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. 19, No. 46
December 28, 1990

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

INSERT FLYER FOR APPLICANTS USING FORM 398 REGARDING IMPLEMENTATION OF THE NIH/ADAMHA POLICY CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

P.T. 34; K.W. 1014006

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

The purpose of this notice is to provide special instructions to research grant and cooperative agreement applicants using Form PHS 398, regarding the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) policies concerning the inclusion of women and minorities in clinical research study populations. These policies were published in the NIH Guide for Grants and Contracts on September 28, 1990, Vol. 19, No. 35 for inclusion of minorities in study populations and on August 24, 1990, Vol. 19, No. 31 for inclusion of women in study populations.

PRIORITY ANNOUNCEMENT

SPECIAL INSTRUCTIONS TO APPLICANTS USING FORM PHS 398 REGARDING IMPLEMENTATION OF THE NIH/ADAMHA POLICY CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NOTE: THESE INSTRUCTIONS APPLY ONLY TO THE LIMITED NUMBER OF GRANT AND COOPERATIVE AGREEMENT APPLICANTS WHO PROPOSE CLINICAL RESEARCH STUDIES THAT INCLUDE 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.

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants, cooperative agreements, and contracts 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 minorites and women in studies of diseases, disorders, and conditions which disproportionately affect them. If women or minorities are not included or are inadequately represented in clinical research, particularly in proposed populations-based studies, a clear compelling rationale should be provided.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH and ADAMHA recognize 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 (American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

Beginning immediately, all applications submitted to NIH/ADAMHA will be required to address this policy.

INSTRUCTIONS TO APPLICANTS

Applicants must include a description of the composition of the proposed study population in terms of gender and racial/ethnic group and 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 objectives 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.

Applications must employ a study design with gender and/or minority representation (by age distribution, risk factors, incidence/prevalence, or other) appropriate to the scientific objectives of the disease, disorder, or condition being studied.

It is not an automatic requirement for the study design to provide statistical power to answer the questions posed for men and women and racial/ethnic groups separately; however, whenever there are scientific reasons to anticipate differences between men and women with regard to the hypothesis under investigation, applicants should include an evaluation of gender and minority group differences in the proposed study.

If adequate inclusion of women or minorities is impossible or inappropriate with respect to the purpose of the research, the health of the subjects, or

other reasons, or if the only available study population has a disproportionate representation of one gender or minority/majority group, the rationale for the study population must be well explained and justified by the applicant.

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.

PEER REVIEW

Executive Secretaries of the Initial Review Groups (IRGs) will request written clarification from the applicant when the application does not describe and justify the gender or minority composition of the study population. If such information is not contained within the application, and is not provided upon request, the application will be deferred without IRG review until it is complete or will be returned to the applicant. In the case of responses to RFAs with single receipt dates, applications that are not brought into compliance will be returned without review rather than deferred.

Executive Secretaries of all scientific IRGs will instruct the IRG members that the assessment of scientific and technical merit of applications must include an evaluation of the proposed gender and minority composition of the study population and its appropriateness to the scientific objectives of the study and to this policy. If the representation of women and minorities in a 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 should be reflected in the assigned score given to the application. When preparing the summary statement, the Executive Secretary will summarize the findings and recommendations of the reviewers on this policy in a special section at the end of the Critique sub-headed: Women and Minority Subjects.

Regardless of the priority score, percentile ranking, or program relevance of the proposed research, the NIH and ADAMHA funding components will not fund/award grants that do not comply with this policy.

APPLICANTS SHOULD CONTACT NIH/ADAMHA PROGRAM STAFF FOR ADDITIONAL GUIDANCE IN INTERPRETING THIS POLICY IN THE CONTEXT OF ANY SPECIFIC INSTITUTE, CENTER OR DIVISION RESEARCH PROGRAM OF NIH/ADAMHA.

