

# NIH GUIDE

# for GRANTS and CONTRACTS

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

Vol. 8, No. 12, September 26, 1979

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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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NATIONAL RESEARCH SERVICE AWARDS

FOR

INDIVIDUAL POSTDOCTORAL FELLOWSHIPS

IN NUTRITION

**ANNOUNCEMENT**

PARTICIPATING INSTITUTES:

NATIONAL CANCER INSTITUTE  
NATIONAL EYE INSTITUTE  
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE  
NATIONAL INSTITUTE ON AGING  
NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM,  
AND DIGESTIVE DISEASES  
NATIONAL INSTITUTE OF DENTAL RESEARCH  
NATIONAL INSTITUTE OF NEUROLOGICAL AND  
COMMUNICATIVE DISEASES AND STROKE

The National Institutes of Health (NIH) announces the continuing availability of support for research training in the areas of clinical and basic sciences. This announcement deals specifically with nutrition, emphasizing the areas delineated in the attachment.

Under authority of Section 472 of the Public Health Service (PHS) Act as amended (42 USC 2891-1), the NIH makes awards directly to individual postdoctoral applicants who are interested in careers in biomedical and behavioral research. Title 42 of the Code of Federal Regulations, Part 66, is applicable to these awards as are the provisions of the PHS Grants Policy Statement.

Eligibility Requirements As of the beginning date of the proposed fellowship, an applicant must have received a Ph.D., M.D., D.D.S., D.O., D.V.M., Sc.D., D.Eng., D.N.S., or equivalent domestic or foreign degree. In cases where the degree has not been formally conferred, there must be a certification, signed by an authorized official of the degree-granting institution, indicating that all degree requirements have been met. The proposed study must encompass biomedical or behavioral research training with an opportunity to carry out supervised research and must offer opportunity to research health scientists, research clinicians, etc., to broaden their scientific background, or to extend their potential for research in health-related areas. National Research Service Awards (NRSAs) are not made for study leading to the M.D., D.O., D.D.S., or other similar professional degrees, nor may these awards support nonresearch clinical training.

The individual to be trained must be either a citizen or a noncitizen national of the United States or else have been lawfully admitted for permanent residence and must possess an alien registration card I-151 or I-551 before appointment.

Prior to formal submission, an applicant must arrange for appointment to an appropriate institution and acceptance by a sponsor who will supervise his or her training and research experience. The institutional setting may be a domestic nonprofit, private, or public institution including the NIH and ADAMHA. The application must document the availability of staff and facilities to provide a suitable environment for performing high-quality research. The major emphasis of the application should be the research training experience and the broadening of scientific competence.

Under exceptional circumstances, when such study and opportunity are not available at any domestic institution, an individual may request support for study abroad. Such applicant will be required to provide detailed justification based on the uniqueness of facilities and/or training opportunity that are of such a nature and caliber that they cannot be found in the U.S., and the particular suitability of the foreign, rather than the domestic, situation to the proposed research.

Documents to be Submitted The applicant must submit: (1) an application (PHS 416-1); (2) a signed assurance that the service or payback requirement will be complied with if an award is made; and (3) if a noncitizen, a notarized statement of permanent residence. Since a complete application includes the sponsor's Facilities and Commitment Statement, that statement (PHS 416) must be included with the application when submitted. In addition, an applicant must arrange for the submission of reference reports (PHS 416-3) on his or her behalf. An individual may not have two competing applications pending review concurrently in the NRSA program. Individuals are encouraged to review the eligibility criteria before requesting application kits which may be obtained from:

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

A self-addressed gummed label enclosed with the request for kits will expedite handling.

Closing dates for receipt of applications are February 1, June 1, and October 1.

Period of Support No individual may receive more than 3 years of post-doctoral NRSA support in the aggregate. Any exception to this requires a waiver from the Agency head, based on a review of the justification submitted by the applicant and sponsor. Although fellowships are awarded for 12-month periods, assurances may be given by the awarding unit for continued support beyond the first year provided progress is satisfactory and funds are available.

Selection of Awardees Applications will be evaluated by initial review groups at the NIH. The application will be evaluated on: past academic and research records; the research training proposal; the sponsor and the training environment; the applicant's research goals, publications, and reference reports; and other relevant information. NIH program interests and the availability of funds are also considered in the final selection.

Activation Date An awardee has 12 months from the issue date on the award notice to activate a new award.

Stipends and Other Training Costs The current stipend for the first year of support is determined in accordance with the accompanying table by the number of years of prior relevant postdoctoral experience at time of award. Relevant experience may include research experience (including industrial), teaching, internship, residency, or other time spent in full-time pursuit of additional degrees, or full-time studies in a health-related field at a level beyond that of the qualifying doctoral degree. The stipend for each additional year of support is based on the level of the first year plus \$400 for each additional year under the NRSA. There is no allowance for dependents.

#### Current Postdoctoral Stipends

Years of relevant experience at time of initial award	Year of award		
	1st year	2nd year	3rd year
0	\$10,000	\$10,400	\$10,800
1	10,800	11,200	11,600
2	11,500	11,900	12,300
3	12,200	12,600	13,000
4	12,800	13,200	13,600
5	13,200	13,600	14,000

Tuition and travel may be requested. Tuition is limited to that required for specified courses. The institution may request tuition and fees (including appropriate medical insurance) only to the extent that the same resident or nonresident tuition and fees are charged to regular non-Federally supported students.

Conditions of Award No fellow may be supported unless an Activation Notice, form PHS 416-5, and a signed Payback Agreement, form PHS 6031, indicating his or her intent to meet the service or payback provisions required under law have been submitted to NIH. Fellowship appointments are made for full-time research and research training. Fellows may use some of the time in academic studies and clinical duties if such work is closely related to their research training experience.

An NRSA may not be held concurrently with another Federally sponsored fellowship or similar Federal award which provides a stipend or otherwise duplicates provisions of the NRSA. NRSA recipients may, however, accept concurrent educational remuneration from the Veterans Administration (e.g. G.I. Bill) and loans from Federal funds. Supplementation of the NRSA stipend from non-Federal funds is permitted. Other Federal funds may be used for supplementation only if explicitly authorized by the program from which such funds are derived. No NIH, ADAMHA, or HRA grant funds may be used for supplementation. This is not intended to discourage in any way the use of Federal loan funds. Such additional support may be provided without the fellow incurring any obligation, or it may be conditioned on his or her performance of certain services such as teaching or serving as a laboratory assistant. Under no circumstances, however, should the

service requirements detract from or prolong the training.

Within 2 years after completion of NRSA support, recipients of NRSAs are expected to engage in continuous health-related biomedical or behavioral research or teaching, or when in academic employment, any combination thereof which is in accordance with the usual patterns of such employment. Alternatively, if the Secretary, DHEW, determines there are no suitable health research or teaching positions available to the individual, the following may be authorized:

- (1) If the individual is a physician, dentist, nurse, or otherwise trained to provide health care directly to patients, the Secretary may authorize service in the National Health Service Corps, or service in his or her specialty in a health maintenance organization serving a medically underserved population.
- (2) If the individual who received the NRSA is not trained to provide health care to patients, the Secretary may authorize the individual to engage in some other health-related activity appropriate to his or her education and training.

For each year for which an individual receives NRSA support, he or she will engage in 1 year of such service.

For individuals who fail to fulfill their obligation through service, the United States is entitled to recover an amount equal to the total amount paid to the individual plus interest. The amount is computed in accordance with a formula which gives full credit for each month of service when the total payback obligation is not completely fulfilled through service. Interest on the amount begins on the date the United States becomes entitled to such amount; it is computed at a rate fixed by the Secretary of the Treasury considering private consumer rates prevailing on that date. Payment must be completed within 3 years. By Federal regulation, there are certain conditions under which the Secretary, DHEW, may extend the period for undertaking service or for repayment, permit breaks in service, or otherwise waive or suspend the payback obligation of an individual where enforcement of the obligation would involve substantial hardship and be against equity and good conscience.

Fellows are not entitled to vacations as such, although those at academic institutions may take the holidays at Christmas, in the Spring, etc., and the short period between semesters or quarters. The time between a summer session and a fall semester is considered an active part of the training period. Those at nonacademic institutions are entitled to the normal holiday and vacation periods of the institution.

Notification of Final Action The applicant will be notified by the awarding unit of the final action on the application by either an award notice or by a letter.

For additional information on these programs, write to the appropriate contact persons indicated in the attachment. For information on individual NRSAs in areas other than nutrition, write to:

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



National Institutes of Health

Research Area List for

Individual Postdoctoral Fellowships in Nutrition

For purposes of assignment to the appropriate Institute and initial review group, applications must be identified as responding to one or more of the research areas listed below. Therefore, all applications submitted in response to this announcement should include the word "Nutrition" and the name of the relevant Institute on the first page.

NOTE: *The NIH does not provide individual fellowships awards at the predoctoral level.*

NATIONAL CANCER INSTITUTE

The Diet, Nutrition, and Cancer Program of the NCI supports training in the broad areas of diet and nutrition research as they may relate to cancer. The following areas of emphasis are examples:

1. Nutritional biochemistry
2. Nutritional physiology - Factors affecting processes of digestion, absorption, assimilation, and transit. Dietary influence on induction and release of dietary enzymes. Role of enterohepatic circulation.
3. Nutritional microbiology - Dietary influences on gastrointestinal microbial populations, both aerobic and anaerobic. Effects of non-nutritive substances (e.g. fiber), vitamins, minerals, as well as nutrients in various combinations, in the formation of bacterial degradation products.
4. Nutritional immunology - Effects of specific nutrients on cell-mediated and humoral defense systems as they may be related to inhibition of carcinogenesis.

5. Nutritional epidemiology - Biostatistical and epidemiologic methods pertinent to dietary studies. Metabolic and biochemical characterization of body fluids, foods, etc., from populations at low or high risk of cancer.

