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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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IN THIS ISSUE:

Notice
Special Edition
National Research Service Awards
Guidelines for Individual Awards -
Institutional GrantsPage 1
Index - NATIONAL RESEARCH SERVICE AWARDS
Notice
ERRATA - Vol. II, No. 5, April 23, 1982
Request for Research Grant Applications:
RFA NIH-NIAID 82-8 Centers for Infectious
DiseasesPage 1
National Institute of Allergy and
Infectious Diseases
Index - NIAID
Notice
Comments Invited on Alert Records
Index - PRIVACY ACT
Reannouncement
Biomedical Research Support Shared
Instrumentation Grants
Division of Research Resources
Index - DIVISION OF RESEARCH RESOURCES
Announcement
Long-Term Effects of Craniofacial Injuries Page 8
National Institute of Dental Research
Index - DENTAL

(Continued)

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

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

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.

Index	c - (Continued)
Anno	ouncement Multipurpose Arthritis CentersPage 9 National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases Index - NIADDK
Notio	Program Project and Center Applications Pre-Application Procedures
Prev	entive Intervention Research Centers
	Index - INSTITUTIONAL GRANTS

NOTICE

SPECIAL EDITION

National Research Service Awards

Guidelines

for

Individual Awards - Institutional Grants

The administrative guidelines for the National Research Service Award program have been published as a special edition to this volume of the <u>NIH Guide for Grants and Contracts</u>. The guidelines have been revised to reflect the legislative changes enacted by the Omnibus Reconciliation Act of August 13, 1981 and other administrative changes.

Copies of the guidelines are being sent directly to the current program directors of institutional training grants, individual fellowship recipients, and the Business Offices and Sponsored Programs Offices of the grantee institutions that receive NRSA Support from NIH, ADAMHA, and HRA/DN.

Additional copies are available upon request from:

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

Telephone: 301 - 496-7441

NOTICE

<u>ERRATA</u>

An Announcement in the April 23, 1982 Guide for Grants and Contracts (Vol. 11, No. 5) entitled "Request for Research Grant Applications: RFA NIH-NIAID 82-8 Centers for Interdisciplinary Research on Immunologic Diseases, National Institute of Allergy and Infectious Diseases, was printed with an incorrect receipt date for applications. The correct application receipt date should be October 15, 1982.

NOTICE

Comments Invited on Alert Records

In accordance with the requirements of the Privacy Act, the Public Health Service (PHS) recently published notice of a new Privacy Act system of records, 09-25-0151, "Administration: Alert Records Concerning Investigations or Determinations of Misconduct by Current or Potential Recipients of Funds for Biomedical Research." PHS has also described routine uses for this system.

The full text of the notice may be found in the Federal Register, Vol. 47, No. 92, May 12, 1982, pages 20381-20383. Briefly, the system establishes a "flagging" procedure for incoming grant applications and contract proposals to enable the National Institutes of Health (NIH) to make informed decisions on appropriate actions regarding awards of research funds to individuals who are subjects of ongoing investigations of possible wrong-doing or have been shown to have engaged in misconduct. It establishes a procedure for alerting the directors of NIH awarding units whenever an individual who is under investigation requests funds, and provides for consideration of that information before a decision about an award is made. The system does not prohibit making an award when an investigation is underway but requires the Director of the awarding unit to consult with the NIH Associate Director for Extramural Research and Training prior to making a funding decision.

Access to information on pending investigations is strictly controlled. Staff who flag incoming requests do not know whether they are doing so for purposes of the alert or for other reasons. No information related to the alert is entered in the central NIH data base.

Please note that although the <u>Federal Register</u> notice establishes June 11, 1982, as the deadline for comments, NIH will accept comments until July 15, 1982, in order to accommodate readers of the <u>Guide</u> who may not have seen the <u>Federal Register</u> notice. Comments should be addressed to:

Dr. Kenneth Thibodeau NIH Privacy Act Coordinator Building 31 - Room 3B07 9000 Rockville Pike Bethesda, Maryland 20205

Telephone: 301 - 496-4606

REANNOUNCEMENT

BIOMEDICAL RESEARCH SUPPORT SHARED INSTRUMENTATION GRANTS

DIVISION OF RESEARCH RESOURCES

Application Receipt Date: October 15, 1982

Council Date: June 1983

I. BACKGROUND

As part of its mission to create, develop, and maintain research resources needed by NIH-supported biomedical investigators throughout the nation, the Division of Research Resources (DRR) is continuing its competitive biomedical shared instrumentation grant program initiated in Fiscal Year (FY) 1982. The program was established in recognition of the long-standing need in the biomedical research community to cope with rapid technological advances in instrumentation and the rapid rate of obsolescence of existing equipment. The objective of the program is to make available, to institutions with a high concentration of NIH extramural research awards, research instruments which can only be justified on a shared use basis and for which meritorious research projects are described.