ANNUAL ASSURANCE UPDATE AND REPORT ON ACTIVITIES RELATED TO POSSIBLE MISCONDUCT IN SCIENCE

P.T. 34; K.W. 1014004, 1014006

Public Health Service

Effective Date: January 1, 1991

The Public Health Service (PHS) scientific misconduct regulations, 42 CFR 50 Subpart A, "Responsibilities of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science", require institutions to make an annual report to the Office of Scientific Integrity (OSI), about the handling of allegations, inquiries, and investigations into possible scientific misconduct, in connection with research for which PHS funds have been requested or received, along with an annual update of the institutional assurance to the OSI.

The official forms for the annual report with a signature page for the required assurance update were mailed by the OSI in December 1990, to the officials of institutions that filed an assurance with OSI for 1990. The completed form must be returned to OSI no later than Janaury 10, 1991. OSI staff will review and use the form to update the PHS assurance files. An updated, active assurance is required in order for each institution to be eligible to apply for and receive PHS grants, fellowhsips, and cooperative agreements for research during calendar year 1991.

For further information contact:

Dr. Alan R. Price or Ms. Carolyn Bowman
Office of Scientific Integrity
NIH
Building 31, Room B1C39
Bethesda, MD 20892
Telephone: (301) 496-2624 (this is not a toll-free number)
Fax: (301) 402-0238

NIDCD RESTRICTIONS ON REQUESTED BUDGETS FOR PROGRAM PROJECT AND CLINICAL RESEARCH CENTER APPLICATIONS

P.T. 04, 34; K.W. 1014006

National Institute on Deafness and Other Communication Disorders

The National Institute on Deafness and Other Communication Disorders (NIDCD) announces a new policy on the maximum amount of direct costs for applications for program projects and clinical research centers. Effective for the submission deadline of June 1, 1991, applications for new program projects and clinical research centers may not request more than $750,000 direct costs for the first year of support. Applications exceeding this limit will be returned to the applicant without further review.

Competing continuation applications for program projects and clinical research centers already received and awaiting review or award may be awarded at an amount in excess of $750,000 for the first year of continuation support (when appropriately recommended by initial review groups and the National Advisory Council). current payment criteria).

Competing continuation applications for program projects and clinical research centers received by the October 1, 1991 deadline may request the amount of the last year of their current project period or $750,000, whichever is greater, for the first year of renewal support.

Principal Investigators (PI) with grants that now exceed or will exceed $750,000 direct costs must prepare to reduce the size of their grant proposal when they apply for a renewal at the end of their current project period. The Health Scientist Administrator responsible for the grant will work with the PI to approach the $750,000 limitation.

The NIDCD regrets that budgetary constraints have dictated the issuance of this new policy. For additional information and for NIDCD Guidelines for the preparation of program project and clinical research grant applications, please contact:

Acting Director for Extramural Activities
National Institute on Deafness and Other Communication Disorders
6120 Executive Plaza South, Suite 750a
Bethesda, MD 20892

NOTICES OF AVAILABILITY (RFPs AND RFAs)

SUPPORT FOR THE PREPARATION OF THE ANNUAL REPORTS ON CARCINOGENS

RFP: NIH-ES-91-07

P.T. 34; K.W. 0715035, 0725000

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), is soliciting a proposal from the source identified below to procure assistance in preparing the Annual Reports on Carcinogens for printing. With respect to chemicals that are known to be or reasonably anticipated to be carcinogens, the Contractor shall assist the Government in identifying, gathering, collating, and summarizing existing data, estimates and information on the nature of exposure, its level, the number of persons exposed, and the regulatory status for each chemical to be included in the Annual Reports on Carcinogens. The Contractor shall provide support for inclusion of approximately 20 new chemicals per year in the Annual Report on Carcinogens, as well as updating the information contained in the immediately preceding report. Each Annual Report shall be a self-contained document. The Government estimates that the project will require

approximately 1.4 professional person years and .8 technical person years of effort per contract year. The proposed contract is set aside for Rao Enterprises, Inc./dba Integrated Laboratory Systems, P.O. Box 13501, Research Triangle Park, NC 27709. The RFP was released on or about December 13, 1990 with the proposal due to be received January 15, 1991.

