For Grants and Contracts

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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.

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NOTICES

ANIMAL WELFARE EDUCATION PROGRAM

P.T. 42; K.W. 1014003, 0201011

National Institutes of Health

The National Institutes of Health (NIH), Office for Protection from Research Risks (OPRR), Division of Animal Welfare is cosponsoring with the University of Washington in Seattle, Washington, an animal welfare education program entitled, "Resolving the Ethical Dilemmas in Animal Use Protocol Review: How to Increase Humaneness Without Weakening the Science." The one and a half day workshop will be held on September 12-13, 1991 at the Holiday Inn Crown Plaza, Sixth and Seneca at Freeway Park, 1113 6th Avenue, Seattle, WA.

The tool used by philosophers to solve ethical problems known as casuistry will be introduced and applied to protocol reviews involving transgenic animals, withholding treatment from controls, and the use of death as an endpoint in studies. The workshop will explore contemporary issues and how protocol reviews can address humane considerations without weakening the science. The agenda will also include presentations from the Public Health Service and United States Department of Agriculture representatives on the policies and regulations related to the humane care and use of laboratory animals.

The workshop is open to institutional administrators, Institutional Animal Care and Use Committee (IACUC) members, laboratory animal veterinarians, scientific investigators, and other institutional staff sharing responsibility for the management of a sound institutional animal care and use program.

For further information, please contact:

University of Washington Continuing Medical Education Telephone: (206) 543-1050 or (800) 869-2633

(206) 543-3195

For information concerning future NIH, OPRR Animal Education Workshops, please contact:

Mrs. Roberta Sonneborn Telephone: (301) 496-7163 FAX: (301) 402-0527

NOTICES OF AVAILABILITY (RFPs AND RFAs)

NATIONAL RESEARCH SERVICE AWARD - INSTITUTIONAL TRAINING APPLICATIONS

RFA AVAILABLE: DE-91-05

P.T. 44; K.W. 0715148, 0404000, 0785040, 0715008

National Institute of Dental Research

Letter of Intent Receipt Date: October 21, Application Receipt Date: November 20, 1991

PURPOSE

The National Institute of Dental Research (NIDR) invites applications from domestic, private or public, nonprofit institutions proposing institutional training programs in basic and clinical sciences pertaining to: (1) oral soft tissue diseases, including oral cancer, oral manifestations of AIDS, and oral herpes simplex virus (HSV) infection; and (2) behavioral science research in dentistry. Applications pertaining to other areas of oral health research are also acceptable. Proposed training must be relevant to the goals of the NIDR, as described in the NIDR Long-Range Research Plan for the Ninetics as described in the NIDR Long-Range Research Plan for the Nineties, "Broadening the Scope".

The primary objective of these training programs is to develop highly qualified, clinical investigators by supporting postdoctoral training of individuals with DDS, DMD, or equivalent clinical degrees, who are committed to a career in oral health research. Applications may include pre- and

postdoctoral training for basic scientists and or short-term training for dental students in the proposed programs.

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 Request for Applications (RFA) is related to the priority area of oral health. 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).

The NIDR expects to make five new and/or renewal institutional training awards in response to this RFA. Institutional awards are made for five years and are renewable. Only one training award will be made to an institution unless the training programs are in distinctly different areas of oral health research.

This RFA is for a single competition with a receipt date of November 20, 1991.

LEVELS OF TRAINING

Applications will be accepted to provide training at one or more of the following levels, given in priority order: (1) dentists pursuing a Ph.D. or equivalent degree in basic science; (2) dentists pursuing postdoctoral research training; (3) baccalaureate degree holders pursuing a Ph.D. or equivalent degree; (4) Ph.D. degree holders pursuing postdoctoral research training; (5) pre-dental degree students pursuing a short-term research experience, usually during, but not limited to, the summer months. Attention must be given to recruiting women and individuals from minority groups that are underrepresented, nationally, in these sciences.

REVIEW PROCEDURES

Applications will be processed as follows:

| Application Receipt Date November 20 | Initial Review Group Meeting Feb/March 1992 | Council Meeting May/June 1992 | Earliest Award Date July 1992 |
|--|--|--|--|
|--|--|--|--|

Applications will be evaluated for scientific and technical merit by the NIDR Special Grants Review Committee. Site visits may be involved. Secondary review will be by the National Advisory Dental Research Council. Funding decisions will be made based on their recommendations, the need for research personnel in specified program areas, and the availability of funds.

