# NIH GUIDE

## For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 20, No. 29
July 26, 1991

## NOTICES OF AVAILABILITY (RFPs AND RFAs)



## ONGOING PROGRAM ANNOUNCEMENTS



## ERRATUM



## NOTICES OF AVAILABILITY (RFPs AND RFAs)

### NATIONAL RESEARCH SERVICE AWARD--INSTITUTIONAL GRANTS

RFA AVAILABLE: HS-91-03

P.T. 44; K.W. 0720005, 0730050, 1004017, 0408006

Agency for Health Care Policy and Research

Application Receipt Date: October 10, 1991

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) awards National Research Service Award (NRSA) institutional grants (T32) to eligible institutions to develop or enhance research training opportunities for qualified individuals of the institution's selection who seek to prepare for careers in health services research. This Request for Applications (RFA) announces the application receipt date for this program (October 10, 1991) and identifies the training areas of special interest.

The purpose of these awards is to assist domestic institutions in supporting predoctoral and postdoctoral academic training. The awards allow trainees to gain experience in applying research methods to the systematic analyses and evaluation of health services. Individuals are selected by institutions on the basis of a demonstrated interest and relevant background in health services research.

MECHANISM OF SUPPORT

This announcement is made subject to availability of funds. AHCPR reserves the right to withdraw this Request for Applications if funds do not become available. This is a one-time announcement. Applications will not be accepted after October 10, 1991. AHCPR expects to fund no more than five new awards in response to this RFA.

LEVELS AND AREAS OF TRAINING

Applicant institutions may apply for support for predoctoral students, postdoctoral students, or a combination. Applicants must include a rationale for their choice of supporting type(s) of students. Research training must provide the conceptual and methodological foundation for investigating some or all of the following health care areas: (1) primary care issues, including development of techniques to measure the effectiveness of managing health care conditions; (2) appropriateness and effectiveness of alternative treatments in terms of patient outcomes and use of services; (3) factors affecting dissemination and assimilation of information on health care technologies and other aspects of clinical practice; (4) alternative approaches to organizing, financing, and reimbursing for health care services and their effects on cost, quality, and access; (5) application of medical informatics to the development of expert systems for treatment selection and diagnosis; (6) practice-based research, including clinical practice variations and guideline development; (7) medical malpractice and liability; (8) delivery of health services to the medically underserved, especially in rural areas; (9) availability, accessibility, and quality of care for low-income groups, minorities, and the elderly; (10) cost-effectiveness and cost-benefit analysis, including allocation of health care resources and relationship to health status; (11) alternative delivery systems, providers, and practice patterns in long-term care, including home and community-based care; (12) organizational structure, resource use, and costs of care for persons with HIV-related illnesses.

ELIGIBILITY REQUIREMENTS

Domestic nonprofit, private or public, institutions may apply for grants to support research training programs. The applicant institution must have the staff and facilities required for the proposed program. The training program director at the institution will be responsible for the selection and appointment of trainees and for the overall direction of the program.

METHOD OF APPLYING

Applications must be made on grant application form PHS 398 (rev. 10/88). This revision contains additional instructions for preparing institutional National Research Service Award applications. Completed applications must be mailed to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCESS AND SCHEDULE

The NRSA training grant receipt date and review cycle for all applications submitted in response to this RFA is indicated below.

| Application receipt date | Initial review group meeting | Council meeting | Earliest possible start date |
|---|---|---|---|
| October 10, 1991 | November 1991 | January 1992 | March 1992 |

Applications will be reviewed by an AHCPR initial review group (IRG) and the National Advisory Council for Health Care Policy, Research, and Evaluation. The IRG will consider the following criteria in its review: the goals of the proposed training program and the probability of achieving them; substantive content of the proposed program and its relevance to current health care concerns, including courses offered; qualifications and responsibilities of the program director; qualifications of the program's faculty, including ongoing health services research, and commitment to tracking graduates following training; program's ability to recruit qualified trainees; commitment to adequate space, curriculum time, financial support, and appropriate facilities; cooperation of related agencies or organizations in providing experience and research training sites for trainees; number and types of students for whom support is requested; proposed methods for monitoring and evaluating the performance of trainees as well as the overall

program; and reasonableness of the proposed budget in relation to the proposed training.

In addition to the recommendations made by the IRG, the Council will consider the applicant institution's plans for (and likely success in) recruitment of individuals from underrepresented minority groups into the training program. Funding decisions will be based on the review groups' recommendations, the need for research personnel in specified program areas, and the availability of funds.

INQUIRIES

The AHCPR supports training in all areas of health services research.

