

# NIH GUIDE

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## For Grants and Contracts

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## NOTICE

### PHS 398 GRANT APPLICATION, REVISED 9/86, NOW AVAILABLE

P.T. 34; K.W. 0710030, 1014002

National Institutes of Health

The newly revised Public Health Service grant application form (PHS 398) is now available. The new version replaces the form presently in use, dated 5/82.

The new PHS 398 application kit includes instructions for applying for new, competing renewal, and competing supplemental research grant support. In addition, the new version incorporates the National Research Service Award (NRSA) Institutional Training Grant form (formerly the PHS 6025 form) as well as supplemental instructions for applying for a Research Career Development Award (RCDA). The new form should be used by NRSA Institutional Training Grant applicants starting with the September 10, 1987 receipt date, and by research grant and RCDA applicants starting with the October 1, 1987 receipt date.

The revised application kit includes several significant changes. Careful attention should be paid to the application instructions that specify page limitations for core elements common to all proposals. For example, Sections A-D of the Research Plan should not exceed 20 pages in length, unless specified differently in a program announcement, a request for applications, or supplemental instructions. In addition, there are important changes in the Face Page, page 2 (abstract and key personnel,) and other sections of the application.

The Public Health Service has sent a specific number of copies to each grantee business office at their institution for a copy of the application. Institutions needing additional copies of the application should contact:

(1) For multiple copies -

Office Services Section (PHS 398)  
Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 436  
Bethesda, Maryland 20892  
Telephone: (301) 496-9797

(2) For a single copy -

Office of Grants Inquiries (PHS 398)  
Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 449  
Bethesda, Maryland 20892

### DATED ANNOUNCEMENTS (RFAs AND RFPs AVAILABLE)

#### DEVELOPING AND IMPROVING INSTITUTIONAL ANIMAL RESOURCES

RFA AVAILABLE: 87-RR-02

P.T. 34; K.W. 1002002, 0201011, 0780000

Division of Research Resources

Application Receipt Date: September 16, 1987

As part of its mission to create, develop, and maintain animal resources needed by NIH-supported biomedical investigators throughout the nation, the Division of Research Resources (DRR) is continuing its competitive grant program to help institutions upgrade and develop their animal facilities. DRR anticipates that \$9.981 million may be available to support such improvement grants in Fiscal Year 1988.

#### RESEARCH GOALS AND SCOPE

Institutional animal resource improvement projects are awarded to assist biomedical research and educational institutions to upgrade their animal facilities and develop centralized programs of animal care. A major objective is to enable institutions to comply with the USDA Animal Welfare Act and DHHS policies on the care and treatment

of animals. These awards are limited to alterations and renovations (A&R) to improve laboratory animal facilities and related equipment, such as animal cages and cage washers. It is not the purpose of the improvement grant to provide general operating costs for the resource; e.g., funding for personnel, consumable supplies for routine animal care, etc. The projects are supported for one year, after which the applicant institution is expected to assume complete financial responsibility for its basic animal resource.

To gain approval and support, both the need for resource improvement and a sound plan to meet the requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals must be presented and described in the context of the biomedical research and research training program of the institution.

#### ELIGIBILITY AND REVIEW

Any domestic public, or private nonprofit institution, organization or association with one or more projects supported by the Public Health Service involving the use of animals is eligible to apply. Applicants are expected to develop a single proposal for campus-wide service.

Applications will be received by the Division of Research Grants. Applicants must use PHS Form 398, "Application for Public Health Service Grant." A receipt date of September 16, 1987 has been established. Applications received after this date will not be accepted for review in this competition. The RFA label available in the 9/86 revision of Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review. All applications submitted in response to this RFA will be reviewed by the DRR Animal Resources Review Committee for scientific merit and the National Advisory Research Resources Council for program considerations.

#### MECHANISM OF SUPPORT

Awards will be made as competitive resource grants for a project period of one year. It is expected that from 30 to 40 awards will be made in Fiscal Year 1988. The number of grants and the specific amount of awards will depend on the merit and scope of the applications received and the availability of funds. All policies and requirements which govern the grant programs of the PHS apply.