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 special justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

It is recommended that prospective applicants contact program staff early in the planning phase of application preparation and submit a letter of intent by October 21, 1991. A letter of intent is not binding nor is it a prerequisite for acceptance of an application. Applications must be prepared on grant application form PHS 398 (rev. 10/88).

Inquiries, requests for copies of the full RFA, and letters of intent should be directed to:

Thomas M. Valega, Ph.D.
Special Assistant for Manpower Development and Training Extramural Program
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 496-6324

For fiscal and administrative matters, contact:

Theresa Ringler
Grants Management Officer
National Institute of Dental Research
Westwood Building, Room 518
Bethesda, MD 20892
Telephone: (301) 496-7437

This program is described in the Catalog of Federal Domestic Assistance No. 93.122. National Research Service Awards are made under authorization of the Public Health Service Act as amended (42 USC 288). Title 42 of the Code of Federal Regulations, Part 66, is applicable to this program.

DIABETES AND ENDOCRINOLOGY RESEARCH CENTERS

RFA AVAILABLE: DK-91-11

P.T. 04; K.W. 0715075, 0785050, 0710030

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: January 10, 1992 Application Receipt Date: February 11, 1992

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for Diabetes and Endocrinology Research Center grants.

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 Request for Applications (RFA), Diabetes and Endocrinology Research Centers, is related to the priority area of diabetes mellitus. 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 objective of the Diabetes and Endocrinology Research Centers (DERCs) is to bring together investigators from relevant disciplines in a manner that will enhance and extend the effectiveness of research related to diabetes and its complications. A diabetes center must be an identifiable unit within a single university medical center or a consortium of cooperating institutions, including an affiliated university. The overall goal of the DERC is to bring together, on a cooperative basis, clinical and basic science investigators in a manner that will enrich the effectiveness of diabetes research. An existing program of excellence in biomedical research in the area of diabetes and related metabolic and endocrine disorders is required. This research must be in the form of NIH-funded research projects, program projects, or other peer-reviewed research that is in existence at the time of submission of a center application. Close cooperation, communication, and collaboration among all involved personnel of all professional disciplines are ultimate objectives. Applicants should consult with NIDDK staff concerning plans for the development of the center.

The DERCs are based on the core concept. Cores are defined as shared resources that enhance productivity or in other ways benefit a group of investigators working in diabetes or diabetes-related areas to accomplish the stated goals of the center. Two other types of activities may also be supported with center funding—a pilot and feasibility program and an enrichment program. The pilot and feasibility program provides modest support for new initiatives or feasibility research studies. This program is directed at new investigators or established investigators in other research disciplines where their expertise may be applied to diabetes research. The center grant may also include limited funds for program enrichment such as seminars, visiting scientists, consultants, and workshops.

Applicants from institutions that 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 must be included with the application.

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

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

NIDDK expects to award up to three DERC grants in Fiscal Year 1993 on a competitive basis. The receipt of three competing continuation applications is anticipated that will be in competition together with other applications received in response to this announcement. Foreign institutions are not eligible to apply. Awards will be for five years, contingent upon the availability of appropriated funds. Requests for support must be limited to no more than \$750,000 in direct costs per year. Any application exceeding this amount will be returned to the applicant.

REVIEW PROCEDURES

Applications for a DERC grant will be evaluated by the NIH grant peer review process. Applications will be reviewed initially by an ad hoc review group convened by the NIDDK and subsequently by the National Diabetes and Digestive and Kidney Diseases Advisory Council.

METHOD OF APPLYING

Applicants should request a copy of "Guidelines for Diabetes Endocrinology Research Centers (DERCs)". These guidelines contain important additional information on the format, content, and review of applications and review criteria.

Letter of Intent:

Potential applicants are strongly encouraged to submit a letter of intent by January 10, 1992. The letter of intent may only include names of the Principal Investigator/program director and principal collaborators, descriptive title of the potential application, and identification of the organization(s) involved. The letter of intent is to be sent to the Chief, Review Branch, NIDDK at the address noted below.