Requests should reference RFP NIH-ES-91-07 and should be forwarded to:

National Institute of Environmental Health Sciences
Contracts and Procurement Management Branch, OM
ATTN: Mr. Donald Gula, Contract Specialist
79 T.W. Alexander Drive, 4401 Research Commons Building
P.O. Box 12874
Research Triangle Park, NC 27709
Telephone: (919) 541-7893

CLINICAL TRIALS TO EVALUATE THERAPIES FOR HIV DISEASE

RFP AVAILABLE: RFP-NIH-NIAID-DAIDS-91-29

P.T. 34; K.W. 0715008, 0755015, 0740012, 0795005

National Institute of Allergy and Infectious Diseases

The Division of Acquired Immunodeficiency Syndrome (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) has a need for organizations having the capability and facilities to conduct Clinical Trials to Evaluate Therapies for HIV Disease. The purpose of this requirement is to evaluate potential therapies for HIV disease and its associated opportunistic infections and malignancies in Phase I, I/II, and II clinical trials.

The DAIDS was established to address national research needs created by the advent and spread of the acquired immunodeficiency syndrome (AIDS) epidemic. Integral to the mission of the Division is responsibility for ensuring that scientific investigation of infection with the human immunodeficiency virus (HIV) is focused on the most critical biomedical research issues engendered by the AIDS epidemic. The Treatment Research Program of the DAIDS directs two national clinical investigation programs for evaluating new treatments for HIV infection and its associated opportunistic infections and cancers. These two programs are the AIDS Clinical Trials Group (ACTG) and the Community Programs for Clinical Research on AIDS (CPCRA).

The purpose of this Request for Proposals (RFP) is to provide the DAIDS with an additional clinical trials mechanism, separate and distinct from both the ACTG and the CPCRA. This mechanism will enable the Division to rapidly address critical questions about therapeutic agents or innovative treatment approaches and to evaluate potentially effective therapies that may fall outside the immediate priorities of the ACTG or the CPCRA. This contract specifically will NOT REPLICATE the research conducted through the existing ACTG and CPCRA systems but, rather, is expected to complement these research activities.

The successful offeror(s) to this RFP must have the demonstrated scientific, technical, and operational capabilities to plan, develop, implement, and manage a clinical trials system to respond to the DAIDS need to rapidly implement pilot and other early studies of new agents and interventions for the treatment of HIV infection and its sequelae. These capabilities include developing, implementing and analyzing protocols, acquiring and distributing investigational agents, and monitoring the progress of the ongoing trials in accordance with Federal regulations and the DAIDS standards, including reporting adverse drug reactions.

This NIAID-sponsored project will take approximately 5 years to complete. It is anticipated two completion type contracts will be made. This is an announcement for an anticipated RFP. RFP-NIH-NIAID-DIADS-91-29 shall be issued on or about January 4, 1991, with a closing date tentatively set for March 13, 1991. Requests for the RFP should be directed in writing to:

William Roberts
Contract Management Branch
National Institutes of Health
Control Data Corp. Building
6003 Executive Blvd., Room 222P
Bethesda, MD 20892

To receive a copy of the RFP, please supply this office with two self-addressed mailing labels. All responsible sources may submit a proposal

that will be considered. This advertisement does not commit the Government to award a contract.

INSTITUTIONAL PHYSICIAN SCIENTIST DEVELOPMENT AWARD PROGRAM

RFA AVAILABLE: MH-91-02

P.T. 34; K.W. 0710030, 0785035

National Institute of Mental Health
National Institute on Drug Abuse

Application Receipt Date: March 20, 1991

The National Institute of Mental Health (NIMH) and the National Institute on Drug Abuse (NIDA) is issuing this Request for Applications (RFA), Institutional Physician Scientist Development Award Program, MH-91-02, whose purpose is to develop exceptional research skills in physicians beginning a research career. It is designed to enable a research career for junior faculty from institutions lacking a strong research base by offering high-quality research career development experience in a research-intensive environment where a critical mass of scientists are available to provide a complete developmental experience.

