

# NIH GUIDE

# for GRANTS and CONTRACTS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

*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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NEW PHS 398 APPLICATION FORM - CLARIFICATION

**NOTICE**

A notice published in the June 6, 1980 *NIH Guide for Grants and Contracts*, Vol. 9, No. 8, page 1, stated that the new grant application form PHS 398 is now available and should be used for research grant applications. This is to clarify that the new form will be used by all PHS research agencies, beginning with the October-November 1980 receipt dates.

NEW INDIVIDUAL NRSA APPLICATION FORM (PHS 416-1)

**NOTICE**

The new individual National Research Service Award research fellowship application form (PHS 416-1 revised November 1979) is now available and should be used for the October 1, 1980 receipt date.

Five or fewer copies of the new NIH application kit may be obtained by writing to the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205. Requests for more than five copies should be forwarded to the Chief, Office Service Branch, Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205.

The Alcohol, Drug Abuse, and Mental Health Administration and the Division of Nursing, Health Resources Administration, also provide support through National Research Service Awards. For information and new application kits in these areas, contact the appropriate agency.

Copies of the old form, PHS 416-1 revised June 1976, and the Facilities and Commitment Statement, PHS 416-2 revised January 1975, should be discarded.

REVISED APPLICATIONS



The latest instructions (10/79) for PHS 398, Grant Application, state the following for revised applications:

"When a revised application is submitted to replace a prior version, provide a statement before the RESEARCH PLAN of the application specifying what significant changes have been made. Include additions, deletions, revisions, and any responses to criticisms in the previous summary statement. These changes must be further identified by appropriate underlining, indenting or changing of typography within the text. When a COMPETING CONTINUATION or SUPPLEMENTAL application has been revised, the PROGRESS REPORT should incorporate any work done since the prior version was submitted."

If a revised application does not satisfy these requirements, the Referral Branch of the Division of Research Grants will return the application without further review.

NRSA SUPPORT AND PAYBACK GUIDELINES



The following guidelines were developed in response to requests by National Research Service Award (NRSA) recipients for clarification as to (1) grounds for waiver of the statutory limits on duration of NRSA support; and (2) the range of activities acceptable as payback service. These guidelines are applicable to the programs of the National Institutes of Health, the Alcohol, Drug Abuse, and Mental Health Administration, and the Division of Nursing of the Health Resources Administration.

I. LENGTH OF TRAINING

The NRSA Act amendments of 1978 provide that the period of any award to an individual may not exceed (a) five years in the aggregate for predoctoral training, and (b) three years in the aggregate for post-doctoral training, unless the Secretary (or designee) allows an extension.

A. Grounds for Approving Extension of Support Period

1. Trainees requiring additional time to complete predoctoral training either as a participant in a combined M.D./Ph.D. program or to undertake additional NRSA-supported training following undergraduate support in the Minority Access to Research Careers (MARC) Program may anticipate favorable consideration of a reasonable request for waiver of the time limitation; this action is contingent upon certification of the recipient's good academic standing.
2. Requests for additional time will also be considered if an unanticipated event unavoidably has altered the planned course of the research training; the interruption has significantly detracted from the nature or quality of the planned research training; and if a short additional period of training would permit completion of the training as planned. Such events include sudden effective loss of the preceptor's services or an accident, illness, or other unavoidable personal situation, which prevents a trainee or fellow from pursuing his other research training in an effective manner for a significant period of time. Requests for extension of support will also be considered if a short additional period would provide the trainee or fellow an opportunity to use an exceptional training resource.
3. Requests that do not arise from circumstances considered in (1) or (2) will be granted only if they are accompanied by an exceptionally strong justification.

B. Procedure for Requesting an Extension

Requests for extension must be made in writing by the trainee or fellow and addressed to the awarding unit. The trainee's program director, or in the case of fellowships, the sponsor, must endorse the request certifying the need for additional time. The request must include a sound supporting justification and specify the amount of additional time for which approval is sought.

II. PAYBACK

As a condition of NRSA support the recipients agree to engage in research or teaching for specified periods of time following termination of such support. If the trainee or fellow is unable to obtain employment in research or teaching, alternate service may be substituted if authorized by the Secretary (or designee).

A. Timing of the Service Obligation

Recipients must begin to undertake the obligated service within two years after termination of NRSA support. Recipients may request an extension of this interval; e.g., to allow the physician to complete residency training, or the graduate student to complete degree requirements. The request must be made in writing to the awarding unit, specifying the extension's purpose and the time required for accomplishment.

B. Service Acceptable as Health Research or Teaching

1. The NRSA payback obligation may be satisfied by either serving in a full-time position in which health-related biomedical or behavioral research and/or teaching constitutes the primary activity;

or if not serving in a full-time position of this kind, engaging in such research and/or teaching for periods that average more than 20 hours/week of a work year.

If the latter, each activity must be described and certified by the appropriate supervisor.