All unfunded applications submitted for the FY 1982 review cycle will be administratively withdrawn by the DRR, unless the applicant is notified to the contrary.

Eligible institutions may submit applications requesting the same, similar or different instrumentation for the FY 1983 review cycle.

II. RESEARCH GOALS AND SCOPE

This program is designed to meet the special problem of acquisition and updating of expensive shared-use instruments which are not generally available through other NIH mechanisms, such as the regular research, program project and center grant programs, the Biomedical Research Support (BRS) Grant Program and other DRR programs such as Animal Resources and the Biotechnology Resources Program. The latter program emphasizes development of the instrument and associated research methodology, research aspects which are not required in the new BRS Shared Instrumentation Program. The BRS Shared Instrumentation Program is intended for a broad community of NIH supported investigators.

This program is described in the Catalog of Federal Domestic Assistance No. 13.337, Biomedical Research Support. Awards will be made under the authority of the Public Health Service Act, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 42 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

III. ELIGIBILITY

The shared instrumentation grant program is a subprogram of the Biomedical Research Support (BRS) Grant Program of DRR. Awards are made under the authority of the BRS program and are made to institutions only, not to individuals. In FY 1983, eligibility is limited to those grantees which received a BRS grant award in FY 1982. NIH records will be used to verify eligibility. Only one application for a single shared instrument may be submitted by each eligible BRS grantee in a review cycle. Applications will be received only once per year. The program is highly competitive. Approximately \$5.0 million have been requested for the program in FY 1983. At this funding level, it is expected that a minimum of 20 and a maximum of 66 awards would be made in 1983. Future funding is contingent on the availability of appropriated funds.

IV. MECHANISM OF SUPPORT

BRS Shared Instrumentation Grants provide support for expensive state-of-the-art instruments utilized in biomedical research. Applications are limited to instruments that cost at least \$75,000 per instrument or system. Types of instrumentation supported include, but are not limited to, nuclear magnetic resonance systems, electron microscopes, mass spectrometers, protein sequencer/amino acid analyzers and cell sorters. Support will not be provided for general purpose equipment or "stand alone" computer systems.

Awards will be made for the direct costs of acquisition of new, or the updating of existing, research instruments. The institution must meet those costs (not covered in the normal purchase price) required to place the instrumentation in operational order as well as the maintenance, support personnel and service costs associated with maximum utilization of the instrument. There is no upper limit on the cost of the instrument, but the maximum award is \$250,000. Grants will be awarded for a period of one year and are not renewable. Supplemental applications will not be accepted. The program does not provide indirect costs or support for construction or alterations and renovations. If the amount of funds requested does not cover the total cost of the instrument, an award will not be made unless the remainder of the funding is assured. Description of the proposed co-funding must be presented with the application. Assurance of co-funding, signed by an appropriate institutional official, must be presented to DRR prior to the issuance of an award. The shared instrument will not be transferable outside of the institution to which it is awarded.

A major user group of three or more investigators should be identified. Each major user must have NIH peer-reviewed research support at the time of the award. The application must show a clear need for the instrumentation by projects supported by multiple NIH research awards and demonstrate that these projects will require at least 75% of the total usage of the instrument. Major users can be individual researchers, or a group of investigators within the same department or from several departments at the applicant institution. NIH extramural awardees from other institutions may also be included.

If the major user group does not require total usage of the instrument, access to the instrument can be made available to other users upon the advice of the advisory committee. These users need not be NIH awardees but priority should be given to NIH-supported scientists engaged in biomedical research. A progress report shall be required for three years. The report will cover the period August 1 through July 31 and be submitted within 30 days following the reporting period. The report must describe the use of the instrument, listing all users, and indicate the value of the instrumentation to the research of the major users and to the institution as a whole.

V. ADMINISTRATIVE ARRANGEMENTS

Each applicant institution must propose a Principal Investigator who can assume administrative/scientific oversight responsibility for the instrumentation requested. An internal advisory committee to assist in this responsibility should also be utilized. It is expected that in most cases, the BRS Program Director and extant BRS advisory apparatus, augmented with members having technical and scientific expertise regarding the instrumentation requested, can serve this function. However, there may be circumstances where other existing or proposed arrangements are more appropriate for the applicant institution.