Domestic, public or private, nonprofit institutions, and professional organizations and associations may apply. For NIMH, junior faculty to be supported by the program must have an M.D. degree and must have completed at least 1 year of postresidency training in psychiatry. For NIDA, junior faculty who have an M.D. and are currently in residency are encouraged. This program should include both women and the broadest possible representation of minority groups. If women and minority group members are not represented, reasons for their exclusion must be explained or justified.

Applications will be accepted by NIMH and NIDA on the single receipt date of March 20, 1991. A maximum of six awards (three from each Institute) will be supported initially. Each Institute will set aside approximately $1,000,000 for this program.

Potential applicants may seek additional information and consultation from NIMH or NIDA:

Leonard Lash, Ph.D.
Division of Clinical Research, NIMH
Room 10-99
Telephone: (301) 443-3264

Kenneth Lutterman, Ph.D.
Division of Applied and Services Research, NIMH
Room 118C-26
Telephone: (301) 443-3685

Harold Jones, Ph.D.
Office of Policy and External Affairs, NIDA
Room 10A-43
Telephone: (301) 443-1801

The mailing address for all of the above is:

5600 Fishers Lane
Rockville, MD 20857

CLINICAL TREATMENT AND CORRELATES OF UPPER GI CARCINOMA

RFA AVAILABLE: CA-91-03

P.T. 34; K.W. 0715035, 0715085

National Cancer Institute

Letter of Intent Date: February 25, 1991
Application Receipt Date: April 8, 1991

PURPOSE

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites research grant applications (R01) from interested investigators to

assess new clinical correlates and develop new treatment modalities in upper gastrointestinal (GI) carcinoma by means of an integrated research program of laboratory experimentation and concurrent clinical trials. New, as well as experienced, investigators in relevant fields and disciplines may apply to fund new therapeutic clinical trials or new correlative laboratory studies that are related to clinical trials.

BACKGROUND

Carcinoma of the organs of the upper GI tract (esophagus and stomach) are lethal tumors. Development of resistance to treatment (as manifested by tumor progression) is rapid even when chemotherapy, with or without radiation therapy, is effective. Taken collectively, the incidence of these tumors represents a major health hazard to 35,000 patients per year. Except for the 11 percent of patients with gastric cancer limited to the stomach, who are able to undergo curative resection, and a similar group of patients with esophageal cancer, the average life span for patients with these cancers is 4 to 6 months. The reported response rates for cytotoxic therapy range from 5 percent to 40 percent. Relatively few complete responses are noted and no patient with metastatic disease is cured. Recently, however, promising results utilizing combinations of radiation or surgery and chemotherapy have been reported for esophageal cancer.

The NCI supports basic research efforts to describe and understand the tumor biology and treatment resistance of malignancies. Such efforts form the basis for the development of new treatment modalities. Relatively few investigations are supported in upper gastrointestinal carcinoma to move new advances in the laboratory into the clinic. This Request for Applications (RFA) encourages applicants to address their research efforts towards the upper GI carcinomas and the development of new clinical therapies. For example, monoclonal antibodies directed against gastrointestinal tumor specific antigens have been developed, characterized, and applied for diagnostic purposes. The potential of these antibodies to improve clinical management and/or therapy of these diseases needs further investigation. Clinical correlations of oncogenes, growth factors, or markers of drug resistance may prove useful in subsets of patients that would respond to specific treatment therapies.

RESEARCH GOALS AND SCOPE

The major goal of this RFA is to foster interactions between basic science laboratories and clinicians performing clinical trials in upper GI carcinoma to improve treatment results and clinical outcome. To accomplish this goal, two types of studies will be supported: (1) the development of new therapeutic clinical trials and (2) new correlative studies relevant to clinical trials. Applications should be focused on integrating clinical goals with laboratory research areas.

This RFA envisions funding new therapeutic clinical trials in upper GI carcinomas that test and exploit basic findings concerning drug resistance or cellular targets of treatment. Clinical studies should be designed to improve cancer treatment. New clinical studies dealing with treatment using chemotherapeutic drugs, biologics, radiation, or surgery, whether used as a single agent/modality or in combination, are appropriate. Examples of clinical trials based on new therapeutic approaches include: (1) treatment therapies for overcoming drug or radiation resistance; (2) treatment therapies based on novel mechanisms of action; (3) biologics in combination with drug or radiation regimens; (4) immunotherapies including monoclonal antibody therapy, radioimmunotherapy, and the use of new immunotoxins; (5) new therapies combining endocrine manipulations with chemotherapeutic agents; (6) more effective combinations of chemotherapy and radiation therapy; or (7) radiation modifiers to enhance cell kill or protect normal tissue.

