherogenesis Branch, NHLBI, wishes to encourage research on endothelium as it may relate to atherogenesis and requests that investigators consider applying for regular grant support in this area.

This is the last of three announcements of this area of research interest to be made during the coming year prior to the regular application receipt dates of November 1, 1978; March 1, 1979; and July 1, 1979. Applications should be made in the usual manner and review will be conducted in the usual manner for regular grant applications. It is hoped that at least 10 new awards may be made as a result of this announcement.

There is a growing body of evidence that changes in the structure and functions of arterial endothelium may be important in the initiation of atherosclerosis. Concepts of endothelial injury, loss of barrier function, metabolic dysfunctions, and repair have become part of current hypotheses about how the intima reacts with the macromolecular and platelet components of the blood to initiate plaque formation. However, the meaning or meanings to be attributed to such general words as "injury" or "repair" have not been elucidated and it is neither clear what specific properties or functions of endothelium are germane, nor how they may best be measured. It is hoped that studies conducted on normal and abnormal endothelium may help to identify and measure endothelial properties of interest, develop criteria and measures of injury and repair, identify agents initiating or modifying these processes, and increase knowledge about their consequences for atherogenesis.

Investigators who may apply in this area are asked to do two things beyond the normal application procedure:

1. Use the STANDARD title: "Studies of Endothelium in Relation to Atherogenesis." Use the regular form PHS 398 and mail directly to the Division of Research Grants as instructed in the application kit.

2. Submit a brief LETTER OF INTENT saying that you have submitted or will submit such an application. The letter should be addressed to:

   Atherogenesis Branch
   National Heart, Lung, and Blood Institute
   National Institutes of Health
   Room 516, Federal Building
   Bethesda, Maryland 20014

Questions about this announcement should be directed to the Atherogenesis Branch: telephone, (301) 496-1978 or (301) 496-3272.

AVAILABILITY OF "EXCHANGE-LABELED TRITIATED SAXITOXIN" FOR BIOMEDICAL RESEARCH PURPOSES

NOTICE

Upon the recommendation of the Toxicology Study Section, Division of Research Grants, National Institutes of Health, it has been undertaken (with the kind assistance of Professor J. Murdoch Ritchie, Yale University School of Medicine) to prepare and make available to meritorious researchers, a batch of radioactively-labeled saxitoxin.

Investigators desiring an allocation of this material should send the usual form PHS 398 grant application (but without budget pages) to:

Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20014

Attention: Toxicology Study Section

A description of this batch of saxitoxin follows:

"The saxitoxin concentration in the solution supplied is 0.9 mM. The apparent specific activity is 18.9 dpm/fmole. The radiochemical purity is 0.48 and the true specific radioactivity is 9.1 dpm/fmole. Binding of this preparation to rabbit brain is comparable (as far as saturable and linear binding components are concerned) to those obtained with purer samples of saxitoxin (for discussion on purity, see Ritchie and Rogart, 1977, Reviews of Physiology, Biochemistry, and Pharmacology, 79, 1-50). If further purification is required, the method described by Henderson, Ritchie, and Strichartz (J. Physiol. 1973, 235, 783-804) may be used. The toxin must be stored in a freezer (non-defrosting); and experiments using it should be done at low temperatures to minimize back exchange of tritium into water."

Additional information may be obtained from:

Dr. Philip S. Chen, Jr.
Assistant Director for Intramural Affairs
National Institutes of Health
Bethesda, Maryland 20014

Telephone: (301) 496-3561

NIH PRIMATE RESEARCH CENTERS:

A MAJOR SCIENTIFIC RESOURCE

NOTICE

NOW AVAILABLE

The publication, *NIH Primate Research Centers: A Major Scientific Resource,* has been totally revised and is available free from the Division of Research Resources, National Institutes of Health.

Containing 64 pages and 84 photos, the new booklet describes in detail the history, principal research emphases, administration, research teams, research facilities, primate colonies, and services of the seven NIH national primate centers which are supported by the Division of Research Resources.

The Primate Research Centers Program of the National Institutes of Health began in 1960. As the largest nonhuman primate research center network in the world, the program's main mission is to identify primate models in which diseases can be studied and duplicated, their causes and effects documented, and effective means of prevention and treatment developed. The primate research center studies include reproductive biology and population control, infectious diseases, neural and behavioral research, metabolic and degenerative diseases, cardiovascular diseases, environmental health sciences, and dental research.

The original edition of *NIH Primate Research Centers: A Major Scientific Resource* was published in December 1971. The 1978 revised edition reflects the changes in emphasis within the individual centers to assure that strong biomedical research programs continue to be focused on important and current problems.

A single free copy of *NIH Primate Research Centers: A Major Scientific Resource* may be secured by writing to:

Office of Science and Health Reports
Division of Research Resources
National Institutes of Health
Bethesda, Maryland 20014

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