NIH GUIDE for GRANTS and CONTRACTS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Vol. 8, No. 5, April 13, 1979

IN THIS ISSUE:

(over)

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 20014, 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.*

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

IN THIS ISSUE: (continued)

NIH's AND ADAMHA's SCHEDULE FOR CONVERSION FROM THE CATEGORICAL REPORTS OF EXPENDITURE TO FINANCIAL STATUS REPORTS

PROCEDURE NOTICE

As a result of DHEW's implementation of OMB Circular A-110 by means of Code of Federal Regulations 45, Part 74, the NIH and ADAMHA will make the transition from a detailed categorical Report of Expenditures format to the noncategorical Financial Status Report prescribed in Part 74.

The new expenditure form (Standard Form 269) for which the PHS approved version is designated as PHS 5154 (see attachment) will be used to report on all budget periods whose start dates were October 1, 1978, and thereafter.

For NIH programs, the mailing, receipt, and initial processing of Financial Status Reports will continue to be the responsibility of the Federal Assistance Accounting Branch, Division of Financial Management, as it has done for other expenditures reports utilized by NIH. In addition, FAAB will stock and supply copies of the Financial Status Report for all users.

Awarding unit staff will receive Financial Status Reports after initial processing by the Division of Financial Management. Although these reports will contain financial information limited essentially to total expenditures and unobligated balances, awarding unit staff will continue to exercise their usual options with respect to the disposition of balances (i.e., carryover to a subsequent budget period as additional income or offset against a current or future award as partial payment). In addition, awarding unit staff will continue to observe the procedures set forth under the Procedure Notice entitled "Research Grant Award Adjustments Related to the Estimated and Actual Unexpended and Unobligated Grant Balances," which appeared in the *NIH Guide for Grants and Contracts*, Vol. 1, No. 6, p. 5, April 26, 1971.

Expenditures reporting for all grants awarded prior to FY 1979 are subject to the terms and conditions in effect at time of award; therefore, reports for budget periods which were effective prior to October 1, 1978, will account for expenditures utilizing the forms required at the time of their issuance. Any subsequent noncompeting continuation award or competing renewal is subject to the Financial Status Report. Supplemental awards (Type 3s) are considered to have the same inclusive dates as the parent grant for purposes of reporting.

Financial Status Reports are due within 90 days following completion of a budget period. All existing requirements regarding the obtaining of delinquent reports, withholding awards in the absence of required reports, and the submission and acceptance of revised expenditures reports continue to pertain.

OMB NO. 80-R0180

FINANCIAL STATUS REPORT

1. Federal Agency and Organizational Element	2. Federal Grant No. or Other Identifying No.

3. Name and Address of Grantee Organization	4. Employer Identification No.	5. Grantee Account No. or Identifying No.	6. Final Report ☐ Yes ☐ No	7. Basis of Report ☐ Cash ☐ Accrued Expenditures

8. Project Period (Month, Day, Year) FROM	TO	9. Report Period (Month, Day, Year) FROM	TO

10. STATUS OF FUNDS	PROGRAMS – FUNCTIONS – ACTIVITIES (1)	(2)	(3)	(4)	(5)	(6)	TOTAL
a. Total outlays previously reported							
b. Total program outlays this period							
c. Less: Program income credits							
d. Net program outlays this period							
e. Total program outlays to date							
f. Less: Non-Federal share of program outlays							
g. Total Federal share of program outlays							
h. Total unpaid obligations							
i. Less: Non-Federal share of unpaid obligations							
j. Federal share of unpaid obligations							
k. Total Federal share of outlays and unpaid obligations							
l. Total Federal funds authorized							
m. Unobligated balance of Federal funds							

11. Indirect Expense: a. Type of rate (Mark box) ☐ Provisional ☐ Final ☐ Predetermined ☐ Fixed	12. REMARKS (Attach additional sheets if necessary)	13. CERTIFICATION – I certify that to the best of my knowledge and belief this report is correct and complete and that all outlays and unpaid obligations are for the purposes set forth in the grant award documents.
b. Rate / c. Base		Name / Title / TELEPHONE (Area Code, Number, Ext.)
d. Total amount / e. Federal share		Signature of Authorized Official / Date Report is Submitted

PHS 5154 (8-73)

ATTACHMENT

INSTRUCTIONS FOR PREPARING THE FINANCIAL STATUS REPORT

Item 1 – Enter the name of the Federal grantor agency and organizational element to which this report is submitted.

Item 2 – Enter the grant number or other identifying number assigned by the Federal grantor agency.

Item 3 – Enter the name and complete mailing address, including the ZIP code for the grantee organization.

Item 4 – Enter the employer identification number assigned by the U.S. Internal Revenue Service.

Item 5 – This space is reserved for an account number or other identifying numbers which may be assigned by the grantee.

Items 6 and 7 – Mark the appropriate boxes.

Item 8 – Enter the month, day, and year of the beginning and ending of this project period. For formula grants which are not awarded on a project basis, show the grant period.

Item 9 – Enter the month, day, and year of the beginning and ending dates of the period for which this report is prepared. The frequency of the report will be established by the Federal grantor agency.

PLEASE READ BEFORE COMPLETING ITEM 10 – The purpose of vertical Columns (1) through (6) is to provide financial data for each program, function, and activity in the budget as approved by the Federal grantor agency. If additional columns are needed, use as many additional forms as needed and mark *"continuation"* on each form; however, the summary totals of all programs, functions or activities should be shown in the *"total"* Column on the first page.