6. Nutritional endocrinology - The role of diet to various endocrine responses as involved in the initiation or inhibition of carcinogenesis.

The above listed areas are given as examples of project interest. They are by no means meant to be all inclusive.

Contact person:

Dr. Barney C. Lepovetsky  
Chief, Research Manpower Branch  
Training and Education Program  
Division of Cancer Research  
Resources and Centers  
National Cancer Institute  
National Institutes of Health  
Room 10A18, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7803

NATIONAL EYE INSTITUTE

The NEI supports research training in animal and clinical studies in nutrition that relate to the structure and function of the eye in health and disease. Such studies include: the role of varying levels of vitamins, amino acids, minerals, or trace elements in the normal diet as they relate to normal ocular function and to such ocular conditions as corneal, lenticular or vitreous opacities, corneal or retinal dystrophies, and corneal or retinal degenerations; to the prevention of ocular symptoms through supplemental or deficient feeding regimens; and to the effects of individual nutrients on metabolic processes involved in the immune response where the eye is used as a model.

Contact person:

Dr. Thomas C. O'Brien  
Chief, Scientific Programs Branch  
National Eye Institute  
National Institutes of Health  
Room 6A49, Building 31  
Bethesda, Maryland 20205

Telephone: (301) 496-5303

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The NHLBI mandate includes research and research training concerning diseases of the heart and blood vessels, lungs, and blood. Within that scope, all aspects of research training are supported including basic, clinical, and behavioral aspects of nutrition research training. The following areas of emphasis are examples:

1. Dietary influences on atherogenesis.
2. Influence of nutrients (such as cholesterol, carbohydrates, alcohol, dietary fiber, and total caloric intake) on the levels of lipid transport proteins.

3. Identification and mode of action of dietary hypo-cholesterolemic factors.
4. Biostatistical and epidemiologic studies concerning nutritional and dietary factors relating to populations at varying risk of cardiovascular disease.
5. Behavioral and physiological aspects of dietary modification.
6. The role of sodium and potassium in the activity of vascular smooth muscle and in the regulation of fluid volumes, hormonal systems, nervous system function, and blood pressure.
7. Effects of diet and metabolism on the development of sodium-sensitive and sodium-insensitive hypertension in humans.

The research areas listed above are examples only and are not meant to be all inclusive.

Contact persons:

Donald MacCanon, Ph.D.  
Division of Heart and Vascular Diseases  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Room 3A-08A, Federal Building  
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Ms. Barbara Liu  
Division of Lung Diseases  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Room 6A-05, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7668

Fann Harding, Ph.D.  
Division of Blood Diseases  
and Resources  
National Heart, Lung, and  
Blood Institute  
National Institutes of Health  
Room 514, Federal Building  
Bethesda, Maryland 20205

Telephone: (301) 496-1817

NATIONAL INSTITUTE ON AGING

The NIA supports research training in the unique problems associated with clinical nutrition in aging adults. Training grant proposals submitted to NIA in response to this announcement should be directed toward the following major areas, or areas closely related to them:

1. Dietary intake, amount and type of food eaten, and food habits and their relationship to acute functional disorders or chronic degenerative change with age.
2. Nutritional requirements of (a) "normal" aging adults, (b) institutionalized aged adults, (c) physically inactive and physically more active aged adults. Investigation of special nutritional supplementation necessary for the aged clinical, surgical, and postoperative patient.
3. Assessment of nutritional status and changes in body composition; development of methods of measuring the above; the interrelationship of nutritional status with oral, sensory, and gastrointestinal function and elimination in the aged.
4. Investigation of risk factors of diet and lifetime food habits in old age and transfer of this information to relevant health personnel. Improved function during old age as a result of beneficial changes in nutrition.

Contact person:

Dr. Zaven Khachaturian  
National Institute on Aging  
National Institutes of Health  
Room 5C35, Building 31  
Bethesda, Maryland 20205

Telephone: (301) 496-1003

NATIONAL INSTITUTE OF ARTHRITIS,  
METABOLISM, AND DIGESTIVE DISEASES

The Nutrition Program, NIAMDD, provides support for research and research training in basic, clinical, and behavioral science areas related to human nutrition. Other programs of the Institute, especially the Digestive Diseases, Diabetes, Hematology, Endocrinology, and Metabolism Programs, also support relevant nutrition research training. The following are examples of emphasis areas:

1. Human nutritional requirements for all stages of the life cycle and for various disease conditions; factors that may influence dietary needs such as bioavailability, nutrient imbalance, activity level, stress, drugs, and environmental toxicants. Of special interest are studies on the need for trace elements, dietary fiber, and vitamins.
2. Study of the metabolic function of nutrients and the role of nutrients as metabolic regulators.
3. Prevention of obesity - the relationship among genetic predisposition, induced metabolic change, and environmental, physiological, and behavioral factors.

4. Supportive nutrition of patients, with efforts aimed toward the development of improved methodologies for the assessment of nutritional status, and the delivery of the proper amounts of the essential nutrients in the prevention and treatment of specific disease states.
5. Nutritional aspects of digestive diseases, diabetes, anemias, and other metabolic diseases.

Contact person:

Dr. Gerald F. Combs  
Director, Nutrition Program  
National Institute of Arthritis,  
Metabolism, and Digestive  
Diseases  
National Institutes of Health  
Room 606, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7823

NATIONAL INSTITUTE OF DENTAL RESEARCH

Examples of areas in which applications dealing with nutrition research training will be accepted by NIDR include:

1. Dental caries - studies of deficiencies relating to tooth development and caries resistance; laboratory and behavioral studies of man's preference for sweet; studies of sugar substitutes and cariogenicity of foods.
2. Periodontal diseases - studies of the need for trace elements in inflammatory oral disease; studies of the role of nutrition on oral immune systems including cell-mediated and secretory immune mechanisms.
3. Oral soft tissues diseases - effects of nutrition variables on epithelial integrity and function, secretory cell

function, ulcerative diseases, and the possible deleterious effects of subclinical deficiencies on general oral health.

4. Craniofacial anomalies - studies dealing with requirements as well as biochemical and/or metabolic effects of nutrient variables which may cause aberrations in growth and development of the face and jaws including developmental anomalies.

Contact person:

Dr. Paul D. Frazier  
Chief, Soft Tissue Stomatology  
and Nutrition Program Branch  
National Institute of Dental  
Research  
National Institutes of Health  
Room 510, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7807

NATIONAL INSTITUTE OF NEUROLOGICAL  
AND COMMUNICATIVE DISORDERS AND  
AND STROKE

The NINCDS supports training in any aspect of the effects of nutritional factors on neurological or communicative disorders; on the effect of malnutrition on the developing nervous system and on hearing; on central nervous system control of feeding and drinking including hunger, thirst, and water metabolism; effects of administered precursors or analogs of neurotransmitters; and on nutritional factors in immune diseases of the nervous system (allergic encephalomyelitis) and disorders of hearing and equilibrium.

Contact person:

Dr. Raymond Summers  
Assistant Director for  
Manpower Programs  
Extramural Activities Program  
National Institute of Neurological  
and Communicative Disorders and Stroke  
National Institutes of Health  
Room 1020A, Federal Building  
Bethesda, Maryland 20205

Telephone: (301) 496-9236

NATIONAL RESEARCH SERVICE AWARDS

FOR

INSTITUTIONAL GRANTS

IN NUTRITION

**ANNOUNCEMENT**

PARTICIPATING INSTITUTES:

NATIONAL CANCER INSTITUTE  
NATIONAL EYE INSTITUTE  
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE  
NATIONAL INSTITUTE ON AGING  
NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM,  
AND DIGESTIVE DISEASES  
NATIONAL INSTITUTE OF DENTAL RESEARCH  
NATIONAL INSTITUTE OF ENVIRONMENTAL  
HEALTH SCIENCES  
NATIONAL INSTITUTE OF NEUROLOGICAL AND  
COMMUNICATIVE DISEASES AND STROKE

The National Institutes of Health (NIH) announces the continuing availability of support for research training in the areas of clinical and basic sciences. This announcement deals specifically with nutrition, emphasizing areas delineated in the attachment.

Under authority of Section 472 of the Public Health Service (PHS) Act as amended (42 USC 2891-1), the NIH makes grants to eligible institutions for research training programs for individuals, selected by the grantee, who are interested in careers in biomedical and behavioral research in areas of nutrition described in the attachment. Title 42 of the Code of Federal Regulations, Part 66, is applicable to these awards as are the provisions of the PHS Grants Policy Statement.

Eligibility Requirements Domestic nonprofit, private, or public institutions may apply for grants to support training programs in nutrition research. Predoctoral and postdoctoral trainees may be supported if either or both level(s) of training are justified in the application and are approved. The applicant institution must have, or be able to develop, the staff and facilities required for the proposed programs. The training program director at the institution will be responsible for the selection and appointment of trainees to receive National Research Service Awards (NRSAs) and for the overall direction of the program.

The proposed program must encompass supervised biomedical or behavioral research in one or more of the areas specified in the attachment, and offer opportunity for research training leading to the research degree or,

for those who have already attained the research degree, opportunity to broaden their scientific background. For those who have attained the health professional degree, the supervised research should be accompanied by training in scientific methodology; this may be part of a research degree program. NRSAs will not support study leading to the M.D., D.O., D.D.S., or other similar professional degrees, nor will they support nonresearch clinical training.

Predocctoral trainees must have received an appropriate baccalaureate degree as of the date of appointment to the approved training program. An individual at the postdoctoral level must have received, as of the date of appointment to the approved training program, a Ph.D., M.D., D.D.S., D.O., D.V.M., O.D., Sc.D., D.Eng., D.N.S., or equivalent domestic or foreign degree. Certification by an authorized official of the degree-granting institution that all degree requirements have been met is also acceptable.