This RFA has a second research goal of funding new correlative laboratory studies that are relevant to therapeutic clinical trials. Some examples of therapeutic correlates include: (1) phenotypic or genotypic alterations which appear to correlate with the development of drug or radiation resistance; (2) oncogenes, growth factors, and specific antigen expression on tumor cells for antibody development; (3) pharmacokinetic and pharmacodynamic measurements; and (4) biochemical pharmacologic parameters. The therapeutic correlates must have a future clinical application such as development of new treatment strategies or identification of patient subsets for specific treatment therapies. This RFA does not support research investigations on diagnostic markers or clinical correlates that will have no impact on the clinical treatment of patients. The laboratory assays must utilize patient specimens from new or ongoing clinical trials and have been demonstrated to be applicable to tissue samples and/or body fluids, etc. Investigators are

encouraged to obtain patient specimens from multi-institutional clinical trials to ensure adequate sample size for statistical analysis.

Research investigators are not limited to the above areas of potential studies. Clinical protocols should be included in the Appendix of the application. A section on statistical support should be included in the grant application to ensure proper correlation of assay parameters with clinical outcome.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

Support of the program will be through the National Institutes of Health (NIH) grant-in-aid. Applicants will be responsible for the planning, direction, and execution of the proposed project. Approximately $1,500,000 in total costs per year for three years will be committed to specifically fund applications that are submitted in response to this RFA. It is anticipated that 6 to 8 awards will be made. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to the present RFA should not exceed three (3) years. The earliest feasible start date for the initial award will be December 1, 1991.

Non-profit organizations and institutions, governments and their agencies are eligible to apply. For-profit organizations are also eligible to apply. Applications can be from single institutions or multiple institutions (collaborating institutions, consortia, cooperative groups). We encourage new, as well as experienced, investigators to apply.

LETTER OF INTENT

Prospective applicants are asked to submit by February 25, 1991, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed.

The letter of intent should be sent to:

BY US POSTAL

Ms. Diane Bronzert
Program Director
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 496-9384

BY DIRECT DELIVERY

Ms. Diane Bronzert
Program Director
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
6130 Executive Blvd.
Rockville, MD 20852

INQUIRIES

Written or telephone inquiries concerning the objectives and scope of this RFA or inquiries about whether or not specific proposed research would be responsive are encouraged and should be directed to Ms. Diane Bronzert at the above address. The program director welcomes the opportunity to clarify any issues or questions from potential applicants.

SPECIALIZED CENTERS OF RESEARCH IN RHEUMATOID ARTHRITIS (RA SCOR)
SPECIALIZED CENTERS OF RESEARCH IN OSTEOARTHRITIS (OA SCOR)
SPECIALIZED CENTERS OF RESEARCH IN OSTEOPOROSIS (OP SCOR)

RFA AVAILABLE: AR-91-01

P.T. 04; K.W. 0715010, 0705050, 0710030

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date for RA and OP SCORs: July 1, 1991
Application Receipt Date for RA and OP SCORs: October 15, 1991

Letter of Intent Receipt Date for OA SCORs: November 1, 1991
Application Receipt Date for OA SCORs: February 14, 1992

BACKGROUND

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites grant applications from interested institutions for Specialized Centers of Research (SCORs) in three areas of special importance to the Institute: rheumatoid arthritis, osteoarthritis, and osteoporosis. This represents the first recompetition of the NIAMS SCOR program, begun in 1987. At this time the number of SCOR grants (nine) and the distribution, three each in RA, OA, and OP, will remain the same.

