

COLLABORATIVE ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES SCIENCE AWARD (CAMSSA)

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Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATIONS:

National Institutes of Health (NIH)
(<http://www.nih.gov/>)

COMPONENTS OF PARTICIPATING ORGANIZATIONS:

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
(<http://www.niams.nih.gov/>)

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 93.846

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PURPOSE OF THIS PA

The objective of the Collaborative Arthritis and Musculoskeletal and Skin Diseases Science Award (CAMSSA) program is to develop and promote competitive scientific research programs in areas within the mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases at institutions with substantial minority enrollment. The CAMSSA program is designed to encourage collaborative investigations among

scientists at institutions with substantial minority enrollment with grantees from research-intensive institutions who have grant support to conduct research in arthritis, musculoskeletal diseases or skin diseases. The nature of the collaborations will include joint research efforts, specialized training in research techniques, and participation in research seminars. The CAMSSA program should develop and expand scientific opportunities among the participating institutions for research in arthritis, musculoskeletal diseases or skin diseases.

RESEARCH OBJECTIVES

o Characteristics of the CAMSSA Program: The CAMSSA will support an investigator-initiated research project in which the applicant and a collaborating scientist will work in a clearly defined area of mutual research interest related to arthritis, musculoskeletal diseases or skin diseases.

Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant and the collaborator. Since the intent of the award is to develop competitive research programs at institutions with substantial minority enrollment, the applicant and collaborating investigators must document the potential for developing scientific approaches to accomplish the objectives of the proposed research project. The project must consist of a scientifically meritorious research plan that involves an efficacious collaborative effort among the participating investigators, each of whom will be conducting a portion of the total research project in his/her own laboratory. Examples of the collaborative interactions include the sharing of ideas, data, and exchanging of research techniques and expertise. It is anticipated that collaboration between the institutions will provide training opportunities for pre- and postdoctoral fellows at both institutions.

o Consortium arrangement between the applicant institution with substantial minority enrollment and the collaborating research-intensive institution: Each of these institutions must provide the appropriate facilities and resources for the applicant and collaborating investigators to accomplish the goals of the proposed research program. The CAMSSA requires effective research collaboration among these investigators, who must be full-time employees of their respective institutions. These investigators must provide a detailed description of the nature and the extent of the research collaboration such that the necessary administrative and fiscal considerations are fully explained in the application. There must be letters from the applicant and collaborating institutions that signify their intent to participate and to provide the necessary resources proposed in the application. The minority-serving institution must allow the applicant a minimum 50% reserved time to devote to the specific aims of the proposed research during the academic year. The collaborator must indicate in the application the percent effort that will be contributed to the proposed research project.

o Before developing the application, the applicants should obtain a copy of the latest published policy governing consortia in the NIH Grants Policy Statement (3/01).

o The NIAMS strategic plans for fiscal years 2000-2004 and for health disparities focus on a multidisciplinary approach to accomplish goals of " Healthy People 2010" as they relate to diseases that affect bones, joints, muscles, and skin. Priority areas outlined in these strategic plans may be reviewed at <http://www.niams.nih.gov/an/stratplan/index.htm> .

MECHANISM OF SUPPORT

o This PA will use the NIH S11 award mechanism. Up to five years of support may be requested for a CAMSSA (S11). The applicant and collaborating investigator will be solely responsible for planning, directing, and executing the proposed project. Awards are not renewable.

o This PA uses just-in-time concepts. The CAMSSA Program will not use the modular budget format. Detailed budget information should be submitted with the grant application. Instructions for non-modular research grant applications may be reviewed at <http://grants.nih.gov/grants/funding/phs398/phs398.html> . This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_i_1.htm.

o Amount of Award: The NIAMS anticipates that the average CAMSSA will total approximately \$200,000 per year in direct costs. This is not meant to be a budget ceiling. Funds may be requested to cover costs traditionally requested in a research grant. Facilities and administrative (indirect) costs will be awarded based on the applicant institution's federally negotiated facilities and administrative cost rate. The application may contain a subcontract for the collaborating investigator to cover specific shared resources and any dedicated effort to the collaboration. The NIAMS support for this PA is contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

ELIGIBLE INSTITUTIONS

The applicant institution must be an institution with substantial minority enrollment that may be a non-Federal, public or private nonprofit institution located in the United States, its possessions or territories. The collaborating institution must also be a non-Federal, public or private nonprofit institution located in the United States, its possessions or territories.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any full-time faculty member at a minority-serving institution who has the skills, knowledge, and resources necessary to develop and implement a research career in arthritis, musculoskeletal diseases or skin diseases related research is eligible to apply. Women and individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities are encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

The applicant investigator must have a doctoral degree in a basic or clinical science area. The ideal applicant investigator should have completed one or more years of postdoctoral research experience and must be a full-time employee of the applicant institution. The applicant investigator must be a citizen or non-citizen national of the United States or its possessions and territories, or must have been lawfully admitted to the United States for permanent residence at the time of application. If the application is funded, permanent residents must submit at the time of award a notarized statement indicating that the candidate has an alien Registration Receipt Card, and that the form number of the card is either 1-551 or 1-151.