The individual to be trained must be either a citizen or a noncitizen national of the United States or else have been lawfully admitted for permanent residence and possess an alien registration card I-151 or I-551 at the time of appointment.

Applicants representing interested institutions are advised to contact the person designated in the attachment to discuss any questions, especially if an application including predocctoral training is planned or if compatibility between institutional and agency training aims is in doubt.

Period of Support Institutional grants may be made for project periods of up to 5 years, and may be renewable. No trainee may receive more than 5 years of aggregate NRSA support at the predocctoral level and 3 years of aggregate NRSA support at the postdoctoral level. Any exception to this requires a waiver from the Agency head based on review of justification from the trainee and the grantee institution.

Application and Receipt Applications should be made on Form PHS-6025, which may be obtained from institutional central application control offices of from:

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

A self-addressed gummed mailing label enclosed with requests for application kits will expedite handling.

Closing dates for receipt of applications are February 1, June 1, and October 1.

Review and Selection NRSA institutional grant applications will be evaluated by initial review groups at the NIH and are subject to review and approval by the National Advisory Council or Board of the NIH institute whose activities relate to the training under the award. The application will be evaluated on: the qualifications of participating faculty, proposed research training objectives and program design, previous training experience of the program director, evidence of his or her ability to attract and retain high caliber students, institutional commitment, facilities and environment, and relationship of the proposed program goals to need for research personnel.

Stipends and Other Training Costs Stipends and allowances are as follows: At the predoctoral level, the annual stipend is currently \$3,900. For postdoctoral awardees, the stipend for the first year of support currently is determined in accordance with the accompanying table by the number of years of prior relevant postdoctoral experience at time of appointment. Relevant experience may include research experience (including industrial), teaching, internship, residency, or other time spent in full-time pursuit of additional degrees, or full-time studies in a health-related field at a level beyond that of the qualifying doctoral degree. The stipend for each additional year of support is based on the level of the first year plus \$400 for each additional year under the NRSA. There is no allowance for dependents.

Current Postdoctoral Stipends

Years of relevant experience at time of initial appointment	Year of award		
	1st year	2nd year	3rd year
0	\$10,000	\$10,400	\$10,800
1	10,800	11,200	11,600
2	11,500	11,900	12,300
3	12,200	12,600	13,000
4	12,800	13,200	13,600
5	13,200	13,600	14,000

Tuition and travel may be requested. Tuition at the postdoctoral level is limited to that required for specified courses. The institution may request tuition and fees (including appropriate medical insurance) only to the extent that the same resident or nonresident tuition and fees are charged to regular non-Federally supported students. The institution may also request actual indirect costs, or 8% of total allowable direct costs (whichever is less), and up to 25% of the total award for costs that are deemed essential to carry out the NRSA training program such as salaries, equipment, research supplies, staff travel, etc.

Conditions of Award No trainee may be supported unless a Statement of Appointment, Form PHS-2271, and a signed Payback Agreement, Form PHS-6031, indicating his or her intent to meet the service or payback provisions required under law have been submitted to NIH. Trainee appointments are made for full-time research and research training. Trainees may use some of the time in academic studies and clinical duties if such work is closely related to their research training experience.



An NRSA may not be held concurrently with another Federally sponsored fellowship or similar Federal award which provides a stipend or otherwise duplicates provisions of the NRSA. NRSA recipients may, however, accept concurrent educational remuneration from the Veterans Administration (e.g. G.I. Bill) and loans from Federal funds.

Supplementation of the NRSA stipend from non-Federal funds is permitted. Other Federal funds may be used for supplementation only if explicitly authorized by the program from which such funds are derived. No NIH, ADAMHA, or HRA grant funds may be used for supplementation. This is not intended to discourage in any way the use of Federal loan funds. Such additional support may be provided without the trainee incurring any obligation, or it may be conditioned on his or her performance of certain services such as teaching or serving as a laboratory assistant. Under no circumstances, however, should the service requirements detract from or prolong the training.

Within 2 years after completion of NRSA support, recipients of NRSAs are expected to engage in continuous health-related biomedical or behavioral research or teaching, or any combination thereof which is in accordance with the usual patterns of academic employment. Alternatively, if the Secretary, DHEW, determines there are no suitable health research or teaching positions available to the individual, the following may be authorized:

1. If the individual is a physician, dentist, nurse, or otherwise trained to provide health care directly to patients, the Secretary may authorize service in the National Health Service Corps, or service in his or her specialty in a health maintenance organization serving a medically underserved population.
2. If the individual who received the NRSA is not trained to provide health care to patients, the Secretary may authorize the individual to engage in some other health-related activity appropriate to his or her education and training.

For each year for which an individual receives NRSA support, he or she will engage in 1 year of such service.

For individuals who fail to fulfill their obligation through service, the United States is entitled to recover an amount equal to the total amount paid to the individual plus interest. The amount is computed in accordance with a formula which gives full credit for each month of service when the total payback obligation is not completely fulfilled through service. Interest on the amount begins on the date the United States becomes entitled to such amount; it is computed at a rate fixed by the Secretary of the Treasury considering private consumer rates prevailing on that date. Payment must be completed within 3 years. By Federal regulation, there are certain conditions under which the Secretary, DHEW, may extend the period for undertaking service or for repayment, permit breaks in service, or otherwise waive or suspend the payback obligation of an individual where enforcement of the obligation would involve substantial hardship and be against equity and good conscience.

Trainees are not entitled to vacations as such, although those at academic institutions may take the holidays at Christmas, in the Spring, etc., and the short period between semesters or quarters. The time between a summer session and a fall semester is considered an active part of the training period. Those at nonacademic institutions are entitled to the normal holiday and vacation periods of the institution.

Notification of Final Action The applicant will be notified by the awarding unit of the final action on the application by either an award notice or by a letter.

For additional information on these programs, write to the appropriate contact person indicated in the attachment.

National Institutes of Health  
Research Area List for  
Institutional Grants in Nutrition

For purposes of assignment to the appropriate Institute and initial review group, applications must be identified as responding to one or more of the research areas listed below. Therefore, all applications submitted in response to this announcement should include the word "Nutrition" and the name of the relevant Institute on the first page.

NATIONAL CANCER INSTITUTE

The Diet, Nutrition, and Cancer Program of the NCI supports training in the broad areas of diet and nutrition research as they may relate to cancer. The following areas of emphasis are examples:

1. Nutritional biochemistry
2. Nutritional physiology - Factors affecting processes of digestion, absorption, assimilation, and transit. Dietary influence on induction and release of dietary enzymes. Role of enterohepatic circulation.
3. Nutritional microbiology - Dietary influences on gastrointestinal microbial populations, both aerobic and anaerobic. Effects of non-nutritive substances (e.g. fiber), vitamins, minerals, as well as nutrients in various combinations, in the formation of bacterial degradation products.
4. Nutritional immunology - Effects of specific nutrients on cell-mediated and humoral defense systems as they may be related to inhibition of carcinogenesis.
5. Nutritional epidemiology - Biostatistical and epidemiologic methods pertinent to dietary studies. Metabolic and biochemical characterization of body fluids, foods, etc., from populations at low or high risk of cancer.

6. Nutritional endocrinology - The role of diet to various endocrine responses as involved in the initiation or inhibition of carcinogenesis.

The above listed areas are given as examples of project interest. They are by no means meant to be all inclusive.

Contact person:

Dr. Barney C. Lepovetsky  
Chief, Research Manpower Branch  
Training and Education Program  
Division of Cancer Research  
Resources and Centers  
National Cancer Institute  
National Institutes of Health  
Room 10A18, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7803

NATIONAL EYE INSTITUTE

The NEI supports research training in animal and clinical studies in nutrition that relate to the structure and function of the eye in health and disease. Such studies include: the role of varying levels of vitamins, amino acids, minerals, or trace elements in the normal diet as they relate to normal ocular function and to such ocular conditions as corneal, lenticular or vitreous opacities, corneal or retinal dystrophies, and corneal or retinal degenerations; to the prevention of ocular symptoms through supplemental or deficient feeding regimens; and to the effects of individual nutrients on metabolic processes involved in the immune response where the eye is used as a model.

Contact person:

Dr. Thomas C. O'Brien  
Chief, Scientific Programs Branch  
National Eye Institute  
National Institutes of Health  
Room 6A49, Building 31  
Bethesda, Maryland 20205

Telephone: (301) 496-5303

NATIONAL HEART, LUNG, AND BLOOD  
INSTITUTE

The NHLBI mandate includes research and research training concerning diseases of the heart and blood vessels, lungs, and blood. Within that scope, all aspects of research training are supported including basic, clinical, and behavioral aspects of nutrition research training. The following areas of emphasis are examples:

1. Dietary influences on atherogenesis.
2. Influence of nutrients (such as cholesterol, carbohydrates, alcohol, dietary fiber, and total caloric intake) on the levels of lipid transport proteins.
3. Identification and mode of action of dietary hypocholesterolemic factors.
4. Biostatistical and epidemiologic studies concerning nutritional and dietary factors relating to populations at varying risk of cardiovascular disease.
5. Behavioral and physiological aspects of dietary modification.
6. The role of sodium and potassium in the activity of vascular smooth muscle and in the regulation of fluid volumes, hormonal systems, nervous system function, and blood pressure.

7. Effects of diet and metabolism on the development of sodium-sensitive and sodium-insensitive hypertension in humans.

The research areas listed above are examples only and are not meant to be all inclusive.

