

This Program Announcement expires on January 10, 2005, unless reissued.

PATHOPHYSIOLOGY AND TREATMENT OF CHRONIC FATIGUE SYNDROME (CFS)

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Office of Research on Women's Health
Office of Dietary Supplements
Office of Behavioral and Social Science Research
National Center for Complementary and Alternative Medicine
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Disease
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Heart, Lung and Blood Institute
National Institute of Environmental Health Sciences
National Institute of Nursing Research

THIS PA USES "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. MODULAR INSTRUCTIONS MUST BE USED FOR RESEARCH GRANT APPLICATIONS UP TO \$250,000 PER YEAR. MODULAR BUDGET INSTRUCTIONS ARE PROVIDED IN SECTION C OF THE PHS 398 (REVISION 5/2001) AVAILABLE AT <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

PURPOSE

The Office of Research on Women's Health (ORWH) and cosponsoring Institutes and Offices (IC) of the National Institutes of Health (NIH) invite submission of investigator-initiated research grant applications to support research on the pathophysiology and treatment of chronic fatigue syndrome (CFS) in diverse groups and across the life span. Applications that address novel hypotheses, heterogeneous population groups, research gaps and common mediators influencing the actions among and between various bodily systems are encouraged. The NIH is interested in funding research that will improve the diagnosis, treatment and quality of life of all persons with this disease.

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 Program Announcement (PA) is related to several priority areas, including chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople/>.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, and laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

MECHANISMS OF SUPPORT

Traditional project research grant (R01) applications may be submitted in response to this program announcement. Funds and time requested should be appropriate to the research proposed. Applicants will be solely responsible for the planning, direction, and execution of the proposed project, which is not to exceed a period of 5 years. Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the National Center for Research Resources (NCRR) may wish to identify the GCRC as a resource for conducting the proposed research.

RESEARCH OBJECTIVES

Background

Chronic fatigue syndrome (CFS) is a debilitating and complex syndrome that may involve multiple bodily systems and is characterized by profound fatigue, which is not improved by bed rest and may be exacerbated or re-kindled by physical or mental activity. Persons with CFS most often function at substantially lower levels of activity from their pre-onset capacities. In addition to these defining characteristics, CFS is also associated with a diverse array of symptoms including, for example, cognitive difficulties, impaired sleep, myalgia, arthralgia, headache, gastrointestinal

symptoms, and tender lymph nodes. Neither a specific cause(s) nor any specific diagnostic test(s) has yet been identified for this illness. The range of symptoms, however, suggests there may be subtle perturbations in multiple physiological pathways that may have been triggered by diverse causes, for example infection, stress, brain structure abnormalities, hormone levels, proinflammatory cytokines, etc. Epidemiological evidence is also limited and requires further study. However, it suggests that CFS occurs 3 to 4 times more frequently among women than among men and 10 times more often in white Americans than in Americans of other racial/ethnic groups. A more recent study disputes these numbers and would narrow the gap between the sexes as well as among racial/ethnic population subgroups.

Research Objectives and Experimental Approaches

Well designed studies are needed to provide a better understanding of both CFS pathogenesis and pathophysiology with the goal of developing improved diagnostic and intervention strategies. Studies should test biologically rational hypotheses. In clinical studies, selection criteria and procedures for CFS case and comparison groups should be carefully delineated and appropriate for the hypothesis under study. The heterogeneity of CFS population should be considered; thus both sub group analysis and collaborative, multidisciplinary research within or across scientific disciplines and institutions are encouraged. Human studies should include appropriate sample sizes to allow for analysis of sex, age /developmental period and racial/ethnic group differences.

Applicants are encouraged to review recommendations from a NIH sponsored CFS science summit held in October 2000 at Arlington, VA. This may be found at <http://www4.od.nih.gov/cfs/finalmeeting.pdf>. They may also wish to consider the "Agenda for Research on Women's Health for the 21st Century, volume 2"(NIH Publication No 99-4386. <http://www4.od.nih.gov/orwh/report.pdf>) as well as "Exploring the Biological Contributions to Human Health. Does Sex Matter" (National Academy Press, Washington DC. <http://www.nap.edu>) to ensure responsiveness to all aims of this Program Announcement.