For grants pertaining to a single Federal grant program (catalog number) or several grant programs which do not require a functional or activity classification, enter under Columns (1) through (6) the title of the program(s). For grants pertaining to 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 separate columns. For grants 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 grantor agency.

Item 10 – STATUS OF FUNDS

Line a. Enter the total outlays reported on Line 10e of the last report. Show zero, if this is the initial report.

Line b. Enter the total gross program outlays for this report period, including disbursements of cash realized as program income. For reports which 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 grantee for goods and other property received and for services performed by employees, contractors, subgrantees, and other payees.

Line c. Enter the amount of all program income realized in this period which is to be used in the project or program in accordance with the terms of the grant. 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 the net increase (or decrease) in the amount of accrued income since the beginning of the report period.

Line d. This amount should be the difference between amounts shown on Lines b and c.

Line e. Enter the sum of amounts shown on Lines a and d above.

Line f. Enter the amount pertaining to the non-Federal share of program outlays included in the amount on Line e.

Line g. Enter the Federal share of program outlays. The amount should be the difference between Lines e and f.

Line h. When the report is prepared on a cash basis, enter the total amount of unpaid obligations for this project or program including unpaid obligations to subgrantees. If the report is prepared on an accrued expenditure basis, enter the amount of undelivered orders and other outstanding obligations. 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.

Line i. Enter the non-Federal share of unpaid obligations shown on Line h.

Line j. Enter the Federal share of unpaid obligations shown on Line h. The amount shown on this line should be the difference between the amounts on Lines h and i.

Line k. Enter the sum of the amounts shown on Lines g and j. If the report is final, the report should not contain any unpaid obligations.

Item l. Enter the total cumulative amount of Federal funds authorized.

Line m. Enter the unobligated balance of Federal funds. This amount should be the difference between Lines k and l.

Item 11 – INDIRECT EXPENSE

a. Type of rate – Mark the appropriate box.

b. Rate – Enter the rate in effect during the reporting period.

c. Base – Enter the amount of the base to which the rate was applied.

d. Total Amount – Enter the total amount of indirect cost charged during the report period.

e. Federal Share – Enter the 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 which shows the 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. (See Office of Management and Budget Circular No. A-87 which contains principles for determining allowable costs of grants and contracts with State and local governments.)

Item 12 – Space is provided for any explanation deemed necessary by the grantee or for the provision of information required by the Federal grantor agencies in compliance with the governing legislation.

Item 13 – Complete the certification before submitting this report.

GPO 862-664

CHANGE IN BASE FOR CALCULATING INDIRECT COSTS FOR TRAINING GRANTS

POLICY

PHS Grants Manual Chapter 6-160, Reimbursement of Indirect Costs on Training Grants, became effective on November 1, 1978. The policy changes the total allowable direct cost (TADC) base to which a rate of up to 8% is to be applied. Previously alterations, tuition, and patient care costs were excluded from the base. The new policy states:

> "The reimbursement of indirect costs under PHS training grants awarded to other than State and local government agencies will be limited to the lesser of the institution's actual indirect costs or 8% of total direct costs exclusive of tuition and related fees and expenditures for equipment."

PRINTING AND BINDING REQUISITIONS FROM GOVERNMENT GRANTEES

In a Circular Letter No. 151, dated September 6, 1978, the U.S. Government Printing Office announced that beginning October 1, 1978, the GPO will no longer accept printing and binding requisitions from Government grantees. Any grantee wishing to purchase government-related printing should ask its grantor agency to submit the requisition to the GPO. After performing the services, the GPO will bill the grantor agency directly and payment will be either by a Treasury check or by the SIBAC system.

NIH CONTRACT COMPLIANCE PROGRAM

The National Institutes of Health is responsible for the awarding of thousands of contracts each year to academic institutions, hospitals, medical research centers, and commercial firms. Many people in various occupational areas are employed through these federally funded contracts. Discrimination is prohibited according to Executive Order 11246, as amended, that states "No federally funded contractor can discriminate against any employee or applicant for employment because of race, creed, color, or national origin." In response to this directive and through authorization of the Public Health Service and DHEW, Office for Civil Rights, NIH, has developed a Contract Compliance Program in the Division of Contracts and Grants (DCG). The NIH is concerned that contractors with which it does business have an updated and approved Affirmative Action Program in employment, and affirmative action measures are taken to ensure that minorities and females receive equal opportunity.

The NIH began the implementation of the Contract Compliance Program on November 1, 1977. Contracting Officers and Contract Specialists are implementing the first phase of the program. During all negotiation site visits or negotiations held at NIH, the contractor will be asked to answer five questions concerning the Contractor's Affirmative Action Program. The questions will be asked of the contractor's authorized representative once a year at each geographical location:

1. Does the institution, organization, or corporation maintain an updated (yearly) Affirmative Action Plan (AAP) based on the requirements of Revised Order No. 4[1]? (Part 60-2)

2. Has any Federal Compliance Agency reviewed and approved the institution's, organization's, or corporation's AAP within the past year?

   Indicate date of most recent compliance review.

   (Date) _____

3. Has the institution's, organization's, or corporation's EEO policy been communicated internally to all units engaged in PHS contract activity?

   (Internal communication may involve meetings with supervisors and employees, training programs, personnel manual, company newspapers, magazines, and annual reports that include the company's Equal Employment Opportunity policy.)