Contact persons:

Donald MacCanon, Ph.D.  
Division of Heart and Vascular  
Diseases  
National Heart, Lung, and Blood  
Institute  
National Institutes of Health  
Room 3A-08A, Federal Building  
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Ms. Barbara Liu  
Division of Lung Diseases  
National Heart, Lung, and Blood  
Institute  
National Institutes of Health  
Room 6A-05, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7668

Fann Harding, Ph.D.  
Division of Blood Diseases and  
Resources  
National Heart, Lung, and Blood  
Institute  
National Institutes of Health  
Room 514, Federal Building  
Bethesda, Maryland 20205

Telephone: (301) 496-1817

NATIONAL INSTITUTE ON AGING

The NIA supports research training in the unique problems associated with clinical nutrition in aging adults. Training grant proposals submitted to NIA in response to this announcement should be directed toward the following major areas, or areas closely related to them:

1. Dietary intake, amount and type of food eaten, and food habits and their relationships to acute functional disorders or chronic degenerative change with age.
2. Nutritional requirements of
  - (a) "normal" aging adults,
  - (b) institutionalized aged adults,
  - (c) physically inactive and physically more active aged adults.Investigation of special nutritional supplementation necessary for the aged clinical, surgical, and postoperative patient.
3. Assessment of nutritional status and changes in body composition; development of methods of measuring the above; the interrelationship of nutritional status with oral, sensory, and gastrointestinal function and elimination in the aged.
4. Investigation of risk factors of diet and lifetime food habits in old age and transfer of this information to relevant health personnel. Improved function during old age as a result of beneficial changes in nutrition.

Contact person:

Dr. Zaven Khachaturian  
National Institute on Aging  
National Institutes of Health  
Room 5C35, Building 31  
Bethesda, Maryland 20205

Telephone: (301) 496-1003

NATIONAL INSTITUTE OF ARTHRITIS,  
METABOLISM, AND DIGESTIVE DISEASES

The Nutrition Program, NIAMDD, provides support for research and research training in basic, clinical, and behavioral science areas related to human nutrition. Other programs of the Institute, especially the Digestive Diseases, Diabetes, Hematology, Endocrinology, and Metabolism Programs,

also support relevant nutrition research training. The following are examples of emphasis areas:

1. Human nutritional requirements for all stages of the life cycle and for various disease conditions; factors that may influence dietary needs such as bioavailability, nutrient imbalance, activity level, stress, drugs, and environmental toxicants. Of special interest are studies on the need for trace elements, dietary fiber, and vitamins.
2. Study of the metabolic function of nutrients and the role of nutrients as metabolic regulators.
3. Prevention of obesity - The relationship among genetic predisposition, induced metabolic change, and environmental, physiological, and behavioral factors.
4. Supportive nutrition of patients, with efforts aimed toward the development of improved methodologies for the assessment of nutritional status, and the delivery of the proper amounts of the essential nutrients in the prevention and treatment of specific disease states.
5. Nutritional aspects of digestive diseases, diabetes, anemias, and other metabolic diseases.

Contact person:

Dr. Gerald F. Combs  
Director, Nutrition Program  
National Institute of Arthritis,  
Metabolism, and Digestive Diseases  
National Institutes of Health  
Room 606, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7823

NATIONAL INSTITUTE OF DENTAL RESEARCH

Examples of areas in which applications dealing with nutrition research training will be accepted by NIDR include:

1. Dental caries - Studies of deficiencies relating to tooth development and caries resistance; laboratory and behavioral studies of man's preference for sweet; studies of sugar substitutes and cariogenicity of foods.
2. Periodontal diseases - Studies of the need for trace elements in inflammatory oral disease; studies of the role of nutrition on oral immune systems including cell-mediated and secretory immune mechanisms.
3. Oral soft tissues diseases - Effects of nutrition variable on epithelial integrity and function, secretory cell function, ulcerative diseases, and the possible deleterious effects of subclinical deficiencies on general oral health.
4. Carniofacial anomalies - Studies dealing with requirements as well as biochemical and/or metabolic effects of nutrient variables which may cause aberrations in growth and development of the face and jaws including developmental anomalies.

Contact person:

Dr. Paul D. Frazier  
Chief, Soft Tissue Stomatology  
and Nutrition Program Branch  
National Institute of Dental  
Research  
National Institutes of Health  
Room 510, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7807

NATIONAL INSTITUTE OF ENVIRONMENTAL  
HEALTH SCIENCES

The NIEHS supports those facets of nutrition research and research training which involve: (1) the effects of dietary modifications on susceptibility to toxic agents; or (2) the relationship between nutritional states and toxic effects of environmental agents. Such studies should emphasize mechanistic and metabolic investigations in an attempt to define basic principles as opposed to empirical observations; i.e., data gathering.

Contact person:

Dr. Christopher O. Schonwalder  
Program Director, Research  
Manpower Section  
Extramural Program  
National Institute of Environ-  
mental Health Sciences  
P.O. Box 12233  
Research Triangle Park, North  
Carolina 27709

Telephone: (919) 755-4022

NATIONAL INSTITUTE OF NEUROLOGICAL  
AND COMMUNICATIVE DISORDERS AND  
STROKE

The NINCDS supports training in any aspect of the effects of nutritional factors on neurological or communicative disorders; on the effect of malnutrition on the developing nervous system and on hearing; on central nervous system control of feeding and drinking including hunger, thirst, and water metabolism; effects of administered precursors or analogs of neurotransmitters; and on nutritional factors in immune diseases of the nervous system (allergic encephalomyelitis) and disorders of hearing and equilibrium.

Contact person:

Dr. Raymond Summers  
Assistant Director for  
Manpower Programs  
Extramural Activities Program  
National Institute of Neurological  
and Communicative Disorders and  
Stroke  
National Institutes of Health  
Room 1020A, Federal Building  
Bethesda, Maryland 20205

Telephone: (301) 496-9236

SEARCH FOR SUCRASE-ISOMALTASE DEFICIENT SUBJECTS,

SPECIAL

NATIONAL INSTITUTE OF DENTAL RESEARCH

ANNOUNCEMENT

The National Caries Program (NCP) of the National Institute of Dental Research is seeking sources who have access to sucrase-isomaltase deficient subjects, or who have knowledge of the location of such subjects. The NCP may be interested in supporting a dental study of these subjects if a sufficient number of these individuals can be geographically and medically identified. Interested investigators and institutions are urged to write or call for more detailed requirements and information regarding this announcement:

Dr. Andrew J. Vargosko  
Deputy Chief, Caries Research Grants  
and Contracts Branch  
National Caries Program  
National Institute of Dental Research  
Room 522, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7884

OR

Dr. Norman S. Ikari  
National Caries Program  
National Institute of Dental Research  
Room 549, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7716

This announcement does not commit the NIH to issue any Request for Proposals or Request for Applications, nor does it commit the NIH to award any contracts or grants directed toward the above described area. However, should responses to this announcement indicate sufficient interest and accessibility to such subjects, suitable support mechanisms (contracts and/or grants) may be initiated.



PHYSIOLOGICAL AND PATHOPHYSIOLOGICAL EFFECTS  
OF MECHANICAL CIRCULATORY SUPPORT DEVICES,  
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

**ANNOUNCEMENT**

The National Heart, Lung, and Blood Institute is interested in encouraging interested investigators to submit grant applications to study the physiology and pathophysiology of host response to chronic mechanical circulatory support in animals.

In 1964 the Institute initiated a targeted research and development program with the goal of providing implantable circulatory support systems to assist or replace the failing heart. Reports from several laboratories have demonstrated that mechanical circulatory support is feasible for periods of weeks to months; this provides the opportunity to describe host response to prolonged mechanical circulatory support and study the underlying mechanisms. Through this program announcement, investigators are urged to study the physiological effects of existing devices or major components. This announcement is not intended to stimulate the development of new devices.

The vast majority of research on mechanical circulatory support devices has utilized "tethered" systems in which the stationary drive console, control circuitry, and, in some instances, the blood pump were all located extracorporeally to the animal or patient. Primary emphasis of this new program will be to investigate ventricular support systems or components which are or can be completely implanted. In such a system, the blood pump and the actuation/control mechanisms are all intracorporeal and are designed to function for a period of several months without interruption.

Investigations should be designed to establish a better understanding of one or more of the fundamental mechanisms responsible for host-device interaction and subsequent events which are likely to occur following implantation of a circulatory support device. The program is open to all applicants and encourages studies in such areas as: adjustments of the device to host requirements (e.g. cardiac output, posture) and environmental conditions (e.g. ambient pressure changes) which may be encountered with ambulatory freedom; right ventricular physiology as a function of left ventricular assistance; influence of chronic ventricular unloading on the myocardium; physiological compensation during elevated blood pump output; effect of device motion on surrounding tissue; platelet physiology and the thrombotic process; effect of calcification of device components; and the influence of mechanical circulatory support on autonomic control mechanisms. This listing is intended to provide examples.

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This program is described in the Catalog of Federal Domestic Assistance number 13.837. 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.

Investigators may utilize a complete assist or replacement system, or a single major component. In vivo and/or in vitro experiments may be proposed; however, studies should be limited to existing pulsatile device concepts. Methods for correlating in vitro results with anticipated in vivo results should be clearly described. New animal models or research techniques may be proposed to meet experimental objectives.

Applicants may fabricate components or purchase the required components by negotiation with other sources including NIH grantees or contractors. The Institute is prepared to advise potential applicants on the availability of devices or components.

Applications in the areas noted above do not preclude the submission of applications involving other research problems relevant to the general subject of mechanically supporting the failing heart and circulation.

#### Application Submission and Review

Application receipt dates are March 1, 1980; July 1, 1980; and November 1, 1980. Applications may also be submitted for other regularly scheduled NIH grant application receipt dates. Applications received after any one receipt date are considered and reviewed together with those received by the next receipt date. The earliest possible award date is approximately nine months after the receipt date.