For the purposes of NRSA, research is defined as activity which involves the design of experiments, development of protocols and collection and interpretation of data. On the other hand, research support functions are not included; e.g., routine laboratory analyses, managerial and administrative activities, a technical advisory role on development or marketing of products. Such research-support functions may be considered as satisfying the alternative service obligation, but only for individuals not trained as health-care professionals, and only for those who have been authorized to undertake alternative service. (See below.)

2. The research setting may be in the academic, governmental, or private (including industrial) sector--domestic or foreign. The academic sector includes universities, professional schools, research institutes, teaching hospitals, colleges, high schools, schools for the handicapped, etc., domestic or foreign.
3. The range of activities acceptable as teaching will take into account the certifying institution's policy in the definition of teaching responsibilities. Teaching activities will be accepted only if they take place in an organized educational or other instructional environment.
4. Payback credit for research and teaching activities undertaken by the recipient after terminating NRSA support, but while still in training status (e.g., activities as graduate student, resident, or clinical fellow), is subject to the following limitations:
  - Credit for service will be given only in instances where the proposed teaching and/or research activities include responsibilities that distinguish them from activities required of trainees and which require 20 hours or more per week. For graduate students the distinguishing feature may be assignment of responsibility as teaching assistant or laboratory instructor, or responsibility for conduct of research; for residents and clinical fellows the distinguishing feature may be teaching responsibility other than clinical supervision, or responsibility for conduct of research that is not a requirement of residency training.
  - Without such distinguishing responsibilities, the dissertation research of graduate students or the clinical supervision characteristic of residency or clinical fellowship training are unacceptable as payback service. In every instance the standard reporting on payback activities must be accompanied by a letter from the supervisor that identifies the kind and extent (hours/week) of the distinguishing responsibilities. These must average more than 20 hours/week of a work year.
  - In no instance will status as "graduate student", "resident", or "clinical fellow" per se be accepted as a full-time position that qualifies as payback service.

C. Alternative Service

1. The NRSA legislation makes provision for discharge of the payback obligation through service other than research or teaching. Before a specific proposal for alternative service can be considered, however, the law requires that a determination must be made that no suitable research or teaching position is available to the individual. Alternative service is thus not at the option of the individual.

2. To request a determination that no suitable research or teaching position is available, the former NRSA recipient shall address a letter to the awarding unit supplying information on at least the following:

- his/her aims in undertaking the NRSA-supported training;
- the extent to which these aims were realized;
- documentation of steps taken to secure a position in health research and/or teaching, including documentation of responses from prospective employers;
- any constraints on the range of employment opportunities which could be considered; e.g., those from family obligations or location of spouse's employment.

To this the individual should add any other consideration that governed the choice of employment.

3. Acceptable Alternative Service

- a. For those trained to provide health care directly to individuals:

Former NRSA recipients so trained who have been authorized to undertake alternative service may discharge the obligation either by service as a member of the National Health Service Corps (NHSC) or by practice with a Health Maintenance Organization (HMO) that meets certain criteria.\* Information as to opportunities for service of either kind is available from the Office of the Regional Health Administrator, in the Regional Offices of the Department of Health and Human Services. If needed, assistance in contacting these offices is available from staff of the awarding Institute.

- b. For those not trained to provide health care directly to individuals:

Such former NRSA recipients may be authorized to undertake alternative service to discharge the payback obligation by engaging in a health activity appropriate to his/her level of training. The Committee Report that accompanied the 1978 extension of the NRSA authority reiterated Congressional intent to keep this option as broad as possible. In addition to examples given above in Section II B1, health-related activities which might be considered include; e.g., counseling, health planning, and community health education.

\*An HMO "to which payments may be made under Section 1867 of Title XVIII of the Social Security Act, and which serves an underserved population (as defined in Section 1302 (7) of the Act...)"



D. Waiver of the Payback Obligation

The regulations make provision for waiver of obligation in the event of permanent and total disability, and for waiver of the financial obligation in cases where repayment would result in substantial hardship to the individual. Such requests should be made in writing to the awarding Institute.

Requests for policy clarification in individual cases should be addressed to the supporting Institute. Requests of additional copies of the guidelines should be addressed to the Office of Grants Inquiries, Division of Research Grants, NIH, Bethesda, Maryland 20205.

Suggestions for additional payback questions to be addressed in any revision of the guidelines may be addressed to the Associate Director for Extramural Research and Training, NIH, Bethesda, Maryland 20205.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

**ANNOUNCEMENT**

NIH-NCI-DCCP-CPC-80-6

NATIONAL CANCER INSTITUTE

TITLE: *INTERSPECIES COMPARISONS IN CARCINOGENESIS*

*Application receipt date, November 1, 1980*

The Division of Cancer Cause and Prevention (DCCP) of the National Cancer Institute (NCI) invites grant applications from interested investigators for both basic and applied studies intended to provide insights and approaches to an understanding of similarities and differences in the response to chemical carcinogens, between experimental animals and humans. In this context there is an intended emphasis on: (a) the use of accessible human cells, tissues, body fluids, and excreta, and (b) studies which focus on quantitative relationships relative to the carcinogenesis process.

