# NIH GUIDE

# for GRANTS

## and **CONTRACTS**

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

Vol. 7, No. 7, May 12, 1978

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#### HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, Division of Research Grants, NIH, Room 219, Westwood Building, Bethesda, Maryland 20014, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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

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

#### SPECIAL INITIATIVE GRANTS

#### FOR RESEARCH ON AGING

This announcement is a revision of, and thus supersedes, the announcement contained in Vol. 6, No. 21, pp. 1-4, of the NIH Guide for Grants and Contracts. The National Institute on Aging (NIA) was established in 1974 to conduct and support clinical, biomedical, social, and behavioral research and research training related to the aging process and the diseases and other special problems and needs of the aged. The NIA recognizes that gerontology would benefit from expansion of the competitive aging-research base and manpower pool. Institutions may need the opportunity to develop their potential as new foci for aging research and research training. Institutions with established research programs in gerontology may benefit from enhancement and expansion of their capacity for aging research and research training.

<u>Purpose</u> NIA Special Initiative Grants for Research on Aging, under the authority of Section 301 of the PHS Act, are for the purpose of stimulating high quality gerontological research at the grantee institution. The purposes include: 1) support of the promising activities of institutions building a capacity for aging research, e.g. support of research in pilot stages and 2) similarly, pilot research leading to expansion, enhancement, or modification of existing aging research programs.

<u>Areas of Interest</u> Special Initiative Grant applications are appropriate for each of the NIA's four mission areas:

- Biology of Aging, including fundamental studies of the biological processes of aging, involving all levels of biological function: molecular aging, cellular aging, organ change with age, changes in immunological and other systems function with age, metabolic alteration with age, and age changes at the organism and population level. Studies in vivo, in vitro, on both humans and experimental organisms are supported, as are studies in theoretical gerontology.
- 2. Medical and Clinical Aspects of Aging, including epidemiology and demography of disease in the aging and the aged, geriatric medicine, the factors associated with prevention of illness and infirmity and maintenance of health in the aging and the aged, e.g. organic brain diseases, nutrition, exercise, environmental and socioeconomic variables, special pharmacological problems affecting the aging and the aged, (such as drug drug interaction and over-prescription, problems of changes in the various body systems and organs with age (e.g. nervous system, reproductive system, musculoskeletal, and skin), connective tissue changes associated with age,

- need for special devices and techniques to increase the mobility and self-care capacity of the frail and handicapped elderly.
- 3. Psychological and Behavioral Aspects of Aging, including studies of cognitive, psychomotor, perceptual, sensory, social, personality, and attitudinal changes associated with the aging process; psychobiological and neuropsychological aspects of aging. Studies in both humans and experimental animals are supported.
- 4. Social and Societal Aspects of Aging, including socialization of aging adults, attitudinal changes as accompaniments of aging, family and intergenerational patterns associated with aging, socioeconomic factors in morbidity and mortality differentials between sexes and among the different subcultural and ethnic segments of the aging population; changing age-structure of population and its impact on economic and social function; retirement decision-making, and effects of retirement at different ages on individuals and the society; objective bases for retirement, such as functional capacity of aging individuals for work; effects of social and institutional factors on health and wellbeing of the aging and the elderly, such as housing, living arrangements and similar factors.

#### Criteria Used in Review of SIA Applications

#### The applicant institution should:

- provide justification that an award would be both necessary and sufficient to stimulate high quality and increased quantity of new gerontological research at the grantee institution.
- 2. establish that the Special Initiative Grant has high probability of generating two or more new applications for gerontology research support within two to three years (especially the NIH research project grants and/or the equivalent from other funding sources, including local and national foundations as well as other government sources).
- 3. establish a direct and clear relationship between research to be supported by the SIA (e.g. pilot studies) and the key scientists who subsequently would seek further research funding in gerontology.

#### 4. provide:

a. an overall research plan featuring the individual substantive areas of aging research the applicant institution wishes to develop.

- b. two or more individual research proposals (such as pilot studies) sufficient to permit scientific merit assessment equal to a regular NIH research project grant application.
- 5. demonstrate evidence of the adequacy of the research environment to support a new and/or increased level of aging research.
- 6. provide evidence of a level of organization adequate to the range of activities contemplated a board, ad hoc group, or committee corresponding to the complexity of the plan presented for the application. For example, a research effort confined to a single department would require a simple organizational base, while a multidisciplinary proposal might require a university-wide committee.
- 7. identify a qualified principal investigator who would devote not less than 10% time to directing the Special Initiative Award and would provide evidence of serious commitment to development or expansion of gerontological research.

General: The standard of scientific merit to be met by the SIA application is equal to that required of the traditional NIH research project grant (RO1). An SIA award should enable the stimulation of meritorious applications for RO1 (or equivalent) support within the SIA award period.