Applicants should use the regular research grant application form PHS 398. Application forms may be obtained at the applicant's institutional grants administration office or upon request from:

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

Please identify responses to this announcement by writing at the top of the face sheet of the grant application "SUBMITTED IN RESPONSE TO NHLBI PROGRAM ANNOUNCEMENT ON EFFECTS OF MECHANICAL CIRCULATORY SUPPORT." The completed application should be mailed to the following address with a copy to Chief, Devices and Technology Branch:

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

The Division of Research Grants will assign applications to study sections for review according to the NIH process for regular research grant applications. Approved applications will compete for available funds with all other approved grant applications assigned to the National Heart, Lung, and Blood Institute.

Additional information may be obtained by contacting:

Dr. John T. Watson  
Chief, Devices and Technology Branch  
Division of Heart and Vascular Diseases  
National Heart, Lung, and Blood Institute  
Room 312, Federal Building  
7550 Wisconsin Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-1586

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NIAID-79-8

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

**ANNOUNCEMENT**

TITLE: *PROGRAM PROJECTS IN MECHANISMS OF IMMUNOLOGIC DISEASES*

*Application receipt date, February 15, 1980*

BACKGROUND INFORMATION

The Allergy and Clinical Immunology Branch of the Immunology, Allergic, and Immunologic Diseases Program of NIAID is concerned with asthma, allergic, and immunologic diseases and with relevant mechanisms of hypersensitivity and inflammation. This request for applications (RFA) is intended to encourage the development of proposals from collaborative basic science and clinical investigative groups, and to coordinate the submission of new and renewal program project applications providing equitable opportunity for both to compete for funds currently available for existing programmatic activities concerned with the study of mechanisms of immunologic diseases. As such, this program is intended to complement the Branch's Asthma and Allergic Disease Center program as well as the Centers for Interdisciplinary Research in Immunologic Diseases program.

Immunologic diseases together with asthma, allergic diseases, and hypersensitivity and inflammatory disorders constitute major areas of endeavor of the Allergy and Clinical Immunology Branch. The programmatic activity on immunologic diseases is designed to further investigate underlying mechanisms of disease and to enhance basic knowledge relevant to the etiology, prevention, and management of immunologic disorders. Studies are effected from either one of two disciplinary approaches: clinical immunology or immunopathology. Clinical immunology studies are directed toward acquired and inherited diseases associated with dysfunctions of the immune system. Immunopathology studies include specific areas of genetics, cytology, biochemistry, physiology, and pharmacology of the immune system and its disorders.

The research to be supported by this announcement is concerned with and seeks to define the etiologic factors, pathogenic mechanisms, development of critical diagnostic measures and approaches to effective prevention, control, and treatment of immunologic abnormalities.

RESEARCH GOALS AND SCOPE

1. Program project grants are awarded to an institution in behalf of a program director for the support of a broadly base, multidisciplinary,

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Legislative authority for this program is found in Section 301 of the Public Health Service Act (Public Law 78-410, 42 USC 241). The Catalog of Federal Domestic Assistance number is 13.855.

long-term research program which has a specific major objective or basic theme. A program project generally involves the organized efforts of groups of investigators, members of which conduct research projects related to the overall program objective. The grant can provide support for the projects and for certain basic resources shared by individuals in a program where the sharing facilitates the total research effort. Each project supported under a program grant is expected to contribute to and be directly related to the common theme of the program; the projects under the direction of a principal investigator should demonstrate an essential element of unity and interdependence. This program does not provide support for nonresearch components, such as a clinical referral service, programs in continuing medical education, or programs for a demonstration and technology transfer.

2. It is planned that awards will be made during fiscal year 1981 to support at least three program project grants. It is anticipated that projects will be initiated April 1, 1981.
3. Proposals should emphasize new ideas and new initiatives and should be concerned with the clinical relevance of new knowledge to the immune system and its disorders deriving from studies in related disciplines.
4. Protocols focused on the study of immune mechanisms in disease should be designed to favor integration and coordination of intra-institutional research projects concerned with immunologic disorders and those in basic biomedical sciences. Programs should include clinical investigative components drawing upon immunologically relevant endeavors in medicine, pediatrics, surgery, and their subspecialties.
5. While proposals should be based on clinical investigation as the major requirement, the value and place of experimental studies are recognized. Inclusion of basic research components utilizing samples of human source materials in in vitro procedures and those involving laboratory animals serving as feasible models for required indepth studies are acceptable. Such work, however, should clearly demonstrate relevance to human diseases.
6. Patient oriented studies and those involving in vitro laboratory procedures and the use of experimental animal models should have an immunologic base or draw upon immunologically relevant areas in the disciplines of biochemistry, pharmacology, microbiology, virology, genetics, or pathology.
7. The proposals should consist of a number of demonstrably integrated projects utilizing multifaceted experimental approaches and investigative probes bearing upon either a well defined immunologic disease or upon immune mechanisms common to multiple human disorders.
8. The proposal should clearly explain how the projected multidisciplinary integrated program can be expected to accomplish the stated goal more efficiently and effectively than a series of independent individual grant supported studies.

9. Designation of a program project director should be based upon accomplishment, experience as a senior scientist, and ability to assume both leadership of the investigative group and responsibility for scientific, professional, and administrative functions, and commitment to devoting a significant amount of his/her time to the project. Each project or subproject in the program should have a designated principal investigator also with a demonstrable record of accomplishment in clinical immunology, immunopathology, or one of the basic science disciplines or clinical specialties relevant to the particular subject of investigation.

#### MECHANISM OF SUPPORT

Support of a program project in Mechanisms of Immunologic Diseases will be limited to a maximum of five years. If a competing renewal application is planned, it should be submitted only in response to an RFA. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years.

The receipt date for applications will be February 15, 1980. They will undergo initial review in June by the Allergy and Immunology Research Committee and subsequent review by the National Advisory Allergy and Infectious Diseases Council in October 1980. April 1, 1981, will be the earliest starting date for successful applicants.

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

#### REVIEW PROCEDURES AND CRITERIA

For preliminary screening by NIAID staff, a "letter of intent" must be submitted by the prospective program director.

Letters of intent should cover the following points:

1. A brief description of the intended project.
2. A description of available laboratory facilities.
3. Ongoing basic and clinical research relating to immunologic diseases, identifying existing projects and sources of support.
4. Past research by members of the proposed investigative group in basic and clinical immunology.
5. A description of all clinic facilities available for use by the proposed project.

6. Specific information on the institution's present patient load and projections for patient involvement in clinical investigation.
7. The academic positions and major research interests of the program director and his professional staff who will be involved in the work of the program project.
8. Collaborative possibilities with other area laboratories and investigators and delineation of the roles and manner of anticipated participation and interaction of the principal investigators, consultants, and collaborators.

Letters of intent are due no later than November 15, 1979, and upon receipt will be screened by NIAID staff to determine the eligibility and suitability of the projected proposals for this announcement.

Inquiries should be directed to:

Robert Goldstein, M.D., Ph.D.  
Chief, Allergy and Clinical Immunology Disease Program  
National Institute of Allergy and Infectious Diseases  
Room 755, Westwood Building  
National Institutes of Health  
Bethesda, Maryland 20205

Telephone: (301) 496-7104

#### CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR OF LATE SUBMISSION

Based upon the letter of intent, potential applicants will be promptly advised whether or not their proposal is found to be within the research goals and scope of the program as defined in this RFA. Applicants will then have an opportunity to correct deficiencies or weaknesses and to restructure their submissions accordingly. Formal applications that are not responsive to the RFA or are not received by February 15, 1980, will not be accepted for review and will be returned to the applicant.

#### METHOD OF APPLYING

Before preparing an application, the prospective applicant should request from NIAID program staff a copy of the NIAID Information Brochure on Program Projects which contains details on the requirements for multi-disciplinary grant applications.

Use the standard research grant application form PHS 398. In addition to following accompanying format instructions for the development of the application, include expanded material listed above under the eight points for the letter of intent. For purposes of identification and processing, the words PROGRAM PROJECT ON MECHANISMS OF IMMUNOLOGIC DISEASES should be typed on the face page of the application and a brief covering letter should be attached indicating submission is in response to this NIAID announcement.

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

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

Forward the completed application to:

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

Please forward a copy (not the original) of the cover letter and the application face page to: (1) the NIAID Program Director in order to alert NIAID to the submission of the proposal, and (2) the Chief, Program and Project Review Branch, NIAID, Room 703, Westwood Building, National Institutes of Health, Bethesda, Maryland 20205.



RESEARCH INTERESTS OF THE  
CHRONIC RENAL DISEASE PROGRAM,  
NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM,  
AND DIGESTIVE DISEASES

**ANNOUNCEMENT**

The Chronic Renal Disease Program of the National Institute of Arthritis, Metabolism, and Digestive Diseases has a special interest in stimulating investigator-initiated research grant applications (ROIs) in both fundamental and clinical investigation of end-stage renal disease, all aspects of its treatment, and pathophysiology of its complications including its related causes.

For specific recommendations of future research directions, potential applicants are encouraged to refer to Research Needs in Nephrology and Urology, Volume 2, Report of the Coordinating Committee (DHEW Publication [NIH] 78-1482), available from Nancy B. Cummings, M.D., NIAMDD, NIH, Room 9A-17, Building 31, Bethesda, Maryland 20205.

METHOD AND CRITERIA OF REVIEW

Assignment of Application - Applications will be received by the NIH's Division of Research Grants, referred to an appropriate study section for scientific review, and assigned to the NIAMDD for possible funding, unless programmatic considerations indicate more appropriate assignment to another Institute. These decisions will be governed by normal programmatic considerations as specified in the DRG Referral Guidelines.

Review Procedures - Applications in response to this announcement will be reviewed on a nationwide basis in competition with each other, and in accord with the usual National Institutes of Health peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (study section). Following study section review, the application will be evaluated for program relevance by the NIAMDD Advisory Council. The review criteria customarily employed by the National Institutes of Health for regular research grant applications will prevail.

