NIH GUIDE for GRANTS and CONTRACTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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HAVE YOU MOVED?

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.

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.

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NOTICE TO NRSA TRAINING PROGRAM DIRECTORS

The Omnibus Reconciliation Act (P.L. 97-35) modified the provision for National Health Service Corps (NHSC) Scholarship recipients explicitly to indicate that they could receive payback credit through either the institutional or individual component of the National Research Service Award (NRSA) program. Prior to the signing of the act on August 13, 1981, only NHSC recipients who received individual NRSA awards were permitted to receive credit towards the NHSC service obligation for any payback obligation performed as a requirement of the NRSA program. This option is being extended to NHSC recipients who wish to participate as trainees under the NRSA Institutional Grant Program.

You may be contacted by one or more of these individuals seeking an appointment as a postdoctoral trainee on your training program. Qualified candidates from the NHSC should be considered along with other applicants when appointments are made. Selection of NHSC applicants would help further the intent of Congress as expressed in the NRSA legislation that special consideration be given to physicians who will spend two years in research.

NOTICE

ERRATA

An Announcement in the March 26, 1982 Guide for Grants and Contracts (Vol. 11, No. 4) entitled "Special Emphasis Research Career Award: Diabetes Mellitus-Obstetrical, Perinatal, and Pediatric Aspects, National Institute of Child Health and Human Development" has a line missing from the text at the top of page 7. The correct wording should be as follows:

> "oriented around the initiation of a specific research program of the applicant's own"

NOTICE

CHANGES IN EXPENDITURES REPORTING FORMS FOR NIH AND ADAMHA GRANTEES

In April 1979, a notice in the "NIH Guide for Grants and Contracts (Vol. 8, No. 5)" apprised grantees of the schedule to be followed by NIH and ADAMHA for conversion from categorical expenditures reporting to non-categorical reporting. This change was the result of DHHS' implementation of OMB Circular A-110. Specifically, the announcement said that a non-categorical Financial Status Report "will be used to report on all budget periods whose start dates were October 1, 1978, and thereafter." However, as an interim measure, the NIH was later authorized to continue using form HEW-489, which was familiar to NIH staff and its grantees, but with revised instructions indicating that the reporting of detailed categorical expenditures was no longer mandatory. ADAMHA also followed this interim approach.

Recently the Office of Management and Budget advised the NIH to adopt form SF-269, "Financial Status Report" (see reduced format attached) for use by all grantees in reporting the status of funds for all nonconstruction grants. This action is in keeping with the intent of OMB Circulars A-102 and A-110 to standardize certain Federal reporting requirements. Therefore, it is now necessary for NIH and ADAMHA grantees to start using the SF-269 Federal-wide reporting form as promptly as possible. Since it will take a little time before the forms are stocked in bulk and the offices responsible for distribution can begin sending out copies routinely, those grantees who must submit reports may continue to use the HEW-489 forms which they have on hand during the transition period.

FINANCIAL STATUS REPORT

(Follow instructions on the back)

1. FEDERAL AGENCY AND ORGANIZATIONAL ELEMENT TO WHICH REPORT IS SUBMITTED	2. FEDERAL GRANT OR OTHER IDENTIFYING NUMBER	OMB Approved No. 80-R0180	PAGE	OF PAGES
3. RECIPIENT ORGANIZATION (*Name and complete address, including ZIP code*)	4. EMPLOYER IDENTIFICATION NUMBER	5. RECIPIENT ACCOUNT NUMBER OR IDENTIFYING NUMBER	6. FINAL REPORT ☐ YES ☐ NO	7. BASIS ☐ CASH ☐ ACCRUAL
	8. PROJECT/GRANT PERIOD (*See instructions*) FROM (*Month, day, year*)	TO (*Month, day, year*)	9. PERIOD COVERED BY THIS REPORT FROM (*Month, day, year*)	TO (*Month, day, year*)

10. PROGRAMS/FUNCTIONS/ACTIVITIES ►	(a)	(b)	(c)	(d)	(e)	(f)	TOTAL (g)
	STATUS OF FUNDS						
a. Net outlays previously reported	$	$	$	$	$	$	$
b. Total outlays this report period							
c. *Less:* Program income credits							
d. Net outlays this report period (*Line b minus line c*)							
e. Net outlays to date (*Line a plus line d*)							
f. *Less:* Non-Federal share of outlays							
g. Total Federal share of outlays (*Line e minus line f*)							
h. Total unliquidated obligations							
i. *Less:* Non-Federal share of unliquidated obligations shown on line h							
j. Federal share of unliquidated obligations							
k. Total Federal share of outlays and unliquidated obligations							
l. Total cumulative amount of Federal funds authorized							
m. Unobligated balance of Federal funds							

11. INDIRECT EXPENSE	a. TYPE OF RATE (*Place "X" in appropriate box*) ☐ PROVISIONAL ☐ PREDETERMINED ☐ FINAL ☐ FIXED			
	b. RATE	c. BASE	d. TOTAL AMOUNT	e. FEDERAL SHARE

12. REMARKS: *Attach any explanations deemed necessary or information required by Federal sponsoring agency in compliance with governing legislation.*

13. CERTIFICATION

I certify to the best of my knowledge and belief that this report is correct and complete and that all outlays and unliquidated obligations are for the purposes set forth in the award documents.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	DATE REPORT SUBMITTED
TYPED OR PRINTED NAME AND TITLE	TELEPHONE (*Area code, number and extension*)

269-102

STANDARD FORM 269 (7-76)
Prescribed by Office of Management and Budget
Cir. No. A-110

2A

INSTRUCTIONS

Please type or print legibly. Items 1, 2, 3, 6, 7, 9, 10d, 10e, 10g, 10i, 10l, 11a, and 12 are self-explanatory, specific instructions for other items are as follows:

Item	*Entry*
4	Enter the employer identification number assigned by the U.S. Internal Revenue Service or FICE (institution) code, if required by the Federal sponsoring agency.
5	This space is reserved for an account number or other identifying numbers that may be assigned by the recipient.
8	Enter the month, day, and year of the beginning and ending of this project period. For formula grants that are not awarded on a project basis, show the grant period.
10	The purpose of vertical columns (a) through (f) is to provide financial data for each program, function, and activity in the budget as approved by the Federal sponsoring agency. If additional columns are needed, use as many additional forms as needed and indicate page number in space provided in upper right; however, the totals of all programs, functions or activities should be shown in column (g) of the first page. For agreements pertaining to several Catalog of Federal Domestic Assistance programs that do not require a further functional or activity classification breakdown, enter under columns (a) through (f) the title of the program. For grants or other assistance agreements containing multiple programs where one or more programs require a further breakdown by function or activity, use a separate form for each program showing the applicable functions or activities in the separate columns. For grants or other assistance agreements containing several functions or activities which are funded from several programs, prepare a separate form for each activity or function when requested by the Federal sponsoring agency.
10a	Enter the net outlay. This amount should be the same as the amount reported in Line 10e of the last report. If there has been an adjustment to the amount shown previously, please attach explanation. Show zero if this is the initial report.
10b	Enter the total gross program outlays (less rebates, refunds, and other discounts) for this report period, including disbursements of cash realized as program income. For reports that are prepared on a cash basis, outlays are the sum of actual cash disbursements for goods and services, the amount of indirect expense charged, the value of in-kind contributions applied, and the amount of cash advances and payments made to contractors and subgrantees. For reports prepared on an accrued expenditure basis, outlays are the sum of actual cash disbursements, the amount of indirect expense incurred, the value of in-kind contributions applied, and the net increase (or decrease) in the amounts owed by the recipient for goods and other property received and for services performed by employees, contractors, subgrantees, and other payees.
10c	Enter the amount of all program income realized in this period that is required by the terms and conditions of the Federal award to be deducted from total project costs. For reports prepared on a cash basis, enter the amount of cash income received during the reporting period. For reports prepared on an accrual basis, enter the amount of income earned since the beginning of the reporting period. When the terms or conditions allow program income to be added to the total award, explain in remarks, the source, amount and disposition of the income.
10f	Enter amount pertaining to the non-Federal share of program outlays included in the amount on line e.
10h	Enter total amount of unliquidated obligations for this project or program, including unliquidated obligations to subgrantees and contractors. Unliquidated obligations are: Cash basis—obligations incurred but not paid; Accrued expenditure basis—obligations incurred but for which an outlay has not been recorded. Do not include any amounts that have been included on lines a through g. On the final report, line h should have a zero balance.
10i	Enter the Federal share of unliquidated obligations shown on line h. The amount shown on this line should be the difference between the amounts on lines h and i.
10k	Enter the sum of the amounts shown on lines g and j. If the report is final the report should not contain any unliquidated obligations.
10m	Enter the unobligated balance of Federal funds. This amount should be the difference between lines k and l.
11b	Enter rate in effect during the reporting period.
11c	Enter amount of the base to which the rate was applied.
11d	Enter total amount of indirect cost charged during the report period.
11e	Enter amount of the Federal share charged during the report period. If more than one rate was applied during the project period, include a separate schedule showing bases against which the indirect cost rates were applied, the respective indirect rates the month, day, and year the indirect rates were in effect, amounts of indirect expense charged to the project, and the Federal share of indirect expense charged to the project to date.

ELIGIBILITY OF FOR-PROFIT ORGANIZATIONS TO APPLY FOR NIH GRANTS AND COOPERATIVE AGREEMENTS

NOTICE

Effective January 4, 1982, for-profit organizations became eligible to apply for assistance awards (research grants and cooperative agreements) under most sections of the Public Health Service Act.

The application, scientific merit review, and award processes are the same as those applicable to nonprofit organizations. All information contained in applications will be kept confidential and will be made available only to NIH staff and to the reviewers who provide an evaluation of the proposed project. Applications for research projects are to be submitted on application form PHS-398 which may be obtained from:

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

Annual application receipt dates are on or before: July 1, November 1, and March 1. Applications are sent to the Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205.

For-profit organizations will be subject to the same administrative requirements applicable to nonprofit organizations with a few exceptions:

1. Cost principles for Contracts with Commercial Organizations set forth in 41 CFR Subpart 1-15.2 will be used.

2. Title to equipment and supplies acquired under the financial assistance award shall vest upon acquisition in the Federal government. Subsequent disposition will be determined by the PHS awarding office.

3. Cost sharing requirements will be met through separate agreements negotiated for each project.

4. Development, reporting, and disposition of patents and inventions, will be governed by the terms of the Patent and Trademark Law Amendments (P.L. 96-517), which was effective July 1, 1981.

5. Program income, as defined in 45 CFR 74.42, earned during the period of PHS grant support, no matter what the purpose, may not be used for costs which are in addition to the allowable costs of the project.

Research scientists from for-profit organizations are encouraged to request a copy of NIH Extramural Programs, a compendium of the scientific programs of the NIH's Bureaus, Institutes, and Divisions. Address such requests to the Office of Grants Inquiries, Division of Research Grants, (address above).

NOTICE

REQUEST FOR NOMINATIONS OF INDIVIDUALS FROM FOR-PROFIT ORGANIZATIONS TO SERVE AS MEMBERS OF NIH SCIENTIFIC REVIEW GROUPS

The National Institutes of Health (NIH) invites nominations of individuals representing for-profit organizations for membership on its scientific peer review groups. These groups provide the technical and scientific merit review of grant and cooperative agreement applications and contract proposals. Scientists serving on these groups advise the NIH on the selection of the most meritorious projects to implement biomedical research programs of the highest quality. Although a number of scientists from commercial organizations now serve on these advisory bodies, because of the recently declared eligibility of for-profit organizations to apply for research grants, NIH has a special interest in adding greater representation from this scientific sector than now exists.

All nominations will be carefully considered; NIH reserves the right to make final selections.

Responsibilities

Each review group is composed of primarily non-Federal scientists selected for their competence in the particular scientific area for which that group has review responsibilities. Review groups usually meet three times yearly; each meeting generally requires several days of intensive review of research proposals. Specific applications are assigned in advance of the meeting to each member who prepares written detailed critiques prior to the meeting and leads discussion at the meeting. Members generally serve terms not to exceed four years.

Criteria for Membership

The primary requirement for serving on a scientific review group is competence as an independent investigator in a basic scientific or clinical discipline or research specialty. Assessment of such competence is based on the quality of research accomplished, publications in refereed scientific journals, and other significant scientific activities, achievements, and honors. Usually a doctoral degree or its equivalent is required. Service also requires mature judgment, balanced perspective, objectivity, ability to work effectively in a group context, commitment to complete work assignments, and assurance that the confidentiality of applications will be protected.

How to Respond to Request

Any person may nominate one or more highly qualified candidates for consideration. Self-nominations are acceptable. Nominations should be made promptly for immediate consideration, and at any time thereafter for future attention. Each nomination should be clearly identified as representing the for-profit sector.

For each nomination:

1. Provide full name of nominee, title, complete mailing address (including organizational affiliation), and telephone number.

2. In not more than two or three lines, provide in key words information concerning the nominee's scientific areas of experience, interest, and expertise.

3. Name, address, telephone number, and signature of nominator.

The nominator may be contacted for more detailed information. Nominees should be informed prior to being nominated. They will be sent a packet requesting relevant information upon receipt of nomination.

Send information to:

NIH Consultant File Project
Suite 212
6400 Goldsboro Road
Bethesda, Maryland 20817

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA NIH-NIAID 82-7

ASTHMA AND ALLERGIC DISEASE CENTERS

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: October 15, 1982

I. BACKGROUND

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for grants to be initiated during FY 1983 for participation in the ongoing Asthma and Allergic Disease Centers (AADC) program.

The Allergy and Clinical Immunology Branch of the Immunology, Allergic, and Immunologic Diseases program of NIAID sponsors fundamental and clinical research grants and contracts and the procurement and application of research resource and reference reagents concerned with asthma, allergic and immunologic diseases and with relevant mechanisms of hypersensitivity and inflammation. This request for applications is intended to encourage the development of proposals from clinical investigative groups meeting the criteria and requirements for an AADC and to coordinate the submission of new and renewal applications providing equitable opportunity for both to compete for funds currently available for this programmatic activity.

