NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Vol. 13, No. 4, March 30, 1984

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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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NOTICE

NIH POLICY RELATING TO REPORTING AND DISTRIBUTION OF UNIQUE BIOLOGICAL MATERIALS PRODUCED

WITH NIH FUNDING

P.T. 36, 16; K.W. 1014002, 1016004, 1200140, 1200490, 1200570, 1200820, 1201190

Scientific and technological advances attributable to biomedical research frequently result in unique biological materials, of which some are patentable inventions. Some examples are: specialized and/or genetically defined cells, including normal and diseased human cells; monoclonal cell lines; hybridoma cell lines; microbial cells and products; viruses and viral products; and recombinant nucleic acid molecules. In accord with the policy of the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), takes the position that such products, when they are developed through the expenditure of NIH funds, should be made available to other research workers and the general public. While the circumstances may vary, the NIH offers the following guidelines concerning materials developed through its awards.

A. NIH Policy on Distribution of Newly Developed Materials

The practice of sharing research results, not only information but also the actual biological materials, has been a major strength of our nation's biomedical enterprise. The NIH recognizes that the vast majority of scientists currently make these newly developed materials readily available to other research workers. The purpose of this announcement is to emphasize the NIH policy that all unique biological materials developed with NIH funding be readily available to the scientific community after publication of the associated research findings or announcement at conferences. Restricted availability of these materials can impede the advancement of basic research and the delivery of medical care to the nation's sick.

In order to facilitate the availability of unique or novel biological materials developed with NIH funds, the investigator may distribute the materials through his/her own laboratory or institution, or submit them, if appropriate, to facilities such as the American Type Culture Collection or similar repositories. In some instances sharing of such material may be impractical, but these are expected to be only infrequent exceptions. Investigators are encouraged to consult the appropriate Health Scientist Administrator at NIH who may be of assistance in determining an appropriate distribution mechanism.

B. NIH Policy on Reporting of Newly Developed Materials

Investigators are reminded that unique or novel biological materials and their products are considered to be inventions and therefore are subject to the various laws and regulations applicable to patents. Accordingly, the NIH

requires that grantees and contractors adhere to grant regulations and contract clauses, respectively, pertaining to the reporting of inventions to the NIH. Only those cell lines or their products for which a demonstrated use exists or which have a potential for commercial development need be reported. However, when reporting is indicated, it should occur at the earliest possible time and should not await the end of the budget period or the expiration of the award. Examples of potentially reportable inventions in the areas of molecular and cell biology include synthesis of molecules with unique properties; special tests, assays or components (diagnostic tests); and cells or products of cells. Some investigators may wish to attempt to patent these materials; if so, the usual criteria for reporting and patenting inventions should be used. All not-for-profit institutions and small businesses should be aware that, as a consequence of Public Law 96-517 and OMB Circular A-124, they have first right to all inventions developed at their institutions with funds from the Federal Government.

For further information on the reporting of inventions and the filing of patent applications contact:

Messrs. Leroy B. Randall or Thomas G. Ferris Patent Branch, Office of the General Counsel Department of Health and Human Services Westwood Building - Room 5A03 Bethesda, Maryland 20205

Other questions or comments on this issuance should be sent to:

Dr. Melvin S. Fish
Special Assistant to the Deputy Director
for Extramural Research and Training
National Institutes of Health
Building 1 - Room 109
Bethesda, Maryland 20205

NOTICE

INTERNATIONAL NUCLEIC ACID SEQUENCE COMPENDIUM AVAILABLE

P.T. 32; K.W. 1200920, 1201190, 1200490 1004008

Nucleotide Sequences 1984, the first international compendium of nucleic acid sequences, will be published as a supplement to the May 1984 issue of GenBank(tm), the Genetic Sequence Data Bank, and the European Molecular Biology Laboratory (EMBL) Nucleotide Sequence Data Library, contains information on over 4000 nucleic acid sequences, representing nearly 3 million base pairs. This includes virtually all sequences reported between 1967 and late 1983.

The compendium is organized into 10 categories, with sequences grouped by organism within each category. The categories are: mammalian sequences, other vertebrate sequences, invertebrate sequences, plant sequences, organelle sequences, bacterial sequences, structural RNA sequences, viral sequences, bacteriophage sequences, and synthetic and recombinant sequences. The publication also contains keyword phrases, taxonomic classification of the nucleic acid source, and author indexes, and lists where the entries appear in GenBank(tm) and the EMBL sequence library.

Entries are annotated to indicate the locations of coding regions and other sites of biological significance. Full bibliographic information and brief summaries of the points made about the sequences in the papers in which they were published are also included.

GenBank(tm) was established in 1982 as a computerized repository of all published nucleic acid sequences greater than 50 nucleotides in length. Data are collected, verified, and annotated at the Los Alamos National Laboratory. Bolt Beranek and Newman Inc., a research, development, and consulting firm in Cambridge, Massachusetts, handles the computerization and distribution of the information to scientists.

The GenBank(tm) database is also available for online use or as computer-readable magnetic tape. Future plans are to provide the data on floppy disks suitable for personal computers as well. For information on access and cost, contact the following:

Bolt Beranek and Newman Inc. 10 Moulton Street Cambridge, Massachusetts 02238

Telephone: (617) 497-2742.

GenBank(tm) is coordinated by the National Institute of General Medical Sciences (NIGMS) National Institutes of Health (NIH), with cosponsorship by three other NIH components—the National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), and the Division of Research Resources (DRR)—well as the National Science Foundation (NSF), Department of Energy (DOE), and the Department of Defense (DoD).

EMBL's sequence library was also created in 1982. It is an activity of the laboratory, which was established in 1974 in Heidelberg, Federal Republic of Germany (FRG), as a component of a treaty organization comprised of Austria, Denmark, the FRG, France, Israel, Italy, the Netherlands, Sweden, Switzerland, and the United Kingdom. Future releases from GenBank(tm) and EMBL will contain listings from both databases.

To order a copy of the 2-volume set, send a check or money order for \$75.00 to:

IRL Press Suite 907 1911 Jefferson Davis Highway Arlington, Virginia 22202

NOTICE

BREAST CANCER SERUM BANK

P.T. 36; K.W. 1200140, 1002014

NATIONAL CANCER INSTITUTE

A bank of serum specimens from women at varying risks of breast cancer has been established in the Diagnosis Branch, Division of Cancer Biology and Diagnosis (DCBD), National Cancer Institute (NCI). Panels of test specimens can be secured to evaluate newly discovered biological markers for breast cancer, to verify preliminary data and to study multiple markers for early detection of breast cancer. Sera are maintained at -70°C in 1 ml sealed glass vials.

Requestors for test panels must document the discriminatory power of their assays. The Bank cannot support feasibility studies based on theoretical considerations nor can it handle large population based epidemiological studies. The assays must not require more than 1 ml of serum for accurate determination. Requestors must agree to accept specimens under a blind code number and report the results to NCI. Some duplicates will be included in each test panel. To request a test panel it is sufficient to write a letter addressing above points to:

Dr. I.J. Masnyk
Division of Cancer Biology
and Diagnosis
National Cancer Institute
Building 31 - Room 3A04
Bethesda, Maryland 20205

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-07

CANCER CONTROL SMALL GRANTS RESEARCH PROGRAM

P.T. 34; K.W. 1200270, 1200280, 0403004, 0413000, 1002014

NATIONAL CANCER INSTITUTE

Application Receipt Date: May 15, 1984

I. BACKGROUND INFORMATION

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites Small Grants Research applications from interested investigators. This program is designed to aid and facilitate the growth of a nationwide cohort of scientists with a high level of scientific research expertise in the field of cancer control. Its major objective is to encourage new investigators from a variety of academic disciplines to apply their skills to scientific research in the field of cancer control intervention research. The intent is to fund up to 10 awards with total costs for all projects not to exceed to \$350,000. 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 availabilty of funds for this purpose.

II. RESEARCH GOALS AND SCOPE

A Cancer Control Small Grants Research Award is designed to encourage scientists from a variety of academic disciplines to apply their skills to scientific investigations in the field of cancer control intervention research.

A. Definition of Cancer Control

Cancer control is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.399, Cancer Control. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and Section 403 (42 USC 284) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

B. Phases of Cancer Control

Cancer control research studies are classified into one of five phases which represent the orderly progression noted in the above definition: (I) hypothesis development; (II) methods development and testing, (III) controlled intervention trials to establish cause and effect relationships; (IV) research in defined populations; and (V) demonstration and implementation studies. The Division is primarily interested in research on cancer control intervention in Phases II through V.

Copies of DCPC's Grant Guidelines for Cancer Control: Areas of Programmatic Interest which outlines specific areas of cancer control research interest, may be obtained from Dr. Robert G. Burnight, Program Director, 301-427-8788.

III. MECHANISMS OF SUPPORT

This RFA will use the NIH Grant-in-Aid. Responsibility for planning, direction, and execution of the proposed research will be solely that of the applicant. Except as otherwise stated below, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50,000 Revised December 1, 1982.

Allowable direct costs include personnel, supplies, publication costs, travel, and equipment expenses, up to a maximum of \$25,000. In general, total costs (direct and indirect) should not exceed \$35,000. The duration of support is one year but may be longer (up to two years) if the funding limits noted above are not exceeded.

Grants may be awarded to profit and non-profit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of 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. The receipt date for this RFA solicitation is May 15, 1984. It will be reissued, approximately annually.

IV. ELIGIBILITY

Investigators are eligible to apply for a small grant to support research on a cancer control topic if they have never received NCI cancer control funding and are interested in conducting exploratory studies in cancer control research.

Submission of an application under this announcement precludes concurrent submission of a regular research grant application containing the same research proposal. In addition, small grant research support may not be used to supplement research projects currently supported by Federal or non-Federal funds, or to provide interim support of projects under review by the Public Health Service (PHS).