The collaborating investigator must be a grantee from a research-intensive institution who has current R01 or R01-level research support to conduct research in arthritis, musculoskeletal diseases or skin diseases. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to serve as collaborators.

Meetings should be held at the minority institution and the collaborating institution with a frequency that is conducive to accomplishing the proposed research. A minimum of one meeting per year is required. To facilitate maximum collaborative efforts, applicants are strongly encouraged to identify collaborators who are located within 100 miles of their minority-serving institution. If the collaborator is geographically distant from the applicant institution, a detailed communication plan must be provided to document the collaborative relationship and level of commitment for the successful implementation and completion of the proposed research and career development program.

Annual progress reports should include a thorough description of accomplishments and setbacks during each fiscal year. Contributions made to the proposed research on behalf of the principal investigator and the collaborator will be evaluated annually. Development of a successful collaboration will be one criterion for continued support.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct questions about scientific/research issues to:

Charisee A. Lamar, Ph.D., M.P.H.
Program Director for Health Disparities and Women's Health Research
National Institute of Arthritis and Musculoskeletal and Skin Diseases

One Democracy Plaza
6701 Democracy Blvd., Suite 800
Bethesda, MD 20892-4872
Phone: 301-451-6514
Fax: 301-480-4543
Email: lamarc@mail.nih.gov

o Direct your questions about peer review issues to:

Teresa Nesbitt, D.V.M., Ph.D.
Chief, Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Blvd, Suite 800
Bethesda, MD 20892-4872
Phone: 301-594-4952
Fax: 301-402-2406
or 301-480-4543
Email: nesbitt@mail.nih.gov

o Direct your questions about financial or grants management matters to:

Melinda Nelson
Chief Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Blvd., Suite 800
Bethesda, MD 20892-4872
Phone: 301-594-3535
Fax: 301-480-5450
Email: nelsonm@mail.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com/>. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

The title and number of this PA must be typed in Item 2 of the face page of the application form and the YES box must be checked.

SUPPLEMENTARY INSTRUCTIONS

All instructions for the PHS 398 (rev. 5/2001) must be followed with this addition: The S11 mechanism is intended to promote productive research interactions between a minority-serving institution and a research intensive institution. If the institutions are not in physical proximity, the distance puts an added burden on justifying the collaboration. Therefore, the applicant must include a section in the research application appearing after the Specific Aims entitled: "Proposed Research Collaborations" to address the following issues:

- a) The proposed plan to enhance communications, cooperation, and scientific collaboration among the participating investigators, as well as the potential for the collaborative research effort to develop and promote competitive NIAMS-related research at the predominantly minority institution.
- b) The intellectual and physical environment in which the research would be conducted, taking into account the proposed activities at applicant's and collaborator's institutions.
- c) Soundness of administrative support and organizational structure that facilitates the attainment of the objectives of the proposed research project.

The collaborating investigator should independently address these issues in the letter and the subcontract should be structured to reflect the interactions outlined.

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at <http://grants.nih.gov/grants/dates.htm>. Application deadlines are also indicated in the PHS 398 application kit.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

In addition, two copies of the application and all five copies of the appendix material should be mailed to:

Teresa Nesbitt, D.V.M., Ph.D.

Chief, Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Blvd., Suite 800
Bethesda, MD 20892-4872

APPLICATION PROCESSING: Applications must be mailed on or before the receipt dates described at <http://grants.nih.gov/grants/funding/submissionschedule.htm>. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an unfunded version of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIAMS. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the PAR will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the NIAMS advisory council.

REVIEW CRITERIA

The application must be sufficiently complete to allow an evaluation of the scientific objectives and proposed research plan. Applications must adequately document the plans for efficacious collaborative interactions and the potential for achieving the scientific goals of the research and for developing a competitive NIAMS-relevant research program by the end of the funding period.

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- o Significance

- o Approach
- o Innovation
- o Investigator
- o Environment

A review by a NIAMS Special Emphasis Panel will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

SIGNIFICANCE: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

INNOVATION: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

INVESTIGATOR: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers?

ENVIRONMENT: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and

subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the section on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL REVIEW CONSIDERATIONS

BUDGET: The reasonableness of the proposed budget and duration in relation to the proposed research.

ADDITIONAL SCIENTIFIC/TECHNICAL MERIT CRITERIA SPECIFIC TO THE OBJECTIVES OF THIS CAMSSA PA ARE:

- a) The proposed plan to enhance communications, cooperation, and scientific collaboration among the participating investigators, as well as the potential for the collaborative research effort to develop and promote competitive NIAMS-related research at the predominantly minority-serving institution.
- b) The intellectual and physical environment in which the research would be conducted, taking into account the proposed activities at applicant's and collaborator's institutions.
- c) Soundness of administrative support and organizational structure that facilitates the attainment of the objectives of the proposed research project.

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o Scientific merit as determined by peer review
- o Availability of funds
- o Relevance to program priorities

Applications will compete for available funds with all other recommended applications. The following will be considered in making funding decisions: Quality of the proposed project as determined by peer review, availability of funds, and program priority.

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II), efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at

<http://grants.nih.gov/grants/funding/children/children.htm>.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <http://escr.nih.gov>). It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force an effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is

administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.healthypeople.gov/>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourages the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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