#### TERMS OF AWARD

Alterations and renovations (A&R) are limited to a maximum award of \$500,000 from this grant program. Equal matching funds from nonfederal sources are required for all A&R. In addition to the A&R request of up to \$500,000, institutions may request needed items of equipment for their animal resource on a nonmatching basis. Support for new construction is not authorized. Funds awarded for A&R may not be obligated until final drawings, specifications, and updated cost estimates are received and approved by the Division of Research Resources.

#### INQUIRIES

A copy of the complete RFA, which describes the research goals and scope, terms and conditions, review procedures and criteria, and method of applying, may be obtained by contacting the Animal Resources Program, DRR:

Dr. William I. Gay  
Chief, Animal Resources Program  
Division of Research Resources  
Building 31, Room 5B59  
National Institutes of Health  
Bethesda, Maryland 20892  
Telephone: (301) 496-5175

#### DEVELOPMENT OF BIOMARKERS OF AGING

RFA AVAILABLE: 87-AG-01

P.T. 34; K.W. 0710010, 0780000, 0755020, 1002004, 0785050, 1002042, 0710040

National Institute on Aging

Application Receipt Date: August 24, 1987

#### INTRODUCTION

The Biomedical Research and Clinical Medicine Program (BRCM), National Institute on Aging (NIA), announces the availability of a request for applications (RFA) for the

development of biomarkers of aging using rodent animal models supplied by the NIA. The goals of this request are to encourage the development of rodent biomarkers of aging in genetically defined rats and mice developed and maintained by the NIA in collaboration with the National Center for Toxicological Research (NCTR) exclusively for biomarker research.

The present RFA Announcement is for a single competition with a specified deadline of August 24, 1987.

#### BACKGROUND

One of the mandates of the National Institute on Aging is to develop research approaches to extending the vigorous and productive years of life. In response to this mandate, the NIA has begun a process with a long-term objective of assessing interventions that affect aging. In order to test the effects of interventions, particularly interventions on humans, a testing strategy which is both scientifically valid and achievable in significantly less than a human lifespan is essential. This need for a workable test strategy has fostered interest in the development of biomarkers of aging.

As one step in a plan to implement testing of potential biomarkers, the NIA, in collaboration with the National Center for Toxicological Research (NCTR), is currently developing a colony of four mouse genotypes and three rat genotypes, maintained with and without calorie restriction, as a resource for rodent biomarker research. This major animal resource will provide a suitable test population for eight to ten investigator-initiated biomarker research projects.

This RFA is to encourage the development of research projects which utilize the available colony of rodents to conduct biomarker research. Although applications are not limited to investigators currently conducting biomarker research, applications will be limited to investigators who are able to accept animals from the NIA/NCTR biomarker colony and who have suitable facilities for housing these animals. All responsive applications from qualified investigators will be considered.

#### RESEARCH GOALS AND SCOPE

The objective of applications submitted in response to this request should be the development and testing of one or more biomarkers of aging using mice and/or rats obtained from the NIA/NCTR biomarker research colony. Collaborative research proposals from investigators will be accepted where biomarker development requires multiple research skills not available in a single institution, where collaboration enhances the value of the research conducted at the cooperating institutions or where multiple use of animals is scientifically feasible and allows significant research cost economies.

In order to allow for the development of a broadly based panel of biomarkers, applications are solicited from a wide variety of approaches. Applications will be accepted for biomarker development for any one or more of the following research areas:

1. Immunologic
2. Sensory and motor function
3. Learning and memory
4. Neuroendocrine
5. Cardio-pulmonary
6. Endocrine-metabolic
7. Renal function
8. Reproductive function
9. Chromosomal
10. Neuromuscular
11. Connective tissue
12. Clinical chemistry
13. Molecular and cellular alterations
14. Other promising biomarkers not included above.