V. REVIEW PROCEDURES AND CRITERIA

Responsive applications will be reviewed for scientific and technical merit by a committee consisting primarily of non-Federal technical and scientific experts and will be evaluated subject to the following criteria:

- 1. Quality of the principal investigator's education and/or scientific training, and potential for contribution as an investigator in the field of cancer control intervention research.
- 2. Evaluation of the research proposal for scientific merit, including (a) originality; (b) feasibility; (c) adequacy of design; (d) plans for analyses and evaluation of data; and (e) soundness of the research plan.
- 3. Adequacy of resources and the supportive nature of the research environment.
- 4. Appropriateness of the proposed budget.
- 5. Significance in relation to cancer control intervention research.

Unresponsive applications, i.e., those applications not meeting the criteria for cancer control intervention research, will be returned.

VI. METHOD OF APPLYING

The regular research grant application form PHS-398, (rev. 5/82) must be used in applying for these grants. These forms are available at most institutional business offices from the following:

Division of Research Grants National Institutes of Health 9000 Rockville Pike Bethesda, Maryland, 20205

or from the Program Director. Cancer Control Small Grants Research, DCPC, NCI, and the RFA number 84-CA-07 should be typed on line 2 of the face page of the application form.

You are requested to submit the application in a package clearly marked CANCER CONTROL SMALL GRANTS RESEARCH PROGRAM, DCPC, NCI on the outside.

1. This package should contain a signed, typewritten original of the application, including the Checklist, and six signed, exact photocopies, in one package to the following address:

Division of Research Grants Westwood Building - Room 240 5333 Westbard Avenue Bethesda, Maryland 20205. The photocopies must be clear and single-sided. A preaddressed mailing label is provided in the application kit. Include the self-addressed three-part postcard, form PHS-3830 provided in the application kit.

2. The following application receipt and review dates apply:

Application Receipt Committee Earliest Possible

Date Review Funding Date

May 15 July September

3. The following additional page limitations (typewritten, single-spaced) apply to sections of the PHS-398 application:

Biographical Sketch - do not exceed one page.

Section 2, Research Plan (page 15 of instructions).

Specific Aims and Significance - one page each.

Progress Report and Preliminary Studies - if applicable, two pages.

Experimental Design and Methods - ten pages.

Human Subjects and Literature Cited - two pages each.

These page limitations and others in the PHS-398 Application Instructions must be observed or the application will not be accepted. If an exception to this requirement is necessary, provide a brief explanation.

For program information contact:

Dr. Robert G. Burnight
Program Director
Career Development Unit
Cancer Control Applications Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building - Room 1A09
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone (301) 427-8788

For grants administration information contact:

Mr. William Wells Grants Management Specialist Grants Administration Branch Office of the Director National Cancer Institute Westwood Building - Room 855 5333 Westbard Avenue Bethesda, Maryland 20205

Telephone (301) 496-7800

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

84-CA-08

CANCER CONTROL RESEARCH UNITS

P.T. 34; K.W. 1200270, 1200280, 1200460, 1002014, 0701042, 0701013, 0413000

NATIONAL CANCER INSTITUTE

Application Receipt Date: December 3, 1984

Letters of Intent Receipt Date: July 2, 1984

The Division of Cancer Prevention and Control (DCCP) of the National Cancer Institute (NCI) invites grant applications from interested investigators for the support of Cancer Control Research Units(CCRU). This RFA is a reissue of the CCRU RFA announced in the NIH Guide for Grants and Contracts, Volume 12, No. 9, September 23, 1983.

The goal of this RFA is to establish CCRU which will plan and implement focused research studies aimed at major cancer control problems. Cancer control is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results. The research will address cancer control interventions with potential for reducing cancer incidence, morbidity and/or mortality, and for generalizability to larger populations. The CCRU will be a long term resource for research and training for the Cancer Control Program of NCI.

The proposed CCRU should have one or more clearly identified "themes" or "programs", each consisting of an integrated group of projects from cancer control research phases II thru V (see below). The general areas of DCPC's cancer control research interest are described in Cancer Control Program Guidelines which were issued in July 1983.

The required components of a CCRU will include:

- o A rationale for the CCRU in terms of the cancer control themes and problems which will be investigated.
- o A CCRU Director with research and administrative experience.
- o A multidisciplinary cancer control research team of qualified investigators, and an underlying research base.
- o At least three high quality research projects which are approved with the CCRU application, of which two must be defined population studies;
- o Organizational, administrative and institutional procedures, committments and support.

CANCER CONTROL RESEARCH UNIT

Optional components of a CCRU are:

- o Limited developmental or research projects, including applied epidemiology studies.
- o Shared resource cores which are integral to two or more projects.
- o The general objectives of the cancer control research phases and examples of the types of requirements needed to meet these objectives are summarized as follows:

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PHASE	TITLE	OBJECTIVE	REQUIREMENTS
I	Hypothesis Development	To develop hypo- theses grounded on scientific evidence	Etiologic or other evidence of of cancer problems. Potential interventions to test.
II	Methods Development and Testing	To validate methods needed to test the hypothesis	Proposed methods to reach and retain the target population. Proposed intervention(s) methods which need validation. Careful study designs which demonstrate reproducibility and accuracy of methods.
III	Controlled Intervention Trials	To determine the potential efficacy of interventions which have been validated	Demonstration of a significant intervention effect compared to control group.
IV	Defined Population Studies	To determine the probably effective- ness of interven- tions if applied on a broader scale to a larger population	An intervention with proven efficacy. A defined population representative of a larger population. Appropriate sampling design for extrapolation of results. Demonstration of a significant intervention effect compared to control group.
IV	Demonstration and Implementation Studies	To reduce cancer rates by the broad systematic application of effective	A system for tracking cancer rates in the large population under study. An appropriate research design.

interventions

An intervention successfully tested in Phase IV studies.

CANCER CONTROL RESEARCH UNIT

The CCRU will be encouraged to establish cancer control research training programs, including field involvement and applications. At this time, however, there will be no funds specifically earmarked for training within the CCRU grant, and potential applicants are encouraged to seek peer-reviewed support through the NCI traininggrant mechanisms. After the CCRU grants are awarded and underway, spin-offs such as training programs may develop.

Applicants are strongly encouraged to submit a letter of intent and consult with NCI program staff before submitting an application because of the need for a clear understanding of cancer control research issues and the P50 guidelines, and to facilitate planning for the review of applications.

Non-profit and for-profit institutions within the United States are eligible to apply for project periods of up to five years. Funds have been set aside during Fiscal Year 1985 to fund the initial year's awards. It is anticipated that a maximum of five awards will be made as a result of this RFA, subject to availability of funds. This RFA is the successor to the RFA entitled "Cancer Control Research Units for Defined Population Studies" which was previously announced in the NIH Guide for Grants and Contracts (Vol. 11, No. 2, January 29, 1982, page 15-18).

Copies of the complete RFA and the 1983 Cancer Control Program Guidelines (NIH Publication No. 84-2659, February 1984) may be obtained from:

Carlos E. Caban, Ph.D.
Program Director
Cancer Control Applications Branch, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 1A01
9000 Rockville Pike
Bethesda, Maryland 20205

Telephone: (301) 427-8735

THE NCI OUTSTANDING INVESTIGATOR GRANT

P.T. 34; K.W. 1002014, 1200180

NATIONAL CANCER INSTITUTE

Application Receipt Date: July 15

Letter of Intent Receipt Date: May 1

I. SUMMARY AND PURPOSE

The National Cancer Institute (NCI) announces the availability of the Outstanding Investigator Grant (OIG) for the purpose of providing long-term support to experienced investigators with outstanding records of research productivity. The initiation of this grant is intended to encourage investigators to embark on projects of unusual potential in cancer research. Emphasis will be placed on evidence of recent substantive contributions, i.e., seminal ideas and innovative approaches to resistant problems.

II. ELIGIBILITY

A. Candidate

Applications may be made by domestic institutions on behalf of investigators who have recently demonstrated outstanding research productivity for at least five years. There are no age restrictions. Only United States citizens, nationals or permanent residents may be presented as candidates for this grant.

B. Letter of Intent

Prospective applicants are strongly encouraged to submit a one to two page letter of intent, accompanied by a curriculum vitae and bibliography. This will enable the Institute to plan the review and advise applicants regarding their eligibility for consideration. Letters should provide a brief statement of the investigator's accomplishments, plus a brief general statement of the project(s) expected to be undertaken with the OIG support. Though application for a Public Health Service (PHS) Grant may be submitted without prior notification of intent, such letters would be appreciated.

Candidates considered to be ineligible based on the stated criteria and the letter of intent will be so informed by the Director, DEA, NCI.

A prospective candidate considered eligible will be so advised and invited to submit an Application for a PHS Grant (PHS 398).

III. PROVISIONS OF THE GRANT

The OIG is nontransferable and is awarded for a maximum period of seven years. The grant is not a lifetime award but is renewable. Application for competitive renewal should be submitted at the end of the fifth year according to the guidelines for the initial award.

The actual dollar award will reflect specifically the investigator's current and projected research needs evaluated by the Initial Reviewers, and reviewed by the Executive Committee, NCI. The award will provide that fraction of the investigator's salary that approximates the total proportion of salary awarded through current grants, but not to exceed 75%. This limit may be waived under exceptional conditions such as evidence of institutional provision of unusual levels of support of other types.

Funds will be provided for the support of technical staff, research staff and graduate students, but not for other academic faculty or institute equivalents. Salaries of other principal investigators may not be included. Other expenses, as would be included in individual project grants, are legitimate costs.

It is required that the OIG Principal Investigator will commit at least 75% of his/her time and effort to the research supported by this instrument.

Candidates for this award may concurrently apply for additional NIH research grant or research contract support for the balance of his/her time and effort, provided the requirement that the candidate institution provide 25% salary support has been waived. Renegotiation of all concurrent NIH funds upon acceptance of this grant is required.