Deadline - Applications will be accepted in accordance with the usual receipt dates for new applications:

November 1                      March 1                      or                      July 1

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This program is described in the Catalog of Federal Domestic Assistance number 13.849. 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.

METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions. The phrase, "PREPARED IN RESPONSE TO PROGRAM ANNOUNCEMENT IN CHRONIC RENAL DISEASE," should be typed across the top of the first page of the application.

The original and six copies of the application should be sent or delivered to:

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

For further information, investigators are encouraged to contact:

R. J. Wineman, Ph.D.  
Chronic Renal Disease Program  
Director, Extramural Programs  
National Institute of Arthritis,  
Metabolism, and Digestive Diseases  
Room 621, Westwood Building  
Bethesda, Maryland 20205

Telephone: (301) 496-7458

In order to alert the Immunologic Diseases Program to the submission of proposals with primary thrust directed to immunopathology, immune mechanisms or hypersensitivity, copies of the face page and summary page of such applications should be forwarded under separate cover to:

Robert A. Goldstein, M.D.  
Chief, Allergy and Clinical  
Immunology Branch  
National Institute of Allergy  
and Infectious Diseases  
Room 750, Westwood Building  
Bethesda, Maryland 20205

GERONTOLOGICAL AND GERIATRIC DERMATOLOGY,

NATIONAL INSTITUTE ON AGING

**ANNOUNCEMENT**

I. INTRODUCTION

The National Institute on Aging (NIA) was established by law in 1974 for the "conduct and support of biomedical, social and behavioral research and training related to the aging process and the diseases and other special problems and needs of the aged." Under this broad mandate, it has fostered the study of a wide variety of topics related to aging.

The nature of dermatologic senescence and the prevention and treatment of problems associated with aging skin are among the NIA's areas of research interest. The Dermatology subprogram, a part of the Basic Aging Program, Biomedical Research and Clinical Medicine, NIA, is specifically concerned with research and training in this field.

II. BACKGROUND

Age-related dermatologic changes, which cause considerable physical discomfort and psychological distress, are well-recognized but poorly understood. Research on the mechanisms by which skin ages may permit more effective management of these changes and perhaps ultimately lead to their prevention. In addition, it is significant that aging skin appears to be an excellent model of senescence in general.

Historically, the public's interests and needs associated with skin aging have not been adequately matched with research; however, in recent years the dermatologic aspects of gerontology and geriatrics have received increasing attention. Among the sources of background information that may be useful to investigators new to the study of dermatologic aging are:

Behnke, J.A., C.E. Finch and G.B. Moment (Editors). 1978.  
The Biology of Aging. Plenum Press, N.Y. 388 pages.

Lombardo, P.C. 1979. Dermatologic Disorders in the Elderly.  
In: Clinical Geriatrics, (Chapter 18, pages 338-353), Rossman, I.  
(Editor).  
2nd Edition. J.B. Lippincott Company, Philadelphia. 704 pages.

This program is described in the Catalog of Federal Domestic Assistance number 13.866. 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.

Proceedings of the 28th symposium on the biology of skin. 1979.  
Journal of Investigative Dermatology (Special Issue on Aging),  
Vol. 73(1):1-134.

### III. GOALS AND SCOPE

The goal of the NIA pertinent to this announcement is to understand the basic mechanisms of dermatologic aging and thus to facilitate the prevention, diagnosis, and management of age-related skin disorders. This objective includes the differentiation of innate aging processes from the results of environmental insults. Further, as aging skin appears to be an excellent model of senescence at the extracellular and cellular levels, its study may provide insight into human aging processes in less accessible organs.

### IV. SPECIFIC OBJECTIVES

The NIA seeks research and research training grant applications in gerontological and geriatric dermatology. Investigation related to aging processes is encouraged in disciplines ranging from basic molecular and cell biology to physiology and clinical medicine. Among possible approaches are studies of human skin, of skin-derived cells in culture, and of animal models, as well as the mathematical and computer simulation of biochemical and cellular events. Appropriate topics include, but are not limited to:

#### Molecular and Cellular Biology

e.g. molecular and cellular changes in epidermis, dermis, and subcutaneous tissue; transcriptional and translational control; DNA vulnerability and repair; cellular growth capacity and epigenetic influence on cell function; correlations of in vitro and in vivo cellular aging; enzymology.

#### Structural Anatomy and Pathology

e.g. hypertrophies, atrophies, and changes in pigmentation; changes in vascularization, innervation, and epidermal appendages; capillary fragility.

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<sup>1</sup> Descriptions of NIA-sponsored resources and services are available: Das, N.K., Murphy, D.G. 1978. National Institute on Aging Cell-Line Repository. Experimental Aging Research. 4 (4), 321-331.

Das, N.K., Murphy, D.G., and Fred, I.J. 1978. National Institute on Aging Mycoplasma Testing Service. Experimental Aging Research. 4 (4) 333-341.

<sup>2</sup> Colonies of laboratory mice and rats for aging research are maintained by the NIA. Applicants interested in using these resources must write to the NIA (see address below) to initiate negotiation for potential access to animals.

Immunology

e.g. changes in function and availability of lymphocytes, Langerhans' cells, and macrophages.

Physiology

e.g. thermoregulation, hormone responsivity, wound repair, sensation; changes in the skin as a barrier.

Clinical Topics

e.g. age-related skin problems (stasis dermatitis, pruritus, decubitus ulcers), nutrition, response to therapeutic agents, vulnerability to environment.

V. MECHANISMS OF RESEARCH AND RESEARCH TRAINING SUPPORT

The primary mechanisms for support of this program are:

1. Research Project Grant (the traditional NIH research support mechanism).
2. Postdoctoral Fellowship (the Individual National Research Service Award).

Additional mechanisms for support are:

1. Program Project Grant\* (for multidisciplinary research involving several projects with a common focus).
2. Special Research Award\*\* (for applicants not previously supported as Principal Investigator by a U.S. Public Health Service research grant; ceiling \$30,000 per year for 3 years).
3. Clinical Investigator Award\*\* (for clinically trained investigators; three years of support: salary up to \$30,000; supplies, etc., up to \$10,000 annually).
4. Research Career Development Award.
5. Institutional Training Grant\* (Institutional National Research Service Award) for clinical research training only.

\*Potential applicants should contact NIA staff.

\*\*Write NIA (see below) for information and instructions.

VI. APPLICATION REVIEW AND FUNDING POLICY

All applications will be assigned for consideration and review by the Division of Research Grants according to the NIH process for regular research grants. Approved applications will compete for available funds with all other approved applications assigned to the National Institute on Aging.

B. Statement of the Problem

DCBD is currently supporting a Cytology Automation Program with the ultimate goal of perfecting automated screening of gynecologic samples to determine the presence or absence of premalignant and malignant cells.

Automated systems currently undergoing development and testing include both flow and static high resolution systems. The program has supported development and evaluation of new markers applicable to gynecologic specimens. Several cytochemical markers have been studied. The program effort has emphasized the application of optical techniques such as fluorochrome and absorption dye staining of macromolecules; light scattering techniques have also been studied.

Technology and instrumentation now exist for the study of physical properties of cells such as nuclear, cytoplasmic and membrane structure and fluidity, and degree of chromatin condensation. These techniques include fluorescence depolarization and inter and intramolecular energy transfer. New probes are desirable since they may reveal distinctive information concerning normal, premalignant, and malignant cells.

II. RESEARCH GOALS AND SCOPE

It is the intent of this RFA to stimulate research in identification and evaluation of new biophysical probes for existing instrumentation in flow and static cell analysis systems. It is hoped that this research will lead to innovative approaches to automated system(s) that can be employed to screen normal and abnormal cells.

The proposed study may employ model cell systems; however, if possible, the applicant should test developing methodology on gynecologic specimens.

III. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional NIH grant-in-aid. Successful applicants will plan and execute their own programs. It is anticipated that at least three awards will be made by the National Cancer Institute and the proposal should not exceed three years. The total approximate level of support for year 1 is \$300,000; \$350,000 for year 2; and \$400,000 for year 3. July 1980 starting dates are anticipated.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Method

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) and the NCI staff for responsiveness to this announcement. If the application is judged unresponsive,

the applicant will be given an option to withdraw the application or to submit it for consideration in the traditional grant program of NIH.

Applications judged responsive will be reviewed initially for scientific merit by an NIH peer review group in February 1980. The recommendations of the peer review group will be considered by the National Cancer Advisory Board in May 1980.

#### B. Review Criteria

The factors considered in evaluating each application will be:

1. The scientific merit of the proposed approach. Technical merit includes adequacy and innovation of methodological approach, research design, and statistical analysis.
2. The expertise and qualifications of the Principal Investigator and proposed staff including pathology support.
3. Documentation of the adequacy of the facilities and appropriate collaboration for clinical specimens.
4. Evaluation plan and timetable for completion of each proposed task.
5. Provision for human subjects protection and copies of informed consent forms as necessary if human derived cells are proposed to be used.
6. Documentation of proper animal welfare provisions if it is proposed to use animals.

#### V. METHOD OF APPLYING

##### A. Application Format

Applications should be submitted on form PHS 398. The conventional presentation for grant applications should be utilized and the points identified under the Review Criteria must be fulfilled. The words "IDENTIFICATION AND EVALUATION OF BIOPHYSICAL PROBES SUITABLE FOR DISTINGUISHING MALIGNANT CELLS IN AUTOMATED INSTRUMENT (CYTOLOGY AUTOMATION)" must be typed in bold letters across the top of the face page of the application.