Since its inception in 1971, the AADC program has progressively expanded with the gradual addition of new Centers on an open application basis. In accordance with established policy announced in the NIH Guide for Grants and Contracts, Vol. 7, No. 8, p.1, June 9, 1978, proposals for AADCs are received only periodically and at designated times. Applications for both renewal of existing AADCs and creation of new Center programs will be expected to compete for funds available through the periodically announced awards.

The AADC program currently consists of 17 centers. During FY 1983, five Centers are scheduled to terminate and may compete for renewal.

NIAID's fundamental objective in continuing the AADC program remains unchanged: acceleration of the application of emerging knowledge on the immune system and from relevant biomedical sciences to clinical investigations concerned with asthma, allergic diseases, and hypersensitivity disorders. Especially sought as the requisite factors within a participating institution are quality research in (a) basic sciences(s), (b) clinical investigation supported by adequate clinical facilities, staff expertise in diagnosis and management of asthmatic and allergic patients, and

This program is described in the Catalog of Federal Domestic Assistance No. 13.855, Immunology, Allergic and Immunologic Diseases Research. 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 74). This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

(c) access to (an) appropriate patient population(s) within a suitable academic/investigative setting designed to favor multidisciplinary interaction.

II. RESEARCH GOALS AND SCOPE

A. There should be indication by the sponsoring university or medical institution of willingness and preparedness to commit resources to ensure development, operation, support, and function of the proposed Center in devoting its efforts to an identified study on asthma and/or allergic disease as a fundamental prerequisite.

B. The applicant's achievements in basic science research should have reached that stage of development where experimental leads are sufficiently encouraging to warrant transition from promising laboratory findings to corresponding investigations at the clinical level with the ultimate goal of developing new and improved methods for diagnosis, prevention, and treatment of asthma and/or the other allergic diseases.

C. A prospective Center should be in a position to present evidence of experience orientation, laboratory and clinical facilities, scientific and professional staff, support personnel and the expertise to design proposals, execute protocols representing a multifaceted long-term approach, and bring diverse institutional strengths to bear upon the study of major problems in asthma, other allergic diseases and/or pathophysiologic mechanisms underlying these disorders.

D. Suitable subjects for study within the provision of this program may include those relevant to:

1. Asthma and its multifactoral aspects;

2. Atopic diseases (e.g., allergic rhinitis, urticaria, atopic dermatitis);

3. Identification, isolation, and characterization of etiologic agents of allergy (e.g., drugs, chemicals, foods, airborne allergens);

4. Pathologic expressions, pathophysiologic mechanisms, and genetic factors of allergic disease and allergic inflammation;

5. Immune mechanisms and agents of immediate hypersensitivity and of related hypersensitivity manifestations of antigen-antibody reactions of cell mediated immunity (e.g., hypersensitivity pneumonitis, allergic dermatitis, vasculitis, allergic gastroenteritis, drug reactions) and the development of corresponding improved diagnostic materials and methods;

6. Immunopharmacology, immunotherapy, and the development of specific pharmacologic agents designed for prevention and treatment of asthma and the other allergic diseases.

E. Study of animal models will be considered acceptable as a partial segment or adjunct to a Center's program only if this line of research is applicable to the character of the primary investigation of asthma or the human allergic disease central to the proposal.

F. Designation of a Center Director should be based upon accomplishment and experience as a senior scientist and ability to assume both leadership of the investigative group and responsibility for scientific, professional, and administrative functions.

G. More than one delineated avenue of research may be pursued within a Center with provision for unified operation and coordination of component projects and collaborative investigators.

H. A Center should not rely upon its ability to conduct research activity solely within the confines of a single discipline, but rather should have established the associations to involve participation by workers in the pertinent biomedical fields and medical specialties allied to asthma, allergy, and clinical immunology (e.g., dermatology, rheumatology, infectious diseases, pulmonary medicine, hematology, otorhinolaryngology, when a high degree of relevance to immunology exists).

I. The Center Director will be expected to communicate freely with the NIAID and other designated Centers for effective exchange of new information, to interact with scientists working in other Centers on related investigative problems, and to present progress reports and share experimental data with other Centers through exchanges and attendance at NIAID sponsored meetings of study groups and AADC workshops.

III. MECHANISM OF SUPPORT

In Fiscal Year 1983, the NIAID plans to fund at least five new or competing renewal Asthma and Allergic Disease Center applications. Each grant will have a duration of not more than five years. Funding beyond the first year of the grant will be contingent upon satisfactory progress during the preceding year and availability of funds.

The receipt date for applications will be October 15, 1982. They will undergo initial review in February-March 1983, and subsequent review by the National Advisory Allergy and Infectious Diseases Council in May 1983. September 1, 1983 will be the earliest starting date for successful applicants.

Grant funds may be utilized to support the research activities of scientific and professional personnel, administration, consultation services, central support services, equipment, supplies, travel, and publication costs. Support for research-related costs of patient involvement and medical care may be authorized. Since the program cannot provide funds for new construction, adequate physical facilities must be available for the primary needs of the Center. However, moderate alterations or renovations to enhance clinical facilities may be allowed if they are necessary to meet objectives of the Center's program.

Only those institutions that can demonstrate expertise in both basic and clinical areas and can direct their resources toward a multifaceted attack on asthma or the other allergic diseases can be supported under the provisions of the AADC program.

IV. REVIEW PROCEDURES AND CRITERIA

A. For preliminary screening by NIAID staff, a "letter of intent" should first be prepared by the prospective Center Director. Letters of intent should cover the following points:

1. A brief description of the intended project.

2. A description of available laboratory facilities.

3. A brief description of ongoing basic immunologic and clinical research relating to asthma, allergy, or hypersensitivity with special reference to any studies of the immediate type.

4. A brief description of, or reference to, published research work by the investigators on asthma, allergy, or hypersensitivity especially pointing out those that may relate to the immediate type and identification of existing projects and sources of support.

5. A description of all clinic facilities available for use by the proposed Center.

6. Specific information on the institution's present patient load and projections for patient involvement in clinical investigation.

7. The academic positions and major research interests of the Center Director and his professional staff who will be involved in the work of the Asthma and Allergic Disease Center.

8. Collaborative possibilities with other area laboratories and investigators and delineation of the roles and manner of anticipated participation and interaction of the principal investigators, consultants, and collaborators.

B. Letters of intent are due no later than July 15, 1982, and upon receipt will be screened by NIAID staff to determine the eligibility and suitability of the projected proposals for the AADC program. Inquiries and letters should be sent to:

Dr. Robert A. Goldstein
Chief, Allergy and Clinical Immunology Branch
Immunology, Allergic and Immunologic
Diseases Program
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building Room 755
Bethesda, Maryland 20205

Telephone: (301) 496-7104

V. CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR LATE SUBMISSION

Based upon the letter of intent, potential applicants will be promptly advised whether or not their proposal is found to be within the research goals and scope of the program as defined in this RFA. Applicants will then have an opportunity to correct deficiencies or weaknesses and to restructure their submissions accordingly. Formal applications that are not responsive to the RFA or are not received by October 15, 1982, will not be accepted for review and will be returned to the applicant.

VI. METHOD OF APPLYING

Before preparing an application, the prospective applicant should request a copy of the NIAID Information Brochure on Program Projects from:

Dr. Nirmal Das
Executive Secretary
Allergy, Immunology and Transplantation
Research Committee
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building Room 706
Bethesda, Maryland 20205

Telephone: (301) 496-7966

Use the standard research grant application form PHS 398 (Rev. 5/80). In addition to following accompanying format instructions for the development of a Center application, include expanded material listed above under the eight points for the "letter of intent." For purposes of identification and processing, the words "ASTHMA AND ALLERGIC DISEASE CENTER" should be typed in item 2 on the face page of the application and a brief covering letter should be attached indicating submission is in response to this NIAID announcement.

Application kits may be obtained from the institution's application control office. If not available there, they may be obtained from:

Office of Grant Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building Room 448
Bethesda, Maryland 20205

Forward the complete application to:

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

Please forward a copy (not the original) of the cover letter and the application face page to Dr. Robert A. Goldstein in order to alert NIAID to the submission of the proposal, and to:

Chief, Program and Project Review Branch
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building Room 703
Bethesda, Maryland 20205

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA NIH-NIAID 82-8

CENTERS FOR INTERDISCIPLINARY RESEARCH ON IMMUNOLOGIC DISEASES

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: October 1, 1982

BACKGROUND

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for grants to be initiated during Fiscal Year 1983 for participation in the ongoing Program of Centers for Interdisciplinary Research on Immunologic Diseases (CIRID).

The Allergy and Clinical Immunology Branch of the Immunology, Allergic, and Immunologic Diseases program of NIAID sponsors fundamental and clinical research grants and contracts and the procurement and application of research resource and reference reagents concerned with asthma, allergic and immunologic diseases and with relevant mechanisms of hypersensitivity and inflammation. This request for applications is intended to encourage the development of proposals from clinical investigative groups meeting the criteria and requirements for a CIRID and to coordinate the submission of new and renewable applications providing equitable opportunity for both to compete for funds currently available for this programmatic activity. Current recipients of Asthma and Allergic Disease Center (AADC) or Program Projects in Mechanisms of Immunologic Diseases Awards are encouraged to apply for a CIRID grant. In the event that such an application is successful, it is NIAID's intention to support only one instrument.

Since its inception in 1978, the CIRID program, which currently consists of four Centers, has progressively matured. Applications for both renewal of existing CIRIDs and creation of new Center programs will be expected to compete for funds available through the periodically announced awards. During FY 1983, four Centers are scheduled to terminate and may compete for renewal.

NIAID's fundamental objective in continuing the CIRID program remains unchanged: acceleration of the application of emerging knowledge on the immune system and from relevant biomedical sciences to clinical investigations concerned with asthma, allergic diseases, hypersensitivity disorders, and immunologically mediated disorders. Especially sought as the requisite factors within a participating institution are quality research in (a) basic science(s), (b) clinical investigation supported by adequate clinical facilities, staff expertise in diagnosis and management of patients with asthma, allergies and other immunologic diseases, and (c) access to (an) appropriate patient population(s) within a suitable academic/investigative setting designed to favor multidisciplinary interaction.

This program is described in the Catalog of Federal Domestic Assistance No. 13.855, Immunology, Allergic and Immunologic Diseases Research. 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 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

RESEARCH GOALS AND SCOPE

1. There should be indication by the sponsoring university or medical institution of willingness and preparedness to commit resources to ensure development, operation, support, and function of the proposed Center.

2. The applicant institution's achievements in basic science research should have reached that stage of development where experimental leads are sufficiently encouraging to warrant transition from promising laboratory findings to corresponding investigations at the clinical level with the ultimate goal of developing new and improved methods for diagnosis, prevention, and treatment of allergic and immunologic disorders.

3. Centers should be based at universities or at university-affiliated medical facilities. Eligible institutions which already have NIAID supported AADC's or Program Projects are eligible to apply for conversion of ongoing programs to a CIRID.

4. Programs should be signed to favor integration and coordination of intra-institutional research projects concerned with immunologic disease and those in basic biomedical sciences, e.g., immunobiology, immunochemistry, microbiology, virology, genetics, biochemistry, pharmacology, general physiology, and pathology. Programs should also draw upon clinical specialities, e.g., allergy, dermatology, pulmonary medicine, hematology, nephrology, rheumatology, infectious diseases, and otorhinolaryngology.

5. Grants in support of the interdisciplinary research program can be given for periods of up to five years; evaluation of the Centers to ascertain productivity and accomplishments may be undertaken after completion of the third year to aid the NIAID in determining possible future directions for the program.

6. Study of a spectrum of allergic diseases, including asthma, should be recognized as one necessary component of a Center's program in immunologic diseases. Applicant institutions that do not now have ongoing programs in asthma and allergic disease will be expected to describe definitive plans for developing capabilities in these areas during the period of the grant. Applications from institutions whose programs are primarily oriented to asthma and allergic diseases should similarly describe institutional plans for interdisciplinary expansion to include pertinent basic science components and investigations in other immunologic disease areas.

7. Suitable subjects for study within the provision of this program may include those relevant to:

   a. Immunologic disorders;

   b. Asthma and its multifactoral aspect and atopic diseases (e.g., allergic rhinitis, urticaria);

   c. Identification, isolation, and characterization of etiologic agents of allergy (e.g., drugs, chemicals, foods, airborne allergens);

   d. Pathologic expressions, pathophysiologic mechanisms, and genetic factors of allergic disease and allergic inflammation.

8. In addition to developing broad interdisciplinary research programs in immunology, the Centers will be expected to carry out other educational or community activities. Within the research framework the applicant should include as many of the following special projects as the applicant can develop and support:

   a. Recruitment and training of clinical investigators in allergy and clinical immunology.

   b. Development of demonstration programs designed to yield new information on the feasibility of diagnostic methods and treatment.

   c. Assessment of the regional socioeconomic impact of immunologic and allergic diseases through interaction with practicing physicians and epidemiologists in the area.

   d. Evaluation of new treatment modalities and development of methods studying efficacy.

   e. Clinical translation and application of promising investigative findings.

   f. Involvement in the continuing medical education of practicing physicians, and in lay community outreach in the region served.

9. Designation of a Center Director should be based upon accomplishment and expeience as a senior scientist and ability to assume both leadership of the investigative group and responsibility for scientific, professional, and administrative functions.

10. More than one delineated avenue of research may be pursued within a Center with provisions for unified operation and coordination of component projects and collaborative investigators.