Inquiries regarding this RFA and requests for a copy of the full RFA may be directed to:

DonnaRae Castillo
NRSA Project Officer
Agency for Health Care Policy and Research
Parklawn Building, Room 18A-10
Rockville, MD 20857
Telephone: (301) 443-2904

Information on grants management issues may be obtained from:

Ralph Sloat, Chief
Grants Management Branch
Agency for Health Care Policy and Research
Parklawn Building, Room 18A-27
Rockville, MD 20857
Telephone: (301) 443-4033

Awards are made under authority of section 487 of the Public Health Service (PHS) Act as amended (42 USC 288). Title 42 of the Code of Federal Regulations, Part 66, is applicable to this program. The program is described under Catalog of Federal Domestic Assistance No. 93.225.

## MEDTEP RESEARCH CENTERS ON MINORITY POPULATIONS

RFA AVAILBLE: HS-91-02

P.T. 34, FF; K.W. 1004017, 0730050

Agency for Health Care Policy and Research

Letter of Intent Receipt Date: August 12, 1991
Application Receipt Date: November 12, 1991

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) invites applications for cooperative agreements from nonprofit organizations to develop and manage research Centers. The centers will conduct and support research, technical assistance, information dissemination, and research training on the appropriateness and effectiveness of health care services and procedures provided to minority populations. Support for these research centers will be provided through the Medical Treatment Effectiveness Program (MEDTEP) of the Department of Health and Human Services. The centers will be known as MEDTEP Research Centers on Minority Populations. For the purposes of this announcement, minority populations are defined to include African Americans, Hispanic Americans, American Indians, Alaska Natives, Asians, and Pacific Islanders. Awards are expected to be made in Fiscal Year 1992.

Preference will be given to applicants that currently devote a major portion of their resources to the training of minority health care providers, employment of minority health care providers, and provision of health care to minority populations. Comments on this preference are being solicited through a separate notice on the program that is being published in the FEDERAL REGISTER.

Applicants must have the scientific, technical, organizational, and physical resources necessary to carry out: (1) multidisciplinary patient outcomes research; (2) technical assistance to health care providers and others; (3) training of health services researchers; and (4) dissemination of research findings and the evaluation of dissemination strategies.

The centers are also expected to work with the AHCPR on analyses and studies. Such joint activities may involve syntheses of research findings, data analyses, or the preparation of background information on various topics relating to health care and minority populations. As part of a cooperative agreement, the AHCPR will also have substantive involvement in the planning and conduct of research, technical assistance, dissemination, and training carried out by each center.

HEALTHY PEOPLE 2000

AHCPR is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This announcement, "MEDTEP Research Centers on Minority Populations," addresses health services and protection objectives 21.3-21.8 and other special populations objectives targeting minorities. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

CENTER STRUCTURE AND MECHANISM OF SUPPORT

AHCPR funds are intended to provide basic support for each center. Core funding will be provided through the cooperative agreement (U01) grant mechanism, in which the recipient is reimbursed for administrative and staff support, the provision of technical assistance, dissemination mechanisms such as center-sponsored newsletters, and a program of training in patient outcomes research. Research projects may also be supported in their initial stages with core funds, although it is expected that research projects will ultimately be sponsored with funds obtained from sources other than the AHCPR cooperative agreement grant.

The center director will be responsible for the organization and operation of the center; liaison with the research community and outside entities such as professional societies, subcontractors, and consumer groups; and communication with the AHCPR on scientific and operational matters. Personnel and institutional resources capable of developing and maintaining a substantial commitment to patient outcomes research must be available. The center may consist of core staff with significant time commitments to the center and affiliate staff with lesser time commitments.

The center may be a consortium of organizations that will provide collateral or supplemental support to the applicant institution.

A maximum of $750,000 annual total costs (direct plus indirect) may be requested for full center support, and a maximum of $3,750,000 in total costs may be requested per application for full centers for the entire project period, not to exceed five years.

Applicants may request developmental funding of up to $400,000 total annual costs for each of a minimum of two years and a maximum of three years if the proposed center needs time to develop and is not likely to meet initially all performance criteria. Funded developmental centers would be expected to apply competitively for funding to become full centers by the end of their developmental period.

The AHCPR expects to commit up to $4 million in competitive awards for MEDTEP Research Centers on Minority Populations in Fiscal Year 1992, depending upon the availability of funds.