##### B. Application Procedure

The present RFA announcement is open to all interested investigators. Applications must be received no later than November 15, 1979. Applications received after this date will be returned. The original and six copies of the application should be sent or delivered to:

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

A brief covering letter should accompany the application indicating that it is in response to this RFA. A copy of the covering letter should be sent to:

K. Robert McIntire, M.D.  
Director for Diagnosis Program  
Chief, Diagnosis Branch  
Division of Cancer Biology and Diagnosis  
National Cancer Institute  
Room 10A10, Westwood Building  
5333 Westbard Avenue  
Bethesda, Maryland 20205



REQUEST FOR RESEARCH GRANT APPLICATION: RFA

FDA-HFD-79-4

BUREAU OF DRUGS  
FOOD AND DRUG ADMINISTRATION

**ANNOUNCEMENT**

TITLE: *THE BIOAVAILABILITY AND PHARMACOKINETICS OF ORAL  
DOSAGE FORMS IN NEWBORN AND INFANT HUMAN PATIENTS*  
*Application receipt date, November 15, 1979*

I. BACKGROUND INFORMATION

The Biopharmaceutics Program of the Bureau of Drugs, FDA, invites applications to be initiated during FY 1980 for research grants for studies of the bioavailability and pharmacokinetics of drugs from oral dosage in newborn and infant human patients.

It has been recognized for some time that newborn infant humans have unique characteristics with regard to drug disposition compared to adults. This uniqueness is due in large part to differences in the physiology of the newborn. The goal of this program is to provide much needed data on this population.

II. RESEARCH GOALS AND SCOPE

Drugs are absorbed, distributed, metabolized and excreted at different rates and to different extents, often because of poorly developed systems responsible for these processes. The bioavailability of drugs is a function of both rate and extent of absorption. A variety of physiological factors will influence absorption including pH, stomach volume, motility, blood flow, and membrane composition. In the first few days of life, the gastric volume is approximately 1cc/kg. Acidity decreases until age 10 days and then gradually increases until age three until the adult pH is attained. Membranes and processes responsible for transport of drugs show marked immaturity for at least three months of age.

These factors may influence the bioavailability of certain drugs, i.e., drugs whose physio-chemical characteristics may lead to anticipated bioavailability problems. For example, poorly soluble drugs such as the anticonvulsants phenytoin and tegretol may be less bioavailable in infants. Highly lipid-soluble drugs may be more bioavailable in infants than in adults.

Considering the fact that newborns and infants may be more sensitive to drug effects, the amount of drug available has increasing importance.

All policies and requirements that govern the research grants programs of PHS apply. This program is supported under the authorization of Section 301 of the Public Health Service Act, as amended (42 USC 241). The Catalog of Federal Domestic Assistance number is 13.103. Cost sharing is required.

It is felt safety and therapeutic efficacy for several drugs could be improved with a more complete understanding of absorption processes in newborn and infant humans.

The liver of a newborn infant is almost nonfunctional with respect to metabolism and detoxification. Shortly after birth anatomic changes, such as closure of the ductus venosus stimulate rapid development which is evidenced in a variety of ways, including a 5- to 10-fold increase in tyrosine transaminase and increasing amount of vitamin K<sup>1</sup>, smooth endoplasmic reticulum, and glucuronyl transferase.

Studies in this age group present special but not insurmountable problems. The number and volumes of biological samples must be greatly reduced. In addition, the physiological nature of the study population is changing with time. Innovative approaches in analytical methodology and experimental design are therefore required. For example, the information required could be gained from routine blood sampling for therapeutic monitoring in large numbers of patients over relatively long periods of treatment. Unlike many bioavailability studies, such an approach to conducting studies would be of immediate and therapeutic benefit to the study population.

Recent studies in pediatric patient population involving a variety of drugs, e.g. theophylline, phenytoin, and aspirin indicate that the metabolic clearance (biologic half-life) may be a function of age. Contrary to expectation, metabolism is not necessarily slower in pediatric patients (e.g. theophylline) and therefore the labeling requirements for drugs should be based on specialized studies in infants.

### III. MECHANISM OF SUPPORT

- A. Eligibility These grants are available to any public or private nonprofit university, college, hospital, laboratory, or other institution, including State and local units of government.
- B. Length of Support The application may not request more than three years of support. Continued support beyond three years is subject to the grantee's performance, the competitive review process, and the availability of funds.
- C. Funding Plan The actual number of projects funded will depend on the quality of the applications received. The total amount of funds available for FY 1980 is anticipated to be approximately \$250,000.

### IV. REVIEW PROCEDURES AND CRITERIA

The receipt date for applications is November 15, 1979. They will undergo initial review in February-March 1980 and subsequent review by a National Advisory Council in May 1980. The earliest starting date for successful applications will be July 1, 1980.

Applications in response to this invitation will be reviewed on a nationwide basis in competition with each other and in accordance with the following criteria:

- the scientific merit of the research design, approach and methodology, including a thorough review of the literature;
- the research experience, training and competence of the principal investigator and staff to carry out the proposed project. This includes published research work by the investigator on pharmacokinetics and bioavailability of drugs;
- the academic positions and major research interests of the project director and the professional staff that will be involved in the project;
- adequacy of time (effort) to be devoted to the project by investigator(s) and technical staff and evidence of institutional commitment to the program;
- specific information on the institution's present patient load and projections for patient involvement in clinical investigations;
- plan for complying with regulations for the protection of human subjects as applicable to the proposed study, including detailed protocol and consent form;
- appropriateness of requested budget to work proposed.

Proposals considered by the Division of Research Grants, NIH, and FDA to be not responsive to the terms outlined in the RFA will be returned to the investigator. Late submissions will be considered not responsive to this RFA. The applicant may then wish to consider submitting the application to the Division of Research Grants, NIH, as a regular research grant applications.

#### V. METHOD OF APPLYING

##### A. Letter of Intent

Prospective applicants are requested to submit a one-page letter of intent which should include a brief description of proposed areas of research to be studied and the research resources to be available (e.g. personnel, facilities, etc.). These letters should be received by no later than October 15, 1979, and addressed to:

Dr. Bernard Cabana  
Division of Biopharmaceutics  
Bureau of Drugs (HFD-520)  
Food and Drug Administration  
Room 16-62, Parklawn Building  
5600 Fishers Lane  
Rockville, Maryland 20857  
Telephone: (301) 443-4750

For further information about this program, investigators are encouraged to contact Dr. Cabana.

The Bureau of Drugs requests such letters only to provide an indication of the number and scope of applications to be reviewed. A letter of intent is not binding, and it will not enter into the review of any application subsequently nor is it a necessary requirement for application.

B. Application Procedure

Applications must be submitted on the standard research grant application form PHS 398 which may be obtained from:

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

or from business or grants and contracts offices at most academic and research institutions. A statement from collaborators (if any) indicating their willingness to participate in the project should be included. For purposes of identification and processing, the words "BIOAVAILABILITY OF ORAL DOSAGE FORMS" must be typed on the face page of the application and a brief covering letter must be attached indicating that the submission is in response to RFA #FDA-HFD-79-4. A copy of the covering letter must also be sent to Dr. Cabana at the above address.

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

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

LABEL THE OUTSIDE OF THE MAILING PACKAGE AND THE TOP OF THE FACE PAGE "IN RESPONSE TO RFA #FDA-HFD-79-4."

This program is not subject to OMB Circular A-95 clearinghouse requirements or Health Systems Agency review.

REQUEST FOR RESEARCH GRANT APPLICATION: RFA

FDA-HFD-79-3

BUREAU OF DRUGS  
FOOD AND DRUG ADMINISTRATION

**ANNOUNCEMENT**

TITLE: *THE PHARMACOKINETICS AND BIOAVAILABILITY  
OF DRUGS IN DISEASE STATES*  
*Application receipt date, November 15, 1979*

#### I. BACKGROUND INFORMATION

The Biopharmaceutics Program of the Bureau of Drugs, FDA, invites applications to be initiated during Fy 1980 for research grants related to studies of the pharmacokinetics and bioavailability of drugs in disease states.

The Bureau of Drugs has supported pharmacokinetic and bioavailability studies in the past through the mechanism of the contract. This RFA is the first attempt by FDA to stimulate investigator interest in this area through the award of grants. Each successful applicant will be expected to plan, direct, and execute his/her own research program.

#### II. RESEARCH GOALS AND SCOPE

Bioavailability/bioequivalency studies are generally done in normal subjects. Yet, the drug is usually administered to unhealthy subjects. As a consequence, our knowledge of this aspect of the performance of drugs is deficient in that we do not know how disease state may influence performance. It is therefore necessary to undertake bioavailability/bioequivalency in individuals in disease states for which a given drug is indicated as well as other disease states. Some examples regarding the possible effect of disease state on drug absorption, metabolism, and action are presented below.

Renal Function Impairment This is probably the most common and most important situation in which dosage adjustment is necessary. The half-life of many drugs that are eliminated from the body predominantly by glomerular filtration has been shown to increase several-fold in oliguric patients. For example, tetracycline has a half-life of 57 to 108 hours in patients with renal disorders compared to 8.5 hours in normal patients. Likewise, the half-life of digoxin increases by almost three-fold in anuric subjects.

Liver Disease The disappearance of many drugs eliminated mainly by metabolism has been shown to be affected by liver diseases. For

All policies and requirements that govern the research grants programs of PHS will apply. This program is supported under the authorization of Section 301 of the Public Health Service Act, as amended (42 USC 241). The Catalog of Federal Domestic Assistance number is 13.103. Cost-sharing is required.

example, the half-life of elimination of tolbutamide in 5 out of 10 cirrhotic patients was found to be 7.8 hours to 11.2 hours compared to an average of 4.4 hours in patients with normal liver function. Also, the elimination of chloramphenicol, phenylbutazone, meprobamate, amobarbital, acetaminophen, lidocaine, and prednisolone, was decreased in liver-diseased patients. Liver diseases are likely to produce qualitative and quantitative changes in plasma proteins and binding of drugs. These changes may affect the pharmacokinetics and, subsequently, the pharmacologic action of drugs. For example, an association was found between low serum albumin levels and adverse effects of prednisone in 240 patients. Protein binding of amylobarbitol was reduced in patients with abnormally low concentrations of albumin in serum, and the half-life of disappearance of the drug was increased by better than two-fold.