11. A Center should not rely upon its ability to conduct research activity solely within the confines of a single discipline, but rather should have established the associations to involve participation by workers in the pertinent biomedical fields and medical specialties allied to asthma, allergy, and clinical immunology (e./g., immunobiology, biochemistry, microbiology, biostatistics, bioinstrumentation and computer science, and the clinical subspecialities, e.g., dermatology, rheumatology, infectious diseases, pulmonary medicine, hematology, otorhinolaryngology, when a high degree of relevance to immunology exists).

12. The Center Director will be expected to communicate freely with the NIAID and other designated Centers for effective exchange of new information, to interact with scientist working in other Centers on related investigative problems, and to present progress reports and share experimental data with other Centers through exchanges and attendance at NIAID sponsored meetings of study groups and AADC-CIRID workshops.

13. Because NIAID intends this program to be as broadly based as possible, attention will be given to geographical dispersion.

MECHANISMS OF SUPPORT

In Fiscal Year 1983, the NIAID plans to fund at least four new or competing renewal CIRID applications. Each Center grant will have a duration of not more than five years. Funding beyond the first year of the grant will be contingent upon satisfactory progress during the preceding year and availability of funds.

The receipt date for applications will be October 15, 1982. They will undergo initial review in February-March 1983, and subsequent review by the National Advisory Allergy and Infectious Diseases Council in May 1983. September 1, 1983 will be the earliest starting date for successful applicants.

Grant funds may be utilized to support the research activities of scientific and professional personnel, administration, consultation services, central support services, equipment, supplies, travel, and publiction costs. Support for research-related costs of patient involvement and medical care may be authorized. Since the program cannot provide funds for new construction, adequate physical facilities must be available for the primary needs of the Center. However, moderate modifications or renovations to enhance clinical facilities may be allowed if they are necessary to meet objectives of the Center's program. Only those institutions that can demonstrate expertise in both basic and clinical areas and can direct their resources toward a multifaceted attack on human immunologic diseases can be supported under the provisions of the CIRID program.

REVIEW PROCEDURES AND CRITERIA

For preliminary screening by NIAID staff, a "letter of intent" should first be prepared by the prospective Center Director.

Letters of intent should cover the following points:

1. A brief description of the intended project.

2. A brief description of available laboratory facilities.

3. A brief description of ongoing basic research and clinical investigations, including reference to published work authored by staff that are relevant to asthma, allergy and immunologic diseases.

4. A brief description of, or reference to, published research work by the investigators on asthma, allergy, or hypersensitivities and identification of existing project and sources of support.

5. A description of all clinical facilities available and plans for their utilization.

6. Specific information on the institution's present patient load and projections for patient involvement in clinical investigations.

7. The academic positions and major research interest of the Center Director and staff who will be involved in the work of the Center.

8. Plans for collaboration with other laboratories and investigators and delineation of the roles and manner of anticipated participation of the principal investigators, consultants, and collaborators and collaborators.

Letters of intent are due no later than July 15, 1982, and upon receipt will be screened by NIAID staff to determine the eligibility and suitability of the projected proposals for the CIRID program.

Inquiries should be sent to:

Dr. Robert A. Goldstein
Chief, Allergy and Clinical Immunology Branch
Immunology, Allergic and Immunologic
Diseases Program
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building Room 755
Bethesda, Maryland 20205

Telephone: (301) 496-7104

CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR LATE SUBMISSION

Based upon the letter of intent, potential applicants will be promptly advised whether or not their proposal is found to be within the research goals and scope of the program as defined in this RFA. Applicants will then have an opportunity to correct deficiencies or weaknesses and to restructure their submissions accordingly. Formal applications that are not responsive to the RFA or are not received by October 15, 1982, will not be accepted for review and will be returned to the applicant.

METHOD OF APPLYING

Before preparing an application, the prospective applicant should request a copy of the NIAID Information Brochure on Program Projects from:

Dr. Nirmal Das
Executive Secretary
Allergy, Immunology and Transplantation
Research Committee
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building, Room 706
Bethesda, Maryland 20205

Telephone: (301) 496-7966

In order to assure adequate review it is important to follow instructions in the Information Brochure, which contains details on the format and requirements for multidisciplinary grant applications.

Use the standard research grant application form PHS 398 (Rev. 5/80). In addition to following accompanying format instructions for the development of a Center application, include expanded material listed above under the eight points for the "letter of intent."

For purposes of identification and processing, the words "CENTERS FOR INTERDISCIPLINARY RESEARCH ON IMMUNOLOGIC DISEASES" should be typed in item 2 on the face page of the application and a brief covering letter should be attached indicating submission is in response to this NIAID announcement.

Application kits may be obtained from the institution's application control office. If not available there, they may be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building Room 448
Bethesda, Maryland 20205

Forward the complete application to:

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

Please forward a copy (not the original) of the cover letter and the application face page to: (1) Dr. Robert A. Goldstein in order to alert NIAID to the submission of the proposal, and to:

Chief, Program and Project Review Branch
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Westwood Building Room 703
Bethesda, Maryland 20205

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA NIH-NHLBI-82G-J

DEMONSTRATION AND EDUCATION RESEARCH IN HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: October 15, 1982

I. PURPOSE

The objective of this Request for Applications (RFA) is to invite grant applications for demonstration or education research in heart, blood vessel, lung, and blood diseases and blood resources. These research projects must be directed toward some significant aspect of heart, blood vessel, lung, or blood diseases and blood resources. The population in which the research would be conducted should be well defined and include health-care professionals, defined groups within a community, or the general population. Staffing for the research should include relevant expertise of professionals in disciplines as needed, including medical disciplines, health education, epidemiology, biostatistics, and behavioral and social science. To be responsive to this announcement, the applicant institution must have basic and clinical research activities related to the general areas of the proposed demonstration or education research.

II. ELIGIBILITY

To be eligible for competition under this RFA, applicants who propose demonstration or education research projects must also concisely

- o describe the institution's ongoing basic and clinical research related to the general area of the proposed demonstration or education project;
- o explain the actual or potential value these ongoing basic and clinical research programs have or would have for the proposed demonstration or education research; and
- o present evidence that cooperation with all relevant groups has been obtained.

III. BACKGROUND

This Request for Applications (RFA) represents another step toward fulfilling the congressional intent of Public Law 92-423 that the National Heart, Lung, and Blood Institute (NHLBI) establish centers ". . . for basic or clinical research into, trainining in, and demonstration of, advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases." The goal of this authorization was to stimulate rapid application of the results of basic laboratory and clinical research to patient care and to the promotion of health. As a first step toward meeting that goal, the National Heart, Lung, and Blood Institute (NHLBI), in 1975, established three National Research and Demonstration Centers: one in heart and blood vessel diseases, one in lung diseases, and one in blood diseases and blood resources.

The National Heart, Lung, and Blood Advisory Council has periodically reviewed the original concept for National Research and Demonstration Centers. The Council has expressed concern about the inadequate amount of demonstration and education research in the United States generally and about the need to enhance the magnitude of this research effort if the number of National Research and Demonstration Centers were to be increased. In September 1980, the Council recommended that the procedure for designating and supporting future National Research and Demonstration Centers be changed. This recommendation was subsequently accepted by the NHLBI. The Council suggested that a two-phase process be instituted in the creation or designation of new Centers and that an RFA for demonstration and education research be the first phase of the process. The RFA for the first phase was released in March 1981. Although the NHLBI awarded seven grants as a result of the first competition, these awards represented only a limited number of the program areas of the NHLBI. Consequently, the National Heart, Lung, and Blood Advisory Council recommended postponing the competition for National Research and Demonstration Centers so that additional institutions could become involved in demonstration and education research. This current RFA thus represents an attempt to stimulate further interest in demonstration and education research.

IV. DEFINITIONS AND PROJECT CONTENT

The application for a demonstration and education research grant may include a demonstration research project, an education research project, or some combination of both or either. An institution may submit more than one application. Generally, a project should be designed so that it can be implemented and evaluated within a maximum of five years.

The following sections define demonstration research and education research within the context of this announcement.

A. Demonstration Research

As defined for the purpose of this RFA, demonstration research is a project designed to test the applicability of new approaches to the prevention, diagnosis, or control of diseases that have been shown to be effective in controlled laboratory or clinical investigation. These new approaches would be tested in an appropriate setting, such as defined groups within communities, physicians' offices or other health-care settings or work sites.

The development of health-significant demonstration research relevant to the goals of the NHLBI should include the following considerations:

- o significance of the problem and anticipation of the expected gains in terms of health promotion, disease prevention, potential for reduction of morbidity or mortality, improvement and extension of health-care services in the community, effective use of health personnel, and enhancement of cost effectiveness;

- o utilization of special features of the specific setting, such as prevalence of a particular disease, unique research resources, specific population groups suitable for the project, special health-

delivery facilities, and local health organizations, but these special features should not be so specific as to preclude appropriate generalization of the findings;

- o evidence that the investigators have the experience, competence, and commitment necessary for the successful implementation of the project, that appropriate disciplines would be represented in the proposed project, that the applicant institution has the resources necessary and is committed to the proposed study, and that participating local groups have indicated their commitment to the study as proposed;

- o descriptions of the theoretical and factual bases for the proposed study, research questions or hypotheses to be tested, the research design to be used, procedures for sample selection, variables to be observed, methods and materials to be used, instruments and procedures to be used for measurements, approaches to data management and analysis, methods for statistical analysis, plans for dissemination of results, and the potential for the effectiveness of the demonstration in other settings; and

- o plans for evaluation that include specific procedures, instruments, and methods to be used in determining whether the objectives have been met.

B. Education Research

As defined for the purpose of this RFA, an education research project is one designed to investigate education methods for the maintenance of health, prevention of disease, or the delivery and utilization of health-care services. The development of health-significant education research relevant to the goals of the NHLBI should include the following considerations:

- o clear identification of the need for a change in health behavior, including a description of the existing health behavior addressed, the anticipated course if no program is instituted, and the significance of attempting to alter behavior;

- o definition of the objectives in terms of the behavioral change desired, the intervention strategies to be used, and the criteria by which change is to be measured;

- o careful definition of the study population, including plans for recruitment of participants and maintenance of the study population, any anticipated changes in the composition of the study population, and plans for measuring the impact of these changes on a project;

- o descriptions of the theoretical and factual bases for the proposed study, the research questions or hypotheses to be tested, the research design to be used, procedures for sample selection, variables to be observed, methods and materials to be used, instrument and procedures to be used for measurement,

approaches to data management and analysis, and methods for statistical analysis; and

- o plans for evaluation that include specific procedures, instruments, and methods to be used in determining whether the objectives have been met.

Continuing medical education with only the goal of information dissemination does not fit these criteria.

V. RESEARCH SCOPE

The following list includes major diseases and areas of interest to the Divisions of the NHLBI. The proposed demonstration and education research projects must be related to the programs of the NHLBI, as exemplified in this list, and should capitalize on the strengths of the applicant institution. The list is neither all-inclusive nor exclusive, nor is it in an order of priority of interest.

Heart and Blood Vessel Diseases:

Risk factor or factors for coronary heart disease in children and (or) adults, including high blood pressure, elevated serum cholesterol, smoking, lack of exercise, overweight, and diabetes; nutrition as it affects the cardiovascular system; rehabilitation after a myocardial infarct; prosthetic devices related to heart and vascular diseases; atherosclerosis; hypertension; coronary heart disease; arrhythmias; heart failure and shock; cerebrovascular disease, excluding the neurological components of completed stroke; peripheral vascular disease; congenital and rheumatic heart disease; cardiomyopathy; and infections of the heart.

Lung Diseases:

Obstructive diseases of the airways; pediatric pulmonary diseases; fibrotic and immunologic interstitial lung diseases; respiratory failure; pulmonary vascular diseases; risk factors for lung disease, including smoking, occupational exposure, and environmental exposure; and maintenance of respiratory health. (Cancer of the lung, upper respiratory infections, and tuberculosis are the responsibility of other program components of the National Institutes of Health and are not included in this program.)

Blood Diseases and Blood Resources:

Thromboembolic disorder, the hemophilias; and other conditions related to the plasma clotting factors; platelet abnormalities; microcirculatory thrombosis; bone marrow physiology and dysfunction; diseases and disorders of the red blood cell, including sickle cell disease, the thalassemias, and similar disorders; optimal utilization of the national blood resource; blood and blood-component therapy; and blood banking functions. (Malignancies of the blood, as well as immunologic and other disorders of the white blood cells, are the responsibility of other components of the National Institutes of Health and are not included in this program.)

VI. MECHANISM OF SUPPORT

Grants for demonstration and education research sponsored by the NHLBI* will be awarded under the authority of the Public Health Service Act, Title III, Section 301, and Public Law 95-622, Section 415, and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. Support may also be derived in part from other sources—Federal, local, public, and private. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

The total amount of funds that will be set aside will be determined at the November 1982 meeting of the National Heart, Lung, and Blood Advisory Council. It is anticipated that there may be from eight to twelve projects awarded at a total cost of about $2,000,000. The specific amount to be funded will, however, depend on the merit and scope of the applications received and the availability of funds.

While each applicant institution is expected to develop its own program in accordance with local expertise, interests, and resources, each must be willing to work with the other grantees in furthering the goals of the NHLBI.

VII. REVIEW PROCEDURES AND CRITERIA

Upon receipt, applications will be reviewed for their responsiveness to the specific objectives described in this announcement. An application judged to be unresponsive will be returned to the applicant. If a proposal submitted in response to this RFA is identical to a grant application already submitted to the NIH for review, the applicant will be asked to withdraw the pending application before the new one is accepted. Simultaneous submission of identical applications will not be allowed.

The Division of Extramural Affairs, NHLBI, will manage the scientific and technical merit review of applications. The initial peer review will be conducted by consultants who have expertise in each area of the proposed program. The subsequent review will be by the National Heart, Lung, and Blood Advisory Council.