Grants are awarded only to nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary NIH grant-in-aid, in accordance with PHS policies applicable to Research Project Grants including cost-sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to the RFA will be reviewed by the same National Institutes of Health (NIH) Initial Review Group.

The present RFA announcement is for a single competition with a specified deadline of November 1, 1980, 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
- II. OBJECTIVE AND SCOPE
- III. MECHANISM OF SUPPORT
- IV. REVIEW PROCEDURES AND CRITERIA
- V. METHOD OF APPLYING
- VI. INQUIRIES

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

## I. BACKGROUND

The initiative for this RFA derives from the desire of the National Cancer Institute (NCI) to encourage studies that are supportive of the Environmental Protection Agency (EPA) in the area of Risk Assessment. In this regard, there is a need to develop scientifically sound methodology for the extrapolation of carcinogenesis data derived from studies on experimental animals, to humans.

Established similarities between the action of chemical carcinogens in experimental animals and in people, are largely represented by the qualitative finding that nearly all of the chemical substances identified as being carcinogenic in humans, are also carcinogenic in one or more species of experimental animals. Also, it would appear that the metabolism of chemical carcinogens in human tissues is, in general, qualitatively similar to that observed in studies on tissues derived from experimental animals; however, this is based on relatively little data. Other efforts at extrapolation between species soon encounter an acute shortage of information, particularly as relates to quantitative relationships, e.g., quantitative relationships between DNA-adducts and the carcinogenesis process. Much additional research is judged to be needed if we are to achieve even a moderate level of confidence in the extrapolation of experimental animal data on chemical carcinogenesis, to humans.

## II. OBJECTIVES AND SCOPE

The research encompassed by the present RFA relates to both basic and applied studies intended to provide insights and approaches to an understanding of similarities and differences in the response to chemical carcinogens, between experimental animals and humans, with an emphasis on the use of accessible human cells, tissues, body fluids, and excreta and on studies which focus on quantitative relationships relative to the carcinogenesis process.

Applications submitted in response to this RFA should be responsive to one or more topics selected from Categories 1 and/or 2:

Category 1. Use of human cells/tissues/body fluids/excreta in chemical carcinogenesis research on one or more of the following: pathways of metabolism of chemical carcinogens; their activation and inactivation; the formation and repair of their adducts with informational cellular macromolecules; their pharmacodynamics in cell, tissue, and organ culture; their induction of mutagenesis and malignant transformation in cell, tissue, and organ culture; the detection and quantitation of their adducts with tissue nucleophiles in body fluids and excreta of humans exposed to low levels of carcinogens in the work-place, or by way of therapy or analogous circumstance. It is highly desirable that these studies on specimens derived from humans be accompanied by comparative studies on counterpart specimens derived from experimental animals.

Category 2. Comparative Inter-Species and/or Intra-Species studies on experimental animals with respect to one or more of the following: effects of different doses of chemical carcinogens on rates and pathways of metabolism, including studies under conditions of chronic exposure; qualitative and quantitative studies on relationships of adduct formation to chemical carcinogenesis; existence of proportionality of blood/tissue levels of carcinogen to dose; relationship of blood level of carcinogen to carcinogenic response; development of improved analytical procedures, sufficiently sensitive to quantitate very small concentrations of chemical carcinogens and their metabolites, for use in studies on chronic administration of chemical carcinogens to experimental animals.

In studies involving the administration of chemical carcinogens to experimental animals, the agent(s) used should be chosen from among those which are organic compounds, are present in the human environment, and are known to be carcinogenic for humans or for experimental animals, or for both. The choice of experimental animal(s) should be from among those commonly used in carcinogenicity testing.

### III. MECHANISM OF SUPPORT

This RFA will use the traditional National Institutes of Health grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years. The intent is to fund multiple projects, with total costs amounting to approximately \$2.0 million for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Also, although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose.

### IV. REVIEW PROCEDURES AND CRITERIA

#### A. Review Method

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the Division of Research Grants, National Institutes of Health, and (2) the National Cancer Advisory Board. All applications will be evaluated on a competitive basis.

#### B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals and fall within one or both of the specified research categories (see II. OBJECTIVES AND SCOPE). If the application is judged by the National Cancer Institute not to be responsive, the applicant will have the opportunity of having the application considered along with other unsolicited applications received by the National Institutes of Health in the review cycle which is current at that time.

The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of research approach, design, and methodology.
2. Research experience and competence of the Principal Investigator and staff to conduct the proposed studies.
3. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.
4. Adequacy of existing/proposed facilities and resources. Applications which specify a proposed use of human cells/tissues/fluids/excreta, need to provide assurance and details concerning the nature, source, and availability of those specimens.
5. Adequacy of practices, procedures, and facilities relative to the safe handling and use of chemical carcinogens.

V. METHOD OF APPLYING

A. Format of Applications

Applications must be submitted on form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants, NIH. The conventional presentation in format and detail applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (IV. B.) must be fulfilled. The words "PROPOSAL IN RESPONSE TO RFA: INTERSPECIES COMPARISONS IN CARCINOGENESIS" must be typed in bold letters across the face page of the application.