Examples of multisystemic factors that may explain or have an impact on CFS pathogenesis and pathophysiology, and that are of interest to the NIH have been arbitrarily sorted into crosscutting categories that include all interested disciplines. Areas in which such scientific opportunities exist include but are not limited to:

Epidemiology

- o Define the extent of the problem and identify appropriate subgroups

- o Identify the antecedent or triggering events that precipitate CFS, including their biologic correlates
- o Identify environmental/geographic and other precipitants of CFS
- o Prospectively study the natural history of incident cases
- o Explore whether pathogenesis and pathophysiology differ as a function of age, sex, developmental period and racial/ethnic background
- o Compare the diagnostic criteria and symptomatology of CFS in children and adolescents with those for adults
- o Investigate long term mental, social and physical health outcomes in children and adolescents with CFS
- o Conduct case-control comparisons of CFS and syndromes with similar or overlapping symptomatology
- o Identify the frequency and severity of primary or secondary sleep loss, impaired sleep and daytime sleepiness

Methodology

- o Develop/refine objective measures for fatigue, severity of associated symptoms and degree of disability that do not rely heavily on self-report
- o Explore multi-systemic factors as precipitants to CFS symptoms
- o Develop/refine technologies to improve the identification and measurement of these precipitating factors
- o Develop novel and objective biological markers for the diagnosis of CFS
- o Conduct longitudinal studies and studies with multiple sampling points to capture the changing nature of CFS symptomatology
- o Explore the role of neuroimaging modalities in the diagnosis, treatment, and natural progression of CFS
- o Conduct genetic epidemiological studies leading to new insights regarding potential genetic risk factors

Basic Scientific Understanding of Symptoms and Disrupted Physiologic Control

- o Study the role of neuroendocrine and neuroimmune functions in CFS pathogenesis and pathophysiology
- o Study the role of neuro-cardiovascular regulation in the loss of the normal control of blood pressure, heart rate and contractility in CFS patients
- o Study the nature of psychiatric comorbidity in CFS patients

- o Elucidate the factors/mechanisms involved in explaining cognitive difficulties, sleep disturbances, pain and inability to sustain physical exertion in CFS patients
- o Elucidate the factors/mechanisms involved in altered sleep state or circadian regulation or other causes of impaired or ineffective sleep
- o Study the role of cytokines, in interaction with physiological systems other than the immune, in CFS pathogenesis and pathophysiology
- o Study the manner and consequences of dysregulation in the major physiologic control systems to better understand the diverse symptom complexes among CFS patients

Treatment, Quality of Life

- o Conduct clinical trials to determine the efficacy in CFS patients of reliable and valid strategies that are used to improve quality of life in other chronic diseases
- o Conduct definitive trials to determine the effectiveness of currently prescribed pharmacologic, behavioral and other treatments used in CFS
- o Develop and test new pharmacologic and nonpharmacologic strategies for ameliorating symptoms common to CFS that impair quality of life
- o Study perceptions, attitudes, and behaviors that influence both the course of CFS and the quality of care provided to CFS patients
- o Examine the role of self-medication with alcohol, illicit and prescription drugs in CFS patients.
- o Examine the use of complementary and alternative therapies, including dietary supplements, in CFS patients

Applications for small studies that explore new ideas or investigative techniques are also encouraged and could provide the basis for submission of a subsequent larger grant application

STUDY DESIGN AND METHODOLOGICAL ISSUES

Multidisciplinary studies and collaboration among investigators with expertise in appropriate disciplines are encouraged. When investigators are at different institutions, individual R01 applications may include consortium arrangements.

Collaborative arrangements with ongoing studies that provide patient populations, specimens and data are encouraged. Such arrangements should be clearly delineated in the application.

The hypotheses to be tested should be clearly stated. The constructs and measurements to be used operationally to obtain biologically and statistically meaningful data should be clearly defined and enumerated. Personnel involved in data collection and statistical/epidemiological analyses should be described. The statistical methods used for analysis of the data should be described and evident in the design of the study.

Methods and procedures used in selecting patients or their specimens should be precisely defined and described in detail. Care should be given to the criteria used for case definition and the manner in which the criteria are applied. Similar care should be given to descriptions of procedures and methods for enrolling subjects in comparison groups. Investigators are encouraged to use the CFS case definition as presented in Fukuda, et al. *Annals of Internal Medicine* 1994; 121: 953-9. If other case definitions are proposed, they should be clearly defined and the rationale for the alternative choice clearly delineated. Similar care should be given to definition of subgroupings for CFS patients, if you chose to consider them.

Sample sizes should reflect the study design and degree of precision needed for statistically and biologically meaningful results. If multiple comparisons and interaction terms are of interest, this must be considered.