The peer review of demonstration and education research projects will include assessment of the following:

- scientific merit of the research project, the importance of the underlying disease or health-related issue, and the relevance to the objectives of the RFA;
- soundness of the project design and of the procedures that would be used;

*The demonstration and education programs that the NHLBI intends to support are related to the provisions of the National Heart, Blood Vessel, Lung, and Blood Act of 1972 (Public Law 92-423), as extended by the Health Research and Health Service Amendments of 1976 (Public Law 94-278), the Biomedical Research Extension Act of 1977 (Public Law 95-83), and subsequent reauthorizations through 1980, and are described in the 1981 Catalog of Federal Domestic Assistance, program numbers 13.837, 13.838, and 13.839.

- o experience, commitment, and leadership ability of the principal investigator and the qualifications and experience of the other responsible investigators to do the proposed research;

- o reasons for selection of the study population or populations, and, for the education project, the significance of attempting to alter existing health-related behavior;

- o availability of necessary resources and the commitment of local population groups to cooperate and participate;

- o plans for evaluation of the progress and of the effect of a project;

- o plans for the collection, storage, retrieval, and analysis of data related to a project;

- o strength of the management plan for assuring the smooth functioning of a project, including

  - an administrative and organizational structure that would facilitate attainment of the proposed objectives of a project, the availability of appropriate consultants, and

  - a plan for the maintenance of quality control in all aspects of a proposed project;

- o availability of necessary physical, professional, and community resources to support a project and to successfully develop and maintain working relationships with the relevant segments of the community; and

- o a willingness to exchange experience and information with other investigators involved in demonstration and education research projects, if appropriate, and with the NHLBI.

VIII. METHOD OF APPLYING

NOTE:

Applicants are urged to consult with appropriate members of the staff of the NHLBI before and during the preparation of their applications regarding questions of policies, procedures, and guidelines.

Letter of Intent

Applicants should submit a letter of intent to the NHLBI not later than August 2, 1982. The NHLBI requests such letters so that the staff can plan for the review. A letter of intent is not binding and will not be considered in the review of any application submitted subsequently.

The letter should be addressed to:

Jerome G. Green, M.D.
Director, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building, Room 7A17
Bethesda, Maryland 20205

Format for Applications

The format for applications is that of the form PHS 398. Please refer to the Instruction Sheet for PHS 398 (Revised 5/80) for specific directions. In addition to the sections specified in the form PHS 398, applicants must include the following information, as appropriate:

- Title page

  Complete this page in the same manner as for a research grant application. Type in item 2: "NHLBI Demonstration and Education Research - RFA NIH-NHLBI-82G-J."

- Ongoing research and relation to proposed project

  Describe concisely the institution's ongoing basic and clinical research related to the general area of the proposed demonstration or education project.

  Explain briefly the actual or potential value these ongoing basic and clinical research programs have or would have for the proposed demonstration or education research.

- Description of the study population

  Describe and define the study population or populations for the demonstration and education research in sufficient detail to provide a clear understnding of the scope of a project and its potential for general application.

  Describe the status of health services, health education activities, and disease areas in the study population if relevant to the proposed project.

- Patient and subject availability

  Provide evidence for the availability and commitment of patients and subjects. This is particularly important for demonstration, prevention, and control efforts that may require cooperation with community physicians and collaboration with existent community health programs.

- Organization and administration

  Describe any relation of the proposed research to other relevant programs within the sponsoring institution.

o Capability of staff

Describe how the staff would fulfill the needs for the different kinds of expertise and capability required to accomplish the proposed study.

o Facilities

Describe facilities available for the proposed research, including, if appropriate, facilities of other collaborating institutions. Describe new facilities necessary for the proposed research and state how they would be obtained. (NHLBI funds to support construction are not available at the present time.)

Describe the geographic distribution of space and personnel and the plans for coordination of efforts in central and outlying facilities. Geographic proximity is desirable, but not mandatory, for demonstration and education research projects.

Application Procedure

The completed application and six (6) signed, exact photocopies of it should be sent or delivered to:

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

In addition, please send eighteen (18) copies to:

Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building Room 5A-10
5333 Westbard Avenue
Bethesda, Maryland 20205

Applications must be received by October 15, 1982.

Label the outside of the mailing package and item 2 of the face page of the application "NHLBI Demonstration and Education Research - RFA NIH-NHLBI-82G-J."

Indicate in a brief covering letter that the application is being submitted in response to this RFA: "Demonstration and Education Research in Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources." Send a copy of the letter to Dr. Jerome G. Green at the address given under the section entitled "Letter of Intent."

Timetable

Letter of intent	August 2, 1982
Receipt of applications	October 15, 1982
Advisory Council review	May 19-21, 1983
Earliest possible start date	July 1, 1983

Inquiries

Inquiries about demonstration and education research in heart and blood vessel diseases may be addressed to:

Dr. Barbara Packard
Director
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building Room 416
Bethesda, Maryland 20205

Telephone: (301) 496-2553

Inquiries about demonstration and education research in lung diseases may be addressed to:

Dr. Suzanne Hurd
Acting Director
Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building Room 6A15
Bethesda, Maryland 20205

Telephone: (301) 496-7208

Inquiries about demonstration and education research in blood diseases and blood resources may be addressed to:

Dr. Amoz I. Chernoff
Director
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building Room 516
Bethesda, Maryland 20205

Telephone: (301) 496-4868

ANNOUNCEMENT

THE AVAILABILITY OF OPPORTUNITIES FOR AMERCIAN SCIENTISTS

TO PERFORM COLLABORATIVE RESEARCH OUTSIDE THE UNITED STATES

FOGARTY INTERNATIONAL CENTER

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) of the National Institutes of Health announces the availability of postdoctoral fellowships to U.S. health scientists who wish to conduct collaborative research abroad. The purpose of these fellowships is to enhance the exchange of research experience and information in the various biomedical and behavioral sciences. The types of activity that are supported by these programs include collaboration in basic or clinical research, and the familiarization with or utilization of special techniques and equipment not otherwise available to the applicant. Applications having any of the following as the major feature cannot be accepted: brief observational visits, attendance at scientific meetings, attendance in formal training courses, or independent research projects within the host country.

PROGRAMS

Five programs are available to U.S. citizens or permanent residents:

SENIOR INTERNATIONAL FELLOWSHIP (SIF)
(Supported and administered by the FIC)

SWEDISH MEDICAL RESEARCH COUNCIL FELLOWSHIPS (SMRC)
(Supported by the Government of Sweden)

SWISS NATIONAL SCIENCE FOUNDATION POSTDOCTORAL FELLOWSHIPS (SNSF)
(Supported by the Government of Switzerland)

FRENCH NATIONAL INSTITUTE OF HEALTH AND MEDICAL RESEARCH (INSERM)
POSTDOCTORAL FELLOWSHIPS
(Supported by the Government of France)

NIH-FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH PROGRAM
FOR SCIENTIFIC COLLABORATION (CNRS)
(Under an agreement between the NIH and the CNRS, the two organizations share in the support of U.S. and French scientists to work at laboratories in France and the U.S., respectively.)

ELIGIBILITY REQUIREMENTS

Applicants must meet the following requirements:

U.S. citizen or permanent U.S. resident;

doctoral degree in clinical, behavioral or biomedical science;

ten years or less or postdoctoral experience;
(SIF applicants should have five years or more postdoctoral experience, not so specified for the CNRS)

professional experience in the health sciences for at least two of the last four years (not so specified for the CNRS);

affiliated with a U.S. public or private nonprofit research, clinical or educational institution (only required for SIF).

APPLICATION AND SELECTION

Applications for these programs are reviewed once a year. The receipt date for applications to the FIC Senior International Fellowship Program is June 1, 1982. The receipt date for all other applications is October 1, 1982. All applications are reviewed for scientific merit by the National Institutes of Health. The organization which provides financial support of the program selects candidates for participation. While the maximum period of support for all programs is one year, the minimum period of support varies with each program.

Information and applications are available from:

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

Prospective applicants for the Senior International Fellowship Program, the FIC sponsored program, may obtain information brochures from the above address. Only the office of the dean or equivalent institutional official may request SIF fellowship applications which will be available until May 15, 1982.

All correspondence should refer to specific programs and must be clearly marked using one of the following:

Senior Fellowships
Swedish Fellowships
Swiss Fellowships
INSERM
CNRS

For an expeditious reply, please send a self-addressed label with your request.

NONHUMAN PRIMATES AVAILABLE

The National Institutes of Health has established supply sources of nonhuman primates for the National Institutes of Health (NIH) and Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) supported projects. Production colonies of rhesus (Macaca mulatta) and cynomolgus (Macaca fascicularis) monkeys have been established. Priority is given to investigators with NIH or ADAMHA supported projects. Other investigators in nonprofit institutions are invited to submit requests for primates for use in biomedical and behavioral projects. All requests should be in letter form and indicate the source of support; and if NIH or ADAMHA, include the title, number and principal investigator of the grant or contract. The request should also include the specifications for the animals required, including number, age, sex or other special characteristics. The entire request need not exceed one typewritten page. All inquiries should be addressed to:

Dr. Carl E. Miller
Building 31, Room 5B59
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5175

The price indicated for each animal includes shipping costs within the continental United States. The funds will be paid directly to the contractor supplying the animals to partially offset the cost of the NIH-supported breeding program. Other inquiries are invited.

Animals currently available are as follows:

Normal rhesus monkeys (Macaca mulatta)	Price
100 females - colony born - 1981	$750
150 males - colony born - 1981	750
30 males - colony born - 1980	850
2 females - colony born - 1979	950
1 female - colony born - 1978	950
Pregnant females - wild-caught colony production stock as available during reproductive season, gestation estimated ± 15 days -	$1,200 each
Specific mating dates -	1,500 each
Retired breeders - as available	850

Normal colony produced cynomolgus monkeys (Macaca fascicularis)	
10 females - colony born - 1981	$350
33 males - colony born - 1981	350
11 males - colony born - 1980	400
27 males - colony born - 1979	400
3 males - colony born - 1978	400
2 males - colony born - 1977	400
14 females - reproductive culls	300
2 males - reproductive culls	300

Prices include delivery in the continental United States.

The above prices are for nonprofit institutions.

NOTICE

AVAILABILITY OF AGED MONKEYS (MACAQUE SPECIES)

NATIONAL INSTITUTE ON AGING

The National Institute on Aging (NIA), National Institutes of Health (NIH), through an Intra-Agency Agreement with the NIH Division of Research Resources (DRR), has established set-aside colonies of aging monkeys. At any of four DRR-supported Regional Primate Research Centers (PRC), collaborating investigators, visiting scientists, and graduate and postgraduate students supported by NIA grants and awards can use the nonhuman primates for gerontological and geriatric research programs.

OBJECTIVES

Objectives of the program are:

1. To provide a research and research training resource for biological, behavioral, social, and clinical studies on the processes, conditions, and characteristics relevant to the aging process, and the diseases and other special problems of aged humans;

2. To determine which gerontological and geriatric research problems are best pursued with nonhuman primates;

3. To supply biological specimens to investigators performing research on the aging process.

AVAILABLE RESOURCES

ANIMALS

The following animals are available for use primarily in experiments which will not cause any long-term or irreversible damage to the animals. However, at centers where aged animals can be replaced from the breeding colony or other sources, some animals may be used for high-priority terminal experiments.

Primate Center	Species	# of Animals	Range of Birth Years
California	M.mulatta	55	1964-67
Oregon	M.mulatta	49	1961-67
Washington	M.nemestrina	27	1957-67
Wisconsin	M.mulatta	56	1956-67

Complete experimental and clinical histories of these animals are on record at the respective PRCs. An independent panel of primatologists and comparative pathologists has selected the monkeys for inclusion in the set-aside colonies from a pool of 360 monkeys, 15 years old or older, on the basis of their experimental and clinical histories. Animals which had experienced such severe interventions as whole body Cobalt-60 exposure, amygdalectomy, or isolation rearing were judged unsuitable for the set-aside colonies. In contrast, animals that had been breeders, or had been exposed to short-acting drugs, or to interventions with expected local or mild effects, were judged suitable.

At present, the major research emphases of the four centers are as follows:

- The main research orientation of the Oregon Regional Primate Research Center, Beaverton, Oregon is in reproductive biology. Other research emphases include cardiovascular and metabolic research, immunology, cutaneous biology, biochemistry, nutrition, and behavior.

- The Regional Primate Research Center at the University of Washington, Seattle, Washington emphasizes developmental biology, neurosciences and behavior, cardiovascular function, disease models, endocrinology and metabolism, and immunogenetics.

- Interactions among hormones, social environment and the brain, and how these factors influence reproductive functions in nonhuman primates are the principal research foci at the Wisconsin Regional Primate Research Center, Madison, Wisconsin.

- The California Primate Research Center at Davis, California, is engaged in studying the effects of environmental factors on nonhuman primates, perinatal biology and reproduction, respiratory diseases, infectious diseases and immunology, and behavioral biology.

SERVICES

Certain services may be provided to NIA grantees by the four PRCs. Investigators interested in availing themselves of these services should contact the Director(s) of the appropriate PRC(s), and negotiate agreements for specific services or collaborative research arrangements prior to submitting a new, renewal, or supplemental research grant application. Appropriate documentation of all such agreements should be appended to the grant application.

Tissue specimens, organs, blood, skeletal structures, viral specimens and other biological samples from these animals may be provided to NIA grantees when available. Such specimens are collected by non-invasive, or minimally damaging techniques.

In most cases, the aged animals should be maintained on location at the respective PRC for the duration of the grant. Under rare circumstances, at the discretion of the Head, Aging Primate Research Resource Program, NIA, and Director of the relevant PRC, however, arrangements may be possible for purchase and transfer of a small number of animals by the grantee institution. Negotiation for purchase of aging animals should be made with the Director of the PRC and coordinated through the Head, Aging Primate Research Resource Program, NIA.