B. Application Procedure

The completed original application and six (6) copies should be sent or delivered to:

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

To ensure their review, applications must be received by close of business, November 1, 1980. Applications received after that date will be returned. Also, the Division of Research Grants (DRG) will not accept any application in response to this announcement, that is the same as one currently being considered by any other NIH awarding unit. A copy of the application should also be sent to Dr. Domanski at the address shown below.

VI. INQUIRIES

Inquiries may be directed to:

Dr. Thaddeus J. Domanski  
Chemical and Physical Carcinogenesis Branch  
Division of Cancer Cause and Prevention  
National Cancer Institute  
Room 8C-29, Landow Building  
Bethesda, Maryland 20205

Telephone: (301) 496-9448

RESEARCH GRANTS IN THE NEUROPHYSIOLOGY OF  
COGNITIVE PROCESSES, NATIONAL INSTITUTE OF  
NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

**ANNOUNCEMENT**

The Fundamental Neurosciences Program (FNP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) encourages the submission of applications for research grants in the neurophysiology of cognitive processes.

**PURPOSE AND SCOPE**

This announcement is intended to stimulate new approaches to the experimental and conceptual aspects of research on those types of cognitive processes which can be studied at the neural level in both animal and human research. A primary goal should be to characterize the sources and time course of neural activity (where feasible in its relation to unit activity) related to these processes.

Projects of the following types illustrate this area:

1. Animal research
  - a) Involving innovative methods and concepts for the definition and analysis of cognitive processes in experiments that are designed in response to new knowledge about the nervous system.
  - b) Applying recently established knowledge about cognitive processes in humans to the design of neurophysiological experiments in animals.
  - c) Requiring collaboration between scientists who are expert in the cognitive sciences and those who are expert in the neurobiological sciences.
2. Human research
  - a) Developing new methods, concepts, and paradigms for research on cognitive processes that lead specifically toward studies of the underlying neural activities.
  - b) Applying recent advances in neurobiology to experiments using clinical neurophysiological and/or neuropsychological approaches to the study of cognitive processes.

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This program is described in the Catalog of Federal Domestic Assistance, number 13.854, Fundamental Neurosciences Research. Grants will be awarded 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.

- c) Bringing experts in neurobiological research into collaboration with cognitive scientists.

#### APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on form PHS 398 following instructions contained in the application kit. Application kits are available at most institutional business offices or from the Division of Research Grants. The applications will be judged solely on scientific merit in accord with NIH policy and procedures involving peer review. Initial review will be by the appropriate study section of the Division of Research Grants. The final review will be by the National Advisory Neurological and Communicative Disorders and Stroke Council. Applications judged more responsive to program interests of other Institutes will be assigned accordingly.

Deadline dates for the receipt of the applications are March 1, July 1, and November 1.

The phrase "PREPARED IN RESPONSE TO NINCDS INVITATION FOR RESEARCH GRANTS IN THE NEUROPHYSIOLOGY OF COGNITIVE PROCESSES" should be typed across the top of the first (face) page of the application. The original and six (6) copies of the application should be mailed to the following address:

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

One copy of the application is to be sent to the address below. Also, for further information applicants may contact:

Dr. W. Watson Alberts  
Deputy Director  
Fundamental Neurosciences Program  
National Institute of Neurological  
and Communicative Disorders and Stroke  
Room 916, Federal Building  
7550 Wisconsin Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-1447



SPECIAL EMPHASIS RESEARCH AREA FOR THE DEVELOPMENT  
OF INVESTIGATORS BLOOD TRANSFUSION SCIENCES  
DIVISION OF BLOOD DISEASES AND RESOURCES  
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

**ANNOUNCEMENT**

BACKGROUND

The rapid evolution and complexity of blood banking has created a significant need for expansion of research in areas related to transfusion practices as well as in disciplines related to the development of and use of blood resources. Enormous opportunities exist for fundamental, clinical, and applied research related to these subjects. Examples are:

Fundamental research - structure and biochemistry of red cells, leukocytes, and platelets as related to their ability to survive in storage and in the transfused recipient; understanding the basis of coagulation and bleeding problems so as to permit more effective component therapy; improved blood-recipient safety through increased knowledge concerning the elimination of transfusion-transmitted viruses; prevention of alloimmunization by improved understanding of immunologic parameters influencing compatibility between donor and the recipient of whole blood and its components; development of effective blood substitutes including oxygen-transporting materials and synthetic volume expanders; and transplantation immunology and immunogenetics.

Clinical and applied research - techniques to improve donor recruitment; improved methods for plasma- and cytopheresis; development of improved materials for storage of blood and blood components in the liquid and frozen states; elucidation of criteria for optimal and safe use of whole blood transfusions and blood components; better compatibility testing; and improvements in the logistic and administrative aspects of blood center and transfusion service operations.

In spite of interest in and awareness of the problems in the blood banking area, the Division of Blood Diseases and Resources (DBDR) receives few research grant applications relating to the considerations listed above. Since gaps in knowledge are known to be extensive and techniques for sophisticated research are available, it would appear that few individual scientists are aware of the opportunities available for progress in the blood transfusion sciences.