4. Has the institution's, organization's, or corporation's EEO policy been disseminated externally?

   (External communication may involve recruiting sources, minority and women's organizations, secondary schools and colleges. Purchase orders, leases, and contracts that are covered by Executive Order 11246 should include the company's Equal Employment Opportunity policy.)

5. Does the AAP include goals and timetables for hiring minorities and women for the organizational units engaged in work on PHS contracts or subject contracts?

1/ Revised Order No. 4 requires each (non-State or local government institution) contractor with 50 or more employees and a contract in excess of $50,000 to develop and maintain a written AAP within 120 days of receipt of such a contract. Since most contractors have received previous Government contracts, they would be expected to have an AAP on file. For contracts where the company employs less than 50 employees, where the contract is under $50,000 but not less than $10,000, the contractor is not required to have an AAP on file; however, the contractor has the responsibility to comply with the equal opportunity requirements of Executive Order 11246.

NCI DIET, NUTRITION, AND CANCER PROGRAM ON NUTRITIONAL ASPECTS OF CANCER AND ITS ETIOLOGY/PREVENTION, TREATMENT, REHABILITATION, AND TRAINING AMENDMENT

Please refer to Vol. 7, No. 14, p. 2, of the *NIH Guide for Grants and Contracts*. The person to be contacted in the Division of Cancer Cause and Prevention regarding questions concerning diet and nutrition as they might relate to the etiology of cancer and the prevention of cancer is:

Donald H. Luecke, M.D.
National Cancer Institute
Room 8C18, Landow Building
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-9600

NOTICE OF PROPOSED RULEMAKING

The Department of Health, Education, and Welfare is proposing regulations to permit the debarment of organizations and individuals from eligibility to receive grants and other forms of financial assistance from the Department for any one of eight specific causes. A Notice of Proposed Rulemaking was published in the Federal Register, pages 16444-16449, Vol. 44, No. 54, on Monday, March 19, 1979. Comments from the public are sought, and should be received no later than May 18, 1979, addressed to Legal Advisor, NIH Office of the General Counsel, Room 2B50, Building 31, National Institutes of Health, Bethesda, Maryland 20205.

The proposed regulations provide Department-wide procedures with appropriate safeguards of due process for the debarment of organizations and individuals from receiving HEW grants or other forms of financial assistance in order to protect the Government's interest and assure public confidence in the Department's programs. Public comment is sought as to whether the proposed grounds for deferment are too broad in scope and whether the due process is considered to be adequate. Grantee institutions, organizations, and interested individuals are urged to review and provide comment on the proposed regulations.

GRANTS ASSOCIATES PROGRAM,

PUBLIC HEALTH SERVICE

ANNOUNCEMENT

Scientists interested in an administrative career with Federal programs supporting research, training, and services in health-related fields may wish to consider the Grants Associates Program of the U.S. Public Health Service. The program is governed by the Grants Associates Board and is administered by the Division of Research Grants, National Institutes of Health.

The program prepares each Grants Associate for a responsible position in health science administration in the Federal government. For a 12-month period, the Grants Associate participates in an individually structured training experience including on the job assignments, courses, and seminars. The program provides opportunities for participation in the development and administration of policies in Federal support of health related research, and in the fundamentals of effective management. The program also attempts to develop a sensitivity to the consequences of program decisions on other Federal health programs, research institutions, and national health needs.

Admission to the program is highly competitive for the few positions available. Motivation for a career in science administration, good interpersonal skills, and evidence of executive potential are important. If you are a U.S. citizen and hold a doctorate or equivalent in a discipline related to the biomedical or behavioral sciences, have significant independent research experience beyond the doctorate (but need not have administrative experience) and are attracted to health science administration as a profession, you should inquire about the Grants Associates Program.

Grants Associates may be appointed either in the U.S. Civil Service at grade levels General Schedule (GS) 12 ($23,087), GS-13 ($27,453), or GS-14 ($32,442) or in the Commissioned Corps of the U.S. Public Health Service at ranks beginning with senior grade (03 Lieutenant, salary dependent on prior military experience, but beginning at $15,798).

The National Institutes of Health does not discriminate in employment on grounds of race, color, sex, national origin, age, or handicap.

For further information, write to:

Executive Secretary
Office of Grants Associates
Division of Research Grants
Room 1A10, Building 31
National Institutes of Health
Bethesda, Maryland 20205

CLINICAL INVESTIGATOR AWARD,

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

ANNOUNCEMENT

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of clinical investigator awards. The clinical investigator award program is intended to:

- encourage newly train clinicians to develop clinical and basic research interests and skills in the areas of cardiovascular, pulmonary, or blood diseases and blood resources;

- increase the pool of physician investigators in the areas of cardiovascular, pulmonary, or blood diseases and blood resources.

These awards provide the opportunity for promising, clinically-trained physicians with a commitment to research to develop into independent biomedical research investigators.

The award, made to a suitable institution, will enable candidates to undertake up to five years of special study and supervised experience tailored to individual needs with a sponsor (or sponsors) competent to provide research guidance. This award is intended to cover the transition between postdoctoral experience and a career in independent investigation. The clinical investigator award differs from the NIH Research Career Development Award (RCDA) in that it seeks to develop research ability in individuals with a clinical background very early in the candidate's career rather than to promote the further development of research skills of individuals already demonstrating significant research achievement.