Candidates for this award may concurrently apply for training grants, construction grants and capital equipment grants.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Applications submitted in response to this Announcement will be assigned to an appropriate subset of a nationwide panel of recognized cancer investigators for review. The summary statements from this Initial Review Group will be submitted by the Executive Secretary, DEA, NCI, to the NCI Executive Committee to prepare its funding recommendations for the National Cancer Advisory Board (NCAB). The NCAB will recommend awards to the Director, NCI, for final action.

B. Review Criteria

Reviewers will consider the following factors in evaluating the scientific merit of each response to this Announcement:

1. What has been the impact of the applicant's work on the field of biomedical research?

MOLECULAR RESEARCH IN STRABISMUS, AMBLYOPIA, AND VISUAL PROCESSING

P.T. 34; K.W. 1002046, 0701038, 1200470, 1200890, 1200900, 1201010, 1201030, 1201150

NATIONAL EYE INSTITUTE

The National Eye Institute (NEI) would like to encourage the submission of research project grant applications for molecular studies in Strabismus, Amblyopia, and Visual Processing. New knowledge derived from neuroanatomical and neurophysiological studies of the visual system and the development of several new techniques, including monoclonal antibody production, more sensitive means of measuring enzyme activity, and recombinant DNA techniques, suggest that additional molecular research on the visual processing and oculomotor systems is likely to lead to a more profound knowledge of the structure and function of these systems.

Listed below are some of the key areas that have been designated as targets for increased molecular research activity in the Strabismus, Amblyopia, and Visual Processing Program:

- o Investigate the development of the visual system at the molecular level.
- o Analyze the effects of visual deprivation or abnormal stimulation at the molecular level.
- o Identify neurotransmitters, peptides, and other chemicals important in signaling between cells in the visual pathways.
- o Identify molecules involved with cell specificity and function in the visual processing and oculomotor systems.
- o Describe at the molecular level the development of the oculomotor system.
- o Study the influence of drugs on neurotransmitters in normal and abnormal oculomotor subsystems.
- o Examine the molecular characteristics of extraocular muscles; examine their molecular organization and function in normal and pathological conditions.
- o Study pharmacological treatments of strabismus.

This program is described in the Catalog of Federal Domestic Assistance No. 13.871, Strabismus, Amblyopia and Visual Processing. Awards will be made under the Authority of the Public Health Service Act, Title III, Part A, Section 301, Public Law 78-410, as amended; (42 USC 241) and administered under PHS Grants Policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Vision Research--A National Plan: 1983-1987, Volume Two/Part Five provides more information about the program development priorities of the Strabismus, Amblyopia, and Visual Processing Program. Copies of this volume can be obtained by writing to:

Mr. Julian Morris
Office of Program Planning and Evaluation
National Eye Institute
Building 31 - Room 6A25
National Institutes of Health
Bethesda, Maryland 20205

I. MECHANISM OF SUPPORT

The mechanism of support for this program will be the individual research grant (R01's - Research Project Grant and R23's - New Investigator Research Grant).

II. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date. This announcement will be effective for two years following the initial receipt date of July 1, 1984.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. The review criteria customarily employed by the NIH for regular grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council.

Applications should be submitted on form PHS 398 (revised 5/82) which is available in the business or grants and contracts offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 on the face page of the application and enter the title "Molecular Research in Strabismus, Amblyopia, and Visual Processing". The original and six (6) copies of the application should be directed to:

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

Inquiries should be directed to:

M. Janet Cardenas, Ph.D.
Strabismus, Amblyopia, and Visual
Processing Program
National Eye Institute
Building 31 - Room 6A49
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5301

RESEARCH ON BASIC MECHANISMS OF RETINAL PHOTOTOXICITY

P.T. 34; K.W. 1002046, 0202022, 0404002, 1200110, 1200750, 1200780

NATIONAL EYE INSTITUTE

The National Eye Institute (NEI) wishes to encourage research which seeks to understand the basic mechanisms of how the metabolic status of the retina influences the susceptibility of photoreceptor cells to damage by light energy. It is important to differentiate between the way in which intrinsic factors (metabolic and nutritional) and extrinsic factors (light energy) may contribute to aging, retinal degeneration, and macular degeneration. This research area is of high programmatic interest to the NEI and its significance is addressed in the report of the National Advisory Eye Council, Vision Research--A National Plan: 1983-1987, Volume Two, Part One. Some of the program development priorities related to this announcement include: examination of the effects of light, age, drugs and antioxidants on lipofuscin (Chapter 8, Retinal Pigment Epithelium); investigation of environmental and nutritional factors affecting photoreceptor function, degeneration, and aging (Chapter 9, Photoreceptors, Visual Pigments, and Phototransduction); studies on retinal metabolism and biochemical processes critical to retinal function (Chapter 10, Retinal Organization, Neurotransmission, and Adaptation).

I. BACKGROUND

Photoreceptor disc membranes have an unusually high content of unsaturated phospholipids. These as well as other membrane components are constantly shed from the outer segments of the visual cells and phagocytized by the retinal pigment epithelium. The normal process of disc membrane turnover requires these polyunsaturated lipids to be catabolized by the pigmented epithelium which degrades and disposes of ingested membrane components. When the unsaturated lipids of these highly specialized biological membranes become oxidized by absorption of electromagnetic radiation, they may become cytotoxic. The shorter (high energy) wavelengths are especially efficient in this regard. Toxic debris may become deposited in the subretinal space and in the pigmented epithelium with possible consequences on degeneration of this tissue. Thus it is important to know how lipids may be altered by interactions with light and to what extent the accumulation of altered biomolecules contribute to cell damage.

This program is described in the Catalog of Federal Domestic Assistance No. 13.867, Retinal and Choroidal Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Part A, Section 301, Public Law 78-410, as amended; (42 USC 241) and administered under PHS Grants Policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Photoreceptor cells contain vitamin E as well as several other antioxidants such as selenium which may function in a protective capacity to prevent buildup of toxic molecules. Nutritional deficiencies which deplete vitamins A and E, taurine, selenium and zinc may cause photoreceptor degeneration, but the mechanisms are unclear. Monkeys on diets deficient in xanthophyll, an important component of macular pigment, develop abnormalities of the macula. These and other animal studies suggest that diet might also influence the progression of human aging-related maculopathy. Studies of the possible relationships between nutrition and the maintenance of optimal photoreceptor function are, therefore, important and of high programmatic interest to the NEI

Vision Research--A National Plan: 1983-1987, Volume Two/Part One provides more information about the program development priorities of the Retinal and Choroidal Diseases Program. Copies of this volume can be obtained by writing to:

Mr. Julian Morris
Office of Program Planning and Evaluation
National Eye Institute
Building 31 - Room 6A25
National Institutes of Health
Bethesda, Maryland 20205

II. MECHANISM OF SUPPORT

The mechanism of support for this program will be the individual research grant (R01's - Research Project Grant and R23's - New Investigator Research Grant).

III. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date. This announcement will be effective for two years following the initial receipt date of July 1, 1984.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council.

Applications should be submitted on form PHS 398 (revised 5/82) which is available in the business or grants and contract offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 on the face page of the

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application and enter the title "Research on Basic Mechanisms of Retinal Phototoxicity". The original and six (6) copies of the application should be directed to:

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

Inquiries should be directed to:

Peter A. Dudley, Ph.D.
Program Director
Fundamental Retinal Processes Program
Retinal and Choroidal Diseases Branch
National Eye Institute
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5983

VERGENCE EYE MOVEMENTS

P.T. 34; K.W. 1002001, 1002034, 0414003, 1200470, 1200410

NATIONAL EYE INSTITUTE

The National Eye Institute (NEI) would like to encourage the submission of research project grant applications for studies on the vergence eye movement system. Research on vergence eye movements is an important part of the Strabismus, Amblyopia, and Visual Processing Program; several areas of emphasis are listed in <u>Vision Research--A National Plan: 1983-1987</u> and are outlined below. These include anatomical, physiological, and behavioral studies of vergence, determination of the factors that are significant in the development of vergence, and elucidation of the relationship between vergence and other ocular disorders, such as strabismus and amblyopia.

Persons with normal binocular vision respond to near objects of interest by converging their eyes to position images on the two foveas. Significant disorders of the vergence system are relatively common and may affect almost as many people as are affected by refractive errors. Disorders of the vergence system include symptom-producing heterophorias; strabismus; and fusional vergence anomalies. Associated symptoms include asthenopia, diplopia, suppression, amblyopia, and loss of depth perception.

The complexity of the vergence system and its component interactions, as well as interactions with accommodation, versions, and the vestibular system, has made research in this area difficult, and there has been considerably less research activity on vergence eye movements than on conjugate eye movements. Nonetheless, steady progress has been made in studies of vergence, and there now is basis to believe that research efforts on the mechanisms of vergence are likely to be very productive. Furthermore, the relationships among various disorders of vergence, including the characteristic and causes of strabismus, can be fruitfully explored at this time. Research on vergence eye movements is likely to benefit from the modification and application to the vergence system of approaches that previously have been valuable in studies of conjugate eye movements, as well as the design and application of entirely new approaches to study vergence.

This program is described in the Catalog of Federal Domestic Assistance No. 13.871, Strabismus, Amblyopia and Visual Processing. Awards will be made under the authority of the Public Health Service Act, Title III, Part A, Section 301, Public Law 78-410, as amended; (42 USC 241) and administered under PHS Grants Policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Some program development priorities related to vergence are:

- o Define in detail the vergence stimuli for neonates, children, and adults, and characterize the developing motor responses.
- o Elucidate the accommodative/vergence relationships in the neonate and ascertain the critical period for influencing this synkinesis.
- o Explain the mechanisms responsible for (1) plasticity of anomalous retinal correspondence associated with certain, but not all, vergence movements, and (2) the relative rigidity of normal correspondence in strabismics and nonstrabismics.
- o Study the basic anatomy, physiology, and behavior of the vergence system in appropriate animal models.