This program is described in the Catalog of Federal Domestic Assistance number 13.839, Blood Diseases and Resources 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. NRSA awards will be made under the authority of the Public Health Service Act, Section 472, 42 USC 291-1, and administered under PHS grants policy and Federal Regulations 42 CFR Part 66. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

#### PURPOSE

The DBDR has a mandate to foster and support research contributing toward the science base needed to enhance the ability of blood transfusion services to function as centers of knowledge in the collection, fractionation, handling, and use of one of our country's most valuable natural resources. To increase that science base, trained professional personnel are required. Consequently, the DBDR announces a SPECIAL EMPHASIS RESEARCH AREA (SERA) for the Development of Investigators in the BLOOD TRANSFUSION SCIENCES. SERA is intended to:

- encourage qualified individuals at different levels of professional development to direct, or redirect, their research interests and skills toward the blood transfusion sciences,
- provide support for qualified individuals at different levels of professional development to pursue a program of research in various fundamental and clinical research disciplines related to the blood transfusion sciences and toward research in the logistic and administrative aspects of blood center and blood transfusion service operations, and
- create a pool of highly qualified investigators with experience and skills in blood transfusion sciences.

The key requirement in the development of investigators under SERA is that an applicant should receive research experience and instruction under the supervision of, or in association with, scientists knowledgeable in the blood banking disciplines and pursue research which is applicable to blood banking problems. A list of research areas which are appropriate for the development of scientists under SERA is included under "BACKGROUND." These areas, however, are intended to be examples only and are not meant to exclude other topics related to blood banking.

#### MECHANISMS OF SUPPORT

Programs for the development of investigators in blood transfusion sciences research should facilitate the movement of individuals at varying levels of research expertise in the biomedical sciences into investigative careers in the blood banking area. The goal of this special effort is to recruit investigators and provide an orientation for scientists not now working in the field, and to encourage them to undertake research projects which will advance the state-of-the-art in the blood transfusion sciences. The number of new awards made each year will depend on the availability of funds.

The programs summarized below may be used for the support of individuals in the SPECIAL EMPHASIS RESEARCH AREA for the Development of Investigators in the BLOOD TRANSFUSION SCIENCES.

##### 1) NRSA (Individual and Institutional)

Provides postdoctoral support for individuals at various levels of career development who wish to receive additional experience and instruction in biomedical and behavioral research in the blood transfusion sciences.

A. Individual Fellowship

- Stipend is \$13,380-\$18,780 relative to 0-7 or more years of relevant postdoctoral experience.
- Training period is not less than one year nor more than three years.
- Stipend supplementation is allowed from non-federal funds.
- Institutional allowance of up to \$5,000 may be requested to defray trainee expenses (e.g., tuition and fees, medical insurance, research supplies and equipment, and travel to scientific meetings).
- One year of payback for NIH-financed training is required for each year of training received by teaching and/or conducting research.
- Receipt dates for applications are:      Starting dates are:

February 1	August/September
June 1	January/February
October 1	May/June
- Award is based on peer review and national competition.

B. Institutional Training Grants

- 5-Year awards are made to institutions on behalf of a training program director.
- Candidate selection results from local review established by training program director at the grantee institution.
- Stipend is \$13,380-\$18,780 relative to 0-7 or more years of relevant postdoctoral experience.
- Training period is not less than one year nor more than three years.
- Stipend supplementation is allowed from non-federal funds.
- Institutional allowance of up to \$5,000/trainee may be requested to defray trainee expenses (e.g., tuition and fees, medical insurance, research supplies and equipment, and travel to scientific meetings). Indirect costs of 8 percent on total direct costs or actual rate, whichever is less, may be requested.
- One year of payback for NIH-financed training is required for each year of training received by teaching and/or conducting research.
- Receipt dates:      Advisory Council Review:      Starting dates:

February 1	October	July 1
June 1	February	July 1
October 1	May	July 1

2) NRSA for Senior Fellows

Provides support to experienced scientists having at least 7 years of relevant post-doctoral research or professional experience who wish to make major changes in the direction of their scientific careers or wish to enhance and enlarge their research capabilities.

- Stipend may be negotiated up to \$30,000/year.
- Training period is one to two years.
- Stipend supplementation is allowed from non-federal funds.
- Institutional allowance of up to \$5,000 may be requested to defray trainee expenses (e.g., tuition and fees, medical insurance, research supplies and equipment, and travel to scientific meetings).
- One year of payback for NIH-financed training is required for each year of training received by teaching and/or conducting research.
- Receipt dates for applications are: Starting dates are:

February 1  
June 1  
October 1

August/September  
January/February  
May/June

- Award is based on peer review and national competition.

3) Clinical Investigator Awards (CIA) for Physicians

Provides support to newly trained physicians, usually after they have completed not less than three years of clinical experience nor more than six years of total postdoctoral clinical and research experience by the time an award is made to encourage development of their clinical and basic research interests toward a career in blood transfusion science.