The research plan for biomarker development should include evaluation of each potential biomarker for reproducibility, sensitivity, significance of rate of change over the lifespan, temporal pattern of changes, non-lethality, degree of invasiveness required, potential functional importance to human aging, simplicity, and cost-effectiveness.

All testing will be carried out using NIA/NCTR biomarker animals. Mice available in this colony will include C57BL/6NNIA, DBA2/NNIA, B6D2F1 (C56BL/6NNIA X DBA2/NNIA), B6C3F1 (C57BL/6 X C3H) ranging in age from 3 to 30 months (approximately 22,000/year). Available rats will include Fischer 344, Brown-Norway, and F344 X BN hybrids ranging in age from 3 to 24 months (approximately 6,000/year). Ad libitum fed and dietary restricted animals will be provided.

## MECHANISM OF SUPPORT

Awards will be made as Research Grant (R01) Awards. The regulations and policies that govern the research grant programs of the Public Health Service will prevail.

The award of grants pursuant to this RFA is contingent upon receipt of appropriated funds for this purpose. This RFA is a one-time invitation. There are no plans for future reissuance. The duration of proposed projects may be up to five years. Projects may be extended, through competitive renewal application. However, there have been no funds specifically reserved for renewals at this time.

The start date for funded projects will be approximately March 1, 1988. A total of \$1,000,000 will be available for this program in FY 1988. Funds for subsequent years are expected to range from \$750,000 to \$1,000,000 per year. Individual awards are expected to range from \$75,000 to \$100,000 per year. Collaborative applications or applications to test more than one type of potential biomarker could be higher with sufficient justification. A maximum of 8 to 10 awards is anticipated.

## REVIEW PROCEDURES AND CRITERIA

All applications received in response to this RFA will be reviewed for scientific and technical merit by an initial review group which will be convened by the NIA solely to review these applications. Applications judged not responsive to the RFA will be returned without review.

The factors to be considered in the evaluation of the scientific merit of each application will be those used in the review of traditional research-project grant applications. Following initial review, the applications will be reviewed by the National Advisory Council on Aging. Awards will be made on the basis of scientific merit and the need to fund applications which provide a broad spectrum of potential biomarkers.

## METHOD OF APPLYING

Prospective applicants are encouraged to submit to the program administrator indicated below a non-binding letter of intent to apply, post-marked no later than July 1, 1987. The letter of intent is not mandatory and does not influence the review or funding decisions, but it will enable the NIA to plan the review, and will ensure that each potential applicant receives relevant program information prior to application preparation.

Applications should be submitted on the standard PHS-398 application form available at most institutional business offices or from the Division of Research Grants, NIH, (301) 496-7441. On item 2 of the face page of the application, applicants should enter: RFA: Development of Biomarkers of Aging.

The deadline for receipt of applications by the NIH Division of Research Grants (DRG) is August 24, 1987. Send the original and five copies to:

Application Receipt Office  
Division of Research Grants  
Room 240, Westwood Building  
National Institutes of Health  
Bethesda, Maryland 20892\*\*

Simultaneously submit a single copy to:

Chief, SRO/OEA/NIA  
Building 31, Room 5C12  
National Institutes of Health  
Bethesda, Maryland 20892

The label provided with the full RFA must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review.

A copy of the complete RFA describing the goals, the available animal resources, the animal housing and feeding requirements, the review criteria, and the method of applying can be obtained from:

Richard L. Sprott, Ph.D.  
Associate Director, BRCM, NIA  
Building 31, Room 5C11  
9000 Rockville Pike  
Bethesda, Maryland 20892  
Telephone: (301) 496-4996

## ONGOING PROGRAM ANNOUNCEMENTS (PA#)

### AGING AND FORMAL HEALTH CARE

P.T. 34, 44; K.W. 0710010, 0730000, 0404000, 0710030

National Institute on Aging

The National Institute on Aging (NIA) invites qualified researchers to submit research and research training grant applications to investigate the complex interrelationships among health care systems, aging processes, and health and functioning in the middle and later years. Social and behavioral research is solicited on all types of health services and treatments including outpatient visits, hospitalizations, institutional care, home care and other alternatives to institutional care for preventive, curative as well as palliative or custodial purposes.