Additional information about the National Eye Institute's interest in research concerning vergence can be found in Vision Research--A National Plan: 1983-1987, Volume Two/Part Five, copies of which can be obtained by writing to:

Mr. Julian Morris
Office of Program Planning and Evaluation
National Eye Institute
Building 31 - Room 6A25
National Institutes of Health
Bethesda, Maryland 20205

I. MECHANISM OF SUPPORT

The mechanism of support for this program will be the individual research grant (R01's - Research Project Grant and R23's - New Investigator Research Grant).

II. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date. This announcement will be effective for two years following the initial receipt date of July 1, 1984.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic consideration as specified in the NIH Referral Guidelines. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council.

Applications should be submitted on form PHS 398 (revised 5/82) which is available in the business or grants and contracts offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 on the face page of the application and enter the title "Vergence Eye Movements". The original and six (6) copies of the application should be directed to:

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

Inquiries should be directed to:

M. Janet Cardenas, Ph.D.
Strabismus, Amblyopia, and Visual
Processing Program
National Eye Institute
Building 31 - Room 6A49
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5301

IMMUNOLOGICAL ASPECTS OF OCULAR DISEASE

P.T. 34; K.W. 1200470, 1002023, 1200670, 1201290

NATIONAL EYE INSTITUTE

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The National Eye Institute (NEI) and the National Institute of Allergy and Infectious Diseases (NIAID) invite qualified investigators to submit research grant applications for the support of studies which seek to gain a better understanding of the role of the immune system both in the normal and diseased eye. Such a need has likewise been expressed by the National Advisory Eye Council when that body identified a number of important research areas in ocular immunology which require expansion in its most recent program planning report Vision Research—A National Plan: 1983-1987. This document focuses on the ongoing requirement for additional investigations which involve immunological approaches to the understanding, treatment and prevention of ocular diseases and calls for recruitment of additional immunologists to vision research in order to conduct these critical laboratory and clinical studies.

I. BACKGROUND

The eye presents a unique organ for immunological study since several of its component structures at developmental maturation, namely, the cornea, lens and vitreous are free of both blood and lymphatic vessels. The normal isolation of these structures from routes which are in direct contact with the reticulo-endothelial system alter the way that these tissues respond to foreign substances, whether desirable, such as exposure to transplanted tissue or undesirable, such as invasion from infecting viruses, bacteria or fungi. Alteration and/or breakdown of the normal functioning of the ocular immune system may represent an important factor in the development and spread of various eye cancers including choroidal melanoma and retinoblastoma.

This program is described in the Catalog of Federal Domestic Assistance No. 13.868, Corneal Diseases Research and No. 13.855, Immunology, Allergic and Immunologic Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Part A, Section 301, Public Law 78-410, as amended; (42 USC 241) and administered under PHS Grants Policies and Federal Regulation 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

Vision Research—A National Plan: 1983-1987, provides more information about the program development priorities of the NEI with respect to ocular immunology. Copies of this plan can be obtained by writing to:

Mr. Julian Morris
Office of Program Planning and Evaluation
National Eye Institute
Building 31 - Room 6A25
National Institutes of Health
Bethesda, Maryland 20205

II. RESEARCH GOALS AND SCOPE

Research proposals are currently requested on those topics in ocular immunology which have received priority identification from each of the five program areas of the National Eye Institute by the National Advisory Eye Council in its recent report entitled Vision Research--A National Plan: 1983-1987. These topics include: determining the neuronal and viral factors contributing to the latent period of ocular herpes infection; evaluating immunological mechanisms of the ocular surface of the eye and the role of such mechanisms in health and disease; improving the understanding of the biochemistry and immunological components of the cornea's response to injury and wound healing; determining the importance of specific immunological factors in corneal transplantation, and developing and testing drugs which can modify or eliminate immune reactions to transplanted tissue; assessing new drug and immunological approaches to the treatment and prevention of uveitis and inflammatory disorders; improving treatment of glaucoma secondary to uveitis through better understanding of the mechanisms of inflammation, and evaluation of the effectiveness of specific anti-inflammatory drugs in its treatment; pursuing new approaches to research on the basic biology, immunology, and genetics of sight- and life-threatening intraocular tumors; investigating the structure, function, and development of the visual system at the molecular level including studies of cellular receptor sites, cell specificity, neurotransmitters and peptides, and immunological approaches--with the ultimate aim of designing drug treatments for visual neurosensory disorders and injuries.

III. MECHANISM OF SUPPORT

The mechanism of support for this activity will be the individual research grant (R01's - Research Project Grant and R23's - New Investigator Research Grant) as applicable.

IV. APPLICATION AND REVIEW PROCEDURES

A. Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date. This announcement will be effective for two years following the initial receipt date of July 1, 1984.

B. Method of Applying

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. It is likely that most applications submitted in response to this announcement would receive dual Institute assignments. In general, applications dealing with ocular immunology where the focus is the visual disorder or function would be assigned to the NEI. Applications which focus on basic immune mechanisms would be assigned to the NIAID. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

Following the initial scientific review, the applications will be evaluated by the applicable National Advisory Council.

Applications should be submitted on form PHS 398 (revised 5/82) which is available in the business or grants and contract offices at most academic and research institutions or from the DRG. To identify the application as a response to this announcement, check "yes" in item 2 on the face page of the application and enter the title "Immunological Aspects of Ocular Disease."The original and six (6) copies of the application should be directed to:

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

Inquiries should be directed to:

Ralph J. Helmsen, Ph.D. Chief, Anterior Segment Diseases Branch National Eye Institute National Institutes of Health Building 31 - Room 6A47 Bethesda, Maryland 20205

Telephone: (301) 496-5301

or

Robert A. Goldstein, M.D., Ph.D.
Chief, Allergy and Clinical Immunology Research
National Institute of Allergy and
Infectious Diseases
Westwood Building - Room 755
Bethesda, Maryland 20205

Telephone: (301) 496-7104

RESEARCH TRAINING AND DEVELOPMENT AREAS AND TYPES OF AWARDS

AVAILABLE

P.T. 44,22,34; K.W. 0202022, 0404019, 0411005, 0701042, 1002019, 1002034, 1200170, 1200120, 1200240, 1200600, 1201090, 1201220

DIVISION OF HEART AND VASCULAR DISEASES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

This announcement consolidates and summarizes the current research training and development programs of the Division of Heart and Vascular Diseases (DHVD) It is a summary intended to be helpful to potential applicants. It is not an announcement of new programs or initiatives. (The number of awards made annually will depend on merit and programmatic emphasis of proposals received, as well as the availability of funds.)

Research training may be in fundamental studies of basic processes and functions, behavioral studies, including risk factor modification (e.g. diet, smoking), genetics (including studies of populations), and primary and secondary prevention of clinical investigations directed toward increasing knowledge and understanding in any cardiovascular disease area. Division activities are categorized into one or more of the following program areas:

Arteriosclerosis
Hypertension
Coronary Heart Disease
Cardiovascular Aspects of Diabetes
Arrhythmias
Heart Failure and Shock
Cerebrovascular Disease
Congential and Rheumatic Heart Disease
Cardiomyopathies and Infections of the Heart
Circulatory Assistance
Cardiovascular Devices and Technology

The awards summarized below may be used for the support of research training and development in the areas listed above.

These programs are described in the Catalog of Federal Domestic Assistance No. 13.837, Heart and Vascular Diseases Research. Awards will be made under the authority of the Public Health Service Act, Section 472 (42 USC 2891-1), and administered under PHS grants policy and Federal Regulations 42 CFR Part 66; and Section 301 (Public Law 78-410, as amended; 42 USC 241), administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. These programs are not subject to Health Systems Agency review.

RESEARCH TRAINING AND DEVELOPMENT BRANCH PROGRAMS

I. National Research Service Award Programs

A. Institutional Research Training Grant Award

- o Predoctoral and postdoctoral trainees.
- o Selection of training institution by national competition.
- o Institutional selection of trainees.
- o Trainee support includes stipend (\$5,292 per year for predoctoral trainees; \$14,040-\$19,716 per year for postdoctoral trainees depending on relevant postdoctoral experience), tuition, fees, health insurance, and travel.
- o Stipend supplementation is allowed from non-federal funds.
- o Institutional support; indirect cost is limited to 8 percent.
- o Duration of award may be up to five years.
- o Maximum predoctoral training duration is five years.
- o Maximum postdoctoral training duration is three years.
- o Each month of NRSA-financed training after the first 12 months requires a month of payback activity in biomedical or behavioral teaching and/or research.
- o Receipt dates for applications are:

Advisory Council Review

February I
June 1
October 1

October February May

B. Individual Postdoctoral Fellowship Award

- o Postdoctoral trainees only.
- o Selection by national competition.
- o Stipend is \$14,040-\$19,716 depending on relevant postdoctoral experience.
- o Stipend supplementation is allowed from non-federal funds.
- o Institutional support.
- o Duration of award is one to three years.
- o Maximum training duration is 36 months.
- o Each month of NRSA-financed training after the first 12 months requires a month of payback activity in biomedical or behavioral teaching and/or research.
- o Receipt dates for

applications are:

Results announced in:

February 1 June 1 October 1

August December April

C. Senior Research Fellowship Award

- o To make major changes in direction of research careers or to acquire new research capabilities.
- o Experienced scientists only (at least seven years of relevant postdoctoral research or professional experience).
- Selection by national competition.
- o Stipend will be negotiated up to \$30,000 per year.
- o Stipend supplementation is allowed from non-federal funds.
- o Institutional support.
- o Duration of award is normally twelve months.
- o Each month of NRSA-financed training after the first 12 months requires a month of payback activity in biomedical or behavioral teaching and/or research.
- o Receipt dates for

applications are:

Results announced in:

February 1 August
June 1 December
October 1 April

D. Short-Term Research Training: Students in Health Professional Schools

- o To increase the number of clinical investigators in biomedical and behavioral research careers.
- o Qualified health professional students only.
- Selection of training institutions by national competition.
- o Institutional selection of trainees.
- o Stipend support for trainees (\$441 per trainee per month for 2-3 months); institutional allowance up to \$125.00 per trainee per month.
- o Stipend supplementation is allowed from non-federal funds.
- o No award made for fewer than four nor more than thirty-two students per year.
- o Duration of award may be up to five years.
- o No payback provision for training periods of up to three months.
- o Application receipt date of February 1 each year with a May 1 award date the following year.