The following guidelines should be used in applying for use of the aging monkey resources. The grant application, whether new, renewal, or supplemental, should be coordinated with the appropriate PRC Director to insure that:

- o the experimental protocol is appropriate to that facility;
- o the necessary animals, equipment, services, and space are available;
- o supplies/equipment essential for the studies can be designated;
- o facilities are available for the proposed studies; and
- o the timing of the studies is not disruptive to the ongoing PRC activities.

Grant applicants should request use of the aged primate resources via the standard research grant form (PHS Form 398) submitted to the Division of Research Grants for review of scientific merit. The grant application should include verification that the above criteria have been met.

Applicants should include itemized budgets for all costs related to maintenance (per diem) and experimental use of the animals. Such itemized costs should include charges for research-related services which may be procured from the Center. All fees (e.g., technical sevices, animal purchases) should be pre-determined through discussions with the PRC Director and documented in the grant application. If transfer of animals to the grantee institution is necessary, costs of the purchase, transfer, per diem maintenance, and related services should be included in the budget of the grant application.

If the requested animal or services are for use in pilot studies by current NIA grantees, the following information should be submitted to Ms. Jane Soban at the Aging Primate Research Resource Program, National Institute on Aging:

- o proposed research protocol and its relevance to aging (4 copies);
- o recent publications related to proposal (2 copies);
- o curriculum vitae (4 copies); and
- o appropriate documentation of agreement with the PRC Director(s).

Upon receipt of this request, and necessary additional materials, the proposal will be sent for review of scientific merit.

SOURCES OF FURTHER INFORMATION

Information pertaining to the research areas, facilities and service of the PRCs are published in the Animal Resources Directory of the DRR. A copy of this may be obtained from:

Office of Science and Health Reports
Division of Research Resources
Building 31, Room 5B-13
Bethesda, Maryland 20205

For further information contact:

Head, Aging Primate Ressearch Resource Program
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-6402

Director, California Primate Research Center
University of California
Davis, California 95616

Telephone: (916) 752-0420

Director, Oregon Primate Research Center
505 N.W. 185th Avenue
Beaverton, Oregon 97005

Telephone: (503) 645-1141

Director, Washington Primate Research Center
University of Washington
Room I-421 - Health Sciences Bldg. J-50
Seattle, Washington 98195

Telephone: (206) 543-1430

Director, Wisconsin Regional Primate
Research Center
University of Wisconsin
1223 Capitol Court
Madison, Wisconsin 53706

Telephone: (608) 263-3500

ANNOUNCEMENT

PREVENTIVE ONCOLOGY ACADEMIC AWARD (POAA)

NATIONAL CANCER INSTITUTE

I. BACKGROUND OF POAA

A. The National Cancer Institute invites competition for Preventive Oncology Academic Awards. Each School of Medicine, Osteopathy, Dentistry, Public Health, or NCI-designated cancer center in the United States and its possessions or territories is eligible to compete for one non-renewable Preventive Oncology Academic Award for a project period not to exceed five years. The number of new awards made each year will depend on the availability of funds.

B. The Preventive Oncology Academic Award Program is intended to stimulate high quality research on which educational programs oriented toward cancer prevention could be based in schools which do not have such programs or to strengthen the research and education programs of schools in which high quality research in preventive oncology already exists. It is expected that each program in cancer prevention will build upon the institution's demonstrable expertise and experience in epidemiology, human genetics, biostatistics, clinical oncology, nutrition and other pertinent basic cancer research.

C. The Preventive Oncology Academic Awards, which are made on the basis of nationwide competition, are available to individual investigators with academic teaching and/or research appointments in their respective institutions. POAA's support these individuals for needed research and educational objectives and development, implementation, and/or improvement of a preventive oncology curriculum.

II. DEFINITION OF PREVENTIVE ONCOLOGY

For purposes of Preventive Oncology Academic Awards (POAA), preventive oncology is mainly concerned with etiologic studies and the primary prevention of cancer. In certain instances it may be appropriate to evaluate the efficacy of preventive measures.

III. OBJECTIVES OF THE AWARD

The Preventive Oncology Academic Award, which is made on the basis of nationwide competition, is available to:

This program is described in the Catalog of Federal Domestic Assistance No. 13.393, Cancer Cause & Prevention Research. 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.

1. Support an outstanding individual faculty member for:

   a. participation in research experiences related to preventive oncology

   b. enhancing relevant scientific skills if a need is demonstrated

   c. strengthening or implementing a preventive oncology curriculum and the research program on which it should be based.

2. Provide superior learning opportunities to students enrolled in the institution through their exposure to research and to courses relevant to preventive oncology.

3. Facilitate exchange of ideas and methods among institutions and centers with special interest and expertise in preventive oncology.

IV. CRITERIA FOR THE POAA

Competitive review for a Preventive Oncology Academic Award will assess the plans of both (a) the sponsoring institution and (B) the proposed candidate.

A. THE INSTITUTION MUST:

1. Select and sponsor a candidate with: (a) demonstrated competence in preventive oncology, as well as (b) a major career interest in research and educational programs. The candidate must be a citizen, a noncitizen national of the U.S., or have been lawfully admitted to the U.S. for permanent residence.

2. Provide the candidate with: (a) the opportunity to acquire the professional skills for which need is demonstrated, and (b) adequate time to develop or improve the preventive oncology program.

3. Present institutional plans for the preventive oncology program which is to be developed under support of the POAA: (a) these plans must state the program's objective in terms of measurable outcomes and provide benchmarks aginst which progress is to be measured. (b) the plan should clearly distinguish between any ongoing activities and those to be accomplished as a result of the POAA, outlining the relationship between the proposed plan and related teaching and research programs of the institution.

4. Identify and demonstrate availability of resources (e.g., populations, patients, manpower, materials) necessary to implement the proposed program.

5. Provide access to physical facilities (e.g., computer, laboratory, clinical, classroom office facilities) for rigorous preventive oncology research.

6. Provide written evidence of commitment from the administration, and chairperson(s) of sponsoring department(s) and curriculum committee to the implementation and/or further development of the proposed program.

7. Propose mechanisms for continued institutional support of the preventive oncology program, following the award period.

B. THE CANDIDATE MUST:

1. Hold a doctoral degree or its equivalent from an accredited institution (e.g., D.D.S., D.O., Dr.P.H., D.V.M., M.D., Ph.D.);

2. Possess an appropriate teaching and/or research appointment in the sponsoring institution at the time the award is activated;

3. Have sufficient training and experience so that no more than two years of intensive supplemental preparation is needed to meet minimal POAA requirements. These requirements include:

   a. demonstrated competence in: biomedical research relevant to cancer prevention, including epidemiology and/or human genetics, clinical oncology and biostatistical research methods, plus

   b. substantive knowledge of: cancer epidemiology and prevention, carcinogenesis research, health service delivery systems, public health regulation and practice, as well as medical education procedures and administration.

4. Specify a program for enhancing personal skills as needed, e.g., further education in epidemiology, biostatistics, genetics, nutrition, clinical oncology and/or other pertinent areas of research in cancer etiology and prevention.

5. Present a program: (a) for developing or improving preventive oncology research and education in the grantee institution, and (b) for evaluating the outcome of the effort. This program should include detailed plans including the proposed curriculum, course description and syllabi, where appropriate.

6. Commit a substantial portion of time and effort to preventive oncology research and to the proposed programs.

7. Submit an annual program performance report along with the continuation support application (Type 5).

8. Agree to meet annually with other recipients of POAA's to exchange ideas, methods and program evaluations, as specified in the POAA objectives. The meeting is to be sponsored by the National Cancer Institute, with travel costs borne by POAA grant.

V. PROVISIONS OF THE PREVENTIVE ONCOLOGY ACADEMIC AWARD (POAA)

A. Within available funds, and consonant with the objectives of the POAA, and with satisfactory progress, the Institute will provide funds annually for a project period up to five years. This award is non-renewable.

B. The POAA funds may be used for:

1. Personnel: salary support for candidate and all other personnel, in direct proportion to the effort expended on the P.O. program, to include, e.g., P.O. assistants and associates; curriculum specialists and other faculty; as justified and specified by level of professional development; and in accordance with institutional policy.

2. Consultants costs: for a limited number of experts in the areas of P.O. research and education.

3. Equipment: necessary to develop P.O. curriculum.

4. Supplies by category: necessary to achieve P.O. program objectives.

5. Travel: domestic travel to other institutions and meetings to enable the candidate to develop essential skills, and also to meet with other candidates to exchange ideas, methods, and program evaluations. (See IV. B-9).

6. Other expenses may include: (a) stipend, tuition and fee costs related to the implementation by the candidate of a proposed program for enhancement of personal skills; (b) computer costs, teaching aids, materials and books relevant to the development of the P.O. program, and, (c) postage, copying costs, telephone costs.

C. The POAA funds may not be used for: patient care costs, alterations and renovations, and contractual or third party payment costs. These are ineligible categories for support under the POAA grant mechanism.

D. Limited funds, if requested, may be used at the discretion of the candidate to support short term research or teaching experiences in preventive oncology. Such experiences may be (1) designed to educate faculty or students in principles and techniques of preventive oncology research or (2) feasibility studies integral to research planning.

VI. REVIEW OF APPLICATIONS

Applications for initial Preventive Oncology Academic Awards will be appraised in terms of criteria outlined for the institution and the candidate in Section IV, "Criteria for the Preventive Oncology Academic Award." Applications will be evaluated by an appropriate NCI peer review group.

VII. METHOD OF APPLYING

1. The annual receipt date for POAA applications will be September 1.

2. The requested begin date for funding should be July 1 of the following year.

3. Application forms (PHS 398, Revised 5/80) may be obtained from the institution's application control office. If not otherwise available, they can be requested from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Room 448 Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

4. Type the phrase "PREVENTIVE ONCOLOGY ACADEMIC AWARD" as the title for the proposal on the front page of the application. Use the Special Guidelines for preparation of a Preventive Oncology Academic Award. These and limited staff consultation relating to eligibility and appropriate areas of emphasis may be obtained from:

Special Programs Branch
National Cancer Institute
National Institutes of Health
Room 8C16 Landow Building
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-9600

ANNOUNCEMENT

DIETARY SODIUM AND ITS ROLE IN THE PREVENTION AND MANAGEMENT OF HYPERTENSION

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Heart, Lung, and Blood Institute (NHLBI) supports a variety of research programs related to the prevention, treatment, and control of hypertension. Since this broad area of research is important to several programs in the Division of Heart and Vascular Diseases (DHVD) of the Institute, the present program announcement is being issued from the Division. A program announcement is designed to focus attention upon a topic or problem. Applications will be considered as applications for the regular research grant program, without special set-aside funds.

The objective of this program announcement is to encourage the submission of scientifically meritorious applications concerning a broad range of investigations, including physiological, clinical, preventive, and therapeutic research, regarding the role of dietary sodium in hypertension and the prevention of hypertension.

It is estimated that 35 million persons in the United States have high blood pressure. This fact, coupled with recent evidence from the Hypertension Detection and Followup Program that significant reductions in mortality can result from sustained drug treatment of high blood pressure, makes research into the role of dietary sodium in the prevention and management of high blood pressure of special interest. This research area has been identified by the Salt and Water Subgroup of NHLBI's Hypertension Task Force, the NHLBI Clinical Applications and Prevention Advisory Committee and the Arteriosclerosis, Hypertension, and Lipid Metabolism Advisory Committee as needing emphasis.

Examples of needed research include studies of:

- o The relationship between sodium and weight.
- o The interrelationship of sodium and weight.
- o Sodium sensitivity.
- o Salt appetite.
- o Methodology for determining sodium intake in humans.

This program is 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, Title III, Section 301 (Public Law 73-410, 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.

Investigations that take account of other dietary factors, caloric intake, and energy expenditure are encouraged.

The above list is intended to provide examples only and does not preclude the submission of applications involving other research approaches to the issues under consideration. In addition, this program announcement is not intended to discourage investigators from their pursuit of promising ideas in related or unrelated topics.

Application Submission and Review

Application receipt dates for new applications are the regular application receipt dates of July 1, November 1, and March 1. Applications received after any one receipt date are considered and reviewed together with those received by the next receipt date. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application form PHS-398, which is available at the applicant's institutional application control office or from the Division of Research Grants, NIH.

In order to identify the response to this announcement, check "yes" and put "Dietary Sodium/Hypertension" under item 2 on page 1 of those grant applications relating to the topics identified herein. The completed application should be mailed to:

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

The Division of Research Grants will assign applications to study sections for review according to the NIH process for regular research grant applications. Approved applications will compete for available funds with all other approved grant applications assigned to the NHLBI. Additional information may be obtained by contacting:

Marilyn Farrand, R.D.
Preventive Cardiology Branch
Division of Heart and
Vascular Diseases
National Heart, Lung, and
Blood Institute
National Institutes of Health
Federal Building Room 6A08
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-3503

Armando Sandoval
Hypertension Branch
Division of Heart and
Vascular Diseases
National Heart, Lung, and
Blood Institute
National Institutes of Health
Federal Building Room 4C08
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1857

ANNOUNCEMENT

PHARMACOLOGY PROGRAM

NATIONAL INSTITUTE ON AGING

I. INTRODUCTION

The National Institute on Aging (NIA) was established in 1974 for the "conduct and support of biomedical, social and behavioral research and training related to the aging process and the diseases and other special problems and needs of the aged." Under this broad mandate, it has encouraged and supported a diversified research program related to aging.

Drug manufacturers routinely test new drugs and determine safe dose levels in healthy, young adults. The largest degree of drug use, however, is among the elderly, who often respond differently to drugs than do young adults. Definitive information is needed to elucidate the mechanisms underlying differences in response between young adults and the elderly and also to provide optimal drug dosage levels for elderly patients.

The increased incidence of multiple diseases among the elderly often leads to the use of combinations of drugs. The effect of such polypharmacy can be undesirable and have potentially dangerous side effects. It is important to learn more about interactions between various drugs as well as interactions between drugs and disease states and nutritional status.