BACKGROUND

Despite a recent decline in the death rate from coronary heart disease, cardiovascular disease continues to be the number one killer in the United States. Arteriosclerosis and hypertension account for almost one million deaths annually. An estimated 30 million Americans have diseases of the heart and blood vessels, resulting in a large burden of acute and chronic illness and disability. Heart and blood vessel diseases cost the economy more than $50 billion per year in wages, lost productivity, and expenses for medical care.

Diseases of the lung constitute a major national health problem. An estimated 10 million Americans, both young and old, are currently affected by these diseases with an annual estimated cost to the nation of over $17 billion. In the newborn, the most common cause of death is neonatal

respiratory distress syndrome. Neonatal RDS is implicated in the development of adult respiratory diseases as well. Fibrotic and immunologic lung diseases are major causes of lung problems in the young adult and may cause chronic obstructive pulmonary diseases. Of the adult respiratory diseases, emphysema and chronic bronchitis are the major causes of death.

Together with asthma, emphysema and chronic bronchitis represent particularly pressing health problems, since the death rate and prevalence of these conditions have increased at an alarming rate over the past 15 years. As a disabling disease, emphysema is the third leading cause of worker retirement on Social Security disability payments.

Blood and clotting disorders underlie or are major contributors to many disease processes and, as a consequence, are major causes of death and disability in the United States. No valid estimate of their adverse economic impact can be realistically made, since disorders of the blood not only affect the blood itself, but all of the organs and tissues through which it flows. Similarly, when estimating the economic consequences of an inadequate blood resource system, quantitative figures are difficult to determine, since the supply and management of blood and blood products underlie much routine and emergency medical practice. Small but significant segments of the population have Sickle Cell Disease or other hemolytic diseases. The economic impact of these disorders is serious.

The clinical investigator award program is designed to encourage recently trained physicians to develop their clinical and basic research interests and capabilities in heart, lung, or blood disease areas. To help bridge the transition from clinical training status to that of a productive research investigator, this special grant program provides early support for clinicians with potential for developing into independent researchers.

IMPLEMENTATION

Beginning in Fiscal 1980, under the authorizations in Public Health Service Act, Section 301(c) and Section 413(a), the National Heart, Lung, and Blood Institute plans to fund new clinical investigator awards. Each grant will have a duration of five years. Funding beyond the first year of the grant will be contingent on satisfactory progress during the preceding year.

The status of the clinical investigator award program will be reviewed four years from the date of the first awards to determine whether the program should be continued. In addition, to assess the effectiveness of the program in fulfilling its objectives, the Institute intends, after completion of each grant, to follow the progress of the recipient for a period of five years to determine (1) the investigator's professional affiliation(s), (2) his/her record of subsequent grant or contract support, and (3) his/her record of scientific publications. It is anticipated that the experience and results achieved by the awardee from this special grant program, in the majority of cases, will provide the basis for successful competition in the regular research support programs of the Institute.

The first receipt date for applications will be October 1, 1979. They will be evaluated by an initial review group in November and by the National Heart, Lung, and Blood Advisory Council in February 1980. July 1, 1980, will be the earliest start date for successful applications.

Subsequent competitions will occur on a once-a-year basis.

PROVISIONS OF THE AWARD

The clinical investigator award is made for a maximum of five years. It is nonrenewable and nontransferable. Support is based on a full-time, twelve-month appointment. The awardee will be provided salary support of up to $25,000 in the first year with annual increases to a ceiling of $30,000, plus fringe benefits from NHLBI funds. The actual salary must be consistent with the established salary structure of the institution for persons of equivalent qualifications, experience, and rank.

Up to a total of $10,000 annually will be provided for supplies, equipment, travel, etc., which are necessary for pursuit of the awardee's research program. An appropriate sponsor must assume responsibility and provide guidance for the research development.

Institutions may apply for awards on behalf of named individuals meeting the criteria for this award. Evidence of the commitment of the institution to the candidate's research and development is to be included in the application.

The grant will be made annually to the awardee's parent institution for each of five budget periods. Costs allowed may include:

1. Awardee's Salary

   Up to a maximum of $25,000 in the first year with annual increases to a ceiling of $30,000 for full-time support. In addition, fringe benefits will be provided. Institutional supplementation is permitted.

2. Research Support

   Up to a maximum of $10,000 per year.

   - Equipment: specialized research equipment essential to the proposed program. The available facilities should should include most of the necessary equipment.
   - Supplies: consumable supplies essential to the proposed program.
   - Travel: domestic travel essential to the proposed program.
   - Tuition for training courses: if essential to the awardee's individual research development program.
   - Other: publication costs, patient costs, etc., necessary for the research program.

3. Indirect Costs

Funds will be provided for the reimbursement of actual indirect costs at a rate of up to, but not to exceed, 8 percent of the total direct costs of each award exclusive of tuition, fees, and expenditures for equipment.

ELIGIBILITY

1. The award is designed to provide intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health-professional degrees in the clinical sciences (M.D., D.O., or equivalent). Candidates ordinarily will have completed their clinical training with generally not less than three nor more than six years of total postdoctoral, clinical experience by the time an award can be made. It is expected that most candidates will have a minimum of two years of clinical experience after a year of internship. In exceptional circumstances, individuals with less than three years of such experience may apply, but must justify those special circumstances.

   Candidates should have broad clinical training, should demonstrate individual competence in clinical activities, and should show research potential in the chosen area of interest. Candidates must provide evidence of a serious intent for research and academic careers.