SPECIAL INSTRUCTIONS TO APPLICANTS CONCERNING INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDY POPULATIONS

The AHCPR adheres to NIH and ADAMHA policy requiring applicants for research grants to include minorities and women in study populations, so that research findings can be of benefit to all. This announcement obviously addresses that policy with regard to minorities. Additional emphasis, however, should be placed on the need to include women of all ages in studies of diseases, disorders, and conditions that affect them.

REVIEW PROCEDURES

Applications for these cooperative agreements will be evaluated by the AHCPR grant peer review process. Applications will initially be assessed by AHCPR staff for responsiveness to this announcement. Nonresponsive applications will be returned without further consideration.

All responsive applications will undergo peer review for scientific merit by an AHCPR review committee of non-Federal experts, and those recommended for approval will also be reviewed by the National Advisory Council for Health Care Policy, Research, and Evaluation.

ELIGIBILITY

Only nonprofit organizations are eligible to apply. Foreign institutions are not eligible to apply.

METHOD OF APPLYING

All applicants, except State and local governments, must use application form PHS 398 (revised 10/88). State and local governments may use form PHS 5161, Application for Federal Assistance. These forms are available at most institutional business offices, from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, and from the AHCPR Office of Scientific Review at the address below.

The original and five copies of the completed application PHS 398 (or the original and two copies of PHS 5161) are to be mailed or delivered to:

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

Completed applications must be received at the Division of Research Grants on or before November 12. Late applications will be returned without review.

Potential applicants are requested to submit a letter of intent to Dr. Miriam A. Kelly at the Rockville address below by August 12, 1991. A letter of intent is neither required nor binding, and does not enter into the review of subsequent applications. The letter of intent should include the name(s) of the proposed Principal Investigator, principal collaborators, and organization(s) involved.

Grant application materials may be obtained from:

Office of Scientific Review
Office of Planning and Resource Management
Agency for Health Care Policy and Research
Room 18A20, 5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3091

TIMETABLE

Letter of intent receipt date: August 12, 1991
Application receipt date: November 12, 1991
Initial (scientific) review date: February 7, 1992
National Advisory Council meeting date: May 1992
Earliest grant award and start date: July-September 1992

For further program information and to request a copy of the RFA, write or call:

Dr. Miriam A. Kelly
Health Scientist Administrator
Center for Medical Effectiveness Research
Agency for Health Care Policy and Research
6001 Montrose Road, Suite 704
Rockville, MD 20852
Telephone: (301) 443-0782

For information on grants and business management aspects, write or call:

Ralph L. Sloat
Chief, Grants Management Branch, OPRM
Agency for Health Care Policy and Research
5600 Fishers Lane, Room 18A27
Rockville, MD 20857
Telephone: (301) 443-4033

Potential applicants should refer to the full RFA for more detailed information, including criteria that will be used in the review of applications.

The requirements of Executive Order 12372 are not applicable to the AHCPR research grant program. This program is described in the Catalog of Federal Domestic Assistance number 93.180. Funded projects will operate under the PHS Grants Policy Statement (10/1/90 Edition) and 42 CFR, Part 67, Subpart A.

## ONGOING PROGRAM ANNOUNCEMENTS

### ANOREXIA NERVOSA AND BULIMIA NERVOSA: BASIC BRAIN, BEHAVIORAL, AND CLINICAL STUDIES

PA: PA-91-79

P.T. 34; K.W. 0404000, 0755030, 0785055, 1002030, 0745020, 0745027

National Institute of Mental Health

The National Institute of Mental Health (NIMH) invites applications that use any of the available research grant mechanisms for the studies relevant to the epidemiology, etiology, treatment, and prevention of anorexia nervosa and bulimia nervosa. The purpose of this announcement is to place additional research emphasis on behavioral, clinical, and central nervous system (CNS) aspects of ingestive behaviors and eating disorders.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00473-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20042-9325 (telephone: 202-783-3238).

ELIGIBILITY

Applications may be submitted by any public or private, nonprofit or for-profit, organizations such as universities, colleges hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

STUDY POPULATIONS

Applications for this grant are encouraged to include both women and minorities in study populations, unless scientific evidence or other justification for not including them is provided. This requirement is intended to ensure that the research findings will be of benefit to all persons at risk of the disease, disorder, or condition under study. For the purpose of these policies, clinical research involves human studies of etiology, treatment, diagnosis, prevention, or epidemiology of diseases, disorders, or conditions, including but not limited to clinical trials; and minorities include U.S. racial/ethnic minority populations (specifically American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics).