II. The Research Career Development Programs

A. Research Career Development Award

- o Research career development of biomedical or behavioral scientists with outstanding research potential.
- o Cannot be an established independent investigator when awarded.
- o Must have at least three years postdoctoral experience.
- o Selection by national competition.
- o Salary support of up to \$30,000 per year plus fringe benefits.
- o Supplementation is allowed from non-federal funds.

o Duration of award is five years; non-renewable.

o Must devote essentially full time to research and research-related activities.

o Receipt dates for applications are:

Advisory Council Review

February 1 June 1 October 1

October February May

B. Clinical Investigator Award

- o To encourage newly trained clinicians to develop clinical and basic research interests and skills in the area of cardiovascular diseases.
- o Newly trained physicians are candidates for the award.
- o Selection by national competition.
- o The grantee institution must have strong, well-established research and training programs.
- o Candidates must have one or more sponsors or advisors from the grantee institution.
- o Salary support of up to \$30,000 per year plus fringe benefits.
- o Supplementation is allowed from non-federal funds.
- o Support for five years; full time effort; non-renewable.
- o Minimum of 75 percent effort to the research program.

0	Receipt dates for	Advisory Council	Earliest
	applications are:	Review	Beginning Date
	February 1	October	December 1
	June 1	February	April 1
	October 1	MayJ	July 1

C. Physician Scientist Award

- o To encourage individuals with clinical training to develop research skills in a fundamental science.
- o Candidates must have a health professional degree such as M.D. or D.O.; physicians holding the Ph.D. degree are not eligible.
- o Selection by national competition.
- o The grantee institution must have strong, well-established research and training programs in clinical and basic sciences.
- o Candidates must have one or more sponsors in a basic science research area.
- o Salary is up to \$30,000 per year plus fringe benefits.
- o Supplementation is allowed from non-federal funds.
- o Support for five years; non renewable.
- o Minimum of 75 percent effort to the research program.
- O Awardee and sponsor must submit special detailed progress report at end of third year.

o Receipt dates for applications are:

Advisory Council Review Earliest

Beginning Date

February 1 June 1 October 1 October February May

December 1 April 1 July 1

D. Preventive Cardiology Academic Award

- o To encourage development of high quality preventive cardiology curriculum in schools of medicine and osteopathy that will attract outstanding students to preventive cardiology research and medical practice.
- The awardee must hold an academic appointment at a school of medicine or osteopathy and have clinical training as well as research and teaching experience in cardiology.
- o The institution must sponsor a candidate with competence in clinical cardiology and provide the awardee with time to acquire the educational skills for personal development as a teacher and for the development of the preventive cardiology curriculum.
- o Awards are limited to one for each eligible school with a project period of five years.
- o Awardee must devote at least 50 percent time or effort.
- o Salary support of up to \$30,000 per year plus fringe benefits.
- o Supplementation is allowed from federal funds.
- o Award provides funds for some other operating costs.
- o Annual receipt date of April 1 for starting date of July 1 the following year.

E. Special Emphasis Research Career Award: Diabetes Mellitus

- o To encourage qualified individuals to develop interdisciplinary research skills in Diabetes Mellitus.
- o Applicant must hold an M.D. or equivalent professional degree with a minimum of three years post-M.D. experience or two years post-M.D./Ph.D. experience.
- o Selection by national competition.
- o Support for five years; non-renewable
- o Full-time salary support up to a maximum of \$30,000 per year.
- o Supplementation is allowed from non-federal funds.
- o Research support for first three years up to a maximum of \$8,000 per year; research support for 4th and 5th year up to a maximum of \$20,000 per year.
- o Annual receipt date of June 1. Advisory Council review in February.

III. Development-Related Program

Although not a training or development grant <u>per se</u>, the New Investigator Research Award (NIRA) may be used to bridge the transition from training status to that of an established investigator. The NIRA has the following features:

- o To encourage new investigators in basic or clinical science disciplines to develop their research interests and capabilities in biomedical and behavioral research and not more than 5 years research experiences after completing formal training.
- o Doctoral degree by time of award.
- Restricted to applicants who have not previously been principal investigators on a PHS supported project.
- o Concurrent applications not permitted for research grant award, research training or research development award.
- o Duration of award up to the three years; non-renewable.
- Salary support up to \$25,000 per year; total direct cost must not exceed \$107,500 for three year period no more than \$37,500 in any one year.
- o Supplementation is allowed from non-federal funds.
- Selection by national competition.
- Receipt dates for applications are:

Advisory Council Review:

March 1 July 1 November 1

October February May

Further information regarding the above programs can be obtained from:

Research Training and Development Branch Division of Heart and Vascular Diseases National Heart, Lung, and Blood Institute National Institutes of Health Federal Building - Room 3A08 Bethesda, Maryland 20205

Telephone: (301) 496-1724

Mensured 9/20/41

ANNOUNCEMENT

STUDIES ON OBESITY

P.T. 34; K.W. 1200930, 0202022, 1200460, 1002019, 1200890, 0404000

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE
AND KIDNEY DISEASES
NATIONAL CANCER INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE ON AGING
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS
AND STROKE
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
NATIONAL INSTITUTE ON DRUG ABUSE

I. BACKGROUND INFORMATION

NATIONAL INSTITUTE OF MENTAL HEALTH

Research on the biomedical and behavioral aspects of obesity is an important component of the NIH and ADAMHA nutrition research programs. Obesity is widely prevalent in the U.S. affecting both children and adults. Children today at one year of age are on the average, 50 percent heavier than they were a generation ago; 40 percent of American women and 32 percent of the American men between the ages of 40 and 49 years are at least 20 percent above desirable weight desirable weight defined by National Health and Nutrition Examination Survey (NHANES) as the average weight of those individuals between the ages of 20-29 years. Moreover, 7.2 percent of women and 4.9 percent of men aged 20-74 years were found to be severely obese in a U.S. survey using a national probability sample. Recent data from the second NHANES survey (1976 to 1980) indicate that the prevalence of obesity persists and that those in the 90th percentile are even heavier than in previous surveys.

Obesity is either a risk factor for, or is associated with, a number of diseases including diabetes, hypertension, coronary heart disease, complications of pregnancy, osteoarthritis, and some cancers and infections. Obesity may also be an adverse prognostic factor in certain diseases, such as early stage breast cancer and cancer of the endometrium.

II. RESEARCH GOALS AND SCOPE

The emphasis of this program announcement is the support of research on the biomedical and behavioral aspects of exogenous obesity. The goals of this research, which includes both basic and clinical research, are to establish a clear understanding of the etiology, prevention and treatment of this multifaceted condition. For example, the determinants of obesity during the early stages of the life cycle need to be identified in order to prevent the onset of obesity early in life and to identify individuals at high risk of becoming obese later in life. The question of whether obesity is a risk factor per se for the development of other disease states needs to be clarified as well as its relationship to mortality. Preventive therapies as well as successful treatment regimens need to be designed. In order to accomplish these goals, further research is needed on the behavioral and

developmental aspects of obesity in terms of its natural history and determinants in infancy, childhood, and adolescence; on the metabolic, genetic and neurological aspects of obesity; on the successful treatment of overnutrition and obesity; and on the effects of obesity on body weight, health and longevity. A major question with respect to the health implications of obesity in terms of body weight, health and longevity is one of determining the relative role of body build on the one hand and of "fatness" on the other on the morbidity and mortality attributed to obesity. Another problem is to learn more about the relationship of adipose tissue morphology and of the pattern of fat distribution to the impaired health and shortened life span associated with obesity.

Examples of research areas in overnutrition and obesity of particular interest follow:

A. METABOLIC AND GENETIC FACTORS

The metabolic and genetic factors related to obesity encompass dietary determinants (nutrient sources, intake and balance) that affect metabolism, particularly of the adipose cell, and its effect in turn on appetite; the effect of various physiological and genetic factors on eating behaviors and subsequent weight gain or weight control; the interactions between metabolic parameters and resulting maladaptive patterns of food ingestion and drug abuse; the mechanisms by which obesity contributes to the development of diseases such as diabetes, coronary heart disease, hypertension, cancer, etc.; and the determinants of genetic/biochemical markers for the different kinds of obesity.

B. NEUROLOGICAL AND ENDOCRINE FACTORS

In order to better understand the role of the central nervous system in the etiology of obesity, studies are encouraged to examine the neurophysiology of ingestive behaviors in terms of the neurochemical and neuroanatomical integrations at the level of the neuron and synapse, as well as the neuroanatomical pathways and neurological mechanisms of taste and smell that affect eating behaviors, and the effects of various drugs in their modification. In addition, studies on all aspects of satiety, anorexia, bulimia and bulimarexia are of special interest.

C. BEHAVIORAL AND DEVELOPMENTAL FACTORS

The need to elucidate the underlying causes of obesity requires investigations on behavioral, psychological, and developmental factors as well as on physiological, metabolic and neuronal factors as previously described. Knowledge of the role of all of these factors contributes to a better understanding of the necessary strategies for the prevention and treatment of obesity.