<u>Preparation of the SIA Application</u> Use form PHS 398 (contained in the NIH Research Grant application kit at your institution). Follow the information and instructions with the following modifications:

- 1. the applicant will present, in Sections I and II of the application, information on the entire proposal, followed by an introduction to and overview of the individual projects to follow: include information responding to the review criteria 1, 2, 3, 4a, 5, 6, and 7 (above). This introductory section includes description of the possible future research support to be sought subsequent to an SIA award.
- 2. review criterion 4b (i.e., adequacy of individual research proposals, such as pilot studies, to permit scientific merit assessment) necessitates a research proposal for each respective project or pilot study: each of the two or more projects or pilot studies must be prepared in the format and with the content of the regular project grant application. For individual projects (with the exception of budget page) omit sections I and II already presented in the introduction. Each such proposal should be organized independently of the others within the SIA, including an individual budget page, allowisg opportunity for each section of an SIA application to be reviewed independently. The research plan for each section is proposed in the standard format as required in the instructions.

#### Allowable Costs Are:

- 1. salary of principal investigator and administrative staff as relevant to the Special Initiative Award;
- 2. salaries for temporary support of investigators and support staff engaged in gerontological research in a developmental stage for which research project grant funding has not been obtained, and for which Biomedical Research support funding is not available:
- appropriate costs of workshops, symposia, visiting lecturers, and consultants on gerontological research to be held at the applicant institution;
- 4. travel costs for selected members of the project for the purpose of obtaining specialized off-campus research experience which would enhance the grantee institution's capability for gerontological research;
- scientific meeting travel costs;
- 6. supplies and/or equipment and other costs as justified.

Other Expenses All other expenses will be judged on an individual basis and must be clearly justified as necessary for and relevant to the Special Initiative Award.

NOTE: A maximum of \$60,000 direct costs per year for no more than three years is allowable.

Receipt Date The receipt and review schedule is listed below:

Receipt Date	Review Completed	Earliest Possible <u>Funding</u>
July 1	early February	April 1
November 1	May	July 1
March 1	early October	December 1

The original and six copies of the proposal should be sent to the Division of Research Grants (DRG). DRG is responsible for the initial SIA application review for scientific merit.

Send two additional copies to:

Associate Director Extramural and Collaborative Research Program National Institute on Aging National Institutes of Health Bethesda, Maryland 20014

#### DEVELOPMENT AND EVALUATION OF NEW THERAPIES

#### FOR RARE GENETIC DISEASES

National Institute of General Medical Sciences (NIGMS)
National Institute of Neurological and
Communicative Disorders and Stroke (NINCDS)
National Institute of Child Health and
Human Development (NICHD)
National Eye Institute (NEI)
National Institute of Arthritis, Metabolism,
and Digestive Diseases (NIAMDD)
National Heart, Lung and Blood Institute (NHLBI)

The above-named Institutes are interested in expanding their research programs regarding the basic understanding of rare genetic diseases and the development of treatment for them.

#### I. PROGRAM SPECIFICATIONS

- A. Program Objectives It has been suggested that significant opportunities now may exist to develop a better understanding of and new therapies for rare genetic diseases and that many potentially useful treatments which have been developed may have been poorly evaluated. The above-named Institutes are encouraging submission of applications focused on an understanding of such diseases and the initial development and evaluation of new therapies.
- B. Research Scope The emphasis of this program announcement is upon the development of new technologies for dealing with rare genetic diseases. These technologies may be drugs, devices, or surgical interventions, and their basic science foundation should already exist. The applicants should, therefore, propose adaptation, application, or developmental research which would bring currently available data to bear on the problem of rare genetic disease.
- C. Mechanism of Support The mechanism of support for this program will be the research grant. The regulations (Code of Federal Regulations, Title 42, Part 52, and Title 45, Part 74) and policies which govern the research grant programs of the National Institutes of Health will prevail.

The award of grants pursuant to this announcement is contingent upon availability of appropriated funds and competition for funds with other research grant applications. This announcement is intended to inform interested individuals of the various

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Institutes' commitment to support of research related to rare genetic diseases, particularly in regard to therapy, as well as their interest in supporting projects of high scientific merit.

#### II. METHOD AND CRITERIA OF REVIEW

- A. 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 individual Institutes for possible funding. These decisions will be governed by normal programmatic considerations as specified in the DRG Referral Guidelines.
- Review Procedures Applications in response to this solicitation 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 appropriate Institute Advisory Council. The review criteria customarily employed by the National Institutes of Health for regular research grant applications will prevail.
- C. <u>Deadline</u> Applications will be accepted in accordance with the usual receipt dates for new applications:

July 1 November 1 March 1

D. 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 NIH RARE GENETIC DISEASES PROGRAM ANNOUNCEMENT" 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 20014

For further information, investigators are encouraged to contact one or more of the following Institutes:

National Institute of Arthritis, Metabolism, and Digestive Diseases National Institute of Neurological and Communicative Disorders and Stroke NIH Guide for Grants and Contracts Vol. 7, No. 7, May 12, 1978

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National Institute of Child Health and
Human Development
National Eye Institute
National Heart, Lung, and Blood Institute
National Institute of General Medical Sciences
Assistant Director for Clinical Research
Room 925, Westwood Building
Bethesda, Maryland 20014

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