Clinical and basic research to gain fundamental knowledge on the nature and causes for differences in the response of the elderly to drugs represents an important element of NIA's responsibility. The Pharmacology program, a part of Biomedical Research and Clinical Medicine, NIA, is specifically concerned with research and training in this area.

II. BACKGROUND

Increased interest by the research community in gerontological pharmacology is strongly encouraged. The following sources of background information may be useful to investigators new to this area.

(1) Steinberg, G.M. and Schneider, E.L.: NIA Second Workshop on Pharmacology and Aging, June, 1981. The Pharmacologist 24: Issue No. 2 (1982).

This program is described in the Catalog of Federal Domestic Assistance No. 13.866, Aging Research. Awards will be made under the authority of the Public Health Service Acts, Sections 301 (Public Law 78-410, as amended; 42 USC 241) and 472 (42 USC 2891-1) and administered under PHS grants policies and Federal Regulation 42 CFR Parts 52 and 66 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

(2) Vestal, Robert E.: Drug Use in the Elderly: A Review of Problems and Special Considerations. Drugs 16:358-382 (1978).

(3) Crooks, J. and Stevenson, I.H.: Drugs and the Elderly. Perspectives in Geriatric Clinical Pharmacology. University Park Press, Baltimore, Maryland, 1979.

(4) Conrad, K.A. and Bressler, R.: Drug Therapy for the Elderly. C.V. Mosby Co., St. Louis, 1982.

(5) Plein, J.B. and Plein, E.M.: Aging and Drug Therapy. Annual Review of Gerontology and Geriatrics (Volume 2), edited by Eisdorfer C., Springer, New York, 1981.

III. GOALS AND SCOPE

A major goal of the NIA is to identify changes in pharmacological responses that occur with aging and to elucidate the basic mechanism involved. This information should lead to development of more appropriate and efficacious therapy, to reduction of adverse drug side effects and to prevention of iatrogenic disease.

IV. SPECIFIC OBJECTIVES

The NIA seeks research and research training grant applications in gerontological and geriatric pharmacology. Investigations are encouraged on the aging process (beyond maturity) in all of the physiological systems that are subject to pharmacological intervention. Among possible approaches are clinical studies of healty and diseased elderly persons and more basic studies in experimental animals. Appropriate topics include, but are not limited to, the areas noted below. These areas are not listed in any order of priority.

Areas of Greatest Needs or Opportunities

General: Drug actions on the peripheral and central nervous systems, and on the cardiovascular system. Effects of drugs and modulators on the immune system and on bone metabolism.

Prevention and treatment of common diseases and disorders of the elderly. Examples include: dementias, osteoporosis, decubitus ulcers, arthritis, incontinence, infection, and cancer.

Basic Pharmacology

Basic and clinical pharmacological research which leads to increasing fundamental knowledge on how and why the elderly differ from younger people in their response to drugs. Emphasis on research having a pharmacodynamic basis is encouraged. Studies of the pharmacokinetic behavior of drugs are encouraged only where there are direct and clear relationships to problems of drug action or to important physiological or homeostatic processes.

Clinical Studies

Evaluation of individual drugs to provide definitive guidance for their use in the elderly. Information to be obtained should include: proper

dosage levels, effectiveness, side effects, interactions with other drugs, interactions with other disease states, nutritional status, etc.

V. SUPPORT MECHANISMS

All of the traditional NIH support mechanisms, e.g., research project grants, program projects, institutional National Research Service Awards, etc., are available for this program. For applicants interested in pilot studies and for those new to gerontological research, consideration may be given to the NIA Small Grants and Special Initiatives awards.

VI. AVAILABILITY OF EXPERIMENTAL ANIMALS

Colonies of laboratory mice, rats and monkeys for aging research are maintained by the NIA. Applicants interested in using these resources must contact (prior to submitting application) the Office of Biological Resources and Resources Development, NIA (Telephone: (301) 496-6402). Note that limited numbers of experimental animals may be made available for preapplication pilot studies.

Where the use of animal models is proposed, the appropriateness of the model should be considered and discussed in the application. The availability of specific species and strains from the NIA does not necessarily imply that these are appropriate for all research purposes.

VII. GENERAL

Applications in response to this announcement should be submitted on a standard NIH application form following the instructions contained in the NIH application packet. Type "NIA Pharmacology Program" on fact page of application. Note that clinical studies may be for research purposes only (this program does not support services) so that only those patient costs that are clearly for research components are appropriate budget items.

Inquiries may be directed to:

George M. Steinberg, Ph.D.
Pharmacology Program
Building 31 Room 5C-23
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-1033

ANNOUNCEMENT

GERIATRIC MENTAL HEALTH ACADEMIC AWARDS

**NATIONAL INSTITUTE OF MENTAL HEALTH
(ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
PUBLIC HEALTH SERVICE)**

BACKGROUND

The serious mental health problems of the increasing elderly population are now being identified as issues for systematic multidisciplinary research. The number of investigators in the area is small, however, and faculty to supervise geriatric mental health is limited. As the National Institute of Mental Health (NIMH) support of research in the mental health of the aging accelerated in the late 1970s, the need for investigations in psychiatry and psychiatric nursing became apparent. To address this need, NIMH is initiating a program to foster the growth of academic investigation and to recruit and prepare faculty dedicated to research and teaching in geriatric mental health.

PURPOSE

The purpose of this award is to assist in the development of a research-oriented resource person in geriatric mental health in academic settings. Upon completion of the award, the nominee is expected to function as (1) a researcher in geriatric mental health; (2) a developer of other researchers with interests in geriatric mental health; and (3) an introducer of research findings in geriatric mental health to other clinical teachers and researchers in the academic setting. This Academic Award will support an experienced faculty member, who is a psychiatrist or psychiatric nurse, in the development of necessary expertise in the research aspects of aging and mental health. This award, made to an institution, provides a superior candidate with opportunity for up to 3 years of special study and supervised experience to prepare the individual to assume a faculty leadership role in geriatric mental health.

The Academic Award is designed to provide support for individuals with high potential for academic research careers in geriatric mental health. The Academic Award differs from the Research Scientist Development Award in that the nominee is expected to assume leadership in teaching and to be a research resource as well as researcher, while the Research Scientist is expected to be a full-time research investigator. The Academic Award differs from the Individual National Research Service Award in that the focus goes beyond pure preparation in research to the development of an institutional resource.

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.

description of the role he/she will play in relation to the major activities of the Geriatric Mental Health Academic Award nominee throughout the award period should be included. If supervision is to be delegated to another faculty person or sponsor, this individual's role and the relation this individual has to the head of the applicant professional school should be described.

C. Experts - If neither the supervisor nor the delegated faculty has suitable proficiency in research methodology and clinical geriatrics, experts in these areas must be identified, and letters of agreement to consult with the nominee and supervisor must be provided. The role of each expert should be identified; the nature of the relationship between expert, supervisor, and nominee should be described; and the financial or other arrangements should be detailed.

NOTE: The Biographical Sketch form provided in the application kit (PHS Form 398) should be completed so that it provides a complete curriculum vitae of the Geriatric Mental Health Academic Award nominee. Biographic sketches for the supervisor and for each expert identified (C., above) should also be included in the application.

D. Applicant Institution - The applicant is expected to demonstrate the need for a specially prepared faculty member to implement a research and education program in geriatric mental health in the professional school; i.e., the applicant must demonstrate that, while there is a commitment to establishing the geriatric mental health research program, current faculty resources do not permit the establishment of such a program. Although priority will be given to those applicants who propose to establish a geriatric mental health program in an institution, some consideration will be given to applicants proposing expansion of a program beyond a limited base presently available in the institution. It is the joint responsibility of both supervisor and nominee to provide general information about the applicant institution, including history, size, and educational philosophy of the sponsoring department or school, and to describe the current curriculum and research activities in mental health of the aging.

II. Plans and Activities

A. Geriatric Mental Health Academic Award Nominee - The nominee should develop a 3-year plan for activities which will result in his/her ability to fulfill the responsibilities involved in this award: researcher, developer of other researchers, and consultation resource in research and clinical settings within the institutional program. The plan should include description of areas where additional preparation will be required and the activities projected to develop competence in these areas. Specific content areas within geriatric mental health and the methodological approaches on which the nominee will focus should also be described. A plan for each year of the award should be presented. The candidate is expected to devote full time to the proposed research and academic development activities. The activities might include collaboration in research projects, development of pilot studies, participation in structured academic courses, tutorial arrangements, consultation with geriatric mental health experts, independent study and supervised clinical experience. Although apportionment of time among activities will be based on the nominee's needs, the total program must be well balanced, and activities to enhance geriatric mental health research expertise must

constitute the major part of the awardee's activities. Approximate distribution of time among categories of activity should be provided. The program may require a period of study specifically on research in mental health of the aging at another institution. Sites of anticipated activity should be identified; financial arrangements between the applicant institution and any other sites should be described, e.g., tutorial services or tuition and fees paid by the applicant institution to the site.

B. Institutional Plans - The applicant institution must assure that the Geriatric Mental Health Academic Award nominee will be released from activities not directly related to his/her development as an academic researcher and resource in geriatric mental health. The nominee may continue to be involved in activities within the school which are appropriate to the accomplishment of the program goals. Thus, the nominee's responsibilities may include, in addition to pursuit of a professional development activity on research projects, development of curricula in geriatric mental health, teaching and/or coordination of educational or clinical activities in geriatric mental health, and provision of consultation to faculty colleagues and community groups. The application should describe the resources of the institution which are or will be committed to the advancement of the nominee and geriatric mental health as a component of its total academic research and teaching program, both during and subsequent to the award.

III. Plans for Post-Award Activities

The nominee and the head of the sponsoring department should describe the long-term goals of the school or department in geriatric mental health research and teaching. How the Geriatric Mental Health Academic Award will help achieve these goals should be discussed.

IV. Evaluation Activities

Each application should include a description of procedures by which progress of the nominee in the program and impact of the program on the institution will be measured and evaluated, along with a description of how the findings from continuous evaluation will be fed back into the program. The evaluation data will be used by NIMH in assessing the strength of the program. Such data could include the amount and types of material and the time devoted to geriatric issues in instructional programs, the type and number of collaborative arrangements for research or teaching between the academic program and treatment or service settings for the elderly, and research projects proposed or developed in geriatric mental health.

APPLICATION AND REVIEW PROCEDURES AND CRITERIA

Applications - All applicants should use form PHS 398 (Rev. 5/80). Application kits are available in university grants offices or from the following office:

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

Instructions for applicants are included in the kit.

The signed original and six (6) copies should be sent directly to the following address:

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

Grant Review Procedures - Research grant applications are reviewed for scientific and technical merit by an initial review group (IRG), composed primarily of non-Federal scientific experts, and by the National Advisory Mental Health Council. By law, only projects recommended for approval by the Council may be considered for funding. Summaries of IRG recommendations are sent to applicants as soon as possible after the Council has completed its review.

Review Schedule - NIMH research grant applications are reviewed according to the following schedule:

Review Schedule

Receipt Dates	Initial Review Group Meetings	National Advisory Mental Health Council Meetings	Approximate Start Date
July 1	Oct. - Nov.	Jan. - Feb.	April 1
Nov. 1	Feb. - March	May	July 1
March 1	June	Sept. - Oct.	Dec. 1

Review Criteria - In the review of Geriatric Mental Health Academic Award applications, Initial Review Groups consider the background and potential of an individual nominee as an investigator, a teacher of other investigators, and a resource in the research, educational, and clinical programs of the institution. In addition, the Initial Review Groups consider the quality and feasibility of the development plan, the merit of the institutional plan and commitment presented, and the quality of the institutional plan to incorporate a strong geriatric mental health component in its research and teaching programs.

Council review also involves questions of policy and program priorities.

Staff Consultation - Potential applicants may seek information and consultation from the staff of the following:

Center for Studies of the Mental Health
of the Aging
National Institute of Mental Health
Parklawn Building - Room 11A16
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301)-443-1185

Inquiries should be directed to:

Gene D. Cohen, M.D., Ph.D., Chief
or
Barry D. Lebowitz, Ph.D., Head
Research Program

Award Criteria - Initial Review Group and Council recommendations, significance of the particular topical approach, program balance, priorities indicated elsewhere in this announcement, and availability of funds are taken into consideration in determining which projects will be funded.

Period of Support - The Geriatric Mental Health Academic Award is made on an annual basis, with additional years of recommended support for a total of up to 3 years. It is not renewable. Support for the second and third year of the award is contingent upon receipt of an application annually which provides a summary report of progress to date, plans for the next year, and appraisal of the awardee's progress submitted by the sponsor. Continuation applications are due 60 days before the termination of the current budget period; application forms will be sent to the awardee.

ANNOUNCEMENT

RESEARCH INTERESTS IN EPIDERMOLYSIS BULLOSA, SKIN DISEASES PROGRAM

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

The Skin Diseases Program of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases is encouraging the submission of applications for research grants in epidermolysis bullosa (EB), a group of inherited skin disorders characterized by the formation of blisters and erosions at the site of mild trauma. In the less severe form, EB simplex, blisters are usually confined to the hands and feet. The more severe recessive dystrophic form may involve the entire body, and is associated with even greater morbidity and significant mortality. Repeated blistering causes infection, malnutrition, flexural contractures, and mitten-like deformities of the hand and feet.

Although the cause of EB is unknown, there is some evidence that in recessive EB there is degeneration and phagocytosis of collagen fibrils in the area of blistering. Increased collagenase activity in organ cultures of blistered skin has recently been demonstrated.

The NIADDK seeks studies aimed at achieving a better understanding of pathophysiologic mechanisms which contribute to the onset of EB as well as further insight into the process of epidermal cleavage in general. Proposals utilizing research advances in genetics, pathology, cell biology, biochemistry, and immunology as they pertain to various types of EB and the blistering process are encouraged.