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) recognizes that it may not be feasible or appropriate in all clinical research projects to include representation of the full array of U.S. racial/ethnic minority populations. However, applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

Applications should include a description of the composition of the proposed study population by gender and racial/ethnic group, and the rationale for the numbers and kinds of people selected to participate. This information should be included in the PHS form 398, Section 2, A-D of the Research Plan and summarized in Section 2, E, Human Subjects.

Applications should incorporate in their study design gender and/or minority representation appropriate to the scientific objectives of the work proposed. If representation of women or minorities in sufficient numbers to permit assessment of differential effects is not feasible or appropriate, the reasons

for this must be explained and justified. The rationale may relate to the purpose of the research, the health of the subjects, or other compelling circumstances (e.g.,if in the only subject population available there is a disproportionate representation in terms of age distribution, risk factors, incidence/prevalence, etc., of one gender or minority/majority group).

If the required information is not contained within the application, the review will be deferred until it is complete. Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If gender and/or minority representation/justification are judged to be inadequate, the reviewers will consider this as a deficiency in assigning the priority score to the application.

All applications/proposals for clinical research submitted to ADAMHA/NIMH are required to address these policies. ADAMHA/NIMH funding components will not award grants that do not comply with these policies.

Applicants should also be aware that the Department of Health and Human Services has regulations for the protection of human subjects and has developed additional regulations for the protection of children. A copy of these regulations, 45 CFR 46, Protection of Human Subjects, is available from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 5B59 Bethesda, Maryland 20892.

REVIEW PROCEDURES

Applications will be received under the usual PHS receipt and review schedule. Applications will be reviewed by an initial review group (IRG) consisting primarily of non-Federal scientific and technical experts. Applications will receive a second-level review by the appropriate Advisory Council based on policy considerations as well as scientific merit. Only applications recommended for approval by Council may be considered for funding.

APPLICATION PROCEDURES

All research applicants must use the current version of the grant application form PHS 398 (rev. 10/88). Support may be requested for a period of up to five years. Annual awards will be made subject to continued availability of funds and progress achieved. A competing supplemental application may be submitted during an approved period of support to expand the scope or protocol of a project during the approved period. A competing continuation (i.e., renewal) application may be submitted before the end of an approved period of support to continue a project.

Grant funds may be used for expenses clearly related and necessary to conduct research projects, including direct costs that can be specifically identified with the project and allowable indirect costs of the institution. Funds may not be used to establish, add a component to, or operate a treatment, rehabilitation, or prevention intervention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for costs required by the research. These costs must be justified in terms of research objectives, methods, and designs that promise to yield generalizable knowledge and/or make significant contribution to theoretical concepts.

MECHANISMS OF SUPPORT

Applications are requested under the traditional research project (R01), First Independent Research Support and Transition (FIRST) Award (R29), small grant (R03), institutional research training (T32), individual fellowship (pre- and post-doctoral) (F series), career development (K series), and program project (P01) mechanisms. In Fiscal Year 1990, it is estimated that approximately $6 million was available to support 20 new and continuation grants on anorexia nervosa and bulimia nervosa. However, the amount of funding will depend upon availability of funds and program priorities at the time of the award.

INQUIRIES

Copies of this full announcement and additional information may be obtained by contacting:

Susan J. Blumenthal, M.D, M.P.A.
Chief, Behavioral Medicine Program
Basic Prevention and Behavioral Medicine Research Branch
Division of Basic Brain and Behavior Sciences
National Institute of Mental Health
5600 Fishers Lane, Room 11C-06
Rockville, MD 20857
Telephone: (301) 443-4337

Information on grants management issues may be obtained from:

Stephen Hudak
Chief, Grants Management Section
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-26
Rockville, MD 20857
Telephone: (301) 443-4456

Awards are made under authority of Section 301 of the Public Health Service Act (42 U.S.C. 241), and Catalog of Federal Domestic Assistance 93.242.

## ANTICANCER MODEL DEVELOPMENT

PA: PA-91-80

P.T. 34; K.W. 0755020, 0740020, 0755010, 0760075

National Cancer Institute

Application Receipt Dates: October 1, February 1, and June 1

### PURPOSE

Cancer treatments with greater specificity for cancer cells and less toxicity for normal tissues are critically needed, especially for common solid tumors that afflict the aging population. As we enter an era of increased understanding of the process of malignancy, opportunities are emerging for defining and exploiting new molecular targets for the discovery of more useful therapies. With the development of a more rational framework for the treatment of cancer, the ability to select therapy for the individual patient should also improve. The objective of this announcement is to encourage research in the development of models that will lead to the discovery and use of more effective therapies. Projects can be multidisciplinary as long as they are well focused and meet the criteria described below.

### HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Anticancer Model Development, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

### RESEARCH OBJECTIVES

The Division of Cancer Treatment of the National Cancer Institute is seeking applications for traditional research grants (R01) with a focus on models that will be more predictive of the clinical usefulness of new anticancer treatments. Examples of studies that might be addressed include, but are not limited to:

- Rapid, resource efficient and cost-effective methods for evaluating new, potential anticancer agents. For example, receptor-based screening techniques have been used effectively in other areas of medicine, such as in the search for drugs that lower blood cholesterol levels. Assays that exploit recent discoveries in the molecular biology of tumor development, such as suppressor genes, are especially attractive. Cell culture assays with cytotoxic endpoints that do not offer a distinct advantage over models in current use are not encouraged. Applications that focus on screening or scale-up of existing procedures are not encouraged.

- Animal models that include the development of valid, surrogate endpoints for survival. Transgenic animals, mice with a genetic predisposition to cancer, and severe combined immunodeficient (SCID) mice are examples of models used in other fields, such as carcinogenesis, differentiation, and tumor biology, that could be adapted for therapeutic studies.

- Models that will help select therapy for individual patients. The expense and time for clinical trials could be reduced by selecting therapies with greater probability of effectiveness for a given patient. Assays now being used to diagnose cancer, such as those involving the polymerase chain reaction, could be adapted for improved therapy selections. Applications are encouraged with an emphasis on the development and evaluation of assays up to the point where they could be used in prospective clinical trials to validate the model.

Whichever model development approach is taken, applicants must provide a rationale for how the model may identify improved therapies or may enhance therapy selections and must outline a research plan involving a testable hypothesis. The nature of the model is limited only by the creativity and ability of the applicant.

MECHANISM OF SUPPORT

This program will be supported through the NIH grant-in-aid mechanism (R01). This program announcement is a continuous announcement until retracted. Applications and future unsolicited competing renewal applications will compete as research project applications with all other investigator-initiated applications and be reviewed in a standing Division of Research Grants study section.

Applications will compete for available funds with all other approved applications within the assigned Institute.

ELIGIBILITY

Applications may be submitted by domestic and foreign, public or private, nonprofit or for-profit, organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by a study section of the Division of Research Grants. Following study section review, the applications will receive a second-level review by the appropriate national advisory council or board.

REVIEW CRITERIA

- Scientific merit and originality of proposed research.

- Appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research.

- Qualifications of the Principal Investigator and support staff in regard to research experience, competence, commitment, and time availability.

- Adequacy of existing physical facilities and the research environment.

- Adequacy of proposed means for protecting against adverse effects upon humans, vertebrate animals, and the environment.

The review group will critically examine the requested budget and will recommend an appropriate budget and period of support for each application recommended for further consideration.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and

women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objective of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in the study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

METHOD OF APPLYING

Applications must be submitted on the grant application form PHS 398 (revised 10/88) and will be accepted at the standard application deadlines. Application kits are available at most institutional business and grant/contract offices and may be obtained from the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. The title and number of this announcement must be typed in line 2 on the face page of the application.

The original application and six signed exact photocopies must be submitted or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

INQUIRIES

Inquiries about the objectives of this program announcement may be addressed to:

Mary K. Wolpert, Ph.D.
Developmental Therapeutics Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Suite 832
Bethesda, MD 20892
Telephone: (301) 496-8783

Inquiries of a budgetary or administrative nature should be directed to:

Ms. Barbara A. Fisher
Grants Management Specialist
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, Ext. 29

This program is described in the Catalog of Federal Domestic Assistance No. 93.395, Cancer Treatment Research. Awards will be made under the authority of Public Health Service Act, Title IV, Sections 301, 410, and 411, Part A (Public Law 78-410, 42 USC 241 as amended, Public Law 99-158, 42 USC 285a) and administered under PHS grant policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health System Agency review. Awards will be administered under Public Health Service grants policy as stated in the PHS Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

## ERRATUM

PROGRAM PROJECTS ON AUTOIMMUNITY

RFA: AI-91-09

P.T. 34; K.W. 0715015, 0745027, 0745070, 0710030

National Institute of Allergy and Infectious Diseases

The fourth paragraph under Mechanisms of Support of the full text online version of the Request for Applications, "Program Projects on Autoimmunity" (NIH Guide for Grants and Contracts, Vol. 20, No. 23, June 14, 1991) states that support will be limited to a maximum of four years. The maximum period of support is in error and is amended to read: Support for a program project in autoimmune mechanisms in disease will be limited to a maximum of FIVE years.

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

5333 Westbard Avenue
Bethesda, Maryland 20816