RESEARCH GOALS AND SCOPE

A SCOR consists of a cluster of individual, but interrelated, basic and clinical research projects, each with high scientific merit and clear research objectives. Examples of disciplines that could contribute to a SCOR include, but are not limited to: biochemistry, genetics, molecular biology, immunology, pathology, epidemiology, rheumatology, orthopedic surgery, bioengineering, and statistics. Each center has a central research theme that provides for research on significant problems of etiology, pathogenesis, diagnosis, prevention, and treatment related to the program area. Other characteristics of the SCOR include: a research plan emphasizing current multidisciplinary fundamental and clinical research; an environment encouraging active collaborations among individual clinical and basic research investigators within the SCOR, and among other SCORs.

Support for large clinical trials or for applications that contain exclusively clinical or exclusively basic studies will not be provided within this SCOR program. Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or principal investigator could be included with the application.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

The administrative and funding mechanism will be the Specialized Center of Research (P50) grant award. Regulations and policies that govern the research grant programs of the Public Health Service will prevail. The award will support research projects and core functions.

To be eligible for an award, an application must include both basic (laboratory-based) and clinical investigation. Each individual research project must stand on its own merit and complement other projects. Thus, a

project, regarded as highly meritorious in isolation could be recommended for deletion from the program if it is perceived as being totally independent from the program as a whole.

Separate cores are not a mandatory component, although experience has shown them to be useful and economic. A core is defined as a resource shared by multiple investigators that should enhance research productivity and increase the functional capacity of the SCOR. Examples of core functions include biochemical analysis, electron microscopy, or data management.

The award of grants pursuant to this Request for Applications (RFA) is contingent upon the receipt of applications judged by peer review to be of excellent to outstanding merit and the availability of appropriated funds for this purpose. The yearly direct cost budget requested must not exceed $1 million. SCOR awards will be issued for a period of five (5) years and may be renewable on a competitive basis.

REVIEW PROCEDURES AND CRITERIA

All applications submitted in response to the RFA will be reviewed first for completeness and responsiveness to this RFA. A preliminary evaluation (triage) by a peer review group to determine the relative merit of an application relative to other applications may be performed. The further evaluation of remaining applications for scientific and technical merit will be by an initial review group which will be convened solely to review these applications. A site visit is not planned. Each proposal should, therefore, be complete in itself and be prepared as if no site visit is expected.

Factors to be considered in evaluation of the scientific merit of each application will be those used in the review of traditional research project grants applications, including the scientific merit of each proposed project and the scientific merit of combining the component parts into a SCOR. Applications judged to be nonresponsive to the RFA will be returned to the applicant.

Following assessment by the initial review group, applications will be evaluated by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

METHOD OF APPLYING

Prospective applicants should obtain the supplemental program guidelines developed by NIAMS for its SCOR program from the Centers Program Director listed below. Prospective applicants are encouraged to submit to the Centers Program Director a nonbinding letter of intent to apply by July 15, 1991 (RA and OP SCORs) or November 14, 1991 (OA SCOR). The letter should include a descriptive title, the name and address of the Principal Investigator and other key investigations, and the names and address of any other participating institutions.

The letter of intent is not mandatory and does not influence review or funding decisions, but it will assist the NIAMS to plan the review. It will also ensure that each potential applicant receives relevant program information prior to expending considerable effort in preparing the application.

Applications must be submitted on the standard PHS 398 application form (rev. 10/88) available at most institutional business offices or from the Division of Research Grants, NIH (telephone number: 301-496-7441). On item 2 of the face page of the application, applicants must enter: RFA AR-91-01 Specialized Centers of Research in Arthritis and Musculoskeletal Diseases. The RFA label (found in the 10/88 revision of application form PHS 398) must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in delayed processing of your application such that it will not reach the review committee in time for review.

Send the original and six copies of the application to the NIH Division of Research Grants (DRG), no later than October 15, 1991, for an RA or OP SCOR and February 14, 1992, for an OA SCOR.