The reliability and validity of all measures used, be they behavioral, physiological, or technical, for addressing quantitative aspects of the relevant populations should be demonstrated. It is important that applicants clearly define the measures to be used, the rationale for those choices, and the methodology for validation/accuracy. Methods of collection, processing and storing of sample specimens and data must be clearly described. When conflicting results have been reported in the literature, applicants should provide putative explanations for the variability and indicate how the methodological approach used might resolve the issue.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

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 AMENDMENT "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>);

a complete copy of 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 IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH 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 was published in the NIH Guide for Grants and Contracts, March 6, 1998 and is available at <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>.

Investigators may also obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

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. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5,

2000, at the following website:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

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 and 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.

URLs IN NIH GRANT APPLICATIONS

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

APPLICATION PROCEDURES

The PHS 398 research grant application instructions and forms (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> must be used in applying for these grants and will be accepted at the standard application deadlines (<http://grants.nih.gov/grants/dates.htm>) as indicated in the application kit. This version of the PHS 398 is available in an interactive, searchable format. Beginning January 10, 2002, however, the NIH will return applications that are not submitted on the 5/2001 version. For further assistance contact Grants Info, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

Applicants planning to submit an investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended/revised version of the preceding grant application types requesting \$500,000 or more in direct costs for any year are advised that he or she must contact the Institute or Center (IC) program staff before submitting the application, i.e., as plans for the study are being developed. Furthermore, the application must obtain agreement from the IC staff that the IC will accept the application for consideration for award. Finally, the applicant must identify, in a cover letter sent with the application, the staff member and Institute or Center who agreed to accept assignment of the application.

This policy requires an applicant to obtain agreement for acceptance of both any such application and any such subsequent amendment. Refer to the NIH Guide for Grants and Contracts, March 20, 1998 at <http://grants.nih.gov/grants/guide/notice-files/not98-030.html>.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and NIH staff. The research grant application form PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> is to be used in applying for these grants, with modular budget instructions provided in Section C of the application instructions.

The title and number of the program announcement must be typed on line 2 of the face page of the application and the YES box must be marked.

Submit a signed, typewritten original of the application, including the checklist, and five 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)

REVIEW CONSIDERATIONS

Upon receipt applications will be reviewed for completeness by the CSR. Incomplete applications will be returned without further consideration. Applications that are complete and responsive to this PA will be assigned on the basis of established NIH referral guidelines. An appropriate scientific review group convened in accordance with standard NIH peer review procedures will evaluate applications for scientific and technical merit. 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 appropriate national advisory board(s).

REVIEW CRITERIA

The goals of NIH supported research are to advance our understanding of biological systems, improve 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. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application need not 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 an important work that by its nature is not innovative but is essential to move the field forward.

(1) 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 each of these studies on the concepts or methods that drive this field?

(2) 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?

(3) 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?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) 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?

(6) In accordance with NIH policy, applications will also be reviewed with respect to

- a. The adequacy of plans to include, in numbers sufficient for meaningful analysis, subjects of both sexes, minorities and their subgroups, and children as appropriate.
- b. The adequacy of plans for recruitment and retention of subjects.
- c. The adequacy of proposed protections for humans, animals and/or the environment to the extent that they may be adversely affected by the project proposed in the application.
- d. The reasonableness of the proposed budget and duration in relation to the proposed research.

AWARD CRITERIA

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.

INQUIRIES

Written and telephone inquiries are welcome. Potential applicants are encouraged to avail themselves of the opportunity to clarify any issues.

Direct inquiries regarding programmatic issues to:

OFFICE OF RESEARCH ON WOMEN'S HEALTH

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NIMH

Although not a formal sponsor of this program announcement, the National Institute of Mental Health (NIMH) accepts applications on mental health disorders that are co-morbid with chronic fatigue syndrome. The NIMH accepts applications if they have explicit relevance to mental disorders, symptoms, or related disability as reflected in the title, abstract, theoretical framework, specific aims, measures and analyses. For more information and pre-application technical

assistance, please contact: Peter Muehrer, Ph.D., Health and Behavior Science Research Branch, National Institute on Mental Health, National Institutes of Health, 6001 Executive Boulevard, Room 6189, MSC9615, Bethesda, MD 20892-9615. Telephone: (301) 443-4708, E-mail: pmuehrer@mail.nih.gov.

Direct Inquiries regarding fiscal matters to:

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are made under authorization of sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. The Office of Dietary Supplements (ODS) was established in 1994 under the Dietary Supplement Health and Education Act (DSHEA), Public Law 103-417, Section 3a to establish standards with respect to dietary supplements. This program is not

subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-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, and 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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