In any event, the Principal Investigator and the advisory group are responsible for the development of guidelines for shared use of the instrument, for preparation of all reports required by the NIH, for relocation of the instrument within the grantee institution if the major user group is significantly altered and for continued support for the maximum utilization and maintenance of the instrument in the post award period.

A plan should be proposed for the day-to-day management of the instrument including designation of a qualified individual to supervise the operation of the instrument and to provide technical expertise to the users. Specific plans for sharing arrangements and for monitoring the use of the instrument should be described.

VI. REVIEW PROCEDURES AND CRITERIA

Applications are reviewed by specially convened initial review groups of the Division of Research Grants for scientific and technical merit and by the BRS Subcommittee of the General Research Support Review Committee and the National Advisory Research Resources Council of the Division of Research Resources for program considerations. Funding decisions are the responsibility of the Division of Research Resources and will not be made prior to June 15, 1983.

Criteria for review of applications include the following:

- The extent to which an award for the specific instrument would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited.
- 2. The availability and commitment of the appropriate technical expertise within the major user group or the institution for use of the instrumentation.
- 3. The adequacy of the organizational plan for administration of the grant including sharing arrangements for use of the instrument.
- 4. The institution's commitment for continued support of the utilization and maintenance of the instrument.

5. The benefit of the proposed instrument to the overall research community it will serve.

VII. METHOD OF APPLYING

A. Application Format

Applications are to be submitted on the standard PHS research grant application form (PHS-398, Rev. 5/80) available from most institutional business offices or the Division of Research Grants, NIH. Instructions supplied with these forms should be followed except for the following;

- 1. Face page of the application
 - a. Item 1. The instrument requested should be named in the title of the proposal.
 - b. Item 2. Write in "DRR-BRS SHARED INSTRUMENTATION GRANT"
 - c. Item 6. Write in August 1, 1983 July 31, 1984.
 - d. Item 12. Complete Item 12 and type in the institution's BRS grant number.

(Note at the bottom of the page if a duplicate application has been sent to another agency.)

- 2. Application page 2. Identify the Principal Investigator, the major user group and the complete grant number(s) for each of the users currently active NIH research support.
- 3. Application page 4. A detailed breakdown of the direct costs requested will be shown on the budget page. Provide a complete description of the instrument including manaufacturer, model number and cost including tax and import duties, if applicable. If possible, the model chosen should be justified by comparing its performance with other available instruments.
- 4. Application page 5. Budget Estimates for All Years. Not applicable; do not submit.
- 5. Biographical Sketch. In addition to the personnel listed on page 2, include a biographical sketch of the person(s) who will be in charge of maintenance and operation of the instrument and a brief statement of the qualifications of the individual. Biographical sketches should not exceed 2 pages for each individual.

Section 2 of the application. Provide information relative to the points identified under criteria for review including:

1. A description of similar instruments existing at the institution or at nearby institutions and a justification why new or updated

- equipment is needed. A clear justification should be given for the choice of the instrument and ancillary accessories requested.
- 2. A description, by major users, of the research projects for which the instrumentation is required. The descriptions need not be of the detail of a regular research grant application (should not exceed 4 pages) but should point out the benefit of the proposed instrument to the research objectives of each major user. An estimate of the percentage use of each project should be given. If there are more than 4 major users, set up a table listing the names of the users, the NIH grant number, the estimated percentage use and the title of each research project.
- 3. A description of the organizational plan for administration of the grant.
- 4. A specific plan and a staement of institutional commitment to operate and maintain the instrument for its useful life at the same utilization level after termination of the 3-year reporting period to DRR.

B. Application Procedure

Applications must be received by October 15, 1982. Applications received after this date will not be accepted for review in this competition. The original and six copies should be sent to:

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

Inquiries and three copies of the application should be addressed to:

Biomedical Research Support Grant Program Division of Research Resources National Institutes of Health Building 31 - Room 5B23 Bethesda, Maryland 20205

ANNOUNCEMENT

LONG-TERM EFFECTS OF CRANIOFACIAL INJURIES

NATIONAL INSTITUTE OF DENTAL RESEARCH

The National Institute of Dental Research (NIDR) invites applications for support of research related to the long-term effects of traumatic injury to the craniofacial structures.

Each year, approximately 10.5 million persons in the United States suffer a facial or head injury requiring medical care or restriction of activity for a period of time. This number is about five percent of the total population. Many of these injuries result from vehicular trauma, thermal burns and gunshot wounds. Athletics, falls, dog bites and interpersonal violence are also known to contribute to the problem.