- Salary is up to \$25,000 and fringe benefits for first year, with annual increases up to \$30,000 and fringe benefits.
- Research support is provided for up to \$10,000/year.
- Training period is five years.
- Salary supplementation is allowed from non-federal funds.
- Indirect costs of 8 percent on total direct costs or actual rate, whichever is less, may be requested.
- No payback is required.
- Annual receipt date is August 1 for starting date of July 1 the following year.
- Award is based on peer review and national competition.

Future considerations for support

The NRSA and CIA programs suggested for support under the SERA: BLOOD TRANSFUSION SCIENCES represent an initial step towards achieving independent investigatorship in this important research area. The investigator should then be adequately prepared to compete for a New Investigator Research Award (NIRA). The NIRA program helps to bridge the transition from training status to that of independent investigator. The NIRA provides support for three years, after which the investigator should be able to compete successfully for a regular research grant.

Applications:

Application forms and detailed instructions specific to the above summarized programs should be requested from:

Fann Harding, Ph.D.  
Special Assistant to the Director  
Division of Blood Diseases and Resources  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Bethesda, Maryland 20205

Telephone: (301) 496-1817

ASSESSMENT OF HEALTH CARE TECHNOLOGIES

**ANNOUNCEMENT**

NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY

I. BACKGROUND INFORMATION

The National Center for Health Care Technology (NCHCT or Center) is a new organization within the Department of Health and Human Services (HHS or Department) and is part of the Office of Health Research, Statistics, and Technology (OHRST) in the Office of the Assistant Secretary for Health (OASH), Public Health Service (PHS). The NCHCT was established in accordance with the provisions of the "Health Services Research, Health Statistics, and Health Care Technology Act of 1978," Public Law 95-623. The law calls upon the Secretary, acting through the Center, to undertake and support a variety of programmatic activities directed at improving the understanding of the issues and consequences associated with the development and application of technology in health care.

The NCHCT is mandated to undertake and support assessments of health care technologies, and research, demonstrations, and evaluations concerning health care technology. Public Law 95-623 broadly defines the term "health care technology" to include "any discrete and identifiable regimen or modality used to diagnose and treat illness, prevent disease, maintain patient well-being, or facilitate the provision of health care services." The objective of a technology assessment is to arrive at the best current judgment on the safety, efficacy and effectiveness of a particular health care technology, as well as its social, economic, and ethical impacts.

Biomedical research often leads to the development of new technologies which are shown to be safe and efficacious under very prescribed (e.g., "laboratory") conditions. Often these developments are diffused rapidly into the very diverse conditions of medical practice without adequate preparation and full understanding of the medical, social, ethical and economic implications for individuals and society. There is also evidence that some technologies have continued to be used even though it has become apparent that they are of marginal value, outmoded, or even harmful. As health care grows more sophisticated, so, also, must the mechanisms for assessing the technologies which have become an increasingly vital component in this growth.

This announcement is intended to provide interested parties with background information concerning the general orientation of the NCHCT's research program, and to call attention to a number of important areas in which the Center seeks to stimulate innovative and timely research.

II. RESEARCH GOALS AND SCOPE

This is the NCHCT's first announcement for research grant applications. It will be followed by additional announcements and solicitations in the future. This announcement is intended to stimulate research, demonstrations, and evaluations in the following general areas:

- 1) The development and testing of methodologies for assessing the safety, efficacy, and effectiveness of particular health care technologies, and their social, economic, and ethical impacts.
- 2) Focused assessments or analyses of particular aspects of a health care technology, e.g., its effectiveness or its social, economic or ethical implications.

These two areas reflect in part the requirements of Public Law 95-623, and are the initial priority areas of the Center and its advisory National Council on Health Care Technology (Council) for research, demonstrations, and evaluations in the field of health care technology. These areas do not, however, exhaust the research and related interests of the Center. Although highest priority will be given to the areas specified in this announcement, innovative and feasible proposals on topics not explicitly covered herein will also receive consideration for funding.

The following discussion highlights those areas of research, demonstration, and evaluation that will be given the highest priority for funding by the NCHCT.

- A. Development and testing of methodologies for assessing the safety, efficacy, and effectiveness of particular health care technologies, and their social, economic, and ethical impacts.

The current state-of-the-art of health care technology assessment is limited by conceptual, methodological, and data problems which constrain the production of useful evaluative information. Accordingly, the investigator(s) should aim to develop and define a methodology that has potential for widespread and universal application.

Examples of the areas where research is needed include:

- Methods for assessing rapidly changing technologies
- Measures of effectiveness, risk, benefit and cost
- Economic evaluation of diagnostic procedures
- Short-term outcome measures in evaluating therapeutic effectiveness
- Improved methods of using existing data sources for technology assessment
- Strategies for information retrieval applicable to technology assessment

B. Focused assessments or analyses of particular aspects of health care technologies, e.g., effectiveness or social, economic, or ethical implications of specific technologies.

The studies envisioned in this category would focus on one or more particular aspects, of the subject technology, e.g., the safety, efficacy, effectiveness or social, economic, or ethical impact of the technology. These studies would focus on those aspects of a technology for which indepth assessments or analyses are particularly essential for health care policy decisionmaking.