IDENTIFICATION OF CONTACT POINTS

Inquiries regarding this announcement, the guidelines for structuring a Specialized Center of Research application, and method of applying should be directed to:

Julia B. Freeman, Ph.D.
Centers Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 496-7496
FAX: (301) 496-7881

This program is described in the Catalog of Federal Domestic Assistance, No. 93.846. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

DIABETES INTERDISCIPLINARY RESEARCH PROGRAM

RFA AVAILABLE: DK-91-05

P.T. 34; K.W. 0715075, 0710030, 1002019, 0710070, 1002004, 1002008

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: March 15, 1991
Application Receipt Date: May 17, 1991

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Juvenile Diabetes Foundation International (JDFI) invite investigator-initiated program project grant applications that incorporate an interdisciplinary research approach to the etiology and pathogenesis of insulin-dependent diabetes mellitus (IDDM) or to the genetic susceptibility for the long-term complications of diabetes. This solicitation is intended to stimulate the application of advances in basic molecular biology, genetics, immunology, cell biology, and biophysics to the study of IDDM and its complications. It is expected that this will be accomplished by bringing to the diabetes arena those who are skilled in these approaches by the support of meritorious, synergistic, multidisciplinary research program project applications. Proposals should include the involvement of both basic and applied scientists in collaborative endeavors.

The mechanism of support will be the program project grant award. A program project grant is for the support of a broadly-based multidisciplinary or multifaceted research program that has a specific major objective or central theme. The award may support research components and core functions. Collectively, these components should demonstrate essential elements of unity and interdependence and result in a greater contribution to program goals than if each activity were pursued individually.

Applications will be submitted to the NIH and will be reviewed by NIH according to normal NIH peer review procedures. Applications judged meritorious but not funded by the NIH may be considered by the JDFI for possible funding. Applicants wishing to have their application considered by the JDFI must authorize the NIDDK to provide a copy of their letter of intent, application, and NIH-prepared summary statement of the initial review to the JDFI.

The NIDDK plans to make one or two awards in FY 1992 contingent on the receipt of highly meritorious applications in response to this solicitation. The JDFI plans to make two to four awards. With respect to post-award administration, the current policies and requirements that govern the research grant programs of the NIH or the JDFI will prevail depending on the funding source. Applicants should note that grants funded by the JDFI will be subject to the indirect cost policy of JDFI.

The criteria for review of applications will be those used regularly for the review of program project grant applications by the NIDDK. These criteria concern the scientific and technical merit, originality, and feasibility of the constituent individual research projects; the utility and quality of the proposed core facilities; the cohesiveness, synergy, significance, and overall scientific and technical merit of the entire program project; and the qualifications, experience, and commitment of the participating personnel. A complete and detailed description of these criteria is contained in the

publication entitled "NIDDK Program Project Grants: Administrative Guidelines" that is available by request.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

Potential applicants are strongly encouraged to submit a letter of intent. The letter of intent may include only 1) names of the Principal Investigator/program director and principal collaborators, 2) descriptive title of the potential application, and 3) identification of the organization(s) involved. The letter of intent should be sent to:

Dr. Robert D. Hammond
Chief, Review Branch
Division of Extramural Activities
NIDDK, NIH
Westwood Building, Room 406
Bethesda, MD 20892

Applicants must submit a brief letter to the NIDDK indicating whether or not they wish their applications to be considered for funding by the JDFI. While applicants may request that their applications be considered only by the NIDDK and not by the JDFI, it is necessary that the record indicate the applicant's consideration of this opportunity. Letters of authorization should be prepared by the Principal Investigator and co-signed by the official signing for the applicant organization. This letter may be combined with Letters of Intent or may be submitted as cover letters accompanying applications.

Requests for the full text of this RFA and inquiries should be directed to the following NIDDK Program Staff:

Joan T. Harmon, Ph.D.
Executive Director, Diabetes Research Program
Diabetes Programs Branch
NIDDK, DDEM
Westwood Building, Room 622
Bethesda, MD 20892
Telephone: (301) 496-7731

PHYSICAL FRAILTY IN MINORITY OLDER POPULATIONS - REVISION

RFA: AG-91-03

P.T. 34, CC, FF; K.W. 0710010, 0715043, 0710095, 1002019, 0745027

National Institute on Aging

The Notice of Availability for this RFA was published in the NIH Guide for Grants and Contracts on December 7, 1990, Vol. 19, No. 44.