It is not known, however, what proportion of craniofacial injuries result in long-term or permanent disfigurement or loss of function. Similarly, data are sparse or lacking entirely on the sources of injuries, the nature of injuries, the kinds of medical treatment required, the costs of such treatment, and the psychosocial consequences of these injuries and defects to the patient and his or her family.

Investigators able to conduct studies to obtain the desired data or who have access to the kinds of data being sought are encouraged to submit a grant application to the NIDR. The deadlines for the receipt of research grant applications by the Division of Research Grants are March 1, July 1, and November 1. Review and award of such applications will be through the usual NIH procedures governing research project grants. The award of grants pursuant to this announcement is contingent upon the receipt of responsive proposals of high scientific merit and the availability of appropriated funds.

Inquiries regarding this announcement may be directed to:

Dr. Jerry D. Niswander or Dr. John D. Suomi Craniofacial Anomalies Program Branch-EP National Institute of Dental Research National Institutes of Health Westwood Building - Room 520 Bethesda, Maryland 20205

Telephone: 301 - 496-7807

This program is described in the Catalog of Federal Domestic Assistance No. 13.842, Craniofacial Anomalies. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject A-95 Clearinghouse or Health Systems Agency review.

NIH GUIDE FOR GRANTS AND CONTRACTS

Vol. 11, No. 7, June 18, 1982

ANNOUNCEMENT

MULTIPURPOSE ARTHRITIS CENTERS

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

Guidelines have been revised for applications for Multipurpose Arthritis Center grants. This announcement by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) supersedes all previous announcements for Multipurpose Arthritis Centers published in the NIH Guide to Grants and Contracts. The revised guidelines for preparing an application for a Center grant are immediately available. These guidelines update the policies governing the Multipurpose Arthritis Centers program. They will become effective beginning June 1982 and will apply to both new and competing continuation applications.

Multipurpose Arthritis Center Grants are awarded under authority of Section 439 of the Public Health Service Act as enacted by the National Arthritis Act of 1974 (42 U.S. Code Sec. 289 c-6).

A Multipurpose Arthritis Center is defined as a resource which consists of the facilities of a single institution or a consortium of cooperating institutions through which a group of formally cooperating health personnel can be brought together to develop new knowledge and to demonstrate and foster the prompt and effective application of available knowledge.

As described in the National Arthritis Act, Multipurpose Arthritis Centers shall carry out the following:

- 1. Conduct basic and clinical research into the cause, diagnosis, control, and treatment of arthritis and complications resulting from arthritis, including research into implantable biomaterials and biomechanical and other orthopedic procedures, and in the development of other diagnostic and treatment methods.
- 2. Conduct training programs for physicians and other health and allied professionals in current methods of diagnosis, control, and treatment of arthritis, and in research in arthritis.
- 3. Conduct information and continuing education programs for physician and other health and allied health professionals who provide care for patients with arthritis.
- 4. Conduct programs for the education of patients, and for the dissemination of information to the general public.

The funds awarded as a Multipurpose Arthritis Center Grant are in support of an Arthritis Center. They are not intended as the total or even necessarily most of the funds used by the Center to accomplish its programs. Instead, funds provided by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases are to be used to coordinate existing activities and to develop new capabilities for progress in rheumatic disease research, education, and community activities at the host institution.

Each Center will have three major operating components: Research, Education, and Community/Health Services Research programs. In addition, each Center will include an Administrative Unit concerned with planning, development, administration, and maintenance of an active and unified Center.

The Center grant may also include support for: 1) developmental and feasibility studies; and 2) core units.

All applications should be prepared in accordance with the revised guidelines dated May 1982. In order to facilitate Institute planning, the NIADDK must receive a letter of intent describing the proposed Arthritis Center. The letter should be received no later than four months before the anticipated submission date of the application. Letters of intent are applicable to both new and competing continuation applications. Applications not preceded by a letter of intent four months prior to the receipt date will be returned.

Consultations between NIADDK staff and potential applicants prior to submission of the formal application are encouraged. Applicants are requested to make arrangements for such consultation early in the application process. It is understood that staff will not be evaluating the merit of the proposal.

A letter of intent is not binding and will not enter into the review of any proposal subsequently submitted.

Receipt dates for applications and respective letters of intent are:

Letter of Intent	Application
October 1	February l
February 1	June 1
June 1	October 1

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases plans to make awards for the Centers program contingent upon the appropriation of funds and in accordance with appropriate peer review.