The Skin Diseases Program also encourages the submission of applications for research training through National Research Service Awards, both individual fellowships and institutional awards; Clinical Investigator Awards, New Investigator Research Awards, and Research Career Development Awards.

METHOD AND CRITERIA OF REVIEW

Assignment of Applications - Applications will be received by the NIH's Division of Research Grants, referred to an appropriate initial review group for scientific review, and assigned to the NIADDK for possible funding. These decisions will be governed by programmatic considerations as specified in the DRG Referral Guidelines.

This program is described in the Catalog of Federal Domestic Assistance No. 13.846, Arthritis, Bone, & Skin Diseases. Awards will be made under the authority of the Public Health Service Acts, Sections 301 (Public Law 78-410, as amended; 42 USC 241) and 472 (42 USC 2891-1) and administered under PHS grants policies and Federal Regulation 42 CFR Parts 52 and 66 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

Review Procedures - Applications in response to this announcement will be reviewed in accordance with the National Institutes of Health peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants. Following initial review, the application will be evaluated for program relevance by the NADDK Advisory Council. Review criteria customarily employed by the National Institutes of Health for regular research grant applications will prevail. Approved applications will compete for available funds with other approved grant applications assigned to the NIADDK.

Deadline - Applications will be accepted in accordance with the announced receipt dates for new applications (see receipt dates and review schedule in Application kits).

Method of Applying - Applications for research grants should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions or from the Division of Research Grants, NIH. The phrase "PREPARED IN RESPONSE TO RESEARCH GRANTS ANNOUNCEMENT IN THE AREA OF EPIDERMOLYSIS BULLOSA" should be typed across the top of the first page of the application.

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 or to obtain application kits, investigators are encouraged to contact the program director:

Alan N. Moshell, M.D.
Skin Diseases Program Director
National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases
National Institutes of Health
Westwood Building Room 405
Bethesda, Maryland 20205

Telephone: (301) 496-7326

ANNOUNCEMENT

ADOLESCENCE RESEARCH

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

I. BACKGROUND

The National Institute of Child Health and Human Development (NICHD) supports and conducts research to improve the health and well-being of the developing infant and child and to prevent conditions that have their origins early in life and may lead to adult disabilities and early death. The events of pregnancy (especially during adolescence), labor, and birth present some of the greatest opportunities for intervention that can prevent many of these disabilities. Adolescence is also a time in human development when profound physical and behavioral changes are taking place. The NICHD, therefore, has a major interest in supporting fundamental research related to biomedical and behavioral aspects of adolescence. The Institute provides this support through two extramural research centers: the Center for Research for Mothers and Children and the Center for Population Research.

II. CENTER FOR RESEARCH FOR MOTHERS AND CHILDREN: RESEARCH GOALS AND SCOPE

The Center for Research for Mothers and Children (CRMC) through two of its extramural branches, supports research concerning adolescence:

The Clinical Nutrition and Early Development Branch (CNED) is concerned with the special nutritional requirements of the adolescent and those factors related to food choice and obesity. The CNED is also concerned with pregnancy during adolescence, particularly in those under sixteen years.

The Human Learning and Behavior Branch (HLB) is concerned with the biobehavioral, cognitive, social and affective development of normal adolescents and those factors which may interfere with normal development.

This program is supported under Title III, Section 301 and Title IV, Section 441 (Public Law 78-410, as amended: 42 USC 241). The Catalog of Federal Domestic Assistance numbers are 18.865, Research for Mothers and Children and 13.864, Population Research. Awards will be administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. These programs are not subject to A-95 Clearinghouse or Health Systems Agency review.

The National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH) are announcing their interest in supporting research on adolescence. Accepted referral guidelines will be followed in assigning applications. Although the missions of these Institutes are different, some research projects could appropriately receive support from either organization. Dual assignment of such applications is intended to assure that projects of the highest quality are able to be supported.

A. Adolescent Nutrition

Adolescence is a time of profound transformation. Growth rates are exceeded only by those occurring during fetal life and early infancy. Assessment of nutritional status is particularly difficult during this period with food patterns often erratic. The following represent some research areas of special interest to NICHD:

1. Definition of nutrient requirements associated with the adolescent growth spurt and the onset of puberty.

2. Development of new methods and validation of existing methods for assessing nutritional status that are particularly applicable to adolescence.

3. Elucidation of the cognitive, emotional, and social processes involved in food choices by adolescents. Attention needs to be focused on the regulation of food intake and the effect of external environmental cues on eating behavior.

4. Investigation of exercise and energy balance as these contribute to the development of obesity during adolescence as well as studies of potential and undesirable health effects of weight reduction regimens on the obese young adolescent still undergoing physiologic maturation.

5. Exploration of the psychological and cultural determinants of adolescent obesity. Studies are encouraged leading to techniques for modifying eating behavior and stimulating obese adolescents to lead more active, healthful life styles.

B. Adolescent Pregnancy

Pregnancy during adolescence, particularly in those under sixteen years of age, impose additional stress on a young woman still undergoing maturation. The following require research attention:

1. Investigation of short-term and long-term biomedical sequalae in the mother of uncomplicated pregnancy in early adolescence.

2. Identification of quantifiable indicators of adolescent maternal and fetal health at various times during pregnancy in order to improve prenatal care, particularly in the highest risk populations.

3. Definition of energy and nutrient demands of lactation superimposed on the growth process in the young adolescent mother in terms of health and development of both mother and child.

4. Exploration of physiologic and metabolic differences between pregnancy as well as non-pregnant young adolescents and older gravidas, including the disposition and action of pharmacologic agents such as ethanol and nicotine, as well as other agents used therapeutically.

For further information about the research support activities related to adolescent nutrition and pregnancy you may contact:

Dr. Merrill S. Read, Chief
Clinical Nutrition and Early Development Branch
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development
National Institutes of Health
Bethesda, Maryland 20205
(301) 496-5575

C. Adolescent Biobehavioral Development

The following areas of research are of major interest:

1. The relationships between alterations in hormone levels and behavioral development during adolescence. Development variables may include gender-role identity, mood, patterns of peer and social interaction and cognition.

2. Electrophysiological studies of brain development during adolescence in relation to cognition, maturation of language and perception. Of particular interest are studies of brain laterality and the normative development of cognition, thinking, memory, perception, and learning.

3. Studies of the effects of rapid changes in physical growth (height, weight, secondary sexual characteristics, muscular development and coordination, etc.) on the development of self-concept in adolescent boys and girls. Of particular interest is the role played by menarche in adolescent females in their development of self-concept and gender-role.

D. Adolescent Cognitive Development

The following areas of research are of major interest:

1. Changes in cognitive style.
2. Changes in thinking styles.
3. Changes in language ability.
4. Changes in reasoning ability.
5. Changes in memory capacity.

E. Adolescent Social and Affective Development

The following areas of research are of major interest:

1. Changes in relationships within the family (parents, siblings), and outside the family, including other adults and peers.

2. Personality development including changes in the adolescent's concept of self from that of immaturity and dependence to a sense of competence, self-regard, autonomy, and the assumption of adult roles (including work and career orientations).

3. Differences related to sex-role behavior and identity, reflecting differing adolescent experiences and expectations between males and females.

4. The nature of the adolescent period, the critical events during that period, and the development of competency in handling such events.

5. Antecedent conditions that lead to risk-taking behaviors.

6. Antecedent conditions that lead to prosocial behaviors, e.g., affiliation, nurturance, generosity, and sharing.

For further information about the research support activities described above you may contact:

Dr. Norman Krasnegor, Chief
Human Learning and Behavior Branch
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-6591

III. CENTER FOR POPULATION RESEARCH: RESEARCH GOALS AND SCOPE

The Center for Population Research has a long-standing and continuing interest in the demographic, psychological, economic, social, and other antecedents and consequences of fertility. The Center has funded research in such areas as fertility regulation and family planning, fertility trends, childbearing patterns, female employment and fertility, adolescent pregnancy and fertility, and consequences of family size.

The Social and Behavioral Sciences Branch of the Center for Population Research is calling attention to a number of important fields in which there has been relatively little research. The areas thus targeted as in need of research include:

A. Antecedents of Risking Unintended Pregnancies

B. Consequences of Pregnancy Losses for Adolescents

C. Adolescent Childbearing and the Family

D. Prevention of Adolescent Pregnancy

The following program announcements have the purpose of encouraging the submission of research grant applications in these designated research areas.

A. Antecedents of Risking Unintended Pregnancies

Even though the use of methods of fertility regulation has increased, the incidence of unprotected intercourse remains fairly high. A large number of

unintended pregnancies, especially among adolescents, continues to occur. Numerous investigators have attempted to discover the factors involved in unintended pregnancies. However, available data on the reasons for unintended pregnancies are fragmentary, few in-depth studies have been conducted, and some important segments of the population have received relatively little attention.

Studies in this area tend to be descriptive and unsystematic, rather than based on comprehensive theoretical and conceptual frameworks, substantiated by empirical evidence. Research is needed that focuses on the antecedents of unprotected sexual relations, thereby elucidating the factors associated with and contributing to the non-use or infrequent use of fertility regulating methods. In developing research design and methodology, attention should be given to why past studies may not have produced sufficiently definitive results.

What are the relative strengths of biological demographic, psychological, social cultural, economic, and other factors that interact as antecedents of the unprotected sexual relations of married and unmarried males and females? Examples of such factors include age, sex, ethnicity, race, educational attainments, occupation, marital status, socioeconomic status, biological development, psychological characteristics (developmental level, maturity, personality, attitudes, motivations, planfulness, etc.), personal/social relationships (with partners, parents, peers, etc.), knowledge of and attitudes toward sex and reproduction, knowledge of and attitudes toward fertility regulating methods and service providers (physicians, clinic staffs, etc.), pregnancy and abortion history, living situations and conditions, and life events.

It may be beneficial to the research to include a conceptual model based on theories in such relevant areas as motivation, decision-making, risk-taking, and cognition. In-depth approaches and innovative designs may contribute to the empirical testing of such a conceptual model focusing on unprotected sexual relations.

Care should be taken to develop efficient and cost-effective research designs. Familiarity with the literature on the antecedents of unprotected sexual relations, including relevant theories and empirical studies, should be demonstrated.

One objective of the research should be to develop findings and test theories and implications for the prevention of unintended pregnancies. Both scientific understanding and practical application may be advanced by approaches that would attempt to develop group and individual profiles of persons with high probability of (a) risking unintended pregnancies, (b) abstaining from sexual relations, or (c) using effective contraception.

B. Consequences of Pregnancy Losses for Adolescents

Adolescents experience about 500,000 pregnancy losses per year, of which approximately 400,000 are induced abortions, and about 100,000 are miscarriages. Considerable research has been done on the consequences of abortion for women who are beyond adolescence. However, there is a paucity of research on the psychological, social, health, and other consequences of abortions for adolescents, and there is practically no research on the consequences of miscarriages for adolescents. In-depth research on these

problems is needed because important differences between adolescents and adults may contribute significantly to differential consequences of pregnancy losses. For example, adults and adolescents differ in biological, psychological, social, and educational maturity. Also there are differences in such factors as life-style and degree of independence, as well as in relationships with parents, other family members, sexual partners, peers, friends, and service providers.

How do various relevant factors interact to contribute to the psychological, social, health and other consequences of pregnancy losses for adolescents, including subsequent sexual and fertility regulating behavior. Factors which may be considered include age, race, ethnicity, educational status, level of development and maturity (biological, psychological, social), personal/social relationships (with parents, partners, peers, etc.), service providers (physicians, clinic staffs, etc.), religion, socioeconomic status, pregnancy and abortion history, use of fertility regulating methods, length of time following abortions and or miscarriages, and life events following abortions and/or miscarriages, and life events following abortions and/or miscarriages (living with parents, marriage, dropping out of school, obtaining employment, etc.). The effect of the pregnancy loss on the male partner is also of interest.

The identification of appropriate comparison groups for adolescents who obtain abortions or have miscarriages is a major problem of the research design, which requires special consideration and innovative approaches. The research design should include a conceptual model of the interrelationships among factors assumed to affect the consequences of pregnancy losses for adolescents. Careful selection of variables and samples within a well-defined conceptual framework should contribute to the development of efficient and cost-effective designs.

An understanding of the consequences of pregnancy losses should provide adolescents with better bases for making decisions about engaging in sexual relations, using contraception, and resolving unintended pregnancies. Such knowledge and understanding should also be of value to parents, counselors, physicians, teachers, and others who make important contributions to adolescent decision-making.

C. Adolescent Childbearing and the Family

Considerable research has addressed the effects of early childbearing on the young mothers involved and on their offspring. However, less attention has been paid to the effects on young fathers and the extended families involved. Similarly, research on the antecedents of early sexual, contraceptive, and fertility-related behavior has focused largely on the characteristics of the young woman, less on the male or the partner relationship, and least on the role of the adolescents' families. This announcement focuses on the role of the adolescents' family in influencing fertility-related behavior and the effects of that behavior on the family. Current research suggests that the families of adolescent parents, especially unmarried mothers, are heavily involved in the consequences of her birth. The grandmother may become a major care-giver for the baby, and the family may provide room and board or direct financial support. It appears that family involvement is beneficial for the adolescent mother, often enabling her to return to school, a key to future economic well-being. Also children of

adolescent mothers appear to benefit from the involvement of another adult, especially an experienced care-giver. There is, however, no comprehensive picture of the social, economic, emotional and other effects of adolescent childbearing on the family. Is the grandmother likely to drop out of the labor force to care for the infant or is she likely to enter the labor force to help defray additional costs? Are there economic impacts for other family members? Does the parental family benefit from the experience of helping to rear the adolescent's baby or does such involvement introduce special strains into the grandparents' marital relationship, the parent-child relationships, or relationships among siblings? There is also interest in research on the role of the family as an antecedent of adolescent sexual and fertility-related behaviors. The likelihood of an adolescent engaging in sexual relationships appears to depend, in part, on family structure, religion, socioeconomic status, educational aspirations and other factors heavily influenced by the attitudes, values and behaviors of parents.