Research is needed on how the relationships and interactions between aging people and health care practitioners and institutions affect health maintenance and disease prevention, coping with chronic illnesses and disabilities, and effective functioning and quality of life. Few studies have systematically addressed how formal health care relates to the physiological, social or psychological changes that people experience as they grow older. Also neglected are organizational linkages, if any, among different types of care as older persons move through the health care system.

Interdisciplinary studies which bring together theoretical concepts and methodologies from the social and behavioral sciences, health services research, and geriatric medicine are needed. The aim is to add to knowledge of how the social and cultural context interacts with various features of the health care system to affect health and functioning as people grow older. The accumulating knowledge of the determinants and consequences of care will aid in the planning and implementation of appropriate health services for older persons.

This announcement adds to but does not replace earlier NIA program announcements. It specifies the general announcement on Health and Effective Functioning in the Middle and Later Years (See NIH Guide for Grants and Contracts, Vol. 12, No. 6, June 17, 1983, pp.10-15) and also complements the existing announcements on the Oldest Old (Vol. 13, No. 13, December 7, 1984) and on Health Behaviors and Aging (Vol.12, No.11, November 11, 1983) which has a primary focus on informal care. The new initiative on aging and formal health care is coordinated with related programs in the National Center for Health Services Research and Health Care Technology Assessment and the National Institute of Mental Health.

### BACKGROUND

There have been dramatic changes in recent years in the organization, delivery and financing of health care for older Americans. Formal health care is now characterized by a variety of forms as well as new modes of payment. Recent changes in health services for older persons are, in part, a response to concerns about (1) the burgeoning health care needs associated with the rapidly growing older population and (2) projections of escalating health care costs. Although older people are indeed more likely than younger people to contact physicians and to utilize hospital, nursing home and home health care, there is marked diversity among the older population, with only a relatively small percentage of the oldest, most severely disabled group using a disproportionate amount of health care. Systematic study of medical and social determinants and consequences of different types of health care as well as factors leading to health care use is needed.

Several key points about aging and health care should be kept in mind. The great majority of day-to-day caregiving for non-institutionalized older persons is provided informally by family and friends. Thus, it is essential to understand the linkages between the formal and informal health care systems. A life course perspective is especially relevant as health and health care experiences of persons in earlier life, or successive episodes of illness or of institutional care, may influence subsequent interactions with health care systems as well as morbidity and mortality outcomes in old age. In addition, research needs to recognize the diversity of the older population in terms of age, functional ability, socioeconomic status and many other factors. In particular, more needs to be known about the use of health services by ethnic and minority populations.

A 1985 conference on Aging and Formal Health Care was co-sponsored by the National Institute on Aging and the National Center on Health Services Research and Health Care Technology Assessment to review substantive research in this area and to identify new directions for future research. The conference highlighted many promising research areas, emphasizing three that require immediate attention by social and behavioral scientists: (1) determinants and consequences of organizational aspects of aging and formal health care; (2) provider-patient

behaviors and interactions in aging populations; and (3) long term institutional care for older adults. Research attention to aging and formal health care has been further spurred by Congressional interest for FY 1987 in "the medical and nonmedical long-term care needs of aged persons with chronic illnesses and their families" (Congressional Report 99-711, p.74).