Copies of the revised guidelines and further information about the Multipurpose Arthritis Centers program are available from, and letters of intent should be addressed to:

Multipurpose Arthritis Center
Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Westwood Building - Room 403
Bethesda, Maryland 20205
Telephone: 301 - 496-7495

NOTICE

PROGRAM PROJECT AND CENTER APPLICATIONS PRE-APPLICATION PROCEDURES

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

This notice is intended to inform prospective new applicants for NIADDK program project and center grants of pre-application procedures.

Letter of Intent: In order to facilitate Institute planning and to provide prospective applicants with advice concerning the preparation of their applications, the NIADDK, beginning with the February 1, 1983 receipt date, will require that applicants submit a letter of intent at least four months prior to submission of an application. The letter should include a brief description of the proposed program project or center including participants and their areas of expertise and an estimate of the requested level of support. This letter of intent is not binding upon any prospective applicant. However, prospective applicants should note that applications not preceded by a letter of intent four months prior to the receipt date will be returned.

<u>Pre-Application Conference</u>: The NIADDK strongly believes that consultation between Institute staff and prospective applicants is essential prior to submission of an application, and suggests that such consultation occur early in the application planning process. Applicants should not construe advice given by the Extramural Program staff as assurance of favorable review. The staff will not evaluate or discuss the merit of the scientific aspects of the proposal.

Letters of intent and inquiries should be addressed as follows:

For Diabetes Research and Training Centers and Diabetes, Endocrinology Research Centers:

Diabetes Centers Program Director, DEMD National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases Bethesda, Maryland 20205

Telephone: 301 - 496-7418

For Multipurpose Arthritis Centers:

Multipurpose Arthritis Centers Program Director, AMSD National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases Bethesda, Maryland 20205

Telephone: 301 - 496-7495

For Clinical Nutrition Research Units:

Nutrition Program Director, DDN
National Institute of Arthritis, Diabetes, and
Digestive and Kidney Diseases
Bethesda, Maryland 20205

Telephone: 301 - 496-7823

For all other Centers or Program Projects:

Director, Division of Extramural Activities National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases Bethesda, Maryland 20205

Telephone: 301 - 496-7277

NIH GUIDE FOR GRANTS AND CONTRACTS Vol. 11, No. 7, June 18, 1982

PREVENTIVE INTERVENTION RESEARCH CENTERS

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NATIONAL INSTITUTE OF MENTAL HEALTH

BACKGROUND

A critical need exists to stimulate and support prevention research, especially research aimed at developing demonstrably effective, well-evaluated, early preventive intervention program models which subsequently can be adapted, replicated, and further refined as a result of the experience of prevention program practitioners.

A distinction must be made between basic or generative (i.e., non-intervention) sources of knowledge and actual or applied preventive intervention programs. The basic research knowledge base for early preventive interventions is large and rooted in diverse sciences and disciplines, and though far from complete, enough is now known for a variety of early preventive intervention efforts to be pursued.

Because Federal funds to support prevention research in mental health are limited, it has been decided to target activities to the development, implementation, evaluation, and dissemination of effective early intervention prevention program models. Preventive Intervention Research Centers (PIRCs) are proposed as a key NIMH-sponsored mechanism for developing and advancing knowledge on early preventive interventions. NIMH is accepting applications for the support of Preventive Intervention Research Centers.

The basic purpose of the Preventive Intervention Research Centers (PIRCs) program is to support the development and maintenance of a productive research environment, in a clinical, academic, or community setting, or an appropriate collaborative relationship between two or more such settings. Behavioral and clinical research scientists, clinicians, and prevention specialists can interact in such an environment and conduct high quality research on problems concerned with early interventions aimed at the prevention of mental illness, significant psychological dysfunction, and/or emotional disturbance among populations at risk.

This announcement defines early preventive intervention as (1) actions taken while it is still possible to either anticipate or reverse an early pathological/maladaptive process, and (2) such interventions occur in time prior to the need for treatment and/or rehabilitative services. The aim of preventive intervention research is to test empirically the benefits of systematic attempts to modify those factors which lead to specific mental disorders, significant psychological dysfunction and/or emotional disturbance. Such interventions are not limited to any age group(s) and may be applicable throughout the life span. Populations at risk refers to groups whose members evidence attributes which are associated with a higher probability of future disorders.