D. THE EFFECTS OF OVERWEIGHT/OBESITY ON HEALTH AND LONGEVITY

In the most recent analysis of the Framingham Heart Study data there is strong evidence that body weights in excess of those recommended as desirable by the 1959 Metropolitan Life Insurance Table are associated with increased mortality. There is a need to develop an appropriate data base relating body weight by age, sex, and possibly frame size to morbidity and

mortality, so as to permit the preparation of reference tables for defining the range of body weight based on morbidity and mortality statistics. Reference data should take into account appropriate attributes (physical activity level, nature of diet, etc.) as well as possible changes in the attributes. This will require new observational studies to quantify, in study populations, the relationship of such factors to morbidity and mortality.

Since obesity has been shown to be a significant independent predictor for cardiovascular disease, there is a need to: investigate the ways in which overweight becomes or acts as a "marker" for premature demise; define the effect of duration of overweight on health in order to ascertain the specific age (how early in life) at which overweight becomes a marker for morbidity and mortality; and identify the various types of obesity that are associated with specific diseases at different stages of the life cycle (e.g. upper trunk obesity with diabetes, fat cell number and hypertension in early adulthood and fat cell size and hypertension in middle age).

E. TREATMENT OF OBESITY

Due to the serious health implications of obesity, research must continue to find successful treatment measures for obesity and to prevent its recurrence. Various treatments that need to be examined include the use of hypocaloric regimens, the effects of exercise on metabolism and subsequent weight loss, and behavioral modification therapies. Such treatments need to be examined across the various stages of the life cycle, as well as in terms of their success and safety in maintaining weight loss without provoking or aggravating other medical disorders.

F. In the next section of this program announcement the research priorities in the aforementioned categories are presented by of each of the Institutes participating in this joint program announcement. However, these priorities are intended as examples of research interest and do not preclude the submission of applications involving other research approaches to the issues under consideration. In addition, this joint program announcement is not intended to discourage investigators from their pursuit of promising ideas in related topics.

METABOLIC AND GENETIC FACTORS

Examples of research interest are listed by Institute.

- 1. National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases
 - o Dietary determinants (nutrient sources, intake and balance) of the proliferation and control of depot fat cell size and number.
 - o Mechanism of the effect of depot adipose cell size, adipocyte number, and overall body composition on appetite.
 - o Physiological abnormalities (e.g. protein depletion) following weight loss and their role in promoting recidivism.

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- o The effect of mild exercise on appetite and its role in weight control.
- o Individual variability in energy metabolism and thermogenesis.

2. National Cancer Institute

- o Mechanisms by which overnutrition and obesity increases the risk of developing cancer.
- o Mechanisms for the development of obesity in patients with breast cancer receiving adjuvant chemotherapy.

3. National Heart, Lung and Blood Institute

- o Mechanisms by which obesity may act as an "independent" coronary heart disease risk factor apart from its known impact on other CHD risk factors (hypertension, hyperlipidemia, etc.)
- o Mechanisms by which weight gain and overweight influence lipoprotein fractions when age, sex, physical activity, smoking, diet, genotype, etc. are considered.
- o Mechanisms involved in the development of hypertension in overweight persons (endocrine/metabolic derangements, blood volume changes, electrolyte metabolism, etc.).

4. National Institute of Child Health and Human Development

o Genetic and physiological factors that influence weight gain and weight control during infancy, childhood, and adolescence.

5. National Institute on Alcohol Abuse and Alcoholism

o Mechanisms by which alcohol may alter metabolic homeostasis and contribute to the development of obesity.

6. National Institute on Drug Abuse

- o Correlations and interactions between metabolic parameters and the resulting maladaptive patterns of food ingestion and psychoactive drug use.
- o Changes in the effects of behaviorally active drugs as a function of weight loss and weight gain, e.g. their mobilization or storage as a function of these conditions.

7. National Institute of Mental Health

o Physiological factors that influence the development of anorexia nervosa and bulimia.

NEUROLOGICAL AND ENDOCRINE FACTORS

Examples of research interest are listed by Institute.

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

o Physiological factors that affect eating behavior; hormones, metabolites and neuropeptides that are signals of satiety and hunger.

2. National Institute of Child Health and Human Development

o Neurochemistry and neurophysiology of the central nervous system in terms of the origin of the feelings of hunger and satiety, and the relationship to food ingestion and meal cessation.

3. National Institute of Neurological and Communicative Disorders and Stroke

- o Mechanisms by which the structure and function of the neuron and synapse affect neuromuscular feeding behaviors in animals, e.g. swallowing.
- o Role of the brain in mediating acquisition, extinction and aversion of associations to gustatory, olfactory and trigeminal stimulation.
- o The electrophysiological activity of the brain resulting from changes in food intake in animals, as well as gustatory, olfactory and trigeminal stimulation.
- o Neuroanatomical pathways connecting the gastrointestinal system to the hypothalamus, and the effect of changes in the gastrointestinal system on electrophysical activity in the hypothalamus.
- o Neuroanatomical organizations and pathways of the somatic and autonomic nervous systems that control food intake and the behavioral, hormonal and metabolic mechanisms by which such pathways influence body weight.
- o Abnormalities in the brain of genetically obese animals.
- o Neurological mechanisms of taste and smell, and their common chemical reception and chemosensory stimuli in a variety of animal models.

4. National Institute on Drug Abuse

o The neurological basis of homeostasis for feeding control, and the effect of various behaviorally active drugs in modification of "set points" leading to nutritional changes.

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5. National Institute of Mental Health

o Neuronal substrates and substances that influence eating behavior.

BEHAVIORAL AND DEVELOPMENTAL FACTORS

Examples of research interest are listed by Institute.

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

- o Psychological factors that influence the development and maintenance of overeating and bulimia, as well as in anorexia nervosa.
- o The attributes of diet, such as nutrient imbalances or source, that promote hyperphagia.

2 National Cancer Institute

- o Behavioral strategies to reduce dietary fat intake and their application to large population groups.
- o Dietary composition that relates to the development of obesity and may increase the risk for developing certain kinds of cancer.

3. National Institute of Child Health and Human Development

o Psychological and social factors that influence weight gain and weight control during infancy, childhood, and adolescence.

4. National Institute on Alcohol Abuse and Alcoholism

o The relationship of eating disorders to alcohol abuse and alcoholism.

5. National Institute on Drug Abuse

- o The specific patterns of types of drug use as a function of nutritional disorders.
- o The development of obesity as either an antecedent or consequent to drug use.
- o The relationship between eating disorders and other stereotypic disorders including drug use.
- o The relationship between mood states, behavioral patterns, food intake and drug use.

6. National Institute of Mental Health

o Behavioral, psychological and social correlates of overeating and obesity.

o The relationship of stress responsiveness to overeating and obesity as well as the relationship of overeating and obesity to psychiatric illness.

THE EFFECTS OF OVERWEIGHT/OBESITY ON HEALTH AND LONGEVITY

Examples of research interest are listed by Institute.

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

o Examination of obesity as a risk factor for diseases such as diabetes, digestive diseases, degenerative joint or bone diseases, renal diseases and hypertension.

2. National Cancer Institute

- o Examination of the adverse prognostic effect of obesity in early stage breast cancer.
- o Determination of the types of cancer for which risk is increased by overnutrition and obesity.

3. National Heart, Lung and Blood Institute

o Examination of different kinds of obesity (juvenile vs. adult onset) in terms of impact on hyperlipidemia, hypertension, and/or hyperglycemia, as well as the effects of weight reduction and long-term maintenance of lowered body weight on the reduction of hyperlipidemia, hypertension and other cardiovascular disease risk factors.

4. National Institute of Neurological and Communicative Disorders and Stroke

o Examination of the relationship between obesity and stroke; i.e., is obesity in itself a risk factor for stroke or is it associated with other risk factors for this disease.

5. National Institute on Aging

- o The effect of overnutrition and the role of obesity on longevity in healthy humans and in suitable animal models.
- o The contribution of overnutrition to the aging of various organ systems.

6. National Institute of Mental Health

o Interrelationship of overeating and obesity, stress responsiveness and psychiatric illness.

TREATMENT OF OBESITY

Examples of research interest are listed by Institute.

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

- o Weight management strategies that include individuals with special dietary requirements due to their stage in the life cycle or to the existence of chronic diseases such as diabetes, renal disease, etc.
- o The effect of mild exercise on appetite and its relationship to weight control.

2. National Heart, Lung and Blood Institute

Treatment regimens that include both changes in diet and physical activity and also relate to other cardiovascular disease risk factors, both in terms of their treatment and prevention.

3. National Institute on Aging

o The effects of weight loss regimens on health and longevity in the obese elderly.

4. National Institute of Child Health and Human Development

- o The use of hypocaloric dietary therapy for obese children and adolescents.
- o Behavioral intervention strategies to treat obesity in infancy, childhood and adolescence.

5. National Institute on Drug Abuse

o Similarities and differences in successful programs designed to treat nutritional and substance abuse disorders.

6. National Institute of Mental Health

o The behavioral, psychological and psychopharmacological treatment of overeating and obesity.