The following list of priority candidate topics for technology assessments was developed by the NCHCT based on recommendations from its advisory bodies. The list illustrates the types of topics to which the Center will be devoting attention in the coming years.

- Maternal serum alpha-fetoprotein test for prenatal detection of fetal neural tube defects
- Coronary bypass surgery
- Total knee replacements
- Ultrasound for cardiac diagnosis
- Cerebral bypass surgery for treatment of stroke
- Positron emission transaxial tomography (P.E.T.T.)
- Heart transplants
- Cardiac nuclear imaging
- Renal dialysis and kidney transplantation in end-stage renal disease (ESRD)
- Electronic fetal monitoring (EFM)
- Computed axial tomography (CT scanning); head and body
- Barium enema
- Endoscopy in upper GI hemorrhage
- Skull films
- Continuous flow analysis
- Electroencephalography



### III. MECHANISM OF SUPPORT

The support mechanism for this program will be the grant-in-aid. Support of grants pursuant to this program announcement is contingent upon ultimate receipt of appropriated funds for this purpose. The award of grants will be influenced by the amount of funds available to the Center, the overall merit of proposals, and the relevance to program goals.

Eligibility. Applications may be submitted by any public or private nonprofit institution, agency or organizations, such as a college or university, hospital, or unit of State (or U.S. territory) and local government. Grants may also be awarded to individuals. Profitmaking organizations are not eligible.

Start Date. The anticipated start-up date for the first awards is April 1, 1981.

Plan for Financing. It is expected that the range of total direct costs of individual projects supported by the NCHCT will be approximately \$35,000-\$250,000/year.

Applicable Policy and Regulations. The grant mechanism for the NCHCT is authorized by Section 309 of the Public Health Service Act, as amended by the "Health Services Research, Health Statistics, and Health Care Technology Act of 1978," Public Law 95-623. Grants will be administered under PHS grant policies and Federal Regulations 42 CFR Part 52. This program is not subject to A-95 Clearinghouse or Health Systems Agency review. This program is described in the Catalog of Federal Domestic Assistance, number 13.986, Assessment of Health Care Technologies.

### IV. REVIEW PROCEDURES AND CRITERIA

Applications submitted in response to this program announcement will be processed for the NCHCT by the Division of Research Grants, NIH. (This administrative arrangement necessitates adherence on the part of the NCHCT to the submission and review schedules specified by the DRG. The schedule is set forth in Section V, METHOD OF APPLYING, following). Upon receipt, these applications will be reviewed by the DRG for responsiveness to this announcement. Applications judged responsive will be referred for review to an appropriate Initial Review Group (Study Section) and to the Council.

Criteria for Review. Irrespective of the amount of the requested budget, all reviewers will take into account, when appropriate, the following factors:

1. The relevance of the proposal to the scope and objectives provided in this announcement.
2. The significance and originality from a scientific and technical standpoint of the goals of the project.

3. The adequacy of the methodology proposed to carry out the project.
4. The availability of data or the proposed plan to collect data where it is essential to the analysis.
5. The adequacy and appropriateness of the plan for organizing, carrying out, and completing the project within the proposed time period.
6. The qualifications of the principal investigator(s) and proposed staff.
7. The adequacy of facilities and other resources to assist in carrying out the project.
8. The reasonableness of the proposed budget in relation to the project.

Consequences of nonresponsiveness to this announcement. Applications that are judged nonresponsive to this announcement will be returned to the applicants.

#### V. METHOD OF APPLYING

Except for applications from State and local governments, all applications must be submitted on form PHS 398, the application for the traditional research grant. Application kits are generally available in the business or grants and contracts offices at most academic and research institutions, or from the Division of Research Grants, National Institutes of Health. The conventional presentation in format and detail for regular research grant applications should be utilized, with care taken to fulfill the points identified under Criteria for Review, in Section IV, preceding.

Applicants from State and local governments are required to submit applications on form PHS-5161-1, Application for Federal Assistance (nonconstruction Programs) to the appropriate address.

Applications will be processed by the Division of Research Grants, NIH, and referred for review to an appropriate Initial Review Group (Study Section), which meets three (3) times a year, and to the Council, which meets at least four (4) times a year and whose subcommittees may meet on an ad hoc basis as necessary.

Approximately 6-7 months should be allowed between the deadline for submission of the applications and the desired starting date of the grant. The submission and review schedule is as follows:

<u>DRG Submission*</u> <u>Deadline</u>	<u>Study Section</u> <u>Review</u>	<u>National Council on</u> <u>Health Care Technology Review</u>
July 1	October	January/February
November 1	March	May
March 1	June	September/October

\*For new research grant applications only. Subsequent applications for competing continuation will be submitted in accordance with the schedule prescribed by the DRG.