#### SPECIFIC OBJECTIVES

##### The organization of health services:

Research is needed to specify the manner in which the structure, financing, and other aspects of health services affect the health and behaviors of aging people and their families. Structural characteristics might include, for example, factors such as type of service, care setting, mix of health care and social service providers, practice characteristics or forms of provider reimbursement. Studies of innovative techniques for coordinating care and of the medical and social correlates of new and developing forms of home and community care are needed. Examples of research topics include:

- o Macro-structural influences (e.g., national health care policies) on informal and formal health care behaviors and patient outcomes.
- o The influence of organizational characteristics of health care institutions on patient behaviors and morbidity and mortality.
- o The nature and consequences of organizational coordination--or lack of coordination--among different systems of care utilized by older persons, e.g., home health, respite or day care, hospital, or nursing home including the links to informal care.
- o The impact of changing social and cultural factors in an aging population on the organization of health care and related health outcomes.
- o The social processes involved in the allocation of specific individuals to specific care settings and the consequences of these assignments with particular attention to special populations such as the oldest old, rural elderly, or minorities.
- o The impact of innovative alternative delivery systems and interventions on the quality of care and the older patient's health and functioning.

##### Patient-provider behaviors and interactions:

Few studies examine how aging processes affect provider-patient relationships. This solicitation calls for a dynamic approach for studying the determinants and consequences of provider, patient, and patient-provider behaviors and interactions. Studies are needed on the process of provider-patient interactions as well as on the outcome of these interactions. Examples of research topics include:

- o The impact of provider characteristics, patient characteristics (e.g., minority status, affliction with Alzheimer's Disease) and the context of care on provider-patient interactions (e.g., time spent with patient, manner of communication) and related patient outcomes.
- o Analyses of the content and processes of provider-patient interactions, including the congruence or discordance of provider and older patient's attitudes and expectations.
- o The effects of provider-patient interactions on health outcomes such as compliance, satisfaction, future health care utilization and health status among elderly patients.
- o The roles of family members, friends and other sources of social support in provider-patient relationships.
- o The effect of new forms of medical practice or modes of payment on physicians' interactions with elderly patients.
- o An examination of the nature of interactions among the variety of practitioners (medical and social) that older people seek help from for illness episodes.
- o Coordination and monitoring of health care across successive episodes of illness, as a person grows older.

##### Social and behavioral aspects of institutional care:

While predictors of institutionalization in nursing homes have been fairly well studied, less is known about the processes of care or the movement through nursing homes and the wide variety of newly emerging types of institutional care (e.g., day



care, respite care, community home care services). Research is needed on how social, behavioral and environmental factors are related to the health and functioning of frail elderly and their various types of caregivers. The issue of heterogeneity of institutional populations has been largely ignored, particularly in linking individual variations to health and functioning outcomes over the course of the institutional stay. Also important are factors affecting the movement in and out of different residential care settings and factors in length of stay. Examples of research topics that need examination are:

- o The process of institutionalization, including the discrete series of events and decisions leading to particular types of institutional placement.
- o Analysis of the major sources of variation in the nursing home or other institutional populations, including development of typologies for classifying the population into relevant subgroups.
- o Descriptive research on the "everyday" living of patients in a variety of institutional settings.
- o Conceptualization and analysis of the relevant parameters of the social and physical environment and the effects of those environments upon resident outcomes.
- o Predictors of family involvement in institutional care and the effects of this involvement upon health and functioning.
- o "Natural history" of therapeutic decisions and service delivery.
- o Factors within the institution (e.g., practices of rehabilitation or encouraging independence) that influence the length of stay.
- o Development and testing of social and behavioral interventions to promote health and functioning of older persons in institutional settings.

#### MECHANISMS OF SUPPORT

Applicants funded under this announcement will be supported through the Public Health service grant award in accordance with PHS policies applicable to research project and training grants.

#### REVIEW CRITERIA

Applications will be assigned to the appropriate group for review and will be reviewed in accordance with the usual NIH peer review procedures. The review criteria are the traditional considerations underlying scientific merit.

#### APPLICATION PROCEDURES

Researchers considering submitting an application in response to this announcement are strongly encouraged to discuss their project and the range of grant mechanisms available with NIA staff in advance of formal submission. This can be done either through a telephone conversation or through a brief written letter of intent describing the proposed project and identifying the principal investigator and, when known, other key participants.