2. The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic departments, and commitment and capability to provide guidance to clinically oriented individuals in the development of independent research careers.

   Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for a research career. Evidence of the commitment of the institution to the candidate's research development must be provided.

3. Candidates must plan with an advisor, who should be a recognized and accomplished investigator in the field at the parent institution, a developmental and research program (which may involve travel to other institutions) in which the awardee will receive development and research experience in preparation for a future career of independent research. The candidate's proposed research development plans for the five-year period of the award must be described. The candidate must be prepared to commit full-time effort to the objectives of this award. It is expected that a minimum of 75 percent effort will be devoted to a research program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with program goals.

4. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of their third year of support. This report is to contain specific information concerning progress and accomplishments and, in particular, an appropriately detailed research plan and protocol.

5. Candidates must agree to inform the National Heart, Lung, and Blood Institute annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

6. Citizenship - Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.

APPLICATION

Applications must be submitted on form PHS 398 which is available at the grantee institution. The original and six copies of the application should be clearly labeled "NHLBI CLINICAL INVESTIGATOR AWARD PROGRAM."

The chairperson of the department sponsoring the candidate should submit a signed statement, as part of the application, detailing the commitment made to the candidate.

Completed grant applications should be mailed to:

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

Upon receipt of each application at NIH, a postal card acknowledging receipt will be mailed to the applicant.

The applicant should ask three present or former supervisors or preceptors to send a letter to the Review Branch, Division of Extramural Affairs, NHLBI, attesting to his/her potential for conducting independent research. The applicant is responsible for making necessary arrangements to ensure that the reference letters are mailed by the supervisors/preceptors directly to the Review Branch. (NIH staff will not be able to respond to individual inquiries concerning the receipt of these reference letters.)

Applications for the first competition for this award are due October 1, 1979. They will be considered at the February 1980 meeting of the National Heart, Lung, and Blood Advisory Council. The earliest start date for awards is July 1, 1980.

Subsequent competitions will occur on a once-a-year basis. Future receipt dates for applications will be October 1.

REVIEW CRITERIA

Applications for clinical investigator awards will undergo initial merit review in the Review Branch, Division of Extramural Affairs, NHLBI. Secondary review will be by the National Heart, Lung, and Blood Advisory Council. Criteria for review include:

- The candidate's potential for a career in independent research;
- The candidate's commitment to a research career;
- The overall merit of the candidate's five-year plan for development of research skills;
- The quality of the candidate's clinical training and experience;
- The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development;
- Presence of highly trained faculty in clinical and basic departments relative to the area of study; and
- The ability and plans of the sponsor (or sponsors) who will provide the candidate with the guidance necessary for career development in research.

NHLBI STAFF CONTACTS

Inquiries about the program or requests for additional instructions for application preparation should be directed to:

Manpower Officer
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Room 514A, Federal Building
Bethesda, Maryland 20205

Telephone: (301) 496-1817

Manpower Officer
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Room 3A-08, Federal Building
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Manpower Officer
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Room 6A05, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7668

Letters of reference and inquiries about review procedures should be directed to:

Centers and Special Projects Section
Review Branch, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Room 553, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7351

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

RESEARCH CENTER WITHOUT WALLS FOR

HUNTINGTON'S DISEASE

ANNOUNCEMENT

(Application receipt date not later than September 15, 1979)

The Neurological Disorders Program of the National Institute of Neurological and Communicative Disorders and Stroke invites grant applications to develop interdisciplinary Research Centers Without Walls for basic and clinical research on Huntington's disease and related disorders. The Research Center should function as a model in basic and clinical research, education, training, and information dissemination including research on services, treatment, and care of Huntington's disease patients.

This type of solicitation (the RFA) is utilized when the program wishes to stimulate investigator interest in a particular research area that is important to the Institute. Unlike the RFP (Request for Contract Proposals), the RFA identifies the scope of the program's interest but does not require that the proposal conform to specified research requirements. Moreover, the RFA is supported through the customary NIH grant-in-aid and is governed by the policies for regular research grants. However, the RFA solicitation represents a single competition with a specified deadline for receipt of applications. All applications in response to the RFA will be reviewed by the same initial review group.

The present announcement is for a single competition with a specified deadline of September 15, 1979, for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

I. BACKGROUND INFORMATION

Huntington's disease is an autosomal dominant disorder with complete penetrance. Although 10% of cases are children, the usual age of onset is between the ages of 35 to 45. There are no diagnostic tests which can determine the presence of the HD gene before symptom onset and treatment is palliative. Duration of illness is generally 12 to 20 years. The disorder produces profound disturbances in mood, movement, and intellectual functioning. Constant choreiform movements or rigidity, severe emotional distress involving hallucinations, delusions and suicidal depression, and dementia are hallmarks of the disease. Cardinal pathological features are neuronal cell loss and glial proliferation particularly in caudate nucleus and putamen, and the

of more sensitive psychological test batteries which can be used to test drug efficacy and to correlate meaningfully an array of neurological, neurochemical, and neurophysiologic findings.

- Research on the impact of genetic counseling including effects on reproductive behavior, social and emotional functioning, need for ongoing counseling, issues of confidentiality, and information comprehension and retention.

- Research on methods of psychological care for patients and families in managing the symptomatology of the disease and the profound stress imposed on all family members in coping with the illnesses.

- Research on ancillary therapies in providing improved treatment, such as rehabilitation programs, physical and speech therapy, patient and family self-care instructions, and other methods.