An original and six (6) copies of the application should be sent or delivered to:

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

A brief covering letter should accompany the application, indicating that it is in response to this program announcement. A copy of the covering letter and one copy of the application should be sent to:

Norman W. Weissman, Ph.D.  
Associate Director for Extramural Programs  
National Center for Health Care Technology  
Room 17A29, Parklawn Building  
5600 Fishers Lane  
Rockville, Maryland 20857

The words "IN RESPONSE TO NCHCT PROGRAM ANNOUNCEMENT: ASSESSMENT OF HEALTH CARE TECHNOLOGIES" must be typed in bold letters across the top of the face page of the application.

VI. IDENTIFICATION OF CONTACT POINT

Inquiries concerning this announcement may be directed to:

Norman W. Weissman, Ph.D. at the above address or by telephone (301) 443-1820 (collect calls will not be accepted).

RESEARCH FELLOWSHIPS TO SWEDEN, SWITZERLAND,  
AND FRANCE, FOGARTY INTERNATIONAL CENTER

**ANNOUNCEMENT**

The Fogarty International Center, National Institutes of Health, has been asked to announce that the Swedish Medical Research Council, the Swiss National Science Foundation, and the French National Institute of Health and Medical Research (INSERM) will each make available in 1981 several research fellowships to qualified U.S. biomedical scientists. These fellowships will provide postdoctoral training in basic or clinical areas of medical research.

Applicants must be U.S. citizens and must have been engaged in independent responsible research in one of the health sciences for at least 2 of the last 4 years. Applicants also must provide evidence of acceptance by a host training institution and preceptor. It is the applicant's responsibility to arrange for his research training with the preceptor and to present in his application a complete and explicit plan for research training.

Application materials may be obtained from:

The International Research Fellowship  
Program Branch  
Fogarty International Center  
National Institutes of Health  
Room 615, Building 38A  
Bethesda, Maryland 20205

Completed applications should be mailed or delivered to the Fogarty International Center at the aforementioned address by December 1, 1980. Applications will be reviewed for scientific merit by the Division of Research Grants and forwarded to Sweden, Switzerland, or France, as appropriate, for final selection and award in late spring or midsummer 1981. All correspondence concerning these fellowships must be clearly made as "SWEDISH MEDICAL RESEARCH COUNCIL FELLOWSHIP," "SWISS NATIONAL SCIENCE FOUNDATION FELLOWSHIP," or "INSERM FELLOWSHIP."

PEPTIDE PURIFICATION



The National Bureau of Standards has developed methodology to analyze the purity of synthetic peptides.

A detailed, technical report on the analysis of ANGIOTENSIN I\* and other peptides of biological interest, such as,

- MET- and LEU-ENKEPHALIN
- SUBSTANCE P
- SOMATOSTATIN
- ELEDOSIN
- LUTEINIZING HORMONE RELEASING HORMONE (LRH)

is also presently available. Single copies of the report entitled "Development of a Standard Reference Material for Angiotensin I" (NBSIR #79-1947) are available free of charge.

Investigators interested in the report or in peptide standards should write to:

Dr. S. A. Margolis  
Center for Analytical Chemistry  
National Measurement Laboratory  
National Bureau of Standards  
Washington, D.C. 20234

\*Purified under interagency agreement with the National Heart, Lung, and Blood Institute.

RESEARCH RELATED TO HEALTH EFFECTS

**ANNOUNCEMENT**

OF MOUNT ST. HELENS VOLCANO

The National Institutes of Health announces a special receipt date of October 1, 1980 for research grant applications related to the health effects of the Mount St. Helens Volcano. Applications received on this date will be reviewed for scientific merit by the Division of Research Grants; Institute assignment will be based on the research objectives of the application. Secondary review by the Institute Advisory Council will be scheduled for January 1981. The earliest possible starting date for applications which receive a meritorious ranking will be April 1, 1981.

Applications should be submitted on Form PHS-398, the application form for the traditional research grant which may be obtained at Institution business or research offices. If form 398 is not available at the Institution, it may be obtained by contacting:

Division of Research Grants  
Administrative Branch  
Room 449, Westwood Building  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-7591

The conventional presentation in format and detail for regular research grant applications should be utilized.

The factors considered in the scientific merit evaluation of each application will be identical to those used in traditional NIH research grant application evaluation, including the scientific, technical or medical significance and originality of the proposed research; appropriateness and adequacy of the experimental approach and methods used; qualifications and experience of the principal investigator and staff in the area of the proposed research; reasonable availability of resources; reasonableness of the proposed budget and duration; and where an application involves activities that could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against such effects.

The completed application and six (6) copies should be sent or delivered no later than October 1, 1980 to:

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

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The face page of the application should indicate in item 2 that it is submitted in response to this program announcement: "Health Effects of Mt. St. Helens Volcano."

This will be the only special deadline for research applications related to the volcano. Applications received after the October 1, 1980 date will be processed according to the regular NIH review cycles.

Research applications related to the Mt. St. Helens Volcano already submitted to meet the June 1/July 1, 1980 deadline may be left in for competition through the regular NIH review cycle or may be withdrawn and resubmitted on or before October 1, 1980 if more time is needed for preparation of the scientific documentation. To withdraw an application contact Dr. Henry Roscoe, Chief, Referral Office, DRG (301) 496-7447.