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

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

Van S. Hubbard, M.D., Ph.D. Nutrition Program Director Westwood Building - Room 3A18 Bethesda, MD 20205 (301) 496-7823

NATIONAL CANCER INSTITUTE

Ritva Butrum, Ph.D.
Program Director
Diet and Cancer Branch
Division of Cancer Prevention
and Control
Blair Building - Room 619
Bethesda, MD 20205 (301) 427-8753

Freddie Ann Hoffman, M.D.
Program Director
Nutrition and Supportive
Care Section
Division of Cancer Treatmemt
Landow Building - Room 4A18
Bethesda, MD. 20205 (301) 496-4844

John Cooper, Ph.D. Chief, Extramural Programs Branch Division of Cancer Etiology Landow Building - Room 8C41 Bethesda, MD 20205 (301) 496-1882

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Barbara Packard, M.D., Ph.D.
Director, Division of Heart
and Vascular Diseases
National Heart, Lung, and
Blood Institute
Federal Building - Room 416A
Bethesda, MD 20205 (301) 496-2553

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Gilman D. Grave, M.D.
Chief, Nutrition and Endocrinology
Section
Clinical Nutrition and Early
Development Branch
Center for Research for Mothers
and Children
Landow Building - Room 7C17
Bethesda, MD 20205 (301) 496-5575

NATIONAL INSTITUTE ON AGING

William A. Kachadorian, Ph.D.
Nutrition Section
Physiology of Aging Branch
Biomedical Research and Clinical
Medicine Program
NIA, Building 31 - Room 5C27
Bethesda, MD 20205 (301) 496-9350

Leonard Jakubczak, Ph.D.
Behavioral Sciences Research Program
National Institute on Aging
Building 31 - Room 4C32
Bethesda, MD 20205 (301) 496-3136

NATIONAL INSTITUTE OF MENTAL HEALTH

Ellen Simon Stover, Ph.D. Chief, Research Resources Branch Division of Extramural Research Programs National Institute of Mental Health Parklawn Building - Room 10-104 5600 Fishers Lane Rockville, MD 20205 (301) 443-4266

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Eugene Streicher, Ph.D.
Fundamental Neurosciences Program
National Institute on Neurological
and Communicative Disorders
and Stroke
Federal Building - Room 1C04
Bethesda, MD 20205 (301) 496-1447

III. 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 Title 45, Part 74) and policies that govern the research grant programs of the Public Health Service will prevail. The award of grants pursuant to this request for grant applications is contingent upon ultimate receipt of appropriated funds for this purpose.

IV. METHOD AND CRITERIA OF REVIEW

- A. Assignment of Applications: Applications will be received by the Division of Research Grants (DRG), NIH, referred to an appropriate study section for scientific review, and assigned to individual Institutes for possible funding. These decisions will be governed by normal programmatic considerations as specified in the DRG Referral Guidelines.
- B. Review Procedures: Applications in response to this announcement will be reviewed on a nationwide basis in competition with other applications received in the same review cycle, and in accord with the usual National Institutes of Health/Alcohol, Drug Abuse and Mental Health Administration peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (study section). Following study section review, the application will be evaluated by the appropriate Institute Advisory Council or Board with respect to the adequacy of the technical merit review and the program relevance of the research proposed. The review criteria customarily employed by the National Institutes of Health/Alcohol, Drug Abuse and Mental Health Administration for regular research grant applications will prevail.
- C. <u>Deadlines</u>: Applications will be accepted in accordance with the usual receipt dates for new applications:

March 1
July 1
November 1

V. METHOD OF APPLYING

Applications should be submitted on forms PHS 398 which is available in the business or grants and contracts office at most academic and research institutions, or on form PHS 5161 for state and local governments. The phrase "PREPARED IN RESPONSE TO NIH/ADAMHA OBESITY PROGRAM ANNOUNCEMENT" should be typed into item 2 of the first page of the application.

For NIMH areas of interest, applicants may apply for small grants in addition to regular research grants. For information about small grants contact the NIMH staff person listed in this announcement. The original and six copies of the application should be sent or delivered to:

Application Receipt Office Division of Research Grants National Institutes of Health Westwood Building - Room 240 Bethesda, Maryland 20205 For further information, investigators are encouraged to contact one or more of the Institute contacts listed above.

This program announcement replaces a previous one published in the NIH Guide for Grants and Contracts, Vol 7, No. 18, November 27, 1978.

ANNOUNCEMENT

ACADEMY OF FINLAND POSTDOCTORAL RESEARCH FELLOWSHIPS

P.T. 22, 48; K.W. 1200170, 1200180, 1200270

FOGARTY INTERNATIONAL CENTER

The Academy of Finland provides a limited number of research fellowships to U.S. biomedical scientists to conduct research in Finland. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical sciences. The types of activity that are supported by this program include collaboration in basic or clinical research, and the familiarization with or utilization of special techniques and equipment not otherwise available to the applicant. The program does not provide support for activities that have as their principal purpose brief observational visits, attendance at scientific meetings, or independent study.

The program is administered for the Academy of Finland by the Fogarty International Center (FIC) National Institutes of Health (NIH).

I. ELIGIBILITY

Applicants for the program must meet the following requirements:

- o U.S. citizenship or permanent U.S. residency.
- o A doctorate in one of the behavioral or biomedical sciences.
- o Ten years or less of postdoctoral experience
- o Professional experience in the health sciences for at least two of the last four years.

II. SUPPORT

The Academy of Finland will provide the following support:

- 1. Stipend: Stipends are between FIM 108,000 and FIM 132,000 per annum.* The appropriate level is determined by the number of years of relevant or professional postdoctoral experience at the time of award. Research experience such as teaching, internship, or residency is considered relevant experience. Fellows may accept sabbatical salary, concurrent royalties, or other income from past services if reported in the application.
- 2. Travel: Roundtrip tourist class air fare expenses are provided for fellows and members of their families (spouse and dependent children)

^{*}Equivalent to \$18,400-\$22,500 per annum as of February 1984.

from point of origin in the United States to the Finnish host institution(No reimbursement will be made for any other expenses enroute, nor for costs of transporting personal or household effects.)

3. Health Insurance. Health and accident insurance coverage are provided for fellows and dependents during their stay in Finland. Each fellow is strongly urged to purchase in the United States insurance to cover the round-trip transit period for himself/herself and accompanying family members.

III. DURATION OF PARTICIPATION

Fellowships are awarded for a 1 year period, but exceptions may be considered if recommended by the host institution and approved by the Academy of Finland. The starting date of the fellowships is set by mutual agreement of the applicant and the institution, provided it is within the 10 month period immediately following the date of the award.

IV. APPLICATION AND SELECTION

Information and application forms are provided by the FIC. In addition to biodata and reference reports, the applicant will be required to include a clear and explicit description of the proposed activity to be carried out in Finland and the benefits expected from the experience. It is the applicant's responsibility to arrange for his or her research program with the sponsor in Finland either through direct correspondence or through correspondence in the applicant's behalf by a senior scientist in the United States with a Finnish colleague. The sponsor's portion of the application should reflect that he or she is prepared to guide and administer the proposed research project, and can provide the necessary facilities.

The receipt date for applications at the FIC is October 1. Applications are reviewed for scientific merit by the NIH and are transmitted to the Academy of Finland for final selection. The selection meeting is held in June of the year following the receipt of applications. Shortly after the selection meeting candidates will be notified of the results.

V. INQUIRIES AND APPLICATION KITS

Chief, International Research and Awards Branch Fogarty International Center National Institutes of Health Bethesda, Maryland 20205

ANNOUNCEMENT

NORWEGIAN RESEARCH COUNCIL FOR SCIENCE AND THE HUMANITIES

POSTDOCTORAL FELLOWSHIPS

P.T. 22, 48; K.W. 1200170, 0404000, 1200170, 0112101

FOGARTY INTERNATIONAL CENTER

The Norwegian Research Council for Science and the Humanities (NAVF) provides a limited number of research fellowships to U.S. health scientists to conduct research in Norway. The purpose of these fellowships is to enhance the exchange of research experience and information in the biomedical and behavioral sciences. The types of activity that are supported by this program include collaboration in basic or clinical research, and the familiarization with or utilization of special techniques and equipment not otherwise available to the applicant. The program does not provide support for activities which have as their principal purpose brief observational visits, attendance at scientific meetings, or independent study.

The program is administered for the NAVF by the Fogarty International Center (FIC), National Institutes of Health (NIH).

I. ELIGIBILITY

Applicants for the program must meet the following requirements:

- 1. U.S. citizenship or permanent U.S. residency;
- 2. a doctorate in a biomedical, clinical, or behavioral science;
- 3. 10 years or less of postdoctoral experience; and
- 4. professional experience in the health sciences for at least 2 of the last 4 years.

II. SUPPORT

The NAVF will provide the following support:

1. Stipends - Stipends are between N.kr 125,000 and N.kr 165,000 per annum.* The appropriate level for an individual fellowship is determined by the number of years of relevant or professional postdoctoral experience at the time of award. Professional experience such as teaching, internship, and residency may be considered relevant experience. Fellows may accept sabbatical salary, concurrent royalties, or other income from past services if reported in the application.

^{*} Equivalent to approximately \$16,000 - \$22,000 per annum as of March 1984.

- 2. Travel Round-trip air fare, tourist class, expenses are provided for the fellow only between the point of origin in the United States and the Norwegian host institution.
- 3. Health insurance Health and accident insurance coverage are provided for fellows and accompanying family members during their stay in Norway. For the fellow, health and accident insurance are provided in transit to Norway. Fellows are strongly urged to purchase insurance in the United States to cover the round-trip transit period for accompanying family members.

III. DURATION OF PARTICIPATION

Fellowships are awarded for a 1 year period, but exceptions may be considered if recommended by the host institution and approved by the NAVF. The starting date of the fellowship is set by mutual agreement of the applicant and the institution, provided it is within the 10-month period immediately following the date of the award.

IV. APPLICATION AND SELECTION

Information and application forms are provided by the FIC. In addition to biodata and reference reports, the applicant will be required to include a clear and explicit description of the proposed activity to be carried out in Norway and the benefits expected from the experience. It is the applicant's responsibility to arrange for his or her research program with the sponsor in Norway either through direct correspondence or through correspondence in the applicant's behalf by a senior scientist in the United States with a Norwegian colleague. The sponsor's portion of the application should reflect that he or she is prepared to guide and administer the proposed research project, and can provide the necessary facilities.