Format for Application:

Applications must be submitted on the form PHS 398 (rev. 10/88) available at most institutional business offices and from the Division of Research Grants, NIH, (301) 496-7441. On item 2 of the face page of the application, applicants must enter: Diabetes Centers, RFA number DK-91-11. The RFA label available in the current revision of application form PHS 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application to the extent that it may not reach the review committee in time for review.

Application Procedures:

Applications must be received by February 11, 1992. The original and four copies of the application must be sent or delivered to:

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

Two additional copies of the application under separate cover must be sent to:

Review Branch National Institute of Diabetes and Digestive and Kidney Diseases Westwood Building, Room 406 Bethesda, MD 20892

INQUIRIES

Inquiries, requests for guidelines, and requests for the full RFA should be directed to:

Dr. Sanford A. Garfield Diabetes Centers Program Director Division of Diabetes, Endocrinology, and Metabolic Diseases National Institute of Diabetes and Digestive and Kidney Diseases Westwood Building, Room 626 Bethesda, MD 20892 Telephone: (301) 496-7418

For fiscal and administrative matters, contact:

Linda Stecklin
Supervisory Grants Management Specialist
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 639
Bethesda, MD 20892
Telephone: (301) 496-7467

DIABETES RESEARCH AND TRAINING CENTERS

RFA AVAILABLE: DK-91-12

P.T. 04, 44; K.W. 0715075, 0710030, 0785035, 0403004

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: November 22, 1991 Application Receipt Date: December 20, 1991

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for Center grants. NIDDK anticipates the competitive awarding of at least five Diabetes Research and Training Center (DRTC) grants in Fiscal Year 1993.

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 Request for Applications (RFA), Diabetes Research and Training Centers, is related to the priority area of diabetes mellitus. 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 objective of the DRTC is to bring together investigators from relevant disciplines in a manner that will enhance and extend the effectiveness of research and training being conducted in the field of diabetes and its complications. It should be stressed that a DRTC, although containing all of the elements present in a Diabetes Endocrinology Research Center (DERC, see RFA DK-91-11), contains substantial additional components described here. Diabetes Centers must be an identifiable unit within a single university medical center or a consortium of cooperating institutions, including an affiliated university. The overall goal of the DRTC is to bring together, on a cooperative basis, clinical and basic science investigators and those involved in diabetes training and information transfer in a manner that will enrich the effectiveness of diabetes research, training, and information transfer. When fully developed, the DRTCs are expected to encompass the following: (1) facilitating and strengthening basic and clinical research related to diabetes and its complications; (2) training health professionals about diabetes and its management; (3) developing a model demonstration facility to contribute to the above endeavors; and (4) transferring advances in the field of diabetes into improved care for people with diabetes through activities that identify and then overcome barriers to the application of new science to diabetes management and treatment. All of these areas need not be developed to the same degree. However, a strong base of biomedical research is the most important function of a center. Accordingly, a program of excellence in biomedical research in the area of diabetes and related metabolic and endocrine disorders in the form of NIH-funded research projects, program projects, or other peer-reviewed research must be in existence at the time of submission of a Center application. Close cooperation, communication, and collaboration among all involved personnel of all professional disciplines

are ultimate objectives. Applicants should request a copy of the DRTC guidelines and consult with NIDDK staff concerning plans for the development of the Center.

The DRTCs are based on the core concept. Cores are defined as shared resources that enhance productivity or in other ways benefit a group of investigators working in diabetes or diabetes-related areas to accomplish the stated goals of the Center. Two other types of activities may also be supported with center funding - a pilot and feasibility program and an enrichment program.

Applicants from institutions that 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 must be included with the application.

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

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.

ELIGIBILITY

Foreign institutions are not eligible to apply.

MECHANISM OF SUPPORT

NIDDK expects to award up to five DRTC grants in Fiscal Year 1993 on a competitive basis. The receipt of five competitive continuation applications is anticipated, and these will be in competition together with other applications received in response to this announcement. Awards will be for five years contingent upon the availability of appropriated funds. Requests for support must not exceed \$1,250,000 per year in direct costs. Any application exceeding this amount will be returned to the applicant.