A Center would also be expected to serve in general most of the following functions:

- Collection of detailed clinical histories and full pedigrees, with special attention to diagnostic problems. These records should be maintained to form the basis of longitudinal studies of patients and persons at risk. Detailed and comprehensive clinical and genetic records are particularly valuable in validating potential presymptomatic tests and in evaluating research results based on pre- and post-mortem patient specimens. The confidentiality of records and the privacy of those participating in Center studies must be ensured.

- Training of both professional and paraprofessional personnel in techniques of research on neurodegenerative disorders, and on the treatment and counseling of patients, at-risk individuals, and other family members. The Center grant support would provide the facilities and environment in which training in research, treatment, and care would be carried out. Center funds cannot be used for trainee stipends. Other sources of support, such as the NIH National Research Service Awards, should be used for this purpose.

- Development and dissemination of educational materials on research findings and techniques and on model treatment.

The clinical facility would be expected to work closely with community agencies in developing programs in rehabilitation, counseling, and other forms of therapy. Community resources should also be developed

for intermediate and long-term care for patients. This might include developing a special relationship with a long-term care facility which would permit residents to participate in Center research if they choose. The community should assume responsibility for funding some of the clinical facility projects.

The research areas described above are not intended to be mandatory nor exhaustive. An interdisciplinary approach emphasizing comprehensive basic and clinical research studies is sought. Utilization of existing resources in a creative and innovative fashion is also encouraged.

The application must specify how cooperation and linkage among the component parts are to occur. The principal investigator applying for support of a Research Center must also give evidence of access to patients and the support of relevant clinicians and health voluntary agencies for the work of the Center.

III. MECHANISM OF SUPPORT

A. Grant-in-aid: Program Project

The mechanism of support for the Research Center(s) Without Walls will be the grant-in-aid, specifically the program project grant. Although this program is included in the financial plans for fiscal year 1980, awards of grants pursuant to this request for grant applications is contingent upon availability of funds. The current policies which govern the research grant programs of the National Institutes of Health will prevail.

B. Number of Centers

The Neurological Disorders Program expects one or possibly two Centers to be funded, depending on Center costs and excellence of applications.

C. Collaboration of two or more institutions: A Consortium Grant

If two or more institutions collaborate in the development and establishment of a Research Center Without Walls, only one application should be submitted. Participating investigators should apply for a consortium grant as described in the *NIH Guide for Grants and Contracts*, Vol. 7, No. 17, p. 9, November 10, 1978. A consortium grant is defined as "a grant to one institution in support of a research project in which any programmatic activity is carried out through a cooperative arrangement between or among the grantee institution and one or more institutions (profit or nonprofit) which are separate legal entities, administratively independent of the grantee. The involvement of the nongrantee (cooperating) institution is that of actually performing a portion of the programmatic activity as opposed to simply providing a routine service to the grantee such as equipment processing, or equipment fabrication."

D. Future reissuance

Future reissuance of this or a similar RFA is possible.

E. Coordination with NINCDS

Although the support mechanism for Research Centers Without Walls will be the grant-in-aid, it will differ from other research grants both in its emphasis on goal orientation and in the degree of coordination by the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS). It is expected that each Research Center Without Walls will plan, direct, and administer its own program, but the Center must also be responsive to the program and direction needs identified by the NINCDS. Center participants should expect to work closely with program staff at NINCDS and program staff will make regular visits to the Center components to evaluate progress.

F. Failure of Responsiveness to RFA

If applications are judged by the Division of Research Grants (DRG) and NINCDS to be unresponsive to this RFA but can compete as regular grants, they will be referred to DRG for handling, should the investigator so choose.

IV. METHOD OF APPLYING

A. Letter of Intent

The NINCDS should receive a letter of intent not later than the close of business on May 30, 1979, from all prospective applicants. The Institute requests such letters in order to have a reasonable estimate of the number of applications to be expected and to begin planning for the review. A letter of intent is not binding and will not enter into the review of any proposal subsequently submitted. The letter should briefly describe the overall approach of the Research Center Without Walls.

Letters should be addressed to:

Dr. Nancy Wexler
Health Scientist Administrator
Room 710, Federal Building
7550 Wisconsin Avenue
Bethesda, Maryland 20205

B. Meeting with Potential Center Applicants

The structure of a Research Center Without Walls is unique and multidisciplinary. Centers are new in the area of research on Huntington's disease. A brief meeting is planned for those intending to apply to enable applicants to question program staff directly regarding the intent of the NINCDS. This meeting will be held on June 8, 1979, in Bethesda, Maryland. Inability to attend this meeting will not prejudice the application of an investigator.

C. Format for Applications

Proposals for Research Centers Without Walls should be submitted on form PHS 398 with any modifications which the applicant deems necessary. Specific attention is directed toward the inclusion of a statement indicating the willingness of all Center components to work cooperatively with each other, with other participants in the program, (e.g. other Research Centers Without Walls, if such be established) and with NINCDS.

D. Application Procedure

The completed application and 6 copies must be received by 5:00 p.m., EST, on September 15, 1979. Late applications will not be accepted. Applications should be sent or delivered to:

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

All material should be clearly identified as a proposal for Research Centers Without Walls for Huntington's Disease. A covering letter should accompany the application indicating that it is submitted in response to this announcement. A copy of the covering letter should be sent to Dr. Wexler (see address in IV.A.)