Cardiovascular The effects of congestive heart failure occurs where decreased cardiac output results in decreased blood perfusion of many parts of the body, including the gastrointestinal tract. Therefore, the rate and extent of a drug product may be affected in an individual with congestive heart failure. For example, patients with congestive heart failure who were administered quinidine have T<sub>max</sub> values approximately two hours later than in normal individuals. Further, the estimated rate of drug absorption in the congestive heart failure patients was only one-third of that in normal subjects. All of the processes involved in drug disposition, absorption, distribution, and elimination may be influenced by perfusion considerations. Alterations in organ perfusion may arise because of either changes in the magnitude and/or the regional distribution of the cardiac output and may involve physiological, pathological, surgical, or drug related events.

### III. MECHANISM OF SUPPORT

- A. Eligibility These grants are available to any public or private nonprofit university, college, hospital, laboratory, or other institution, including State and local units of government.
- B. Length of Support The application may not request more than three years of support. Continued support beyond three years is subject to the grantee's performance, the competitive review process, and the availability of funds.
- C. Funding Plan The actual number of projects funded will depend on the quality of the applications received. The total amount of funds available for FY 1980 is anticipated to be approximately \$250,000.

### IV. REVIEW PROCEDURES AND CRITERIA

The receipt date for applications is November 15, 1979. They will undergo initial review in February-March 1980 and subsequent review by a National Advisory Council in May 1980. The earliest starting date for successful applicants will be July 1, 1980.

Applications in response to this invitation will be reviewed on a nationwide basis in competition with each other and in accordance with the following criteria:

- the scientific merit of the research design, approaches and methodology including a thorough review of the literature;
- the relevance of the research experience, training, and competence of the principal investigator and staff to carry out the proposed project. This includes published research work by the investigator on pharmacokinetics and bioavailability of drugs;
- a description of ongoing research in the area of pharmacokinetics and bioavailability of drugs;
- adequacy of time (effort) to be devoted to the project by investigator(s) and technical staff and evidence of institutional commitment to the program;
- specific information on the institution's present patient load and projections for patient involvement in clinical investigation;
- the academic positions and major research interests of the project director and the professional staff that will be involved in the project;
- plan for complying with regulations for the protection of human subjects as applicable to the proposed study, including detailed protocol and consent form;
- appropriateness of requested budget to work proposed.

Proposals considered by the Division of Research Grants, NIH, and FDA to be not responsive to the RFA will be returned to the investigator. The applicant may then wish to consider submitting the application to the Division of Research Grants, NIH, as a regular research grant application.

## V. METHOD OF APPLYING

### A. Letter of Intent

Prospective applicants are requested to submit a one-page letter of intent which should include a brief description of the proposed areas of research to be studied and the research resources to be available (e.g. personnel, facilities, etc.). These letters should be received no later than October 15, 1979, and addressed to:

Dr. Bernard Cabana  
Division of Biopharmaceutics  
Bureau of Drugs (HFD-520)  
Food and Drug Administration  
Room 16-62, Parklawn Building  
5600 Fishers Lane  
Rockville, Maryland 20857

Telephone: (301) 443-4750

For further information about this program, investigators are encouraged to contact Dr. Cabana.

The Bureau of Drugs requests such letters only to provide an indication of the number and scope of applications to be received. A letter of intent is not binding, and it will not enter into the review of any application subsequently nor is it a necessary requirement for application.

B. Application Procedure

Applications must be submitted on the standard research grant application form PHS 398 which may be obtained from:

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

or from business or grants and contracts offices at most academic and research institutions. A statement from collaborators (if any) indicating their willingness to participate in the project should be included. For purposes of identification and processing, the words "PHARMACOKINETICS AND BIOAVAILABILITY OF DRUGS" must be typed on the face page of the application and a brief covering letter must be attached indicating that the submission is in response to RFA #FDA-HFD-79-3. A copy of the covering letter must also be sent to Dr. Cabana at the above address.

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

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

LABEL THE OUTSIDE OF THE MAILING PACKAGE AND THE TOP OF THE FACE PAGE "IN RESPONSE TO RFA #FDA-HFD-79-3."

This program is not subject to OMB Circular A-95 clearinghouse requirements or Health Systems Agency review.



EXTRAMURAL ASSOCIATES PROGRAM

**ANNOUNCEMENT**

The National Institutes of Health (NIH) announces a special program under the Intergovernmental Personnel Act (IPA) of 1970 (Public Law 91-648) to promote the entry and participation of ethnic minorities and women in NIH-supported research.

Participation in NIH-supported research is facilitated by a thorough knowledge of the research concerns of the NIH, the support mechanisms through which this research is being accomplished, and the policies and procedures which govern the awarding of grants and contracts. The IPA offers an opportunity to disseminate needed knowledge by authorizing, for work of mutual concern and benefit, temporary appointments of employees between Federal executive agencies, State and local governments, institutions of higher education, and Indian tribal governments.

In recent years, significant numbers of personnel from academic institutions have effected temporary assignments at the NIH using the IPA mechanism. Yet, institutions which traditionally contribute to the basic preparation of minorities and women for biomedical science are not utilizing this opportunity to an equal extent. While not excluding any individuals or institutions from the available options under the IPA, the NIH is initiating a special effort, the Extramural Associates Program, in order to redress a noticeable inequity in the current use of an available opportunity.

Under the Extramural Associates Program, the NIH, in each of two groups, will invite up to eight key administrators, involved with science, from schools which contribute significantly to the pool of minorities and women in science, to spend six months in residence in Bethesda, Maryland. Salary, travel, and related expenses will be reimbursed by the NIH to the limit allowed under the IPA. In addition, a per diem allowance has been arranged to cover normal cost of living while in Bethesda.

While in the program, the Associates will work in rotating assignments with senior members of the staff of the NIH and other Federal agencies. They will attend seminars, committee meetings, workshops, and site visits and will have the opportunity to obtain, on site, information about Federal health-related programs and associated granting and contracting activities.

The NIH expects that such information will primarily benefit the institutions from which the Associates come in the sense that, when the Associates return to their schools, they will be resources from whom faculty and students (many of whom will be minority and/or female), can obtain information on NIH-funded health-research programs. The information gained will also benefit the Associates themselves in their professional development as administrators of science. In addition, the NIH expects immediate benefits from the special contributions to be made by these experienced administrators while at the NIH.

Nomination of a candidate will be accepted from the president or an equivalent official of an eligible institution. In addition to the general requirements of the IPA, emphasis for selection of Associates will be on the demonstrated contribution of an institution to the advancement of ethnic minorities and women; on its plan to utilize the Associate's newly gained knowledge to promote entry of minorities or women into health-related sciences; and on the qualifications, experience, and interest of the nominee. Consideration will be given to a representative distribution of Associates from among the nominating colleges and universities.

All Associates will be required to participate in the program for six months beginning approximately August 1, 1980, or February 1, 1981. Nominations and completed applications are due by January 31, 1980; selections will be announced by April 30, 1980.

Additional information concerning this program and instructions for completing the application may be obtained by writing or calling:

Administrator  
Extramural Associates Program  
National Institutes of Health  
Room 1A10, Building 31  
Bethesda, Maryland 20205

Telephone: (301) 496-9728

REVISED INSTRUCTIONS

FOR

COMPLETION OF

RESEARCH GRANT APPLICATIONS

(Form PHS 398)

**NOTICE**

The *NIH Guide for Grants and Contracts*, Vol. 8, No. 10, July 23, 1979, edition described certain changes effective immediately in the research grant application form PHS 398. The page limitation for biographical sketches was incorrectly noted as two pages in the announcement. Until the new form PHS 398 itself is available, biographical sketches may be three pages in length. Three pages are needed because other research support is currently described in the biographical section. In the new form PHS 398 that will be available in several months, the biographical sketch page limitation will be two pages, other research support will be described in another section.

Fliers in current PHS 398 application kits dated June 1979 or August 7, 1979, correctly indicate three pages as the current biographical sketch limitation.

Numerous inquiries have been received about applications that have been submitted or are nearly completed which used the "old" instructions in the PHS 398 kits. Although PHS will accept applications prepared using the Instruction Sheet in current PHS 398 kits dated "Rev. 2-73," applicants are asked to begin using at the earliest possible time the new format specified in the July 23, 1979, issue of the *Guide* and fliers in the application kits entitled Revised Instructions for Research Grant Applications dated June 1979 or August 7, 1979.

NURSING RESEARCH PROGRAM GRANTS  
DIVISION OF NURSING

**NOTICE**

The Division of Nursing, Health Resources Administration, today announced that a site visit will no longer be required prior to review of a Nursing Research Program Grant Application. This announcement is effective for all applications submitted for the November 1 review cycle. Nursing Research Program Grants are awarded to eligible institutions to stimulate the conduct of clusters of studies focused upon a single theme, and pre-review site visits have been required. A site visit will now be made only when it is essential to obtain additional information.

Applicants should contact Dr. Doris Bloch early in the process of developing an application to determine programmatic eligibility. Dr. Bloch may be contacted by telephone (301) 436-6204 or by writing to:

Research Support Section  
Nursing Research Branch  
Division of Nursing, BHM, HRA  
3700 East-West Highway, Room 3-50  
Hyattsville, Maryland 20782

NURSING RESEARCH PROJECT GRANTS  
DIVISION OF NURSING

**NOTICE**

The Division of Nursing is continuing to accept applications for Nursing Research Project Grants for individual research studies in areas of interest to nursing. This long-standing program has not been replaced by the "cluster of studies" program described above. Additional information may be obtained by contacting the Research Support Section of the Division of Nursing.