This program is described in the Catalog of Federal Domestic Assistance No. 13.242, Mental Health Research Grants. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

I. PROGRAM SPECIFICATIONS

A. PROGRAM OBJECTIVE

The objective of this program announcement is to encourage and stimulate high quality research on early preventive interventions for specific populations known to be at high risk for mental/emotional disorder. Integral to that objective, the intent of grants for Preventive Intervention Research Centers (PIRCs) is to support the growth and foster the productivity of problem-focused, multidisciplinary programs of early preventive intervention research.

The following operating framework provides a guide for characterizing appropriate early preventive intervention activities:

- 1. There is a knowledge base derived from existing research sufficient to support an early preventive intervention research effort;
- 2. Existing research data indicate that it is possible to identify groups not yet experiencing the specific significant dysfunction, but who are at high risk for developing these dysfunctions;
- 3. There is significant potential for achieving the main objective of early intervention, namely, preventing the occurrence of mental/emotional disorders or maladaptive psychological conditions.

B. CENTER CHARACTERISTICS

There is no prescribed model for these Centers. To give substance to the definition of a PIRC, however, the following characteristics must be present in each:

- Each Center will provide an environment which assures the highest quality research and leadership in its chosen area of investigation. Through its activities, the Center should be regarded as a major research center by the surrounding scientific and clinical communities and, in time, might well become a regional or national research resource.
- 2. The program of each Center must be problem-oriented and multidisciplinary. Each Center must formulate a research program around a specific, clearly defined mental health problem or set of problems of major scientific and public health importance, such as the mental health/physical health interface, stress in the workplace, the psychological/physical environmental interface, the prevention of specific childhood disorders, or stress in the family.
- The Principal Investigator will be the Director of the Center, who provides leadership for the scientific program and has final responsibility for the scientific, administrative, and operational aspects of the Center. He/she is responsible for the overall development of the Center as a valuable resource to the parent institution and to the scientific and clinical communities. The Director should be a

focuses on early preventive interventions in connection with the prevention of <u>specific</u> disorders. Problem areas within this category will frequently (but not always) meet relevant diagnostic criteria in DSM-III or ICD-9.

2. Preventing psychological dysfunction.

- a. Among populations which are at high risk as a function of severely debilitating developmental circumstances or other multiple causes.
- b. Among populations which have experienced significant acute transitional life crises and/or stressful life event(s) expected to increase the probability of pscyhopathological disorders.

When appropriate, the intervention modalities may be both preventive and promotive in that the intended outcomes aim toward both a reduction in rates of future disorders and the enhancement of specified aspects of mental health, and may have psychological, biological, or environmental components. Many types of program emphases and intervention modalities are appropriate as long as they are consistent with the types of problems cited above and the spirit of early preventive interventions cited earlier.

II. APPLICATION REQUIREMENTS

- A. The <u>research plan</u> section of the application must include (Asterisks relate to Sections A-D, Research Plan, in the Specific Instructions of the application packet.):
 - 1. A five-year research plan. This plan should include an introductory section which specifies problem focus, intervention strategies, rationale for these in terms of the framework described on page 2, and specific research approaches. For each project in the research plan, the applicant should (a) present a scholarly summary of the existing knowledge base, sufficient to justify the merit and importance of the proposed intervention, (b) specify the objectives, characteristics, staffing, magnitude, and target groups for the proposed intervention, (c) specify time frames and anticipated activities, (d) describe the design and the methodological approaches to be used in assessing and analyzing data on the effects of interventions, (e) specify the meaning and potential impact of findings, and discuss the cost-effectiveness of the intervention(s) proposed for study, and (f) attend both to the effects of relevant demographic characteristics (e.g., age, sex, social class, ethnicity, etc.) of the at-risk target groups, and to developmentally relevant methodology for the age range of the groups to be studied. Applicants should also describe the types of further programmatic steps that might be taken in later years to build upon and elucidate early findings.*
 - A plan for dissemination of program/research findings.*

knowledgeable, experienced research investigator with appropriate administrative skills who will assure the highest standards of investigation.