The research design should include a conceptual model of the interrelationships among factors associated with adolescent behavior and the role of the family. Careful selection of variables and samples within a well-defined conceptual framework should contribute to the development of efficient and cost-effective designs.

D. Prevention of Adolescent Pregnancy

There are approximately a million teenage pregnancies a year, of which about seventy-five percent are unintended. There are indications that these figures will increase unless ways are found to prevent the pregnancies. A major determinant of future trends is the continuing increase of sexual activity among unmarried adolescents with the majority of these sexually active teenagers either never practicing contraception or practicing it inconsistently.

Basic, non-operational research is needed to develop theories and evidence upon which attempts to prevent adolescent pregnancies may be based. A major aim of such research is the development of theory and data bases regarding the malleability of behavior in these areas. While much can be done in the area of teen fertility regarding program evaluation, that is not the goal of this announcement. The goal here is to support basic research on the factors associated with adolescent pregnancies, the likelihood that behavior can be modified, and the circumstances under which it can be changed.

Hypotheses concerning the modification of adolescent fertility-related behavior could be tested in research with clear and direct implications for initiating or developing practicable, feasible and balanced approaches to preventing adolescent pregnancies. The formulation of hypotheses could be based on analyses of the literature concerning determinants and consequences of adolescent pregnancies. However, fruitful leads may also be discovered by analyzing selected literature on relevant aspects of adolescent development and behavior.

What are the characteristics and behavior of adolescents to which attention should be given when attempting to develop theories and findings upon which approaches to the prevention of pregnancy might be based? Examples of such

characteristics and behavior include developmental level (biological, psychological, social, etc.), age, sex, race/ethnicity, socioeconomic status, education, religion, motivation, attitudes, personality, emotion, values, morals, knowledge, learning and congnitive skills, and decision-making.

What are the life experiences, situations, or activities that may influence adolescent behavior and characteristics toward the prevention of pregnancies? Examples include educational activities (sex, health, parental, and other kinds of education), socialization processes (peer, family, community, etc.), counseling (individual, group, etc.), contraceptive practices, kinds and accessibility of service-providers, religion, and couple relationships.

Investigators may study the role of one or two factors in the prevention of pregnancy. However, since pregnancy prevention is a multifaceted problem, investigators may also study the implications of a number of interacting factors for feasible pregnancy prevention activities. Investigators may use interdisciplinary or disciplinary approaches to the problems of pregnancy prevention.

There is need for ingenious and innovative research designs that will make it possible to compare and evaluate the roles which one or more factors may play in the prevention of pregnancy. Innovative designs may be able to accomplish the objectives with relatively small-scale studies in which there has been careful selection of variables and study participants with a well-developed conceptual framework. Investigators may be able to locate existing situations which can be subjected to meaningful, comparative analyses. These suggestions are not intended to limit research designs or the scale of the studies, but to request that careful attention be paid to developing efficient, cost-effective designs. Research must be planned with the aim of developing theories and findings with implications for feasible, workable approaches to preventing pregnancy.

Correspondence, including request for advice on further development of applications in any of the areas targeted by the Center for Population Research as needing research, should be directed to:

Dr. Sidney H. Newman
Social and Behavioral Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building, Room 7C25
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1174

IV. MECHANISMS OF SUPPORT

A variety of mechanisms are available for obtaining grant support under this program:

1. The research project grant, the traditional NICHD research support mechanism;

2. The New Investigator Research Award, a mechanism described in the NIH Guide for Grants and Contracts Volume 9, No. 1, January 3, 1980; and

3. The program project grant, a mechanism available for multidisciplinary research involving at least three projects with a common focus.

V. CRITERIA FOR REVIEW

Applications compete on the basis of relative scientific merit with all grant applications before the NICHD. They are formally reviewed by NIH peer review groups and by the NICHD National Advisory Council. The number of awards made will reflect both relative merit and the availability of grant funds. Some applications reflect overlapping interests of more than one Institute for funding purposes. The criteria for review are the traditional considerations underlying scientific merit which include adequacy and appropriateness of the approach; training, experience, and research competence or promise of the investigator(s); the adequacy of the research design; the suitability of the facility; and the appropriateness of the requested budget relative to the work proposed.

VI. METHOD OF APPLYING

Applicants are asked to notify the NICHD representative at least one month prior to formal submission of an application. Include name of principal investigator, institutional address, title of application, and abstract of the proposed research. Indicate that the application is in response to this announcement.

For research projects and New Investigator Research Awards, use form PHS 398 (Revised 5/80). If your institution does not have these, copies may be obtained from:

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

Telephone: (301) 496-7441

Information concerning program project grants and how to apply can be obtained from SBSB staff.

After you have completed the application, expedite its routing within NIH by:

1. Checking the box, item 2, on the application form indicating that your proposal is in response to this announcement: NICHD ADOLESCENCE RESEARCH. Indicate also the Center and the topic to which the application is addressed.

2. Attaching a cover letter repeating that this application is in response to the announcement: NICHD ADOLESCENCE RESEARCH.

Forward application and cover letter to:

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

Receipt dates for research project grants and New Investigator Research Award applications are: July 1, November 1, and March 1; receipt dates for the program project grant: June 1, October 1, and February 1.

ANNOUNCEMENT

RESEARCH ON STRESS REACTIVITY IN ADOLESCENCE

**NATIONAL INSTITUTE OF MENTAL HEALTH
(ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION,
PUBLIC HEALTH SERVICE)**

Subject to availability of funds, applications for mental health research grants will be accepted by NIMH under receipt dates indicated herein.

I. PURPOSE

This is a request for research grant applications to increase our knowledge of the mechanisms and conditions of stress reactivity in adolescence.

Research on both adolescence and stress is part of a continuing concern of the National Institute of Mental Health. However, we need to specify the mechanisms and conditions of stress reactivity in adolescence that influence mental health or illness. The goal of the National Institute of Mental Health in issuing this announcement is to encourage basic and applied adaptational coping in adolescence.

II. BACKGROUND

Adolescence is the only age group in the country in which the death rate is rising. Improved health measures have prolonged the life of the elderly and have increased survival in early childhood, but teenagers are dying in increasing numbers due to suicide, homicide, drug abuse, and alcohol-related automobile accidents. High rates of teenage pregnancy and juvenile crime are problems acknowledged by society while many parents are concerned about the prolonged and painful transition of their own children into adult roles.

Many of these problems are the concerns of agencies other than the National Institute of Mental Health. Our specific interest is in the stress and turmoil which may be implicated in the etiology of mental, emotional and behavioral disorders.*

Under authority of Section 301 of the Public Health Service Act, as amended, P.L. 78-410, 42 U.S.C. 241 (42 CFR Part 52), the National Institute of Mental Health (NIMH) is accepting applications for research grants for the support of research on stress reactivity in adolescence. This program is described in the Catalog of Federal Domestic Assistance No. 13.242, Mental Health Research, 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.

* The National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH) are announcing their interest in supporting research on adolescence. Accepted referral guidelines will be followed in assigning applications. Although the missions of these Institutes are different, some research projects could appropriately receive support from either organization. Dual assignment of such applications is intended to assure that projects of the highest quality are able to be supported.

While the past portrayal of adolescence carried too heavy an emphasis on turmoil and maladaption, current studies support a more benign view of "normative crisis" in which the adolescent process is seen as difficult but normal. This is not to say that all adolescents have a difficult time. But many do because adolescence is a period of extraordinary change, multiple conflicts, and marked societal demands upon the individual.

On the side of change, there are the hormonal, physiologic, and somatic changes reflected in pubertal development. Equally important psychological changes are spurred on by this rapid physical development, or perhaps occur concomitantly and interact with it. Cognitive changes during this period, including formal logic, may account for some of the shifts that take place. Among the psychosocial demands induced by puberty are: a heightened sexuality, the growth of peer attachments, a striving to achieve autonomy from and to reduce dependency on parents, the assumption of specific gender roles, and a heightened search for personal identity.

These multiple changes can be viewed as stressors in the sense that they entail significant adaptation needed to restore a sense of homeostasis to the individual.

III. SPECIFIC AREAS OF INTEREST

In order to improve our ability to understand, treat, and prevent mental, emotional, and behavioral disorders, we are interested in increasing our knowledge about stress from a developmental perspective. There are complex interactions that occur among biological, cognitive, affective, and behavioral aspects within the individual as well as between any of these aspects and features of the external environment. Furthermore, this process involves reciprocal influences between aspects. Proposals may involve interdisciplinary research approaches between biological, cognitive, affective, and behavioral aspects of stress, as well as between any of these aspects and the environment.

The timing of developmental changes, the extent of preparation for the changes, individual vulnerability, and social supports all serve to mediate the effects of developmental stress in adolescence. These same mediators operate not only with normative developmental stressors but with unpredictable stressors as well.

The developmental tasks of adolescence can be associated with normative stresses that have intrapsychic or environmental origins. The stressors trigger a range of responses that vary from adaptive to maladaptive. The responses can be mediated by psychosocial and/or physiological mechanisms. What are the relationships between the normative stressors of adolescence, coping mechanisms, and adaptive and maladaptive responses? How are defense mechanisms utilized to effectively channel intense affects? How are disruptive arousal states avoided? What are the factors that lead to the failure of defensive operations?

Many researchable issues fall within the realm of stress reactivity in adolescence. It should especially be noted that in speaking of stress reactivity, we are speaking of functional as well as dysfunctional reactions to stress and we would like to know how some adolescents cope in spite of great obstacles or handicaps.

The following are offered as illustrations of appropriate topics, but applications need not be limited to these issues:

Biological Development

Puberty involves dramatic internal endocrine changes as well as dramatic external physical changes. What are the important psychological changes spurred by this development and how do they affect stress reactivity? How are such stresses mediated? What are characteristic relationships between stressors, physiological mechanisms, and maladaptive behavior? How can neuroendocrine responses to stress facilitate adaptation in adolescence?

Cognitive Development

Young people develop the capacity to think about thinking during the adolescent years. Does cognitive change amplify the stress of adolescence or does it facilitate coping?

Peer Relations

What are the functions and costs of peer conformity in relationship to normative stresses during adolescence?

Parents

Relationships with parents change during adolescence. The transition in the nature of the adolescent/parent relationship may proceed smoothly or it may be very difficult. Under what circumstances do the changes of this perioc create stress and under what circumstances do parental relationships help modulate stress?

Preparation for Change

The extent of preparation for the changes of adolescence tends to mediate the effects of developmental stress. The adolescent must observe situational cues; understand the meaning of situational demands in relation to individual, familial, peer, and societal values; define and select from alternative plans of action; and finally to consummate plans. What developmental limitations increase the stress of negotiating these tasks?

In addition to the above substantive topics, methodological projects which promise new understanding of the complex processes which influence adolescent stress reactivity will be considered. The employment of pre-existing data sets and their secondary analysis is encouraged provided they meet all the criteria of scientific merit.

IV. ELIGIBILITY REQUIREMENTS

Grants may be made to public or private nonprofit or for-profit institutions, organizations, qualified Federal entities, state or local governments and their agencies.

V. FUNDING AND TERMS AND CONDITIONS OF SUPPORT

Funds estimated at one million dollars per year are available to support applications submitted in response to this announcement.

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 the research project, and must be expended in conformance with DHHS cost principles, the Public Health Service Grants Policy Statement, applicable Federal regulations, and conditions set forth in 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. The maximum initial period of grant support will, in general, be limited to three years. Applications will undergo full review and compete for available funds with other approved projects.

VI. APPLICATION PROCEDURES

Applicants should use form PHS 398 (Rev. 5/80). State and local government agencies should use form PHS 5161. Form PHS 398 can ordinarily be obtained from the Office of Sponsored Programs of a university. Both application kits are also available from the following:

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

Telephone: (301) 443-4414

Instructions for applicants are included in the kit. The phrase, "STRESS REACTIVITY IN ADOLESCENCE" should be entered in item 2 on the face page of the application.

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

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

VII. CONTACT OFFICE

Investigators considering submitting an application in response to this program announcement are strongly encouraged to discuss their project with NIMH staff in advance of formal submission. This can be done either through a telephone conversation or through a written and brief (4-5 pages) research prospectus. For further information, investigators are encouraged to contact:

Sigmund E. Dragastin, Ph.D.
Chief, Personality and Emotional Processes
and Problems Section
Behavioral Sciences Research Branch
National Institutes of Mental Health
Parklawn Building Room 10C-09
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-3942

VIII. RECEIPT AND REVIEW SCHEDULE

Applications will be accepted under an initial receipt date of July 1, 1982. Applications received by that date will receive initial scientific review in October-November 1982, and review by the National Advisory Mental Health Council in February 1983, with possible funding by April 1983. The initial and subsequent receipt dates are:

Receipt Date	Initial Review	Council Review	Earliest Award Date
July 1	Oct. - Nov.	February	April
November 1	Feb. - March	May	July
March 1	June	September	November

IX. REVIEW PROCEDURES AND CRITERIA

Applications submitted in response to this announcement will be reviewed in accordance with the usual Public Health Service peer review procedures for research grants. They will be reviewed first for scientific and technical merit by a review group composed primarily of non-Federal scientific consultants (Initial Review Group) and then by the National Advisory Mental Health Council. Only those applications recommended for approval by Council will be considered for funding.

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

- Scientific and technical merit of the research design, approach, and methodology.
- Originality and appropriateness of the conceptualization of the research.
- Potential contribution of the research to the field.
- Qualifications and experiences of the principal investigator and proposed staff.
- Availability of resources necessary to the research.
- Reasonableness of the proposed budget in terms of the research proposal.

X. AWARD CRITERIA

Award decisions will be based on scientific merit as judged by initial review committee and Council and on the potential of the research for contributing to our understanding of the etiology, treatment or prevention of mental and behavioral disorders.

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