V. CRITERIA FOR SCIENTIFIC REVIEW

The applications for Research Centers Without Walls solicited in this announcement will be evaluated in national competition with each other. Initial review will be conducted by a primary review group of predominantly non-Federal consultants with selected scientific and clinical expertise, and may involve a site visit. Secondary review will be by the National Advisory Neurological and Communicative Disorders and Stroke Council. Applicants will be informed of the results of the competition as soon as possible after the meeting of the Council.

The criteria for evaluation will include: (not in order of priority)

- The scientific merit of the Research Center Without Walls overall application and its relevance to understanding the etiology, pathogenesis, treatment, prevention, and care of Huntington's disease.

- The scientific merit and thoughtfulness of each individual project (i.e., the questions posed, the research design, the methodology, and the analysis and interpretation of data) and the project's relationship to the central theme of the overall proposal.

- Demonstration of the capacity to address research questions on the efficacy of a range of health services.

- Assurances of cooperation from relevant patient groups and the assistance and support of involved health professionals and paraprofessionals and relevant health voluntary agencies.

- Assurances of good cooperation and communication among Research Center components through formal and informal mechanisms which must be specified.

- Assurances of willingness to cooperate with other Research Centers Without Walls and the NINCDS.

- The administrative leadership of the Research Center director and the competence of all personnel.

- The clinical and experimental experience with Huntington's disease of the principal investigator.

- The quality of institutional arrangements for the administration and organization of all Center components. Mechanisms for ongoing internal and external quality control and evaluation must be specified.

- Documentation of capacity to disseminate research findings to the relevant research and care communities.

- Documentation of good cooperation and communication with community resources for the purposes of information dissemination and the development of new programs.

- Assurances of the capability to provide appropriate research training, or experience in methods of basic and clinical biomedical research, including research on the efficacy of clinical services and the development of educational and training materials for professional or lay use, as necessary.

VI. TIMETABLE FOR REVIEW

A. Letters of Intent: May 30, 1979

B. Meeting for Potential Applicants: June 8, 1979

C. Deadline for Receipt of Applications: September 15, 1979

D. Final review of applications will be conducted by the National Advisory Neurological and Communicative Disorders and Stroke Council in January 1980.

VII. INQUIRIES

Questions regarding the Centers Without Walls for Huntington's Disease and Related Disorders should be addressed to:

Dr. Nancy Wexler
Health Scientist Administrator
Room 710, Federal Building
7550 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-1431

The staff will strive to provide consultation to all who desire it regarding preparation of the application or on any other matter relevant to the Center Without Walls program.

HEALTH SCIENTIST EXCHANGE PROGRAMS WITH

- POLAND
- ROMANIA
- UNION OF SOVIET SOCIALIST REPUBLICS
- YUGOSLAVIA

FOGARTY INTERNATIONAL CENTER

ANNOUNCEMENT

The Fogarty International Center, NIH, administers joint cooperative programs with the short- and long-term exchange of health and biomedical scientists with the above countries. An intergovernmental agreement covers the terms of the particular program with each country, such as the number of persons to be exchanged each year, duration of visits, elements of support, and areas of program interest. There are differences of terms among the individual programs but, in general, costs are shared through support of international travel by the sending side and in-country costs by the receiving side. Duration of visits may be from one to twelve months, depending on the program and nature of the work to be accomplished.

U.S. health and biomedical specialists who have particular scientific interests with respect to any of these countries for which a period of work, observation, or consultation in that country would be of mutual benefit may submit a proposal for consideration as an exchange visitor under one of these programs. In addition to such special requirements as may pertain to a particular country program, the following are general eligibility requirements:

- be a U.S. citizen or permanent U.S. resident,
- hold an advanced degree (normally doctorate) in one of the health sciences or related fields,
- have had professional experience in health or biomedical fields appropriate to the proposed study,
- be affiliated with a U.S. public or private nonprofit educational, research, or clinical institution.

Those considering the submission of a proposal should first contact the Fogarty International Center for further information with respect to the terms and requirements of the particular country program of interest.

Inquiries should be addressed to:

Director
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5903

NIH - FRENCH NATIONAL CENTER FOR SCIENTIFIC RESEARCH

PROGRAM FOR BIOMEDICAL SCIENTIFIC COOPERATION,

FOGARTY INTERNATIONAL CENTER

ANNOUNCEMENT

PROGRAM DESCRIPTION

Under an agreement between the U.S. National Institutes of Health (NIH) and the French National Center for Scientific Research (CNRS), the two organizations share in the support of well-qualified U.S. scientists selected to work at laboratories in France and similar French scientists selected to work at U.S. laboratories. The purpose of the program is to advance biomedical knowledge through cooperation between U.S. and French scientists in fields of special interest to the NIH and CNRS. Approximately five scientists of each country will be exchanged annually. It is expected that these exchanges will serve as the basis for further and continuing substantive joint relationships, such as collaborative research projects and seminars.

The type of activity undertaken with a host laboratory may include the conduct of a basic or clinical research study, familiarization with or utilization of special techniques and equipment not otherwise available, and/or related cooperative efforts. The program does not provide support for activities which have as principal purposes brief observational visits, attendance at scientific meetings, or independent study. Priority will be given to certain biomedical areas specified by the NIH and the CNRS. (See attachment.)

The period of interaction of the foreign scientist with the host institution is expected to be of sufficient duration to achieve substantive, specific goals. Except under very unusual and strongly justified circumstances, the minimum period of support will be for 6 months and the maximum, 12 months. Requests for extension beyond 12 months will be considered.