- 4. The Center is expected to have an administrative structure that will assure maximum effectiveness and efficiency of operation and sound financial practices. The administration will be responsible for program planning, monitoring, and execution, as well as preparation of the budget, control of expenditures, staff appointments, etc. A Center should have sufficient authority to establish the necessary administrative and management procedures for carrying out its total responsibility.
- 5. Each Center should have sufficient collaboration with community agencies (for example, a community mental health center) and with relevant departments and professional schools to carry out preventive intervention research.
- 6. The primary purpose of each Center is to carry out early preventive intervention research. An important byproduct of the research effort is the development of research competencies in promising scientists in the complex techniques and advanced theories of mental health preventive intervention research. Accordingly, each Center will provide research experiences for at least two preceptees annually, to be selected from the mental health and related disciplines. Precepteeships are defined as supervised work experience. Each Center should relate functionally with relevant departments of professional and graduate schools, as may be appropriate to the needs of the preceptees.
- 7. Each Center's overall program plan must include appropriate dissemination activities as research findings emerge, for example: (a) preparing manuscripts for publication in appropriate scientific and professional outlets, (b) preparing detailed program manuals and program evaluation guides, (c) providing consultation to agencies and groups seeking to develop early preventive intervention programs, and (d) participating and taking leadership conjointly with other PIRCs in workshop, conferences, and meetings designed to share established early preventive intervention technology and knowledge with other researchers and interested agencies and groups.

Each proposed activity within the total research program must conform both to the problem focus and to the operating framework stated above as a guide for early preventive interventions. Early preventive interventions may be directed to high-risk populations of any age, sociodemographic, or ethnic group, and may use a variety of intervention strategies.

C. PROBLEM AREAS

Problem areas for early preventive intervention research may include relatively low incidence but severe disorders or high incidence but relatively less debilitating disorders, or dysfunctions. Illustrative problem areas include:

1. Preventing specific psychopathologies or disorders. This approach

- 3. A description of the administrative organization and of the Center, including its relationship to the applicant institution, and arrangements for planning, coordinating, and evaluating the Center programs.*
- 4. A plan for selection, activities, and supervision of research preceptees, including delineation of relationships with appropriate departments of professional and graduate schools to serve as resources for the development of research scientists in early intervention research.*
- 5. In Section H of the PHS 398 application, there should be a description of the interest, support, cooperation, and nature of existing and proposed collaboration of community agencies or other entities or settings within which proposed intervention programs are to be conducted. Documentation of such arrangements should be included in appendices.

B. The biographical sketches must include:

- 1. Evidence that the Principal Investigator has an established record of productive involvements in preventive intervention research and program development. Also, that he/she will devote a substantial portion of time (e.g., thirty percent or more) to administrative, program development, research supervisory, and writing activities essential to a PIRC's effective program development.
- 2. A demonstrated history for other participating researchers of early preventive intervention research, as evidenced, for example, by ongoing project grant support and publications.
- C. The <u>budget section</u> must include, in the justification, estimated percentages of first-year and total costs by budget category for (a) core program costs, and (b) associated costs with each specific research project.

III. PRE-APPLICATION CONSULTATION

For NIMH staff to provide early and targeted pre-application consultation, potential applicants are encouraged to submit a letter of intent, no longer than 12 pages, to the PIRC program at least four weeks prior to initial submission of an intended PIRC grant application. The letter should summarize the present state of planning and development for establishing the proposed Center by providing the following information:

- 1. The Center's objectives.
- 2. A brief description of the problem focus, and the operational and research plans and methods to be used to reach the objectives of the program.

Preventive Intervention Research Centers Program
National Institute of Mental Health
Parklawn Building - Room 18-105
5600 Fishers Lane
Rockville, Maryland 20857

- 3. A chart showing the institutional organization of the Center and its relationship to the applicant institution and, where relevant, to other community facilities.
- 4. An estimated first-year budget for the Center. (Use page 3 of a regular research grant application for a guide.) List the staff--names and to-be-named--who will participate in the Center, including titles, research roles, disciplines of investigators, their vitae, and percentage of time. Include an estimate of the level of support staffing.
- 5. Current and pending research, and research training grant support from all sources which will be available to the Center program.
- 6. Information about resources and facilities currently available to the Center.

Appropriate NIMH staff will be assigned to study each letter of intent, to review the preliminary plan, and to consult with prospective applicants to provide information regarding program relevance and purpose in order to help applicants comply with administrative requirements, meet program standards, and provide sufficient information to permit an adequate scientific merit review.

IV. PROCEDURES FOR REVIEW OF APPLICATIONS

Applications submitted in response to this Announcement will be reviewed on a nationwide basis in accord with the usual Public Health Service peer review procedures for research grants. They will be reviewed for scientific and technical merit by a review group composed primarily of non-Federal scientific experts (Initial Review Group) and by the National Advisory Mental Health Council. By law, only applications recommended for approval by Council will be considered for funding.