REVIEW PROCEDURES

Applications for a DRTC grant will be evaluated by the NIH grant peer review process. Applications will be reviewed initially by an ad hoc review group convened by the NIDDK and subsequently by the National Diabetes and Digestive and Kidney Diseases Advisory Council.

METHOD OF APPLYING

Applicants should request a copy of "Guidelines for Diabetes Research and Training Centers (DRTCs)." These guidelines contain important additional information on the format, content, and review of applications and review criteria.

Letter of Intent:

Potential applicants are strongly encouraged to submit a letter of intent by November 22, 1991. The letter of intent may only include names of the Principal Investigator/program director and principal collaborators, descriptive title of the potential application, and identification of the organization(s) involved. The letter of intent is to be sent to the Chief, Review Branch, NIDDK at the address noted below.

Format for Application:

Applications must be submitted on the form PHS 398 (rev. 10/88) available at most institutional business offices and from the Division of Research Grants, NIH, (301) 496-7441. On item 2 of the face page of the application, applicants must enter: Diabetes Centers, RFA number DK-91-12. The RFA label available in the current revision of application form PHS 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application to the extent that it may not reach the review committee in time for review.

Application Procedures:

Applications must be received by December 20, 1991. The original and four copies of the application must be sent or delivered to:

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

Two additional copies of the application under separate cover must be sent to:

Review Branch National Institute of Diabetes and Digestive and Kidney Diseases Westwood Building, Room 406 Bethesda, MD 20892

INQUIRIES

Inquiries, requests for guidelines, and requests for the full RFA should be directed to:

Dr. Sanford A. Garfield
Diabetes Center Program Director
Division of Diabetes, Endocrinology, and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 626
Bethesda, MD 20892
Telephone: (301) 496-7418

For fiscal and administrative matters, contact:

Linda Stecklin
Supervisory Grants Management Specialist
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 639
Bethesda, MD 20892
Telephone: (301) 496-7467

ONGOING PROGRAM ANNOUNCEMENTS

MOLECULAR BIOLOGY OF SKELETAL MUSCLE AND ITS DISEASES

PA: PA-91-65

P.T. 34; K.W. 0705050, 1002004, 0760070, 1002058, 1003018, 0775000, 745030

National Institute of Arthritis and Musculoskeletal and Skin Diseases

INTRODUCTION

The Muscle Biology Program of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports research on skeletal muscle, its diseases and disorders. This includes studies on normal muscle structure, function, development, and homeostasis. NIAMS, through this program announcement, encourages submission of grant applications in the specific area of molecular events responsible for muscle specialization during development, regeneration, and reconstruction, including changes induced by patterns of muscle activity.

BACKGROUND

Skeletal muscle is a major tissue of the human body, responsible for 40 percent of total body weight in normal adults. Its primary function is generating and controlling body motion and maintaining body posture. Extensive observation and research, motivated by this major role, have enhanced our understanding of many aspects of muscle action. Skeletal muscle has many unique properties as a tissue, with enzymatic, mechanical, and thermal properties that are easy to control and measure. These properties can be changed; muscle responds rapidly to patterns of use or disuse by modifying the total contractile protein content and by shifting relative concentrations of various alternative forms.

Skeletal muscle precursor cells are established early in development via processes involving one or more myogenic determination factors (the myd1 gene

product, MyoD, myogenin, myf5, and mrf4). The mechanisms by which these factors are initially induced and by which they cause pluripotential mesodermal cells to enter the myogenic cell lineage are not understood. Early myoblasts are apparently interchangeable, in that factors responsible for specialization are acquired during development from external cues such as location and activity.

Studies of muscle gene regulation have concentrated upon identifying muscle-specific control elements and the myogenic transcription factors with which they interact. DNA sequence motifs that are common to many muscle genes are known to affect muscle gene expression, but knowledge of gene-specific and modulatory control elements is lacking. Transcription mediated via the common control elements appears to involve interactions with protein complexes composed of both myogenic and ubiquitous nuclear factors. In myoblasts, the activity of these complexes is controlled by environmental factors such as mitogens, but neither the mechanism of this process nor how the expression of specific muscle genes is modulated in differentiated muscle cells is understood.