The receipt date for applications at the FIC is October 1. Applications are reviewed for scientific merit by the NIH and are transmitted to the NAVF for final selection by the Medical Research Council. The selection meeting is held in June of the year following the receipt of applications. Shortly after the selection meeting candidates will be notified of the results by the NAVF.

V. INQUIRIES AND APPLICATION KITS

Chief, International Research and Awards Branch Fogarty International Center Building 38A - Room 613 National Institutes of Health Bethesda, Maryland 20205

ANNOUNCEMENT

PSYCHODYNAMIC TREATMENT OF NONPSYCHOTIC DISORDERS

P.T. 34; K.W. 0414004, 0414013, 0415000, 0701029, 1201160, 1201170

NATIONAL INSTITUTE OF MENTAL HEALTH

I. PROGRAM SPECIFICATIONS

A. Program Objectives

The objective of this special announcement is to encourage and stimulate research on the evaluation of short-term or long-term psychodynamic psychotherapy with chronic or severe nonpsychotic disorders. A second objective is to stimulate the development and refinement of methods and instruments for the evaluation of process and outcome of psychodynamic psychotherapy. For purposes of this announcement, psychodynamic psychotherapy refers to a broadly defined class of psychotherapies whose theoretical basis clearly lies within the psychoanalytic tradition. common goal in all psychodynamic therapies is insight. Primarily through the therapist's interpretation of the patient's in-therapy behavior in the context of his or her relationship with the therapist, a patient acquires insight into his or her interpersonal conflicts whose origins and recurrent enactments lie beyond the patient's awareness. These transferential reenactments of earlier consolidated patterns of conflictual interpersonal relationships are considered critical to the appearance of insight in therapy and therefore change in the patient. Transference phenomena are therefore assumed to mediate change in the patient's underlying core conflicts which are the presumed causes of the patient's symptomatology.

Nonpsychotic disorders, for purposes of this announcement, refer to those listed in the DSM-III. Particular interest centers on the anxiety and somatoform disorders, but the applicant is free to consider the full range of nonpsychotic disorders covered in the DSM-III. It is recognized that the DSM-III presents certain difficulties for diagnosing the kinds of chronic, interpersonal disorders that are particularly amenable to treatment by psychodynamic therapies. Axis I syndromic diagnoses are not adequate in themselves, while Axis II personality disorders thus far have been found to be unreliable. A combined diagnosis involving an Axis I syndromic diagnosis and an Axis II personality disorder diagnosis recently has been suggested as an appropriate compromise between the requirements of DSM-III and the particular emphases and foci of psychodynamic therapy. The applicant, however, need not be restricted to this suggestion.

B. Research Areas of Interest

Research grant applications are sought for the following kinds of efficacy and method development studies:

- 1. Efficacy Studies of Psychodynamic Psychotherapy
 - Pilot studies evaluating the efficacy of short-term, time-limited, and long-term forms of psychodynamic therapy. There are a few existing systematic empirical studies demonstrating the efficacy of psychodynamic therapy with any disorder. Preliminary pilot studies need to be conducted establishing initial effects. These studies should include follow-up assessments that would evaluate the durability of these effects associated with psychodynamic therapy. These pilot studies may involve intensive longitudinal designs or treatment/no-treatment comparisons applied to the same homogeneous diagnostic category.
 - Pilot studies indicating the efficacy of short-term or time-limited versus long-term forms of psychodynamic therapy. years, several different forms of short-term and time-limited psychodynamic therapy have been developed which from the practicing clinician's point of view appear to be quite promising. But few controlled evaluations have been undertaken. therefore important to obtain data on several issues relating to the evaluation of their efficacy. First it is necessary to conduct pilot studies comparing short-term and time-limited therapy with Once their general efficacy in relation to nono-treatment. treatment has been established, the renewal phase of this research would be the appropriate time to study whether short-term therapy can produce as much or more change than long-term psychodynamic psychotherapy applied to the same diagnostic grouping of patients. Process studies attempting to elucidate the basic mechanisms of effective short-term or time-limited therapy would follow.
 - o <u>Pilot studies of psychodynamic versus nonpsychodynamic psychotherapy</u>. Initial pilot studies may also be considered comparing psychodynamic and nonpsychodynamic forms of psychotherapy. These comparisons may involve short-term, timelimited, or long-term therapy.
 - Pilot studies of patients characteristics predicting success and failure in psychodynamic psychotherapy. Most therapies are found to be efficacious for a limited subset of patients in a particular diagnostic category. Pilot studies are needed to determine for which subtypes of a given diagnostic category psychodynamic therapy is effective.

2. Method Development Studies

The greatest stumbling block to progress in research on psychodynamic therapy is the relative paucity of reliable and valid measures to assess the key constructs in psychodynamic therapy theory. The conduct of a scientifically valid clinical trial designed to evaluate the efficacy of psychodynamic therapy is predicted on the development of these reliable and valid measures. It is believed, however, that the best strategy for undertaking the development of these measures is to carry out this work within the context of the preliminary outcome studies mentioned above. Applicants are therefore encouraged to include, as an integral part of their efficacy study research proposals, plans for measurement development. This recommendation is not meant to exclude those applicants who may be interested in applying for modest research funds primarily in order to develop or refine a particular instrument or measure. Several areas have been identified as being in particular need of measurement development.

- Measures of the core interpersonal conflicts. Reliable and valid measures are needed to identify the core interpersonal conflicts that presumably underlie a patient's psychopathology. Particular attention should be paid to the fact that underlying core conflicts represent a continuous variable and thus a determination must be made as to how much conflict is enough to require therapy and a diagnosis of severe psychopathology. Measures will need to be sensitive enough to identify the conflicts, establish that they are significantly interfering with or dominating a patient's life, identify the conditions either intrinsic or extrinsic that may be contributing to why the conflict is becoming a problem at this time, and determine the degree of penetrance that these conflicts have into other areas of the patient's functioning (e.g., work functioning, social functioning, degree of physical health disturbances). These measures should be able to detect changes in the various core conflicts.
- Measures of repetitive maladaptive interpersonal patterns. Reliable and valid measures are needed to identify the repetitive maladaptive interpersonal patterns that presumably result from the patient's core conflicts. These patterns may be exhibited both within and outside the therapy session. Attention must be paid to the same considerations that are obtain with measures of core conflicts.
- Measures of transference phenomena. In many, if not most, versions of psychodynamic therapy, a major mediator of therapeutic change involves the transference relationship that the patient develops with the therapist. It has been hypothesized that it is through the evocation and analysis of the transference relationship that patients in dynamic therapy eventually gain insight into their repetitive scenarios and core conflicts. Currently there are a few established measures which identify the appearance of transference phenomena, indicate changes in the

transference relationship, and/or specify the relationship between changes in the transference relationship and therapy outcome.

- o Measures of therapeutic alliance. Continued work is required on the further development and refinement of existing measures on the therapeutic alliance. The therapeutic alliance also has been hypothesized to be a critical element in the psychodynamic therapy process.
- Measures of interpersonal change. Research is needed on the development of change along various interpersonal dimensions. Interpersonal variables are of particular significance to psychodynamic therapy; therefore, the development of measures which are sensitive to changes in the interpersonal domain may reveal the special potential of psychodynamic therapies.
- Measures of therapeutic skill in conducting psychodynamic therapy. Research is needed on the development of reliable and valid measures of therapeutic skill in conducting dynamic therapy. Such measures are necessary in order to distinguish poorly conducted from competently conducted psychodynamic therapy.

II. CONSULTATION AND FURTHER INFORMATION

Preapplication consultation can be obtained from:

National Institute of Mental Health

Barry E. Wolfe, Ph.D.
Assistant Chief
Psychosocial Treatments Research Branch
Division of Extramural Research Programs
Parklawn Building - Room 10C-05
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4527

III. APPLICATION RECEIPT AND REVIEW SCHEDULE

Receipt of	Initial	Advisory	Earliest
Applications	<u>Review</u>	<u>Coucil Review</u>	Award Date
July 1, 1984	Oct/Nov. 1984	February 1985	April 1, 1985

Applications will be reviewed for scientific merit by a peer review group consisting primarily of non-Federal experts. Applications will receive a secondary review for scientific/technical merit and policy consideration by the National Advisory Mental Health Council (NAMHC). Notification of review outcome will be sent to the applicant by the National Institute of Mental Health (NIMH). Only applications recommended for approval by the NAMHC can be considered for funding.

IV. REVIEW CRITERIA

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

- o Potential contributions to the field in areas covered by the objectives and scope of this special announcement.
- o Adequacy of the conceptual and theoretical framework for the research.
- o Evidence of familiarity with relevant clinical research literature.
- o Scientific merit of the research design, approaches, and methodology.
- o Adequacy of the data analysis plan.
- o Qualifications and experience of the investigative team.
- o Adequacy of the existing and proposed facilities and resources.
- o Appropriateness of the budget, staffing plan, and time frame to complete the project.
- o Adequacy of proposed procedures for protecting human subjects.

V. AWARD CRITERIA

The following criteria will be used in deciding to make an award for an application which has been recommended for approval:

- o Quality of the proposed project as determined during the review process.
- o Programmatic relevance of the proposed project.
- o Availability of funds.

VI. TERMS AND CONDITIONS OF SUPPORT

Grants will be administered in accordance with the <u>PHS Grants Policy Statement*</u> including the policy regarding cost sharing.

VII. AVAILABILITY OF FUNDS

Applications received under this announcement will be considered for funding in Fiscal Year 1985. It is estimated that up to \$500,000 will be available for approximately 5 to 8 new awards.

VIII. PERIOD OF SUPPORT

Applications may request support for up to 5 years; however, the typical period of support for pilot studies is expected to be 3 years. Applications for future submission deadlines are encouraged and will be considered under the regular program.

Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50-000 GPO-017-020-0090-1 (rev.) December 1, 1982, available for \$5.00 from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. \$10402.