Applicants should use the regular research grant application form (PHS 398, rev. 9/86), or, for individual fellowship applications, form PHS 416.1. These forms are available at the applicant's institutional Application Control Office or from:

Office of Grants Inquiries  
Division of Research Grants  
Westwood Building, Room 449  
National Institutes of Health  
Bethesda, Maryland 20892\*\*  
Telephone: (301) 496-7441

In order to expedite the application form's routing within NIH, please (1) check the box on the application form's face sheet indicating that your proposal is in response to this announcement and print (next to the checked box) NIA AGING AND FORMAL HEALTH CARE and (2) enclose a cover letter repeating that your application is in response to this announcement. Standard receipt dates for all mechanisms are in effect.

Mail the cover letter and the completed application (with 6 copies) to:

Division of Research Grants  
National Institutes of Health  
Westwood Building - Room 240  
Bethesda, Maryland 20892\*\*

## **Inquiries**

Applications will be received by the NIH Division of Research Grants. It should also be recognized that along with the NIA, other Federal components, such as the National Center for Health Services Research and Health Care Technology Assessment and the National Institute of Mental Health also support research on formal health care. Responsive applications will be assigned according to the standard Public Health Service referral guidelines. Dual and multiple assignments will be used in situations of mutual interest. Address requests for additional information, research prospectuses, and/or letters of intent to:

National Institute on Aging  
Behavioral and Social Research  
Attention: AGING and HEALTH CARE  
Building 31C - Room 4C32  
Bethesda, Maryland 20892  
Telephone: (301) 496-3136

This program is described in the Catalog of Federal Domestic Assistance No. 13.866, Aging Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 1 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

### **STUDIES IN COLLABORATION WITH MATERNAL-FETAL, PERINATAL, AND NEONATAL RESEARCH UNITS SUPPORTED BY THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)**

P.T. 34; K.W. 0710030, 0785130

#### **National Center for Nursing Research**

The National Center for Nursing Research is interested in supporting research by nurse investigators who wish to collaborate with, and contribute to, the research in the ongoing networks supported by the NICHD. Nurse scientists who are interested in carrying out research projects in conjunction with any of the established units should contact the appropriate medical director for information about their network/center research focus.

For further information about the intent of this announcement, contact:

Dr. Deidre M. Blank  
Chief, Health Promotion and Disease Prevention Branch  
National Center for Nursing Research  
Building 38A, Room B2E17  
National Institutes of Health  
Bethesda, MD 20894  
Telephone: (301) 496-0526

#### **MATERNAL-FETAL MEDICAL UNIT NETWORK**

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Chairman/Professor  
Department of Obstetrics and Gynecology  
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#### NEONATAL INTENSIVE CARE UNIT

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Professor, Departments of Pediatrics, OB/GYN  
The University of Tennessee Newborn Center  
853 Jefferson Avenue, Room 301  
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Telephone: (901) 528-5950

**PERINATAL EMPHASIS RESEARCH CENTERS**

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Reproductive Biology Sciences  
University of Texas Health Sciences Center  
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Dr. William Oh  
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Dr. Edgard Makowski  
Professor and Chairman  
Department of Obstetrics and Gynecology  
University of Colorado School of Medicine  
Denver, CO 80262  
Telephone: (303) 394-7616

Dr. Reginald Tsang  
Professor of Pediatrics and  
Obstetrics and Gynecology  
University of Cincinnati Medical Center  
College of Medicine  
231 Bethesda Avenue  
Cincinnati, OH 45267-0541  
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5333 Westbard Avenue  
Bethesda, Maryland 20816

**ERRATUM**

**REVISIONS TO PHS CLAUSES: "PROTECTION OF HUMAN SUBJECTS" AND "CARE OF VERTEBRATE ANIMALS"**

P.T. 34,16; K.W. 0201011, 0783005

The notice on the above topic that appeared in the May 29, 1987 issue of the GUIDE (Vol. 16, No. 18) included an incorrect citation to a Federal Register notice. The final rule revising these PHS clauses appeared in the March 24, 1987 Federal Register (Vol. 52, No. 56).