There has been considerable success recently in sequencing the coding regions for muscle proteins, including the characterization of many genes that can be transcribed in various ways (alternative splicing) to produce considerable isoform diversity for each protein. In many cases, such as the contractile proteins, several isoforms are present within single muscle fibrils. Considerable efforts are being made to identify and characterize factors that promote or inhibit expression of various isoforms and the ways these factors interact with genetic material. Changes in rates of expression and alterations in splicing have major impact on the reconstruction of muscle that occurs in response to patterns of activity.

Other major contractile, regulatory, and structural proteins have been isolated and characterized. Molecular genetic techniques allow for altering sequences and hence provide a way to explore the functional contributions of different parts of proteins. Such techniques are already being used to explore the protein chemistry of calcium binding and transport in troponin-C and the membrane calcium ATPase transport protein.

RESEARCH GOALS AND SCOPE

The purpose of this program announcement is to encourage the submission of high-quality applications that further increase our knowledge of the molecular biology of skeletal muscle and its diseases. This includes, but is not restricted to, the following specific areas:

- o Studies characterizing genes of muscle proteins, substances, and membranes. Examples are the proteins of force production and regulation, including actin, myosin, tropomyosin, troponin; calcium binding proteins, such as calmodulin; ion channel proteins; cytoskeletal proteins, such as spectrin, actinin, dystrophin; surface receptors, and substances of the basal lamina and extracellular matrix.
- o Mechanistic molecular genetic studies of muscle protein functions.
- o Studies on nuclear factors that promote or inhibit gene expression and transcription in muscle during development, regeneration, and response to altered levels of muscle activity (e.g., isoform switching).
- o Studies to determine mechanisms whereby external factors, such as growth hormones or signal transduction, influence transcriptional regulation and the expression of alternate isoforms.
- o Studies on the genetic basis of inherited diseases of skeletal muscle, its membranes, and its constituent proteins.
- o Studies of possible therapies and clinical interventions that are based on modifying genetic expression in muscle. Such studies should be focused on understanding mechanisms by which such interventions alter cellular function.

Investigators are encouraged to use the full range of current disciplines and techniques, including biochemistry, biophysics, molecular genetics, recombinant techniques, and cell biology.

Applicants may apply for research project grants (R01), program project awards (P01), First Independent Research Support and Transition (FIRST) (R29) awards, and fellowships and research career development awards.

APPLICATION AND REVIEW PROCEDURES

Applications in response to this announcement will be reviewed and assigned in accordance with the usual Public Health Service peer review procedures. Review criteria include significance and originality of the research goals and approaches; feasibility of the research and adequacy of the experimental design; training, research competence, and dedication of the investigator(s); adequacy of available facilities; and provision for the humane care of animals. Funding decisions will be based on initial review group and National Advisory Council recommendations.

Applications must be submitted on form PHS 398 (rev. 10/88) or the training/fellowship application form, available in the business or grants office at most academic or research institutions, and from the Division of Research Grants, National Institutes of Health, telephone (301) 496-7441. Applications will be accepted in accordance with the submission dates for research applications on a continuing basis: February 1, June 1, October 1. Fellowship receipt dates are January 10, May 10, September 10.

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 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 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.

The phrase "MOLECULAR BIOLOGY OF SKELETAL MUSCLE AND ITS DISEASES, PA-91-65" must be typed on line 2 of the face page of the application form PHS 398. The original and six copies must be sent or delivered to:

Grant Application Receipt Office Division of Research Grants Westwood Building, Room 240 National Institutes of Health Bethesda, MD 20892-4500**

The original and two copies of the fellowship application must be sent to the DRG address above.

For further information, investigators are encouraged to contact the following individual:

Richard W. Lymn, Ph.D.
Muscle Biology Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 496-7495

Some areas outlined in this announcement are also of interest to the National Institute of Neurological Disorders and Stroke. Applicants may wish to contact:

Paul L. Nichols, Ph.D.
Developmental Neurology Branch
Division of Convulsive, Developmental, and Neuromuscular Disorders
National Institute of Neurological Disorders and Stroke
Federal Building, Room 8C08
Bethesda, MD 20892
Telephone: (301) 496-5821

For fiscal and administrative matters, contact:

Mary Graham
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 417E
Bethesda, MD 20892
Telephone: (301) 496-2665

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under the authority of the Public Health Service Act, administered under PHS grants policies and Federal Regulations 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