V. CRITERIA FOR REVIEW BY INITIAL REVIEW GROUP

- A. Factors to be considered in evaluating applications include, but are not limited to:
 - Adequacy of the conceptual and theoretical framework for the overall research program and specific components, including adequacy of research base to indicate the existence of, ability to identify, and potential for successful intervention with groups at risk for specific mental disorders or other significant psychological dysfunction, and/or emotional disturbance.
 - 2. Scientific merit of the research design, approaches, and methodology, including:
 - a. Quality of a PIRC's specific plans for early preventive interventions, using a variety of intervention strategies consistent with a specific problem focus.
 - b. Adequacy of the research methods and data analysis plans.

- c. Qualifications and experience of the investigative team.
- d. Adequacy of the existing and proposed facilities, resources, and administrative structure for achieving the proposed objectives.
- e. Feasibility of the research activities in terms of documentation of needed cooperation from service providers/agencies.
- 3. Potential for Center demonstrating a leadership role in early preventive intervention research.
- 4. Potential replicability of the proposed interventions.
- 5. Adequacy of protection of human subjects.
- 6. Availability of, or prospects for, individual investigators to secure and/or have project grant support.
- 7. Appropriateness of the budget, staffing plan, and time frame to complete the research.
- 8. Capacity of the applicant to provide research precepteeships.
- 9. Anticipated cost-effectiveness of the interventions.
- 10. Adequacy and appropriateness of the plan for dissemination of research findings.

VI. AWARD DECISION CRITERIA

- The following criteria will be used in the decision to make an award for an application which has been recommended for approval, provided the applicant has complied with all legislative, regulatory, and policy requirements of the Public Health Service:
 - 1. Quality of the research program as determined during the review process.
 - 2. Programmatic relevance of the proposed research program, including consideration of types of populations being addressed, interventions, and strategies.
 - 3. Highest priority will be given to funding research programs on early interventions addressed to individuals in "at-risk" populations who have not evidenced the psychopathology which is the target of the preventive interventions.
 - 4. Potential for direct applicability of the research.
 - 5. Availability of funds.

VII. PROGRAM INFORMATION

Potential applicants may receive consultation concerning submission of applications in response to this Special Announcement by contacting:

Juan Ramos, Ph.D.
Director, Division of Special
Mental Health Programs
National Institute of Mental Health
Parklawn Building - Room 18-105
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: 301-443-3533

In view of the special significance of this program, an NIMH staff member will have the responsibility for monitoring each supported Center and for continuing liaison with the Center Director.

VIII. APPLICATION INFORMATION

A. ELIGIBILITY REQUIREMENTS

These grants are available to any public or private, profit or non-profit institution such as a university, college, hospital, or community agency, including community mental health centers, and units of State or local governments and authorized units of the Federal Government.

B. FUNDING AND TERMS OF SUPPORT

Funds estimated at about \$800,000 will be available in FY 83 to support applications submitted in response to this Announcement. It is anticipated that up to four awards will be made for PIRCs in FY 83. Applications may request a maximum period of five (5) years of support.

Grants are awarded directly to the applicant institution. Grant funds may be used only for those expenses which are directly related to and necessary to carry out research projects and must be expended in conformance with the Public Health Service Grants Policy Statement, applicable Federal regulations, and conditions set forth in this Announcement and on the grant award document. In general, grant funds may be used for: (1) direct costs which are necessary to carry out the project, including salaries, consultant fees, supplies and equipment, and essential travel; and (2) actual indirect costs to cover related overhead.

Funds may be requested for staff training and/or services only to the extent necessary to carry out the research and not available from other sources, and must be specifically justified.

Vol. 11, No. 7, June 18, 1982

C. APPLICATION PROCEDURES

Applicants should use Form PHS 398 (Rev. 5/80). State and local government agencies should use Form PHS 5161. Application kits may be obtained from the grants office of a university or are available from the following:

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

Telephone: 301 - 443-4414

Instructions for applicants are included in the kit. The phrase "PREVENTIVE INTERVENTION RESEARCH CENTER" should be entered in item #2 of the face page of the Application Form PHS 398 or item #7 of the face page of Form PHS 5161.

The signed original and six copies of the application should be sent directly to the following address:

Division of Research Grants National Institutes of Health Bethesda, Maryland 20205

D. RECEIPT, REVIEW, AND AWARD SCHEDULE

Applications Received by:	Review Committee	Council	Earliest Possible Funding
November 1 *	February/March	Мау	July 1
March l	June	September	December 1
July 1	October/November	January/February	April 1

^{*} Applications submitted for the November 1, 1982 deadline will be considered for funding in FY 1983