The program is administered for the NIH by the Fogarty International Center (FIC).

ELIGIBILITY

U.S. applicants for the program must meet the following basic requirements:

- be a U.S. citizen or permanent U.S. resident,
- hold a doctorate degree in one of the biomedical sciences or related fields,
- have had professional experience in the health or biomedical fields appropriate to the proposed study,
- be affiliated with a U.S. public or private nonprofit educational, research, or clinical institution.

Working knowledge of the French language is highly desirable. It is primarily the responsibiliity of the applicant to ascertain if a language barrier might exist at the proposed foreign institution which would be a significant hindrance. Prospective long-term participants are urged to study the language intensively in preparation for their visits.

SUPPORT

Under the agreement between the two agencies, the sending side pays for all international transportation costs to the place of assignment and the receiving side provides in-country support costs. For U.S. participants, the following pertain:

- Travel The FIC will provide round-trip, jet economy class fare for the participant between the U.S. home city and the French host city. Travel will be in accordance with U.S. Government travel regulations, which require maximum use, where available, of U.S. air carriers. Additional costs of indirect routing at the option of the participant must be at his personal expense. An allowance for 22 pounds or unit of excess accompanied baggage will also be included. A travel allowance for dependents cannot be provided.

- Subsistence The CNRS will provide a subsistence allowance at the rate of 3,000 to 5,000 francs per month as determined on the basis of the research experience of the participant, the number of accompanying dependents, and the cost of living in the locale where he or she works. The CNRS will also provide for the costs of travel within metropolitan France and to and from European centers in neighboring countries to the extent that such travel is judged by the host institution to be required for research or study program of the participant.

- Health Insurance The CNRS will provide the participant and any officially accompanying family members with comprehensive health care for accidents or unanticipated medical needs during their stay in France.

Support for French participants for work in the U.S. under the auspices of the program is provided in a reciprocal manner.

DURATION OF PARTICIPATION

The period of participation which may be initially requested is a minimum of 6 months up to a maximum of 12 months. Requests for extension beyond 12 months will be considered.

APPLICATION AND SELECTION

Specific application information and material for U.S. health professionals interested in participation are provided by the Fogarty International Center. In addition to biodata and other supporting documentation, the applicant will

be required to submit a summary narrative description of the proposed activity to be carried out in France and of the expected benefits to be derived from the experience. It is expected that in most instances the applicant will have had prior contact with a colleague in France who can serve as host and be able to provide necessary facilities.

Selection of U.S. participants from among applicants is made by the Fogarty International Center with the concurrence of CNRS authorities in accordance with the number of participants agreed to and funding availability. Notification of selection decisions is made to U.S. applicants by the Fogarty International Center.

The initial deadline for receipt of applications of U.S. scientists is August 1, 1979. Thereafter, regular deadlines will be November 1 and May 1 for review in the following January and July respectively. Because of advance scheduling for the limited number of participants permitted annually, it may be necessary to defer or decline consideration of applications at certain times. Usually at least three months will be required to finalize arrangements after selection before travel of a participant can begin.

PASSPORTS AND VISAS

It is the responsibility of the individual U.S. participant to obtain his or her passport. The Fogarty International Center will assist the participant in applying for the appropriate French visa.

REPORTS AND PUBLICATIONS

U.S. participants must submit a summary report to the Fogarty International Center following their visit which covers the work accomplished. Technical articles may be submitted to scientific publications without prior clearance of the NIH or CNRS authorities. However the support of the program should be acknowledged.

INQUIRIES AND APPLICATION MATERIALS

For U.S. applicants:

Director
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205

U.S. NIH - FRENCH CNRS PROGRAM FOR BIOMEDICAL SCIENTIFIC COLLABORATION

PRIORITY INTEREST AREAS

The following areas are of priority interest to NIH and its component Institutes for support of U.S. scientists for work in France under the program:

NHLBI Lung Diseases:

- Structure, function, and development of the lung
- Emphysema and chronic bronchitis
- Fibrotic and immunologic interstitial lung diseases

Blood Diseases and Blood Resources:

- Bleeding and clotting disorders
- Disorders of the red blood cell
- Development of blood component therapy

NCI

- Diseases of the lung - particularly basic and clinical research on lung cancer
- Nucleic acids - research pertaining to radiation, viral, or chemical carcinogenesis, e.g., misrepair and repair of DNA
- Toxicology - testing, screening, and mechanism of action of nutagenic and carcinogenic substances

NICHD Center for Population Research:

- Reproductive hormones and reproductive diseases
- Fertility; fertility trends; demography; population change, movement, and distribution

Center for Research for Mothers and Children

- Problems of pregnancy, embryonic and fetal growth, labor and neonatal adaption
- Congenital anomalies; structural, metabolic, and behavioral

NIA

- Basic biomedical science
- Retirement
- Animal resources

NINCDS	• Neurophysiology • Clinical investigation • Sensory physiology and biophysics
NIAID	• Molecular biology • Immunology • Arbovirology
NIEHS	• Pharmacology • Environmental mutagenesis • Environmental toxicology

The following areas have been identified by the CNRS for the support of French scientists for work in the U.S.:

Pneumology
Structure and sequences of nucleic acids
Microbiology
Dermatology
Toxicology

*U.S. GOVERNMENT PRINTING OFFICE: 1979 281-233/2 1-3