No award will be made in excess of $200,000 in total cost (direct plus indirect) for first year expenses and, in general, increments no more than four percent for each succeeding year.

For further information, contact:

Stanley L. Slater, M.D.
Geriatrics Program
National Institute on Aging
Building 31, Room 5C27
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-6761

SURGICAL ONCOLOGY

PA: PA-91-16

P.T. 34; K.W. 0785140, 0785210

National Cancer Institute

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

PURPOSE

The treatment of cancer has evolved as a multi-disciplinary effort involving (but not limited to) the disciplines of surgical oncology, medical oncology, pediatric oncology, and radiation oncology. The disciplines of medical oncology, pediatric oncology, and radiation oncology have developed strong cadres of academic investigators while academic development in surgical oncology has not kept pace. It is believed that surgical oncology is not keeping pace because of an insufficient number of surgical oncology research programs and an insufficient number of surgeons undertaking research related to cancer. Continued development of superior multi-disciplinary treatment of cancer is the long-range objective of the Division of Cancer Treatment (DCT) and the attainment of the goal requires sufficient academic strength in investigative surgical oncology.

RESEARCH OBJECTIVES

The DCT, National Cancer Institute, is seeking applications for research grants (R01, R29, P01) concerned with research in surgical oncology. Examples of relevant studies include mechanisms of metastases, effect of surgery on tumor cell kinetics, and tumor host responses to surgery. Preclinical and clinical research is encompassed in this program. Categories of research include (but are not confined to) the following: (1) Pathophysiologic studies related to surgery and cancer in laboratory models or in humans; (2) Laboratory and clinical studies that examine the biochemical, cytokinetic, immunological, or nutritional effects of cancer surgery; (3) Therapeutic studies in which surgery or a surgical question is the primary treatment modality; (4) Novel immunotherapy procedures such as assessment of specific lymphokines, stimulated cells, and autologous vaccines which require surgical input; (5) New surgical techniques relevant to staging or care of patients; (6) Studies to identify prognostic factors relevant to the treatment of cancer patients; (7) Surgical supportive care; (8) Regional chemotherapy or hyperthermia or radiation in which a surgical approach to the treatment site is a major aspect of the procedure. This Program Announcement is not restricted to the areas of surgical oncology research listed above.

MECHANISM OF SUPPORT

This program will be supported through the NIH grant-in-aid mechanism (R01, R29, P01). Awards will be administered under Public Health Service grants policy as stated in the PHS Grants Policy Statement, DHHS Publication No. (OASH) 82-50,000, revised January 1, 1987. The total project period for applications submitted in response to the Program Announcement should not exceed five years.

This Program Announcement is a continuous announcement until retracted. Generally future unsolicited competing renewal applications will compete as research project applications with all other investigator-initiated applications. Applications will compete for available funds with all other approved applications.

ELIGIBILITY

Applications may be submitted by 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 regular study sections of the NIH, or in the case of P01s, by the review group of the relevant institute in accordance with the usual NIH peer review procedures and criteria. Following study section review, the

applications will receive a second-level review by the appropriate national advisory council.

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. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives 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 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 a 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 should be submitted on the grant applications for PHS 398 (Rev. 10/88) and will be accepted at the regular application deadlines. Application kits are available at most institutional business and grant/contract offices or may be obtained from the Division of Research Grants, National Institutes of Health, Bethesda, MD 20892. The title and number of this announcement should be typed in line 2 on the face page of the application.

The original application and six (6) signed exact photocopies should be submitted or delivered to:

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

Applicants are strongly encouraged to contact Dr. Wu prior to application preparation:

Roy S. Wu, Ph.D.
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
EPN, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866

Request for further information should be directed to Dr. Wu at the address given above.

Before submitting a P01 application, please submit a letter of intent to Dr. Wu.

This program is described in the Catalog of Federal Domestic Assistance No 93.395, Cancer Treatment Research. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Feral 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 Health Systems Agency review.

**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

*U.S.G.P.O:281-826:20026